suiteDXT

Instructions for Use

NeoSoft, LLC

Revision History

Document Revision	Date of Issue	Description
1	14-July-2014	Initial Release
2	5-August-2014	Updated Prerequisites
3	19-November-2014	Add Medical device directive

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:

$$C\,\epsilon$$
0086

European Representatives:

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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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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 version 2.1.0 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.

Installation & Configuration

Prerequisites

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

- Supported Operating Systems:
    - Windows 7 Professional or Enterprise with SP1 (64 bit version)
    - Windows 8.1 Professional or Enterprise (64 bit version)
- Video card and monitor shall support 1920 x 1080 resolution.
- Anti-Virus software installed.
- Minimum 4GB memory.
- Available hard drive space minimum 5GB.
- 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 7.

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."
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."
8. Select "Finish."

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
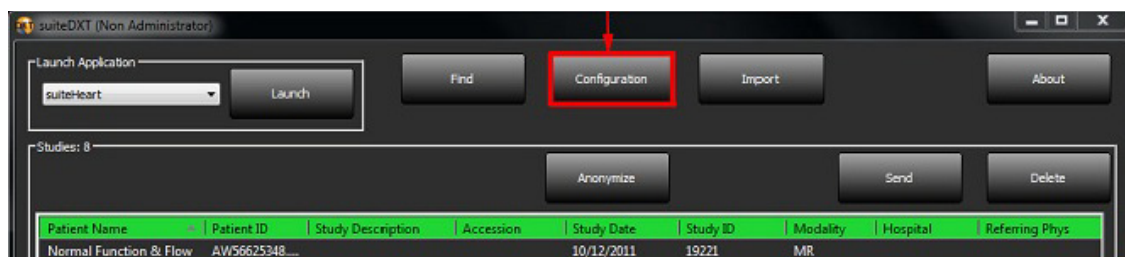
3. On the DICOM Configuration tab, enter information for the local host: (Figure 2)
    • Description (enter any descriptor of your choosing).
    • AE Title (case sensitive) is the name used to identify the host by other hosts.
    • Port (104).
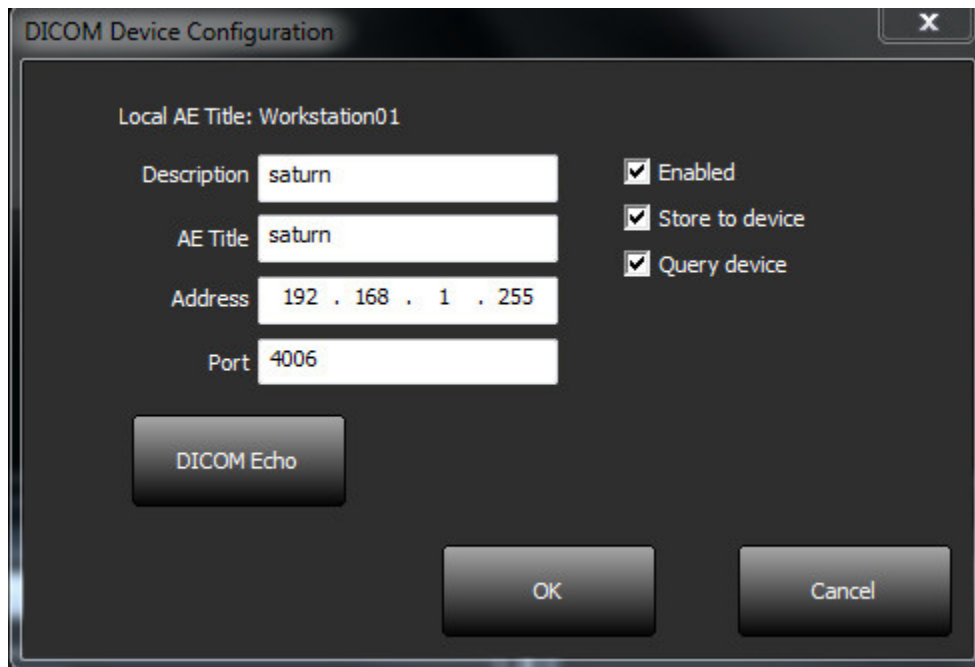
NOTE: The information entered on this tab must be entered exactly the same on any remote device for suiteDXT to retrieve or accept images from the remote host.

