suiteHEART® Software

Service Manual

NeoSoft, LLC

Revision History

Rev	Date	Description of Change	Safety Related Update (Yes/No)
1	13Oct2022	Initial creation for 5.1.0.	No
2	15Sep2023	Updated for 5.1.1 release	No
3	04Apr2025	Updated for 5.1.2 release	No

Manufacturer

NeoSoft, LLC
N27 W23910A Paul Road
Pewaukee, WI 53072 USA

Phone: 262-522-6120
website: www.neosoftllc.com

Sales: orders@neosoftmedical.com
Service: service@neosoftmedical.com

Table of Contents

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.

⚠️

CAUTION: Federal Law restricts this device to sale, distribution and use by or on the order of a physician.

⚠️

CAUTION: This software is limited by Federal Law to investigational use for indications not in the Indications Statement.

Safety 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.
⚠️ CAUTION:	Caution is used to identify conditions or actions for which a potential hazard is known to exist.

Indications for Use

suiteHEART® Software is an analytical tool, which provides reproducible tools for the review and reporting of medical images. suiteHEART® Software can import medical images from a MR system and display them in a viewing area on the computer screen. The viewing area allows access to multiple studies and series of multi-slice, multi-phase images. Multi-phase sequences of images can be displayed in cine mode to facilitate visualization.

⚠️

CAUTION: Data stored as a DICOM image that has been imported by an external PACS may be ignored by suiteHEART® Software.

A report input interface is also available. Measurement tools on the report interface make it possible to quickly and reliably fill out a complete clinical report of an imaging exam. Available tools include: point, distance, area, and volume measurement tools such as ejection fraction, cardiac output, end-diastolic volume, end-systolic volume, and volume flow measurements.

Semi-automatic tools are available for left ventricular contour detection, valve plane detection, vessel contour detection for flow analysis, signal intensity analysis for myocardium and infarct sizing measurement, and T2 star analysis.

The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians.

When interpreted by a trained physician these tools may be useful in supporting the determination of a diagnosis.

Safety Notices

⚠️

WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

⚠️

WARNING: Artifacts on an image can be misinterpreted, leading to inaccurate results. Do not use images containing artifacts for diagnosis. Analysis should only be performed by a properly trained and qualified user.

⚠️

WARNING: Diagnosis for the wrong patient could occur if images do not contain patient name or ID. Do not use images that do not contain patient name and ID for diagnosis. Visually confirm the patient information prior to analysis.

⚠️

CAUTION: Using images upon which an image filter has been applied could result in inaccurate results. The user must exercise discretion before analyzing pixel intensity corrected images. The software will display a warning message if loading images that have been filtered.

Equipment Hazards

⚠️

CAUTION: Using equipment that is damaged or has been compromised can put the patient at risk due to delay in diagnosis. Make sure that equipment is in proper working order.

⚠️

CAUTION: Application runs 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.

Overview

Available Documentation

suiteDXT	
NS-03-043-0004-EN Instructions for Use - English	NS-03-043-0004-ES Instructions for Use - Spanish
NS-03-043-0004-NL Instructions for Use - Dutch	NS-03-043-0004-SV Instructions for Use - Swedish
NS-03-043-0004-FR Instructions for Use - French	NS-03-043-0004-TR Instructions for Use - Turkish
NS-03-043-0004-DE Instructions for Use - German	NS-03-043-0004-VI Instructions for Use - Vietnamese
NS-03-043-0004-EL Instructions for Use - Greek	NS-03-043-0004-ZH-CN Instructions for Use - Chinese
NS-03-043-0004-HU Instructions for Use - Hungarian	NS-03-043-0004-PT-BR Instructions for Use - Brazilian Portuguese
NS-03-043-0004-IT Instructions for Use - Italian	NS-03-043-0004-JA Instructions for Use - Japanese
NS-03-043-0004-LT Instructions for Use - Lithuanian	NS-03-043-0004-ET Instructions for Use - Estonian
NS-03-043-0004-PT-PT Instructions for Use - Portuguese	NS-03-039-0018 DICOM Conformance Statement - English
NS-03-043-0004-RO Instructions for Use - Romanian	NS-03-043-0012 Release Notes - All languages

