

suiteDXT

Instructions for Use

NeoSoft, LLC



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Revision History

Rev	Date	Description of Change	Safety Related Update (Yes/No)
1	14JULY2014	First Release	No
2	05Aug2014	Removed Support for 32 bit Operating Systems	No
3	19Nov2014	Add Medical Device Directive Information	No
4	07MAY2015	Updated for 3.0.0 product release	No
5	15June2015	Updated the About screen shot and removed duplicate step on page 14	No
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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:



European Representatives:



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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Table of Contents

Medical device directive i

Safety 1

Introduction 1
Intended Use 1
Indications for Use 1
Supported DICOM Image Formats 1
Terminology 2
Equipment Hazards 2

Getting Started 3

Main Screen Functions 3
Right Mouse Click Menu in Study Pane 4
Right Mouse Click Menu in Series Pane 4
Query/Retrieve Window 5
Right Mouse Click Menu in Query/Results Pane 6
Right Mouse Click Menu in Series Pane 6

Using suiteDXT 7

Launch an Application 7
Retrieve Study or Series from Remote Host 8
Create a Filter 10
Send Study to Remote Host 10
Send Series to Remote Host 11
Import Studies 11
Anonymize a Study 11
Delete a Study 12
Delete a Series 12
Delete Secondary Capture Series 13
About suiteDXT 14

Study Preprocessing 15

Configure Preprocessing 15
Using Preprocessing 16
suiteDXT Study Pane Indicator 17

Service and Support 19

DICOM Network Failure 19
Study Launch Error 20
Restart Service 21
Contact 21

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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

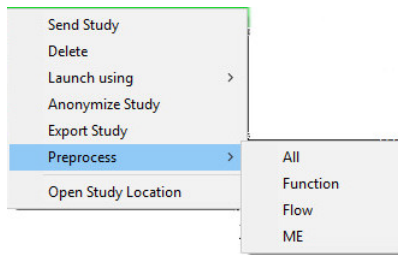


1. **Launch Application pull-down Menu** - lists configured applications.
2. **Launch Button** - launches configured NeoSoft, LLC applications.
3. **Find Button** - opens Query/Retrieve Window.
4. **Import Button** - allows study information to be imported from the file system, CD, DVD or USB media.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

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

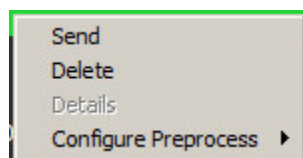
FIGURE 2. Right Mouse Click Menu



- **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** - 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.
- **Preprocess** - preprocesses all configured series or only Function, Flow or ME.
- **Open Study Location** - shows location of DICOM data on the local file system.

NOTE: Preprocess is not applicable to the NeoSoft CAKE™ application.

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.
- **Configure Preprocess** - auto fills the series name for a Function, Flow or ME series.

NOTE: Configure Preprocess is not applicable to the NeoSoft CAKE™ application.

Query/Retrieve Window

FIGURE 3. Query/Retrieve Window

The screenshot shows the 'Query and Retrieve' window. At the top, the title bar reads 'Query and Retrieve'. Below it, the 'Query Filter' section (1) contains input fields for Patient Last Name, Patient First Name, Patient ID, Study ID, Accession Number, Modality (set to MR), and Date (set to All). A 'Query' button (2) and a 'Save Filter' button (4) are to the right. Below the filter section, it says 'Query Results: 435 Matches Found.' (5). The main 'Query Results' table (6) has columns: Patient Name, Patient ID, Study Description, Accession, Study Date, and Study. It lists 12 cases, with 'SH Case 04' highlighted in green. Below this table are buttons for 'Clear Query Results' (7), 'Retrieve' (8), and 'Retrieve and Preprocess' (9). The 'Series: 55' section (10) has a table with columns: Series #, Images, Description, Modality, and Manufacturer. It lists two series, with the first highlighted in green. Below this is a 'Retrieve' button (11). The 'Retrieve Results' section (12) has a table with columns: Patient Name, Patient ID, Accession, Status, Progress, and Details. It lists two cases, with 'SH Case 04' highlighted in green. At the bottom are buttons for 'Clear Retrieve Results' (13) and 'Cancel' (14).

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.

