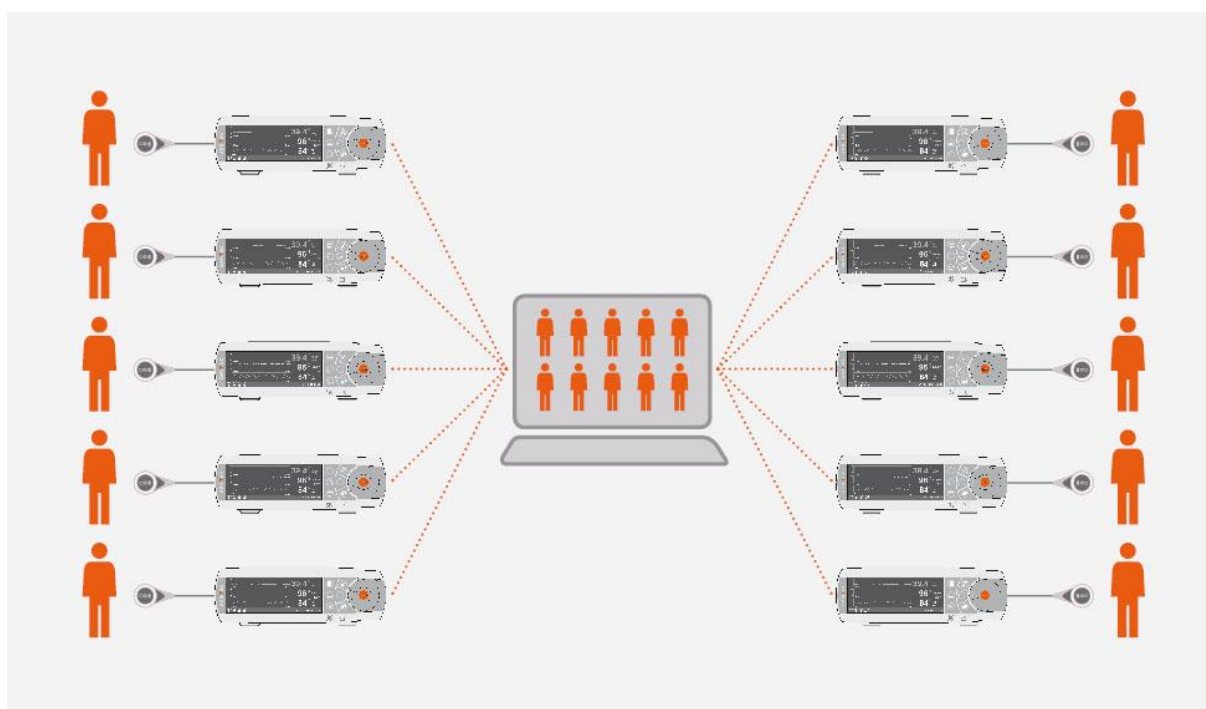# senTec

Installation Manual and Quick Reference Guide

for

V-STATS 5.00

with

V-CareNeT Package

Copyright:

SenTec AG
Ringstrasse 39
4106 Therwil
Switzerland

Tel.: +41 61 726 97 60
Fax : +41 61 726 97 61
info@sentec.com
www.sentec.com

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Content

1. General Notes

V-STATS 5.00 is PC-based software that offers the following three main features:

- Download of SDM Trend Data stored in the internal memory of SenTec Digital Monitors (SDMs) via their serial or their LAN interface for subsequent display, analysis, and reporting within V-STATS. The analysis criteria and the analysis interval 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. Reports are highly customizable and can be printed or stored as a PDF. 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.

- Configuration of the SDM connected to V-STATS via its serial interface. 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'.

- Remote monitoring and secondary alarm surveillance of multiple SDMs connected to the same network as the PC by means of V-CareNeT. 'Operator Events', 'Baselines' (for PCO2, PO2, SpO2, and RHP), and certain SDM settings can be set/ controlled remotely on the included SDMs. Using V-CareNeT, download of SDM Trend Data is simultaneously possible for multiple SDMs.

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

  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:** 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 is continuously overwritten. To avoid overwriting of measurement data, the data must be downloaded before the memory is full.

⚠ **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 containing V-STATS and 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 are discharged from the V-CareNeT System without the appearance of an alert-dialog.