suiteHEART® Software	
NS-03-043-0003-EN Instructions for Use - English	NS-03-043-0003-SV Instructions for Use - Swedish
NS-03-043-0003-NL Instructions for Use - Dutch	NS-03-043-0003-TR Instructions for Use - Turkish
NS-03-043-0003-FR Instructions for Use - French	NS-03-043-0003-VI Instructions for Use - Vietnamese
NS-03-043-0003-DE Instructions for Use - German	NS-03-043-0003-ZH-CN Instructions for Use - Chinese
NS-03-043-0003-EL Instructions for Use - Greek	NS-03-043-0003-PT-BR Instructions for Use - Brazilian Portuguese
NS-03-043-0003-HU Instructions for Use - Hungarian	NS-03-043-0003-JA Instructions for Use - Japanese
NS-03-043-0003-IT Instructions for Use - Italian	NS-03-043-0003-ET Instructions for Use - Estonian
NS-03-043-0003-LT Instructions for Use - Lithuanian	NS-03-039-0017 DICOM Conformance Statement - English
NS-03-043-0003-PT Instructions for Use - Portuguese	NS-03-043-0011 Release Notes - All languages
NS-03-043-0003-RO Instructions for Use - Romanian	NS-03-043-0008 Strain Analysis Manual - All languages
NS-03-043-0003-ES Instructions for Use - Spanish	NS-03-043-0009 Perfusion Manual - All languages

Other	
NS-01-000-0119 Software Terms and Conditions - Domestic	NS-03-043-0005 Installation Manual - All languages
NS-01-000-0193 Software Terms and Conditions - International	NS-03-043-0006 Remote Connectivity Addendum - All languages
NS-01-000-0263 Software Terms and Conditions - Japanese	NS-03-043-0016 Integration Manual - All languages
NS-01-000-0250 Software Terms and Conditions - Chinese	

Prerequisites

The suiteHEART® Software application can only be launched after suiteDXT software is installed and licensed.

In order to operate suiteHEART® Software a valid software license must be obtained. Directions for obtaining the software license are contained within the Installation Manual.
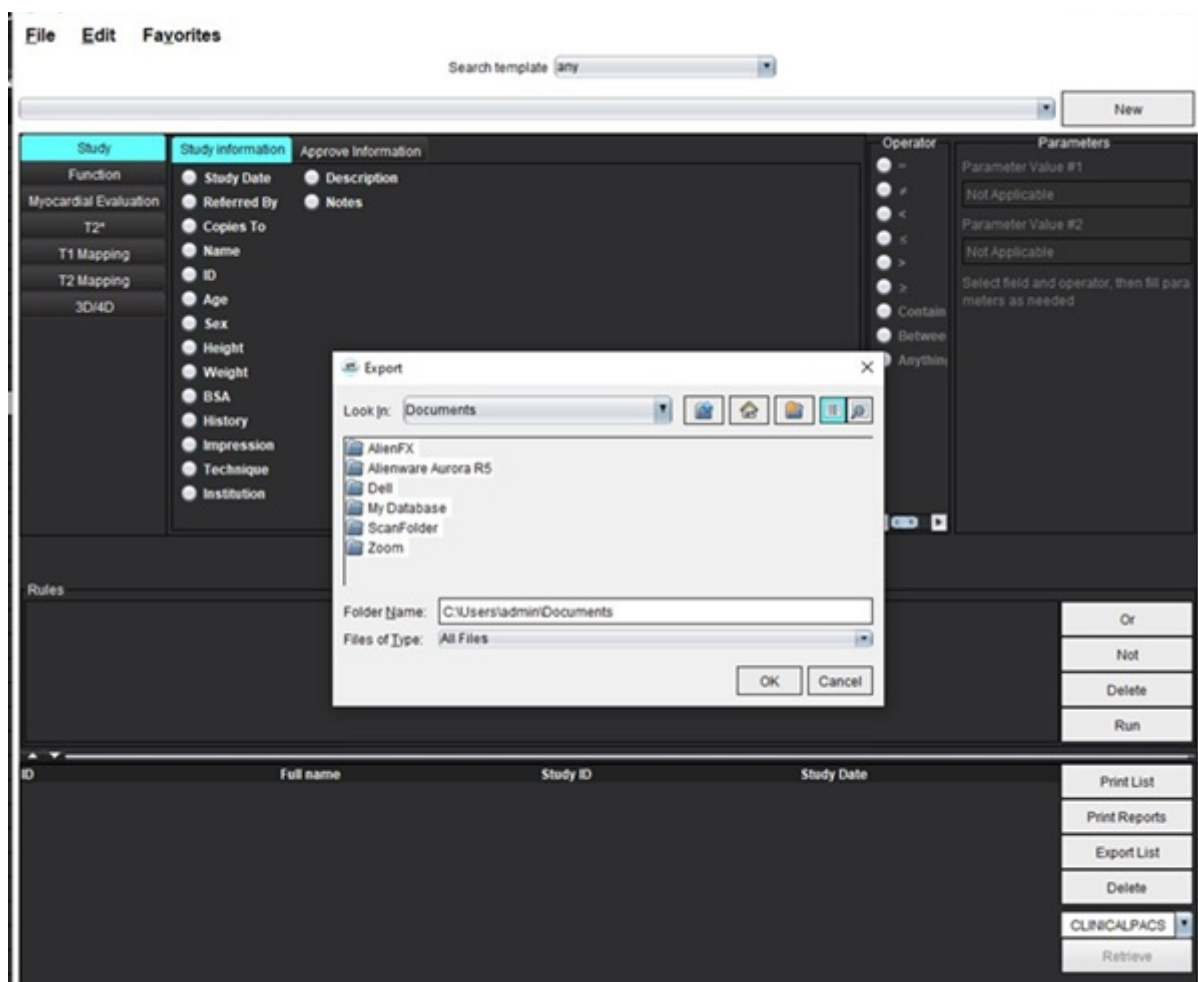
Report Database

