

January 31, 2016

**Subject:** Overview of the Main Features & Modifications introduced by V-STATS 4.01 (including V-CareNeT Package)

Dear V-STATS user

This document provides an overview of the main features & modifications being introduced by V-STATS 4.01 (see page 2).

Furthermore, a description of the main features & modifications that were introduced by

- V-STATS 4.00 on April 22, 2016 is provided on pages 3 – 4,
- V-STATS 3.02 on March 21, 2014 is provided on pages 5 – 11,
- V-STATS 3.01.1 on June 1, 2013 is provided on page 12,
- V-STATS 3.01 on December 21 2012 is provided on pages 13 – 17,
- V-STATS 3.00 on August 16, 2010 is provided on pages 18 – 19.

In case of questions related to the new V-STATS version or V-STATS in general do not hesitate to contact the V-STATS Hotline (+49747193740) or SenTec at [info@sentec.com](mailto:info@sentec.com).

Best Regards,

Your V-STATS support team

## Main features & modifications introduced by V-STATS 4.01

### A) Modifications related to V-CareNeT

- If a SDM with software version SMB-SW V08.00.x/V08.01.x is remotely monitored with V-CareNeT it is additionally possible to remotely monitor the parameter **PO2** (new).

*Note: PO2 is only monitored if the patient type is set to "neonate" and enabled parameters are PCO2 and PO2.*

*Note: in analogy to PCO2 dx-values and/or baseline values for PO2 in remote monitoring window are available*

- Full support of alarm functionality for **PO2**
- Additional button in V-CareNeT Settings for changing **PO2** color

### B) Other features and modifications introduced by V-STATS 4.01

- V-STATS 4.01 is compatible with the following software versions of the SenTec Digital Monitor: SMB-SW V07.03.x, V08.00.x. and V08.01.x
- Update to V-STATS 4.01 is only supported if the installed V-STATS license is registered and has version 4.00 or newer.

## Main features & modifications introduced by V-STATS 4.00

### A) Modifications related to SDM Trend Data download, display, analysis, and reporting

- 'SDM Trend Data' that were recorded by a SDM with software version SMB-SW V08.00.x can include data of up to 6 measurement parameters, namely PCO2, **PO2** (new), SpO2, PR, **PI** (new), and **HP** (new). Starting from V-STATS 4.00 it is, consequently, possible to display or print up to 6 channels.

*Note: Use the menu 'Measurement/ Show/Hide' to show/hide channels of the measurement currently being displayed in the main window of V-STATS.*

*Note: In analogy to the 'PCO2 Baseline' a 'PO2 Baseline' is available (can also be set manually).*

*Note: V-STATS 4.00 supports Data Analysis/ Reporting only for PCO2, SpO2, and PR. **Data Analysis/ Reporting is not available for PO2, PI, and HP.***

*Note: As for PCO2, SpO2, and PR data it is possible to export PO2, PI, and HP data to the PC (e.g. in an Excel-Compatible format or in EDF+-Format).*

- As for the PCO2, SpO2, and PR channels it is possible to pre-configure the settings (channel color, channel label, etc.) that will be used to display the PO2, PI, and/ or HP channels in the dialog "Channel-settings". In particular, it is also possible to pre-define which channels will be displayed in the main window of V-STATS after downloading/ importing SDM Trend Data to V-STATS.

*Note: Only channels for which the parameter "Display" is set to "On" will be displayed in the main window of V-STATS after downloading/ importing SDM Trend Data to V-STATS (in default configuration this is only the case for PCO2, SpO2, and PR).*

- In the dialog 'V-STATS Settings' the parameter 'PCO2 Unit' has been renamed to 'PCO2/ PO2 Unit'.
- When downloading SDM Trend Data from an SDM with software version SMB-SW V08.00.x download speed may be reduced compared to earlier monitor firmware versions, since more data are included in the download.
- New PO2-specific SDM Event "PO2 High Ambient Light" (default color of corresponding SDM Event Markers is orange).

### B) Modifications related to the SDM's configuration (Parameters & SDM Profiles)

- Starting from V-STATS 3.01 it is possible to configure all parameters of the connected SDM on an individual basis in the dialog 'Profiles/ SDM Settings'. To ensure that the nine (9) new SDM parameters that are introduced by SDM software version SMB-SW V08.00.x can also be configured on an individual basis, V-STATS 4.00 adds these nine (9) new SDM parameters to the dialog 'Profiles/ SDM Settings'.

*Note: The nine (9) new SDM parameters are: PO2 High Limit, PO2 Low Limit, RMI AUDIO OFF Disable Volume, Min. select. Sensor Temperature, RHP Range for Online Trends, PO2 Range for Online Trends, PO2 Color, RHP Color, DNS Mode. To unambiguously identify each new SDM parameter in the dialog 'Profiles/ SDM Settings' the string 'SMB V08.00:' is printed in front of each new SDM parameter*

- With V-STATS 3.02 it is possible a) 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 b) to customize/manage SDM Profiles stored in the 'SDM Profiles Database'. Furthermore, upon installation of or upgrade to V-STATS 3.02 nine (9) 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'.

Starting from SDM software version SMB-SW V08.00.x SDM Profiles will include most of the new SDM parameters. The SenTec preconfigured SDM Profiles that are stored in the 'SDM Profiles Database' upon installation of or upgrade to V-STATS 4.00, consequently, have been expanded to include new SDM parameters.

