suiteDXT

Instructions for Use

NeoSoft, LLC

NS-03-039-0008 Rev. 6
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Revision History

Rev	Date	Description of Change	Safety Related Update (Yes/No)
1	23APR2019	Updated for the 5.0.0 product release. Previous manual NS-03-009-0001, Rev 12	No
2	22NOV2019	Updated for the 5.0.1 product release.	No
3	12AUG2020	CE Mark update.	No
4	19OCT2020	Updated for the 5.0.2 product release.	No
5	5JAN2021	Added Malaysian authorized representative.	No
6	11JUNE2021	Added MD symbol, importer reference, serious incident reporting note.	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, EL - Greek, IT - Italian, LT - Lithuanian, ES - Spanish, SV - Swedish, TR - Turkish, RO - Romanian, NL - Dutch, PT-PT - Portuguese, HU - Hungarian.
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, EL - Greek, IT - Italian, LT - Lithuanian, ES - Spanish, SV - Swedish, TR - Turkish, RO - Romanian, NL - Dutch, PT-PT - Portuguese, HU - Hungarian.
4. Electronic copies of Instructions for Use are also available at www.neosoftllc.com/neosoft/product_manuals/ for at least 15 years from last date of manufacture.

Medical device regulation

This product conforms with the requirements of Medical Device Regulation (EU) 2017/745 concerning medical devices when it bears the following CE mark of Conformity:

CE

This product is a Medical Device: MD

European Representatives:

EC REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

EU Importer:

MedEnvoy Global B.V.
Pr. Margrietplantsoen 33, Suite 123,
2595 AM The Haag,
The Netherlands

Canada:

Health Canada device license number: 99490

Malaysian Medical Device Registration Number: GB10979720-50888

Malaysia Authorized Representative:
Emergo Malaysia Sdn. Bhd.
Level 16, 1 Sentral Jalan Stesen Sentral 5 KL Sentral, 50470
Kuala Lumpur MALAYSIA

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

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* ***9***
- *Send Study to Remote Host* ***9***
- *Send Series to Remote Host* ***10***
- *Study Pane Indicators* ***10***
- *Send NeoSoft DICOM Files* ***11***
- *Import Studies* ***11***
- *Export Studies* ***11***
- *Perform a Search* ***12***
- *Create Folders* ***13***
- *Anonymize a Study* ***14***
- *Delete Protection* ***14***
- *Delete a Study* ***15***
- *Delete a Series* ***15***
- *Delete Secondary Capture Series* ***15***
- *About suiteDXT* ***16***

Study Preprocessing **17**
- *Configure Preprocessing* ***17***
- *Using Preprocessing* ***18***
- *Study Pane Indicators* ***19***

Virtual Fellow® **20**
Turning Virtual Fellow® On/Off ***20***
Image Preview Window ***21***

Service and Support **22**
DICOM Network Failure ***22***
Study Launch Error ***23***
Restart Service ***24***
Contact ***24***

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.

Any serious incident that has occurred in relation to this device should be reported to NeoSoft and the competent authority of your Member State.

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 will 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 may 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 can cause minor personal injury or property damage if the instructions are ignored.

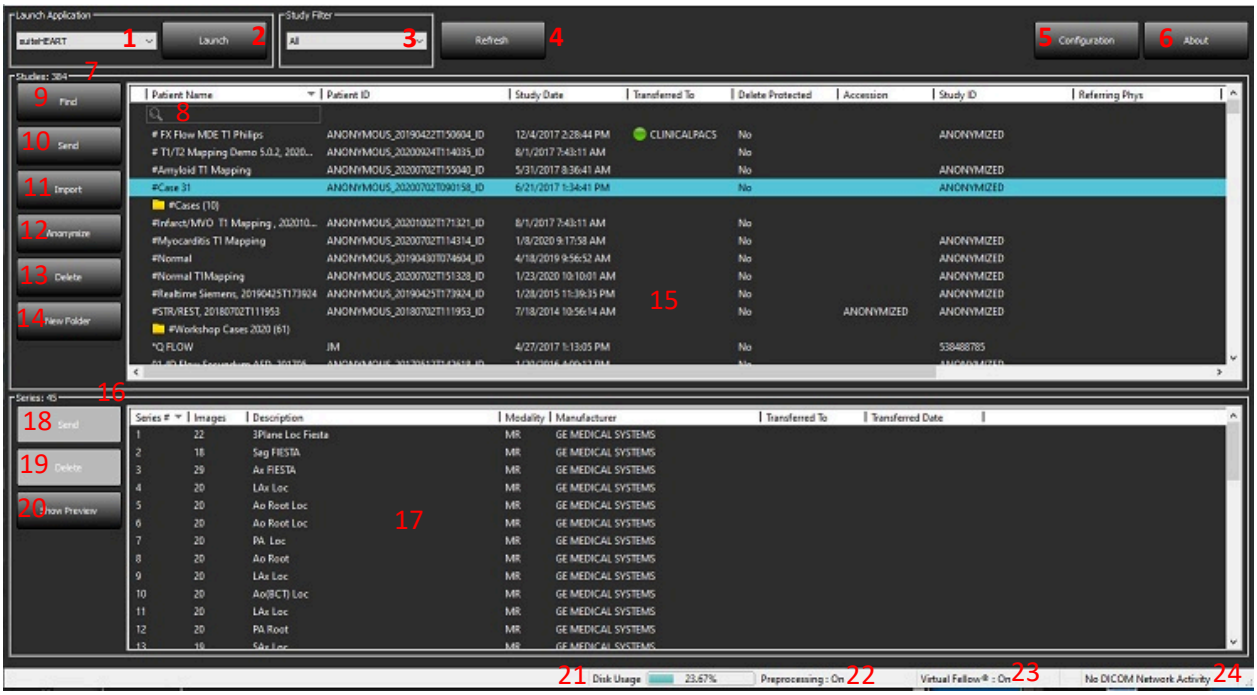
Equipment Hazards

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.

Main Screen Functions

FIGURE 1. Main Screen

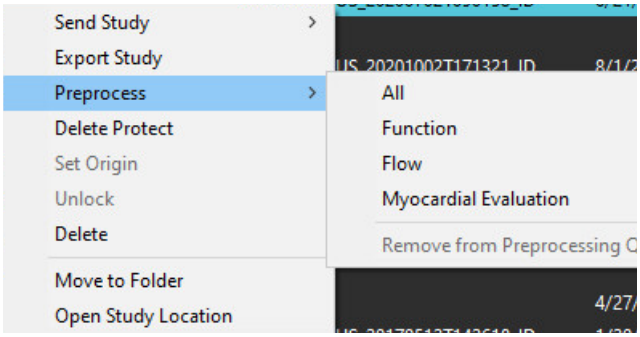


1. **Launch Application pull-down Menu** - lists configured applications.
2. **Launch** - launches configured NeoSoft, LLC applications.
3. **Study Filter** - defines the date range for which studies are displayed in the study list.
4. **Refresh** - updates the view based on the user selected criteria.
5. **Configuration** - opens Configuration Window.
6. **About** - 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. **Search Field** - automatically search under any column, with or without being sorted.
9. **Find** - opens Query/Retrieve Window.
10. **Send** - pushes local study to remote host.
11. **Import** - allows study information to be imported from the file system, CD, DVD or USB media.
12. **Anonymize** - creates a new study with patient specific data removed.
13. **Delete** - removes study from suiteDXT study list and deletes DICOM data from local host.
14. **New Folder** - creates a folder to organize studies.
15. **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.

