

suiteHEART[®] Software

Installation Manual

NeoSoft, LLC



NS-03-028-0003 Rev 4
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Revision History

Rev	Date	Description of Change	Safety Related Update (Yes/No)
1	23MAR2017	First Release	No
2	15SEPT2017	Updated for 4.0.4 product release	No
3	24MAR2018	Updated for 4.0.6 product release	No
4	30OCT2018	Updated for 4.0.7 product release	No

Manufacturer



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Service: service@neosoftmedical.com

The Instructions for Use for this device are provided electronically in Portable Document Format, (.pdf). A pdf viewer is required to view the Instructions for Use. A paper copy of the Instructions for Use can be provided upon request, at no cost, within 7 calendar days, by emailing service@neosoftmedical.com.

Instructions for Use may be accessed in the following ways:

1. After launching the application, click “Help” or “About” from the main screen. Select the “Instructions for Use” option. The Instructions for Use will open in a pdf viewer.
2. If the original installation package received from NeoSoft is available, open the zip file and navigate to the “Documentation” folder, then the “Instructions for Use” folder and double click on the Instructions for Use.pdf in your language, denoted by EN - English, FR - French, DE - German, EL - Greek, IT - Italian.
3. Navigate to the folder where the application is installed. Locate the “Documentation” folder, open the “Instructions for Use” folder and double click on the Instructions for Use.pdf in your language, denoted by EN - English, FR - French, DE - German, EL - Greek, IT - Italian.
4. Electronic copies of Instructions for Use are also available at www.neosoftllc.com/neosoft/product_manuals/.

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Medical device directive

This product conforms with the requirements of council directive 93/42/EEC concerning medical devices when it bears the following CE mark of Conformity:



European Representatives:



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Canada:

Health Canada device license number: 99490

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Safety

Introduction

To assure efficient and safe use it is essential to read this safety section and all associated topics before attempting to use the software. It is important for you to read and understand the contents of this manual before attempting to use this product. You should periodically review the procedures and safety precautions.

The software is intended for use by trained and qualified personnel only.



CAUTION: Federal Law restricts this device to sale, distribution and use by or on the order of a physician.

The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level of seriousness. Hazard is defined as a source of potential injury to a person. Familiarize yourself with the terminology descriptions listed in the following table:

Table 1: Safety Terminology

Graphic	Definition
 DANGER:	Danger is used to identify conditions or actions for which a specific hazard is known to exist which <u>will</u> cause severe personal injury, death, or substantial property damage if the instructions are ignored.
 WARNING:	Warning is used to identify conditions or actions for which a specific hazard is known to exist.
 CAUTION:	Caution is used to identify conditions or actions for which a potential hazard is known to exist.

Indications for Use

suiteHEART® Software is an analytical software tool, which provides reproducible tools for the review and reporting of medical images. suiteHEART® Software can import medical images from a MR system and display them in a viewing area on the computer screen. The viewing area allows access to multiple studies and series of multi-slice, multi-phase images. Multi-phase sequences of images can be displayed in cine mode to facilitate visualization.

A report input interface is also available. Measurement tools on the report interface make it possible to quickly and reliably fill out a complete clinical report of an imaging exam. Available tools include: point, distance, area, and volume measurement tools such as ejection fraction, cardiac output, end-diastolic volume, end-systolic volume, and volume flow measurements.

Semi-automatic tools are available for left ventricular contour detection, valve plane detection, vessel contour detection for flow analysis, signal intensity analysis for myocardium and infarct sizing measurement, and T2 star analysis.

The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians.

When interpreted by a trained physician these tools may be useful in supporting the determination of a diagnosis.

Intended Use

suiteHEART® Software is intended to assist trained clinical personnel in the qualification and quantification of cardiac function. The software provides the tools to adjust the parameters of the DICOM images and provides presentation states where the user can appreciate various MRI acquired images of the heart and vasculature over time. Additionally, the software provides tools for measuring linear distances, areas, and volumes that can be used to quantify cardiac function. Finally, the software provides the tools for volumetric flow measurements and the ability to calculate flow values.

