suiteHEART® Software

Addendum to Instructions for Use

NeoSoft, LLC

Revision History

Rev	Date	Description of Change	Safety Related Update (Yes/No)
1	06JAN2016	First Release	No
2	08MAR2016	Updated for 3.0.1 product release	No
3	26AUG2016	Updated for 4.0.0 product release	No
4	23MAR2017	Updated for 4.0.2 product release	No
5	15SEP2017	Updated for 4.0.4 product release	No

Manufacturer

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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.

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.

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:

$$\mathsf{C}\,\mathsf{E}$$
0086

European Representatives:

EC	REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Canada:

Health Canada device license number: 99490

⚠ **CAUTION:**   *United States federal law restricts this device to sale by, or on the order of, a physician.*

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System Requirements

Minimum System Requirements (Citrix Multiuser Environment)
Supported Operating Systems: • Windows Server 2012R2 Standard Edition (64 bit version)
Citrix XenApp Enterprise version 7.7 and 7.12
Video card shall support 1920 x 1080 resolution or higher
Monitor shall support 1920 x 1080 resolution or higher
Anti-Virus/Malware software installed
Minimum 32GB 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(s)
Intel® Core™ processor(s) (4 cores)
Citrix XenApp client displays must not exceed scaling/zoom levels greater than 125%

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Addendum

This addendum applies to suiteHEART® Software Instructions for Use, part number NS-03-008-0001 and suiteDXT Instructions for Use, part number NS-03-009-0001.

suiteHEART® Software supports remote connectivity capability, as well as running in a multiuser environment. The remote connectivity capability 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. Remote connectivity is supported for only a single concurrent remote connection, whereas the multiuser environment supports up to five concurrent users.

Remote Connectivity - Single User

suiteHEART® remote connectivity needs to be installed/configured/supported by your Information Technology personnel. Remote connectivity has been verified by NeoSoft using the following platforms:

- TeamViewer (version 11)
- Citrix GoToMyPC (version 8.4)
- 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 or GoToMyPC).

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)

Multiuser Environment

The suiteDXT/suiteHEART® Software application allows up to five concurrent users when installed in a Citrix XenApp version 7.7 or 7.12 (running on Windows Server 2012 R2) environment.

Using suiteDXT Software in the Multiuser Environment

For complete installation instructions review the Installation Manual, NS-03-028-0003.
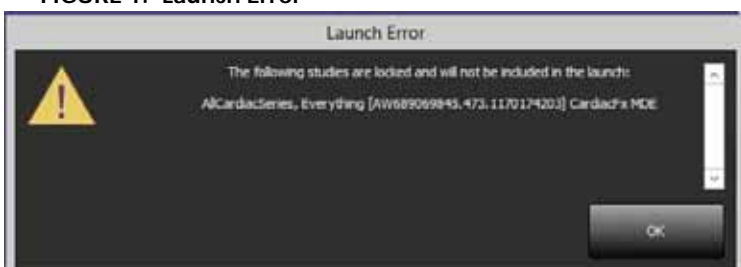
Configuration

Local Storage (i.e. Restart Service, Browse, and Rebuild Database) configuration changes affect all system users and therefore should be managed by the system administrator for your facility.

Launching a Study from suiteDXT

If a study has been opened in suiteHEART® Software by one user, that study is locked and a warning message will appear when a second user attempts to open the same study. The study can only be opened after it's closed by the first user. (Fig 1)

