

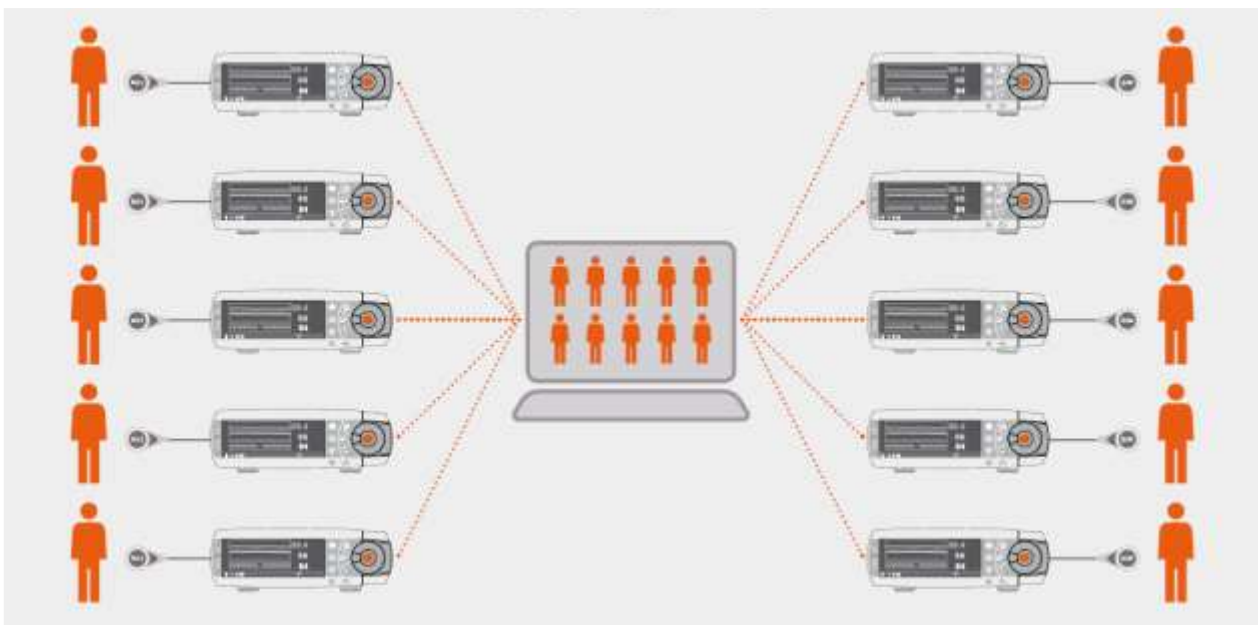
Instruction Manual

for

V-STATS 5.01.1

with

V-CareNeT Package



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1. General Notes

V-STATS 5.01.1 is a PC-based software that offers the following three main features:

- 1) Download of SDM Trend Data (6) stored in the internal memory of Sentec Digital Monitors (SDMs) via their serial or their LAN interface for subsequent display (4.2), analysis (9, 9.2), and reporting within V-STATS (9.5, 7.3). The analysis criteria (9.2) and the analysis interval (9.3) are adjustable. For split night analysis, for example, it is possible to split a measurement into multiple analysis periods and to generate a report for each period. Multiple data ranges, which are separated from each other, can be excluded from data analysis (9.4). Reports (9.5) are highly customizable and can be printed or stored as a PDF (7.3). To optimally fit the specific needs of varying clinical settings, customizable 'Analysis Criteria Profiles' and 'Report Profiles' help to ensure that measurements can be analyzed and reports can be printed/saved in the desired way.
- 2) Configuration of the SDM connected to V-STATS via its serial interface (13). Within a password-protected area it is possible a) to configure all parameters of the connected SDM on an individual basis, b) to store up to 4 SDM Profiles in the connected SDM and to select one of these profiles as 'Standard Profile' if the connected SDM is operated in 'Institutional Mode', and c) to customize/manage SDM Profiles stored in the 'SDM Profiles Database'.
- 3) Remote monitoring and secondary alarm surveillance of multiple SDMs connected to the same network as the PC by means of V-CareNeT (14, 14.3). 'Operator Events', 'Baselines' (for PCO, PO₂, SpO₂, and RHP), and certain SDM settings can be set/ controlled remotely on the included SDMs (14.8.3, 14.8.2.1). Using V-CareNeT, download of SDM Trend Data is simultaneously possible for multiple SDMs (14.6).

Note: To use V-CareNeT, the V-CareNeT Package incorporated within V-STATS must be activated (15.2). To get familiar with V-CareNeT before its full activation you may use the 'V-CareNeT Demo Mode' (12.3) or – after registration of V-STATS (15.1) – activate a 'V-CareNeT Trial' (15.3) or an 'Extended V-CareNeT Trial' (15.4).

Note: The SDM and its use are described in the Technical Manual for the SDM (HB-005752) and in the 'Instruction Manual' for the SDMS (HB-005771).



WARNING: V-STATS provides no diagnosis. The interpretation of the measurement data is the sole responsibility of the investigator or medical practitioner.



WARNING: See 14.1 for V-CareNeT specific warnings and cautions.

Warranty

Sentec AG guarantees the functionality of the software but not that it is absolutely free of errors. Sentec AG assumes no liability for any occurring errors.

Warranty Exclusions and System Performance

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2. Introduction / Short description

V-STATS 5.01.1 is a PC-based software that offers the three main features being summarized in sections 2.1, 2.2, and 2.3:

2.1 Downloading/Importing, displaying, analyzing and reporting SDM Trend Data

2.1.1 Patient Assignment while Downloading/ Importing SDM Trend Data

Download of SDM Trend Data from the internal memory of a SDM is possible via the SDM's serial interface (8.1) or with V-CareNeT via its LAN interface (14.6). SDM Trend Data, furthermore, can be imported from a file stored on the PC or an external drive (7.7). Initiating download/import of SDM Trend Data opens a dedicated dialog (6.1) displaying the start- and end-times of all measurement period(s) available in the internal memory of the SDM or in the file. In this dialog, the measurement period(s) to be downloaded/ imported can be selected and assigned to the respective patient. The 'Analysis Criteria Profile' (9.2) that will be applied to analyze the data is indicated and can be changed with the ease of a mouse click. Furthermore, automatic export of the data into a '*.vex-file' (7.5) or an 'EDF+-file' (7.6) for subsequent data processing by third party applications can be enabled in this dialog when downloading SDM Trend Data via the SDM's serial interface. During download/import of the selected measurement period(s), the contained data are analyzed, stored in the currently selected 'Data Storage Folder' (12.1), and subsequently displayed in V-STATS' Main Window (4.2).

Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.

2.1.2 Main Window of V-STATS

If no measurement is open, the Main Window of V-STATS features three buttons in the center, which provide quick access to the main functions of V-STATS (4.1). If a measurement is open (4.2), the Main Window of V-STATS displays measurement data for all parameters/channels above the corresponding measurement time along with the most important statistical results set for the current 'Analysis Interval'. TC-channels (PCO2 and PO2) additionally display 'Baselines' (11.5, 11.7) and the PCO2 channel - if enabled - drift corrected data (11.6) as a blue curve. The name, respectively the unique key of the corresponding patient (11.3), the recording date, and the filename of the displayed measurement are indicated at the bottom of the Main Window. Colored markers in the curves highlight physiological events, artifacts, excluded data ranges, SDM events, or invalid data (4.2.6, 12.1.2). If the cursor is set (4.2.3), the value of each parameter, the delta-baseline (dB) values for PCO2 and PO2 (the difference between the PCO2 (PO2) value at the cursor position and the PCO2 (PO2) baseline) as well as the date/time at the cursor position are indicated. Scrolling (4.2.2) and zooming in/out functions (10) permit to adjust the 'Displayed Range' indicated in the top right of V-STATS' Main Window.

The name of the currently selected 'Analysis Criteria Profile' (9.2) is displayed in the menu bar on the right of the 'Help Icon'. It displays in bold black if the settings of the currently selected 'Analysis Criteria Profile' and those that were last used to analyze the open measurement are identical, otherwise in red with an asterisk (*). Left-click on the 'Analysis Criteria Profile' opens a popup menu permitting to re-analyze the currently open measurement with the currently selected or a different 'Analysis Criteria Profile' (9.1). The current 'Analysis Interval' (9.3) is indicated by a blue bold label underneath the 'Analysis Criteria Profile' and visualized by a blue bar above the measurement curves and two blue vertical lines at the start and end of the Analysis Interval, respectively. Left-click on the 'Analysis Interval Indicator' opens a popup menu permitting to select a different 'Analysis Interval'. Colored triangles (if any) represent Operator Events (11.1). If a measurement is split into multiple Analysis Periods (e.g. to analyze the different phases of a split night) a grey vertical line at the position of an 'Operator Event' represents the start of a new Analysis Period (see below).

2.1.3 PCO2 Baseline and PO2 Baseline

After downloading / importing SDM Trend Data, V-STATS sets the PCO2 baseline to the PCO2 reading at the end of the (first) PCO2 stabilization period in the measurement and the PO2 baseline to the PO2 reading at the end of the (first) PO2 stabilization period in the measurement. Optionally, the PCO2 (PO2) baseline can be set manually (11.5, 11.7). If drift corrected PCO2 data are displayed (11.6), the PCO2 baseline is established using drift corrected data. The PCO2 (PO2) baseline is shown in the PCO2 (PO2) channel as a red-dashed horizontal line. A red vertical line indicates the instant at which the PCO2 (PO2) baseline was determined. Subsequent deviations of the PCO2 (PO2) readings (e.g. caused by nocturnal or sedation/ pain management induced hypoventilation) from the red-dashed horizontal lines are readily seen. The numerical value of the PCO2 (PO2) baseline is displayed on the left of the PCO2 (PO2) channel. The numerical value for the PCO2 baseline is also displayed at various locations of the report and is taken into consideration when analyzing the PCO2 data for the criteria 'Deviation from baseline' (please note that PO2 data are currently not included in the report).

The delta-baseline (dB) value for PCO2 (PO2), finally, indicates the difference between the PCO2 (PO2) value at the cursor position (if set) and the PCO2 (PO2) baseline.

2.1.4 Correction of residual PCO2 Drift

V-STATS' PCO2 drift correction recognizes the residual technical PCO2 drift of Sentec TC Sensors. Drift corrected PCO2 data (11.6) are available in V-STATS, if the PCO2 calibration data before and after the measurement are available. In the PCO2 channel, drift corrected PCO2 data are displayed as blue curve (alone or in addition to the green curve of the original PCO2 data). Note that if the drift corrected PCO2 curve is displayed, determined of the PCO2 baseline, the dB value for PCO2, and statistical data analysis are performed using the drift corrected PCO2 data.

Note: Correction of residual PCO2 drift is important for longer measurements (e.g. sleep studies, etc.). [Chhajed et al.](#), for example, have shown that by using drift corrected PCO2 data the titration of NPPV pressures can be optimized.

Note: The PO2 measurement of Sentec TC Sensors is virtually free of drift and, hence, residual PO2 drift of Sentec TC Sensors is usually minimal or even non-existent. Correction of residual PO2 drift, consequently, is usually not required.

2.1.5 Data Analysis/ Analysis Criteria Profiles/ Analysis Interval/ Exclusion of data ranges

V-STATS' data analysis comprises a set of predefined statistical criteria as well as user-adjustable analysis criteria (9.2) for the detection of physiological events (PCO2, SpO2, PR) and artifacts. Moreover, it allows for identifying the time SpO2 readings are below and PCO2 readings are above a predefined value, respectively. V-STATS evaluates the following physiological events:

- PCO2-related events: a) Dynamic Events (PCO2 Fall/ Rise), b) Baseline Events ('> PCO2 Baseline +X'; '< PCO2 Baseline - Y'), and c) Threshold Events (above upper threshold; below lower threshold).
- SpO2-related events: a) Dynamic Events ('Desaturations'), b) Threshold Events (above upper threshold; below lower threshold).
- PR-related events: a) Dynamic Events (PR Rise), b) Threshold Events (above upper threshold; below lower threshold).

Note: Data analysis currently does not include analysis of PO2, PI, and HP data.

In order to ensure that you can analyze your measurement the way you want them to in varying clinical settings, V-STATS provides 'Analysis Criteria Profiles' (9.2). It is possible to customize 'Analysis Criteria Profiles'. Once you have created your own 'Analysis Criteria Profiles' you can switch between them with the ease of a few 'mouse-clicks', for example, a) before activating download/ import of SDM Trend Data to V-STATS (see 6) or b) to re-analyze the currently open measurement with the currently selected or a different 'Analysis Criteria Profile' (4.2). The 'Analysis Interval' (9.3), i.e. the time range of a measurement is considered for data analysis, is also selectable. The 'Analysis Interval' can be set to 'Full Measurement', to 'Displayed range', to a range to be 'manually' spanned with the mouse in the curves, or – if the measurement is split into multiple Analysis Periods – to one of the available Analysis Periods (AP x). In case of a split night study, for example, a 'Partial Report' can be generated/printed for each 'Analysis Period' by setting the 'Analysis Interval' to one 'Analysis Period' after another.

V-STATS excludes episodes with invalid data, artifacts (either detected by V-STATS or marked by the operator with the mouse (4.2.4)), and – if enabled by the operator (9.2) – certain SDM events (potentially containing data with questionable quality) from statistical data analysis. Furthermore, the operator can exclude multiple data ranges (9.4), being separated from each other, from statistical data analysis. Note that in contrast to episodes with invalid data, artifacts, or excluded SDM events, such data ranges typically contain data of good quality being excluded from statistical data analysis for other reasons. If data ranges are excluded from data analysis, an 'Invert' function permits to invert data range exclusion with the ease of a mouse click. If for example, all episodes during which a patient was awake were excluded from data analysis in order to analyze sleep episodes only, the 'Invert' function will exclude all sleep episodes and, consequently, only those episodes during which the patient was awake will be analyzed.

Important Note: *Unless otherwise specified, all statistical results are, for each channel, based on the evaluation of the artifact free part of valid, non-excluded measurement data contained within the current 'Analysis Interval'.*

2.1.6 Markers, Operator Events, and Analysis Periods

Colored markers in the measurement curves (4.2) highlight a) physiological events for PCO2, SpO2, and PR evaluated by V-STATS (9.2), b) artifacts evaluated by V-STATS (9.2) or manually marked by the operator (4.2.4), c) excluded data ranges manually marked by the operator (4.2.4, 9.4), d) SDM events, or e) invalid data ranges. SDM Event Markers are displayed separately from the other markers at the bottom edge of the channels. SDM Event Markers being related to SDM Events that are excluded from data analysis (see 9.2) are duplicated by 'Invalid Data Markers'. If the mouse is hovered over an event marker a tooltip providing information on the respective event appears. Furthermore, markers are labeled for displayed time ranges of up to 30 minutes (4.2.5). Note that in each channel physiological events are only displayed for the event type (dynamic events; baseline events (for PCO2 only); threshold events) currently selected to be visualized (9.2). The color of the markers is selectable (12.1.2). Markers related to physiological events, artifacts or 'Excluded Data Ranges' can be edited (4.2.6). Right-click on one of these markers, for example, activates a popup menu permitting, among other, to reclassify or

delete the selected marker (4.2.4). Markers exhibiting a black triangle in the upper left corner identify physiological event or artifact markers that have been manually modified.

Operator Events (11.1) marked on the SDM during patient monitoring by using its 'Quick Access Menu' or remotely with V-CareNeT (see 14.8.3) are displayed in the measurement curves as colored triangles. To unequivocally identify 'Operator Events' within V-STATS the colored triangles as well as the corresponding 'Operator Events' in the list of operator events are alphabetically labeled in chronological order of their occurrence. If the mouse is hovered over a colored operator event triangle a tooltip providing information on the respective 'Operator Event' appears. If a measurement is split into multiple 'Analysis Periods' a grey vertical line at the position of an operator event indicates the start of a new Analysis Period. It is possible to a) edit or delete existing Operator Events/Analysis Periods or b) to add new Operator Events/Analysis Periods if a measurement is open.

2.1.7 Report (on screen)

A comprehensive report (9.5) can be generated and displayed on the screen for the current 'Analysis Interval'. Comments and findings can be added (9.5.2, 9.5.11).

Note: The report currently does not include statistical results for PO2, PI, and HP.

The report is organized in eleven sections and contains 12 pages/tabs. The 'Summary' page/tab (9.5.2) summarizes the most important results for the PCO2, SpO2 and PR channels.

The report provides the following statistical results:

- Distribution curve and table, minimum, maximum, mean, median for the PCO2, SpO2 and PR channels, along with standard deviation for PR;
- SpO2 only: Time below a selectable level (default 88%), number of events with SpO2 values smaller than a selectable level (default 88%) that last longer than 5 minutes (according to NPPV Guideline, CHEST 1999; 116:521-534);
- PCO2 only: Time above a selectable level (default 50mmHg), number of events with PCO2 values above a selectable level (default 50 mmHg) that last longer than 5 minutes (according to criteria recommended by various national bodies (e.g. Haute Autorité de Santé in France) to identify nocturnal hypoventilation).

The report (9.5) provides for each of the 12 physiological events (PCO2, SpO2, and PR) the following information:

- Statistical results: Number of events, duration of the longest event, average duration of an event, time in events, time in events/hour, index (number of events per hour).
- Event distribution: the number of events within a selectable time interval (0.25h, 0.5h, 1h, 2h, 4h) is displayed as a function of the measurement time (9.5.7, 9.5.8, 9.5.9).
- List of Events: The list of events is a chronological list of all events and the time they occurred. A double click on an event in the list of events brings the measurement curves to the front, positions the cursor at the beginning of the selected event, activates the '15-minutes' zoom level and centers the displayed time range around the cursor (9.5.10).

2.1.8 Printout of the report / PDF Report

The printout of the report is highly configurable / customizable (9.5). Among other, it is possible to select the pages of the report (7.3) and the individual elements of the report 'Summary' page (9.5.2) to be printed/ stored. In order to ensure that you can print/ save reports the way you want them to for various clinical settings, V-STATS provides 'Report Profiles' (7.3.1). It is possible to customize 'Report Profiles' (7.3.1). Once you have created your own 'Report Profiles' you can switch between the different available 'Report Profiles' with the ease of a few mouse clicks before printing/ storing the report. Furthermore, the header of the report (12.1.4) as well as the 'Font Size', the 'Language', the 'Format of Date', the 'Unit of weight', and the 'Unit of length/height' can be customized in a password-protected area of V-STATS (12.1).

The report can be stored as a PDF. To ensure that the PDF Report can be integrated into 'Electronic Medical Records', the 'Default File Name' and 'Default Storage Folder' that are proposed when storing the report as PDF can be predefined (12.1.5). The 'Default Storage Folder' can be located on a server of your institution's network. The 'Default File Name' consists of up to five elements. Selectable options for each element include the Patient Number, the Last Name, the First Name, the Date of Birth, the Date of Measurement Start, the Time of Measurement Start, the Date of Analysis Interval Start, the Time of Analysis Interval Start, the Current Date, and the Current Time.

Note: The report currently does not include statistical results for PO2, PI, and HP.

Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.

2.1.9 Channel Configuration

With V-STATS the channels can be configured as follows:

- The channel labels are selectable (12.1.1).

- For each channel the colors used for the channel label/curve and channel background are selectable (12.1.1).
- For each channel the mode for the display range ('autoscale' or 'manual') and the horizontal grid (auto or manual (only selectable if manual is selected for the display range)) are selectable (11.9, 12.1.1).
- The 'Displayed Range' can be selected between 30 sec and 10 days with 15 zoom-levels (10). The mode used for the vertical grid and time scale can be configured (4.2). Scrolling through the measurement is supported (4.2.2).
- It is possible to show / hide individual channels (11.8).
- The pressure unit for PCO₂/PO₂ is selectable ('mmHg' or 'kPa') (12.1).

2.1.10 File manager / import and export of data in various formats

When downloading/importing SDM Trend Data to V-STATS, the measurements are stored in the currently selected 'Data Storage Folder' (12.1). In default settings, the 'Target Folder of the File Manager' is set to the 'Data Storage Folder', i.e. when opening the 'File Manager' (7.1) it displays in default settings the list of measurements stored in the current 'Data Storage Folder'. Once the 'File Manager' is opened, it is possible to select an arbitrary folder available in the file system by using the file explorer on the left side of the 'File Manager'.

Note: The 'Data Storage Folder' and the 'Target folder of File Manager' are selectable within a password-protected area of V-STATS (12.1). If located on a server of your institution's network, these folders can be accessed from any V-STATS client with read/write access. Furthermore, backup of the measurement data is ensured in the course of the server's routine backup procedures.

For each measurement available in the selected folder, the File Manager displays either information related to the patient ('Last name', 'First name', 'Date of birth', 'Patient number') if access must be enabled and related to the measurement ('Date of Registration', 'Comment', 'Measurement duration', 'Filename'). Available measurements can be opened, copied or moved to another folder, or deleted. The list of measurements can be printed or searched for the 'Last name', the 'First name', the 'Patient number', the 'Comment', or the 'Filename'. Furthermore, each column of the 'File Manager' can be sorted in increasing/decreasing order. Measurements can be exported in different file formats (SDM Trend Data files (7.8), customized data files (7.5), EDF+-Files (7.6), and V-STATS Files (7.11)). Import of SDM Trend Data files (7.7), of customized data files (7.4), or of V-STATS Files (7.10) is also possible.

2.2 Configuration of the SDM (Parameters & SDM Profiles)

V-STATS 5.01.1 allows the configuration of SDMs with software version SMB-SW V08.00 or higher within a password-protected section (13). In particular, it is possible to

- 1) configure all **menu parameters** as well as all so-called **safety relevant parameters** of the connected SDM on an individual basis (13.2.4). Safety relevant parameters cannot be changed in the menu of the SDM, several of these parameters permit to disable or restrict operator-access to certain menu parameters. Examples include the restriction of the 'Maximal selectable Sensor Temperature', restriction of the 'Maximal selectable Site Time' or enabling/disabling the possibility that the operator can switch-off the 'AUDIO OFF Reminder' in the menu of the SDM;
- 2) select the '**Profile Mode**' of the connected SDM (13.2.1). In '**Basic Mode**', the SDM maintains the parameter settings from previous use at power-up. In '**Institutional Mode**', it is possible to store up to four SDM Profiles in the connected SDM and select one of these profiles as 'Standard Profile'. If modified the operator can at any time restore the 'Standard Profile' in the menu of the SDM. Furthermore, if at power-up of the SDM the LAST settings are different from the settings of the 'Standard Profile' the menu 'Profiles' activates and offers the option to restore the 'Standard Profile', to keep the modified profile, or to select another 'Profile';

Note: A 'SDM Profile' is a file which contains a specific setting for all those SDM parameters that are displayed in black in the dialog 'Profiles / SDM Settings - <SN>' (see 13.2, 13.2.4). 'SDM Profiles' therefore are helpful to ensure that all SDMs within your institution work the way you want them to.

- 3) customize/manage 'SDM Profiles' stored in the 'SDM Profiles Database' (7.13, 13.2.3). It is possible a) to import 'SDM Profiles' to the database (either from the SDM or from the PC), b) to export 'SDM Profiles' from the database to the PC (e.g. to exchange them with other users) as well as c) to rename, print or delete 'SDM Profiles' currently available in the 'SDM Profiles Database'.

Note: Upon installation of or upgrade to V-STATS 5.01.1 the following write-protected SDM Profiles preconfigured by Sentec and tailored to optimally fit the specific needs of varying clinical settings are stored in the 'SDM Profiles Database': CRITICAL CARE, GEN. CARE FLOOR, HOME, NICU, OPERATING ROOM, PACU, SLEEP, SMB621 STYLE, V-CHECK (enabling Ventilation Spot Check), and NEO_PO2. Please refer to 'RF-006679 Preconfigured SDM Profiles' to view all parameters and their respective settings in the preconfigured SDM Profiles.

2.3 V-CareNeT – Remote monitoring and alarm surveillance of multiple SDMs

The V-CareNeT System (14, 14.3) enables remote monitoring and alarm surveillance for multiple Sentec Digital Monitors (SDMs) connected to the same network as the central station, i.e. the PC running V-STATS with activated V-CareNeT Package. For all admitted patients, the central station displays all relevant SDM data online; alarms appear visually and audibly at the central station (14.4, 14.9). Furthermore, 'Operator Events', 'Baselines' (for PCO₂, PO₂, SpO₂, and RHP), and certain SDM settings can be set/ controlled remotely on the SDMs (14.8.3, 14.8.2.1). Trend Data stored in the internal memory of the SDMs can be downloaded to V-STATS via the network (6, 14.6) for subsequent display, analysis, and reporting within V-STATS (4.2, 9, 9.5, 7.3). Up to 40 SDMs can be included in V-CareNeT. Download of SDM Trend Data is simultaneously possible for multiple SDMs.

Note: Remote Monitoring and alarm surveillance is currently only supported for PO₂ if an OxiVenT sensor is connected and enabled patient type is set to 'neonate'.

Note: The number of beds/ patients simultaneously available for remote monitoring is determined by the number of beds/ patients included in the 'V-CareNeT Package Registration Code' that was used to activate/ upgrade the 'V-CareNeT Package' (15.2, 16.6.1). 'V-CareNeT Package Registration Codes' are available for 5, 10, 20, 30, or 40 beds/ patients or upon request for a customized number of up to 40 beds/ patients.

Note: V-CareNeT evaluates the size/resolution of the central station's screen and limits the number of bed/stations simultaneously available for remote monitoring to ensure that the 'V-CareNeT Control Window' and all active stations (remote monitoring windows) are fully visible and can be arranged without overlapping each other. For remote monitoring of 40 beds/ patients, a screen size/ resolution of approx. 2560 x 1440 is required (approx. 1024 x 768 for 5 beds/ patients, 1152 x 864 for 10 beds/ patients, 1600 x 1024 for 20 beds/ patients, 1920 x 1200 for 30 beds/ patients). Smaller screen sizes/resolutions will support fewer beds/ patients regardless of the 'V-CareNeT Package Registration Code' that was used to activate/ upgrade the 'V-CareNeT Package'.

Note: It is at any time possible to (further) upgrade V-CareNeT to a higher number of beds/ patients (see 16.6.1).

3. Installation, Update and Configuration

3.1 Compatibility of V-STATS 5.01.1 with SDM software versions

V-STATS 5.01.1 is compatible with Sentec Digital Monitors (SDMs) with software version SMB-SW 8.00.x, 08.01.x, 08.02.x, 08.03.x or V08.04.x. The SMB software version is indicated in the SDM menu 'System Information'.

Note: V-STATS 5.01.1 supports communication via the serial interface (see 8.1) only for SDMs with software versions SMB-SW V08.00.x, V08.01.x, V08.02.x, V08.03.x or V08.04.x. You must use V-STATS 3.01, 3.01.1, 4.00, 4.00.1, 4.01 if your SDM uses software version SMB-SW V06.21, V07.00.x, V07.01.x, V07.02.x or V07.03.x. Contact your local Sentec distributor regarding V-STATS compatibility with older SDM software versions.

Note: V-STATS 5.01.1 supports V-CareNeT (see 14) only for SDMs with software versions SMB-SW V08.00.x, V08.01.x, V08.02.x, V08.03.x or V08.04.x. Contact your local Sentec distributor to use V-CareNeT with SDMs with software version SMB-SW V07.00.x, V07.01.x, V07.02.x, V07.03.x. If your SDM uses a software version prior to SMB V07.00 V-CareNeT cannot be used.

*Note: V-STATS 5.01.1 only supports import of SDM Trend Data (see 7.7) or '**vex-files' (see 7.4) if the included data has been downloaded from the internal memory of a SDM with software version SMB-SW V08.00.x, V08.01.x, V08.02.x, V08.03.x or V08.04.x. Use V-STATS 3.01, 3.01.1, 4.00, 4.00.1, 4.01 to import SDM Trend Data from a raw data file, if the data has been downloaded from the internal memory of a SDM with software versions SMB-SW V06.21, V07.00.x, V07.01.x, V07.02.x or V07.03.x. Contact your local Sentec distributor regarding import of SDM Trend Data including data that has been downloaded with older software versions.*

3.2 System requirements for V-STATS 5.01.1

V-STATS 5.01.1 can be installed on most PCs. The minimum system requirements are:

	V-STATS (without using V-CareNeT)	V-STATS with V-CareNeT activated
CPU	2 GHz and higher	Multi core at 2 GHz and higher
Operating System	Microsoft Windows 7 (32 and 64 bits), 8 (32 and 64 bits), 8.1 (32 and 64 bits), 10 (32 and 64 bits)	Microsoft Windows 7 (32 and 64 bits), 8 (32 and 64 bits), 8.1 (32 and 64 bits), 10 (32 and 64 bits)
Memory	4 GB	4 GB
Free space on hard disk	1 GB	1 GB
Communication Port (Serial or Serial via USB2Serial Converter USB 2.0)	YES	YES
Network connection	Recommended	100/1000 Mbit BaseT
Screen	XGA (1024 x 768)	approx. 1024 x 768 for 5 beds approx. 1152 x 864 for 10 beds approx. 1600 x 1024 for 20 beds approx. 1920 x 1200 for 30 beds approx. 2560 x 1440 for 40 beds smaller resolutions will support fewer beds
AUDIO	Recommended	Integrated speaker system required for auditory alarm signals
Printer	Recommended	Recommended

Note: Up-to date antivirus and firewall protection must be installed and enabled on the computer running V-STATS.

Note: It is highly recommended to limit the number of open ports to those that are absolutely essential. Ports which are not required must be closed by the system administrator.

3.3 Installation and how to update V-STATS 5.01.1 on a PC

To **install** V-STATS 5.01.1 on a PC proceed as follows:

1. Turn your computer on and start Windows.
2. Download the full V-STATS installation setup from www.sentec.com/v-stats/download/
Note: This download link is also accessible via Sentec's webpage (see www.sentec.com/v-stats)
3. Once the download is completed, unzip the installation folder 'fullvstats.zip'.
Note: The resulting folder "fullvstats" can be copied to a storage medium such as a USB-Stick or CD.
4. Open the folder 'fullvstats' and double-click **setup.exe** to start the installation

Starting from V-STATS 4.01 or higher, an installed and registered V-STATS license can be **updated** to V-STATS 5.01.1 as follows:

1. Download the updater from <http://registration.sentec.com/downloads/updatervstats.zip>
Note: This download link is also accessible via Sentec's webpage (see <https://www.sentec.com/v-stats>)
2. Once the download is completed, unzip the updater 'updatervstats.zip'.
Note: The resulting folder "updatervstats" can be copied to a storage medium such as a USB-Stick or CD.
3. Open the folder "updatervstats" and double-click on **setup.exe** to start the update.

The following steps must be carried out during a **new installation** as well as during an **update** of V-STATS software:

1. Select the desired language.
2. Click on 'Installation Manual' if you want to open the installation manual as .pdf file and then on 'Next' to resume the installation.
3. A 'License Agreement Dialog' will appear. Click 'I Agree' to accept the license terms and to continue installation. If you click 'I do not agree', the installation of V-STATS will be aborted. Click 'Print' to print the license terms.
4. Carefully read the dialog containing information on V-STATS compatibility with SDM software versions and click 'yes' to acknowledge the information and to resume the installation.
5. Select the target drive

Note: All necessary files will be copied in the folder 'Target Drive:\fglvstats'. Please note that the installer will not overwrite existing measurement files and patient data if a V-STATS license is already installed on the target drive.

Important Note: *During use, V-STATS needs read and write access to certain files within the folder 'Target Drive:\fglvstats'. To work with V-STATS, every user needs full access rights to this folder after installation.*

Note: If the installed license has a version prior to 4.01, you must update this version to V-STATS 4.01 first by using the appropriate updater before updating to V-STATS 5.01.1.

Note: If the installed V-STATS license is not registered, you must register the license first before updating to V-STATS 5.01.1. Please access the dialog 'Registration' by using the sub-menu 'Tools/ Register V-STATS' and then follow the instructions provided therein to register the V-STATS license that is installed on your PC.

6. If a V-STATS license is already installed on the target drive:
 - a) the message 'Take over the settings of the present installed version?' pops up. Press 'Yes' to take over the settings. To install V-STATS with factory settings click on 'No'.


Note: During use, it is possible at any time to restore factory settings for all V-STATS and V-CareNeT settings in the dialog 'V-STATS Settings' (see sub-menu 'Settings / V-STATS Settings ...').

Note: We recommend that you do NOT take over the present settings of the already installed V-STATS version when updating to the current V-STATS version.

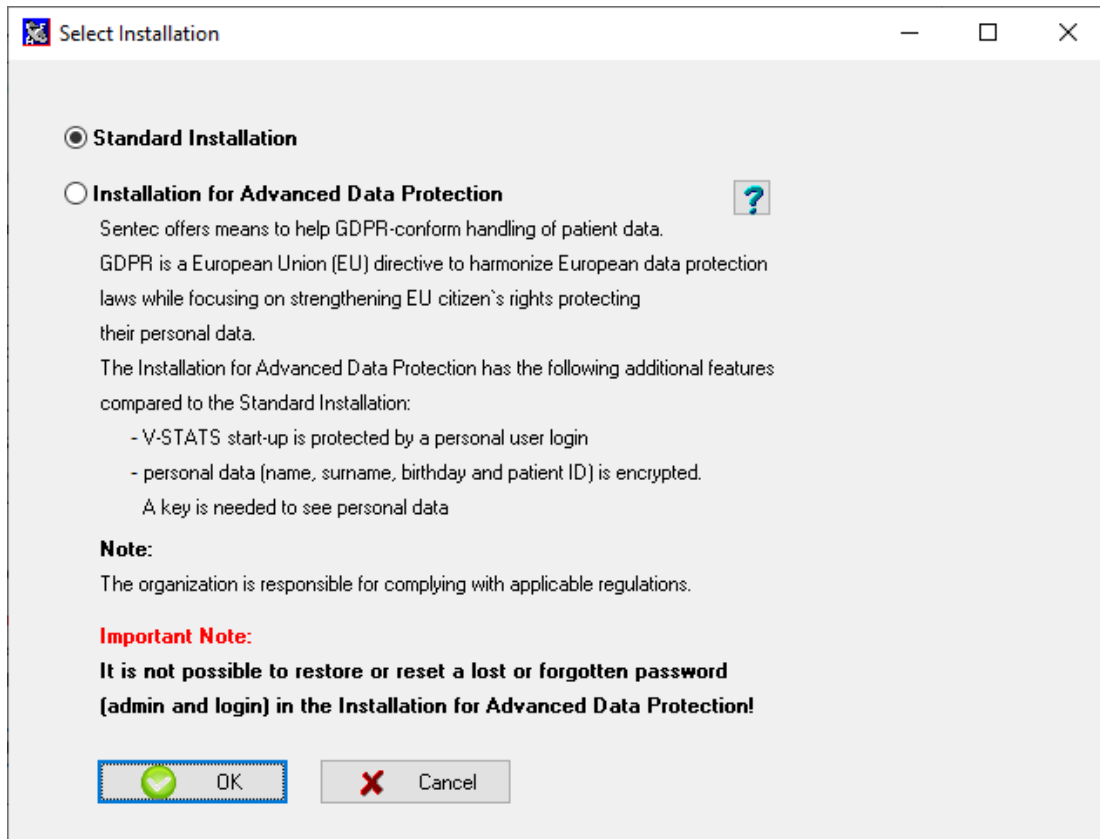
Note: All passwords (admin / login) remain if you do not take over present settings.

- b) An information dialog appears if user-configured SDM Profiles are stored in V-STATS' SDM Profiles Database under the same file name as those SDM Profiles preconfigured by Sentec. These preconfigured profiles will be added during the update, and V-STATS will overwrite the former with the latter. Before overwriting user-configured SDM Profiles, an information dialog window lists all user-configured SDM Profiles that will be overwritten. Therein, check the user-configured SDM Profiles you want to save and click

on 'Yes' to save the selected profiles in a backup folder on the desktop. Click on 'No' if you do not want to save any of the listed profiles. Clicking on 'Cancel' aborts the update.

7. A 'Select Installation' dialog appears, offering two installation types – the 'Standard Installation' or the 'Installation for Advanced Data Protection'. Read the information about the Installation for Advanced Data Protection carefully and click  or refer to [Annex 1: Installation for Advanced Data Protection](#) for more information. Make a selection and click OK.

Note: Check with your local IT department whether you need to use the Installation for Advanced Data Protection.



8. To install example measurements, click on 'Yes' when the message 'Install example measurements in the folder Target Drive:\fg\vstats\daten\examples' prompts.

Note: Before the new/updated example measurements are installed in the folder Target Drive:\fg\vstats\daten\examples, all files stored therein will be deleted.

If you have selected 'Standard Installation' (see step 7.), continue with step 11.

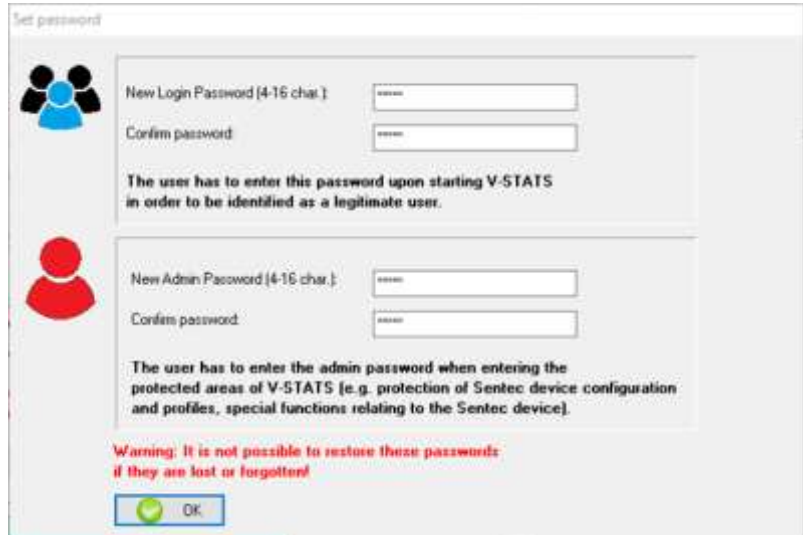
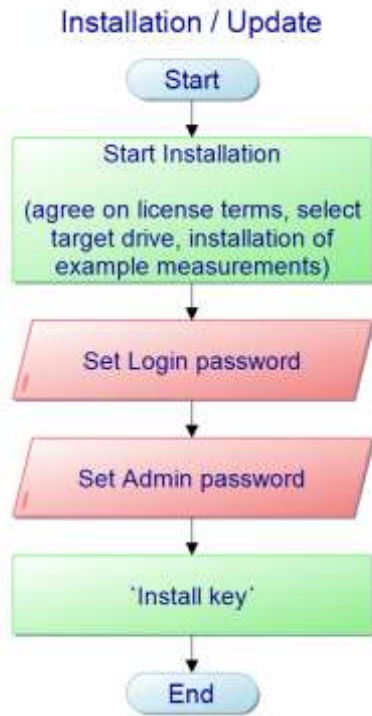
If you have selected 'Installation for Advanced Data Protection' (see step 7.)

- For a **new installation** of V-STATS, proceed with step 9.
- For an **update of an existing V-STATS installation** with activated data protection feature (e.g. V-STATS 4.10.1 or Installation for Advanced Data Protection), continue with step 11 (Existing login and admin password of your previous advanced data protection installation will remain).
- For any **other update**, proceed with step 9.

9. A 'Set Password' dialog displays (This dialog window does not display for 'Standard Installation'). Enter a new Login password and confirm

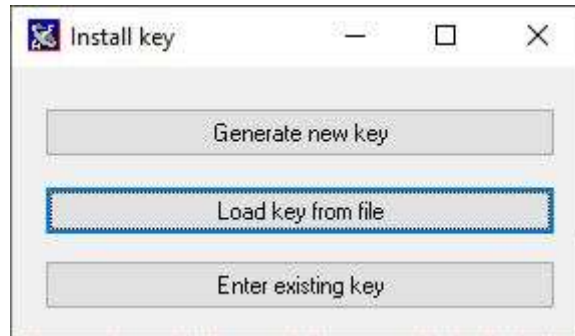
Enter a new Admin password and confirm

For more detailed information regarding passwords refer to [Annex 1: Installation for Advanced Data Protection](#).



Note: Both passwords may be changed at a later stage. However, it is not possible to reset the admin password as in previous V-STATS versions (protection against circumvention of admin password to gain additional admin rights).

10. An 'Install key' dialog displays (This dialog window does not display for 'Standard Installation').



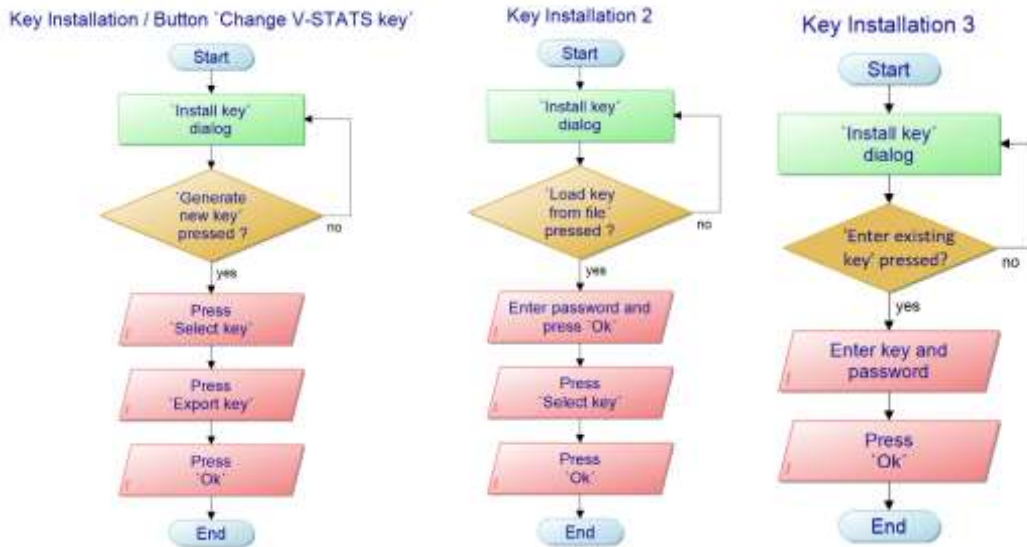
If you do **not** have an existing key available, generate a new unique key for encrypting patient data by following these steps:

- Click 'Generate new key'
- Click 'Export key' to save the unique key locally (backup function)



- Click 'OK'

Alternatively, an existing key may be loaded from a file ('Load key from file') or entered manually ('Enter existing key'). Decryption of encrypted data is only possible if the key used for encryption is currently active.



Note: If a key already exists, you will not be asked to generate/upload or enter a key. Your existing key will be used and stored in V-STATS automatically.

Note: During installation or update, V-STATS does not automatically encrypt personal data of existing measurements.

Note: Ensure to save the key in a secure storage location.

- To create a shortcut to your desktop, click 'Yes' when the message 'Create a link to your desktop' prompts.

Note: Regardless of your selection, the installer will add a shortcut to the start menu. Administrator rights are required to create both the desktop link and Windows start menu shortcut. Provide Administrator rights by confirming the "V-STATS Setup Administrator Process" which opens in a pop up window.

Once the **Installation/update** is completed, the information message 'Installation successful' appears.

If the update was successful, a PDF file summarizing the most important new features and modifications included in V-STATS 5.01.1 appears.

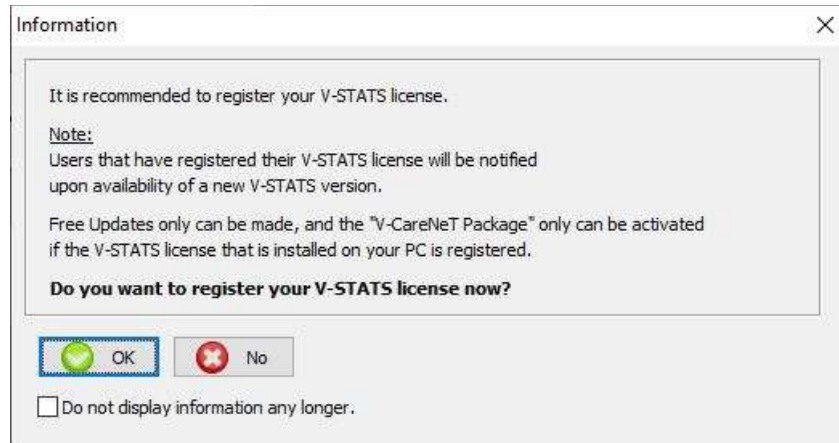
If a previously installed V-STATS license was registered, the **installation** of V-STATS is finished at this stage. If no V-STATS license was previously installed or if a previously installed license was not registered, the installer will automatically start V-STATS and display the dialog 'Settings for the communication with the SDM'.



Select the appropriate COM port

Note: During use of V-STATS, you can change the COM port at any time in the dialog 'Communication with Sentec device (via Serial Interface)'.

Finally, the installer will automatically display the following license information dialog:



Sentec AG recommends that you register your V-STATS license, as registered users are notified about new V-STATS versions. Furthermore, you may only receive free updates and activate the 'V-CareNeT Package' if the V-STATS license installed on your PC is registered.

12. Click 'OK' to open the dialog 'Registration'.
13. Click 'No' to close the information dialog without activating the registration process.

Note: As long as your V-STATS license is not registered, the license registration information dialog will automatically reappear after starting V-STATS 10-times. Check the respective box if you do not want this information to appear any longer.

Note: As long as your V-STATS license is not registered, you can access the dialog 'Registration' via the sub-menu 'Tools / Register V-STATS ...' at any time.

3.4 Printer Selection

V-STATS allows the printout of various items such as reports (see 7.2) or SDM Profiles (see 7.10 and 13.2), on most ink jet, laser, or matrix printers that are installed under Windows. Select your printer in the print dialog window that opens when initiating a print job.

Note: If a PDF-printer is installed on the PC these items can be printed into a PDF-file.

Note: Reports, related measurement curves and various other items can be stored as a PDF (even if no PDF-printer is installed on the PC).

3.5 How to activate the V-CareNeT Package

This requires V-STATS 3.00 or higher. To activate the V-CareNeT Package for the desired number of beds/ patients the installed V-STATS license must be registered and you need a 'V-CareNeT Package Registration Code' (CPRC) for the corresponding number of beds/ patients.* Once you have received the respective CPRC you must generate the corresponding 'V-CareNeT Package Activation Code' (CPAC) on the website registration.sentec.com/vstats_CPAC.html. To activate the V-CareNeT Package you finally must enter the CPAC within V-STATS into the appropriate field of the dialog 'V-CareNeT Package Activation' (see 15.2).

*To purchase a CPRC, please contact your local Sentec representative or Sentec (info@sentec.com / www.sentec.com). CPRCs are available for 5, 10, 20, 30, or 40 beds/ patients or upon request for a customized number of up to 40 beds/patients.

Note: V-CareNeT evaluates the size/resolution of the central station's screen and limits the number of bed/ patients simultaneously available for remote monitoring to ensure that the 'V-CareNeT Control Window' and all active stations (remote monitoring windows) are fully visible and can be arranged without overlapping each other. For example, remote monitoring of 40 beds/ patients requires a screen size/ resolution of approx. 2560 x 1440 (approx. 1024 x 768 for 5 beds/ patients, 1152 x 864 for 10 beds/ patients, 1600 x 1024 for 20 beds/ patients, 1920 x 1200 for 30 beds/ patients). Smaller screen sizes/ resolutions support fewer beds/ patients, regardless of the CPRC that was used to activate the 'V-CareNeT Package'.

Note: It is at any time possible to upgrade an activated V-CareNeT Package to a higher number of beds/ patients (see 16.6.1).

3.6 V-CareNeT Trial

This requires V-STATS 3.00 or higher. If the installed V-STATS license is registered it is possible to test V-CareNeT for free. To initiate the V-CareNeT Trial use the menu 'Tools / V-CareNeT Trial' (see [15.3](#)). The trial duration is 30 minutes. The 'V-CareNeT Trial' can be (re)activated an unlimited number of times (after restarting V-STATS).

Note: During a 'V-CareNeT Trial', download of SDM Trend Data via the network is not supported; otherwise, V-CareNeT is fully functional.

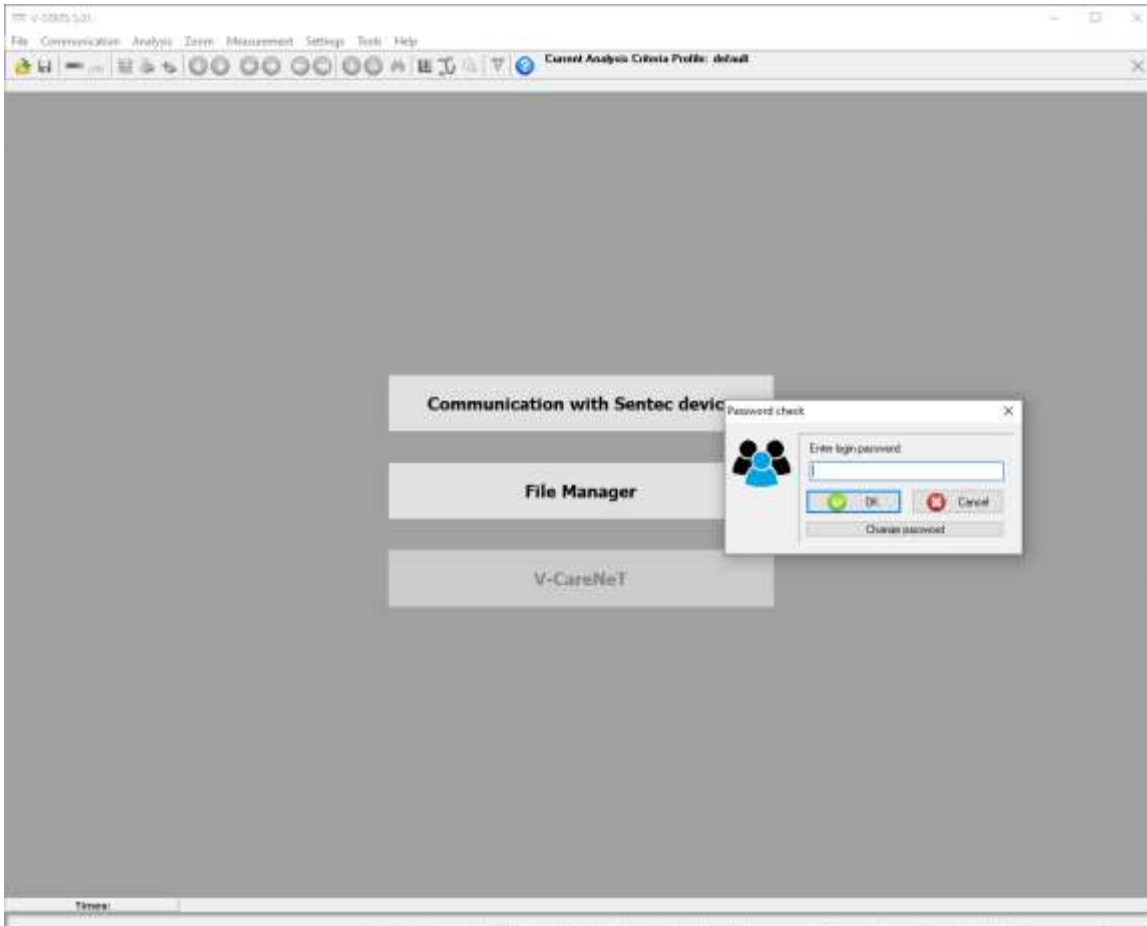
3.7 Extended V-CareNeT Trial

This requires V-STATS 3.01 or higher. If the installed V-STATS license is registered, it is possible to activate an Extended V-CareNeT Trial. To initiate the Extended V-CareNeT Trial, use the menu 'Tools / Extended V-CareNeT Trial' (see [15.4](#)). The trial duration is ten days and is limited to a period of up to four weeks. An 'Extended V-CareNeT Trial' can only be activated once.

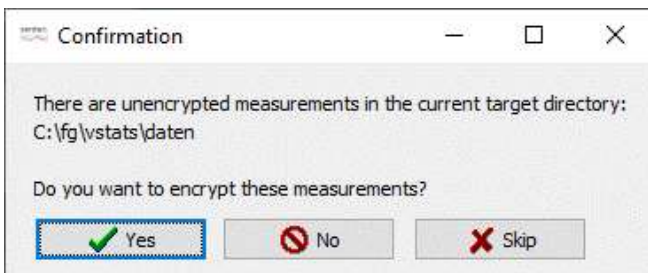
Note: V-CareNeT is fully functional during an 'Extended V-CareNeT Trial'.

4. 'Main Window' of V-STATS

When starting-up V-STATS a login password has to be entered first if Installation for Advanced Data Protection has been installed.



After entering the login password, a dialog opens only if unencrypted measurements are available in the current target directory.



It asks if the unencrypted measurements shall be encrypted. Clicking 'Yes' opens the file manager with the unencrypted measurement. The dialog will open with each start up of V-STATS when clicking 'Skip' and will never pop up again when clicking 'No' (regardless of whether there are unencrypted measurements in the File Manager).

The 'Main Window' of V-STATS displays

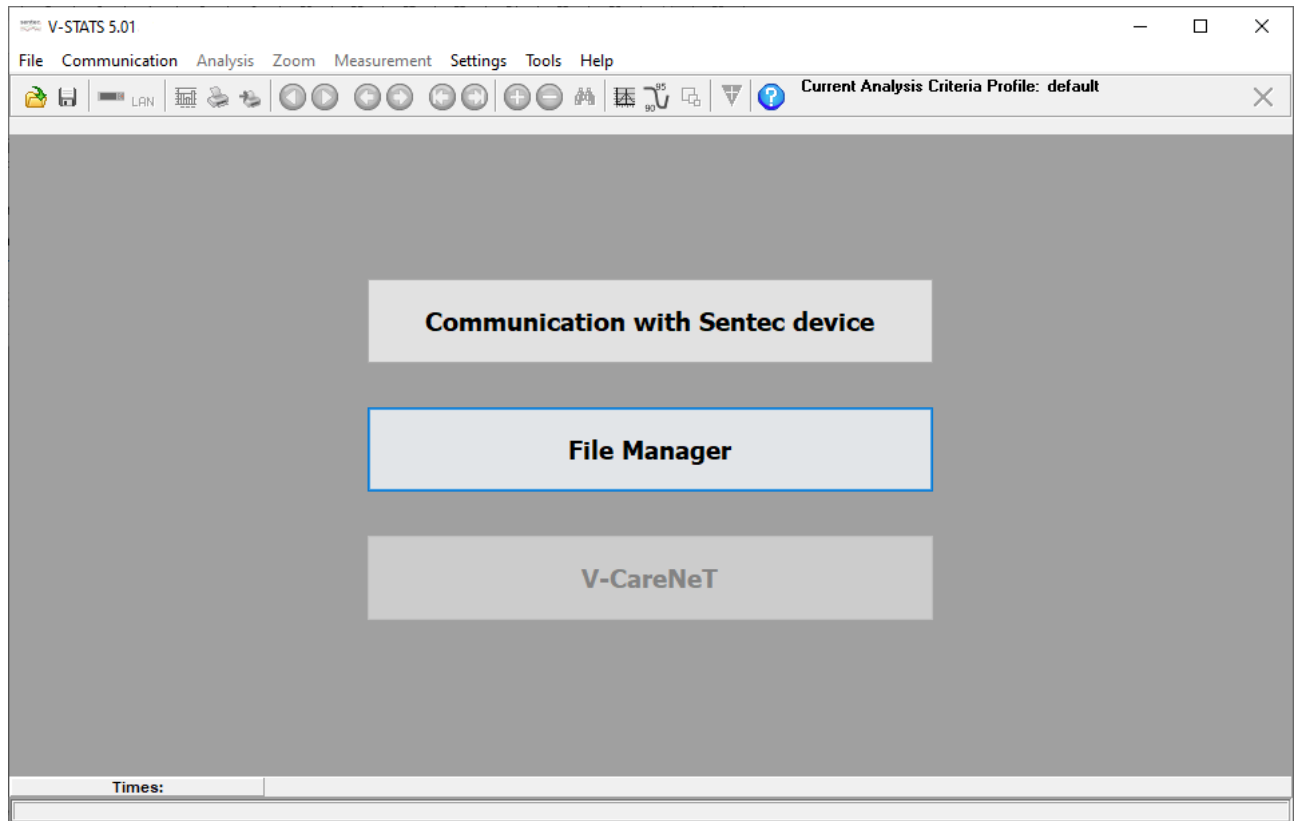
- after starting-up V-STATS
- after closing V-CareNeT (see 14.5) or
- after bringing the 'Main Window' of V-STATS temporarily to the front while V-CareNeT is active.

If no measurement is open the 'Main Window' features three buttons in the center which provide quick access to the main functions of V-STATS (see 4.1). If a measurement is open the 'Main Window' displays the trend data of the respective measurement along with the most important statistical results for the current 'Analysis Interval' (see 4.2).

4.1 The 'Main Window' of V-STATS if no measurement is open (start-up window)


If no measurement is open the 'Main Window' of V-STATS features

- three buttons in the center which provide quick access to the main functions of V-STATS and
- a menu bar with pull-down menus and control icons in the top



Button 'Communication with Sentec device (serial)': Clicking on this button opens the dialog 'Communication with Sentec device (via Serial Interface)' (see 8.1) which gives access to the functions a) to download SDM Trend Data from the internal memory of the connected SDM (see 6), b) to clear the internal memory of the connected SDM, c) to set the 'Date & Time' of the connected SDM to the 'Date & Time' of the PC, d) to configure profiles and settings of the connected SDM (see 13), and e) to functions that are helpful for troubleshooting ('Full Memory Dump', 'Raw Dump', 'Screenshots', and 'SDM Factory Reset').

Note: If the mouse is hovered over this button the text 'Trend Data Download from SDM / Configuration of the SDM (Profiles / SDM Settings)' appears in a tool tip.

Note: This button duplicates the sub-menu 'Communication / with SDM (via Serial Interface)' (see 8.1) as well as the control icon  in the menu bar of the 'Main Window' (see 4.2.1).

Button 'File Manager': Clicking on this button opens the dialog 'File Manager' which provides access to all measurements stored in the 'Target Folder of the File Manager' (see 7.1). Measurements stored in other folders of the PC's file system to which the current user has read/write permission can be accessed as well. This also includes folders that are located on a server of your institutions network. Selecting and opening a measurement will display the respective trend data in the 'Main Window' of V-STATS (see 4.2).

Note: The 'Target Folder of the File Manager' can be configured in the dialog 'V-STATS Settings' (see 12.1).

Note: If the mouse hovers over this button, the text 'Viewing, analyzing, printing of SDM Trend Data' appears in a tool tip.


Note: This button duplicates the sub-menu 'File / File Manager' (see 7.1) as well as the control icon  in the menu bar of the 'Main Window' (see 4.2.1).

Button 'V-CareNeT': Clicking on this button first opens a dialog which offers the possibility to edit/ reactivate the 'Last V-CareNeT Session' (see 14.4.1) and then activates V-CareNeT by opening the V-CareNeT Main Screen with the 'V-CareNeT Control Window' in the upper right or left (see 12.2, 14.4).

Note: As long as the 'V-CareNeT Package' has not been activated, this button is not accessible (dimmed grey).

Refer to the sub-menu 'Tools / V-CareNeT Package Activation' (see 15.2) to activate the 'V-CareNeT Package'. For a trial activation of V-CareNeT, please refer to the sub-menu 'Tools / V-CareNeT Trial' (see 15.3) or the sub-menu 'Tools / Extended V-CareNeT Trial' (see 15.4). Use the sub-menu 'Settings / V-CareNeT Demo Mode' (see 12.3) to use V-CareNeT in Demo Mode.

Note: If the mouse hovers over this button, the text 'Remote Monitoring and secondary alarm surveillance of SDMs' appears in a tool tip.

Note: This button duplicates the sub-menu 'Communication / V-CareNeT' (see 8.2) as well as the control icon  in the menu bar of the 'Main Window' (see 4.2.1).

Menu Bar: A menu bar with pull-down menus (see 7, 8, 9, 10, 11, 12, 15, and 16) and control icons (see 4.2.1) is displayed in the top of the 'Main Window'. On the left of the 'Help Icon', furthermore, the 'Analysis Criteria Profile Indicator' is displayed in bold, black the name of the currently selected 'Analysis Criteria Profile' (see 9.2).

Note: If no measurement is open, a left click on the 'Analysis Criteria Profile Indicator' in the V-STATS' Main Window opens a popup menu offering the possibility to select a different 'Analysis Criteria Profile' from the 'Analysis Criteria Profiles Database' (see 9.2).

4.2 The 'Main Window' of V-STATS if a measurement is open

If a measurement is open, the 'Main Window' of V-STATS

- displays the trend data of the respective measurement along with the most important statistical results for the current 'Analysis Interval'
- features a menu bar with pull-down menus (see 7, 8, 9, 10, 11, 12, 15, and 16) and control icons (see 4.2.1).

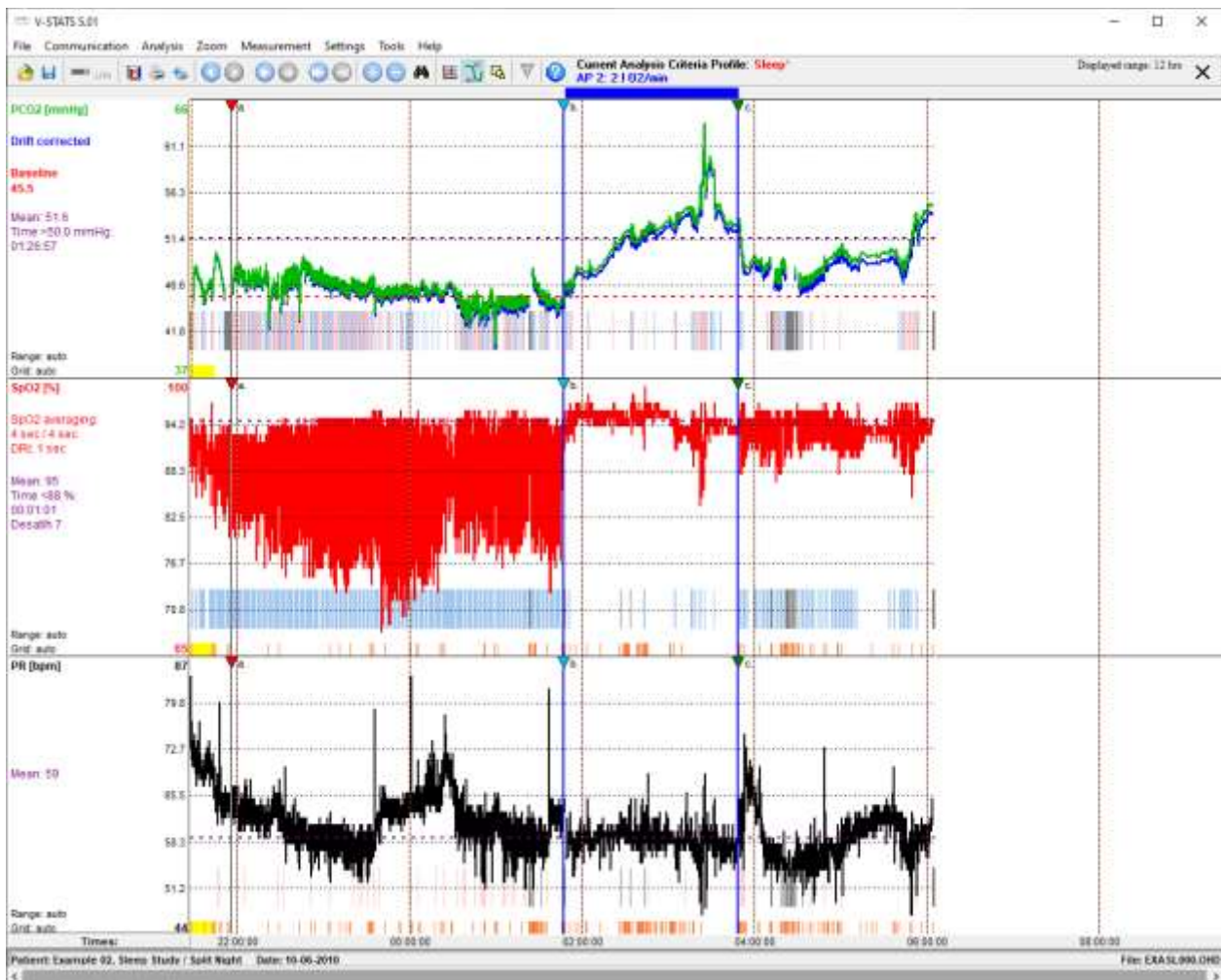
The following elements are provided in the 'Main Window' of V-STATS

- 1) **Trend Data Curves / Patient Name / File Name:** For each channel the measurement data are displayed versus the time. The channels are labeled on the left along with the unit of the respective parameter. The unique key or the name of the corresponding patient as well as the recording date and filename of the displayed measurement are indicated at the bottom of the 'Main Window'. A click on the patient name in the lower left corner of the window opens the dialog 'Patient Data' (see 11.3).

Note: For each channel a) the 'Parameter Label', b) the color used for the 'Parameter Label' and the respective curve as well as c) the background of the channel can be defined in the dialog 'Channel Settings' (see 12.1.1). The unit used for PCO₂/PO₂ (mmHg or kPa) can be selected in the dialog 'V-STATS Settings' (see 12.1).

Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.

- 2) **Analysis Criteria Profile Indicator:** On the left of the 'Help Icon' the 'Analysis Criteria Profile Indicator' - a bold, black label in the control icon panel - indicates the profile name of the currently selected 'Analysis Criteria Profile' (see 9.2). If the settings of the currently selected 'Analysis Criteria Profile' and those that were last used to analyze the open measurement are identical the profile name is displayed in **black**, otherwise (i.e. if the open measurement has not yet been analyzed with the currently selected 'Analysis Criteria Profile') in **red** with an asterisk (*). Left click on the 'Analysis Criteria Profile Indicator' opens a pop-up menu (see 9.1) offering the possibility a) to select and then analyze the open measurement with a different 'Analysis Criteria Profile' (see 9.2) or b) to re-analyze all or individual channels of the open measurement with the currently selected 'Analysis Criteria Profile' (options dimmed grey if the settings that were last used to analyze the respective channel are identical with those of the currently selected 'Analysis Criteria Profile').



Note: 'Analysis Criteria Profiles' can be selected, created/ customized, and managed in the dialog 'Analysis Criteria Profile' (see 9.2). To open this dialog use a) the sub-menu 'Analysis / Analysis Criteria Profile' if a measurement is open (see 9.2) or b) the sub-menu 'File / Analysis Criteria Profile' if no measurement is open (see 7.14). It is recommended to create/ customize 'Analysis Criteria Profiles' if no measurement is open.

Note: Once you have created your own 'Analysis Criteria Profiles' you can switch between them with the ease of a few 'mouse-clicks', for example, a) before activating download/ import of SDM Trend Data to V-STATS in the dialog 'Assign measurement period(s) to patients' (see 6.1) or b) to re-analyze the currently open measurement with a different 'Analysis Criteria Profiles' (see above).

Note: When saving a measurement (see 7.2), the settings last used to analyze the measurement are saved along with the measurement, the name of the corresponding 'Analysis Criteria Profile', however, is not saved.

Note: Opening a previously analyzed measurement (see 7.1) neither does activate the 'Analysis Criteria Profile' that was last used to analyze the measurement nor is the measurement automatically re-analyzed with the currently selected 'Analysis Criteria Profile'. After opening a measurement, the name of the current 'Analysis Criteria Profile', consequently, will display in **black**, if the settings that were last used to analyze the respective measurement and those of the currently selected 'Analysis Criteria Profile' are identical, otherwise it will display in **red** with an asterisk (*).

- 3) **Analysis Interval Indicator:** The 'Analysis Interval Indicator' - a blue, bold label displaying on the right of the 'Help Icon' in the control icon panel - indicates the current Analysis Interval, i.e. the measurement's time range that is currently considered for data analysis (see 9.2, 9.5). In the example shown above it indicates 'AP 2: 21 O₂/min'. The current Analysis Interval is visualized by a blue bar above the measurement curves and two blue vertical lines at the start and end of the Analysis Interval, respectively. It can be selected/changed a) in the popup-menu which opens after left click on the 'Analysis Interval Indicator', b) by using the sub-menu 'Analysis / Analysis Interval' (see 9.3), or c) by selecting the option 'Analysis Period' which is selectable in the popup menu that activates after right click on an operator event triangle, if at the position of the respective operator event a new 'Analysis Period' starts (see 11.1).

The 'Analysis Interval Indicator' displays

- a) 'Full Measurement' if the Analysis Interval corresponds to the full measurement
- b) 'AP x: <description>' if the Analysis Interval corresponds to an Analysis Period which starts at one of the Operator Events and where x is the number of the Analysis Period (see 11.1), or '<Start-Date/Time>-<End-Date/Time>' if the Analysis Interval was determined by using the options 'Displayed Range' or 'Manually'.
- 4) **Displayed range:** Indicates the displayed time range at the top right in hh:mm:ss. Section 10 (menu 'Zoom') describes how the displayed time range can be modified. Scrolling through the measurement is explained in 4.2.2.
- 5) **Time Axis and Vertical Grid:** The time axis (x-axis) is displayed below the measurement channels. Left mouse click on the time axis opens the dialog 'Vertical Grid' where it is possible to select the mode that will be used for the vertical grid and the time scale. Note that this selection will affect all measurements. If 'In relation to time of day' is selected, the equispaced vertical grid lines are plotted such that the time scale indicated at the bottom of the vertical grid lines corresponds - depending on the displayed time range - to full hours, full half-hours, full quarter-hours, full minutes, etc... If 'In relation to measurement begin' is selected, the start and end time are considered as vertical grid lines as well. Consequently, the time scale indicated at the bottom of the equispaced vertical grid lines is in relation to the time of the measurement begin.
- 6) **Range & Grid:** For each channel the mode currently active for the display range (y-axis) and for the horizontal grid is indicated at the bottom left of the respective channel. Mouse click on the area highlighted yellow in figure below (display range & horizontal grid indicator / y-axis) opens for the respective channel the dialog '<Channel>: Range & Horizontal grid' (see 11.9). In this dialog it is possible to adjust for the currently open measurement and the selected channel the display range (y-axis) and horizontal grid settings.



Note: The display range (y-axis) and horizontal grid settings that will be used by default when downloading/importing SDM Trend Data to V-STATS can be predefined for each channel in the dialog 'Channel Settings' (see 12.1.1).

Note: If 'Autoscale' is used for the display range of a channel, the respective channels display range is determined based on valid, non-excluded data within the current 'Analysis Interval'. Furthermore, if drift corrected PCO2 data is displayed the display range of the PCO2 channel is determined using drift corrected PCO2 data if 'Autoscale' is used for the display range (y-axis) of the PCO2 Channel.

- 7) **Correction of Residual PCO2 Drift:** If the sub-menu 'Measurement / Correction of Residual PCO2 Drift' (see 11.6) is set to 'Both', drift corrected PCO2 data is displayed as a blue curve in addition to the green curve of the uncorrected data. If set to 'On' only the blue curve representing drift corrected PCO2 data is displayed.

Note: The drift correction mode that will be used by default when downloading/importing SDM Trend Data to V-STATS can be predefined in the dialog 'Channel Settings' (see 12.1.1). For an open measurement, the drift correction mode subsequently can be changed by using the sub-menu 'Measurement / Correction of Residual PCO2 Drift' (see 11.6). If for a measurement correction of the residual PCO2 drift is not possible the PCO2 drift correction mode is automatically set to 'Off' for the respective measurement. If for a measurement uncorrected PCO2 data is not available (e.g. after import of a '*.vex-file' which contains only drift corrected PCO2 data (see 7.4 and 7.5)), the PCO2 drift correction mode is automatically set to 'On' for the respective measurement.

Note: Whenever drift corrected PCO2 data is displayed the text 'Drift corrected' is displayed in blue below the PCO2 label. Statistical results for PCO2 are determined using drift corrected PCO2 data. If 'Autoscale' is used for the display range (y-axis) of a TC channel, the display range of the PCO2 channel is determined using drift corrected data.

Note: The color used for the PCO2 label and for the curve representing uncorrected PCO2 data can be selected in the dialog 'Channel Settings' (see 12.1.1). The default color for these PCO2 elements is green.

Note: If both uncorrected PCO2 data and drift corrected PCO2 data are displayed, the blue curve representing

drift corrected PCO2 data is displayed in the background of the green curve representing uncorrected PCO2 data.

*Note: Print-out of uncorrected PCO2 data and drift corrected PCO2 data is made with different fonts to ensure that the two curves can be distinguished if printing is made on a black&white printer. The 'drift corrected' curve is printed in **black, bold** font whereas the uncorrected curve is printed in light, grey font.*

- 8) **PCO2 Baseline/PO2 Baseline:** The PCO2 (PO2) baseline (see 11.5, 11.7) is shown in the PCO2 (PO2) channel as a red-dashed horizontal line. A red vertical line indicates the instant at which the PCO2 (PO2) baseline was determined. The numerical value of the PCO2 (PO2) baseline is displayed in red, bold on the left of the PCO2 (PO2) graph. If drift corrected PCO2 data are displayed, the PCO2 baseline is determined using drift corrected PCO2 data (see 11.6).
- 9) **SpO2 Averaging / DRI:** 'SpO2 Averaging' on the left of the SpO2 graph indicates the minimal and maximal setting of the SDM internal parameter 'SpO2 Averaging' (see 13.2.4.6). The minimal and maximal values only differ if the parameter 'SpO2 Averaging' was changed while recording the currently displayed measurement. Note that the longer the averaging time the slower the SDM's response to changes in patient's oxygen saturation. 'DRI' on the left of the SpO2 graph indicates the Data Recording Interval that was used while recording the currently displayed measurement. DRI can vary between 1 sec and 8 sec. (for additional details refer to 13.2.4.6 and to the Technical Manual of the SDM (HB-005752)).
- 10) **Important Statistical Results:** For each channel important statistical results are indicated in purple for the current 'Analysis Interval'. The 'mean' is indicated for all channels. Additionally, 'Time >XX.X mmHg' for PCO2 as well as 'Time <YY%' and 'Desaturations per hour' for SpO2 are indicated. In each channel the mean of the respective parameter is furthermore displayed as a purple-dashed horizontal line. If drift corrected PCO2 data is displayed, statistical results for PCO2 are determined using drift corrected PCO2 data (see 11.6).

Note: The levels XX.X and YY used for 'Time <YY%' (default=88%) and 'Time >XX.X mmHg' (default=50.0mmHg) are adjustable in the dialog 'Analysis Criteria Profile' (see 9.2).

Important Note: Episodes with excluded data ranges (see 9.4), artifacts, and invalid data will be excluded from statistical data analysis. Furthermore, episodes with certain SDM events optionally can be excluded from statistical data analysis (see 4.2.5, 9.2). Unless otherwise specified for each channel all statistical results, therefore, are based on evaluation of the analyzed duration, i.e. the artifact free part of valid, non-excluded measurement data contained within the current 'Analysis Interval'.

- 11) **Cursor/ numerical values at cursor position/ dB values for PCO2 and PO2:** The Cursor (if set) is a bold, orange, vertical line running from the top to the bottom of the graphs. The time corresponding to the cursor position is indicated in the upper menu bar below the label 'Displayed range'. The numeric values displayed below each channel label correspond to the value of the respective parameter at the cursor position. Next to the numeric PCO2 (PO2) value the delta-baseline (dB) value is displayed in brackets. This corresponds to the difference of the PCO2 (PO2) value at the cursor position from the PCO2 (PO2) baseline (see 11.5, 11.7). See 4.2.3 for additional information on the cursor and its usage.

Note: If drift corrected PCO2 data is displayed, a) the value of the drift corrected PCO2 curve at the cursor position is displayed in blue below the blue colored label 'Drift corrected', and b) the dB value for PCO2 is only displayed for drift corrected PCO2 data.

Note: The dB value for PCO2 (PO2) (see above) is only displayed if the cursor is set after the point the respective PCO2 (PO2) baseline was determined (visualized by a red vertical line).

- 12) **Markers:** Markers highlight a) physiological events for PCO2, SpO2, and PR evaluated by V-STATS by using adjustable analysis criteria (see 9.2, 9.5.12), b) SDM events (see 9.2), c) artifacts evaluated by V-STATS (see 9.2, 9.5.12) or manually marked by the operator (see 4.2.4), d) ranges with invalid data, and e) 'Excluded data ranges' (see 9.4). Markers related to physiological events, artifacts or 'Excluded Data Ranges' can be edited (see 4.2.6, 12.1.2). In particular, right mouse click on one of these markers activates a popup menu permitting, for example, to reclassify or delete the selected marker (see 4.2.4).

Note: To maintain lucidity in the graphs, physiological event markers are only displayed for the selected event types (dynamic events: baseline events (for PCO2 only); threshold events). The type of events that will be visualized for a channel can be changed in the dialog 'Analysis Criteria Profile' (see 9.2) or in the pop-up menu that opens after right click on the respective channel's measurement curve (see 4.2.4).

Note: Automatically detected as well as manually marked artifacts (see 4.2.4) are independent from the type of physiological event (dynamic events: baseline events (for PCO2 only); threshold events) that is currently selected to be visualized with colored event markers.

Note: If the mouse is hovered over a marker a tooltip appears with information about the respective marker (see 4.2.4, 4.2.6). Furthermore, markers are labeled for displayed time ranges up to 30 minutes (see 4.2.5).

Note: Markers exhibiting a black triangle in the upper left corner identify physiological events or artifacts that have been manually modified (added, reclassified, modified duration). In the tooltip that appears when the mouse is hovered over a modified physiological event or artifact marker 'M' is added behind the event description to

indicate that the marker was manually modified. '(A)' is added behind the event description if the mouse is hovered over an unmodified marker.

Note: SDM Event Markers are displayed separately from the other markers at the bottom edge of the channels. The color of SDM Event Markers can be selected in the dialog 'Color of Markers' (see 12.1.2), their size is not affected by the setting of the control icon 'Marker Size' (see 4.2.1). SDM Event Markers being related to SDM Events that are excluded from data analysis (see 9.2) are duplicated by 'Invalid Data Markers', i.e. corresponding episodes are not evaluated during data analysis.

Note: If a certain period of the measurement contains more than one colored marker, markers are displayed in V-STATS 'Main Window' with the following priority, i.e. always the marker with the highest priority is displayed: 1) Excluded Data Range markers, 2) Invalid Data markers, 3) Artifact markers, and 4) Physiological event markers.

- 13) **Operator Events / Analysis Periods:** Colored triangles (if any) represent Operator Events (see 11.1). Operator Events typically are marked on the SDM during patient monitoring by using a) the respective functions of the SDM's 'Quick Access Menu' or b) the dialog 'Set Operator Events' within V-CareNeT (see 14.8.3) and subsequently transferred to V-STATS when downloading SDM Trend Data. To unequivocally identify 'Operator Events' within V-STATS the colored triangles as well as the corresponding 'Operator Events' in the list of operator events are alphabetically labeled in chronological order of their occurrence. If the mouse is hovered over a colored operator event triangle a tooltip providing information on the respective 'Operator Event' appears (see 4.2.7). The triangle color associated to a specific event type can be defined in the dialog 'Define Operator Events' (see 12.1.3). By selecting the start of a new 'Analysis Period' at the position of 'Operator Events' it is possible to split a measurement into multiple 'Analysis Periods'. A grey vertical line at the position of an 'Operator Event' represents the start of new Analysis Period. If a measurement is split into multiple 'Analysis Periods' (e.g. to analyze the different phases of a split night) the current 'Analysis Interval' can be set to one 'Analysis Period' after another, i.e. a report conveniently can be generated/printed for each 'Analysis Period'.

Note: For the currently open measurement 'Operator Events' and/or 'Analysis Periods' can be edited/added/deleted at any time (see 4.2.1, 4.2.7, 11.1, and 11.2).

Note: If the current 'Analysis Interval' starts/ends at the beginnings of two new 'Analysis Periods' the grey vertical lines at the position of the respective 'Operator Events' are in the background of the two blue vertical lines indicating the start and end of the current 'Analysis Interval'.




Note: In the example shown above the measurement is split into 4 'Analysis Periods': 'Analysis Period 0' (AP0) corresponds to the Initial Phase (from the beginning to the first grey line), during 'Analysis Period 1' (AP1) the patient was breathing room air (from the first to the second grey line), during 'Analysis Period 2' (AP2) two liters of oxygen were administered (from the second to the third grey line), and during 'Analysis Period 3' (AP3) one liter of oxygen was administered (from third grey line to end). Please note that in the example shown above 'Analysis Period 2' (AP 2: 2l O₂/min) is selected as 'Analysis Interval' and, consequently, the second and third grey lines are hidden by the two vertical blue lines indicating the start and end of the 'Analysis Interval'.


















Note: In the dialog 'Define Operator Events' (see 12.1.3) a) the standard description that will be assigned to operator events of a specific type and b) whether or not a new 'Analysis Period' shall start at each occurrence of operator events of a specific type when downloading/importing SDM Trend Data to V-STATS can be predefined for each operator event type. The dialog 'Define Operator Events' can be printed such that its printout can be used as a caption for the operator event types available in the 'Quick Access Menu' of SDM's with software SMB-SW V07.01.x and newer.



- 14) **'Remote Monitoring Active' Indicator:** If at least one patient is admitted to V-CareNeT, the red blinking indicator 'Remote Monitoring active' displays at the bottom center of the 'Main Window'.

4.2.1 Control icons in the menu bar of the 'Main Window'

Note: The control icons 'File Manager', 'Communication with Sentec device (via Serial Interface)', 'V-CareNeT', and 'Help' are always operable. All other control icons are only operable if a measurement is open.

Symbol	Designation (Tool tip)	Description
	File Manager	Opens the 'File manager' (see 7.1).
	Save	Saves changes made to measurement file (see 7.2) <i>Note:</i> Dimmed grey if no changes were made since the measurement was opened or last saved.
	Communication with Sentec device (via	Activates the dialog 'Communication with Sentec device (via Serial Interface)' (see 8.1).

Symbol	Designation (Tool tip)	Description
	Serial Interface)	
	V-CareNeT	Opens a dialog which offers the possibility to edit/ reactivate the 'Last V-CareNeT Session' (see 14.4.1) and then activates V-CareNeT by opening the V-CareNeT Main Screen with the 'V-CareNeT Control Window' in the upper right or left (see 12.2, 14.4). <i>Note: As long as the 'V-CareNeT Package' has not been activated this button is not accessible (dimmed grey). Refer to 15.2 to activate the 'V-CareNeT Package'. For a trial or extended trial activation of V-CareNeT please refer to 15.3 and 15.4. To use V-CareNeT in Demo Mode refer to 12.3.</i>
	Report	Opens the report (see 9.5) for the current 'Analysis Interval' (see 9.3).
	Print Report / PDF Report	Opens the dialog 'Print Report / PDF Report' (see 7.2). Here it is possible to print the report or to store the report as a PDF.
	Print Screenshot	Prints the currently displayed range of the measurement curves. <i>Note: The default printer of your PC will be used.</i>
	Show previous half of the screen	Scrolls half a page to the left (backwards) – see 4.2.2.
	Show next half of the screen	Scrolls half a page to the right (forward) – see 4.2.2.
	Show previous screen	Scrolls one page to the left (backwards) – see 4.2.2.
	Show next screen	Scrolls one page to the right (forwards) – see 4.2.2.
	Move to the beginning	Scrolls to the beginning of the measurement – see 4.2.2.
	Move to the end	Scrolls to the end of the measurement – see 4.2.2.
	Zoom in	Magnifies the displayed time range by one zoom-level – see 10.
	Zoom out	Reduces the displayed time range by one zoom-level – see 10.
	Full Study	Selects the smallest zoom level that contains the full (complete) measurement curves – see 10.
	Vertical Cursor	To activate/deactivate the display of the 'Vertical Cursor' (<i>Note: not activated in factory default settings</i>). If activated, black cross-lines move with the mouse. For the channel in which the mouse is currently positioned the following information appears in a box: <ul style="list-style-type: none"> – Channel: displays the label of the channel in which the mouse is currently positioned. – Time: indicates the time at the current mouse position – Value Curve: indicates the value of the parameter displayed in the respective channel at the current mouse position (<i>Note: the drift corrected PCO2 value displays in parenthesis behind the uncorrected value if the uncorrected and drift corrected PCO2 curves are displayed</i>).
	Numeric values in curve	To activate/deactivate the display of 'Numeric values in curve' (<i>Note: activated in factory default settings</i>) If activated, numeric values of local minima and/or maxima in the curves will display if the 'Displayed Time Range' is smaller or equal to 1 hour.
	Marker size	Changes the marker size. <i>Note: The size of the markers related to SDM Events is not affected by the setting of this parameter.</i>
	Add Operator Event	To add an Operator Event at the current cursor position. Clicking on this icon opens the dialog 'Edit/Add Operator Event' (see 11.2). The date/time which will be proposed for the new operator event corresponds to the date/time at the cursor position.

Symbol	Designation (Tool tip)	Description
		<p><i>Note: This control icon is only accessible if the cursor (see 4.2.3) is placed on a measurement.</i></p> <p><i>Note: Optionally, the start of a new Analysis Period can also be added by checking the respective box in the dialog 'Edit/Add Operator Event'.</i></p>
	Help	Click on this icon to open the context-sensitive on-line help.
	Analysis Criteria Profile Indicator	<p>The currently selected 'Analysis Criteria Profile' (see 9.2) is displayed in bold black on the left of the 'Help Icon'. If the settings of the currently selected 'Analysis Criteria Profile' and those that were last used to analyze the open measurement are <u>identical</u>, the profile name is displayed in black, otherwise in red with an asterisk (*).</p> <p>Left click on the 'Analysis Criteria Profile Indicator' opens a pop-up menu offering the possibility a) to select/ analyze the open measurement with a different 'Analysis Criteria Profile' or b) to re-analyze all/ individual channels of the open measurement with the currently selected 'Analysis Criteria Profile' (for details refer to the description of an equivalent popup-menu in 9.1).</p>
	Analysis Interval Indicator	The current 'Analysis Interval' is indicated by the 'Analysis Interval Indicator', a blue, bold label displaying in the upper menu bar on the right of the 'Help Icon'. It can be selected/changed in the popup-menu which opens after right click on the 'Analysis Interval Indicator' (see 9.3).
	Close	<p>Click on this icon to close the open measurement.</p> <p><i>Note: Upon closure of a measurement that contains unsaved changes, VSTATS prompts the messages "Do you want to save changes? Yes/ No/ Cancel".</i></p> <p><i>Note: When attempting to close a measurement that has been opened by another user during your session a warning message displays indicating the ID of the user that has opened the measurement and pointing out that your changes may be overruled by the other user's changes when he closes the measurement. In this situation it is possible to close the measurement without saving the changes.</i></p>







4.2.2 Scrolling through the measurement

Scrolling through a measurement can be done with the mouse or with the keyboard.





Scrolling with the mouse

Move the scroll bar below the graphs with the mouse to the left or right to scroll backwards or forward, respectively.

Scrolling can also be done by clicking on one of the following control-icons of the menu bar (see 4.2.1):

- | | |
|---|--|
|  : Scroll half a page to the left (backwards). |  : Scroll half a page to the right (forwards) |
|  : Scroll one page to the left (backwards). |  : Scroll one page to the right (forwards). |
|  : Scroll to the beginning of the measurement. |  : Scroll to the end of the measurement. |

Scrolling with the keyboard

- | | | | |
|---|--|--|---|
|  (left arrow): | Scroll a little step to the left (backw.). |  (right arrow): | Scroll a little step to the right (forwards). |
|  (arrow up): | Scroll half a page to the left (backw.). |  (arrow down): | Scroll half a page to the right (forwards). |
| Pg dn (page down): | Scroll a page to the left (backwards). | Pg up (page up): | Scroll a page to the right (forwards). |
| Home (Pos1): | Scroll to the beginning of the meas. | End (End): | Scroll to the end of the measurement. |

Note: You can scroll in arbitrary steps by locating the cursor at the new position and reselecting the current zoom level using the Zoom Menu (see 10). The new time range will be centered on the cursor position.

4.2.3 The Cursor

Description of the cursor

The Cursor (if set) is a bold, orange, vertical line running from the top to the bottom of the graphs. If the cursor is set on the graphs a) the time corresponding to the cursor position is indicated in the upper menu bar below the label 'Displayed range',


b) for each channel the value at the cursor position is displayed below the channel label and c) the delta-baseline value ('dB') is indicated for PCO₂ (PO₂), i.e. the difference between the PCO₂ (PO₂) value at the cursor position from the PCO₂ (PO₂) baseline (see 11.5, 11.7).