Supported DICOM Image Formats

suiteHEART® Software supports the following DICOM format; MR and Enhanced MR. Refer to the suiteHEART® Software DICOM Conformance Statement manual for further detail on supported formats.



CAUTION: Data stored as a DICOM image that has been imported by an external PACS may not be compatible viewing for suiteHEART® Software.

Safety Notices



WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.



WARNING: Artifacts on an image can be misinterpreted, leading to misdiagnosis. Do not use images containing artifacts for diagnosis. Analysis should only be accomplished by a properly trained and qualified user.



WARNING: Diagnosis for the wrong patient could occur if images do not contain patient name or ID. Do not use images that do not contain patient name and ID for diagnosis. Visually confirm the patient information prior to analysis.



CAUTION: Using images upon which an image filter has been applied could result in altered results. The user must exercise discretion before analyzing pixel intensity corrected images. The software will display a warning message if loading images that have been filtered.

Equipment Hazards



CAUTION: Using equipment that is damaged or has been compromised can put the patient at risk by delaying diagnosis. Make sure that equipment is in proper working order.



CAUTION: Applications may run on equipment that includes one or more hard disk drives, which may hold medical data related to patients. In some countries, such equipment may be subject to regulations concerning the processing of personal data and free circulation of such data. Release of personal data may result in legal action depending on the applicable regulatory body. It is strongly recommended that access to patient files be protected. The user is responsible for understanding the laws regulating patient information.

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suiteDXT Installation & Configuration

Prerequisites

Prior to installation of the software, the following prerequisites must be met:

Table 1: System Requirements

Minimum System Requirements
Supported Operating Systems: <ul style="list-style-type: none">• Windows 7 Professional or Enterprise with SP1 (64 bit version)• Windows 10 Professional or Enterprise (64 bit version)
Video card (NVIDIA); 4GB RAM, minimum of 1664 CUDA Cores, support for OpenGL 4.0, support 1920 x 1080 resolution or higher
Monitor shall support 1920 x 1080 resolution or higher
Anti-Virus/Anti-Malware software installed
Minimum 16GB memory
Available hard drive space minimum 25GB
PDF viewer, Adobe Reader 11.0 or higher
An open network port for DICOM transfer over network
Static IP address (recommended)
Solid-State hard drive
Intel® Core™ i7 processor
27" Monitor

NOTE: In the event that the host system loses or is reassigned its IP address, remote devices will need to be manually reconfigured to request and accept network traffic.

NOTE: You must be logged into your operating system as Administrator in order to install the software, restart the DICOM service, and move the Local DICOM Storage.

Installation

1. Double click suiteDXT-windows-installer.
2. If prompted, select "Yes" on the User Account Control pop-up.
3. Select the desired language, then click "OK."

NOTE: If another version of the software is already installed on the system, a pop-up will ask permission to continue. Click "Yes" to continue with the installation.

4. Select "Next" on the suiteDXT setup screen.
5. Check the box for "I accept the agreement" and select "Next."
6. Accept or change the installation directory and select "Next."
7. Select "Next" in ready to install setup screen.
8. Select "Finish" in the setup screen.

NOTE: DECISION POINT! Customer and NeoSoft should discuss enabling user level permissions.

Configuration

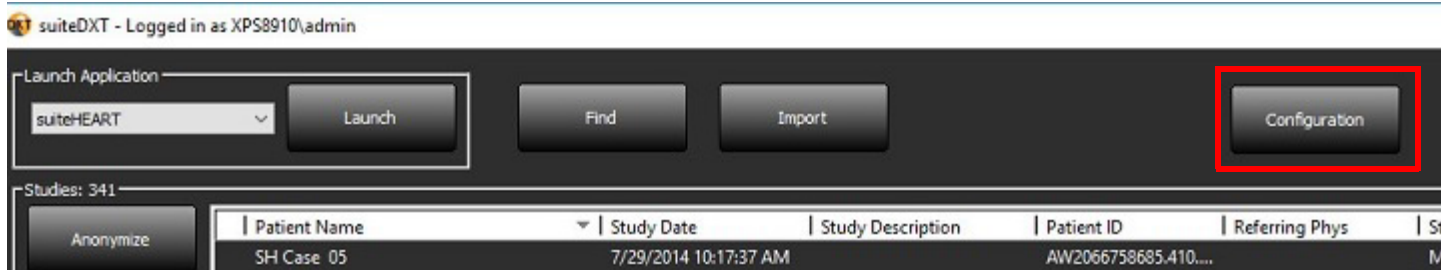
You will need to run through the configuration steps when suiteDXT is newly installed or when/if the static IP address is renewed.

