

NeuWave™

**NEUWAVE™ Ablation Confirmation
User Reference Manual**
Software Version 3.1.X



ETHICON

PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

User Responsibility

This Product will perform in conformity with the description contained in this user guide and accompanying labels and/or inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted, or contaminated should be replaced immediately. Should repair or replacement become necessary, NeuWave Medical recommends that a written request or request by phone for service advice be made to the nearest Ethicon™ Customer Service Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by NeuWave Medical and by NeuWave Medical trained personnel. The Product must not be altered without the prior written approval of NeuWave Medical. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than NeuWave Medical.

CAUTION U.S. Federal law restricts this device to sale by or on the order of a physician. Outside the United States, check local laws for any restrictions that may apply.

Ablation Confirmation is a trademark of NeuWave Medical, Inc.

Other brand names or product names used in this manual are trademarks or registered trademarks of their respective holders.

pat. www.ethicon.com/patentmarking

Company Contact Information

Ethicon Customer/Technical Service +1-877-ETHICON (384-4266) +1-513-337-8901

NeuWave Medical

3529 Anderson Street

Madison, WI 53704 USA

www.neuwave.com - click on "Contact Us"

Contents

1 Introduction.....	1-1
Indications for Use	1-1
System Overview	1-1
Additional System Features	1-2
Navigating the Software.....	1-3
Using the View Steps Menu to Navigate the Software	1-4
Screen Guidance.....	1-5
Network Connectivity.....	1-5
Handling Network Connectivity Problems	1-6
Using this Guide.....	1-6
2 Warnings and Cautions.....	2-1
3 Using the Software.....	3-1
CT Protocol Guidance for Ablation Confirmation	3-1
Installing and Setting Up the Software	3-2
Starting the Procedure	3-2
Examining the Image Series.....	3-5
Using the Image Views to Examine the Setup Series	3-6
Defining Targets	3-6
Selecting a Comparison Series.....	3-9
Comparing Images from the Define Targets Screen	3-10
Placing and Reviewing the Probes	3-12
Registering the Setup Images with Probe Placement Images.....	3-13
Evaluating Probe Placement.....	3-15
Manually Editing Probe Displays.....	3-16
Tip Distances	3-17
Performing the Ablation and Creating an Ablation Zone	3-18
Registering the Ablation Series and Evaluating the Ablation.....	3-21
4 Using Image Views and Tools.....	4-1
Using the Image Views.....	4-2
Using the Mouse in Image Views.....	4-3
Using the Zoom Tool	4-3
Using the Pan Tool	4-4
Using the Window Level Tools	4-4
Using the Measure Tool	4-5
Using the Rotate Tool in 2D Views	4-6
Using the Rotate Tool in 3D Views	4-6
Using the Snapshot Tool.....	4-7
Using the Reset Tool	4-7
Using the Create Tool to Define an Ablation Target	4-7
Using the Sphere Tool.....	4-7
Using the Edit Tool	4-9

Using the Move Tool 4-9

Using the Refinement Tools to Improve Registration..... 4-10

Using the Create Tool to Define an Ablation Zone 4-10

5 System Setup and Configuration 5-1

Admin Tab Functions 5-2

Handling Network Connectivity Problems 5-3

Cybersecurity Information..... 5-5

6 Appendix A..... 6-1

Physician Lesion/Ablation Segmentation Measurement Variability Assessment 6-1



Introduction

Indications for Use

Ablation Confirmation™ (AC), is a Computed Tomography (CT) image processing software package available as an optional feature for use with the NEUWAVE Microwave Ablation System. AC is controlled by the user via an independent user interface on a second monitor separate from the NEUWAVE Microwave Ablation System user interface. AC imports images from CT scanners and facility PACS systems for display and processing during ablation procedures. AC assists physicians in identifying ablation targets, assessing proper ablation probe placement and confirming ablation zones. The software is not intended for diagnosis.

System Overview

AC is resident on the NEUWAVE Ablation System and is accessible to physicians via a second, dedicated monitor with its own user interface that is separate from the ablation user interface. AC functions are controlled via a USB-connected mouse. AC connects to a facility PACS and CT scanner, and receives CT and magnetic resonance (MR) images via a Digital Imaging and Communications in Medicine (DICOM) protocol. DICOM is a standard for handling, storing, printing, and transmitting information in medical imaging; it includes a file format definition and a network communications protocol that uses TCP/IP to communicate between systems. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format. DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a PACS.

AC contains a wide range of image processing tools, including:

- 2D image manipulation
- 3D image generation (from 2D images)
- 3D image manipulation
- Region of interest (ROI) identification, segmentation, and measurement
- Automatic identification of ablation probes
- Registration of multiple images into a single view

Prior to an ablation procedure, physicians can use AC to semi-automatically segment and visualize ablation target lesions in soft tissue, including liver, lung, and kidney. The physician initiates the segmentation using on-screen tools, and AC then uses segmentation algorithms to construct a 2D visualization of the selected target lesion. The physician can accept the initial segmentation results or use AC tools to manually adjust the defined target lesion. Once accepted, the identified target is rendered into a 3D image.

In some cases, lesions cannot be well defined on CT images. For example, image quality or lesion characteristics might make it difficult to distinguish the lesion from surrounding tissue. (For more details, see *CT Protocol Guidance for Ablation Confirmation* at the beginning of Chapter 3.) In these situations, the software allows physicians to manually place a sphere on the image to represent the target. When placing the spherical target, the physician relies on lesion location information from other imaging modalities, such as MR or ultrasound. Once the target is placed and confirmed, the AC software processes it exactly as the software would process a target segmented from a CT scan.

After the placement of ablation probes and a CT scan, AC automatically imports the scan, processes the images, and identifies up to three probes. AC then performs a registration of the initial CT scan that contains the identified target with a second scan that contains the ablation probes in place. The resulting image allows the physician to visualize the ablation probe(s) in relation to the identified target and to ensure proper probe placement before starting the ablation.

