suiteDXT

Instructions for Use

NeoSoft, LLC

Manufacturer ▲▲▲

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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:

EC	REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

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

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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.

suiteDXT software has an expected useful service life of 7 years from its original release date.

Intended Use

suiteDXT is intended to allow users the ability to manage DICOM network communication, storage of supported DICOM images, importing of supported DICOM images from the local file system, perform study anonymization, and launching of related imaging applications. This software is intended to be a temporary storage location.

Indications for Use

suiteDXT is intended to allow users the ability to import, export, anonymize DICOM images, and launch related imaging applications. This product has no diagnostic medical function or purpose.

Supported DICOM Image Formats

suiteDXT supports the following DICOM format; MR and Enhanced MR.

> **NOTE:** suiteDXT supports JPEG Lossless compression, however subsets of this format are not supported.

Refer to the suiteDXT DICOM Conformance Statement manual for further detail on supported formats.

Terminology

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 which <u>may</u> cause severe personal injury, death, or substantial property damage if the instructions are ignored.
⚠️ CAUTION:	Caution is used to identify conditions or actions for which a potential hazard is known to exist that will or <u>can</u> cause minor personal injury or property damage if the instructions are ignored.

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.
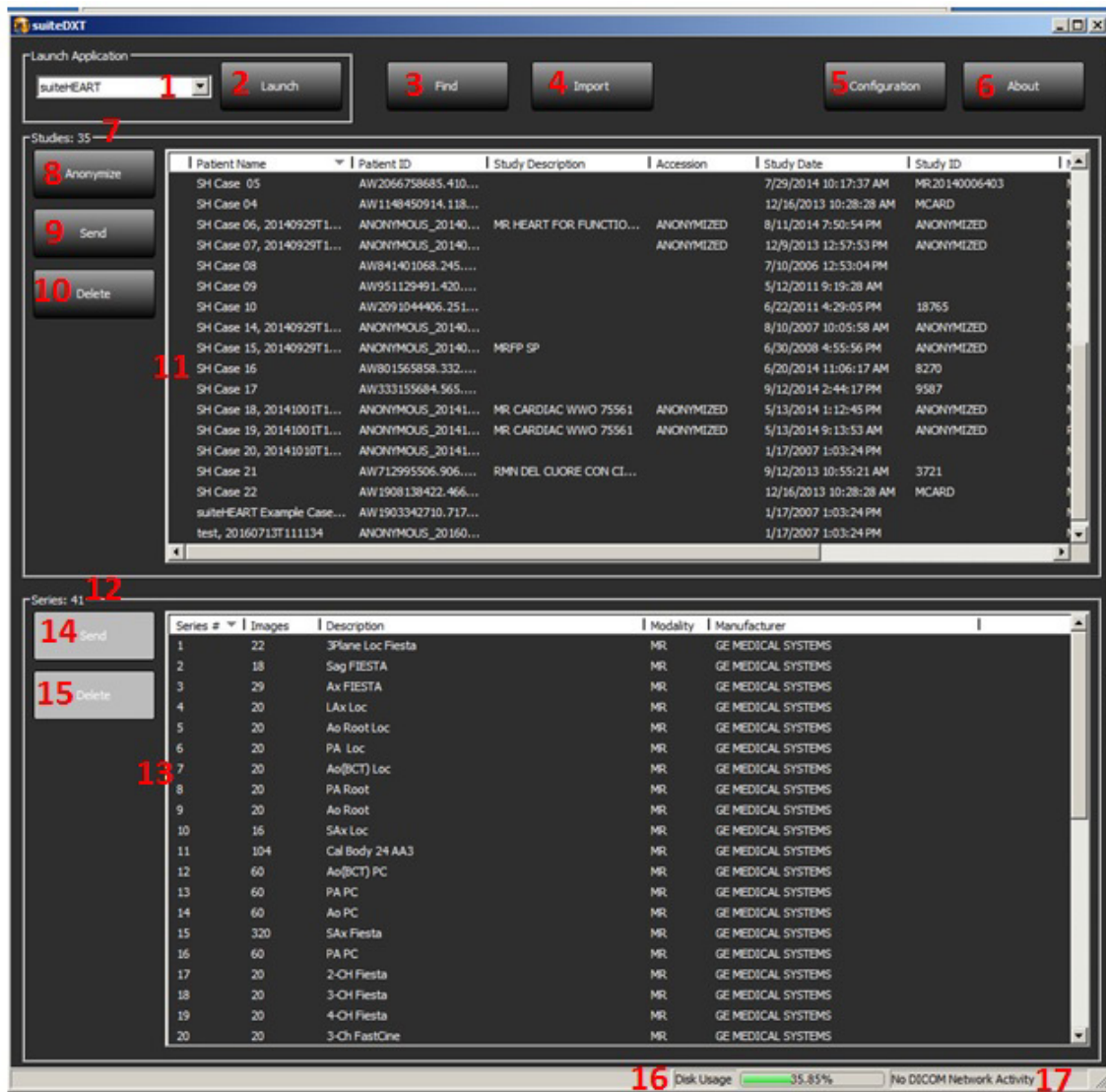
⚠️

CAUTION: Applications 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.