16. **Series Headline** - displays number of series in a selected study.
17. **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.
18. **Send** - pushes local series to remote host.
19. **Delete** - removes a series from the selected study and deletes DICOM data.
20. **Show Preview** - previews suiteHEART Virtual Fellow®, CAS cine, and CAS report series.
21. **Disk Usage Indicator** - shows percentage of total local disk space used.
22. **Preprocessing Status** - indicates the current configuration status of preprocessing (On/Off).
23. **Virtual Fellow® Status Indicator** - indicates the current configuration status of Virtual Fellow® (On/Off).
24. **Network Status** - shows if suiteDXT is currently transferring DICOM data over the network.

Right Mouse Click Menu in Study Pane

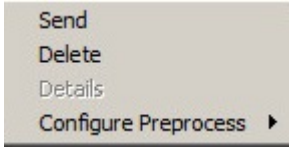
FIGURE 2. Right Mouse Click Menu



- **Send Study** - pushes study from local host to remote host. Can be configured to only send NeoSoft DICOM series. (See Installation manual)
- **Export Study** - saves the study data, for a selected group of studies, in a compressed .zip file.
- **Preprocess** - preprocesses all configured series or only Function, Flow or Myocardial Evaluation; to remove the study from the queue, select “Remove from Preprocessing Queue.”
- **Delete Protect** - set Delete Protect for a study (Yes/No)
- **Set Origin** - used by your network administrator to set the AE title for access control.
- **Unlock** - reset the lock and open a locked study after a system crash.
- **Delete** - removes study from suiteDXT study list and deletes DICOM data from local host.
- **Move to Folder** - move study to a created folder.
- **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

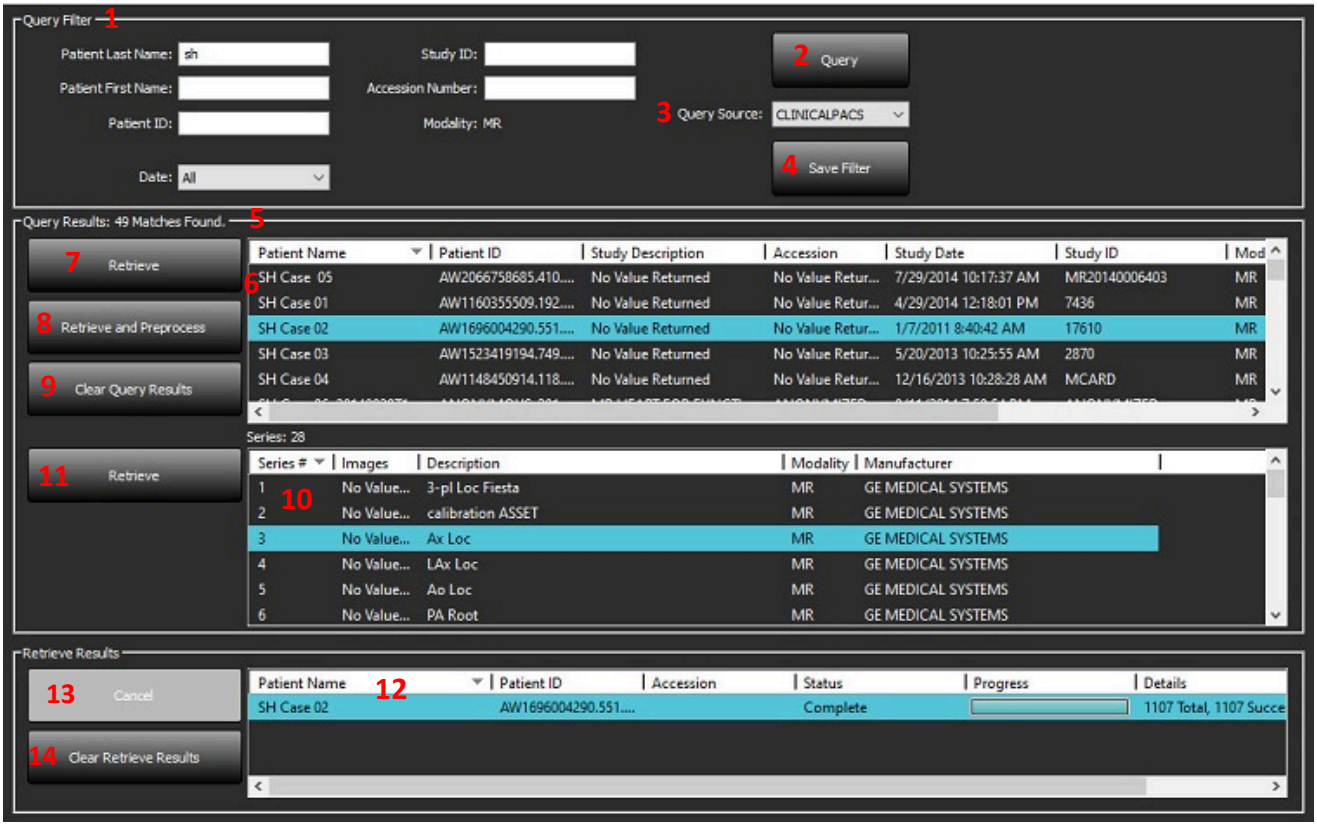


- **Send** - pushes local series to remote host.
- **Delete** - removes a series from the selected study and deletes DICOM data.
- **Details** - opens the series details window.
- **Configure Preprocess** - auto fills the series name for a Function, Flow or Myocardial Evaluation series.

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

Query/Retrieve Window

FIGURE 3. Query/Retrieve Window

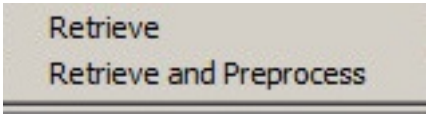


1. **Query Filter** - can be used to search for specific studies by Patient First and Last Name, Patient ID, Study ID, Accession Number, and Date. The * (asterisk) may be used as a wild card in any field (except date).
2. **Query** - executes query of remote device. If all fields are left blank, query will return all results.
3. **Query Source Pull-down Menu** - displays configured remote devices available to query / retrieve.
4. **Save Filter** - 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. **Retrieve** - executes retrieval of the selected study from remote device.
8. **Retrieve and Preprocess** - executes retrieval and preprocessing of the selected study from the remote device.
9. **Clear Query Results** - clears query results in study pane.
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** - 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. **Cancel** - stops the transfer activity.
14. **Clear Retrieve Results** - 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.

Right Mouse Click Menu in Query/Results Pane

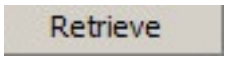
FIGURE 4. Right Mouse Click Menu



- **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



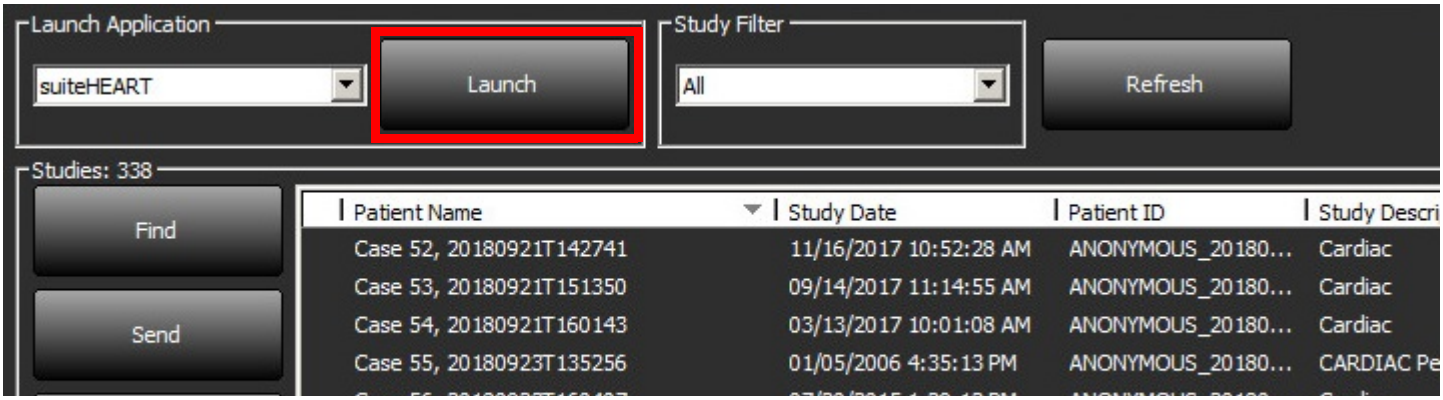
- **Retrieve** - executes retrieval of series from a remote host.