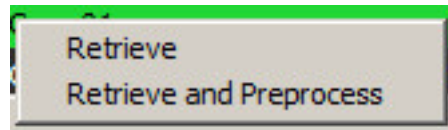
7. **Clear Query Results Button** - clears query results in study pane.
8. **Retrieve Button** - executes retrieval of the selected study from remote device.
9. **Retrieve and Preprocess** - executes retrieval and preprocessing of the selected study from the remote device.
10. **Series Pane** - shows 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.
11. **Retrieve Button** - executes retrieval of the selected series from remote device.
12. **Transfer Status Pane** - shows current and completed retrieve actions.
 - Column titles can be reordered by clicking and dragging the title of the column.
13. **Clear Retrieve Results Button** - clears transfer activity in the transfer pane for studies whose transfers have been completed.
14. **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/Results Pane

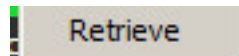
FIGURE 4. Right Mouse Click Menu



- **Retrieve** - executes retrieval of a study from a remote host.
- **Retrieve and Preprocess** - executes retrieval and preprocessing of the selected study from the remote host.

Right Mouse Click Menu in Series Pane

FIGURE 5. Right Mouse Click Menu



- **Retrieve** - executes retrieval of series from a remote host.

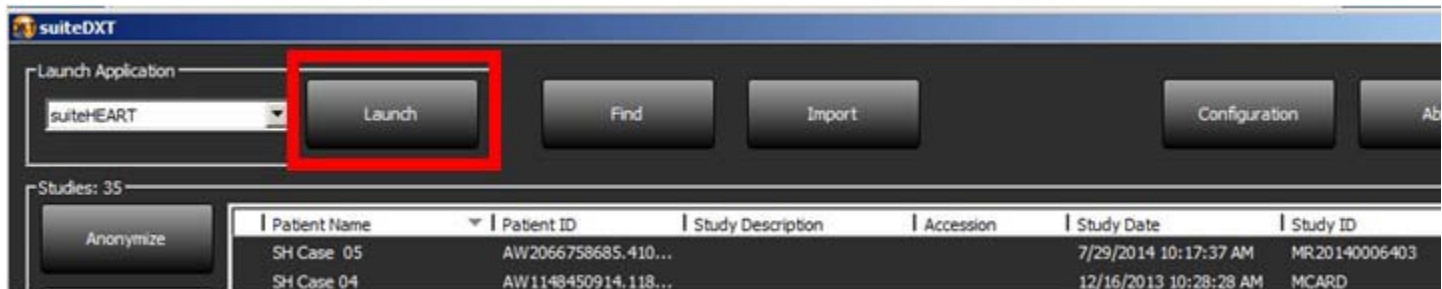
Using suiteDXT

Launch an Application

Applications can be added by following instructions in the Installation Manual.

1. Go to the Main Screen.
2. From the Launch Application drop-down menu, select the desired application.

FIGURE 1. Launch Application Menu



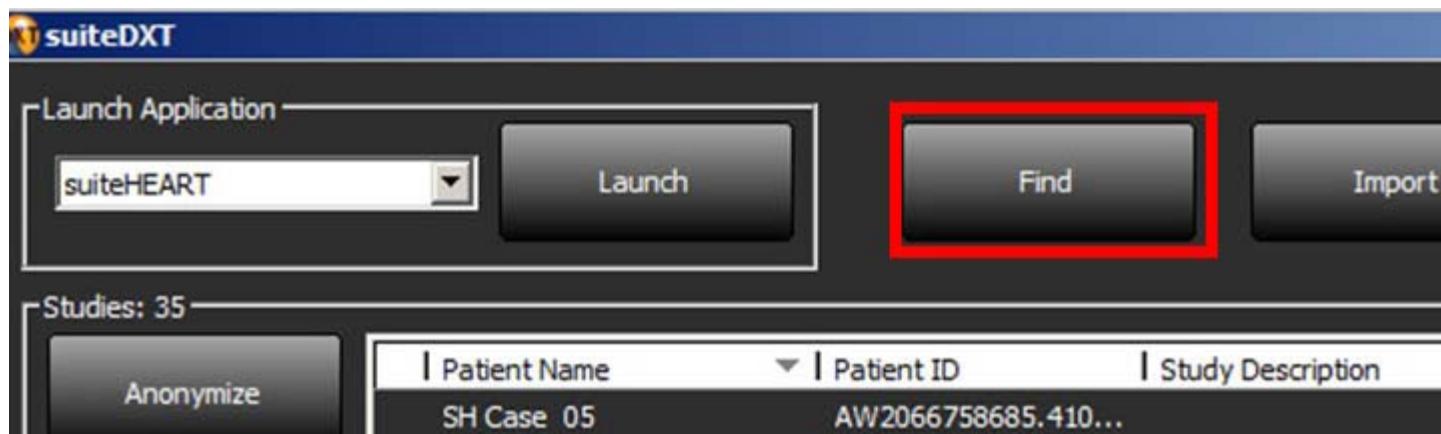
3. Select a study from the study list and do one of the following:
 - Select the Launch button.
 - Right mouse click and select "Launch using <selected application>."
 - Double click the study.