1. Launch suiteDXT via the desktop shortcut or navigate through the start menu, Start > All Programs> suiteDXT> suiteDXT

If prompted, select "Yes" on the user account pop-up.

2. Select the Configuration button, outlined in the figure below.

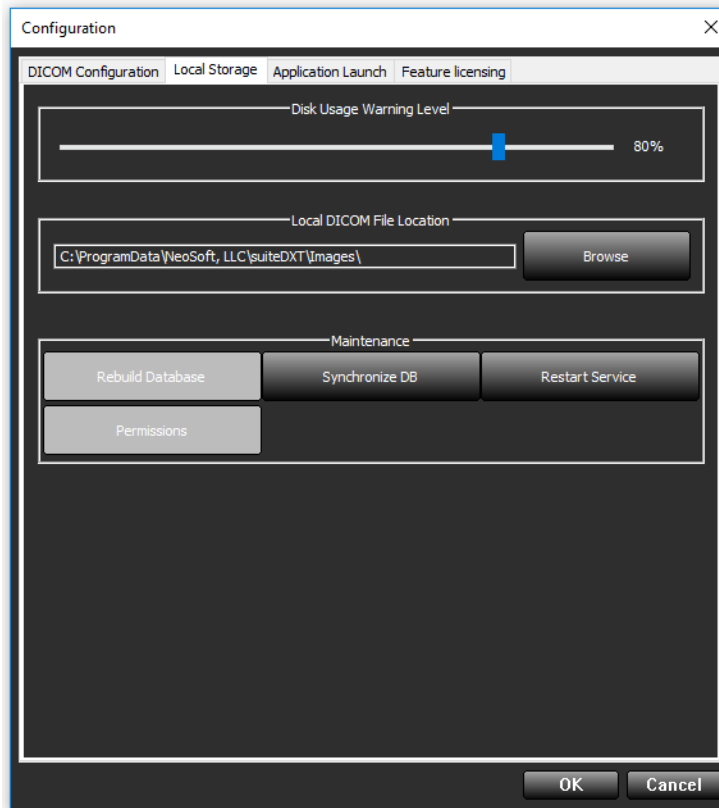
FIGURE 1. suiteDXT Main Screen



3. On the DICOM Configuration tab, enter information for the local host: (Figure 3)
 - Description (enter any descriptor of your choosing).
 - AE Title (case sensitive) is the name used to identify the host by other hosts.
 - Port (104).

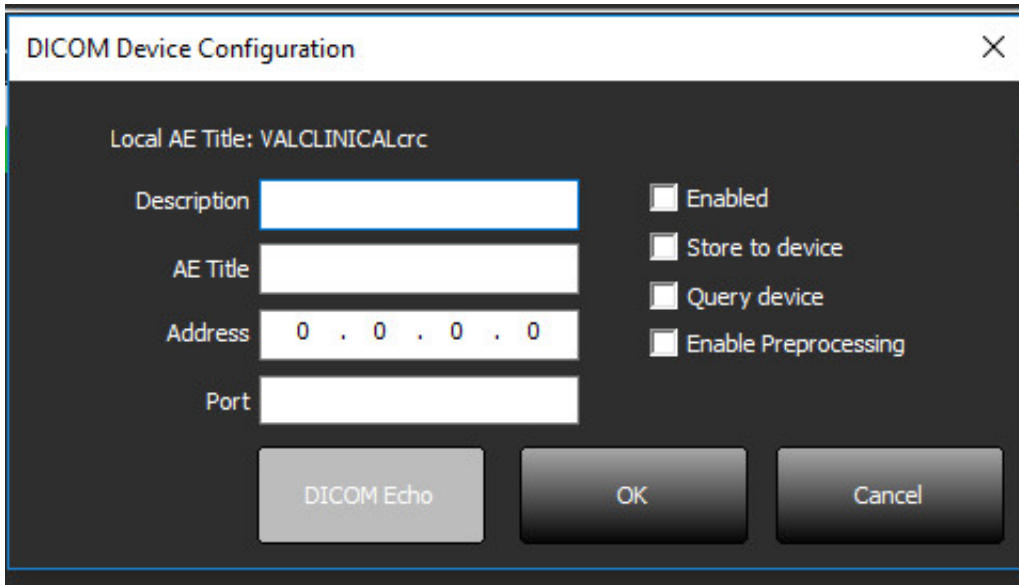
NOTE: The information entered on this tab must be entered exactly the same on any remote device for suiteDXT to retrieve or accept images from the remote host.