Note: If drift corrected PCO₂ data is displayed, a) the value of the drift corrected PCO₂ curve at the cursor position is displayed in blue below the blue colored label 'Drift corrected', and b) the dB value for PCO₂ is only displayed for drift corrected PCO₂ data.

Note: The dB value for PCO₂ (PO₂) (see above) is only displayed if the cursor is set after the point the respective PCO₂ (PO₂) baseline was determined (visualized by a red vertical line).

Placing / moving the cursor

Click with the left mouse key to place the cursor on the graphs.

To move the cursor to the right press down the <STRG> (or <CTRL>) key together with the  key (right arrow).

To move the cursor to the left press down the <STRG> (or <CTRL>) key together with the  key (left arrow).

Removing the cursor from the graphs

Clicking on the text 'Cursor <time>' in the upper right corner of the V-STATS Main Window (next to the close button) removes the cursor from the graphs.

Note: Any action that moves/ places the cursor outside the displayed range, e.g. when scrolling through the measurement (see 4.2.2) or zooming with the mouse (see 4.2.4), will also remove the cursor from the graphs.

Effect of the cursor on zooming

The zoom behavior (see 10) depends on the placement of the cursor on the graphs:

- If the cursor is not placed on the graphs, the left border of the displayed range is maintained.
- If the cursor is placed on the graphs, the new displayed range is centered around the cursor position.

Exception: Zoom with mouse (see below)

Note: The cursor will be removed from the screen if the measurement is zoomed outside of the cursor position.

Placing the cursor at the beginning of a marker

Double clicking on a marker in the list of events in the Report page 'List of events' (see 9.5.10)

- closes the report
- positions the cursor at the beginning of the selected event
- activates the "15-minutes" zoom level and centers the displayed time range around the cursor.

Placing the cursor at the position of an operator event

Double clicking on an operator event in the list of operator events in the dialog 'Operator Events' (see 11.1)

- closes the dialog 'Operator Events'
- positions the cursor at the selected 'Operator Event'
- activates the '15-minutes' zoom level and centers the displayed time range around the cursor.

Adding an Operator Event (start of a new Analysis Period) at the Cursor Position


- Place the cursor at the position where you want to add an Operator Event or the start of a new Analysis Period
- Click on the control icon 'Add Operator Event' (see 4.2.1) will open the dialog 'Edit/add Operator Event' (see 11.2). The date/time of the cursor position will be proposed as date/time for the new operator event.
- Enter the requested information and then click on 'OK' to close the dialog 'Edit/Add Operator Event' and to add the new Operator Event and – if the respective check box was selected – the start of a new Analysis Period.

4.2.4 Functions of the mouse in the measurement curves

The following table summarizes the various functions that can be activated with the mouse in V-STATS' Main Window.

Action	Location	Action
Left-Click	On 'Analysis Criteria Profile Indicator'	Opens a pop-up menu offering the possibility a) to select/ analyze the open measurement with a different 'Analysis Criteria Profile' or b) to re-analyze the open measurement with the current 'Analysis Criteria Profile' (also see 9.2).
Left-Click	On 'Analysis Interval Indicator'	Opens a popup menu that permits to select the 'Analysis Interval' (see 9.3)
Left-Click	On 'Display range/horizontal grid Mode Indicator' or on the y-axis (see 4.2)	Opens the dialog '<Channel>: Range & Horizontal grid' for the respective channel (see 11.9). In this dialog it is possible to adjust for the currently open measurement and the selected channel the display range (y-axis) and horizontal grid settings.
Left-Click	On time axis	Opens the dialog 'Vertical Grid' where it is possible to select the mode that will be used for the vertical grid and the time scale (see 4.2).
Left-click	Arbitrary position in curves	Sets the cursor at the respective position (see 4.2.3)
Right-click	Arbitrary position in curves (excluding click-on physiological event, artifact, or excluded data range markers)	Opens the dialog 'Edit/Add Operator Event' (see 11.2) to add an 'Operator Event' and (optionally) the start of a new Analysis Period at the position the right click was made.
Right-click	On an 'Operator Event Triangle'	Opens a popup menu with the following options: <u>Edit Operator Event</u> (Opens the dialog 'Edit / Add Operator Event' (see 11.2) where the respective information for the selected Operator Event can be edited) <u>Delete Operator Event</u> (Deletes the selected Operator Event) <u>Operator Events</u> (Opens the dialog 'Operator Events' (see 11.1) with the selected Operator Event being highlighted) <u>Analysis Period APx</u> (sets the 'Analysis Interval' (see 9.3) to the Analysis Period that starts at the position of the selected 'Operator Event'. Note that this option is dimmed grey, if no Analysis Period starts at the respective Operator Event). <u>Cancel</u> (Closes the popup menu without executing an action)
Right-click	On a physiological event, artifact, or excluded data range marker <i>See above for behavior after right-click on a SDM Event or 'Invalid Data' marker</i>	Displays the duration and - in parenthesis - the start and end time of the selected marker in red, bold font on the bottom right of V-STATS' Main Window and opens the following pop-up menu with the selected marker being highlighted with a checkmark: <u>Zoom</u> (dimmed grey in this situation) <u>Analyze <Channel></u> (Analyzes the respective channel of the open measurement by using the currently selected 'Analysis Criteria Profile' (see 9.2). Option dimmed grey if the settings that were last used to analyze the respective channel of the open measurement and those of the current 'Analysis Criteria Profile' are <u>identical</u> . For a detailed description see 9.1.) <u>Physiological Events ►</u> (Permits to select the type of physiological events (dynamic events; baseline events (for PCO2 only); threshold events) that will be visualized with colored markers (see 9.2). A check mark indicates the current selection.) <u>Physiological Event 1 (. 2)</u> (Converts the type of the selected marker. The available selection(s) depend on the set of physiological events currently selected to be visualized in the respective channel (see 9.2 and option 'Physiological Events ►'). Dimmed grey after click on an excluded data range marker) <u>Artifact</u> (converts the selected marker into an Artifact marker. Dimmed grey after click on an excluded data range marker) <u>Artifact All Channels</u> (Converts the selected marker into an Artifact marker and adds Artifact Markers in all other channels at the corresponding time range) <u>Delete</u> (Deletes the selected marker) <u>Reset modified Marker(s)</u> (Resets the selected marker (if modified). Dimmed grey after click on an unmodified or an excluded data range marker. Note that modified markers are identified by a black triangle in the upper left corner. Also refer to 9.1, 9.2). <u>Reset all modified Markers</u> (Resets all modified/ deleted markers in the respective channel. Dimmed grey if the channel does not contain

Action	Location	Action
		<p>modified/ deleted markers. Also refer to 9.1, 9.2).</p> <p><u>Excluded Data Range</u> (Opens the dialog 'Edit / Add Excluded Data Range' (see 9.4.1). Therein the proposed data range to be excluded corresponds to the range covered by the selected marker)</p> <p><u>Add Operator Event</u> (Opens the dialog 'Edit/Add Operator Event' (see 11.2) to add an 'Operator Event' and (optionally) the start of a new Analysis Period at the position the right click was made. Dimmed grey after click on an Excluded Data Range)</p> <p><u>Cancel</u> (Closes the popup menu without executing an action)</p>
Spanning a range with left mouse	In curves	<p>While spanning the range with the left mouse, the duration and - in parenthesis - the start and end time of the spanned range are indicated in red, bold font on the bottom right of V-STATS' Main Window.</p> <p>When releasing the mouse, the following pop-up menu opens:</p> <p><u>Zoom</u> (Positions the start time of the spanned range at the left border and activates the smallest zoom level that completely contains the spanned range (see 10)).</p> <p><u>Analyze <Channel></u> (Analyzes the respective channel of the open measurement by using the currently selected 'Analysis Criteria Profile' (see 9.2). Option dimmed grey if the settings that were last used to analyze the respective channel of the open measurement and those of the current 'Analysis Criteria Profile' are <u>identical</u>. For a detailed description see 9.1)</p> <p><u>Physiological Events ►</u> (Permits to select the type of physiological events (dynamic events; baseline events (for PCO2 only); threshold events) that will be visualized with colored markers (see 9.2). A check mark indicates the current selection.)</p> <p><u>Physiological Event 1 (. 2)</u> (Adds a new marker of the respective type covering the spanned range. The available selection(s) depend on the set of physiological events currently selected to be visualized in the respective channel (see 9.2 and option 'Physiological Events ►'). <i>Note: If spanned range includes Invalid Data Ranges, multiple markers will be added outside those ranges.</i></p> <p><u>Artifact</u> (Adds an Artifact Marker covering the spanned range) <i>Note: If spanned range includes Invalid Data Ranges, multiple markers will be added outside those ranges.</i></p> <p><u>Artifact All Channels</u> (Adds Artifact Markers covering the spanned range in all channels) <i>Note: If spanned range includes Invalid Data Ranges, multiple markers will be added outside those ranges.</i></p> <p><u>Delete</u> (dimmed grey in this situation)</p> <p><u>Reset modified Marker(s)</u> (Resets all modified/ deleted markers within the spanned range. Dimmed grey if no modified/ deleted markers are contained in spanned range. Note that modified markers are identified by a black triangle in the upper left corner. Also refer to 9.1, 9.2).</p> <p><u>Reset all modified Markers</u> (Resets all modified/ deleted markers in the respective channel. Dimmed grey if no modified/ deleted markers are contained in the channel. Also refer to 9.1, 9.2).</p> <p><u>Excluded Data Range</u> (Opens the dialog 'Edit / Add Excluded Data Range' (see 9.4.1). Therein the proposed data range to be excluded corresponds to the spanned range)</p> <p><u>Add Operator Event</u> (dimmed grey in this situation)</p> <p><u>Cancel</u> (closes the popup menu without executing an action)</p>
Spanning a range with left mouse while pressing the 'CTRL'-key	In curves	<p>While spanning the range with the left mouse, the duration and - in parenthesis - the start and end time of the spanned range are indicated in red, bold font on the bottom right of V-STATS' Main Window.</p> <p>When releasing the mouse, the following pop-up menu opens:</p> <p><u>Zoom</u> (dimmed grey in this situation).</p> <p><u>Analyze <Channel></u> (dimmed grey in this situation).</p> <p><u>Physiological Events ►</u> (dimmed grey in this situation).</p> <p><u>Physiological Event(s)</u> (Converts the type of all markers <u>fully included</u> within the spanned range. The available selection(s) depend on the set of physiological event criteria selected for the respective (see 9.2 and option 'Physiological Events ►'. Dimmed grey if no marker is fully included within the spanned range).</p> <p><u>Artifact</u> (Converts all markers <u>fully included</u> within the spanned range to artifacts. Dimmed grey if no marker is fully included within the spanned range)</p>

Action	Location	Action
		<p><u>Artifact All Channels</u> (dimmed grey in this situation)</p> <p><u>Delete</u> (Deletes all markers fully included within the spanned range. Dimmed grey if no marker is fully included within the spanned range)</p> <p><u>Reset modified Marker(s)</u> (dimmed grey in this situation).</p> <p><u>Reset all modified Markers</u> (dimmed grey in this situation).</p> <p><u>Excluded Data Range</u> (dimmed grey in this situation)</p> <p><u>Add Operator Event</u> (dimmed grey in this situation)</p> <p><u>Cancel</u> (closes the popup menu without executing an action)</p>
Left-mouse and shift key	Start or end of a physiological event, artifact, or excluded data range marker in curves	<p>Once the mouse cursor has changed its shape to , it is possible decrease or increase the size of the marker by moving the mouse while holding down the left mouse.</p> <p><i>Note: Manually modified physiological event and artifact marker exhibit a black triangle in the upper left corner.</i></p>
Hovering mouse over	A marker (in curves)	<p>Activates a tooltip specifying the type of the marker. In case of physiological event and artifact markers 'A' or 'M' is added behind the event description if the marker is unmodified or has been manually modified, respectively. Also displayed is the duration followed by the start and end-time of the marker in parenthesis.</p> <p><i>Note: By using the hotkeys defined in the dialog 'Color of markers' (see 12.1.2) it is possible to reclassify the type of the selected marker (see 4.2.6).</i></p>
Hovering mouse over	An Operator Event Triangle	<p>Activates a tooltip providing the following information:</p> <ul style="list-style-type: none"> - 'Analysis Period x', where x is the number of the Analysis Period that starts at the position of the 'Operator Event' (if applicable) - Description of the Operator Event and its type - Date/time at the position of the 'Operator Event'.

4.2.5 Labels of Markers

If the displayed time range is smaller or equal to 30 minutes, the markers in the measurement curves are labeled.

Label	Description	Specific to
D	Desaturation (<i>physiological event</i>)	SpO2
RI	Rise (<i>physiological event</i>)	PCO2, PR
FA	Fall (<i>physiological event</i>)	PCO2
AB	Above Baseline (<i>physiological event</i>)	PCO2
BB	Below Baseline (<i>physiological event</i>)	PCO2
UT	Upper threshold (<i>physiological event</i>)	PCO2, SpO2, PR
LT	Lower threshold (<i>physiological event</i>)	PCO2, SpO2, PR
EDR	Excluded Data Range. Operator excluded corresponding data ranges from data analysis (see 4.2.4, 9.4)	all channels
Art	Artifact: Artifacts evaluated by V-STATS (see 9.2) or manually marked by the operator. Corresponding episodes are excluded from data analysis.	all channels
INV	Invalid Data. Corresponding episodes contain invalid data and are therefore excluded from data analysis.	all channels
SQ	SpO2 Signal Quality (<i>SDM event*</i>)	SpO2, PR
LS	SpO2 Low signal (<i>SDM event*</i>)	SpO2, PR
HA	High ambient light (<i>SDM event*</i>)	PO2, SpO2, PR
CS	Calibration recommended (<i>SDM event*</i>)	PCO2
PS	PCO2 slow (<i>SDM event*</i>)	PCO2
IC	PCO2 In-Vivo Corrected (<i>SDM event</i>)	PCO2
OT	Temperature limiter was active after sensor over temperature was detected (<i>SDM event</i>)	all channels
IH	Sensor temperature was temporarily increased by INITIAL HEATING (<i>SDM event</i>)	all channels
HR	Sensor heating was reduced by SITE PROTECTION (<i>SDM event</i>)	all channels
TE	Site time was elapsed (<i>SDM event</i>)	all channels

Note: 'SDM Event Markers' are displayed separately from the other markers at the bottom edge of the channels. 'SDM Events' marked with an asterisk () in the table above optionally can be excluded from data analysis by checking the respective box in the dialog 'Analysis Criteria Profile' (see 9.2). Excluded SDM Events are duplicated*

by 'Invalid Data Markers', i.e. corresponding episodes are not evaluated during data analysis.

Note: Markers with a black triangle in the upper left corner identify physiological events or artifacts that have been manually modified (see 4.2.6).

Note: Automatically detected as well as manually marked artifacts (see 4.2.4) are independent from the type of physiological event (dynamic events; baseline events (for PCO₂ only); threshold events) that is currently selected to be visualized with colored event markers (see 4.2).

4.2.6 Editing Markers

'Markers' can be edited as follows.

- **To examine an existing marker:**

Move the mouse over the marker and leave it there. After a short time, a tooltip will appear specifying the type of the marker. In case of physiological event and artifact markers '(A)' or '(M)' is added behind the event description if the marker is unmodified or has been manually modified, respectively. Also displayed is the duration followed by the start and end-time of the marker in parenthesis.

Note: After right click on a marker the duration and - indicated in parenthesis - the start and end-time of the marker display at the bottom right of the screen in red, bold font.

- **To edit the color of markers:**

The color used for the markers can be modified in the dialog 'Color of markers' (see 12.1.2), which can be opened by click on the respective button in the dialog 'V-STATS Settings' (see 12.1).

- **To reclassify / delete a single existing marker:**

With the mouse: Move the mouse over the marker and then click on the marker using the **right** mouse button. A popup menu appears listing all marker types that make sense for this particular channel. A tick indicates the current marker type. Now click the new marker type (select 'Artifact' or 'Artifact all channels' if the corresponding data range contains data with questionable quality; select 'Delete' to delete the marker). The popup menu disappears and the marker is reclassified.

Note: If 'Exclude Data Range' is selected the dialog 'Edit/Add Excluded Data Range' (see 9.4.1) opens. The indicated data range will correspond to the data range defined by the marker. Adjust the data range if necessary and then press 'OK' to exclude the corresponding data range (statistical results displayed in the V-STATS Main Window (see 4.2)/ included in the report (see 9.5) will be updated, if excluded data ranges were modified/ added/ deleted within the current 'Analysis Interval').


With the keyboard: Position the mouse over the marker and press the desired hotkey defined in the dialog 'Color of markers' (see 12.1.2) to reclassify the marker.

Note: Not applicable for SDM Event and Invalid Data markers

- **To reclassify / delete several existing markers:** Press the <CTRL> key and keep it held down. Move the mouse in front of the first marker that you want to edit and press the **left** mouse button without releasing it afterwards (keep holding down the <CTRL> key). Now, with the **left** mouse button still held down, move the mouse all the way to the end of the last marker that you want to edit. As you release the mouse a popup menu will appear listing all marker types that make sense for this particular channel. Now click on the new marker type (select 'Artifact' or 'Artifact all channels' if the corresponding data range contains data with questionable quality; select 'Delete' to delete the markers). The popup menu disappears and the markers are reclassified.

Note: Not applicable for Excluded Data Range, SDM Event and Invalid Data markers

- **To edit the start or end of an existing marker:**

While holding down the <Shift> key, move the mouse to the start or the end of an existing marker. The mouse cursor will change into the shape . You can now decrease or increase the size of the marker by moving the mouse whilst holding down the **left** mouse button.

Note: If an 'Exclude Data Range' is modified the dialog 'Edit/Add Excluded Data Range' (see 9.4.1) opens. The indicated data range will correspond to the modified data range. Adjust the data range if necessary and then press 'OK' to exclude the corresponding data range (statistical results displayed in the V-STATS Main Window (see 4.2)/ included in the report (see 9.5) will be updated, if excluded data ranges were modified/ added/ deleted within the current 'Analysis Interval').

Note: Markers highlighting Invalid Data and SDM Events can't be modified.

- **To add a new marker:** Move the mouse to the position where the marker shall start and press the **left** mouse button without releasing it. Now, with the mouse button still held down, move the mouse to the end of the maker. Now release the left mouse button. A popup menu appears listing all marker types that make sense for this particular channel. Click on the desired marker type (select 'Artifact' or 'Artifact all channels' if the corresponding data range contains data with questionable quality).

Note: If 'Exclude Data Range' is selected the dialog 'Edit/Add Excluded Data Range' (see 9.4.1) opens. The

indicated data range will correspond to the data range spanned with the mouse. Adjust the data range if necessary and then press 'OK' to exclude the corresponding data range (statistical results displayed in the V-STATS Main Window (see 4.2)/ included in the report (see 9.5) will be updated, if excluded data ranges were modified/ added/ deleted within the current 'Analysis Interval').

Note: Not applicable for SDM Event and Invalid Data markers

- **To reset manually modified/ deleted physiological event or artifact markers:** To reset an individual manually modified marker right-click on the marker to open a pop-up menu and therein select the function 'Reset modified Marker(s)'. To reset all modified/ deleted markers within a certain time range, span the range with the left mouse to open a pop-up menu and therein select the function 'Reset modified Marker(s)'. To reset all manually modified/ deleted markers within the entire channel select the function 'Reset all modified Markers' in the aforementioned pop-up menu (also see 4.2.4 and 9.1).
 - Note: Modified physiological event and artifact markers are identified by a black triangle in the upper left corner. Deleted markers are not shown or specifically labeled.*
 - Note: If the measurement contains manually modified/ deleted physiological event or artifact markers, V-STATS prompts the message 'Reset all modified markers? (Yes/ No/ Cancel)' before executing data analysis (see 9.1, 9.2). If 'Yes' is selected, all manually markers (including the manually modified markers) are replaced by the newly evaluated event markers. If 'No' is selected manually modified markers are maintained. Similar, if analysis is executed only for an individual channel (see 9.1, 4.2.4).*

4.2.7 Editing Operator Events

'Operator Events' can be edited as follows:

- **To edit the color of operator events triangles:**

The color used for the operator event triangles can be selected in the dialog 'Define Operator Events' (see 12.1.3), which can be opened by click on the respective button in the dialog 'V-STATS Settings' (see 12.1).
- **To examine an existing 'Operator Event':**

A tooltip providing the following information appears if the mouse is hovered over a colored operator event triangle:

 - 'Analysis Period x', where x is the number of the Analysis Period that starts at the position of the 'Operator Event' (only if applicable)
 - Description of the Operator Event and its type
 - Date/time at the position of the 'Operator Event'.
- **To edit an existing 'Operator Event' or to add/delete the start of an Analysis Period:**

Right click with the mouse on a colored 'Operator Event' triangle opens a popup menu. Selection of

 - 1) **'Edit Operator Event'** opens the dialog 'Edit/Add Operator Event' (see 11.2) where it is possible to edit the date/time (position), the type and the description of the selected 'Operator Event'. Furthermore, the start of an Analysis Period can be added/deleted at the position of the 'Operator Event' by checking/unchecking the respective box in the dialog 'Edit/Add Operator Event'.
 - 2) **'Delete Operator Event'** will delete the respective 'Operator Event' and – if applicable – merge the 'Analysis Periods' ending/starting at the position of the 'Operator Event'.
 - 3) **'Operator Events'** opens the dialog 'Operator Events' listing all 'Operator Events' of the actual measurement and providing various options to edit 'Operator Events' and 'Analysis Periods' (see 11.1).
- **To add a new 'Operator Event' or the start of a new Analysis Period**

There are three options to add a new 'Operator Event' and – optionally – the start of a new Analysis Period:

 - 1) Set the cursor at the position where you want to add the new 'Operator Event' and then click on the control icon 'Add Operator Event' or use the sub-menu 'Measurement / Add Operator Event' (see 11.2) to open the dialog 'Edit/Add Operator Event'. Therein, the date/time proposed for the new operator event will correspond to the date/time at the cursor position. If necessary, adjust the date/time and then enter the information required to specify the new Operator Event. Click on 'OK' to close the dialog 'Edit/Add Operator Event' and to create the 'Operator Event'.
 - 2) **Right click** with the mouse at the position you want to add a new 'Operator Event' opens the dialog 'Edit/Add Operator Event'. Therein, the date/time proposed for the new operator event will correspond to the date/time of the position the right mouse click was made. If necessary adjust the date/time, enter the information required to specify the new Operator Event. Click on 'OK' to close the dialog 'Edit/Add Operator Event' and to create the 'Operator Event'.
 - Note: Right click with the mouse on an existing marker will open a popup menu. Selection of the option 'Add Operator Event' therein will also open the dialog 'Edit/Add Operator Event'.*
 - 3) Open the dialog 'Operator Events' and use the option provided therein to add a new 'Operator Event' (see 11.1).
 - Note: If changes affect the 'Analysis Period' that is currently selected as 'Analysis Interval' a warning dialog will prompt when attempting to delete an Operator Event or to close the dialog 'Edit/Add Operator Events' indicating that if you proceed the Analysis Interval will be set to the Full Measurement instead.*

4.2.8 Determining the duration of a measurement segment

To determine the duration of a measurement segment in the graphs proceed as follows:

- 1) Move the mouse to the start of the segment and press the left mouse button without releasing it.
- 2) Now, while keeping the left mouse button pressed, move the mouse to the end of the segment. As you move the mouse, the selected region will be highlighted in black and you can read the duration and – indicated in parenthesis - the start and end-time of the selection at the bottom right of the screen in red, bold font.
- 3) Now release the left mouse button. A popup menu appears. Click 'Cancel' to close the popup-menu.

5. Recording SDM Trend Data

Using V-STATS SDM, Trend Data can be downloaded from the internal memory of Sentec Digital Monitors (see 6).

5.1 Recording data in the internal memory of the SDM

The SDM automatically stores the measured data in its internal memory according to the FIFO (First In, First Out) principle. To avoid overwriting of measurement data, the data must be downloaded before the memory is full. For additional information refer to the Technical Manual for the Sentec Digital Monitor (HB-005752).

SDM Trend Data can be downloaded with V-STATS either via the serial interface (see 8.1) or – if the V-CareNeT Package has been activated (see 15.2) – via the network if the PC with V-CareNeT is connected to the same network as the SDM (see 14.6).

Note: On the SDM, the free and total memory capacities are displayed in the menu 'Trend Data'. Within V-STATS, the free and total memory capacities are indicated in the dialog 'Assign measurement period(s) to patients' (see 6.1) and 'Communication with Sentec device (via Serial Interface)' (see 8.1).

Note: It is recommended to clear the data stored in the internal memory of the SDM and to set the 'Date & Time' of the SDM to the 'Date & Time' of the PC after download of SDM Trend Data to V-STATS.

Note: Using V-CareNeT, download of SDM Trend Data is simultaneously possible from multiple SDMs (see 14.6).



WARNING: If the internal memory of your SDM is volatile, the Trend Data will be deleted if the SDM is switched off!



WARNING: The SDM automatically stores the measured data in its internal memory according to the FIFO (First In, First Out) principle. Once the memory is full, the oldest data will be continuously overwritten. To avoid overwriting of measurement data, the data must be downloaded before the memory is full.

Note: The memory type of your SDM is indicated in the SDM's menu 'Trend Data'.

6. Downloading / Importing SDM Trend Data

V-STATS offers three options to download/import SDM Trend Data:

- 1) Download of SDM Trend Data from the internal memory of the SDM via the SDM's serial interface (see 8.1).

Note: When downloading SDM Trend Data from an SDM with V08.00.x or higher download speed may be reduced compared to earlier monitor software versions, since more data are included in the download.

- 2) Download of SDM Trend Data from the internal memory of the SDM with V-CareNeT (see 14.6).

Note: With V-CareNeT download of SDM Trend Data is simultaneously possible for multiple SDMs.

- 3) Import of SDM Trend Data from a file stored on the PC or an external drive (see 7.7).

*Note: See 3.1 for compatibility information between V-STATS 5.01.1 and the various SDM software versions/ the various file versions containing SDM Trend Data. See 7.4 for import of '**.vex-files' (vex=V-STATS Export File).*

Irrespective of the selected option the dialog 'Assign measurement period(s) to patients' (see 6.1) will open when initiating download/import of SDM Trend Data.

6.1 Dialog 'Assign measurement period(s) to patients'

The dialog 'Assign measurement period(s) to patients' which opens when initiating download/import of SDM Trend Data (see below) permits assigning measurement periods to patients by means of the start-time and end-time of the respective measurement periods.

Assign measurement period(s) to patients X

Current Analysis Criteria Profile: default
Data Storage Folder: C:\vg\vstats\daten
Minimal Measurement Duration = 5 mins

No.	From: (MM-DD-YYYY)	To:	ID:	Type:
<input type="checkbox"/>	12. 2019-10-01 08:35:41 - 2019-10-01 08:46:58	---	Adult	
<input type="checkbox"/>	11. 2019-10-01 07:18:35 - 2019-10-01 07:53:23	---	Adult	
<input type="checkbox"/>	10. 2019-09-30 09:16:32 - 2019-09-30 09:22:41	---	Adult	
<input type="checkbox"/>	9. 2019-09-26 09:58:05 - 2019-09-26 10:42:39	---	Adult	
<input type="checkbox"/>	8. 2019-09-26 07:35:02 - 2019-09-26 08:22:49	---	Adult	
<input type="checkbox"/>	7. 2019-09-20 11:06:53 - 2019-09-20 12:04:54	---	Adult	
<input type="checkbox"/>	6. 2019-09-17 11:51:50 - 2019-09-17 12:00:15	---	Adult	
<input type="checkbox"/>	5. 2019-09-17 10:13:37 - 2019-09-17 10:21:17	---	Adult	
<input type="checkbox"/>	4. 2019-09-17 09:56:11 - 2019-09-17 10:13:19	---	Adult	
<input type="checkbox"/>	3. 2019-09-09 11:44:30 - 2019-09-09 11:57:47	---	Adult	
<input type="checkbox"/>	2. 2019-09-09 10:22:36 - 2019-09-09 10:34:35	---	Adult	
<input type="checkbox"/>	1. 2019-08-06 11:34:37 - 2019-08-06 11:43:37	---	Neo	

Selection of two or more measurement periods will automatically merge the periods with zero values added to fill the gaps.

It is recommended to clear the Trend Data of SDM after the data-download.

Last name:

First name:

Date of birth (MM-DD-YYYY):

Height (cm):

Weight (kg):

Sex:

Comment:

Pat. number:

Activate personal data

Automatic Export: Export Data EDF+ Export

Memory Capacity [hrs]: 61.7 (68.3)

Assign measurement period(s) to patients

Current Analysis Criteria Profile: default
Data Storage Folder: C:\Vg\svstats\daten
Minimal Measurement Duration = 5 mins

No.	From: (MM-DD-YYYY)	To:	ID:	Type:
<input checked="" type="checkbox"/>	12. 2019-10-01 08:35:41 - 2019-10-01 08:46:58	---	---	Adult
<input type="checkbox"/>	11. 2019-10-01 07:18:35 - 2019-10-01 07:53:23	---	---	Adult
<input type="checkbox"/>	10. 2019-09-30 09:16:32 - 2019-09-30 09:22:41	---	---	Adult
<input type="checkbox"/>	9. 2019-09-26 09:58:05 - 2019-09-26 10:42:39	---	---	Adult
<input type="checkbox"/>	8. 2019-09-26 07:35:02 - 2019-09-26 08:22:49	---	---	Adult
<input type="checkbox"/>	7. 2019-09-20 11:06:53 - 2019-09-20 12:04:54	---	---	Adult
<input type="checkbox"/>	6. 2019-09-17 11:51:50 - 2019-09-17 12:00:15	---	---	Adult
<input type="checkbox"/>	5. 2019-09-17 10:13:37 - 2019-09-17 10:21:17	---	---	Adult
<input type="checkbox"/>	4. 2019-09-17 09:56:11 - 2019-09-17 10:13:19	---	---	Adult
<input type="checkbox"/>	3. 2019-09-09 11:44:30 - 2019-09-09 11:57:47	---	---	Adult
<input type="checkbox"/>	2. 2019-09-09 10:22:36 - 2019-09-09 10:34:35	---	---	Adult
<input type="checkbox"/>	1. 2019-08-06 11:34:37 - 2019-08-06 11:43:37	---	---	Neo

Reset

Selection of two or more measurement periods will automatically merge the periods with zero values added to fill the gaps.
It is recommended to clear the Trend Data of SDM after the data-download.

Last name:
First name:
Date of birth (MM-DD-YYYY):
Height (cm):
Weight (kg):
Sex:
Comment:
Pat. number:

Activate personal data
 Automatic Export: Export Data EDF+ Export

Memory Capacity [hrs]: 61.7 (68.3)

The left hand side of the dialog displays for all available measurement periods that are longer than the '**Minimal Measurement Duration**' (see top left in bold, red) the start-time, the end-time, the patient ID, and the patient type. To assign a measurement period to a patient, check the box on the left of the respective measurement period and enter the data of the corresponding patient into the patient data fields on the right hand side of the dialog (max. 25 characters supported for 'Last name' and 'First name'). If Installation for Advanced Data Protection has been installed, entry of patient information is only enabled after clicking the checkbox 'Activate personal data' (unchecking the checkbox denies patient data access). Enter the patient's date of birth, height and weight by using the format/units indicated in parenthesis.

Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.

Note: The format used for dates and the units used for height and weight can be changed in the dialog V-CareNeT Settings (see 12.1).

Note: Measurement periods that are shorter than the 'Minimal Measurement Duration' indicated in the bold, red information text are not displayed in the dialog 'Assign measurement period(s) to patients'. To adjust this parameter please see 13.2.4.6 when downloading data from the SDM or 7.7 when importing SDM Trend Data from a file.

Note: A measurement period starts when the SDM detects that the sensor has been applied to the patient. A measurement period terminates when the SDM detects that the sensor has been removed from the patient 2 minutes ago or if the sensor is inserted into the Docking Station (for additional cases when a measurement period ends refer to the Technical Manual of the SDM (HB-005752)).

Note: Selection of two or more measurement periods will automatically merge the measurement periods with zero values added to fill the gaps when downloading / importing SDM Trend Data to V-STATS.

Note: Patient data later on can be edited in the dialog 'Patient Data' (see 11.3).

Note: The button '**Admitted Patient**' is only available when downloading SDM Trend Data with V-CareNeT (see 14.6 and screenshot below). Click on this button fills in the data of the patient that was last admitted to the respective remote monitoring station (see 14.7 and 14.8) into the patient data fields. If a measurement is ongoing a click on this button will fill in the data of the patient currently being admitted to the respective station.

Note: Click on the button '**Clear**' on the right of the patient data fields to clear the patient data fields.

Note: When downloading SDM Trend Data from the internal memory of an SDM with V-CareNeT, a status message displays above the patient data fields (see screenshot below). Remember that correction of residual PCO2 drift for a measurement is only possible if the PCO2 calibration data before and after the measurement are available (to obtain drift corrected TC data follow detailed description under 11.6). Furthermore, note that if the message 'Monitoring in progress' displays (i.e. sensor on patient) download of SDM Trend Data is significantly slower than if no measurement is ongoing (i.e. sensor not on patient). Also note that an ongoing (not terminated) measurement can only be downloaded via V-CareNeT (see 14.6); it cannot be downloaded via the Serial Interface.

*Note: When downloading SDM Trend Data from the internal memory of the SDM via the SDM's serial interface (see screenshot above), it is optionally possible – after the data download is finished - to **automatically export** the data as '*.vex'-file' (see 7.5) or as 'EDF+-File' (see 7.6) in a 'Default Storage Folder' with a 'Default File Name', both predefined in the dialog 'Data Export Configuration' (see 12.1.6) or in the dialog 'EDF+ Export Configuration' (see 12.1.7), respectively. If the filenames contain patient and measurement specific information third party applications which subsequently import these files can assign each file to the respective patient and intervention/investigation. To automatically export data as '*.vex'-file' or as 'EDF+-File' after the data download is finished via the serial interface check the box 'Automatic Export' and then select the respective radio button.*

Clicking '**Convert**' downloads / imports the selected measurement period(s) to V-STATS, assigns it to the patient specified in the dialog if access to enter patient information is enabled, analyzes it by using the currently selected '**Analysis Criteria Profile**' being indicated in bold, black in the top left corner of the dialog window and stores it in the '**Data Storage Folder**' being indicated in bold, blue in the top left of the dialog window.

Note: Before activating download/ import of SDM Trend Data Mouse-click on the 'Analysis Criteria Profile Indicator' opens a popup menu permitting to select a different 'Analysis Criteria Profile' from the 'Analysis Criteria Profiles Database' (see 9.1, 9.2).

Note: The 'Data Storage Folder' can be selected in the dialog 'V-STATS Settings' (see 12.1). The default Data Storage Folder is <Installation-Drive>:\fg\vstats\daten.

Note: If you use multiple PC's with V-STATS within your organization, we recommend for all V-STATS installations a) to select the same 'Data Storage Folder' being localized on a server of your institutions network and b) to set the 'Target Folder of File Manager' to 'Data Storage Folder' and in case of using advanced data protection c) to use the same key for all V-STATS installations which will share all their data. All V-STATS installations will then store measurements in the same folder when downloading / importing SDM Trend Data and the File Managers of all V-STATS installations will access by default this common 'Data Storage Folder'. Furthermore, if the 'Data Storage Folder' is localized on a server of your institutions network backup of the measurement data can be accomplished in the course of the server's routine backup procedures.

Note: If no measurement period is selected when clicking on the button 'Convert', the following error message is triggered.



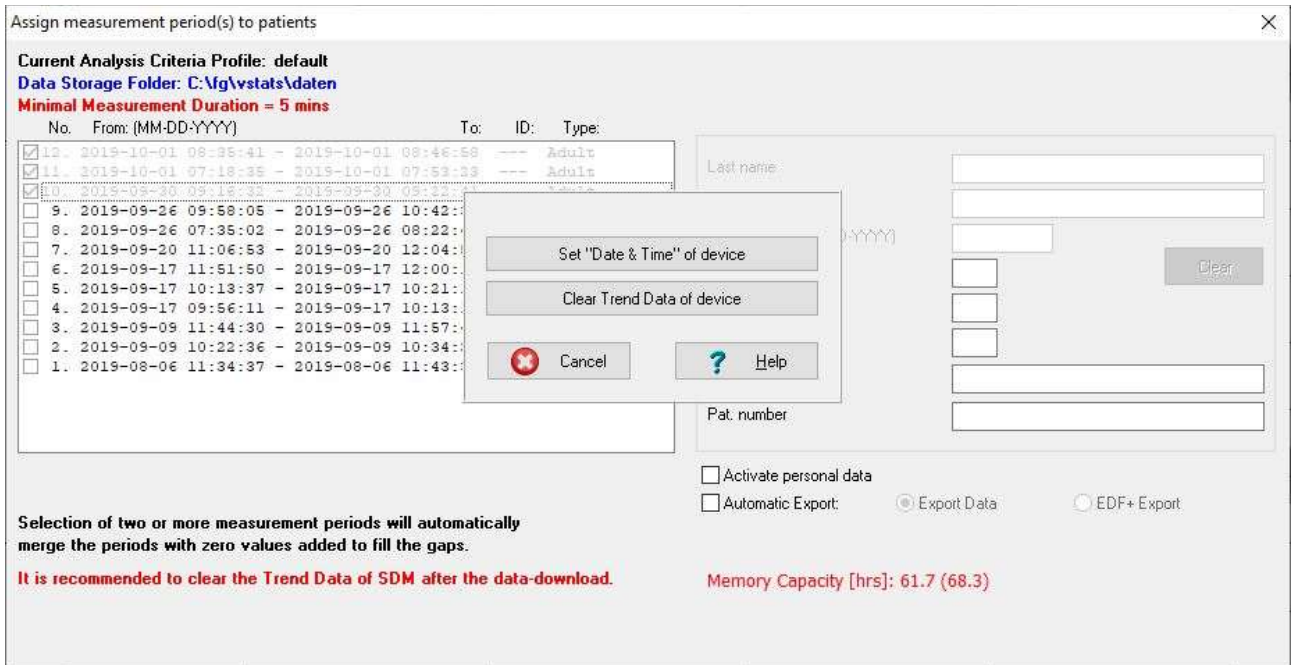
Click on 'OK' to acknowledge the message and to return to the dialog 'Assign measurement period(s) to patients'.

The dialog 'Assign measurement period(s) to patients' remains open as long as not all currently available measurement periods have been downloaded / imported to V-STATS. Measurement periods that have already been downloaded / imported to V-STATS are dimmed grey and the respective check boxes remain selected. In analogy to the above-discussed procedure additional measurement period(s) can be selected, assigned to a patient and imported / downloaded to V-STATS.

*Note: Click on the button '**Reset**' below the list of measurement periods to reset the list of measurement periods, i.e. to uncheck the boxes on the left of the measurement periods.*

Once all currently available measurement periods have been downloaded / imported to V-STATS or when clicking on the button 'Cancel'

- 1) while importing SDM Trend Data from a raw data file the dialog 'Assign measurement period(s) to patients' closes and the measurement period(s) that was (were) assigned to the last patient is (are) displayed in V-STATS' Main Window (see 4.2). If more than one measurement period(s) to patient assignments were made while importing SDM Trend Data from a raw data file use the file manager to open the (other) measurements (see 7.1).
- 2) while downloading SDM Trend Data from the SDM the dialog shown below is displayed in front of the dialog 'Assign measurement period(s) to patients'.



Clicking 'Set Date & Time of device' sets the 'Date & Time' of the SDM to the 'Date & Time' of the PC, clears the Trend Data stored in the internal memory of the SDM, and closes the dialog 'Assign measurement period(s) to patients'.

Clicking 'Clear Trend Data of device' clears the Trend Data stored in the internal memory of the SDM and closes the dialog 'Assign measurement period(s) to patients'.

Note: Trend Data cannot be deleted during an ongoing measurement. Therefore, the buttons 'Set Date & Time of device' and 'Clear Trend Data of device' are not accessible (dimmed grey) during patient monitoring.


Note: It is recommended to clear the data stored in the internal memory of the SDM and to set the 'Date & Time' of the SDM to the 'Date & Time' of the PC after download of SDM Trend Data to V-STATS. The free and total memory capacities are displayed in the bottom of the dialog 'Assign measurement period(s) to patients'.

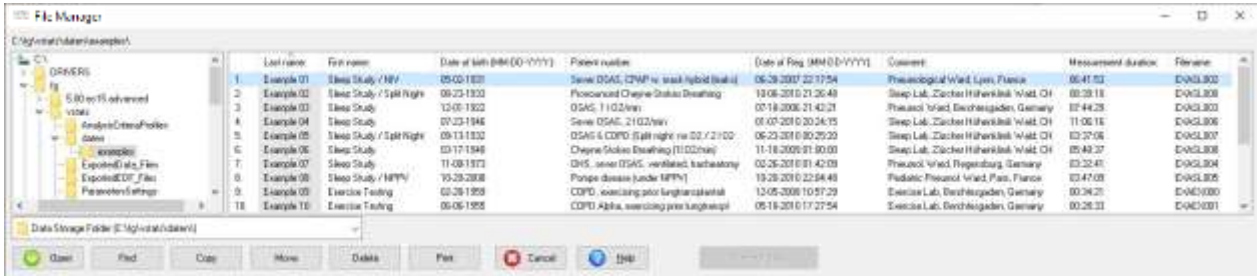
Clicking 'Cancel' closes the dialog 'Assign measurement period(s) to patients'.

If SDM Trend Data were imported from file or downloaded via the SDM's serial interface the measurement period(s) that was (were) assigned to the last patient is (are) displayed in V-STATS' Main Window (see 4.2). If more than one measurement period(s) to patient assignments were made or if SDM Trend Data that were downloaded with V-CareNeT use the file manager to open the (other) measurements (see 7.1).

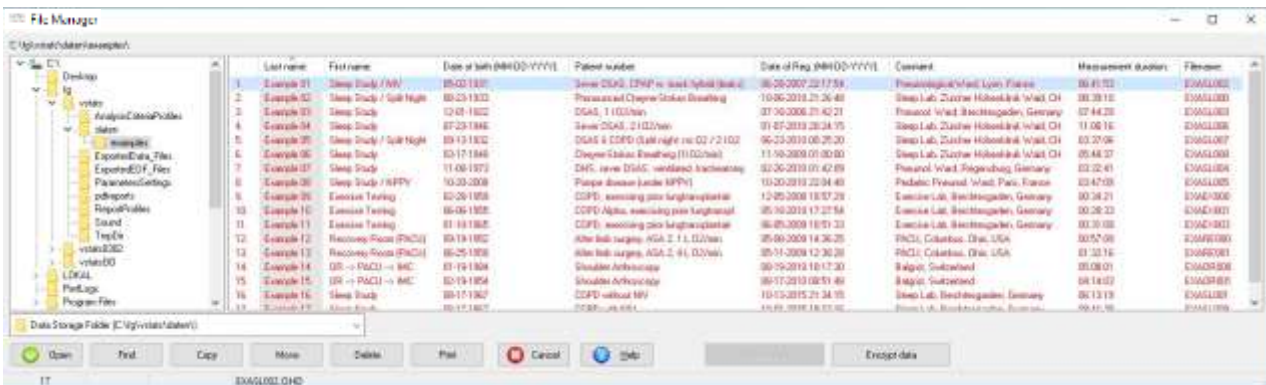
7. File Menu

7.1 Sub-menu 'File / File manager'

The dialog 'File Manager' can be opened a) by selecting the sub-menu 'File / File Manager', b) by clicking on the  icon in the menu bar of V-STATS' Main Window (see 4.2.1) or c) by clicking on the File Manager Button which displays in the center of the V-STATS' Main Window if no measurement is open (see 4.1).



Example (Standard Installation): File manager with selected examples folder



Example (Installation for Advanced Data Protection): File manager with selected examples folder

The 'File Manager' displays on the right side all measurements that are stored in the folder whose path is indicated in the top left of the dialog. For each measurement information related to the patient ('Last name', 'First name', 'Date of birth', 'Patient number') and related to the measurement ('Date of Registration', 'Comment', 'Measurement duration', 'Filename') is displayed, if this information was entered during data download (see 6.1). A measurement can be selected with the mouse. Multiple measurements can be selected with the mouse while holding the <ctrl> or >STRG< key down.

Note: Left-click on one of the column headers sorts the list of measurements in increasing/decreasing order by the criteria indicated in the respective column header.

Note: The folder that the 'File Manager' accesses by default when it is opened is the so-called 'Target Folder of the File Manager'. In the dialog 'V-STATS Settings' (see 12.1) the 'Target Folder of the File Manager' can be set to either 'Data Storage Folder' (default setting) or to 'Last'. If set to 'Data Storage Folder' the folder which the 'File Manager' accesses by default when it is opened, is identical to the folder into which V-STATS stores measurements when importing/downloading SDM Trend Data (see 6). If set to 'Last' the folder which the 'File Manager' access by default when it is opened, is identical to the folder in which the measurement the 'File Manager' last opened is stored.

Note: If within your institution you use multiple PC's with V-STATS, we recommend for all V-STATS installations a) to select the same 'Data Storage Folder' being localized on a server of your institutions network and b) to set the 'Target Folder of File Manager' to 'Data Storage Folder' and c) (only applicable for Installation for Advanced Data Protection) to use the same key for all V-STATS installations which will share all their data. All V-STATS installations will then store measurements in the same folder when downloading / importing SDM Trend Data, and the File Managers of all V-STATS installations will access by default this common 'Data Storage Folder'. Furthermore, if the 'Data Storage Folder' is localized on a server of your institutions network, backup of the measurement data can be accomplished in the course of the server's routine backup procedures.

Important Note (Installation for Advanced Data Protection only): Sub-directories have to be manually encrypted.

Important Note (Installation for Advanced Data Protection only): Contact your IT administrator if you are

not sure whether the unencrypted data are still needed. Sentec recommends deleting all files containing non-encrypted personal data and only storing encrypted personal data.

Note: Once the 'File Manager' is opened it is possible to select an arbitrary folder available in the file system by using the file explorer on the left side of the 'File Manager'.

Note: The folder 'Target Drive:\fg\lstats\daten\examples' (see figure above) contains several example measurements from different application areas (sleep, exercise testing, recovery room, OR). Three examples of split night studies contain multiple 'Analysis Periods'. AP 5 is selected in Example 01, AP2 is selected in Example 02, and AP1 is selected in Example 05. In Example 03 the 'Analysis Interval' was selected by using the option 'manually' or 'displayed range'.

Note: If at least one patient is admitted to V-CareNeT the red blinking message 'Remote Monitoring active' displays on the top right of the File Manager.

The buttons provided in the bottom of the 'File Manager' enable to perform the following actions.

Button 'Open': Click on this button opens the selected measurement (see 4.2)

Note: Double-Click on a measurement opens the measurement as well.

Note: This button is dimmed grey (not selectable) if no measurement is selected or if multiple measurements are selected.

Note: Opening a previously analyzed measurement neither activates the 'Analysis Criteria Profile' that was last used to analyze the measurement nor is the measurement automatically re-analyzed with the currently selected 'Analysis Criteria Profile'. In the V-STATS Main Window (see 4.2) the name of the current 'Analysis Criteria Profile', consequently, will - after opening a measurement - display in **black**, if the settings that were last used to analyze the respective measurement and those of the currently selected 'Analysis Criteria Profile' are identical, otherwise it will display in **red** with an asterisk (*).

Note: When attempting to open a measurement that is already opened by another user a warning message displays indicating the ID of the user that has already opened the measurement and that - if proceeding - you may overrule changes made by the other user.

Button 'Find: After click on this button a drop-down list and a text input field appear at the bottom of the list of measurements, provided that patient data has been entered.



Note: It is currently not possible to find key numbers.

Use the drop-down list to select the search criteria (Last name, First name, Patient number, Comment, or Filename) and enter the search string in the text input field. The first matching measurement will be highlighted. Click on the double-arrow on the right of the text input field to find other matching measurements.

Button 'Copy': Click on this button opens a pop-up dialog with the following options:

- **Data Storage Folder (<path>):** The selected measurement(s) will be copied into the 'Data Storage Folder'. **Note:** Dimmed grey if the selected measurement(s) is(are) already located in the 'Data Storage Folder'.
- **Target Folder of File Manager (<path>):** The selected measurement(s) will be copied into the 'Target Folder of the File Manager'
 - Note:** Dimmed grey if the selected measurement(s) is(are) already located in the 'Data Storage Folder' or if the 'Data Storage Folder' and the 'Target Folder of File Manager' are identical.
- **Select Folder:** Opens a Windows-Dialog which permits to select the folder into which the selected measurement(s) will be copied.

Note: The button 'Copy' is dimmed grey (not selectable) if no measurement is selected.

Button 'Move': Click on this button opens a pop-up dialog with the following options:

- **Data Storage Folder (<path>):** The selected measurement(s) will be moved into the 'Data Storage Folder'. **Note:** Dimmed grey if the selected measurement(s) is(are) already located in the 'Data Storage Folder'.
- **Target Folder of File Manager (<path>):** The selected measurement(s) will be moved into the 'Target Folder of the File Manager'

Note: Dimmed grey if the selected measurement(s) is(are) already located in the 'Data Storage Folder' or if the

'Data Storage Folder' and the 'Target Folder of File Manager' are identical.

- **Select Folder:** Opens a Windows-Dialog which permits to select the folder into which the selected measurement(s) will be moved.

Note: The button 'Move' is dimmed grey (not selectable) if no measurement is selected.

Button 'Delete': Click on this button will delete the selected measurement(s).

Note: The button 'Delete' is dimmed grey (not selectable) if no measurement is selected.

Note: The 'Delete' key also deletes the selected measurement(s).

Button 'Print': Click on this button will allow printing the list of measurements contained in the folder which the 'File Manger' currently accesses either a) on paper (select 'Printer') or b) as pdf-file (select 'PDF'). If 'Printer' is selected a dialog opens in which it is possible to select the printer and print settings such as paper size. If 'PDF' is selected a windows dialog opens permitting to specify the storage folder and filename of the pdf-file.

Button 'Cancel': Click on this button closes the File Manager

Note: The 'Esc' key also closes the File Manager.

Button 'Decrypt Data': Clicking on this button decrypts measurement data that have been encrypted with another key beforehand. After decryption of the data, the data is automatically encrypted again using the key which was generated / loaded for the currently open V-STATS.

Button 'Encrypt Data' (Installation for Advanced Data Protection only): Clicking on this button encrypts measurement data that have not been encrypted yet. The data are encrypted with the key that is generated / loaded for the currently open V-STATS.

7.2 Sub-menu 'File / Save'

Saves changes to the currently open measurement.


Note: Dimmed grey if no changes were made since the measurement was opened or last saved.

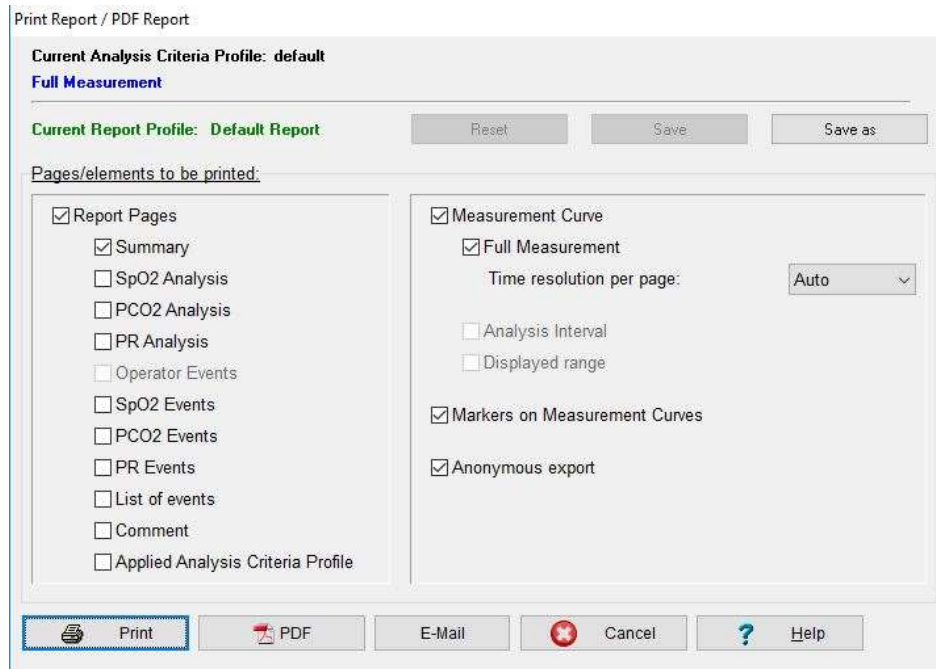
Note: When saving a measurement, the settings last used to analyze the measurement are saved along with the measurement, the name of the corresponding 'Analysis Criteria Profile' (see 9.2), however, is not saved.

7.3 Sub-menu 'File / Print Report / PDF Report'

Note: The report currently does not include statistical results for PO2, PI, and HP.

The dialog 'Print Report / PDF Report' can be opened

- by selecting the sub-menu 'File / Print Report / PDF Report' or by clicking on the -icon in the menu bar if a measurement is open (see 4.2.1)
- by selecting the sub-menu 'Report / Print Report / PDF Report' or by clicking on the -icon in the menu bar if the report window is open (see 9.5.1).



The following elements are provided in dialog 'Print Report/ PDF Report'

- 1) **Analysis Criteria Profile Indicator:** The currently selected 'Analysis Criteria Profile' (see 4.2, 9.2) is indicated in **bold, black** in the top left corner of the dialog window. If the settings of the currently selected 'Analysis Criteria Profile' and those that were last used to analyze the open measurement are identical the profile name is displayed in **black**, otherwise (i.e. if the open measurement has not yet been analyzed with the currently selected 'Analysis Criteria Profile') in **red** with an asterisk (*).

Note: The 'Analysis Criteria Profile' cannot be changed in the dialog 'Print Report/ PDF Report'. Refer to 4.2, 9.1, and 9.2 for a description how the open measurement can be (re-)analyzed with the currently selected or another 'Analysis Criteria Profile'.

Note: The 'Analysis Criteria Profile Indicator' will be included in the report print-out/ PDF- Report (underneath the box with the patient related data)

- 2) **Analysis Interval Indicator:** The current 'Analysis Interval' (see 4.2, 9.3), which will be considered when generating the report, is indicated in **bold, blue** in the top left corner of the dialog window.

Note: The 'Analysis Interval' cannot be changed in the dialog 'Print Report/ PDF Report'. Refer to 4.2, 9.3 for a description how the 'Analysis Interval' can be changed.

Note: The 'Analysis Interval Indicator' will be included in the report print-out/ PDF-Report.

- 3) **Report Profile Indicator:** The currently selected 'Report Profile' (see 'Note' below) is indicated in **bold, green** below the 'Analysis Interval Indicator'. If at least one of the parameters of the current 'Report Profile' differs from the respective parameter of the currently selected 'Report Profile', **** (modified)** is added to the profile name and an asterisk (**) displays adjacent to each parameter that differs from its setting in the currently selected 'Report Profile'. **Left click** on the 'Report Profile Indicator' opens the dialog 'Report Profiles Database' (see 7.3.1). Therein a different 'Report Profile' can be selected and 'Report Profiles' can be managed (renamed, deleted, imported to/ exported from 'Report Profiles Database' ...).

Note: A 'Report Profile' (see 9.5) specifies a setting for each parameter included in the dialog 'Print Report/ PDF Report' and for each parameter included in the 'Report Summary' page (see 9.5.2).

Note: Upon installation of or upgrade to V-STATS 3.02 or higher the preconfigured and write-protected 'Report Profiles' 'Default Report', 'Full Report', and 'V-CHECK Report' are installed in the 'Report Profiles Database'.

The buttons 'Reset', 'Save', and 'Save as' on the left of the 'Report Profile Indicator' are duplicated in the **middle section** of the dialog 'Report Profiles Database' (see 7.3.1) and in the 'Report Summary' page (see 9.5.2). Please refer to 7.3.1 for a description of their function and how to create a customized 'Report Profile'.

- 4) **Pages/ Elements to be printed – Report Pages:** The pages of the report (see 9.5.2 to 9.5.12) to be printed can be selected on the left side of the dialog 'Print Report / PDF Report' by checking the respective boxes.

Note: Report Pages that are not available for the currently open measurement are dimmed grey (not selectable).

Note: Uncheck the box 'Report pages' if you do not want to print any of the report pages. Note that the individual

sub-boxes will be dimmed grey but their settings will be maintained when unchecking the box 'Report pages'.

Note: Statistical data for the PO₂, PI, HP channels is currently not available and are thus not included in the report. However, PO₂, PI, and HP measurement curves can optionally be printed (see below).

- 5) **Pages/ Elements to be printed – Measurement Curve:** To print the measurement curve select the respective check boxes on the right side of the dialog 'Print Report / PDF Report'.

Note: Uncheck the box 'Measurement curve' if you do not want to print the measurement curve on individual pages. Note that the three sub-boxes will be dimmed grey but their settings will be maintained when unchecking the box 'Measurement curve'.

*Note: If the box 'Full Measurement' is checked, the full measurement curve will be printed with the time resolution per page specified in the respective drop-down menu. If the measurement duration, for example, is 8 hours and the parameter 'Time resolution per page' is set to 30 minutes, the measurement curve will be printed on 16 pages. If the parameter 'Time resolution per page' is set to 'Auto' V-STATS automatically adjusts the time resolution per page to ensure that the full measurement curve, regardless of the measurement duration, will be printed on one single page. **Warning:** Selection of a small 'Time resolution per page' may cause the printout of the measurement curve to require a large number of pages.*

Note: If the box 'Analysis Interval' is checked V-STATS will print the range of the measurement curve that corresponds to the current 'Analysis Interval' (see 9.3) on one page. Note that if the current 'Analysis Interval' corresponds to the full measurement curve V-STATS dims this box grey and inhibits twofold printout of the full measurement curve (even if the box 'Analysis Interval' is selected).

Note: If the box 'Displayed range' is checked V-STATS will print the range of the measurement curve that is currently displayed in V-STATS' Main Window on one page. Note that if the full measurement curve is displayed V-STATS dims this box grey and inhibits twofold printout of the full measurement curve (even if the box 'Displayed range' is selected).

*Note: Print-out of uncorrected PCO₂ data and drift corrected PCO₂ data is made with different fonts to ensure that the two curves can be distinguished if printing is made on a black&white printer. The 'drift corrected' curve is printed in **black, bold** font whereas the uncorrected curve is printed in light, grey font.*

Note: PO₂, PI, and HP measurement curves can be included in the report provided a) the respective parameter is included in the measurement file; b) the respective measurement curve is displayed in the currently open measurement, and c) in the 'Print Report / PDF Report' dialog box the checkbox for 'Measurement curves' is selected.

- 6) **Pages/ Elements to be printed – Markers on Measurement Curve:** To print/ store the measurement curve with markers select the respective check boxes on the right side of the dialog 'Print Report / PDF Report'.

Note: The printout of the measurement curve on the 'Report Summary' page (if enabled) is also affected by the setting of this check box (see 9.5.2).

- 7) **Pages/ Elements to be printed – Anonymous:** Checking this checkbox prohibits printing patient information on the PDF Report.

- 8) **Report Printout / PDF Report:**

Button 'Print': Opens a windows dialog permitting to select the printer/ printer settings (e.g. paper size), and then to activate printing of the report for the currently open measurement.

Important Note: Reports may contain patient data. Make sure that patient privacy will be warranted in accordance with local ordinances. It is your responsibility to ensure that non-authorized persons cannot access reports.

Button 'PDF': Opens a warning dialog (see 'Important Note' below) and then a Windows dialog permitting to specify the storage folder and filename for the PDF Report.

Note: In order to ensure that PDF Reports can be integrated into 'Electronic Medical Records' the 'Default File Name' and 'Default Storage Folder' that are proposed in this dialog can be predefined in the dialog 'PDF Report Configuration' (see 12.1.5). The 'PDF Report Configuration' is only integrated if access to enter patient information is enabled beforehand and patient data has been entered. If PDF Reports are stored in a dedicated folder, an application may automatically integrate PDF Reports into the 'Electronic Medical Records'. If the filenames contain patient and measurement specific information, it will be possible for this application to assign each PDF Report to the respective patient and intervention/investigation.

Button 'E-Mail': Opens a warning dialog (see 'Important Note' below), then the standard email client and creates a new Email with the PDF Report attached

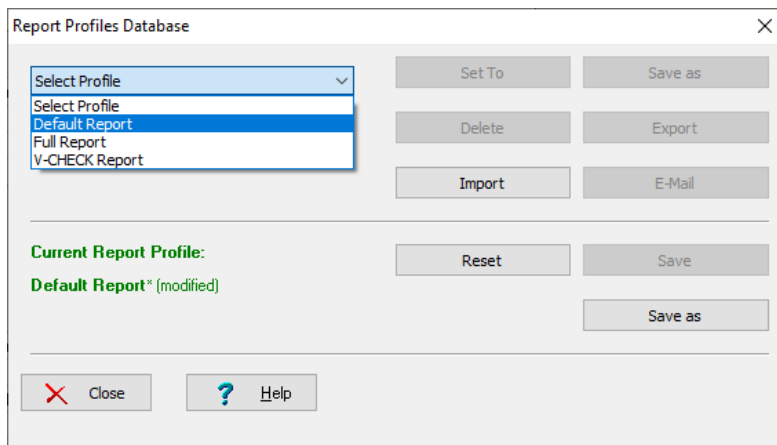
Note: The 'Default File Name' predefined in the dialog 'PDF Report Configuration' (see 12.1.5) will be used as file name for the attached PDF Report.

Important Note: The resulting PDF Report may contain patient data. Prior generating a PDF Report containing patient information make sure that patient privacy will be warranted in accordance with local ordinances. It is your responsibility to ensure that non-authorized persons cannot access PDF Reports containing patient information. Before generating a PDF Report V-STATS will prompt a corresponding warning dialog.

7.3.1 Dialog 'Report Profile Database'

In order to ensure that you can print/ save reports the way you want them to in varying clinical settings, V-STATS provides 'Report Profiles' (see 9.5) that are stored in the 'Report Profiles Database'. A 'Report Profile' specifies a setting for each parameter included in the dialog 'Print Report/ PDF Report' (see 7.3) and for each parameter included in the 'Report Summary' page (see 9.5.2).

To open the dialog 'Report Profile Database' click on the 'Report Profile Indicator' in the dialog 'Print Report/ PDF Report' (see 7.3) or in the 'Report Summary' page (see 9.5.2).



The following functions are provided in the **upper section** of the dialog 'Report Profiles Database'

Control	Description
Drop-down list 'Select Profile'	Lists all 'Report Profiles' currently available in the Report Profiles Database in alphabetical order and permits to select one of these profiles. <i>Note: The buttons 'Set To', 'Save as', 'Export', 'Delete', and 'Email' are dimmed grey (no function) as long as no 'Report Profile' is selected.</i>
Button 'Set To'	Click on this button to apply/ confirm the 'Report Profile' selected in the drop-down list. Thereafter each parameter in the dialog 'Print Report/ PDF Report' (see 7.3) and in the 'Report Summary' (see 9.5.2) page will be set to the respective setting stored in the just selected 'Report Profile' and the 'Report Profile Indicator' will display the respective profile name. <i>Note: This button is dimmed grey (not selectable) if in the drop-down list 'Select Profile' the currently selected 'Report Profile' is chosen.</i>
Button 'Save as'	Permits to store the 'Report Profile' selected in the drop-down list with a different name to the Report Profiles Database. Click on this button opens the dialog 'Save Report Profile' permitting to specify a different profile name and then to store a copy of the selected 'Report Profile' with the specified name to the 'Report Profiles Database'. <i>Note: Maximum 16 characters permitted for file names of 'Report Profiles'</i>
Button 'Delete'	Click on this button activates a confirmation dialog and – after confirmation - deletes the 'Report Profile' selected in the drop-down list. <i>Note: This button is dimmed grey (not selectable) if in the drop-down list 'Select Profile' a write-protected Report Profile preconfigured by Sentec or the current 'Report Profile' is selected.</i>
Button 'Export'	Click on this button opens a windows dialog permitting to export the 'Report Profile' selected in the drop-down list to the PC as '*.rpf file', e.g. for importing to another V-STATS application. <i>Note: Maximum 16 characters permitted for file names of 'Report Profiles'</i>

Control	Description
Button 'Import'	Click on this button first opens a windows dialog which permits to select a 'Report Profile' stored on the PC. After selection of the 'Report Profile' to be imported the dialog 'Save Report Profile' opens. In this dialog it is then optionally possible to modify the profile name. Click on 'OK' imports the selected 'Report Profile' with the specified name to the Report Profiles Database. <i>Note: Maximum 16 characters permitted for file names of 'Report Profiles'. The file extension of Report Profile Files is '*.rpf'.</i>
Button 'Email'	Click on this button opens the standard email client and creates a new Email with the 'Report Profile' selected in the drop-down list attached.

The following information/ functions are provided in the **middle section** of the dialog 'Report Profiles Database'

Note: These elements are duplicated in dialog 'Print Report/ PDF Report' (see 7.3) as well as on the 'Report Summary' page (see 9.5.2).

Control	Description
Report Profile Indicator	The currently selected 'Report Profile' is indicated in bold, green . If at least one of the settings of the current 'Report Profile' differs from the respective setting of the currently selected 'Report Profile', * (modified) is added to the profile name and an asterisk (*) displays adjacent to each setting that differs from its setting in the currently selected profile. <i>Note: A 'Report Profile' specifies a setting for each parameter included in the dialog 'Print Report/ PDF Report' (see 7.3) and for each parameter included in the 'Report Summary' page (see 9.5.2).</i>
Button 'Reset'	Resets all settings currently selected in the dialog 'Print Report/ PDF Report' (see 7.3) as well as on the 'Report Summary' page (see 9.5.2) to those of the currently selected 'Report Profile' <i>Note: This button is dimmed grey (not selectable) if all currently selected settings are identical with those of the currently selected 'Report Profile'.</i>
Button 'Save'	Save changes to the currently selected 'Report Profile' <i>Note: This button is dimmed grey (not selectable) if the currently selected 'Report Profile' is write-protected or if all currently selected settings are identical with those of the currently selected 'Report Profile'.</i>
Button 'Save as'	Click on this button opens the dialog 'Save Report Profile' which allows to specify a profile name and then to store the currently selected settings as a new profile to the 'Report Profiles Database'. Note that thereafter the new, just saved 'Report Profile' is activated as currently selected 'Report Profile'. <i>Note: Maximum 16 characters permitted for file names of 'Report Profiles'</i>

Write-protected 'Report Profiles' preconfigured by Sentec:

Note: The report currently does not include statistical results for PO₂, PI, and HP.

Upon installation of or upgrade to V-STATS 3.02 the following write-protected 'Report Profiles' preconfigured by Sentec are stored in the 'Report Profiles Database':

- **Default Report:** Select this profile to generate two-page reports containing on the first page the 'Report Summary' page (see 9.5.2) with all elements but the 'Measurement Curve' and the 'System Information' and on the second page the full measurement curve with the 'Time resolution per page' set to Auto and the check box 'Markers on curve' selected.

Note: If the printer supports two-sided printing the 'Report Summary' page and the full measurement curve can be printed on one sheet of paper.

- **V-CHECK Report:** Select this profile to generate one-page reports containing the 'Report Summary' page (see 9.5.2) with the following elements only: a) minimum, maximum mean, and median for PCO₂, SpO₂, PR and b) the range of the measurement curve that corresponds to the current 'Analysis Interval'.

Note: Reports generated with the profile 'V-CHECK Report' provide the same information as is available on the SDM's V-Check Results Screen (for details refer to 9.3.1 and to the Technical Manual for the SDM (HB-005752)).

- **Full Report:** Select this profile to generate full reports (see 9.5.2 to 9.5.12) including the full measurement curve (time resolution set to Auto), the displayed range of the curve (if different from full measurement curve), and the range of the measurement curve corresponding to the current 'Analysis Interval' (if different from full measurement curve).

Measurement curves include markers.

To create a customized 'Report Profile' please proceed as follows:

- 1) Open the 'Report Summary' page (see 9.5.2). Select the check boxes of all elements of the 'Report Summary' page you want to include in your reports, deselect the other elements.
- 2) Open the dialog 'Print Report/ PDF Report' (see 7.3). Select the check boxes of all report pages (see 9.5.2 to 9.5.12) you want to include in your reports, deselect the other pages. Select the desired 'Time resolution per page' if the 'Full Measurement' curve will be included in the reports. If the measurement curves will be included in the reports (on the 'Report Summary' page and/ or on (an) individual page(s)) specify whether or not markers shall be added to the measurement curves.
- 3) In the dialog 'Print Report/ PDF Report' (see 7.3) (or in the 'Report Summary' page (see 9.5.2) or in the dialog 'Report Profiles Database' (see below)) click on the button 'Save as' to store the customized settings. This will open the dialog 'Save Report Profile' permitting to specify a profile name and then to store your customized 'Report Profile' with the specified name to the 'Report Profiles Database'. Note that thereafter the just saved 'Report Profile' is activated as currently selected 'Report Profile'.

7.4 Sub-menu 'File / Import data'

The functions 'Export data' (see 7.5) and 'Import data' allow the exchange of data between different V-STATS applications. As the data export is highly configurable (see 7.5 for details) the format of the resulting, so-called '*.vex-files' (vex=V-STATS Export File) can be customized. This helps to ensure that '*.vex-files' can be imported into various third party applications such as Excel.

To import a '*.vex-file' select the sub-menu 'File / Import data'. First an information dialog indicating the current 'Data Storage Folder' (see 12.1) opens. After acknowledgement of this dialog a windows dialog to select the '*.vex-file' to be imported opens. The selected file will be stored in the 'Data Storage Folder' and the corresponding measurement will be displayed in V-STATS' Main Window.

Note: When encrypted data are exchanged between different V-STATS applications, ensure to use the correct key with the corresponding password to import and open the data.

Note: V-STATS 5.01.1 only supports import of '.vex-files' which have been generated by V-STATS 4.00 or newer provided a) the included data has been downloaded from the internal memory of a SDM with firmware version SMB-SW V08.00.x, V08.01.x, V08.02.x or V08.03.x and b) the files contain heading lines, data for at least one measurement parameter as well as the status code and date/time columns (refer to 7.5 for details). Please see 3.1 for additional compatibility information between older V-STATS versions and the various versions of '*.vex-files'.*

Note: If the '.vex-file' that is imported contains only drift corrected PCO2 data, uncorrected PCO2 data are not available. Consequently drift correction mode (see 11.6) will be automatically set to 'On' for this measurement.*

Note: The 'Data Storage Folder' can be selected in the dialog 'V-STATS Settings' (see 12.1). The default Data Storage Folder is <Installation-Drive>:\fg\vstats\daten.

Note: If within your institution you use multiple PC's with V-STATS we recommend for all V-STATS installations a) to select the same 'Data Storage Folder' being localized on a server of your institutions network and b) to set the 'Target Folder of File Manager' to 'Data Storage Folder' and in case of using advanced data protection c) to use the same key for all V-STATS installations which will share all their data. All V-STATS installations will then store measurements in the same folder when downloading / importing SDM Trend Data and the File Managers of all V-STATS installations will access by default this common 'Data Storage Folder'. Furthermore, if the 'Data Storage Folder' is localized on a server of your institutions network backup of the measurement data can be accomplished in the course of the server's routine backup procedures.

7.5 Sub-menu 'File / Export data'

The sub-menus 'File/ Export data' and 'File/ Import data' (see 7.4) allow the exchange of data between different V-STATS applications. As the data export is highly configurable (see below for details) the format of the resulting, so-called '*.vex-files' (vex=V-STATS Export File) can be customized. This helps to ensure that '*.vex-files' can be imported into various third party applications such as Excel.

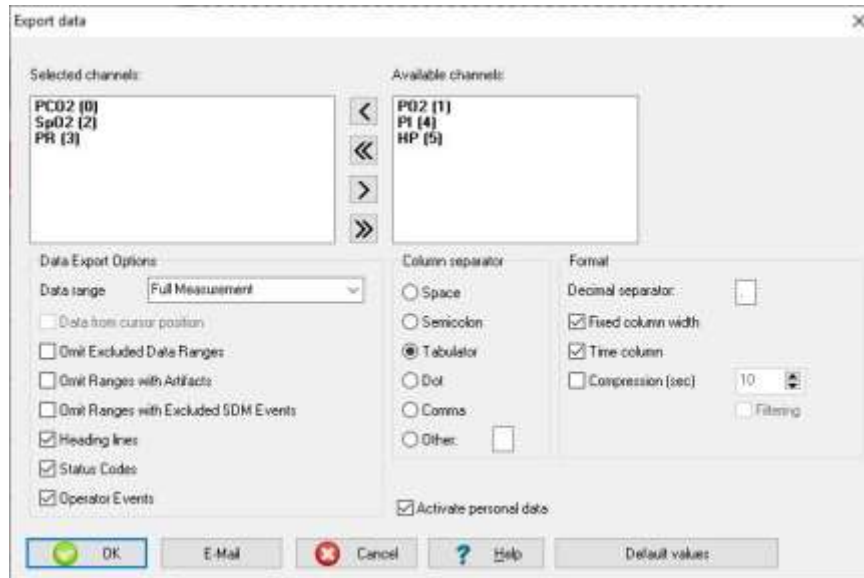
Note: When encrypted data are exchanged between different V-STATS applications, ensure to use the correct key with the corresponding password to import and open the data (only applicable if Installation for Advanced Data Protection is installed).

Note: The sub-menu 'File / Export data' is dimmed grey, if no measurement is open.

*Note: If PCO2 drift correction (see 11.6) is set to 'ON' only drift corrected PCO2 data will be exported. Consequently, the resulting *.vex-file' does not contain uncorrected data and vice versa if PCO2 drift correction is set to 'OFF'. Select 'Both', for exporting the drift corrected as well as the uncorrected PCO2 data.*

Note: The function 'Export data' does not export the results of data analysis (e.g. physiological events, artifacts, etc.). To exchange the complete data set contained within V-STATS for a measurement please use the functions 'Export/Import V-STATSFile' (see 7.10, 7.11).

Select the sub-menu 'File / Export data' to export the currently opened measurement in a *.vex-file'. This will open the dialog 'Export data':



There are numerous options to configure the format and content of the resulting *.vex-file'.

'Channel Selection': The data columns that will be exported can be selected/deselected by moving the corresponding parameter labels from the box 'Available channels' to 'Selected channels' and vice versa, respectively.

The field 'Data Export Options' offers various options to configure the content of the exported file:

- 1) **Data range:** The data range to be exported can be specified by selecting one of the three available options: 'Analysis Interval', 'Displayed Range', and 'Full Measurement'.

Note: If 'Analysis Interval' is selected, the data ranged spanned by the current 'Analysis Interval' (see 9.3) will be exported. If 'Displayed range' is selected the data range currently displayed in V-STATS's Main Window (see 4.2) will be exported.

Note: The setting of the last use will be proposed at next use. 'Full Measurement' is the factory default setting.

- 2) **Data from cursor position:** if this box is checked, data export starts from the current cursor position
Note: This check box is dimmed grey, if the cursor is not set within the data range to be exported.
- 3) **Omit Excluded Data Ranges:** if this box is checked numerical values within excluded data ranges (see 9.4) are omitted while exporting the data into the *.vex-file'.
Note: This check box is always selectable (even if the range to be exported contains no excluded data ranges).
*Note: If this box is checked 'Excluded Data Ranges' (if any) are exported, and, consequently, are available after re-importing the resulting *.vex-file'.*
- 4) **Omit Ranges with Artifacts:** if this box is checked numerical values within ranges marked as artifacts are omitted while exporting the data into the *.vex-file'.
Note: This check box is always selectable (even if the range to be exported contains no artifacts).
- 5) **Omit Ranges with Excluded SDM Events:** if this box is checked values within 'Excluded SDM Event' ranges (see 9.2) are omitted while exporting the data into the *.vex-file'.
Note: This check box is always selectable (even if the range to be exported contains no Excluded SDM Events).

*Note: Ranges that have been omitted during data export by one of the three options explained above, will be displayed as 'Invalid data' (see 4.2.5, 12.1.2) after re-importing the corresponding *.vex-file' into V-STATS (see 7.4).*

- 6) **Heading lines:** if this box is checked, the data will be exported with heading lines (default: box checked).

Note: The heading lines contain the following information: Patient (Last name, First name, date of birth, height, weight, sex, Pat. Number, and Comment); Name of corresponding raw data file; Date at which the measurement has been performed; Time at which the measurement was started; V-STATS version used to export the data into the present file; Monitor used to perform the measurement (Serial number, MPB software version; SMB software version); Sensor used to perform the measurement (serial number of the sensor; software version of the sensor); Indication whether or not the exported PCO2 data are drift corrected.

7) **Status Codes:** if this box is checked, the data will be exported with Status Codes (default: box checked).

Note: Status Codes carry important information on the quality/validity of the measurement (see Technical Manual for the Sentec Digital Monitor (HB-005752) for a complete list of Status Codes).

8) **Operator Events:** if this box is checked, the data will be exported with Operator Events (see 11.1) (default: box checked).

The field '**Column separator**' offers the possibility to select the symbol that will be used to separate columns (default: Tabulator)

The field '**Format**' offers additional format options

1) **Decimal separator:** the decimal separator can be defined (default: '.')

2) **Fixed column width:** if this box is checked, the values will be arranged in a tabular form (default: box checked)

3) **Time column:** if this box is checked a time column in the 'YYYY-MM-DD hh:mm:ss' format will be saved along with the measurement values (default: box checked)

4) **Compression (sec):** if this box is checked the file size will be down-sampled according to the selectable compression factor. Check the box 'Filtering' if you want to filter the data with a moving average prior down sampling. **Example:** To get a data-point once every twenty (20) minutes in the resulting '*.vex-file' set this parameter to 1200 secs.

5) **Activate personal data:** if this box is checked patient information is not exported.

Note: This checkbox is only available if Installaton for Advanced Data Protection has been installed.

Click on the button '**OK**' opens a warning dialog (see 'Important Note' below) and then a windows dialog permitting to specify the storage folder and filename of the '*.vex-file'.

Note: In order to ensure that '.vex-files' can be automatically integrated into third party applications the 'Default File Name' and 'Default Storage Folder' that are proposed in this dialog can be predefined in the dialog 'Data Export Configuration' (see 12.1.6). The 'Data Export Configuration' is only integrated if access to enter patient information is enabled beforehand and patient data has been entered. If '*.vex-files' are stored in a dedicated folder a (third party) application may automatically import '*.vex-files'. If the filenames contain patient and measurement specific information, it will be possible for this application to assign each '*.vex-file' to the respective patient and intervention/investigation.*

*Note: When downloading SDM Trend Data from the internal memory of the SDM via the SDM's serial interface, it is optionally possible (see 6.1) – after the data download is finished - to **automatically export** the data as '*.vex-file' into the 'Default Storage Folder' and if patient data has been entered with the 'Default File Name' predefined in the dialog 'Data Export Configuration' (see 12.1.6)*

Clicking on '**E-Mail**' opens a warning dialog (see 'Important Note' below), then the standard email client and creates a new Email with the '*.vex-file' attached.

Note: The 'Default File Name' predefined in the dialog 'Data Export Configuration' (see 12.1.6) will be used as file name for the attached '.vex-file'.*

Important Note:

If data are exported with heading lines then the '.vex-file' may contain patient data. Prior generating a '*.vex-file' containing patient information make sure that patient privacy will be warranted in accordance with local ordinances. It is your responsibility to ensure that non-authorized persons cannot access '*.vex-files' containing patient information.*

Before exporting data that contain heading lines V-STATS will prompt a corresponding warning dialog.

Click on the button '**Default values**' to reactivate the factory default values of the adjustable parameters contained in this dialog.

7.6 Sub-menu 'File / Convert data to EDF+'

The sub-menu 'File / Convert data to EDF+' permits to convert the currently opened measurement into an 'EDF+-File'

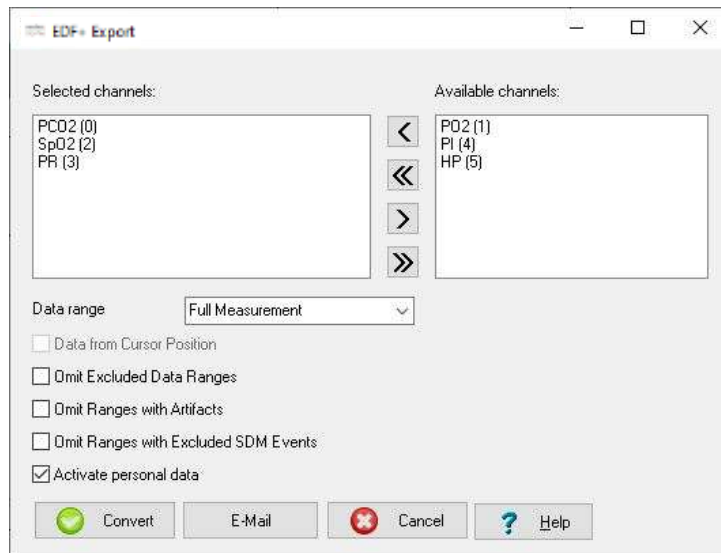
Note: The European Data Format (EDF), published in 1992, is a simple and flexible format for exchange and storage of multichannel biological and physical signals. Since then, EDF became the de-facto standard for EEG and PSG recordings in commercial equipment. An extension of EDF, named EDF+, was published in 2003. For additional information refer to www.edfplus.info. EDF+ data can be imported into most PG and PSG software packages.

Note: The sub-menu 'File / Convert data to EDF+' is dimmed grey, if no measurement is open.

Note: If PCO2 drift correction (see 11.6) is set to 'ON' only drift corrected data will be converted. Consequently, the resulting 'EDF+-file' does not contain uncorrected PCO2 data and vice versa if PCO2 drift correction is set to 'OFF'. Select 'Both', for converting the drift corrected as well as the uncorrected PCO2 data.

Note: EDF+ files cannot be imported into V-STATS.

Select the sub-menu 'File / Convert data to EDF+' to convert the currently opened measurement into an 'EDF+-File'. This will open the dialog 'EDF+ Export':



'Channel Selection': The data columns that will be exported can be selected/deselected by moving the corresponding parameter labels from the box 'Available channels' to 'Selected channels' and vice versa, respectively.

The following options permit to specify the data range to be converted:

- 1) **Data range:** The data range to be exported can be specified by selecting one of the three available options: 'Analysis Interval', 'Displayed Range', and 'Full Measurement'.

Note: If 'Analysis Interval' is selected, the data range spanned by the current 'Analysis Interval' (see 9.3) will be converted. If 'Displayed range' is selected the data range currently displayed in the V-STATS Main Window (see 4.2) will be converted.

Note: The setting of the last use will be proposed at next use. 'Full Measurement' is the factory default setting.

- 2) **Data from cursor position:** if this box is checked, data conversion starts from the current cursor position
Note: This check box is dimmed grey, if the cursor is not set within the data range to be exported.
- 3) **Omit Excluded Data Ranges:** if this box is checked numerical values within excluded data ranges (see 9.4) are omitted while converting the data into the 'EDF+-file'.
Note: This check box is always selectable (even if the range to be converted contains no excluded data ranges).
- 4) **Omit Ranges with Artifacts:** if this box is checked numerical values within ranges marked as artifacts are omitted while converting the data into the 'EDF+-file'.
Note: This check box is always selectable (even if the range to be converted contains no Artifacts).
- 5) **Omit Ranges with Excluded SDM Events:** if this box is checked values within 'Excluded SDM Event' ranges (see 9.2) are omitted while converting the data into the 'EDF+-file'.
Note: This check box is always selectable (even if the range to be converted contains no Excluded SDM Events).

6) Activate personal data: if this box is checked, patient information is not exported.

Note: This checkbox is only available if Installaton for Advanced Data Protection has been installed.

Click on the button 'Convert' opens a warning dialog (see 'Important Note' below) and then a windows dialog permitting to specify the storage folder and filename of the 'EDF+-file'.

Note: In order to ensure that 'EDF+-files' can be automatically integrated into third party applications the 'Default File Name' and 'Default Storage Folder' that are proposed in this dialog can be predefined in the dialog 'EDF+ Export Configuration' (see 12.1.7). The 'EDF+ Export Configuration' is only integrated if patient data has been entered. If 'EDF+-files' are stored in a dedicated folder a (third party) application may automatically import 'EDF+-files'. If the filenames contain patient and measurement specific information, it will be possible for this application to assign each 'EDF+-file' to the respective patient and intervention/investigation.

*Note: When downloading SDM Trend Data from the internal memory of the SDM via the SDM's serial interface, it is optionally possible (see 6.1) – after the data download is finished - to **automatically export** the data as 'EDF+-file' into the 'Default Storage Folder' and (if patient data has been entered) with the 'Default File Name' predefined in the dialog 'EDF+-Export Configuration' (see 12.1.7)*

Click on 'E-Mail' opens a warning dialog (see 'Important Note' below), then the standard email client and creates a new Email with the 'EDF+-file' attached.

Note: The 'Default File Name' predefined in the dialog 'EDF+ Export Configuration' (see 12.1.7) will be used as file name for the attached 'EDF+-file'.

Important Note:

'EDF+-files' may contain patient data. Prior generating an 'EDF+-file' make sure that patient privacy will be warranted in accordance with local ordinances. It is your responsibility to ensure that non-authorized persons cannot access 'EDF+-files' containing patient information.

Before generating an 'EDF+-Files' V-STATS will prompt a corresponding warning dialog.

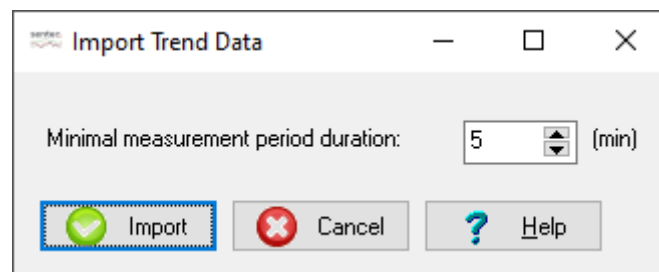
7.7 Sub-menu 'File / Import SDM Trend Data'

The sub-menus 'File/ Import SDM Trend Data' and 'File/ Export SDM Trend Data' (see 7.8) allow the exchange of data, e.g. for trouble-shooting. SDM Trend data contain: status codes, operator events, information on calibration and PCO2 drift. SDM Trend Data do not contain patient data, settings of applied analysis criteria, or analysis results.

Select the sub-menu 'File / Import SDM Trend Data' to import SDM Trend Data from a file to V-STATS, e.g.

- 1) after receiving a SDM Trend Data file by Email (see 7.9).
- 2) after exporting a SDM Trend Data file, e.g. on an external drive (see 7.8).

The sub-menu 'File / Import SDM Trend Data' opens the dialog 'Import SDM Trend Data'.



Click 'Import' and then select the raw data file to be imported. Thereafter the dialog 'Assign measurement period(s) to patients' displays (see 6.1). As described in 6.1 the selected measurement period(s) therein can be assigned to a patient and then be imported, analyzed and displayed in the V-STATS Main Window (see 4.2).

Note: The parameter 'Minimal measurement period duration' defines how long a measurement must last to be accepted by V-STATS as a valid measurement period. Measurement periods that are shorter than the time selected here will not be listed in the dialog 'Assign measurement period(s) to patients' (see 6.1) and, consequently, are not available to be imported to V-STATS. The setting of the parameter 'Minimal measurement period duration' is indicated in the dialog 'Assign measurement period(s) to patients' in the top left as 'Minimal Measurement Duration'.

Note: Please see 3.1 for compatibility information between V-STATS and the various versions of SDM Trend Data files.

7.8 Sub-menu 'File / Export SDM Trend Data'

The sub-menus 'File/ Import SDM Trend Data' (see 7.7) and 'File/ Export SDM Trend Data' allow the exchange of data, e.g. for trouble-shooting. SDM Trend data contain: status codes, operator events, information on calibration and PCO2 drift. SDM Trend Data do not contain patient data, settings of applied analysis criteria, or analysis results.

