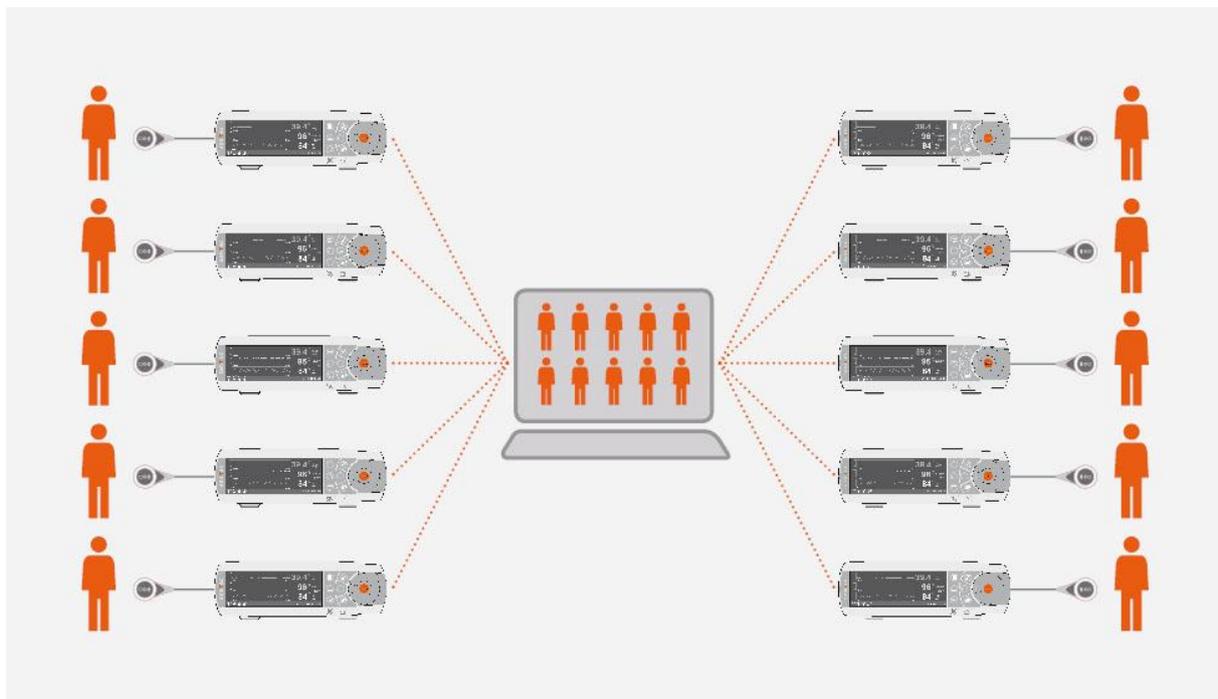# Installation Manual

for

V-STATS 4.10

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

HB-006144-h

Compatibilities

1. Compatibility of V-STATS 4.10 with SDM firmware versions

V-STATS 4.10 is compatible with SenTec Digital Monitors (SDMs) with firmware version SMB-SW   V08.00.x., V08.01.x. or V08.02.x. The SMB firmware version is indicated in the SDM's menu 'System Information'.

> *Note*: *V-STATS 4.10 supports communication via the serial interface only for SDMs with firmware versions SMB-SW V08.00.x or V08.01.x, V08.002.x. You must use V-STATS 3.01.1, 3.01, 4.00, 4.00.1 or 4.01 if your SDM uses firmware version SMB-SW V07.03.x, V07.02.x, V07.01.x, V07.00.x or V06.21.x. Contact your local SenTec distributor regarding V-STATS compatibility with older SDM firmware versions.*

> *Note*: *V-STATS 4.10 supports V-CareNeT only for SDMs with firmware versions SMB-SW SMB-SW V08.00.x, V08.01.x or V08.02.x. Contact your local SenTec distributor to use V-CareNeT with SDMs with firmware version SMB-SW V07.03.x, V07.02.x, V07.01.x, V07.00.x. If your SDM uses a firmware version prior to SMB V07.00 V-CareNeT cannot be used.*