FIGURE 2. Configuration Tab Window



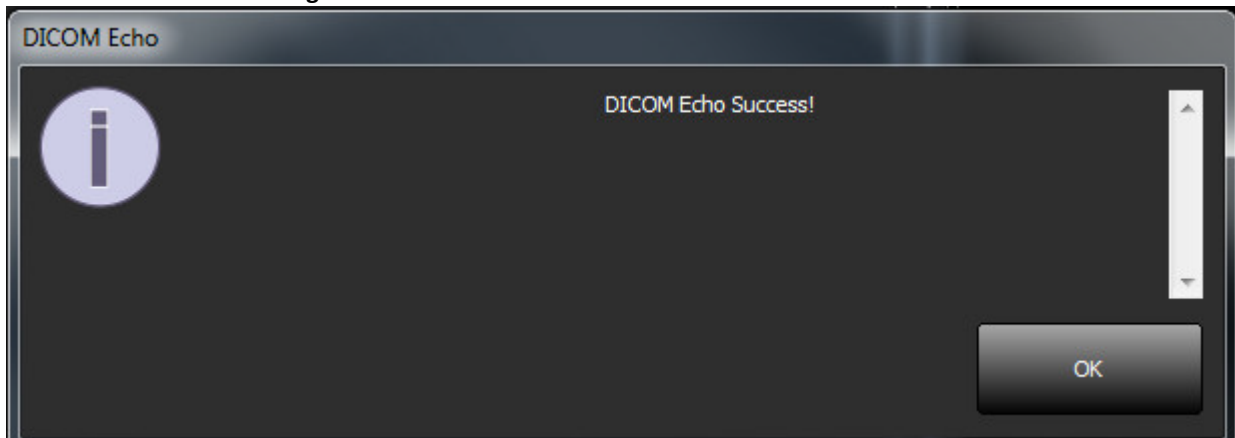
4. If available, perform a DICOM echo from any remote device to this host to ensure DICOM connectivity.
5. Select the "Add" button to input all DICOM destinations (remote hosts).
 - Description
 - AE Title
 - Address
 - Port
 - Select the checkboxes for: Enabled; Store to device, Query device and Enable Preprocessing.(Figure 3).

FIGURE 3. DICOM Configuration Window



6. Select the “DICOM Echo” button.
 - If you don’t see the DICOM Success Message window (Figure 4) contact your network administrator.