⚠ **WARNING:** Do not ignore audible medical device 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 familiar with the particular requirements for wireless networks in hospital environments. Ensure that the WiFi-Specialist evaluates how many access points are needed and where they have to be located by considering the structural surroundings (construction, shielding, interfering devices, etc.) 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.

⚠️ **WARNING:** Remote alarm surveillance for an individual SDM/patient is inhibited if remote monitoring is suspended for the respective SDM.

⚠️ **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.

⚠️ **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, there will only be a visual alarm indication and no auditory alarm signal.

⚠️ **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.

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

Warranty Exclusions and System Performance
SenTec AG can neither guarantee or verify instrument performance characteristics nor accept warranty claims or product liability claims if the recommended procedures are not carried out, if the product has been subject to misuse, neglect or accident, if the product has been damaged by extraneous causes, if accessories other than those recommended by SenTec AG are used, if the warranty seal on the lower side of the monitor is broken, or if instrument repairs are not carried out by SenTec authorized service personnel.

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

Patents/Trademarks/Copyright
International Industrial Design No. DM/054179, Japanese Design No. 1137696, U.S. Design Patent No. D483488.
Canadian Patent No. 2466105, European Patent No. 1335666, German Patent No. 50111822.5-08, Spanish Patent No. 2278818, Hongkong Patent No. HK1059553, U.S. Patent No. 6760610.
Chinese Patent No. ZL02829715.6, European Patent No. 1535055, German Patent No. 50213115.2, Spanish Patent No. 2316584, Indian Patent No. 201300, Japanese Patent No. 4344691, U.S. Patent No. 7862698.
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0123   SenTec AG, Ringstrasse 39, CH-4106 Therwil, Switzerland, www.sentec.com

2. Introduction / Short description

V-STATS 5.00 is a PC-based software that offers the three main features 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 (6.1) or with V-CareNeT via its LAN interface. SDM Trend Data, furthermore, can be imported from a file stored on the PC or an external drive. Initiating download/import of SDM Trend Data opens a dedicated dialog 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' 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' or an 'EDF+-file' 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', and subsequently displayed in V-STATS' Main Window.

> 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. If a measurement is open, 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' and the PCO2 channel - if enabled - drift corrected data as a blue curve. The name, respectively the unique key of the corresponding patient, 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. If the cursor is set, 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 and zooming in/out functions permit to adjust the 'Displayed Range' indicated in the top right of V-STATS' Main Window.

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. If drift corrected PCO2 data are displayed, the PCO2 baseline is established using drift corrected data. 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 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 a blue curve (individually or in addition to the green curve of the original PCO2 data). Note that if the drift corrected PCO2 curve is displayed, determination 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 for the detection of physiological events (PCO2, SpO2, PR) and artifacts. Moreover, it allows for identifying if 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.

2.1.6 Report (on screen)

A comprehensive report can be generated and displayed on the screen for the current 'Analysis Interval'. Comments and findings can be added.

   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 summarizes the most important results for the PCO2, SpO2 and PR channels.

2.1.7 Printout of the report / PDF Report

The printout of the report is highly configurable / customizable. Among other, it is possible to select the pages of the report and the individual elements of the report 'Summary' page 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'. It is possible to customize 'Report Profiles'. 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 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.

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. 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.

2.1.8 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'. In default settings, the 'Target Folder of the File Manager' is set to the 'Data Storage Folder', i.e. when opening the 'File Manager', the list of measurements stored in the current 'Data Storage Folder' are displayed in default settings. 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. 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 is 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, customized data files, EDF+-Files, and V-STATS Files). Import of SDM Trend Data files, of customized data files, or of V-STATS Files is also possible.

2.2 Configuration of the SDM (Parameters & SDM Profiles)

By using V-STATS 5.00 within a password-protected area, the Responsible Organization can configure SDMs with software version SMB-SW V08.00 or higher. 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. 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.

2) select the '**Profile Mode**' of the connected SDM. 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'.

3) customize/manage 'SDM Profiles' stored in the 'SDM Profiles Database'.