FIGURE 2. Configuration Tab Window
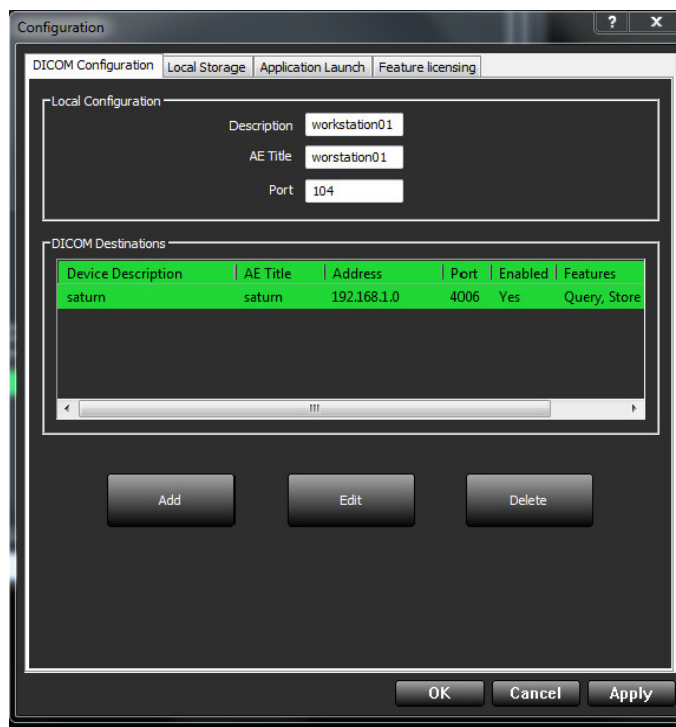
4. If available, perform a DICOM echo from any remote device to this host to ensure DICOM connectivity.

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 and Query device (Figure 3).
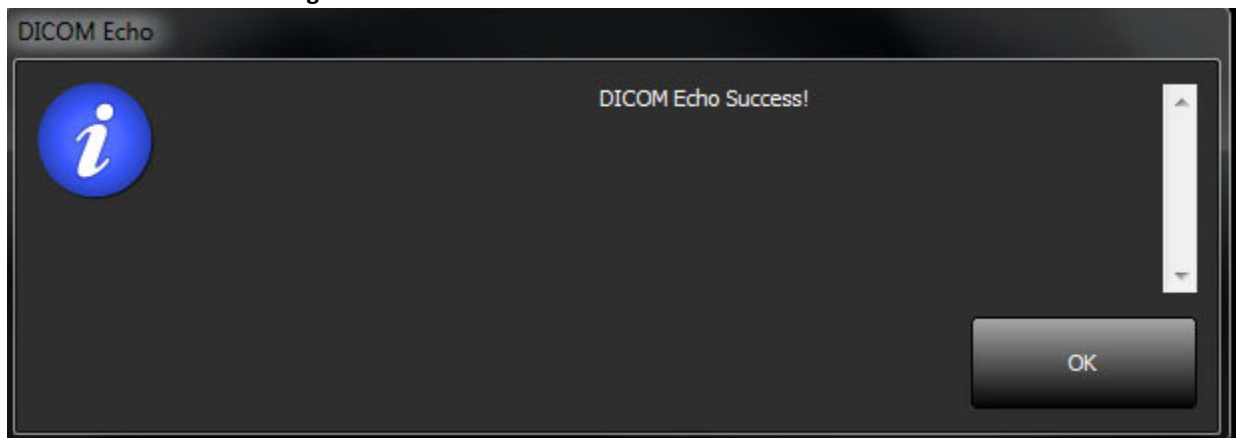
FIGURE 3. DICOM Configuration Window