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



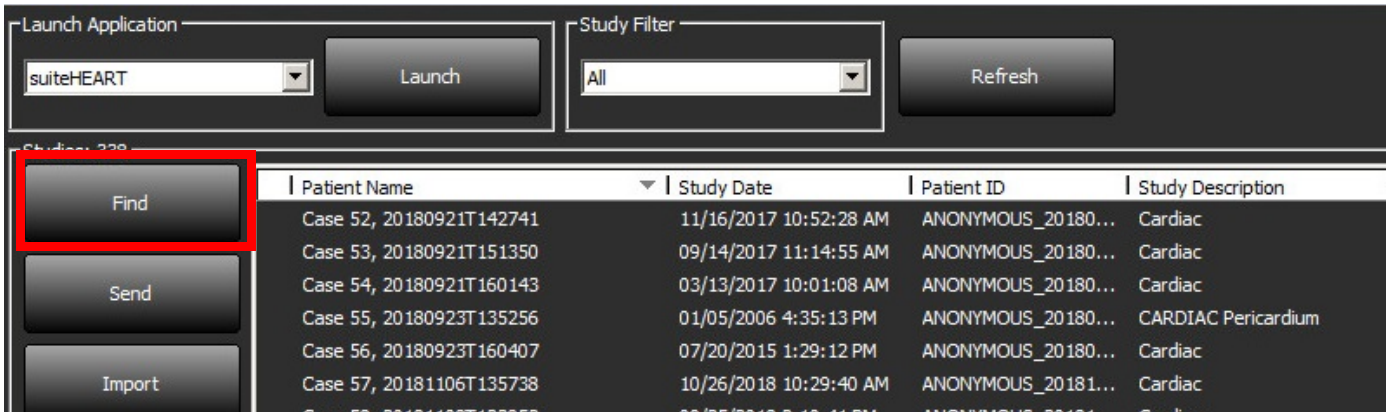
3. Select a study from the study list and do one of the following:
   - Select Launch.
   - Double click the study.

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 Find on the Main Screen.

FIGURE 2. Find on Main Screen

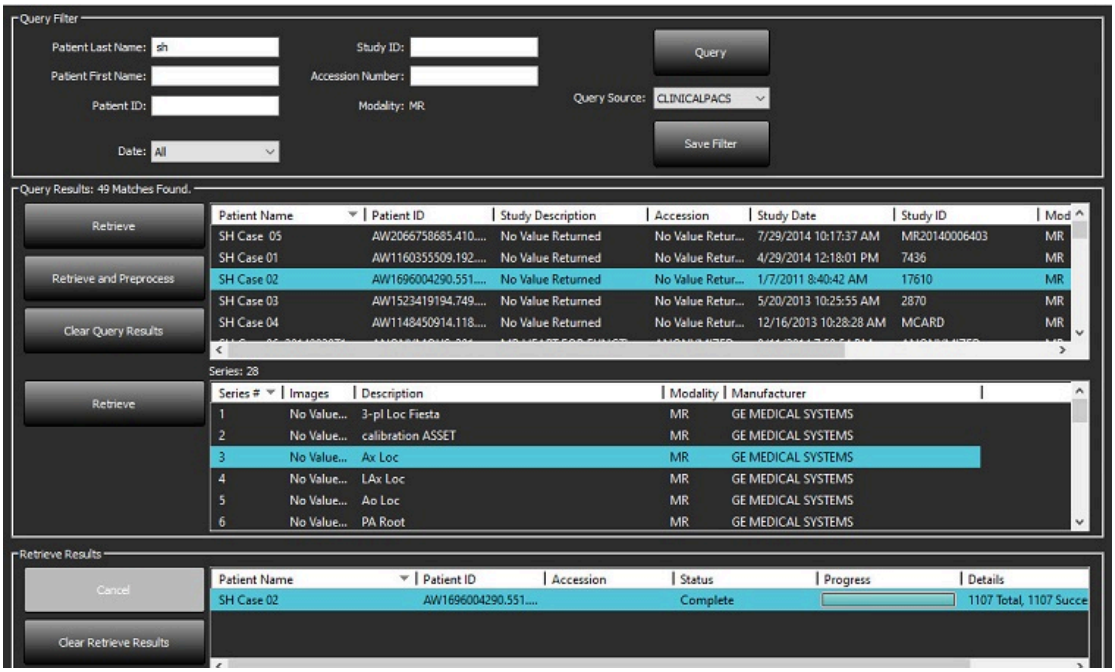


2. In the Query/Retrieve Window enter any study information criteria in the Query Filter area.

   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 Query.

   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 Retrieve 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.
8. To retrieve by series, select the series and click the Retrieve 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 Save Filter. 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.

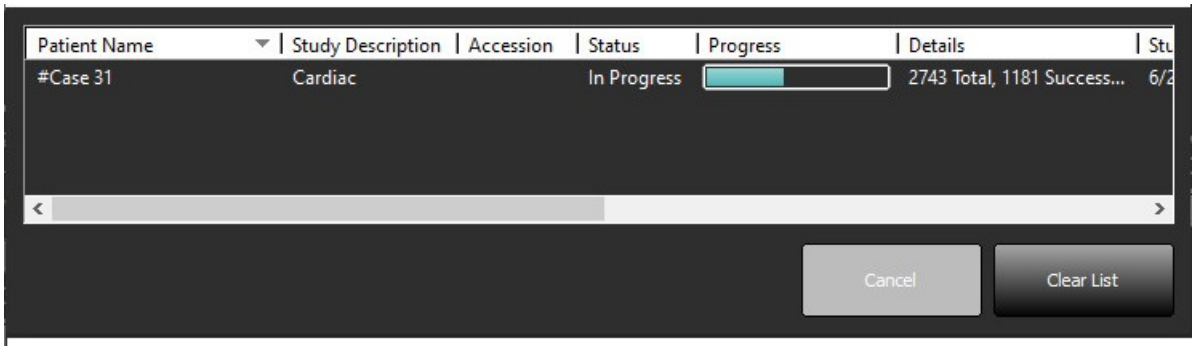
NOTE: suiteDXT supports JPEG Lossless compression, however subsets of this format are not supported.

1. Highlight the study to send.
2. Select Send or right mouse click and choose Send Study from the pop-up menu.
3. Select the destination to which to send.
4. Select Send on the pop-up window.