Getting Started

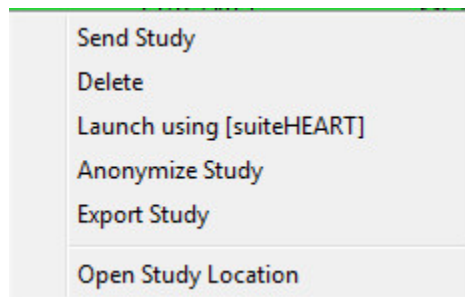## Main Screen Functions

FIGURE 1. Main Screen

1. **Launch Application pull-down Menu** - lists configured applications.
2. **Launch Button** - launches configured NeoSoft, LLC applications.
3. **Find Button** - opens Query/Retrieve Window.
4. **Import Button** - allows study information to be imported from the file system, CD, DVD or USB media.
5. **Configuration Button** - opens Configuration Window.
6. **About Button** - displays suiteDXT software version/links to Instructions for use and DICOM Conformance Statement.

7. **Studies Headline** - displays number of studies stored on local host.

8. **Anonymize Button** - creates a new study with patient specific data removed.

9. **Send Button** - pushes local study to remote host.

10. **Delete Button** - removes study from suiteDXT study list and deletes DICOM data from local host.

11. **Study Pane** - shows study information for studies stored on local host.
    - Column titles can be reordered by clicking and dragging the title of the column and sorted by clicking the column title.

12. **Series Headline** - displays number of series in a selected study.

13. **Series Pane** - shows series information for selected study.
    - Column titles can be reordered by clicking and dragging the title of the column and sorted by clicking the column title.

14. **Send Button** - pushes local series to remote host.

15. **Delete** - removes a series from the selected study and deletes DICOM data.

16. **Disk Usage Indicator** - shows percentage of total local disk space used.

17. **Network Status** - shows if suiteDXT is currently transferring DICOM data over the network.
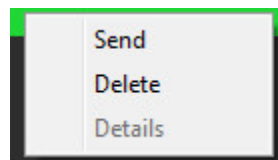
Right Mouse Click Menu in Study Pane

FIGURE 2. Right Mouse Click Menu

- **Send Study** - pushes study from local host to remote host.
- **Delete** - removes study from suiteDXT study list and deletes DICOM data from local host.
- **Launch using [suiteHEART® Software]** - launches the configured application using selected study.
- **Anonymize Study** - creates a new study with patient specific data removed.
- **Export Study** - Saves the study data in a compressed .zip file.
- **Open Study Location** - shows location of DICOM data on the local file system.

Right Mouse Click Menu in Series Pane

- **Send** - pushes local series to remote host.
- **Delete** - removes a series from the selected study and deletes DICOM data.
- **Details** - opens the series details window.

Query/Retrieve Window

FIGURE 3. Query/Retrieve Window

1. **Query Filter** - can be used to search for specific studies by Patient First and Last Name, Patient ID, Study ID, Accession Number, and Date. The * (asterisk) may be used as a wild card in any field (except date).

2. **Query Button** - executes query of remote device. If all fields are left blank, query will return all results.

3. **Query Source Pull-down Menu** - displays configured remote devices available to query / retrieve.

4. **Save Filter Button** - sets the default query parameters.

5. **Query Results** - shows count of studies that match query criteria.

6. **Query Results Pane** - shows study information of queried remote device.
   - Column titles can be reordered by clicking and dragging the title of the column and sorted by clicking the column title.

7. **Clear Query Results Button** - clears query results in study pane.

8. **Retrieve Button** - executes retrieval of the selected study from remote device.

9. **Series Pane** - shows series information of highlighted study in study pane.
    - Column titles can be reordered by clicking and dragging the title of the column and sorted by clicking the column title.

10. **Retrieve Button** - executes retrieval of the selected series from remote device.

11. **Transfer Status Pane** - shows current and completed retrieve actions.
    - Column titles can be reordered by clicking and dragging the title of the column.

12. **Clear Retrieve Results Button** - clears transfer activity in the transfer pane for studies whose transfers have been completed.

13. **Cancel** - stops the transfer activity.

CAUTION: Images that have transferred will remain local and show in the suiteDXT Main Screen, even though not all images for the study may have transferred.

Right Mouse Click Menu in Query/Retrieve Window

FIGURE 4. Right Mouse Click Menu

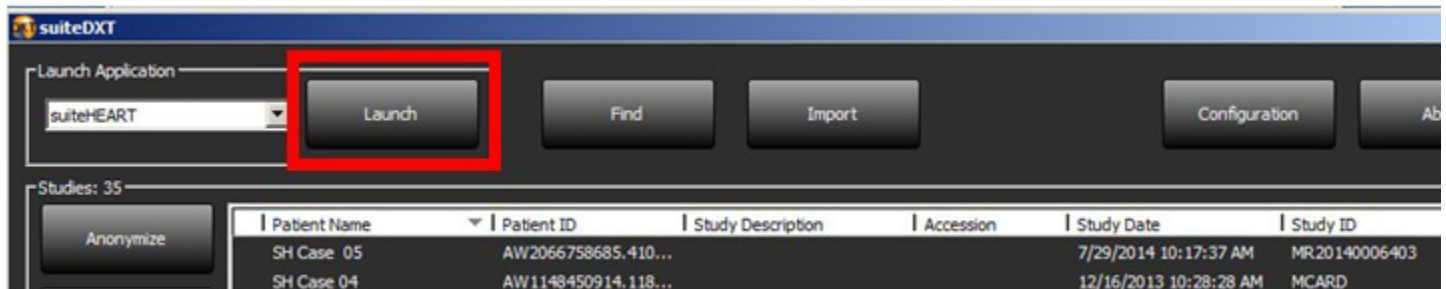- Retrieve - executes retrieve of study from remote host.

