

CAKE™

Installation Manual

NeoSoft, LLC



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Revision History

Rev	Date	Description of Change	Safety Related Update (Yes/No)
1	24-MAR-2018	Initial Release	No

The Instructions for Use for this software is 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 "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.
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.
4. Electronic copies of Instructions for Use are also available at www.neosoftllc.com/neosoft/product_manuals/.

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Table of Contents

Safety	1
<i>Introduction</i>	1
<i>Product Overview</i>	1
<i>Indications for Use</i>	2
<i>Limitations</i>	2
<i>Safety Notices</i>	3
suiteDXT Installation & Configuration	5
Prerequisites	5
Installing suiteDXT Software	6
<i>Configuration</i>	6
<i>Local Storage Tab</i>	8
<i>Application Launch Tab</i>	9
<i>Feature Licensing Tab</i>	10
CAKE™ Software Installation	13
Prerequisites	13
Installing CAKE™ Software	14
<i>Licensing Schemes</i>	15
<i>Remote Connectivity</i>	15
Install Verification	16

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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.



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

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.

Product Overview

Computer Aided Kinetic Evaluation (CAKE™) is an application that can be used for analysis, review and reporting of breast MRI (Magnetic Resonance Imaging) studies. The application supports DICOM based MR images acquired on a high field (1.5T or 3T) magnet. This manual provides a detailed explanation of the software user interface and the work flow for performing quantitative analysis on breast MR images. CAKE™ is installed on a standalone workstation.

To assure efficient and safe use, it is essential to read the limitations, warnings and precautions, as well as all associated topics before attempting to use the software.

Indications for Use

NeoSoft's CAKE™ product is a post-processing, productivity software package designed to assist radiologists in the analysis of dynamic breast MR images. The software provides image display, supplemental information and visual enhancement of time/ intensity changes extracted from MR temporal datasets. Single or multi-slice datasets, using standard acquisition protocols, are used for input.

The results may be displayed as either a grayscale enhancement or a color overlay on the selected image. CAKE may perform additional functions to aid in the analysis and viewing of dynamic studies including registration of serial MR acquisitions, labeling of tissue types based upon user specified enhancement characteristics, visualization and quantification of lesion morphology in 3D, segmentation of tissues, multi-planar reformats, maximum intensity projections, image averaging, and subtractions.

When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. Patient management decisions should not be made based solely on the results of CAKE™ analysis.

Limitations

All medical professionals and personnel using CAKE™ must be trained in the use of the product.

Effective use of CAKE™ requires adherence to imaging protocol requirements and the imaging manufacturer's instructions regarding maintenance and calibration of the imager.

Refer to the CAKE™ DICOM Conformance statement for details on supported formats.

Safety Notices



WARNING: 3D surfaces created from medical images use Gouraud shading when calculating surface colors. Gouraud shading can alter the grayscale intensity independent of the original image intensities and window and level contrast adjustments. This is applicable to all viewports that show 3D images.



WARNING: 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: Adjusting the size of the bounding box is at the discretion of the user and should only be done by a properly trained and qualified user. Under estimation of lesion size can occur if the bounding box does not include the entire enhancing lesion.



WARNING: CAKE™ may fail to launch if the disk is full. Check disk capacity before launching the application.

Patient motion in dynamic series



CAUTION: Do NOT perform CAKE™ animation analysis if patient movement has corrupted data. Patient motion corruption is determined by image artifact seen in subtraction images.

Installation and service



CAUTION: CAKE™ shall be installed only by authorized personnel. Only technically qualified personnel, trained by NeoSoft, shall perform troubleshooting and service procedures on the software and internal components. If necessary, contact NeoSoft's support team for additional installation instructions (support@NeoSoftmedical.com).

Patient orientation



CAUTION: CAKE™ is configurable per site to put chest wall on top or bottom of the viewport. The user can also set preferences for left and right.

Series types



CAUTION: It is the user's responsibility to provide one pre-contrast series and a minimum of two matching post-contrast series for the dynamic dataset.

Threshold toolbars



CAUTION: The difference threshold filters noise pixels in the image which is used for parametric maps. The threshold is set during installation. Do NOT change this threshold without contacting NeoSoft's support team for additional instructions (support@NeoSoftmedical.com).