Note: The sub-menu 'File / Export SDM Trend Data' is dimmed grey, if no measurement is open or if no '.sdl' file is available for the open measurement.*

Note: Data that have been downloaded from the SDM are stored in files with the extension '.sdl'. Optionally it is possible to store the SDM Trend Data as '*.txt' files.*

To export the SDM Trend Data of the currently open measurement select the sub-menu 'File / Export SDM Trend Data'. This opens a Windows dialog permitting to specify the storage folder and filename of the SDM Trend Data File.

Note: SDM Trend Data can be imported to V-STATS with the sub-menu 'File / Import SDM Trend Data' (see 7.7).

Note: Provided you do not indicate any patient information in the file name, SDM Trend Data do not contain any patient data. SDM Trend Data therefore can be shared with third parties without the risk to violate patient privacy.

7.9 Sub-menu 'File / Send SDM Trend Data by Email'

Selecting the sub-menu 'File / Send SDM Trend Data by Email' opens the standard email client and creates a new Email with the SDM Trend Data file of the currently opened measurement attached. Enter the Email address of the recipient and send the Email.

Note: The sub-menu 'File / Send SDM Trend Data by Email' is dimmed grey, if no measurement is open or if no '.sdl' file is available for the open measurement.*

Note: The recipient can import SDM Trend Data files into V-STATS by using the sub-menu 'File / Import SDM Trend Data' (see 7.7).

Note: Provided you do not indicate any patient information in the file name, SDM Trend Data files do not contain any patient data. SDM Trend Data files therefore can be shared with others without the risk to violate patient privacy.

7.10 Sub-menu 'File / Import V-STATS File'

The sub-menus 'File/ Import V-STATS File' and 'File/ Export V-STATS File' (see 7.11) allow to exchange all information (i.e. the complete data set) contained within V-STATS for a measurement (patient data, measurement data with status codes, channel settings last used to display the measurement, operator events, start/end of analysis periods, current analysis interval, results of data analysis (including the settings of applied analysis criteria), event markers (including manually modified/ deleted markers), excluded data ranges,...).

Note: V-STATS Files have the file extension 'sdmzip'.

Note: As V-STATS Files contain the complete data set related to a measurement they are helpful to troubleshoot problems/ errors related to measurements that are already imported/ downloaded to V-STATS. In this case please send the corresponding V-STATS File to Sentec authorized technicians or to Sentec along with the description of the problem and/or your question.

Select the sub-menu 'File / Import V-STATS File' to import V-STATS files (*.sdmzip-file), e.g.

- 1) after receiving a '*.sdmzip-file' by Email (see 7.12).
- 2) after exporting a '*.sdmzip-file', e.g. on an external drive (see 7.11).

First an information dialog indicating the current 'Data Storage Folder' (see 12.1) opens. After acknowledgement of this dialog a windows dialog to select the '*.sdmzip-file' to be imported opens. The selected file will be stored in the 'Data Storage Folder' and the corresponding measurement will be displayed in the V-STATS Main Window.

7.11 Sub-menu 'File / Export V-STATS File'

The sub-menus 'File/ Import V-STATS File' (see 7.10) and 'File/ Export V-STATS File' allow to exchange all information (i.e. the complete data set) contained within V-STATS for a measurement (patient data, measurement data with status codes, channel settings last used to display the measurement, operator events, start/end of analysis periods, current analysis interval, results of data analysis (including the settings of applied analysis criteria), event markers (including manually modified/ deleted markers), excluded data ranges,...).

Note: V-STATS Files have the file extension ‘sdmzip’.

Note: As V-STATS Files contain the complete data set related to a measurement they are helpful to troubleshoot problems/ errors related to measurements that are already imported/ downloaded to V-STATS. In this case please send the corresponding V-STATS File to Sentec authorized technicians or to Sentec along with the description of the problem and/or your question.

Note: The sub-menu ‘File / Export V-STATS File’ is dimmed grey, if no measurement is open.

Select the sub-menu ‘File / Export V-STATS File’ to export the V-STATS File of the currently open measurement. This will first open a warning dialog (see ‘Important Note’ below) and then a windows dialog permitting to specify the storage folder and filename of the ‘*.sdmzip-file’.

Important Note:

‘V-STATS Files’ may contain patient data. Prior generating a ‘*.sdmzip-file’ make sure that patient privacy will be warranted in accordance with local ordinances. It is your responsibility to ensure that non-authorized persons cannot access ‘*.sdmzip-file’ containing patient information.

Before generating an ‘*.sdmzip-file’ V-STATS will prompt a corresponding warning dialog.

7.12 Sub-menu ‘File / Send V-STATS File by Email’

Select the sub-menu ‘File / Send V-STATS File by Email’ to email the V-STATS File of the currently open measurement. This will first open a warning dialog (see ‘Important Note’ below) and then the standard email client and creates a new Email with the ‘*.sdmzip-file’ of the currently open measurement attached.

Note: The sub-menu ‘File / Export V-STATS File’ is dimmed grey, if no measurement is open.

Important Note:

‘V-STATS Files’ may contain patient data. Prior generating a ‘*.sdmzip-file’ make sure that patient privacy will be warranted in accordance with local ordinances. It is your responsibility to ensure that non-authorized persons cannot access ‘*.sdmzip-file’ containing patient information.

Before generating an ‘*.sdmzip-file’ V-STATS will prompt a corresponding warning dialog.

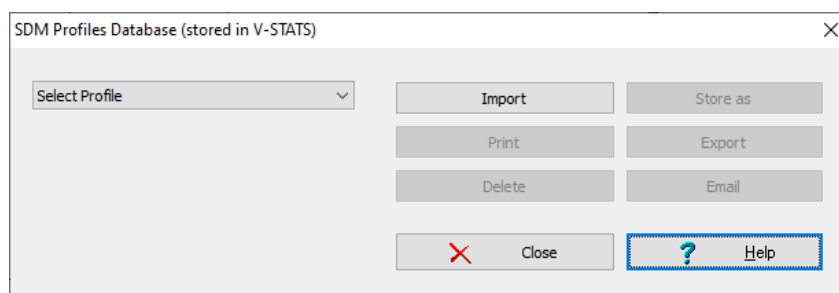
7.13 Sub-menu ‘File / SDM Profiles Database (stored in V-STATS)’

Select the sub-menu ‘File / SDM Profiles Database (stored in V-STATS)’ to open the dialog ‘SDM Profiles Database (stored in V-STATS)’. In this dialog it is possible to import a SDM Profile to the ‘SDM Profile Database’ or to print, delete, export, or rename a SDM Profile available in the ‘SDM Profiles Database’ (see 13.2.3).

Note: Upon installation of or upgrade to V-STATS 5.01.1, the following write-protected SDM Profiles preconfigured by Sentec are stored or updated in the ‘SDM Profiles Database’: CRITICAL CARE [CRITICAL_CARE], GEN. CARE FLOOR [GCF], HOME [HOME], NICU PO2 [NICU_pO2], NICU [NICU], OPERATING ROOM [OR], PACU [PACU], SLEEP [SLEEP], SMB621 Style [SMB621_Style], V-CHECK [V_CHECK]

Note: Please refer to 13.2 for a description of the syntax that is used for the profile name of SDM Profiles.

Note: If a corrupt profile is detected when opening the dialog ‘SDM Profiles Database (stored in V-STATS)’ the following warning dialog displays: ‘The following profiles seem to be corrupt and will be deleted (list with profile names). Do you want to save these profiles in another folder before (Yes | No)?’ Click on ‘Yes’ to create a backup folder and to move the corrupt profile(s) into this folder, click on ‘No’ to delete the corrupt profile(s) without a backup copy.



Control	Description
Drop-down list 'Select Profile'	<p>Lists all 'SDM Profiles' currently available in the SDM Profiles Database in alphabetical order and permits to select one of these profiles.</p> <p><i>Note: The buttons 'Store as', 'Print', 'Export', 'Delete', and 'Email' are dimmed grey (no function) as long as no 'SDM Profile' is selected.</i></p> <p><i>Note: Elements of the following syntax can be available in this drop-down list '<Display Name> [<File Name>]' or '[<File Name>]'.</i></p>
Button 'Import'	<p>Permits to import a 'SDM Profile' from the PC to the SDM Profiles Database.</p> <p>Click on this button opens a window dialog which permits to select a 'SDM Profile' stored on the PC. Upon selection of a 'SDM Profile' the dialog 'Store profile as' (see 13.2.3.1) opens. Click on 'OK' imports the selected 'SDM Profile' with the specified display and file name to V-STATS' SDM Profiles Database.</p> <p><i>Note: The file extension of SDM Profile files is '.spf'.</i></p>
Button 'Store as'	<p>Permits to store the 'SDM Profile' selected in the drop-down list in the SDM Profiles Database with a different display name and/or file name.</p> <p>Click on this button opens the dialog 'Store profile as' (see 13.2.3.1). In this dialog it is possible to modify the display and/or filename. Click on 'OK' stores a copy of the selected 'SDM Profile' with the specified display and file name to the SDM Profiles Database.</p> <p><i>Note: If a different file name is selected in the dialog 'Store profile as' (see 13.2.3.1) a copy of the selected SDM Profile will be stored in the SDM Profiles Database with the specified file name. If only a different display name is selected but the file name is not modified in the dialog 'Store profile as' (see 13.2.3.1) the display name of the selected SDM Profile will be modified accordingly.</i></p>
Button 'Print'	<p>Click on this button opens a windows dialog permitting to print the 'SDM Profile' selected in the drop-down list either a) on paper (select 'Printer') or b) as pdf-file (select 'PDF').</p> <p>If 'Printer' is selected a dialog opens in which it is possible to select the printer and print settings such as paper size. If 'PDF' is selected a windows dialog opens permitting to specify the storage folder and filename of the pdf-file. The syntax of the proposed file name is 'SDM Profile <Display Name> [<File Name>].pdf'.</p> <p>Refer to 13.2.3 for a description of the elements that are included in the print-out.</p>
Button 'Export'	<p>Click on this button opens a windows dialog permitting to export the 'SDM Profile' selected in the drop-down list to the PC.</p> <p><i>Note: When exporting a 'SDM Profile' to the PC only the file name can be modified but not the display name.</i></p>
Button 'Email'	<p>Click on this button opens the standard email client and creates a new Email with the 'SDM Profile' selected in the drop-down list attached. Enter the Email address of the recipient and send the Email.</p>
Button 'Delete'	<p>Click on this button activates a confirmation dialog and - after confirmation - deletes the 'SDM Profile' selected in the drop-down list.</p> <p><i>Note: This button is dimmed grey (no function) if one of the <u>write-protected</u> SDM Profiles preconfigured by Sentec is selected.</i></p>

7.14 Sub-menu 'File / Analysis Criteria Profile'

The sub-menu 'File / Analysis Criteria Profile' opens the dialog 'Analysis criteria' (see 9.2). In this dialog it is possible to create/ customize 'Analysis Criteria Profiles' and to change the settings of all analysis criteria on an individual basis.

Note: The sub-menu 'File/ Analysis Criteria Profile' is not accessible (dimmed grey) if a measurement is open. In this case use the sub-menu 'Analysis/ Analysis Criteria Profile' (see 9.2) to open the dialog 'Analysis Criteria Profile'.

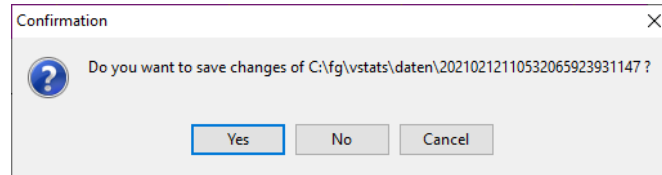
Note: It is recommended to create/ customize 'Analysis Criteria Profiles' if no measurement is open.

7.15 Sub-menu 'File / Close measurement'

The open measurement can be closed in the sub-menu 'File / Close measurement'.

If the measurement file contains unsaved changes when attempting to close the measurement V-STATS will prompt the

following message:



Note: A measurement can also be closed by clicking on the respective icon in the menu bar of the V-STATS Main Window (see 4.2.1).

Note: When attempting to close a measurement that has been opened by another user during your session a warning message displays indicating the ID of the user that has opened the measurement and pointing out that your changes may be overruled by the other user's changes when he closes the measurement. In this situation it is possible to close the measurement without saving the changes.

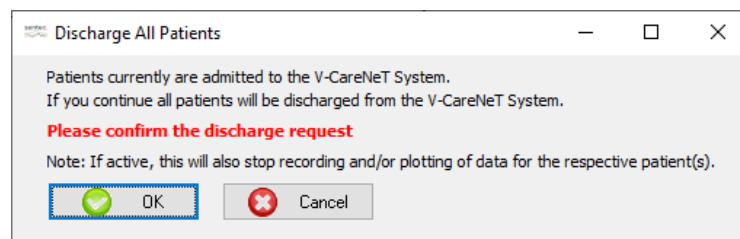
Note: Do not turn off the computer before saving/ closing the measurement or exiting V-STATS. Otherwise changes you have made may be lost!

7.16 Sub-menu 'File / Exit'

Use the sub-menu 'File / Exit' to exit V-STATS. If V-CareNeT is active, this will also terminate V-CareNeT (see 14.4).

Note: If a measurement is open that contains unsaved changes VSTATS prompts the messages "Do you want to save changes? Yes/ No/ Cancel" before exiting.

Note: When exiting V-STATS while patients are admitted to the V-CareNeT System, the alert dialog 'Discharge All Patients' displays (see 14.7.5). In this case V-STATS will terminate only after you have confirmed the discharge request.



8. Communication Menu

8.1 Sub-menu 'Communication / with Sentec device (via Serial Interface)'

A: Setting up the SDM and V-STATS

1. On the SDM: Selection of the serial protocol and the baud rate

- 1) Set the menu option 'Interfaces / Serial Interface / Protocol' to 'SentecLink'
- 2) Select the baud rate in the menu 'Interfaces / Serial Interface / Baud rate'.

Note: It is recommended to use the maximal baud rate (115'200), as download of Trend Data is faster the higher the baud rate. However, in certain cases, e.g. if older PC's or a long/old serial cable is used, it might be necessary to reduce the baud rate in order to obtain a stable communication.

2. Establish the connection between the SDM and the PC with V-STATS


Connect one end of a serial cable to the serial data port (RS-232) of the SDM and connect the other end of the cable to the serial port of your PC. If your computer has no serial port but USB-ports an USB/RS232 Converter Cable can be used.

Important Note: Ensure to use good quality **USB2.0** USB232 Converter Cables.

3. In V-STATS: Adjust the Communication Settings

Select the appropriate COM-port in the dialog 'Communication with Sentec device (via Serial Interface)' (see below).

B: Communication with Sentec device (via the Serial Interface)

The dialog 'Communication with Sentec device (via Serial Interface)' can be opened by selecting the sub-menu 'Communication / with Sentec device (via Serial Interface)', by clicking on the  -icon in the menu bar of the V-STATS Main Window (see 4.2.1) or by clicking on the button 'Communication with Sentec device (serial)' which is displayed in the center of the V-STATS Main Window if no measurement is open (see 4.1).

The dialog 'Communication with Sentec device (via Serial Interface)' gives access to the functions a) to download SDM Trend Data from the internal memory of the connected SDM (see 6), b) to clear the internal memory of the connected SDM, c) to set the 'Date & Time' of the connected SDM to the 'Date & Time' of the PC, d) to configure profiles and settings of the connected SDM (see 13), and e) to functions that are helpful for troubleshooting ('Full Memory Dump', 'Raw Dump', 'Screenshots', and 'Device Factory Reset').

Note: V-STATS does not support communication via the Serial Interface to a SDM with a software older than V08.00.



In the top of the dialog 'Communication with Sentec device (via Serial Interface)' the drop-down list 'Com port:' permits to select one of the PC's currently available COM ports.

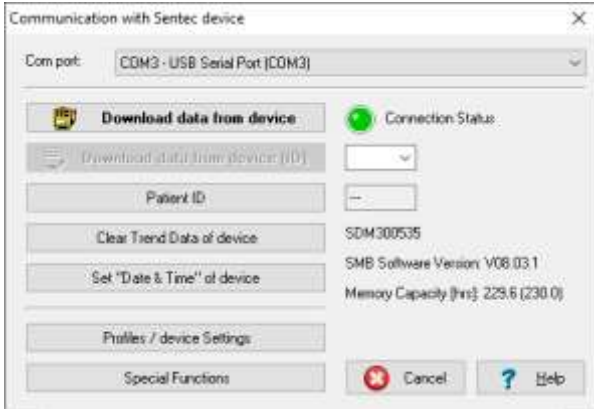
Note: COM ports assigned to a USB/RS232 Converter Cable are usually only available if the USB/RS232 Converter Cable is connected to the PC.

Not Connected

The 'Connection Status' indicator is red if V-STATS is unable to establish communication with the connected SDM. The various control buttons are dimmed grey. The red blinking text displayed in the bottom summarizes how to set-up the SDM and V-STATS (see A above).

Note: As long as V-STATS is unable to establish communication with the SDM, the dialog 'Communication with Sentec device (via Serial Interface)' remains in this state.

Note: The dialogs which open after clicking on the buttons 'Download data from device', 'Download data from device (ID)', 'Patient ID', 'Profiles / device Settings', and 'Special Functions' are closed if the communication is interrupted.



Connected

Once communication between V-STATS and the connected SDM is established

- the 'Connection Status' indicator is green
- the red blinking text disappears
- various buttons (see below) become accessible
- the serial number and the SMB software version of the connected SDM are displayed. The free and total memory capacities are also displayed.


Buttons of the dialog 'Communication with Sentec device (via Serial Interface)'

Button	Description
Download data from device	Click on this button opens the dialog 'Assign measurement period(s) to patients' (see 6.1) where all measurement periods stored in the internal memory of the SDM <u>that are longer</u> than the current setting of the SDM internal parameter 'Minimal Measurement Duration' are listed. As described in 6.1 the selected measurement period(s) therein can be assigned to a patient if patient data has been entered and then be downloaded, analyzed and displayed in V-STATS' Main Window. <i>Note: An ongoing (not terminated) measurement can only be downloaded via V-CareNeT (see 14.6); it cannot be downloaded via the Serial Interface.</i> <i>Note: On SDM's with software version SMB V07.00.x or newer the current setting of the SDM internal parameter 'Minimal Measurement Duration' is displayed in the menu 'Trend Data'. It only can be changed by the Responsible Organization by using V-STATS (see 13.2.4.6).</i>
Download data from device (ID)	The popup menu on the right of this button displays all patient IDs for which measurement periods are available in the internal memory. Click on this button opens the dialog 'Assign measurement period(s) to patients' (see 6.1) where <u>for the selected Patient ID</u> all measurement periods stored in the internal memory of the SDM <u>that are longer</u> than the current setting of the SDM internal parameter 'Minimal Measurement Duration' are listed. As described in 6.1, the selected measurement period(s) therein can be assigned to a patient if patient data has been entered. It can then be downloaded, analyzed and displayed in V-STATS' Main Window. <i>Note: The same notes as for the function 'Download data from device' (see above) apply.</i>
Patient ID	This function will change the Patient ID. The patient ID that is active at the <u>beginning</u> of a new measurement period will be assigned to this measurement period. The patient ID that is currently active on the SDM is displayed on the left of the respective control. <i>Note: The patient ID cannot be changed during a running measurement.</i> <i>Note: The patient ID can only be changed by using V-STATS, i.e. it cannot be changed in the menu of the SDM.</i>
Clear Trend Data of device	Deletes the data stored in the internal memory of the SDM. <i>Note: Trend Data of the SDM cannot be deleted during a running measurement.</i>
Set 'Date & Time' of the device	This function will set the 'Date & Time' of the SDM to the 'Date & Time' of the PC. <i>Note: 'Date & Time' of the SDM cannot be changed during a running measurement.</i> <i>Note: The Trend Data of the SDM are deleted when setting 'Date & Time'.</i>

Button	Description										
Profiles / device Settings	<p>Opens a password-dialog and – after having successfully entered the password - the dialog 'Profiles / device Settings - <SN>', where <SN> is the serial number of the connected SDM. Please see 13.2 for details.</p> <p><i>Note:</i> The dialog 'Profiles / device Settings - <SN>' is not accessible if patient monitoring is ongoing with the connected SDM.</p> <p><i>Note:</i> The default password for the Standard Installation is the Identification Code, which is displayed in the dialog 'Product-Info' (see 16.6). The password can be changed in the dialog 'Change Password'. In case you have forgotten your password enter the Password Unlock Key 'RememberPassword' in the field 'Current Password' and select a new password.</p> <p><i>Note:</i> The password (admin password) to open the dialog 'Profiles / device Settings - <SN>' is the same password that is required to open the dialog 'Special Functions' (see below) and the dialog 'V-STATS Settings' (see 12.1).</p>										
Special Functions	<p>Opens a password-dialog and – after having successfully entered the password - the dialog 'Special Functions'. The following special functions are supported.</p> <table border="1" data-bbox="486 705 1433 1798"> <thead> <tr> <th data-bbox="486 705 722 739">Special Function</th> <th data-bbox="722 705 1433 739">Description</th> </tr> </thead> <tbody> <tr> <td data-bbox="486 750 722 1171">Full Memory Dump</td> <td data-bbox="722 750 1433 1171"> <p>Reads the entire internal memory of the connected SDM and stores the data in a file on the PC. Therein numeric values of measurement parameters that are flagged as unstable or invalid are replaced by 'u' or 'i', respectively. The 'Current SDM Profile' is additionally stored at the end of the file.</p> <p><i>Note:</i> The default file name proposed by V-STATS is 'MemoryDump_SDMxxxxxx.txt (where xxxxxx corresponds to the Serial Number of the SDM. If the Serial Number of the SDM is not available the default file name will be 'MemoryDump_SDM.txt'.</p> <p><i>Note:</i> This function mostly will be used for troubleshooting purposes. Please send the Full Memory Dump File to Sentec authorized technicians or to Sentec along with the description of the problem and/or your question.</p> </td> </tr> <tr> <td data-bbox="486 1182 722 1541">Raw Dump</td> <td data-bbox="722 1182 1433 1541"> <p>Reads the entire internal memory of the connected SDM and stores the data in a file on the PC. Irrespective of the quality numeric values of parameters are output, i.e. a 'Raw Dump' provides even more details than a 'Full Memory Dump'. The 'Current SDM Profile' is additionally stored at the end of the file.</p> <p><i>Note:</i> The default file name proposed by V-STATS is 'RawDump_SDMxxxxxx.txt (where xxxxxx corresponds to the Serial Number of the SDM). If the Serial Number of the SDM is not available the default file name will be 'RawDump_SDM.txt'.</p> <p><i>Note:</i> This function mostly will be used for troubleshooting purposes. Please send the Raw Dump File upon request of Sentec.</p> </td> </tr> <tr> <td data-bbox="486 1552 722 1720">Screenshot</td> <td data-bbox="722 1552 1433 1720"> <p>Captures a screenshot of the SDM's currently active screen and permits to save it as a bitmap (*.bmp file) on the PC.</p> <p><i>Note:</i> This function can be useful to prepare educational material or for troubleshooting. Please send the Screenshot to Sentec authorized technicians or to Sentec along with the description of the problem and/or your question.</p> </td> </tr> <tr> <td data-bbox="486 1731 722 1798">SDM Factory Reset</td> <td data-bbox="722 1731 1433 1798"> <p>Restores the connected SDM's factory configuration and clears the Trend Data of the connected SDM</p> </td> </tr> </tbody> </table> <p><i>Note:</i> The password (admin password) to open the dialog 'Special Functions' is the same password that is required to open the dialog 'Profiles / device Settings - <SN>' (see above) and the dialog 'V-STATS Settings' (see 12.1).</p> <p><i>Note:</i> The default password for the Standard Installation is the Identification Code, which is displayed in the dialog 'Product-Info' (see 16.6). The password can be changed in the dialog 'Change Password'. In case you have forgotten your password enter the Password Unlock Key 'RememberPassword' in the field 'Current Password' and select a</p>	Special Function	Description	Full Memory Dump	<p>Reads the entire internal memory of the connected SDM and stores the data in a file on the PC. Therein numeric values of measurement parameters that are flagged as unstable or invalid are replaced by 'u' or 'i', respectively. The 'Current SDM Profile' is additionally stored at the end of the file.</p> <p><i>Note:</i> The default file name proposed by V-STATS is 'MemoryDump_SDMxxxxxx.txt (where xxxxxx corresponds to the Serial Number of the SDM. If the Serial Number of the SDM is not available the default file name will be 'MemoryDump_SDM.txt'.</p> <p><i>Note:</i> This function mostly will be used for troubleshooting purposes. Please send the Full Memory Dump File to Sentec authorized technicians or to Sentec along with the description of the problem and/or your question.</p>	Raw Dump	<p>Reads the entire internal memory of the connected SDM and stores the data in a file on the PC. Irrespective of the quality numeric values of parameters are output, i.e. a 'Raw Dump' provides even more details than a 'Full Memory Dump'. The 'Current SDM Profile' is additionally stored at the end of the file.</p> <p><i>Note:</i> The default file name proposed by V-STATS is 'RawDump_SDMxxxxxx.txt (where xxxxxx corresponds to the Serial Number of the SDM). If the Serial Number of the SDM is not available the default file name will be 'RawDump_SDM.txt'.</p> <p><i>Note:</i> This function mostly will be used for troubleshooting purposes. Please send the Raw Dump File upon request of Sentec.</p>	Screenshot	<p>Captures a screenshot of the SDM's currently active screen and permits to save it as a bitmap (*.bmp file) on the PC.</p> <p><i>Note:</i> This function can be useful to prepare educational material or for troubleshooting. Please send the Screenshot to Sentec authorized technicians or to Sentec along with the description of the problem and/or your question.</p>	SDM Factory Reset	<p>Restores the connected SDM's factory configuration and clears the Trend Data of the connected SDM</p>
Special Function	Description										
Full Memory Dump	<p>Reads the entire internal memory of the connected SDM and stores the data in a file on the PC. Therein numeric values of measurement parameters that are flagged as unstable or invalid are replaced by 'u' or 'i', respectively. The 'Current SDM Profile' is additionally stored at the end of the file.</p> <p><i>Note:</i> The default file name proposed by V-STATS is 'MemoryDump_SDMxxxxxx.txt (where xxxxxx corresponds to the Serial Number of the SDM. If the Serial Number of the SDM is not available the default file name will be 'MemoryDump_SDM.txt'.</p> <p><i>Note:</i> This function mostly will be used for troubleshooting purposes. Please send the Full Memory Dump File to Sentec authorized technicians or to Sentec along with the description of the problem and/or your question.</p>										
Raw Dump	<p>Reads the entire internal memory of the connected SDM and stores the data in a file on the PC. Irrespective of the quality numeric values of parameters are output, i.e. a 'Raw Dump' provides even more details than a 'Full Memory Dump'. The 'Current SDM Profile' is additionally stored at the end of the file.</p> <p><i>Note:</i> The default file name proposed by V-STATS is 'RawDump_SDMxxxxxx.txt (where xxxxxx corresponds to the Serial Number of the SDM). If the Serial Number of the SDM is not available the default file name will be 'RawDump_SDM.txt'.</p> <p><i>Note:</i> This function mostly will be used for troubleshooting purposes. Please send the Raw Dump File upon request of Sentec.</p>										
Screenshot	<p>Captures a screenshot of the SDM's currently active screen and permits to save it as a bitmap (*.bmp file) on the PC.</p> <p><i>Note:</i> This function can be useful to prepare educational material or for troubleshooting. Please send the Screenshot to Sentec authorized technicians or to Sentec along with the description of the problem and/or your question.</p>										
SDM Factory Reset	<p>Restores the connected SDM's factory configuration and clears the Trend Data of the connected SDM</p>										

Button	Description
	<i>new password.</i>

8.2 Sub-menu 'Communication / V-CareNeT'

V-CareNeT can be activated a) by selecting the sub-menu 'Communication / V-CareNeT', b) by clicking on the  LAN -icon in the menu bar of V-STATS' Main Window (see [4.2.1](#)) or c) by clicking on the button 'V-CareNeT' which displays in the center of V-STATS' Main Window if no measurement is open (see [4.1](#)). All these options will first open a dialog which offers the possibility to edit/ reactivate the 'Last V-CareNeT Session' (see [14.4.1](#)) and then activate the V-CareNeT Main Screen with the 'V-CareNeT Control Window' in the upper right or left (see [12.2](#), [14.4](#)).

Please refer to [14](#) for a comprehensive description of V-CareNeT, which offers the following main features:

- Remote monitoring and secondary alarm surveillance for up to 40 beds/ patients (see [14.7](#)).
- Downloading SDM Trend Data from the internal memory of Sentec Digital Monitor (SDMs) via their LAN interface (see [14.6](#)). Please note that with V-CareNeT Download of SDM Trend Data is simultaneously possible from multiple SDMs.
- Setting 'Baselines' (for PCO₂, PO₂, SpO₂, and RHP) & 'Operator Events' on the included SDMs remotely (see [14.8.3](#)).
- Setting certain parameters/ settings of included SDMs remotely (see [14.8.2.1](#)).

9. Analysis Menu

Note: The sub-menus and functions of the Analysis Menu are accessible only if a measurement is open. Changes that are made with functions of the Analysis Menu will only affect the measurement that is currently displayed in the V-STATS Main Window.

Note: Data analysis currently does not include analysis of PO2, PI, and HP data.



WARNING: V-STATS provides no diagnosis. The interpretation of the measurement data is the sole responsibility of the investigator or medical practitioner.

V-STATS' data analysis comprises a set of predefined statistical criteria as well as user adjustable analysis criteria (see 9.2) for the detection of physiological events (PCO2, SpO2, PR) and artifacts as well as for the determination of the time SpO2 readings were below and PCO2 readings were above a predefined value, respectively. Furthermore, in the dialog 'Analysis Criteria Profile' episodes with certain SDM Events optionally can be excluded from data analysis (see 4.2.5). In this dialog, the settings of these criteria can be changed on an individual basis.

In order to ensure that you can analyze your measurement the way you want them to in varying clinical settings, V-STATS provides 'Analysis Criteria Profiles' (see 9.2). It is possible to customize 'Analysis Criteria Profiles' (see 9.2). Once you have created your own 'Analysis Criteria Profiles' you can switch between them with the ease of a few 'mouse-clicks', for example, a) before activating download/ import of SDM Trend Data to V-STATS (see 6) or b) to re-analyze the currently open measurement with a different 'Analysis Criteria Profiles' (see 4.2).

The current 'Analysis Interval' (see 9.3), i.e. the time range of a measurement that is currently considered for data analysis, can also be selected/ modified with a few mouse clicks (see 4.2). Note that in the V-STATS Main Window the current 'Analysis Interval' is unambiguously identified by the 'Analysis Interval Indicator', a blue bold label, and by a blue bar above the measurement curves. User selectable data ranges can be marked as artifacts (see 4.2.6) or can be excluded from data analysis (see 9.4).

Important Note: *Unless otherwise specified for each channel all statistical results are based on the evaluation of the analyzed duration, i.e. of the artifact free part of valid, non-excluded measurement data contained within the current 'Analysis Interval'.*

Once data analysis with the currently selected 'Analysis Criteria Profile' is accomplished for the selected 'Analysis Interval' markers highlight the detected physiological events and artifacts on the measurement curves and the most important statistical results are displayed on the left of the respective channel (see 4.2). The associated report (see 9.5) comprises numerous pages displaying all results of the data analysis for the open measurement. In the report, finally, it is possible to add comments and findings (see 9.5.2, 9.5.11).

The report print-out/ PDF Report is configurable/customizable (see 7.3). Among other it is possible to select the pages of the report and the individual elements of the report 'Summary' page (see 9.5.2) that will be printed/ stored. In order to ensure that you can print/ save reports the way you want them to for various clinical settings, V-STATS provides 'Report Profiles' (see 7.3.1). It is possible to customize 'Report Profiles' (see 7.3.1). Once you have created your own 'Report Profiles' you can switch between the different available 'Report Profiles' with the ease of a few 'mouse-clicks' before printing/ storing the report.

Note: Currently V-STATS' 'Analysis Criteria' are only available for the parameters PCO2, SpO2 and PR. This means that the report contains statistical analyses for PCO2, SpO2 and PR only. However, PO2, PI, HP measurement curves can optionally be included in the report and the report-printout. Please note that in order to include the measurement curves in the report a) the respective parameter must be included in the measurement file; b) must be displayed in the currently open measurement file (see 11.8); and c) must be selected to be included in the print-out of the report (see 7.3).

9.1 Sub-menu 'Analysis / Analyze'

The sub-menu 'Analysis / Analyze' opens a pop-up menu offering various options to re-analyze the open measurement without the need to open the dialog 'Analysis Criteria Profile' (see 9.2).

Note: If a measurement is open, an equivalent popup-menu opens after left click on the 'Current Analysis Criteria Profile Indicator' in both, the V-STATS Main Window (see 4.2) and the V-STATS Report Window (see 9.5.1).

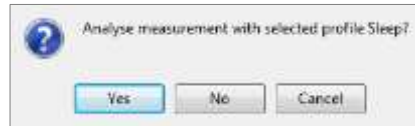
Note: If no measurement is open, left click on the 'Analysis Criteria Profile Indicator' in the V-STATS Main Window (see 4.2) opens a popup menu just offering the possibility to select a different 'Analysis Criteria Profile' from the 'Analysis Criteria Profiles Database' (see 9.2).

Note: Before activating download/ import of SDM Trend Data (see 6) the 'Analysis Criteria Profile' optionally can

be selected in the dialog 'Assign measurement period(s) to patients' (see 6.1). In this dialog left click on the 'Analysis Criteria Profile Indicator' opens a popup-menu listing all 'Analysis Criteria Profiles' currently available in the 'Analysis Criteria Profiles Database' (see 9.2).

The following options are selectable in this popup-menu:

- **'Select Analysis Criteria Profiles'**: Opens a further popup-menu listing all 'Analysis Criteria Profiles' currently available in the 'Analysis Criteria Profiles Database' (see 9.2) with a check mark identifying the currently selected 'Analysis Criteria Profile'. Select the desired 'Analysis Criteria Profile' with the mouse. If the settings that were last used to analyze the open measurement and those of the selected 'Analysis Criteria Profile' are identical the selected profile is directly applied. Otherwise the following dialog is triggered:

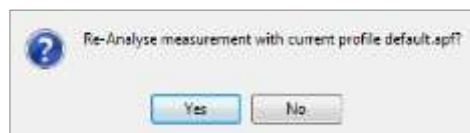


Click on 'Cancel' to abort the process without applying the 'Analysis Criteria Profile' just selected in the popup-menu. Select 'No' to apply the 'Analysis Criteria Profile' just selected in the popup-menu without analyzing the measurement. Select 'Yes' to analyze the measurement with the 'Analysis Criteria Profile' just selected in the popup-menu. Note that if in this case manually modified/ deleted physiological event or artifact markers (see 4.2, 4.2.4, 4.2.6) are present in the measurement the following dialog triggers prior analyzing the measurement:

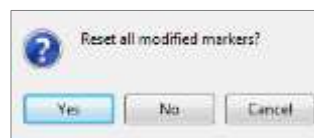


Click on 'Cancel' to abort the process without applying the just selected 'Analysis Criteria Profile' / without analyzing the measurement. Click on 'No' to analyze the measurement with the just selected 'Analysis Criteria Profile' without resetting manually modified markers. Click on 'Yes' to reset all modified/ deleted markers and to analyze the measurement with the 'Analysis Criteria Profile' just selected in the popup-menu.

- **'Analyze All Channels'**: If the settings that were last used to analyze the open measurement and those of the currently selected 'Analysis Criteria Profile' are identical this option is dimmed grey and cannot be selected. Otherwise, selection of this option triggers the following dialog:



Click on 'No' to abort the process without re-analyzing the measurement. Select 'Yes' to re-analyze the measurement with the currently selected 'Analysis Criteria Profile'. Note that if in this case manually modified/ deleted physiological event or artifact markers (see 4.2, 4.2.4, 4.2.6) are present in the measurement the following dialog triggers prior analyzing the measurement:

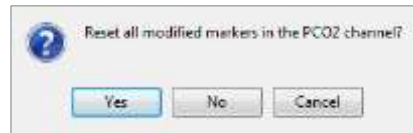


Click on 'Cancel' to abort the process without re-analyzing the measurement. Click on 'No' to re-analyze the measurement with the currently selected 'Analysis Criteria Profile' without resetting manually modified markers. Click on 'Yes' to reset all modified/ deleted markers and to re-analyze the measurement with the currently selected 'Analysis Criteria Profile'.

- **'Analyze PCO2'**: If the PCO2 related analysis settings that were last used to analyze the open measurement and those of the currently selected 'Analysis Criteria Profile' are identical this option is dimmed grey and cannot be selected. Otherwise, selection of this option triggers the following dialog:



Click on 'No' to abort the process without re-analyzing the PCO₂ channel. Select 'Yes' to re-analyze the measurement's PCO₂ channel with the currently selected 'Analysis Criteria Profile'. Note that if in this case manually modified/ deleted physiological event or artifact markers (see 4.2, 4.2.4, 4.2.6) are present in the measurement's PCO₂ channel the following dialog triggers prior analyzing the measurement's PCO₂ channel:



Click on 'Cancel' to abort the process without re-analyzing the measurement's PCO₂ channel. Click on 'No' to re-analyze the measurement's PCO₂ channel with the currently selected 'Analysis Criteria Profile' without resetting manually modified markers in the measurement's PCO₂ channel. Click on 'Yes' to reset all modified/ deleted markers in the measurement's PCO₂ channel and to re-analyze the measurement's PCO₂ channel with the currently selected 'Analysis Criteria Profile'.

Note: Re-Analysis of the PCO₂ channel can also be initiated in the popup-menu which opens upon right click on plus spanning a range with the mouse in the PCO₂ channel's measurement curve (see 4.2.4).

Note: Resetting all modified markers in the PCO₂ channel can also be initiated in the popup-menu which opens upon right click on plus spanning a range with the mouse in the PCO₂ channel's measurement curve (see 4.2.4). Resetting modified markers individually is possible in the popup menu that opens after right click on a modified marker (in this situation the popup menu will offer the option to reset just the selected marker).

- 'Analyze SpO₂': If the SpO₂ related analysis settings that were last used to analyze the open measurement and those of the currently selected 'Analysis Criteria Profile' are identical this option is dimmed grey and cannot be selected. Otherwise, selection of this option is possible. Refer to the description of the equivalent option 'Analyze PCO₂' above.
- 'Analyze PR': If the PR related analysis settings that were last used to analyze the open measurement and those of the currently selected 'Analysis Criteria Profile' are identical this option is dimmed grey and cannot be selected. Otherwise, selection of this option is possible. Refer to the description of the equivalent option 'Analyze PCO₂' above.

9.2 Sub-menu 'Analysis / Analysis Criteria Profile'

In the dialog 'Analysis Criteria Profile' V-STATS provides numerous customizable analysis criteria for the detection of physiological events (PCO₂, SpO₂, PR) and artifacts as well as for the determination of the time SpO₂ readings are below and PCO₂ readings are above a predefined value, respectively. Furthermore, in the dialog 'Analysis Criteria Profile' episodes with certain SDM Events optionally can be excluded from data analysis (see 4.2.5). The settings of these criteria can be changed on an individual basis.

In order to ensure that you can analyze your measurement the way you want them to in varying clinical settings, V-STATS provides 'Analysis Criteria Profiles' that are stored in the 'Analysis Criteria Profiles Database' (see below). An 'Analysis Criteria Profile' specifies a setting for each parameter included in the dialog 'Analysis Criteria Profile'. As described below it is possible to customize/ create/ manage 'Analysis Criteria Profiles' in the dialog 'Analysis Criteria Profile'. Once you have created your own 'Analysis Criteria Profiles' you can switch between the different 'Analysis Criteria Profiles' that are available in the 'Analysis Criteria Profiles Database' with the ease of a few 'mouse-clicks', i.e. without the need to open the dialog 'Analysis Criteria Profile'. Before activating download/ import of SDM Trend Data (see 6), for example, the 'Analysis Criteria Profile' can be selected in the dialog 'Assign measurement period(s) to patients' (see 6.1). Similarly, a click on the 'Analysis Criteria Profile Indicator' in the V-STATS Main Window (see 4.1, 4.2) or in the V-STATS Report Window (see 9.5.1) opens a pop-up menu (see 9.1) that offers the possibility a) to select and then analyze the open measurement with a different 'Analysis Criteria Profile' (see 9.2) or b) to re-analyze all or individual channels of the open measurement with the currently selected 'Analysis Criteria Profile' (options dimmed grey if settings that were last used to analyze the respective channel are identical with those of the currently selected 'Analysis Criteria Profile').

The dialog 'Analysis Criteria Profile' can be opened

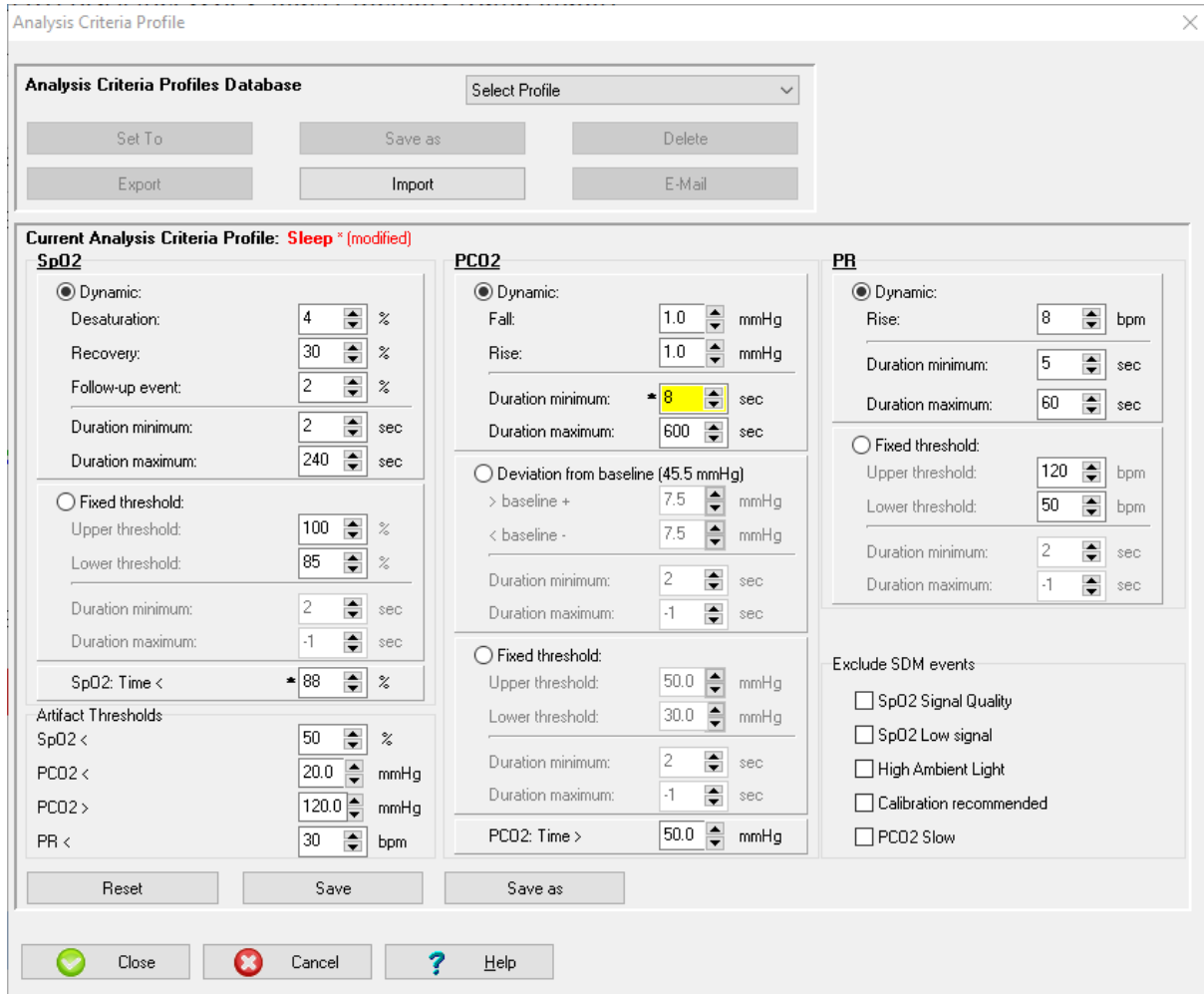
- by selecting the sub-menu 'File / Analysis Criteria Profile' if no measurement is open (see 4.1).

Note: In this case the settings displayed immediately after opening the dialog 'Analysis Criteria Profile' correspond to those of the currently selected 'Analysis Criteria Profile'.

- by selecting the sub-menu 'Analysis / Analysis Criteria Profile' if a measurement is open.

Note: In this case the settings displayed immediately after opening the dialog 'Analysis Criteria Profile' correspond to those that were last used to analyze the open measurement (i.e. the settings last used to analyze the open measurement are 'loaded' into the dialog 'Analysis Criteria').

Note: It is recommended to create/ customize 'Analysis Criteria Profiles' while no measurement is open.



The dialog 'Analysis Criteria Profile' contains **two main areas**: A) the 'Analysis Criteria Profile Database' area and B) the 'Current Analysis Criteria Profile' area. Both are described in the following.

A) Area 'Analysis Criteria Profile Database'

Within the 'Analysis Criteria Profile Database' area the following functions are available:

Control	Description
Drop-down list 'Select Profile'	Lists all 'Analysis Criteria Profiles' currently available in the Analysis Criteria Profiles Database in alphabetical order and permits to select one of these profiles. <i>Note: The buttons 'Set To', 'Save as', 'Export', 'Delete', and 'Email' are dimmed grey (not selectable) as long as no 'Analysis Criteria Profile' is selected.</i>
Button 'Set To'	Click on this button to apply/ confirm the 'Analysis Criteria Profile' selected in the drop-down list. Thereafter each parameter in the dialog 'Analysis Criteria Profile' will be set to the respective setting stored in the just selected 'Analysis Criteria Profile' and the 'Analysis Criteria Profile Indicator' will display the respective profile name. <i>Note: Clicking on 'Set To' does not activate analysis of the open measurement. If applicable, V-STATS will prompt the message 'Analyze measurement?' when closing the dialog 'Analysis Criteria Profile'.</i> <i>Note: This button is dimmed grey (not selectable) if in the drop-down list 'Select Profile' the currently selected 'Analysis Criteria Profile' is chosen.</i>
Button 'Save as'	Permits to store the 'Analysis Criteria Profile' selected in the drop-down list with a different name to the Analysis Criteria Profiles Database. Click on this button opens the dialog 'Save Analysis

	Criteria Profile' permitting to specify a different profile name and then to store a copy of the selected 'Analysis Criteria Profile' with the specified name to the 'Analysis Criteria Profiles Database'. <i>Note: Maximum 16 characters permitted for file names of 'Analysis Criteria Profiles'</i>
Button 'Delete'	Click on this button activates a confirmation dialog and – after confirmation – deletes the 'Analysis Criteria Profile' selected in the drop-down list. <i>Note: This button is dimmed grey (not selectable) if in the drop-down list 'Select Profile' a <u>write-protected</u> Analysis Criteria Profile preconfigured by Sentec or the current 'Analysis Criteria Profile' is selected.</i>
Button 'Export'	Click on this button opens a windows dialog permitting to export the 'Analysis Criteria Profile' selected in the drop-down list to the PC as *.apf file, e.g. for importing to another V-STATS application. <i>Note: Maximum 16 characters permitted for file names of 'Analysis Criteria Profiles'</i>
Button 'Import'	Click on this button first opens a windows dialog which permits to select an 'Analysis Criteria Profile' stored on the PC. After selection of the 'Analysis Criteria Profile' to be imported the dialog 'Save Analysis Criteria Profile' opens. In this dialog it is then optionally possible to modify the profile name. Click on 'OK' imports the selected 'Report Profile' with the specified name to the Analysis Criteria Profiles Database. <i>Note: Maximum 16 characters permitted for file names of 'Analysis Criteria Profiles'. The file extension of Analysis Criteria Profile Files is *.apf.</i>
Button 'Email'	Click on this button opens the standard email client and creates a new Email with the 'Analysis Criteria Profile' selected in the drop-down list attached.

Upon installation of or upgrade to V-STATS 5.01.1 the write-protected 'Report Profile' 'Default' preconfigured by Sentec is stored in the 'Analysis Criteria Profiles Database'. The settings of this 'Analysis Criteria Profile' are shown above in the screenshot of the dialog 'Analysis Criteria Profile'. Note that with this profile physiological event markers will be visualized for the dynamic events (desaturations in SpO2 Channel, PCO2 Fall/ Rise events in PCO2 channel, PR Rise events in PR channel). Also note that in this profile none of the SDM Events are excluded (see below).

To create a **customized** 'Analysis Criteria Profile' proceed as follows:

- 1) Open the dialog 'Analysis Criteria Profile' if no measurement is open by using the menu 'File / Analysis Criteria Profile' (see 7.14)

Note: We recommend creating / customizing 'Analysis Criteria Profiles' while no measurement is open.

- 2) Adjust the settings of the various analysis criteria as desired.
- 3) In the area 'Current Analysis Criteria Profile' (see below) click on the button 'Save as' to store your customized settings. This will open the dialog 'Save Analysis Criteria Profile' permitting to specify a profile name and then to store your customized 'Analysis Criteria Profile' with the specified name to the 'Analysis Criteria Profiles Database'. Note that thereafter the just saved 'Analysis Criteria Profile' is activated as currently selected 'Analysis Criteria Profile'.

B) Area 'Current Analysis Criteria Profile'

The area 'Current Analysis Criteria Profile' displays the 'Current Analysis Criteria Profile Indicator' and the current setting of all analysis criteria. Furthermore, three buttons ('Reset', 'Save', and 'Save as') are provided in this area:

- **Current Analysis Criteria Profile Indicator:** Displays the profile name of the currently selected 'Analysis Criteria Profile'. '*' (modified) is added behind the profile name if the current setting of at least one criterion differs from its setting in the currently selected 'Analysis Criteria Profile'.

The name of the currently selected 'Analysis Criteria Profile' is displayed in

- **bold, black** if no measurement is open (see 4.1)
- **bold, green** if the settings of the analysis criteria that were last used to analyze the open measurement and the settings currently displayed in the dialog 'Analysis Criteria Profile' are **identical**.
- **bold, red** if the settings of the analysis criteria that were last used to analyze the open measurement and the settings currently displayed in the dialog 'Analysis Criteria Profile' are **different**.
- **Current settings of all analysis criteria:** the current settings of all analysis criteria are displayed (see below for an explanation of the individual settings). An asterisk (*) adjacent to a criterion indicates which setting differs from the respective setting in the currently selected 'Analysis Criteria Profile'.
- **Button 'Reset':** Resets all settings currently displayed in the dialog 'Analysis Criteria Profile' to those of the currently

selected 'Analysis Criteria Profile'

Note: This button is dimmed grey (not selectable) if all currently displayed settings are identical with the corresponding settings in the currently selected 'Analysis Criteria Profile'.

- **Button 'Save':** Saves changes to the currently selected 'Analysis Criteria Profile'

Note: This button is dimmed grey (not selectable) if the currently selected 'Analysis Criteria Profile' is write-protected or if all currently displayed settings are identical with the corresponding settings in the currently selected 'Analysis Criteria Profile'.

- **Button 'Save as':** Click on this button opens the dialog 'Save Analysis Criteria Profile' permitting to specify a profile name and then to store the currently displayed settings as a new profile to the 'Analysis Criteria Profiles Database'. Note that thereafter the new, just saved 'Analysis Criteria Profile' is activated as currently selected 'Analysis Criteria Profile'.

Note: Maximum 16 characters are permitted for file names of 'Analysis Criteria Profiles'

Button 'Close': Depending on the display status of the profile name (color; modified/ unmodified) indicated in the 'Current Analysis Criteria Profile Indicator' the following actions will be triggered when clicking on the button 'Close'

Display Status of Profile Name	Action triggered after click on 'Close' button
Bold, black	None (the dialog 'Analysis Criteria Profile' simply closes.) <i>Note: In this case no measurement is open. The settings currently displayed in the dialog 'Analysis Criteria Profile' and the settings of the currently selected 'Analysis Criteria Profile' are identical.</i>
Bold, black ** (modified) added behind name	The dialog 'Save changes in profile <Profilename>? (Yes No Cancel)' opens. Click on 'Cancel' to abort the process and to return to the dialog 'Analysis Criteria Profile'. Click on 'No' to close the dialog 'Analysis Criteria Profile' without saving changes. Click on 'Yes' to save the settings currently displayed in the dialog 'Analysis Criteria Profile' and to close the dialog 'Analysis Criteria Profile'. <i>Note: In this case no measurement is open. The settings currently displayed in the dialog 'Analysis Criteria Profile' and the settings of the currently selected 'Analysis Criteria Profile' are different.</i> <i>Note: If attempting to save changes to a write-protected profile a dialog requesting to select a different profile name will be displayed.</i>
Bold, green	None (the dialog 'Analysis Criteria Profile' simply closes without re-analyzing the open measurement) <i>Note: In this case the settings currently displayed in the dialog 'Analysis Criteria Profile' and the settings of the analysis criteria that were last used to analyze the open measurement are identical (the settings of the currently selected 'Analysis Criteria Profile' are identical as well).</i>
Bold, green ** (modified) added behind name	None (the dialog 'Analysis Criteria Profile' simply closes, without re-analyzing the open measurement and without saving the settings currently displayed in the dialog 'Analysis Criteria Profile' to the currently selected 'Analysis Criteria Profile') <i>Note: In this case the settings currently displayed in the dialog 'Analysis Criteria Profile' and the settings of the analysis criteria that were last used to analyze the open measurement are identical (the settings of the currently selected 'Analysis Criteria Profile' are different).</i>
Bold, red	The dialog 'Analyze measurement? (Yes No Cancel)' opens. Click on 'Cancel' to abort and to return to the dialog 'Analysis Criteria Profile'. Click on 'No' to close the dialog 'Analysis Criteria Profile' without analyzing the measurement. Click on 'Yes' to analyze the measurement with the settings currently displayed in the dialog 'Analysis Criteria Profile'. Note that if in this case <u>manually modified/ deleted</u> physiological event or artifact markers (see 4.2, 4.2.4, 4.2.6) are present in the measurement the dialog 'Reset all modified markers? (Yes No Cancel)' appears first. Click on 'Cancel' to abort and to return to the dialog 'Analysis Criteria Profile'. Click on 'No' to analyze the measurement with the settings currently displayed in the dialog 'Analysis Criteria Profile' without resetting manually modified markers. Click on 'Yes' to reset all modified/ deleted markers and to analyze the measurement with the settings currently displayed in the dialog 'Analysis Criteria Profile'. <i>Note: In this case the settings currently displayed in the dialog 'Analysis Criteria Profile' and the settings of the analysis criteria that were last used to analyze the open measurement are different (whereas the currently displayed settings and the settings of the currently selected 'Analysis Criteria Profile' are identical).</i>

<p>Bold, red ** (modified) added behind name</p>	<p>The dialog 'Analyze measurement? (Yes No Cancel)' opens. See case above for a description of the next steps. Additionally note that this process will not save the settings currently displayed in the dialog 'Analysis Criteria Profile' to the currently selected 'Analysis Criteria Profile'. <i>Note: In this case the settings currently displayed in the dialog 'Analysis Criteria Profile' and the settings of the analysis criteria that were last used to analyze the open measurement are different (the currently displayed settings and the settings of the currently selected 'Analysis Criteria Profile' are different as well).</i></p>
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Note: To view the analysis criteria that were applied during the last analysis of a measurement activate the report and select the report page 'Applied analysis criteria' (see 9.5.12).

Button 'Close': Click on the button 'Cancel' rejects all changes in the currently displayed settings, that were made since a) the dialog 'Analysis Criteria Profile' was last opened, b) the displayed settings were last saved to the currently selected 'Analysis Criteria Profile', or c) a different 'Analysis Criteria Profile' was selected/ activated (including cases in which the displayed settings were stored with the 'Save as' option (see above)).

Description/ explanation of the individual analysis criteria / settings

Detection of **physiological events** is performed for each channel for dynamic and for fixed threshold criteria. In case of PCO2 events related to deviations of the data from baseline (see 11.5) are additionally evaluated.

Please note that the data of each channel are always analyzed for all types of available physiological events. However, to maintain lucidity on the graphs, for each channel the type of physiological events (dynamic events; baseline events (for PCO2 only); threshold events) that shall be visualized with colored markers (see 4.2.5, 12.1.2) must be selected by selecting the **Radio Button** next to the respective set of criteria. **Note that selection status of these Radio buttons is also a setting of 'Analysis Criteria Profiles'.**

Note: The type of physiological events (dynamic events; baseline events (for PCO2 only); threshold events) that will be visualized with colored markers for a specific channel can also be selected in the pop-up menu that opens after right click on the respective channel's measurement curve (see 4.2.4).

Dynamic analysis

Dynamic Event	Range (Factory Default in Bold) / Description
Desaturation (SpO2 drop)	<p>Range: 1 – 50% (4%)</p> <p>If the SpO2 readings drop within a predefined time interval (see related Duration minimum/ maximum) by more than a predefined value the <u>beginning</u> of the Desaturation Event is set to the point at which the SpO2 readings started to decline. The <u>endpoint</u> of the event is set to the minimum.</p>
Recovery / Follow-up event: (SpO2) (for desaturations)	<p>Range for Recovery: 0 – 100% (30%)</p> <p>Range for Follow-up event: 0 – 100% (2%)</p> <p>A desaturation has ended if – after the SpO2 value has reached its minimum – the SpO2 readings increase. If however another breathing cessation arises during this recovery phase the SpO2 value can no longer regenerate itself completely, i.e. a new desaturation has set in before the SpO2 levels have completely recovered. The purpose of the recovery and follow-up event parameters is to ensure that these events are recorded as separated desaturations: Recovery specifies by how many percent of the previous desaturation the SpO2 value needs to have recovered again in order to be classified as a new desaturation event if the SpO2 curve falls off again before the SpO2 levels have completely recovered. The Follow-up event parameter determines by how many percent the SpO2 value needs to decrease again in order to be classified as a new event.</p>
Duration minimum (for desaturations)	<p>Range: 1 – (Duration maximum-10) sec (2 sec)</p> <p>Indicates the minimal duration for a SpO2 drop to be detected as a desaturation event</p>
Duration maximum (for desaturations)	<p>Range: (Duration minimum+10) – 999 sec (240 sec)</p> <p>Indicates the maximal duration for a SpO2 drop to be detected as a desaturation event</p>
PCO2 Rise PCO2 Fall	<p>Range: 0.1 – 200.0 mmHg (1.0 mmHg) / 0.01 – 26.60 kPa (0.13 kPa)</p> <p>If the PCO2 readings rise/ fall within a predefined time interval (see related Duration minimum/ maximum) by more than a predefined value, the <u>beginning</u> of the PCO2 Rise/ PCO2 Fall Event is</p>

Dynamic Event	Range (Factory Default in Bold) / Description
	set to the point at which the PCO2 readings started to rise/ fall. The <u>endpoint</u> of the event is set to the maximum/ minimum.
Duration minimum <i>(for PCO2 Rise/ Fall)</i>	Range: 1 - (Duration maximum-10) sec (5 sec) Indicates the minimal duration for a PCO2 increase/ decrease to be detected as a PCO2 Rise/ Fall event
Duration maximum <i>(for PCO2 Rise/ Fall)</i>	Range: (Duration minimum+10) - 999 secs (600 sec) Indicates the maximal duration for a PCO2 increase/ decrease to be detected as a PCO2 Rise/ Fall event
PR Rise	Range: 1 - 250 bpm (8 bpm) If the PR readings rise within a predefined time interval (see related Duration minimum/ maximum) by more than a predefined value, the <u>beginning</u> of the PR Rise Event is set to the point at which the PR readings started to rise. The <u>endpoint</u> of the PR Rise Event is set to the maximum.
Duration minimum <i>(for PR Rise)</i>	Range: 1 - (Duration maximum-10) secs (5 secs) Indicates the minimal duration for a PR increase to be detected as a PR Rise event
Duration maximum <i>(for PR Rise)</i>	Range: (Duration minimum+10) - 999 secs (60 secs) Indicates the maximal duration for a PR increase to be detected as a PR Rise event

Note: If an artifact occurs during a reading increases/ decreases (e.g. because the readings violate the respective Artifact Threshold) respective 'Dynamic events' are terminated at the beginning of the artifact.

Note: If the change of a parameter occurs too fast (see respective 'Duration Minimum') / too slow (see respective 'Duration Maximum') neither a respective 'Dynamic Event' nor an artifact are triggered.

Fixed Threshold analysis – SpO2, PCO2, und PR

Threshold Events	Range (Factory Default in Bold) / Description
> Baseline + X	Range: 0.0 – 100.0 mmHg (7.5 mmHg) / 0 – 13.40 kPa (1.00 kPa) PCO2 channel only: X is the threshold for deviations above the baseline, i.e. values that are within a predefined time interval (see related Duration minimum/ maximum) above (baseline + X) are detected as event (“> Baseline + X”).
< Baseline – Y	Range: 0.0 – 100.0 mmHg (7.5 mmHg) / 0.00 – 13.40 kPa (1.00 kPa) PCO2 channel only: Y is the threshold for deviations below the baseline, i.e. values that are within a predefined time interval (see related Duration minimum/ maximum) below (baseline – Y) are detected as event (“< Baseline – Y”).
Upper threshold	Range for PCO2: (Lower+5.0)–200.0 mmHg (50.0 mmHg)/(Lower+0.66)–26.60 kPa (6.67 kPa) Range for SpO2: (Lower+5) - 100% (100%) Range for PR: (Lower+5) - 250 bpm (120 bpm) Values that are within a predefined time interval (see related Duration minimum/ maximum) above the selected upper threshold are detected as event (“Above threshold”).
Lower threshold	Range for PCO2: 0.0 – (Upper–5.0) mmHg (30.0 mmHg) / 0.00 – (Upper – 0.66) kPa (4.0 kPa) Range for SpO2: 0 – (Upper–5)% (85%) Range for PR: 30 – (Upper–5) bpm (50 bpm) Values that are within a predefined time interval (see related Duration minimum/ maximum) below the selected lower threshold are detected as event (“Below threshold”).
Duration minimum <i>(for all Threshold Events)</i>	Range: 0 – (Upper–10) sec (2 sec) (0 – 99'989 sec if Duration Maximum = -1 sec) Indicates the minimal duration for a fixed threshold event to be detected
Duration maximum <i>(for all Threshold Events)</i>	Range: (Lower+10) – 99'999 sec (-1 sec) Indicates the maximal duration for a fixed threshold event to be detected. If -1 sec is selected maximal duration of fixed threshold events is unlimited.

Note: If an artifact occurs while a parameter violates one of its threshold limits (e.g. because the readings additionally violate the respective Artifact Threshold) 'Threshold Events' are interrupted by the artifact (i.e. if after

the artifact a value still violates its respective threshold limit, a new threshold event is triggered).

***Note:** If the duration of a 'Threshold Event' is too short (see respective 'Duration Minimum') / too long (see respective 'Duration Maximum') neither a respective 'Threshold Event' nor an artifact are triggered.*

Artifact Thresholds – SpO2, PCO2, und PR

Artifact Threshold	Range (Factory Default in Bold) / Description
SpO2 <	Range: 0 – 100 % (100%) Episodes with SpO2 values below this artifact threshold are marked as artifacts.
PCO2 <	Range: 0.0 – ('PCO2>' -5.0) mmHg (20.0 mmHg) / 0.00 – ('PCO2>' -0.66) kPa (2.67 kPa) Episodes with PCO2 values below this artifact threshold are marked as artifacts.
PCO2 >	Range: ('PCO2<' +5.0)–200.0 mmHg (120.0 mmHg) / ('PCO2<' +0.66)–26.60 kPa (16.00 kPa) Episodes with PCO2 values above this artifact threshold are marked as artifacts.
PR <	Range: 0 – 250 bpm (30 bpm) Episodes with PR values below this artifact threshold are marked as artifacts.

***Note:** There are currently no other situations causing an automatically created artifact.*

***Note:** Automatically detected as well as manually marked artifacts (see 4.2.4) are independent from the type of physiological event (dynamic events; baseline events (for PCO2 only); threshold events) that is currently selected to be visualized with colored event markers (see 4.2).*

Time SpO2 readings are below and PCO2 readings are above predefined values

Criteria	Range (Factory Default in Bold) / Description
SpO2 Time <	Range: 0 – 100 % (88%) Permits to adjust the level xx for used to determine the following statistical results <ul style="list-style-type: none"> • Time < xx% • Time < xx% [%] • Events < xx%, duration > 5 min.
PCO2 Time >	Range: 0.0 – 200.0 mmHg (50.0 mmHg) / 0.00 – 26.60 kPa (6.67 kPa) Permits to adjust the level yy for used to determine the following statistical results <ul style="list-style-type: none"> • Time > yy mmHg • Time > yy mmHg [%] • Events > yy mmHg, duration > 5 min.

Excluded SDM events

SDM Event Markers are displayed separately from the other markers at the bottom edge of the channels (see 4.2, 4.2.5). The color of SDM Event Markers can be selected in the dialog 'Color of Markers' (see 12.1.2). SDM Event Markers being related to SDM Events being excluded from data analysis (see 9.2) are duplicated by 'Invalid Data Markers', i.e. corresponding episodes are not evaluated during data analysis.

SDM Event	Range (Factory Default in Bold) / Description
SpO2 Signal Quality	Range: Checked, Not checked If this box is checked episodes with 'SpO2 Signal Quality' markers will be excluded from data analysis. <i>Note: Such episodes correspond to periods during which the SDM's oximetry algorithm detected that the quality of the signals measured by the connected sensors photodiode is moderately degraded.</i>
SpO2 Low Signal	Range: Checked, Not checked If this box is checked episodes with 'SpO2 Low Signal' markers will be excluded from data analysis.

SDM Event	Range (Factory Default in Bold) / Description
	<i>Note: Such episodes correspond to periods during which the SDM's oximetry algorithm detected a weak pulsatile signal independently from its severity or the impact on PCO₂, SpO₂ or PR values. This may be caused by low perfusion at the measurement site.</i>
High Ambient Light	<p>Range: Checked, Not checked</p> <p>If this box is checked episodes with 'High Ambient Light' markers will be excluded from data analysis.</p> <p><i>Note: Such episodes correspond to periods during which the SDM's oximetry algorithm detected a high ambient light level independently from its severity or the impact on the SpO₂, PR, or PI values.</i></p>
Calibration recommended	<p>Range: Checked, Not checked</p> <p>If this box is checked episodes with 'Calibration recommended' markers will be excluded from data analysis.</p> <p><i>Note: Such episodes correspond to periods during which calibration of the PCO₂/PO₂ part of the Sentec TC Sensor was recommended (but not yet mandatory).</i></p>
PCO ₂ slow	<p>Range: Checked, Not checked</p> <p>If this box is checked episodes with 'PCO₂ slow' markers will be excluded from data analysis.</p> <p><i>Note: Such episodes correspond to periods during which PCO₂/PO₂ measurement of the Sentec TC was marked to be slow</i></p>

9.3 Sub-menu 'Analysis / Analysis Interval'

The 'Analysis Interval' defines the time range of a measurement that is currently considered for data analysis. In V-STATS' Main Window the current 'Analysis Interval' is visualized by a blue bar above the measurement curves and two blue vertical lines at the start and end of the 'Analysis Interval', respectively. The 'Analysis Interval Indicator' – a blue, bold label displaying on the right of the 'Help Icon' in the main and in the report window as well as in the dialog 'Print Report / PDF Report' - indicates the current 'Analysis Interval'.

Note: White dots on the left (right) side of the blue bar indicate that the 'Analysis Interval' starts (ends) before (after) the currently displayed range of the measurement curves. If the full measurement is selected as Analysis Interval the two blue vertical lines that usually display at the start and end of the Analysis Interval are omitted.

The sub-menu 'Analysis / Analysis Interval' opens a popup menu which permits to select the 'Analysis Interval' with the current 'Analysis Interval' being checked.

Note: The same popup menu opens after right click on the 'Analysis Interval Indicator' in both, V-STATS' Main Window (see 4.2) and V-STATS' Report Window (see 9.5.1) and – if the report window displays – when using the menu 'Report / Analysis Interval'.

The following options are selectable in this popup-menu:

- 1) '**Full Measurement**': If 'Full Measurement' is selected, the entire measurement will be analyzed. The 'Analysis Interval Indicator' will display 'Full Measurement'
- 2) '**Displayed Range**': If 'Displayed Range' is selected, only the data contained within the currently displayed time range will be analyzed, i.e. by using the various zooming (see 10) and scrolling functions (see 4.2.2) the time range to be analyzed can be selected. The 'Analysis Interval Indicator' will display '<Start-Date/Time> - <End-Date/Time>'
- 3) '**Manually**': If 'Manually' is selected, the range to be analyzed must – after confirmation of an information dialog – be spanned with the mouse. The 'Analysis Interval Indicator' will display '<Start-Date/Time> - <End-Date/Time>'
- 4) '**AP x: <description>**': If 'AP x: <description>' is selected, only the data corresponding to 'Analysis Period x', where x is the number of the 'Analysis Period', will be analyzed (see 11.1, 11.2). The 'Analysis Interval Indicator' will display 'AP x: <description>'.

Note: The options 'AP x: <description>' are only available if the measurement is split into multiple 'Analysis Periods'.

Note: The 'Analysis Interval' can also be set to an 'Analysis Period' by selecting the option 'Analysis Period APx' in the popup menu that activates after right click on a colored operator event triangle, if at the position of the respective operator event a new 'Analysis Period' starts.

9.3.1 V-Check Measurements

If the SDM is operated in V-Check Mode, the SDM automatically stores V-Check Events in its internal memory at the start and at the end of each V-Check Measurement Phase (for details refer to the Technical Manual of the SDM (HB-005752)).

If in the dialog 'Define Operator Events' the box 'New Analysis Period' is checked for the event type VC (see 12.1.3) a new Analysis Period will be initiated at each occurrence of a V-Check Event when downloading/importing SDM Trend data (see 6). Within V-STATS the start and the end of a V-Check Measurement Phase is, consequently, marked by two respectively colored operator event triangles and two vertical grey lines at the position of these operator events, each indicating the start of a new Analysis Period. By selecting the respective Analysis Period, the 'Analysis Interval' is set to the data interval that corresponds to the V-Check Measurement Phase, i.e. data analysis is made for the V-Check Measurement Phase.

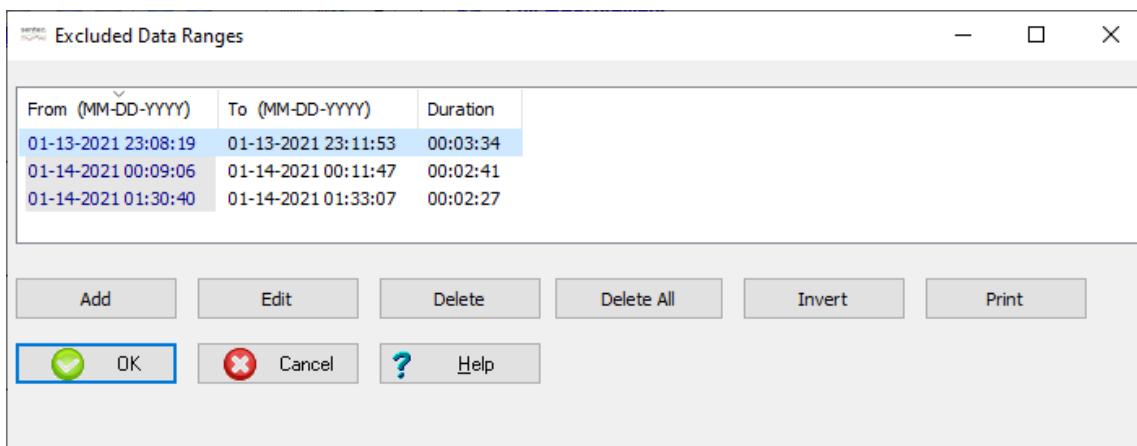
Note: The default color of operator event triangles related to V-Check Events is grey and the default description used for V-Check Events is 'V-Check' (see 12.1.3). In default settings, furthermore, a new Analysis Period will be initiated at each occurrence of a V-Check Event when downloading/importing SDM Trend data.

Note: If data analysis was made for a 'V-Check Measurement Phase' and if 'V-CHECK Report' – one of the preconfigured 'Report Profiles' (see 7.3.1) – is selected when printing/ storing the report (see 7.3) the identical information as is available on the SDM's V-Check Results Screen will be included in the print-out/ PDF Report.

Note: V-Check Measurements currently only support PCO2, SpO2 and PR.

9.4 Sub-menu 'Analysis / Excluded Data Ranges'

The sub-menu 'Analysis / Excluded Data Ranges' opens the dialog 'Excluded Data Ranges'. It lists all data ranges of the open measurement which are currently exclude from data analysis. As shown in the figure below the start date/time ('From'), the end date/time ('To'), and the duration are indicated for each excluded data range.



Note: 'Excluded Data Ranges' usually contain good quality data which the user for a specific reason currently wants to exclude from data analysis (e.g. exclusion of all episodes during which the patient was awake in order to analyze sleep episodes only). The data of all channels will be excluded from data analysis.

Note: 'Excluded data ranges' are visualized in the measurement curves by markers. The default color of 'Excluded Data Range' markers is light grey (see 12.1.2). If the displayed time range is smaller or equal to 30 minutes they are labeled with 'EDR' (see 4.2.5).

Note: 'Excluded Data Ranges' are different from artifacts. Artifacts - either marked by the operator with the mouse (see 4.2.6) or determined by V-STATS based on operator-adjustable criteria (see 9.2) - correspond to data ranges with questionable data quality and are therefore permanently excluded from statistical data analysis. Also note that an artifact may be present in a single channel.

The following functions are available to edit excluded data ranges:

- **Sort:** Left-click on one of the column headers sorts the list of excluded data ranges in increasing/decreasing order by the criteria indicated in the respective column header.
- **Button 'Add':** Opens the dialog 'Edit / Add Excluded Data Range' (see 9.4.1). The start date/time ('From') and the end date/time ('To') which will be proposed in this dialog both correspond to the date/time of the measurement start of the currently open measurement.
- **Button 'Edit':** A click on this button opens the dialog 'Edit / Add Excluded Data Range' (see 9.4.1) displaying the information of the selected 'Excluded Data Range'. Both, the start date/time and the end date/time of the selected excluded data range can be modified.

Note: This button is dimmed grey (not operable) if no 'Excluded Data Range' is selected.

- **Button 'Delete':** Click on this button deletes the selected 'Excluded Data Range'.

Note: This button is dimmed grey (not operable) if no 'Excluded Data Range' is selected.

- **Button 'Delete All':** Click on this button deletes ALL 'Excluded Data Ranges'.

Note: This button is dimmed grey (not operable) if no 'Excluded Data Ranges' are available.

- **Button 'Invert':** Click on this button inverts data range exclusion, i.e. all data ranges which currently are excluded from data analysis will be included by this function (and vice versa).

Note: This button is dimmed grey (not operable) if no 'Excluded Data Ranges' are available.

Note: If all episodes during which a patient was awake were excluded from data analysis in order to analyze sleep episodes only, the 'Invert' function will exclude all sleep episodes and, consequently, only those episodes during which the patient was awake will be analyzed.

- **Button 'Print':** Permits to print the list of currently 'Excluded Data Ranges' of the open measurement either a) on paper (select 'Printer') or b) as pdf-file (select 'PDF').

Click on the button 'OK' to close the dialog and to maintain/store changes. If within the current 'Analysis Interval' excluded data ranges were modified/ added/ deleted all statistical results displayed in the V-STATS Main Window (see 4.2)/ included in the report (see 9.5) are updated to account for all non-excluded data ranges within the current 'Analysis Interval'.

Click on the button 'Cancel' to close the dialog and to reject changes.

9.4.1 Edit/Add Excluded Data Range

In the dialog 'Edit / Add Excluded Data Range' it is possible to specify/modify the data range to be excluded from statistical data analysis.

Column 'From' (to specify / modify the start date/time of the data range to be excluded):

The start date/time of the data range to be excluded can be entered manually.

Click on the 'Start of Measurement' Button to exclude data from the start of the measurement.

Click on the 'Start of Analysis Interval' Button to exclude data from the start of the current 'Analysis Interval' (*note: this button is dimmed grey (not operable) if the current 'Analysis Interval' starts at the start of the measurement*).

Column 'To' (to specify / modify the end date/time of the data range to be excluded):

The end date/time of the data range to be excluded can be entered manually.

Click on the 'End of Measurement' Button to exclude data to the end of the measurement.

Click on the 'End of Analysis Interval' Button to exclude data to the end of the current 'Analysis Interval' (*note: this button is dimmed grey (not operable) if the current 'Analysis Interval' ends at the end of the measurement*).

Click on the button 'OK' to close the dialog and to return to the dialog 'Excluded Data Ranges' (see 9.4) or to the measurement curve. Note that if in the latter case excluded data ranges were modified/ added/ deleted within the current 'Analysis Interval' all statistical results displayed in the V-STATS Main Window (see 4.2)/ included in the report (see 9.5) are updated to account for all non-excluded data ranges within the current 'Analysis Interval'.

Click on the button 'Cancel' to close the dialog and to reject changes.

Opening the dialog 'Edit / Add Excluded Data Range' from the Dialog 'Excluded Data Ranges'

Click on the buttons 'Add' or 'Edit' in the dialog 'Excluded Data Ranges' (see 9.4) opens the dialog 'Edit / Add Excluded Data Range'. In the first case the date/time of the measurement start of the currently open measurement will be proposed in the columns 'From' and 'To'. In the second case the start date/time and the end date/time of the selected excluded data

range will be proposed in the columns 'From' and 'To', respectively. Adjust the data range (if required) and then click 'OK' to return to the dialog 'Excluded Data Ranges'.

Opening the dialog 'Edit / Add Excluded Data Range' from the measurement curves (see 4.2.4, 4.2.7)

Add an 'Excluded Data Range':

- Span the data range to be excluded with the left mouse key (the spanned range is indicated as a black bar, the spanned duration as well as the start/end time are indicated in red in the bottom right of the V-STATS Main Window). Select 'Excluded Data Range' in the popup menu that opens when releasing the left mouse to open the dialog 'Edit / Add Excluded Data Range'. The start date/time and the end date/time of the spanned range will be proposed in the columns 'From' and 'To'. Adjust the data range (if required) and then click 'OK' to return to the measurement curves and to exclude the selected data range (statistical results displayed in the V-STATS Main Window (see 4.2)/ included in the report (see 9.5) will be updated, if excluded data ranges were modified/ added/ deleted within the current 'Analysis Interval').
- Right click with the mouse on an existing physiological event or an artifact marker (e.g. a desaturation marker) opens a popup menu. Select 'Excluded Data Range' to open the dialog 'Edit / Add Excluded Data Range'. The start date/time and the end date/time of the selected marker will be proposed in the columns 'From' and 'To'. Adjust the data range (if required) and then click 'OK' to return to the measurement curves and to exclude the selected data range (statistical results displayed in the V-STATS Main Window (see 4.2)/ included in the report (see 9.5) will be updated, if excluded data ranges were modified/ added/ deleted within the current 'Analysis Interval').

Edit an 'Excluded Data Range':


- Right-click on an existing 'Excluded Data Range' marker opens a popup menu. Select 'Excluded Data Range' to open the dialog 'Edit / Add Excluded Data Range'. The start date/time and the end date/time of the selected marker will be proposed in the columns 'From' and 'To'. Adjust the data range and then click 'OK' to return to the measurement curves and to exclude the selected data range (statistical results displayed in the V-STATS Main Window (see 4.2)/ included in the report (see 9.5) will be updated, if excluded data ranges were modified/ added/ deleted within the current 'Analysis Interval').

Delete an 'Excluded Data Range' with the mouse (see 4.2.4, 4.2.7)

- Right-click on an existing 'Excluded Data Range' marker opens a popup menu. Select 'Delete' to delete the 'Excluded Data Range' (statistical results displayed in the V-STATS Main Window (see 4.2)/ included in the report (see 9.5) will be updated, if excluded data ranges were modified/ added/ deleted within the current 'Analysis Interval').

9.5 Sub-menu 'Analysis / Report'

Note: Data analysis currently does not include analysis of PO₂, PI, and HP data.

Selecting the sub-menu 'Analysis / Report' or clicking on the report-icon  in the menu bar of the V-STATS Main Window (see 4.2.1) displays the report for the current 'Analysis Interval' of the open measurement. In the report it is possible to add comments and findings (see 9.5.2, 9.5.11). Furthermore, it is possible to export the most important numerical results included in the report in an Excel-compatible text-file (see 9.5.1).

Important Note:

Reports may contain patient data. Make sure that patient privacy will be warranted in accordance with local ordinances. It is your responsibility to ensure that non-authorized persons cannot access reports.

Report print-outs/ PDF Reports are configurable/ customizable:

- In the dialog 'Print Report / PDF Report' (see 7.3) it is possible to specify a) the report pages to be included, b) the time resolution per page if the 'Full Measurement Curve' is included, c) whether or not the range of the measurement curve that corresponds to the current 'Analysis Interval' (see 9.3) and/ or the currently 'Displayed Range' shall be included (each on an individual page), and d) whether or not the measurement curves shall be printed/ stored with markers.
- In the 'Report Summary' page (see 9.5.2) it is possible to specify the elements to be included a) several physiological events for PCO₂, SpO₂, and PR, b) several statistical results for PCO₂, SpO₂, and PR, c) distribution curves for PCO₂, SpO₂, and PR, d) operator events, e) the range of the measurement curve that corresponds to the current 'Analysis Interval' (see 9.3), f) a 'Comment', g) the 'Findings', and h) Technical System Information.

In order to ensure that you can print/ save reports the way you want them to in varying clinical settings, V-STATS provides 'Report Profiles' that are stored in the 'Report Profiles Database' (see 7.3.1). A 'Report Profile' specifies a setting for each parameter included in the dialog 'Print Report/ PDF Report' (see 7.3) and for each parameter included in the 'Report

Summary' page (see 9.5.2).

Note: The header of the report (typically your institution's address) is not included in 'Report Profiles'. It can be customized in the dialog 'Change report heading' (see 12.1.4) which opens by clicking on the button 'Report Heading' in the dialog 'V-STATS Settings' (see 12.1). Among other it is possible to individually define the font for each of the up to 5 heading lines, to select the alignment of the report heading and to add your institution's logo.

Note: The parameters 'Font Size for Report', 'Language', 'Format of Date', 'Unit of weight', and 'Unit of length/height' are not included in 'Report Profiles'. These parameters can be customized in the dialog 'V-STATS Settings' (see 12.1).

Note: Currently V-STATS 'Analysis Criteria' are only available for the parameters PCO₂, SpO₂ and PR. This means that the report contains statistical analyses for PCO₂, SpO₂ and PR only. However, PO₂, PI, HP measurement curves can optionally be included in the report and the report print-out / PDF report. Please note that in order to include the measurement curves in the report a) the respective parameter must be included in the measurement file; b) must be displayed in the currently open measurement file (see 11.8); and c) must be selected to be included in the print-out of the report (see 7.3).





9.5.1 Description of the report window

The report-window is structured as follows:

1) Upper menu bar:

- Sub-menu 'Report / Print Report / PDF Report': Opens the dialog 'Print Report / PDF Report' (see 7.2).
- Sub-menu 'Report / Analysis Interval': Opens a popup menu which permits to select the 'Analysis Interval' (see 9.3).
- Sub-menu 'Report / Export (Text-file)': Opens a windows dialog to export the most important numerical results included in the report in a file with the extension '.csv'. This file subsequently can be imported into other programs (e.g. Excel). The following information / results are exported:
 - Summary page of report: Patient and measurement related data/ information; results of event analysis and general statistical results for SpO₂, PCO₂, and PR; system information; comment and findings (see 9.5.2)
 - SpO₂ analysis page of report: all numerical results provided in the tables of this page (see 9.5.3)
 - PCO₂ analysis page of report: all numerical results provided in the tables of this page (see 9.5.4)
 - PR analysis page of report: all numerical results provided in the tables of this page (see 9.5.5)
 - Comment page of report (see 9.5.11)
 - Applied analysis criteria page of report (see 9.5.12)
- Sub-menu 'Report / Close': closes the report.
- Menu 'Event distribution': to select the time resolution of the event-distribution report pages (see 9.5.7, 9.5.8, 9.5.9).
- Menu 'Help': to open the context-sensitive on-line help.

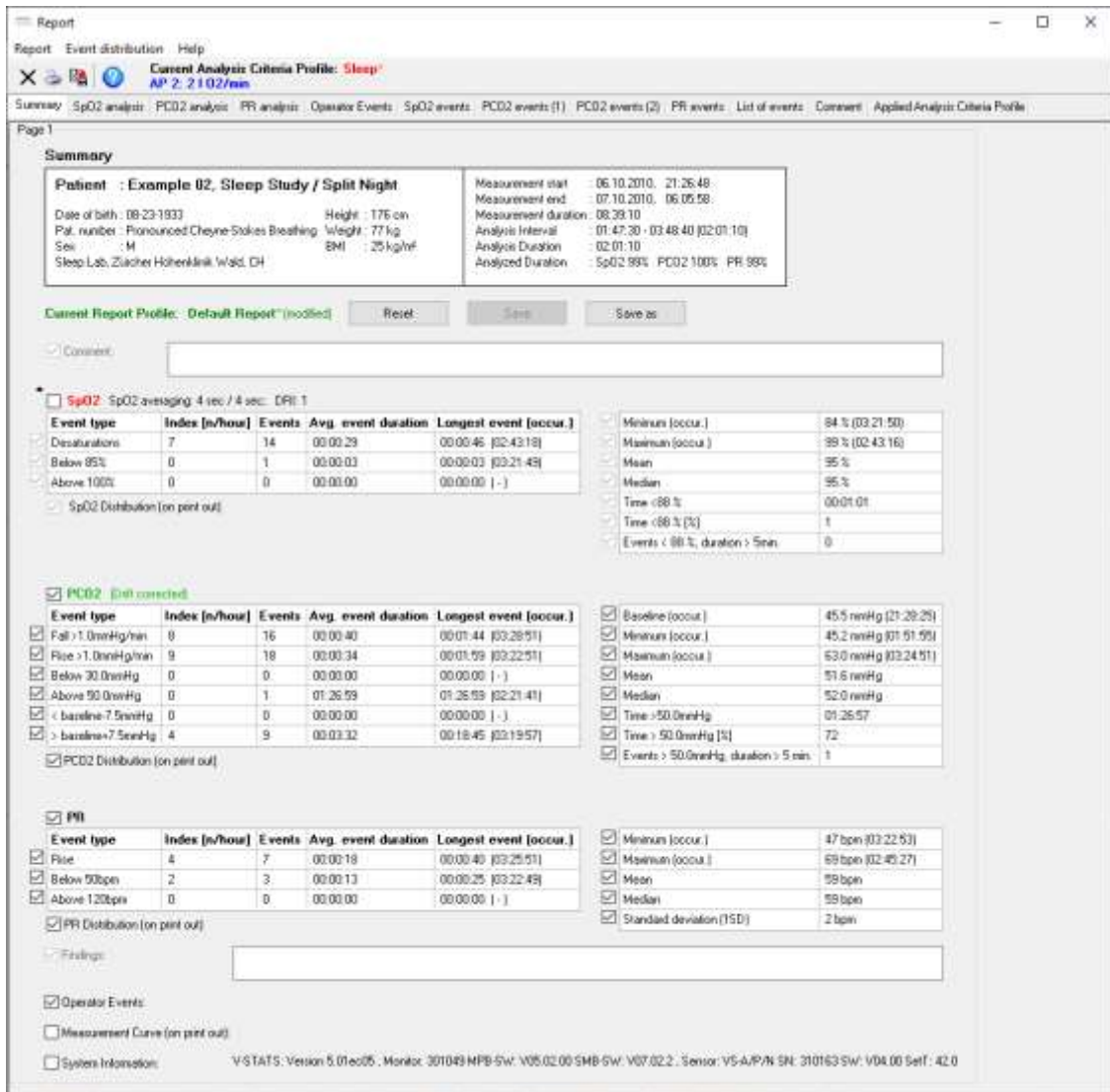
2) Icons in the upper menu bar / 'Analysis Criteria Profile Indicator' / 'Analysis Interval Indicator'

Icon	Designation (Tool tip)	Description
	Close report	Click on this icon to close the report.
	Print Report / PDF Report	Click on this icon opens the dialog 'Print Report / PDF Report' (see 7.2). <i>Note: The part of the measurement data that is considered by V-STATS when creating/printing/storing the report is defined by the current 'Analysis Interval' (see 9.3).</i>
	Export report as text file	Click on this icon opens a windows dialog to export the most important numerical results included in the report in a file with the extension ".csv" (for details refer to sub-menu 'Report / Export (Text-file)' – see above).
	Help	Click on this icon to open the context-sensitive on-line help.
Analysis Criteria Profile Indicator		The currently selected 'Analysis Criteria Profile' (see 9.2) is displayed in bold black on the left of the 'Help Icon'. If the criteria of the currently selected 'Analysis Criteria Profile' and those that were last used to analyze the open measurement are <u>identical</u> the profile name is displayed in black , otherwise in red with an asterisk (*). Left click on the 'Analysis Criteria Profile Indicator' opens a pop-up menu offering the

Icon	Designation (Tool tip)	Description
		<p>possibility a) to select/ analyze the open measurement with a different 'Analysis Criteria Profile' or b) to re-analyze all/ individual channels of the open measurement with the currently selected 'Analysis Criteria Profile' (for details refer to the description of an equivalent popup-menu in 9.1).</p> <p><i>Note: The 'Analysis Criteria Profile Indicator' will be included in the report print-out/ PDF- Report (see 7.3) (underneath the box with the patient related data)</i></p>
<p>Analysis Interval Indicator</p>		<p>The current 'Analysis Interval' is indicated by the 'Analysis Interval Indicator', a blue, bold label displaying in the upper menu bar on the right of the 'Help Icon'. It can be selected/changed in the popup-menu which opens after right click on the 'Analysis Interval Indicator' (see 9.3).</p> <p><i>Note: If at least one patient is admitted to V-CareNeT the red blinking message 'Remote Monitoring active' displays on the right of the 'Analysis Interval Indicator'.</i></p> <p><i>Note: The 'Analysis Interval Indicator' will be included in the report print-out/ PDF-Report (see 7.3).</i></p>

- 3) Page-selection tabs: The report is organized in eleven sections and contains 12 pages. Each page can be selected by clicking on the respective page-selection tab. In the following each of the eleven sections is described.