Following the ablation procedure and a post-ablation CT (CECT) scan, if appropriate, AC allows the physician to semi-automatically segment and visualize the ablation zone using the same process as that in the initial target segmentation. AC then performs a registration of the initial CT scan that contains the identified target with the final CT scan that contains the segmented ablation zone. For more details, see *CT Protocol Guidance for Ablation Confirmation* at the beginning of Chapter 3. The resulting image includes the ablation zone overlaid with the initial target lesion segmentation to help physicians determine the technical success of the ablation procedure.

All AC processing and viewing is accomplished at the NEUWAVE Ablation System; the physician does not have to leave the procedure area to use separate image processing tools.

The system is designed for facility use and should only be used under the orders of a physician.

Additional System Features

Additional system features include:

- Connections that enable electronic access to the hospital's PACS and CT scanners.
- On-screen data that identifies the case at hand.
- A screen navigation system that presents screens in a logical sequence and permits a flexible workflow.
- On-screen guidance that displays general instructions for using the active screen.
- An image viewing area that permits images to be segmented and viewed in varying orientations, and in views that highlight tissue based on associated image density.
- Display of radiologic data, visual signs, and reference points that indicate patient orientation in CT images.
- A deformable image registration algorithm that aligns spatial relationships between images acquired at different points during the procedure.
- An on-screen, three-dimensional image constructed from selected two-dimensional image series that have been pulled into the system.
- Mouse-controlled tools that can be used to move, manipulate, investigate, and analyze on-screen images in ways that can augment the monitoring of ablation procedures and results.

The software performs processing of images imported from CT stations and PACS. The quality of the source images affects the effectiveness of tools in the software. NeuWave recommends the use of images acquired using standard clinical diagnostic protocols. For more details, see *CT Protocol Guidance for Ablation Confirmation* at the beginning of Chapter 3.

Navigating the Software

AC is designed to guide you logically through the ablation procedure. The system is a series of screens that reflects the sequence of a typical procedure.

Use the navigation bar at the top of the screen to move forward or backward through the software.

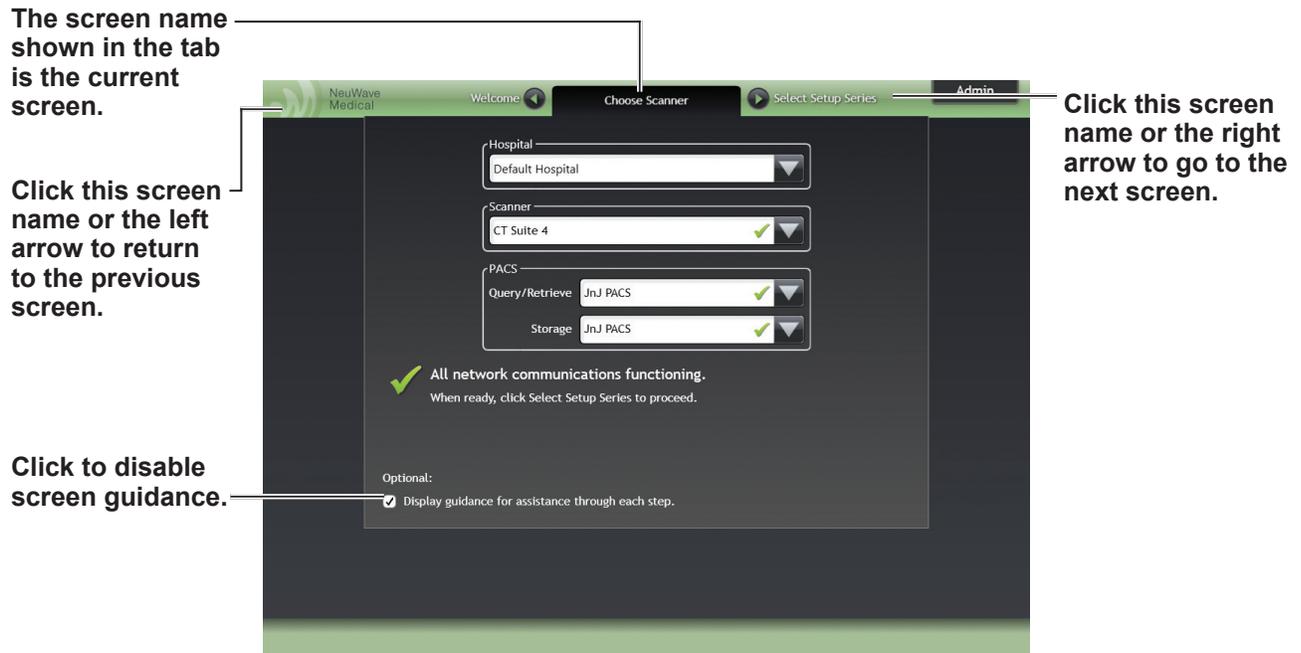


Figure 1-1: Screen navigation and guidance

Using the View Steps Menu to Navigate the Software

When working through the ablation procedure, especially as a new user, it makes sense to use the arrow button in the navigation bar to move forward through the software one screen at a time. If you complete the procedure and determine that you need to make adjustments, you can move to any preceding screen using the View Steps menu (see Figure 1-2), which you can open by clicking the View Steps button in the upper-right corner of the screen. Experienced users will find the menu handy if they need to return to a previous screen at any time to make a quick adjustment.

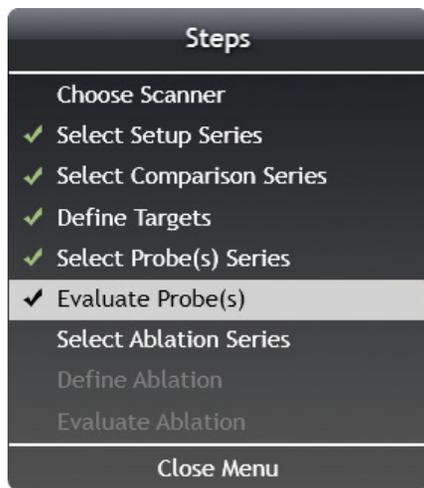


Figure 1-2: View Steps menu

To move immediately to a screen listed in the menu, simply click the screen name. The screens are listed in order as they appear in the software. The active screen is highlighted in the menu. Note that some screens, such as the registration screen, are not shown in the menu. If a screen is not currently available for selection, its screen name is shown in gray in the menu.