SenTec, furthermore, has preconfigured two new, PO2 specific SDM Profiles (NEO\_PO2 and Adult\_PO2) that will also be stored in the 'SDM Profiles Database' upon installation of or upgrade to V-STATS 4.00.

*Note: Please refer to 'RF-006679-c- Preconfigured SDM Profiles' to view all parameters and their respective settings in the 11 SenTec-preconfigured SDM Profiles. Remember that it is also possible to print SDM Profiles or to store them as a PDF.*

- For documentation purposes a **profile-sign-off area** has been added at the bottom of the print out of SDM Profiles.
- The parameter description that appears in a tool tip if the mouse is hovered over a SDM parameter in the dialog "Profiles/ SDM Settings" has been improved/ updated for various SDM parameters. Furthermore, the selectable range has been updated for various SDM parameters.
- To point out that a) at sensor temperatures below approx. 40°C the measured tcPCO2 values do not reliably reflect arterial blood gases and b) at sensor temperatures below 39°C SpO2/ PR readings intermittently might be switched off to maintain sensor temperature a corresponding warning message will appear when attempting to select/ activate a Sensor Temperature below 40°C.

## C) Modifications related to V-CareNeT

- If a SDM with software version SMB-SW V08.00.x is remotely monitored with V-CareNeT it is additionally possible to remotely control the PO2 High Limit and the PO2 Low Limit.

## D) Other features and modifications introduced by V-STATS 4.00

- V-STATS 4.00 is compatible with Windows XP (32 Bit), Vista (32/ 64 Bit), 7 (32/ 64 Bit), 8 (32/ 64 Bit), and 8.1 (32/ 64 Bit)

*Note: To use V-STATS 4.00 on a Mac you must run one of the above mentioned Windows versions on it.*

- V-STATS 4.00 is compatible with the following software versions of the SenTec Digital Monitor: SMB-SW V07.01.x, V07.02.x, V07.03.x, and V08.00.x.
- Update to V-STATS 4.00 is only supported if the installed V-STATS license is registered and has version 3.01 or newer.

## Main features & modifications introduced by V-STATS 3.02

### A) Modifications related to SDM Trend Data download, display, analysis, and reporting

- In order to ensure that you can print/ save reports the way you want them to for various clinical settings, V-STATS 3.02 introduces **'Report Profiles'**. It is possible to manage/ 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.

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

Note: 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 settings of these parameters are not included in 'Report Profiles'

Note: Upon installation of or upgrade to V-STATS 3.02 the preconfigured and write-protected 'Report Profiles' 'Default Report' (generates 2 page reports), 'Full Report' (generates reports with at least 13 pages), and 'V-CHECK Report' (generates a one-page report) are installed in the 'Report Profiles Database'.

- In order to ensure that you can analyze your measurement the way you want them to in varying clinical settings, V-STATS introduces **'Analysis Criteria Profiles'**. It is possible to manage/ 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'.

Note: An 'Analysis Criteria Profile' specifies a setting for each parameter included in the dialog 'Analysis Criteria Profile'.

Note: When downloading/ importing SDM Trend Data to V-STATS the 'Analysis Criteria Profile' that will be applied to analyze the data is indicated in the dialog 'Assign measurement period(s) to patients' and therein can be changed with the ease of a mouse click.

Note: In V-STATS's Main Window and in the report window the name of the selected profile displays right of the 'Help-Icon'. If the settings of the selected profile and those that were last used to analyze the open measurement are identical the name is displayed in **black**, otherwise in **red** and "\*" is added. Click on the 'Analysis Criteria Profile' opens a popup menu permitting to re-analyze the open measurement with the currently selected or a different 'Analysis Criteria Profile'.

Note: If no measurement is open use the new menu-function 'File / Analysis Criteria Profile' to open the dialog 'Analysis Criteria Profile'. In this case the settings being displayed therein correspond to those of the currently selected 'Analysis Criteria Profile' and its name is displayed in black. It is recommended to create/ customize your own 'Analysis Criteria Profiles' if no measurement is open.

Note: If a measurement is open use the menu 'Analysis/ Analysis Criteria Profile' to open the dialog 'Analysis Criteria Profile'. In this case the settings being displayed therein correspond to those that were last used to analyze the measurement that is currently open. The name of the selected 'Analysis Criteria Profile' is displayed in **green**, if the settings of the currently selected profile and those that were last used to analyze the open measurement are **identical**, i.e. no data analysis will be activated when closing the dialog. The name of the selected 'Analysis Criteria Profile' is displayed in **red**, if the settings of the currently selected profile and those that were last used to analyze the open measurement are **different**, i.e. the measurement can be re-analyzed when closing the dialog.

Note: Upon installation of or upgrade to V-STATS 3.02 the preconfigured and write-protected 'Analysis Criteria Profile' 'Default' is stored in the 'Analysis Criteria Profiles Database'. 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).

- Improved detection/ determination of dynamic physiological events

Note: Starting from V-STATS 3.02 **drops in SpO2 (desaturations)** will be determined as follows: If the SpO2 readings drop within a predefined time interval (default within 2 to 240 sec) by more than a predefined value (default 4%) the beginning of the Desaturation Event is set to the point at which the SpO2 readings started to decline. The endpoint of the event is set to the minimum. If an artifact occurs (e.g. because the SpO2 readings drop below the SpO2 Artifact Threshold) the desaturation event is terminated at the beginning of the artifact. Note that neither a Desaturation Event nor an artifact is triggered if the SpO2 drop occurs too fast/ too slow.