Export Report Database

The Report Database contains signed reports generated by suiteHEART® Software. As the database becomes larger it is advisable to archive the data.

1. Select ReportDB from suiteDXT or follow the steps below.

2. Launch suiteHEART® Software.

3. Select **Tools > Report Database**.

4. Select **File > Export** from the Report Database menu bar.
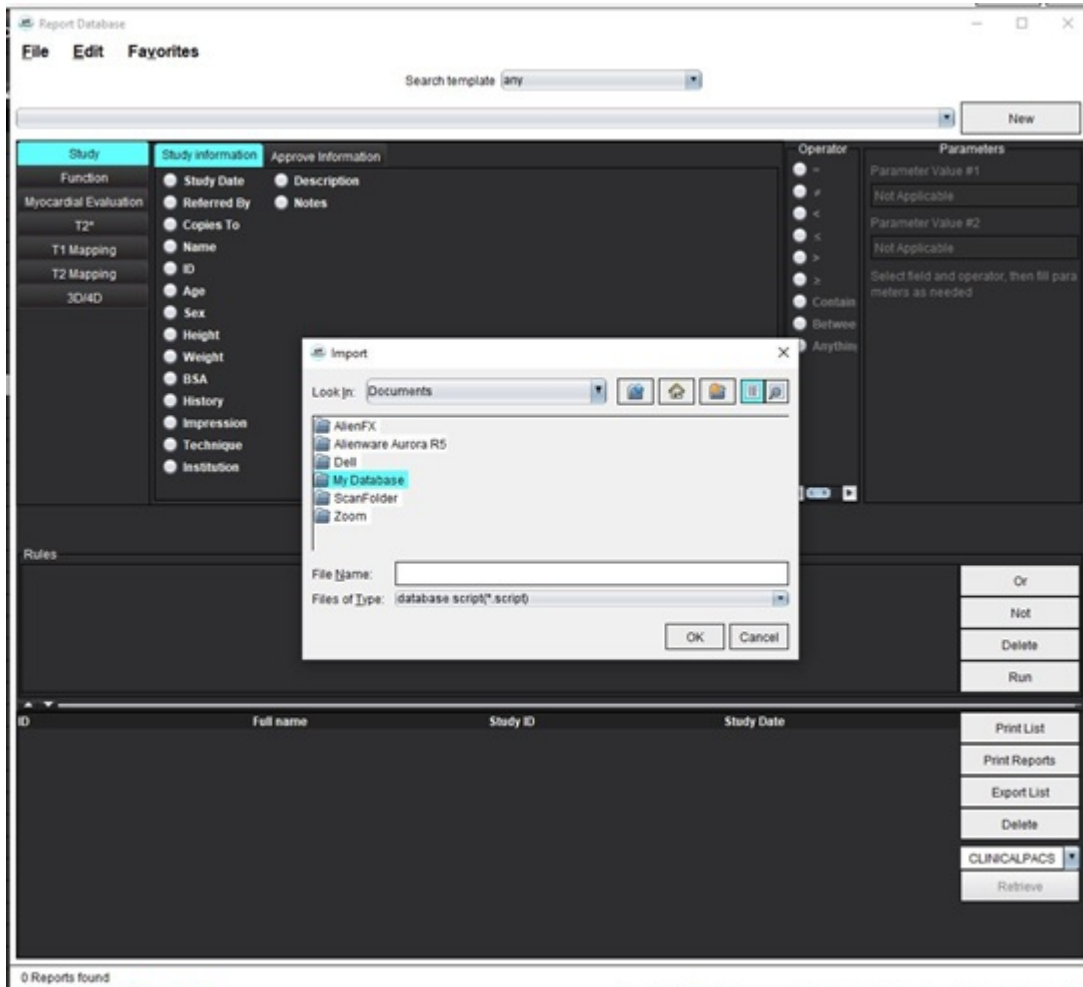
FIGURE 1. Export Window