> *Note*: *V-STATS 4.10 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 firmware version SMB-SW V08.00.x, V08.01.x or V08.02.x. Use V-STATS 3.01.1, 3.01, 4.00, 4.00.1, 4.01 to import SDM Trend Data if the included data has been downloaded from the internal memory of a SDM with firmware versions SMB-SW V07.03.x, V07.02.x, V07.01.x, V07.00.x or V06.21.x. Contact your local SenTec distributor regarding import of SDM Trend Data including data that has been downloaded from SDMs with older firmware versions.*

2. System requirements

V-STATS 4.10 can be installed on most PCs. The minimum system requirements are:

	V-STATS (without using V-CareNeT)	V-STATS with V-CareNeT activated
CPU	2 GHz and higher	Multi core at 2 GHz and higher
Operating System	Microsoft Windows 7 (32 and 64 bits), 8 (32 and 64 bits), 8.1 (32 and 64 bits), 10 (32 and 64 bits)	Microsoft Windows 7 (32 and 64 bits), 8 (32 and 64 bits), 8.1 (32 and 64 bits), 10 (32 and 64 bits)
Memory	4 GB	4 GB
Free space on hard disk	1 GB	1 GB
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

Installation and Configuration

GDPR (https://www.eugdpr.org/) is a European Union (EU) directive, replacing the Data Protection Directive 95/46/EC. The transitional period ends on May 25, 2018. From this date on, only the GDPR shall apply. The objective is to harmonize European data protection laws while focusing on strengthening EU citizens' rights protecting their personal data. All companies and organizations, which process EU citizens' data, are affected, regardless of where these companies or organizations are based and where the data are being processed. Particularly in the healthcare sector, this implies that every person dealing with personal (patient) data must adhere to the GDPR. In addition to hospitals, medical practices, pharmacies, laboratories and health insurances (to name but a few), manufacturers of medical technology products are equally affected.

SenTec therefore revised V-STATS including V-CareNeT in order for the user to adhere to GDPR. Each individual organization (hospital, medical practice) may determine whether they save patient data and which data should be saved. The organization is responsible for complying with applicable regulations. With this new release, SenTec offers measures which allow GDPR-conform handling of patient data. For more information see Annex I of the V-STATS Instruction Manual.

3. Installation of V-STATS 4.10 on a PC

To install V-STATS 4.10 on a PC proceed as follows:

- Switch on your computer and start Windows

- Insert the V-STATS installation CD into the CD-ROM

- Open Windows Explorer, select the CD-ROM drive, and double-click on **setup.exe** to start the installation.

- Select the desired language

- Click on `Installation Manual´ if you want to open the installation manual as .pdf file and then on `Next´ to resume the installation

- A 'License Agreement Dialog' displays. Press 'I Agree' to accept the license terms and to continue installation. If you press 'I do not agree', the installation of V-STATS will be aborted. Press 'Print' to print the license terms.

- Carefully read the dialog with information regarding V-STATS compatibility with SDM firmware versions open and click `yes´ to acknowledge the information and to resume the installation

- 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 or 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._

- If a V-STATS license is already installed on the target drive:

   a) the message 'Take over the settings of the present installed version?' prompts. 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 (applies to software versions higher than 4.10).
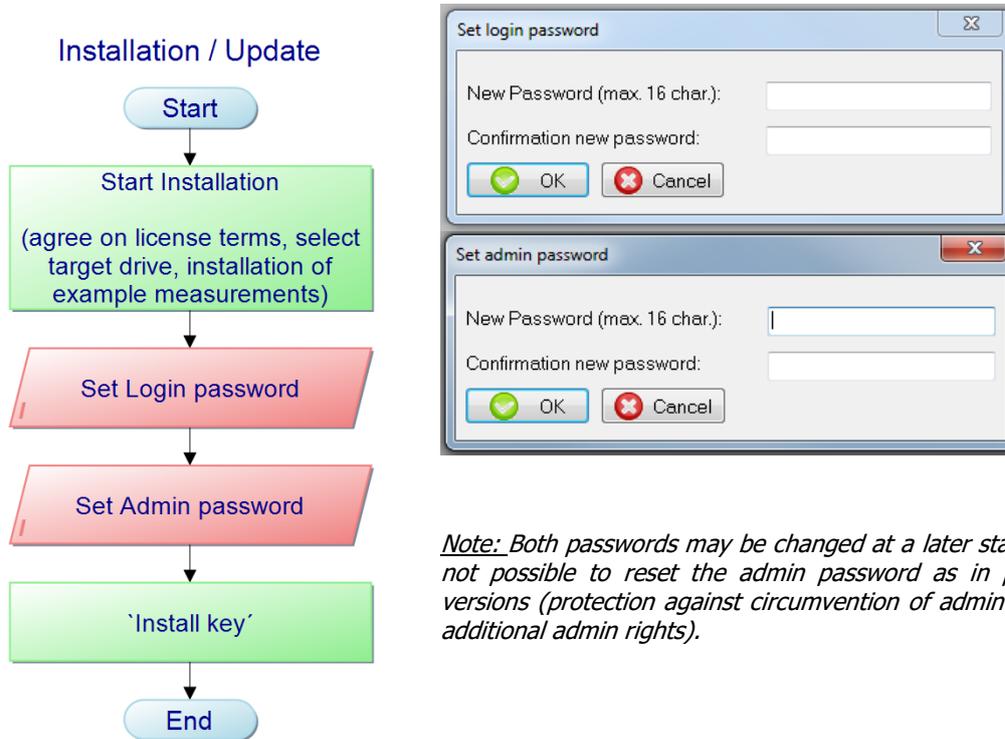
   b) an information dialog appears if user-configured SDM Profiles are stored in V-STATS' SDM Profiles Database under the same file name as those SDM Profiles preconfigured by SenTec. These preconfigured profiles will be added during the update, and V-STATS will overwrite the former by the latter. Before 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.

- 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.
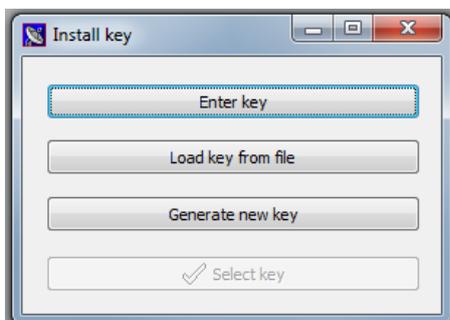
- Enter a new password for the login

- Enter a new password for the admin

Upon installation, a dialogue window appears for setting both passwords – initially for the standard user login ("Login"), followed by the administration password for V-STATS ("Admin").
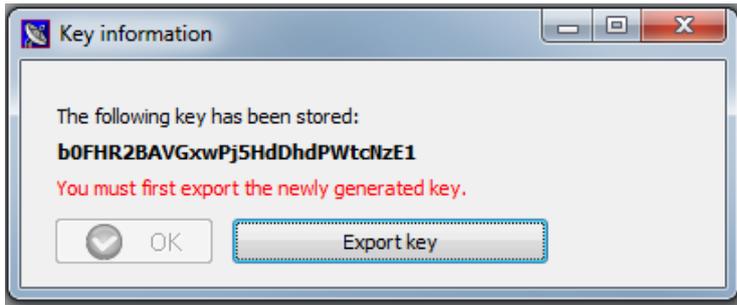