Note: Starting from V-STATS 3.02 **PCO2 Rise/ Fall events** will be determined as follows: If the PCO2 readings rise/ fall within a predefined time interval (default 5 to 600 secs) by more than a predefined value (default 1 mmHg) the beginning of the PCO2 Rise/ PCO2 Fall Event is set to the point at which the PCO2 readings started to rise/ fall. The endpoint of the event is set to the maximum/ minimum. If an artifact occurs (e.g. because the PCO2 readings are below/ above the PCO2 Artifact Thresholds) the PCO2 Rise/ PCO2 Fall Event is terminated at the beginning of the artifact. Note that neither a PCO2 Rise/ Fall event nor an artifact is triggered if the PCO2 Rise/ Fall occurs too fast/ too slow.

Note: Starting from V-STATS 3.02 **PR Rise events** will be determined as follows: If the PR readings rise within a predefined time interval (default 5 to 60 secs) by more than a predefined value (default 8 bpm) the beginning of the PR Rise Event is set to the point at which the PR readings started to rise. The endpoint of the PR Rise Event is set to the maximum. If an artifact occurs (e.g. because the PR readings are below the PR Artifact Threshold) the PR Rise Event is terminated at the beginning of the artifact. Note that neither a PR Rise event nor an artifact is triggered if the PR Rise occurs too fast/ too slow.

- In line with the new clinical consensus a) the default value for the upper PCO2 threshold is 50 mmHg and b) the default value for deviations from the PCO2 baseline is 7.5 mmHg.

Note: Similarly, the default level for the calculation of the time PCO2 values are above a selectable value now is 50 mmHg.

- Introduction of an upper artifact threshold for PCO2.

Note: Altogether, the following four artifact-thresholds (being grouped in a dedicated area of the dialog 'Analysis Criteria Profile') are now available: a) SpO2 < xx (default '< 50 %'); b) PCO2 < xx (default '< 20 mmHg'); c) PCO2 > xx (default '>120 mmHg'); d) PR < xx (default '< 30 bpm').

Note: V-STATS marks episodes with values below/ above these artifact thresholds as artifacts. All other situations causing an automatically created artifact have been discontinued.

- Various improvements being related to data analysis

- So far manually marked artifacts were linked to the event type that was displayed while marking the artifact. When activating the display of another event type, the manually marked artifact "disappeared". Starting from V-STATS 3.02 manually marked (and automatically evaluated) artifacts are independent from the event type that is currently selected to be displayed.
- In each channel physiological event markers are visualized for one event type only (dynamic events; baseline events (for PCO2 only); threshold events). So far selection of the event type to be visualized was only possible in the dialog 'Analysis Criteria Profile' by selecting the Radio Button next to the respective set of criteria. Starting from V-STATS 3.02 this can also be done in the popup menu which appears upon click on an event marker or after spanning a range with the mouse.



- The PCO<sub>2</sub> Median is now calculated with higher resolution (xx.x if mmHg / x.xx if kPa) and the PCO<sub>2</sub> baseline value is updated when (de)activating the display of drift-corrected PCO<sub>2</sub> data.
- Calculation of the time PCO<sub>2</sub> values are above a selectable value (new default 50 mmHg) and of the time SpO<sub>2</sub> values are below a selectable value (default 88%) improved.
- SpO<sub>2</sub>- and PCO<sub>2</sub> Distribution curves: a) calculation of the duration during which a value fell within a certain interval (indicated as percentage of the 'Analyzed Duration') improved and resolution of displayed result increased (xx.x% for all parameters); b) maximal number of intervals restricted to 7.
- In contrast to V-STATS 3.01.1 or older editing Excluded Data Ranges does neither cause the measurement to be re-analyzed nor reset manually modified markers.
- In the PCO<sub>2</sub> channel the dB value for PCO<sub>2</sub> (difference between PCO<sub>2</sub> value at cursor position and PCO<sub>2</sub> baseline level) is now displayed left of the measurement curve (behind the value at the cursor position).
- Identification of modified event markers/ possibility to reset modified event markers
  - Starting from V-STATS 3.02 physiological events or artifacts that have been manually modified (added, reclassified, modified duration) by the operator are identified by markers exhibiting a black triangle in the upper left corner. Deleted markers are not identified.
  - In the tooltip that appears when the mouse is hovered over a modified physiological event or artifact marker '(M)' is now 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.
  - The popup menu that appears upon right click on a marker now includes an option to reset the marker (dimmed grey if unmodified) and an option to reset all markers in the channel (dimmed grey if none). Similar, the popup menu that appears after spanning a range with the left mouse includes an option to reset all modified markers within the spanned range (dimmed grey if none) and an option to reset all modified markers in the channel (dimmed grey if none).
  - To ensure that manually modified markers are not reset inadvertently when re-analyzing a measurement (as this was the case in older V-STATS versions) V-STATS 3.02 prompts the dialog 'Reset all modified markers (Yes | No | Cancel)?' before executing data analysis. Click on 'Yes' to reset all manually modified markers during the data analysis, click on 'No' to maintain modified markers.
- Separate display of SDM Event markers
  - Starting from V-STATS 3.02 SDM Event Markers are displayed separately from the other event markers at the bottom edge of the channels. SDM Event Markers cannot be modified, deleted or added manually.
  - Markers of SDM Events being excluded from data analysis by selecting the respective check box in the dialog 'Analysis Criteria Profile' are now duplicated by 'Invalid Data Marker', i.e. corresponding episodes are not evaluated during data analysis.
- Various modification and improvements related to the report
  - To print the measurement curves on one page irrespective of its duration the parameter 'Time resolution per page' in the dialog 'Print Report/ PDF Report' must be set to the new option 'Auto'.
  - The representation of the histograms and the distribution curves in the report pages 'SpO<sub>2</sub> Analysis' and 'PCO<sub>2</sub> Analysis' is improved/ clearer.
  - The layout of the event distribution has been modified/ improved and the selectable time resolution has been refined in the report pages 'SpO<sub>2</sub> Events'; 'PCO<sub>2</sub> Events'; 'PR Events'.
  - In the report page 'List of events' only one list of events is now provided per channel. For each event the following information is provided: a) date/ time of its occurrence as well as

