

CAKE™

Breast Analysis Software

Instructions for Use

NeoSoft, LLC



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Revision History

Rev	Date	Description of Change	Safety Related Update (Yes/No)
1	26-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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Introduction

Please read the information in this manual before using this software.

Safety

To assure efficient and safe use it is essential to read this 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



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

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.

Warnings



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.

Precautions

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).

Launching CAKE™

Launching and Exiting the Application

1. Launch suiteDXT via the desktop shortcut.

NOTE: Both suiteDXT and CAKE™ applications must remain running (simultaneously) to facilitate the necessary file transfer(s) between the applications.

2. On the Main Screen go to the Launch Application drop-down menu and select CAKE™.
3. Select a study from the study list in suiteDXT and confirm that all necessary series are available by reviewing the series list and slice count. To open the exam in CAKE™, do one of the following:
 - Select the Launch button.
 - Right-mouse click and select “Launch using [CAKE].”

Two instances of CAKE™ can be running at the same time for study comparison, but each study can only be launched in a single instance.

NOTE: Modifications made to settings in the first instance of CAKE™ are not transferred/used in the second instance.



WARNING: Using images with pixel intensity filters applied for analysis may cause inaccurate results.

To exit the application, click on the X in the red box located in the upper right corner of the window.

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Image Review Mode

Image Review Mode offers a multi-viewport display. Each window is configurable and can be saved as a Hanging Protocol (HP) for later use.

The dynamic time slider is used to view dynamic datasets and subtractions at any time point, allowing for exploration of datasets and eliminating the need to view several windows simultaneously.

Table 1: Image Review Features

Feature	Description
Subtraction	Displays the visual result of the digital subtraction of the pre-contrast image from the dynamic image as determined by the manual positioning of the time slider located on the tool bar.
Registered Subtraction	Displays the visual result of the digital subtraction of the pre-contrast from the dynamic image currently specified by the time slider. When scrolling stops, registration is performed within a user-defined region and the corrected subtraction is displayed. Registration aligns the image time points from two series so that common features overlap. Registration can correct for small amounts of patient motion between series and help improve image detail.
Maximum Intensity Projection (MIP)	Displays the 3D subtraction of the pre-contrast image from the dynamic image currently specified by the positioning of the time slider.
Curve Tool	Displays a graphical representation of contrast agent uptake and washout rates.
Dynamic Series	Displays the dynamic image currently specified by the time slider.
Dynamic Multi-Planar Reformatting (MPR)	Displays orthogonal views of the Dynamic Series currently specified by the time slider
DICOM Series	Displays all series in the study in their original DICOM format.
Spatially Sync All	Synchronizes all series acquired in the same image plane as the dynamic series. The closest image is chosen when the slice position is not identical.
Measurement Tool	Allows for measurement of a lesion in two-dimensional orientation using the 2D distance measuring tool. It also labels the measurement.
Add Label	Applies user defined annotation to the image.
Send Image for Archive	Saves the image in the active window as a DICOM image.
Save as JPEG Picture	Saves any viewport as a JPEG image.
Save as MPEG Movie	Saves any dynamic series viewport as an MPEG movie file.

Application Layout

The CAKE™ Breast MRI Application window is divided into two sections:

- Image window
- Toolbar

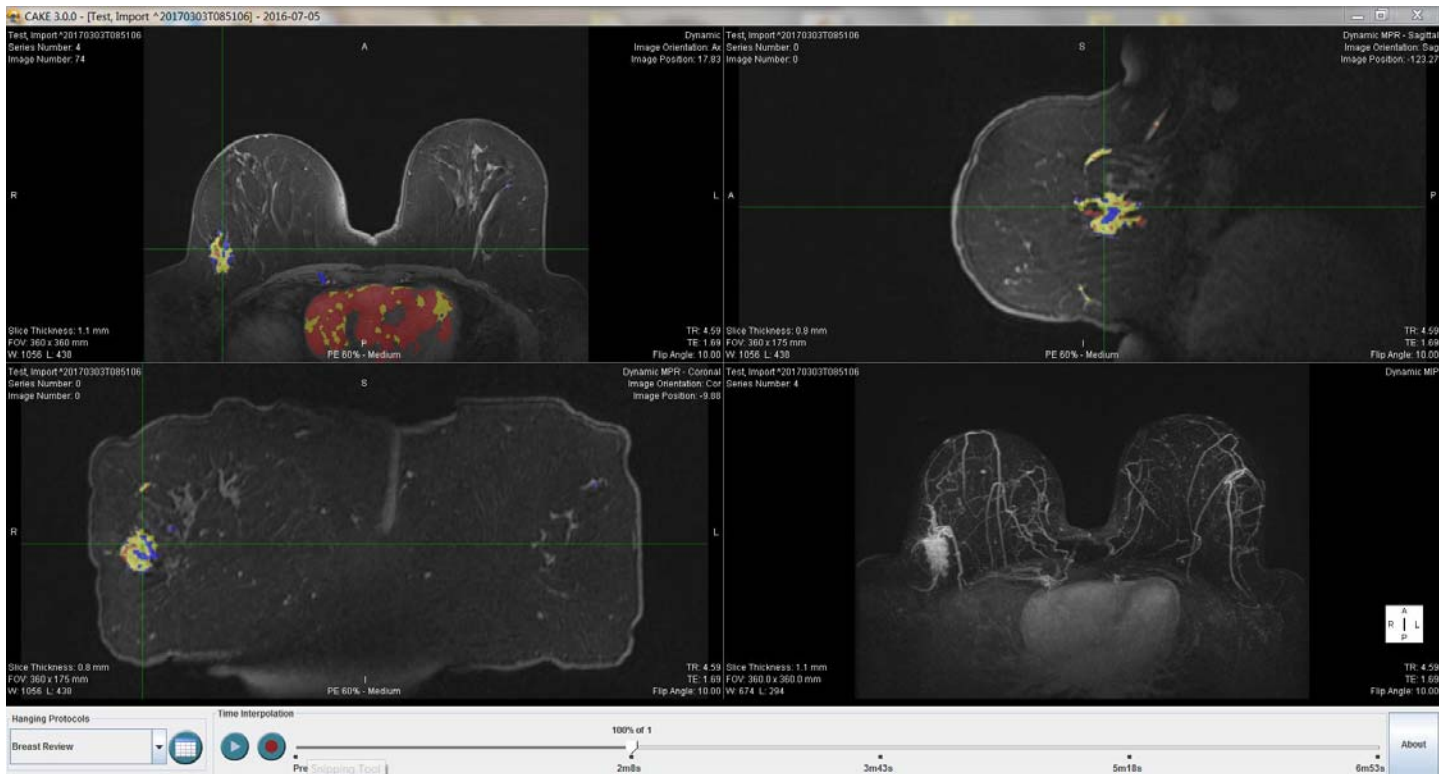






Image Window

The image window can be configured to allow grid arrangements up to 12 viewports. The available functionality within the image window is defined in the following pages.

Mouse Functions

Table 2: Mouse Functions in the Image Window

Function	Description
<p>Zoom</p> 	<p>Shift Key + Left-Mouse Click & Hold</p> <p>Moving the mouse up and down with the shift key and left-mouse button pressed zooms the image in and out. Moving the mouse up zooms in and moving down zooms out.</p> <p>NOTE: Due to the nature of CAKE™ visualization, it may not be apparent if the image is zoomed beyond clinical utility. Always refer to the original image for diagnosis.</p>
<p>Translate</p> 	<p>Right- & Left-Mouse Buttons + Hold & Drag</p> <p>Dragging the mouse with both the left- and right-mouse buttons pressed translates (moves) the image. This is particularly useful with zoomed images.</p>
<p>Window/Level</p> 	<p>Right-Mouse Button + Hold & Drag</p> <p>Dragging up or down changes the level while dragging left and right changes the width of the window.</p>
<p>Image Scroll</p>	<p>Scroll Wheel</p> <p>Scroll the mouse wheel up and down to scroll through image slices. Alternately, the keyboard arrow keys can be used to scroll through the images.</p>
<p>Select Series Menu</p> 	<p>Right-Mouse Click</p> <p>Right-mouse click on the image window to select a series from the menu.</p>
<p>Full Screen</p>	<p>Double Left-Mouse Click</p> <p>Double left-mouse click in a viewport to make it full screen mode. Double mouse clicking again will restore the normal view.</p>

Menu Functions

Many of the right-mouse menu functions are available in all viewports, but there are functions that are specific to the type of viewport. The following table lists all functions available and identifies in which type of viewport they are found.