NOTE: **The suiteHEART® Software will close after 60 minutes of inactivity and all analysis performed on open studies will be saved. The automatic closing of the suiteHEART® Software application will unlock open studies. It is recommended to always close the study after the analysis session is completed.**
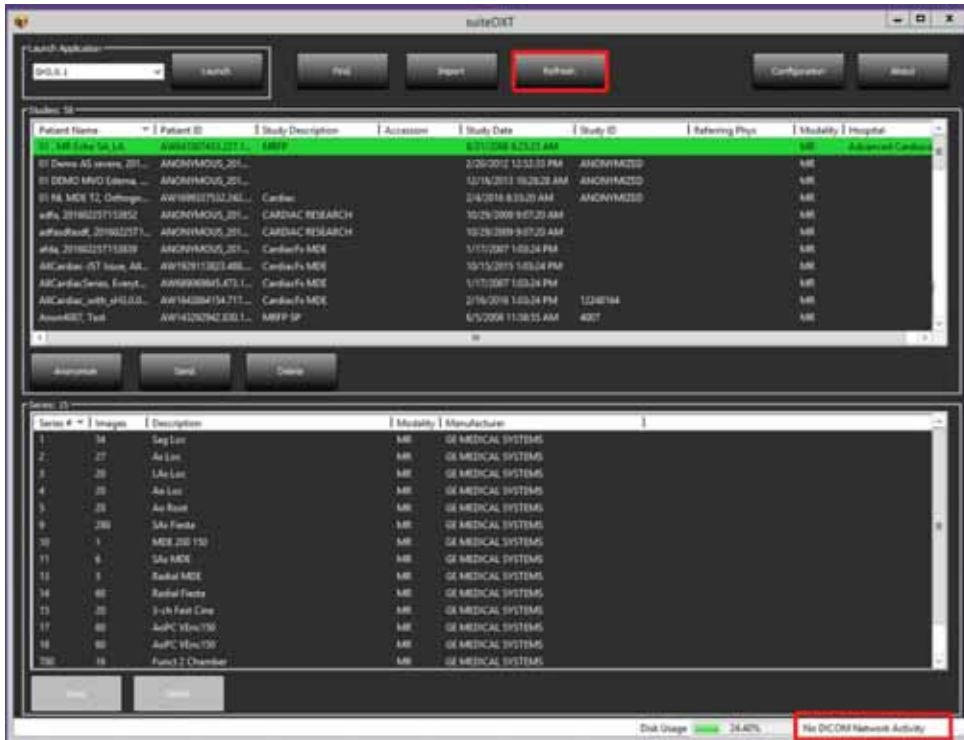
FIGURE 1. Launch Error

Query/Retrieve from suiteDXT

During Query/Retrieve the Network status indicator, in the lower right of the main DXT screen, will not be active (Fig. 2). The status of a Query/Retrieve can be viewed on the Query/Retrieve Window.

Any new study that has been networked or imported into suiteDXT may not appear automatically in the directory listing. Click on the **Refresh** button, on the main DXT screen, to refresh the study and series listings (Fig. 2).
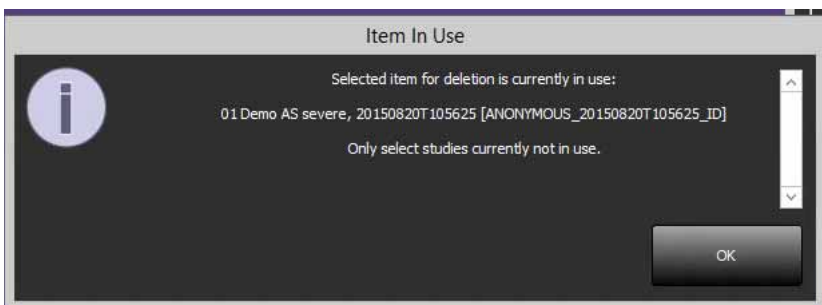
FIGURE 2. Query/Retrieve

Deletion of a Study or Series from suiteDXT

Deletion of a study and its associated series that is opened and locked by another user is prohibited. A warning message (Fig 3) will appear if this is attempted. Deletion can only be performed when the study is closed by the other user.

NOTE: The suiteHEART® Software will close after 60 minutes of inactivity and all analysis performed on open studies will be saved. The automatic closing of the suiteHEART® Software application will unlock open studies. It is recommended to always close the study after the analysis session is completed.

FIGURE 3. Warning Message

Using suiteHEART® Software in the Multiuser Environment

For complete installation instructions review the Installation Manual, NS-03-028-0003.

Setting up Preferences

Editing report preferences and templates should be managed by the system administrator for your facility. Any changes to report preferences, templates, polar plot colors, print preferences and add measurements for reporting will impact all users and should only be performed by the system administrator.

Image Management Tools

When performing export to Matlab, excel, export pdf report, export of JPEG, PNG, TIFF, AVI movies or Quicktime movie files, verify the selection of the desired destination directory is on your local machine.

Report Database

Search queries created in the Report Database can be overwritten if other users are simultaneously creating search queries.

A fully qualified share folder (i.e. //192.168.3.82/test) must be used when defining a (SECONDARY_REPORT_FOLDER=) to be used to send approved exams from suiteHEART® Software in a Citrix XenApp environment.

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