Using suiteDXT

Launch an Application

Applications can be added by following instructions in the Installation Manual NS-03-028-0003.

1. Go to the Main Screen.

2. From the Launch Application drop-down menu, select the desired application.

   FIGURE 1. Launch Application Menu
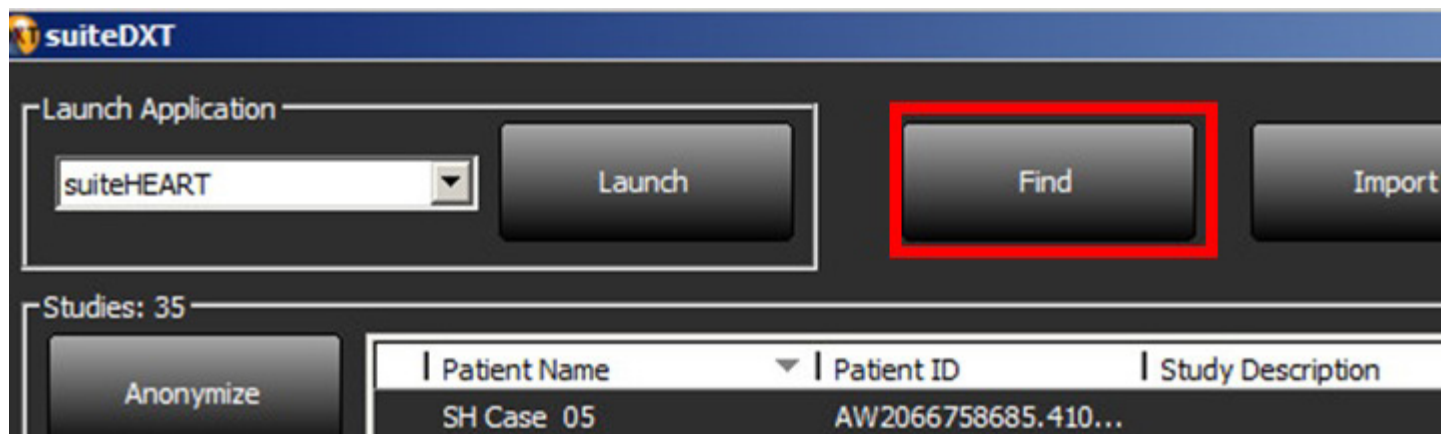

3. Select a study from the study list and do one of the following:
   - Select the Launch button.
   - Right mouse click and select "Launch using <selected application>."
   - Double click the study.

Retrieve Study or Series from Remote Host

Remote hosts must already be configured to be accessible. For information on how to configure a remote host see the Installation Manual NS-03-028-0003.

1.   Select the Find button on the Main Screen.

FIGURE 2. Find Button on Main Screen

2.   In the Query/Retrieve Window enter any study information criteria in the Query Filter area.

Filter options include:

- Patient Last Name
- Patient First Name
- Patient ID
- Study ID
- Accession Number
- Date Range

FIGURE 3. Query/Retrieve Window

3. From the Query Source pull-down menu select the remote host.

4. Select the Query button.

    Studies matching the criteria you entered will populate the study list.

    Clicking on a study will populate the series information list.

5. Select the desired study.

6. Select the Retrieve button below the study list or right mouse click and select Retrieve from the pop-up menu.

7. To retrieve by series, select the series and click the Retrieve button below the series list.

Progress of the retrieval is shown in the Retrieve Results section at the bottom of the window. While at the bottom of the Main Screen, the status "No DICOM Network Activity" is changed to "DICOM Network Active."

   NOTE: In the event that the study does not transfer in its entirety, the progress indicator will turn red.

Create a Filter

A filter can be created and saved to use the same search parameters each time, for example the date range. Input the criteria to be used, more than one parameter can be filled in, and select the Save Filter button. All future queries will use the saved filter. Whenever a new filter is created, it overwrites the previous filter.

Send Study to Remote Host

Remote hosts must already be configured to be accessible. For information on how to configure a remote host see the Installation Manual NS-03-028-0003.

   NOTE: suiteDXT supports JPEG Lossless compression, however subsets of this format are not supported.

1.   Highlight the study to send.

2.   Select the Send button or right mouse click and choose Send Study from the pop-up menu.

3.   Select the destination to which to send.

4.   Select the Send button on the pop-up window.

The DICOM Send window will display showing progress of the transfer. This window can be closed, using the X button in the upper right corner, while the transfer runs in the background.

To check the progress once the DICOM Send window is closed, select the Send button, then select the Status button.