Table 3: Right-Mouse Menu Functions

Function Click on the function name to be taken to the description.	DICOM View	Dynamic View	Curve Tool
Select Series	✓	✓	✓
Measurement Tool	✓	✓	NA
Add Label	✓	✓	NA
Clear Lines	✓	✓	NA
Delete Label	✓	✓	NA
Save as JPEG Picture	✓	✓	✓
Reset W/L	✓	✓	NA
Reset View	✓	✓	NA
Show Annotations	NA	✓	NA
Show Parametric Map	NA	✓	NA
Spatially Sync All	NA	✓	NA
Show MPR Reference Lines	NA	✓	NA
Save as MPEG Movie	NA	✓	NA
Reset Scale	NA	NA	✓
Show All Curves	NA	NA	✓
Clear Saved Points	NA	NA	✓*
Set SER Threshold	NA	NA	✓
Set Difference Threshold	NA	NA	✓
Send Image for Archive	✓	✓	✓

*Only available when a curve is displayed.

Select Series

NOTE: Choosing this feature in a viewport that contains a series will overwrite the current display with the new series.

1. Open the right-mouse menu.
2. Cursor over Select Series to open a list of series from which to choose.
3. Move the cursor to highlight the desired series and left-mouse click on it to select.

Measurement Tool

The measurement tool is used to measure distances in an image. Measurements cannot be saved, but they can be captured by selecting “Send Image for Archive” or “Save as JPEG Picture” before exiting the study.



CAUTION: Measurements made in CAKE™ are not saved; they will be removed when the study is closed.

1. Click on “Measurement Tool” from the menu.
2. Click and hold the left-mouse button at the starting point of the measurement.
3. Drag the mouse over the area to measure.
4. Release the left-mouse button to drop the end point of the measurement.
5. (Optional) Enter a name for the measurement.
6. Click the OK button.

Cancel Line

To turn off the measurement tool without taking a measurement choose “Cancel Line” from the right-mouse menu.

Clear Lines

Deletes all measurements visible on a particular image slice.

Send Image for Archive

This feature allows any image to be archived to the suiteDXT series list, from which it can be sent to the PACS.

1. Place your cursor in the viewport of the image to be archived.
2. Select “Send Image for Archive” from the right-mouse menu.



CAUTION: Labels made in CAKE™ are not saved; they will be removed when the study is closed.

Add Label

Adding a label will create user defined annotation on the image.

1. Move the mouse cursor over the area of the image that you want to place the label.
2. Click on “Add Label” from the menu.
3. Enter a description.
4. Click the OK button.

Delete Label

1. Open the right-mouse menu.
2. Choose “Delete Label” from the menu options.
3. Select the label for deletion from the drop-down menu.
4. Click the OK button to delete.

Save as JPEG Picture

Labels and measurements on the image will be shown on the JPEG.

1. Select “Save as JPEG Picture” from the menu.
2. Enter the file name.
3. Select “JPEG Images” from the Files of Type drop-down menu.
4. Navigate to the destination in which to save the picture.
5. Click the Save button.



WARNING: Images saved to a harddrive as JPEG pictures or MPEG movies are for educational purposes only. Medical files should always be stored on PACS.

Save as MPEG Movie

This function can only be used in viewports displaying a dynamic series.

1. Select “Save as MPEG Movie” from the menu.
2. Enter the file name.
3. Select MPEG-1 Videos from the Files of Type drop-down menu.
4. Navigate to the destination in which to save the movie.
5. Click the Save button.

A recording window will display on the screen. When the window disappears the recording is complete.

Reset W/L

The window level will return to default DICOM when this option is selected from the menu.

Reset View

The view will return to default size and location when this option is selected from the menu.

Show Annotations

Patient identification annotations within the viewport can be toggled on and off by clicking on the check-box next to the function.

Show Parametric Map

NOTE: The parametric map can only be displayed on a dynamic series or a series originating from dynamic data. For example, subtraction reformat.

Applies a color map to the displayed image slice. Parametric map will change if the enhancing threshold, in the Curve Tool, is changed. This function can be toggled on and off by clicking on the check-box next to the function name.

Spatially Sync All

Use the scroll wheel on the mouse or the keyboard arrows to scroll images within the same scan plane, but in different viewports. This function can be toggled on and off by clicking on the check-box next to the function name.