9.5.2 Report page 1: Summary



Note: The boxes in front of the various elements permit to define/ customize the **printout / PDF Report** of the 'Report Summary' page. Elements will only be printed/ stored if the associated box is checked.

Note: To create a **one-page report** that includes the most important statistical results and distribution curves for PCO2, SpO2, and PR, operator events and the part of the measurement curve that corresponds to the current 'Analysis Interval' check in the dialog 'Print Report / PDF Report' (see 7.2) only the boxes 'Report Pages' and 'Summary' and on the 'Summary' page the boxes in front of the desired elements.

The summary page is organized in the following areas:

- **Patient data (left top):** Last name, first name, Date of birth, Height, Weight, Sex, Pat. Number, Comment; BMI (Body-Mass-Index) is calculated from the height [m] und weight [kg]: BMI = Weight/Height²

Note: Left-Click on the patient data area opens the dialog 'Patient data' (see 11.3) where it is possible to dis-/enable patient data entry and edit the patient data.

Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.

- **Measurement start/end/duration, Analysis Interval/duration, Analyzed Duration (right top):**

- **Measurement start:** Indicates the date and time of the measurement start
- **Measurement end:** Indicates the date and time of the measurement end

- **Measurement duration:** Indicates the duration of the measurement (from measurement start to measurement end)
- **Analysis Interval:** Indicates the start and end time of the current 'Analysis Interval' (see 9.3). The duration of the 'Analysis Interval' is indicated in parenthesis.
- **Analysis Duration:** Indicates the duration of analyzed data, i.e. the duration of the current 'Analysis Interval' minus the total duration of all excluded data ranges (see 9.4) within the current 'Analysis Interval'.
- **Analyzed Duration:** Indicates for each parameter the analyzed duration in percentage of the 'Analysis Duration'.

Note: If the mouse is hovered over the area indicating the 'Analysis Duration' and the 'Analyzed Duration' the following information box displays in a tool tip.

Analysis Duration: hh:mm:ss
 Analyzed: SpO2 hh:mm:ss (percentage) / PCO2 hh:mm:ss (percentage) / PR hh:mm:ss (percentage)
 Artifact: SpO2 hh:mm:ss (percentage) / PCO2 hh:mm:ss (percentage) / PR hh:mm:ss (percentage)
 Invalid: SpO2 hh:mm:ss (percentage) / PCO2 hh:mm:ss (percentage) / PR hh:mm:ss (percentage)
 Excluded SDM Events: SpO2 hh:mm:ss (percentage) / PCO2 hh:mm:ss (percentage) / PR hh:mm:ss (percentage)

Important Note: Episodes with excluded data ranges (see 9.4), artifacts, and invalid data will be excluded from statistical data analysis. Furthermore, episodes with certain SDM events optionally can be excluded from statistical data analysis (see 4.2.5, 9.2). Unless otherwise specified for each channel all statistical results, therefore, are based on the evaluation of the analyzed duration, i.e. the artifact free part of valid, non-excluded measurement data contained within the current 'Analysis Interval'.

- **Report Profile Indicator:** The currently selected 'Report Profile' (see also the 'Note' below) is indicated in **bold, green** below the 'patient data field'. If at least one of the parameters of the current 'Report Profile' differs from the respective parameter of the currently selected 'Report Profile', * **(modified)** is added to the profile name and an asterisk (*) adjacent to a parameter indicates which setting differs from its setting in the currently selected 'Report Profile'. **Left click** on the 'Report Profile Indicator' opens the dialog 'Report Profiles Database' (see 7.3.1). Therein a different 'Report Profile' can be selected and 'Report Profiles' can be managed (renamed, deleted, imported to/ exported from 'Report Profiles Database' ...).

Note: A 'Report Profile' (see 9.5) specifies a setting for each parameter included in the dialog 'Print Report/ PDF Report' (see 7.3) and for each parameter included in the 'Report Summary' page.

Note: Upon installation of or upgrade to V-STATS 5.01.1 the preconfigured and write-protected 'Report Profiles' 'Default Report', 'Full Report', and 'V-CHECK Report' are installed in the 'Report Profiles Database'.

The buttons 'Reset', 'Save', and 'Save as' on the left of the 'Report Profile Indicator' are duplicated in the **middle section** of the dialog 'Report Profiles Database' (see 7.3.1) and in the dialog 'Print Report / PDF Report' (see 7.3). Please refer to 7.3.1 for a description of their function and how to create a customized 'Report Profile'.

- **Comment:** In this field it is possible to enter a comment (up to 240 characters). The check box is not accessible (dimmed grey) as long as no comment is entered.
- **SpO2 Results**

Note: Unchecking the box in front of 'SpO2' dims all boxes in front of SpO2 related results and will omit all SpO2 related results/elements in the print-out / PDF Report of the 'Report Summary' page.

Note: 'SpO2 Averaging' indicates the minimal and maximal setting of the SDM internal parameter 'SpO2 Averaging' within the entire measurement. The longer the averaging time the slower the SDM's response to changes in patient's saturation.

Note: 'DRI' indicates the Data Recording Interval that was used while recording the currently displayed measurement. DRI can vary between 1 sec and 8 sec, in steps of 1 sec.

SpO2 – event analysis (left side): For each of the 3 SpO2 event types (desaturation, upper/lower threshold) the following statistical results are provided:

- **Index [n/hour]:** Number of events per hour
- **Events:** Number of events
- **Avg. event duration:** Average duration of an event (total duration/total number).
- **Longest event (occur.):** Duration of the longest event and the time it occurred.

SpO2 – general results (right side): For the SpO2 data the following statistical results are provided:

- **Minimum (occur.):** Lowest SpO2 value and the time it occurred.

- Maximum (occur.): Highest SpO2 value and the time it occurred.
- Mean: Average of all SpO2 values.
- Median: Median of all SpO2 values.

If in the criteria below $xx=88$ is used, the criteria correspond to those recommended in the NPPV consensus guideline, CHEST 1999; 116:521-534

- Time < xx%: Time with SpO2-values smaller than xx%.
- Time < xx% [%]: Time with SpO2-values smaller than xx% indicated as the percentage of the 'Analyzed Duration' (see above).
- Events < xx%: Duration > 5 min.: Number of events with SpO2-values smaller than xx% that last longer than 5 minutes.

Note: The level xx is adjustable in the dialog 'Analysis Criteria Profile' (see 9.2).

SpO2 Distribution (on print-out): If this box is checked the SpO2 Distribution is added to the print-out / PDF Report of the summary page. Note that in this case the column 'Longest event (occur.)' of the table 'SpO2 event analyses' is omitted in the print-out / PDF Report of the summary page. The scale for the x-axis is adjustable on the report page 'SpO2 Analysis' (see 9.5.3).

• PCO2 Results

Note: Unchecking the box in front of 'PCO2' dims all boxes in front of PCO2 related results and will omit all PCO2 related results/elements in the print-out / PDF Report of the summary page.

PCO2 – event analysis (left side): For each of the 6 PCO2 event types (upper/lower threshold; Fall/Rise; > Baseline + X / < Baseline - Y) the following statistical results are provided:

- Index [n/hour]: Number of events per hour
- Events: Number of events
- Avg. event duration: Average duration of an event (total duration/total number).
- Longest event (occur.): Duration of the longest event and the time it occurred.

PCO2 – general results (right side): For the PCO2-data the following statistical results are provided:

- Baseline (occur.): The PCO2 Baseline used in the data analysis and the time it occurred.
- Minimum (occur.): Lowest PCO2-value and the time it occurred.
- Maximum (occur.): Highest PCO2-value and the time it occurred.
- Mean: Average of all PCO2-values.
- Median: Median of all PCO2 values.

If in the criteria below $yy=50$ mmHg / $yy^*=6.67$ kPa is used, the criteria correspond to those recommended by various national bodies (e.g. Haute Autorité de Santé in France) to identify nocturnal hypoventilation.

- Time > yy mmHg / yy* kPa: Time with PCO2-values above yy mmHg (yy* kPa).
- Time > yy mmHg / yy* kPa [%]: Time with PCO2-values above yy mmHg (yy* kPa) indicated as the percentage of the 'Analyzed Duration' (see above).
- Events > yy mmHg / yy* kPa: Duration > 5 min.: Number of events with PCO2-values above yy mmHg (yy* kPa) that last longer than 5 minutes.

Note: The level yy/yy is adjustable in the dialog 'Analysis Criteria Profile' (see 9.2).*

PCO2 Distribution (on print-out): If this box is checked the PCO2 Distribution is added to the print-out / PDF Report of the summary page. Note that in this case the column 'Longest event (occur.)' of the table 'PCO2 event analyses' is omitted in the print-out / PDF Report of the summary page. The scale for the x-axis is adjustable on the report page 'PCO2 Analysis' (see 9.5.4).

• PR Results

Note: Unchecking the box in front of 'PR' dims all boxes in front of PR related results and will omit all PR related results/elements in the print-out / PDF Report of the summary page.

PR – event analysis (left side): For each of the 3 PR event types (Rise; upper/lower threshold) the following statistical results are provided:

- Index [n/hour]: Number of events per hour

- Events: Number of events
- Avg. event duration: Average duration of an event (total duration/total number).
- Longest event (occur.): Duration of the longest event and the time it occurred.

PR – general results (right side): For the PR-data the following statistical results are provided:

- Minimum (occur.): Lowest PR-value and the time it occurred.
- Maximum (occur.): Highest PR-value and the time it occurred.
- Mean: Average of all PR-values.
- Median: Median of all PCO2 values.
- Standard deviation (1SD): Standard deviation of all PR-values.

PR Distribution (on print-out): If this box is checked the PR Distribution is added to the print-out / PDF Report of the summary page. Note that in this case the column 'Longest event (occur.)' of the table 'PR event analyses' is omitted in the print-out / PDF Report of the summary page. The scale for the x-axis is adjustable on the report page 'PR Analysis' (see 9.5.5).

- **Findings**: In this field it is possible to enter findings (up to 240 characters). The check box is not accessible (dimmed grey) as long as no findings are entered.
- **Operator Events**: If the box in front of 'Operator Events' is checked the list of operator events is printed (see 9.5.6, 11.1). On the print-out the list of operator events will be sorted as on the report page 'Operator Events' (see 9.5.6). This check box is only selectable if operator events are available in the measurement.
- **Measurement Curve (on print-out)**: If this box is checked the part of the measurement curve that corresponds to the current 'Analysis Interval' will be added to the print-out / PDF Report of the summary page.

Note: Check/uncheck the respective box in the dialog 'Print Report / PDF Report' (see 7.3) to print the measurement curve with/without markers.

Note: If with the current settings there is not enough space to properly print the measurement curve on the summary page V-STATS will prompt a corresponding warning dialog. In this case either a) remove elements to be printed on the 'Report Summary' page by unchecking the boxes in front of the respective elements, b) reduce the font size for the report (see 12.1) or for the heading of the report (see 12.1.4), or c) consider to print the measurement curve on a separate sheet of paper (see 7.3).

- **System information (bottom)**: Technical information about V-STATS, the monitor and sensor use to record the data:
 - V-STATS: Software version of V-STATS
 - Monitor: Serial Number of the monitor used to record the data
 - MPB-SW: Software version of the SDM's signal analyses board
 - SMB-SW: Software version of the SDM's controller board
 - Sensor: Type and Serial Number of the sensor used to record the data (*Note: If an oximetry sensor was connected to the SDM with a 'SpO2 Adapter Cable' the Serial Number of the SpO2 Adapter Cable additionally is indicated in parenthesis.*)
 - SW: Software version of the sensor or SpO2 Adapter Cable
 - SET-T [°C]: Sensor SET temperature

9.5.3 Report page 2: SpO2 analysis

The page SpO2 analysis is organized in four areas:

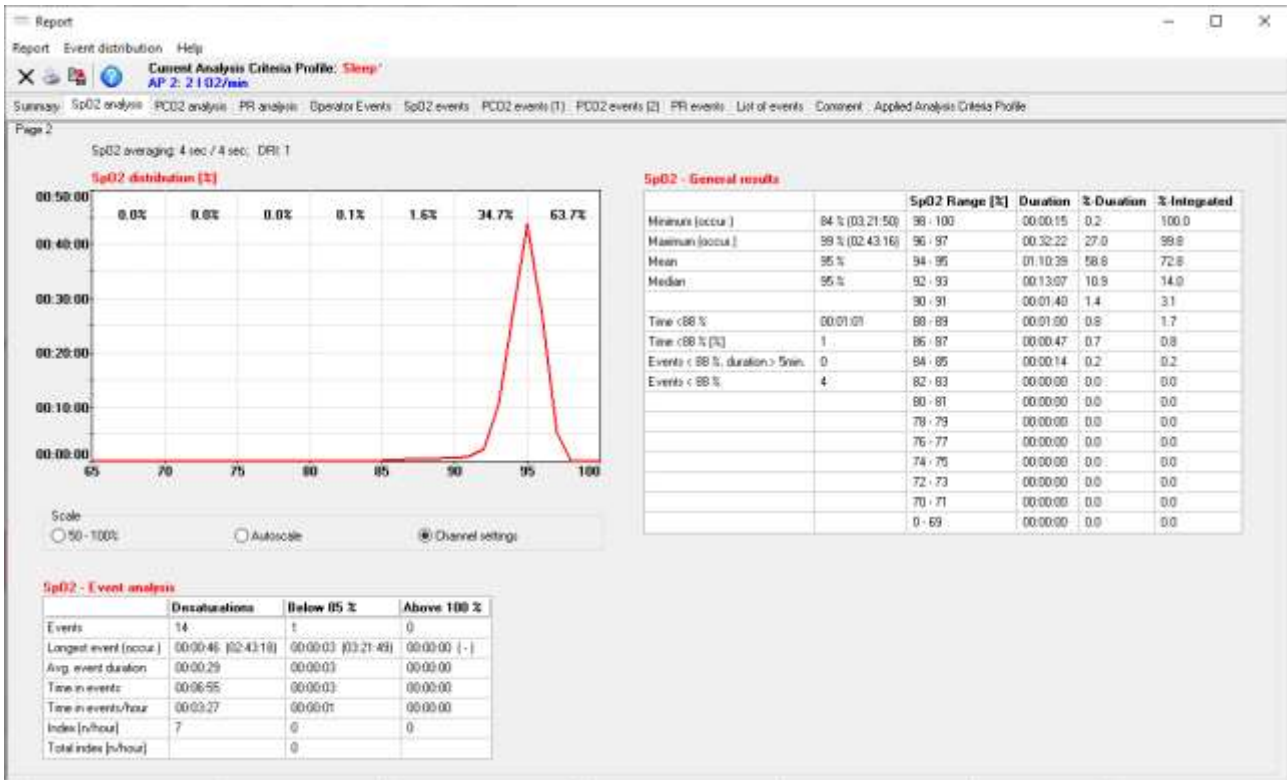
- **SpO2 – distribution (left top)**: the distribution curve indicates for each SpO2-value how long it occurred. The time during which SpO2 values fell into the respective interval is indicated as the percentage of the 'Analyzed Duration' (see 9.5.2). The scale of the x-Axis is adjustable (50-100%SpO2; Autoscale; Channel settings).

Note: A maximum of 7 intervals is possible; the interval-width is 5% (or multiples thereof).
- **SpO2 – general results (right top)**: For the SpO2-data the following statistical results are provided:
 - Minimum (occur.): Lowest SpO2-value and the time it occurred.
 - Maximum (occur.): Highest SpO2-value and the time it occurred.

- **Mean:** Average of all SpO2 values.
- **Median:** Median of all SpO2 values.

If in the criteria below xx=88 is used, the criteria correspond to those recommended in the NPPV consensus guideline, CHEST 1999; 116:521-534

- **Time < xx%:** Time with SpO2-values smaller than xx%.



- **Time < xx% [%]:** Time with SpO2-values smaller than xx% indicated as the percentage of the 'Analyzed Duration' (see 9.5.2).
- **Events < xx%: Duration > 5 min.:** Number of events with SpO2-values smaller than xx% that last longer than 5 minutes.
- **Events < xx%:** Number of Events with SpO2-values smaller than xx%.

Note: The level xx is adjustable in the dialog 'Analysis Criteria Profile' (see 9.2).

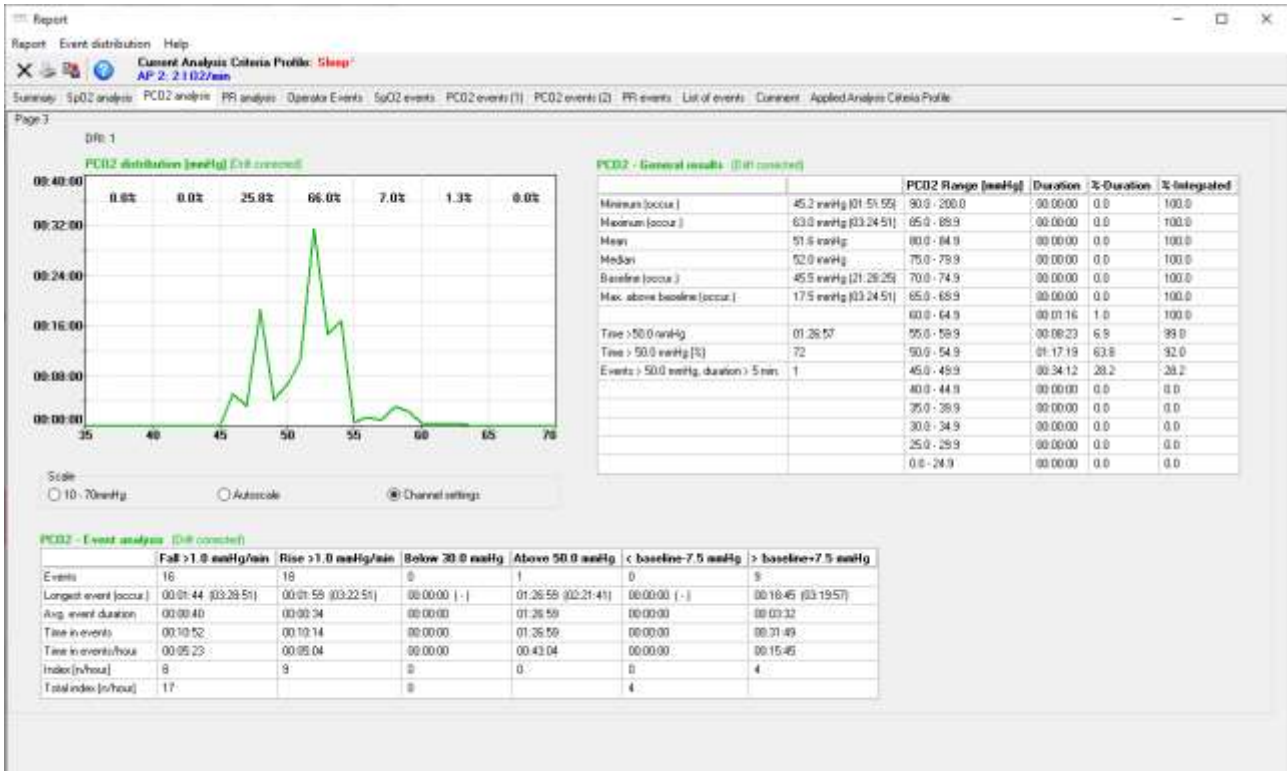
- **SpO2 - histogram (right top):** the SpO2 distribution curve is supplemented by a tabular histogram:
 - **SpO2 Range [%]:** The intervals used for the histogram (**Note:** the intervals are user-adjustable, they can be edited in the file 'Target drive:\fg\vstats\raster.txt').
 - **Duration:** time during which SpO2 values fell into the respective interval
 - **%-Duration:** time during which SpO2 values fell into the respective interval indicated as the percentage of the 'Analyzed Duration' (see 9.5.2).
 - **%-Integrated:** the integrated (accumulated) %-duration.
- **SpO2 - event analysis (bottom):** For each of the 3 SpO2 event types (upper/lower threshold, desaturation) the following statistical results are provided:
 - **Events:** Number of events
 - **Longest event (occur.):** Duration of the longest event and the time it occurred.
 - **Avg. event duration:** Average duration of an event (total duration/total number).
 - **Time in events:** Sum of all event durations.
 - **Time in events/hour:** Averaged time of all events per hour.
 - **Index [n/hour]:** Number of events per hour.

- **Total Index [n/hour]:** Number of all upper/lower threshold events together per hour.

Note: 'SpO2 Averaging' indicates the minimal and maximal setting of the SDM internal parameter 'SpO2 Averaging' within the entire measurement. The longer the averaging time the slower the SDM's response to changes in patient's saturation.

Note: 'DRI' indicates the Data Recording Interval that was used while recording the currently displayed measurement. DRI can vary between 1 sec and 8 sec, in steps of 1 sec.

9.5.4 Report page 3: PCO2 analysis



The page PCO2 analysis is organized in four areas:

- **PCO2 – distribution (left top):** the distribution curve displays for each PCO2-value how long it occurred. The time during which PCO2 values fell into the respective interval is indicated as the percentage of the 'Analyzed Duration' (see 9.5.2). The scale of the x-Axis is adjustable (10-70mmHg (0.0-10.0kPa); Autoscale; Channel settings).

Note: A maximum of 7 intervals is possible, the interval-width is 5mmHg (1kPa) (or multiples thereof).

- **PCO2 – general results (right top):** For the PCO2-data the following statistical results are provided:

- **Minimum (occur.):** Lowest PCO2-value and the time it occurred.
- **Maximum (occur.):** Highest PCO2-value and the time it occurred.
- **Mean:** Average of all PCO2values.
- **Median:** Median of all PCO2values.
- **Baseline (occur.):** The PCO2 Baseline used in the data analysis and the time it occurred.
- **Max. above baseline (occur.):** The maximal deviation above the PCO2 baseline and the time it occurred.

If in the criteria below $yy=50$ mmHg / $yy^*=6.67$ kPa is used, the criteria correspond to those recommended by various national bodies (e.g. Haute Autorité de Santé in France) to identify nocturnal hypoventilation.

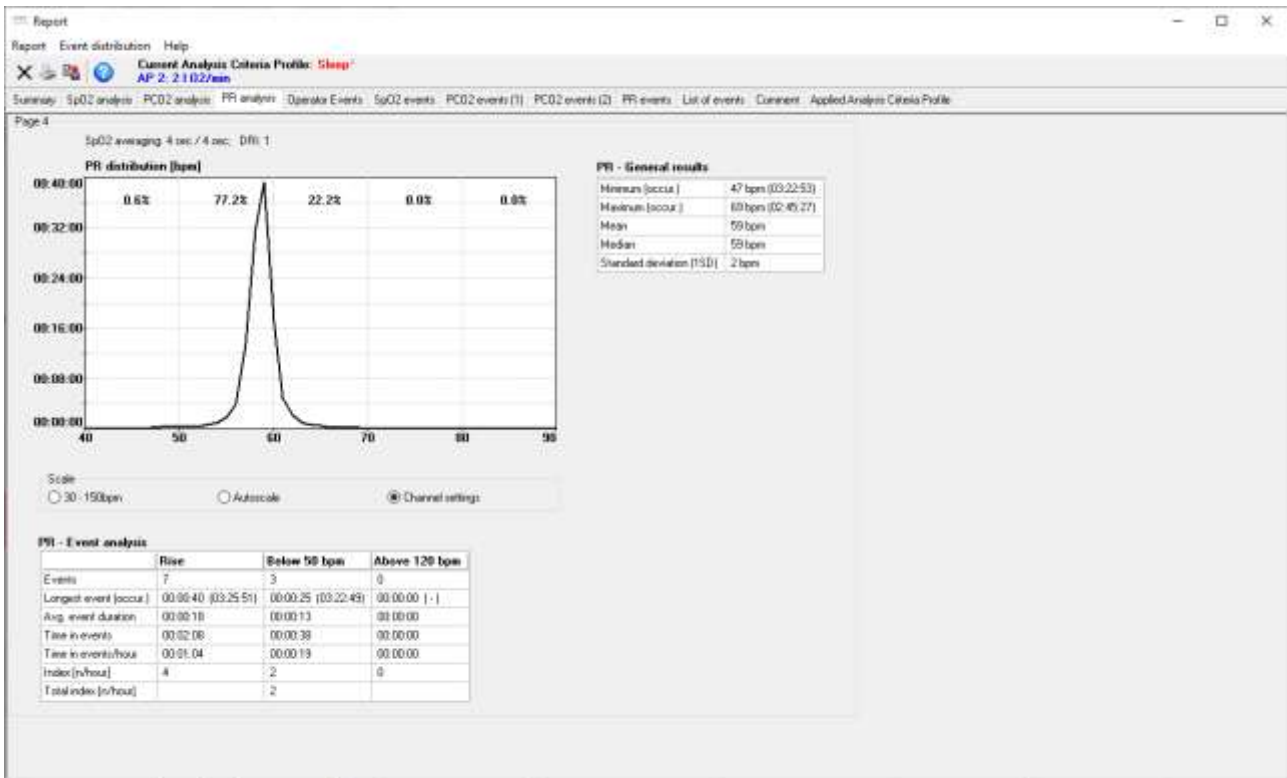
- **Time > yy mmHg / yy* kPa:** Time with PCO2-values above yy mmHg (yy* kPa).
- **Time > yy mmHg / yy* kPa [%]:** Time with PCO2-values above yy mmHg (yy* kPa) indicated as the percentage of the 'Analyzed Duration' (see 9.5.2).
- **Events > yy mmHg / yy* kPa: Duration > 5 min.:** Number of events with PCO2-values above yy mmHg (yy* kPa) that last longer than 5 minutes.

Note: The level yy/yy is adjustable in the dialog 'Analysis Criteria Profile' (see 9.2).*

- **PCO2 – histogram (right top):** the PCO2 distribution curve is supplemented by a tabular histogram:
 - PCO2 Range [mmHg] / PCO2 Range [kPa]: The intervals used for the histogram (Note: the intervals are user-adjustable, they can be edited in the file 'Target drive:\fg\vstats\raster.txt').
 - Duration: time during which PCO2-values fell into the respective interval
 - %-Duration: time during which PCO2-values fell into the respective interval indicated as the percentage of the 'Analyzed Duration' (see 9.5.2).
 - %-Integrated: the integrated (accumulated) %-duration.
- **PCO2 – event analysis (bottom):** For each of the 6 PCO2 event types (upper/lower threshold; Fall/Rise; > Baseline + X / < Baseline - Y) the following statistical results are provided:
 - Events: Number of events.
 - Longest event (occur.): Duration of the longest event and the time it occurred.
 - Avg. event duration: Average duration of an event (total duration/total number).
 - Time in events: Sum of all event durations.
 - Time in events/hour: Averaged time of all events per hour
 - Index [n/hour]: Number of events per hour
 - Total Index [n/hour]: For each event-pair the number of all events together per hour.

Note: 'DRI' indicates the Data Recording Interval that was used while recording the currently displayed measurement. DRI can vary between 1 sec and 8 sec, in steps of 1 sec.

9.5.5 Report page 4: PR-analysis



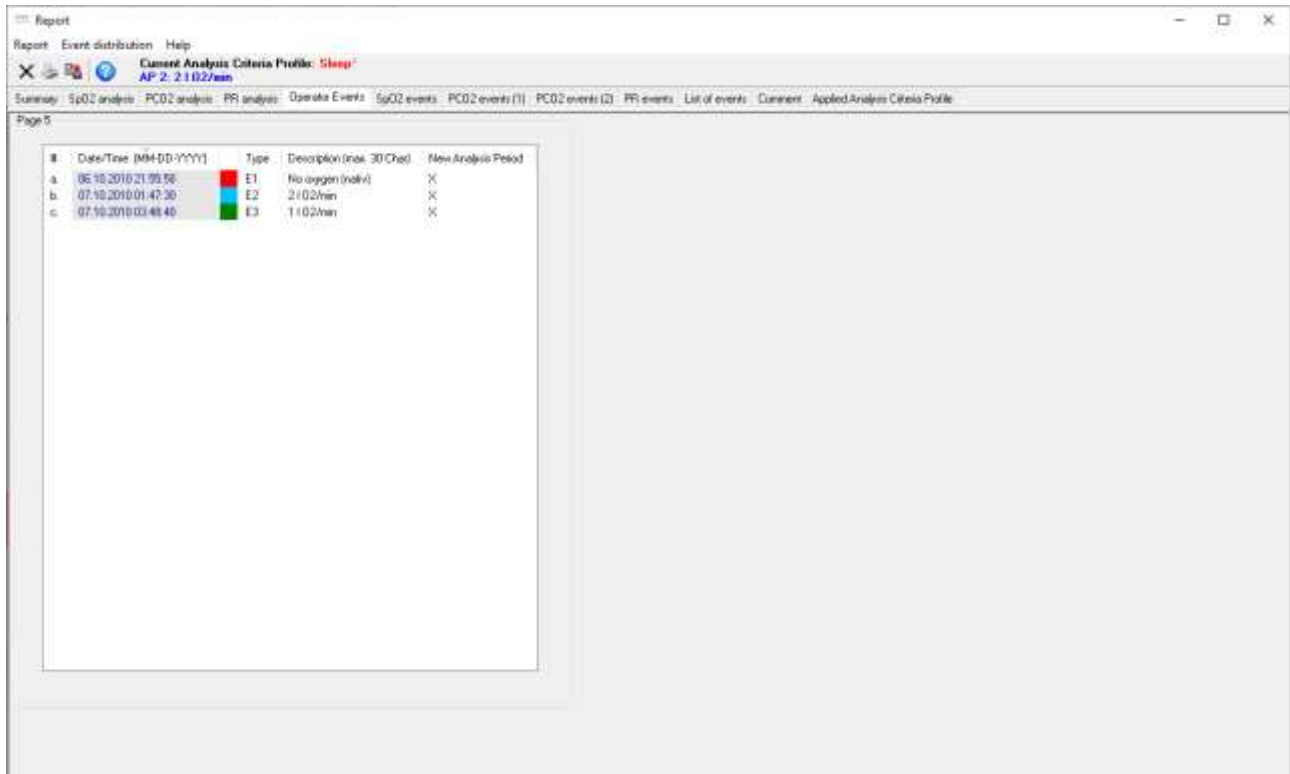
The page PR analysis is organized in three areas:

- **PR – distribution (left top):** the distribution curve displays for each PR-value how long it occurred. The time during which PR-values fell into the respective interval is indicated as the percentage of the ‘Analyzed Duration’ (see 9.5.2). The scale of the x-Axis is adjustable (30-150bpm; Autoscale; Channel settings).
 - Note: A maximum of 7 intervals is possible; the interval-width is 10bpm (or multiples thereof).*
- **PR – general results (right top):** For the PR-data the following statistical results are provided:
 - Minimum (occur.): Lowest PR-value and the time it occurred.
 - Maximum (occur.): Highest PR-value and the time it occurred.
 - Mean: Average of all PR-values
 - Median: Median of all PR-values.
 - Standard deviation (1SD): Standard deviation of all PR-values.
- **PR – event analysis (bottom):** For each of the 3 PR event types (upper/lower threshold, rise) the following statistical results are provided:
 - Events: Number of events.
 - Longest event (occur.): Duration of the longest event and the time it occurred.
 - Avg. event duration: Average duration of an event (total duration/total number).
 - Time in events: Sum of all event durations.
 - Time in events/hour: Averaged time of all events per hour
 - Index [n/hour]: Number of events per hour
 - Total Index [n/hour]: Number of all upper/lower threshold events together per hour.

Note: ‘SpO2 Averaging’ indicates the minimal and maximal setting of the SDM internal parameter ‘SpO2 Averaging’ within the entire measurement. The longer the averaging time the slower the SDM’s response to changes in patient’s saturation.

Note: 'DRI' indicates the Data Recording Interval that was used while recording the currently displayed measurement. DRI can vary between 1 sec and 8 sec, in steps of 1 sec.

9.5.6 Report page 5: Operator Events



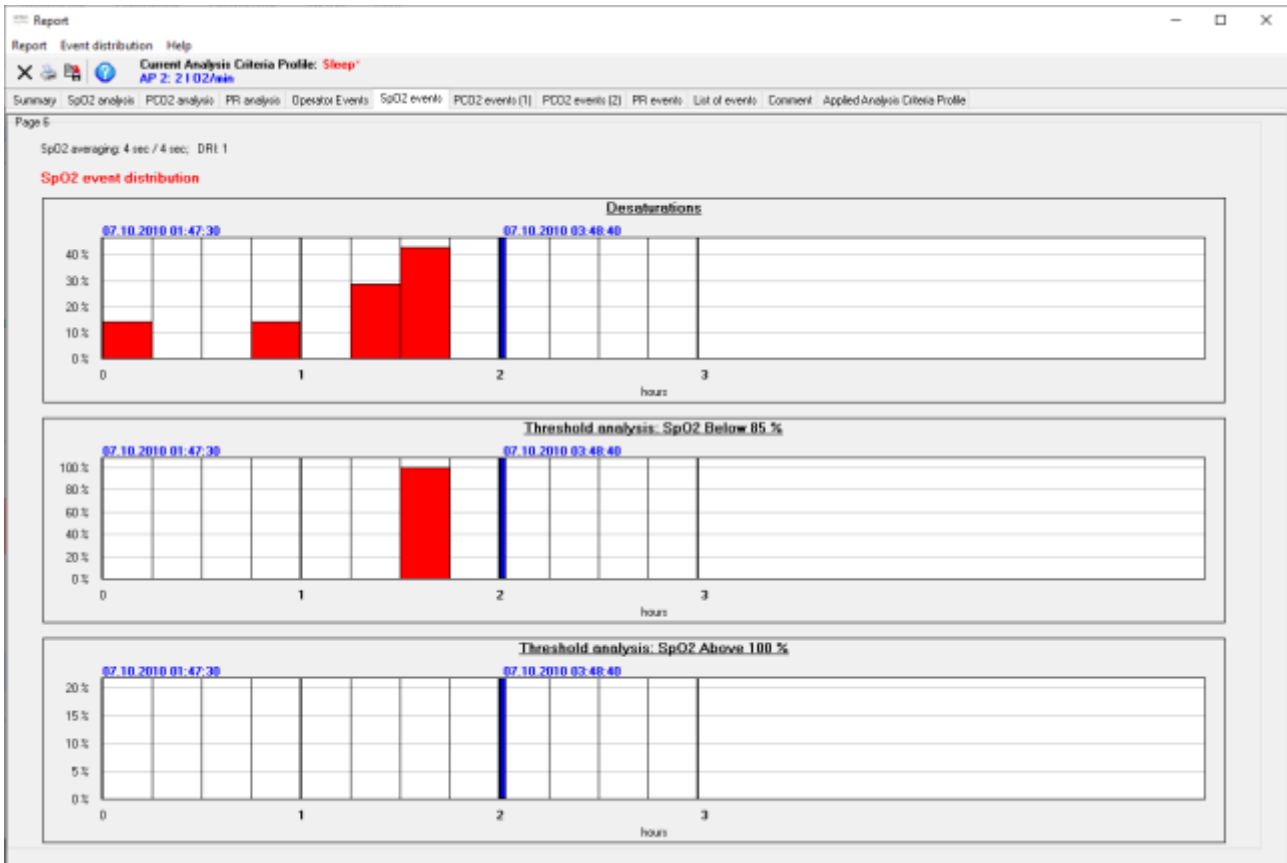
#	Date/Time (MM-DD-YYYY)	Type	Description (max. 30 Char)	New Analysis Period
a.	06.10.2010 21:59:56	E1	No oxygen (nadir)	X
b.	07.10.2010 01:47:30	E2	2 fO2/min	X
c.	07.10.2010 03:48:40	E3	1 fO2/min	X

The report page Operator Events lists all 'Operator Events' of the currently open measurement in tabular form. Please refer to the dialog 'Operator Events' (see [11.1](#)) for a description of the different columns.

Note: Left-click on one of the column headers sorts the list of operator events in increasing/decreasing order by the criteria indicated in the respective column header.

9.5.7 Report page 6: SpO2 events

The page ‘SpO2 events’ displays for each of the three event types (desaturations; lower/upper threshold violations) the distribution of these events over the current ‘Analysis Interval’ (see 9.3) in a bar chart.



The start date/time and end date/time of the current ‘Analysis Interval’ are displayed in blue bold above each event distribution bar chart. Furthermore, the end of the ‘Analysis Interval’ is visualized in the event distribution bar charts with a thick, blue vertical line.

Note: If – in an event distribution bar chart - the mouse is hovered over an individual bar a tooltip indicating the absolute and percental number of events that occurred within the associated time interval.

The time resolution (i.e. the interval width) used for the event distribution bar charts can be selected in the menu ‘Event distribution’. The selectable intervals are 0.25 h; 0.5h; 1h; 2 h; 4 h. Depending on the duration of the current ‘Analysis Interval’ the following restrictions apply for the time resolution:

Analysis Interval	Time resolution selectable?				
	0.25 h	0.5 h	1 h	2 h	4 h
≤2.0h	yes	no	no	no	no
>2.0, ≤ 4.0h	yes	yes	no	no	no
>4.0, ≤ 8.0h	yes	yes	yes	no	no
>8.0h, ≤12.0h	yes	yes	yes	yes	no
>12h; ≤1 d	no	yes	yes	yes	yes
>1d; ≤2d	no	no	yes	yes	yes
>2d; ≤5d	no	no	no	yes	yes
>5d; ≤10d	no	no	no	no	yes

Note: ‘SpO2 Averaging’ indicates the minimal and maximal setting of the SDM internal parameter ‘SpO2 Averaging’ within the entire measurement. The longer the averaging time the slower the SDM’s response to changes in patient’s saturation.

Note: ‘DRI’ indicates the Data Recording Interval that was used while recording the currently displayed measurement. DRI can vary between 1 sec and 8 sec, in steps of 1 sec.

9.5.8 Report pages 7 and 8: PCO2 events

The page 'PCO2 events' displays for each of the six event types (Fall/Rise; lower/upper threshold; < Baseline - Y / > Baseline + X) the distribution of these events over the current 'Analysis Interval' (see 9.3) in a bar chart. Please refer to 9.5.7 for a description of the bar charts and for instructions how the time resolution (i.e. the interval width) can be changed.

Note: 'DRI' indicates the Data Recording Interval that was used while recording the currently displayed measurement. DRI can vary between 1 sec and 8 sec, in steps of 1 sec.

9.5.9 Report page 9: PR events

The page 'PR events' displays for each of the three event types (Rise; lower/upper threshold) the distribution of these events over the current 'Analysis Interval' (see 9.3) in a bar chart. Please refer to 9.5.7 for a description of the bar charts and for instructions how the time resolution (i.e. the interval width) can be changed.

Note: 'SpO2 Averaging' indicates the minimal and maximal setting of the SDM internal parameter 'SpO2 Averaging' within the entire measurement. The longer the averaging time the slower the SDM's response to changes in patient's saturation.

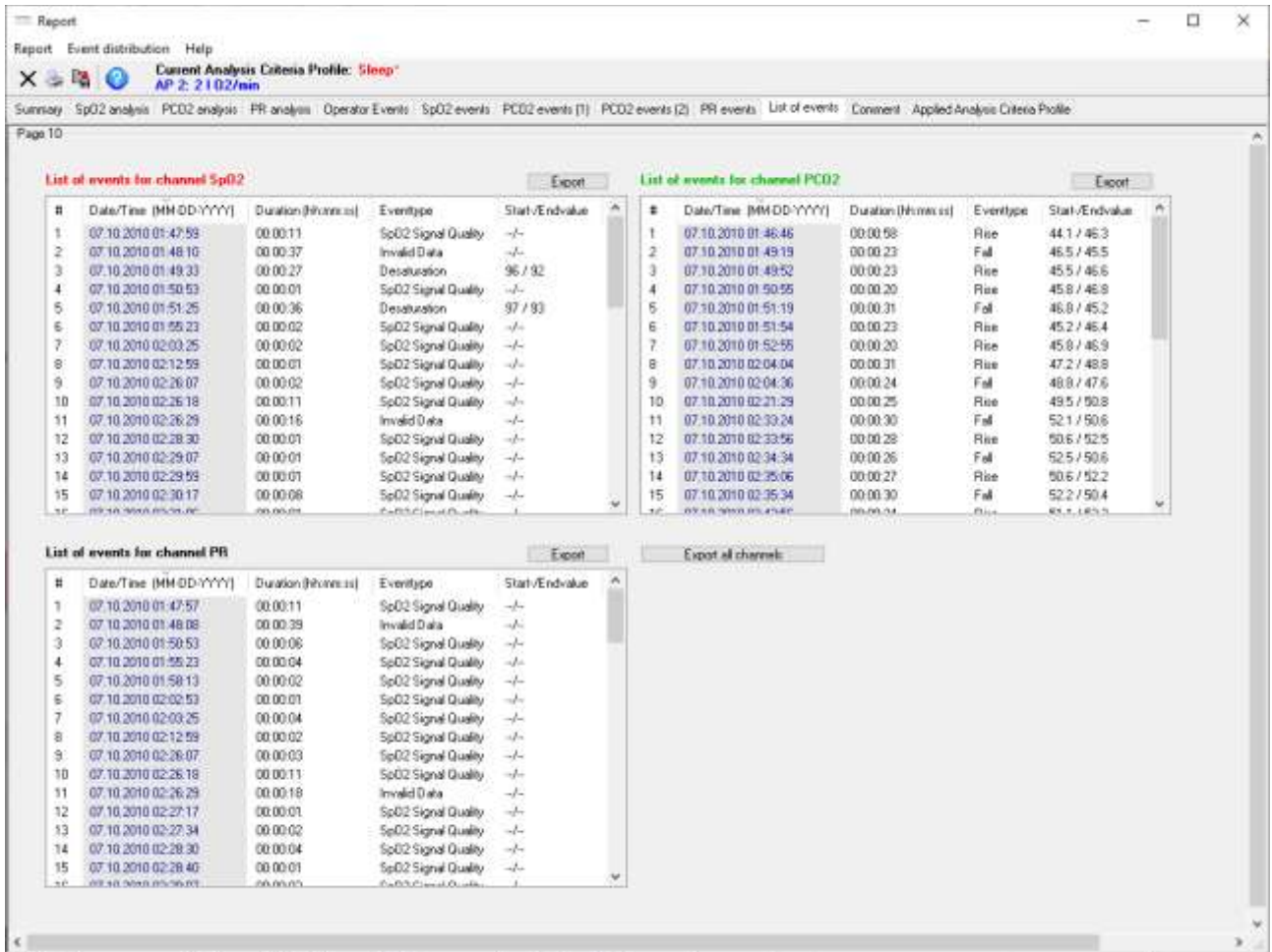
Note: 'DRI' indicates the Data Recording Interval that was used while recording the currently displayed measurement. DRI can vary between 1 sec and 8 sec, in steps of 1 sec.

9.5.10 Report page 10: List of events

The page 'List of events' provides for each channel a chronological list of all events (Physiological Events, Artifacts, Invalid Data, SDM Events) within the current 'Analysis Interval' (see 9.3). Please note that for each channel only those physiological events are listed that are currently selected to be visualized in the measurement curves with colored markers (see 4.2).

Note: For each channel the type of physiological events (dynamic events; baseline events (for PCO2 only); threshold events) that will be visualized with colored markers and, hence, be listed in the 'List of events' can be selected in the dialog 'Analysis Criteria Profile' (see 9.2) or in the pop-up menu that opens after right click on the respective channel's measurement curve (see 4.2.4)

Note: Note that neither 'Excluded Data Ranges' nor other events that occurred within 'Excluded Data Ranges' are listed.



For each event the following information is provided: a) the start date/time, b) the duration in 'hh:mm:ss', c) the event type, and - in case of physiological events - d) the respective parameter values at the start and end of the event. To export the 'List of events' click on the button 'Export' above a channel to export the event list of the respective channel or on the button 'Export all channels' to export the event lists of all channels. The file name that is proposed when exporting the 'List of Events' is identical to the file name that is proposed when creating a PDF Report (see 12.1.5).

Note: Left-click on one of the column headers sorts the respective 'List of events' in increasing/decreasing order by the criteria indicated in the respective column header.

Double clicking on an event in the list of events, finally, a) closes the report, b) positions the cursor at the beginning of the selected event, and c) activates the "15-minutes" zoom level and centers the displayed time range around the cursor.

9.5.11 Report page 11: Comment

A Comment (e.g. a diagnosis) can be entered at the keyboard for printing. The comment will be stored with the measurement.

Note: A comment and findings can also be entered on the 'Report Summary' Page (see 9.5.2).



WARNING: V-STATS provides no diagnosis. The interpretation of the measurement data is the sole responsibility of the investigator or medical practitioner.

9.5.12 Report page 12: Applied 'Analysis Criteria Profile'

To ensure reproducibility of the report the 'Analysis Criteria Profile' (see 9.2) applied for the data analysis of the present report is displayed in tabular form.

Note: Refer to the dialog 'Analysis Criteria Profile' (see 9.2) for the definition/ customization of 'Analysis criteria Profiles'.

The screenshot shows a software window titled "Report" with a menu bar (Report, Event distribution, Help) and a toolbar. The main content area is titled "Applied Analysis Criteria Profile" and displays the following data:

Exclude SOM events:

High Ambient Light	No
SpO2 Signal Quality	No
SpO2 Low signal	No
Calibration recommended	No
PCO2 Slow	No

Artifical Thresholds:

SpO2 <	50 %
PCO2 <	20.0 mmHg
PCO2 >	120.0 mmHg
PR <	30 bpm

SpO2:

Time <	80 %
Fixed threshold:	Upper threshold: 100 %
Marker: Off	Lower threshold: 85 %
	Duration minimum: 2 sec
	Duration maximum: -1 sec
Dynamic:	Desaturation: 4 %
Marker: On	Recovery: 30 %
	Follow-up event: 2 %
	Duration minimum: 2 sec
	Duration maximum: 240 sec

PCO2:

Time >	50.0 mmHg
Fixed threshold:	Upper threshold: 50.0 mmHg
Marker: Off	Lower threshold: 30.0 mmHg
	Duration minimum: 2 sec
	Duration maximum: -1 sec
Deviation from baseline (45.5 mmHg):	> baseline +: 7.5 mmHg
Marker: Off	< baseline -: 7.5 mmHg
	Duration minimum: 2 sec
	Duration maximum: -1 sec
Dynamic:	Fall: 1.0 mmHg
Marker: On	Rise: 1.0 mmHg
	Duration minimum: 5 sec
	Duration maximum: 600 sec

PR:

Fixed threshold:	Upper threshold: 120 bpm
Marker: Off	Lower threshold: 50 bpm
	Duration minimum: 2 sec
	Duration maximum: -1 sec
Dynamic:	Rise: 8 bpm
Marker: On	Duration minimum: 5 sec
	Duration maximum: 60 sec

10. Zoom Menu

Note: The sub-menus and functions of the Zoom Menu are accessible only if a measurement is open. Changes that are made with functions of the Zoom Menu will only affect the measurement that is currently displayed in the V-STATS Main Window.

Available zoom levels

The displayed time range of a measurement curve can be selected using one of the 15 available zoom levels: 30 sec, 1 min, 2 min, 5 min, 15 min, 30 min, 1 hrs, 2 hrs, 4 hrs, 8 hrs, 12 hrs, 1 d, 2 d, 5d and 10d

Note: The displayed time range is indicated at the top right of the V-STATS Main Window (see 4.2).


Influence of the cursor on the zoom behavior

The zoom behavior depends on the placement of the cursor on the measurement curves:

- 1) If the cursor is not placed on the measurement curves, the left border of the displayed time range is maintained.
- 2) If the cursor is placed on the measurement curve, the new displayed time range is centered around the cursor position




Exception: Zoom with mouse (see below)

Full study

The sub-menu 'Zoom / Full study' or clicking on the -icon in the menu bar of the V-STATS Main Window (see 4.2) selects the smallest zoom level that contains the full (complete) measurement curve. The start of the measurement is automatically placed on the left border of the displayed time range.

Different zoom possibilities

V-STATS offers the following zoom possibilities:

- 1) Menu: Left-click on the 'Zoom' menu displays the 15 available zoom levels. The active zoom level is highlighted with a checkmark. A new zoom level can be selected with the mouse.
- 2) Zoom-icons: Clicking on the control-icons  or  in the menu bar of the V-STATS Main Window (see 4.2.1) increases or decreases the zoom by one level. A click on  activates the zoom level 'Full study' (see above).
- 3) Mouse: The left mouse key can be used to span the desired time window. Position the mouse at the beginning of the desired time range, click the left mouse key (do not release). Move the mouse to the end of the desired time range. The spanned range is indicated as a black bar. The duration and – indicated in parenthesis – the start and end time of the spanned range are indicated in red bold, font in the bottom right of the V-STATS Main Window. When releasing the left mouse, a popup menu opens. Click Zoom. The popup menu closes, the start time of the spanned range is positioned at the left border, and the smallest zoom level completely containing the spanned range is automatically activated (also see 4.2.4).
- 4) Keyboard: The following options can be used to zoom with the keyboard:
 - a) Pressing the + (plus) or - (minus) key automatically increases or decreases the zoom by one level.
 - b) Pressing the keys 0 to 9 selects zoom-levels as follows: **1:** 1min; **2:** 2 min; **3:** 5 min; **4:** 15 min; **5:** 30 min; **6:** 1 hrs; **7:** 4 hrs; **8:** 12 hrs; **9:** 2d; **0:** 10d

Center the '15-minutes' zoom level on the beginning of a marker

Double clicking on an event in the list of events (refer to report page 10: List of events (see 9.5.10))

- 1) closes the report
- 2) positions the cursor at the beginning of the selected event
- 3) activates the '15-minutes' zoom level and centers the displayed time range around the cursor

Center the '15-minutes' zoom level at the position of an 'Operator Event'

Double clicking on an operator event in the dialog 'Operator Events' (see [11.1](#))

- 1) closes the dialog 'Operator Events'
- 2) positions the cursor at the selected 'Operator Event'
- 3) activates the '15-minutes' zoom level and centers the displayed time range around the cursor.

11. Measurement Menu

Note: The sub-menus and functions of the Measurement Menu are accessible only if a measurement is open. Changes that are made with functions of the Measurement Menu will only affect the measurement that is currently displayed in the V-STATS Main Window.

11.1 Sub-menu 'Measurement / Operator Events'

'Operator Events' are typically marked on the SDM during patient monitoring by using a) the respective functions of the SDM's 'Quick Access Menu' or b) the dialog 'Set Operator Events' within V-CareNeT (see 14.8.3). For each operator event marked on the SDM the time it was marked and its type are stored in the internal memory of the SDM. When downloading SDM Trend Data from the internal memory of the SDM this information (time, type) is transferred to V-STATS for each operator event that occurred within the selected measurement period(s) (see 6) and to each 'Operator Event' the standard settings predefined for the respective event type are assigned.

Note: On the SDM different operator event types (EO – E7, VC) are supported. Event type EO is triggered each time a 'baseline' (for the parameters PCO2, PO2, SpO2, RHP, if enabled) is set on the SDM (either via its 'Quick Access Menu' or remotely with V-CareNeT). Event type E1 is triggered each time an RHP reference value is set on the SDM via its 'Quick Access Menu'. The event type 'VC' is used for V-Check Events being automatically stored by the SDM at the start and the end of V-Check Measurement Phases (refer to the Technical Manual for the SDM (HB-005752)).

Note: In the dialog 'Define Operator Events' (see 12.1.3) a) the standard description that will be assigned to operator events of a specific type and b) whether or not a new 'Analysis Period' shall start at each occurrence of operator events of a specific type when downloading/importing SDM Trend Data to V-STATS can be predefined for each operator event type. The dialog 'Define Operator Events' can be printed such that its printout can be used as a caption for the operator event types available in the 'Quick Access Menu' of SDMs.

Within V-STATS operator events are visualized by colored triangles in the measurement curves. The triangle color associated to a specific event type can be defined in the dialog 'Define Operator Events' (see 12.1.3). To unequivocally identify 'Operator Events' the colored triangles as well as the corresponding 'Operator Events' in the list of operator events are alphabetically labeled in chronological order of their occurrence. If the mouse is hovered over a colored operator event triangle a tooltip providing information on the respective operator event (its type, description, time of occurrence, and – if applicable – the number x of the analysis period that starts at its position) appears (see 4.2.7).

It is possible to split a measurement into multiple 'Analysis Periods' by adding the start of a new 'Analysis Period' at the position of 'Operator Events'. A grey vertical line at the position of an 'Operator Event' represents the start of new Analysis Period. If a measurement is split into multiple 'Analysis Periods' (e.g. to analyze the different phases of a split night) the current 'Analysis Interval' can be set to one 'Analysis Period' after another (see 9.3), i.e. a report conveniently can be generated/printed for each 'Analysis Period'. For V-Check Measurements the current 'Analysis Interval' can be set to the V-Check Measurement Phase (see 9.3.1).

Note: If the current 'Analysis Interval' starts/ends at the beginnings of two new 'Analysis Periods' the grey vertical lines at the position of the respective 'Operator Events' are in the background of the two blue vertical lines indicating the start and end of the current 'Analysis Interval'.

For the currently open measurement 'Operator Events' and/or 'Analysis Periods' can be edited/added/deleted at any time (see 4.2, 4.2.1, 4.2.4, 4.2.7, 11.2). The list of operator events of the currently open measurement can be displayed in the dialog 'Operator Events' (see below) and in the report page 'Operator Events' (see 9.5.6). If the report is printed it is optionally possible to add the list of operator events as a caption to the printout of the summary page (see 9.5.2) and/or to print/store the report page 'Operator Events' (see 7.3).

The dialog 'Operator Events' can be opened by selecting the sub-menu 'Measurement / Operator Events' or by selecting the option 'Operator Events' in the popup menu that opens upon right-click on an operator event triangle (see 4.2.4).

#	Date/Time (MM-DD-YYYY)	Type	Description (max. 30 Char)	New Analysis Period
a.	06.10.2010 21:55:58	E1	No oxygen (nativ)	X
b.	07.10.2010 01:47:30	E2	2 l O2/min	X
c.	07.10.2010 03:48:40	E3	1 l O2/min	X

The dialog 'Operator Events' lists all 'Operator Events' of the currently open measurement in table form. The columns provide the following information:

- **#:** 'Operator Events' are alphabetically labeled in chronological order of their occurrence, whereby the oldest event of the currently open measurement is labeled with the letter a.
 - Note:* The colored operator event triangles are identically labeled, i.e. the list of operator events may serve as caption for the operator event triangles in the measurement curves.
- **Date/Time:** Indicates the date/time of the operator event.
- **Type:** Indicates the type of the respective operator event.
 - Note:* The color assigned to a specific type of operator events can only be changed in the dialog 'Define Operator Events' (see 12.1.3). The color assigned to an individual operator event cannot be changed.
- **Description:** Indicates the description associated to the respective operator event.
 - Note:* The description of an 'Operator Event' will be visualized a) in the tooltip that appears if the mouse is hovered over a colored operator event triangle (see 4.2.7), b) in the 'Analysis Interval Indicator' if the 'Analysis Interval' is set to an 'Analysis Period' that starts at the position of an 'Operator Event' (see 9.3) and c) in the 'List of Operator Events' (see 9.5.2, 9.5.6).
- **New Analysis Period:** Displays a cross if at the position of the respective operator event a new Analysis Period starts.

The following functions are available:

- **Double click** on an operator event in the dialog 'Operator Events' closes the dialog, positions the cursor at the position of the selected 'Operator Event', and activates the '15-minutes' zoom level and centers the displayed time range around the cursor.
- **Sort:** Left-click on one of the column headers sorts the list of operator events in increasing/decreasing order by the criteria indicated in the respective column header.
- **Button 'Add Event':** Opens the dialog 'Edit/Add Operator Event' with empty fields (see 11.2). The date/time which will be proposed for the new operator event corresponds to the date/time of the measurement start of the currently open measurement.
- **Button 'Edit Event':** Click on this button opens the dialog 'Edit/Add Operator Event' displaying the information of the selected 'Operator Event' (see 11.2). Therein the date/time, type, description and the selection whether or not a new Analysis Period shall start at the position of the operator event can be edited for the selected Operator Event.
 - Note:* This button is dimmed grey (not operable) if no operator event is selected.
- **Button 'Delete Event':** Click on this button deletes the selected operator event
 - Note:* This button is dimmed grey (not operable) if no operator event is selected.
 - Note:* If changes affect the 'Analysis Period' that is currently selected as 'Analysis Interval' a warning dialog will prompt when attempting to close the dialog 'Edit/Add Operator Events' indicating that if you proceed the Analysis Interval will be set to the Full Measurement instead.
- **Button 'Restore':** Click on this button deletes ALL manually made changes that are related to operator events of the currently open measurement, i.e. the list of operator events as available immediately after download/import of SDM Trend Data is restored.
- **Button 'Clear All':** Clears the list of 'Operator Events', i.e. all operator events are deleted.
 - Note:* The 'Restore - Button' cannot recover manually added 'Operator Events', if the 'Clear All - Button' has been

pressed accidentally. The restore function always recovers the situation immediately after data download.

- **Button 'Print':** Permits to print the list of operator events of the currently open measurement either a) on paper (select 'Printer') or b) as pdf-file (select 'PDF').

Click on the button 'OK' to maintain/store changes and to close the dialog.

Click on the button 'Cancel' to reject changes and to close the dialog.

11.2 Sub-menu 'Measurement / Add Operator Event'

For the currently opened measurement it is possible to edit/add/delete 'Operator Events' and/or 'Analysis Periods'.

Adding a new 'Operator Event'

The following options can be used to open the dialog 'Edit/Add Operator Event' with empty fields:



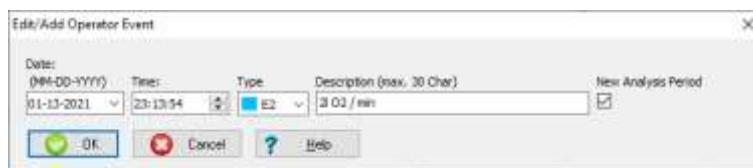
- Click on the button 'Add Event' in the dialog 'Operator Event' (see 11.1). The date/time which will be proposed for the new operator event corresponds to the date/time of the measurement start of the currently open measurement.
- Place the cursor at the position you want to add a new operator event and then use the sub-menu 'Measurement / Add Operator Event' or click on the ▼-icon in the menu bar of the V-STATS Main Window (see 4.2.1). The date/time which will be proposed for the new operator event corresponds to the date/time at the cursor position.

Note: The sub-menu 'Measurement / Add Operator Event' and the ▼-icon are dimmed grey (not accessible) if the cursor (see 4.2.3) is not placed on a measurement.

- Right click on the measurement curve. The date/time which will be proposed for the new operator event corresponds to the date/time of the position the right mouse click was made (see 4.2.4).
- Right click on a physiological event or artifact marker to open a popup menu and selection of the option 'Add Operator Event' therein. The date/time which will be proposed for the new operator event corresponds to the date/time of the position the right mouse click was made (see 4.2.4).

Editing an existing 'Operator Event'

The following options can be used to open the dialog 'Edit/Add Operator Event' displaying the information of the 'Operator Event' to be edited:



- In the dialog 'Operator Events' selection of an operator event with the mouse and then mouse click on the button 'Edit Event' (see 11.1)
- Right click with the mouse on a colored 'Operator Event Triangle' to open a popup menu and selection of the option 'Edit Operator Event' therein (see 4.2.4).

For each new or existing operator event the following parameters can be edited:

Parameter	Description
Time / Date	Permits to define/adjust the date/time of the operator event. The selected date/time must be within the current measurement.
Type	Drop down list which permits to define/modify the operator event type. <i>Note: The color assigned to a specific type of operator events can only be changed in the dialog 'Define Operator Events' (see 12.1.3). The color assigned to an individual operator event cannot be changed.</i>

Parameter	Description
Description	<p>Permits to define/modify the description (up to 30 characters) of the 'Operator Event'.</p> <p><i>Note:</i> When changing the operator event type the respective event description predefined in the dialog 'Define Operator Events' will be used (see 12.1.3). The description subsequently can be modified.</p> <p><i>Note:</i> When adding a new Operator Event this field can only be edited after selection of an event type.</p> <p><i>Note:</i> The description of an 'Operator Event' will be visualized a) in the tooltip that appears if the mouse is hovered over a colored operator event triangle (see 4.2.7), b) in the 'Analysis Interval Indicator' if the 'Analysis Interval' is set to an 'Analysis Period' that starts at the position of an 'Operator Event' (see 9.3), and c) in the 'List of Operator Events' (see 9.5.2, 9.5.6, 11.1).</p>
Box 'New Analysis Period'	<p>Check this box to define the start of a new Analysis Period at the position of the Operator Event.</p> <p><i>Note:</i> When changing the operator event type the respective selection of the box 'New Analysis Period' predefined in the dialog 'Define Operator Events' will be used (see 12.1.3). The selection subsequently can be modified.</p> <p><i>Note:</i> If changes affect the 'Analysis Period' that is currently selected as 'Analysis Interval' a warning dialog will prompt when attempting to close the dialog 'Edit/Add Operator Events' indicating that if you proceed the Analysis Interval will be set to the Full Measurement instead.</p>

Click on the button 'OK' to maintain/store changes and to close the dialog.

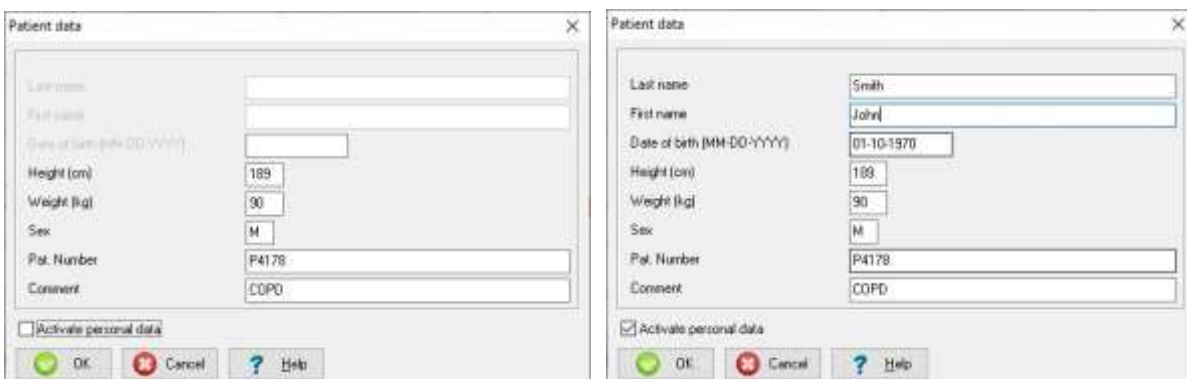
Click on the button 'Cancel' to reject changes and to close the dialog.

11.3 Sub-menu 'Measurement / Patient data'

Selecting the sub-menu 'Measurement / Patient data' or mouse-click into the area of the report's Summary Page which displays patient data (see 9.5.2) opens the dialog 'Patient data'. Additionally, a click on the patient name in the lower left corner of the 'Main Window' (see 4.2) also opens the dialog 'Patient data'. The checkbox 'Activate personal data' in the lower left corner needs to be checked to enable the access for entering patient information if Installation for Advanced Data Protection has been installed.

Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.

In this dialog the data of the patient being associated to the currently opened measurement can be edited.

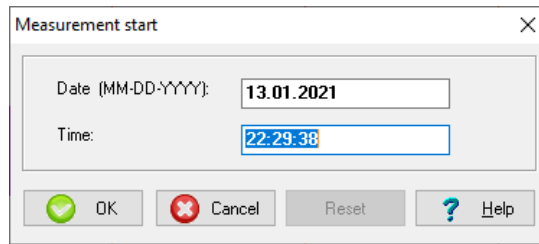


Note: Patient data are stored with the measurement. For a patient for whom multiple measurements exist, the changes of the respective patient data, therefore, must be performed for each measurement individually.

Note: A maximum of 25 characters is supported for the 'Last name' and the 'First name'. For the 'Pat. Number' and the 'Comment' a maximum of 40 characters are supported.

11.4 Sub-menu 'Measurement/ Measurement start'

The sub-menu 'Measurement/ Measurement start' opens the dialog 'Measurement start'. In this dialog the start date and time of an open measurement can be set manually, e.g. if time synchronization is required with measurement data from other devices (e.g. ventilators, PG-, or PSG-systems).



The selected date and time is applied by clicking 'OK'. Once the measurement start has been changed manually, the original start date and time can be restored by clicking 'Reset'.

11.5 Sub-menu 'Measurement / Select PCO2 baseline'

After downloading / importing SDM Trend Data V-STATS sets the PCO2 baseline to the PCO2 reading at the end of the (first) PCO2 stabilization period in the measurement ('Automatic' determination of baseline). If 'Manual' is selected, the next click on the measurement curve determines the instant for which the PCO2 baseline shall be determined.

The PCO2 baseline is shown in the PCO2 channel as a red-dashed horizontal line. A red vertical line indicates the instant at which the PCO2 baseline was determined. Subsequent deviations of the PCO2 readings (e.g. caused by nocturnal or sedation/ pain management induced hypoventilation) from the red-dashed horizontal line are readily seen. The numerical value of the PCO2 baseline is displayed on the left of the PCO2 channel. The numerical value for the PCO2 baseline is also displayed at various locations of the report and is taken into consideration when analyzing the PCO2 data for the criteria 'Deviation from baseline'. The delta-baseline (dB) value for PCO2, finally, indicates the difference between the PCO2 value at the cursor position (if set) and the PCO2 baseline.

Note: If drift corrected PCO2 data is displayed, the PCO2 baseline is determined using drift corrected PCO2 data (see 11.6).

Note: If during a measurement the sensor was applied multiple times, multiple PCO2 stabilization periods will be contained in the data. V-STATS will use the first PCO2 reading at the end of the first PCO2 stabilization period to determine the PCO2 baseline. A different baseline can be set manually as described above.

11.6 Sub-menu 'Measurement / Correction of Residual PCO2 Drift'

By using the Sub-menu 'Measurement / Correction of Residual PCO2 Drift' the correction of the residual PCO2 drift for the currently displayed measurement can be set to 'Off', 'Both' or 'On'.

Note: The drift correction mode that will be used by default when downloading/importing SDM Trend Data to V-STATS can be predefined in the dialog 'Channel Settings' (see 12.1.1).

*Note: If for a measurement correction of the residual PCO2 drift is not possible the drift correction mode is automatically set to 'Off' for the respective measurement. If for a measurement uncorrected PCO2 data is not available (e.g. after import of a *.vex-file which contains only drift corrected PCO2 data (see 7.4 and 7.5)) the drift correction mode is automatically set to 'On' for the respective measurement.*

Note: Correction of residual PCO2 drift is important for longer measurements (e.g. sleep studies, etc.). [Chhajed et al.](#), for example, have shown that with drift corrected PCO2 data the titration of NPPV pressures can be optimized.

Note: The PO2 measurement of Sentec TC Sensors is virtually free of drift and, hence, residual PO2 drift of Sentec TC Sensors is usually minimal or even non-existent. Correction of residual PO2 drift, consequently, is usually not required.

If set to 'Both' or 'On' residual technical (electrochemical) PCO2 drift of the Sentec TC Sensor is corrected in first approximation. If 'Correction of Residual PCO2 Drift' is set to

- 'Off' only the curve representing uncorrected PCO2 data is displayed
- 'Both' drift corrected PCO2 data is displayed as a blue curve in addition to the curve of the uncorrected PCO2 data
- 'On' only the blue curve representing drift corrected PCO2 data is displayed.

Note: The color used for the PCO2 label and for the curve representing uncorrected PCO2 data can be selected in the dialog 'Channel Settings' (see 12.1.1). The default color for these PCO2 elements is green.

Note: If both uncorrected PCO₂ data and drift corrected PCO₂ data are displayed, the blue curve representing drift corrected data is displayed in the background of the green curve representing uncorrected PCO₂ data.

*Note: Print-out of uncorrected PCO₂ data and drift corrected PCO₂ data is made with different fonts to ensure that the two curves can be distinguished if printing is made on a black&white printer. The 'drift corrected' curve is printed in **black, bold** font whereas the uncorrected curve is printed in light, grey font.*

Whenever drift corrected PCO₂ data is displayed

- the text 'Drift corrected' is displayed in blue below the PCO₂ label, at different locations in the report as well as in files that are created by exporting data using the Sub-menu 'File / Export data'.
- statistical results for PCO₂ are determined using drift corrected PCO₂ data
- the PCO₂ baseline (see 11.5) is determined using drift corrected PCO₂ data
- the delta-baseline ('dB') value for PCO₂ (see 4.2) is determined using drift corrected PCO₂ data.
- the display range (y-axis) of the PCO₂ channel is determined using drift corrected PCO₂ data if 'Autoscale' is used for the display range of the PCO₂ Channel

Correction of residual PCO₂ drift- steps to follow when recording data!

Correction of residual PCO₂ drift within V-STATS is only possible if the PCO₂ calibration data before and after the measurement is available. To ensure that correction of residual PCO₂ drift is possible you must follow the following steps:

- Prior monitoring ensure that the SDM displays the message 'Ready for use' while the sensor is in the Docking Station.
- Apply the sensor to perform the measurement
- Remove the sensor from the patient at the end of the measurement and calibrate the Sentec TC Sensor (if possible immediately)

Note: PCO₂ drift correction is only supported, as long the sensor calibration after the measurement is not yet mandatory, i.e. within 12 hours of the measurement start after an initial calibration or within 13 or 16 hours of the measurement start if the calibration interval was 9 or 12 hours, respectively. Please note that if the SDM displays the status message 'Sensor calibration recommended' the calibration is not yet mandatory. If the SDM displays the status message 'Calibrate sensor' the sensor calibration is mandatory.

- Wait to download SDM Trend Data until successful termination of the sensor calibration (status message 'Ready for use' displays).

Note: When downloading SDM Trend Data from the internal memory of a SDM with V-CareNeT the status messages of the respective SDM are duplicated in the dialog 'Assign measurement period(s) to patients' (see 6.1). To ensure that correction of residual PCO₂ drift is possible wait to download SDM Trend Data until the status message changes from 'Calibration in progress' to 'Ready for use'.

11.7 Sub-menu 'Measurement / Select PO₂ baseline'

After downloading / importing SDM Trend Data V-STATS sets the PO₂ baseline to the PO₂ reading at the end of the (first) PO₂ stabilization period in the measurement ('Automatic' determination of baseline). If 'Manual' is selected, the next click on the measurement curve determines the instant for which the PO₂ baseline shall be determined.

The PO₂ baseline is shown in the PO₂ channel as a red-dashed horizontal line. A red vertical line indicates the instant at which the PO₂ baseline was determined. Subsequent deviations of the PO₂ readings (e.g. caused by nocturnal or sedation/pain management induced hypoventilation) from the red-dashed horizontal line are readily seen. The numerical value of the PO₂ baseline is displayed on the left of the PO₂ channel. The delta-baseline (dB) value for PO₂, finally, indicates the difference between the PO₂ value at the cursor position (if set) and the PO₂ baseline.

Note: If during a measurement the sensor was applied multiple times, multiple PO₂ stabilization periods will be contained in the data. V-STATS will use the first PO₂ reading at the end of the first PO₂ stabilization period to determine the PO₂ baseline. A different baseline can be set manually as described above.

11.8 Sub-menu 'Measurement / Show / Hide'

The sub-menu 'Measurement / Show / Hide' allows showing or hiding channels for the currently displayed measurement.

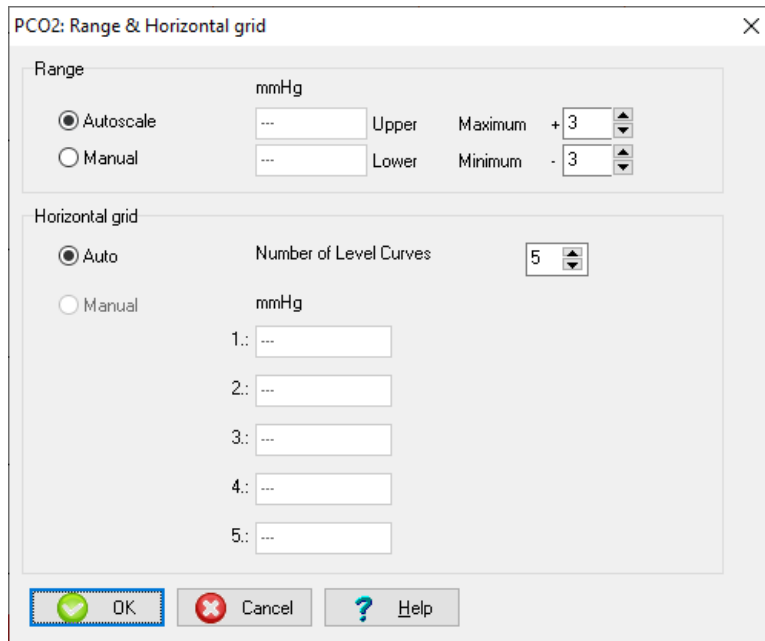
11.9 Sub-menu 'Measurement / Range & Horizontal Grid / <Channel>'

The sub-menu 'Measurement / Range & Horizontal Grid / <Channel>' opens for the selected channel (PCO₂, PO₂, SpO₂, PR, PI or HP) the dialog '<Channel>: Range & Horizontal Grid'. In this dialog it is possible to adjust for the currently

open measurement and the selected channel the display range (y-axis) and horizontal grid settings.

Note: The dialog '<Channel>: Range & Horizontal Grid' can also be opened by clicking with the mouse a) on the area indicating the current mode of the display range and the horizontal grid or b) on the y-axis of the respective channel (see 4.2).

Note: The display range (y-axis) and horizontal grid settings that will be used by default when downloading/importing SDM Trend Data to V-STATS can be predefined for each channel in the dialog 'Channel Settings' (see 12.1.1).



The mode for the display range (y-axis) and horizontal grid for the currently open measurement can be adjusted as follows:

Parameter	Description																				
Range Mode	<p>The mode used for the display range (y-axis) can be set to 'Autoscale' or to 'Manual'.</p> <p>If set to 'Manual' the lower and upper end of the display range can be entered manually into the respective fields. If set to 'Autoscale' these input fields are dimmed grey and V-STATS automatically determines the display range (y-axis) for the respective channel as follows:</p> <ul style="list-style-type: none"> • Upper end of range = Maximum value within 'Analysis Interval' + A • Lower end of range = Minimum value within 'Analysis Interval' - B <p>A and B are adjustable as follows:</p> <table border="1"> <thead> <tr> <th></th> <th>A</th> <th>B</th> <th>Range restricted to</th> </tr> </thead> <tbody> <tr> <td>PCO2 (mmHg)</td> <td>0 - 20 in steps of 1</td> <td>0 - 20 in steps of 1</td> <td>1 - 200.0</td> </tr> <tr> <td>PCO2 (kPa)</td> <td>0 - 3 in steps of 0.1</td> <td>0 - 3 in steps of 0.1</td> <td>0.1 - 26.7</td> </tr> <tr> <td>SpO2</td> <td>Upper end of SpO2 range set to 100%</td> <td>0 - 20 in steps of 1</td> <td>1 - 100</td> </tr> <tr> <td>PR</td> <td>0 - 20 in steps of 1</td> <td>0 - 20 in steps of 1</td> <td>30 - 250</td> </tr> </tbody> </table> <p><i>Note: If 'Autoscale' is used for the display range of a channel, the respective channels display range is determined based on valid, non-excluded data within the current 'Analysis Interval'. Furthermore, if drift corrected PCO2 data is displayed the display range of the PCO2 channel is determined using drift corrected PCO2 data if 'Autoscale' is used for the</i></p>		A	B	Range restricted to	PCO2 (mmHg)	0 - 20 in steps of 1	0 - 20 in steps of 1	1 - 200.0	PCO2 (kPa)	0 - 3 in steps of 0.1	0 - 3 in steps of 0.1	0.1 - 26.7	SpO2	Upper end of SpO2 range set to 100%	0 - 20 in steps of 1	1 - 100	PR	0 - 20 in steps of 1	0 - 20 in steps of 1	30 - 250
	A	B	Range restricted to																		
PCO2 (mmHg)	0 - 20 in steps of 1	0 - 20 in steps of 1	1 - 200.0																		
PCO2 (kPa)	0 - 3 in steps of 0.1	0 - 3 in steps of 0.1	0.1 - 26.7																		
SpO2	Upper end of SpO2 range set to 100%	0 - 20 in steps of 1	1 - 100																		
PR	0 - 20 in steps of 1	0 - 20 in steps of 1	30 - 250																		

Parameter	Description
	<i>display range (y-axis) of the PCO2 Channel.</i>
Horizontal Grid Mode	<p>The mode used for the horizontal grid can be set to 'Auto' (default setting) or to 'Manual'.</p> <p><i>Note: 'Manual' is not selectable for the horizontal grid if 'Autoscale' is used for the display range.</i></p> <p>If set to 'Manual' it is possible to specify manually up to five horizontal grid levels by entering the corresponding values into the respective fields. If set to 'Auto' these input fields are dimmed grey and V-STATS evenly distributes the currently selected number of level curves within the current display range.</p> <p><i>Note: In 'Auto' mode it is possible to select up to 6 level curves (default=5). In 'Manual' mode it is possible to define up to 5 level curves. Ensure to enter values for the level curves which fall within the manually selected display range. To use less than five level curves simply leave the respective number of input fields blank.</i></p>

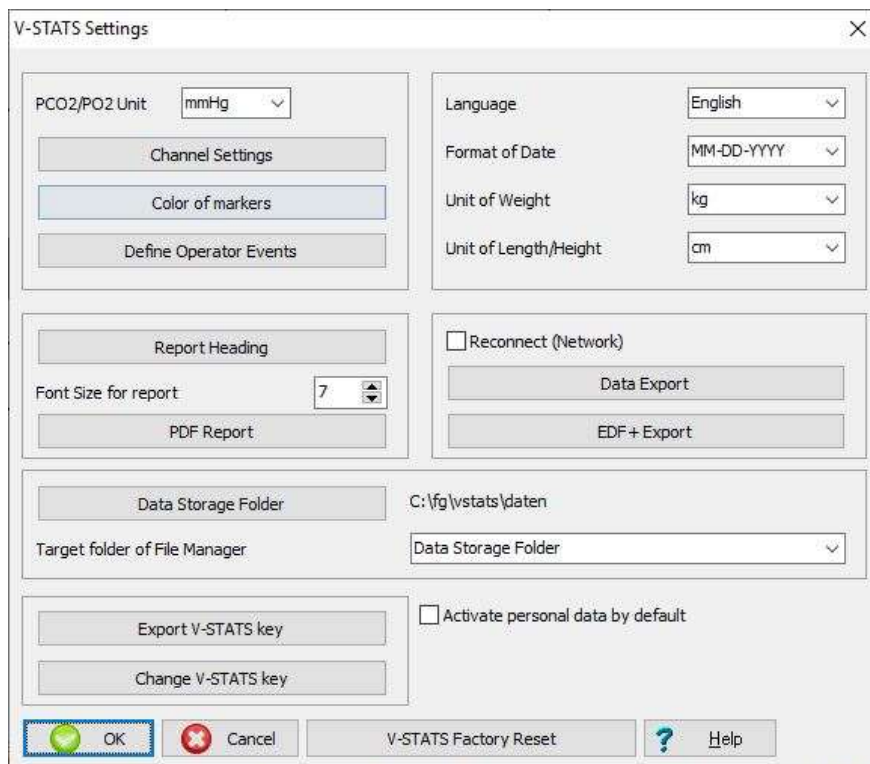
12. Settings Menu

12.1 Sub-menu 'Settings / V-STATS Settings'

The sub-menu 'Settings / V-STATS Settings' activates a password dialog and – after having successfully entered the admin password - the dialog 'V-STATS Settings'.

Note: The password (admin password) to open the dialog 'V-STATS Settings' is the same password that is required to open the dialogs 'Profiles / device Settings - <SN>' and 'Special Functions' (see 8.1).

Note: The default password for the Standard Installation is the Identification Code, which is displayed in the dialog 'Product-Info' (see 16.6). The password can be changed in the dialog 'Change Password'. In case you have forgotten your password enter the Password Unlock Key 'RememberPassword' in the field 'Current Password' and select a new password.



In the dialog 'V-STATS Settings' the following settings can be configured:

Parameter / Button	Range (Factory Default in Bold) / Description
PCO2/PO2 Unit	Type: Parameter (global) Range: mmHg , kPa To select the unit for PCO2 and PO2 and the barometric pressure used by V-STATS <u>and</u> V-CareNeT <i>Note: 1 kPa corresponds to 7.5 mmHg.</i>
Channel Settings	Type: Button Clicking this button opens the dialog 'Channel-settings' (see 12.1.1). In this dialog it is possible to predefine for each channel various settings that will be used to display SDM Trend Data in the V-STATS Main Window.
Color of Markers	Type: Button Clicking this button opens the dialog 'Color of markers' (see 12.1.2). In this dialog the color of markers that are displayed in the measurement curves can be selected.
Define Operator Events	Type: Button Clicking this button opens the dialog 'Define Operator Events' (see 12.1.3). In this dialog the settings which V-STATS uses for each of the different operator event types (E0 – E7, VC) when

Parameter / Button	Range (Factory Default in Bold) / Description
	downloading/importing SDM Trend Data can be predefined.
Report Heading	<p><u>Type:</u> Button</p> <p>Clicking this button opens the dialog 'Report Heading' (see 12.1.4). In this dialog it is possible to define the heading of the report (typically your institution's address). Among other it is possible to individually define the font for each of the up to 5 heading lines, to select the alignment of the report heading and to add your institution's logo.</p>
Font Size for Report	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> 6, 7, 8, 9</p> <p>To select the font size that will be used for the printout of the report (see 7.2). Note that for font size 9 it will not be possible to properly print the report's 'Summary' page if all available elements are printed (see 9.5.2).</p>
PDF Report	<p><u>Type:</u> Button</p> <p>Clicking this button opens the dialog 'PDF Report Configuration' (see 12.1.5). In this dialog it is possible to specify the Paper Size, the Target Folder, the Default Storage Folder and the Default File Name that will be used/proposed when storing reports as a PDF (see 7.2).</p> <p><i>Note: The possibility to specify the Target folder, Default Storage Folder and Default File Name that will be used/proposed when storing reports as a PDF is useful if you want to integrated/import PDF Reports into your 'Electronic Medical Records'. If PDF Reports are stored in a dedicated folder a (third party) application may automatically integrate PDF Reports into the 'Electronic Medical Records'. If the filenames contain patient and measurement specific information it will be possible for this application to assign each PDF Report to the respective patient and intervention/investigation.</i></p>
Language	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Deutsch, English, Español, Français, Italiano</p> <p>To select the language that will be used for V-STATS (including the various printouts) and for V-CareNeT.</p> <p><i>Note: Should changing the language reduce the maximal number of stations that are available at the V-CareNeT Central Station and should this cause the discharge of patients currently admitted to these stations (if any), then the alert dialog Discharge Patient(s)' (see 14.7.5) displays.</i></p>
Format of Date	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> MM-DD-YYYY, DD-MM-YYYY, YYYY-MM-DD</p> <p>To select the format used by V-STATS (including the various printouts) and V-CareNeT to indicate the date.</p>
Unit of Weight	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> kg, lbs</p> <p>To select the unit used by V-STATS (including the various printouts) and V-CareNeT to indicate the weight.</p>
Unit of Length/Height	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> cm, ft</p> <p>To select the unit used by V-STATS (including the various printouts) and V-CareNeT to indicate the length/height</p>
Reconnect (Network)	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Checked, Not Checked</p> <p>Check this box if you use Windows Vista.</p>
Data Export	<p><u>Type:</u> Button</p> <p>Clicking this button opens the dialog 'Data Export Configuration' (see 12.1.6). In this dialog it is possible to configure the Target folder, Default Storage Folder and the Default File Name that will be used/ proposed to export data as '*.vex-files' (see 7.5).</p> <p><i>Note: The possibility to specify the Target folder, Default Storage Folder and Default File Name that will be used/proposed when exporting data as '*.vex-files' is useful if you want to integrated/import '*.vex-files' into (third party) applications. If '*.vex-files' are stored in a dedicated folder an application may automatically integrate '*.vex-files' and if the filenames</i></p>

Parameter / Button	Range (Factory Default in Bold) / Description
	<i>contain patient and measurement specific information it will be possible for this application to assign each *.vex-file to the respective patient and intervention/investigation.</i>
EDF+ Export	<p><u>Type:</u> Button</p> <p>Clicking this button opens the dialog 'EDF+ Export Configuration' (see 12.1.7). In this dialog it is possible to configure the Target folder, Default Storage Folder and the Default File Name that will be used/proposed when converting data into an 'EDF+-File' (see 7.6).</p> <p><i>Note:</i> The possibility to specify the Target Folder, Default Storage Folder and Default File Name that will be used/proposed when converting data into 'EDF+-Files' is useful if you want to integrated/import 'EDF+-Files' into (third party) applications. If 'EDF+-Files' are stored in a dedicated folder an application may automatically integrate 'EDF+-Files'. If the filenames contain patient and measurement specific information it will be possible for this application to assign each 'EDF+-File' to the respective patient and intervention/investigation.</p>
Data Storage Folder	<p><u>Type:</u> Button</p> <p>Clicking this button opens a Windows dialog where it is possible to select a folder that will be used as data storage folder when downloading / importing SDM Trend Data to V-STATS (see 6, 6.1, 7.4, 7.7)</p> <p>The default 'Data Storage Folder' is <Installation-Drive>:\fg\stats\daten.</p> <p><i>Note:</i> If within your institution you use multiple PC's with V-STATS we recommend for all V-STATS installations a) to select the same 'Data Storage Folder' being localized on a server of your institutions network and b) to set the 'Target Folder of File Manager' to 'Data Storage Folder'. All V-STATS installations will then store measurements in the same folder when downloading / importing SDM Trend Data and the File Managers of all V-STATS installations will access by default this common 'Data Storage Folder'. Furthermore, if the 'Data Storage Folder' is localized on a server of your institutions network backup of the measurement data can be accomplished in the course of the server's routine backup procedures.</p>
Target Folder of File Manager	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Data Storage Folder, Last</p> <p>After opening the 'File Manager' the 'File Manager' lists all measurements that are saved in its current target folder (see 7.1). This drop-down list offers two options to define the target folder of the 'File Manager':</p> <ul style="list-style-type: none"> - 'Data Storage Folder': after opening the file manager lists all measurements that are saved in the current data storage folder, i.e. the folder into which V-STATS stores measurements that are downloaded / imported to V-STATS (see 6, 6.1, 7.4, 7.7) - 'Last': after opening the file manager lists all measurements that are saved in the folder that was last used to open a measurement. <p><i>Note:</i> To open measurements that are stored in different folders it is possible to access the file system from the 'File Manager' and to select an arbitrary folder.</p>
Export V-STATS key (only applicable if Installation for Advanced Data Protection is installed)	<p><u>Type:</u> Button</p> <p>Clicking this button opens a dialog where a password for the current used key has to be set to save the key locally</p>
Change V-STATS key (only applicable if Installation for Advanced Data Protection is installed)	<p><u>Type:</u> Button</p> <p>Clicking this button opens a warning that has to be confirmed if a new key / already existing key should be generated / uploaded or entered for the current used V-STATS. When the warning is confirmed the dialog "Installation of key" opens.</p> <p><i>Note:</i> When changing the key all saved measurement data are encrypted with the new key automatically.</p>
Activate personal data by default (only applicable if Installation for Advanced Data Protection is installed)	<p><u>Type:</u> Check box</p> <p>Checking the box activates all check boxes within V-STATS for export and entering patient data by default.</p>
V-STATS Factory Reset	<p><u>Type:</u> Button</p> <p>Clicking this button will - after confirmation of a warning dialog - restore factory settings for all parameters of V-STATS and V-CareNeT and then close the dialog 'V-STATS Settings'.</p>

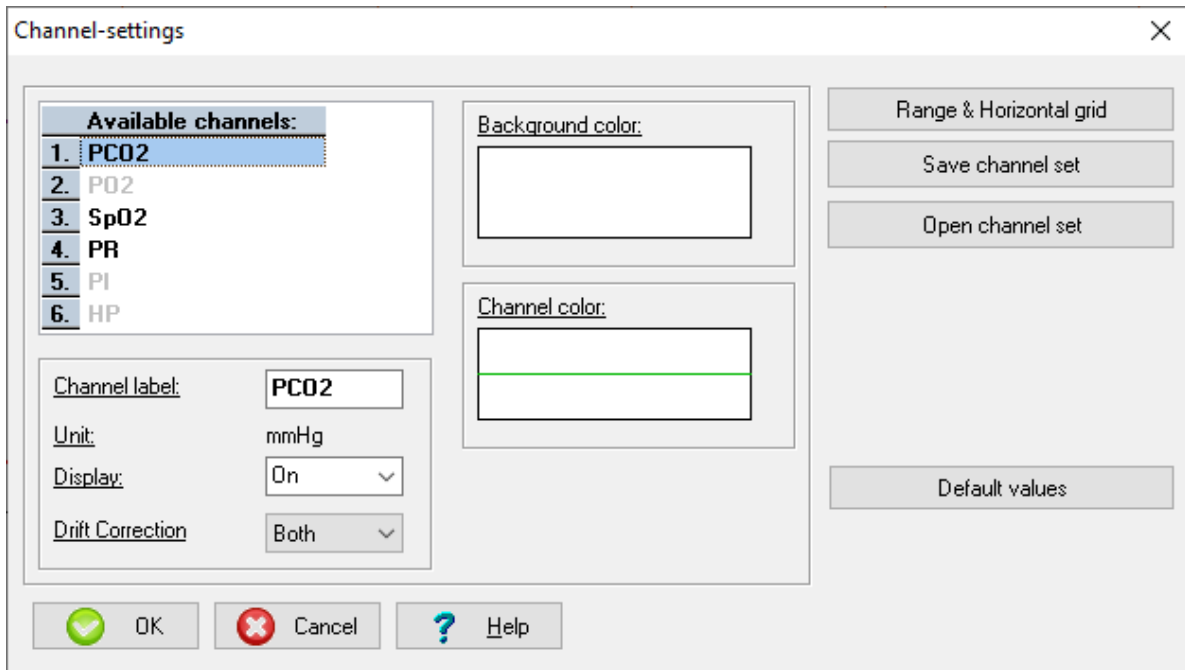
Parameter / Button	Range (Factory Default in Bold) / Description
OK	Type: Button Clicking this button closes the dialog 'V-STATS Settings' and maintains/stores changes.
Cancel	Type: Button Clicking this button closes the dialog 'V-STATS Settings' and rejects changes.
Help	Type: Button Clicking this button opens the context-sensitive on-line help.