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
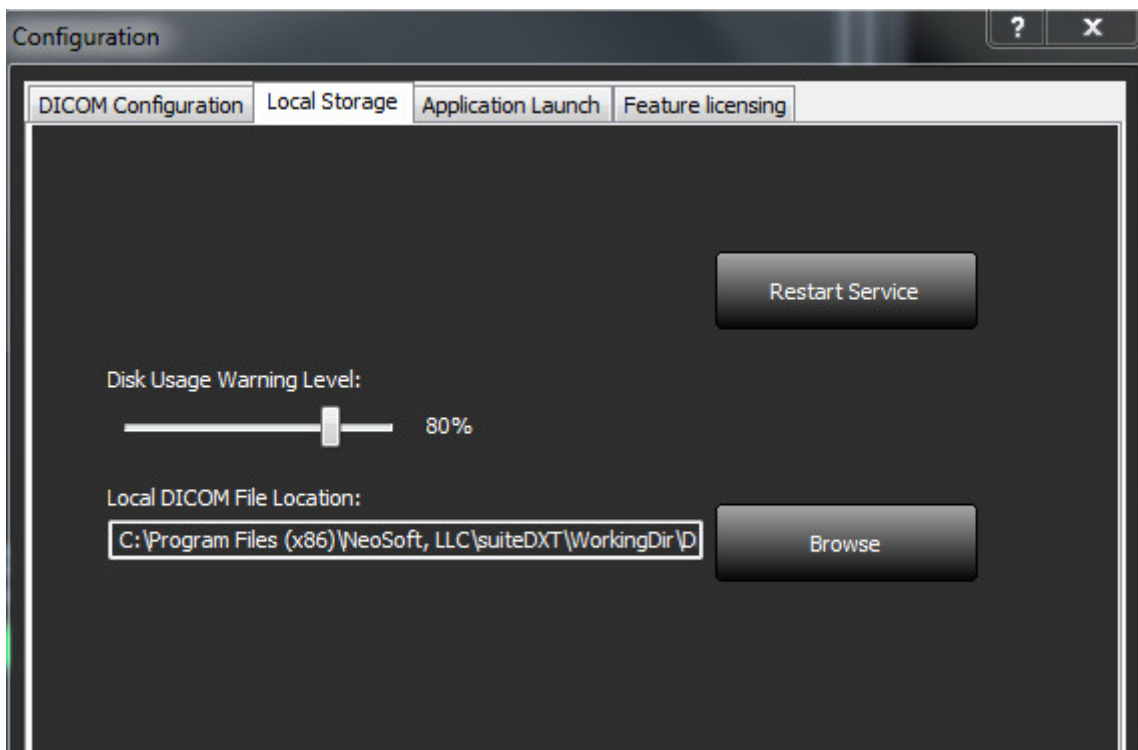
The Disk Usage Warning Level can be modified to alert you when disk space is low. When disk usage exceeds the limit set, the indicator on the main screen (Figure 6) will change from green to yellow.
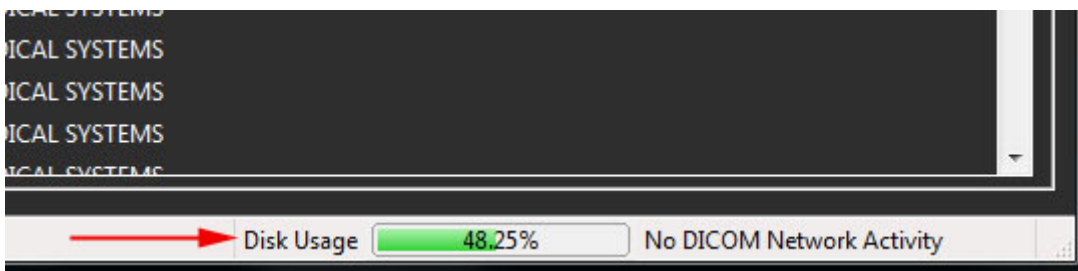
The Local DICOM File Location Selection allows you to change the directory where DICOM data is stored. If data already exists in the location you've selected, it will be deleted before assigning a new folder. A warning message will appear to alert you to potential data loss.

Application Launch Tab

Use this tab to configure compatible NeoSoft, LLC 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
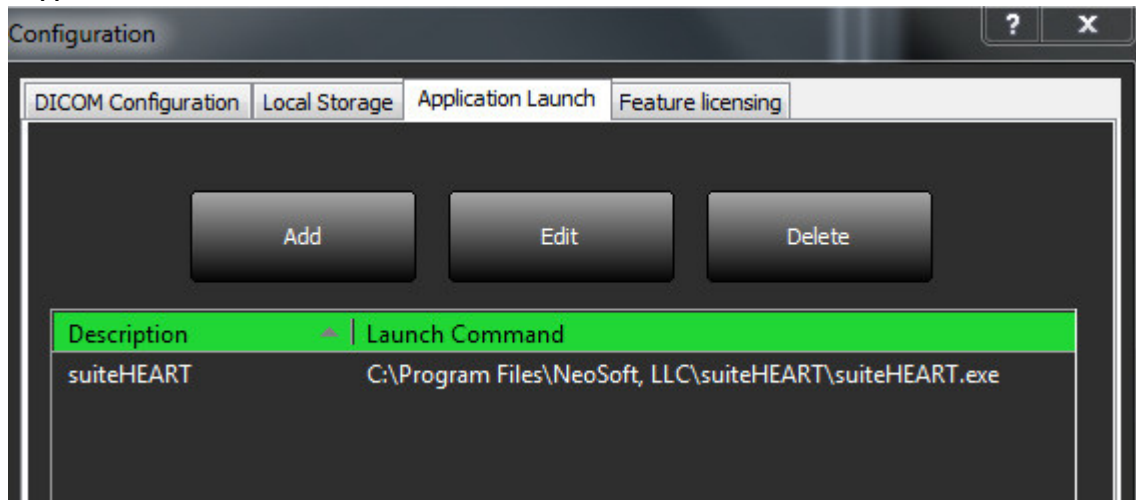
FIGURE 8. Edit Application Window
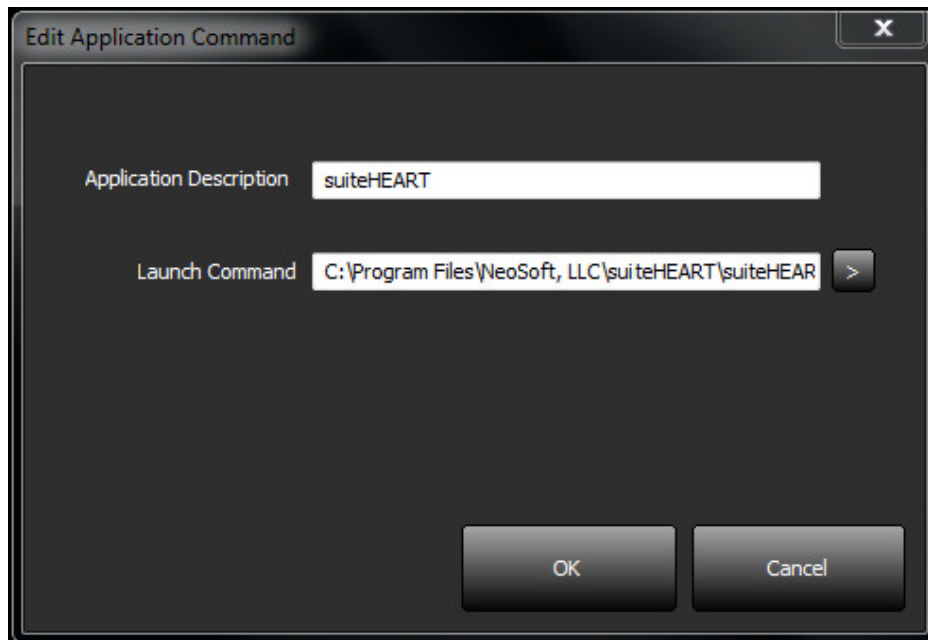
2. Enter the name or a description of the application.