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.

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

The screenshot shows the 'Query and Retrieve' window with the following sections:

- Query Filter:**
 - Patient Last Name:
 - Patient First Name:
 - Patient ID:
 - Study ID:
 - Accession Number:
 - Modality: MR
 - Query Source: CLINICALPACS (dropdown)
 - Date: All (dropdown)
 - Buttons: Query, Save Filter
- Query Results: 435 Matches Found.**

Patient Name	Patient ID	Study Description	Accession	Study Date	Study
SH Case 02	AW1696004290.551...	No Value Returned	No Value Retur...	1/7/2011 8:40:42 AM	17610
SH Case 03	AW1523419194.749...	No Value Returned	No Value Retur...	5/20/2013 10:25:55 AM	2870
SH Case 04	AW1148450914.118...	No Value Returned	No Value Retur...	12/16/2013 10:28:28 AM	MCAR
SH Case 06, 20140929T162031	ANONYMOUS_20140...	MR HEART FOR FUNCTIO...	ANONYMIZED	8/11/2014 7:50:54 PM	ANON
SH Case 07, 20140929T163557	ANONYMOUS_20140...	No Value Returned	ANONYMIZED	12/9/2013 12:57:53 PM	ANON
SH Case 08	AW841401068.245...	No Value Returned	No Value Retur...	7/10/2006 12:53:04 PM	No Val
SH Case 09	AW951129491.420...	No Value Returned	No Value Retur...	5/12/2011 9:19:28 AM	No Val
SH Case 10	AW2091044406.251...	No Value Returned	No Value Retur...	6/22/2011 4:29:05 PM	18765
SH Case 11, 20140929T164545	ANONYMOUS_20140...	No Value Returned	ANONYMIZED	1/15/2014 6:20:17 PM	ANON
SH Case 12, 20140929T165123	ANONYMOUS_20140...	MR HEART FOR FUNCTIO...	ANONYMIZED	7/28/2014 7:36:18 PM	ANON
- Buttons:** Clear Query Results, Retrieve, Retrieve and Preprocess
- Series: 55**

Series #	Images	Description	Modality	Manufacturer
1	No Value ...	trufi_loc_multi_iPAT@c	MR	SIEMENS
8	No Value ...	sa cine	MR	SIEMENS
- Buttons:** Retrieve
- Retrieve Results**

Patient Name	Patient ID	Accession	Status	Progress	Details
SH Case 03	AW1523419194.749...		Complete	<div></div>	1737 Total, 1737 S
SH Case 04	AW1148450914.118...		Complete	<div></div>	714 Total, 714 Suc
- Buttons:** Clear Retrieve Results, Cancel

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. Perform preprocessing by selecting the Retrieve and Preprocess button.
8. 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.

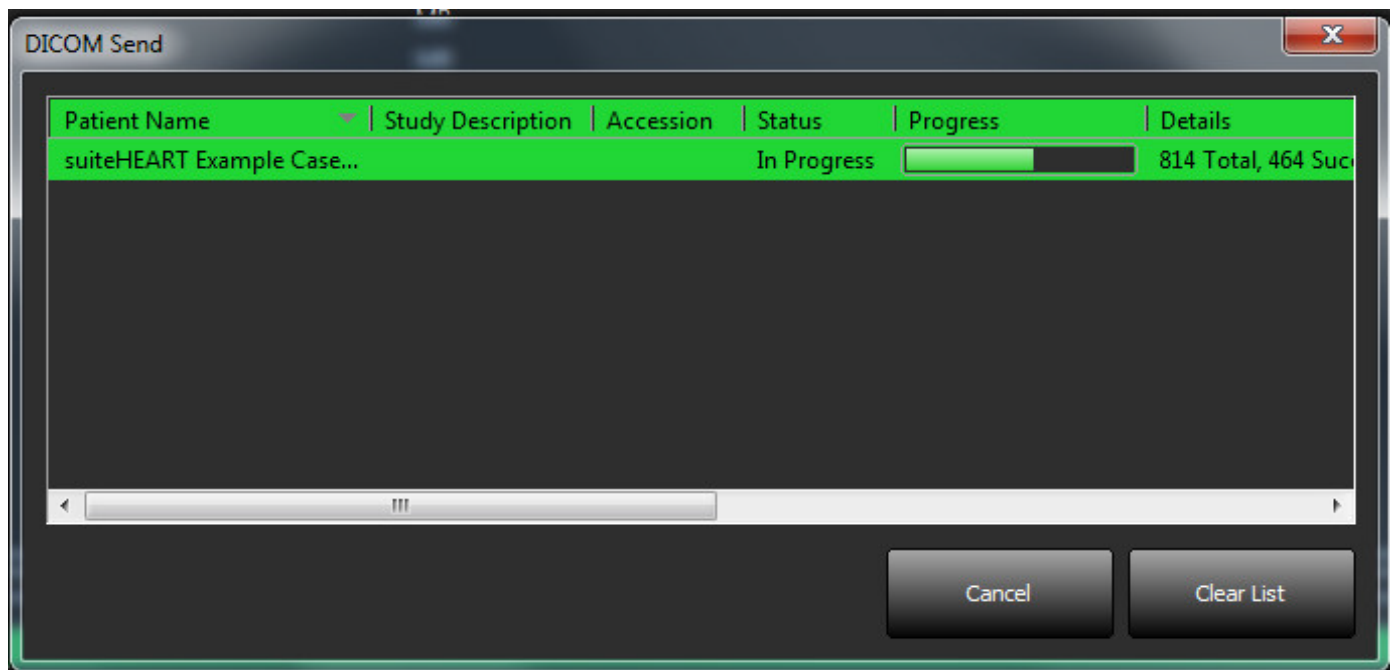
NOTE: suiteDXT supports JPEG Lossless compression, however subsets of this format are not supported.

