

suiteHEART[®] Software

Addendum to Instructions for Use

NeoSoft, LLC



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Revision History

Document Revision	Date of Issue	Description
1	7-January-2016	Initial release
2	9-March-2016	Update for multiuser environment



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Medical device directive

This product conforms to the requirements of the council directive 93/42/EEC concerning medical devices when it bear the following CE Mark of Conformity.



European representatives:

EC	REP	EMERGO EUROPE Molenstraat 15 2513 BH, The Hague The Netherlands
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CAUTION: *United States federal law restricts this device to sale by, or on the order of, a physician.*

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Addendum

This addendum applies to suiteHEART® Software (version 3.0.1) Instructions for Use, part number NS-03-008-0001 and suiteDXT Instructions for Use, part number NS-03-009-0001.

suiteHEART® Software now 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 7/8/10 Professional/Enterprise)

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

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 (running on Windows Server 2012 R2) environment.

Using suiteDXT Software in the Multiuser Environment

For complete software instructions please review the suiteDXT Instructions for Use NS-03-009-0001 Rev 7.

Configuration

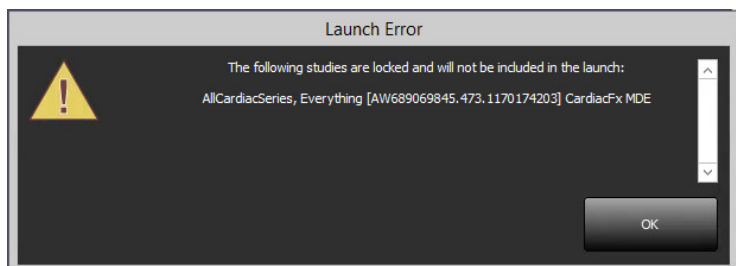
Local Storage (i.e. Restart Service, Browse, and Rebuild Database) configuration changes affect all system users and therefore should be managed by the system administrator for your facility.

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

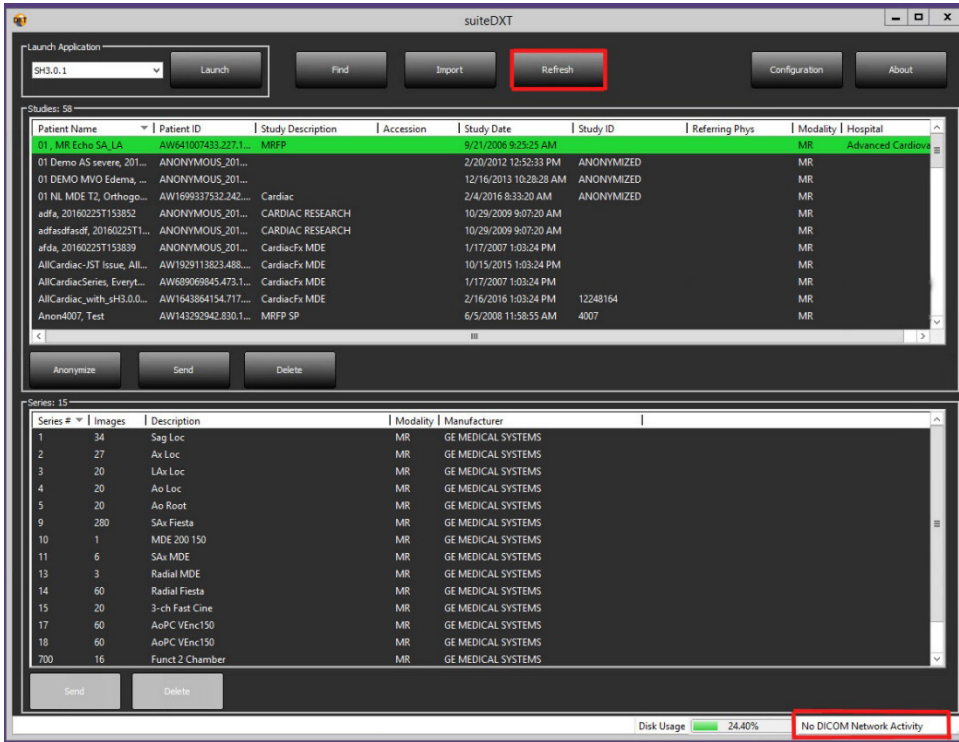


Query/Retrieve from suiteDXT

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

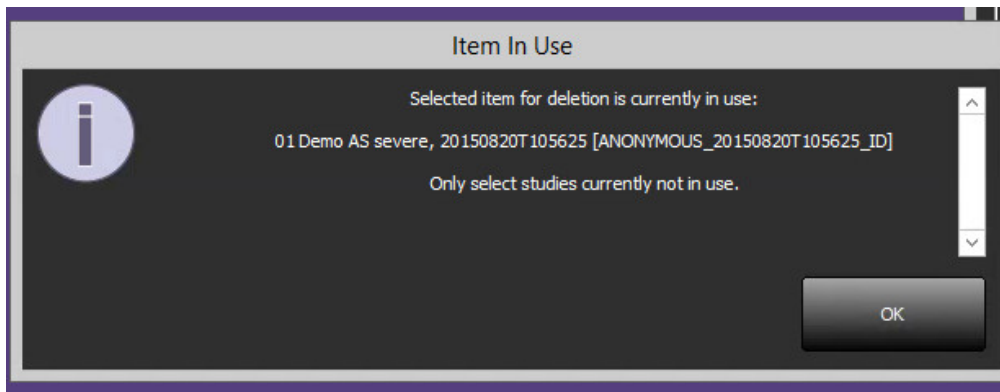


Deletion of a Study or Series from suiteDXT

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 software instructions please review the suiteHEART® Software Instructions for Use NS-03-008-0001 Rev 10.

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

During the creation of a custom series it may not be immediately available in the custom series viewer. If this occurs, wait a few seconds or switch to another analysis mode and then switch back to the custom series viewer.

When performing export to 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.