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

The V-CareNeT System 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. Furthermore, 'Operator Events', 'Baselines' (for PCO2, PO2, SpO2, and RHP), and certain SDM settings can be set/ controlled remotely on the SDMs. Trend Data stored in the internal memory of the SDMs can be downloaded to V-STATS via the network for subsequent display, analysis, and reporting within V-STATS. 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'. '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.

3. Compatibilities

3.1 Compatibility of V-STATS 5.00 with SDM software versions

V-STATS 5.00 is compatible with SenTec Digital Monitors (SDMs) with software version SMB-SW V08.00.x., V08.01.x., V08.02.x or V08.03.x. The SMB software version is indicated in the SDM menu 'System Information'.

Note: V-STATS 5.00 supports communication via the serial interface only for SDMs with software versions SMB-SW V08.00.x, V08.01.x, V08.002.x or V08.003.x. You must use V-STATS 3.01.1, 3.01, 4.00 or 4.00.1 if your SDM uses software version SMB-SW V06.21.x, 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 5.00 supports V-CareNeT only for SDMs with software versions SMB-SW V08.00.x, V08.01.x, V08.02.x or V08.03.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 5.00 only supports import of SDM Trend Data or '.vex-files' 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 or V08.03.x. Use V-STATS 3.01.1, 3.01, 4.00, 4.00.1 to import SDM Trend Data if the included 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 from SDMs with older software versions.

3.2 System requirements

V-STATS 5.00 can be installed on most PCs. The minimum system requirements are:

	V-STATS (without using V-CareNeT)	V-STATS with activated V-CareNeT
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
CD ROM	YES	YES
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

4. Installation, Update and Configuration

4.1 Installation and how to update V-STATS 5.00 on a PC

To **install** V-STATS 5.00 on a PC, proceed as follows:
- Switch on your computer and start Windows
- After start up, insert the V-STATS installation CD into the CD-ROM drive
- Open Windows Explorer, select the CD-ROM, and double-click on **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 5.00 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/products/sentec-data-management/v-statstm/*)*

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 a .pdf file and then on `Next´ to resume the installation

3. A 'License Agreement Dialog' is displayed. 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:\fg\vstats'. 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:\fg\vstats'. 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 5.00.

   Note: If the installed V-STATS license is not registered, you must register the license first before updating to V-STATS 5.00. 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.

   Note: If no license is installed on your PC, contact your local distributor to purchase a V-STATS installation CD.

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 at any time possible 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 NOT taking 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 by 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.
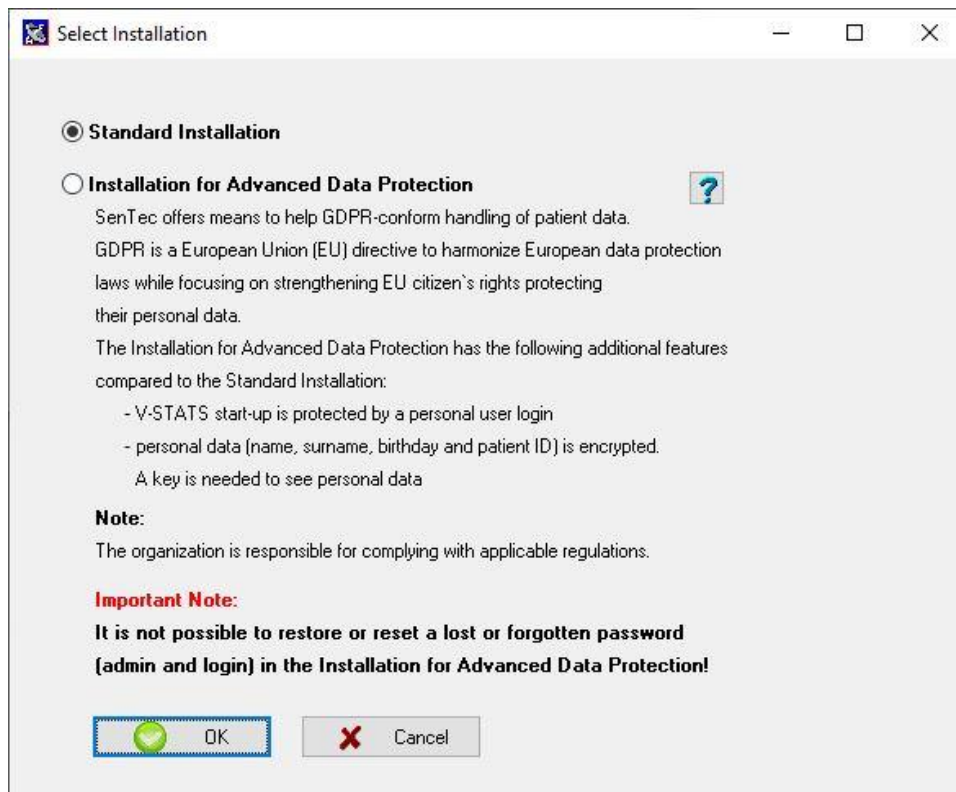
8. To install example measurements, click on 'Yes' when the message 'Install example measurements in the folder Target Drive:\fg\vstats\daten\examples' prompts.
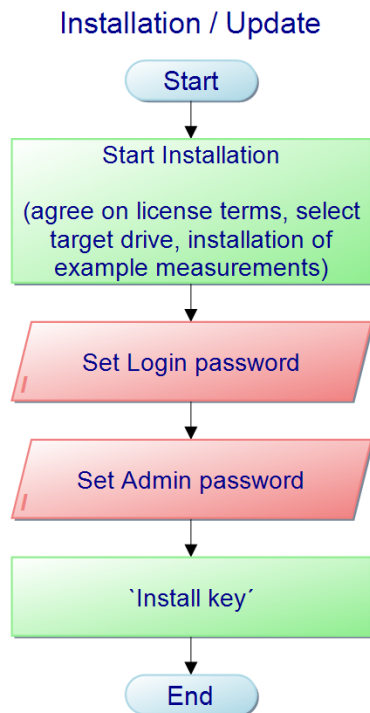
   Note: Before the new/updated example measurements are installed in the folder Target Drive:\fg\vstats\daten\examples', all files stored therein will be deleted.