its duration (in hh:mm:ss), b) the type of the respective event, and c) the respective parameter's values at the start/ end of the event (for physiological events only).

- New menu function 'Measurement/ Measurement start' permitting to modify/ reset the 'Measurement Start' of the open measurement.

Note: Use this function if time synchronization with data from other devices (e.g. ventilators, PG-, or PSG-Systems) is required.

- V-STATS 3.02 introduces the possibility to save changes to the currently open measurement by using the menu-function 'File/ Save' or by clicking on the "Save-Icon" in the menu-bar of V-STATS' Main Window.

Note: When attempting to close a measurement with unsaved changes V-STATS 3.02 prompts the dialog 'Do you want to save changes of <measurement name>?'.

Note: With V-STATS 3.01 and older changes in a measurement are only saved when closing the measurement (without the possibility to reject changes).

Note: V-STATS 3.02 also optimizes access to measurements being stored on a network drive. As a result the time needed to open/ store measurements over the network is significantly reduced.

- Possibility to export/ import (entire) 'V-STATS Files' introduced (see new sub-menus File / Export V-STATS File', 'File / Import V-STATS File', and 'File / Send V-STATS File by Email').).

Note: A 'V-STATS File' has the file extension '\*.sdmzip' and contains all information (i.e. the complete data set) that are available for a measurement within V-STATS.

Note: These new functions permit to exchange (entire) 'V-STATS Files' between V-STATS users be it to share measurements with other clinicians or be it for troubleshooting.

- Starting from V-STATS 3.02 EDF-Export of the currently open measurement is made by using the 'EDF+ Format'. Consequently the menu function now is called 'File/ Convert data to EDF+'.

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](http://www.edfplus.info).

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 will be proposed upon EDF+ Export can be predefined. If the filenames contain patient and measurement specific information, it will be possible for a third party application to assign each 'EDF+-file' to the respective patient and intervention/investigation. If 'EDF+-files' are stored in a dedicated folder a third party application may automatically import 'EDF+-files'.

Note: Various options permit to adjust/ select the data to be converted. Among other, EDF+-Export can be made for only uncorrected PCO2 data, only drift-corrected PCO2 data, or both. Optionally EDF+-Files can be sent by Email.

- The menu-function "File/ Export data..." now supports both, export of uncorrected and of drift-corrected PCO2 data. Furthermore, the 'Default File Name' and 'Default Storage Folder' that will be proposed for the resulting '\*.vex-file' now can be predefined and various options now permit to adjust/ select the data to be exported. Optionally the resulting '\*.vex-file' now can be sent by Email.
- When downloading SDM Trend Data via the serial interface it is now optionally possible to automatically export the data in the background as '\*.vex-file' or as EDF+-File by using the corresponding default storage folder and default file name.



- Various other points

- The sub-menus 'File/ Import raw data', 'File/ Export raw data', and 'File/ Send raw data by Email' are renamed to 'File/ Import SDM Trend Data', 'File/ Export SDM Trend Data', and 'File/ Send SDM Trend Data by Email', respectively. Furthermore, the menus 'File/ Export SDM Trend Data' and 'File/ Send SDM Trend Data by Email' now are dimmed grey, if for the displayed measurement the original 'SDM Trend Data' are not available (as this is the case after import of a '\*.vex-file').
- Optionally the PDF-Report now can be attached to an Email.
- Up to 60 characters are now supported in each of the 5 report heading lines (previously restricted to 40 characters).
- In addition to information related to the patient ('Last name', 'First name', 'Date of birth', 'Patient number') and to the measurement ('Date of Registration', 'Comment', 'Measurement duration') the 'File Manager' starting from V-STATS 3.02 also displays the 'Filename' of each measurement. Furthermore, the 'File Manager' additionally can be searched for the 'Filename'.
- If a measurement is displayed in the 'Main Window' of V-STATS, the name of the corresponding patient is displayed in the bottom left corner. Starting from V-STATS 3.02 a click on this area opens the dialog 'Patient data'.
- Cursor now better distinguishable (thicker and orange colored) from vertical grid lines.
- Improved cursor handling: a) while scrolling in the measurement the cursor now stays on the graph as long the cursor stays in the displayed area; b) if set, the cursor now can be removed by clicking on the "Cursor Position Time Indicator" at the top right of V-STATS' Main Window.
- V-STATS 3.01 introduced the possibility to create PDF reports. V-STATS 3.02 additionally provides the possibility the create PDF-files of 'SDM Profiles', the preview of the report heading, the list of operator events (if any), and the list of excluded data ranges (if any).
- Starting from V-STATS 3.02 the selection of the COM-port can be made within the dialog "Communication with the SDM (via Serial Interface)". Consequently, the menu-function "Communication/ Settings" has been discontinued.
- Improved design of the Connection Status Indicator in the dialog 'Communication with the SDM (via Serial Interface)'.