CAUTION: The SER threshold for parametric maps defines the percentage change between washout plateau and persistence, which is set during installation, has a default of 10%. Do NOT change this threshold without contacting NeoSoft's support team for additional instructions (support@NeoSoftmedical.com).

suiteDXT Installation & Configuration

Prerequisites

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

Table 1: System Requirements

Minimum System Requirements
Supported Operating Systems: <ul style="list-style-type: none">• Windows 7 Professional or Enterprise with SP1 (64 bit version)• Windows 10 Professional or Enterprise (64 bit version)
Video card; Support 1920 x 1080 resolution or higher, support OpenGL 2.
Anti-Virus/Anti-Malware software installed
Minimum 16GB memory
Available hard drive space minimum 25GB
PDF viewer, Adobe Reader 11.0 or higher
An open network port for DICOM transfer over network
Static IP address (recommended)
Solid-State hard drive
Intel® Core™ i7 processor
JAVA Runtime Environment (JRE) version 9
27" Monitor

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.

Installing suiteDXT Software

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."

NOTE: If another version of the software is already installed on the system, a pop-up will ask permission to overwrite.

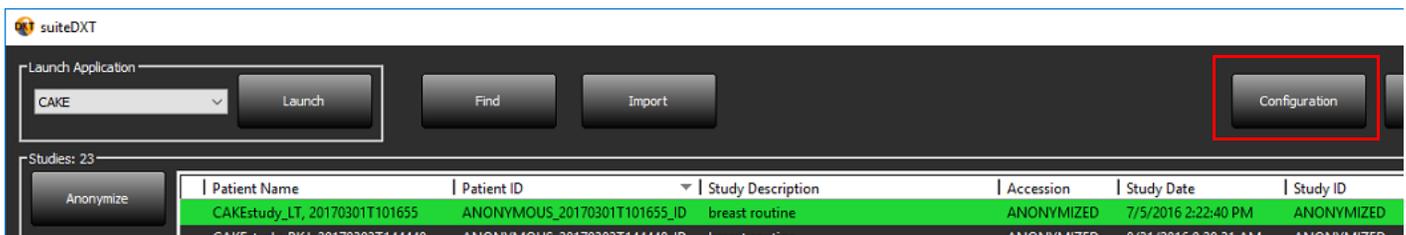
4. Click "Yes" to continue with the installation.
5. Select "Next" on the suiteDXT setup screen.
6. Check the box for "I accept the agreement" and select "Next."
7. Accept or change the installation directory and select "Next."
8. Select "Next" in ready to install setup screen.
9. Select "Finish" in the setup screen.

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.

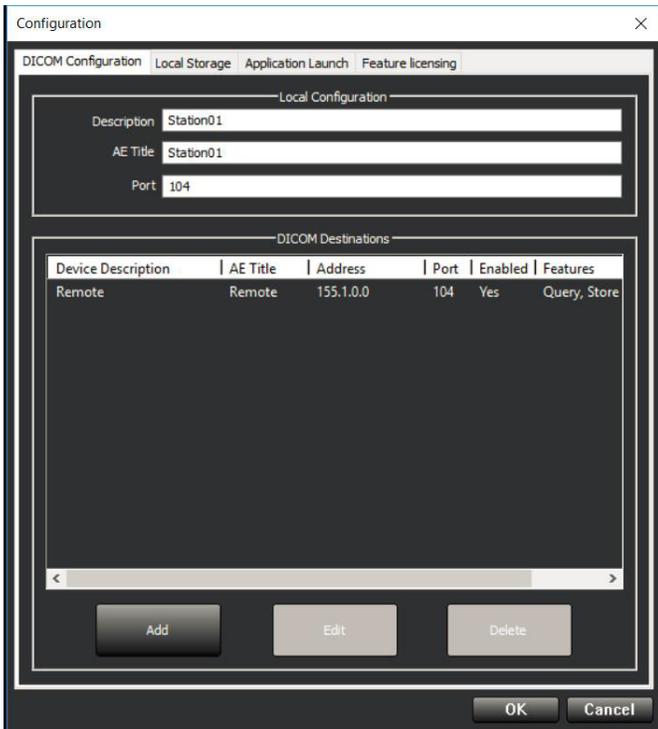
FIGURE 1. suiteDXT Main Screen



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).