Note: Both passwords may be changed at a later stage. However, it is not possible to reset the admin password as in previous V-STATS versions (protection against circumvention of admin password to gain additional admin rights).
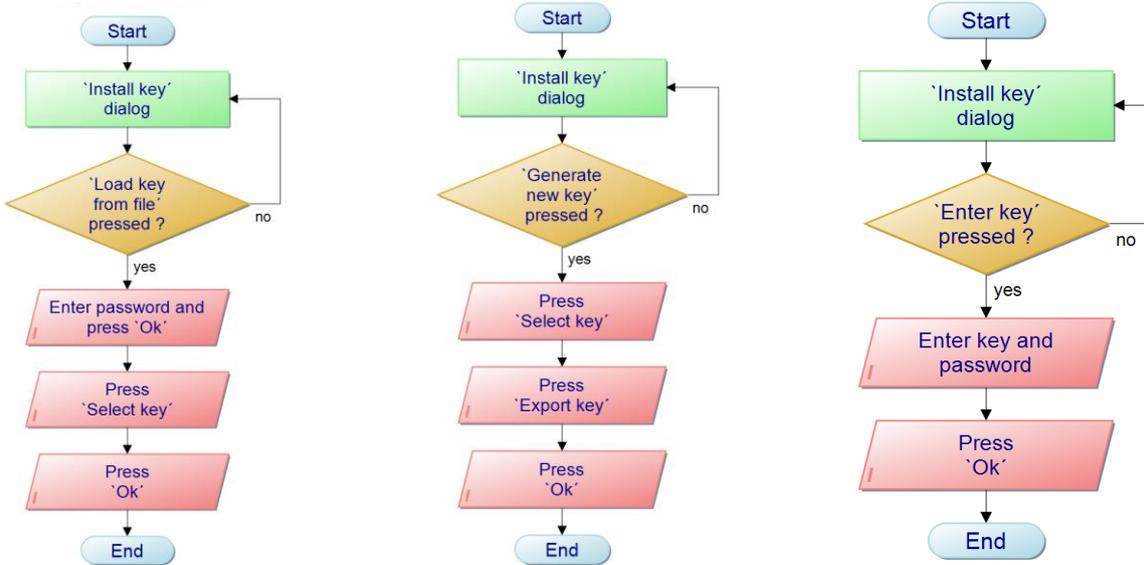
- A 'Install key' Dialog displays. Firstly, a new key must be generated during installation ("Generate new key"). Alternatively, an existing key may be entered manually ("Enter key") or loaded from a file ("Load key from file"). If you do not have a key, generate a unique key for encrypting patient data by following these steps:

    ➢ Press "Generate new key"

    ➢ Press "Select key"

    ➢ Press "Export key" to save the unique key locally

    ➢ Press "OK".

If a new key is generated, it initially has to be exported (backup function). Without a key, the data that were encrypted by using this key cannot be decrypted.

Key information

The following key has been stored:

b0FHR2BAVGxwPj5HdDhdPWtcNzE1

You must first export the newly generated key.

OK   Export key

Key Installation / Button `Change V-STATS key´

Start → `Install key´ dialog → `Load key from file´ pressed ? — no (loops back)
yes → Enter password and press `Ok´ → Press `Select key´ → Press `Ok´ → End

Start → `Install key´ dialog → `Generate new key´ pressed ? — no (loops back)
yes → Press `Select key´ → Press `Export key´ → Press `Ok´ → End

Start → `Install key´ dialog → `Enter key´ pressed ? — no (loops back)
yes → Enter key and password → Press `Ok´ → End

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

Important Note: *Ensure not to cancel the key installation. Otherwise, the key to decrypt patient information cannot be used anymore and patient information is lost.*

Note: Only files in the default directory are automatically encrypted. Files in other directories are not encrypted.
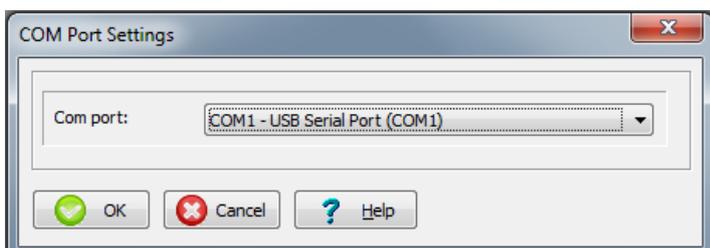
Note: Ensure to save the key in a secure storage location.

- To create a shortcut to your desktop, click on '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.
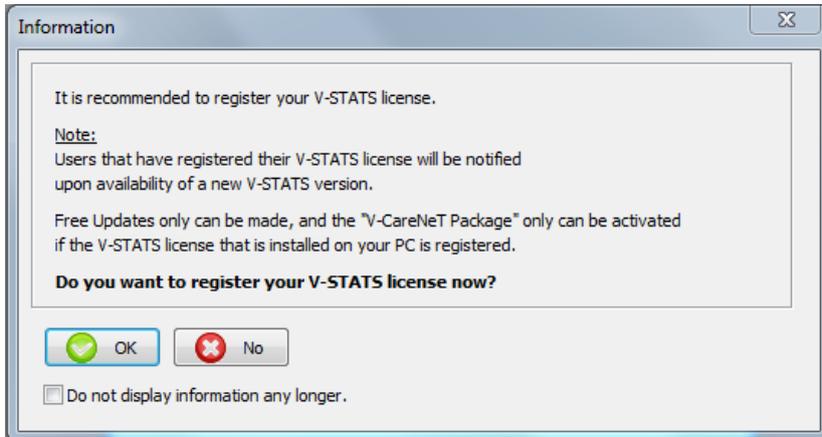
Once the installation is completed, the information message 'Installation successful' displays.