The View Steps menu becomes available when you reach the Select Setup Series screen. Until then, the Admin button appears in the upper-right corner.

If a check mark appears next to a screen name, requirements have been satisfied for that screen. If a snapshot has been taken on a screen, the screen name appears in the menu with a camera icon next to it.

Click Close Menu to dismiss the View Steps menu.

Screen Guidance

The software comes with a guidance system that briefly describes the function of each screen. To disable guidance in subsequent screens, uncheck the box shown at the bottom of Figure 1-1.

To clear the guidance box from any subsequent screen in the software, click the dash next to the Hide button in the upper-right corner of the guidance box.



If you have hidden the guidance boxes, you can display one at any time by clicking the question mark beside the active screen name (see Figure 1-3).

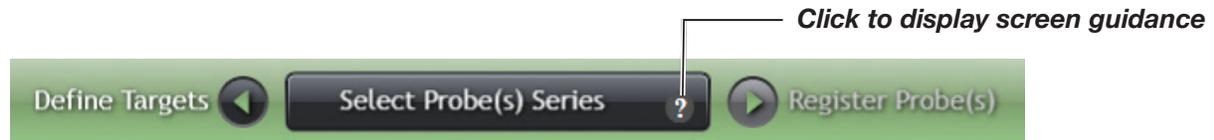


Figure 1-3: Clicking the question mark displays screen guidance

Network Connectivity

The NEUWAVE Ablation System, with the Ablation Confirmation software, communicates with configured CT scanners and the hospital PACS via a wired Ethernet RJ-45 connection in the CT suite. The ablation system cart is configured for the network in the same manner as other networked medical devices or computers.

The DICOM communication protocol is used to access and transmit images during the ablation treatment. To recognize the ablation system cart as a DICOM node, configuration is needed for CT scanners and the hospital PACS used during an ablation procedure prior to the first treatment. This is a one-time configuration; it does not need to be done for each procedure. The communication between the cart and other DICOM devices is illustrated in Figure 1-4.

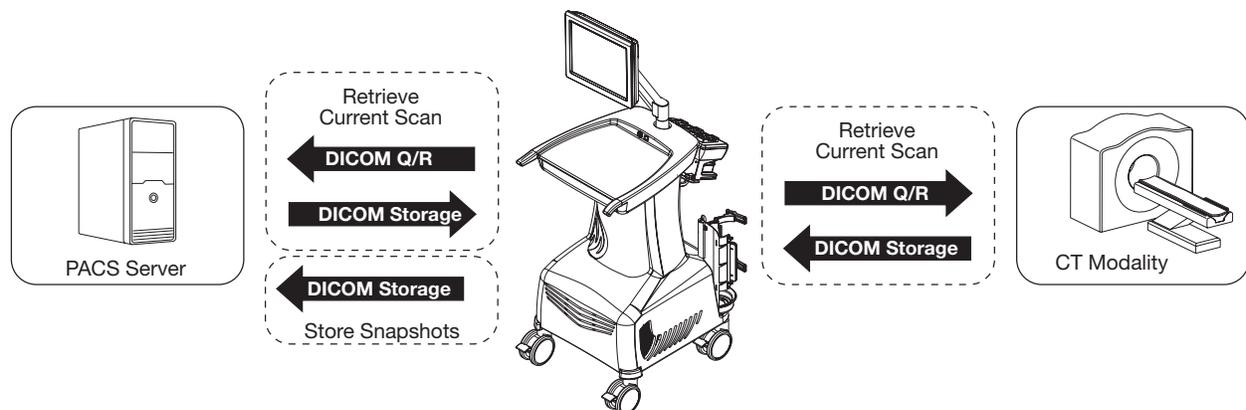


Figure 1-4: Network connectivity

Handling Network Connectivity Problems

The Ablation Confirmation system includes communication monitoring to ensure that the software can communicate with the facility PACS and CT scanner. Some network problems are easy to fix yourself—for example, you might have forgotten to connect an Ethernet cable to the system. Other problems might require assistance from your IT department or Ethicon™ Customer Service to troubleshoot and resolve. For more information on resolving these problems, see *Handling Network Connectivity Problems* at the end of Chapter 5.

Using this Guide

This user guide contains instructions for operating the Ablation Confirmation software. Refer to the NEUWAVE Ablation System user manual for operating instructions, warnings, and cautions associated with the NEUWAVE Ablation System.

Warnings and cautions describe dangerous conditions that can occur if the instructions in this guide are not followed. Read and follow all warnings and cautions.

WARNING Warnings describe conditions that can cause injury to the operator or the patient. In this guide, the word **WARNING** appears in all caps and bold text, and the warning text is indented. If more than one warning is listed in a row, the word **WARNING** is only shown once.

CAUTION Cautions describe conditions that can cause damage to the equipment. In this guide, the word **CAUTION** appears in all caps and italic text, and the caution text is indented. If more than one caution is listed in a row, the word **CAUTION** is only shown once.

The guide contains the following chapters:

- **Chapter 2** includes precautionary statements that you should read before using the system.
- **Chapter 3** is a step-by-step tutorial for using the software during a typical procedure. The chapter describes each screen in the system sequence and instructions for using each screen.
- **Chapter 4** is a reference that describes how to use the system's image views and tools.
- **Chapter 5** explains how to set up and configure the system for use.

2

Warnings and Cautions

You should be familiar with all warnings and cautions before using Ablation Confirmation (AC). Refer to the NEUWAVE™ Microwave Ablation System user manual for operating instructions, warnings, and cautions associated with the NEUWAVE Ablation System.