12.1.1 Dialog 'Channel-settings'

Click on the button 'Channel Settings' in the dialog 'V-STATS Settings' opens the dialog 'Channel-settings'. In this dialog you can predefine for each channel various settings that are used to display SDM Trend Data in the V-STATS Main Window.

Note: Changing settings for parameters related to 'Range & Horizontal Grid' and for the parameter 'Drift Correction' will not affect an already opened measurement or measurements already stored in the File Manager (see 7.1). For an already opened measurement or a measurement already stored in the File Manager these settings can only be changed by using the corresponding options of the Measurement Menu (see 11.6, 11.9).

The available channels are listed on the left. The currently selected channel is highlighted. Channels for which the option 'Display' is currently set to 'Off' are dimmed grey.



For the selected channel, the following parameters can be configured:

Parameter	Description
Channel label	Permits to define the label that will be used for a channel throughout V-STATS. <i>Note: The maximal supported length for the channel labels is 6 characters.</i> <i>Note: When changing the language, the channel label is reset to the default value of the corresponding language ('PCO2', 'PO2' and 'SpO2' for all languages; 'PR' for English and Polish, 'PF' for German, and 'FP' for French, Italian, and Spanish, 'FC' for Portuguese)</i> Important Note: 'Channel label' is a global parameter, i.e. the channel labels defined in the dialog 'Channel-setting' will be used for all measurements.
Unit	Information only (dimmed grey, not changeable) <i>Note: The PCO2/PO2 Unit can be selected in the dialog 'V-STATS Settings' (see 12.1).</i>

Parameter	Description
Display	Permits to define if the respective channel is displayed ('On') or not ('Off'). <i>Note: In order to display the measurement curve of the respective channel in an open measurement file, the respective channel must be selected as 'show' in the menu 'Measurement / Show / Hide' (see 11.8).</i>
Drift Correction	Permits to predefine the drift correction mode for PCO2 (see 11.6) that will be used by default when downloading/importing SDM Trend Data to V-STATS. Can be set to 'Off', 'Both' (default setting), or 'On'. Important Note: Changing the drift correction mode in the dialog 'Channel-settings' will not affect the drift correction mode of the currently opened measurement or of measurements already stored in the 'File Manager' of V-STATS. To change the drift correction mode for an existing measurement, the measurement must be opened and its drift correction mode must be changed by using the sub-menu 'Measurement / Correction of Residual PCO2 Drift' (see 11.6).
Background color	Permits to define the background color that will be used to display the selected channel in the V-STATS Main Window. <i>Note: When selecting a new background color verify that the measurement curve and the markers can be distinguished from the new background.</i> Important Note: 'Background color' is a global parameter, i.e. the background colors defined in the dialog 'Channel-setting' will be used for all measurements.
Channel color:	Permits to define the color that will be used to display the measurement curve and the channel label of the selected channel in the V-STATS Main Window. <i>Note: The color to display drift corrected PCO2 data is always blue (not selectable). The color to display drift corrected PO2 data is always violet (not selectable).</i> Important Note: 'Channel color' is a global parameter, i.e. the channel colors defined in the dialog 'Channel-setting' will be used for all measurements. <i>Note: The color used to display PCO2, PO2, SpO2, and PR within V-CareNeT related dialog windows must be changed in the dialog 'V-CareNeT Settings' (see 12.2). V-CareNeT currently does not support the option to change the color of PI, HP under V-CareNeT Settings'.</i>
Range & Horizontal Grid:	Click on this button opens for the currently selected channel the dialog '<Channel>: Range & Horizontal grid' where it is possible to predefine for the selected channel the display range (y-axis) and horizontal grid settings that will be used by default when downloading/importing SDM Trend Data to V-STATS. See 11.9 for a description of the dialog '<Channel>: Range & Horizontal grid'. The default settings used in the dialog '<Channel>: Range & Horizontal grid' if opened from the dialog 'Channel-settings' are: <ul style="list-style-type: none"> - 'Range Mode' = 'Autoscale' - PCO2/PO2: Maximum = 3 for PCO2/PO2 (mmHg), Maximum = 0.4 for PCO2/PO2 (kPa); Minimum = -3 for PCO2 (mmHg), Minimum = 0.4 for PCO2/PO2 (kPa) - SpO2: Maximum = 0; Minimum = -3 - PR: Maximum = 3; Minimum = -3 - PI: Maximum = 0.5; Minimum = -0.5 - HP: Maximum = 5; Minimum = -5 - 'Horizontal Grid Mode' = 'Auto' - 'Number of Level Curves' = 5 Important Note: If opened from the dialog 'Channel-settings' changes made in the dialog '<Channel>: Range & Horizontal grid' will not affect the currently opened measurement or measurements already stored in the 'File Manager' of V-STATS. To change the display range (y-axis) and horizontal grid settings for an existing measurement, the measurement must be opened and then the dialog '<Channel>: Range & Horizontal grid' must be activated by using the sub-menu 'Measurement / Range & Horizontal Grid' (see 11.9) or by clicking with the mouse on the area indicating the current mode of the display range and horizontal grid or on the y-axis of the respective channel (see 4.2).

Click on the button 'Save channel set' to save the currently active channel settings into a 'channel setting file'.

Click on the button 'Open channel set' to load channel settings from a file.

Click on the button 'Default values' to reactivate the default values for the channel settings.

Click on the button 'OK' to close the dialog and to maintain/store changes.

Click on the button 'Cancel' to close the dialog and to reject changes.

Click on the button 'Help' opens the context-sensitive online help.

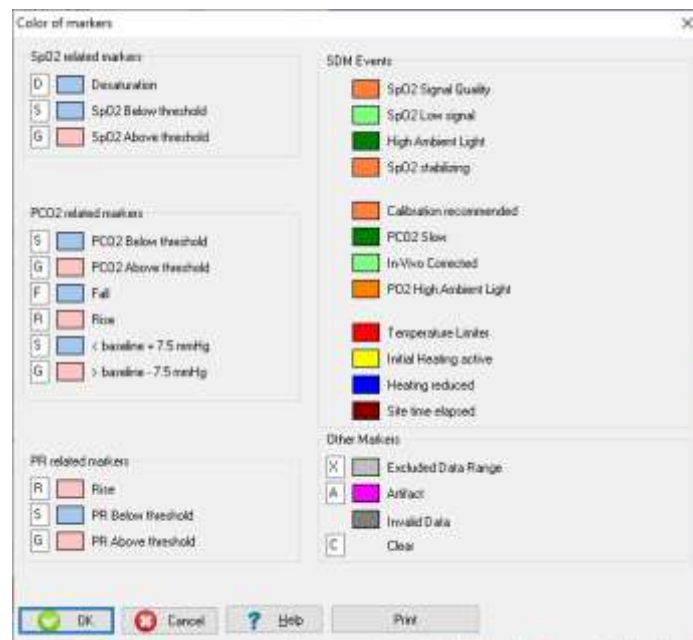
12.1.2 Dialog 'Color of markers'

Events - physiological events (PCO₂, SpO₂, PR), artifacts, SDM events, excluded data ranges, or ranges with invalid data - are highlighted in the measurement curves with markers (see 4.2). Click on the button 'Color of markers' in the dialog 'V-STATS Settings' activates the dialog 'Color of markers'. In this dialog the color of the markers that are displayed in the V-STATS Main Window can be modified.

Important Note: The colors selected for markers are global parameters, i.e. the colors for markers defined in the dialog 'Color of markers' will be used for all measurements.

In front of all SpO₂, PCO₂, and PR related markers a hotkey is defined which in the V-STATS Main Window allows fast reclassification of physiological events with the keyboard. By using the keyboard events, furthermore, can be deleted, classified as Artifact or Excluded Data Range by typing the respective hotkey (see 4.2.4, 4.2.6).

The dialog 'Color of Markers' can be printed such that its printout can be used as a caption to identify the color of the various markers and hotkeys.



Click on the button 'OK' to close the dialog and to maintain/store changes.

Click on the button 'Cancel' to close the dialog and to reject changes.

Click on the button 'Help' to open the context-sensitive online help.

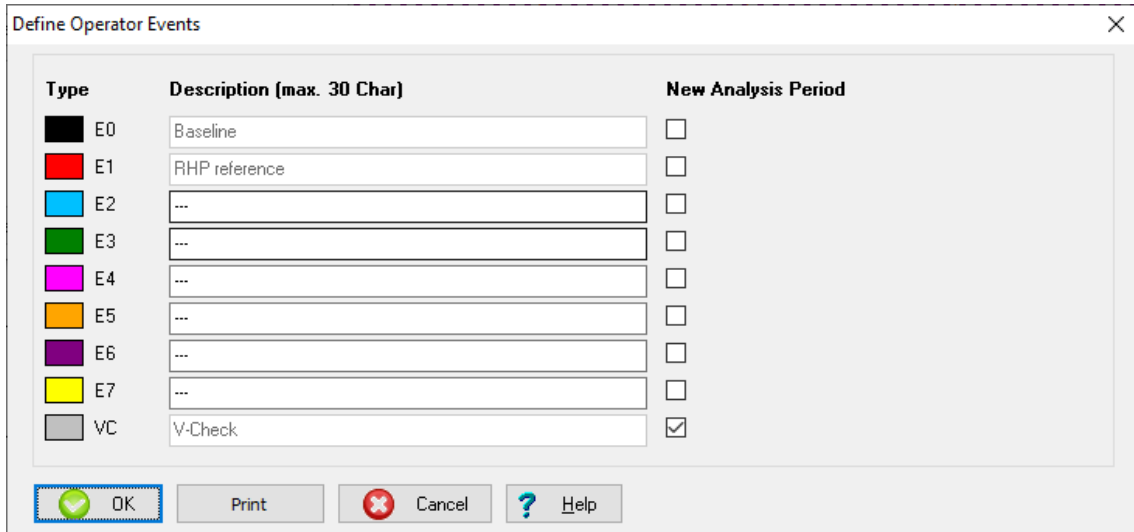
Click on the button 'Print' to print color settings for markers.

12.1.3 Dialog 'Define Operator Events'

Click on the button 'Define Operator Events' in the dialog 'V-STATS Settings' (see 12.1) activates the dialog 'Define Operator Events'. In this dialog it is possible to predefine for each of the different operator event types (EO - E7, VC) the standard settings that will be used by V-STATS when downloading/importing SDM Trend Data (see 6). The dialog 'Define Operator Events' can be printed such that its printout can be used as a caption for the operator event types available in the 'Quick Access Menu' of SDMs with software SMB-SW V07.01.x and newer.

Note: The dialog 'Set Operator Events' which permits to mark 'Operator Events' within V-CareNeT duplicates the

information of the dialog 'Define Operator Events' (see 14.8.3).



The following settings can be defined for each type of operator event:

<p>Color of Operator Event Triangle</p>	<p>Left-click on a colored square on the left of an event type label opens a dialog in which the color that will be used for the respective operator event triangle in the V-STATS Main Window (see 4.2) can be selected.</p> <p><i>Important Note:</i> The colors selected for the operator event triangles are global parameters, i.e. the colors for operator event triangles defined in the dialog 'Color of markers' will be used for all measurements.</p> <p><i>Note:</i> The labels of the event types (E0 – E7, VC) cannot be modified.</p>
<p>Description</p>	<p>Permits to predefine for each operator event type the event description (up to 30 characters) that will be used for each event of the respective type when downloading/importing SDM Trend Data or when changing the type of an existing operator event to the respective type in the dialog 'Edit/Add Operator Events' (see 11.2).</p> <p><i>Note:</i> The default description is 'baseline' for event type 'E0', 'RHP reference' for event type 'E1' and 'V-Check' for event type 'VC', respectively. See 11.1 for a short description of these events.</p> <p><i>Note:</i> The description for the other event types (E2 – E7) is undefined ('---') and can be modified.</p> <p><i>Note:</i> After downloading/importing SDM Trend Data or when changing the type of an existing operator event, the description of each individual operator event can be modified within the dialog 'Edit/Add Operator Event' (see 11.2).</p> <p><i>Note:</i> The description of an 'Operator Event' will be visualized a) in the tooltip that appears if the mouse is hovered over a colored operator event triangle (see 4.2.7), b) in the 'Analysis Interval Indicator' if the 'Analysis Interval' is set to an 'Analysis Period' that starts at the position of an 'Operator Event' (see 9.3) and c) in the 'List of Operator Events' (see 9.5.2, 9.5.6, 11.1).</p>
<p>Box 'New Analysis Period'</p>	<p>If this box is <u>checked</u> a new 'Analysis Period' will be initiated a) at each occurrence of an operator event of the respective type when downloading/importing SDM Trend Data or b) when changing the type of an existing operator event to the respective type in the dialog 'Edit/Add Operator Events' (see 11.2).</p> <p><i>Note:</i> In default settings the check box next to 'VC' is selected, i.e. a new 'Analysis Period' will be initiated at each occurrence of a V-Check Event and the 'Analysis Interval' conveniently can be set to the V-Check Measurement Phase (see 9.3, 9.3.1).</p>

Click on 'Print' will print a screenshot of the dialog 'Define Operator Events'.

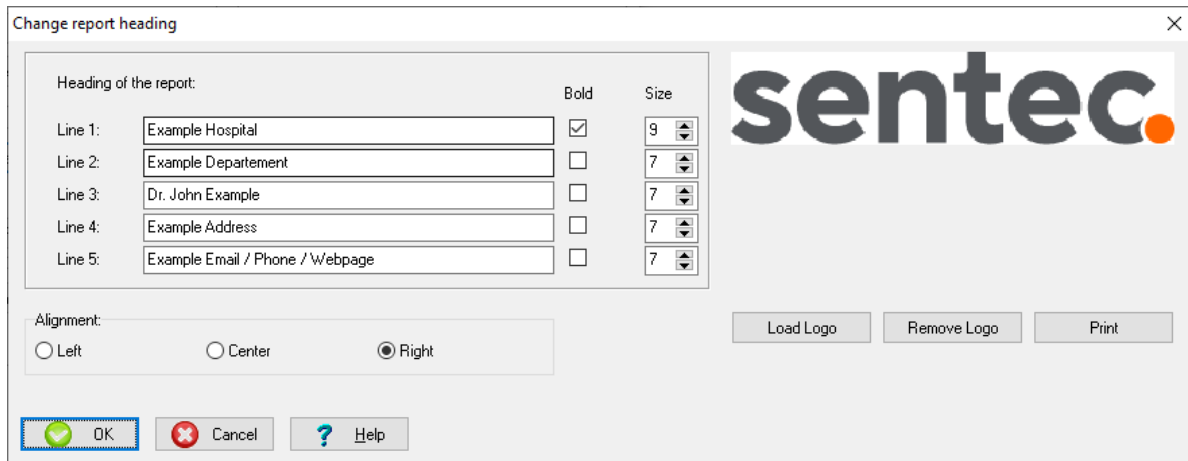
Click on the button 'OK' to close the dialog and to maintain/store changes.

Click on the button 'Cancel' to close the dialog and to reject changes.

Click on the button 'Help' to open the context-sensitive online help.

12.1.4 Dialog 'Report Heading'

Click on the button 'Report heading' in the dialog 'V-STATS Settings' (see 12.1) activates the dialog 'Change report heading'. In this dialog it is possible to define the heading of the report (typically your institution's address). Among other it is possible to individually define the font for each of the up to 5 heading lines, to select the alignment of the report heading and to add your institution's logo.



The following settings permit to customize the report heading:

- **Lines 1-5:** The heading of the report (typically the address of your institution) can be modified. The length of each line is limited to 60 symbols. The font of each of the up to 5 heading lines can be defined individually (plain or bold; font size 6 to 10; default settings for line 1: bold, font size=9; default settings for lines 2-5: plain; font size=7)
- **Alignment:** The alignment of the report heading can be selected (left, center, or right (default)). If a logo is loaded it will be placed in the upper left corner of the report for right and center alignments and in the upper right corner for left alignment.
- **Load Logo:** Click on this button opens a windows dialog which permits to select and load a graphic file containing a logo (e.g. your institution's logo). The following graphic files are supported: '.jpeg', '.jpg', '.ico', '.bmp', and '.gif'.

Note: The resulting printout size of the logo depends on the printer's resolution and on the size (pixels) of the loaded logo. To obtain the desired printout size of a logo with a specific printer it may be necessary to test different pixel-sizes of your logo.

Note: The properties of the graphic file containing the 'Sentec example logo' are 865x169 pixels and 96dpi.

- **Remove Logo:** Click on this button removes the logo that is currently loaded from the header.
- **Print:** Click on this button activates the printout of a test page with the report heading either a) on paper (select 'Printer') or b) as pdf-file (select 'PDF')

Click on the button "OK" to close the dialog and to maintain/store changes.

Click on the button "Cancel" to close the dialog and to reject changes.

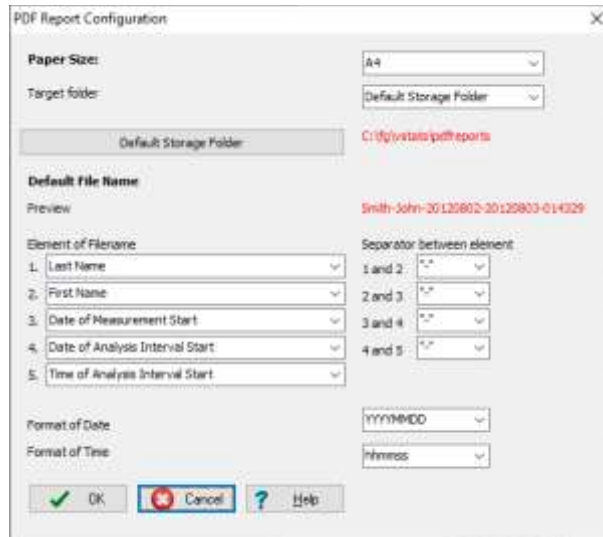
Click on the button 'Help' to open the context-sensitive online help.

12.1.5 Dialog 'PDF Report Configuration'

Click on the button 'PDF Report' in the dialog 'V-STATS Settings' (see 12.1) opens the dialog 'PDF Report Configuration'. In this dialog it is possible to configure the Paper Size, the Target folder, the Default Storage Folder and the Default File Name used/proposed to store reports as a PDF (see 7.2).

Note: The possibility to specify the Target Folder, Default Storage Folder and Default File Name that will be used/proposed when storing reports as a PDF is useful if you want to integrated/import PDF Reports into your 'Electronic Medical Records'. If PDF Reports are stored in a dedicated folder a (third party) application may automatically integrate PDF Reports into the 'Electronic Medical Records'. If the filenames contain patient and measurement specific information it will be possible for this application to assign each PDF Report to the respective patient and intervention/investigation.

Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.



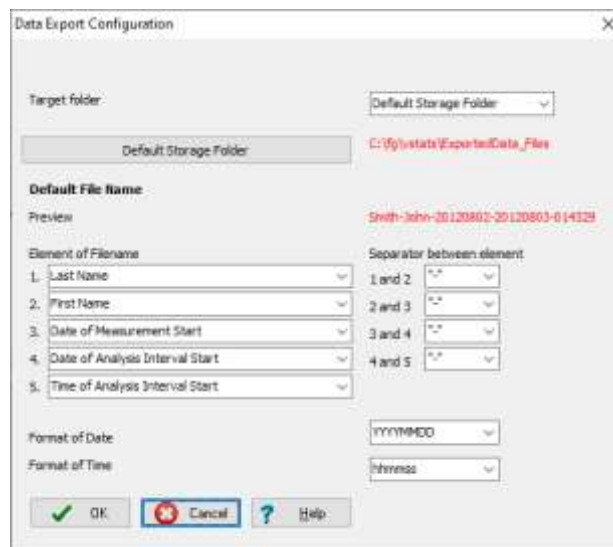
Parameter	Range (Factory Default in Bold) / Description
Paper Size	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> A4, Letter</p> <p>To select the paper size that will be used when storing reports as a PDF.</p>
Target folder	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Data Storage Folder, Last</p> <p>When storing PDF reports, the 'File Manager' opens to allow selection of the target folder for PDF report storage. This drop-down list offers two options to define the folder which will be proposed as target folder when storing PDF reports:</p> <ul style="list-style-type: none"> - 'Default Storage Folder': the file manager opens the default data storage folder selected for PDF report storage (see line below) - 'Last': the file manager selects the folder that was last used to store PDF reports. <p><i>Note:</i> To store the PDF in a different folder it is possible to access the file system from the 'File Manager' and to select an arbitrary folder.</p>
Default Storage Folder	<p><u>Type:</u> Button</p> <p>Clicking this button opens a windows dialog which permits to select the Default Storage Folder, i.e. the folder that will be proposed when storing reports as a PDF (see 7.2).</p> <p><i>Note:</i> On the right of this button the current Default Storage Folder is displayed in red.</p> <p><i>Note:</i> The folder Target Drive:\fg\vstats\pdfreports is the factory Default Storage Folder.</p> <p><i>Note:</i> Ensure to select a folder to which the user under which V-STATS has been installed has read/write access. The folder can be localized on a server of your institutions network.</p>
Default File Name	<p>In this area it is possible to define the Default File Name that will be proposed when storing reports as a PDF (see 7.2). The filename consists of <u>up to</u> 5 elements, which can be separated from each other by selectable separators.</p> <p>Element of filename</p> <p>For each of the 5 elements the following options are selectable in the respective drop-down list:</p> <ul style="list-style-type: none"> • '---' (no selection, i.e. element not included in file name) • Pat. Number • Last Name (factory default selection for element 1) • First Name (factory default selection for element 2) • Date of Birth • Date of Measurement Start (factory default selection for element 3) • Time of Measurement Start • Date of Analysis Interval Start (factory default selection for element 4) • Time of Analysis Interval Start (factory default selection for element 5) • Current Date • Current Time <p><i>Note:</i> The first element is always selectable. The following elements are only selectable, if a selection is</p>

Parameter	Range (Factory Default in Bold) / Description
	<p><i>made for the previous element.</i></p> <p><i>Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.</i></p> <p>Separator between element</p> <p>To separate the up to 5 filename elements (see above) from each other up to 4 separators are required. For each of them the following options are individually selectable in a drop-down list: ‘-’ ‘_’ ‘;’ ‘.’ ‘ ’ (space) ‘’ (none, i.e. the two respective filename elements are not separated)</p> <p><i>Note: ‘-’ is the factory default separator for all 4 options.</i></p> <p>Format of Date</p> <p>For filename elements that contain dates one of the following date formats can be selected: YYYYMMDD YYYY.MM.DD YYYY-MM-DD MMDDYYYY MM.DD.YYYY MM-DD-YYYY DDMMYYYY DD.MM.YYYY DD-MM-YYYY</p> <p><i>Note: ‘YYYYMMDD’ is the factory default date format used in PDF file names.</i></p> <p>Format of Time</p> <p>For filename elements that contain times one of the following time formats can be selected: hhmms hh.mm.ss</p> <p><i>Note: ‘hhmms’ is the factory default time format used in PDF file names.</i></p> <p>Preview of the ‚Default File Name’</p> <p>A preview of the resulting ‘Default Filename’ is shown in red.</p> <p><i>Note: For the preview the following data are used: Pat. Number=2132921 Last Name=Smith First Name=John Date of Birth=19481010 (i.e. October 10, 1948) Date of Measurement Start= 20120802 (i.e. August 2, 2012) Time of Measurement Start=210320 (i.e. 3 minutes and 20 seconds past 9pm) Date of Analysis Interval Start=20120803 (i.e. August, 3, 2012) Time of Analysis Interval Start=014329 (i.e. 43 minutes and 29 seconds past 1am).</i></p>

12.1.6 Dialog ‘Data Export Configuration’

Click on the button ‘Data Export’ in the dialog ‘V-STATS Settings’ (see 12.1) opens the dialog ‘Data Export Configuration’. In this dialog it is possible to configure the Default Storage Folder and the Default File Name used/ proposed to export data as ‘*.vex-files’ (see 7.5).

***Note:** The possibility to specify the Default Storage Folder and Default File Name that will be used/proposed when exporting data as ‘*.vex-files’ is useful if you want to integrated/import ‘*.vex-files’ into (third party) applications. If ‘*.vex-files’ are stored in a dedicated folder an application may automatically integrate ‘*.vex-files’ and if the filenames contain patient and measurement specific information it will be possible for this application to assign each ‘*.vex-file’ to the respective patient and intervention/investigation.*

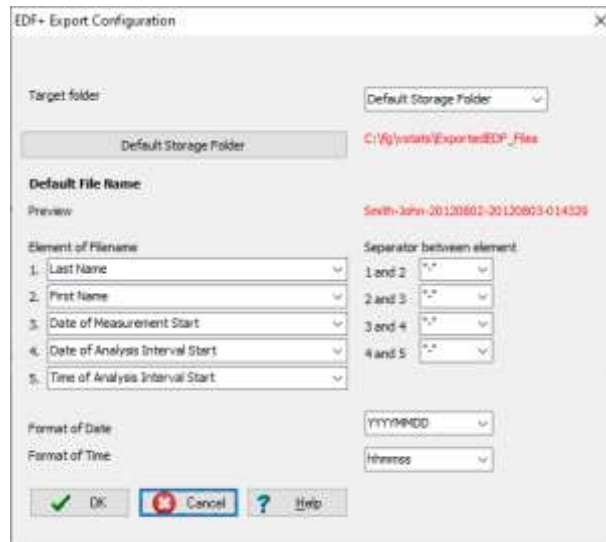


Parameter	Range (Factory Default in Bold) / Description
Target folder	<p>Type: Parameter</p> <p>Range: Data Storage Folder, Last</p> <p>When storing '*.vex-files'</p> <p>, the 'File Manager' opens to allow selection of the target folder for file storage. This drop-down list offers two options to define the folder which will be proposed as target folder when storing '*.vex-files':</p> <ul style="list-style-type: none"> - 'Default Storage Folder': the file manager opens the default data storage folder selected for '*.vex-files' storage (see line below) - 'Last': the file manager selects the folder that was last used to store '*.vex-files'. <p><i>Note:</i> To store the '*.vex-files' in a different folder it is possible to access the file system from the 'File Manager' and to select an arbitrary folder.</p>
Default Storage Folder	<p>Type: Button</p> <p>Clicking this button opens a windows dialog which permits to select the Default Storage Folder, i.e. the folder that will be proposed when exporting data as '*.vex-files' (see 7.5).</p> <p><i>Note:</i> On the right of this button the current Default Storage Folder is displayed in red.</p> <p><i>Note:</i> The folder Target Drive:\fg\vstats\ExportedData_Files is the factory Default Storage Folder.</p> <p><i>Note:</i> Ensure to select a folder to which the user under which V-STATS has been installed has read/write access. The folder can be localized on a server of your institutions network.</p>
Default File Name	<p>In this area it is possible to define the Default File Name that will be proposed when exporting data as '*.vex-files' (see 7.5). The filename consists of <u>up to</u> 5 elements, which can be separated from each other by selectable separators.</p> <p>Element of filename</p> <p>For each of the 5 elements the following options are selectable in the respective drop-down list:</p> <ul style="list-style-type: none"> • '---' (no selection, i.e. element not included in file name) • Pat. Number • Last Name (factory default selection for element 1) • First Name (factory default selection for element 2) • Date of Birth • Date of Measurement Start (factory default selection for element 3) • Time of Measurement Start • Date of Analysis Interval Start (factory default selection for element 4) • Time of Analysis Interval Start (factory default selection for element 5) • Current Date • Current Time <p><i>Note:</i> The first element is always selectable. The following elements are only selectable, if a selection is made for the previous element.</p> <p><i>Note:</i> Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.</p> <p>Separator between element</p> <p>To separate the up to 5 filename elements (see above) from each other up to 4 separators are required. For each of them the following options are individually selectable in a drop-down list: '-' '_' ';' ':' ' ' (space) "" (none, i.e. the two respective filename elements are not separated)</p> <p><i>Note:</i> '-' is the factory default separator for all 4 options.</p> <p>Format of Date</p> <p>For filename elements that contain dates one of the following date formats can be selected: YYYYMMDD YYYY.MM.DD YYYY-MM-DD MMDDYYYY MM.DD.YYYY MM-DD-YYYY DDMMYYYY DD.MM.YYYY DD-MM-YYYY</p> <p><i>Note:</i> 'YYYYMMDD' is the factory default date format used in file names.</p> <p>Format of Time</p> <p>For filename elements that contain times one of the following time formats can be selected: hhmmss hh.mm.ss</p> <p><i>Note:</i> 'hhmmss' is the factory default time format used in file names.</p>

12.1.7 Dialog 'EDF+ Export Configuration'

Click on the button 'EDF+ Export' in the dialog 'V-STATS Settings' (see 12.1) opens the dialog 'EDF+ Export Configuration'. In this dialog it is possible to configure the Default Storage Folder and the Default File Name that will be used/proposed when converting data into an 'EDF+-File' (see 7.6).

Note: The possibility to specify the Default Storage Folder and Default File Name that will be used/proposed when converting data into 'EDF+-Files' is useful if you want to integrated/import 'EDF+-Files' into (third party) applications. If 'EDF+-Files' are stored in a dedicated folder an application may automatically integrate 'EDF+-Files'. If the filenames contain patient and measurement specific information it will be possible for this application to assign each 'EDF+-File' to the respective patient and intervention/investigation.



Parameter	Range (Factory Default in Bold) / Description
Target Folder	<p>Type: Parameter</p> <p>Range: Data Storage Folder, Last</p> <p>When storing 'EDF+-Files', the 'File Manager' opens to allow selection of the target folder for file storage. This drop-down list offers two options to define the folder which will be proposed as target folder when storing 'EDF+-Files':</p> <ul style="list-style-type: none"> - 'Default Storage Folder': the file manager opens the default data storage folder selected 'EDF+-File' storage (see line below) - 'Last': the file manager selects the folder that was last used to store 'EDF+-File'. <p><i>Note: To store the 'EDF+-File' in a different folder it is possible to access the file system from the 'File Manager' and to select an arbitrary folder.</i></p>
Default Storage Folder	<p>Type: Button</p> <p>Click on this button opens a windows dialog which permits to select the Default Storage Folder, i.e. the folder that will be proposed when converting data (see 7.5).</p> <p><i>Note: On the right of this button the current Default Storage Folder is displayed in red.</i></p> <p><i>Note: The folder Target Drive: \fg\vstats\ExportedEDF_files is the factory Default Storage Folder.</i></p> <p><i>Note: Ensure to select a folder to which the user under which V-STATS has been installed has read/write access. The folder can be localized on a server of your institutions network.</i></p>
Default File Name	<p>In this area it is possible to define the Default File Name that will be proposed when exporting data (see 7.5). The filename consists of up to 5 elements, which can be separated from each other by selectable separators.</p> <p>Element of filename</p> <p>For each of the 5 elements the following options are selectable in the respective drop-down list:</p> <ul style="list-style-type: none"> • '---' (no selection, i.e. element not included in file name) • Pat. Number • Last Name (factory default selection for element 1) • First Name (factory default selection for element 2) • Date of Birth • Date of Measurement Start (factory default selection for element 3)

Parameter	Range (Factory Default in Bold) / Description
	<ul style="list-style-type: none"> • Time of Measurement Start • Date of Analysis Interval Start <i>(factory default selection for element 4)</i> • Time of Analysis Interval Start <i>(factory default selection for element 5)</i> • Current Date • Current Time <p><i>Note: The first element is always selectable. The following elements are only selectable, if a selection is made for the previous element.</i></p> <p><i>Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.</i></p> <p>Separator between element</p> <p>To separate the up to 5 filename elements (see above) from each other up to 4 separators are required. For each of them the following options are individually selectable in a drop-down list: ‘-’ ‘_’ ‘;’ ‘.’ ‘ ’ (space) “ (none, i.e. the two respective filename elements are not separated)</p> <p><i>Note: ‘-’ is the factory default separator for all 4 options.</i></p> <p>Format of Date</p> <p>For filename elements that contain dates one of the following date formats can be selected: YYYYMMDD YYYY.MM.DD YYYY-MM-DD MMDDYYYY MM.DD.YYYY MM-DD-YYYY DDMMYYYY DD.MM.YYYY DD-MM-YYYY</p> <p><i>Note: ‘YYYYMMDD’ is the factory default date format used in file names.</i></p> <p>Format of Time</p> <p>For filename elements that contain times one of the following time formats can be selected: hhmmss hh.mm.ss</p> <p><i>Note: ‘hhmmss’ is the factory default time format used in file names.</i></p>

12.1.8 Dialog ‘Export V-STATS Key’ (only Installation for Advanced Data Protection)

Clicking the button ‘Export V-STATS Key’ opens a dialog for setting a password for the key in order to save it locally. You will also need this password for uploading the key in different V-STATS versions.

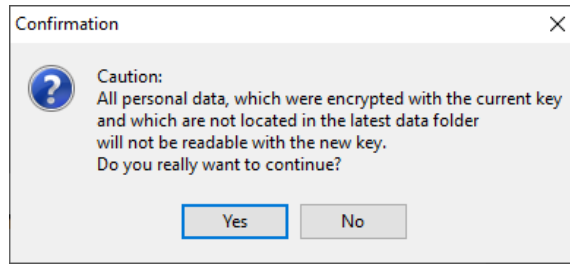
Note: If you forget or lose the password for the specific exported key, access to patient information that was encrypted with the key is lost.



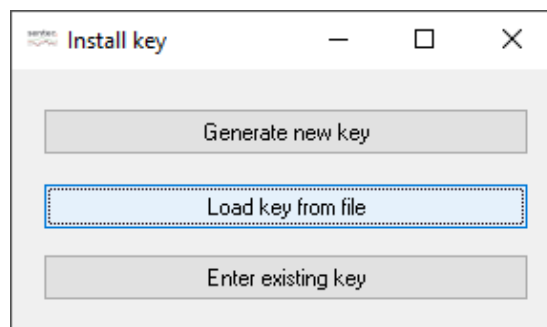
12.1.9 Dialog ‘Change V-STATS Key’ (only Installation for Advanced Data Protection)

Clicking the button 'Change V-STATS Key' opens a warning that has to be confirmed when changing the key.

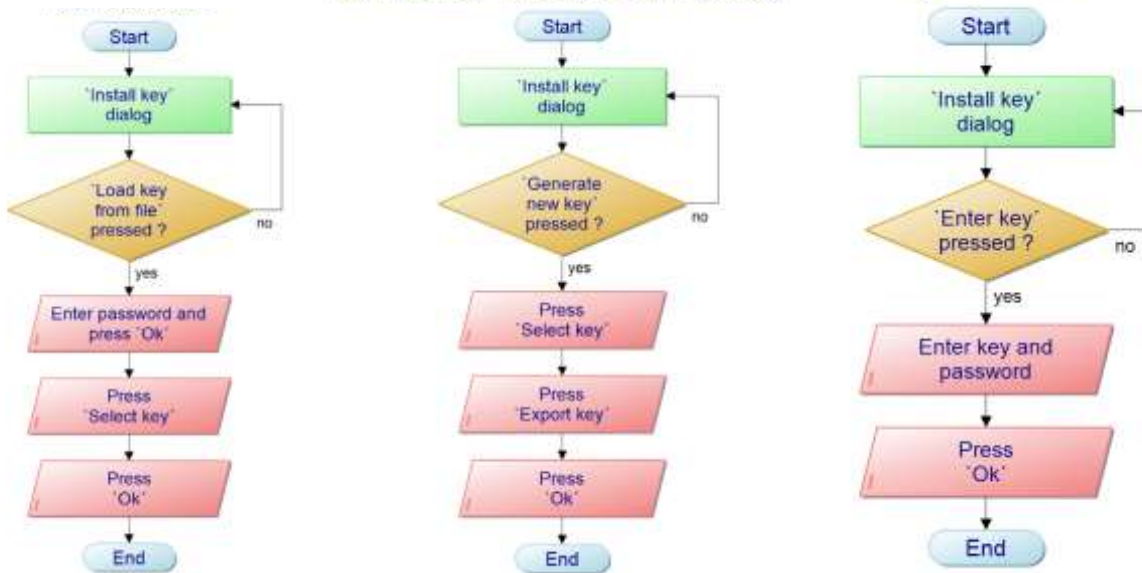
Note: Encrypted data in sub-directories remain encrypted with the previous key and will not be encrypted again with the new/changed key. Data in sub-directories will have to be encrypted again by using the new/changed key.



When the warning is confirmed, the dialog 'Install key' opens



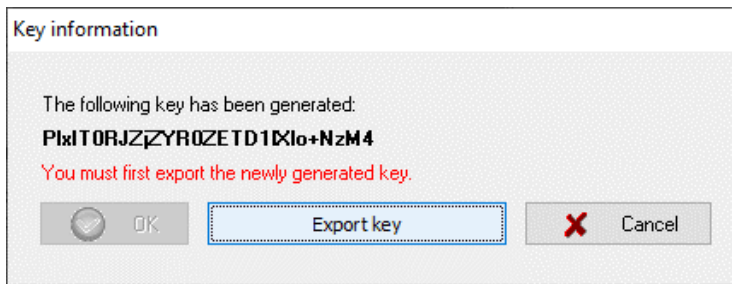
Key Installation / Button 'Change V-STATS key'



Parameter	Range (Factory Default in Bold) / Description
Enter Key	Type: Button Clicking this button opens a dialog that permits to enter an existing key manually.
Load Key from file	Type: Button Clicking this button opens a dialog that permits to select different key. <i>Note: A password is needed to upload a key.</i>

Parameter	Range (Factory Default in Bold) / Description
Generate new Key	Type: Button Clicking this button enables the button 'Select Key' (see below).
Select Key	Type: Button Clicking this button opens a dialog that displays the new key. The new key can only be confirmed by clicking 'OK' when the new key is exported. <i>Note: If you forget or lose the password for the specific exported key, access to patient information that have been encrypted with the key is lost.</i> Important Note: Ensure not to cancel the key installation, otherwise the key to decrypt patient information cannot be used anymore and patient information is lost.

If a new key is generated, it initially has to be exported (backup function). Without a key, the data that were encrypted by using this key cannot be decrypted.



When importing a key, users are asked for the corresponding password. If the key was exported during installation, the key password is the same as the login password. If the key is exported at a later stage (e.g. to transmit data to another hospital), the password may be freely selected.

12.2 Sub-menu 'Settings / V-CareNeT Settings'

The sub-menu 'Settings / V-CareNeT Settings' or a click on the icon 'V-CareNeT Settings' in the 'V-CareNeT Control Window' (see 14.5) activates a password-dialog and - after having successfully entered the password - the dialog 'V-CareNeT Settings'.

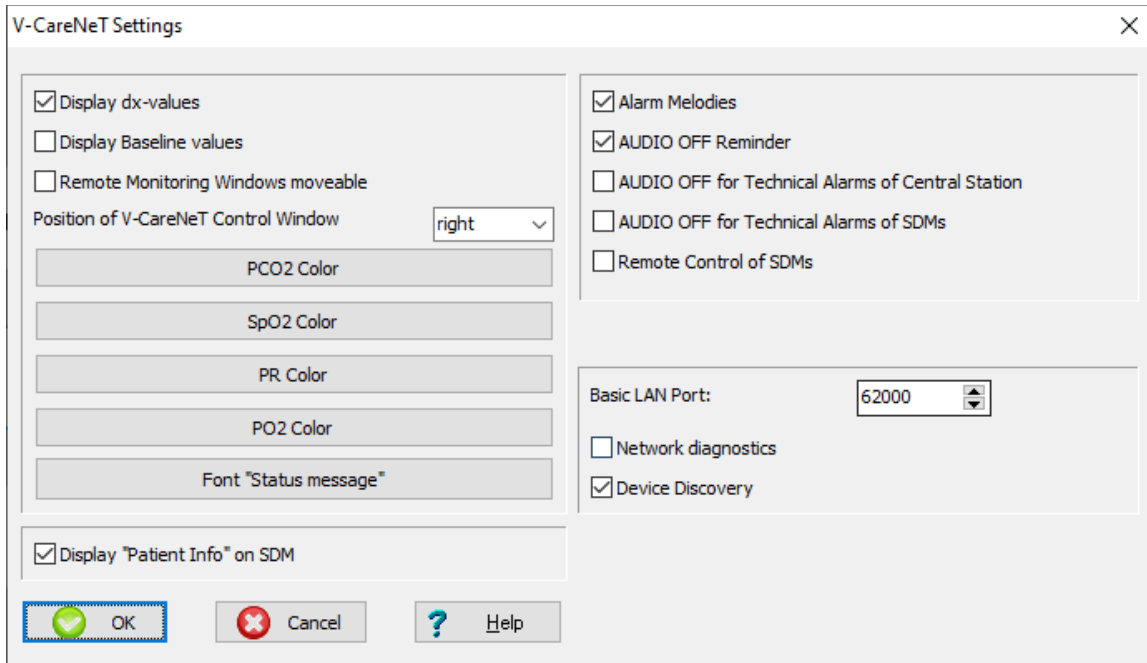
Note: As long the 'V-CareNeT Package' has not yet been fully activated (see 15.2) this sub-menu is only accessible if a 'V-CareNeT Trial' (see 15.3), an 'Extended V-CareNeT Trial' (see 15.4) or the 'V-CareNeT Demo Mode' (see 12.3) is active.

Note: The default password is the 'V-CareNeT Package Registration Code', which after activation/ upgrade of the V-CareNeT Package is displayed in the dialog 'Product-Info' (see 16.6). The password can be changed in the dialog 'Change Password'. In case you have forgotten your password, enter the Password Unlock Key 'RememberPassword' in the field 'Current Password' and select a new password.

Note: The password to open the dialog 'V-CareNeT Settings' is the same password that is required to open the dialog 'Edit SDM Device/Host Names' (see 14.5.1).

Note: During a 'V-CareNeT Trial' (see 15.3) and an 'Extended V-CareNeT Trial' (see 15.4), the password to open the dialog 'V-CareNeT Settings' is 'trial'.


Note: If the 'V-CareNeT Demo Mode' (see 12.3) is active, the password to open the dialog 'V-CareNeT Settings' is 'Demo'.



Parameter / Control	Range (Factory Default in Bold) / Description
Display dx-values	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Checked, Not checked</p> <p>If this box is checked dx-values will display for PCO2, PO2 and SpO2 in the remote monitoring window (see 14.8.1)</p> <p><i>Note: 'dx' is the difference between the current reading and the reading x minutes ago (default value for x is 10 minutes).</i></p>
Display baseline values	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Checked, Not checked</p> <p>If this box is checked baseline values (baseline, dB, and time elapsed since setting the baseline) will display for PCO2, PO2, SpO2 and RHP (if enabled) in the remote monitoring window (see 14.8.1). Please note that V-CareNeT currently only supports remote monitoring of PCO2, PO2, SpO2 and PR.</p> <p><i>Note: 'dB' is the difference between the current reading and the reading at the moment the baseline was set.</i></p>
Remote Monitoring Windows moveable	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Checked, Not checked</p> <p>If this box is checked the 'V-CareNeT Control Window' (see 14.5) and the 'Remote Monitoring Windows' (see 14.8.1) can be moved in the V-CareNeT Main Screen, i.e. their positions can be customized. Unchecking this box, will arrange all windows in their default positions in the V-CareNeT Main Screen (see 14.4).</p> <p><i>Note: As long the function 'Arrange Windows' is not activated/ executed (be it when starting up V-CareNeT (see 14.4.1) or by clicking on the 'Arrange Windows' Icon in the V-CareNeT Control Window if V-CareNeT is being executed), all windows - even those that are currently not displayed/ active - will maintain their customized position.</i></p>
Position of V-CareNeT Control Window	<p><u>Type:</u> Pull-down menu</p> <p><u>Range:</u> left, right</p> <p>Determines position of the 'V-CareNeT Control Window' (see 14.5) in the V-CareNeT Main Screen, i.e. left or right side (see 14.4).</p> <p><i>Note: Should changing the position of the V-CareNeT Control Window from left to right (or vice versa) reduce the maximal number of stations that are available at the V-CareNeT Central Station and should this cause the discharge of patients currently admitted to these stations (if any), then the alert dialog Discharge Patient(s)' (see 14.7.5) displays.</i></p>

Parameter / Control	Range (Factory Default in Bold) / Description
	<i>Note: Changing the position of the V-CareNeT Control Window from left to right (or vice versa) will arrange all windows in their default positions in the V-CareNeT Main Screen (see 14.4).</i>
PCO2 Color	<u>Type:</u> Button Click on this control opens a Windows dialog which permits to change the color that is used by V-CareNeT for PCO2 related parameters (default color = green). <i>Note: The PCO2 color used to display the measurement curve and channel label in the V-STATS Main Window must be changed in the dialog 'Channel settings' (see 12.1.1).</i>
PO2 Color	<u>Type:</u> Button Click on this control opens a Windows dialog which permits to change the color that is used by V-CareNeT for PO2 related parameters (default color = blue). <i>Note: The PO2 color used to display the measurement curve and channel label in the V-STATS Main Window must be changed in the dialog 'Channel settings' (see 12.1.1).</i>
SpO2 Color	<u>Type:</u> Button Click on this control opens a Windows dialog which permits to change the color that is used by V-CareNeT for SpO2 related parameters (default color = red). <i>Note: The SpO2 color used to display the measurement curve and channel label in the V-STATS Main Window must be changed in the dialog 'Channel settings' (see 12.1.1).</i>
PR Color	<u>Type:</u> Button Click on this control opens a Windows dialog which permits to change the color that is used by V-CareNeT for PR related parameters (default color = white). <i>Note: The PR color used to display the measurement curve and channel label in the V-STATS Main Window must be changed in the dialog 'Channel settings' (see 12.1.1).</i>
Font 'Status Message'	<u>Type:</u> Button Click on this control opens a Windows dialog which permits to change the font of the 'Status Message' displayed in the remote monitoring window (see 14.8.1). <i>Note: The default font is Arial Unicode MS / Standard / Size=10.</i> <i>Note: When changing the font ensure to select a font that is properly supported by your PC. After changing the font verify legibility of the status messages and ensure that all status messages fit into the available space.</i>
Display 'Patient Info' on SDM	<u>Type:</u> Parameter <u>Range:</u> Checked , Not checked If this box is checked the 'Patient Info' (the patient's name, a comment or the patient number) being displayed in a station's remote monitoring window (see 14.8.1) will be duplicated on the corresponding SDM a) on the 'Ready for use' and 'Calibration' screens (next to the patient type indicator) b) in the SDM's main menu c) in the SDM's status bar enclosed in "[" and "]" (only if no status message has to be displayed). <i>Note: The 'Patient Info' is defined by the information which is provided in the patient data field that is selected in the dialog '<X>: <Device/Host Name> - Patient Data' (see 14.7.1, 14.7.2). Before selecting one of the check boxes next to the patient data entry fields in this dialog and/or the check box 'Display Patient Info on SDM' verify that patient privacy will be warranted in accordance with local ordinances.</i> <i>Note: It is strongly recommended not to include special characters in the 'Patient Info' since they might not be displayed correctly on the SDM itself.</i>
Alarm Melodies	<u>Type:</u> Parameter <u>Range:</u> Checked , Not checked V-CareNeT uses 'Alarm Melodies' for its auditory high, medium, and low priority alarm signals if this box is <u>checked</u> . <i>Note: V-CareNeT's auditory alarm signals are priority encoded and meet the requirements of IEC 60601-1-8:2006 (Table 3 and Table 4). 'Alarm Melodies' are based on the recommendations provided in Annex F of IEC 60601-1-8:2006.</i>
AUDIO OFF Reminder	<u>Type:</u> Parameter

Parameter / Control	Range (Factory Default in Bold) / Description
	<p><u>Range:</u> Checked, Not checked</p> <p>The 'AUDIO OFF Reminder' is a short signal tone that sounds every 60 seconds if all auditory alarm signals of V-CareNeT have been switched OFF permanently by using the 'AUDIO Icon' in the V-CareNeT Control Window (see 14.5).</p> <p><i>Note:</i> If the 'Speaker Test' is required (see 14.9.3) V-CareNeT's auditory signals, including the 'AUDIO OFF Reminder', are inactive.</p> <p><i>Note:</i> The 'AUDIO OFF Reminder' is not active if auditory alarm signals of an individual station/SDM are permanently switched off (see 14.8.1).</p>
AUDIO OFF for Technical Alarms of Central Station	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Checked, Not checked</p> <p>At the V-CareNeT Central Station auditory alarm signals being related to technical alarm conditions occurring at the central station itself are permanently switched off / inhibited if this box is checked. In this case the message 'AUDIO OFF Tech. Alarms CS' displays in the V-CareNeT Control Window (see 14.5).</p> <p><i>Note:</i> The 'Remote Monitoring Interrupted' alarm condition (see 14.8.1 and 14.10) is currently the only alarm condition that is evaluated by the V-CareNeT Central Station.</p> <p><i>Note:</i> If the boxes 'AUDIO OFF for Technical Alarms of Central Station' and 'AUDIO OFF for Technical Alarms of SDMs' are simultaneously checked, the message 'AUDIO OFF Tech. Alarms' displays in the V-CareNeT Control Window.</p>
AUDIO OFF for Technical Alarms of SDMs	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Checked, Not checked</p> <p>At the V-CareNeT Central Station auditory alarm signals being related to technical alarm conditions occurring at SDMs with admitted patients are permanently switched off / inhibited if this box is checked. In this case the message 'AUDIO OFF Tech. Alarms SDMs' displays in the V-CareNeT Control Window (see 14.5).</p> <p><i>Note:</i> Auditory alarm signals being related to physiological alarm conditions (alarm limit violations of PCO₂, PO₂, SpO₂, or PR) occurring at SDMs with admitted patients continue to be audible at the V-CareNeT Central Station if this box is checked.</p> <p><i>Note:</i> The SDMs auditory alarm signals are not affected by this setting.</p> <p><i>Note:</i> If the boxes 'AUDIO OFF for Technical Alarms of Central Station' and 'AUDIO OFF for Technical Alarms of SDMs' are simultaneously checked, the message 'AUDIO OFF Tech. Alarms' displays in the V-CareNeT Control Window.</p>
Remote Control of SDMs	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Checked, Not checked</p> <p>If this box is checked it is possible to remotely control certain parameters/ settings of the included SDMs from the V-CareNeT Central Station (see 14.8.2.1).</p>
Basic LAN Port :	<p><u>Type:</u> Parameter</p> <p><u>Default:</u> 62'000</p> <p>The Basic LAN port defines the LAN port (or IP port) V-CareNeT uses when connecting to a first SDM being connected to the same network as the PC. When connecting to a second SDM V-CareNeT uses the next higher LAN port.</p> <p><i>Note:</i> If you want to simultaneously connect to multiple SDM's make sure to select the 'Basic LAN port' such that at least as many LAN ports are available / free as the number of devices you want to connect to V-CareNeT.</p> <p><i>Note:</i> V-CareNeT supports simultaneous communication via LAN for up to 40 SDM's.</p>
Network Diagnostics	<p><u>Type:</u> Parameter</p> <p><u>Range:</u> Checked, Not checked</p> <p>If this box is checked a tool tip providing quantitative information on the connection quality between the V-CareNeT Central Station and the respective SDM displays if the mouse is placed over a 'Connection Status Indicator' in the V-CareNeT Control Window (see 14.5). The tool tip indicates for the respective connection the current CRC failure rate and the current Lan Rejection Rate (LRR). It displays 'SDM not reachable' if communication with the respective SDM is erroneous or cannot be established at all.</p> <p><i>Note:</i> To secure communication between the V-CareNeT Central Station and each individual SDM CRC protected frames are used. To determine the connection/network</p>

Parameter / Control	Range (Factory Default in Bold) / Description
	<p><i>quality the V-CareNeT Central Station monitors for each connection the CRC failure rate, the answer/question ratio (Lan Rejection Rate (LRR)), and the plausibility of received data. In the V-CareNeT Control Window the connection quality is visualized in the respective 'Connection Status Indicator'.</i></p>
<p>Device Discovery</p>	<p>Type: Parameter Range: Checked, Not checked</p> <p>If this box is checked V-CareNeT uses DHCP broadcast for automatic device discovery in the network (BOOTP). All SDMs within the broadcast range will respond to the broadcast with their IP address and subsequent communication is then possible. The broadcast range is usually within the same subnet, but can also be across subnets depending on the router configuration.</p> <p>If this box is not checked (or if V-CareNeT is not able to discover a SDM if the box is checked) a SDM must be added to V-CareNeT by entering the respective SDM's IP Address/IP Port in the dialog 'Add SDM to V-CareNeT' (see 14.5.1).</p> <p><i>Note: This check box is dimmed grey (not accessible) if V-CareNeT is open, i.e. device discovery cannot be activated/deactivated while V-CareNeT is running.</i></p> <p><i>Note: If this check box is deselected the following warning-dialog appears:</i></p> <div data-bbox="466 815 1182 1274" style="border: 1px solid gray; padding: 10px; margin: 10px 0;"> <p>If Device Discovery is deactivated V-CareNeT requires a network environment with fixed IP address assignment. You either must set DHCP Mode to OFF and select an IP address / IP port for all SDMs you want to connect to V-CareNeT or you must have a DHCP Sever configuration that assigns fixed IP addresses based on MAC address.</p> <p>Contact your IT administrator in case of doubts.</p> <p>Important Note: By proceeding you confirm, that your selected network configuration is or will be based on SDMs with fixed IP address assignments.</p> <p>Do you want to proceed?</p> <p style="text-align: center;"> <input type="radio"/> Yes <input checked="" type="radio"/> No </p> </div> <p><i>Click on 'No' to abort. A click on 'Yes' will activated the following warning dialog:</i></p> <div data-bbox="466 1368 1259 1536" style="border: 1px solid gray; padding: 10px; margin: 10px 0;"> <p> If you proceed all SDMs will be removed from the V-CareNeT Control Window!</p> <p style="text-align: center;"> <input type="button" value="OK"/> <input type="button" value="Cancel"/> </p> </div> <p><i>Click on 'Cancel' to abort and to keep device discovery active. Click on OK to remove all SDMs from V-CareNeT and to deactivate device discovery.</i></p>

12.3 Sub-menu 'Settings / V-CareNeT Demo Mode'

For demonstration and training/education purposes V-STATS includes the 'V-CareNeT Demo Mode' which can be activated by using the sub-menu 'Settings / V-CareNeT Demo Mode'.

The V-CareNeT Demo Mode includes patient data of 40 Demo Patients. Note that in Demo Mode the maximal number of beds/ patients for which remote monitoring can be simulated/ demonstrated is **only limited by the computer's screen size/ resolution**. To simulate remote monitoring for 40 beds/ patients, for example, a screen size/ resolution of approx. 2560 x 1440 is required (approx. 1024 x 768 for 5 beds/ patients, 1152 x 864 for 10 beds/ patients, 1600 x 1024 for 20 beds/ patients, 1920 x 1200 for 30 beds/ patients). Smaller screen sizes/ resolutions will support fewer beds/patients.

Note: Registration of V-STATS (see 15.1) or full activation of the V-CareNeT Package (see 15.2) is not required to use the V-CareNeT Demo Mode.

The sub-menu 'Settings / V-CareNeT Demo Mode' first activates a password-dialog and – after having successfully entered the password – the dialog 'Last V-CareNeT Demo Session'.

Note: The password to activate the 'V-CareNeT Demo Mode' is 'Demo'.

Note: Once the 'V-CareNeT Demo Mode' is active the password to open the dialog 'V-CareNeT Settings' (see 12.2) is 'Demo'.

Note: The sub-menu 'Settings / V-CareNeT Demo Mode' is dimmed grey if 'V-CareNeT' is running or if a 'V-CareNeT Trial', an 'Extended V-CareNeT Trial', or the 'V-CareNeT Demo Mode' is active.

Note: For a description of the dialog 'Last V-CareNeT Demo Session' please refer to the description of the comparable dialog 'Last V-CareNeT Session' which displays when starting-up of V-CareNeT (see 14.4.1).

Edit / Reactivate last V-CareNeT Demo Session (to edit double-click on respective line)

Last Admitted Patient

Station	SDM Device/Host Name	Connect	Admit Patient	Last Name, First Name	Patient Number	Location
1	SenTec-SDM301001	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Mueller, Hugo	P22134	Room 2, Bed 2
2	SenTec-SDM301002	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Watkins, Sarah	P45671	Room 1, Bed 1
3	SenTec-SDM301003	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Lehmann, John	P41234	Room 2, Bed 1
4	SenTec-SDM301004	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Agostino, Raphaelae	P23185	Room 2, Bed 4
5	SenTec-SDM301005	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Aebi, Felicitas	P34290	Room 1, Bed 2
6	SenTec-SDM301006	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Smith, Angela	P89342	Room 1, Bed 3
7	SenTec-SDM301007	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Weber, Jim	P78130	Room 2, Bed 3
8	SenTec-SDM301008	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Weitzel, Isabelle	P98123	Room 1, Bed 4
9	SenTec-SDM301009	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Keller, Maria	P88991	Room 3, Bed 4
10	SenTec-SDM301010	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Schneuwly, Anna	P12786	Room 3, Bed 1
11	SenTec-SDM301011	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Bruegger, Robert	P77123	Room 4, Bed 3
12	SenTec-SDM301012	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Solbeck, Mark	P33671	Room 4, Bed 2
13	SenTec-SDM301013	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Menegon, Jaqueline	P87912	Room 3, Bed 3
14	SenTec-SDM301014	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Favre, Jose	P76540	Room 4, Bed 1
15	SenTec-SDM301015	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Shonyo, Paul	P67812	Room 4, Bed 4
16	SenTec-SDM301016	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Gardner, Julia	P77688	Room 3, Bed 2
17	SenTec-SDM301017	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Franklin, Catherine	P99112	Room 5, Bed 1
18	SenTec-SDM301018	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Clinton, Danielle	P76859	Room 5, Bed 2
19	SenTec-SDM301019	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Goldberg, Bill	P92831	Room 6, Bed 1
20	SenTec-SDM301020	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Weisskopf, Peter	P17782	Room 6, Bed 2
21	SenTec-SDM301021	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Weber, John	P12134	Room 12, Bed 2
22	SenTec-SDM301022	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Mueller, Belinda	P35671	Room 11, Bed 1
23	SenTec-SDM301023	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Meier, Raphaelae	P31234	Room 12, Bed 1
24	SenTec-SDM301024	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Grossrieder, Kurt	P13185	Room 12, Bed 4
25	SenTec-SDM301025	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Aebi, Angela	P24290	Room 11, Bed 2
26	SenTec-SDM301026	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Schuler, Alexandra	P79342	Room 11, Bed 3
27	SenTec-SDM301027	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Weber, Daniel	P68130	Room 12, Bed 3
28	SenTec-SDM301028	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Bruegger, Margrit	P78123	Room 11, Bed 4
29	SenTec-SDM301029	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Gonzales, Maria	P78991	Room 13, Bed 4
30	SenTec-SDM301030	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Tinguely, Caroline	P02786	Room 13, Bed 1
31	SenTec-SDM301031	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Eichhorn, Walter	P67123	Room 14, Bed 3
32	SenTec-SDM301032	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Schneuwly, Adrian	P23671	Room 14, Bed 2
33	SenTec-SDM301033	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Kamber, Andrea	P77912	Room 13, Bed 3
34	SenTec-SDM301034	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Hoegger, Patrick	P66540	Room 14, Bed 1
35	SenTec-SDM301035	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Corba, Pascal	P57812	Room 14, Bed 4
36	SenTec-SDM301036	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Marthaler, Katrin	P67688	Room 13, Bed 2
37	SenTec-SDM301037	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Rudaz, Astrid	P89112	Room 15, Bed 1
38	SenTec-SDM301038	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Zosso, Barbara	P66859	Room 15, Bed 2
39	SenTec-SDM301039	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Aeby, Anton	P82831	Room 16, Bed 1
40	SenTec-SDM301040	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Diedrich, Leon	P07782	Room 16, Bed 2

Arrange Windows

Click on the button 'OK' to reactivate the last 'V-CareNeT Demo Session' according to the settings in the dialog 'Last

V-CareNeT Demo Session

During V-CareNeT Demo Mode the label DEMO MODE displays - as shown in the figure below - a) in the V-CareNeT Control Window (see 14.5), b) in each remote monitoring window as status message (see 14.8.1), and c) in the center of those station cells for which remote monitoring is not active (see 14.4).



In default configuration the 'V-CareNeT Control Window' in Demo Mode lists 40 'SDM Device/Host Names' (Sentec-SDM301001, Sentec-SDM301002,..., Sentec-SDM301040). A simulated connection with each of these virtual SDMs can be established by selecting the respective 'Connect' check box. To each station for which an 'Admit Patient' check box is available, it is possible to admit a patient once the 'simulated' connection is established (see 14.7.1).

Note: In Demo Mode the control icon 'Edit SDM Device/Host Name' is disabled. Instead, the list of 'SDM Device/Host Names' that is used in Demo Mode can be edited in the file 'Target drive:\fg\stats\DemoSDM.txt'.

Note: Trend Data Download from the virtual monitors is not supported during Demo Mode. The respective 'OK'-buttons therefore remain dimmed during Demo Mode.

Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.

Once a patient is admitted to a virtual SDM, the Demo Mode displays in the respective remote monitoring window a sequence of simulated PCO2, SpO2, and PR data which is repeated every 30 minutes. The sequence illustrates the typical behavior of the readings during apnea, hyperventilation, and hypoventilation episodes. If enabled calculated dx-values are displayed, whereas baseline values are not supported in V-CareNeT Demo Mode (see 12.2, 14.8.1). All other parameters available in the remote monitoring and the additional data windows are either kept at constant values or display no value at all during demo mode. In normal operation mode alarm conditions are evaluated by the SDM and duplicated in V-CareNeT. Consequently, no alarms will be triggered if V-CareNeT is used in Demo Mode.

Note: During V-CareNeT Demo Mode all remote monitoring windows (see 14.8.1) display a constant value of 4.5 hours in the 'Remaining Monitoring Time' icon and a constant value of 42°C in the 'Sensor Temperature' icon with Site Protection in OFF mode. A click on the 'E'-button opens the dialog 'Set Operator Events' (see 14.8.3), however, during V-CareNeT Demo Mode it is neither possible to set a baseline nor to mark operator events.

Note: During V-CareNeT Demo Mode the dialog 'Additional Data' (see 14.8.2) of all stations displays a constant value of 2.0 for the Pulsation Index (PI) and a constant value of 5 mW for the 'Relative Heating Power' (RHP) displays. The 'Patient Type' icon indicates 'Adult' and the 'AC Power / Battery Indicator' icon shows a remaining capacity of 50% with the SDM being powered by the internal battery for all stations. The indicated date/time corresponds to the date/time of the PC.

Note: Even if the parameter 'Remote Control of SDMs' is enabled in the dialog 'V-CareNeT Settings' (see 12.2) the dialog 'Remote Control' (see 14.8.2.1) cannot be opened during V-CareNeT Demo Mode.

To terminate the V-CareNeT Demo Mode simply close V-CareNeT or V-STATS.

13. SDM Configuration - Profiles & Parameters

13.1 Introduction

After manufacturing the factory configuration of the Sentec Digital Monitor (SDM) is active, i.e. all parameters of the SDM are pre-set to factory defaults.

In the menu of the SDM the **operator** can configure all **menu-parameters** on an individual basis, whereby operator-access to certain menu-parameters may be disabled or restricted by the Responsible Organization. If a SDM is used in 'Institutional Mode' the operator, furthermore, can in the menu 'Profiles' a) restore the 'Standard Profile' as well as b) select / activate one of the other 'SDM Profiles' stored in the SDM as 'Standard Profile'. Please refer to the Technical Manual for the SDM (HB-005752) for additional details.

Note: A 'SDM Profile' is a file which contains a specific setting for all those SDM parameters that are displayed in black font in the dialog 'Profiles / device Settings - <SN>' (see 13.2, 13.2.4).

The **Responsible Organization** by using V-STATS within a password protected area (see 13.2) can

- configure all **menu-parameters** as well as all **safety relevant parameters** of a SDM on an individual basis.

Note: Safety relevant parameters cannot be changed in the menu of the SDM. Several of these parameters permit to disable or restrict operator-access to certain menu-parameters. Examples include the restriction of the 'Maximal selectable Sensor Temperature', restriction of the 'Maximal selectable Site Time' or enabling/disabling the possibility that the operator can switch-off the 'AUDIO OFF Reminder' in the menu of the SDM.

- select the 'Profile Mode' of a SDM (see 13.2, 13.2.1). In 'Basic Mode' the SDM at power-up maintains the parameter settings from previous use and the SDM menu 'Profile' is not accessible. In case of a SDM being operated in 'Institutional Mode' the Responsible Organization can store up to 4 SDM Profiles in the connected SDM and select one of these profiles as 'Standard Profile' (see 13.2.1, 13.2.2). If modified the operator can at any time restore the 'Standard Profile' in the menu of the SDM. Furthermore, if at power-up of the SDM the LAST settings are different from the settings of the 'Standard Profile' the menu 'Profiles' activates and offers the option to restore the 'Standard Profile', to select another 'Profile', or to keep the modified profile. On the SDM the display name of the 'Current SDM Profile' is displayed on the 'Calibration' screen, the 'Ready for use' screen, in the main menu, and in the sub-menu 'Profiles'. An asterisk displays behind the display name of the 'Current SDM Profile' if at least one of the menu-parameters or one of the safety relevant parameters has been modified.

Note: For the connected SDM the Responsible Organization at any time can restore a) the 'Default SDM Profile' in the dialog 'Profiles / device Settings - <SN>' (see 13.2) or b) the factory configuration in the dialog 'Special Functions' by executing the function 'SDM Factory Reset' (see 8.1).

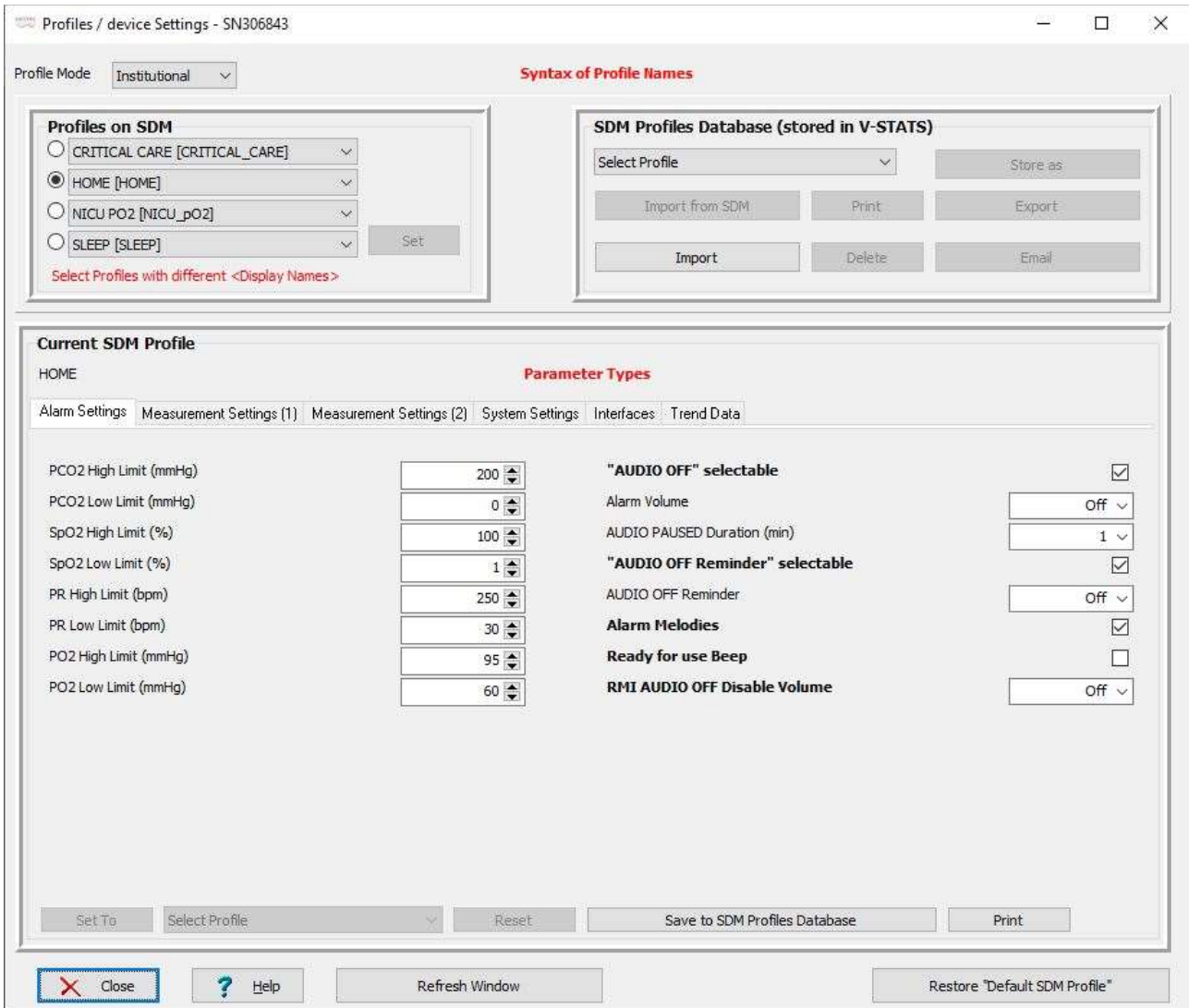
V-STATS stores 'SDM Profiles' in the so-called 'SDM Profiles Database' and provides the functions required to customize and manage 'SDM Profiles' within the password-protected dialog 'Profiles / device Settings - <SN>' (see 13.2, 13.2.3) or – if no serial connection to a SDM is available – within the dialog 'SDM Profiles Database (stored in V-STATS)' (see 7.10). It is possible a) to import 'SDM Profiles' to the database (either from the SDM or from the PC), b) to export 'SDM Profiles' from the database to the PC (e.g. to exchange them with other users) as well as c) to rename, print (on paper or as pdf-file) or delete 'SDM Profiles' currently available in the 'SDM Profiles Database'.

Note: Upon installation of or upgrade to V-STATS 5.01.1 the following write-protected SDM Profiles preconfigured by Sentec and tailored to optimally fit the specific needs of varying clinical settings are stored in the 'SDM Profiles Database': CRITICAL CARE [CRITICAL_CARE], GEN. CARE FLOOR [GCF], HOME [HOME], NICU PO2 [NICU_pO2], NICU [NICU], OPERATING ROOM [OR], PACU [PACU], SLEEP [SLEEP], SMB621 Style [SMB621_Style], V-CHECK [V_CHECK].

13.2 Dialog 'Profiles / device Settings - <SN>'

Click on the button 'Profiles / device Settings' in the dialog 'Communication with device (via Serial Interface)' (see 8.1) opens a password-dialog and – after having successfully entered the password – the dialog 'Profiles / device Settings - <SN>', where <SN> is the serial number of the connected SDM or the admin password if Installation for Advanced Data Protection is used.

Note: The dialog 'Profiles / device Settings - <SN>' is not accessible if patient monitoring is ongoing with the connected SDM. If open the dialog 'Profiles / device Settings - <SN>' closes when patient monitoring is initiated with the connected SDM. It will also close if serial communication with the connected SDM interrupts.



The dialog 'Profiles / device Settings - <SN>' is divided in the following main areas:

- **Profile Mode:** This drop-down list at the top left of the dialog 'Profiles / device Settings - <SN>' indicates the current 'Profile Mode' ('Basic' or 'Institutional') of the connected SDM. By using the drop-down list the 'Profile Mode' of the connected SDM can be changed (see 13.2.1).
- **Syntax of Profile Names:** The name of a SDM Profile consists of its display name and its file name. The file name is the name under which the profile is stored on the PC. The file extension of SDM Profile files is '.spf'. The display name is the part of the profile name that will be displayed on the SDM (on the 'Calibration' screen, on the 'Ready for use' screen, in the main menu, and in the sub-menu 'Profiles'). Its length is restricted to 16 characters.

If the mouse is hovered over the red bold label '**Syntax of Profile Names**' in the top center of the dialog 'Profiles / device Settings - <SN>' the syntax that is used for profile names to univocally identify 'SDM Profiles' within V-STATS appears in a tool-tip. The syntax that is used for profile names is:

<Display Name> [<File Name>]: This notation is used for SDM Profiles that are available in the SDM Profiles Database. Consequently, this notation is also used for SDM Profiles being stored on the SDM with a matching profile in the SDM Profiles Database.

<Display Name> (standard): This notation is used for profiles that are stored in one of the SDM's four profile slots with no matching profile in the SDM Profiles Database.

<Display Name> (current): This notation is used if the Current SDM Profile is different from the active 'Standard Profile' and no matching profile is available in the SDM Profiles Database.

Note: In certain (older) profiles the <Display Name> may not be available. In this case the syntax of the profile names reduces to [<File Name>], (standard), or (current).

- **Profiles on SDM:** In 'Basic Mode' this area of the dialog 'Profiles / device Settings - <SN>' is dimmed grey (not

accessible). In 'Institutional Mode' the drop-down lists display the profile names of the SDM Profiles that are currently stored in the corresponding profile slots of the connected SDM. The selected Radio Button on the left of the drop-down lists indicates the 'Standard Profile'. See 13.2.2 for instructions how to store different SDM Profiles on the connected SDM and/or to activate a different 'Standard Profile'.

Note: If no profile is stored in a profile slot the corresponding pull-down list displays '---'.

- **SDM Profiles Database (stored in V-STATS):** This area of the dialog 'Profiles / device Settings - <SN>' offers the possibility to customize and manage 'SDM Profiles'. The drop-down list in this area permits to select a 'SDM Profile' available in the 'SDM Profiles Database' or in the connected SDM. Available functions include a) import of 'SDM Profiles' to the database (either from the SDM or from the PC), b) export of 'SDM Profiles' from the database to the PC as well as c) the possibility to rename, print (on paper or as pdf-file) or delete 'SDM Profiles'. See 13.2.3 for details.
- **Current SDM Profile:** This area of the dialog 'Profiles / device Settings - <SN>' displays for the connected SDM the current settings of all parameters (i.e. all menu-parameters and all safety relevant parameters being available only within V-STATS).

*Note: In 'Institutional Mode' the display name of the 'Current SDM Profile' displays underneath the 'Current SDM Profile' label. If at least one parameter of the 'Current SDM Profile' differs from the respective parameters of the 'Standard Profile' *(modified)* additionally displays in red font behind the display name and an asterisk displays behind each parameter that differs from its setting in the 'Standard Profile'.*

The parameters are grouped in multiple tabs that are arranged in the same order as the SDM's menu. If the mouse is hovered over a parameter a description of the respective parameter appears in a tool tip (also see 13.2.4). If the mouse is hovered over the red bold label '**Parameter Types**' the following description of the font-/color-coding that is used to characterize the different types of parameters appears in a tool-tip:

Black, Plain: Parameters being accessible in the SDM's menu and within V-STATS, part of profiles

Black, Bold: Parameters only being accessible within V-STATS, part of profiles

Blue, Plain: Parameters being accessible in the SDM's menu and within V-STATS, not part of profiles.

Blue, Bold: Parameters only being accessible within V-STATS, not part of profiles.

Red, Plain: Parameters only being accessible in the SDM's menu, not part of profiles.

Yellow, Plain: Non-changeable parameters, not part of profiles.

Dimmed gray: Parameters are currently not accessible.

In the dialog 'Profiles / device Settings - <SN>' the Responsible Organization can configure all parameters of the connected SDM on an individual basis by means of check boxes, drop-down lists, and text entry fields.

Note: Mouse click on a check box (if accessible) immediately modifies the current setting of the respective parameter on the connected SDM. Mouse click on other parameters highlights the respective drop-down list or text entry field yellow to indicate that editing-mode has been activated. To exit editing-mode and to write the new value of the respective parameter to the connected SDM click with the mouse on an arbitrary position of the dialog window but the respective parameter itself.

Note: Changes of individual parameters only affect the Current SDM Profile, i.e. SDM Profiles stored in the four profile slots of the SDM or in the SDM Profiles Database within V-STATS are not affected.

Rather than configuring parameters on an individual basis as described above it is

- in '**Basic Mode**' possible to select a 'SDM Profile' by using the drop-down list on the bottom left of the 'Current SDM Profile' area and then to set the 'Current SDM Profile' to the selected 'SDM Profile' by clicking on the button '**Set To**'. *Note: Elements of the following syntax can be available in this drop-down list: <Display Name> [<File Name>], [<File Name>]. For a description of the syntax used for profile names see above.*
- in '**Institutional Mode**' possible a) to reset the 'Current SDM Profile' (if modified) to the 'Standard Profile' by clicking on the button '**Reset**' or b) to set the 'Current SDM Profile' to a different SDM Profile by activating this profile as 'Standard Profile' in the 'Profiles on SDM' area of the dialog 'Profiles / device Settings - <SN>'.

Note: SDM Profiles that were created with/for SDM's with older software versions will not include parameters that were introduced by more recent software versions. If such an 'old' SDM Profile is used to configure a SDM with a more recent software version default setting will be used for those parameters that are not included in the 'old' SDM Profile.

Click on the button '**Save to SDM Profiles Database**' to save the 'Current SDM Profile' to the 'SDM Profile Database'. The dialog 'Store profile as' (see 13.2.3.1) will open. In this dialog it is possible to select a display and a filename for the profile. A click on 'OK' stores a copy of the 'Current SDM Profile' with the specified display and file name to the 'SDM Profiles Database'.

Click on the button 'Print' to print the 'Current SDM Profile', i.e. all parameters and their current settings, either a) on paper (select 'Printer') or b) as pdf-file (select 'PDF'). Refer to 13.2.3 for a description of the elements that are included in the print-out.

- **Restore 'Default SDM Profile':** A click on this button in the bottom right of the dialog 'Profiles / device Settings - <SN>' restores the 'Default SDM Profile' and clears the 'Trend Data' of the connected SDM.

Note: The function 'Restore Default SDM Profile' sets 'Profile Mode' to 'Basic' and restores factory default settings of all parameters that are part of profiles. This function does not affect the settings of parameters that are not part of profiles (parameters 'Language', 'Profile Mode', 'Demo Mode', and 'Patient ID' as well as all parameters related to the Serial Interface and the LAN Interface). Parameters that are part of profiles are displayed in the dialog 'Profiles / device Settings - <SN>' in black, whereas parameters that are not part of the profile are displayed in blue, red, or orange.

Note: Use the function 'Device Factory Reset' available in the dialog 'Special Functions' (see 8.1) to restore the factory configuration of the SDM, i.e. to restore factory defaults for all parameters (regardless whether or not they are part of profiles or not).

- **Refresh Window:** A click on this button in the bottom center of the dialog 'Profiles / device Settings - <SN>' reads all settings of the connected SDM and updates all elements (drop-down lists, radio buttons, check boxes, and text entry fields) of the dialog 'Profiles / device Settings - <SN>'.

Note: This function can be used to cancel modifications made in the area 'Profiles on SDM' (drop-down lists, radio buttons) that have not yet been saved to the SDM by clicking on the 'Set' button.

Note: A refresh of the dialog 'Profiles / device Settings - <SN>' is automatically made when a) opening the dialog 'Profiles / device Settings - <SN>', b) adding / deleting a SDM Profile to the SDM Profiles Database and – if in 'Institutional Mode' – c) a parameter of the 'Current SDM Profile' is modified or if the profile configuration on the connected SDM is modified.

Note: If V-STATS detects a corrupt profile in the 'SDM Profiles Database' when executing the 'Refresh Window' function the following warning dialog displays: 'The following profiles seem to be corrupt and will be deleted (list with profile names). Do you want to save these profiles in another folder before (Yes / No)? Click on 'Yes' to create a backup folder and to move the corrupt profile(s) into this folder, click on 'No' to delete the corrupt profile(s) without a backup copy.'

13.2.1 Selection of the 'Profile Mode'

The drop-down list 'Profile Mode' at the top left of the dialog 'Profiles / device Settings - <SN>' permits to select/change the 'Profile Mode' of the connected SDM. The available selections are 'Basic' (default setting) and 'Institutional'.

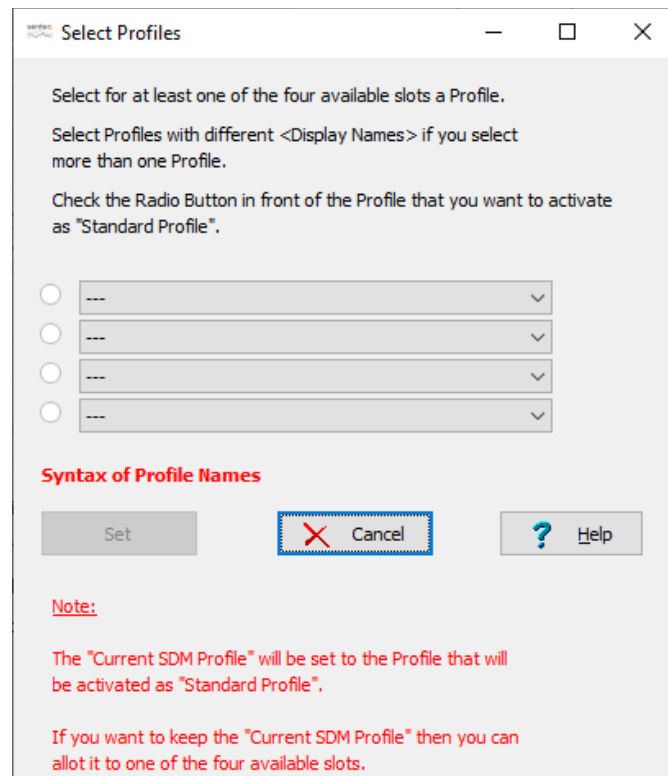
In 'Basic Mode' no 'SDM Profiles' are stored in the SDM, i.e. the 'Current SDM Profile' is the only available profile. At power-up the SDM maintains the parameter settings from previous use and the menu 'Profiles' is not accessible.

In 'Institutional Mode' the Responsible Organization must store at least one 'SDM Profile' in the connected SDM. It is possible to store up to 4 SDM Profiles in the connected SDM. One of these profiles must be selected as 'Standard Profile'. If modified the operator can at any time restore the 'Standard Profile' in the menu of the SDM. Furthermore, if at power-up of the SDM the LAST settings are different from the settings of the 'Standard Profile' the menu 'Profiles' activates and offers the option to restore the 'Standard Profile', to select another 'SDM Profile', or to keep the modified profile. On the SDM the display name of the 'Current SDM Profile' is displayed on the 'Calibration' screen, on the 'Ready for use' screen, in the main menu, and in the sub-menu 'Profiles'. An asterisk displays behind the display name of the 'Current SDM Profile' if at least one of the menu-parameters or one of the special parameters, which are only changeable within V-STATS, has been modified.

13.2.1.1 Activating 'Institutional Mode'

Left-click on the drop-down list 'Profile Mode' while it displays 'Basic' and selection of 'Institutional' activates the dialog 'Select Profiles' (see below). The four drop-down lists available in the center of the dialog 'Select Profiles' represent the four profile slots available in SDMs. In 'Basic Mode' no 'SDM Profiles' are stored in the SDM. At this stage all four drop-down lists, therefore, display '---'.

Note: The Radio Buttons on the left of the drop-down lists are not selected and dimmed grey at this stage. The button 'Set' is dimmed grey as well.



To store at least one SDM Profile in the connected SDM and to activate a Standard Profile proceed as follows:

- 1) Select the desired SDM Profile by using the respective drop-down list for each profile slot.

Note: You must select a SDM Profile for at least one of the four available slots. If you select more than one profile you must select profiles with different '<display names>'. Select '---' if you don't want to store a profile in the respective profile slot.

Note: If the mouse is hovered over the red bold label '**Syntax of Profile Names**' above the button 'Set' a description of the syntax that is used for profile names to univocally identify 'SDM Profiles' within V-STATS appears in a tooltip (see 13.2 for details).

Note: Elements of the following syntax can be available in the drop-down lists of the dialog 'Select Profiles': '<Display Name> [<File Name>], [<File Name>], (current), and '---'. Refer to 13.2 for a description of the syntax used for profile names.

Note: SDM Profiles that were created with/for SDM's with older software versions will not include parameters that were introduced by more recent software versions. If an 'old' SDM Profile is used to configure a SDM with a more recent software version default setting will be used for those parameters that are not included in the 'old' SDM Profile.

- 2) Check the Radio Button in front of the SDM Profile that you want to use as 'Standard Profile'

Note: The 'Current SDM Profile' will be set to the Profile that will be activated as 'Standard Profile'.