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



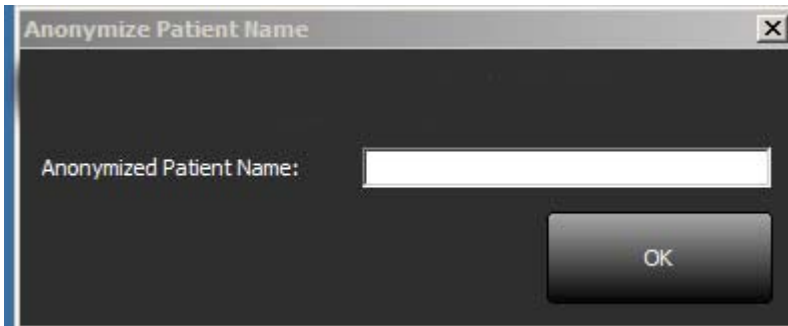
CAUTION: Anonymizing a study does not remove patient data from the images that were created from other post-processing software.



CAUTION: The anonymized study should only be used with NeoSoft, LLC applications.

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. To save analysis on studies analyzed with suiteHEART® Software prior to 4.0.0, first launch the study and if only the suiteHEART® approved secondary capture is present, perform a new approved exam prior to closing then close the suiteHEART® Software.

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 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: 6

Send

Delete

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

- 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 or click **Close**.

FIGURE 7. Series Details

Series Details

Series Details

Description:[suiteHEART DATA] Number:[1302] Modality:[MR] Manufacturer:[NeoSoft LLC]

SOP Instance UID	Date	Number
1.2.826.0.1.3680043.9.1400.2.1454521077....	2/3/2016 11:37:57 AM	1
1.2.826.0.1.3680043.9.1400.2.1503602990....	8/24/2017 2:29:50 PM	2
1.2.826.0.1.3680043.9.1400.2.1503603008....	8/24/2017 2:30:08 PM	3

Delete

Close

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 Preprocessing

NOTE: This section is not applicable to the NeoSoft CAKE™ application.

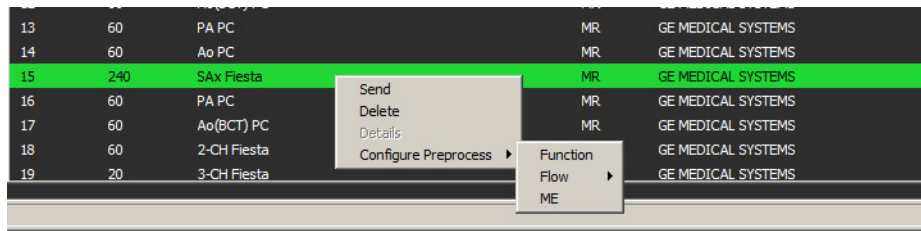
The Study Preprocessing feature is only available with the suiteHEART® Software application. This feature allows for the preprocessing of Function, Flow and Delayed Enhancement.

NOTE: suiteDXT must be open and running for preprocessing to complete.