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

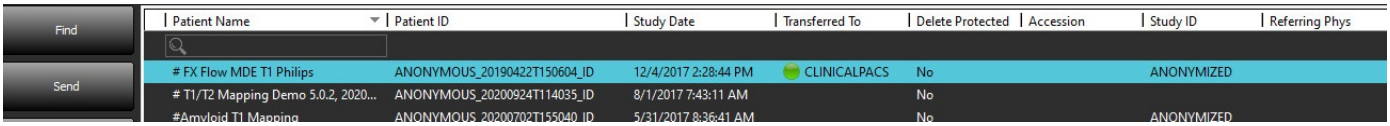
To check the progress once the DICOM Send window is closed, select Send, then select Status.

FIGURE 4. DICOM Send Window



5. Studies that have been transferred successfully will show the Remote Host in the Transferred To column on the main study listing.

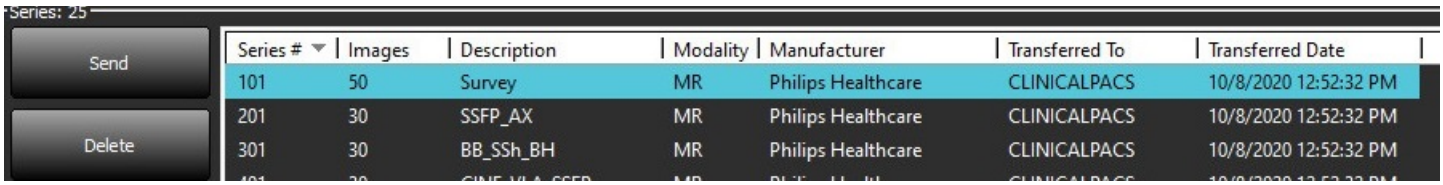
FIGURE 5. Transferred To



Send Series to Remote Host

1. Highlight the study.
2. Highlight the required series.
3. Select Send or right mouse click and choose Send from the pop-up menu.
4. Select the destination to which to send.
5. Select Send on the pop-up window.
6. Series that have been transferred successfully will show the Remote Host in the Transferred To column in the series pane.

FIGURE 6. Transfer Series Pane



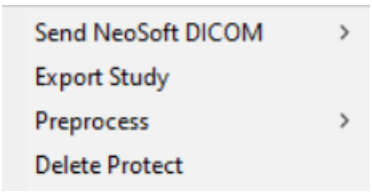
Study Pane Indicators

Indicator	Status
Light blue circle	Incomplete transfer of images or images have been transferred to multiple remote hosts.
Green circle	All images in the study have been transferred to a single remote host.

Send NeoSoft DICOM Files

Files that are created by the software can be networked separately. Refer to the Installation Manual for configuration.

1. Highlight the study.
2. Right mouse click and select Send NeoSoft DICOM.
3. Select the DICOM destination.



Import Studies

Studies containing DICOM data can be imported from the local file system, mapped drives, CD, DVD and USB; including the importing of zipped folders. 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 Import.
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.

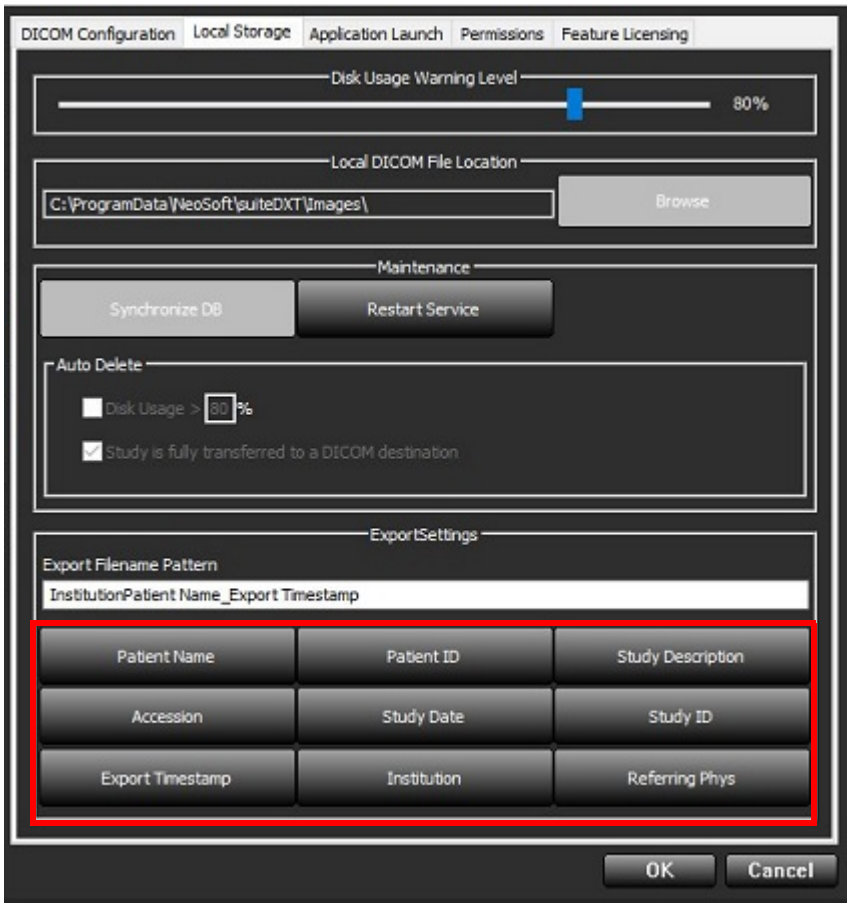
NOTE: If the study does not import completely, click the Retry on the Import Summary screen.

Export Studies

Studies that have been analyzed can be exported from the main study directory as a .zip file.

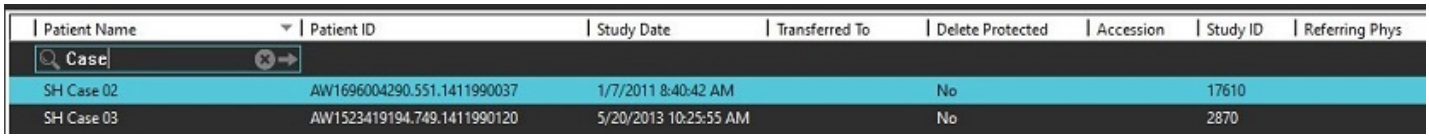
1. Highlight the study or select a group of studies using Ctrl +Shift.
2. Right mouse click and select Export.
3. Customize the file name by clicking Configuration > Local Storage tab.
4. Select the desired file attributes as shown in Figure 7.

FIGURE 7. Export Filename Pattern



Perform a Search

Each column can be automatically searched with or without being sorted. The search is not case sensitive and will automatically bring results to the top of the list.



- After obtaining the first result, pressing the ENTER key on the keyboard or the arrow in the search field will advance to the next result.
- Simultaneously pressing ENTER and the SHIFT key on the keyboard will select the previous result.
- Pressing the ENTER key, with or without the SHIFT key, on the keyboard when the end of the results are reached will return you to the start of the search results.
- The search field will be cleared after pressing .

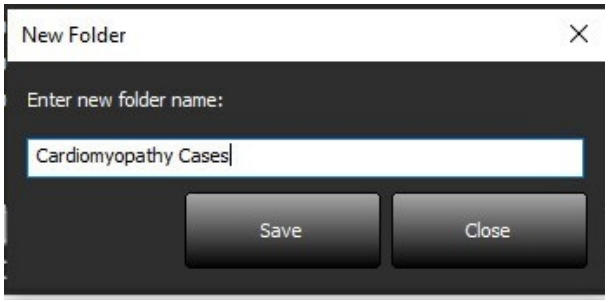
NOTE: For the search to include folders in the study listing the folders must be expanded. Right mouse click on the folder and select Expand All.