   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 installation **update of an existing Advanced V-STATS installation**, continue with step 11 (Existing login and admin password of your previous advanced installation 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.

Installation / Update

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)
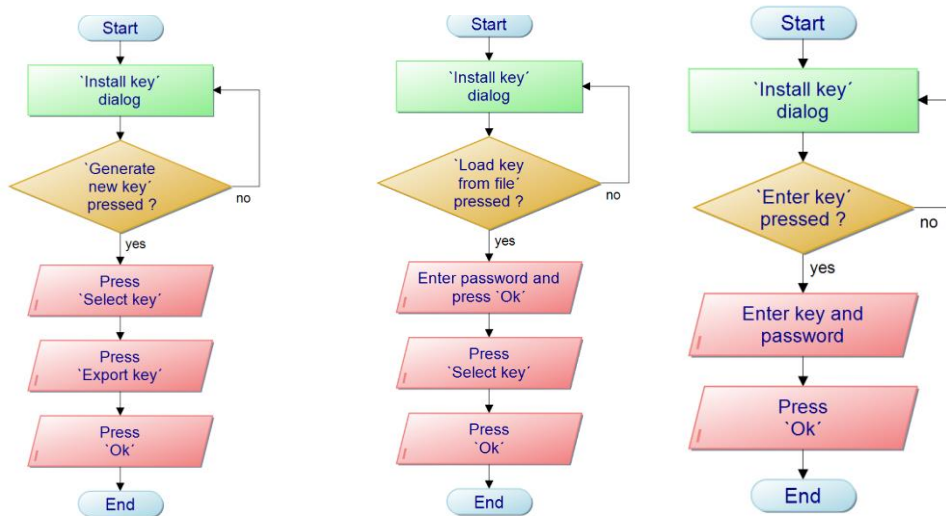

> ➢ Click 'OK'

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

Note: If there is an existing key, 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.

11. 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.

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

A PDF file summarizing the most important new features and modifications included in V-STATS 5.00 pops up if the **update** was successful.