## **B) Modifications related to the SDM's configuration (Parameters & SDM Profiles)**

- Only minor modifications were made in the dialog 'Profiles/ SDM Settings':
  - The parameter 'Demo Mode' was added (to set the Demo Mode of the connected SDM ON or OFF);
  - The parameters 'LAN selectable' and 'LAN' now are dimmed grey if the connected SDM is factory-preconfigured in V-CareNeT Only Mode.
  - Possible selections for the 'Sensor Temperature' and the 'Site Time' now are restricted to the currently supported range.

## **C) Modifications related to V-CareNeT**

- In V-STATS 3.00 and 3.01 the maximum number of beds/ patients being simultaneously available for remote monitoring was limited to 20 beds/ patients. Starting from V-STATS 3.02 V-CareNeT supports up to 40 beds/ patients. Consequently, V-CareNeT licenses are now available for 5, 10, 20, 30, or 40 beds/ patients.

Note: V-CareNeT evaluates the size/resolution of the central station's screen and limits the number of bed/ patients 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 CPRC that was used to activate/ upgrade the 'V-CareNeT Package'.*

- Starting from V-STATS 3.02 it is possible to upgrade an already activated V-CareNeT Package, i.e. to upgrade the maximum number of beds/ patients for which remote monitoring simultaneously is possible.
- If enabled in a password protected area, it is now possibility to remotely control/ modify the following parameters of the connected SDM: high/ low alarm limits for PCO<sub>2</sub>, SpO<sub>2</sub>, and PR, 'Alarm Volume', 'Enabled Parameters', 'Delta-Time', 'Sensor Temperature', 'Site Time', 'SITE PROTECTION', 'INITIAL HEATING', 'Brightness', and 'Display in Sleep Mode'.

Note: The four parameters 'Sensor Temperature', 'Site Time', 'SITE PROTECTION', and 'INITIAL HEATING' cannot be changed during patient monitoring.

- V-STATS 3.02 introduces the possibility to position the V-CareNeT Control Window either in the upper right or the upper left corner of the V-CareNeT Main Screen.
- Flexibility to re-activate the last V-CareNeT session now enhanced
  - When starting up V-CareNeT the dialog 'Last V-CareNeT Session' now activates in most situations. Therein the configuration of the last V-CareNeT session is now completely summarized and, if desired, the configuration for the next V-CareNeT session can be edited/ modified before activating V-CareNeT.
  - If at the end of the last V-CareNeT session the V-CareNeT Control Window and/ or the remote monitoring windows were not arranged in default position, it is now – when starting up V-CareNeT - possible to maintain/ restore the customized windows arrangement of the last session.
- The process to transfer a patient to another station/ SDM has been improved.
  - The dialog 'Assign another station/ SDM' now displays for all stations the status ('current', 'available', 'occupied', or 'locked') as well as the data of the assigned patient.
  - A help dialog will display at the end of the patient transfer to ensure that the patient's location is verified/ updated.
- Various other modifications and improvements being related to V-CareNeT
  - In the V-CareNeT Control Window the position of the 'Close' Icon and the Software Activity Indicator have been exchanged and the design of the 'Connection Status Indicators' has been improved.
  - Respective messages in the V-CareNeT Control Window now visualize if auditory alarm signals being related to technical alarm conditions occurring at SDMs and/ or at the central station itself are permanently switched off/ inhibited at the central station.
  - Selection of all elements in the list 'Currently selected' in the dialog "Edit SDM Device/Host Name" is now possible with the CTRL+A keys.
  - V-STATS 3.01 introduced the possibility to duplicate the 'Patient Info' being displayed in the remote monitoring window on the corresponding SDM. Starting from V-STATS 3.02 duplication of most (not all) special characters will be supported.
  - During an (extended) V-CareNeT Trial it is not any longer possible to admit a patient to a station if the associated SDM is configured in 'V-CareNeT Only Mode' ('Admit Patient' check box dimmed).
  - When downloading trend data via V-CareNeT the list of measurements displayed in the dialog '<x>:<SDM Device/Host Name>- Assign measurement period(s) to patients' is now updated if a measurement is initiated/ terminated on the corresponding SDM.

## D) Other features and modifications introduced by V-STATS 3.02

- V-STATS 3.02 is compatible with Windows XP, Vista, 7 (32/ 64 Bit), 8 (32/ 64 Bit), and 8.1 (32/ 64 Bit).
- V-STATS 3.02 is compatible with the following firmware versions of the SenTec Digital Monitor: SMB-SW V07.01.x, V07.02.x, and V07.03.x.
- Update to V-STATS 3.02 is only supported if the installed V-STATS license is registered and has version 3.00 or newer.
- V-STATS 3.02 supports Deutsch, English, Español, Français, Italiano
- Starting from V-STATS 3.02 a PDF copy of the Installation Manual (HB-006144) will be included in the V-STATS 3.02 Installer/ Updater.

Note: The PDF copy of the Installation Manual can also be downloaded from SenTec's [webpage](#). Paper copies will not any longer be provided with each installation CD.