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**':

COM Port Settings

Com port: COM1 - USB Serial Port (COM1)

OK   Cancel   Help

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.

*   Click on the 'OK' button to open the dialog 'Registration'

*   Click on the 'No' button 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 display 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 cover. Remove the installation CD after successful installation and keep it in safe custody.

4. Printer Selection

V-STATS 4.10 allows the printout of various items, such as reports or SDM Profiles, on most ink jet, laser, or matrix printers that have been 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).

Updates, Upgrades and LAN Package Activation

5. How to update your V-STATS software (requires V-STATS 4.00 or higher)

Starting from V-STATS 4.00 or higher, an installed and registered V-STATS license can be updated to V-STATS 4.10 as follows:

*   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/int/products/sentec-data-management/v-statstm/)

*   Once the download is completed, unzip the updater 'updatervstats.zip'.

    Note: The resulting folder "updatervstats" can be copied to a storage medium such as an USB-Stick or CD.

- Open the folder "updatervstats" and double-click on **setup.exe** to start the update.

- Select the desired language.

- Click on `Installation Manual´ if you want to open the installation manual as .pdf file and then on `Next´ to resume the installation.

- A 'License Agreement Dialog' displays. Press 'I Agree' to accept the license terms and to continue installation. If you press 'I do not agree', the installation of V-STATS will be aborted. Press 'Print' to print the license terms.

- Carefully read the dialog containing information about V-STATS' compatibility with SDM firmware versions and click `yes´ to acknowledge the information and to resume the installation.

- Select the target drive.

  Note: All necessary files will be copied in the folder 'Target Drive:\fg\vstats'. Please note that the updater will not overwrite existing measurement files and patient data.

  Important Note: *During use, V-STATS needs read or 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 4.00, you first must update this version to V-STATS 4.00 by using the appropriate updater before updating to V-STATS 4.10.

  Note: If the installed V-STATS license is not registered, you first must register the license before updating to V-STATS 4.10. 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.

- Next, the message 'Take over the settings of the present installed version?' will prompt. 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 V-STATS 4.10.
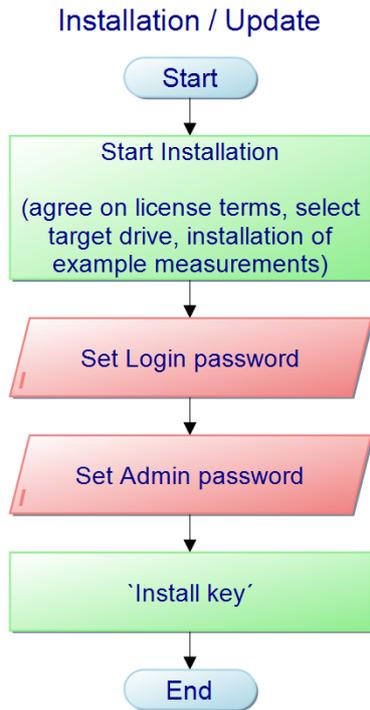
  Note: All passwords (admin/login) remain if you do not take over present settings (applies to software versions higher than 4.10).

- 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, an information dialog appears. 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.

- 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.

- Enter a new password for the login

- Enter a new password for the admin

Upon installation, a dialogue window appears for setting both passwords – initially for the standard user login ("Login"), followed by the administration password for V-STATS ("Admin").

Installation / Update

Start

Start Installation

(agree on license terms, select target drive, installation of example measurements)

Set Login password

Set Admin password

`Install key´

End

Set login password

New Password (max. 16 char.): [_____]

Confirmation new password: [_____]

OK   Cancel

Set admin password

New Password (max. 16 char.): [_____]

Confirmation new password: [_____]