5. Select the directory to which to export the list.

6. Select **OK** to perform the export procedure as defined.
    - Select **Cancel** to exit the window without exporting.
    - If OK is selected, the export status is displayed. Data will be in a folder named "rbd_export" at the selected location.

Import Report Database

suiteHEART® Software can import a Report Database previously exported from the same or a different system. The database being imported will be merged with the existing database.

1. Select ReportDB from suiteDXT or follow the steps below.

2. Launch suiteHEART® Software.

3. Select **Tools > Report Database**.

4. Select **File > Import** from the Report Database menu bar.

FIGURE 2. Import File Browse Window

5. In the Import file browse window, navigate to the directory containing the exported Report Database.

6. Open the path rbd_export/database.

7. Select the ResearchDB.script file.

8. Select **OK** to perform the import procedure as defined.
   - Select **Cancel** to exit the window without importing.
   - If OK is selected, the import status is displayed.

Restore Report Database

In the rare circumstance when importing a Report Database is unsuccessful, the database can be manually restored.

⚠️

CAUTION: This procedure should only be preformed by a service engineer or experienced user.

1. Close suiteHEART® Software, if running.
2. Navigate to the location in which the suiteHEART® Software application is stored.
   - For example: "c:/Program files/NeoSoft/suiteHEART"
3. Open the resource folder and rename the database folder to database_orig.
4. Navigate to the directory in which the exported Report Database is stored and open rdb_export/database folder.
   - The database folder must contain at minimum "ReasearchDatabase.xml," "ResearchDB.script," and a "report" folder. If any of these three are missing, the restore will not be successful.
5. Copy the "database" folder.
6. Navigate back to where the suiteHEART® Software application is stored.
   - For example: "c:/Program files/NeoSoft/suiteHEART
7. Open the "resources" folder and paste the "database" folder you copied from the exported Report Database.
8. Launch suiteHEART® Software.
9. Select Tools > Report Database.
10. Run a query to confirm expected results are displayed.
11. If the restore was successful, delete the "database_orig" folder created in step 3.

⚠️

CAUTION: Deletion of the "database_orig" folder will delete all content associated with that database.

Or

12. If the restore failed, close the suiteHEART® Software application and delete the database folder from step 7 and rename the "database_orig" folder back to "database," and contact NeoSoft Service at service@neosoftmedical.com.

Software Configuration Options

suiteHEART (configured in product.properties file)

"SECONDARY_REPORT_FOLDER" - Use to specify a directory path in which the user wants to store an additional copy of all approved exams.

"SHIDLE_GRACE_TIMEOUT" - Use to set the length of time the user has to click on the pop-up message before shutting down the application.

"CUDA DEVICE CAPABILITY CHECK PROPERTIES"- Use to set the video card capabilities for auto-segmentation and prepro-cessing.