- WARNINGS**
- AC should only be used by physicians and staff who are properly trained in the use of this technology and its associated warnings and cautions. Physicians should avail themselves of preclinical training, a review of pertinent literature, and other appropriate education before attempting to use AC.
 - No modification of this equipment by the user is authorized by NeuWave Medical Inc.
 - During initial setup, inspect the system for any damage that may have been caused by shipping and transportation. If the system appears damaged, do not use or attempt to repair it. Call Ethicon™ Customer Service for service assistance.
 - Inspect the system before each use. If there is evidence of damage, do not use the system. Call Ethicon™ Customer Service for service assistance.
 - In the event of a display failure, use the system ON/OFF switch to turn the system OFF. Discontinue use of the system until it is repaired.
 - Repairs should only be attempted by trained NeuWave Medical personnel or by people who have completed service training that is approved by NeuWave Medical.
 - When evaluating registration in the Register Probe(s) screen or the Register Ablation screen, note that if significant amounts of the image sets are shaded in green and/or purple, a large shift has occurred between the two image sets. In such cases, an additional CT scan should be performed and the registration process repeated. If re-registration does not improve the registration differences, stop using AC for that procedure. Refer to the CT scans on your CT review station to evaluate the ablation procedure.

- WARNINGS**
- If you are not authorized to set up or configure the system, *do not* change settings in the Administration screen. The screen is password-protected to prevent unauthorized access. For example, *do not* click the Config Query button and configure DICOM data attributes. Incorrect configuration can disable communication with scanners and PACS devices.

- CAUTIONS**
- Use caution when adjusting the moveable display arm to avoid pinching hands or fingers.
 - Position the system in the procedure room so that the dual monitors do not interfere with the procedure.
 - Position the system as close as possible to power and network connections to minimize tripping hazards.
 - The patient's position (for example, supine or decubitus) should remain consistent across all scans. Variations in patient position may result in the inability to properly register image sets.

3

Using the Software

This chapter takes you step by step through each screen of AC. The screens are sequenced to match the typical order used during the ablation procedure.

Workflow may vary from case to case or from site to site. In some procedures, you will not need to acquire certain image series and might choose to skip screens in the sequence. In other cases, procedural steps must be repeated, so you can navigate backward through the screen sequence as needed.

CT Protocol Guidance for Ablation Confirmation

NeuWave recommends that you observe the following guidelines when configuring CT scanners:

Scan slice spacing of 2.5 mm or less is required for AC. If you use slice spacing that is greater than 2.5 mm, probes may not be detected and the registration accuracy will be reduced. NeuWave discourages scanning at a coarser resolution and reformatting to achieve a finer slice spacing.

Ensure that the scan's field of view fully encompasses at least the target and ablation area; preferably, the field of view should also encompass several cm beyond the planned ablation area.

Reducing the scan's axial range to the minimum amount necessary will reduce transfer time and speed up image processing operations. To manage the amount of computation time required, it is best to limit the number of slices in each scan to 250 or fewer. Larger numbers of slices in the loaded series may result in longer processing times.

The scanner field of view, patient position, hydro-dissection, and breath hold should be kept constant across all scans. Maintaining this consistency will improve registration times.

The scanner must be in helical (or spiral) mode. Series acquired in Sequential mode will be rejected by Ablation Confirmation.

The use of Fluoro images is not supported and will be rejected by Ablation Confirmation.

Do not enable automatic push of CT scans to the Ablation Confirmation system. If manual push of CT images to Ablation Confirmation is required, select only the relevant series to be transferred.

Keep one CT exam open for all scans throughout the entire procedure.

GE Scanners: select "Repeat Series" between scans. DO NOT select "Repeat Last Group". Ablation Confirmation will automatically separate a multiphasic scan into separate phases after transfer from the CT Scanner, but it must be part of the same Study as the other treatment series.

Toshiba Scanners: select "Quit Series" between scans.

Philips scanners: DO NOT select 'Extend Series', select 'Repeat Series'.

This is because Ablation Confirmation queries a single DICOM Study and requires that each scan be in a separate series. The exception to this rule is a multiphasic scan protocol.

CAUTION Probe placement and post-ablation evaluations are based on the user-defined target; therefore, accurate target definition is important. NeuWave Medical recommends care when defining targets. Latent tissue properties and imaging parameters may result in targets that are difficult to define. Administering a small amount of contrast prior to the setup scan may be helpful in target definition.

Installing and Setting Up the Software

- WARNINGS**
- During initial setup, inspect the system for any damage that may have been caused by shipping and transportation. If the system appears damaged, do not use or attempt to repair it. Call NeuWave Medical for service assistance.
 - Inspect the system before each use. If there is evidence of damage, do not use the system. Call Ethicon™ Customer Service for service assistance.

Administrative setup is needed before you can use the software. These setup procedures and network connections will be completed by a hospital representative or a NeuWave representative. For a description of administrative settings in AC and possible network connectivity problems, see Chapter 5.

Starting the Procedure

- WARNINGS**
- AC should only be used by physicians and staff who are properly trained in the use of this technology and its associated warnings and cautions. Physicians should avail themselves of preclinical training, a review of pertinent literature, and other appropriate education before attempting to use AC.
 - No modification of this equipment by the user is authorized by NeuWave Medical.
 - In the event of a display failure, use the system ON/OFF switch to turn the system OFF. Discontinue use of the system until it is repaired.
 - Repairs should only be attempted by trained NeuWave Medical personnel or by people who have completed service training that is approved by NeuWave Medical.

The application should be ready to use. The Welcome screen of the application should appear on the monitor, as shown in Figure 3-1.



Figure 3-1: Welcome screen of Ablation Confirmation software

1. Click the  button at the top of the screen to advance to the Choose Scanner screen (see Figure 3-1).
2. The patient must be properly positioned on the CT scanner bed and the system cart must be positioned where the system's power and network connections can be made. If there is no Ethernet connection or you have other network connectivity problems, or if the system does not have a valid license (as indicated in Figure 3-2), contact Ethicon Customer Service and see *Handling Network Connectivity Problems* at the end of Chapter 5. You might be able to fix the Ethernet connection yourself; check the lower-left side of the cart and make sure that a CAT5 Ethernet cable is attached between the ablation system network data port and the hospital network data port (see Figure 3-3).