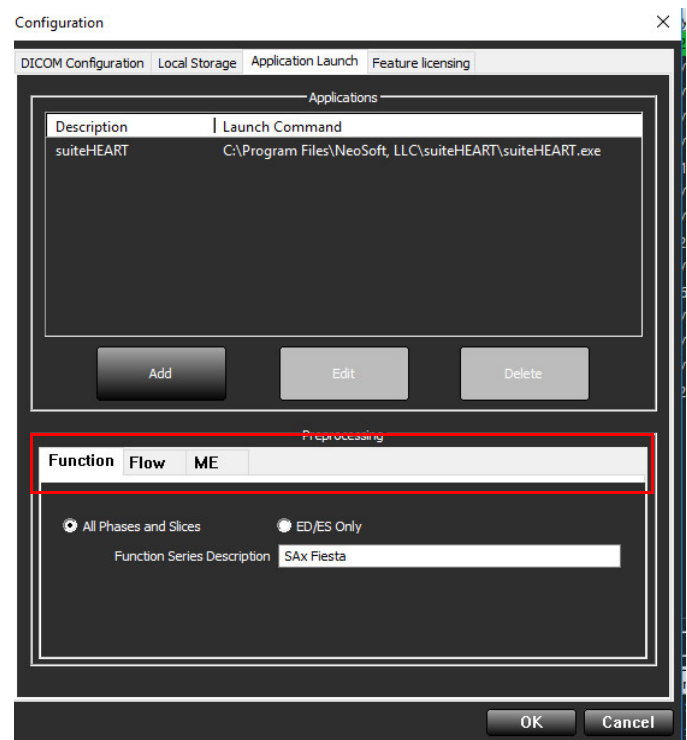
NOTE: Preprocessing will be disabled if the hardware does not meet the minimum system requirements.

Configure Preprocessing

1. On the Main Screen, select a study from the study pane.
2. Select a series from the series pane.
3. Perform a right mouse click on the series name and select the appropriate analysis type for that series. The series name will be automatically entered in the Preprocessing configuration tab.



4. Repeat for all other series types.
5. On the Main Screen, select the configuration button.
6. Select the Application Launch tab.
7. Review the Preprocessing series selections for each analysis type.
 - Changes in series names can be performed manually.
8. Click OK.



Using Preprocessing

Preprocessing can be performed for cardiac MRI studies that are being sent/pushed directly to suiteDXT from another DICOM node.

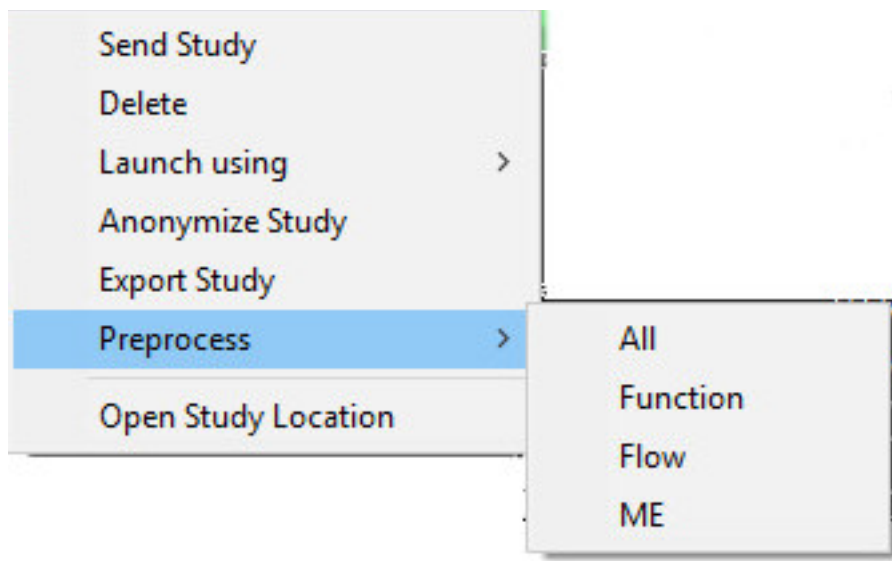
NOTE: When Preprocessing is activated, studies will not be available for viewing until the preprocessing is complete.

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

Preprocessing can be used three ways:

Study Pane

1. Select a patient from the study pane.
2. Right mouse click and choose Preprocessing from the menu.

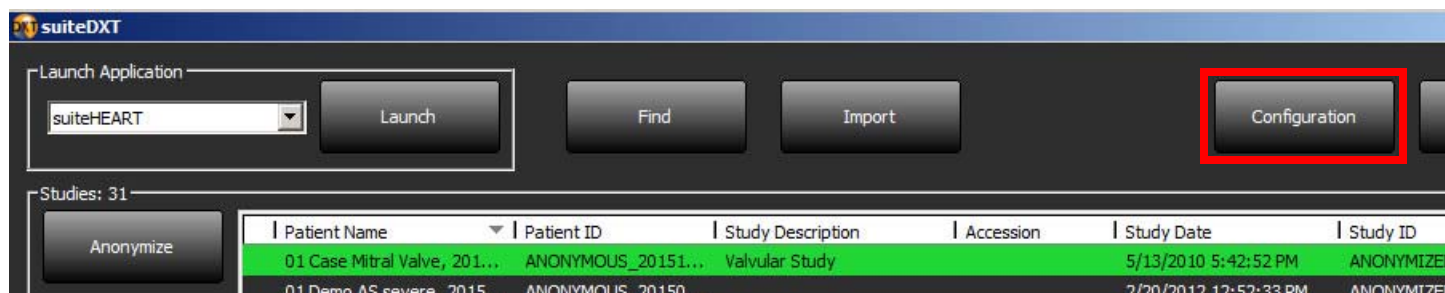


Query/Retrieve Window

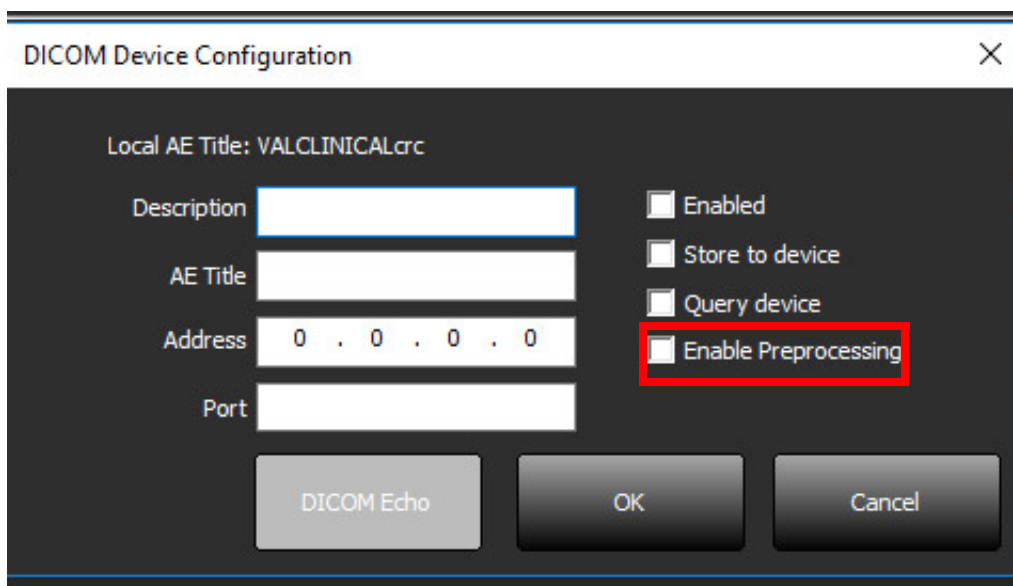
Refer to the Query/Retrieve sections in “Getting Started” and “Using suiteDXT”.

DICOM Node Send to suiteDXT

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



2. Select DICOM configuration.
3. Select the DICOM node and click Edit.
4. Select Enable Preprocessing.
5. Click OK.



The image shows a 'DICOM Device Configuration' dialog box. It has a title bar with a close button. Inside, the 'Local AE Title' is 'VALCLINICALrc'. There are input fields for 'Description', 'AE Title', 'Address' (0 . 0 . 0 . 0), and 'Port'. To the right of these fields are four checkboxes: 'Enabled', 'Store to device', 'Query device', and 'Enable Preprocessing'. The 'Enable Preprocessing' checkbox is highlighted with a red rectangle. At the bottom are three buttons: 'DICOM Echo', 'OK', and 'Cancel'.

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



suiteDXT Study Pane Indicator

Studies that have completed preprocessing 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. Studies that are identified with a red circle have failed to preprocess successfully. Please contact NeoSoft by emailing service@neosoftmedical.com

Studies: 17

	Patient Name	Patient ID	Study Description	Accession	Study Date	Study ID	Moda...	Hospital	Referring Phys
Anonymize	AllCard_2.0.0, 2014...	ANONYMOUS...	CardiacFx MDE		1/17/07 1:03:24 PM		MR		
Send	Demo T1 Mapping...	ANONYMOUS...	MRI CARDIAC		11/6/08 10:48:36 ...	ANONYMIZED	MR		
	SH Case 20, 201410...	ANONYMOUS...			1/17/07 1:03:24 PM		MR		
Delete	AllCardiacSeries, Ev...	AW689069845...	CardiacFx MDE		1/17/07 1:03:24 PM		MR	Advanced Card...	
	GH	U12005	Phantom test		1/20/05 8:32:09 A...	4651	MR	Advanced Card...	
	Anon4007, Test	AW143292942...	MRFP SP		6/5/08 11:58:55 A...	4007	MR	Advanced Card...	
	Demo Edema Inf In...	AW336533028...			1/13/14 12:00:00 ...	0000	MR		