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**'.
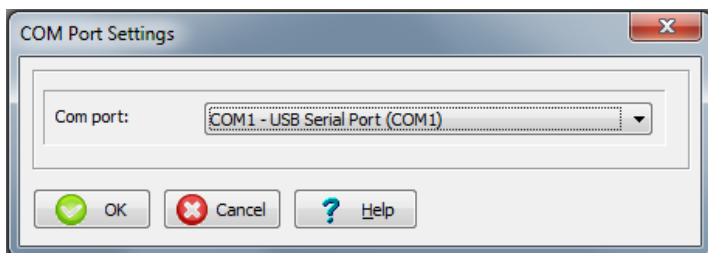
Select the appropriate COM port

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

Finally, the installer will automatically display the following license information dialog:
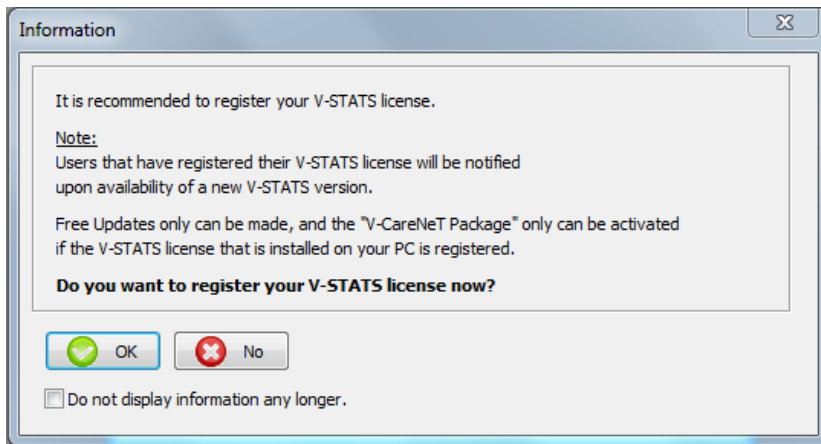
SenTec AG recommends that you register your V-STATS license, as registered users are notified about new V-STATS versions. Furthermore, you may only receive free updates and activate the 'V-CareNeT Package' if the V-STATS license installed on your PC is registered.

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.

Note: For the registration, you need the license number, which is printed on the CD. Remove the CD after successful installation and keep it in safe custody.

4.2 Printer Selection

V-STATS 5.00 allows the printout of various items, such as reports or SDM Profiles, 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 as well as various other profiles and settings can be stored as a PDF (even if no PDF-printer is installed on the PC).

5. Upgrades and LAN Package Activation

5.1 Activating the V-CareNeT Package

To activate the V-CareNeT Package for the desired number of beds/patients, the installed V-STATS license must be registered. A 'V-CareNeT Package Registration Code' (CPRC) for the corresponding number of beds/patients is required.* 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, enter the CPAC within V-STATS in the appropriate field of the dialog 'V-CareNeT Package Activation' (see sub-menu 'Tools / V-CareNeT Package Activation').

*To purchase a CPRC, please contact your local SenTec representative or SenTec (info@sentec.com/ www.sentec.com). CPRCs are currently available for 5, 10, 20, 30, or 40 beds/patients or upon request for a customized number of up to 40 beds/patients. Refer to chapter 2.3 for further information.

5.2 Upgrading the V-CareNeT Package

If your V-CareNeT Package is already activated and if you want to increase the maximum number of beds/ patients for simultaneous remote monitoring, 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' (in which the current number of beds/patients is indicated). 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_CPAC.html. To upgrade the V-CareNeT Package, enter the CPUC within V-STATS into the appropriate field of the dialog 'V-CareNeT Package Upgrade'.

Note: To open the dialog 'V-CareNeT Package Upgrade' use the V-STATS menu 'Help/Info' to open the dialog 'Product Info' and then click on the respective link.

Note: All "Notes" of the paragraph "How to activate the V-CareNeT Package" also apply for this paragraph.

5.3 V-CareNeT Trial

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'. 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.

5.4 Extended V-CareNeT Trial

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'. 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'.

5.5 V-CareNeT Demo Mode

For demonstration and training/education purposes, it is possible to activate the 'V-CareNeT Demo Mode' by using the menu 'Settings / V-CareNeT Demo Mode'.

Note: Registration of V-STATS or activation of the V-CareNeT Package is not required for using the V-CareNeT Demo Mode.

Note: The password required to activate the 'V-CareNeT Demo Mode' is **'Demo'**.

Note: V-STATS 3.02 and higher versions include data of 40 demo patients. Note that the maximum number of beds/patients, for which remote monitoring can be simulated/demonstrated, is limited by the computer's screen size/resolution. Refer to chapter 2.3 for further information.