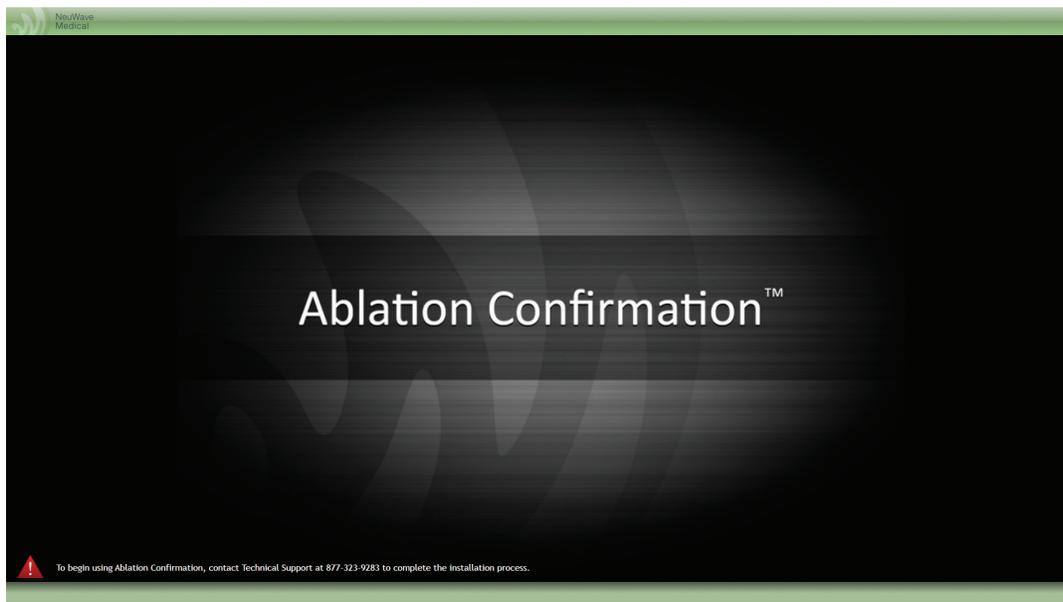


Figure 3-2: Welcome screen if system starts without a valid license

- CAUTIONS**
- Use caution when adjusting the moveable display arm to avoid pinching hands or fingers.
 - Position the system in the procedure room so that the dual monitors do not interfere with the procedure.
 - Position the system as close as possible to power and network connections to minimize tripping hazards.

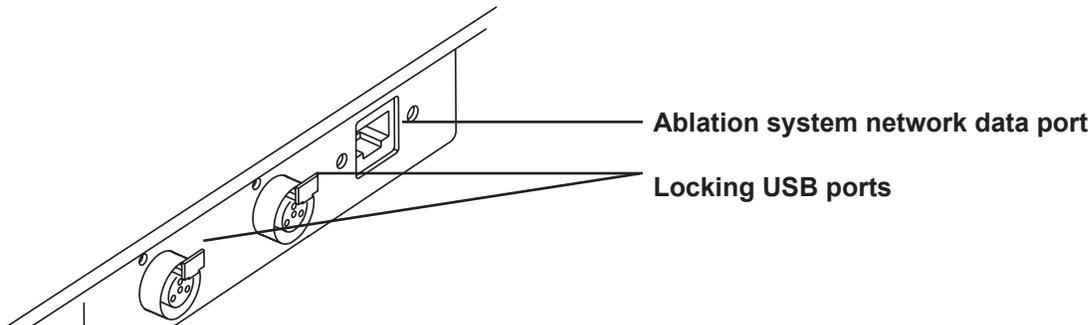


Figure 3-3: Ablation system network connection

3. In the Choose Scanner screen, use the drop-down lists to select the name of the hospital, the CT scanner that will deliver images to the system, the PACS for querying and retrieving data, and the PACS to use for storage.
This information might already have been selected.
4. Click the  button at the top of the screen to advance to the Select Setup Series screen.
5. Perform the scan. A CT image series, called the setup series, is acquired.
To help limit computation time, it is best to limit the number of slices in the scan to 250 or fewer.
6. Verify that the correct patient scan is being displayed by checking the patient's name and ID number in the upper-left corner of the screen.
7. Select the newly acquired series from the list in the lower-left corner of the screen.
The list shows the scans taken for the selected patient at the current scanner. Note that the application only displays data for one patient at a time. Use the scroll bar to view longer lists.
Note also that the description of series are those entered at the scanner console.
8. After selecting the series, click the Pull Series button beneath the list (see Figure 3-4).
The application “pulls” the series in from the scanner for examination. A spinning wheel appears in the center of the screen while the series is being downloaded. Click Cancel if necessary.

If the pulled series is multiphasic (i.e., if it consists of more than one phase), the first phase will be displayed and entries for each of the phases will be added to the list of available series. The series description for each phase will be preceded by the number of the phase. If you want to view a different phase, select the phase and then click Pull Series.

Examining the Image Series

Take a moment to look at the Select Setup Series screen, as shown in Figure 3-4. It contains several sets of tools and windows that help you examine the image series and locate the lesion. These tools and windows are available in many subsequent screens of the software.

The left side of the screen is divided into three parts. The section at top left displays patient data associated with the image. At bottom left, the series selection list allows you to choose an image series for examination, as you saw in the previous steps.

The Image Tools panel contains several tools that help you scroll through, manipulate, and annotate the image slices in the selected image series. You cannot use these tools unless image slices are shown in the image views on the right side of the screen:

- The Zoom tool increases or decreases the size of an image within a view.
- The Pan tool allows you to move an image within a view.
- The Window Level tools adjust an image's contrast and brightness, which helps display features within an image more prominently.