## Main features & modifications introduced by V-STATS 3.01.1

### A) Modifications related to V-CareNeT

- Support of SenTec Digital Monitors being factory-preconfigured in V-CareNeT Only Mode

Note: When starting up an SDM that is factory-preconfigured in 'V-CareNeT Only Mode' the 'V-CareNeT required' screen appears after the POST screen. As long as the 'V-CareNeT required' screen displays, the SDM is not operational, i.e. no measurement data is displayed and no menu functions can be accessed. Furthermore, no vital data are shown on the online outputs of all supported protocols (Philips Vuelink / Intellibridge I+II, Spacelabs Flexport, TCB, SenTecLink Online).

Note: V-STATS 3.01.1 or higher with a fully activated V-CareNeT Package is required to unlock a SDM that is factory-preconfigured in 'V-CareNeT Only Mode', i.e. such an SDM must be connected to V-CareNeT to enable full SDM operation.

Note: If the connection to V-CareNeT is interrupted for a time period exceeding 4 hours a SDM being factory-preconfigured in 'V-CareNeT Only Mode' will lock again once the V-Sign Sensor is inserted into the 'Docking Station'. In this case the 'V-CareNeT required' screen re-appears until the connection to V-CareNeT is re-instated.

### B) Other features and modifications introduced by V-STATS 3.01.1

- Compatibility with Windows 8 (32/ 64 Bit)

Note: V-STATS 3.01.1 is also compatible with Windows XP, Vista and 7 (32/ 64 Bit).

- Installation of V-STATS on network drives will not any longer be supported.

Note: Consequently, update of a V-STATS license (version 3.01 or older) that is installed on a network drive to version 3.01.1 or newer will not be supported.

- Compatibility with firmware version SMB-SW V07.02.x of the SenTec Digital Monitor.

Note: V-STATS 3.01.1 is also compatible with the following firmware versions of the SenTec Digital Monitor: SMB-SW V06.21.x, V07.00.x, and V07.01.x

## Main features and modifications introduced by V-STATS 3.01

### A) Modifications related to SDM Trend Data download, display, analysis, and reporting

- Possibility to select the 'Analysis Interval', i.e. the time range of a measurement that is analyzed and considered when generating the report. Selectable options are 'Full Measurement', 'Displayed range', 'Manual' range, and – if the measurement is split into multiple Analysis Periods – one of the available Analysis Periods (AP x)

Note: In the Main Window of V-STATS the current 'Analysis Interval' is indicated by the 'Analysis Interval Indicator', a blue, bold label displaying in the upper menu bar and visualized by a blue bar above the measurement curves as well as two blue vertical lines at the start and end of the 'Analysis Interval', respectively.

Note: If a measurement is split into multiple 'Analysis Periods' (e.g. for split night analysis) the current 'Analysis Interval' can be set to one 'Analysis Period' after another to generate/print a 'Partial Report' report for each 'Analysis Period'.

- Operator Events marked on the SDM during patient monitoring are displayed in the Main Window of V-STATS as colored triangles. 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.

Note: Whenever a measurement is displayed in the Main Window it is possible to a) edit or delete existing Operator Events/Analysis Periods or b) to add new Operator Events/Analysis Periods.

Note: In the dialog "Define Operator Events" you can a) predefine for each of the 8 operator event types a default color and description as well as b) determine whether a new Analysis Period starts at the position of respective operator event. This pre-definition can be printed and placed with the SDM.

- Possibility to exclude multiple data ranges, being separated from each other, from statistical data analysis. An 'Invert' function is available to invert data range exclusion. 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.

Note: 'Excluded Data Ranges' are different from artifacts. Excluded Data Ranges usually contain good quality data which for a specific reason shall be excluded from statistical data analysis. Artifacts in contrast - marked by the operator with the mouse or determined by V-STATS based on operator-adjustable criteria - correspond to data ranges with questionable data quality and are therefore permanently excluded from statistical data analysis.

Note: In default settings 'Excluded data ranges' are visualized in the measurement curves by light grey colored markers.

- The print-out of the report is highly configurable / customizable. For example it is possible to create a one-page report that includes the most important statistical results, the distribution curves for PCO<sub>2</sub>, SpO<sub>2</sub>, and PR, operator events as well as the part of the measurement curve that corresponds to the current 'Analysis Interval'.

Note: The most important elements that can be selected / customized are: a) the report pages to be printed, b) the heading of the report, c) the elements to be included in the print-out of the summary page, and d) the font size used for the print-out.

Note: Most customers just print the 'Summary' page of the report and the 'Full Measurement Curve'. If the printer supports two-sided printing, these two elements can be printed on one sheet of paper.

- Possibility to store the report as PDF. In order 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.

Note: The 'Default Storage Folder' can be located on a server of your institution's network. The 'Default File Name' consists of up to 5 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. The characters used to separate the elements are selectable as well (- | \_ | , | ; | (space) | (none)).

- The 'File Manager' has been expanded to additionally display the 'Patient number', the 'Comment', and the 'Measurement duration'. Furthermore, each column of the 'File Manager' can be sorted in increasing/decreasing order. The number of permitted characters for the 'Last Name' and the 'First Name' is increased from 15 to 25 characters.

Note: 15 Sample Files are provided in the folder "Installation Drive:\vg\lvstats\daten\examples"

- The **Target Folder of File Manager** and the **Data Storage Folder** are selectable in the dialog 'V-STATS Settings'. The 'Target Folder of File Manager' can be set to LAST or to 'Data Storage Folder'.