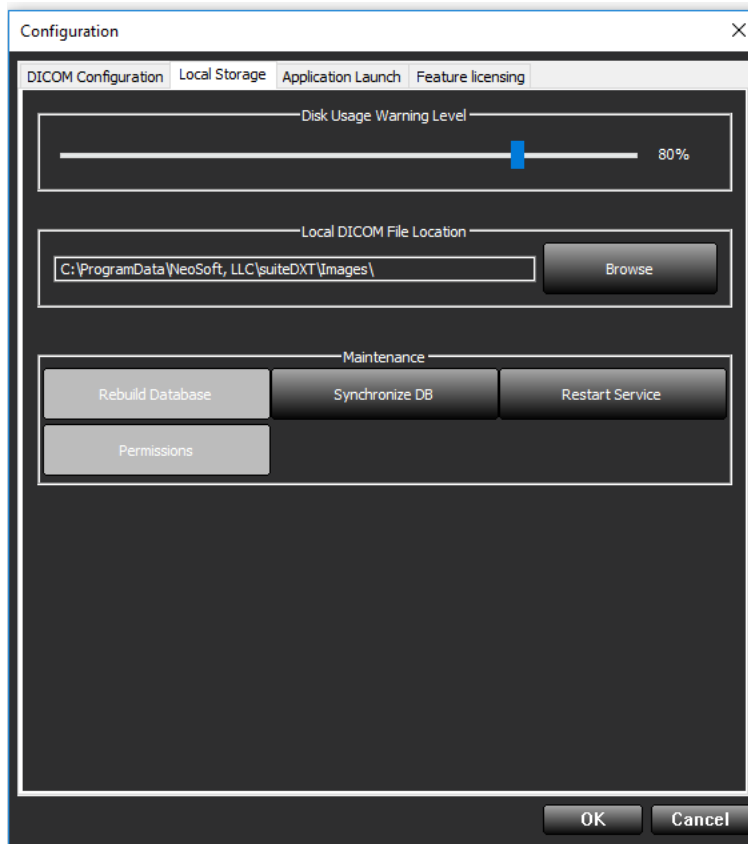
FIGURE 4. DICOM Success Message



NOTE: DICOM Destinations can be modified and a DICOM echo performed via the Edit button and destinations can be deleted via the Delete button.

Local Storage Tab

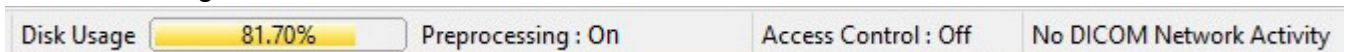
FIGURE 5. Local Storage Tab Window



The Disk Usage Warning Level can be modified to alert you when disk space is low. When disk usage exceeds the limit set, the indicator on the main screen (Figure 6) will change from green to yellow.

To restore the study listing, click the Synchronize DB button. This refreshes the data currently stored on the local DICOM file location.

FIGURE 6. Disk Usage Indicator on Main Screen



The Local DICOM File Location Selection allows you to change the directory where DICOM data is stored. If data already exists in the location you've selected, it will be deleted before assigning a new folder. A warning message will appear to alert you to potential data loss.



CAUTION: Do not delete DICOM data from the file system.

Application Launch Tab

Use this tab to configure compatible applications to launch from suiteDXT.

1. Select the Add button (Figure 7) to open the Edit Application Window (Figure 8).

FIGURE 7. Application Launch Tab Window

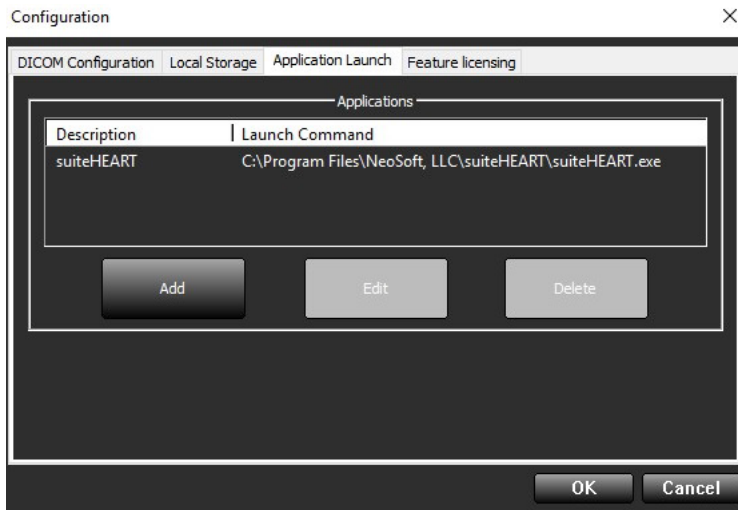
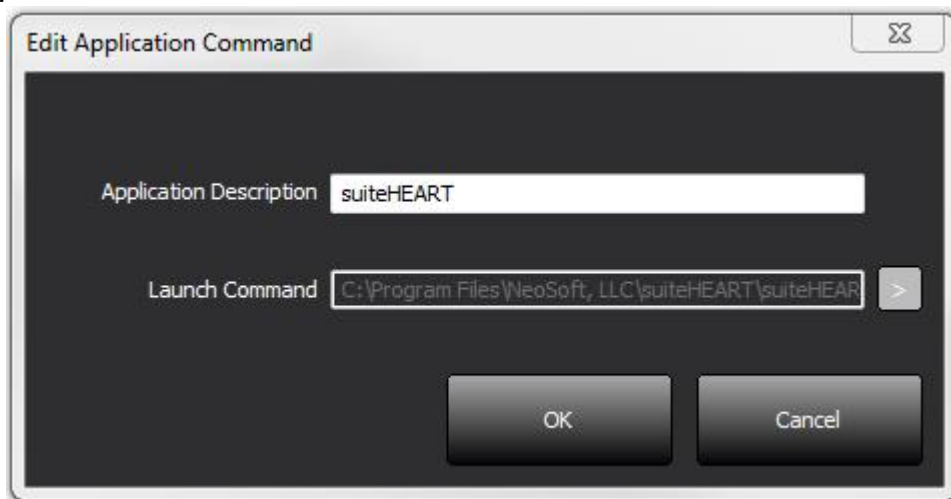