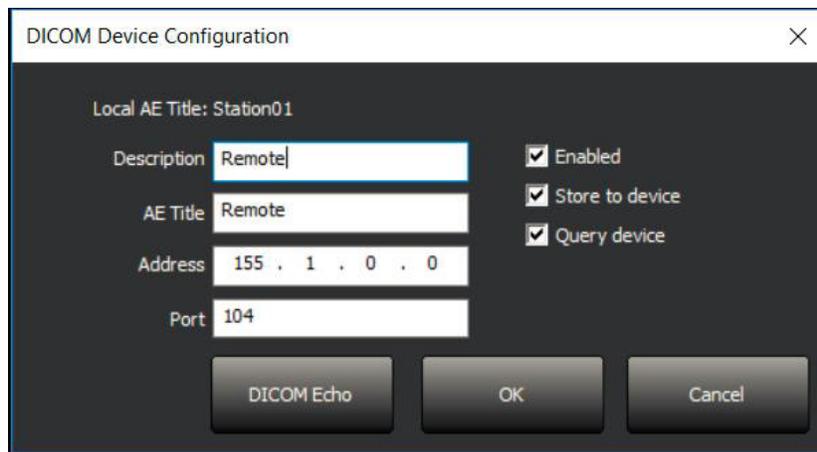
NOTE: The information entered on this tab must be entered exactly the same on any remote device for suiteDXT to retrieve or accept images from the remote host.

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).

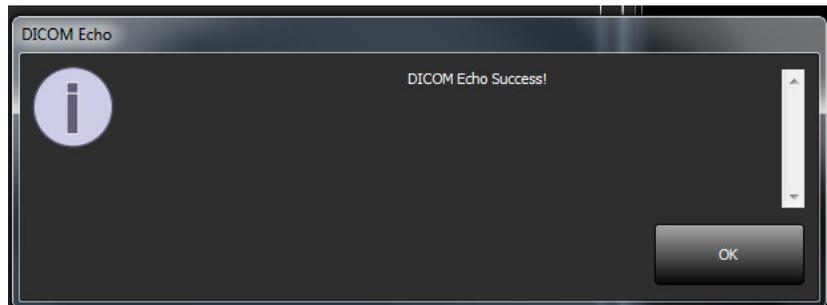
FIGURE 3. DICOM Configuration Window



6. Select the “DICOM Echo” button.

- If you don’t see the DICOM Success Message window (Figure 4) contact your network administrator.

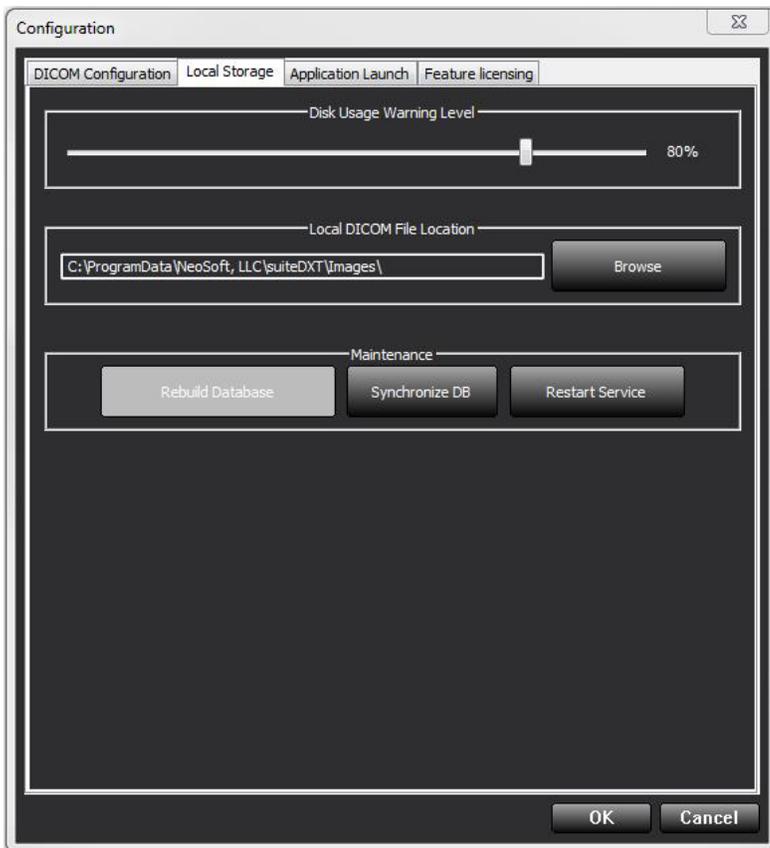
FIGURE 4. DICOM Success Message



NOTE: DICOM Destinations can be modified and a DICOM echo performed via the Edit button and destinations can be deleted via the Delete button.