Note: The 'Data Storage Folder' and the 'Target folder of File Manager' can be located on a server of the hospital network and, consequently, can be accessed from any V-STATS client having read/write access to these folders. Furthermore, backup of the measurement data is accomplished in the course of the server's routine backup procedures.

- Provided the sensor was properly calibrated prior and after the measurement retrospective correction of residual PCO2 Drift is possible since V-STATS 2.02. V-STATS 3.01 now introduces the possibility to display only the drift corrected PCO2 Curve.

Note: Print-out of the uncorrected 'PCO2 trend curve' and the 'drift corrected PCO2 trend curve' is now made with different thickness 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

- Enhanced options to adjust the display range and the horizontal grid as well as the reference for the vertical grid / time scale for the display of measurements in V-STATS
- Expanded options to "Export Data" (e.g. export of data contained within Analysis Interval only)

## B) Modifications related to the SDM's configuration (Parameters & SDM Profiles)

- All functions necessary to configure the SDM and to manage/ customize 'SDM Profiles' have been consolidated into the password protected dialog 'Profiles / SDM Settings'.
- In Basic Mode all parameters of the connected SDM can be changed on an individual basis and the Current SDM Profile of the connected SDM can be printed, saved to the SDM Profiles Database or set to an existing profile.
- In Institutional Mode up to 4 SDM Profiles can be stored on the connected SDM and one of these profiles can be selected as 'Standard Profile', all parameters of the connected SDM can be changed on an individual basis, and the Current SDM Profile of the connected SDM can be printed, saved to the SDM Profiles Database, or reset to the 'Standard Profile' (if modified).
- 'SDM Profiles' are stored in the 'SDM Profiles Database'. The functions to customize and manage 'SDM Profiles' include the possibility 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 3.01 the following write-protected SDM Profiles preconfigured by SenTec and tailored to optimally fit the specific needs of different clinical settings are stored in the 'SDM Profiles Database': CRITICAL CARE, GEN. CARE FLOOR, HOME, NICU, OPERATING ROOM, PACU, SLEEP, SMB621 STYLE, and V-CHECK (enabling Ventilation Spot Check). If the profile SMB621 STYLE is activated the SDM is configured as closely as possible to the factory settings of a SDM with firmware version SMB 6.21.x and MPB 4.04.x. Please refer to 'RF-006679 Preconfigured SDM Profiles' to view all parameters and their respective settings in the 9 preconfigured SDM Profiles.*

## C) Modifications related to V-CareNeT

- Simultaneous download of SDM Trend Data from up to 20 SDMs to V-STATS is now supported. 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: Downloading trend data from the internal memory of a device (such as the SDM) to a PC based trend data analysis and reporting software (such as V-STATS) is a very time consuming procedure, especially if trend data have to be downloaded consecutively from multiple devices. In such a setting the possibility to simultaneously download SDM Trend Data from multiple SDMs, consequently, can result in daily time savings easily exceeding one hour.*

*Note: Starting from V-STATS 3.01 download of SDM Trend Data via V-CareNeT is also supported for the currently active measurement period.*

- Possibility to remotely set a baseline for PCO<sub>2</sub> and SpO<sub>2</sub> or to mark operator events on the respective SDM during patient monitoring

*Note: Operator Events are not displayed on the SDM. The instant an operator event was set and its type are stored in the memory of the SDM and are transferred to V-STATS when downloading SDM Trend Data.*

*Note: Baseline and Operator Events can also be set in the Quick Access Menu of the SDM*

- Possibility to display dx-values and/or baseline values in the remote monitoring window

*Note: The '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 PCO<sub>2</sub>' of '+ 2.1 mmHg', for example, indicates that the current PCO<sub>2</sub> reading is 2.1 mmHg higher than the PCO<sub>2</sub> reading 10 minutes ago. x is called 'Delta-Time' and is adjustable within a password-protected area of V-STATS. The default value for the 'Delta-Time' is 10 minutes. Note that dx-values are only available for SDM's with firmware version SMB-SW V07.01 or newer.*

*Note: 'Baseline values' for a parameter comprise a) the baseline itself, i.e. the reading of the parameter at the instant the baseline was set, b) 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 c) the time that elapsed since the baseline was set in hh:mm format. 'Baseline values for PCO<sub>2</sub>' of '32.2 + 9.8 mmHg (00:21)', for example, indicate that the current PCO<sub>2</sub> reading is 9.8 mmHg higher than the baseline of 32.2 mmHg which was set 21 minutes ago. Note that baseline values are only available for SDM's with firmware version SMB-SW V07.01 or newer.*

- Possibility to reactivate the 'Last Remote Monitoring Session' when starting-up V-CareNeT.

*Note: This feature is particularly helpful if the operator terminated V-CareNeT accidentally.*

- Possibility to duplicate the patient info displayed in a station's remote monitoring window on the associated SDM.

- Possibility to disable auditory alarm signals of Technical Alarms of all SDMs included in the V-CareNeT System and/or of the V-CareNeT Central Station.
- Possibility to individually pause or permanently switch off auditory alarm signals of each remote monitoring station.
- Addition of an 'Extended V-CareNeT Trial' permitting to extensively trial V-CareNeT during up to 10 days within 4 weeks. During an extended V-CareNeT Trial V-CareNeT is fully functional. An Extended V-CareNeT Trial can be activated only once.
- For demonstration and training/education purposes V-STATS 3.01 introduces the 'V-CareNeT Demo Mode'. In Demo Mode connection to 40 SDMs and remote monitoring for up to 20 SDMs can be simulated.