The Zoom, Pan, and Window Level tools help you locate the lesion in an image slice. Simply click the tool, move the mouse to an image view, and then click and drag.

- The Measure tool allows you to measure items of interest on an image slice. For example, it can measure a lesion or the distance between a lesion and the edge of an organ.
- The Rotate tool allows you to rotate a 2D or 3D image.
- The Snapshot tool acquires a screen shot of the displayed study data. You have the option of sending the screen shot to the storage PACS of the active study. All screen shots will be placed in a new series and stored with the active study.
- The Reset tool returns all image views to their default zoom, pan, and rotation settings.

To read complete descriptions for using the Image tools, see Chapter 4.

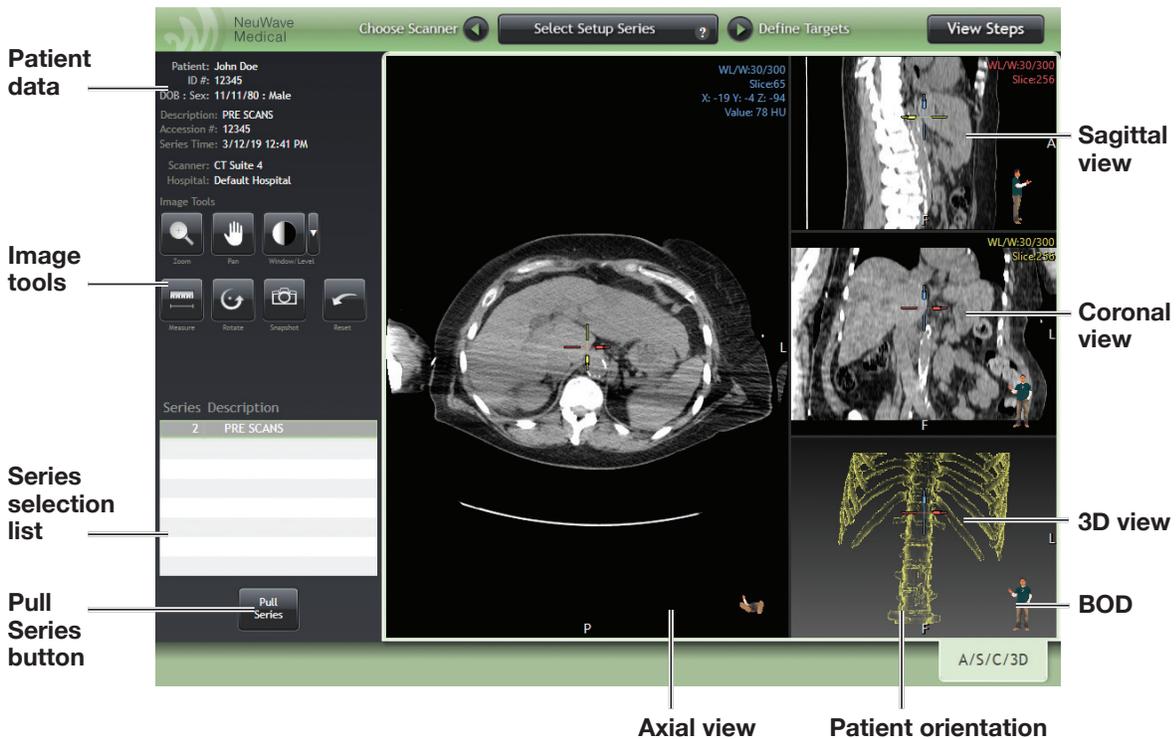


Figure 3-4: Select Setup Series screen

Using the Image Views to Examine the Setup Series

The right side of the Select Setup Series screen displays the image views. Review these images to make sure the scan is sufficient for your needs. Roll the mouse wheel to move through the slices and locate the lesion. You can also locate the lesion by clicking and dragging the mouse to move through the slices. For more information, see *Using the Mouse in Image Views* in Chapter 4.

The screen includes four views, as shown in Figure 3-4, and the edges of each view contain letters that indicate the orientation of the patient:

- Axial (horizontal view)
- Sagittal (vertical, left/right view)
- Coronal (vertical, front/back view)
- 3D view
- A, P Anterior, posterior
- L, R Left, right
- H, F Head, foot

Double-click an image to make it full size. Double-click it again to return to the default display of four views. You can change the size of image views by clicking and dragging their borders.

The lower-right corner of each image view displays a body orientation diagram (BOD), which shows the position of the patient's body with respect to the image slice shown. Radiologic data appears in the upper-right corner of each 2D view.

The colors of the crosshairs (reference points) and radiologic data correspond in all four views of the slices:

- Blue Axial image view
- Red Sagittal image view
- Yellow Coronal image view

Defining Targets

When you finish with the Select Setup Series screen, click the  button at the top of the screen to move to the Define Targets screen. Use the Define Targets screen to draw ablation targets on areas to be treated in the patient. You can define targets on an image slice in any 2D view. You can create up to three targets on an image in the setup series, each in a different color.

NOTE: See Appendix A for information that helps characterize potential measurement variability you may observe with the segmentation of lesions and ablation zones on image sets while using the software.

If you have trouble locating a lesion in the just-acquired scan, you can use a comparison series for assistance. Click the Select Comparison Series button and then see the next section for details. If you have no trouble determining the location of the lesion in the current scan, the comparison is not necessary.

CAUTION Probe placement and post-ablation evaluations are based on the user-defined target; therefore, accurate target definition is important. NeuWave Medical recommends care when defining targets. Latent tissue properties and imaging parameters may result in targets that are difficult to define. Administering a small amount of contrast prior to the setup scan may be helpful in target definition. For more details, see *CT Protocol Guidance for Ablation Confirmation* at the beginning of this chapter.

To define targets:

1. If necessary, locate the lesion in the image views.
2. In the target selection table on the left side of the screen (see Figure 3-5), click a row to associate the target with the lesion you will identify. By default, the top row is selected in the table.