    MINIMUM_CUDA_CORES = 1664
    MINIMUM_DEVICE_GLOBAL_MEMORY = 4096
    SUPPORTED_CUDA_ARCHITECTURES = 35,37,50,52,53,60,61,62,70,72,75,80,86,87,89,90

"Cross reference threshold filter min/max" - Use to configure an orthogonal slice within an angle of 45 degrees and 135 degrees of the displayed image in the editor window.

    THRESHOLD_MIN = 45
    THRESHOLD_MAX = 135

 "License Server IP and Port" - Use to configure the TCP/IP address and Port of the license server.

    LICENSE_SERVER_IP=127.0.0.1
    LICENSE_SERVER_PORT=5678

    NOTE: If a change to the port is required, you must also edit the NeoSoftLicenseConfig (this file can be found where the suiteDXT application is stored).

suiteDXT (configured in AppSettingDB.xml file)

"CheckJavaVersion" - Use to check and change whether 64-bit java is on/off. Default = on.

"ImportFeature" - Use to turn on/off import functionality. Default = on.

"NetworkCommandTimeoutInSeconds" - Use to set the amount of time the application will wait on an unplugged network connection before it fails the network transfer.

"LicenseServer Address" - Use to configure the TCP/IP address and Port of the license server.

    NOTE: If a change to the port is required, you must also edit the NeoSoftLicenseConfig (this file can be found where the suiteDXT application is stored).

 "IdleTimeout Seconds"- Use to set the length of time (in seconds) suiteDXT should be idle before automatically closing. The value cannot be less than 180 seconds. suiteDXT will not auto close if it is busy, ie. suiteHEART is open, performing anonymization, or if send or retrieve is in process, etc.

"ActiveDirectoryProvider Name=" - Use to define what is used to provide domain user and group information. Default value = LDAP; WinNT is alternative setting.

Setting Up User Permissions

It is recommended that user permissions be configured according to your facility's policies for users performing analysis. Controlled access to studies can be set by configuring user permissions for either Institutions or DICOM nodes.

> NOTE: Multiple instances of suiteDXT can be opened under the same desktop if a different suiteDXT login accounts are used.
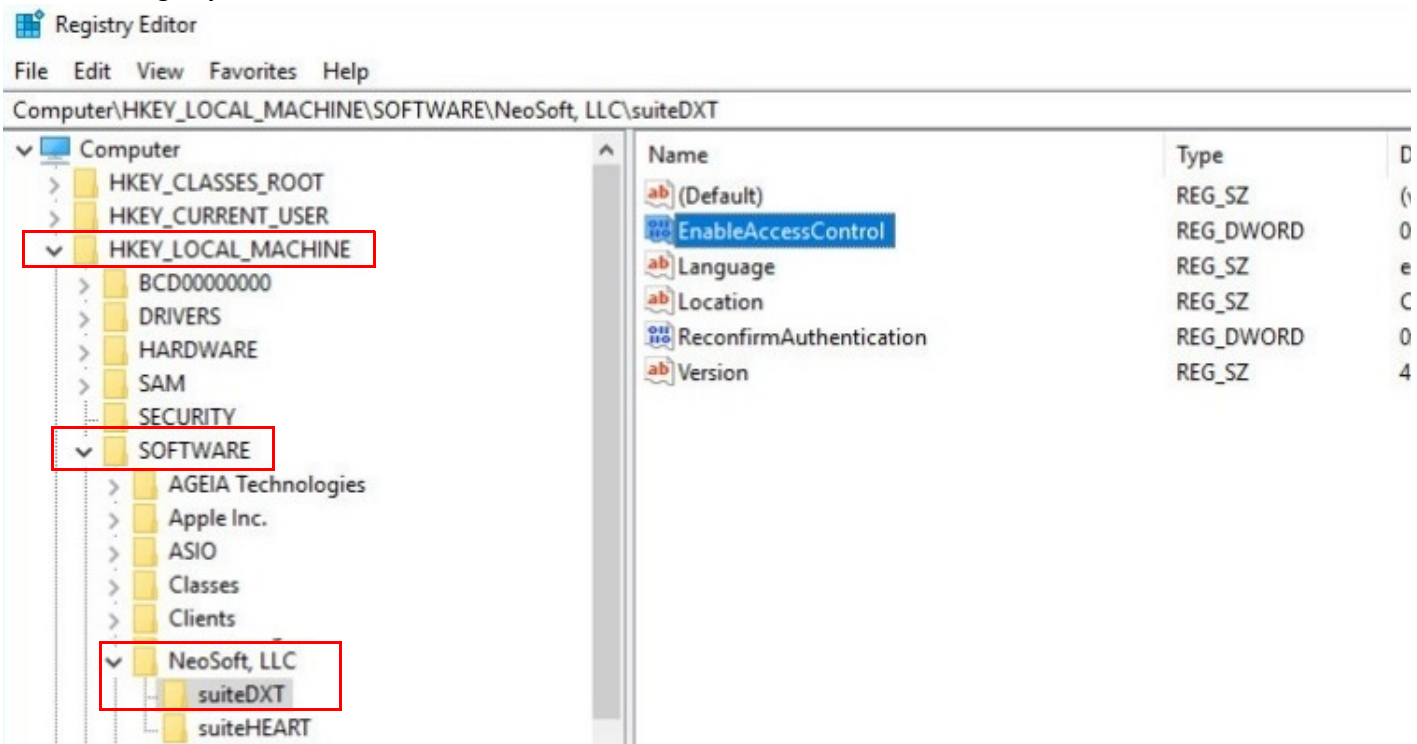
⚠️