Series: 3

	Series #	Images	Description	Moda...	Manufacturer
Send	21	60	Normal	MR	GE MEDICAL SYSTEMS
Delete	22	61	c ON slice	MR	GE MEDICAL SYSTEMS
	23	60	All Only	MR	GE MEDICAL SYSTEMS

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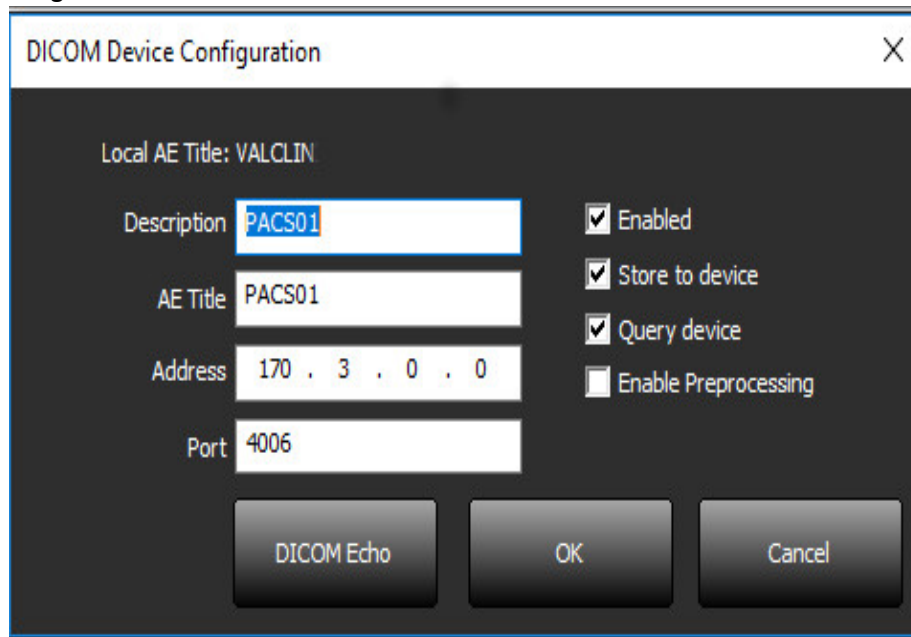
Service and Support

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 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.
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.