Create Folders

Folders can be created to organize studies at the study listing level.

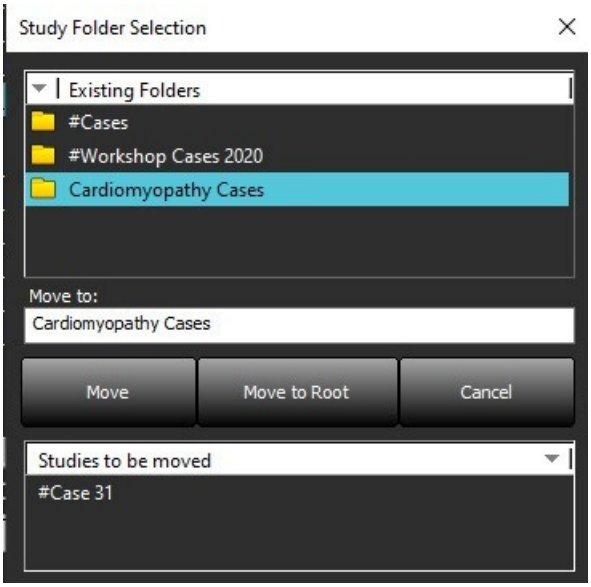
1. Click New Folder.
2. Type in a folder name and click Save.

   The folder will now be in the study listing.



3. Move a study to the folder by right mouse clicking on the study and selecting Move to Folder.
4. When the Folder dialog box opens, select the correct folder into which to move the study.

FIGURE 8. Folder Selections



1. Move the study back to the main directory by clicking on the study and selecting Move to Folder.
2. Click Move to Root.

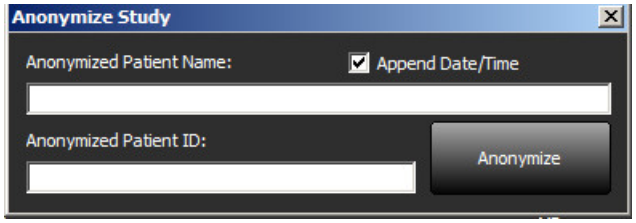
Anonymize a Study

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 Anonymize.
3. Enter an anonymized patient name, patient ID.
4. To append the date and time of the anonymization click Append Date/Time.
5. Click Anonymize to confirm anonymization.

FIGURE 9. Anonymized Patient Name



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

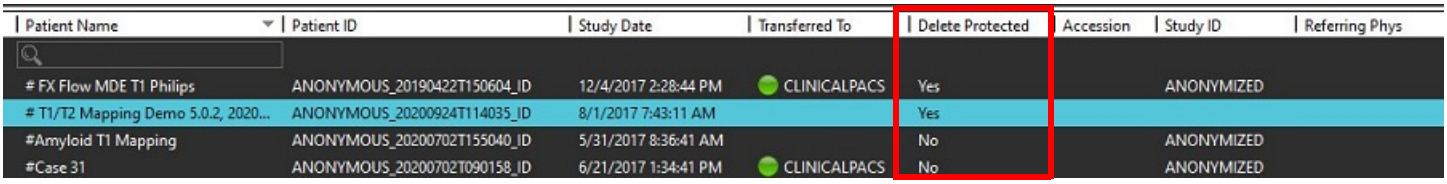
6. Click “OK” on the Anonymize Study pop-up.

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

Delete Protection

To set delete protection for a study, right mouse click on the study and select Delete Protect. The indicator column will display “Yes” for studies that are protected and “No” for those that are not, as shown in Figure 10. To turn off delete protect right mouse click and select Remove Delete Protection.

FIGURE 10. Delete Protect Column Indicator



Patient Name	Patient ID	Study Date	Transferred To	Delete Protected	Accession	Study ID	Referring Phys
# FX Flow MDE T1 Philips	ANONYMOUS_20190422T150604_ID	12/4/2017 2:28:44 PM	CLINICALPACS	Yes		ANONYMIZED	
# T1/T2 Mapping Demo 5.0.2, 2020...	ANONYMOUS_20200924T114035_ID	8/1/2017 7:43:11 AM		Yes			
#Amyloid T1 Mapping	ANONYMOUS_20200702T155040_ID	5/31/2017 8:36:41 AM		No		ANONYMIZED	
#Case 31	ANONYMOUS_20200702T090158_ID	6/21/2017 1:34:41 PM	CLINICALPACS	No		ANONYMIZED	

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 Delete 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 Delete. 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.

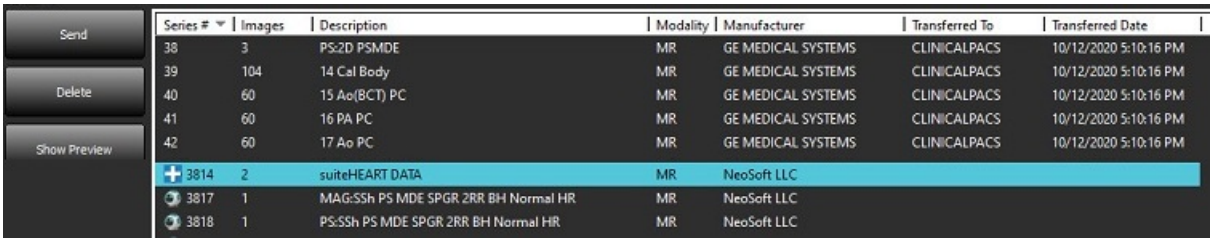
Delete Secondary Capture Series

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.

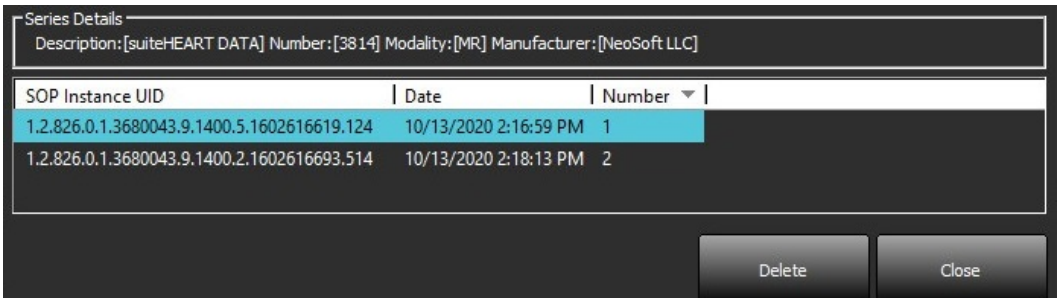
1. Select the study and locate the suiteHEART DATA series.
2. Click on the series number or + icon to open the Series Details window.

FIGURE 11. Series Select



3. Select the appropriate row, click Delete. To close, click on the X (upper right hand corner of the window) or click **Close**.

FIGURE 12. Series Details



About suiteDXT

Selecting About 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 13. About Screen

Study Preprocessing

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

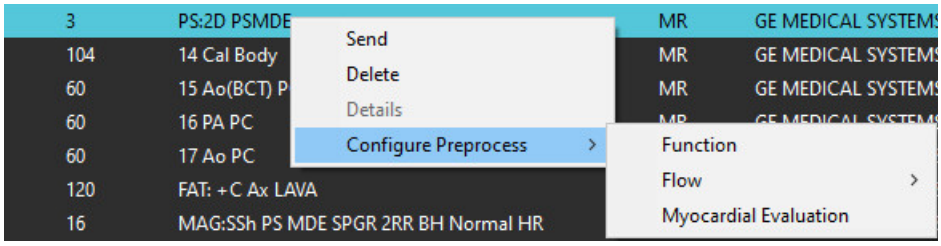
The Study Preprocessing feature is only available with the suiteHEART® Software application. This feature allows for the preprocessing of Function, Flow and Myocardial Evaluation. Preprocessing can be used in conjunction with the Virtual Fellow® feature.