   FIGURE 4. DICOM Send Window

Send Series to Remote Host

1. Highlight the study.

2. Highlight the required series.

3. Select the Send button or right mouse click and choose Send from the pop-up menu.

4. Select the destination to which to send.

5. Select the Send button on the pop-up window.

Import Studies

Studies containing DICOM data can be imported from the local file system, CD, DVD and USB. After inserting one of these media containing the desired DICOM data, follow the steps below.
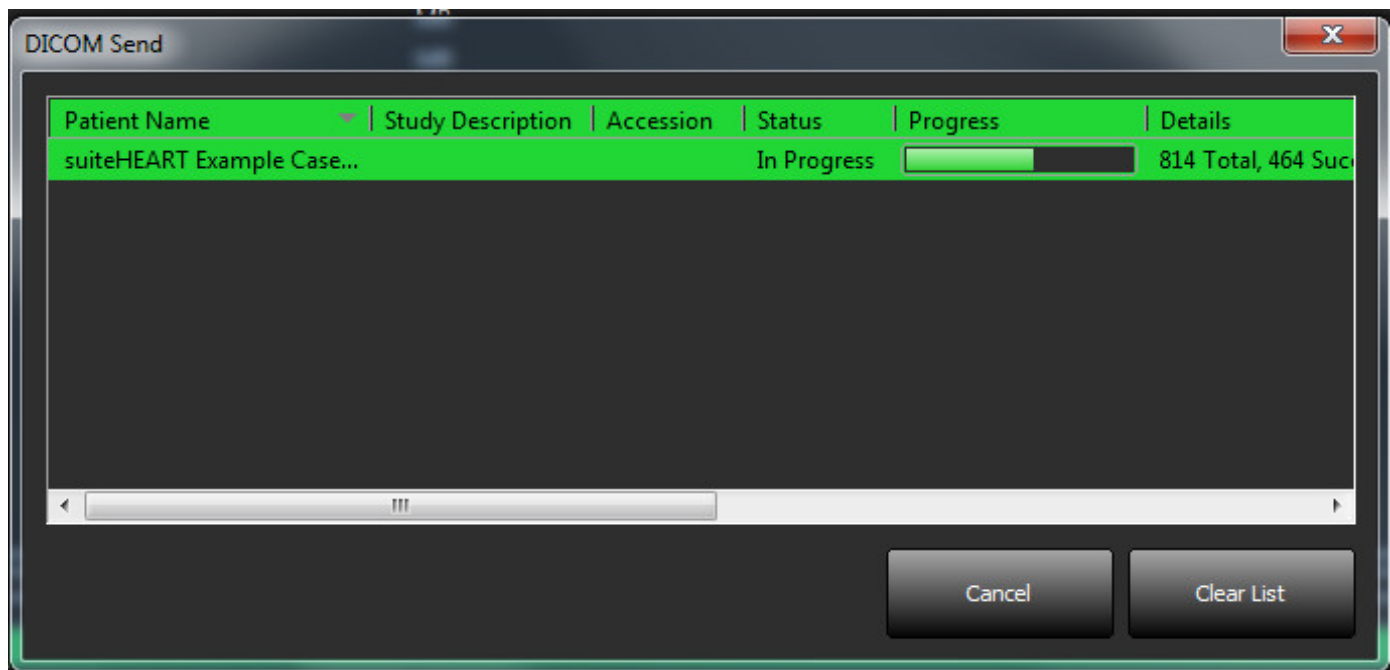
   NOTE: suiteDXT supports JPEG Lossless compression, however subsets of this format are not supported.

1. On the Main Screen, select the Import button.
2. Navigate to the location containing the DICOM data.
3. Select OK.

The Import File Progress window displays the DICOM file import status. The Import Summary displays the total number of files found, files imported, study count, and study imported information.

The newly imported study(s) are added to the study list of suiteDXT's Main Screen.

Example data provided can be imported into suiteDXT.

Anonymize a Study

⚠️ CAUTION: Anonymizing a study does not remove patient data from the images that were created from other post-processing software.
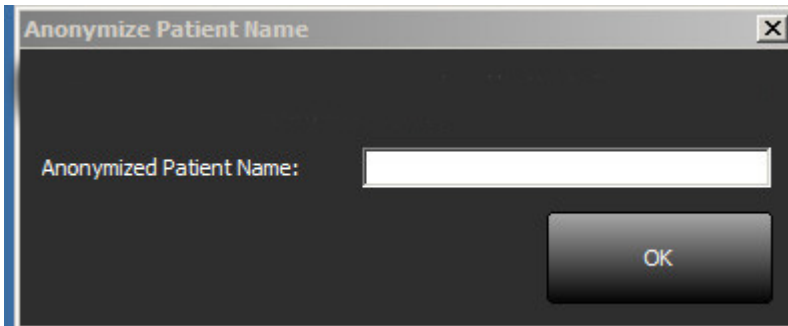
⚠️ CAUTION: The anonymized study should only be used with NeoSoft, LLC applications.

⚠️ CAUTION: Anonymizing removes any suiteHEART® Software created custom series and secondary capture reports from the study.

1. On the Main Screen, select the study to anonymize.

2. Select the Anonymize button.

3. Enter an anonymized patient name.

4. Click "OK" to confirm anonymization.

FIGURE 5. Anonymized Patient Name

A progress indicator will display. The newly anonymized study will appear in the study list named:
User Entered Name^YYYYMMDDHHMMSS.

5. Click "OK" on the Anonymize Study pop-up.

   NOTE: The anonymize function is available for NeoSoft support purposes.

   NOTE: Anonymized studies will retain prior analysis if performed on suiteHEART® Software version 4.0.0 or above.

Delete a Study

CAUTION: Deleting data from the file system, including files for the current open study, could cause loss of analysis/image data.