Show MPR Reference Lines

Moving the reference line cross-references the slice to the orthogonal plane in the other viewports. It is used to triangulate the area of interest in three planes. This function can be toggled on and off to display or remove the reference line from all MPR viewports.

Toolbar Functions

Viewport creation, static and dynamic image display and saving are functions controlled through the toolbar.

Table 4: Toolbar Functions

Function	Description
<p>Play/Stop</p> 	<p>Start and stop cine. To change the duration, or frames per second, right- mouse click on the play/stop button to display the duration slider. Left-mouse click on the slider arrow and move up or down to the desired value. The default is 11 fps.</p>
<p>Screen Capture</p> 	<p>Save a screen capture of all the viewports to the local disk. Left-mouse click on the button to bring up the Save screen. Make a selection from the Files of Type pull-down menu, enter a file name, navigate to the location to which to save and click the Save button.</p> <p>NOTE: The screen capture will include everything shown on the screen, including the patient's name.</p>
<p>Time Interpolation Slider</p> 	<p>View an entire dynamic series within one viewport. Manually adjust by clicking and dragging on the slider or by using the left and right arrow keys on the keyboard. The slider will display 'Img' rather than a time when the two series' image acquisition times are the same.</p>
<p>Hanging Protocol</p> 	<p>Choose a protocol to use or delete or set the default hanging protocol from the drop-down menu. Also used to launch Mass Characterization.</p>
<p>Layout Selector</p> 	<p>Change the layout to add or remove viewports from the image window.</p> <p>NOTE: Changes to the layout is disabled in Mass Characterization mode.</p>
<p>About</p> 	<p>Use to access this manual and the DICOM Conformance Statement, as well as view the copyright, software version and list of acknowledgments.</p>

Change the Layout

Layouts can be changed on the fly along with the ability to save protocols for future use.

1. Click on the Layout Selector.
2. Choose your desired layout by left-mouse clicking in the final square for your desired configuration.
3. The layout selector will automatically close.

Example: For a 3x2 layout, click the square located in the second row of the third column.

Create a Hanging Protocol

Hanging protocols are saved layouts.

1. Create a viewport configuration using the Layout Selector.
2. Populate each viewport with the desired series.
3. Click the arrow on the hanging protocol window to open.
4. Select "Save Hanging Protocol" from the menu.
5. Enter a name for the new protocol.
6. Click OK.

Set the Default Hanging Protocol

The default hanging protocol will be the layout into which a study always launches.

1. Select a hanging protocol from the hanging protocol drop-down menu.
2. Open the hanging protocol drop-down menu again and select "Set Default Hanging Protocol".

Multi-Planar Reformatting

CAKE™ will automatically generate the orthogonal multi-planar reformats from the dynamic image data. The reformatted images are listed in the “Select Series” menu. To load the orthogonal reformat into a viewport, refer to [“Select Series” on page 11](#).

Maximum Intensity Projection (MIP)

CAKE™ will automatically generate the MIP from the dynamic image data. The MIP is listed in “Select Series” menu. To load the MIP, refer to [“Select Series” on page 11](#).

Carving a Region of Interest

To isolate a region of interest on the MIP, press the Ctrl key and left-mouse button and drag the mouse to expand the red box over the region of interest to carve out of the image. Everything within the red box will be saved and all else will be removed from the view.