CAUTION: Using Registry Editor incorrectly can cause serious, system-wide problems that may require you to re-install Windows to correct them.

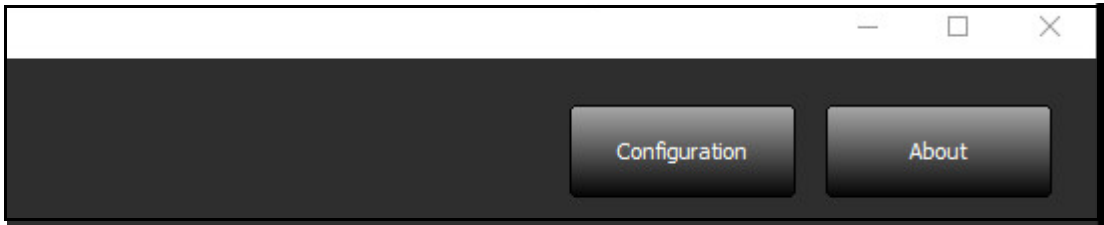To turn on the user permissions feature access the system registry editor.

1. Open a command prompt window and type **regedit**
2. In the registry window navigate to directory: Computer\HKEY_LOCAL_MACHINE\SOFTWARE\NeoSoft, LLC\suiteDXT

FIGURE 1. Registry Editor Window

3. Double-click on EnableAccessControl. Set Value Data=1
4. For a second layer of permission, double-click ReconfirmAuthentication, Set Value Data=1
5. Right mouse click on the suiteDXT icon on the desktop and Run as Administrator.
6. Log in with the appropriate "User Name" and "Password".
7. From suiteDXT's Main Screen select Configuration in the upper right.
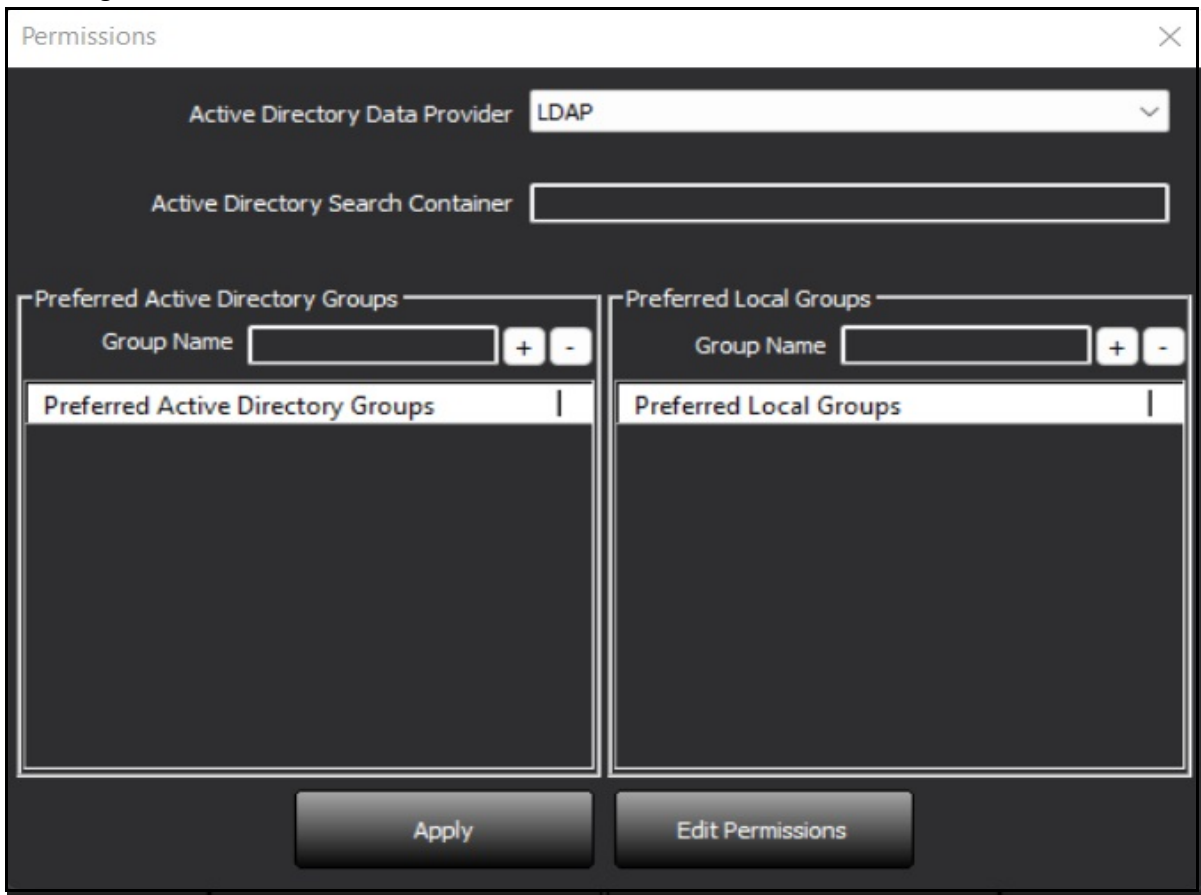
FIGURE 2. suiteDXT Main Screen Buttons

8. Select Permissions Button.

   NOTE: Permissions are only enabled when logged in as an Administrator on the local hardware. If the ReconfirmAuthentication in the registry has been turned on, log in with the appropriate "User Name" and "Password".

   NOTE: When the user permission feature is initially enabled, by default no user will have any permissions defined.

   NOTE: The suiteDXT title bar includes a Logged in as domain\user, message. If the logged in as description is followed with (Administrator) then the user will have permissions to assign permissions.