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

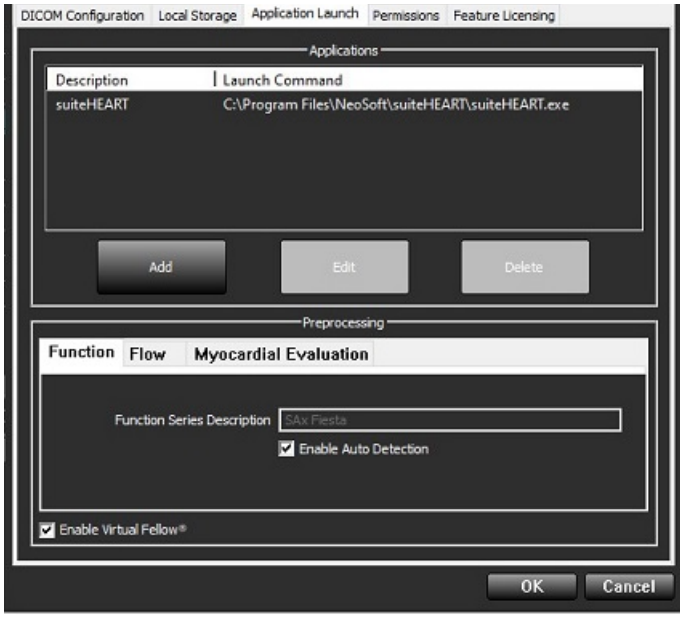
NOTE: Preprocessing will be disabled if the hardware does not meet the minimum system requirements.

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 configuration.
6. Select the Application Launch tab.
7. Review the Preprocessing series selections for each analysis type.
   - Changes in series names can be performed manually.
   - If “Enable Auto Detection” is checked, the user defined series will be ignored for the preprocessing.
8. Check “Enable Virtual Fellow®” to perform image optimization.
9. Click OK.



Using Preprocessing

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

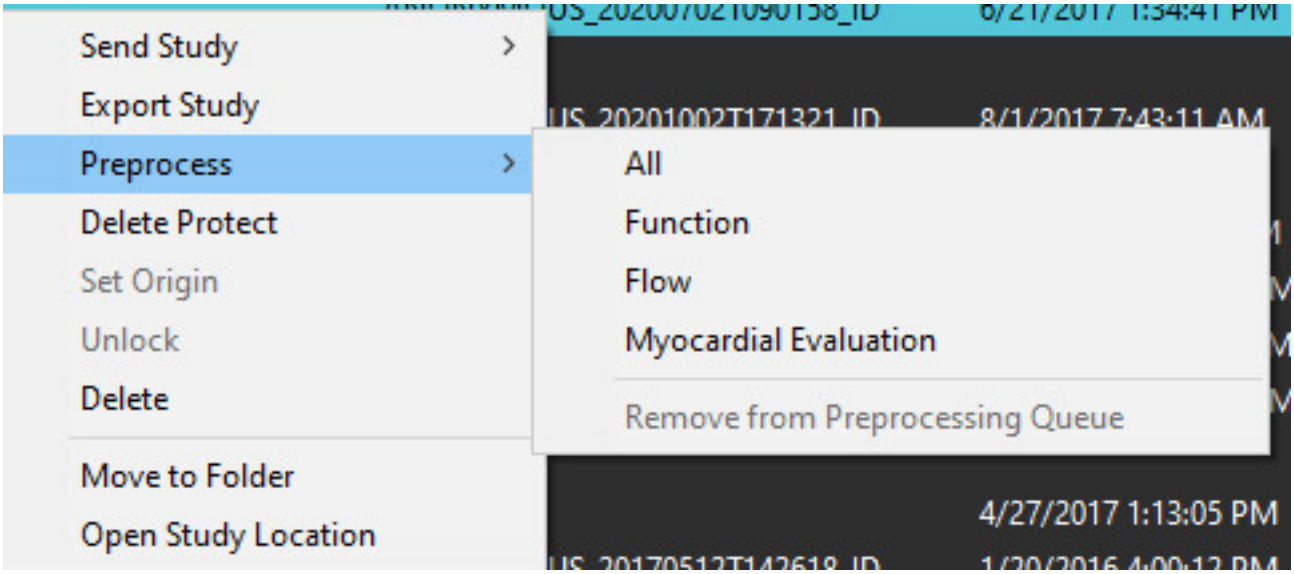
NOTE: When Preprocessing is activated, studies will not be available for viewing until the preprocessing is complete.

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 Preprocess from the menu.

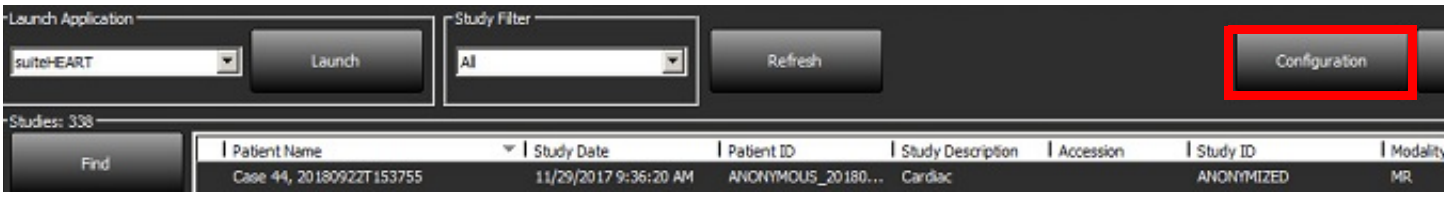


Query/Retrieve Window

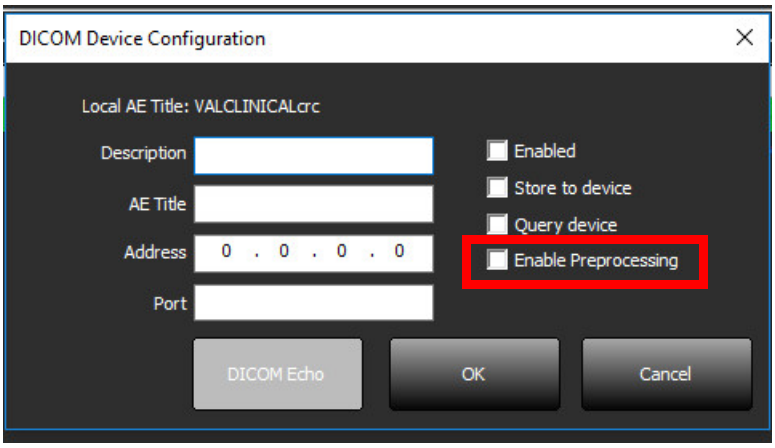
Refer to the Query/Retrieve sections in “Getting Started” and “Using suiteDXT”.

DICOM Node Send to suiteDXT

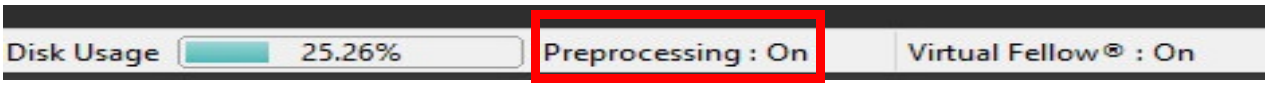
1. On the Main Screen, select Configuration.