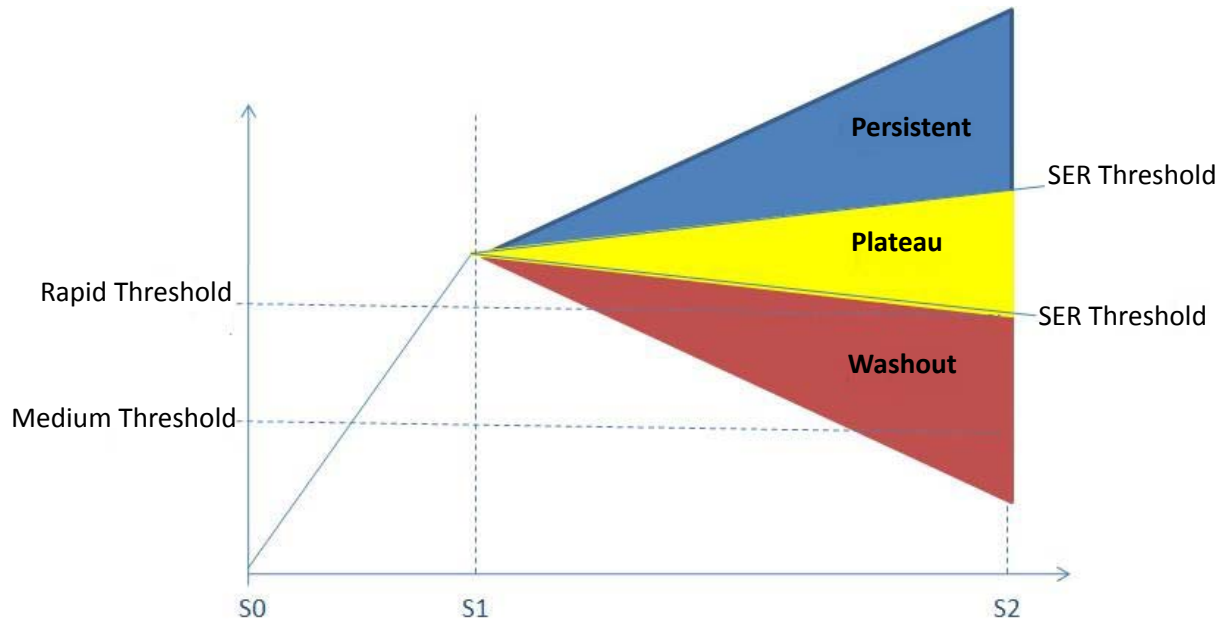
Reset Carving

To restore the tissue removed with the carving tool, select “Reset Carving” from the right-mouse menu.

Curve Tool

The curve tool shows how pixel intensity changes throughout a dynamic data set. Curves are colored based on their uptake and washout characteristics. If the intensity increases above the uptake threshold at the S1 time point, the curve will be colored. Uptake thresholds can be set at medium or rapid. The color is then based on how the intensity changes at the S2 time point, which is defined as the Signal Enhancement Ratio (SER) threshold.

FIGURE 1. SER Graph



The interactive curve tool is used to define the parametric map. It displays a contrast agent curve correlating to the area that the mouse is positioned over on the dynamic series. A 2mm x 2mm area is evaluated to determine the curve. The S0, S1 and S2 points used to compute parametric maps can be manually adjusted. As can the medium and rapid enhancement thresholds. Lastly, the curve tool displays the Signal Enhancement Ratio which can be manually defined, if desired.

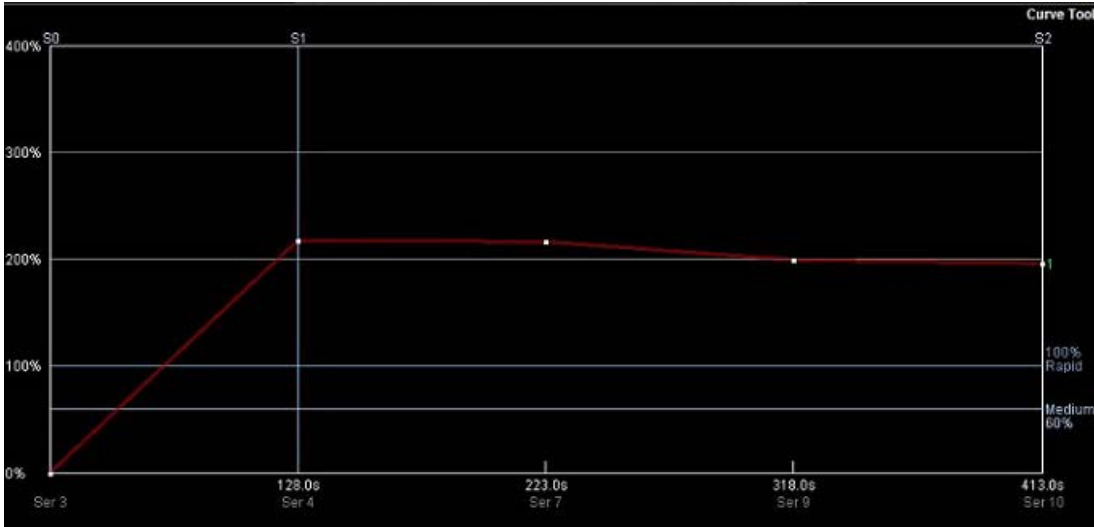
IMPORTANT: The parametric map is not saved upon closing.