From the Main Screen, select the study to be deleted and select the Delete button or right mouse click and select Delete from the pop-up menu. Using "Shift-Click" or "Ctrl-Click" selects multiple studies for deletion from the list.

Delete a Series

From the Main Screen, select the study then the series and select the Delete button. Using "Shift-Click" or "Ctrl-Click" selects multiple series from the list.

   NOTE: It is recommended to perform any series deletion prior to starting any analysis.

Delete Secondary Capture Series

Secondary capture series created by suiteHEART, including "suiteHEART DATA" and "suiteHEART APPROVED" that are identified as NeoSoft LLC as the manufacturer can be deleted.

⚠️ CAUTION: The deletion of the suiteHEART data series will remove all analysis results.

1. Select the study and locate the suiteHEART DATA series.

2. Click on the series number or + icon.

FIGURE 6. Series Select

Series # ▼	Images	Description	Modality	Manufacturer
20	11	SAx MDE	MR	GE MEDICAL SY
21	60	Radial Fiesta	MR	GE MEDICAL SY
22	20	3-ch Fast Cine	MR	GE MEDICAL SY
23	8	IRON Heart	MR	GE MEDICAL SY
1201	150	TC Short Axis	MR	GE MEDICAL SY
➕ 1210	1	suiteHEART DATA	MR	NeoSoft LLC

Series: 6 — Buttons: Send, Delete

3. The Series Details window will open. Select the appropriate row, click the Delete button. To close, click on the X in the upper right hand corner of the window.

FIGURE 7. Series Details

Series Details

Description:[suiteHEART DATA] Number:[30] Modality:[MR] Manufacturer:[NeoSoft LLC]

SOP Instance UID	Date	Number
1.2.826.0.1.3680043.9.1400.2.1404418259.145	7/3/2014 8:10:59 PM	1
1.2.826.0.1.3680043.9.1400.2.1404418279.676	7/3/2014 8:11:19 PM	2
1.2.826.0.1.3680043.9.1400.2.1404418303.661	7/3/2014 8:11:43 PM	3
1.2.826.0.1.3680043.9.1400.2.1404418358.266	7/3/2014 8:12:38 PM	4
1.2.826.0.1.3680043.9.1400.2.1405099180.424	7/11/2014 5:19:40 PM	5
1.2.826.0.1.3680043.9.1400.2.1405099195.914	7/11/2014 5:19:55 PM	6
1.2.826.0.1.3680043.9.1400.2.1405099233.103	7/11/2014 5:20:33 PM	7
1.2.826.0.1.3680043.9.1400.2.1405099255.652	7/11/2014 5:20:55 PM	8
1.2.826.0.1.3680043.9.1400.2.1405099271.618	7/11/2014 5:21:11 PM	9

Delete

About suiteDXT

Selecting the About button on the Main Screen will display the software version of suiteDXT

Click the "Instructions for Use" link to launch the Instructions for Use (IFU).

Click the "DICOM Conformance Statement" link to launch the DICOM Conformance Statement document.

> **NOTE:** A PDF reader is required to open the documents.

> **NOTE:** Click "Archive log files for Support" to create a file to be used for troubleshooting by Service.

FIGURE 8. About Window and Manual Button
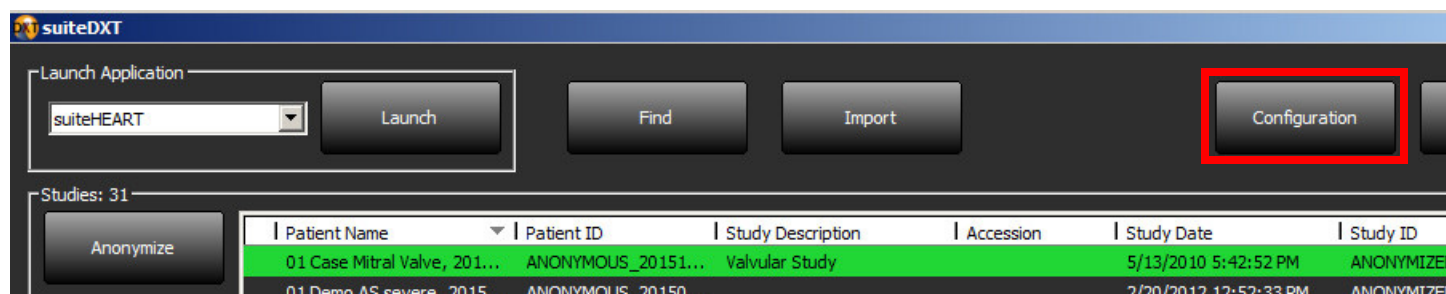
Study Pre-Processing

The Study Pre-Processing feature is only available with the suiteHEART® Software application. This feature allows for the pre-processing of a short axis cine series under Function Analysis and phase contrast under Flow Analysis.