3. Select the arrow button next to the Launch Command field to select the directory which contains the NeoSoft 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).

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

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

Request a License

1. Select the product to license from the drop-down menu.

2. 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.

3. Select the Generate License Request button.

4. Navigate to a memorable directory (e.g. the desktop) in which to save the license request (c2v) file.

5. Email the license request (c2v) file to licensing@neosoftmedical.com

Apply the License

1. From NeoSoft's 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.

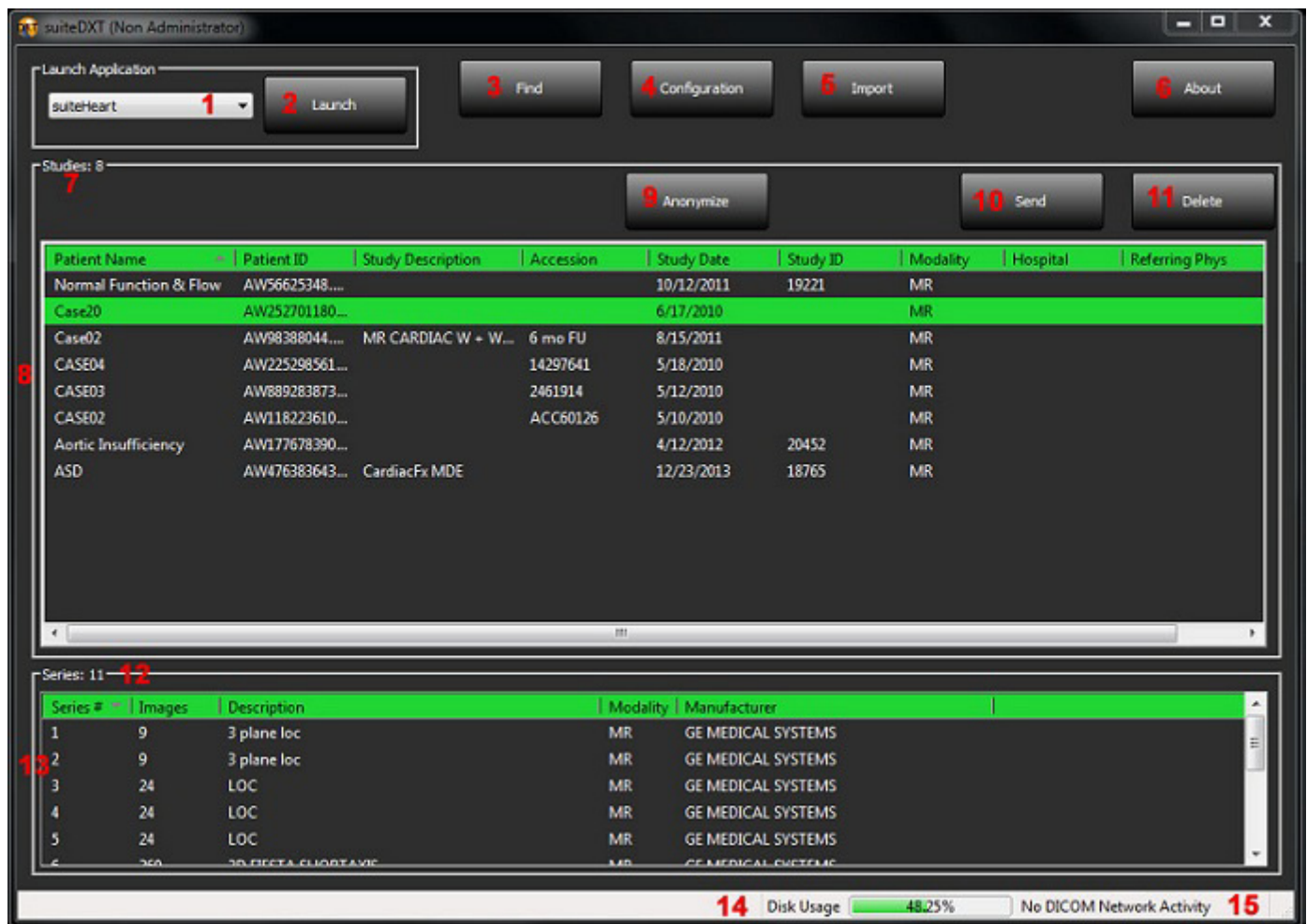4. Select OK.