OK   Cancel

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).
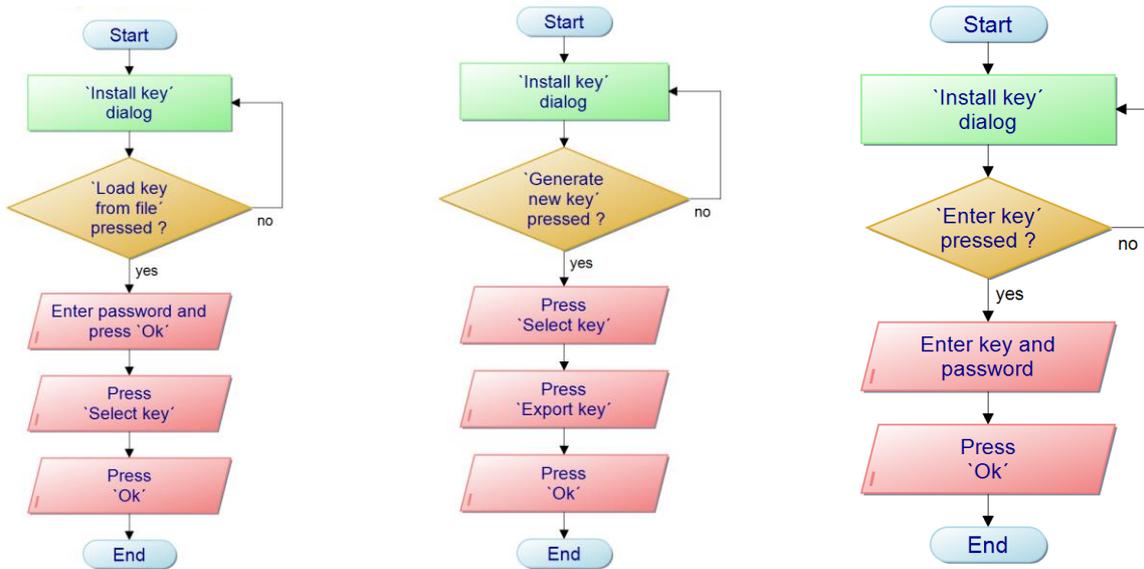
- A 'Install key' Dialog displays. Firstly, a new key must be generated during installation ("Generate new key"). Alternatively, an existing key may be entered manually ("Enter key") or loaded from a file ("Load key from file"). If you do not have key, generate a unique key for encrypting patient data by following these steps:

  ➢ Press "Generate new key"

  ➢ Press "Select key"

  ➢ Press "Export key" to save the unique key locally

  ➢ Press "OK".

Install key

Enter key

Load key from file

Generate new key

Select key

If a new key is generated, it initially has to be exported (backup function). Without a key, the data that were encrypted by using this key cannot be decrypted.

Key information

The following key has been stored:

b0FHR2BAVGxwPj5HdDhdPWtcNzE1

You must first export the newly generated key.

OK   Export key

Key Installation / Button `Change V-STATS key´

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

Important Note: Ensure not to cancel a key installation, otherwise the key to decrypt patient information cannot be used anymore and patient information is lost.

Note: Only files in the default directory are automatically encrypted. Files in other directories are not encrypted.

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

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

    Note: Regardless of your selection, the updater will add a shortcut to the start menu.

Once the update is completed, the information dialog 'Installation successful' as well as a PDF file summarizing the most important new features and modifications included in V-STATS 4.10 pop up.

6. Activating the V-CareNeT Package (requires V-STATS 3.00 or higher)

To activate the V-CareNeT Package for the desired number of beds/patients, the installed V-STATS license must be registered. 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.

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

7. Upgrading the V-CareNeT Package (requires V-STATS 4.00 or higher)

If your V-CareNeT Package is <u>already activated</u> and if you want to <u>increase</u> 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.

8. V-CareNeT Trial (requires V-STATS 3.00 or higher)

If the installed V-STATS license is registered, it is possible to test V-CareNeT for free. To initiate the V-CareNeT Trial, use the menu 'Tools / V-CareNeT Trial'. 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.

9. Extended V-CareNeT Trial (requires V-STATS 3.01 or higher)

If the installed V-STATS license is registered, it is possible to activate an Extended V-CareNeT Trial. To initiate the Extended V-CareNeT Trial use the menu 'Tools / Extended V-CareNeT Trial'. 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'.

10. V-CareNeT Demo Mode (requires V-STATS 3.01 or higher)

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. For example, to simulate remote monitoring for 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 support fewer beds/patients.