6. Communication Menu and Main Window

6.1 Communication Menu

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** *USB/RS232 converter cables.*

3. In V-STATS: Adjust the Communication Settings

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

B: Communication with the 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 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.

6.2 Main Window

Button 'Communication with SenTec device (serial)': Clicking on this button opens the dialog 'Communication with SenTec device (via Serial Interface)', which gives access to the functions a) to download SDM Trend Data from the internal memory of the connected SDM, 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, and e) to functions that are helpful for troubleshooting ('Full Memory Dump', 'Raw Dump', 'Screenshots', and 'SDM 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.
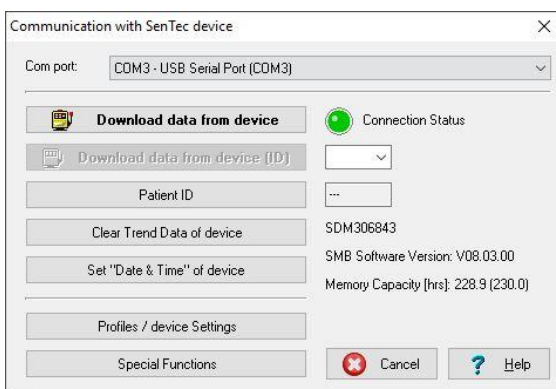
Not Connected

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 device (via Serial Interface)' remains in this state.

Note: The dialogs which open after clicking on the buttons 'Download data from SDM', 'Download data from SDM (ID)', 'Patient ID', 'Profiles / SDM 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.

Figure 1: `Communication with SenTec device´ dialog with red indicator light (top) and green indicator light (bottom) to indicate the `Connection Status´

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'. 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.

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

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' as well as the control icon 📂 in the menu bar of the 'Main Window'.

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

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' to activate the 'V-CareNeT Package'. For a trial activation of V-CareNeT, please refer to the sub-menu 'Tools / V-CareNeT Trial' or the sub-menu 'Tools / Extended V-CareNeT Trial'. Use the sub-menu 'Settings / V-CareNeT Demo Mode' 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 is duplicated the sub-menu 'Communication / V-CareNeT' as well as the control icon ⏹ in the menu bar of the 'Main Window'.

Menu Bar: A menu bar with pull-down menus and control icons 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'.

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'.

If <u>a measurement is open,</u> 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 and control icons.

7. Analysis Menu

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

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.

8. Zoom Menu

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, 5 d and 10 d.

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.

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

9. Measurement Menu

In the `Measurement´ menu

- it is possible to set/edit/add/delete 'Operator Events' and `Analysis Periods´ for a currently opened measurement.
- patient data can be assigned in the `Patient Data´ dialog.
- start date and time can be set manually for an open measurement.
- PCO2/PO2 baselines are shown in the corresponding channel as a red-dashed horizontal line.
- the correction of the residual PCO2 drift can be set to `Off´, `Both´ or on for the currently displayed measurement.
- the sub-menu `Show/Hide´ allows showing or hiding channels for a <u>currently displayed measurement</u>.
- it is possible to adjust the display range (y-axis) and horizontal grid settings for the <u>currently open measurement</u> and the selected channel.

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.

10.   Settings Menu

The sub-menus `V-STATS Settings´, `V-CareNeT Settings´ and `V-CareNeT Demo Mode´ can be entered in the `Settings Menu´.

The sub-menu **'V-STATS Settings'** activates a password dialog in which a(n) (admin) password must be entered to open the dialog.

>   *Note: The password to open the dialog 'V-STATS Settings' is the same password that is required to open the dialogs 'Profiles / SDM Settings - <SN>´ and 'Special Functions' in the `Standard Installation´. In the `Installation for Advanced Data Protection´ the admin password is requested.*

The following settings can be selected and changed in the `V-STATS Settings 'dialog: In the sub-menu

- `Channel-settings' - you can predefine various settings for each channel that are used to display SDM Trend Data in the V-STATS Main Window.

- `Color of markers' - the color of the markers that are displayed in the V-STATS Main Window can be modified.