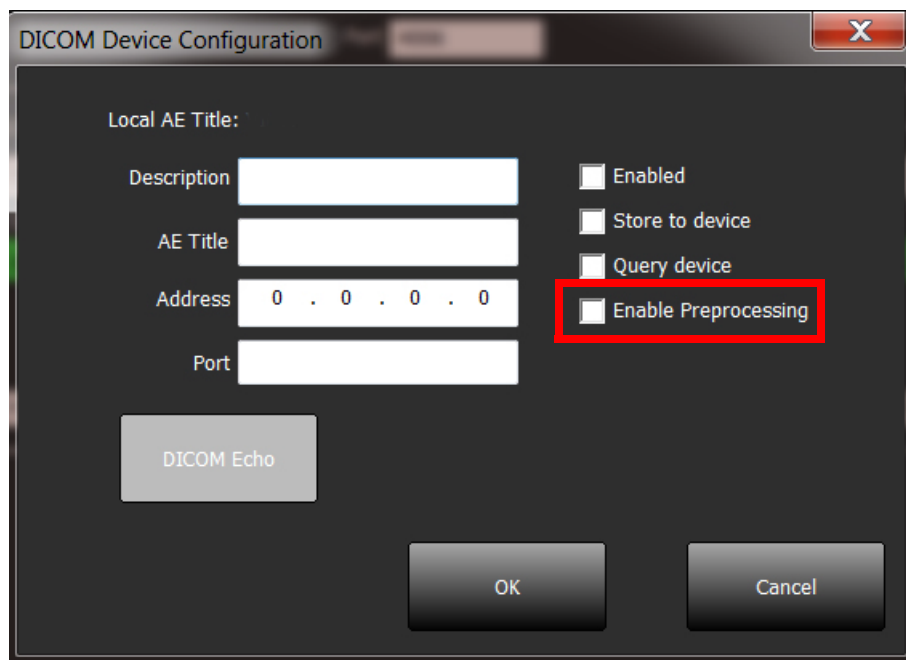**NOTE:**   suiteDXT must be open and running for pre-processing to complete.

NOTE: Pre-processing will be disabled if the hardware does not meet the minimum system requirements.

Turn On Pre-Processing

1. On the Main Screen, select the Configuration button.

2. Select DICOM configuration.
3. Select the DICOM destinations and click Edit.
4. Select Enable Pre-Processing.
5. Click OK.

When Pre-Processing is turned on, there will be an indication at the bottom of the Main screen.
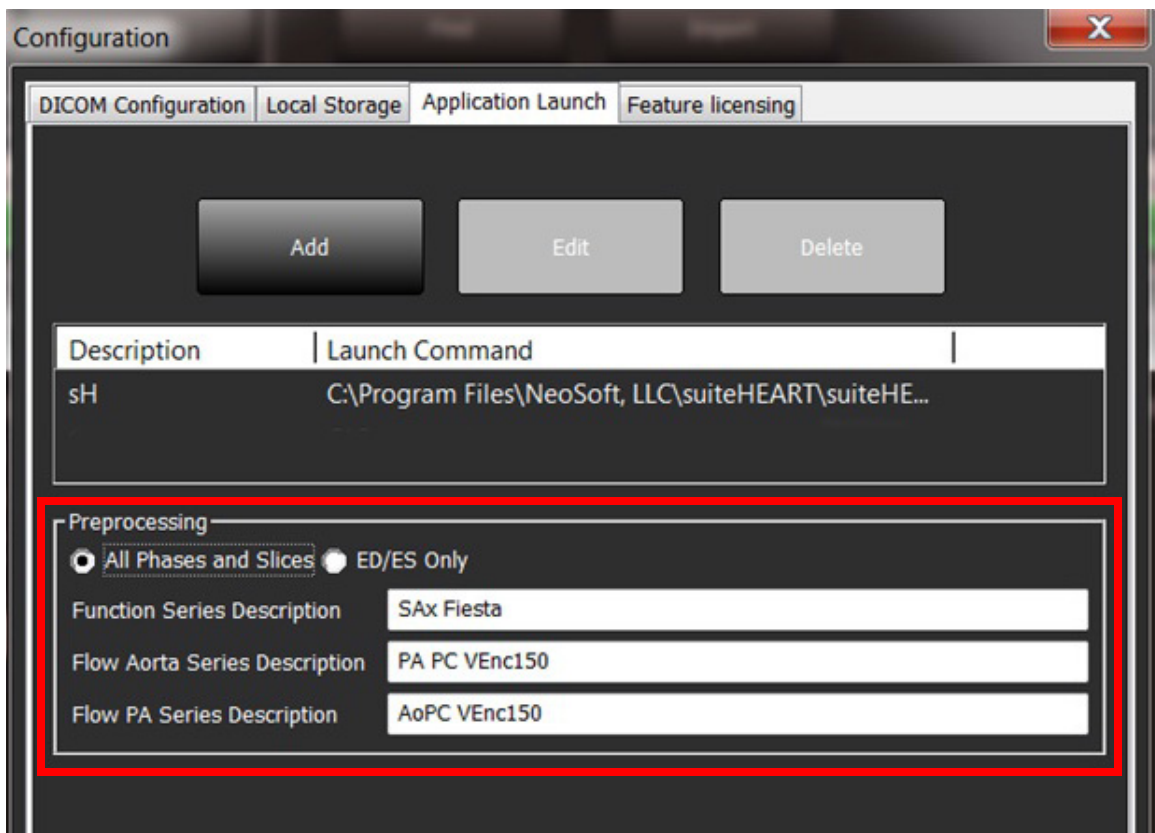

NOTE: It's recommended to use pre-processing for cardiac MRI studies that are being networked directly to suiteDXT from the MRI scanner, because the feature is not available for retrieved studies.

NOTE: When pre-processing is activated, studies will not be available for viewing until the pre-processing is complete.