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

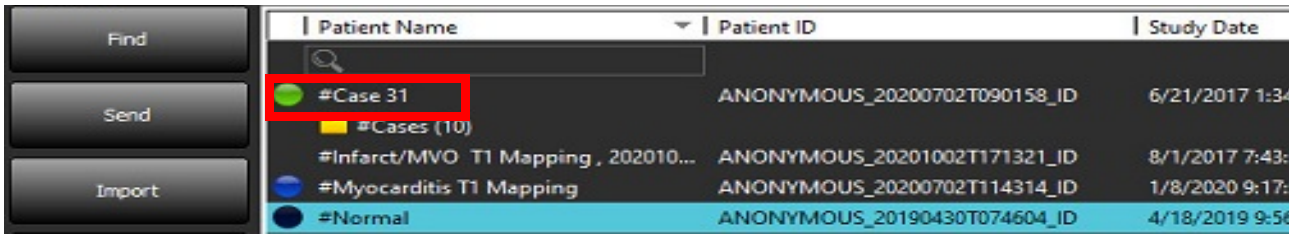


When "Enable Preprocessing" is checked and preprocessing is configured then a "Preprocessing: ON" indicator will be displayed in the status panel.



Study Pane Indicators

Indicator	Status
Light blue circle	Study is being preprocessed.
Dark blue circle	Study in queue.
Green circle	Preprocessing complete. Indicator will remain until the study has been opened or suiteDXT has been restarted.
Red circle	Preprocessing failed, contact NeoSoft by emailing service@neosoftmedical.com



Turning Virtual Fellow® On/Off

From the suiteDXT main screen click configuration to select “Application Launch” tab. Check “Enable Virtual Fellow®” to perform image optimization.

FIGURE 1. suiteDXT Configuration Screen

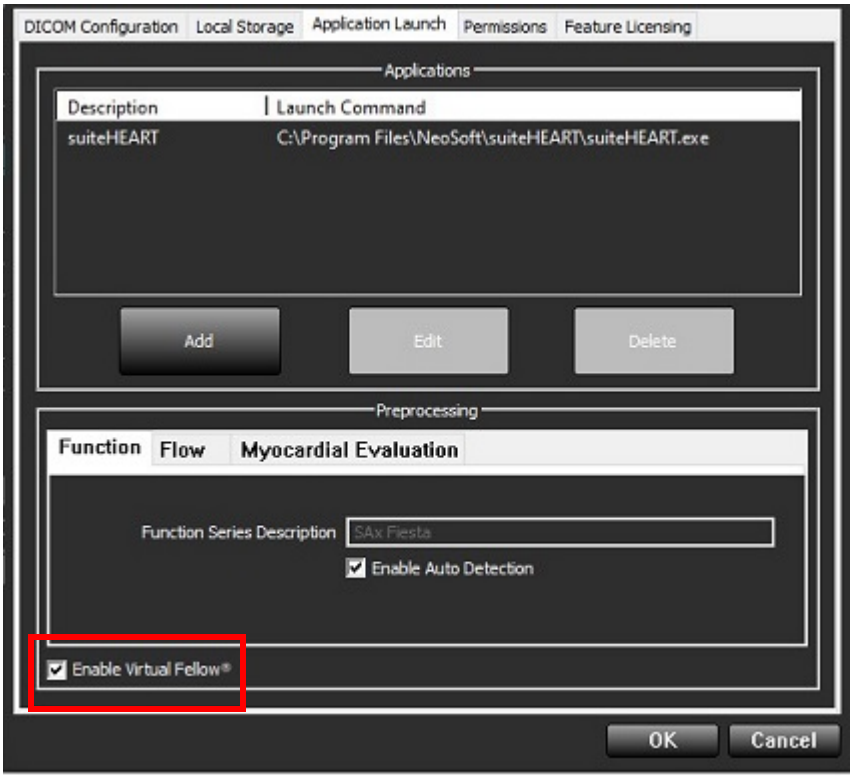


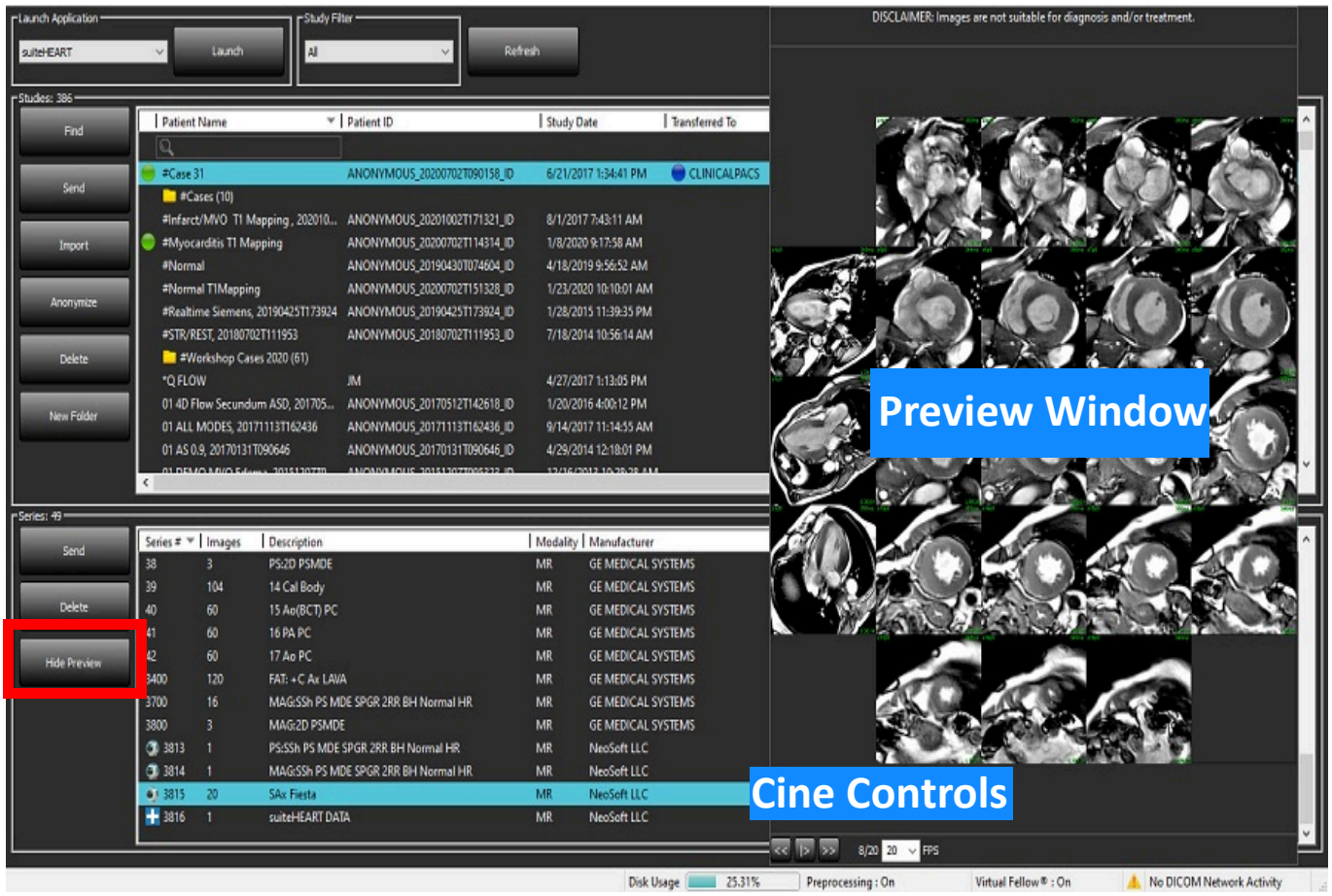
Image Preview Window

WARNING: Images are not suitable for diagnosis and/or treatment.