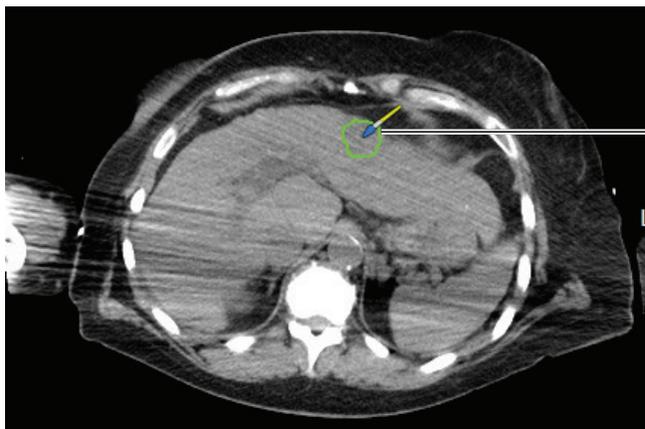
Show	Target	Intended Margin	Stats	Clear
<input checked="" type="checkbox"/>	■ A	0 mm		<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	■ B	0 mm		<input type="checkbox"/>
<input checked="" type="checkbox"/>	■ C	0 mm		<input type="checkbox"/>

Figure 3-5: Target selection table

3. In the Target Tools panel, click the Create tool and then move the mouse pointer to a 2D image view.
4. Begin to create the first target.



In the active image view, try to move to a slice near the center of the targeted lesion and try to center the mouse over tissue that you want to target. The tool previews the area by creating a green outline where you first placed the tool pointer. Based on where the preview area is displayed, the tool looks for tissue of similar characteristics and will propagate the target through the other slices when you finish defining the target.



Creating a target

Figure 3-6: Creating a target

NOTE: Using the Create tool becomes more challenging when the edges of targets are not well delineated. As an alternative, you can use the Sphere tool to quickly define a perfectly spherical target over a lesion. For details, see Using the Sphere Tool in the next chapter.

5. To expand the target outline, roll the mouse wheel forward and let the tool expand the target radius as it identifies tissue of like density. Roll the wheel backward to reduce the radius. Left-click when the desired target area is encompassed by the green preview outline. The target becomes the color assigned in the target selection table on the left side of the screen.

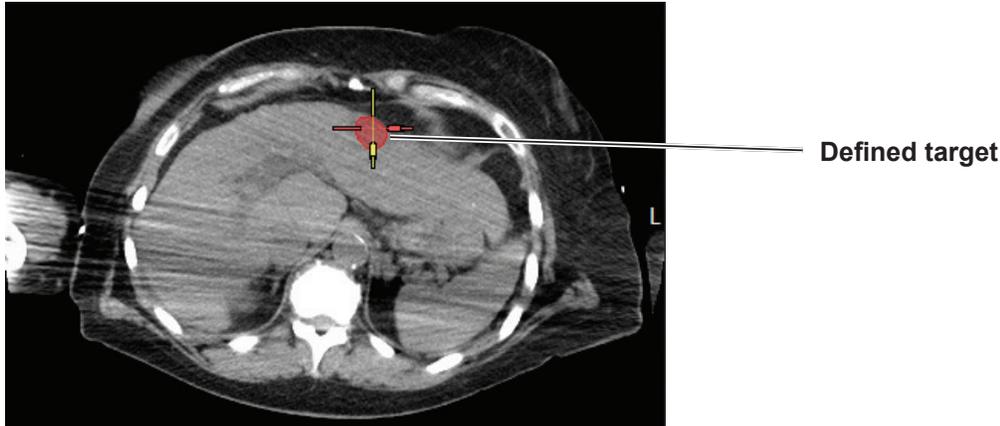


Figure 3-7: Defined target

6. If you want to refine the target, click the Edit tool in the Target Tools panel and then move the mouse pointer to the target you just defined.



- Choose a large, medium, or small diameter for refining the target. The Medium option is selected by default, but you can select a larger or smaller diameter.
- Choose single or multiple slice edit for refining the target. The single slice option is selected by default, but selecting the multiple slice edit option will edit slices above and below the displayed slice using a sphere of the selected size.
- To remove portions of the target, place the mouse pointer just outside the target's area; a red sphere appears. Click and hold the mouse, using the pointer to guide the sphere. Slowly drag the red sphere along the target's border.
- To expand portions of the target, place the mouse pointer just inside the target's area; a green sphere appears. Click and hold the mouse, using the pointer to guide the sphere. Slowly drag the green sphere along the target's border.

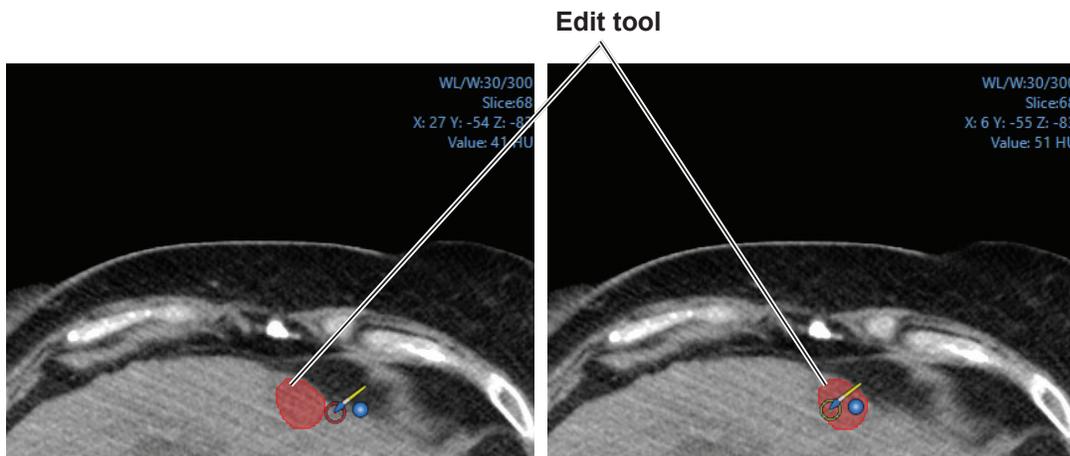


Figure 3-8: Using the Edit tool to decrease and expand the target area

7. If necessary, repeat the preceding steps to create up to two more targets.
8. The Undo and Redo buttons can be used to undo or redo creation of a target or changes to a target.
9. In the target selection table, you can select the size of a margin to display around the target(s). The margin display allows you to visualize the ablation zone with or without the margin to help identify the desired area. The margin area is shown in a different shade from the rest of the target area. The size of the margin ranges from 1 to 10 millimeters.