IMPORTANT: If a study is open while a new series for that study is received, pre-processing on the new series will not take place.

Set Up Pre-Processing

1. On the Main Screen, select the Configuration button.

2. Select Application Launch.

3. Type in the appropriate series name for a short axis function series.

4. Type in the appropriate series name for a phase contrast series for Ao.

5. Type in the appropriate series name for a phase contrast series for PA.

6. Click OK.

DXT Study Pane Indicator

Studies that have completed pre-processing will be indicated by a green circle. The indicator will remain on the screen until the study has been opened or suiteDXT has been restarted.
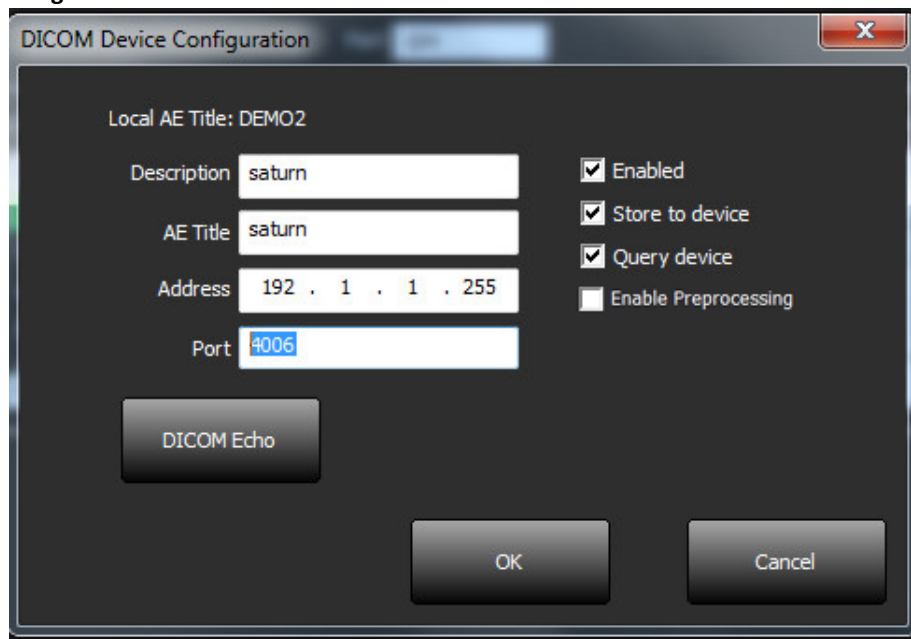
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Service and Support

DICOM Network Failure

If a retrieval failed to transfer a study, confirm that a firewall is not preventing the transfer. If a firewall is not the issue, check that suit-eDXT can DICOM echo the remote host and that the remote host can DICOM echo suiteDXT.

1.   From the Main Screen, select the Configuration button.

2.   On the DICOM Configuration tab, select the remote host from which the retrieval was attempted and select the Edit button.

3.   Select the checkboxes for: Enable, Store to device and Query device.

4.   Verify that the IP address for the DICOM Destination is correct.

FIGURE 1. DICOM Configuration Window

5.   Select the DICOM Echo button.

6.   Check the network settings and confirm that port 104 is open and accessible on the suiteDXT host.

7.   Retrieve the study again.

If after performing the above steps the retrieval fails again, contact your network administrator.
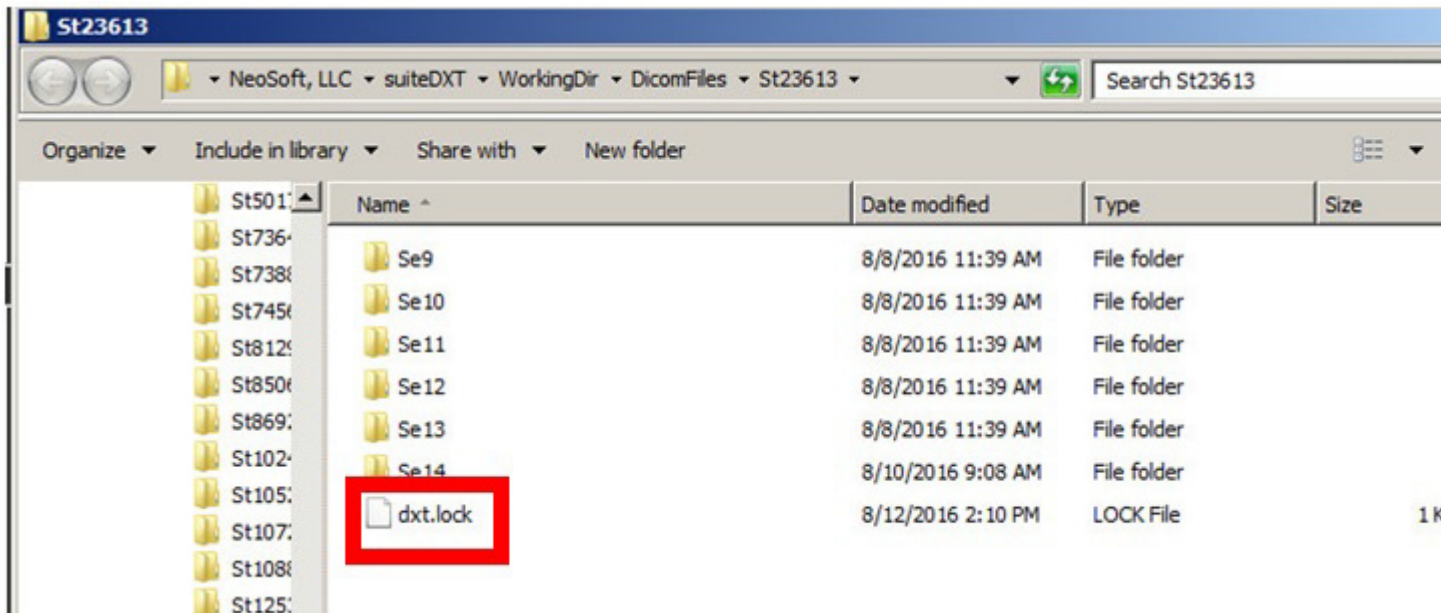
Study Launch Error