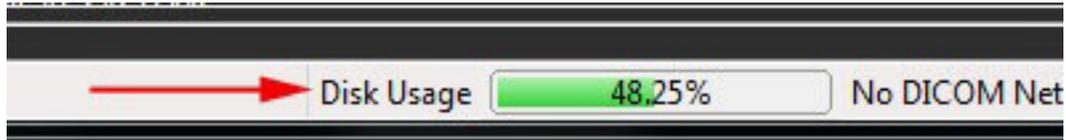
Local Storage Tab

FIGURE 5. Local Storage Tab Window



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.

FIGURE 6. Disk Usage Indicator on Main Screen



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.



CAUTION: Do not delete DICOM data from the file system.

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

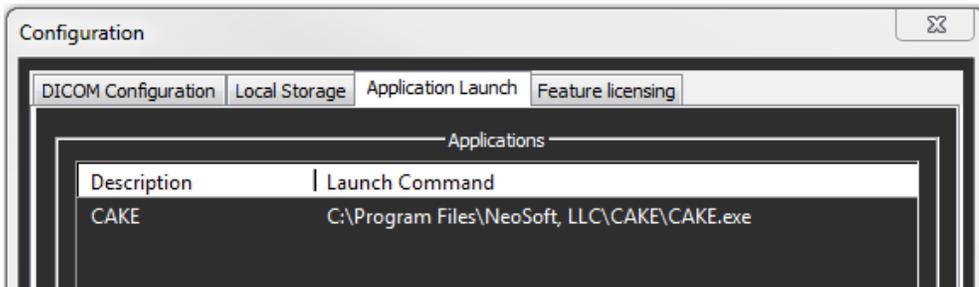
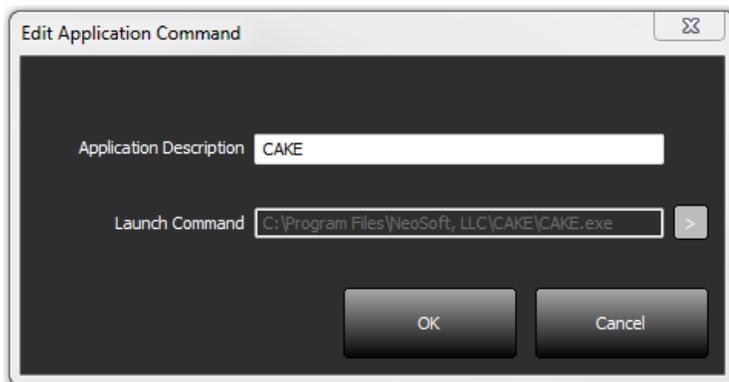


FIGURE 8. Edit Application Window



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 third party application from the launch list, use the Edit or Delete button (Figure 7).

NOTE: NeoSoft, LLC applications are automatically added to the Application Launch list. The launch command is not editable and nor can an application be manually deleted from the list.

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

The screenshot shows a software window titled "DICOM Configuration" with four tabs: "Local Storage", "Application Launch", "Feature licensing", and "Feature licensing" (the active tab). The "Feature licensing" tab contains two main sections: "Request License" and "Apply License File".

The "Request License" section is divided into two sub-sections:

- Company Information:** Includes three text input fields labeled "Name", "Telephone", and "Billing Address".
- Contact Information:** Includes three text input fields labeled "First Name", "Last Name", and "Email".

Below the "Request License" section is a button labeled "Generate License Request".

The "Apply License File" section contains a button labeled "Apply License".

At the bottom of the window are two buttons: "OK" and "Cancel".

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

Request a License

1. 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.

2. Select the Generate License Request button.
3. Navigate to a memorable directory (e.g. the desktop) in which to save the license request file.
4. Email the license request file to licensing@neosoftmedical.com

Apply the License

1. From NeoSoft's response 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.

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CAKE™ Software Installation

Prerequisites

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

Table 1: System Requirements

Minimum System Requirements
Supported Operating Systems: <ul style="list-style-type: none">• Windows 7 Professional or Enterprise with SP1 (64 bit version)• Windows 10 Professional or Enterprise (64 bit version)
Video card; Support 1920 x 1080 resolution or higher, support OpenGL 2.
Anti-Virus/Anti-Malware software installed
Minimum 16GB memory
Available hard drive space minimum 25GB
PDF viewer, Adobe Reader 11.0 or higher
An open network port for DICOM transfer over network
Static IP address (recommended)
Solid-State hard drive
Intel® Core™ i7 processor
JAVA Runtime Environment (JRE) version 9
27" Monitor

NOTE: CAKE™ software is not supported in Virtual Machine environments.