# 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. **Configuration Button** - opens Configuration Window.

5. **Import Button** - allows study information to be imported from the file system, CD, DVD or USB media.

6. **About Button** - displays suiteDXT software version.

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

8. **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.

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

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

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

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.

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

15. **Network Status** - shows if suiteDXT is currently transferring DICOM data over the network.

Right Mouse Click Menu in Main Screen

FIGURE 2. Right Mouse Click Menu
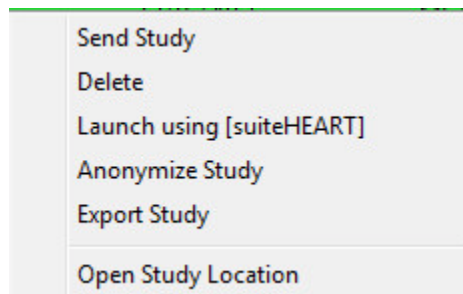
- **Send Study** - pushes study from local host to remote host.
- **Delete** - removes study from suiteDXT study list and deletes DICOM data from local host.
- **Launch using [NeoSoft, LLC application]** - launches configured application using selected study.
- **Anonymize Study** - creates a new study 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.

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

6. **Retrieve Button** - executes retrieve of study from remote device.

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

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

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.

10. **Transfer Status Pane** - shows current and completed retrieve actions.
    - Column titles can be reordered by clicking and dragging the title of the column.
11. **Clear Retrieve Results Button** - clears transfer activity in the transfer pane for studies whose transfers have been completed.

⚠️

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.

12. **Cancel Button** - halts study retrieve of the study that is currently selected.

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

> **NOTE:** This feature is available only after a license has been applied via the "Feature Licensing Tab" on page 8.

NeoSoft, LLC applications can be added by following instructions in "Application Launch Tab" on page 7.