If the message "The following studies are locked and will not be loaded in the launch" appears when trying to launch a study, do the following:

1. Navigate to the DXT study directory.

2. Right-mouse click on the study that produced the error message.

3. Select "Open Study Location."

4. Delete the the dxt.lock file.

   NOTE: In a multiuser environment, deleting a dxt.lock file can cause data loss. Deletion of a dxt.lock file should be done by your system administrator, who can ensure the study is no longer in use by another user.
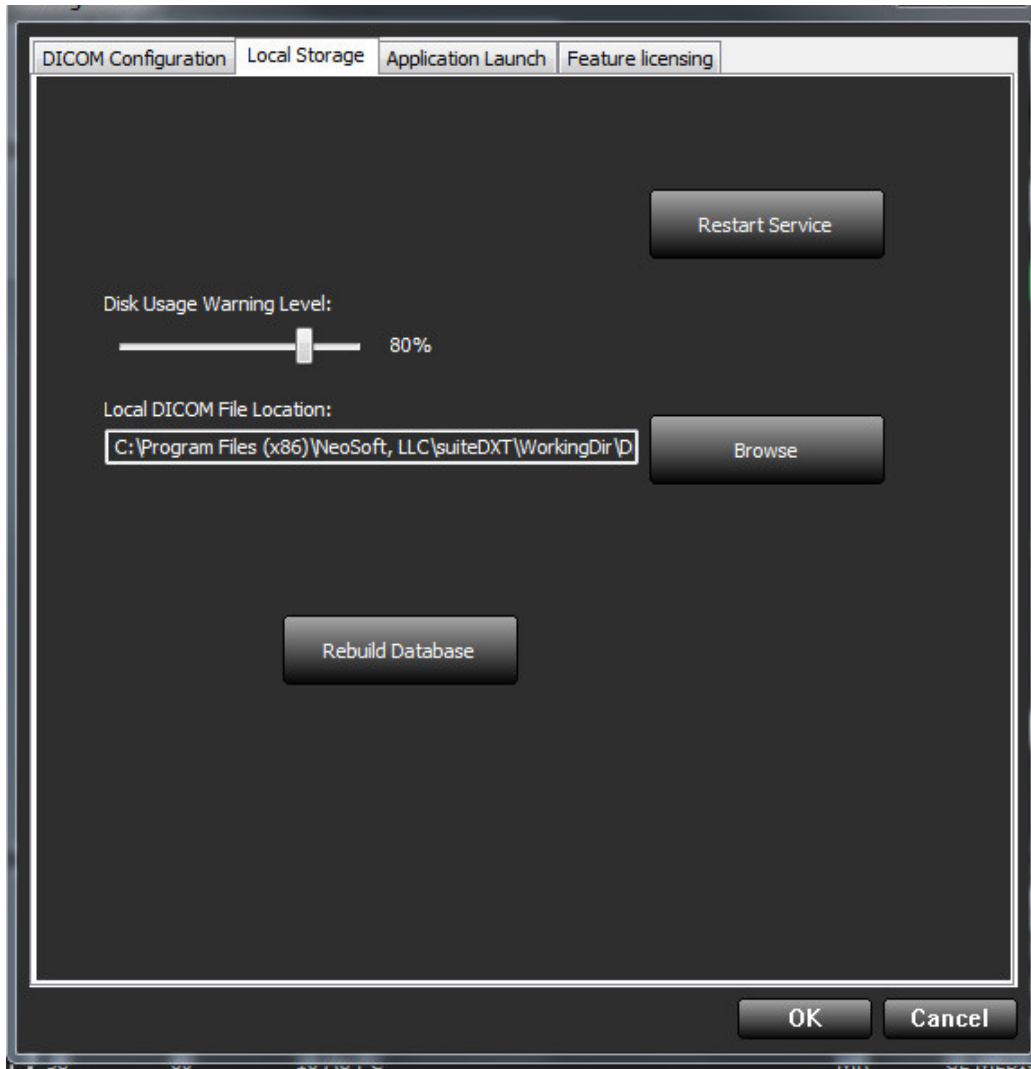
FIGURE 2. Study Lock File

Restart Service

If network failures persist, the suiteDXT DICOM service can be restarted.

1.   From the Main Screen, select the Configuration button.

2.   Select the Local Storage tab.

3.   Click on Restart Service button.

FIGURE 3. Restart Service

Contact

If you experience problems during installation or use of suiteDXT, please contact NeoSoft, LLC service at service@NeoSoftmedical.com.

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