Note: The Radio Button on the left of a drop-down list is only selectable after selection of a 'SDM Profile' in the respective drop-down list. It is dimmed grey or will be cleared if '---' is selected in the respective drop-down list.

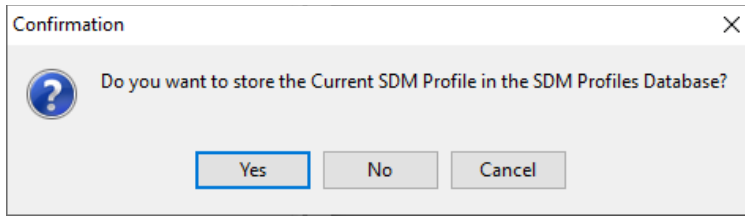
Note: Only one Radio Button is selectable at a time.

- 3) Click on the button 'Set' to activate your selection on the SDM, to set the 'Current SDM Profile' to the selected 'Standard Profile' and then to return to the dialog 'Profiles / device Settings - <SN>'

Note: The button 'Set' is dimmed grey if a) profiles with identical display names are selected in at least two profile slots, b) no Radio Button is selected, or c) no profile is selected at all.

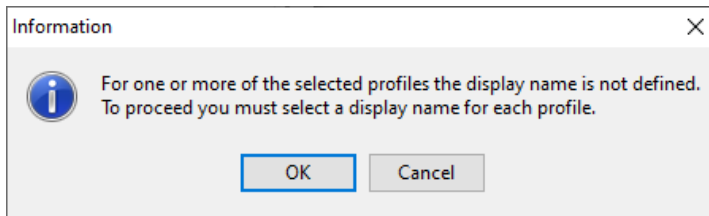
Note: Before storing your selection on the SDM, V-STATS checks various points and, if applicable, displays various control dialogs:

- A) If for the 'Current SDM Profile' no matching profile is available in the 'SDM Profiles Database' the following dialog is triggered:



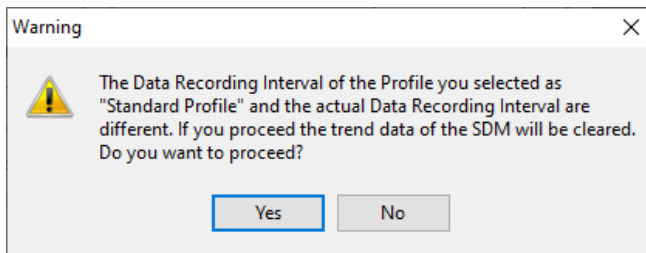
If 'Yes' is selected the dialog 'Store profile as' (see 13.2.3.1) opens permitting to select a display and file name and then to store the 'Current SDM Profile' in the SDM Profiles Database. If 'No' is selected the 'Current SDM Profile' will not be stored. Click on 'Cancel' to return to the dialog 'Select Profiles' without storing your profile selection on the SDM.

- B) If one or more 'SDM Profiles' were selected in the dialog 'Select Profiles' for which no display name is available, V-STATS will force you to define a display name for each profile by displaying the dialog:



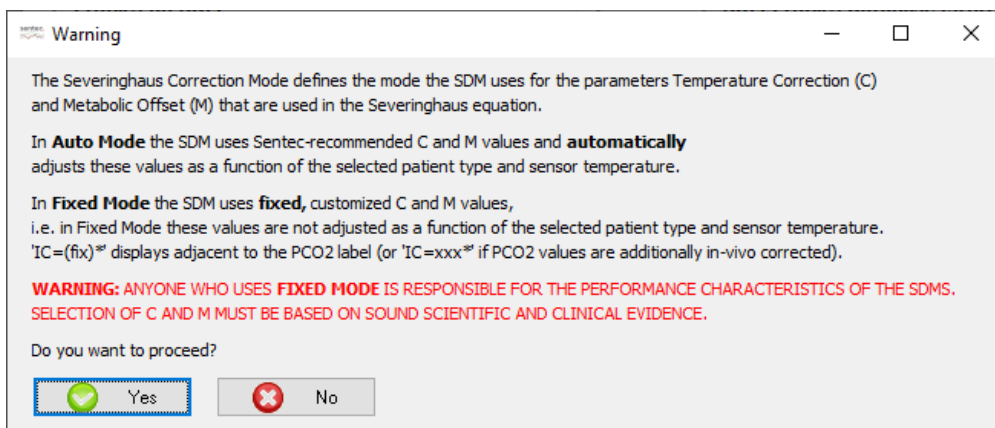
If 'OK' is selected the dialog 'Store profile as' (see 13.2.3.1) opens permitting to select a display and file name and then to store the respective SDM Profile in the SDM Profiles Database. Click on 'Cancel' to return to the dialog 'Select Profiles' without storing your profile selection on the SDM (Note: this step will be repeated as many times as SDM Profiles were selected in the dialog 'Select Profiles' for which no display name is available).

- C) If the Data Recording Interval (DRI) of the SDM Profile that you selected in the dialog 'Select Profiles' to become the 'Standard Profile' and the actual Data Recording Interval are different, V-STATS will display the following warning:



Click on 'Yes' to continue. Click on 'No' to return to the dialog 'Select Profiles' without storing your profile selection on the SDM.

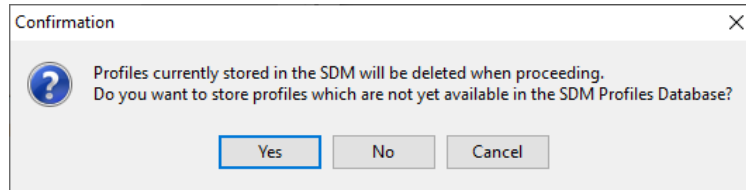
- D) If in at least one of the selected 'SDM Profiles' the parameter 'Severinghaus Correction Mode Selectable' is set to ON the following warning dialog displays:



Click on 'Yes' to continue. Click on 'No' to return to the dialog 'Select Profiles' without storing your profile selection on the SDM.

13.2.1.2 Activating 'Basic Mode'

Left-click on the drop-down list 'Profile Mode' while it displays 'Institutional' and selection of 'Basic' first causes V-STATS to check if SDM Profiles are currently available in the SDM with no matching profile in the 'SDM Profiles Database'. If this is the case, V-STATS triggers the following dialog:

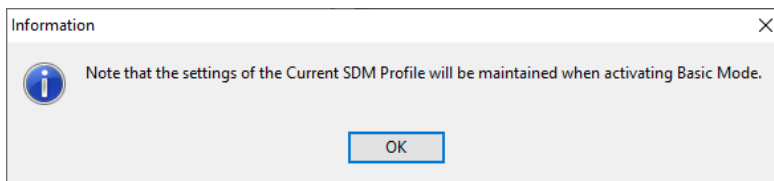


If 'Yes' is selected the dialog 'Store profile as' (see 13.2.3.1) opens permitting to select a display and file name and then to store the respective SDM Profile in the SDM Profiles Database before it is cleared in the SDM. If 'No' is selected the respective 'SDM Profile' will be cleared on the SDM without storing it in the 'SDM Profiles Database'. Click on 'Cancel' to abort the process on to remain in 'Institutional Mode'.

Note: This step will be repeated as many times as there are 'SDM Profiles' available in the SDM with no matching profile in the 'SDM Profiles Database'.

Note: SDM Profiles stored in the SDM's profile slots will be cleared when activating 'Basic Mode'.

Thereafter the following information dialog displays to remind the user that the settings of the 'Current SDM Profile' will be maintained when activating Basic Mode.



Click on 'OK' to acknowledge this information and to activate 'Basic Mode'.

Note: In 'Institutional Mode' the area 'Profiles on SDM' of the dialog 'Profiles / device Settings - <SN>' is dimmed grey (not accessible).

13.2.2 Profiles on the SDM

The four drop-down lists available in the area 'Profiles on SDM' of the dialog 'Profiles / device Settings - <SN>' represent the four profile slots available in the SDMs. In 'Basic Mode' this area is dimmed grey. In 'Institutional Mode' the drop-down lists display the profile names of the SDM Profiles stored in the connected SDM's corresponding profile slots. The Radio Button on the left of the drop-down list that corresponds to the profile slot with the 'Standard Profile' is selected.

Note: If no SDM Profile is stored in a profile slot the corresponding drop-down list displays '---'.

Note: The button 'Set' is dimmed grey after each refresh of the dialog 'Profiles / device Settings - <SN>'. It only becomes accessible after making a valid modification in the profile selection (see below).

To store different SDM Profiles on the connected SDM and/or to activate a different 'Standard Profile' proceed as follows:

- 1) Select the desired SDM Profile by using the respective drop-down list for each profile slot.

Note: You must select a SDM Profile for at least one of the four available slots. If you select more than one profile you must select profiles with different '<display names>'. Select '---' to clear the SDM Profile stored in the respective profile slot.

Note: Elements of the following syntax can be available in the drop-down lists of the area 'Profiles on SDM': <Display Name> [<File Name>], [<File Name>], <Display Name> (standard), (standard), <Display Name> (current), (current), and '---'. Refer to 13.2 for a description of the syntax used for profile names.

Note: SDM Profiles that were created with/for SDM's with older software versions will not include parameters that were introduced by more recent software versions. If such an 'old' SDM Profile is used to configure a SDM with a more recent software version default setting will be used for those parameters that are not included in the 'old' SDM Profile.

- 2) Check the Radio Button in front of the SDM Profile that you want to activate as 'Standard Profile'

Note: The 'Current SDM Profile' will be set to the Profile that will be activated as 'Standard Profile'.

Note: The Radio Button on the left of a drop-down list is only selectable after selection of a 'SDM Profile' in the respective drop-down list. It is not selectable (dimmed grey) or will be cleared if '--' is selected in the respective drop-down list.

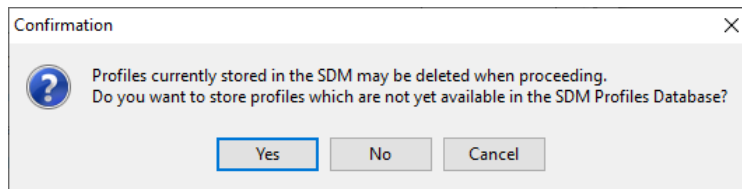
Note: Only one Radio Button is selectable at a time.

- 3) Click on the button 'Set' to activate your selection on the connected SDM and to set the 'Current SDM Profile' to the selected 'Standard Profile'.

Note: The button 'Set' is dimmed grey if a) profiles with identical display names are selected in at least two profile slots, b) no Radio Button is selected, or c) no profile is selected at all.

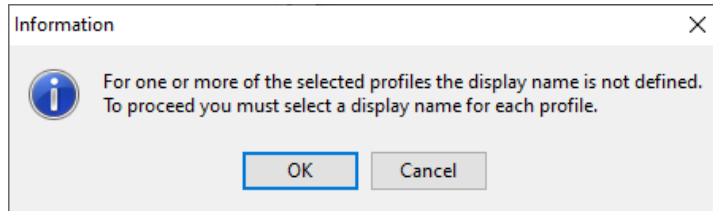
Note: Before storing your selection on the SDM, V-STATS checks various points and, if applicable, displays various control dialogs:

A) If SDM Profiles are currently available in the SDM with no matching profile in the 'SDM Profiles Database' the following dialog is triggered:



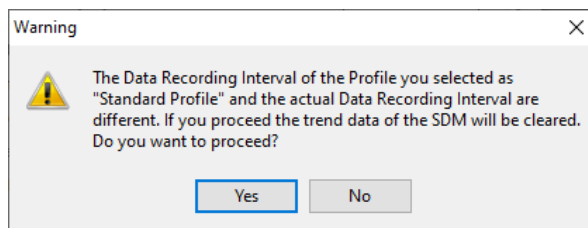
If 'Yes' is selected the dialog 'Store profile as' (see 13.2.3.1) opens permitting to select a display and file name and then to store the respective SDM Profile in the 'SDM Profiles Database' before it is cleared in the SDM. If 'No' is selected the respective 'SDM Profile' may be cleared on the SDM without storing it in the 'SDM Profiles Database'. Click on 'Cancel' to return to the dialog 'Profiles / device Settings - <SN>' without storing your profile selection on the SDM. (*Note:* This step will be repeated as many times as there are 'SDM Profiles' available in the SDM with no matching profile in the 'SDM Profiles Database').

B) If one or more 'SDM Profiles' were selected in the area 'Profiles on SDM' for which no display name is available, V-STATS will force you to define a display name for each profile by displaying the dialog:



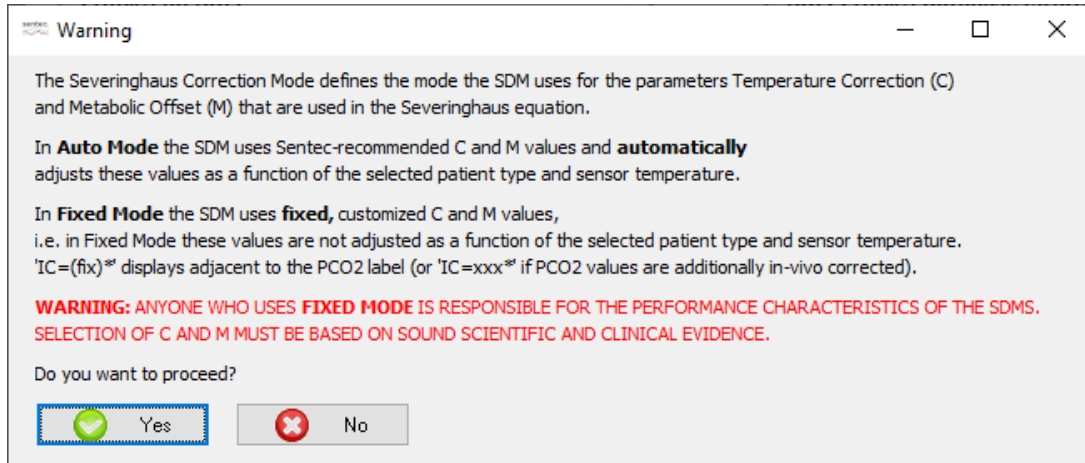
If 'OK' is selected the dialog 'Store profile as' (see 13.2.3.1) opens permitting to select a display and file name and then to store the respective SDM Profile in the 'SDM Profiles Database'. Click on 'Cancel' to return to the dialog 'Profiles / device Settings - <SN>' without storing your profile selection on the SDM. (*Note:* this step will be repeated as many times as SDM Profiles' were selected in the area 'Profiles on SDM' for which no display name is available).

C) If the Data Recording Interval (DRI) of the SDM Profile that you selected in the dialog 'Select Profiles' to become the 'Standard Profile' and the actual Data Recording Interval are different, V-STATS will display the following warning:



Click on 'Yes' to continue. Click on 'No' to return to the dialog 'Profiles / device Settings - <SN>' without storing your profile selection on the SDM.

D) If in at least one of the selected 'SDM Profiles' the parameter 'Severinghaus Correction Mode Selectable' is set to ON the following warning dialog displays:



Click on 'Yes' to continue. Click on 'No' to return to the dialog 'Profiles / device Settings - <SN>' without storing your profile selection on the SDM.

13.2.3 SDM Profiles Database / customize and edit SDM Profiles

A 'SDM Profile' is a file which contains a specific setting for all those SDM parameters that are displayed in black in the dialog 'Profiles / device Settings - <SN>' (see 13.2, 13.2.4). 'SDM Profiles' therefore are helpful to ensure that all SDMs within your institution work the way you want them to. In case of SDMs being used in 'Institutional Mode' it is possible a) to store up to 4 SDM Profiles and to activate one of these SDM Profiles as 'Standard Profile' within a password-protected area of V-STATS as well as b) to restore the 'Standard Profile' if modified and to select / activate one of the other SDM Profiles stored in the SDM by using the menu 'Profiles'.

V-STATS stores 'SDM Profiles' in the so-called 'SDM Profiles Database' and provides the functions required to customize and manage 'SDM Profiles' within the dialog 'Profiles / device Settings - <SN>' in the area 'SDM Profiles Database (stored in V-STATS)' (see 13.2) or – if no serial connection to a SDM is available – within the dialog 'SDM Profiles Database (stored in V-STATS)' (see 7.10).

Note: Upon installation of or upgrade to V-STATS 5.01.1 the following write-protected SDM Profiles preconfigured by Sentec and tailored to optimally fit the specific needs of varying clinical settings are stored in the 'SDM Profiles Database': CRITICAL CARE [CRITICAL_CARE], GEN. CARE FLOOR [GCF], HOME [HOME], NICU PO2 [NICU_pO2], NICU [NICU], OPERATING ROOM [OR], PACU [PACU], SLEEP [SLEEP], SMB621 Style [SMB621_Style], V-CHECK [V_CHECK]. Please refer to 'RF-006679 Preconfigured SDM Profiles' to view all parameters and their respective settings in the 9 preconfigured SDM Profiles.

Note: If V-STATS detects a corrupt profile in the 'SDM Profiles Database' when executing the 'Refresh Window' function the following warning dialog displays: 'The following profiles seem to be corrupt and will be deleted (list with profile names). Do you want to save these profiles in another folder before (Yes | No)?' Click on 'Yes' to create a backup folder and to move the corrupt profile(s) into this folder, click on 'No' to delete the corrupt profile(s) without a backup copy.

In the area 'SDM Profiles Database (stored in V-STATS)' of the dialog 'Profiles / device Settings - <SN>' the following functions / controls are available.

Control	Description
Drop-down list 'Select Profile'	Lists all 'SDM Profiles' in alphabetical order that are currently available in the SDM Profiles Database as well as all SDM Profiles currently available in the SDM with no matching profile in the SMD Profiles Database. One of the listed SDM Profiles can be selected. <i>Note: The buttons 'Import from SDM', 'Store as', 'Print', 'Export', 'Delete', and 'Email' are dimmed grey (no function) as long as no 'SDM Profile' is selected.</i> <i>Note: Elements of the following syntax can be available in this drop-down list <Display Name> [<File Name>], [<File Name>], <Display Name> (standard), (standard), <Display Name> (current), and (current). Please refer to 13.2 for a description of the syntax that is used for the profile name of SDM Profiles.</i>
Button 'Import from SDM'	Permits to import a SDM Profile currently stored in the SDM with no matching profile in the SDM Profiles Database to the database.

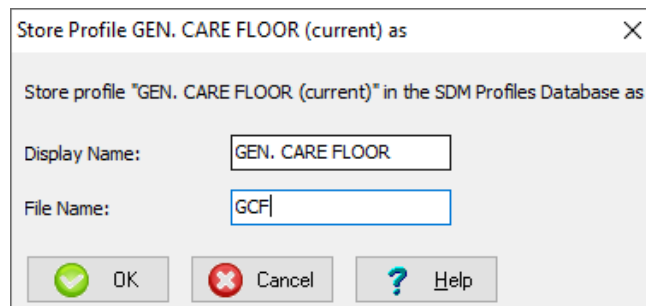
Control	Description
	<p>A click on this button opens the dialog 'Store profile as' (see 13.2.3.1). A click on 'OK' imports the selected 'SDM Profile' with the specified display and file name to the SDM Profiles Database.</p> <p><i>Note: This button is only accessible, if a SDM Profile currently stored in the SDM with no matching profile in the SDM Profiles Database is selected in the drop-down list, i.e. a SDM Profile with (standard) or (current) in its profile name.</i></p> <p><i>Note: Click on the button 'Save to SDM Profiles Database' in the area 'Current SDM Profile' of the dialog 'Profiles / device Settings - <SN>' permits to store the 'Current SDM Profile' in the 'SDM Profiles Database'.</i></p>
Button 'Import'	<p>Permits to import a 'SDM Profile' from the PC to the SDM Profiles Database.</p> <p>A click on this button opens a windows dialog which permits to select a 'SDM Profile' file stored on the PC. Upon selection of a 'SDM Profile' the dialog 'Store profile as' (see 13.2.3.1) opens. A click on 'OK' imports the selected 'SDM Profile' with the specified display and file name to V-STATS' SDM Profiles Database.</p> <p><i>Note: The file extension of SDM Profile files is '.spf'.</i></p>
Button 'Store as'	<p>Permits to store the 'SDM Profile' selected in the drop-down list in the SDM Profiles Database with a different display name and/or file name.</p> <p>A click on this button opens the dialog 'Store profile as' (see 13.2.3.1). In this dialog it is possible to modify the display and/or filename. A click on 'OK' stores a copy of the selected 'SDM Profile' with the specified display and file name to the SDM Profiles Database.</p> <p><i>Note: If a different file name is selected in the dialog 'Store profile as' (see 13.2.3.1) a copy of the selected SDM Profile will be stored in the SDM Profiles Database with the specified file name. If only a different display name is selected but the file name is not modified in the dialog 'Store profile as' (see 13.2.3.1) the display name of the selected SDM Profile will be modified accordingly.</i></p>
Button 'Print'	<p>A click on this button opens a windows dialog permitting to print the 'SDM Profile' selected in the drop-down list either a) on paper (select 'Printer') or b) as pdf-file (select 'PDF'). If 'Printer' is selected a dialog opens in which it is possible to select the printer and print settings such as paper size. If 'PDF' is selected a windows dialog opens permitting to specify the storage folder and filename of the pdf-file. The syntax of the proposed file name is 'SDM Profile <Display Name> [<File Name>].pdf'.</p> <p>The print-out/ PDF-file of the selected SDM Profile will include</p> <ul style="list-style-type: none"> – a <u>header</u> line with the profile name (and serial number of the SDM if a profile that is available in the SDM is printed) on the left and the Identification Code on the right – a <u>title</u> line with the profile name. If the Current SDM Profile is printed 'Current SDM Profile' is added to the title – a line with <u>information on the SDM</u> (serial number, software versions) if a SDM Profile available in the connected SDM is printed – a box explaining the font-/color-coding that is used to characterize the different types of parameters (see 13.2) – all parameters and their respective settings of the selected SDM Profile. The parameters are listed in the same order and grouped as in the tabs of the dialog 'Profiles / device Settings - <SN>'. For parameters that are not part of profiles the respective setting will only be printed if the Current SDM Profile is printed. Otherwise 'non-setting' or 'not available' will be printed instead. – an 'SDM Profile Approval' box: This box is intended to be used by the Responsible Organization in order to officially approve the settings of the respective profile. – a <u>footer</u> line with the V-STATS Version on the left, the page number in the center, and the current date on the right
Button 'Export'	<p>A click on this button opens a windows dialog permitting to export the 'SDM Profile' selected in the drop-down list to the PC.</p> <p><i>Note: When exporting a 'SDM Profile' to the PC only the file name can be modified but not the display name.</i></p> <p><i>Note: This button is dimmed grey if a SDM Profile currently available in the connected SDM with</i></p>

Control	Description
	<i>no matching profile in the SMD Profiles Database is selected.</i>
Button 'Email'	A click on this button opens the standard email client and creates a new Email with the 'SDM Profile' selected in the drop-down list attached. Enter the Email address of the recipient and send the Email. <i>Note: This button is dimmed grey if a SDM Profile currently available in the connected SDM with no matching profile in the SMD Profiles Database is selected.</i>
Button 'Delete'	A click on this button activates a confirmation dialog and – after confirmation - deletes the 'SDM Profile' selected in the drop-down list. <i>Note: This button is dimmed grey (no function) if one of the <u>write-protected</u> SDM Profiles preconfigured by Sentec is selected or if a SDM Profile currently available in the connected SDM with no matching profile in the SMD Profiles Database is selected.</i>

13.2.3.1 Dialog 'Store profile as'

The dialog 'Store profile as' is a help dialog that activates

- if a SDM Profile is imported to the SDM Profiles Database (from the SDM or the PC)
- if the Current SDM Profile is stored in the SDM Profiles Database
- if a copy of a SDM Profile already available in the SDM Profiles Database is stored in the SDM Profile Database with a different display and/or file name
- if the profile configuration on the SDM is modified and if profiles are available on the SDM with no matching profile in the SDM Profiles Database and/or without display name.



Note: The title of the dialog 'Store profile as' also includes the profile name (if available), i.e. its syntax is 'Store Profile <Display name> [<File name>] as'. Refer to 13.2 for a description of the syntax used for profile names.

The following elements are available in the dialog 'Store profile as':

Element	Description
Text entry field 'Display Name'	Here you can enter the display name of the profile (maximal 16 characters) <i>Note: On a SDM being operated in 'Institutional Mode' the display name of the 'Current SDM Profile' is displayed on the 'Calibration' screen, the 'Ready for use' screen, in the main menu, and in the sub-menu 'Profiles'.</i> <i>Note: It is strongly recommended not to include special characters in the SDM Profile name, since they might not be displayed correctly on the SDM itself.</i>
Text entry field 'File Name'	Here you can enter the file name of the profile, i.e. the name under which the profile is stored on the PC. The file extension of SDM Profile files is '.spf'.
Button 'OK'	A click on this button stores the respective SDM Profile with the selected display and file name into the SDM Profiles Database. <i>Note: SDM Profiles preconfigured by Sentec (see RF-006679) are write-protected. If the SDM Profiles Database already contains a <u>write-protected</u> SDM Profile with the same filename V-STATS will trigger the dialog: "V-STATS Profiles Database already contains a write-protected profile with this filename. Please select a different filename. (OK cancel)". Select 'OK' to return to the dialog 'Store profile as' and to enter a different filename. Click on 'Cancel' to abort the process and to return to the dialog from which the dialog 'Store profile as' was opened.</i>

Element	Description
	<i>Note: If the SDM Profiles Database already contains a SDM Profile with the same filename V-STATS will trigger the dialog: "V-STATS' Profiles Database already contains a profile with this filename. Do you want to replace profile <Filename>? (Yes No Cancel)". Select 'Yes' to replace the existing profile with the profile you are about to store in the SDM Profiles Database. Select 'No' to return to the dialog 'Store profile as' and to enter a different filename. Click on 'Cancel' to abort the process and to return to the dialog from which the dialog 'Store profile as' was opened.</i>
Button 'Cancel'	<i>Click on 'Cancel' to abort the process and to return to the dialog from which the dialog 'Store profile as' was opened.</i>

13.2.4 Current settings of all parameters of the connected SDM

The area 'Current SDM Profile' of the dialog 'Profiles / device Settings - <SN>' (see 13.2) displays for the connected SDM the current settings of all parameters (i.e. all menu-parameters and all safety relevant parameters being available only within V-STATS). The parameters are grouped in multiple tabs that are arranged in the same order as the SDM's menu.

In the dialog 'Profiles / device Settings - <SN>' the Responsible Organization can configure all parameters of the connected SDM on an individual basis by means of check boxes, drop-down lists, and text entry fields.

Note: A mouse click on a check box immediately modifies the current setting of the respective parameter on the connected SDM. A mouse click on other parameters highlights the respective drop-down list or text entry field yellow to indicate that editing-mode has been activated. To exit editing-mode and to write the new value of the respective parameter to the connected SDM click with the mouse on an arbitrary position of the dialog window but the respective parameter itself.

Note: Changes of individual parameters only affect the Current SDM Profile, i.e. SDM Profiles stored in the four profile slots of the SDM or in the SDM Profiles Database within V-STATS are not affected.

In the following sub-sections each tab of the area 'Current SDM Profile' and the parameters contained therein are covered. For each tab a screenshot is shown for a SDM with software version SMB-SW V08.03 with all parameters preset to factory defaults. Please refer to the Technical Manual for the SDM (HB-005752) for a description, the default setting as well as the selectable range for each parameter. Refer to 'RF-006679 Preconfigured SDM Profiles' for the settings of the SDM's parameters in the SDM Profiles preconfigured by Sentec and tailored to optimally fit the specific needs of different clinical areas. Remember that if the mouse is hovered over a parameter a description of the respective parameter appears in a tool tip. If the mouse is hovered over the red bold label 'Parameter Types' the font-/color-coding that is used to characterize the different types of parameters appears in a tool-tip (see 13.2).

13.2.4.1 Tab 'Alarm Settings'

The tab 'Alarm Settings' includes all parameters that are available to configure the alarm system of the connected SDM.

The screenshot shows the 'Current SDM Profile' configuration window with the 'Alarm Settings' tab selected. The window is titled 'Current SDM Profile' and has a sub-header 'Parameter Types'. Below this, there are several tabs: 'Alarm Settings', 'Measurement Settings (1)', 'Measurement Settings (2)', 'System Settings', 'Interfaces', and 'Trend Data'. The 'Alarm Settings' tab is active, displaying a list of parameters and their values, along with checkboxes for various alarm options.

Parameter	Value	Option	Value
PCO2 High Limit (mmHg)	55	"AUDIO OFF" selectable	<input checked="" type="checkbox"/>
PCO2 Low Limit (mmHg)	0	Alarm Volume	OFF
SpO2 High Limit (%)	100	AUDIO PAUSED Duration (mins)	2
SpO2 Low Limit (%)	85	"AUDIO OFF Reminder" selectable	<input checked="" type="checkbox"/>
PR High Limit (bpm)	140	AUDIO OFF Reminder	OFF
PR Low Limit (bpm)	50	Alarm Melodies	<input type="checkbox"/>
PO2 High Limit (mmHg)	95	Ready for use Beep	<input type="checkbox"/>
PO2 Low Limit (mmHg)	0	RMI AUDIO OFF Disable Volume	OFF

At the bottom of the window, there are several buttons: 'Set To', 'Select Profile' (dropdown), 'Reset', 'Save to SDM Profiles Database', 'Print', 'Close', 'Help', 'Refresh Window', and 'Restore "Default SDM Profile"'. The 'Set To' button is highlighted in blue.

13.2.4.2 Tab 'Measurement Settings (1)'

The tab 'Measurement Settings (1)' includes parameters being related to V-Check Mode, to the Sensor Temperature and Site Time as well as the parameters 'Timer Range for Online Trends', 'Patient', 'Enabled Parameters', and 'Delta-Time'.

Note: In the menu 'Measurement Settings' of the SDM the parameter 'Time Range for Online Trends' is called 'Time Range for Trends'.

Note: The parameters 'Max. select. Sensor Temperature' and 'Max. select. Site Time' correspond to the maximal 'Sensor Temperature' and maximal 'Site Time' the Responsible Organization allows the operator to select in the menu of the SDM. In certain cases, safety control of the SDM will overrule the settings of the Responsible Organization and enforce safer values for these two parameters. The corresponding values are displayed in the non-changeable parameters 'Select. Sensor Temp. Range on SDM' and 'Max. select. Site Time on SDM' (highlighted in orange). *Example:* By default, the 'Max. select. Sensor Temperature' is set to 44°C and the 'Max. select. Site Time' is set to 12 hours when using a V-Sign™ Sensor in Neonatal Mode (i.e. PO2 is disabled). However, safety control of the SDM will enforce a maximal operator-selectable Site Time - Sensor Temperature combination, e.g. a Site Time of 6 hours at 42°C, and display the respective values in the non-changeable parameters 'Select. Sensor Temp. Range on SDM' and 'Max. select. Site Time on SDM'.

Current SDM Profile

Parameter Types

Alarm Settings | **Measurement Settings (1)** | Measurement Settings (2) | System Settings | Interfaces | Trend Data

Time Range for Online Trends	120min	Sensor Temperature / Site Time Settings	
Patient	Adult	Max. select. Sensor Temperature (°C)	43.5
Enabled Parameters	PCO2 PO2 SpO2 PR	Min. select. Sensor Temperature (°C)	40.0
Delta-Time (mins)	10	Select. Sensor Temp. Range on SDM (°C)	40.0-43.5
"V-Check Mode" selectable	<input type="checkbox"/>	Sensor Temperature (°C)	42.0
V-Check Mode	Off	Max. select. Site Time (hrs)	6.0
V-Check Stabilization Duration (mins)	8	Max. select. Site Time on SDM (hrs)	6.0
V-Check Analysis Duration (mins)	2	Site Time (hrs)	4.0
V-Check Data Validity (%)	80	"SITE PROTECTION" selectable	<input checked="" type="checkbox"/>
		SITE PROTECTION	On
		"INITIAL HEATING" selectable	<input checked="" type="checkbox"/>
		INITIAL HEATING	Off
		Heating Power Mode	relative
		RHP Range for Online Trend (mW)	-20-20

Set To | Select Profile | Reset | Save to SDM Profiles Database | Print

Close | Help | Refresh Window | Restore "Default SDM Profile"

13.2.4.3 Tab 'Measurement Settings (2)'

The tab 'Measurement Settings (2)' includes parameters being related to the parameters PCO2, PO2, SpO2 and PR.

Current SDM Profile

Parameter Types

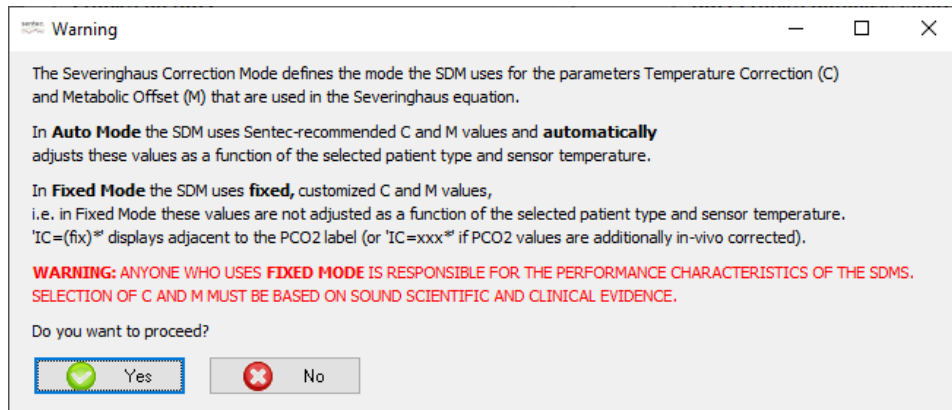
Alarm Settings | Measurement Settings (1) | **Measurement Settings (2)** | System Settings | Interfaces | Trend Data

<u>SpO2/PR Settings</u>		<u>PCO2 Range for Online Trend (mmHg)</u>	
SpO2 Range for Online Trend (%)	70-100	PCO2 Range for Online Trend (mmHg)	25-75
PR Range for Online Trend (bpm)	30-140	"PCO2 In-Vivo Correction" selectable	<input checked="" type="checkbox"/>
Pulse Beep	Off	"Severinghaus Correction Mode" selectable	<input type="checkbox"/>
Pleth Speed (mm/sec)	7.5	Severinghaus Correction Mode	auto
"SpO2 Averaging" selectable	<input checked="" type="checkbox"/>	Temperature Correction	--
SpO2 Averaging (secs)	16	Metabolic Offset (mmHg)	--
<u>PCO2/PO2 Settings</u>		Max. permitted Calibration Interval (hrs)	1.0
PCO2/PO2 Unit	mmHg	Message "Recommended Sensor Stabilization"	<input checked="" type="checkbox"/>
PO2 Range for Online Trend (mmHg)	40-160	PCO2 Calibration Curve	<input type="checkbox"/>
		Membrane Change Interval (days)	28.0

Set To | Select Profile | Reset | Save to SDM Profiles Database | Print

Close | Help | Refresh Window | Restore "Default SDM Profile"

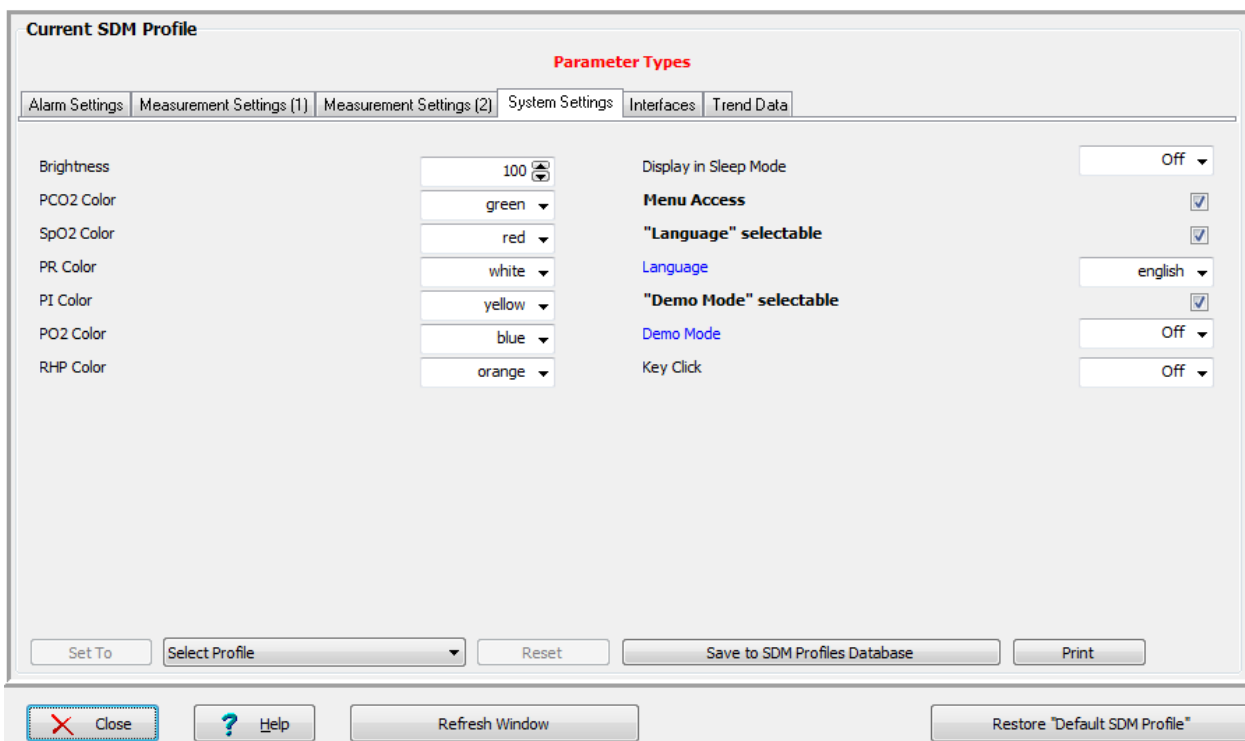
Note: When attempting to select the check box 'Severinghaus Correction Mode selectable', the following warning dialog displays:



Click on 'Yes' to select the check box and to activate operator-access to the menu parameter 'Severinghaus correction mode'. Click on 'No' to abort the process and to return to the dialog 'Profiles / device Settings - <SN>'.

13.2.4.4 Tab 'System Settings'

The tab 'System Settings' includes parameters being related to various display settings of the SDM, the 'Language', the 'Demo Mode' and the Key Click. Menu Access can be disabled as well.



13.2.4.5 Tab 'Interfaces'

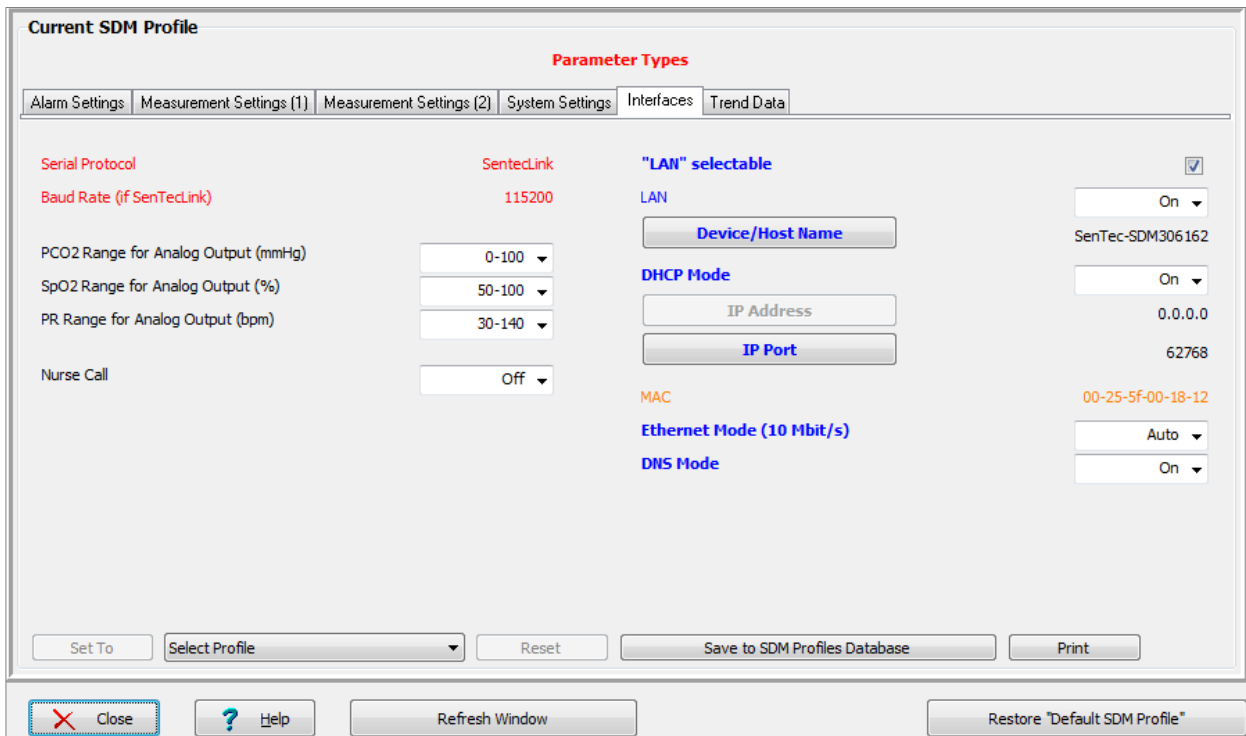
The tab 'Interfaces' includes parameters being related to the 'Serial Interface', to the 'Analog Outputs' and 'Nurse Call', as well as to the 'LAN Interface'.

Note: The menu-parameter 'Serial Protocol' and 'Baud Rate (if SentecLink)' are not changeable within V-STATS, they can only be changed in the menu of the SDM.

Note: In the menu 'Analog Outputs' of the SDM the parameters 'PCO2 Range for Analog Output', 'SpO2 Range for Analog Output', and 'PR Range for Analog Output' are called 'PCO2 Range', 'SpO2 Range', and 'PR Range', respectively.

Note: For SDMs configured in V-CareNeT Only Mode the parameters 'LAN selectable' and 'LAN' are both forced

to ON and cannot be set to OFF. Within V-STATS these two parameters, consequently, are not accessible (dimmed grey), if the connected SDM is configured in V-CareNeT Only Mode.



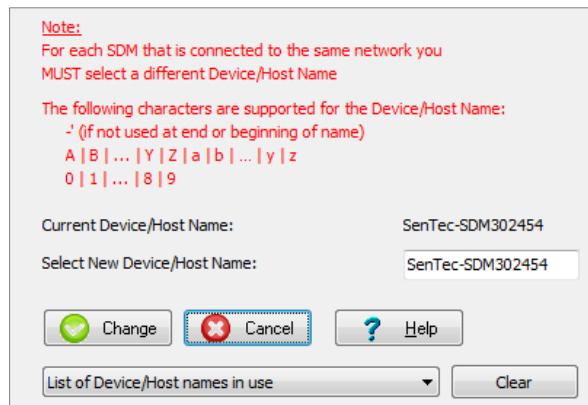
Dialog 'Device/Host Name'

The Device/Host Name is the network name of the SDM published over DHCP and is visible within the network (router, switches, etc.). Furthermore, it identifies a SDM in the V-CareNeT System, where it is, among other, displayed in the 'V-CareNeT Control Window' (see 14.5), in the window name of the respective station's remote monitoring window (see 14.8.1) and Trend Data download window (see 14.6) as well as in the sub-menu 'LAN Interface' of the SDM itself.

Note: The default Device/Host Name of a SDM is Sentec-SDM<SN>, where <SN> is the serial number of the SDM.

Note: If a SDM is always used in the same location (e.g. 'Room 5' or 'PACU Bed 1'), the location may be stored in the SDM's 'Device/Host Name' (see 14.7.1).

A click on the button 'Device/Host Name' opens the dialog 'Change Device/Host Name' where the 'SDM Device/Host Name' of the connected SDM can be changed.



Enter the new Device/Host Name in the text entry field 'Select New Device/Host Name'. Ensure to select a different Device/Host Name for each SDM that is connected to the same network.

Click on the button 'Change' to change the 'Device/Host Name' of the connected SDM. Click on 'Cancel' to reject changes and close the dialog.

Note: The 'SDM Device/Host Name' is an alphanumeric string with maximal 16 characters. Permitted characters

are letters (A, B, ..., Y, Z, a, b, ..., y, z), digits (0, 1, ..., 9) and '-' if not used at end or beginning of the 'SDM Device/Host Name'. V-STATS prevents entry of other characters and/or issues an appropriate error message when clicking on the button 'Change' if invalid characters are used.

Note: V-STATS prompts an error message when clicking on the button 'Change', if you have selected a Device/Host Name, which previously was or currently is used in the network or was used for a SDM with which serial communication previously was established. To view the list of Device/Host names already used, click on the drop-down list 'List of Device/Host names in use'.

Note: When changing the 'SDM Device/Host Name' the old 'SDM Device/Host Name' will be removed from and the new 'SDM Device/Host Name' will be added to the 'List of Device/Host names in use'. To clear the 'List of Device/Host names in use' click on the button 'Clear'. Clearing the list of 'Device/Host Names in use' may be required when using the PC with V-STATS to configure SDM's that are (will be) connected to different networks.

Note: On the SDM the current setting of this parameter is displayed in the sub-menu 'LAN Interface'.

DHCP Mode

If DHCP Mode is set to OFF a static IP Address is used, if set to ON a dynamic IP Address is used.

Note: If 'Device Discovery' is enabled in the dialog 'V-CareNeT Settings' (see 12.2) V-STATS / V-CareNeT uses DHCP broadcast for automatic device discovery in the network (BOOTP) (see 12.2). All SDMs within the broadcast range will respond to the broadcast with their IP address and subsequent communication is then possible. The broadcast range is usually within the same subnet, but can also be across subnets depending on the router configuration. If Device Discovery is disabled V-CareNeT requires a network environment with fixed IP address assignment. Either you then set DHCP Mode to OFF and select an IP address / IP port for all SDMs you want to connect to V-CareNeT or you must use a DHCP Server configuration that assigns fixed IP addresses based on MAC address.

Note: On the SDM and on the PC with V-CareNeT a static IP Address must be used if you want to directly connect the PC with V-CareNeT to a SDM by using an Ethernet crossover cable. We recommend that – after having set DHCP Mode to OFF for the SDM – you increment the last number of the SDM's IP Address by 1 (one) and use the resulting IP Address as static IP address for the PC (e.g. static IP Address for the SDM: 192.168.1.99 → static IP Address for the PC: 192.168.1.100).

Note: If DHCP Mode = ON a new IP Address typically is assigned to the SDM, if the Device/Host Name is changed.

Note: On the SDM the current setting of this parameter is displayed in the sub-menu 'LAN Interface'.

Dialog 'Change IP Address'

A click on the button 'IP Address' (only selectable if DHCP Mode = OFF) opens the dialog 'Change IP Address' where the IP Address of the connected SDM can be changed. Ensure that the IP Address you select is not already in use in the network to which you want to connect the SDM.

Click on the button 'Change' to change the 'IP Address' of the connected SDM. Click on 'Cancel' to reject changes and close the dialog.



Note: The values for the 4 parts of the IP Address must be between 0 and 255. The following IP Addresses are not permitted: '0.0.0.0'; '127.xxx.xxx.xxx'; '255.255.255.255'. V-STATS issues an appropriate error message when clicking on the button 'Change' if an invalid IP Address format is used.

Note: The dialog 'Change IP Address' is not accessible if DHCP Mode = ON.

Note: The default IP Address is 192.168.1.99

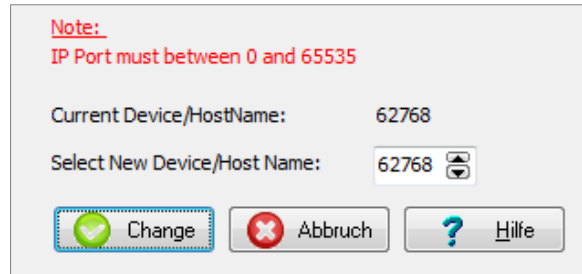
Note: The DHCP Mode must be set to OFF if you want to directly connect the PC with V-STATS to a SDM by using an Ethernet crossover cable.

Note: On the SDM the current setting of this parameter is displayed in the sub-menu 'LAN Interface'.

Dialog 'Change IP Port'

A click on the button 'IP Port' opens the dialog 'Change IP Port' where the TCP/UDP Port over which the communication via the SDM's LAN port will run can be changed. Ensure that the IP Port you select is between 0 and 65535 (default is 62768).

Click on the button 'Change' to change the 'IP Port' of the connected SDM. Click on 'Cancel' to reject changes and close the dialog.



Note: Ensure that no firewall is blocking this port.

Note: On the SDM the current setting of this parameter is displayed in the sub-menu 'LAN Interface'.

MAC Address

Indicates the MAC Address of the SDM (not changeable).

Ethernet Mode (10 Mbit/s)

The SDM supports an Ethernet network speed of 10 Mbit/s and can run in half or full duplex mode. The negotiation between the device and the network is usually done automatically. For certain network environments it might be required to force the SDM into a specific mode (consult your IT manager). It is therefore possible to adjust the SDM into three different modes: auto-negotiation (default and recommended setting), 10 Mbit/s half duplex and 10 Mbit/s full duplex. Do not change this setting if uncertain what it does, consult your IT manager first as it might have undesired effects on your network.

DNS Mode

'On' and 'Off' selectable (default setting 'On'). Please contact Sentec AG for more information.

13.2.4.6 Tab 'Trend Data'

The tab 'Trend Data' includes parameters being related to the Trend Data that are stored in the internal memory of the SDM and their subsequent review and statistical analysis in the menu of the SDM.

Note: In the menu 'Review / Print Trend Data' of the SDM the parameters 'PCO2 Range for review/print-out', 'SpO2 Range for review/print-out', and 'PR Range for review/print-out' are called 'PCO2 Range', 'SpO2 Range', and 'PR Range', respectively.

Note: The parameter 'Patient ID' can only be changed in the dialog 'Communication with device (via Serial Interface)' (see 8.1)

Current SDM Profile

Parameter Types

Alarm Settings | Measurement Settings (1) | Measurement Settings (2) | System Settings | Interfaces | Trend Data

PCO2 Range for review/print-out (mmHg) 25-75 ▾

SpO2 Range for review/print-out (%) 70-100 ▾

PR Range for review/print-out (bpm) 30-140 ▾

Data Recording Interval (sec.) 4

Minimal Measurement Duration (min.) 5 ▾

Patient ID ---

Ranges for Histograms

PCO2 (mmHg)	SpO2 (%)	PR (bpm)
200.0	100	250
100.0	96	210
85.0	92	180
70.0	88	150
55.0	84	120
40.0	80	90
25.0	76	60
0.1	1	30

A click on the button 'Data Recording Interval' activates a warning dialog indicating that if the Data Recording Interval will be changed the Trend Data currently stored in the SDM will be cleared and – after confirmation of this warning dialog – the dialog 'Selection of Data Recording Interval' appears.

Data Recording Interval (sec.): 4 ▾

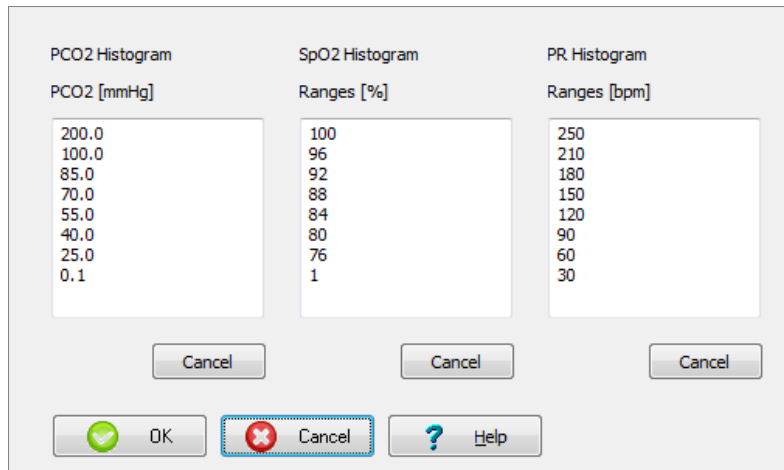
Resulting Memory capacity of SDM(days): 5.3

The drop-down list 'Data Recording Interval' permits to select a different data recording interval. The text field 'Resulting Memory Capacity of SDM' displays the resulting memory capacity of the SDM in days that will result for the selected data recording interval. Press 'OK' to activate the new data recording interval. Press 'Cancel' to close the dialog without changing the data recording interval.

Note: Refer to the Technical Manual of the SDM (HB-005752) for a table which shows how the memory capacity of the SDM changes with the data recording interval as well as memory type (volatile / non-volatile).

Note: If the 'Data Recording Interval' is > 1 sec, the data are not additionally filtered prior down sampling.

For each parameter (PCO2, SpO2, PR) a histogram can be viewed in the SDM's sub-menu 'Trend Data Review – Statistics' as well as on the printouts, whereby the histogram represents the percentiles duration the readings of the respective parameter were within the specified ranges. A click on the button 'Ranges for Histograms' opens the dialog 'Ranges for Histograms'.



In the dialog 'Ranges for Histograms' the ranges used for the PCO2, SpO2, or PR Histograms can be edited/modified in the respective box. For each parameter at least 2 values (1 range) must and at most 8 values (7 ranges) can be entered. With the exception of the smallest value - which represents the lower border of the lowest range - all values represent the upper limit of the respective range. A Click on the 'OK' button sorts the values entered for the respective parameter downwards and then stores the values as range limits in the SDM.

	PCO2 (mmHg)	PCO2 (kPa)	%SpO2	PR
Maximal selectable upper limit	200.0	26.67	100	250
Minimal selectable lower limit	0.1	0.01	1	30
Factory default ranges	200.0, 100.0, 85.0, 70.0, 55.0, 40.0, 25.0, 0.1	26.67, 13.33, 11.33, 9.33, 7.33, 5.33, 3.33, 0.01	100, 96, 92, 88, 84, 80, 76, 1	250, 210, 180, 150, 120, 90, 60, 30

13.3 Configuring multiple SDM's identically

The following example describes how the Responsible Organization in 'Institutional Mode' can first customize a 'SDM Profile' and then store this 'SDM Profile' on multiple SDM's:

Step	Description
1	Take a SDM, activate 'Institutional Mode' and select an existing 'SDM Profile' as 'Standard Profile'. If possible, select a 'SDM Profile' whose settings are as close as possible to your desired settings. <i>Note: Please refer to 'RF-006679 Preconfigured SDM Profiles' to view all parameters and their respective settings in the 9 preconfigured SDM Profiles.</i>
2	Within the area 'Current SDM Profile' of the dialog 'Profiles / device Settings - <SN>' adjust parameters as required to customize your desired profile.
3	Click on the button 'Save to SDM Profiles Database' to store the customized profile in the 'SDM Profiles Database'. Select an adequate display name and filename.
4	Take the other SDM's one by one. Activate 'Institutional Mode' and always store the 'SDM Profile' you have customized in step 2 in the same profile slot and select it as 'Standard Profile'. <i>Note: On each SDM you can store up to 4 profiles. Always store the same profiles in the same profile slot.</i>

The following example describes how the Responsible Organization in 'Basic Mode' can define and set the same 'Current SDM Profile' for multiple SDM's:

Step	Description
1	Take a SDM, activate 'Basic Mode'. Then select a 'SDM Profile' whose settings are as close as possible to your desired settings and set the Current SDM Profile to this SDM Profile by using the function 'Set To' in the lower left of the dialog 'Profiles / device Settings - <SN>'.
2	Within the area 'Current SDM Profile' of the dialog 'Profiles / device Settings - <SN>' adjust parameters as required to customize your desired profile.
3	Click on the button 'Save to SDM Profiles Database' to store the customized profile in the 'SDM Profiles Database'. Select an adequate display name and filename.
4	Take the other SDM's one by one. Activate 'Basic Mode' and then always select the 'SDM Profile' you have customized in step 2 and click on 'Set To' to set the Current SDM Profile to your customized SDM Profile

14. V-CareNeT Package

14.1 Safety Information /Warnings



WARNING: The V-CareNeT System is not intended to be a substitute for clinical supervision. Patients on life-support equipment should be appropriately monitored by competent/trained medical personnel and suitable monitoring devices.



WARNING: The V-CareNeT System is a secondary alarm notification system. It is intended to supplement and not to replace any part of the hospital's device monitoring procedures (including procedures regarding bedside SDMs and responding to bedside SDM alarms). Do not rely on the V-CareNeT System as the sole source of SDM alarms.



WARNING: It is essential that the computer with V-STATS that serves as the central station of the V-CareNeT System is visually and audibly monitored at all times to assure prompt response to alarms.



WARNING: The data displayed at the V-CareNeT Central Station is limited to that provided by the included SDMs.



WARNING: Decreasing the central station's screen resolution while remote monitoring is active may cause interruption of remote monitoring for one or multiple SDMs. In this case, patients admitted to the respective stations will be discharged from V-CareNeT System without an alert-dialog being displayed.



WARNING: Do not ignore medical device audible alarms. Alarms indicate conditions that require immediate attention.



WARNING: Reducing the volume of the central station's internal and/or external speakers or disconnecting external speakers from the central station may result in an inaudible alarm signal.



WARNING: Ensure that the central station's internal and/or external speakers are clear of any obstructions. Failure to do so could result in an inaudible alarm signal.



WARNING: Do not use a computer as central station that appears to be damaged or that does not meet the minimum system requirements set forth in the 'System Requirements' chapter of this manual.



WARNING: Do not use an unstable network and make sure that devices connected to the network are not sending too many broadcast packets into the network. If a WLAN is used as a network, it should be implemented and tested by a WiFi-Specialist being familiar with the particular requirements for wireless networks in hospital environments. Ensure that the WiFi-Specialist by taking account for the structural surroundings (construction, shielding, interfering devices, etc.) evaluates how many access points are needed and where they have to be located to guarantee full, interference-free coverage. Proper function of the network that is used is not the responsibility of Sentec.



WARNING: Do not use energy-saving modes or screensavers that switch-off the screen of the central station.



WARNING: Refer to the Technical Manual for the Sentec Digital Monitor (HB-005752) for SDM specific warnings and cautions.

Note: The mains power supply of the Sentec Digital Monitor (SDM) is separated by two Means of Patient Protection (MOPPs) between the sensor port (for the applied part, the sensor) and the interface connectors. The three interface connectors (serial data port, Multipurpose I/O port (analog outputs, nurse call), LAN port) of the SDM are not separated from each other. If at a time only one external device is connected to one of the three interface connectors no additional safety measures are necessary to comply with the requirements of IEC 60601-1. If, however two or three external devices are connected at the same time to two or three of the SDM's interface connectors additional safety measures may be required to be compliant with the requirements of IEC 60601-1.

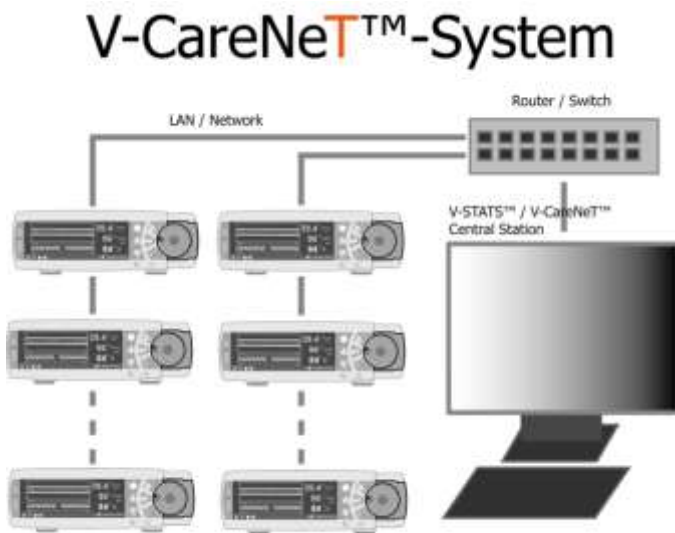
14.2 Intended use of the V-CareNeT System

The V-CareNeT System transmits data from the Sentec Digital Monitor (SDM) to the central station for patient monitoring via a network. The central station displays for all admitted patients relevant SDM data and alarms online.

The V-CareNeT System has the same intended use as the Sentec Digital Monitoring System (please refer to the Technical Manual for the SDM (HB-005752).

14.3 Introduction

14.3.1 The V-CareNeT System / Required Components



The V-CareNeT System enables remote monitoring and alarm surveillance for multiple Sentec Digital Monitors (SDMs) being connected to the same network as the PC with V-CareNeT. The central station is the PC running V-STATS with activated V-CareNeT Package. If remote monitoring is active the central station displays for all admitted patients all relevant SDM data and alarms online (14.4). Alarms appear visually and audibly at the central station (14.9). 'Operator Events', 'Baselines' (for PCO₂, PO₂, SpO₂, and RH; please note that V-CareNeT currently only supports remote monitoring of PCO₂, PO₂, SpO₂ and PR), and certain SDM settings can be set/ controlled remotely on the SDMs (14.8.3, 14.8.2.1). Trend Data stored in the internal memory of the SDMs conveniently can be downloaded via the network to V-STATS (6, 14.6) for subsequent display (4.2), analysis (9), and reporting in V-STATS. Reports can be generated (9.5) and printed or stored as a PDF (7.2). Download of SDM Trend Data is simultaneously possible for multiple SDMs. Up to 40 SDMs can be included in V-CareNeT.

The number of beds/patients being simultaneously available for remote monitoring is determined a) by the number of beds/patients included in the 'V-CareNeT Package Registration Code' that was used to activate/ upgrade the 'V-CareNeT Package' (15.2, 16.6.1) and b) by the number of stations that can be placed for the current size/ resolution of the PC's screen that is use as central station (whichever number is smaller).

Note: Remote Monitoring and alarm surveillance is currently only supported for PO₂ if OxIvenT sensor is connected to SDM and patient type is set to 'neonate'.

Note: 'V-CareNeT Package Registration Codes' are available for 5, 10, 20, 30, or 40 beds/patients or upon request for a customized number of up to 40 beds/patients. The two first digits after the letter C encode the number of beds/patients included in the code. The 'V-CareNeT Package Registration Code' that was used to activate V-CareNeT is displayed in the dialog 'Product-Info' (see 16.6).

Note: V-CareNeT evaluates the size/resolution of the central station's screen and limits the number of bed/stations being simultaneously available for remote monitoring to ensure that the 'V-CareNeT Control Window' and all active stations (remote monitoring windows) are fully visible and can be arranged without overlapping each other. For remote monitoring of 40 beds/patients, for example, a screen size/ resolution of approx. 2560 x 1440 is required (approx. 1024 x 768 for 5 beds/patients, 1152 x 864 for 10 beds/patients, 1600 x 1024 for 20 beds/patients, 1920 x 1200 for 30 beds/patients). Smaller screen sizes/resolutions will support fewer beds/patients regardless of the 'V-CareNeT Package Registration Code' that was used to activate/ upgrade the V-CareNeT Package.

Note: It is at any time possible to (further) upgrade V-CareNeT to a higher number of beds/patients (see 16.6.1).

As shown in the figure above the components required for V-CareNeT System are:

- **A network** with router/switch running at 100/1000 Mbit BaseT, preferably with a DHCP server in subnet.
 - Note: The use of a Local-Area Network (LAN) is recommended, use of a wireless LAN (WLAN) is possible as well. Use of powerline adapters is possible but not recommended.*
 - Note: Consider to use existing IT infrastructure when possible. Alternatively, V-CareNeT System can operate as a standalone system on its own network.*
 - Note: Proper function of the network that is used for V-CareNeT is not the responsibility of Sentec.*
- **A PC** with V-STATS being used as central station and being connected to the network.
 - Note: The V-CareNeT Package being incorporated within V-STATS must be activated (see 15.2) or one of the two trial options ('V-CareNeT Trial' (see 15.3), 'Extended V-CareNeT Trial' (see 15.4)) must be used.*
 - Note: For minimal PC system requirements see 3.2. A 100/1000 Mbit BaseT Ethernet connector is required for the network connection; an integrated speaker system is required for auditory alarm signals at the central station.*
- **Sentec Digital Monitors (SDMs)** supporting their LAN interface and with software version SMB SW-V07.01.x or newer (see 3.1), each being connected to the network.
 - Note: The message 'LAN Interface supported' displays on a SDM's Power-On Self-Test screen, if the hardware version of the SDM supports the LAN interface. If your monitor does not support the LAN Interface, please contact your local Sentec representative for upgrade information.*

Note: The LAN port of the SDM is located on its rear panel. It is a standard 10Mbit BaseT Ethernet connector.

Note: Should V-CareNeT detect SDMs with a software version prior to SMB SW-VO7.01.x (see 3.1) (e.g. at first use after upgrading V-STATS (see 3.3), V-CareNeT will trigger an appropriate warning and remove these SDMs from V-CareNeT (see 14.5.1).

- **Shielded Category 5 (Cat5) Ethernet cables** for connection of the SDMs to the network.

14.3.2 Configuration of the network and network settings

When setting up V-CareNeT you must configure the network as well as the network settings of V-CareNeT, of the PC with V-CareNeT and of the SDMs to be connected to V-CareNeT. Please contact a responsible IT person for correct network configuration of the different components.

Network related V-CareNeT Settings

Use the password protected dialog 'V-CareNeT Settings' (see 12.2)

- to select the 'Basic LAN Port'.
Note: The Basic LAN port defines the LAN port (or IP port) V-CareNeT uses when connecting to a first SDM being connected to the same network as the PC. When connecting to a second SDM V-CareNeT uses the next higher LAN port. Ensure to select the 'Basic LAN port' such that at least as many LAN ports are available / free as the number of devices you want to connect to V-CareNeT.
- to enable/disable 'Network Diagnostics' (disabled in default setting)
Note: If 'Network Diagnostics' is enabled quantitative information on the connection quality between the V-CareNeT Central Station and a connected SDM is displayed in a tool tip if the mouse is placed over the respective 'Connection Status Indicator' in the V-CareNeT Control Window.
- to enable/disable 'Device Discovery' (enabled in default setting)
*Note: If Device Discovery is enabled V-CareNeT uses DHCP broadcast for automatic device discovery in the network (BOOTP). All SDMs within the broadcast range will respond to the broadcast with their IP address and subsequent communication is then possible. After Device Discovery V-CareNeT provides a list of SDMs found in the network in the dialog 'Edit SDM/Device Host Names' (see 14.5.1). Therein SDMs can be selected and added to V-CareNeT. If Device Discovery is disabled (or if V-CareNeT is not able to discover a SDM if the box is checked) SDMs can be added to V-CareNeT by entering the respective SDM's IP Address/IP Port in the dialog 'Add SDM to V-CareNeT' (see 14.5.1.1).
*Note: The broadcast range is usually within the same subnet, but can also be across subnets depending on the router configuration.**

Network settings of the PC

Refer to your PC's manual to configure the PC's network settings.

Note: If device discovery is enabled (see 12.2) firewall settings of the PC have to allow the sending / receiving of DHCP discovery frames for automatic device discovery to work.

Note: For direct connection of the SDM to a computer without a hub or switch you must use a shielded Category 5 (Cat5) crossover Ethernet cable and use a static IP Address on the PC and on the SDM (see 13.2.4.5).

Network settings of the SDMs

By using V-STATS within a password protected area the Responsible Organization can define the network settings of a SDM (see 13.2.4.5). The following parameters can be configured: 'Device / Hostname', 'DHCP Mode', 'IP Address', 'IP Port', and 'Ethernet Mode'.

Note: On the SDM the settings of the parameters 'Device Name / Host name', 'DHCP Mode', 'IP Address', 'IP Port', and 'Ethernet Mode' as well as the SDM's 'MAC Address' are displayed in the sub-menu 'Interfaces / LAN Interface'.

Note: If Device Discovery is disabled V-CareNeT requires a network environment with fixed IP address assignment. Either you set DHCP Mode to OFF and select an IP address / IP port for all SDMs you want to connect to V-CareNeT or you must use a DHCP Server configuration that assigns fixed IP addresses based on MAC address.

Note: The approximated network traffic per SDM is 250 Bytes/second.

Network Configuration

Please contact your network administrator to configure the network.

Note: Do not use an unstable network and make sure that devices connected to the network are not sending too many broadcast packets into the network.

Note: If a WLAN is used as a network it should be implemented and tested by a WiFi-Specialist being familiar with the particular requirements for wireless networks in hospital environments. Ensure that the WiFi-Specialist, by

taking account for the structural surroundings (construction, shielding, interfering devices, etc.), evaluates how many access points are needed and where they have to be located to guarantee full, interference-free coverage.

Note: V-CareNeT requires UDP access on configurable ports (default 62000 and subsequent ports). Ensure to adjust firewall settings accordingly.

Note: If DHCP broadcast is used for device discovery in the network (see 12.2) a DHCP-Service which allocates the IP addresses to the devices is required within the network.

Note: If Device Discovery is enabled (see 12.2) firewall settings of the network have to allow the sending / receiving of DHCP discovery frames for automatic device discovery to work.

Note: If Device Discovery is enabled (see 12.2) and if V-CareNeT needs to communicate across subnets the router has to be configured to forward DHCP broadcast packets. Usually this is already the case in a network setting where one DHCP server serves several subnets. Usually device discovery will work within a DHCP domain.

Note: If Device Discovery is disabled (see 12.2) V-CareNeT requires a network environment with fixed IP address assignment. Either you set DHCP Mode to OFF and select an IP address / IP port for all SDMs you want to connect to V-CareNeT or you must use a DHCP Server configuration that assigns fixed IP addresses based on MAC address.

14.3.3 Monitoring data integrity and connection/network quality

V-CareNeT continuously monitors data integrity and connection/network quality between the V-CareNeT Central Station and each individual SDM being connected. To secure communication between the V-CareNeT Central Station and each individual SDM being connected to V-CareNeT CRC protected frames are used. To determine the connection/network quality the CRC failure rate, the answer/question ratio (LAN Rejection Rate (LRR)), and the plausibility of received data is monitored.

In the V-CareNeT Control Window the overall connection/network quality is visualized for each connection to a SDM in the respective 'Connection Status Indicator'. In case of a good quality connection it lights green, it lights yellow if a poor quality connection could be established (increased number of CRC verification failures, a high LRR). The Connection Status Indicator lights red, if the connection quality is too bad (implausible answers, too high number of CRC verification failures, or too high LRR) or no connection could be established at all.

Note: If 'Network Diagnostics' is enabled (see 12.2) quantitative information on the network/connection quality between the V-CareNeT Central Station and a connected SDM is displayed in a tool tip if the mouse is placed over the respective 'Connection Status Indicator' in the V-CareNeT Control Window (see 14.5). The tool tip indicates for the respective connection the current CRC failure rate and the current LRR. It displays 'SDM not reachable' if communication with the respective SDM is erroneous or cannot be established at all.

Note: Contact Sentec to adjust the levels which discriminate between good, poor, and too bad quality.

14.3.4 Avoiding potential mistake of SDMs/patients

Within V-CareNeT a SDM is unequivocally identified by its 'SDM Device/Host Name' and its 'IP Address/IP Port'. To avoid potential mistake of SDMs and patients being remotely monitored, V-CareNeT continuously monitors the 'SDM Device/Host Names' and the 'IP Address/IP Port' of all SDMs currently included in the V-CareNeT System (included SDMs are listed in the V-CareNeT Control Window (see 14.5) or in the list 'Currently selected' in the dialog 'Edit SDM Device/Host Names' (see 14.5.1)).

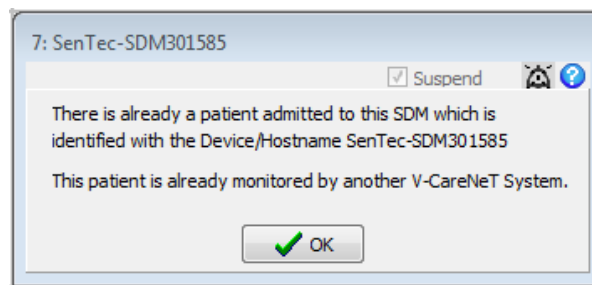
- Should the 'SDM Device/Host Name' of a SDM be changed while it is connected to V-CareNeT without that its IP Address/IP Port and MAC-Address change, V-CareNeT will trigger an appropriate dialog to alert/inform the operator.
- Should two or more SDMs currently be included in the V-CareNeT System that have an identical 'SDM Device/Host Name' or identical 'IP Address/IP Port' V-CareNeT will trigger an appropriate warning. To avoid potential mistake of patients being admitted to the corresponding SDMs V-CareNeT will discharge these patients and remove SDMs with identical 'SDM Device/Host Name' or identical 'IP Address/IP Port' from V-CareNeT.
- Should the operator attempt to add a SDM to V-CareNeT with a 'SDM Device/Host Name' and/or an 'IP Address/IP Port' already included in V-CareNeT, V-CareNeT will trigger an appropriate warning and prevent the user to add the selected SDM to V-CareNeT.
- If the operator attempts (erroneously) to manually add a device that is not a SDM to V-CareNeT by specifying its IP Address/IP Port in the dialog 'Add SDM to V-CareNeT' (see 14.5.1.1) V-CareNeT will – if connection to that device can be established - trigger an appropriate warning and prevent the user to add the selected device to V-CareNeT. If connection cannot be established at that stage, it is possible to add such a device to V-CareNeT. However, when attempting to connect to such a device, connection either will not be possible (corresponding Connection Status Indicator will light red, the Network Diagnostic's tooltip will display 'SDM not reachable') or – in certain cases - V-CareNeT will be able to trigger an appropriate warning and - after user-confirmation - remove the none SDM device from V-CareNeT.

Note: Whenever available both, the 'SDM Device/Host Name' and the 'IP Address/IP Port' are displayed in the dialog 'Edit SDM Device/Host Names' (see 14.5.1) for each SDM currently included in V-CareNeT System. This is immediately the case for devices found in the network by automatic device discovery. In case of devices that were added to V-CareNeT by specifying the 'SDM Device/Host Name' or the 'IP Address/IP Port' in the dialog 'Add SDM to V-CareNeT' (see 14.5.1.1) only the manually entered information will be available as long no connection has been established with the corresponding SDM.

14.3.5 Locking Mechanism

The performance of a SDM potentially could be compromised if multiple V-CareNeT instances simultaneously would remotely monitor the same SDM. The V-CareNeT Central Station, therefore, locks the SDM when admitting (see 14.7.1) a patient to the corresponding station. Other central stations subsequently can establish a connection to a locked SDM; however, activation of remote monitoring for a locked SDM is not possible.

When attempting to admit a patient to a locked SDM/station the dialogs to specify patient data (see 14.7.1) therefore will be skipped. Instead the following information will display in the station's remote monitoring window.




Click on 'OK' to acknowledge the information and to close the respective station's remote monitoring window. In the V-CareNeT Control Window the respective 'Admit Patient' check box will be deselected thereafter.

Note: If you want to display/duplicate data from the same patient/SDM on multiple PCs we recommend using one V-CareNeT Central Station to remotely monitor the patient and to share the desktop of the PC with V-CareNeT by using remote desktop applications such as [Team Viewer](#) or [LogMeIn](#).

14.4 Starting-up V-CareNeT / V-CareNeT Main Screen

To start-up V-CareNeT

- click on the button 'V-CareNeT' in the center of the V-STATS Main Window if no measurement is open (see 4.1), or
- click on the  LAN -icon in the menu bar of the V-STATS Main Window (see 4.2.1), or
- select the sub-menu 'Communication / V-CareNeT' (see 8.2)

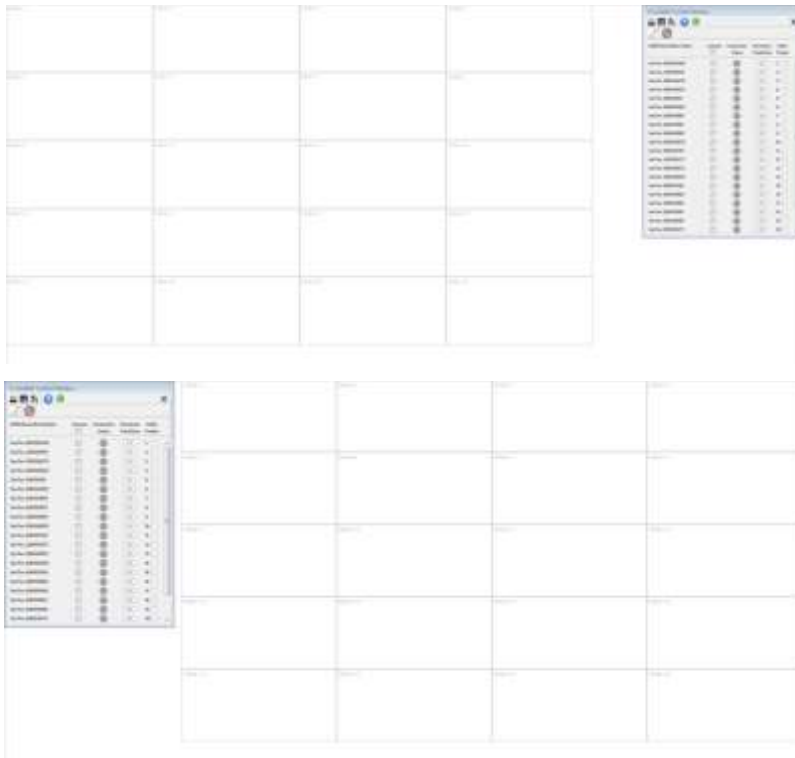
All these options will first open the dialog 'Last V-CareNeT Session' (see 14.4.1) which offers the possibility to edit/ reactivate the [last V-CareNeT session](#) and then activate the V-CareNeT Main Screen with the 'V-CareNeT Control Window' in the upper right or left (see 12.2).

Note: The dialog 'Last V-CareNeT Session' will only be skipped if no SDMs are included in V-CareNeT when starting-up V-CareNeT, i.e. a) when using V-CareNeT the first time, b) at first use after deactivating 'Device Discovery' (see 12.2, 14.3.2), or c) when during the last session all SDMs were removed from V-CareNeT in the dialog 'Edit SDM/Device Host Names' (see 14.5.1).

Note: Activating V-CareNeT when a measurement is open in the V-STATS Main Window will (after user confirmation) close the measurement and send the V-STATS Main Window to the background.

Note: Any of the three options mentioned above will bring the V-CareNeT Main Screen to the foreground.

Note: To activate V-CareNeT in Demo Mode please use the menu 'Settings / V-CareNeT Demo Mode' (see 12.3).



The V-CareNeT Main Screen displays the 'V-CareNeT Control Window' (see 14.5) optionally in the upper right or in the upper left corner (see 'V-CareNeT Settings' 12.2) and a grid of numbered cells defining the default position of each station's remote monitoring window (see 14.8.1).

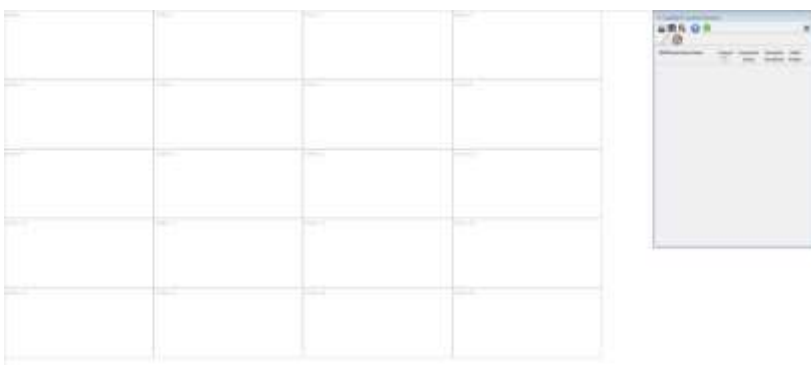
The cells are numbered from left to right and top to down. As indicated by the number next to the 'Admit Patient' Check boxes in the V-CareNeT Control Window, station 1 corresponds to the first SDM in the V-CareNeT Control Window, station 2 to the second SDM and so forth. The number of cells available corresponds to the maximal number of beds/stations supported in the current setup.

Note: If remote monitoring is active for a station the dialog title of the corresponding remote monitoring window (see 14.8.1) displays the station number <X> along with the respective SDM's Device/Host Name and – if specified in the dialog patient data (see 14.7.1, 14.7.2) – the location, i.e. '<X>: <Device/Host Name> - Location'.

Note: V-CareNeT adjusts the height of the V-CareNeT Control Window to ensure that all SDMs for which remote monitoring is possible are/will be visible in the V-CareNeT Control Window. Additional SDMs included in V-CareNeT (if any) can only be accessed by scrolling in the V-CareNeT Control Window. As for these SDMs remote monitoring cannot be initiated, no 'Admit Patient' check box is available for these SDMs in the V-CareNeT Control Window.

Important Note:
 V-CareNeT evaluates the size/resolution of the central station's screen and limits the number of bed/stations being simultaneously available for remote monitoring to ensure that the 'V-CareNeT Control Window' and all active stations (remote monitoring windows) are fully visible and can be arranged without overlapping each other. For remote monitoring of 40 beds/ patients a screen size/ resolution of approx. 2560 x 1440 is required (approx. 1024 x 768 for 5 beds/ patients, 1152 x 864 for 10 beds/ patients, 1600 x 1024 for 20 beds/ patients, 1920 x 1200 for 30 beds/ patients). Smaller screen sizes/resolutions will support fewer beds/patients regardless of the 'V-CareNeT Package Registration Code' that was used to activate/ upgrade the 'V-CareNeT Package'.

After starting up V-CareNeT the Main Screen of V-CareNeT can be in one of the following configurations:



No SDMs in the V-CareNeT Control Window / No active remote monitoring windows:

This configuration is active when no SDMs are included in V-CareNeT, i.e. a) when using V-CareNeT the first time, b) at first use after device discovery was disabled (see 12.2, 14.3.2), or c) if at the end of the last session no SDMs were included in V-CareNeT. To add SDMs to V-CareNeT refer to 14.5.1 and 14.5.1.1.



SDMs in the V-CareNeT Control Window / No active remote monitoring windows:

This configuration is active if no 'Admit Patient' box was selected in the dialog 'Last V-CareNeT Session' (see 14.4.1) before activating V-CareNeT.

To admit patients to V-CareNeT refer to 14.7.1. To add/ remove SDMs to/ from V-CareNeT refer to 14.5.1 and 14.5.1.1.



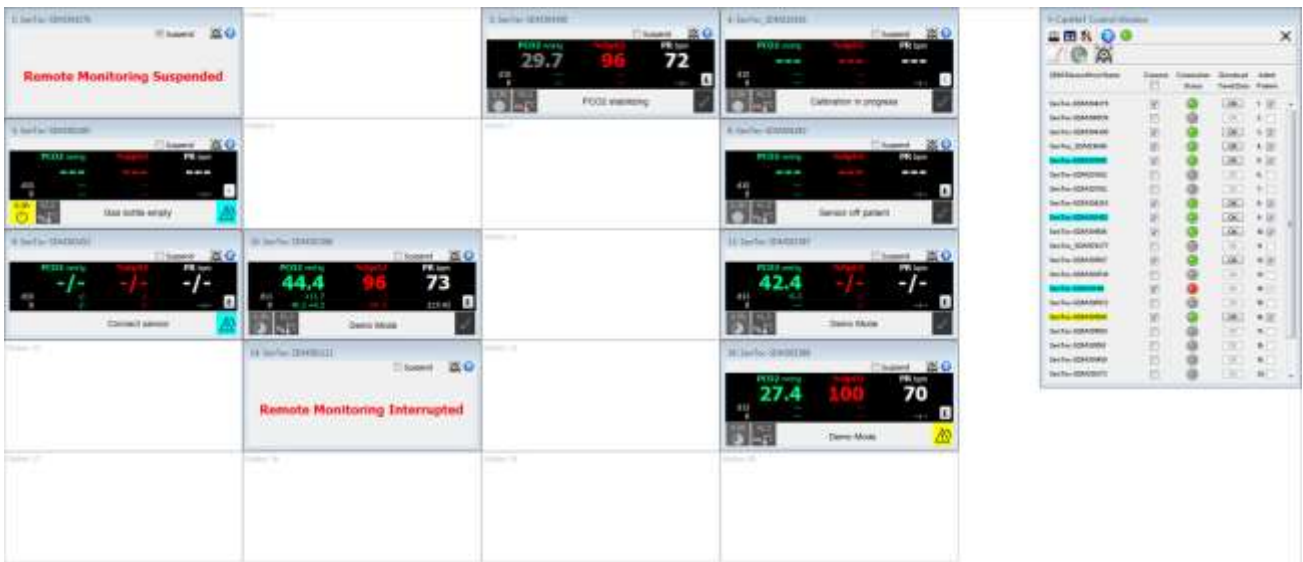
SDMs in the V-CareNeT Control Window / Active remote monitoring windows:

This configuration is active if at least one 'Admit Patient' box was selected in the dialog 'Last V-CareNeT Session' (see 14.4.1) before activating V-CareNeT.

To admit/ discharge patients to/ from V-CareNeT refer to 14.7.1 and 14.7.5. To add/ remove SDMs to/ from V-CareNeT refer to 14.5.1 and 14.5.1.1.

Please refer to 14.5 for a description of the V-CareNeT Control Window and to 14.8.1 for a description of the individual remote monitoring windows (stations).

The next figure shows an example with active remote monitoring for multiple SDMs. For station 1 remote monitoring is suspended, for station 14 remote monitoring is interrupted, for station 3 remote monitoring is active for a real patient, in case of stations 4 ("Ready for use") and 5 ("Gas bottle empty") the sensor is in the Docking Station, in case of station 8 the sensor is off patient and in case of station 9 no sensor is connected to the corresponding SDM. The SDMs corresponding to stations 10, 12, and 16, finally, are operated in Demo Mode.



Note: In standard configuration the position of the remote monitoring windows and the V-CareNeT Control Window is fixed. If you want to have the possibility to customize the windows positions with the mouse, select the check box 'Remote Monitoring Windows moveable' in the dialog 'V-CareNeT Settings' (see 12.2). In this case it is at any time possible to arrange all remote monitoring windows in their default positions by clicking on the 'Arrange Windows' icon in the 'V-CareNeT Control Window' or by unselecting the check box 'Remote Monitoring Windows moveable'.

14.4.1 Last V-CareNeT Session

The dialog 'Last V-CareNeT Session' provides an 'at-a-glance-summary' of the last V-CareNeT session when starting up V-CareNeT (see 14.4). As described below, the configuration of the last V-CareNeT session can be edited/ modified, before activating the V-CareNeT Main Screen. Among other, it is possible to admit/ discharge patients, to assign to a patient to another station, or to edit data of already included patients.

Note: When starting up V-CareNeT the dialog 'Last V-CareNeT Session' will only be skipped if no SDMs are included in V-CareNeT, i.e. a) when using V-CareNeT the first time, b) at first use after deactivating 'Device Discovery' (see 12.2, 14.3.2), or c) when during the last session all SDMs were removed from V-CareNeT in the dialog 'Edit SDM/Device Host Names' (see 14.5.1).

Edit / Reactivate last V-CareNeT Session				(to edit double-click on respective line)		
Station	SDM Device/Host Name	Connect	Admit Patient	Last Name, First Name	Patient Number	Location
1	SenTec-SDM304279	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Bond, James	P 13455	Bed 1
2	SenTec_SDM210416	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
3	SenTec-SDM301587	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Muster, Jürg	P 45677	Bed 8
4	SenTec-SDM301588	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Ravel, Maurice	P 88123	Bed 3
5	SenTec-SDM301585	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Wayne, John	P 14812	
6	SenTec-SDM201302	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
7	SenTec-SDM307912	<input type="checkbox"/>	<input type="checkbox"/>			
8	SenTec-SDM302530	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Brandt, Dave	P 98421	Bed 7
9	SenTec-SDM301586	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Meier, Kurt	P 72845	Bed 6
10	SenTec-SDM304283	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Weber, Angelika	P 83452	Bed 15
11	SenTec-SDM300572	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
12	SenTec-SDM304300	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Hoffmann, Fritz	P 99223	Bed 5
13	SenTec-SDM210373	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
14	SenTec-SDM302453	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Mahler, Peter	P 12334	Bed 2
15	SenTec-SDM301112	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
16	SenTec-SDM301589	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Lehmann, Maria	P 77622	Bed 16
17	SenTec-SDM301581	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
18	SenTec-SDM301458	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
19	SenTec-SDM301462	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
20	SenTec-SDM300517	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
21	SenTec-SDM300535	<input type="checkbox"/>	<input type="checkbox"/>			
22	SenTec_SDM178277	<input type="checkbox"/>	<input type="checkbox"/>			
23	SenTec-SDM302481	<input type="checkbox"/>	<input type="checkbox"/>			

Arrange Windows

In the upper part of the dialog window, the configuration of the last V-CareNeT session is summarized in the following seven columns:

Column 1 – Station: provides the station numbers.