1. Go to the Main Screen.

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

FIGURE 1. Launch Application Menu
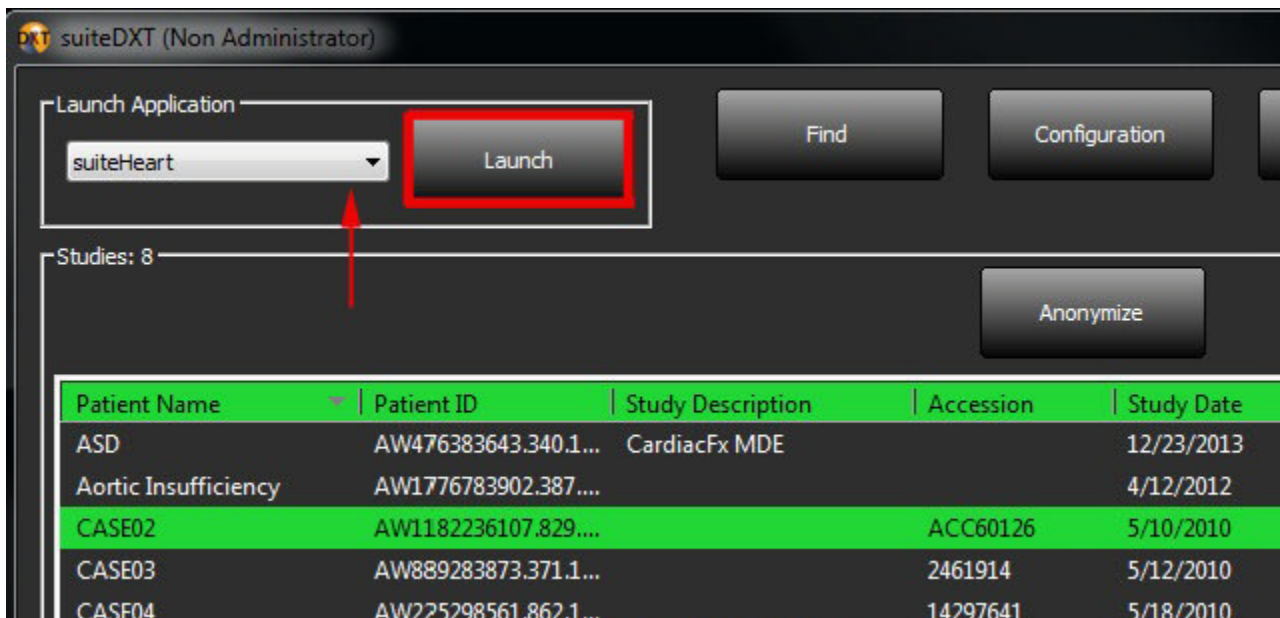

3. Select a study from the study list and do one of the following:
   - Select the Launch button.
   - Right mouse click and select "Launch using <selected application>."
   - Double click the study.

Retrieve Study from Remote Host

Remote hosts must already be configured to be accessible. For information on how to configure a remote host see "Configuration" on page 4.

1. Select the Find button on the Main Screen.

FIGURE 2. Find Button on Main Screen
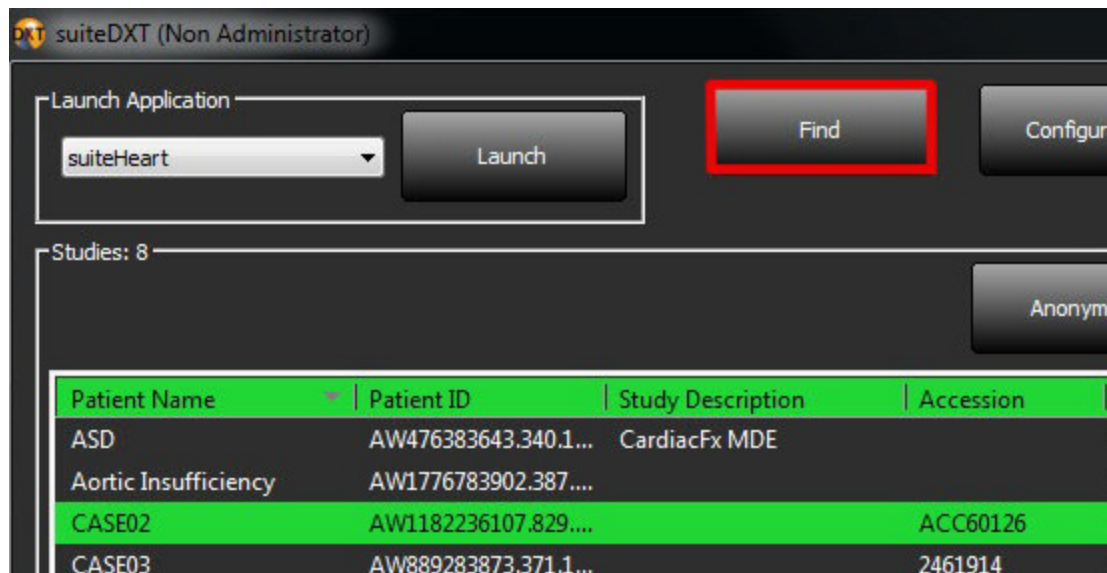
2. In the Query/Retrieve Window enter any study information criteria in the Query Filter area.

    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 or right mouse click and select Retrieve from the pop-up menu.