FIGURE 8. Edit Application Window



2. Enter the name or a description of the application.
3. Select the arrow button next to the Launch Command field to select the directory which contains the application executable file.
4. Select the OK button.

To edit or delete an existing application from the launch list, use the Edit or Delete button (Figure 7).

NeoSoft, LLC applications are automatically added into the application launch list. The launch command is not editable and nor can an application be manually deleted from the list.

Feature Licensing Tab

Use this tab to request and apply the license for all software distributed by NeoSoft, LLC.

FIGURE 9. Feature Licensing Tab Window

The image shows a software configuration window titled "Configuration" with a close button (X) in the top right corner. The window contains several tabs: "DICOM Configuration", "Local Storage", "Application Launch", and "Feature licensing". The "Feature licensing" tab is active and contains two main sections: "Request License" and "Apply License File".

The "Request License" section includes a "Company Information" group box with three text input fields: "Name", "Telephone", and "Billing Address". Below this is a "Contact Information" group box with three text input fields: "First Name", "Last Name", and "Email". A "Generate License Request" button is positioned below the contact information fields.

The "Apply License File" section contains a single "Apply License" button.

At the bottom of the window are "OK" and "Cancel" buttons.

NOTE: Access to email will be needed to request a license.

Request a License

1. Enter complete company and contact information.

NOTE: Selecting the Generate License Request button will create a machine specific file that locks the software for which you are requesting a license, to the hardware (host) on which suiteDXT is installed.

2. Select the Generate License Request button.
3. Navigate to a memorable directory (e.g. the desktop) in which to save the license request file.
4. Email the license request file to licensing@neosoftmedical.com

Apply the License

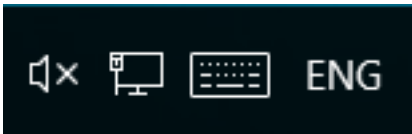
1. From NeoSoft's response email, copy the license to an easily accessible location (e.g. the desktop).
2. Open suiteDXT, select the Configuration button and navigate to the Feature Licensing tab (Figure 9).
3. Select the Apply License button and navigate to the directory to which you saved the license.
4. Select OK.

Tablet Mode

suiteDXT is supported on tablets with a 64-bit processor running on Windows 10 Professional or Windows 10 Enterprise operating system.

To activate the keyboard click on the windows keyboard icon located in the lower right corner.

FIGURE 10. Keyboard



suiteHEART[®] Software Installation

Prerequisites

Prior to installation of the software, the following prerequisites must be met:

Table 1: System Requirements

Minimum System Requirements
Supported Operating Systems: <ul style="list-style-type: none">• Windows 7 Professional or Enterprise with SP1 (64 bit version)• Windows 10 Professional or Enterprise (64 bit version)
Video card (NVIDIA); 4GB RAM, minimum of 1664 CUDA Cores, support for OpenGL 4.0, support 1920 x 1080 resolution or higher
Monitor shall support 1920 x 1080 resolution or higher
Anti-Virus/Anti-Malware software installed
Minimum 16GB memory
Available hard drive space minimum 25GB
PDF viewer, Adobe Reader 11.0 or higher
An open network port for DICOM transfer over network
Static IP address (recommended)
Java Runtime Environment (JRE) version 9
Solid-State hard drive
Intel [®] Core [™] i7 processor
27" Monitor

NOTE: suiteHEART[®] Software is not supported in Virtual Machine environments.