Curve Tool Functionality

Display the Curve Tool

In 2D Image Review Mode, right-mouse click on the blank viewport in which you want the curve displayed and select “Curve Tool” from the pop-up menu.

FIGURE 2. Curve Tool



Plot a Curve

Press the keyboard Ctrl key then left-mouse click on the desired location within the dynamic or dynamic subtraction series.

Delete a Curve

Right-mouse click on the curve and choose “Delete this Curve” from the pop-up menu.

Change S0, S1 and S2 Timepoints

By default the software selects Pre-contrast or S0 series as the first series, Peak or S1 series as the second series and Delayed or S2 series as the last series.

To change any of these timepoints, left-mouse click mid-way down on the line and drag to the desired location. The cursor will change from an arrow to the translate cursor.

Enhancement Thresholds



CAUTION: Changing the enhancement threshold will directly affect the parametric map.

The enhancement threshold defines the signal intensity change required between pre (S0) and peak (S1) for labeling on the parametric map. If the percent change from Pre to Peak is less than the set thresholds, color will not be assigned. By default, the settings are 60% (medium) and 100% (rapid).

To change the enhancement threshold, click and drag either Rapid or Medium lines on the curve tool.

Curve Tool Menu Functions

With the cursor on the curve tool viewport, right-mouse click to open up the menu. Choose from the following functions.

Set Difference Threshold

The noise threshold filters noise pixels in the image which is used for parametric maps The threshold is set during installation.



CAUTION: Do NOT change this threshold without contacting NeoSoft's support team for additional instructions (support@NeoSoftmedical.com).

Set SER Threshold

The SER threshold for parametric maps defines the percentage change between washout plateau and persistence and is set during installation.



CAUTION: Do NOT change this threshold without contacting NeoSoft's support team for additional instructions (support@NeoSoftmedical.com).

Reset Scale

Clicking, holding and dragging the left-mouse button on the left margin of the curve scale will provide additional or fewer values. The "Reset Scale" function on the menu sets the scale values back to default.

Show All Curves

Adjusts the scale so that all curves are visible.

Clear Saved Points

Removes all curves from the Curve Tool graph.

Example Workflow

1. Send a breast MR case to suiteDXT from the MRI scanner or PACS.
2. Open suiteDXT from the system desktop.
3. Select a patient study.
4. Choose a study with a minimum of one pre- and two post series contrast sequence series.
5. Launch the CAKE™ software.
 - The study will be loaded into the hanging protocol defined during installation.
6. Scroll the images to evaluate for lesions of interest.
7. If a lesion is found, do one or all of the following:
 - A.) Apply a parametric map to the dynamic series.
 - B.) Use the curve tool to find most enhancing area of the lesion(s).
 - C.) Use the measurement tool to determine the size of the lesion(s).
 - D.) Localize the area in three planes using the reformatted images.
 - E.) Use the mass characterization protocol for additional size and enhancement information.
 - F.) Save the images and export to PACS.
8. Exit CAKE™ and return to suiteDXT.