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

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

- Expanded functions to monitor data integrity and connection/network quality between the V-CareNeT Central Station and each individual SDM. In the V-CareNeT Control Window the overall connection/network quality is visualized in the respective 'Connection Status Indicator'.

Note: Optionally quantitative information on the network/connection quality between the V-CareNeT Central Station and a connected SDM can be displayed in a tool tip that appears if the mouse is placed over the respective 'Connection Status Indicator'.

- As a safety precaution the V-CareNeT Central Station will lock the SDM when admitting 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.

Note: To display/duplicate the data from the same patient/SDM on different 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](#)

- Possibility to disable Device Discovery

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'. 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'.

Note: If Device Discovery is deactivated 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.

## D) Other features and modifications introduced by V-STATS 3.01

- The following three buttons, which provide direct access the three main functions of V-STATS, have been added to the center of V-STATS' Main Window: 'Communication with SDM (serial)'; 'File Manager'; 'V-CareNeT'
- Customers that forgot their V-STATS and/or V-CareNeT password can define a new password by using a 'Password Unlock Key' (PUK).

- V-STATS related settings are now consolidated in the password-protected dialog 'V-STATS Settings'.

Note: Among other the 'Format of Date' (MM-DD-YYYY, DD-MM-YYYY, or YYYY-MM-DD), the 'Units of weight' (kg or lbs), and the 'Units of length/height' (cm or feet) are selectable. Furthermore, a button which permits to reset all V-STATS and V-CareNeT settings to their factory defaults is provided.

- The following additional functions are provided in the dialog 'Special functions':
  - a) Raw Dump (*providing a raw dump of the data stored in the internal memory of the connected SDM*)
  - b) Screenshot (*Permitting to make a screen shot of the connected SDM's currently active screen and to store it as a bitmap*)
  - c) SDM Factory Reset (*Resets the connected SDM to its factory configuration, i.e. all parameters will be reset to factory settings, all profiles and all trend data will be cleared*)
- Compatibility with Windows XP, Vista and 7 (32 und 64 Bit) (Windows 98 not any longer supported).
- V-STATS 3.01 is compatible with the following firmware versions of the SenTec Digital Monitor: SMB-SW, V06.21.x, V07.00.x, and V07.01.x.

## Main features and modifications introduced by V-STATS 3.00

### A) Modifications related to SDM Trend Data download, display, analysis, and reporting

- Possibility to import data that previously have been exported from V-STATS in a spreadsheet compatible format.
- Automatic PCO2 drift correction when importing data to V-STATS can be disabled.
- Possibility to activate printing of the currently displayed range of the curves by clicking the new 'Print Screenshot' Icon in the upper menu bar of Graphic Window.
- Possibility to enable/disable a 'Vertical Cursor' which displays the values of the measurement curves at the cursor position by clicking the respective icon in upper menu bar of Graphic Window.
- Possibility to enable/disable display of minima and/or maxima in the curves by clicking the respective icon in upper menu bar of Graphic Window.

### B) Introduction of SDM Configuration / Management of SDM Parameters Settings

- Within a password protected area of V-STATS it is now possible to configure special (safety-relevant) settings of the SDM depending on the individual needs of the particular clinical settings. Examples include the restriction of the 'Maximal operator-selectable Sensor SET Temperature' and the 'Maximal operator-selectable Preset Site Time' or enabling/disabling the possibility that the operator can switch-off the 'AUDIO OFF Reminder'.
- Possibility to manage SDM Parameters Settings. Examples of available functions include 'Restoring Factory Parameters Setting', 'Defining the Standard Parameters Setting' in 'Institutional Mode', 'Copying a SDM Parameters Setting from the SDM to V-STATS', or 'Exporting a SDM Parameters Setting from V-STATS to the PC'. Pre-configured SDM Parameters Settings are included. Furthermore it is possible to select between 'Basic Mode' and 'Institutional Mode' to handle the SDM's parameters settings. In 'Institutional Mode' the institution can define a 'Standard Parameters Setting' which is used as power-up setting or which can be restored by the operator in the menu of the SDM.

### C) Introduction of the V-CareNeT Package

- Once activated the V-CareNeT Package being incorporated in V-STATS 3.00 enables remote monitoring and secondary alarm surveillance for multiple SenTec Digital Monitors (SDM) being connected to the same network as the PC with V-STATS, i.e. the PC with V-CareNeT is used as a central station for patient monitoring. For all admitted patients the central station displays all relevant SDM data and alarms.
- Once activated the V-CareNeT Package also enables download of trend data stored in the internal memory of the SDM via the network for subsequent display, analysis and reporting in V-STATS.

*Note: Setup of V-CareNeT is easy and only requires a conventional Ethernet network, at least one SDM, a PC serving as a central station with V-STATS installed and V-CareNeT Package activated.*

### D) Other features and modifications introduced by V-STATS 3.00

- Various improvements related to the registration of V-STATS and V-STATS updates.



- V-STATS 3.00 is compatible with the following firmware versions of the SenTec Digital Monitor: SMB-SW V06.10.x, V06.20.x, V06.21.x, and V07.00.x.
- Starting from V-STATS 3.00 all functions related to the SenTec Datalogger, the memory card of the SenTec Datalogger, and raw data files that have been recorded with the SenTec Datalogger (e.g. Import of raw data files) which were available in previous V-STATS versions are discontinued.