NOTE: suiteHEART[®] Software does not support scaling/zoom levels greater than 125%.

NOTE: You must be logged into your operating system as Administrator in order to install the software.

NOTE: For support of application frame rates of 30FPS at display resolutions in the range of 2K/4K, the NVIDIA video card hardware must support a minimum of 1920 CUDA Cores.

NOTE: Java 10 and 11 are not supported.

Installation

1. Double-click on the suiteHEART® Software windows application installer.

NOTE: Installing the software on a machine could result in a Open File - Security Warning indicating that the publisher could not be verified. Click Yes when asked if you are sure you want to run the software.

2. Select the appropriate language for your installation and click **OK**.

NOTE: If another version of the software is already installed on the system, a pop-up will ask permission to uninstall. Click “Yes” to continue with the installation.

3. In the “Welcome to suiteHEART® Software Setup Wizard window, click **Next**.
4. On the License Agreement Window, select “I accept the agreement” and click **Next**.
5. Browse to the directory in which to install the software or use the default directory (recommended). Click **Next**.
6. Click **Next** on the Ready to Install screen.
A progress bar will display.
7. Click **Finish** to complete the installation.

Anti-Virus Exclusions

To increase the performance of the application, the following Anti-Virus and Windows Defender exclusions should be made:

- C:\Program Files\NeoSoft, LLC or C:\Program Files\NeoSoft
- C:\ProgramData\NeoSoft, LLC

Application Inactivity Setting

The suiteHEART® Software application will automatically close, save all analysis for any open study and remove the associated lock file when the application has been inactive for 60 minutes. To set this setting configure it in suiteHEART® Software using Tools > Preferences.

Licensing Schemes

suiteHEART® Software has 3 different licensing schemes. They are Evaluation, Unlimited and Per-Case Pack Limited.

1. **Evaluation:** This is a time limited license which does not allow the saving of analysis results or exam approval. Evaluation Version will be indicated on the report footer and splash screens. If the approval of an exam is attempted a message will appear stating: Evaluation version: Analysis state will not be saved.
2. **Unlimited:** No restrictions on analysis and is not case-limited.
3. **Per-Case Pack Limited:** The software will use the unique study instance id to identify the number of cases analyzed against the Per-Case Pack that has been purchased.

Once 100% of the Per-Case Pack has been used the software will indicate this condition by a pop-message prior to starting a new exam or an existing exam.

Per-Case Packs can be purchased in increments of 25, 50 and 100. Website: <http://neosoftllc.com/> T: (262)522-6120
email: orders@neosoftmedical.com

Exams that have been counted once towards the Per-Case Pack limit can be re-opened and reviewed within the software and will not be counted against the Per-Case Pack limit.

Exams that are opened only for image viewing or if image manipulation tools are performed (Pan, Zoom, Window level, Rotate) will not be counted against the Per-Case Pack limit.

An exam is considered "consumed" or "counted" against the Per-Case Pack limit when any of the following actions are performed:

- a.) Starting of any analysis mode by placing any ROI on an image.
- b.) Creating a custom series.
- c.) Report sign off.
- d.) Export Cine DICOM.
- e.) Export Report.
- f.) DICOM series creation.
- g.) Preprocessed study.

suiteHEART® Software has an expected useful service life of 7 years from its original release date.

Remote Connectivity

Remote connectivity allows suiteHEART® Software users remote access from computers not loaded with suiteHEART® Software. The remote user will have the ability to access the suiteHEART® Software system and have full functionality.

suiteHEART® remote connectivity needs to be installed/configured/supported by your Information Technology personnel.