Mass Characterization Mode

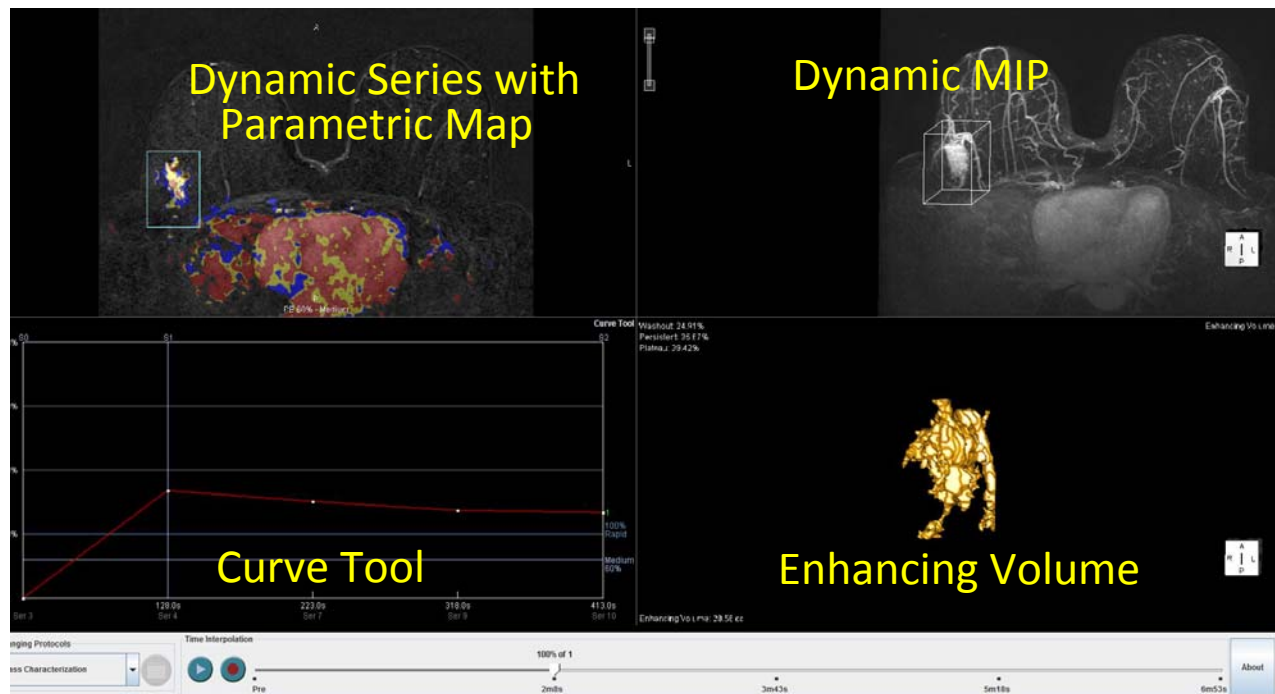
Mass Characterization mode assists in the characterization of enhancing regions. This mode allows you to place a bounding box around a region of enhancement in order to define a Volume of Interest (VOI). A 3D image of the enhancing VOI and 3D ellipsoid are displayed with quantitative information including the size of the enhancing region and composition curve type. Using the curve tool to change the thresholds, the enhancing region can be updated in real time.

Table 1: 3D Mass Characterization Features

Feature	Description
VOI Selection	Defines two dimensions of a bounding volume of Interest (VOI) from the dynamic series and selects a seed point to grow the VOI.
Dynamic MIP	Visualizes and adjusts the third dimension of a bounding volume. The MIP can be set to different views which can carve away unwanted tissue images.
Curve Tool	Displays a graphical representation of contrast agent uptake and washout rates.
Enhancing Volume	Shows the 3D image of the VOI.

Image Window Layout

FIGURE 1. Mass Characterization Fixed Viewports.



Using Mass Characterization Mode

Mouse & Keyboard Functions

Table 2: Mouse Functions in Mass Characterization Mode

Action	Function within Viewport Type			
	Dynamic Series VOI	Dynamic MIP	Curve Tool	Enhancing Volume
Left-Mouse Click	Places bounding box on image.	NA	NA	NA
Left-Mouse Click & Drag	Moves the box.	Changes MIP viewing angle.	Moves the S1 line along the x-axis. Changes the values on the y-axis.	Changes viewing angle of the 3D VOI.
Scroll Wheel	Scrolls slices	NA	NA	NA
Shift Key + Left-Mouse Click & Drag Alternately you can use the keyboard + (plus) and - (minus) keys	Zooms the view.	Zooms the view.	NA	Zooms the view.
Left & Right-Mouse Click + Hold & Drag	Moves the image.	Moves the image.	NA	Moves the image.
Right-Mouse Click + Hold & Drag	Changes W/L	Changes W/L	NA	NA
Right-Mouse Click	Displays Menu.	Displays Menu.	Displays Menu.	Displays Menu.
Press & Hold Ctrl Button while Left-Mouse Clicking and Dragging.	NA	Displays carving tool.	NA	NA
Double Left-Mouse Click	Displays view in full screen.	Displays view in full screen.	Displays view in full screen.	Displays view in full screen.

Menu Functions

Many of the right-mouse menu functions are available in all viewports, but there are functions that are specific to the type of viewport. The following table lists all functions available and identifies in which type of viewport they are found.