- 'Define Operator Events' - it is possible to predefine the standard settings for each of the different operator event types (E0 – E7, VC) that will be used by V-STATS when downloading/importing SDM Trend Data.

- `Report heading' - it is possible to define the heading of the report (typically your institution's address).

- 'PDF Report' - it is possible to configure the Paper Size, the default storage folder and the default file name that used/proposed to store reports as a PDF.

- `Data Export' and 'EDF+ Export' - it is possible to configure the default storage folder and the default file name used/ proposed to export data as '*.vex-files' and convert data into an 'EDF+-File'.

Two additional sub-menus can be entered when the `Installation for Advanced Data protection´ has been installed: In the sub-menu

- `Export V-STATS Key´ - a dialog for setting a password for the key opens 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.*

- `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.*

The sub-menu **'V-CareNeT Settings'** or a click on the icon 'V-CareNeT Settings' in the 'V-CareNeT Control Window' 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, this sub-menu is only accessible if a 'V-CareNeT Trial', an 'Extended V-CareNeT Trial' or the 'V-CareNeT Demo Mode' 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'. 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.*

>   *Note: During a 'V-CareNeT Trial' and an 'Extended V-CareNeT Trial', the password to open the dialog 'V-CareNeT Settings' is '**Trial**'.*

>   *Note: If the 'V-CareNeT Demo Mode' is active, the password to open the dialog 'V-CareNeT Settings' is '**Demo**'.*

For demonstration and training/education purposes, V-STATS includes the **'V-CareNeT Demo Mode'** that can be activated by using the sub-menu 'V-CareNeT Demo Mode'. The V-CareNeT Demo Mode includes patient data of 40 demo patients.

>   *Note: Registration of V-STATS or full activation of the V-CareNeT Package is not required to use the V-CareNeT Demo Mode.*

>   *Note: The password to activate the 'V-CareNeT Demo Mode' 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.*

11.   Tools Menu

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.

Note: Once your V-STATS license is registered and V-CareNeT is activated, the 'Tools Menu' is no longer needed and will, therefore, be removed from the menu.

Figure 2: `Registration´ dialog – provides instructions to register V-STATS

12. Help Menu

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.

Sub-menu 'Help / Instruction manual'
The sub-menu 'Help / Instruction manual' opens the PDF-version of the Instruction Manual.

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.

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.

Sub-menu 'Help / Hotline'
The hotline is operated by Dr. Fenyves und Gut Deutschland GmbH: +49 7471 93740.

Sub-menu 'Help / Info'
The sub-menu 'Help / Info' opens the dialog 'Product-Info', which – besides contact information for SenTec AG 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 5.00	Version 5.00	Version 5.00
Unregistered Version	Registered Version	Registered Version
License number: not available	**License number: xxxxx^a**	**License number: xxxxx**
Identification Code: Cyyyyy	**Identification Code: Cyyyyy**	**Identification Code: Cyyyyy**
To register V-STATS see menu 'Tools / Register V-STATS'	The current V-STATS Updater[d] can be downloaded from registration.sentec.com/downloads/updatervstats.zip	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] The license number is not available after updating V-STATS 2.02 or older
[b] Indicates 'Extended V-CareNeT Trial' during an 'Extended V-CareNeT Trial'.
[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 'C2000450208', for example, includes 20 beds/ patients.
[d] see also 4.1
[e] Clicking on the link 'V-CareNeT Package Upgrade' opens the dialog 'V-CareNeT Package Upgrade'. 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 / SDM Setting', the dialog 'Special Functions' and the dialog 'V-STATS Settings' upon completion of the Standard Installation (see 4.1). The '**V-CareNeT Package Registration Code**' is the factory default password to access the dialog 'V-CareNeT Settings' and the dialog 'Edit SDM Device/Host Name'.*

Annex 1: Installation for Advanced Data Protection

SenTec offers means to help GDPR-conform handling of patient data. GDPR is a European Union (EU) directive to harmonize European data protection laws while focusing on strengthening EU citizen's rights protecting their personal data.

V-STATS 5.0.0 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: • 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.

> Note: Should you require support from SenTec, never send any patient data to SenTec or your local SenTec representative.

In order to prevent unauthorized access of data, 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).

Upon **installation**, existing unencrypted data are not being 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.

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 a previous installation of V-STATS version 4.10.

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