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 "Configuration" on page 4.
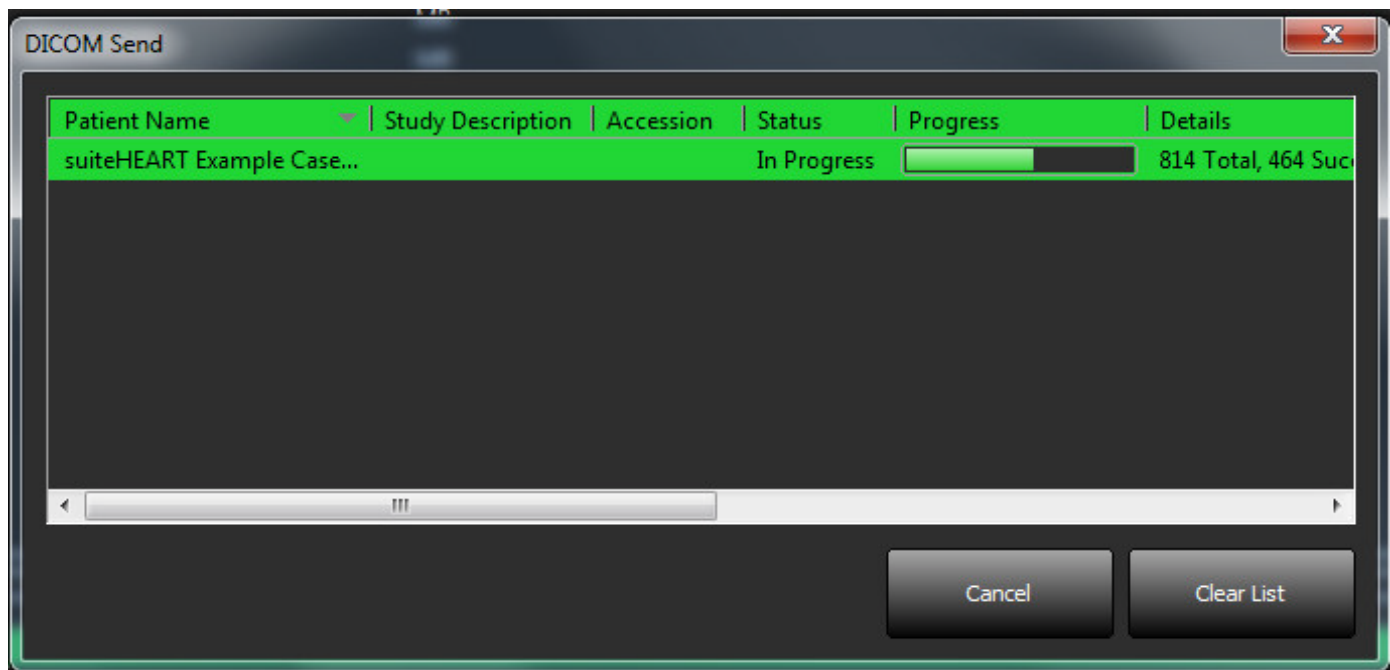
> **NOTE:** suiteDXT supports JPEG Lossless compression, however subsets of this format are not supported.

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

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.

CAUTION: The secondary capture files produced by NeoSoft, LLC applications will not be available in the anonymized study.
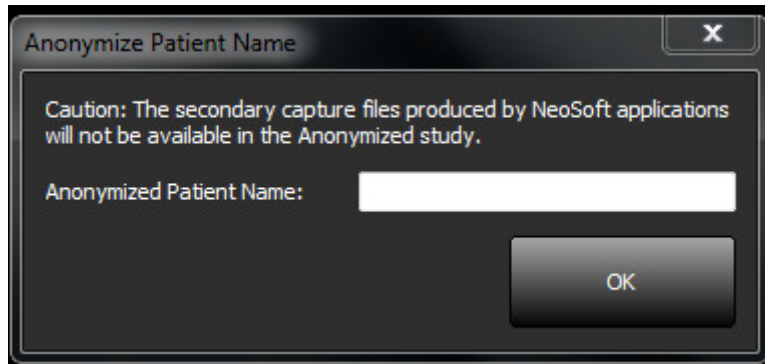
CAUTION: The anonymized study should only be used with NeoSoft, LLC applications.

CAUTION: Secondary captures may contain patient information.

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^YYYYMMDDTHHMMSS.

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

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

Delete a Study

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 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 these files will remove all analysis results and approved studies for the study selected.

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

2. Click on the series number or icon.

FIGURE 6. Series Select

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

FIGURE 7. Series Details

About suiteDXT

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

Click the "User Manual" 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

Service and Support

License Application

In the event that your NeoSoft product appears unlicensed even though the applied license is valid, follow these steps to reset your license:

1. Locate the license file sent at the time of initial installation.

    The license file (*.lic) was emailed to you from licensing@neosoftmedical.com. If you cannot locate the original license, please request it again using the licensing@neosoftmedical.com email address.