Column 2 – SDM Device/Host Name: provides for each station the SDM Device/Host Name of the SDM assigned to this station in the V-CareNeT Control Window at the end of the last V-CareNeT session.

Note: The SDM-to-station assignment cannot be changed in the dialog 'Last V-CareNeT Session'. This is only possible in the password protected dialog 'Edit SDM Device/Host Names' (see 14.5.1) when V-CareNeT is being executed.

Column 3 – Connect: indicates for each station the status of the 'Connect' check box in the V-CareNeT Control Window at the end of the last V-CareNeT session. It is possible to change the status of the 'Connect' check boxes with the mouse.

Note: Deselecting a 'Connect' check box will also deselect the corresponding 'Admit Patient' check box (if selected).

Note: Selecting the checkbox above the column 'Connect' will select all stations/SDMs in the list.

Column 4 – Admit Patient: indicates for each station the status of the 'Admit Patient' check box in the V-CareNeT Control Window at the end of the last V-CareNeT session. It is possible to change the status of the 'Admit Patient' check boxes with

the mouse.

Note: The 'Admit Patient' check box is unselected and dimmed grey (not selectable) if the corresponding 'Connect' check box is not selected.

Note: Selecting the checkbox above the column 'Admit Patient' will select all stations/SDMs in the list.

Columns 5, 6 and 7 – Last Admitted Patient: indicates for each station the last/ first name (column 5), the patient number (column 6), and the location (column 7) of the patient that was admitted to the respective station at the end of the last V-CareNeT session. To enable access/edit/view patient data double-click on the respective line to open the dialog '<X>: <Device/Host Name> - Patient Data' (also see 14.7.1, 14.7.2):

Click on 'OK' to store changes and close the dialog, click on 'New Patient' to clear all text fields (i.e. to clear the data of the last admitted patient). Click on 'Assign another station/SDM' to assign the current patient to a different station/SDM (see 14.7.4). Click on 'Discharge Patient' to discharge the patient (see 14.7.5), i.e. to deselect the 'Admit Patient' check box in the dialog 'Last V-CareNeT Session' (see 14.7.5). Click on 'Cancel' to close this dialog without applying changes.

Check-box 'Activate personal data' (applies only to Installation for Advanced Data Protection): If this box is checked, the access to enter patient information is enabled.

Note: Patient information is only available in remote monitoring windows if the responsible institution enables the access. Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.

Note: It is possible to edit patient data irrespective of the status of the corresponding station's 'Connect' and 'Admit Patient' check boxes. The button 'Discharge Patient' is dimmed grey, if for the corresponding station the check box 'Admit Patient' is not selected in the dialog 'Last V-CareNeT Session'. The button 'Assign another station/SDM' is dimmed grey, if all patient data fields are empty (i.e. as long/ if no patient data are specified).

In the lower part of the dialog 'Last V-CareNeT Session' the following functions are provided:

Check-box 'Arrange Windows': If this box is checked, the V-CareNeT Control Window (see 14.5) and all remote monitoring windows will be arranged in their default positions in the V-CareNeT Main Screen after starting up V-CareNeT (see 14.4). If this box is un-checked, V-CareNeT will - after starting up V-CareNeT - restore the customized windows arrangement used during the last V-CareNeT session.

Note: As long the function 'Arrange Windows' is not activated/ executed (be it when starting up V-CareNeT or by clicking on the 'Arrange Windows' icon in the V-CareNeT Control Window if V-CareNeT is being executed), all windows - even those that are currently not displayed/ active - will maintain their customized position.

Note: The box 'Arrange Windows' is only operable (not dimmed grey), if at least for one station that has not been arranged in the default positions at the end of the last V-CareNeT session, the 'Admit Patient' box is selected in the dialog 'Last V-CareNeT Session'.

Note: If at least one station will not be arranged in default position after starting up V-CareNeT (box 'Arrange Windows' operable and not selected) and if you added at least one additional station to your new session, the following message will display when clicking on the 'OK' button in the dialog 'Last V-CareNeT Session': 'You added stations to your new session that were not active during the last session. As a result, station windows may overlap. Do you want to continue? (YES | Cancel)'. Click on 'Cancel' to return to the dialog 'Last V-CareNeT Session', click on 'Yes' to proceed.

Note: In order to be able to move the V-CareNeT Control Window/ the remote monitoring windows in the V-CareNeT Main Screen the checkbox 'Remote Monitoring Windows moveable' must be selected in the dialog 'V-CareNeT Settings' (see 12.2).

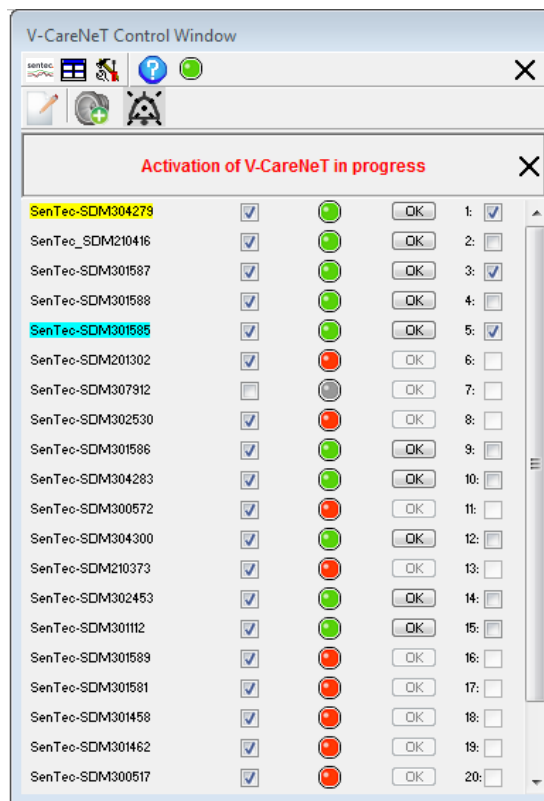
A click on the button 'Clear' will (after user confirmation) deselect all 'Connect' and 'Admit Patient' check boxes and delete the patient data for all stations.

A click on the button 'Restore' rejects all changes made since opening the dialog 'Last V-CareNeT Session', i.e. the configuration of the last V-CareNeT session is restored.

A click on the button 'Cancel' closes the dialog 'Last V-CareNeT Session' without storing changes and aborts startup of V-CareNeT.

A click on the button 'OK' stores the changes (if any) and activates V-CareNeT according the selection in the dialog 'Last V-CareNeT Session'. Activation of V-CareNeT is done in the following sequence:

- The dialog 'Speaker Test' opens (see 14.9.3) if at least one 'Admit Patient' check box was selected.
- Confirm the 'Speaker Test' as requested.
- The V-CareNeT Main Screen opens:
 - The 'Connect' check boxes that have been selected in the dialog 'Last V-CareNeT Session' are immediately selected in the V-CareNeT Control Window and V-CareNeT attempts to establish connection to the respective SDMs.
 - The 'Admit Patient' check boxes that have been selected in the dialog 'Last V-CareNeT Session' are processed one by one (approx. 1 check box per second), i.e. the corresponding remote monitoring window open one by one. During this time the message 'Activation of V-CareNeT in progress' displays in the top area of V-CareNeT Control Window.

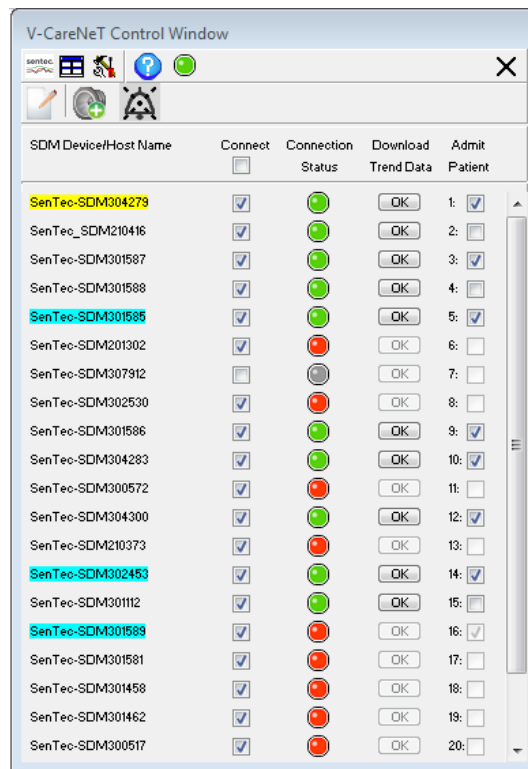


Note: Click on the cross nearby the message 'Activation of V-CareNeT in progress' to abort further activation of V-CareNeT or if activation of V-CareNeT cannot be completed due to a technical problem.





14.5 V-CareNeT Control Window





The 'V-CareNeT Control Window' is the main (control) window of V-CareNeT. It contains a list of 'SDM Device/Host Names' (see 13.2.4.5), each representing/identifying a SDM in the V-CareNeT System. If the 'Connect' check box is selected for a 'SDM Device/Host Name' V-CareNeT tries to establish communication with the respective SDM via the network. For each 'SDM Device/Host Name' a 'Connection Status Indicator' indicates the connection status. If the connection is established with a SDM the respective 'Connection Status Indicator' lights green (good quality connection) or yellow (poor quality connection) and it is possible to download Trend Data from the internal memory of the respective SDM (see 14.6).

For each SDM for which connection is established it furthermore is possible to admit a patient to the V-CareNeT System for remote monitoring and alarm surveillance (see 14.7).



The 'V-CareNeT Control Window' contains the following elements:

Element	Description
	<p>Icon: V-STATS Main Window</p> <p>Click this Icon to bring the V-STATS Main Window to the foreground, thereby enabling operator access to sub-menus and functions that are only accessible via the V-STATS Main Window.</p> <p><i>Note:</i> If at least one patient is admitted to the V-CareNeT System, the alert-dialog 'Remote Monitoring active' opens when clicking this icon. In this case the V-STATS Main Window will come to the foreground only after confirmation of this dialog.</p> <p><i>Note:</i> If an alarm condition occurs on a remotely monitored SDM while the V-STATS Main Window is in the foreground the following alert-dialog will be triggered:</p> <div data-bbox="687 1431 1123 1608" style="border: 1px solid gray; padding: 5px; text-align: center;"> <p>Remote Monitoring Alarm active!</p> <p>Please return to V-CareNeT to view the alarm!</p> <p></p> </div> <p>Click on OK closes this alert-dialog for two minutes where after it reactivates should the/another remote monitoring alarm condition be present. It closes automatically as soon as no remote monitoring alarm condition is present.</p>
	<p>Icon: Arrange Windows</p> <p>Click this Icon to arrange the 'V-CareNeT Control Window' in the upper right or left of the screen (see 12.2) and all open remote monitoring windows in their default positions in the V-CareNeT Main Screen (see 14.4).</p> <p><i>Note:</i> As long the function 'Arrange Windows' is not activated/ executed (be it when starting up V-CareNeT (see 14.4.1) or by clicking on the 'Arrange Windows' Icon in the V-CareNeT Control Window if V-CareNeT is being executed), all windows – even those that are currently not displayed/ active - will maintain their customized position.</p>
	<p>Icon: V-CareNeT Settings</p>

Element	Description	
	A click on this Icon activates a password-dialog and – after having successfully entered the password – the dialog ‘V-CareNeT Settings’ (see 12.2). Please refer to 12.2 for information regarding the password. <i>Note: To restore default V-CareNeT Settings use the function ‘V-STATS Factory Reset’ which is provided in the password protected dialog ‘V-STATS Settings’ (see 12.1).</i>	
	Icon: Help Click this Icon to open the context-sensitive on-line help.	
Remaining Trial time	When V-CareNeT is running (open) during a ‘V-CareNeT Trial’ (see 15.3) or an ‘Extended V-CareNeT Trial’ (see 15.4) the remaining trial time is indicated on the right of the ‘Close V-CareNeT’ Icon in blue bold font.	
	Software Activity Indicator This indicator is blinking with 0.5 Hz (65% duty), indicating that the V-CareNeT software is active.	
Technical Alarms AUDIO OFF Indicator <i>(displayed next to the ‘Help’ icon, if activated)</i>	Message	Description / Function
	AUDIO OFF Techn. Alarms SDMs	At the V-CareNeT Central Station auditory alarm signals being related to technical alarm conditions occurring at SDMs with admitted patients are permanently switched off / inhibited . Settings can be adjusted in the dialog ‘V-CareNeT Settings’ (see 12.2). <i>Note: Auditory alarm signals being related to physiological alarm conditions (alarm limit violations of PCO₂, PO₂, SpO₂, or PR) occurring at SDMs with admitted patients continue to be audible at the V-CareNeT Central Station.</i> <i>Note: The SDMs auditory alarm signals are not affected by this setting.</i>
	AUDIO OFF Techn. Alarms CS	At the V-CareNeT Central Station auditory alarm signals being related to technical alarm conditions occurring at the central station itself are permanently switched off / inhibited . Settings can be adjusted in the dialog ‘V-CareNeT Settings’ (see 12.2). <i>Note: The ‘Remote Monitoring Interrupted’ alarm condition (see 14.8.1 and 14.10) is currently the only alarm condition that is evaluated by the V-CareNeT Central Station.</i>
	AUDIO OFF Techn. Alarms	All technical alarms on the monitored SDMs and on the V-CareNeT Central Station are switched OFF. Settings can be adjusted in the dialog ‘V-CareNeT Settings’ (see 12.2).
	Icon: Close V-CareNeT Click this Icon to close/terminate V-CareNeT. The V-STATS Main Window will come to the foreground. <i>Note: Clicking this icon while patients are admitted to the V-CareNeT System displays the alert dialog ‘Discharge All Patients’ (see 14.7.5). In this case V-CareNeT will close/terminate after confirmation of the discharge request.</i> <i>Note: Clicking this icon while the V-CareNeT Demo Mode is enabled, will terminate/disable V-CareNeT Demo Mode.</i>	
	Icon: Edit SDM Device/Host Names Click on this Icon activates a password-dialog and – after having successfully entered the password - the dialog ‘Edit SDM Device/Host Names’ (see 14.5.1) where it is possible to add or remove SDMs to/from V-CareNeT and to adjust the order of the ‘SDM Device/Host Names’ in the respective column of the V-CareNeT Control Window. <i>Note: The default password is the ‘V-CareNeT Package Registration Code’, which after activation/upgrade of the V-CareNeT Package is displayed in the dialog ‘Product-Info’ (see 16.6). The password can be changed in the dialog ‘Change Password’. In case you have forgotten your password enter the Password Unlock Key ‘RememberPassword’ in the field ‘Current Password’ and select a new password.</i> <i>Note: During a ‘V-CareNeT Trial’ and an ‘Extended V-CareNeT Trial’ the default password to open the dialog ‘Edit SDM Device/Host Names’ is ‘Trial’.</i> <i>Note: The password to open the dialog ‘Edit SDM Device/Host Names’ is the same password that is required to open the dialog ‘V-CareNeT Settings’ (see 12.2).</i> <i>Note: In V-CareNeT Demo Mode this Icon is hidden/not available.</i>	
Speaker Test	Icon	Description / Function

Element	Description			
Icon		Speaker Test Required: This Icon displays if the PC's speaker was <u>not confirmed</u> to be functional/audible or if the 'Interval for automatic Speaker Test' has elapsed. A click on this icon activates the 'Speaker Test' (see 14.9.3).		
		Speaker Test Confirmed: This icon displays if the PC's speaker was <u>confirmed</u> to be functional/audible. A click on this icon activates the 'Speaker Test' (see 14.9.3).		
AUDIO Icon and AUDIO Message	<i>Note: The AUDIO Icon and the AUDIO Status Message only display if at least one patient is admitted to the V-CareNeT System.</i>			
	Icon	Message	Speaker Test	Description / Function
		none	 (confirmed)	Auditory alarm signals of V-CareNeT active. Click this icon to pause auditory alarm signals for 120 seconds.
		AUDIO PAUSED xxx	 (confirmed)	Auditory alarm signals of V-CareNeT paused (xxx indicates remaining pause time in seconds). Click this icon to permanently switch off auditory alarm signals.
		AUDIO OFF	 (confirmed)	Auditory alarm signals of V-CareNeT permanently switched-off; 'AUDO OFF Reminder' ON (can be switched OFF in the dialog 'V-CareNeT Settings' (see 12.2)). Click this icon to re-enable auditory alarm signals (only if 'Speaker Test' is <u>confirmed</u>).
			 (required)	Auditory alarm signals of V-CareNeT permanently switched-off; Clicking this icon has no function if the 'Speaker Test' is <u>required</u> . <i>Note: If the 'Speaker Test' is required (see 14.9.3) V-CareNeT's auditory signals, including the 'AUDIO OFF Reminder', are disabled.</i>
Message over column headers	The message ' Activation of V-CareNeT in progress ' displays over the column header area while activation of V-CareNeT is in progress (see 14.4.1). <i>Note: Click on the cross nearby the message 'Activation of V-CareNeT in progress' to abort further activation of the V-CareNeT or if activation of the V-CareNeT cannot be completed due to a technical problem.</i>			
'SDM Device/Host Name' column	This column displays for each SDM currently included in the V-CareNeT System its 'SDM Device/Host Names' (see 13.2.4.5). <i>Note: It is possible that instead of the 'SDM Device/Host Name' the IP Address/IP Port of a SDM is displayed in this list. This is the case if V-CareNeT could not yet successfully contact this SDM after adding it to V-CareNeT by entering its IP Address/IP Port in the dialog 'Add SDM to V-CareNeT' (see 14.5.1.1). Once V-CareNeT could successfully contact this SDM the IP Address/IP Port will be replaced by the 'SDM Device/Host Name'.</i> <i>Note: After starting-up V-CareNeT this column in most cases will display the same configuration as during last use (see 14.4, 14.4.1).</i> <i>Note: To add or remove SDMs to/from V-CareNeT or to adjust the order of the elements in this list click on the 'Edit SDM Device/Host Names Icon' (see above) to open the dialog 'Edit SDM Device/Host Names' (see 14.5.1). It is possible to include up to 40 SDMs in V-CareNeT.</i> <i>Note: SDMs displayed in the 'SDM Device/Host Name' column currently may not be available in the network to which the PC is connected. If this is the case, the Connection Status Indicator will light red if the 'Connect' check box of the respective SDM is selected.</i> <i>Note: If an alarm is active on a SDM during remote monitoring the respective 'SDM Device/Host Name' highlights red (for a high priority alarm), yellow (for a medium priority alarm) or cyan (for a low priority alarm). If remote monitoring is interrupted (see 14.10) the respective 'SDM Device/Host Name' highlights cyan.</i> <i>Note: To avoid potential mistake of SDMs/patients V-CareNeT continuously monitors the 'SDM Device/Host Names' of all SDMs currently listed in the V-CareNeT Control Window. Should V-CareNeT detect any irregularities (e.g. two or more identical 'SDM Device/Host Names') V-CareNeT will trigger an appropriate warning and – after user acknowledgement – take the necessary action to resolve the issue (e.g. removing SDMs with identical 'SDM Device/Host Names' from V-CareNeT). For details please refer to 14.3.4.</i>			

Element	Description
	<p><i>Note: V-CareNeT continuously monitors the software version of all SDMs included in V-CareNeT. Should V-CareNeT detect SDMs with a software version prior to SMB SW- VO7.01.x (see 3.1), V-CareNeT will trigger an appropriate warning and remove these SDMs from V-CareNeT.</i></p>
'Check boxes' in the 'Connect' column	<p>Select the 'Connect' check box next to a 'SDM Device/Host Name' to establish connection to the respective SDM via the network.</p> <p>De-selecting the 'Connect' check box interrupts the connection with the respective SDM, and closes all V-CareNeT related windows for the respective SDM/station.</p> <p>If a patient is admitted for the respective SDM the alert dialog 'Discharge Patient(s)' displays when de-selecting the 'Connect' check box. Pressing the 'OK' button in the dialog 'Discharge Patient(s)' discharges the patient from the V-CareNeT System, deselects the respective 'Admit Patient' check box and closes all windows related to this patient (see 14.7.5).</p> <p><i>Note: If during start-up of V-CareNeT all 'Connect' check boxes were de-selected in the dialog 'Last V-CareNeT Session' (see 14.4, 14.4.1), not any 'Connect' check box will be selected after startup of V-CareNeT.</i></p> <p><i>Note: When adding a SDM to V-CareNeT the 'Connect' check box of the respective SDM will not be selected after closing the dialog 'Edit SDM/Device Host Names' (see 14.5.1).</i></p> <p><i>Note: Selecting (de-selecting) the check box in the heading-line selects (de-selects) the check boxes of all devices. If patients are admitted the alert dialog 'Discharge All Patients' displays when de-selecting all 'Connect' check boxes (see 14.7.5).</i></p> <p><i>Note: Interruption of the communication between V-CareNeT and a SDM does not change the status of the respective 'Connect' check box (see 14.10).</i></p>
'Connection Status Indicators' in the 'Connection Status' column	<p>V-CareNeT continuously monitors data integrity and connection/network quality between the V-CareNeT Central Station and each individual SDM being connected (see 14.3.3).</p> <p>For each SDM listed in the 'SDM Device/Host Name' column a 'Connection Status' indicator shows the status/quality of the connection between the central station and the respective SDM. It lights</p> <ul style="list-style-type: none"> – grey (●) if the corresponding ,Connect' check box is <u>not selected</u>. – red (●) if the corresponding ,Connect' check box is <u>selected</u> but connection (with sufficient quality) cannot be established with the respective SDM or is interrupted. If this is the case the dialog 'No communication with at least one SDM' (see 14.10) will display. – yellow (●) if the corresponding ,Connect' check box is <u>selected</u> and a <u>poor</u> quality connection with the respective SDM is established. – green (●) if the corresponding ,Connect' check box is <u>selected</u> and a <u>good</u> quality connection with the respective SDM is established. <p><i>Note: If the option 'Network diagnostics' is selected in the dialog 'V-CareNeT Settings' (see 12.2) a tool tip providing quantitative information on the Network Quality displays if the mouse is placed over the 'Connection Status Indicator' (see 14.3.3).</i></p>
'OK' Buttons in the 'Download Trend Data' column	<p>To download SDM Trend Data from a SDM via the network click on the corresponding 'OK' button. The dialog '<x>:<SDM Device/Host Name>- Assign measurement period(s) to patients' (see 6.1) will open. Here <X> represents the station number. In this dialog all measurement periods stored in the internal memory of the respective SDM <u>that are longer</u> than the current setting of the SDM's internal parameter 'Minimal Measurement Duration' are listed. As described in 6.1 the selected measurement period(s) therein can be assigned to a patient and then be downloaded, analyzed and displayed in the V-STATS Main Window. For details please refer to 14.6.</p> <p><i>Note: Download of SDM Trend Data via V-CareNeT is simultaneously possible for multiple SDMs. An ongoing (not terminated) measurement can <u>only</u> be downloaded via V-CareNeT (see 14.6); it cannot be downloaded via the Serial Interface.</i></p> <p><i>Note: While SDM Trend Data are downloaded via the LAN interface the serial interface of the SDM cannot be used for another SDM Trend Data download. Other serial data access works normally.</i></p> <p><i>Note: On the SDM the current setting of the SDM internal parameter 'Minimal Measurement Duration' is displayed in the menu 'Trend Data'. When initiating download of SDM Trend Data from the internal memory it also is displayed in the dialog 'Assign measurement period(s) to patients' (see 6.1). It only can be changed by the Responsible Organization by using V-STATS (see 13.2.4.6).</i></p> <p><i>Note: The 'OK' button of a SDM included in V-CareNeT is dimmed grey (not accessible) a) if connection with this SDM is not established or interrupted (corresponding 'Connection Status Indicator' lights grey or red), b) if download of SDM Trend Data via the network is already in progress for this SDM, or c) if download of SDM Trend Data via the network is already simultaneously in progress for 40 SDMs.</i></p>

Element	Description
	<i>Note: Download of SDM Trend Data via V-CareNeT is not supported during a 'V-CareNeT Trial' (see 15.3) or if the 'V-CareNeT Demo Mode' (see 12.3) is active.</i>
'Check boxes' in 'Admit Patient' column	<p>Selecting the 'Admit Patient' check box corresponding to a SDM first activates two dialogs to specify patient data (see 14.7.1) and then activates remote monitoring for the respective patient/SDM. For the admitted patient/respective SDM real-time data subsequently are displayed in the station's remote monitoring window, i.e. in the dialog '<X> - <Device/Host Name>:<Location>' (see 14.8). Here <X> represents the station number.</p> <p>De-selecting the 'Admit Patient' check box for a SDM displays the alert-dialog 'Discharge Patient(s)'. Pressing the 'OK' button in the dialog 'Discharge Patient(s)' discharges the patient from the V-CareNeT System and closes all windows related to this patient (see 14.7.5).</p> <p><i>Note: The number next to the 'Admit Patient' check box represents the station/cell number in which the data for the respective SDM will be displayed.</i></p> <p><i>Note: The 'Admit Patient' check box associated to a SDM is not accessible (dimmed grey) if connection with the respective SDM is not established or interrupted. If selected, interruption of the connection dims but does not de-select the respective 'Admit Patient' check box.</i></p> <p><i>Note: If the 'Speaker Test' is required when admitting the first patient to the V-CareNeT System the dialog 'Speaker Test' (see 14.9.3) will display after the two above mentioned dialogs which permit to specify patient data and before activating remote monitoring for the first patient.</i></p> <p><i>Note: Admitting a patient to a SDM that is locked by another V-CareNeT Central Station is not possible. If selecting the 'Admit Patient' check box of a locked SDM, the two above mentioned dialogs to specify patient data, therefore, will be skipped. Instead corresponding information will display in the station's remote monitoring window (see 14.3.5).</i></p> <p><i>Note: By taking account a) of the number of beds/patients included in the 'V-CareNeT Package Registration Code' that was used to activate/ upgrade the 'V-CareNeT Package' (15.2) and b) of the current size/resolution of the central station's screen, V-CareNeT evaluates the number of beds/patients being simultaneously available for remote monitoring. In the V-CareNeT Control Window 'Admit Patient' check boxes, consequently, are available only for the corresponding number of SDMs. If for a SDM for which you want to activate 'Remote Monitoring' no 'Admit Patient' check box is available, you must – by using the dialog 'Edit SDM Device/Host Names' (see 14.5.1) - move the respective SDM upwards in the list of 'SDM Device/Host Names'. If your V-CareNeT setup does not support the required number of beds/patients you must consider to increase the size/resolution of the central station's screen and/or to (further) upgrade V-CareNeT to a higher number of beds/ patients (see 16.6.1).</i></p>

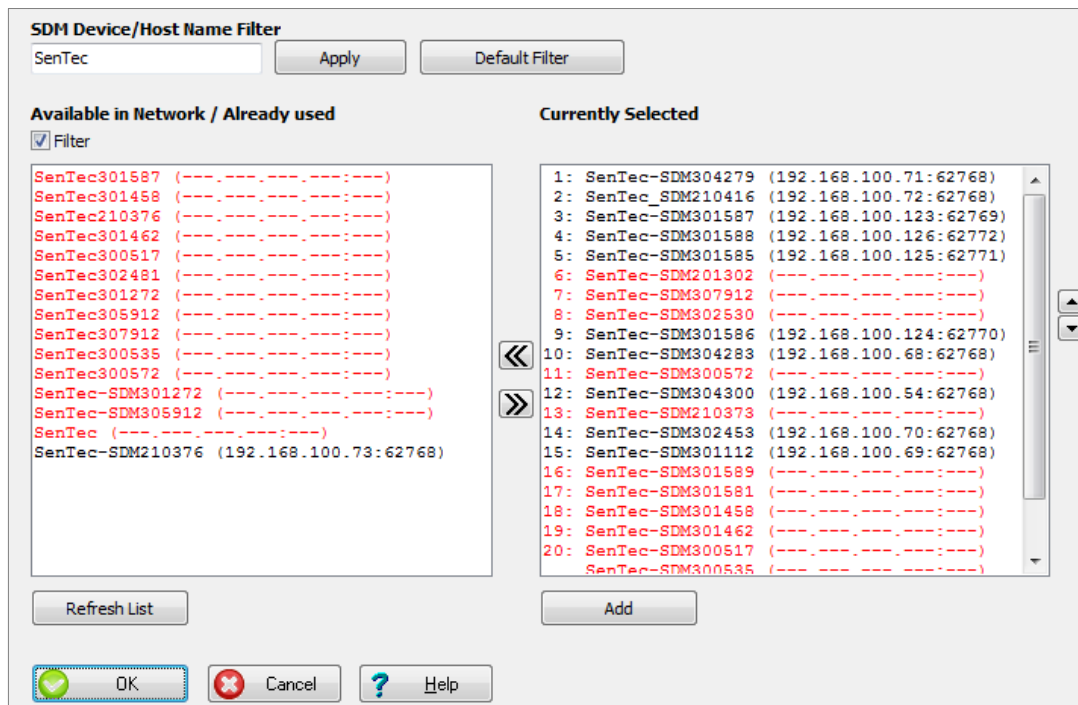
14.5.1 Dialog 'Edit SDM Device/Host Names'

A click on the 'Edit SDM Device/Host Names' Icon in the dialog 'V-CareNeT Control Window' (see 14.5) opens a password-dialog and – after having successfully entered the password - the dialog 'Edit Device/Host Names'. In this dialog it is possible to add or remove SDMs to/from V-CareNeT and to adjust the order of the 'SDM Device/Host Names' in the respective column of the V-CareNeT Control Window (see 14.5).

Note: The default password is the 'V-CareNeT Package Registration Code', which after activation/ upgrade of the V-CareNeT Package is displayed in the dialog 'Product-Info' (see 16.6). The password can be changed in the dialog 'Change Password'. In case you have forgotten your password enter the Password Unlock Key 'RememberPassword' in the field 'Current Password' and select a new password.

Note: During a 'V-CareNeT Trial' and an 'Extended V-CareNeT Trial' the default password to open the dialog 'Edit SDM Device/Host Names' is 'Trial'.

Note: The password to open the dialog 'Edit SDM Device/Host Names' is the same password that is required to open the dialog 'V-CareNeT Settings' (see 12.2).



Important Note: Within V-CareNeT a SDM is unequivocally identified by its 'SDM Device/Host Name' and its 'IP Address/IP Port'. The dialog 'Edit SDM Device/Host Names', therefore, displays for the respective SDMs whenever possible the 'SDM Device/Host Name' followed by the 'IP Address/IP Port' in parenthesis (syntax <SDM Device/Host Name> (<IP Address>:<IP Port>)). If SDMs were added to V-CareNeT by entering the 'SDM Device/Host Name' or the 'IP Address/IP Port' in the dialog 'Add SDM to V-CareNeT' (see 14.5.1.1) only the entered information will be available as long no connection has been established with the corresponding SDM. In this case '<SDM Device/Host Name> (---.---.---.---:---)' or '*<IP Address>:<IP Port>*' will display.

Note: On the SDM the settings of the parameters 'Device/Host name', 'DHCP Mode', 'IP Address', 'IP Port', and 'Ethernet Mode' as well as the SDM's 'MAC Address' are displayed in the sub-menu 'Interfaces / LAN Interface'. By using V-STATS within a password protected area the Responsible Organization can define for each SDM the 'Device / Hostname', the 'DHCP Mode', the 'IP Address', the 'IP Port', and the 'Ethernet Mode' (see 13.2.4.5).

The two lists of the dialog 'Edit SDM Device/Host Names' display all SDMs that

- are currently included in V-CareNeT and/or
- previously have been included in V-CareNeT and/or
- are currently contactable in the network by automatic device discovery (if enabled, see 12.2, 14.3.2)

In these two lists SDMs currently contactable in the network by automatic device discovery (if enabled) and/or by using their 'IP Address/IP Port' or 'SDM Device/Host Name' are displayed in **black**, whereas SDMs that are currently not contactable in the network are displayed in **red**. SDMs with a software version prior to SMB SW-VO7.03.x (see 3.1)) are displayed in **blue**.

The list 'Available in Network / Already Used' (on the left) displays all SDMs that are currently not included in V-CareNeT but either are contactable in the network and/or previously had been included to V-CareNeT. To remove all SDMs currently not being contactable in the network (i.e. displayed in red font) click on the button 'Refresh List'.

If the check box 'Filter' is selected, the list 'Available in Network / Already used' is filtered to only display SDMs whose 'SDM Device/Host Name' starts with the 'Filter String' specified in the respective text entry field in the top left of the dialog 'Edit SDM Device/Host Names'. To view only SDMs in the list whose 'SDM Device/Host Names' start with a different string, modify the 'Filter String' accordingly and then press the ENTER key or click on the button 'Apply'. Uncheck the box 'Filter' to view all SDMs available in the list.

Note: In default settings the check box 'Filter' is selected.

Note: As the default 'SDM Device/Host Names' of SDMs starts with 'Sentec' (see 13.2.4.5) the default 'Filter String' is 'Sentec'. If the 'Filter String' is modified click on the button 'Default Filter' to restore the default 'Filter String'.

Note: When opening the dialog 'Edit SDM Device/Host Names' the 'Filter String' from previous use is active.

The list 'Currently Selected' displays the 'SDM Device/Host Names' of all SDMs currently included in V-CareNeT. After

opening the dialog 'Edit SDM Device/Host Names' this list is identical with the list of 'SDM Device/Host Names' in the respective column of the 'V-CareNeT Control Window'.

Note: By taking account a) of the number of beds/patients included in the 'V-CareNeT Package Registration Code' that was used to activate/ upgrade the 'V-CareNeT Package' (15.2) and b) of the current size/resolution of the central station's screen, V-CareNeT evaluates the number of beds/patients being simultaneously available for remote monitoring. In the V-CareNeT Control Window 'Admit Patient' check boxes, consequently, are available only for the corresponding number of SDMs. The top positions of the list 'Currently Selected' therefore are numbered on the left indicating that for those devices an 'Admit Patient' check box will be available in the dialog 'V-CareNeT Control Window'. The number represents the station/cell number in which the data for the respective SDM will be displayed.

To **rearrange the order** of the SDMs in the list 'Currently Selected', select a SDM with the left mouse and then move it upwards or downwards by clicking the Up (▲) or Down (▼) button, respectively.

To **remove a SDM from V-CareNeT** (i.e. remove the corresponding element from the list 'Currently Selected'), select it with the left mouse and then remove it by clicking the [<] button. The removed SDM will be added to the list 'Available in Network / Already Used'. To **add a SDM to V-CareNeT** (i.e. add the corresponding element to the list 'Currently Selected') select it with the left mouse in the list 'Available in Network / Already Used' and then add it by clicking the [>] button. If the SDM you want to add to V-CareNeT is not available in the (unfiltered) list 'Available in Network / Already Used' it is possible to add it manually. In this case click on the button 'Add' to open the dialog 'Add SDM to V-CareNeT' (see 14.5.1.1). In this dialog it is possible to enter either the 'SDM Device/Host Name' or the IP Address/IP Port of the SDM to be added to V-CareNeT.

Note: To add or remove multiple SDMs simultaneously to/from V-CareNeT selection of multiple list elements is possible by pressing the <Shift> or <CTRL> key while selecting the elements with the left mouse. By pressing the combination <CTRL> <A> all SDMs in the list are selected.

Note: After adding a SDM to the list 'Currently Selected' it may be required to move the respective list item upwards to a position which is numbered on the left, if you subsequently want to admit patients to this SDM.

Note: When removing a SDM from V-CareNeT if the check box 'Filter' is selected the removed SDM will only be visible in the list 'Available in Network / Already Used' if the beginning of its 'SDM Device/Host Name' matches the 'Filter String'.

Note: It is possible to add up to 40 SDMs to V-CareNeT. Consequently, the following alert dialog will prompt if you attempt to add more than 40 SDMs to the list 'Currently selected': 'Maximal possible number of devices reached (OK)'. A click on the button 'OK' will close this alert dialog without (after clicking on the [>] button) adding a SDM to the list 'Currently Selected' or without (after clicking on the button 'Add') opening the dialog 'Add SDM to V-CareNeT' (see 14.5.1.1).

Note: To avoid potential mistake of SDMs/patients V-CareNeT continuously monitors the 'SDM Device/Host Names' and the 'IP Address/IP Port' of all SDMs currently included in V-CareNeT (i.e. listed in the 'V-CareNeT Control Window or the list 'Currently selected' in the dialog 'Edit SDM Device/Host Names'). Should V-CareNeT detect any irregularities (e.g. two or more SDMs with identical 'SDM Device/Host Names') V-CareNeT will trigger an appropriate warning and – after user acknowledgement – take the necessary action to resolve the issue (e.g. removing the affected SDMs from V-CareNeT). For details please refer to 14.3.4.

Note: V-CareNeT continuously monitors the software version of all SDMs included in V-CareNeT. Should V-CareNeT detect SDMs with a software version prior to SMB SW-VO7.03.x (see 3.1), V-CareNeT will trigger an appropriate warning and remove these SDMs from V-CareNeT.

Note: Should the operator attempt to add a SDM to V-CareNeT with a software version prior to SMB SW-VO7.03.x (see 3.1), V-CareNeT will trigger an appropriate warning and prevent the user to add the selected SDM to V-CareNeT.

Click on 'Cancel' to close the dialog 'Edit SDM Device/Host Name' and to reject all changes. Click on 'OK' will close the dialog 'Edit SDM Device/Host Name' and all changes will become effective.

Note: After adding a SDM to V-CareNeT the respective 'Connect' check box in the 'V-CareNeT Control Window' will not be selected.

Note: Any change that causes the removal of a SDM from V-CareNeT will terminate the connection (if active) to the respective SDM.

Note: If the changes cause the discharge of patients (i.e. if a SDM to which a patient currently is assigned is a) removed from V-CareNeT or b) if – in the V-CareNeT Control Window - the SDM is moved downwards to a position in the list "SDM Device/Host Names' for which no 'Admit Patient' check box is available and, consequently, remote monitoring is not supported) the alert dialog 'Discharge Patient(s)' (see 14.7.5) will display. In this case the changes will become effective only if you confirm the discharge request.

14.5.1.1 Dialog 'Add SDM to V-CareNeT'

A click on the button 'Add' in the bottom right of the dialog 'Edit SDM Device/Host Names' (see 14.5.1) opens the dialog 'Add SDM to V-CareNeT'. In this dialog it is possible to manually enter either the 'SDM Device/Host Name' or the 'IP Address/IP Port' of the SDM you want to add to V-CareNeT.

Note: On the SDM the settings of the parameters 'Device/Host name', 'DHCP Mode', 'IP Address', 'IP Port', and 'Ethernet Mode' as well as the SDM's 'MAC Address' are displayed in the sub-menu 'Interfaces / LAN Interface'. By using V-STATS within a password protected area the Responsible Organization can define for each SDM the 'Device / Hostname', the 'DHCP Mode', the 'IP Address', the 'IP Port', and the 'Ethernet Mode' (see 13.2.4.5).

To manually enter a 'SDM Device/Host Name' proceed as follows:

- Select the radio button 'SDM Device/Host Name'

Note: If device discovery is disabled (see 12.2, 14.3.2) the radio button 'SDM Device/Host Name' is not selectable.

- Enter the 'SDM Device/Host Name' of the SDM you want to add to V-CareNeT in the respective text entry field.

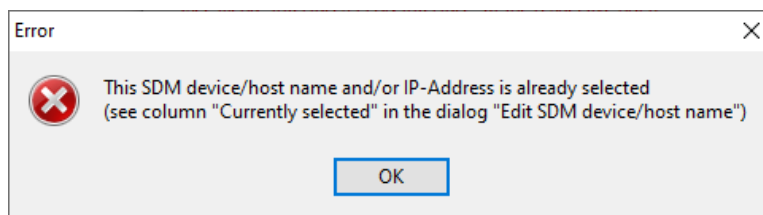
Note: The 'SDM Device/Host Name' is an alphanumeric string with maximal 16 characters. Permitted characters are letters (A, B, ..., Y, Z, a, b, ..., y, z), digits (0, 1, ..., 9) and '-' if not used at end or beginning of the 'SDM Device/Host Name'. V-STATS prevents entry of other characters and/or issues an appropriate error message when clicking on the button 'Change' if invalid characters are used.

- Click on the button 'OK' to add the SDM with the respective 'SDM Device/Host Name' to V-CareNeT, to close the dialog and to return to the dialog 'Edit SDM Device/Host Names'.

Note: In the dialog 'Edit SDM Device/Host Names' the SDM you added will appear in the list 'Currently selected'. If this SDM is currently contactable in the network the display of this SDM in the list 'Currently selected' will immediately be completed with its IP Address/IP Port. Otherwise '<SDM Device/Host Name> (---.---.---.---)' will display as long the SDM could not be contacted by V-CareNeT.

Note: Should you attempt to add a SDM to V-CareNeT with a software version prior to SMB SW-VO7.03.x (see 3.1); V-CareNeT will trigger an appropriate warning and prevent you to add the selected SDM to V-CareNeT.

Note: If you have entered a 'SDM Device/Host Name' that is already in use within V-CareNeT the following error message will display when clicking on the button 'OK'



Click on 'OK' to acknowledge the error message, to return to the dialog 'Add SDM to V-CareNeT' and to select a different 'SDM Device/Host Name'.

To manually enter an 'IP Address / IP Port' proceed as follows:

- Select the radio button 'IP Address'

Note: If device discovery is disabled (see 12.2, 14.3.2) the radio button 'IP Address' is preselected after opening the dialog 'Add SDM to V-CareNeT'.

- Enter the 'IP Address' and 'IP Port' of the SDM you want to add to V-CareNeT in the respective text entry fields.

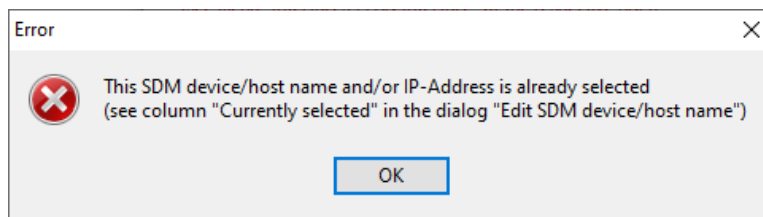
Note: The values for the 4 parts of the IP Address must be between 0 and 255. The following IP Addresses are not permitted: '0.0.0.0'; '127.xxx.xxx.xxx'; '255.255.255.255'. Ensure that the IP Port you select is between 0 and 65535.

- Click on the button 'OK' to add the SDM with the respective 'IP Address' and 'IP Port' to V-CareNeT, to close the dialog and to return to the dialog 'Edit SDM Device/Host Names'.

Note: In the dialog 'Edit SDM Device/Host Names' the SDM you added will appear in the list 'Currently selected'. If this SDM is currently contactable in the network the display of this SDM in the list 'Currently selected' will immediately be completed with its 'SDM Device/Host Name'. Otherwise '<IP Address>:<IP Port>*' will display as long the SDM could not be contacted by V-CareNeT.*

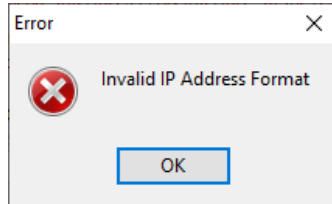
Note: Should you attempt to add a SDM to V-CareNeT with a software version prior to SMB SW-V07.03.x (see 3.1), V-CareNeT will trigger an appropriate warning and prevent you to add the selected SDM to V-CareNeT

Note: If you have entered an 'IP Address/IP Port' that is already in use within V-CareNeT the following error message will display when clicking on the button 'OK'.



Click on 'OK' to acknowledge the error message, to return to the dialog 'Add SDM to V-CareNeT' and to select a different 'IP Address/IP Port'.

Note: If an invalid IP Address format was entered V-CareNeT will issue the following error message 'when clicking on the button 'OK'.



Click on 'OK' to acknowledge the error message, to return to the dialog 'Add SDM to V-CareNeT' and to correct the IP Address.

Note: If you (erroneously) have entered an 'IP Address/IP Port' that corresponds to a device that is not a SDM V-CareNeT will as soon this device could be contacted trigger an appropriate warning message and – after user acknowledgement – take the necessary action to resolve the issue. For details please refer to 14.3.4.

14.6 Downloading SDM Trend Data via the network

Downloading trend data from the internal memory of devices such as pulse oximeters or capnometers to a PC based trend data analysis and reporting software is a very time consuming procedure. Depending on the device and its settings the download time of a single overnight study, for example, can easily exceed 10 minutes. Furthermore, to download trend data the devices have to be carried to a PC which is typically located in another room, on another floor, or even in a different building.

To eliminate the need to carry the SDM to the PC V-STATS offers the possibility to download SDM Trend Data from the internal memory of a SDM via the network. Furthermore, in order to reduce the total download time for customers using multiple SDMs V-STATS supports the possibility to simultaneously download SDM Trend Data from multiple SDMs via V-CareNeT. For customers several multiple SDMs the resulting daily time savings can easily exceed an hour. Furthermore, at the end of the download the internal memory of the SDM can be cleared and the 'Date&Time' of the SDM and PC can be synchronized via the network with the ease of a mouse click.

Note: While SDM Trend Data are downloaded via the LAN interface the serial interface of the SDM cannot be used for another SDM Trend Data download. Other serial data access works normally.

To initiate download of SDM Trend Data from the internal memory of a SDM currently included in V-CareNeT click on the corresponding 'OK' button in the V-CareNeT Control Window (see 14.5). If measurements are available in the internal memory of the respective SDM the dialog '<x><SDM Device/Host Name>- Assign measurement period(s) to patients' (see 6.1 and below) will open. Therein measurement period(s) can be assigned to a patient and then be downloaded, analyzed and displayed in the V-STATS Main Window. If no measurements are available in the internal memory of the SDM the information dialog 'No measurement found (OK)' will display.

Note: The 'OK' button of a SDM included in V-CareNeT is dimmed grey (not accessible) a) if connection with this SDM is not established or interrupted (corresponding 'Connection Status Indicator' lights grey or red), b) if download of SDM Trend Data via the network is already in progress for this SDM, or c) if download of SDM Trend Data via the network is already simultaneously in progress for 40 SDMs.

Note: Download of SDM Trend Data via V-CareNeT is not supported during a 'V-CareNeT Trial' (see 15.3) or if the 'V-CareNeT Demo Mode' (see 12.3) is active.

Note: Whenever possible the dialog window '<x><SDM Device/Host Name>- Assign measurement period(s) to patients' is positioned over the respective station's cell (see 14.4).

1: SenTec-SDM306843 - Assign measurement period(s) to patients

Current Analysis Criteria Profile: default
Data Storage Folder: C:\g\vsstats\daten
Minimal Measurement Duration = 5 mins

No.	From: (MM-DD-YYYY)	To:	ID:	Type:
<input type="checkbox"/>	12. 2019-10-01 08:35:41 -	2019-10-01 08:46:58	---	Adult
<input type="checkbox"/>	11. 2019-10-01 07:18:35 -	2019-10-01 07:53:23	---	Adult
<input type="checkbox"/>	10. 2019-09-30 09:16:32 -	2019-09-30 09:22:41	---	Adult
<input type="checkbox"/>	9. 2019-09-26 09:59:05 -	2019-09-26 10:42:39	---	Adult
<input type="checkbox"/>	8. 2019-09-26 07:35:02 -	2019-09-26 08:22:49	---	Adult
<input type="checkbox"/>	7. 2019-09-20 11:06:53 -	2019-09-20 12:04:54	---	Adult
<input type="checkbox"/>	6. 2019-09-17 11:51:50 -	2019-09-17 12:00:15	---	Adult
<input type="checkbox"/>	5. 2019-09-17 10:13:37 -	2019-09-17 10:21:17	---	Adult
<input type="checkbox"/>	4. 2019-09-17 09:56:11 -	2019-09-17 10:13:19	---	Adult
<input type="checkbox"/>	3. 2019-09-09 11:44:30 -	2019-09-09 11:57:47	---	Adult
<input type="checkbox"/>	2. 2019-09-09 10:22:36 -	2019-09-09 10:34:35	---	Adult
<input type="checkbox"/>	1. 2019-08-06 11:34:37 -	2019-08-06 11:43:37	---	Adult

Calibration in progress

Last name:
 First name:
 Date of birth (MM-DD-YYYY):
 Height (cm):
 Weight (kg):
 Sex:
 Comment:
 Pat. number:

Activate personal data

Memory Capacity [hrs]: 61.7 (68.3)

Reset

Selection of two or more measurement periods will automatically merge the periods with zero values added to fill the gaps.

It is recommended to clear the Trend Data of SDM after the data-download.

Please refer to 6.1 for a detailed description of the dialog '<X><SDM Device/Host Name>- Assign measurement period(s) to patients'. Please remember the following particularities that apply if downloading SDM Trend Data via the network:

- The status message above the patient data fields only displays if SDM Trend Data are downloaded via V-CareNeT. It displays
 - 'Monitoring in progress' if on the respective SDM a measurement is ongoing. Please note that if this is the case download of SDM Trend Data is significantly slower than if no measurement is ongoing.
 - 'Sensor off patient' if the sensor connected to the respective SDM is neither placed on the patient nor stored in its Docking Station.
 - the same status message as the respective SDM, if the sensor is placed in the Docking Station or if no sensor is connected to the SDM.

Remember: Correction of residual PCO2 drift is only possible if the PCO2 calibration data before and after the measurement are available (see 11.6).

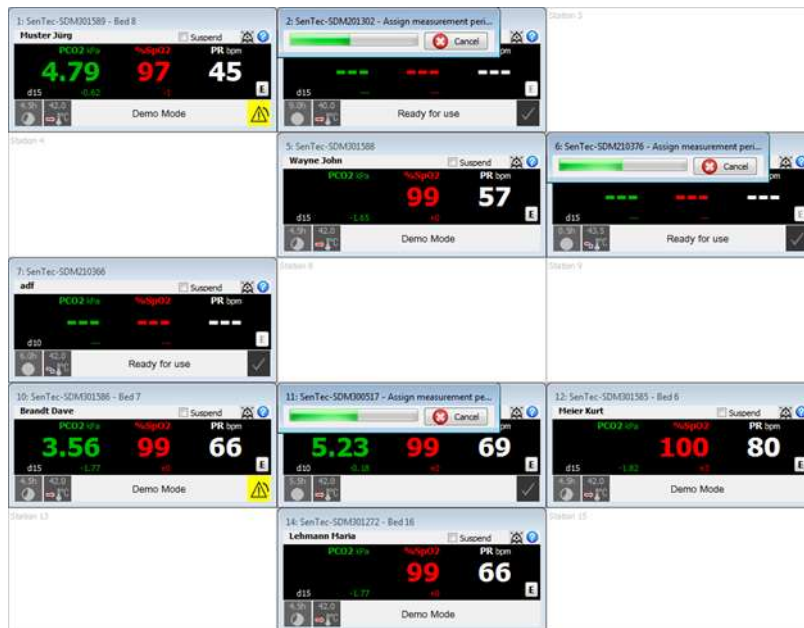
- Download of the SDM Trend Data of an ongoing (not terminated) measurement period is only possible via V-CareNeT. In the example shown above the status message 'Monitoring in progress' displays above the patient data entry fields and in case of the most recent measurement period no end time displays, i.e. it is still ongoing. In the present example the most recent measurement period is selected and, consequently, can be downloaded. Note that if an ongoing measurement is downloaded correction of residual PCO2 drift will not be possible for this measurement. The data for this measurement will span the time period from the start time to the time the download is finished.
- The button 'Admitted Patient' is only available when downloading SDM Trend Data with V-CareNeT. Click on this button fills in the data of the patient that was last admitted to the respective remote monitoring station into the patient data fields (see 14.6, 14.7, and 14.8). If a measurement is ongoing, click on this button will fill in the data of the patient currently being admitted to the respective station.

After having selected measurement period(s) and having entered the desired patient data into the patient data fields (see 6.1) a click on the 'Convert' button will activate the download of the selected measurement period(s). If the download is made with V-CareNeT the size of the dialog '<X>:<SDM Device/Host Name>- Assign measurement period(s) to patients' will minimize and it will be positioned in the top left corner of the respective station's cell.



While the data download is in progress only the download progress bar and the 'Cancel' button (permitting to abort the download at any time) display in the minimized dialog window.

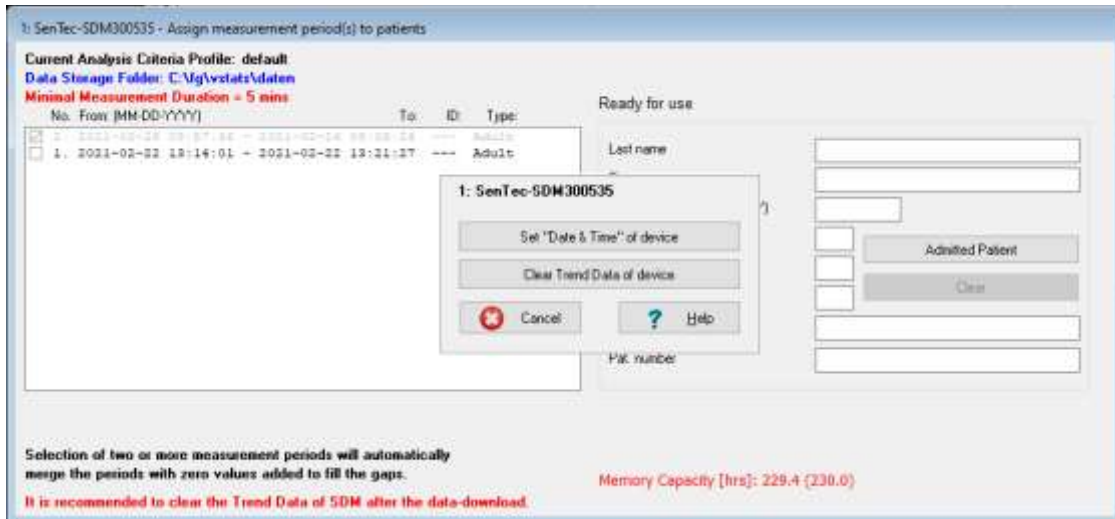
Scaling down the size of the dialog '<X>:<SDM Device/Host Name>- Assign measurement period(s) to patients' is important to permit simultaneous download of SDM Trend Data from multiple SDMs. The figure below shows an example with SDM Trend Data download being simultaneously in progress for station 2, 6 and 11.



At the end of the download the dialog '<X>:<SDM Device/Host Name>- Assign measurement period(s) to patients' resumes its normal size.

Note: If SDM Trend Data are simultaneously downloaded from multiple SDMs (see figure above) V-CareNeT will resume normal size only for one dialog at a time. Normal size is first resumed for that dialog, for which the download was first finished. Only after completion of the required user interactions (e.g. activation of a further download) in this dialog normal size is resumed for that dialog for which the download was finished second (and so forth).

As described in section 6.1, the dialog '<X>:<SDM Device/Host Name>- Assign measurement period(s) to patients' remains open as long as not all currently available measurement periods have been downloaded to V-STATS thereby offering the possibility to download additional measurement period(s). Once all currently available measurement periods have been downloaded to V-STATS or when clicking on the button 'Cancel' the dialog shown below is displayed in front of the dialog 'Assign measurement period(s) to patients'.



Click on the button 'Cancel' to close the dialog 'Assign measurement period(s) to patients'.

Click on the button 'Set Date & Time of device' to set the 'Date & Time' of the SDM to the 'Date & Time' of the PC and to close the dialog '<X>: <SDM Device/Host Name>- Assign measurement period(s) to patients'.

Click on the button 'Clear Trend Data of device' to clear the SDM Trend Data stored in the internal memory of the SDM and closes the dialog '<X>: <SDM Device/Host Name>- Assign measurement period(s) to patients'. For details please refer to 6.1.

If SDM Trend Data that were downloaded with V-CareNeT use the 'File Manager' to open the measurements (see 7.1).

14.7 Remote Monitoring – Patient Administration

The Patient Administration process includes:

- Admitting a (new) patient into V-CareNeT System (see 14.7.1) if access to enter patient data is enabled.
- Editing patient data of a patient already being admitted to V-CareNeT System (see 14.7.2).
- Assigning a patient to another location (Patient Transfer with SDM – Option A) (see 14.7.3).
- Assigning a patient to another station/SDM (Patient Transfer without SDM – Option B) (see 14.7.4).
- Discharging the patient from V-CareNeT System (see 14.7.5).

14.7.1 Admit a patient into V-CareNeT System

- Before admitting a patient into the V-CareNeT System:
 - make sure to determine which SDM you (will) use to monitor the patient and to determine the location of the patient (e.g. floor, room number, step down unit, ...).
 - make sure the SDM selected in step 1a is turned on and connected to the same network as the PC with V-CareNeT.
 - access the sub-menu 'LAN Interface' of the SDM selected in step 1a to verify that the menu-parameter 'LAN' is set to ON and to take note of its 'SDM Device/Host Name' (identifies the SDM in the V-CareNeT System).
 - startup V-CareNeT (see 14.4) and verify that in the 'V-CareNeT Control Window' (see 14.5) the 'SDM Device/Host Name' of the SDM selected in step 1a is available and that an 'Admit Patient' check box is available for the respective SDM. If needed add the SDM to V-CareNeT and/or move it upwards until an 'Admit Patient' check box is available for it (see 14.5.1).

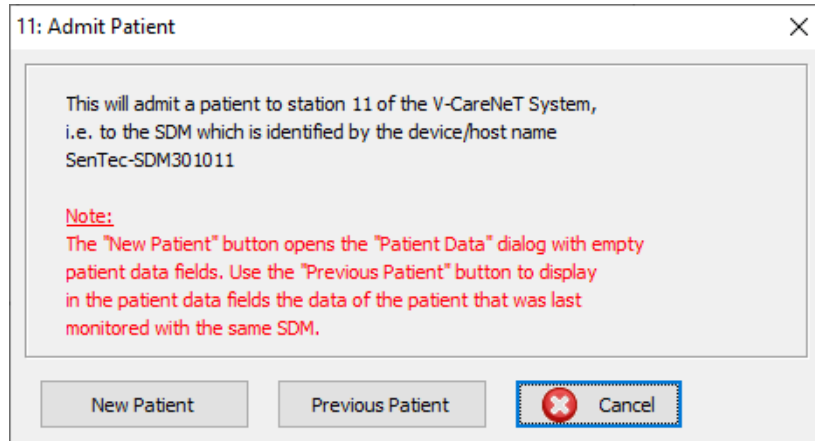
Note: By taking account a) of the number of beds/patients included in the 'V-CareNeT Package Registration Code' that was used to activate/ upgrade the 'V-CareNeT Package' (15.2, 16.6.1) and b) of the current size/resolution of the central station's screen, V-CareNeT evaluates the number of beds/patients being simultaneously available for remote monitoring. In the V-CareNeT Control Window 'Admit Patient' check boxes, consequently, are available only for the corresponding number of SDMs. If your V-CareNeT setup does not support the required number of beds/patients you must consider to increase the size/resolution of the central station's screen and/or to (further) upgrade V-CareNeT to a higher number of beds/patients (see 16.6.1).

- In the 'V-CareNeT Control Window' select the 'Admit Patient' check box associated with the SDM you have selected in step 1a. The dialog '<X>: Admit Patient' appears.

Note: <X> - the number next to the 'Admit Patient' check box - represents the station/cell number in which the data for the respective SDM will be displayed.

Note: A patient can only be admitted to a station if connection with the associated SDM is established. Consequently, the 'Admit Patient' check box of a station is not accessible (dimmed grey) if connection with the associated SDM is not established or interrupted.

Note: If attempting to admit a patient to a SDM that is locked by another V-CareNeT Central Station V-CareNeT will skip the dialog '<X>: Admit Patient'. Instead corresponding information will display in the station's remote monitoring window (see 14.3.5). Acknowledgement of the information will close the respective station's remote monitoring window and deselect the respective 'Admit Patient' check box.



A click on the 'Cancel' button aborts patient admission, closes this dialog, and deselects the respective 'Admit Patient' check box in the 'V-CareNeT Control Window' (see 14.5).

The dialog '<X>: <Device/Host Name> - Patient Data' (see below) opens upon a click on the

- 'New Patient' button with empty patient data fields (i.e. the last patient's data (if any) will be deleted).
- 'Previous Patient' button displaying the data of the patient that was last monitored with the same SDM in the patient data fields. Use this option to restart remote monitoring for the patient that was last monitored with this station/SDM (for example after having discharged a patient unintentionally).

Note: The button 'Previous Patient' is dimmed grey if no patient data is available for station <X> (e.g. at first use of the station <X> or if the last patient's data were deleted with the 'New Patient' function).

Note: If another patient is already admitted to the SDM you have selected in step 1a you must – by using the function of the 'New Patient' button in the dialog '<X>: <Device/Host Name> - Patient Data' – first discharge the current patient from and then assign the new patient to the respective SDM (see 14.7.2).

- 3) In the dialog '<X>: <Device/Host Name> - Patient Data' (see below) enable access and enter the patient data in the patient data fields if it was opened by a click on the 'New Patient' button. Verify the data of the patient that was last monitored with this station/SDM, if it was opened by a click on the 'Previous Patient' button. If necessary edit the data or clear the patient data fields by a click on the 'New Patient' Button.

A maximum of 25 characters can be entered for the 'Last name' and for the 'First name'. A maximum of 30 characters can be entered for the 'Comment', the 'Location' and the 'Pat. Number'. Enter the patient's date of birth, height, and weight by using the format/units indicated in parenthesis. The text entered in the 'Location' field will display in the name of the station's remote monitoring window (syntax '<X>: <Device/Host Name>< - Location>').

Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.

Note: The 'SDM Device/Host Name' of a SDM displays in the name of all windows that are related with the associated station. If a SDM is always used at the same location we therefore recommend to keep vacant the 'Location' field in the dialog '<X>: <Device/Host Name> - Patient Data' and instead to store the location in the 'SDM Device/Host Name' by using V-STATS within a password-protected area (see 13.2.4.5).

Note: The format used for dates and the units used for height and weight can be changed in the dialog V-STATS Settings (see 12.1).

Note: When admitting a patient, the buttons 'Discharge Patient' and 'Assign another station/SDM' are not accessible (dimmed grey). These buttons are only accessible while editing the data of an already admitted patient (see 14.7.2) or when assigning an already admitted patient to another station/ SDM (see 14.7.4).

Important: Display of Patient Info in the remote monitoring window and its duplication on the SDM

By selecting one of the four check boxes next to the patient data fields you can define which part of the patient data will a) display as customized 'Patient Info' in the station's remote monitoring window (<X>: <Device/Host Name>< - Location>) (see 14.8.1) and b) be duplicated on the associated SDM if the check box 'Display Patient Info on SDM' is selected in the dialog 'V-CareNeT Settings' (see 12.2). Verify that patient privacy will be warranted in accordance with local ordinances before selecting one of the above mentioned check boxes.

The field 'Preview Patient Info' above the 'OK' button provides a preview of the customized 'Patient Info'. In order to ensure that the 'Patient Info' will be fully visible in the remote monitoring window and on the SDM verify that it does not transcend the 'Suspend' check box in the preview area.

Note: It is strongly recommended not to include special characters in the 'Patient Info', since they might not be displayed correctly on the SDM itself.

Note: The 'Last Name' and 'First Name' can be checked simultaneously, otherwise only one patient data field can be checked at once.

Click on the 'Cancel' button aborts patient admission, closes this dialog, and deselects the respective 'Admit Patient' check box in the 'V-CareNeT Control Window' (see 14.5).

A click on the 'OK' button admits the patient to the respective SDM, saves the patient data, opens the remote monitoring window <X>: <Device/Host Name>< - Location> (see 14.8.1), and activates remote monitoring for this patient.

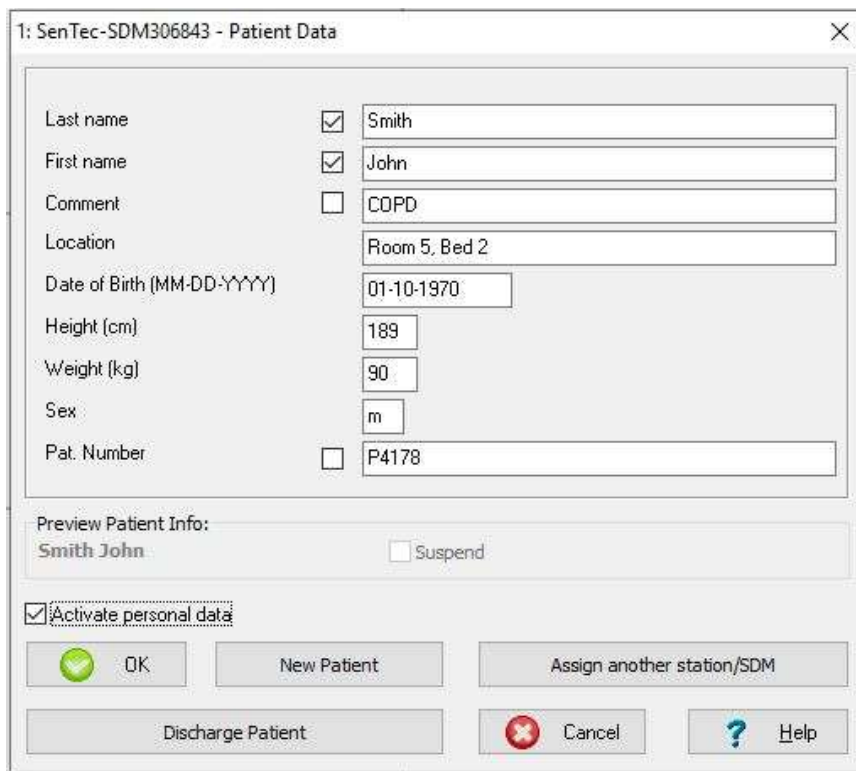
Note: If the 'Speaker Test' is required when admitting the first patient to the V-CareNeT System the dialog 'Speaker Test' (see 14.9.3) will display before activating remote monitoring for the first patient.

14.7.2 Editing patient data of a patient admitted to V-CareNeT System

In the remote monitoring window (see 14.8.1) the customized 'Patient Info' displays - as highlighted by a red rectangle in the following figure - in the <Patient Info> field underneath the window's name.



To edit the patient data of a patient that is admitted to a station click on the <Patient Info> field. The dialog '<X>: <Device/Host Name> - Patient Data' - displaying the data for the patient admitted to this station - will open:



Verify the displayed patient data. If necessary edit the data.

Note: When editing patient data of an already admitted patient the button 'Discharge Patient' is accessible. The button 'Assign another station/SDM' is discussed in the paragraph 'Assigning a patient to another station/SDM' (see 14.7.4). Note that the button is not accessible (dimmed grey) if all patient data fields are empty. The button 'Discharge Patient' and the function of the button 'New Patient' while editing patient data are discussed below in the paragraph 'Discharging the patient from the V-CareNeT System' (see 14.7.5).

Important: Display of Patient Info in the remote monitoring window and its duplication on the SDM

By selecting one of the four check boxes next to the patient data fields you can define which part of the patient data will a) display as customized 'Patient Info' in the station's remote monitoring window (<X>: <Device/Host Name>< - Location>) (see 14.8.1) and b) be duplicated on the associated SDM if the check box 'Display Patient Info on SDM' is selected in the dialog 'V-CareNeT Settings' (see 12.2). Verify that patient privacy will be warranted in accordance with local ordinances before selecting one of the above mentioned check boxes.

The field 'Preview Patient Info' above the 'OK' button provides a preview of the customized 'Patient Info'. In order to ensure that the 'Patient Info' will be fully visible in the remote monitoring window and on the SDM verify that

it does not transcend the 'Suspend' check box in the preview area.

Note: It is strongly recommended not to include special characters in the 'Patient Info', since they might not be displayed correctly on the SDM itself.

A click on the 'Cancel' button while editing patient data rejects all changes, closes the dialog '<X>: <Device/Host Name> - Patient Data' and returns to the remote monitoring window (<X>: <Device/Host Name>< - Location>).

A click on the 'OK' button saves the changes and returns to the remote monitoring window (<X>: <Device/Host Name>< - Location>).

Note: When reactivating the Last V-CareNeT Session at startup of V-CareNeT (see) it is also possible to edit patient data of patients already being admitted to V-CareNeT System (see 14.4.1).

14.7.3 Assigning a patient to another location (Patient Transfer with SDM – Option A)

If a patient is transferred to another location and if the SDM is transferred along with the patient, you need to update the settings in the V-CareNeT System.

Open the dialog '<X>: <Device/Host Name> - Patient Data' (see 14.7.2) for the respective patient/station, modify the 'Location' field accordingly, and then click on the 'OK' button to save the changes and to return to the respective patients remote monitoring window. The updated location will display in the window name of the remote monitoring window (<X>: <Device/Host Name>< - Location>).

Note: When transferring the SDM to a new location you may be required to disconnect the SDM from the network and, hence, the connection between V-CareNeT and the SDM will interrupt during the transfer. As soon as the SDM is reconnected to the network connection between V-CareNeT and the SDM will automatically re-establish and remote monitoring will resume. In certain cases, connection between V-CareNeT and the SDM will re-establish automatically only if the SDM is reconnected to the network within the same subnet.

14.7.4 Assigning a patient to another station/SDM (Patient Transfer without SDM – Option B)

In certain situations, you may be required to assign the patient being admitted to a station/SDM to another station/SDM (e.g. if the patient is transferred to another location without the SDM or if the SDM which is currently in use is replaced by another SDM).

- 1) Before assigning the patient to another SDM
 - a) make sure to determine to which station/SDM you want to transfer the patient and to verify the (new) location of the patient.
 - b) make sure the SDM selected in step 1a is turned on and connected to the same network as the PC with V-CareNeT.
 - c) access the sub-menu 'LAN Interface' of the SDM selected in step 1a to verify that the menu-parameter 'LAN' is set to ON and to take note of its 'SDM Device/Host Name' (identifies the SDM in the V-CareNeT System).
 - d) verify that in the 'V-CareNeT Control Window' (see 14.5) the 'SDM Device/Host Name' of the SDM selected in step 1a is available and that an 'Admit Patient' check box is available for the respective SDM. If needed add the SDM to V-CareNeT and/or move it upwards until an 'Admit Patient' check box is available for it (see 14.5.1).
 - e) verify that for the station that is associated with the SDM you selected in step 1a communication between V-CareNeT and the SDM can be established (see 14.5).
 - f) verify that no other patient is currently admitted to the SDM to which you want to transfer your patient.
- 2) Open the dialog '<X>: <Device/Host Name> - Patient Data' (see 14.7.2) for the respective patient/station. Verify the patient data. If necessary update the patient data.

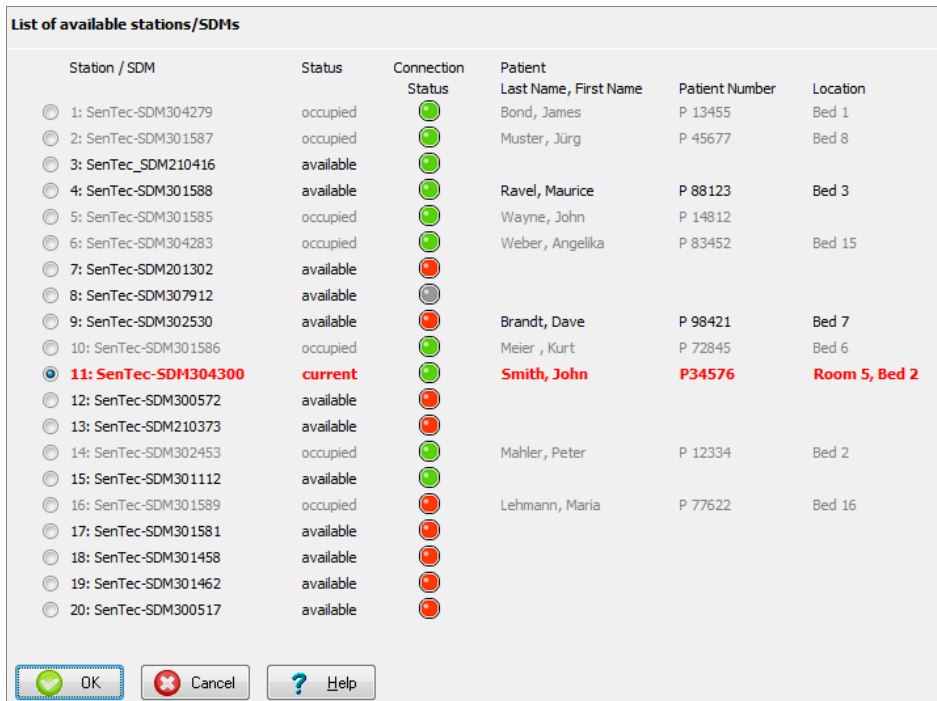
Note: The location of the SDM/ the device must be updated at the end of the transfer process (see below).

Note: The 'SDM Device/Host Name' of a SDM displays in the name of all windows that are related with the associated station. If a SDM is always used at the same location we therefore recommend to keep vacant the 'Location' field in the dialog '<X>: <Device/Host Name> - Patient Data' (see 14.7.2) and instead to store the location in the 'SDM Device/Host Name' by using V-STATS within a password-protected area (see 13.2.4.5).

- 3) Click on the 'Assign another station/SDM' button in the dialog '<X>: <Device/Host Name> - Patient Data' to open the dialog 'Assign another station/SDM'.

Note: The button 'Assign another station/SDM' is not accessible (dimmed grey) if all patient data fields are empty.

Note: The function 'Assign another station/SDM' is also available when starting up V-CareNeT (see 14.4, 14.4.1).



The dialog 'Assign another station/SDM' displays for each station (from left to right)

- the station number <X>
- the 'SDM Device/Host Name' of the associated SDM
- the station's (availability) 'Status' (either 'current', 'available', 'occupied', or 'locked' (see 14.3.5))

Note: A station/SDM is 'available' if it is neither locked by another V-CareNeT System (see 14.3.5) nor a patient is assigned to it (i.e. corresponding 'Admit Patient' check box in the V-CareNeT Central Station (see 14.5) not selected).

- the station's 'Connection Status' (see 14.5), and
- the data of the patient assigned to it.

The current station/SDM is highlighted in **bold, red** and its 'Radio Button' is selected.

4) Select the radio button in front of the station/SDM to which you want to transfer the patient.

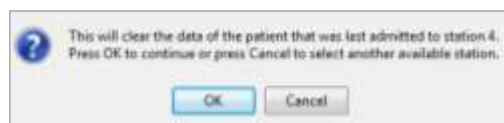
Note: 'Available' stations/SDMs are selectable irrespective of their 'Connection Status'.

Note: 'Occupied' and 'locked' stations/SDMs are dimmed grey and their 'Radio Buttons' are not selectable.

Note: If the dialog 'Assign another station/SDM' is opened from the dialog 'Last V-CareNeT Session' when starting up V-CareNeT (see 14.4.1), V-CareNeT does neither verify the 'Connection Status' nor assess whether or not the SDMs are locked by another V-CareNeT System. Consequently, a station/SDM is classified to be 'available' if the corresponding 'Admit Patient' check box is not selected in the dialog 'Last V-CareNeT Session'; its 'Connection Status' lights green if the corresponding 'Connect' check box is selected and grey if not selected.

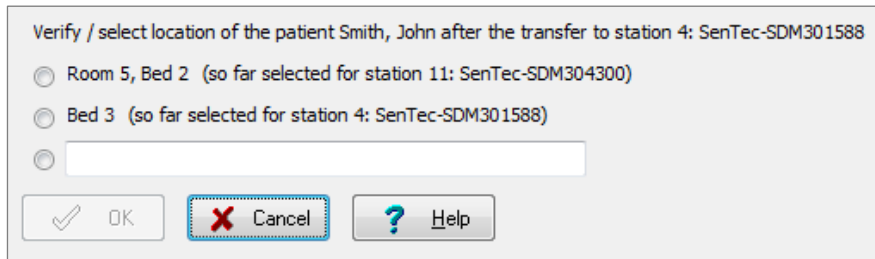
5) Click on 'OK' to transfer the patient to the selected station/SDM.

Note: If the data of the last patient that was admitted to the station/SDM to which you want to transfer the current patient are still available V-CareNeT will trigger the following warning:



Click on 'Cancel' to abort the process and to return to the dialog 'Assign another station/SDM'. Click on 'OK' to clear the data and to proceed.

Note: V-CareNeT will request you to verify/ specify the patient's location after the transfer in the following confirmation:



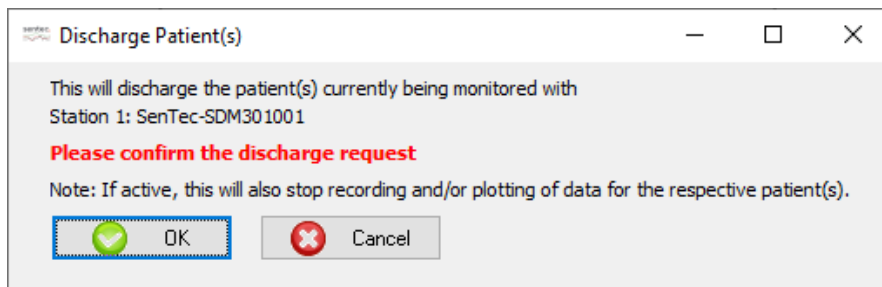
In this dialog either select a) the location of the station/ SDM to which the patient was assigned before the transfer, b) the station/ SDM to which the patient was assigned after the transfer, or c) specify a different location in the respective text entry field. Click on 'OK' to confirm the patient's updated location.

Note: Options for which no location was specified when starting the transfer process will not be displayed.

Note: In the example above, the patient is transferred from station 11: Sentec-SDM304300 (so far located in Room 5, Bed 2) to station 4: Sentec-SDM301588 (so far located in Bed 3).

14.7.5 Discharging the patient from V-CareNeT System

There are four options to discharge patients from the V-CareNeT System. For each option you must - if remote monitoring is active for the respective station - confirm the discharge request in the dialog 'Discharge Patient(s)':



Option	Description
'Discharge Patient' button in dialog '<X>: <Device/Host Name> - Patient Data' (see 14.7.2)	The dialog 'Discharge Patient(s)' appears after clicking this button. Click the 'OK' button to discharge the patient from the V-CareNeT System, to close all windows related to this patient and to uncheck the 'Admit Patient' check box in the 'V-CareNeT Control Window'. <i>Note:</i> The patient's data are not deleted by the 'Discharge Patient' function.
'New Patient' button in dialog '<X>: <Device/Host Name> - Patient Data' (see 14.7.2)	The dialog 'Discharge Patient(s)' appears after clicking this button. Click the 'OK' button to discharge the current patient from the V-CareNeT System and to close all windows related to this patient. The 'Admit Patient' check box in the 'V-CareNeT Control Window' remains selected and the dialog '<X>: <Device/Host Name> - Patient Data' displays with <u>empty</u> patient data fields (i.e. the last patient's data (if any) are deleted), permitting you to admit a new patient. <i>Note:</i> Pressing the 'Cancel' button in the dialog '<X>: <Device/Host Name> - Patient Data' while admitting a patient (see 14.7.1) closes the dialog '<X>: <Device/Host Name> - Patient Data' and returns to the 'V-CareNeT Control Window' (corresponding 'Admit Patient' check box de-selected)
Uncheck the 'Admit Patient' check box in 'V-CareNeT Control Window' (see 14.5)	The dialog 'Discharge Patient(s)' appears when unchecking the 'Admit Patient' check box. Click the 'OK' button to discharge the patient from the V-CareNeT System and to close all windows related to this patient. <i>Note:</i> The patient's data are not deleted by deselecting the 'Admit Patient' box.
Uncheck the 'Connect' check box in 'V-CareNeT Control Window' (if the 'Admit Patient' check box is	The dialog 'Discharge Patient(s)' appears when unchecking the 'Connect' check box. Click the 'OK' button to discharge the patient from the V-CareNeT System and to close all windows related to this patient. This will de-select the 'Admit Patient'

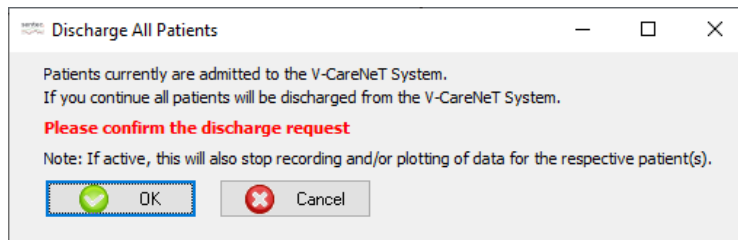
Option	Description
selected) (see 14.5)	check box. <i>Note: The patient's data are not deleted by deselecting the 'Connect' box.</i>

Note: The dialog 'Discharge Patient(s)' also displays when attempting to exit the dialog 'Edit SDM Device/Host Names' if the changes will cause interruption of remote monitoring for one or multiple devices (see 14.5.1). Changes will become effective only after confirmation of the discharge request.

Note: Should changing the language (see 12.1) and/or the position of the V-CareNeT Control Window from left to right (or vice versa) (see 12.2) reduce the maximal number of stations that are available at the V-CareNeT Central Station and should this cause the discharge of patients currently admitted to these stations (if any), then the alert dialog Discharge Patient(s)' would also display.

WARNING: Decreasing the central station's screen resolution while remote monitoring is active may cause interruption of remote monitoring for one or multiple SDMs. In this case, patients admitted to the respective stations will be discharged from V-CareNeT System without an alert-dialog being displayed.

When clicking the 'Close V-CareNeT' icon in the 'V-CareNeT Control Window' (see 14.5) or when attempting to exit V-STATS while patients are admitted to the V-CareNeT System the alert dialog 'Discharge All Patients' displays. In this case V-CareNeT and or V-STATS will close/terminate only after you have confirmed the discharge request. The alert dialog 'Discharge All Patients' will also display, if the 'Connect' check box in the heading-line of the V-CareNeT Control Window is deselected while at least one patient is admitted.



14.8 Remote Monitoring

14.8.1 Description of an individual remote monitoring window

Admitting a patient to a SDM being identified within the V-CareNeT System by its 'SDM Device/Host Name' (see 14.7.1) opens the remote monitoring window '<X>: <Device/Host Name> - Location' and activates remote monitoring for this patient. Here <X> identifies the **station number**.

Depending on whether or not the display of dx-values and/or Baseline values is enabled in the dialog 'V-CareNeT Settings' (see 12.2) the remote monitoring window(s) will display in one of the four following configurations:

	'Display Baseline values' disabled	'Display Baseline values' enabled
'Display dx-values' disables		

Display dx-values' enabled		
Display dx-values' disables		
Display dx-values' enabled		

Note: A 'dx-value' for a parameter corresponds to the difference between the current reading of the parameter and its reading x minutes ago. A 'd10-value for PCO2' of '+2.1 mmHg', for example, indicates that the current PCO2 reading is 2.1 mmHg higher than the PCO2 reading 10 minutes ago. 'x' is called 'Delta-Time' (see 13.2.4.2) and can be remotely controlled with V-CareNeT (see 14.8.2.1). The default value for 'Delta-Time' is 10 minutes.

Note: During patient monitoring a baseline for PCO2, PO2, SpO2 and RHP (note that V-CareNeT currently only supports remote monitoring of PCO2, PO2, SpO2 and PR) can be set on the SDM a) by either using the quick access menu of the SDM (refer to the Technical Manual of the SDM (HB-005752) or b) remotely by using the V-CareNeT dialog 'Set Operator Events' (see 14.8.3). 'Baseline values' for a parameter comprise

- the baseline itself, i.e. the reading of the parameter at the instant the baseline was set,
- the dB-value, i.e. the difference between the current reading of the parameter and its value at the moment the baseline was set, and
- the time that elapsed since the baseline was set in hh:mm format.

'Baseline values for PCO2' of '32.2 + 9.8 mmHg (00:21)', for example, indicate that the current PCO2 reading is 9.8 mmHg higher than the baseline of 32.2 mmHg which was set 21 minutes ago.

Note: Remote Monitoring and alarm surveillance is currently only supported for PO2 if OxiVenT sensor is connected to SDM and patient type is set to 'neonate'.

Window Name

The window name '<X>: <Device/Host Name> - Location' consists of three elements:

- <X> corresponds to the station number to which the patient was assigned.
- <Device/Host Name> corresponds to the 'SDM Device/Host Name' of the SDM to which the patient was admitted.
- <Location> displays the information currently stored in the 'Location' field in the dialog '<X>: <Device/Host Name> - Patient Data' (see 14.7.2) of the respective patient/station.

Note: If in the dialog '<X>: <Device/Host Name> - Patient Data' the 'Location' field is empty no location is indicated in the window name.

<Patient Info> text field (in this example displaying "Smith John")

The <Patient Info> field displays the customized 'Patient Info' which is determined by the patient data field - either the patient's last name/first name, a comment, or the patient number - that is selected in the dialog '<X>: <Device/Host Name> - Patient Data' (see 14.7.2). A click on the <Patient Info> field opens the dialog '<X>: <Device/Host Name> - Patient Data' where you can edit the patient data of the current patient (see 14.7.2).

Note: The customized 'Patient Info' can be duplicated on the associated SDM by selecting the box 'Display Patient Info on SDM' in the dialog 'V-CareNeT Settings' (see 12.2).

Note: It is strongly recommended not to include special characters in the 'Patient Info', since they might not be displayed correctly on the SDM itself.

Note: Ensure compliance with local data protection regulations before entering personal data. Non-authorized persons must not have access to patient information.

Black data field

The PCO₂, PO₂, SpO₂ and PR data displayed in the black data field correspond to current data measured by the SDM to which the patient is admitted. Values of measured parameters are updated every 2 seconds. If a measurement parameter violates a SDM internal alarm limit the respective parameter flashes (with 1.4 Hz for SpO₂, with 0.7 Hz for PCO₂, PO₂ and PR). If enabled, dx-values and/or baseline values are displayed for PCO₂ and SpO₂ (see above).

The SDM continuously evaluates the quality of the measured data (PCO₂, PO₂, SpO₂, and PR) and the dx-values and /or baseline values derived thereof by assessing the severity of conditions presented to the SDM. The results of this evaluation are used to display status messages (see below) and/or quality attributes for the different parameters (for details refer to the Technical Manual for the SDM (HB-005752)). While a parameter is marked as

- **valid:** alarm surveillance for the respective parameter (if applicable) is active on the SDM; V-CareNeT displays the parameter in the selected color;
- **questionable:** alarm surveillance for the respective parameter (if applicable) is active on the SDM; V-CareNeT displays the parameter in the selected color and a '?' adjacent to the parameter;
- **unstable:** alarm surveillance for the respective parameter is not active on the SDM; V-CareNeT displays the parameter in grey. PCO₂, for example, is displayed in grey during 'PCO₂ stabilization' after sensor application or after occurrence of a 'PCO₂ artifact';
- **invalid:** alarm surveillance for the respective parameter is not active on the SDM; V-CareNeT replaces parameter with '-';
- **not available:** alarm surveillance for the respective parameter is not active on the SDM; V-CareNeT replaces parameter with '-/-'.

'IC' displays nearby the PCO₂ label if PCO₂ values are in-vivo corrected and/or if the SDM menu-parameter 'Severinghaus Correction Mode' is set to **fix** (please refer to the Technical Manual of the SDM (HB-005752) for details). PCO₂ (PO₂) units ('mmHg' or 'kPa') can be changed in the dialog 'V-STATS Settings' (see 12.1). The display color for PCO₂, PO₂, SpO₂ and PR can be changed in the dialog 'V-CareNeT Settings' (see 12.2).

Note: The PCO₂ (PO₂) unit of the SDM and the PCO₂ (PO₂) unit of V-CareNeT can be selected independently from each other.

*Note: Details of the correction are displayed in the dialog 'Additional Data' (see 14.8.2) if PCO₂ values are in-vivo corrected and/or if the SDM menu-parameter 'Severinghaus Correction Mode' is set to **fix**. The use of PCO₂ In-Vivo Correction can be enabled and the 'Severinghaus Correction Mode' can be selected in a password protected area of V-STATS (see 13.2.4.3).*

A click on the black data field opens the dialog '<X>: <Device/Host Name> - Additional Data' (see 14.8.2). In this dialog additional measurement data such as the heating power as well as detailed information of the status/ configuration of the associated SDM are provided. Remote control of certain settings of the associated SDM is possible in the sub-dialog '<X>: <Device/Host Name> - Remote Control' (see 14.8.2.1).