NOTE: CAKE™ software does not support scaling/zoom levels greater than 125%.

NOTE: You must be logged into your operating system as Administrator in order to install the software.

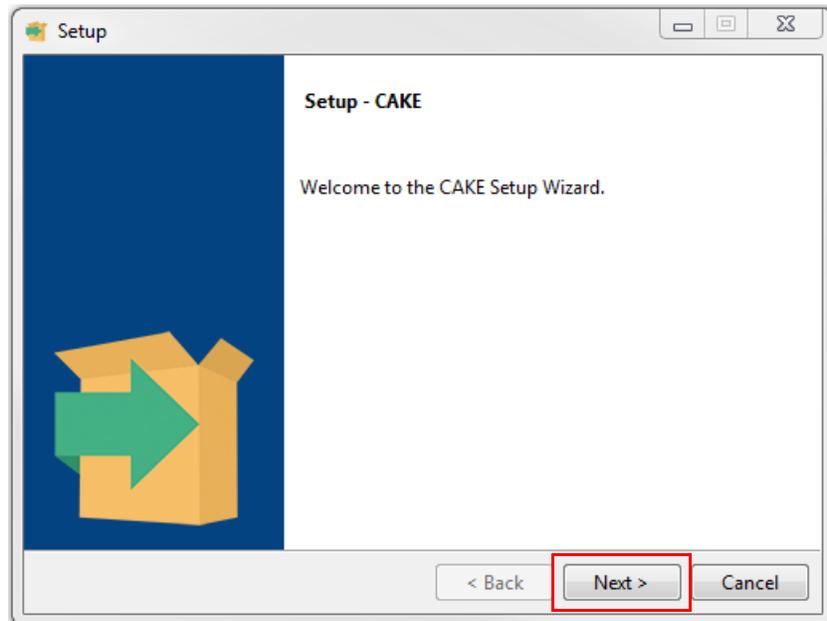
Installing CAKE™ Software

IMPORTANT: JAVA must be installed prior to installation of CAKE™ software.

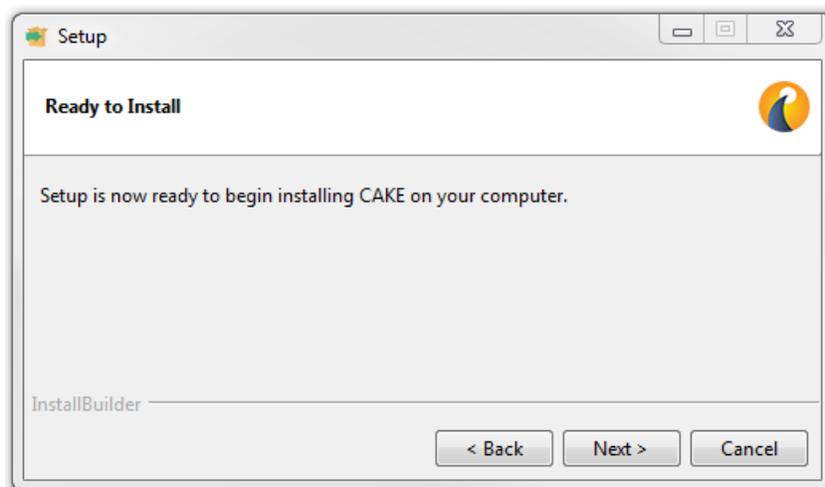
1. Double-click on the CAKE™ software window's application installer.

NOTE: Installing the software on a machine could result in an Open File - Security Warning indicating that the publisher could not be verified. Click "Yes" when asked if you are sure you want to run the software.

2. In the Welcome to CAKE™ Software Setup Wizard window, click **Next**.



3. On the License Agreement Window, select "I accept the agreement" and click **Next**.
4. Browse to the directory in which to install the software or use the default directory (recommended). Click **Next**.
5. Click **Next** on the Ready to Install screen. A progress bar will display.



6. Click **Finish** to complete the installation.

Licensing Schemes

CAKE™ software has 3 different licensing schemes: Evaluation, Unlimited and Per-Case Pack Limited.