2. Navigate to the location listed below and delete the contents under the "installed" folder.

    For Windows 7 and Windows 8:

    C:\Program Data\SafeNet Sentinel\Sentinel LDK\installed

    NOTE: By default, these folders are hidden by the OS. To view hidden folders, open 'Folder Options,' select the 'View' tab, and click 'Show hidden files, folders, and drives.'
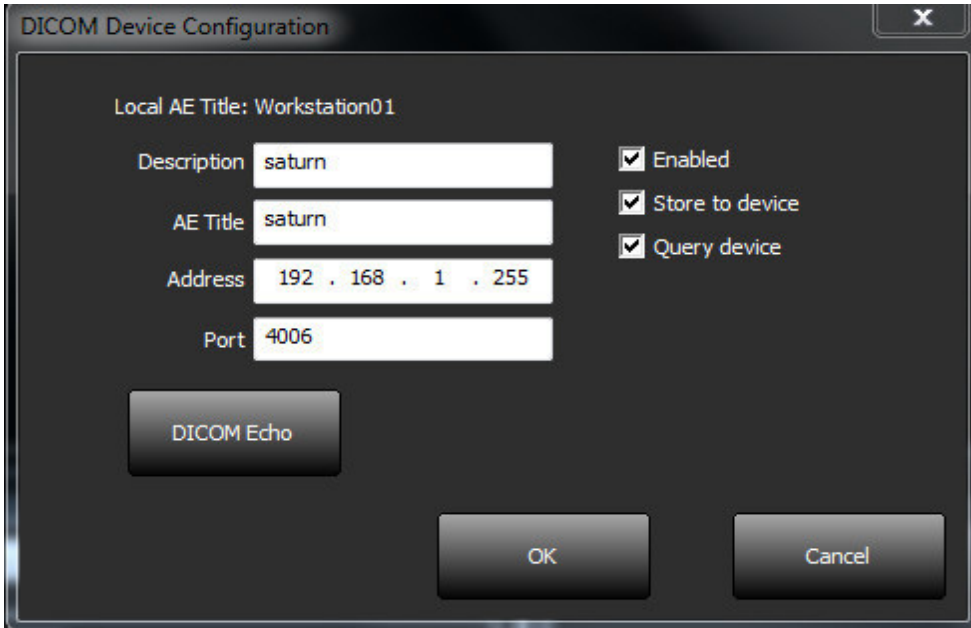
3. Restart your machine and then reapply the original license using the instructions "Apply the License" on page 9.

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 suiteDXT 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.

FIGURE 1. DICOM Configuration Window

4. Select the DICOM Echo button.

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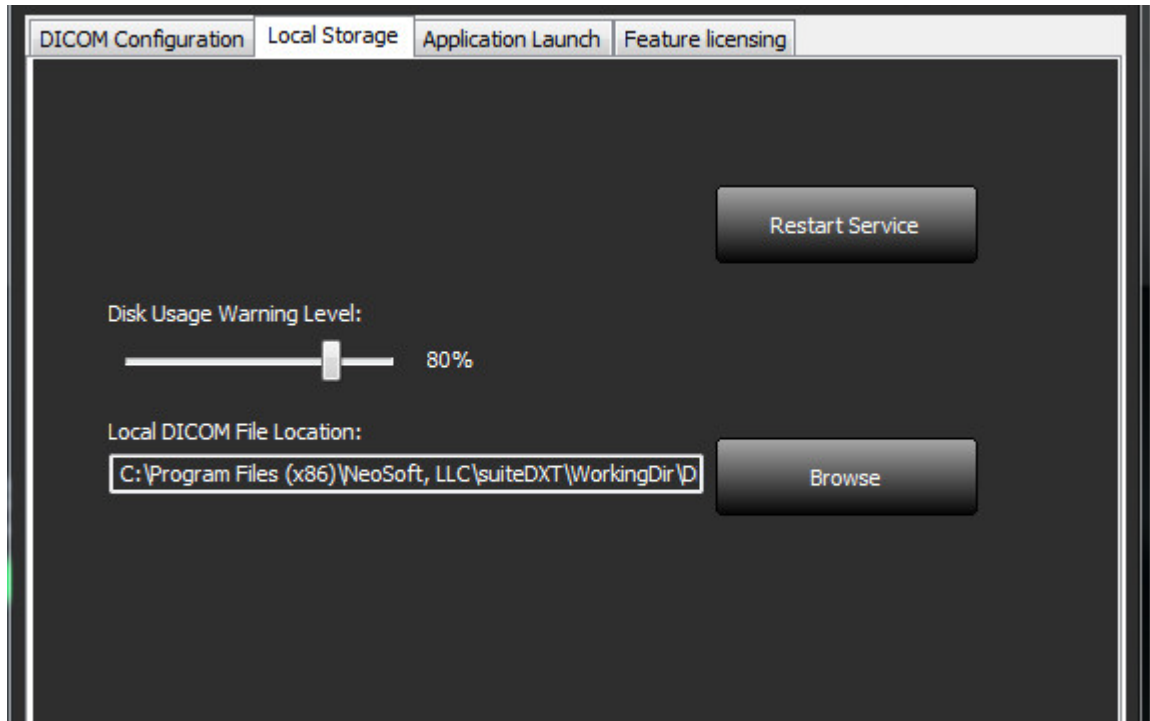
6. Retrieve the study again.

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

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 2. Restart Service

Contact

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