Remote connectivity has been verified using the following platforms:

- TeamViewer (version 13)
- Windows Remote Desktop (Microsoft Windows 7/10 Professional/Enterprise)

NOTE: When using Windows Remote Desktop, screen resolution on the remote computer must be set to 1920x1080 or higher video display resolution.

NOTE: When remotely accessing suiteHEART® Software using Windows Remote Desktop, the suiteHEART® 3D/4D viewer is not operational. The workaround is to use one of the other qualified remote access software packages (TeamViewer).

The performance of the suiteHEART® Software via the remote connection cannot be guaranteed. Performance is dependent upon factors that are outside the scope of the suiteHEART® Software application. These factors include:

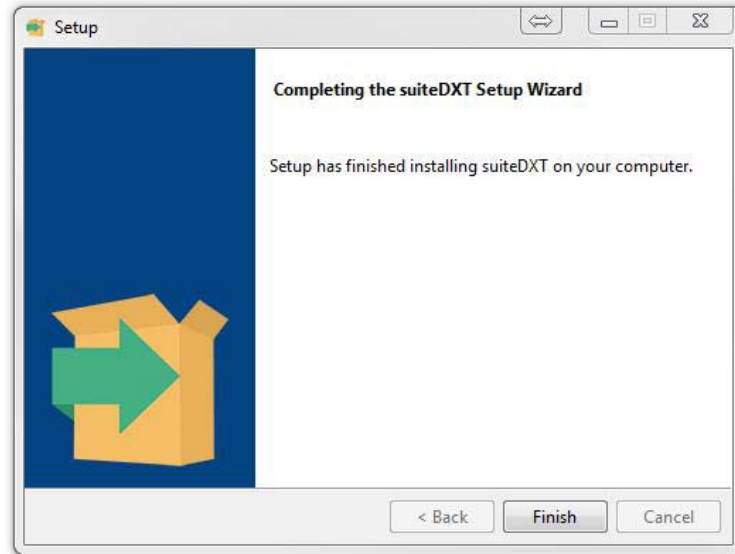
- Remote computer performance
- Internet download/upload speeds (Mbps)
- Network bandwidth speed (wired ethernet or wireless connection)

For more information on remote connectivity, refer to the suiteHEART® Software Addendum to Instructions for Use manual, NS-03-015-0006.

Install Verification

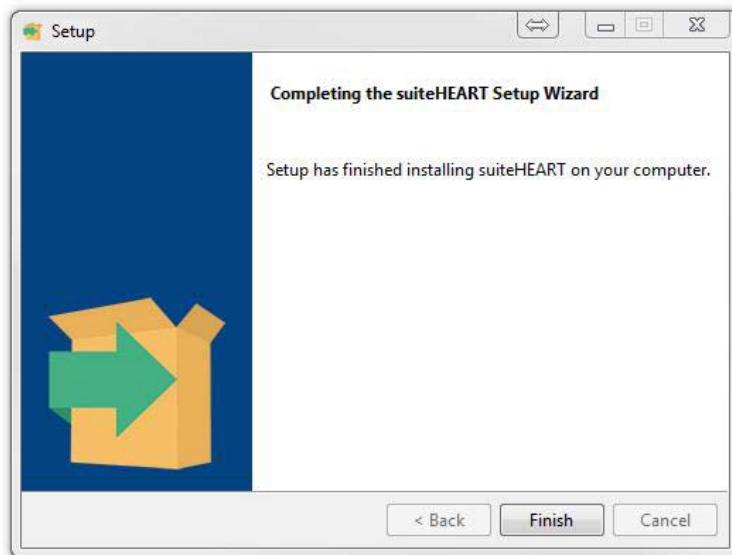
After a successful installation of suiteDXT this screen is displayed.

FIGURE 1. suiteDXT Setup Wizard



Following the successful installation of suiteHEART® Software this screen displays.

FIGURE 2. suiteHEART® Software Setup Wizard



To further verify the successful installation of both software packages:

1. Double click the suiteDXT icon to verify suiteDXT is launched.
2. Highlight a study in the suiteDXT study list and select launch with suiteHEART to verify that the study is launched and that various analysis can be selected.