A click on the 'E' button in the bottom right of the black data field area opens the dialog '<X>: <Device/Host Name> - Set Operator Events' (see 14.8.3). In this dialog it is possible to remotely set a baseline for PCO₂ and SpO₂ or to mark operator events (see 11.1, 12.1.3) on the respective SDM during patient monitoring.

Note: The 'E' button is dimmed grey (not accessible) if the Sentec TC Sensor that is connected to the associated SDM is in the Docking Station or if no sensor is connected to the associated SDM.

Status Bar

A 'Status Bar' is provided at the bottom of the Remote Monitoring window, displaying from left to right:

- **Remaining Monitoring Time Icon:** Indicates the remaining monitoring time in hours until the 'Preset Site Time' elapses or - if PCO₂ is enabled - until a calibration will be required (whichever will occur first). The pie chart - which is updated in steps of 20% - indicates the remaining monitoring time in percentage. Note, that the 'Remaining Monitoring Time' Icon displays the same information as the 'Remaining Monitoring Time' Icon of the SDM (refer to the Technical Manual for the SDM (HB-005752) for additional information).

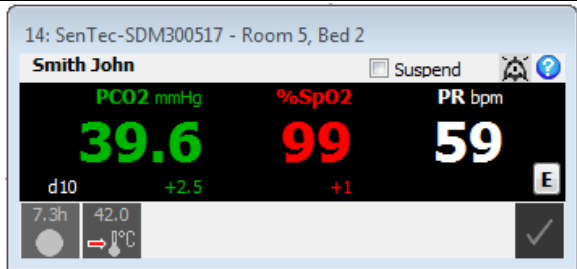

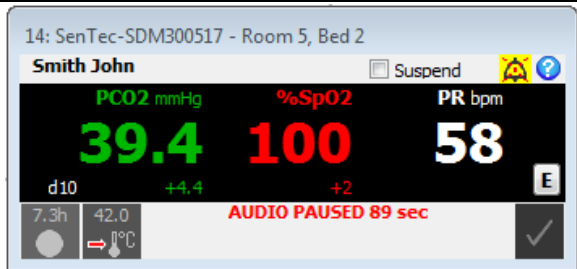

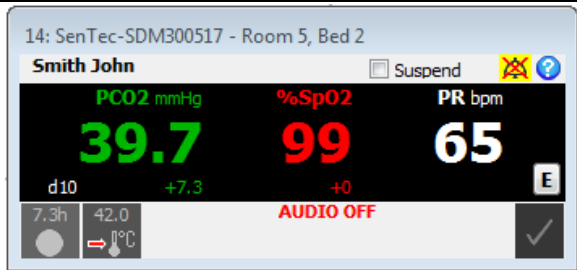

- **Sensor Temperature Icon:** Indicates the measured sensor temperature (°C) and the current setting of SITE PROTECTION. If INITIAL HEATING is active the sensor temperature icon displays in yellow. It displays in blue if SITE PROTECTION reduced the sensor temperature. This icon displays only for heated sensors. **Note, that the 'Sensor Temperature' Icon displays the same information as the 'Sensor Temperature' Icon of the SDM (refer to the Technical Manual for the SDM (HB-005752) for additional information).**
- **Status Message:** Status Messages are alarm or information messages. Note, that the same status message is displayed as on the respective SDM (refer to the Technical Manual for the SDM (HB-005752)). The message is displayed in the same language that is active on the SDM. The font used to display the status message in the station windows can be changed in the dialog 'V-CareNeT Settings' (see 12.2).
- **Alarm Status Icon:** Indicates the priority of the highest priority alarm condition for the respective SDM (see 14.9.1). If for the respective SDM two or more alarm conditions occur at the same time it indicates the highest currently active alarm priority. **Note, that the 'Alarm Status' Icon displays the same information as the 'Alarm Status' Icon of the SDM (refer to the Technical Manual for the SDM (HB-005752) for additional information).**

AUDIO Icon

After confirming the 'Speaker Test' (see 14.9.3) all (enabled) auditory alarm signals of V-CareNeT, i.e. the (enabled) auditory alarm signals of each individual station and (if enabled) of the central station itself, are active (see 14.9.2).

Note: Auditory alarm signals being related to technical alarm conditions of the SDMs and/or the V-CareNeT Central Station can be permanently switched off/ inhibited in the dialog 'V-CareNeT Settings' (see 12.2).

By clicking on the 'AUDIO Icon' in the V-CareNeT Control Window (see 14.5) it is possible to pause or to permanently switch off all auditory alarm signals (see 14.5). As summarized in the following table the 'AUDIO Icons' provided on the right of the 'Suspend' check box of each remote monitoring window additionally offers the possibility to pause or to permanently switch off auditory alarm signals of each station individually. If the 'Speaker Test' is confirmed (see 14.9.3) the AUDIO Icon of an individual station displays/represents one of the 3 following states:

Screenshot	Description / Function
	The 'AUDIO Icon' displays  Auditory alarm signals of the station active. No 'AUDIO Status Message' displays in the station's window. A click on the 'AUDIO Icon' will pause auditory alarm signals of the station for 120 seconds.
	The 'AUDIO Icon' displays  Auditory alarm signals of the station paused The message 'AUDIO PAUSED xxx' displays above the station's status message (xxx indicates remaining pause time in seconds). A click on the 'AUDIO Icon' will permanently switch off auditory alarm signals of the station.
	The 'AUDIO Icon' displays  Auditory alarm signals of the station permanently switched-off The message 'AUDIO OFF' displays above the station's status message. A click on the station's 'AUDIO Icon' will re-enable auditory alarm signals of the station.

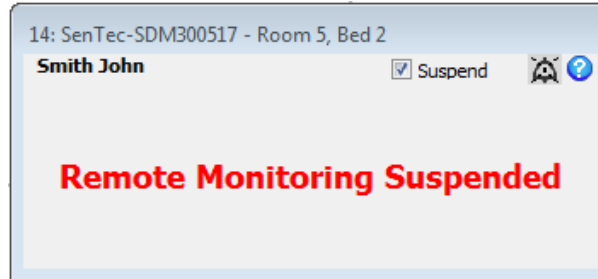
Note: Pausing, permanently switching off, or re-enabling the auditory alarm signals of V-CareNeT by clicking on the 'AUDIO Icon' in the V-CareNeT Control Window does not modify the status indicated by the 'AUDIO Icons' in the individual remote monitoring windows. If, for example, the auditory alarm signals of an individual station as well as the overall auditory alarm signals of V-CareNeT are permanently switched off, the auditory alarm signals of the individual station will remain switched-off when re-enabling the overall auditory alarm signals of V-CareNeT.

Note: If the 'Speaker Test' is required (see 14.9.3) all auditory alarm signals of V-CareNeT (including the AUDIO OFF Reminder) are switched off. If in this case remote monitoring is active for at least one patient, the 'AUDIO OFF' message displays in the 'V-CareNeT Control Window' (see 14.5) and the 'AUDIO Icons' of the V-CareNeT

Control Window and of all active remote monitoring windows indicate the 'AUDIO OFF' symbol. A click on one of the 'AUDIO Icons' (be it in the V-CareNeT Control Window or in one of the station windows) has no function in this situation.

Suspend Check Box

You may find it necessary to temporarily suspend remote monitoring for the respective patient (if the patient is off the floor getting x-rays, for example, or if the patient is being transferred to a new location with the SDM). Selecting the 'Suspend' check box suspends remote monitoring (without interrupting the connection between V-CareNeT and the respective SDM). The message 'Remote Monitoring Suspended' replaces the black data field and the Status Bar, i.e. no current SDM data are displayed when remote monitoring is suspended. Furthermore, all alarms (including auditory alarm signals) are inhibited for the respective SDM.



Note: If the connection between V-CareNeT and a SDM interrupts while the 'Suspend' check box is selected the 'Remote Monitoring Interrupted' alarm is inhibited. In this situation the only indication that the connection with the associated SDM is interrupted is provided by the respective 'Connection Status Indicator' in the 'V-CareNeT Control Window'.

Note: Selecting the 'Suspend' check box while remote monitoring is interrupted inhibits the 'Remote Monitoring Interrupted' alarm as well as all other alarms (including auditory alarm signals) for the associated SDM.

De-select the 'Suspend' check box to resume remote monitoring for the associated SDM.



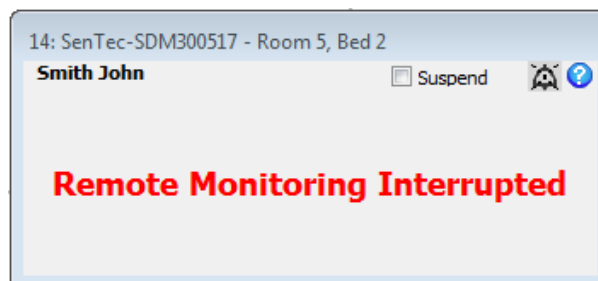
WARNING: Remote alarm surveillance for an individual SDM/patient is inhibited if remote monitoring is suspended for the respective SDM.

Important Note: If the 'Remote monitoring interrupted' alarm condition is triggered while the SDM's alarm system is in the AUDIO OFF state, the SDM will terminate the AUDIO OFF state. Refer to the Technical Manual for the SDM (HB-005752) for further details.

Remote Monitoring Interrupted

When the V-CareNeT System stops receiving data from a SDM while a patient is admitted, the central station triggers the 'Remote Monitoring Interrupted' alarm condition (see also 14.10). If this is the case

- the associated 'SDM Device/Host Name' in the 'V-CareNeT Control Window' highlights cyan
- an audible low priority alarm sounds at the central station (if not disabled (see 12.2, 14.9.2) or already acknowledged (see below)), and
- the message 'Remote Monitoring Interrupted' replaces the black data field and the Status Bar of the respective remote monitoring window as no current SDM data are available when remote monitoring interrupts.



Note: The 'Remote Monitoring Interrupted' alarm may be indicative of a system or equipment (network or monitor) problem causing interruption of the connection between V-CareNeT and the respective SDM.

Furthermore, if the connection between V-CareNeT and at least one SDM for which the 'Connect' check box is selected in the V-CareNeT Control Window cannot be established within 10 seconds or is interrupted for more than 10 seconds the alert dialog 'No communication with at least one SDM' (see 14.10) activates (regardless whether or not patients are admitted to these SDMs). Acknowledgement of the alert-dialog 'No communication with at least one SDM' will also mute the auditory alarm signal of the 'Remote Monitoring Interrupted' alarm condition.

Note: Selecting the 'Suspend' check box while remote monitoring is interrupted inhibits the 'Remote Monitoring

Interrupted' alarm as well as all alarms (including auditory alarm signals) for the respective SDM. In this situation the only indication that the connection is interrupted is provided by the respective 'Connection Status Indicator' in the 'V-CareNeT Control Window'.

When communication between the SDM and V-CareNeT is restored, the 'Remote Monitoring Interrupted' alarm condition resets and remote monitoring for the respective SDM automatically resumes at the central station.



WARNING: Remote alarm surveillance for the respective SDM/patient is interrupted if the connection between V-CareNeT and the respective SDM is interrupted.

Important Note: If the 'Remote monitoring interrupted' alarm condition is triggered while the SDM's alarm system is in the AUDIO OFF state, the SDM will terminate the AUDIO OFF state. Refer to the Technical Manual for the SDM (HB-005752) for further details.

14.8.2 Dialog 'Additional Data'

A click on the black data field area in the remote monitoring window (see 14.8.1) opens the dialog '<X>:<Device/Host Name> - Additional Data'.

<Patient Info> text field (in this example displaying "Smith John")

The <Patient Info> field displays the customized 'Patient Info' which is determined by the patient data field - either the patient's last name/first name, a comment, or the patient number - that is selected in the dialog '<X>: <Device/Host Name> - Patient Data' (see 14.7.2).

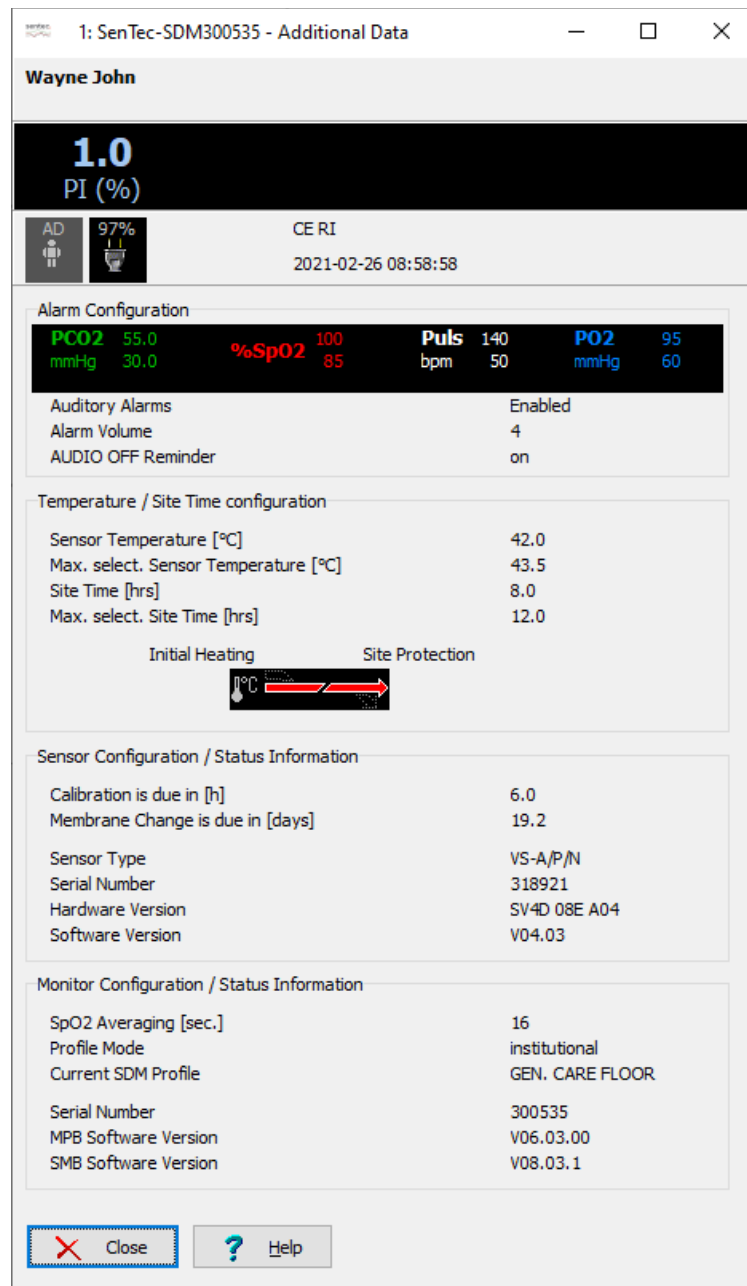
Black data field

The Pulsation Index (PI) and - if enabled on the SDM - the 'Absolute Heating Power' (AHP) or 'Relative Heating Power' (RHP) data displayed in the black data field correspond to current data measured by the SDM to which the patient is admitted. Values of measured parameters are updated every 2 seconds. For details refer to the Technical Manual for the SDM (HB-005752).

Status Bar

A 'Status Bar' is provided below the 'Black data field', displaying from left to right:

- Patient Type Icon: Indicates the current patient type selected on the SDM. The icon displays 'AD' for adult/pediatric patients and 'NEO' for neonatal patients. Note, that the 'Patient Type Icon' displays the same information as the 'Patient Type Icon' of the SDM (for additional information refer to the Technical Manual for the SDM (HB-005752)).



- AC Power / Battery Indicator Icon:** Indicates the remaining battery capacity (%). If the SDM is connected to AC power the Icon displays a power plug symbol. If the SDM is powered by the internal battery the icon displays a battery symbol. In this case the icon highlights yellow below 10% battery capacity and red if the remaining battery capacity is critical. (Format: xxx%).
- Barometric Pressure Icon:** Indicates the measured ambient barometric pressure ('mmHg' or 'kPa', depending on the SDM's menu parameter 'PCO2 (PO2) unit'). The icon highlights red if a barometer fault is detected and yellow if the barometric pressure is unstable during sensor calibration. (Format: xxx.x if 'mmHg'; xx.xx if 'kPa').

Note: The 'Barometric Pressure Icon' only displays, if on the associated SDM PCO2 is enabled and the connected sensor is placed in the 'Docking Station'. If displayed, it displays the same information as the associated SDM's 'Barometric Pressure Icon' (for additional information refer to the Technical Manual for the SDM (HB-005752)).
- Gas Icon:** Indicates the remaining capacity of the calibration gas bottle (%). The 'Gas Icon' highlights yellow if the remaining capacity is < 10% and red if the gas bottle is empty. (Format: xxx%). Note, that the 'Gas' Icon displays the same information as the 'Gas' Icon of the SDM (for additional information refer to the Technical Manual for the SDM (HB-005752)).

Note: The 'Gas Icon' only displays, if on the associated SDM PCO2 is enabled and the connected sensor is placed in the 'Docking Station'. If displayed, it displays the same information as the associated SDM's 'Gas Icon' (for additional information refer to the Technical Manual for the SDM (HB-005752)).
- Status Codes:** The status codes are abbreviations of the SDM's status messages. As two or more alarm conditions/system information concurrently can be present, the SDM internally ranks the possible Status Codes and

outputs the Status Codes in order of decreasing rank (for additional information refer to the Technical Manual for the SDM (HB-005752)).





- **Date/Time:** On the right (below the Status Code), the Status Bar indicates the SDM’s date and time in the “yyyy-mm-dd hh:mm:ss” format.
- **IC-Indicator:** It displays on the right of Date/Time if PCO2 values are in-vivo corrected (IC=xx.x (if ‘mmHg’); IC=x.xx (if ‘kPa’), where xx.x/ x.xx is the current offset) and/or if ‘Severinghaus Correction Mode’ is set to fix (IC=* (fix) if PCO2 is not in-vivo corrected and IC=2.5* if PCO2 is in-vivo corrected (in this example by 2.5 mmHg)).

Alarm Configuration

- **Alarm limits:** Indicates the current high and low alarm limits for PCO2, PO2, SpO2, and PR, which are active on the SDM. Alarm limits can be adjusted in the menu of the SDM or remotely with V-CareNeT (see 14.8.2.1).
- **Auditory Alarms:** Indicates the current setting of the SDM’s auditory alarms (Enabled, PAUSED, OFF). Unless the parameter ‘Alarm Volume’ is set to ‘OFF’, this parameter only can be changed on the SDM.
- **Alarm Volume:** Indicates the current setting of the SDM’s menu parameter ‘Alarm Volume’ (OFF, 1, 2, 3, 4, 5, 6, Rising). That this parameter can be adjusted in the menu of the SDM or remotely with V-CareNeT (see 14.8.2.1).
- **AUDIO OFF Reminder:** Indicates the current setting of the SDM’s menu parameter ‘AUDIO OFF Reminder’ (ON, OFF). That this parameter can be adjusted in the menu of the SDM.
- If ‘Remote Control of SDMs’ is enabled in the password-protected dialog ‘V-CareNeT Settings’ (see 12.2) a click in the black ‘Alarm Configuration’ data field of the dialog ‘Additional Data’ first opens a warning dialog and – after acknowledgement of the warning dialog - the dialog ‘<X>: <Device/Host Name> - Remote Control’ (see 14.8.2.1).

Sensor Temperature / Site Time Configuration

- **Sensor temperature [°C]:** Indicates the current setting of the SDM’s menu parameter ‘Sensor Temperature’ in °C. That this parameter can be adjusted in the menu of the SDM or remotely with V-CareNeT (see 14.8.2.1).
- **Max. select. Sensor Temperature [°C]:** Indicates the current setting of the SDM’s parameter ‘Max. select. Sensor Temperature’ in °C. This parameter only can be changed in a password protected area of V-STATS (see 13.2.4.2).
- **Site Time [hours]:** Indicates the current setting of the SDM’s menu parameter ‘Site Time’ in hours. This parameter can be adjusted in the menu of the SDM or remotely with V-CareNeT (see 14.8.2.1).
- **Max. select. Site Time [hours]:** Indicates the current setting of the SDM’s parameter ‘Max. select. Site Time’ in hours. This parameter only can be changed in a password protected area of V-STATS (see 13.2.4.2).
- **Special Heating Setting Indicator:** Displays the SDM’s current configuration of the parameters INITIAL HEATING and SITE PROTECTION. Both parameters can be adjusted in the menu of the SDM or remotely with V-CareNeT (see 14.8.2.1). Note that this indicator only displays if the connected sensor is heated. The following table summarizes the possible configuration for a SDM with software version SMB-SW V08.03.x and higher:

	Site Protection OFF (or ON and T ≤ 41.0 °C in adults/T ≤ 40.0 °C in neonates)	Site Protection ON (if T > 41.0 °C in adults/T > 40.0 °C in neonates)
Initial Heating OFF (or *)		
Initial Heating ON (if **)		

* ON and T = 44.5 °C in adults ** T < 44.5 °C in adults

Sensor Configuration / Status Information

- **Calibration is due in [h]:** Indicates the number of hours left until next sensor calibration is mandatory (only if PCO2 enabled).
- **Membrane Change is due in [h]:** Indicates the number of days left until next membrane change is mandatory (only if PCO2 enabled).
- **Sensor Type:** Indicates type (model) of the sensor that currently is connected to the SDM.
- **Serial Number:** Indicates the serial number of the connected sensor.
- **Hardware Version:** Indicates the hardware version of the connected sensor.
- **Software Version:** Indicates the software version of the Sentec TC Sensor.

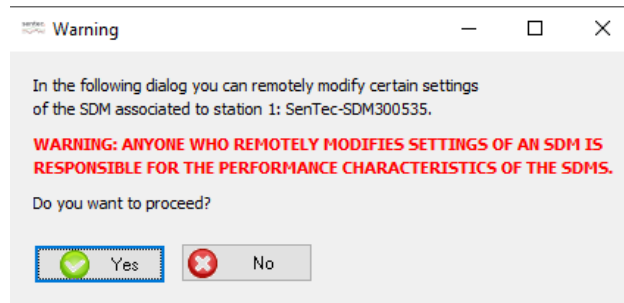
Monitor Configuration / Status Information

- **SpO2 Averaging [sec]:** Indicates the current setting of the SDM’s menu-parameter ‘SpO2 Averaging’. Note, that this parameter can be adjusted in the menu of the SDM.
- **Profile Mode:** Indicates the current setting of the SDM’s parameter ‘Profile Mode’ (‘basic’ or ‘institutional’). Note, that this parameter only can be changed by the Responsible Organization by using V-STATS (see 13.2.1).

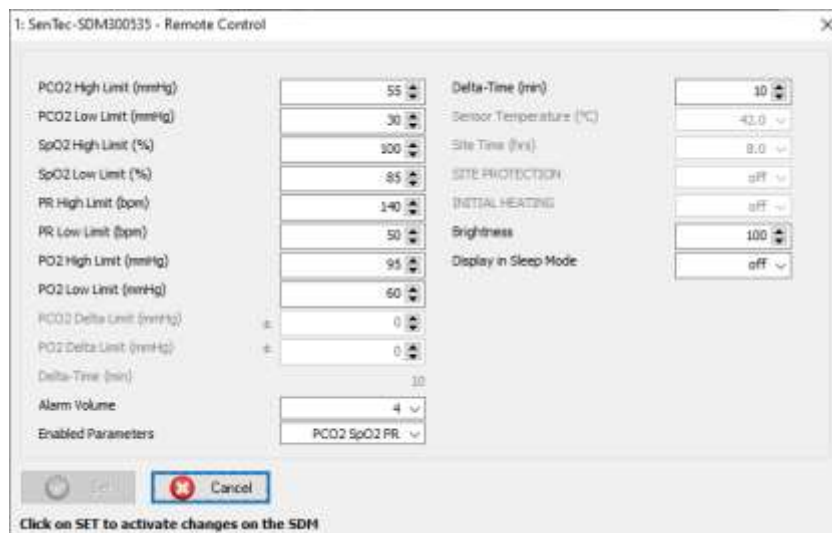
- **Current SDM Profile:** Indicates the name of the SDM's 'Current SDM Profile' in 'Institutional Mode'. An asterisk displays behind the name of the profile if at least one setting has been modified. In 'Basic Mode' it indicates '-'.
- **Serial Number:** Indicates the serial number of the SDM
- **MPB Software Version:** Indicates the software version of the SDM's 'Multi-parameter Board'
- **SMB Software Version:** Indicates software version of the SDM's 'Controller Board'

14.8.2.1 Dialog 'Remote Control'

If 'Remote Control of SDMs' is enabled in the password-protected dialog 'V-CareNeT Settings' (see 12.2) a click in the black 'Alarm Configuration' data field of the dialog '<X>: <Device/Host Name> - Additional Data' opens the following warning dialog.



After acknowledgment of this warning dialog the dialog '<X>: <Device/Host Name> - Remote Control' opens.



After opening the dialog, the button 'Set' is dimmed grey (not accessible). The parameter listed in the dialog '<X>: <Device/Host Name> - Remote Control' can be remotely controlled on the associated SDM. Refer to the Technical Manual for the SDM (HB-005752) for a description of the available settings.

Note: During patient monitoring with the associated SDM, the parameters 'Sensor Temperature', 'Site Time', 'SITE PROTECTION', and 'INITIAL HEATING' are not changeable (dimmed grey).

Note: The parameters 'SITE PROTECTION' and 'INITIAL HEATING' are not changeable (dimmed grey), if the option 'SITE PROTECTION selectable' and 'INITIAL HEATING selectable' are not enabled under 'Profiles / SDM Settings' (see 13.2.4.2).

Note: Upon changing the 'Enabled Parameters' the parameters 'Sensor Temperature (°C)' and 'Site Time (hrs.)' become automatically changeable (dimmed grey).

Adjust the settings as desired and then click on 'Set' to activate changes on the SDM and to close the dialog '<X>: <Device/Host Name> - Remote Control'.

Note: As for changes that are made in the menu of the SDM, remotely modified settings will affect the 'Current Profile of the SDM' only. Profiles stored in one of the SDM's four profile slots will not be modified.



WARNING: Setting alarm limits for PCO₂, PO₂, SpO₂, or PR to extreme values may render the SDM's alarm system for the respective parameter useless.

14.8.3 Dialog 'Set Operator Events'

A click on the 'E' button in the bottom right of the black data field area of the remote monitoring window (see 14.8.1) opens the dialog '<X>: <Device/Host Name> - Set Operator Events'. In this dialog it is - during patient monitoring - possible to remotely set a baseline for PCO₂, PO₂, SpO₂ and RHP or to remotely mark operator events (see 11.1) on the corresponding SDM. Baseline values for PCO₂, PO₂, SpO₂ and RHP subsequently will be displayed numerically and graphically on certain measurement screens of the SDM (see Technical Manual for the SDM (HB-005752)) and - if enabled (see 12.2) - in the respective station's remote monitoring window (see 14.8.1). Please note that V-CareNeT currently only supports remote monitoring of PCO₂, PO₂, SpO₂ and PR.

Note that operator events currently are neither displayed on the SDM nor within V-CareNeT. Only the instants operator events were marked and their type are stored in the internal memory of the SDM for their subsequent display within V-STATS after downloading SDM Trend Data (see 6).

Note: On a SDM it is possible to set a baseline for PCO₂, PO₂, SpO₂ and RHP (if enabled) or to mark one of the different operator event types (EO - E7) by using the respective functions of the 'Quick Access Menu' that opens by pressing on the ENTER button while the connected sensor is outside the docking station.

Event	Description	New Analysis Period
<input type="radio"/> E0	Baseline	<input type="checkbox"/>
<input type="radio"/> E1	RHP reference	<input type="checkbox"/>
<input type="radio"/> E2	...	<input type="checkbox"/>
<input type="radio"/> E3	...	<input type="checkbox"/>
<input type="radio"/> E4	...	<input type="checkbox"/>
<input type="radio"/> E5	...	<input type="checkbox"/>
<input type="radio"/> E6	...	<input type="checkbox"/>
<input type="radio"/> E7	...	<input type="checkbox"/>

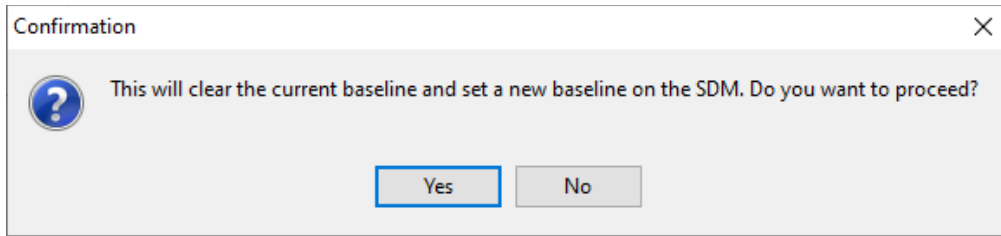
Note:
To define Operator Events go to V-STATS' password-protected Menu "Settings / V-STATS Settings"

The dialog '<X>: <Device/Host Name> - Set Operator Events' duplicates for each of the different operator event types (EO - E7) the standard settings that are predefined in the dialog 'Define Operator Events' (see 12.1.3) and that will be used for each operator event when downloading/importing SDM Trend Data to V-STATS. Note that in the dialog '<X>: <Device/Host Name> - Set Operator Events' it is not possible to edit the standard settings predefined for the different operator event types, in this dialog it is only possible to select a specific operator event type by selecting the radio button next to it.

Note: In the dialog 'Define Operator Events' (see 12.1.3) it is possible to predefine for each operator type a) the color of the operator event triangles that will be used for all operator events of a specific type, b) the standard description that will be assigned to all operator events of a specific type, and c) whether or not a new 'Analysis Period' shall start at each occurrence of operator events of a specific type when downloading/importing SDM Trend Data to V-STATS.

After opening the dialog '<X>: <Device/Host Name> - Set Operator Events' none of the radio buttons next to the different event types is selected and, consequently, the button 'Set' is dimmed grey (not accessible)

To set a baseline for PCO₂, PO₂, SpO₂ and RHP (if enabled) on the corresponding SDM select the radio button in front of 'Event E0' and then click on the 'Set' button (note that V-CareNeT remote monitoring currently only supports monitoring of PCO₂, PO₂, SpO₂ and PR). The following dialog will appear:



Click on 'NO' to abort and to return to the dialog '<X>: <Device/Host Name> - Set Operator Events'.

Click on 'Yes' to close the dialog '<X>: <Device/Host Name> - Set Operator Events' and to set a new baseline as well as to store an event of type EO in the internal memory of the SDM.

Note: On the SDM the baseline is reset if the sensor is back in 'Docking Station' for more than 30 minutes, the SDM is turned off, the sensor is changed, or the patient type is changed.

To mark an Operator Event on the corresponding SDM first select the radio button in front of the appropriate event type. Then click on the 'Set' button to store the instant the operator event was marked and its type in the internal memory of the SDM. When downloading SDM Trend Data from the internal memory of the SDM this information (time, type) will be transferred to V-STATS for each operator event that occurred within the selected measurement period(s) (see 6) and to each operator event the standard settings predefined for the respective event type (see 12.1.3) will be assigned.

14.9 Remote Monitoring - V-CareNeT's Alarm System

If the connection between the SDM and the V-CareNeT Central Station is established and a patient has been admitted to the respective SDM (i.e. once remote monitoring is active for the respective SDM) all alarm conditions evaluated on the SDM as well as the current status messages displayed by the SDM are transferred to and duplicated by the central station. If during active remote monitoring the connection with a SDM interrupts, the central station, furthermore, triggers the 'Remote Monitoring Interrupted' alarm condition (see 14.8.1 and 14.10).

Note: The 'Remote Monitoring Interrupted' alarm condition is currently the only alarm condition that is evaluated by the V-CareNeT Central Station. All other alarm conditions available within V-CareNeT are evaluated on the SDMs.

As for the individual SDMs (see HB-005752), the alarm system of V-CareNeT is designed to meet the requirements of the applicable international standards. The alarm system of V-CareNeT uses visual and auditory alarm signals, to alert the operator when a physiological parameter (PCO2, PO2, SpO2, PR) violates its alarm limits during patient monitoring or to indicate technical conditions of the equipment that require operator response or operator awareness. By the degree of urgency, the alarm conditions are assigned to the following priorities:

Priority	Explanation	Alarm Condition(s) evaluated by individual SDM(s)	Alarm Condition(s) evaluated by V-CareNeT
High	Immediate operator response required	SpO2 violates its upper/lower alarm limit	--
Medium	Prompt operator response required	PR violates its upper/lower alarm limit PCO2 violates its upper/lower alarm limit PO2 violates its upper/lower alarm limit Battery critical (monitor not connected to AC power)	--
Low	Operator awareness required	Various technical conditions	Remote monitoring interrupted for at least one SDM
Information	General system / status information	No alarm	No alarm

WARNING: Remote alarm surveillance for the respective SDM/patient is interrupted if the connection between V-CareNeT and the respective SDM is interrupted.

WARNING: Setting alarm limits for PCO2, PO2, SpO2, or PR to extreme values may render the SDM's alarm system for the respective parameter useless.

Note: Monthly check the alarm system of V-CareNeT. Activate the 'Demo Mode' on and remote monitoring for a

SDM. Adjust the alarm limits on the SDM (either in its menu or remotely (see 14.8.2.1)) so that the respective parameter is outside the alarm limit and verify the alarm function (see 14.9.1, 14.9.2, 14.9.3). Furthermore disconnect a SDM from the network while a patient is admitted and verify proper function of the 'Remote Monitoring Interrupted' alarm condition (see 14.8.1, 14.10).

Note: If five or fewer minutes remain until a 'V-CareNeT Trial' (see 15.3) or an 'Extended V-CareNeT Trial' (see 15.4) expires an audible low priority alarm occurs at the central station and V-CareNeT opens the alert-dialog 'V-CareNeT Trial Expiring' or 'Extended V-CareNeT Trial Expiring', respectively.

14.9.1 Visual Alarm Signals

Alarm conditions can be concurrently present for two or more SDMs. In order to ensure that the operator readily can recognize for which SDMs alarm conditions are present, V-CareNeT

- indicates for each patient/ SDM the priority of the currently present alarm condition (if any) in the 'Alarm Status Icon' of the associated station's remote monitoring window (see 14.8.1 and table below);
- highlights 'SDM Device/Host Names' in the 'V-CareNeT Control Window' (see 14.5) a) **red**, if the highest priority alarm condition currently being present at the associated SDMs is a high priority alarm condition, b) **yellow**, if this is a medium priority alarm condition, or c) **cyan** if this is a low priority alarm condition.

Note: As two or more alarm conditions can be concurrently present for an individual SDM, the color indicates the priority of the highest priority alarm condition currently being present on the respective SDM.



For each individual station/SDM V-CareNeT additionally provides the following visual alarm signals.



Alarm Condition	Flashing Parameter	Status Message / Codes	Status Icon	Alarm Status Icon
Physiological alarm condition (PCO ₂ , PO ₂ , SpO ₂ , PR violating lower/upper alarm limit)	SpO ₂ : 1.4 Hz PCO ₂ , PO ₂ , PR: 0.7 Hz (see 14.8.1)	No	Not applicable	Yes (see below)
Technical alarm condition of the SDM (various reasons)	Not applicable	Yes (see 14.8.1) Status Codes in dialog 'Additional Data' (see 14.8.2)	Only if alarm condition arises from one of the variables displayed in the Status Icons (see 14.8.1 and 14.8.2)	
Remote Monitoring Interrupted	Not applicable	Yes (see 14.8.1 and 14.10)	Not applicable	Not applicable

Note: As measurement parameters independently flash from each other multiple physiological alarm conditions can be visualized in a station window should they occur simultaneously on the associated SDM.

Note: In a station's remote monitoring window V-CareNeT duplicates the Status Message that is currently displayed on the associated SDM. Note that on the associated SDM two or more alarm conditions (or system information) of equal priority can be present concurrently and the SDM, therefore, internally ranks the display priority of the possible Status Messages. The SDM and, hence, V-CareNeT only display the Status Message corresponding to the alarm condition / system information with the highest internal rank. Additionally status codes (if any) are displayed in the dialog 'Additional data' (see 14.8.2) in order of decreasing rank (for additional information please refer to the Technical Manual for the SDM (HB-005752)).

The 'Alarm Status Icon' in the bottom right corner of the remote monitoring window meets the requirements of IEC 60601-1-8:2006 (Table 2) and indicates the priority of the highest priority alarm condition on the associated SDM. If two or more alarm conditions occur at the same time on the associated SDM it indicates the highest currently active alarm priority.


Alarm Status Icon	Description
	High Priority Alarm Condition: White triangle with curved line and exclamation mark on red background (flashing with 1.4 Hz).
	Medium Priority Alarm Condition: Black triangle with curved line and exclamation mark on yellow background (flashing with 0.7 Hz).

	Low Priority Alarm Condition: Black triangle with curved line and exclamation mark on cyan background (constant on).
	No Alarm Condition present: Light grey check mark symbol on dark-grey background (constant on).

Alarm Inhibition

Alarms for an individual SDM can be inhibited by pressing the ‘Suspend’ check box in the respective remote monitoring window (see 14.8.1).

Note: Visual alarm signals cannot be inhibited on the SDM. If the SDM’s menu-parameter ‘Sleep Mode’ is set to ON, however, no data and in particular no visual alarm signals will display.

 **WARNING:** Remote alarm surveillance for an individual SDM/patient is inhibited if remote monitoring is suspended for the respective SDM.

Important Note: If the ‘Remote monitoring interrupted’ alarm condition is triggered while the SDM’s alarm system is in the AUDIO OFF state, the SDM will terminate the AUDIO OFF state. Refer to the Technical Manual for the SDM (HB-005752) for further details.

14.9.2 Auditory Alarm Signals / Inactivation of auditory alarm signals

Multiple alarm conditions can be concurrently present for two or more SDMs. At the same time remote monitoring furthermore may be interrupted for one or more SDMs. V-CareNeT therefore first must evaluate the highest currently active alarm priority within the entire V-CareNeT System and then activate the respective auditory alarm signal at the V-CareNeT Central Station.

V-CareNeT’s auditory alarm signals are priority encoded and meet the requirements of IEC 60601-1-8:2006 (Table 3 and Table 4). In the password protected dialog ‘V-CareNeT Settings’ (see 12.2) it is furthermore possible to switch ON or OFF ‘Alarm Melodies’ as specified in Annex F of IEC 60601-1-8:2006. The volume of auditory alarm signals generated at the V-CareNeT Central Station can be adjusted by adjusting the volume of your PC’s loudspeaker. By performing the ‘Speaker Test’ (see 14.9.3) you periodically must verify and confirm that the auditory alarm signals generated at the V-CareNeT Central Station are audible in the intended environment.

Alarm Priority	Description
High Priority Alarm	<p><u>Alarm Melodies OFF:</u> A high-pitched fast pulsing tone indicating a SpO2 limit violation (two bursts of five short pulses (1 triad and 1 dyad) repeated every 10 seconds).</p> <p><u>Alarm Melodies ON:</u> Same time sequence as if Alarm Melodies disabled. For each of the two bursts</p> <ul style="list-style-type: none"> • ‘cba-gf’ (major scale downwards) sounds for a SpO2 limit violation
Medium Priority Alarm	<p><u>Alarm Melodies OFF:</u> A medium-pitched pulsing tone indicating a Battery Critical Alarm (only if SDM not connected to AC) or a PCO2, PO2 or PR limit violation (one burst of three pulses (1 triad) repeated every 10 seconds).</p> <p><u>Alarm Melodies ON:</u> Same time sequence as if Alarm Melodies disabled.</p> <ul style="list-style-type: none"> • ‘Caf’ (inverted major chord) sounds for a PCO2 limit violation • ‘cba’ (top of major scale downwards) sounds for a PO2 limit violation • ‘Ceg’ (major chord) sound for a PR limit violation • ‘cCC’ (octave down) sound for a Battery Critical Alarm (only if SDM not connected to AC power)
Low Priority Alarm	<p><u>Alarm Melodies OFF:</u> A low-pitched slow pulsing tone indicating a system status that requires operator awareness (one burst of two pulses (1 dyad) repeated every 15 seconds).</p> <p><u>Alarm Melodies ON:</u> Same time sequence as if Alarm Melodies disabled. For each of the two bursts.</p> <ul style="list-style-type: none"> • ‘eC’ (major third downwards) sounds for any cause.

Inhibition of auditory alarm signals

Important Note:

During remote monitoring V-CareNeT's auditory alarm signals are only active if the 'Speaker Test' is confirmed (see 14.9.3). If the 'Speaker Test' is required, all auditory alarm signals of V-CareNeT (including the AUDIO OFF Reminder) are permanently switched off. If in this case remote monitoring is active for at least one patient, the 'AUDIO OFF' message displays in the 'V-CareNeT Control Window' (see 14.5) and the 'AUDIO Icons' of the V-CareNeT Control Window and of all active remote monitoring windows indicate the 'AUDIO OFF' symbol.

Note: Auditory alarm signals on the SDM and on the V-CareNeT Central Station can be active, paused or permanently switched off independently from each other.



WARNING: If an alarm condition occurs while auditory signals are paused or permanently switched off on the SDM as well as on the V-CareNeT Central Station the only alarm indication will be visual; no auditory alarm signal will sound.

Once the 'Speaker Test' is confirmed all (enabled) auditory alarm signals of V-CareNeT are activated. As summarized below there are numerous possibilities to pause or permanently switch off auditory alarm signals of V-CareNeT partially or entirely:

- 1) Selecting the 'Suspend' check box in a remote monitoring window completely inhibits remote alarms (including auditory alarm signals) for the corresponding station/SDM (see 14.8.1).
- 2) A click on the 'AUDIO Icon' in a remote monitoring window (see 14.8.1) pauses auditory alarm signals for 120 seconds and a second click (while auditory alarm signals are paused) permanently switches off auditory alarm signals for the corresponding station/SDM. A renewed click on the 'AUDIO Icon' re-activates (enabled) auditory alarm signals for the corresponding station/SDM.

Note: If auditory alarm signals being related to an individual station/SDM are permanently switched off the AUDIO OFF Reminder is not active.

Note: The message 'AUDIO PAUSED xxx' displays above the station's status message and the 'AUDIO Icon' indicates the 'AUDIO PAUSED' symbol if auditory alarm signals of a station are paused. xxx indicates the remaining pause time in seconds. If auditory alarm signals are permanently switched off the message 'AUDIO OFF' displays and the 'AUDIO Icon' indicates the 'AUDIO OFF' symbol.

- 3) A click on the 'AUDIO Icon' in the 'V-CareNeT Control Window' (see 14.5) pauses all auditory alarm signals of V-CareNeT for 120 seconds and a second click (while auditory alarm signals are paused) permanently switches off all auditory alarm signals of V-CareNeT. A renewed click on the 'AUDIO Icon' re-activates all (enabled) auditory alarm signals of V-CareNeT.

Note: If all auditory alarm signals of V-CareNeT are permanently switched off the AUDIO OFF Reminder – a short signal tone that sounds every 60 seconds – is active. The 'AUDIO OFF Reminder' can be disabled in the dialog 'V-CareNeT Settings' (see 12.2).

Note: The message 'AUDIO PAUSED xxx' displays in the V-CareNeT Control Window and the 'AUDIO Icon' indicates the 'AUDIO PAUSED' symbol if all auditory alarm signals of V-CareNeT are paused. xxx indicates the remaining pause time in seconds. If all auditory alarm signals of V-CareNeT are permanently switched off the message 'AUDIO OFF' displays in the V-CareNeT Control Window and the 'AUDIO Icon' indicates the 'AUDIO OFF' symbol.

- 4) In the password-protected dialog 'V-CareNeT Settings' (see 12.2) it is possible to permanently switch off/inhibit auditory alarm signals being related to technical alarm conditions a) of all remotely monitored SDMs and/or b) of the V-CareNeT Central Station.

Note: Auditory alarm signals being related to physiological alarm conditions (alarm limit violations of PCO₂, PO₂, SpO₂, or PR) occurring at remotely monitored SDMs continue to be audible at the V-CareNeT Central Station if auditory alarm signals being related to technical alarm conditions occurring at remotely monitored SDMs are disabled.

Note: The message 'AUDIO OFF Tech. Alarms SDMs' displays in the V-CareNeT Control Window if auditory alarm signals related to technical alarm conditions of all remotely monitored SDMs are permanently switched off/inhibited, 'AUDIO OFF Tech. Alarms CS' displays if auditory alarm signals related to technical alarm conditions of the Central Station are permanently switched off/inhibited. If auditory alarm signals related to all technical alarm conditions the message 'AUDIO OFF Tech. Alarms' displays.

- 5) A click on the 'Speaker Test' Icon in the 'V-CareNeT Control Window' (see 14.5) and then pressing on the 'Not functional' button in the dialog 'Speaker Test' (see 14.9.3) inhibits all auditory alarm signals of V-CareNeT.

Note: During the 'Speaker Test' (see 14.9.3), all auditory alarm signals of V-CareNeT are inhibited. Instead the 'Speaker Test signal tone', which is repeated every 5 seconds, sounds.

Note: If the 'Speaker Test' is required and if remote monitoring is active for at least one patient, the 'AUDIO OFF' message displays in the 'V-CareNeT Control Window' (see 14.5) and the 'AUDIO Icons' of the V-CareNeT Control Window and of all active remote monitoring windows indicate the 'AUDIO OFF' symbol.

14.9.3 Speaker Test

When starting-up V-CareNeT (see 14.4), V-CareNeT assumes that the speaker of the PC with V-CareNeT is not functional and, consequently, all auditory alarm signals of V-CareNeT are inhibited and the 'Speaker Test' Icon in the V-CareNeT Control Window displays the 'Speaker Test Required' symbol (see 14.5).

The dialog 'Speaker Test' opens (i.e. the 'Speaker Test' activates) each time when starting-up V-CareNeT (see 14.4, 14.4.1). When V-CareNeT is already active, it opens

- upon a click on the 'Speaker Test' Icon in the 'V-CareNeT Control Window' (see 14.5);
- when activating remote monitoring for at least one SDM if the 'Speaker Test' is required (see, 14.7.1); or
- if the 'Interval for automatic Speaker Test' elapsed if remote monitoring is active for at least one SDM (see below).

Speaker Test

Please check proper function of your PC's speaker and adjust the speaker volume to ensure that auditory alarm signals generated by V-CareNeT are audible for the operator in the intended environment.

Test Signal Indicator V-CareNeT currently generates an auditory test signal (one burst of three short pulses) which is repeated every 5 seconds.

To test the speaker you additionally can activate V-CareNeT's different acoustical alarm signals by clicking on the respective button.

High Priority Medium Priority Low Priority

Confirmation of proper function

By clicking on the "I Confirm" button you confirm that you tested proper function of your PC's speaker and that the speaker's volume is adjusted such that V-CareNeT auditory alarm signals are audible for the operator in the intended environment.

I Confirm

Speaker does not properly function

If based on the above tests you conclude that your PC's speaker is not properly functioning then click on the "Not functional" button. During Remote monitoring V-CareNeT permanently will prompt the message "AUDIO OFF".

Not functional

Automatic Repetition of the speaker test

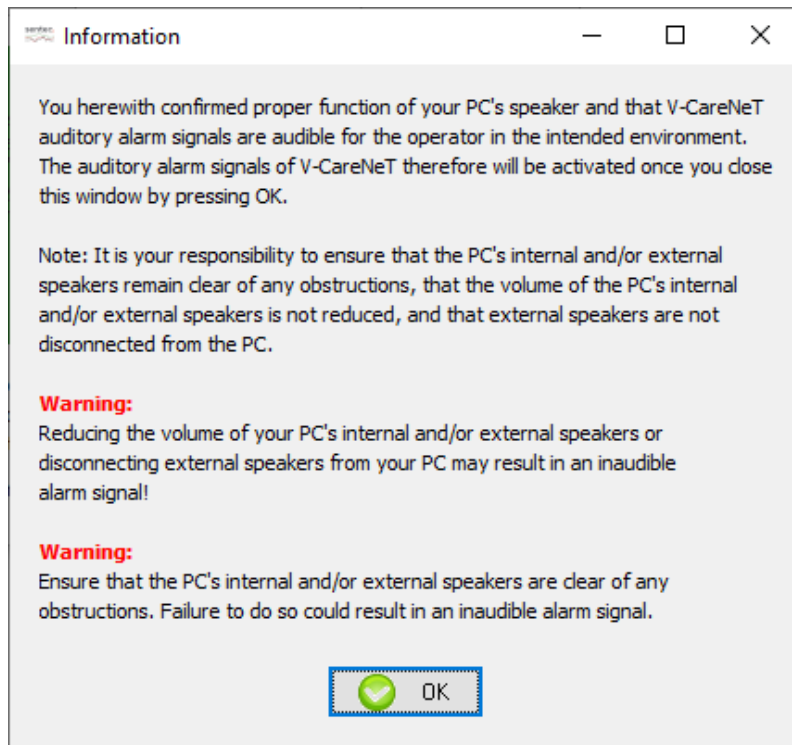
During Remote Monitoring V-CareNeT periodically will reactivate the speaker test. Within certain limits (0.5 to 24 hours) you can adjust the test interval:

Interval for automatic speaker test (hours) 4.0

WARNING: During the 'Speaker Test', all auditory alarm signals of V-CareNeT are inhibited. Instead the 'Speaker Test signal tone', which is repeated every 5 seconds, sounds.

A click on the 'Not functional' button closes the dialog 'Speaker Test' and inhibits all auditory alarm signals of V-CareNeT. Activation of the auditory alarm signals requires execution of the 'Speaker Test'. Consequently, the 'Speaker Test' Icon in the V-CareNeT Control Window displays the 'Speaker Test Required' symbol.

A click on the 'I confirm' button opens the following information dialog



A click on the 'OK' button closes this dialog, confirms proper function of the PC's speaker and then activates auditory alarm signals of V-CareNeT. Subsequently, the 'Speaker Test' icon in the V-CareNeT Control Window displays the 'Speaker Test Confirmed' symbol.

Once the 'Interval for automatic Speaker Test' has elapsed the 'Speaker Test' is required again. If the 'Interval for automatic Speaker Test' elapses while remote monitoring is active for at least one SDM the dialog 'Speaker Test' activates automatically.

Note: In the dialog 'Speaker Test' the 'Interval for automatic speaker test (hours)' can be adjusted in the 0.5 to 24.0 hours range.

Note: After having declared the PC's speaker as not functional by pressing the 'Not functional' button in the 'Speaker Test' dialog, V-CareNeT will not automatically activate the dialog 'Speaker Test' if remote monitoring is active. Click on the 'Speaker Test' icon in the 'V-CareNeT Control Window' to activate the dialog 'Speaker Test' in this situation.

Note: V-CareNeT stores a log of the occurrence of the different events related with testing the speaker on the PC with V-CareNeT.

Note: Contact Sentec to permanently declare the PC's speaker as functional and, hence, to suppress automatic activation of the 'Speaker Test'.

14.9.4 Alarm condition delay

IEC 60601-1-8:2006 defines 'Alarm Condition Delay' as the time from the occurrence of a triggering event either in a) the patient, for physiological alarm conditions, or b) in the equipment, for technical alarm conditions, to when the alarm system determines that an alarm condition exists. It furthermore defines 'Alarm Signal Generation Delay' as the time from the onset of an alarm condition to the generation of the associated alarm signal(s).

Alarm Signal Generation Delay

In case of the SDM the 'Alarm Signal Generation Delay' is < 2 s for all alarm conditions, i.e. once the SDM has determined that an alarm condition exists, the corresponding alarm signal is generated instantly. The alarm signals available at the SDM's communication interfaces (serial, LAN) are activated upon occurrence of an alarm condition with a delay of max. 2 seconds. Data transmission (including transmission of alarm conditions) from the SDM to V-CareNeT may be delayed by several seconds.

Alarm Condition Delays for physiological alarm conditions

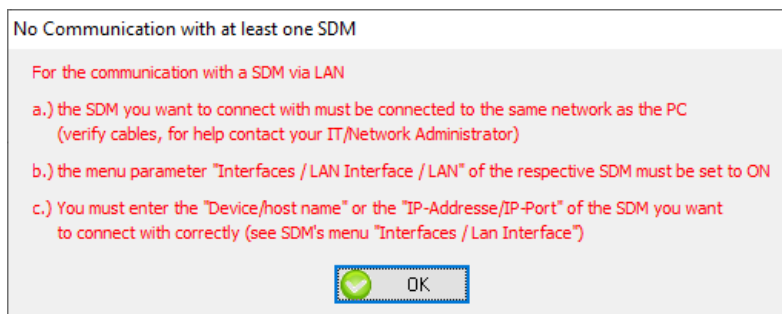
Alarm conditions for physiological alarms are determined by the SDM. Refer to the Technical Manual of the SDM (HB-005752).

Alarm Condition Delays for technical alarm conditions

For alarm conditions that are determined by the SDM refer to the Technical Manual for the SDM (HB-005752). The 'Alarm Condition Delay' for V-CareNeT's alarm 'Remote Monitoring Interrupted' is < 5 seconds.

14.10 Interruption of the connection between V-CareNeT and (a) SDM(s)

Whenever the 'Connect' check box in the V-CareNeT Control Window is selected for a SDM, V-CareNeT tries to establish/maintain connection with the respective SDM (see 14.3.3, 14.5). If the connection between V-CareNeT and at least one SDM for which the 'Connect' check box is selected in the V-CareNeT Control Window cannot be established within 10 seconds or is interrupted for more than 10 seconds, the alert dialog 'No communication with at least one SDM' activates.



Click on the 'OK' button to acknowledge and to close the alert dialog 'No communication with at least one SDM'.

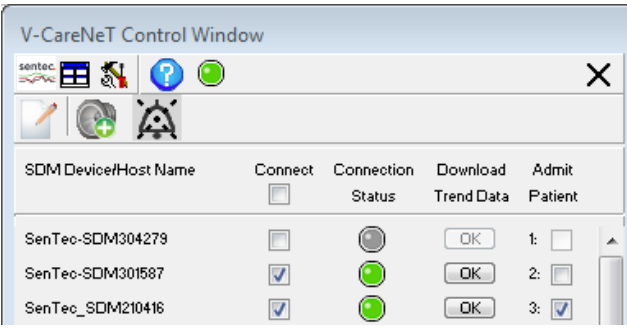
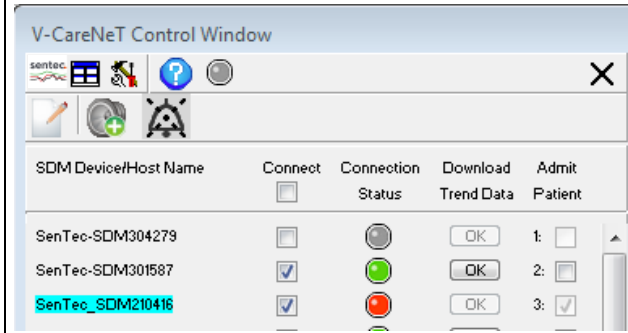
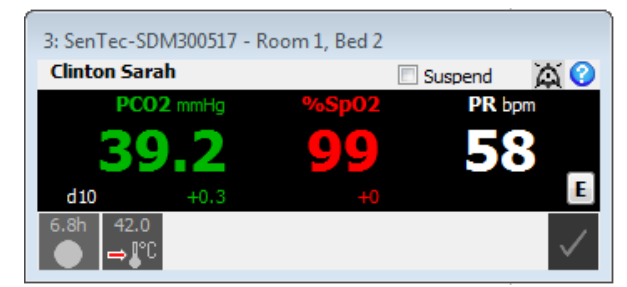
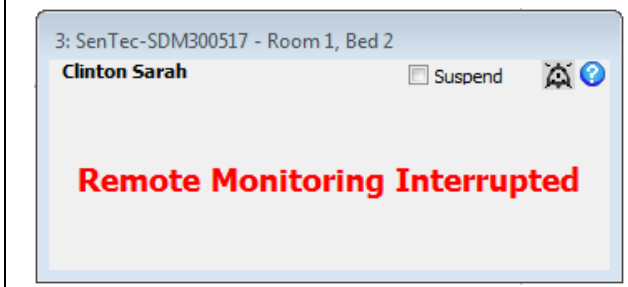
Note: V-CareNeT closes the dialog 'No communication with at least one SDM' as soon as the connection between V-CareNeT and all SDMs for which the 'Connect' check box in the 'V-CareNeT Control Window' is selected is (re)established.

Note: Once acknowledged the alert dialog 'No communication with at least one SDM' only reappears a) if for at least one SDM the connection interrupts again after it was re-established, or b) if the connection with a further SDM cannot be established/maintained.

Note: If a patient is admitted to a SDM with which the connection cannot be established/maintained the central station will (if not disabled (see 12.2, 14.9.2)) output a low priority auditory alarm signal along with the alert dialog 'No communication with at least one SDM'. In this case acknowledgment of the alert-dialog 'No communication with at least one SDM' will mute this alarm signal.

Note: If a patient is admitted to a SDM with which the connection cannot be established/maintained the SDM also will give a 'Remote monitoring interrupted' alarm. Refer to the Technical Manual for the SDM (HB-005752) for further details.

The following table summarizes how interruption of the connection between V-CareNeT and a SDM affects the 'V-CareNeT Control Window' and – if a patient is admitted – the remote monitoring window. The column on the left shows the V-CareNeT Control window and the remote monitoring window of the 3rd SDM if the connection is established between V-CareNeT and the 3rd SDM whereas the right column shows these dialog windows with the connection between V-CareNeT and the 3rd SDM being interrupted.

V-CareNeT connected to 3 rd SDM via the network	Connection between V-CareNeT and 3 rd SDM interrupted
	
<p>The 'SDM Device/Host Name' of the 3rd SDM is not highlighted.</p>	<p>The 'SDM Device/Host Name' of the 3rd SDM highlights cyan (only if a patient is admitted to the respective station).</p>
<p>The 'Connect' check box of 3rd SDM is accessible</p>	<p>The 'Connect' check box of 3rd SDM is accessible <i>Note: The interruption of the communication with the SDM does not change the selection status of the respective station's 'Connect' check box.</i></p>
<p>The 'Connection Status Indicator' of the 3rd SDM lights green (●)</p>	<p>The 'Connection Status Indicator' of the 3rd SDM lights red (●), indicating that the communication between V-CareNeT and the 3rd SDM is interrupted/not established.</p>
<p>The 'OK' button of the 3rd SDM in the 'Download Trend Data' column is accessible</p>	<p>The 'OK' button of the 3rd SDM in the 'Download Trend Data' column is not accessible (dimmed grey)</p>
<p>The 'Admit Patient' check box of 3rd SDM is accessible</p>	<p>The 'Admit Patient' check box of 3rd SDM is not accessible (dimmed grey) <i>Note: The interruption of the communication with the SDM does not change the selection status of the respective station's 'Patient Admit' check box</i></p>
	
<p>Online data of the 3rd SDM are displayed.</p>	<p>The message 'Remote Monitoring Interrupted' replaces the online data of the 3rd SDM.</p>
<p>Other remote monitoring related windows can be opened.</p>	<p>Other remote monitoring related windows are closed / cannot be opened.</p>
	<p>A low priority auditory alarm signal is triggered if a patient is admitted. <i>Note: If the connection interrupts between V-CareNeT and a SDM a low priority auditory alarm signal is only triggered if a patient is admitted to the respective station. This low priority alarm signal will only be audible a) if technical alarms of the central station are not disabled (see 12.2), b) if V-CareNeT's auditory alarm signals are not paused or permanently switched off (14.5, 14.9.2), c) if remote monitoring for the respective station is not suspended (see 14.8.1), and d) if auditory alarm signals of the respective station are not paused or permanently switched off (14.8.1, 14.9.2).</i></p>

15. Tools Menu

Note: Once your V-STATS license is registered (see 15.1) and V-CareNeT is activated (see 15.2), the 'Tools Menu' is no longer needed and will, therefore, be removed from the menu.

15.1 Sub-menu 'Tools / Register V-STATS'

Sentec AG recommends that you register your V-STATS license, as registered users are notified upon availability of new V-STATS versions. Furthermore, free updates can only be made and the 'V-CareNeT' only can be activated if the V-STATS license that is installed on your PC is registered.

The sub-menu 'Tools / Register V-STATS' opens the dialog 'Registration'. Please follow the instructions provided in the dialog 'Registration' to generate a 'Registration Code' and to activate the registration of your V-STATS license after having obtained the 'Registration Code'.

Note: Once the registration of your V-STATS license is activated, this sub-menu is no longer needed and therefore no longer available.

Registration

V-STATS **sentec.**

To register your V-STATS license you need a "Registration Code".

To generate a "Registration Code" you will need the
Identification Code: C7189031707263

You can generate the "Registration Code" by yourself on the website:
<http://registration.sentec.com/vstats.html>

Alternatively you can request a "Registration Code" by sending an Email to:
vstats_req@sentec.com
or a fax to +41 61 726 97 61 with the following contents:

Subject: V-STATS Registration
Contact details: (max. 50 characters)
Email address: (only required if requesting "Registration Code" by fax)
FAX number: (mandatory if requesting "Registration Code" by fax)
User name under which V-STATS will be registered (max. 50 characters)
Identification Code: C7189031707263

Once you have obtained the "Registration Code" you must enter it in the field below and press the button "Activate registration"

User name:

Registration code:

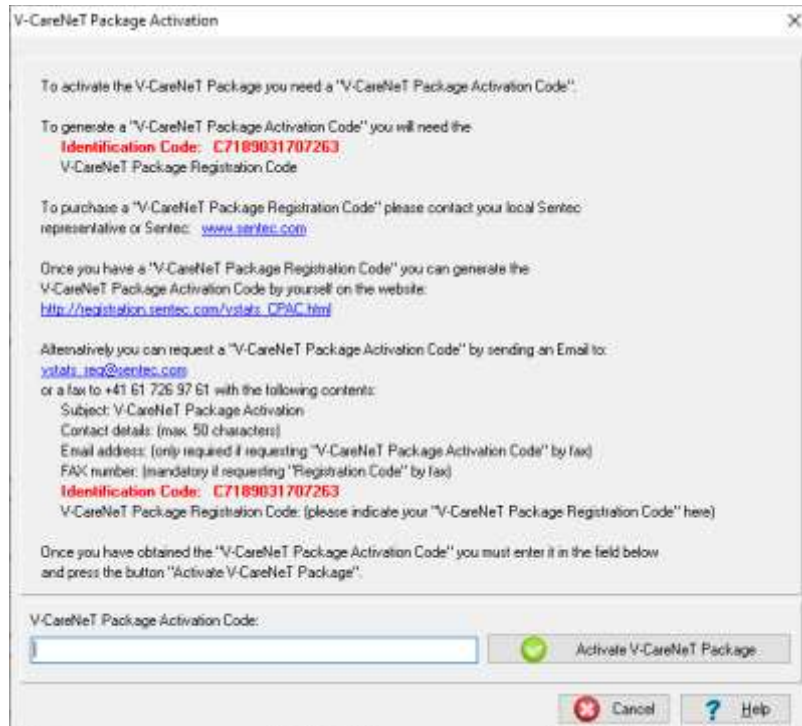
15.2 Sub-menu 'Tools / V-CareNeT Package Activation'

In order to activate the 'V-CareNeT Package' (see 14) you need a 'V-CareNeT Package Activation Code'. This code can be generated on a webpage by using a 'V-CareNeT Package Registration Code', which can be purchased from your local Sentec representative or from Sentec. 'V-CareNeT Package Registration Codes' are available for 5, 10, 20, 30 or 40 beds/patients (order codes V-STATS_CPRC_5, V-STATS_CPRC_10, V-STATS_CPRC_20, V-STATS_CPRC_30, V-STATS_CPRC_40). 'V-CareNeT Package Registration Codes' start with the letter C followed by a (typically) 10-digit number. The two first numbers after the letter C encode the number of beds/patients included in the 'V-CareNeT Package Registration Code'. The code 'C2000450208', for example, includes 20 beds/patients.

The sub-menu 'Tools / V-CareNeT Package Activation' opens the dialog 'V-CareNeT Package Activation'. Please follow the instructions provided in the dialog 'V-CareNeT Package Activation' to generate a 'V-CareNeT Package Activation Code' and to activate the V-CareNeT Package after having obtained the 'V-CareNeT Package Activation Code'.

Note: This sub-menu is not accessible (dimmed grey) as long your V-STATS license is not registered. Once the V-CareNeT Package has been activated this sub-menu is not any longer needed and therefore not any longer available.

Note: See 15.3 to activate a 'V-CareNeT Trial', 15.4 to activate an 'Extended V-CareNeT Trial', and 12.3 to activate the 'V-CareNeT Demo Mode'.

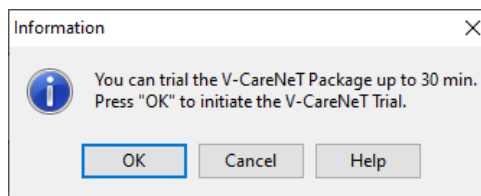


Note: After activation of the V-CareNeT Package the 'V-CareNeT Registration Code' that was used to generate the 'V-CareNeT Activation Code' is displayed in the dialog 'Product-Info' (see 16.6).

Note: After activation of your V-CareNeT Package it is at any time possible to upgrade V-CareNeT to a higher number of beds/patients (see 16.6.1).

15.3 Sub-menu 'Tools / V-CareNeT Trial'

The sub-menu 'Tools / V-CareNeT Trial' opens the following information dialog.



Click on 'Cancel' to abort activation of a 'V-CareNeT Trail'. Click on 'OK' to activate the 'V-CareNeT Trial'. The trial time is 30 minutes. The 'V-CareNeT Trial' can be (re)activated an unlimited number of times (after restarting V-STATS).

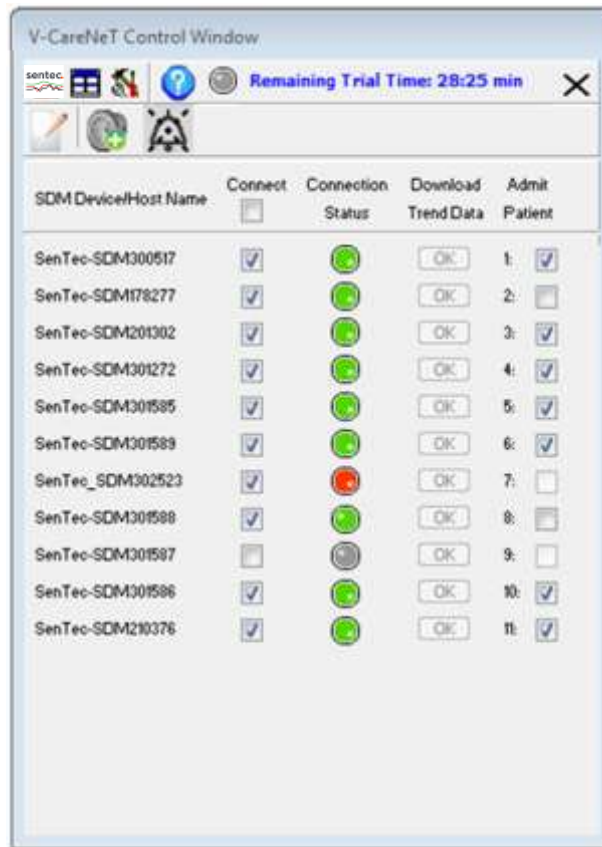
Note: During a 'V-CareNeT Trial' download of SDM Trend Data via the network (see 6, 14.6) is not supported, otherwise, V-CareNeT is fully functional.

Note: If a SDM is configured in 'V-CareNeT Only Mode' it is not possible to admit a patient to the respective station during a 'V-CareNeT Trial'.

Note: The sub-menu 'V-CareNeT Trial' is not accessible (dimmed grey) as long your V-STATS license is not registered. It is also dimmed grey if a 'V-CareNeT Trial', an 'Extended V-CareNeT Trial', or the 'V-CareNeT Demo Mode' is active.

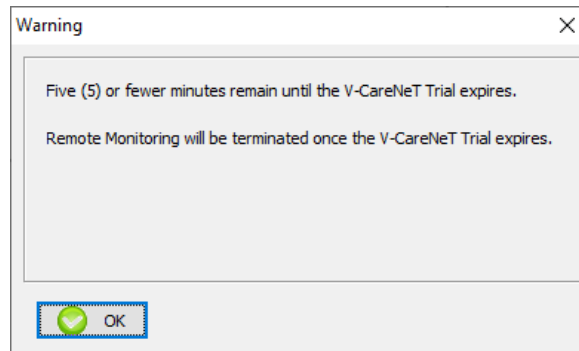
Note: Once the 'V-CareNeT Package' has been activated (see 15.2) this sub-menu is not any longer needed and therefore not any longer available.

When V-CareNeT is running (open) during a V-CareNeT Trial the remaining trial time is indicated in the V-CareNeT Control Window (see 14.5).



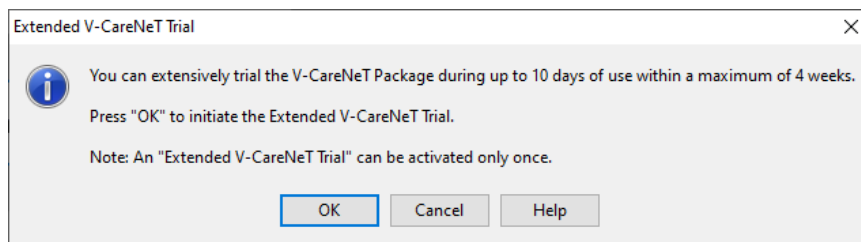
Note: The time available for trailing V-CareNeT is only used up if V-CareNeT is running (open).

If patients are admitted to V-CareNeT (see 14.7) when five or fewer minutes remain until the V-CareNeT Trial expires an audible low priority alarm occurs at the central station and V-CareNeT opens the following alert-dialog:

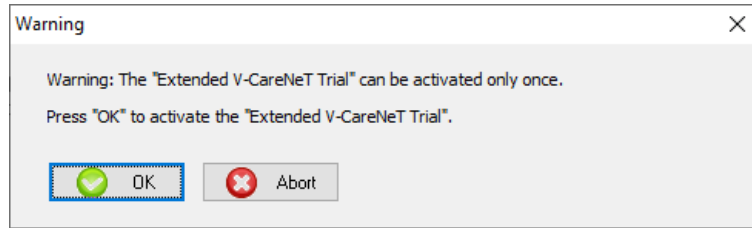


15.4 Sub-menu 'Tools / Extended V-CareNeT Trial'

The sub-menu 'Tools / Extended V-CareNeT Trial' opens the following information dialog:



Click on 'Cancel' to abort activation of the 'Extended V-CareNeT Trail'. A click on 'OK' activates the following warning dialog:



Click on 'Cancel' to abort activation of the 'Extended V-CareNeT Trial'. A click on 'OK' activates the 'Extended V-CareNeT Trial'. The trial time is 10 days which have to be used within 4 weeks. An 'Extended V-CareNeT Trial' can be activated only once.

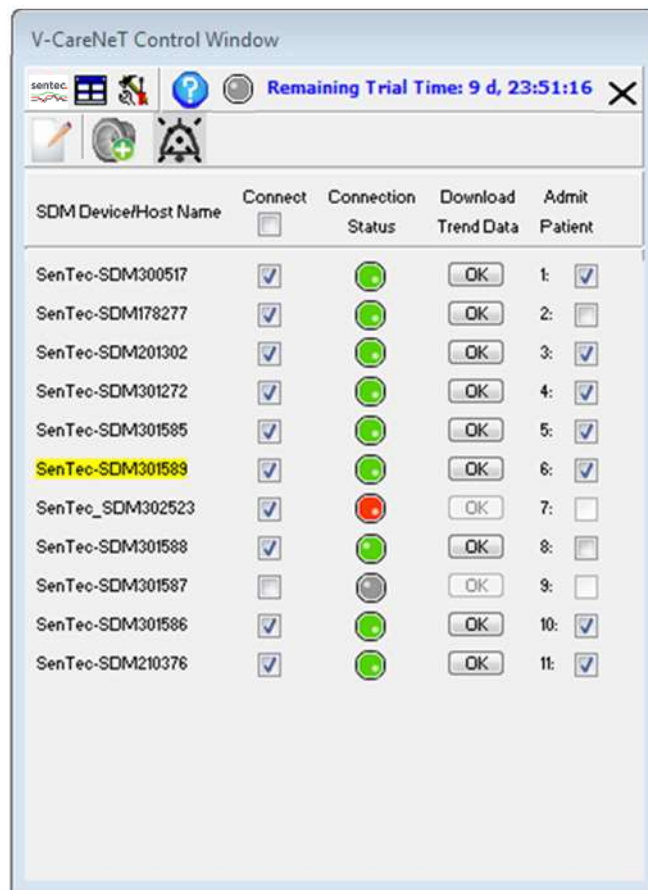
Note: V-CareNeT is fully functional during an 'Extended V-CareNeT Trial'; in contrast to a 'V-CareNeT Trial' (see 15.3) download of SDM Trend Data via the network (see 6, 14.6) is supported during an 'Extended V-CareNeT Trial'.

Note: If a SDM is configured in 'V-CareNeT Only Mode' it is not possible to admit a patient to the respective station during an 'Extended V-CareNeT Trial'.

Note: The sub-menu 'Extended V-CareNeT Trial' is not accessible (dimmed grey) as long your V-STATS license is not registered. It is also dimmed grey if a 'V-CareNeT Trial' or the 'V-CareNeT Demo Mode' is active.

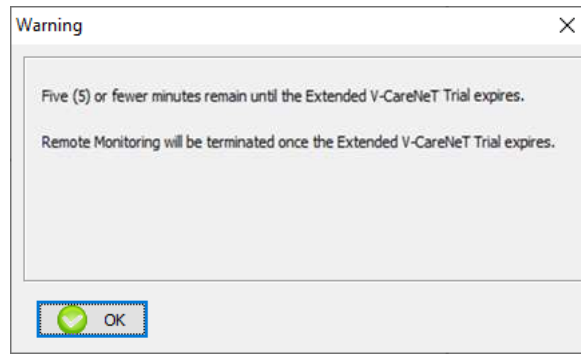
Note: Once an 'Extended V-CareNeT Trial' has been initiated or after activation of the 'V-CareNeT Package' (see 15.2) this sub-menu is not any longer needed and therefore not any longer available.

When V-CareNeT is running (open) during an Extended V-CareNeT Trial the remaining trial time is indicated in the V-CareNeT Control Window (see 14.5).



Note: The time available for trailing V-CareNeT is only used up if V-CareNeT is running (open).

If patients are admitted to V-CareNeT (see [14.7](#)) when five or fewer minutes remain until the Extended V-CareNeT Trial expires, an audible low priority alarm occurs at the central station and V-CareNeT opens the following alert-dialog:



16. Help Menu

16.1 Sub-menu 'Help / Contents; Search for'

V-STATS provides context-sensitive online help. To activate the online help, please click on the help icon or press the [F1] key.

16.2 Sub-menu 'Help / Instruction manual'

The sub-menu 'Help / Instruction manual' opens the PDF-version of the Instruction manual.

16.3 Sub-menu 'Help / License Terms'

The sub-menu 'Help / License Terms' opens the dialog 'License Terms' which displays the V-STATS license terms, which were accepted by installing V-STATS. The license terms can be printed.

16.4 Sub-menu 'Help / New features of V-STATS x.xx'

The sub-menu 'Help / New features of V-STATS x.xx' opens a document that summarizes the most important new features and modifications introduced by the current V-STATS version.

16.5 Sub-menu 'Help / Hotline'

The Hotline is operated by FuG: +49 7471 93740.

16.6 Sub-menu 'Help / Info'

The sub-menu 'Help / Info' opens the dialog 'Product-Info', which – besides contact information for Sentec and for FuG – provides update/upgrade information as well as the following information:

Prior Activation of the V-STATS Registration	After Activation of the V-STATS Registration / Prior Activation of the V-CareNeT Package	After Activation of the V-CareNeT Package
Version 5.01.1 UDI (01)07640121880773(0812)5011 ^a Unregistered Version Identification Code: Cyyyyy To register V-STATS see menu 'Tools / Register V-STATS'	Version 5.01.1 UDI (01)07640121880773(0812)5011 ^a Registered Version Identification Code: Cyyyyy The current V-STATS Updater ^d can be downloaded from registration.sentec.com/downloads/updatervstats.zip	Version 5.01.1 UDI (01)07640121880773(0812)5011 ^a Registered Version Identification Code: Cyyyyy The current V-STATS Updater ^d can be downloaded from registration.sentec.com/downloads/updatervstats.zip
V-CareNeT Package: not activated V-CareNeT Package Registration Code: not available	V-CareNeT Package: not activated ^b V-CareNeT Package Registration Code: not available To activate the V-CareNeT Package see menu 'Tools / V-CareNeT Package Activation'	V-CareNeT Package: activated (kk bed license) V-CareNeT Package Registration Code: Ckkzzzzz^c V-CareNeT Package Upgrade^e

^a Unique Device Identification (UDI)

^b Indicates 'Extended V-CareNeT Trial' during an 'Extended V-CareNeT Trial' (see 15.4). For activation of the V-CareNeT Package see 3.5 and 15.2.

^c The two first numbers (kk) after the letter C encode the number of beds/patients included in the 'V-CareNeT Package Registration Code' that was used to activate/ upgrade the 'V-CareNeT Package'. The code 'C2Q00450208', for example, includes 20 beds/ patients.

^d see also 3.3

^e Clicking on the link 'V-CareNeT Package Upgrade' opens the dialog 'V-CareNeT Package Upgrade' (see 16.6.1). Therein, all steps and information required to upgrade an already activated 'V-CareNeT Package' to a higher number of beds/ patients are displayed.

*Note: The information shown in **red, bold font** in the table above, can be copied via mouse-click on the respective line.*

*Note: The '**Identification Code**' is the factory default password to access the dialog 'Profiles / device Setting' (see 13.2), the dialog 'Special Functions' (see 8.1) and the dialog 'V-STATS Settings' (see 12.1) upon completion of the Standard Installation. The '**V-CareNeT Package Registration Code**' is the factory default password to access the dialog 'V-CareNeT Settings' (see 12.2) and the dialog 'Edit SDM Device/Host Name' (see 14.5.1).*

16.6.1 Dialog 'V-CareNeT Package Upgrade'

To open the dialog 'V-CareNeT Package Upgrade' use the sub-menu 'Help/ Info' to open the dialog 'Product Info' (see 16.6) and then click on the respective link.

V-CareNeT Package Upgrade

Your V-CareNeT Package license currently supports a maximum of 10 beds / patients being simultaneously available for remote monitoring.

To upgrade your V-CareNeT Package to the desired number of beds / patients you need to generate a corresponding "V-CareNeT Package Upgrade Code". To do so you need the

Identification Code: C7189031707263
Current "V-CareNeT Package Registration Code": C1000294191
 New "V-CareNeT Package Registration Code" (to be purchased)

When requesting a new "V-CareNeT Package Registration Code" from your local Sentec representative or Sentec (www.sentec.com) please indicate the desired number of beds / patients and send a screenshot of the present dialog.

Once you have received the new "V-CareNeT Package Registration Code" you can generate the "V-CareNeT Package Upgrade Code" by yourself on the website http://registration.sentec.com/vstats_CPUC.html

Enter the "V-CareNeT Package Upgrade Code" in the field below and then click on "Upgrade V-CareNeT Package"

V-CareNeT Package Upgrade Code:

If your V-CareNeT Package is already activated and if you want to upgrade the maximum number of beds/ patients for which remote monitoring simultaneously shall be possible you need a new 'V-CareNeT Package Registration Code' (CPRC) for the corresponding number of patients/ beds. When requesting a new CPRC from your local Sentec representative please indicate the desired number of beds/ patients and send a screenshot of the dialog 'V-CareNeT Package Upgrade'. Once you have received the new CPRC you must generate the corresponding 'V-CareNeT Package Upgrade Code' (CPUC) on the website registration.sentec.com/vstats_CPUC.html. To upgrade the V-CareNeT Package you finally must enter the CPUC within V-STATS into the appropriate field of the dialog 'V-CareNeT Package Upgrade'.

Note: After upgrade of your V-CareNeT Package it is at any time possible to further upgrade your V-CareNeT Package to a higher number of beds/ patients.

Annex 1: Installation for Advanced Data Protection

GDPR (<https://www.eugdpr.org/>) is a European Union (EU) directive, which replaced the Data Protection Directive 95/46/EC on May 25, 2018. The objective is to harmonize European data protection laws while focusing on strengthening EU citizens' rights protecting their personal data. All companies and organizations, which process EU citizens' data, are affected, regardless of where these companies or organizations are based and where the data are being processed. Particularly in the healthcare sector, this implies that every person dealing with personal (patient) data must adhere to the GDPR. In addition to hospitals, medical practices, pharmacies, laboratories and health insurances (to name but a few), manufacturers of medical technology products are equally affected.

Sentec therefore revised V-STATS including V-CareNeT in order for the user to adhere to GDPR. Each individual organization (hospital, medical practice) may determine whether they save patient data and which data should be saved. The organization is responsible for complying with applicable regulations. With this release, Sentec offers measures which allow GDPR-conform handling of patient data.

Starting with Version 5.00, V-STATS may be installed as Standard Installation or Installation for Advanced Data Protection. The following table provides an overview of the main differences between these two installations. All the other main functions of V-STATS/V-CareNeT (Downloading/ Importing SDM Trend Data, Administration of Profiles, etc.) not listed in this table are available in both installations.

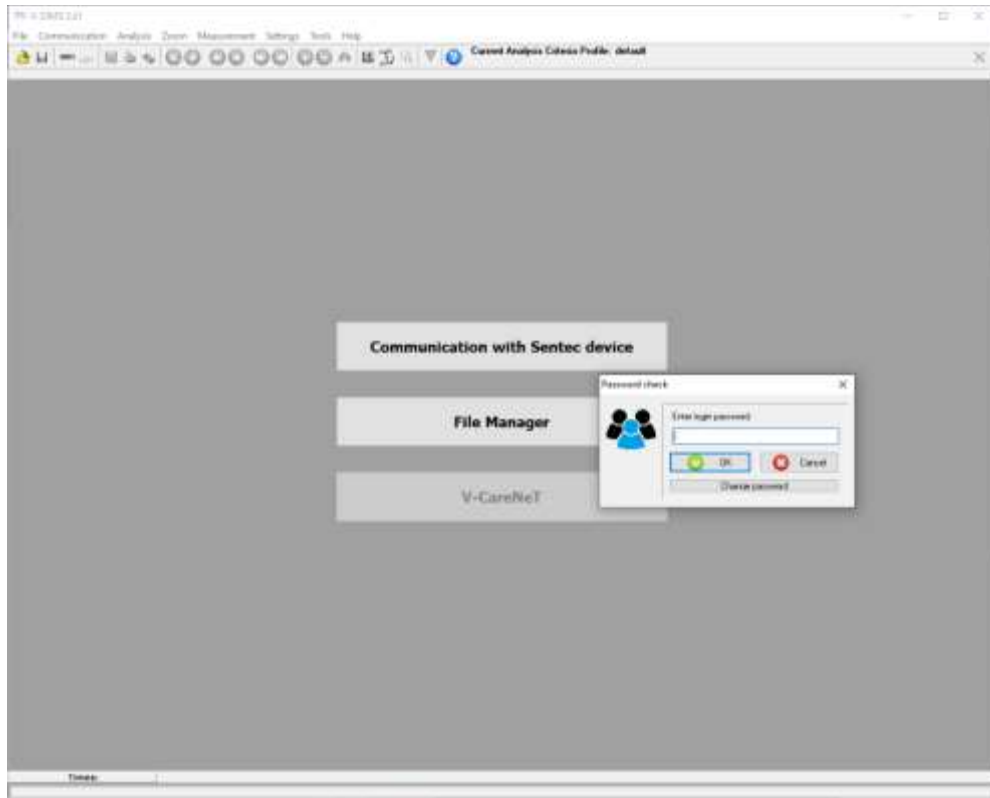
V-STATS/V-CareNeT Installation and functionality	Standard Installation	Installation for Advanced Data Protection
Additional features to support fulfilment of GDPR (General Data Protection Regulation) requirements	-	✓
Login Password	-	✓
Admin Password allows access to: <ul style="list-style-type: none"> • V-STATS Settings • SDM Profiles • SDM Configuration Special Functions	✓	✓
Encryption of patient data	-	✓
Handling of encryption keys	-	✓
Restoring forgotten passwords	✓	-

Note: Check with your local IT department whether you need to use the Installation for Advanced Data Protection. The organization is responsible for complying with applicable regulations.

The following points provide an overview of the GDPR (General Data Protection Regulation) requirements, indicate where V-STATS/V-CareNeT are affected and how these requirements are met with installing the Installation for Advanced Data Protection in particular.

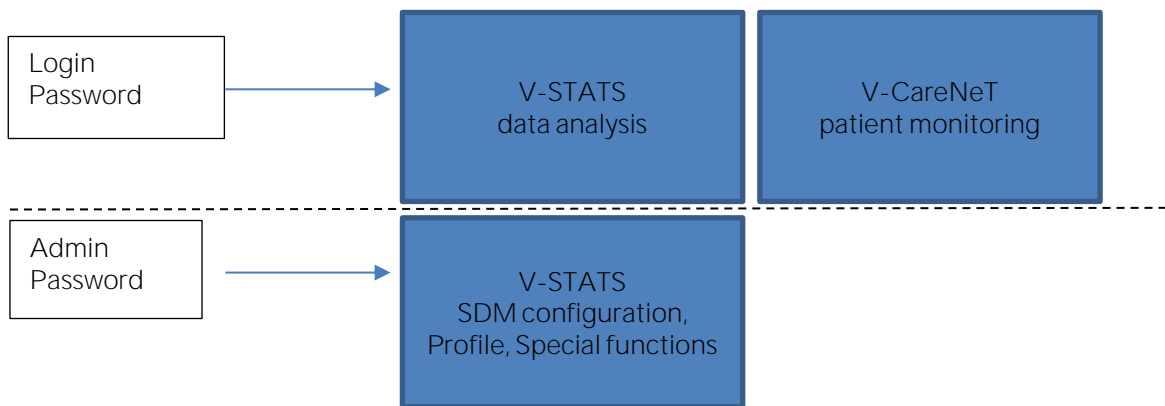
- A) Preventing unauthorized access of patient data, protection of unauthorized use of the infrastructure needed for patient data processing.

V-STATS' Installation for Advanced Data Protection has a login function. A login window appears upon starting the program where the user must enter a password in order to be identified as a legitimate user. Thus, unauthorized persons may not access V-STATS. Authorized users may only view data which they are permitted to view.



The password for protecting V-STATS Settings, SDM Profiles & Configuration and Special Functions is referred to as Admin password in order to differentiate it from the Login password.

Note: Using V-CareNeT (licensed version) does not require a separate login. For changing V-CareNeT settings see V-CareNeT Settings 12.2.



- B) Unauthorized access of data must be prevented. If necessary, supervisory authorities and the data owner (patient) must be informed. The encryption of patient data is a measure for preventing unauthorized access. This encryption is a sufficient measure for preventing infringement of protection.

For this reason, Sentec implemented patient data encryption with the AES256 encryption algorithm. In order to encrypt patient data, a key needs to be created upon Installation for Advanced Data Protection if the previous version is lower than version 4.10. Key creation happens at a click of a button as V-STATS has a dedicated function for doing so. Subsequently, V-STATS will use this key automatically; a copy must be stored safely and may be exported if necessary (e.g. to hand over patient data to another authorized person).

- C) Upon **installation**, existing unencrypted data are being not encrypted automatically with the new key. Upon **Update** from V-STATS version lower than version 4.10, unencrypted data in the target folder as well as sub-

directories are also not encrypted automatically. Users may do this manually at a later stage. After first start-up of V-STATS a dialog pops up if unencrypted data exist in the target folder. The user may then select whether unencrypted data shall be encrypted (see 4).

Encrypted data that have been encrypted with a key from V-STATS version 4.10 remain readable / changeable upon Installation for Advanced Data Protection. During update the User is not asked to generate a new key or to load an existing key if a key is already available from previous version 4.10.

- D) It is still possible to enter patient data. However, before entering data the user must check the box "Activate personal data" and confirm the subsequent data protection warning. This applies to both, V-STATS and V-CareNeT.

When downloading data (from an SDM), these data are automatically encrypted. Measurement values and patient data are saved separately, whereby the patient data are encrypted.

Note: Should you require support from Sentec, never send any patient data to Sentec or your local Sentec representative.

- E) Patients have the right to receive their data in a common, machine-readable format. The already present data export within V-STATS fulfils this requirement, for example even converting and exporting in the EDF+ format.



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