- Evaluation: A time limited license which does not allow the send image for archive option. If Send Image for Archive is selected, a message will appear stating: "Evaluation version: Image will not be saved." Check the About screen to see if you have an Evaluation type of license.
- Unlimited: No restrictions on analysis and not case-limited.
- Per-Case Pack Limited: The software will use the unique study instance id to identify the number of cases analyzed against the Per-Case Pack that has been purchased. Exams that are opened in CAKE™ count once towards the Per-Case Pack limit the first time the exam is opened. Check the About screen to see how many cases have been consumed.

Per-Case Packs can be purchased in increments of 25, 50 and 100. Website: <http://neosoftllc.com/> T: (262)522-6120
email: orders@neosoftmedical.com

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

Remote Connectivity

Remote connectivity allows CAKE™ software users remote access from computers not loaded with CAKE™ software. The remote user will have the ability to access the CAKE™ software system and have full functionality.

CAKE™ remote connectivity needs to be installed/configured/supported by your Information Technology personnel.

Remote connectivity has been verified using the following platforms:

- TeamViewer (version 13)
- Citrix GoToMyPC (version 9.6)

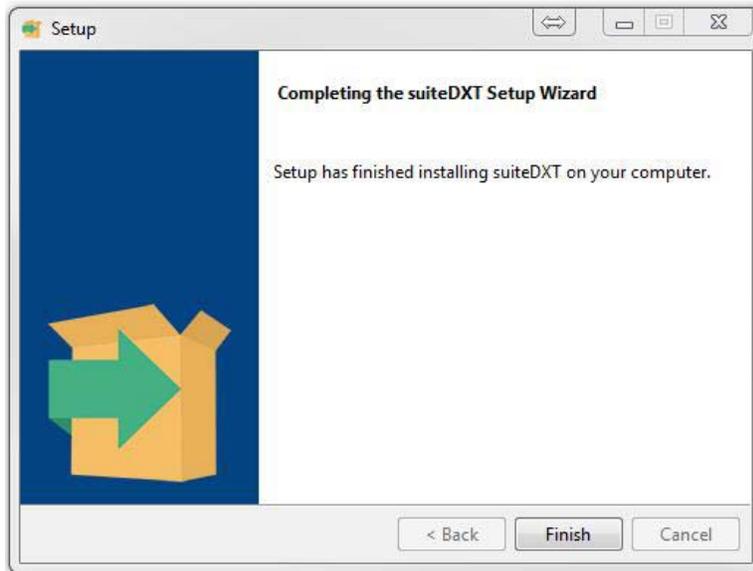
The performance of the CAKE™ software via the remote connection cannot be guaranteed. Performance is dependent upon factors that are outside the scope of the CAKE™ software application. These factors include:

- Remote computer performance
- Internet download/upload speeds (Mbps)
- Network bandwidth speed (wired ethernet or wireless connection)

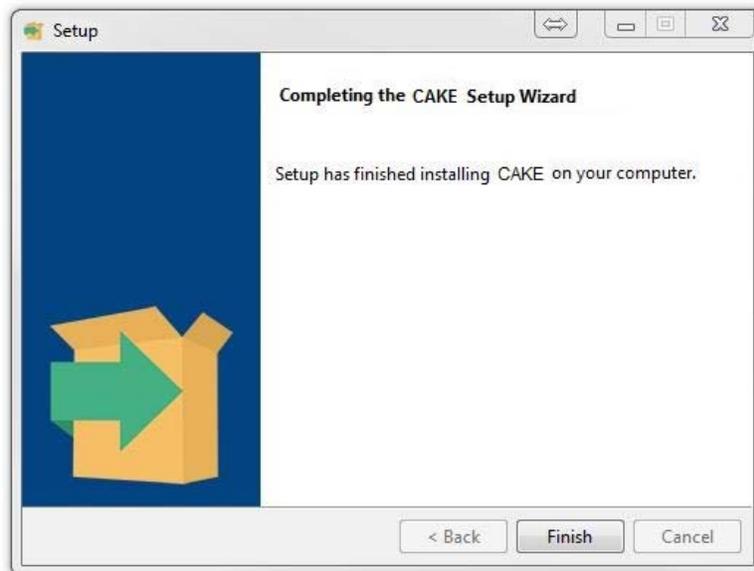
Install Verification

After a successful installation of suiteDXT this screen is displayed.

FIGURE 1. suiteDXT Setup Wizard



Following the successful installation of CAKE™ software this screen displays.



To further verify the successful installation of both software packages:

1. Double click the suiteDXT icon to verify suiteDXT is launched.
2. Highlight a study in the suiteDXT study list and select launch with CAKE™ to verify that the study is launched.