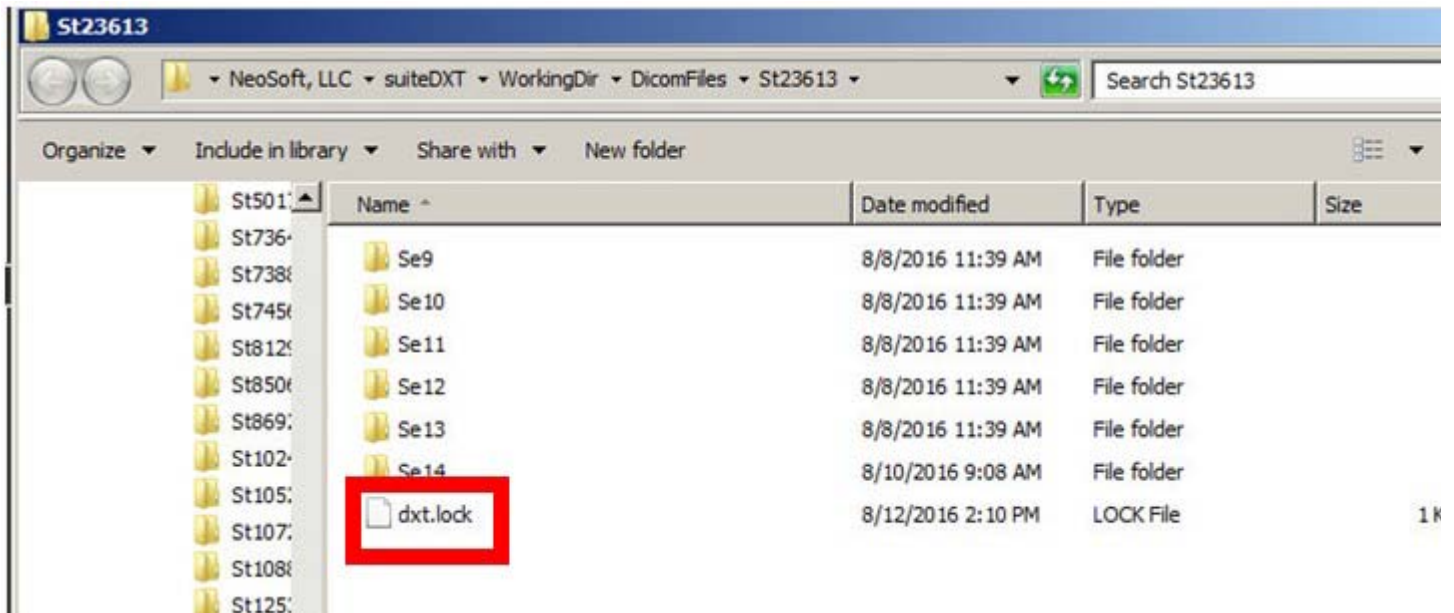
Study Launch Error

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 suiteDXT study directory.
2. Right-mouse click on the study that produced the error message.
3. Select "Open Study Location."
4. Delete 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

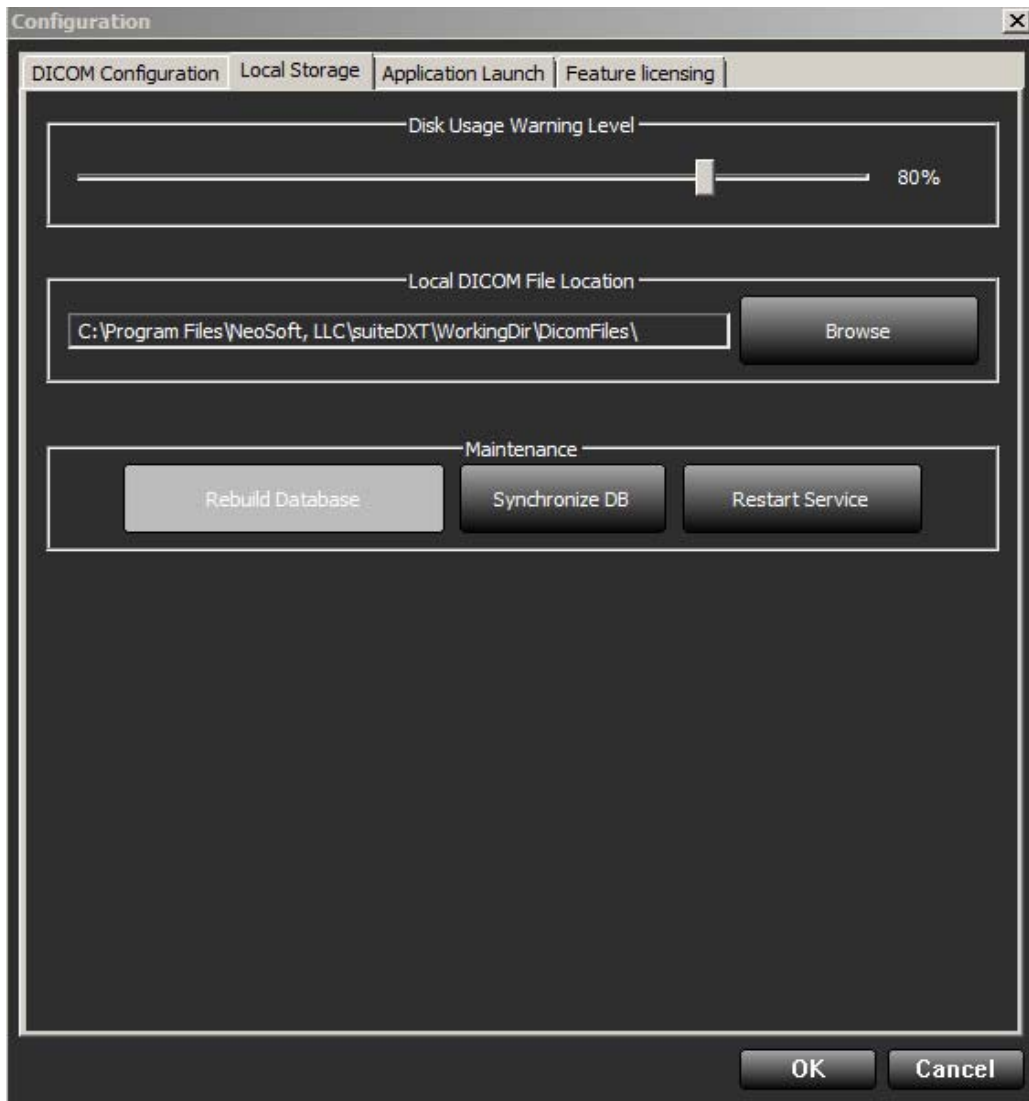


Restart Service

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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