FIGURE 3. Configuration Window

9. In the permissions window, set permissions for users or groups.
10. Use the right arrow buttons to add institution or DICOM node permissions.
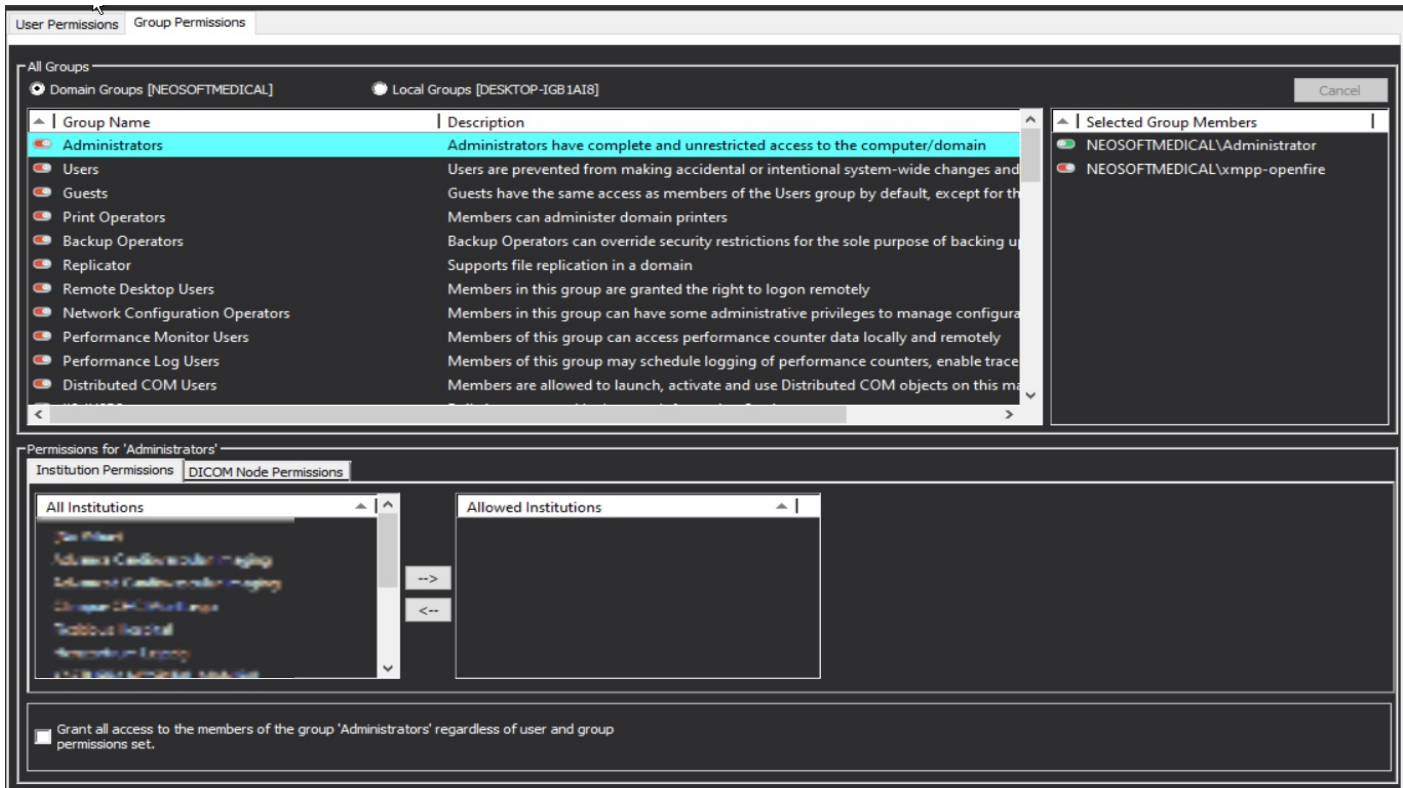11. Use the left arrow buttons to remove institution or DICOM node permissions.

    If the study fields satisfies the permission for that user then the user will be able to view those studies.

NOTE: The administrator can always override permissions set to a user/group and grant all permissions by selecting the user or group and clicking the corresponding check box at the bottom of the permissions window.

NOTE: The Institution Permissions list of institutions includes a (No Value) option. When this selection is assigned to a user, that user will be able to see a list of all studies that do not have an institution defined.

NOTE: The DICOM Node Permissions list of All DICOM Nodes includes a (No Value) option. When this selection is assigned to a user, that user will be able to see a list of all studies that do not have any DICOM Node defined.

FIGURE 4. Permissions Window

When permissions are set the indicators will be green.

NOTE: When logged in as an administrator, the administrator will have a study list right click option of "Set Origin". Set Origin can be used to associate a study with a particular Origin or by using the Remove AETitle option will remove an associated Origin.

NOTE: If a user with no defined permissions attempts to log in to suiteDXT they will be presented with a "suiteDXT permissions are not defined. Contact your System Administrator." message and suiteDXT will close.

NOTE: A logged in user will only be able to Send to, or Query an AE title that they have permissions to see.

NOTE: Studies that are Imported are not by default associated with any AE Title and may have a blank Institution name. In this case an administrator will need to manually assign the study to an AE title.

VMWare Installation

When VMWare is installed, the potential exists for the customer to see an additional viewer window when dragging DXT. To rectify this, follow these steps:

1. Open **System Properties**.

2. Select the **Advanced** tab.

3. Click **Settings** under the Performance heading.

4. Uncheck the box next to Show window contents while dragging.

5. Click **OK**.