Table 3: Right-Mouse Menu Functions

Function Click on the function name to be taken to the description.	Dynamic Series	Dynamic MIP	Curve Tool	Enhancing Volume
Select Series	✓	✓	✓	✓
Reset W/L	✓	✓	NA	NA
Reset View	✓	✓	NA	✓
Show Annotations	✓	✓	NA	NA
Show Subtraction	✓	✓	NA	NA
Delete Bounding Volume	✓	✓	NA	NA
Measurement Tool	✓	NA	NA	NA
Add Label	✓	NA	NA	NA
Send Image for Archive	✓	✓	✓	✓
Clear Lines	✓	NA	NA	NA
Delete Label	✓	NA	NA	NA
Save as JPEG Picture	✓	✓	✓	✓
Save as MPEG Movie	✓	✓	NA	NA
Reset Carving	NA	✓	NA	NA
Coronal MIP	NA	✓	NA	NA
Axial MIP	NA	✓	NA	NA
Sagittal MIP	NA	✓	NA	NA
Reset Scale	NA	NA	✓	NA
Show All Curves	NA	NA	✓	NA
Set SER Threshold	NA	NA	✓	NA
Set Difference Threshold	NA	NA	✓	NA
Clear Saved Points	NA	NA	✓	NA

Launching Mass Characterization

After reviewing the images in the 2D Image Review, select Mass Characterization from the Hanging Protocols list.

Identify the VOI

The Volume of Interest (VOI) provides a 3D rendering of selected enhancing lesions by detailing the characteristics of the volume and enhancement pattern.

1. In the Dynamic Series viewport, left-mouse click on the enhancing lesion to place a bounding volume around the region of interest. Be sure to incorporate the entire enhancing lesion.

NOTE: The application assumes that you place the box on a slice that is near the center of the enhancing region in the orthogonal dimension to the image.

NOTE: The size of the bounding volume can be adjusted by clicking on it and dragging with the mouse.

2. In the MIP viewport, left-mouse click and drag the slider bar to enlarge bounding box to fully encapsulate the depth of the region of interest. Rotate the MIP in order to better visualize the extent of the lesion.

Delete Bounding Volume

The bounding volume can be deleted by selecting the deletion function from the right-mouse menu.

Navigate Using the MIP

The MIP is used to change the size of the orthogonal dimension. When the lesion is selected in the 2D view, a box will appear on the MIP view displaying the lesion in 3D.

The view angle of the MIP can be changed for better visualization, by clicking and dragging with the left-mouse button depressed. The 3D bounding box on the MIP corresponds to the location on the dynamic view. The bounding box remains on that location even as the image is rotated. The size of the bounding box can be changed by using the slider at the left margin of the viewport.

If you left-mouse click on a location in the MIP, the image series displayed in other viewports will display the selected location in the MIP. **NOTE:** All other viewports must contain dynamic series.

The view plane can be changed by using the right-mouse menu. Options are:

- Coronal MIP
- Axial MIP
- Sagittal MIP

Extraneous tissue can be removed from the image by using the carving tool (refer to [“Mouse & Keyboard Functions” on page 22](#)), which removes all but that which is covered by the red carving box.

Curve Tool

The curve tool in Mass Characterization mode works identically as in Image Review mode. For information on using the curve tool, refer to [“Curve Tool” on page 17](#).

Enhancing Volume

The enhancing volume viewport provides quantitative measurement for the enhancing volume, including total volume (in cubic centimeters), and composition by curve type (by percentage). The enhancing volume can be changed by changing the curve thresholds (See [“Curve Tool” on page 17](#)), to ensure the entire enhancing volume is captured in the rendering and quantitative measurements. An image from any of the viewports can be archived to the suiteDXT series list. (See [“Send Image for Archive” on page 11](#)).

NOTE: Time slider toolbar can only be updated by using the keyboard arrow keys.

Troubleshooting and Maintenance

Please refer to the CAKE™ Service Manual NS-03-022-0002 for more detailed instruction on troubleshooting and maintenance.

Software Version

The software version can be found on the CAKE™ title bar or by pressing the About button.

Software Licensing

Software licenses are provided and installed at the time of installation. If you do not have a valid license key, contact NeoSoft's support team (support@NeoSoftmedical.com).

Error Messages

For assistance in locating the error log files, please refer to the CAKE™ Service Manual or contact NeoSoft's support team (support@NeoSoftmedical.com).

Product Upgrades

Product upgrades are provided and installed by NeoSoft.

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