From the suiteDXT main screen, toggle the preview window to show or hide.

NOTE: If the study selected contains, suiteHEART Virtual Fellow®, CAS Cine, and/or CAS Report series, these series will automatically display in the preview window, as shown in Figure 2.

FIGURE 2.

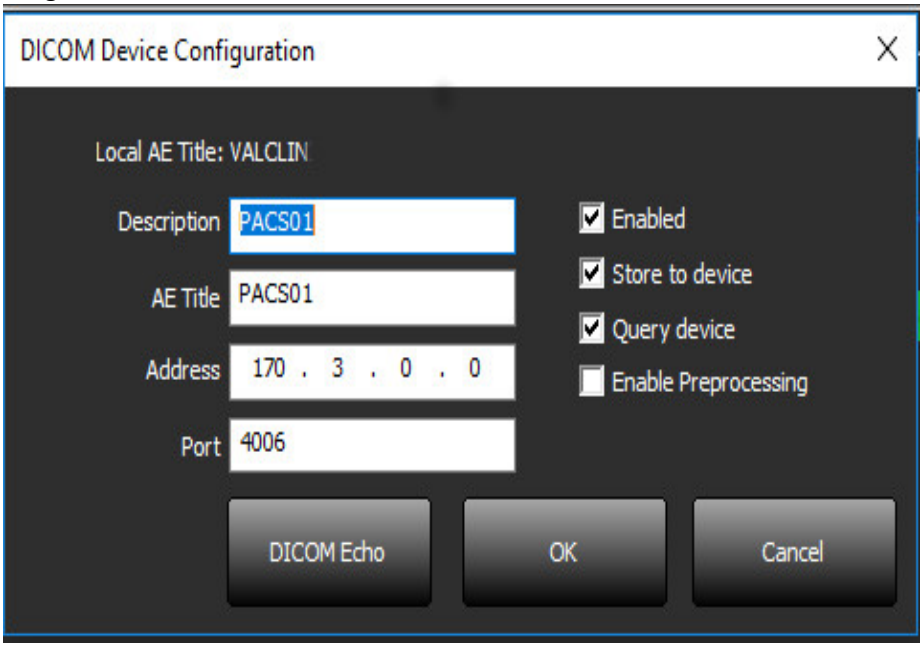


DICOM Network Failure

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 Configuration.
2. On the DICOM Configuration tab, select the remote host from which the retrieval was attempted and select Edit.
3. Select the checkboxes for: Enable, Store to device and Query device.
4. Verify that the IP address, Port, and AE title for the DICOM Destination are correct.

FIGURE 1. DICOM Configuration Window



5. Select DICOM Echo.
6. Check the network settings and confirm that the selected port 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.

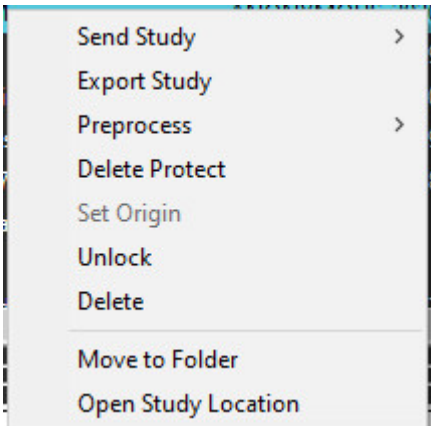
Study Launch Error

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 “Unlock”

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. Unlock Study

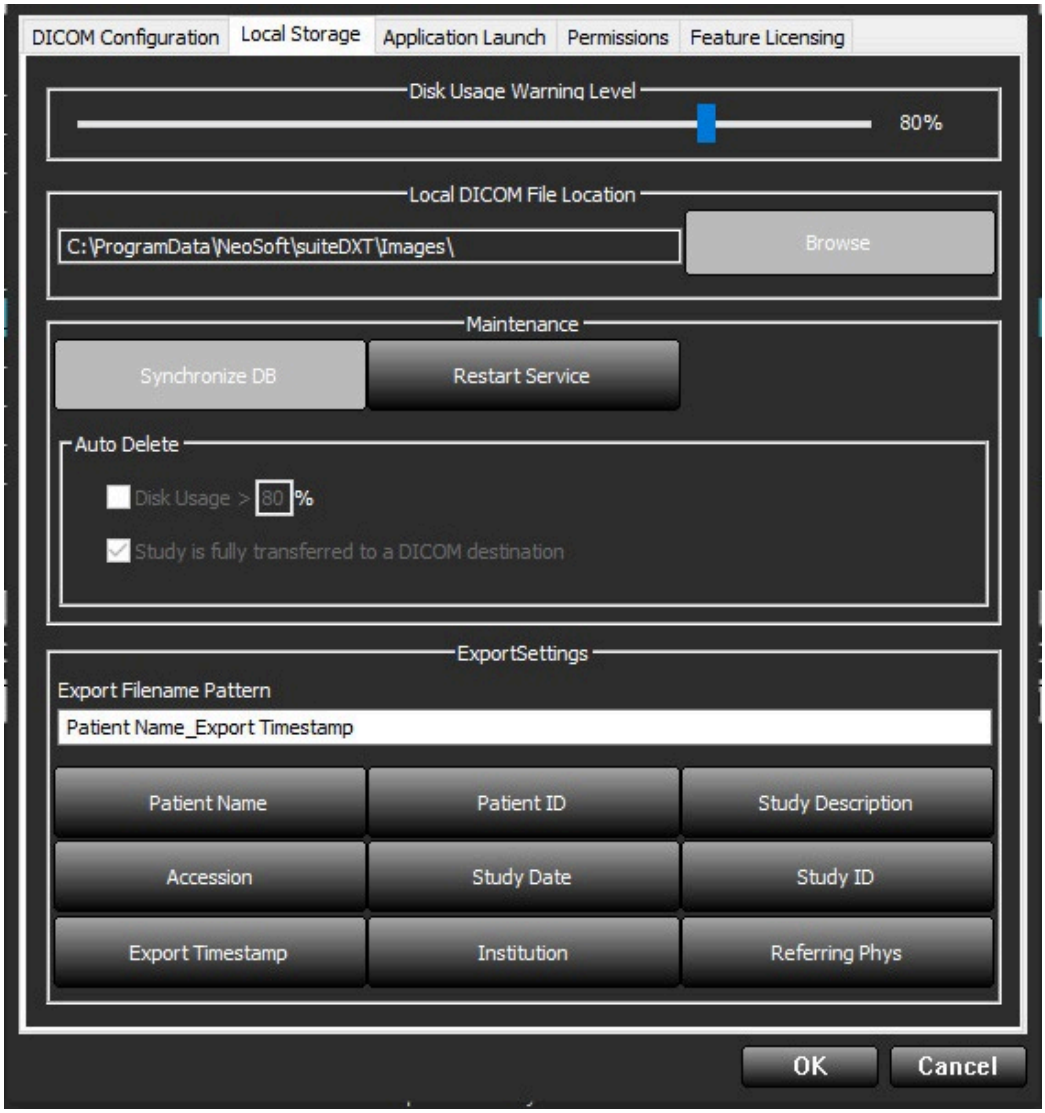


Restart Service

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

1. From the Main Screen, select Configuration.
2. Select the Local Storage tab.
3. Click Restart Service.

FIGURE 3. Restart Service



Contact

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