Show	Target	Intended Margin	Stats	Clear
<input checked="" type="checkbox"/>	■ A	0 mm		<input type="checkbox"/>
<input checked="" type="checkbox"/>	■ B	0 mm		<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	■ C	0 mm		<input checked="" type="checkbox"/>

Figure 3-9: Target selection table for defining margins and displaying targets

10. To see statistics for a target area, click its Stats arrow in the target selection table. The statistics show the target’s length in millimeters along the X-, Y-, and Z-axes, and its total volume in cubic centimeters.
11. To temporarily hide a target from view and display only its outline in the 2D views, click its Show button in the target selection table. Hiding a target can be useful if its color fill is obscuring or intruding upon the subtlety of grayscale variations and shadings that help identify features of interest.
12. To delete a target and start over, click the appropriate X in the Clear column.

Selecting a Comparison Series

The Select Comparison Series screen allows you to select a previously acquired image series from the PACS and compare it to the setup series you just acquired. The comparison scan can be a previously acquired set of CT, MR, or Fused PET images. Fused PET images must be created, by the PACS or other workstation, prior to use in Ablation Confirmation. If Fused PET images are used, not all functionality, including measurement functionality, will be available for the comparison displays (see Figure 3-10).

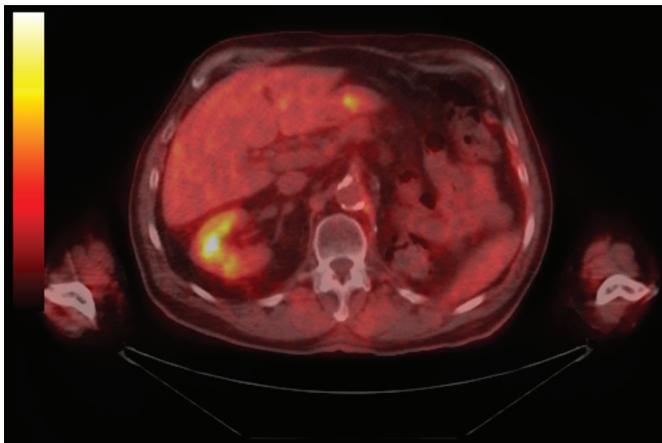


Figure 3-10: Example Fused PET image

To reach this screen, click the Select Comparison Series button in the Define Targets screen.

A comparison series sometimes can help you locate a lesion in the just-acquired scan. For example, a series acquired a week or a month ago might highlight the lesion better. In some cases, an MR scan might display lesions better than a CT scan. If you have trouble locating or seeing a lesion in the current scan, the older comparison scan might help you find the lesion.

If you have no trouble seeing the lesion in the current scan, the comparison screen is not necessary.

To select an image series for comparison:

1. Refer to the list of studies on the lower-left side of the Select Comparison Series screen. The list shows studies that are available on the PACS for the current patient. A date and description are displayed for each study. Each study can be expanded to reveal the series associated with it. Only CT, MR, or Fused PET series are available.
2. Click the plus sign to the left of the desired study description or double-click the study description. A list of image series appears for the study. Use the scroll bar below the list to view longer study and series descriptions, if necessary.
3. To select a series, click its name in the list.
4. Click the Pull Series button below the image series list to bring the selected series into the system. After you return to the Define Targets screen, you can compare the series with the setup series you just acquired.

If the pulled series is multiphasic (i.e., if it consists of more than one phase), the first phase will be displayed and entries for each of the phases will be added to the list of available series. The series description for each phase will be preceded by the number of the phase. If you want to view a different phase, select the phase and then click Pull Series.

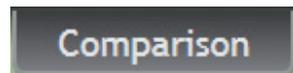
Once a comparison series has been selected, the Select Comparison Series screen appears in the navigation bar between the Select Setup Series screen and Define Targets screen. The Select Comparison Series screen also becomes available from the View Steps menu.

5. Click the  button at the top of the screen to return to the Define Targets screen.

Comparing Images from the Define Targets Screen

If you selected a comparison series in the previous screen, you can compare it with the setup series from the Define Targets screen. You can use the comparison series to help locate the lesion in the setup series.

1. In the lower-right corner of the Define Targets screen, click the Comparison tab.



The screen changes to display side-by-side axial views, as shown in Figure 3-11. The comparison series appears on the left and the setup series appears on the right. You cannot move the border between the two image views, nor can you view the comparison images in 3D.

2. Click the Link tool if you want your actions in one image view to affect both image views.



The Link tool is available when you are viewing the Comparison tab. When the Link tool is not selected, your actions only affect the selected image view.

NOTE: The linked scrolling action is relative; when the slice is changed in one image view, the software will attempt to change the slice in the other view by the same slice spacing. If no slice exists at that spacing in the other view, the closest slice will be displayed.

3. Use the Image tools and mouse actions to compare images. You can also define targets, as explained earlier in this section, but only in the setup series on the right side of the screen.

For example, you might want to use the Measure tool in the comparison series (see Figure 3-11) to measure the width of a lesion or the distance from the edge of a lesion to the edge of an organ or other known fiducial. You can then apply that knowledge to the setup series.

Measurements can also be useful when you are comparing images and you already know specific distances between features of interest in the comparison image.

The Measure tool and other Image tools are described in detail in the next chapter.

NOTE: Again, you cannot define a target in the comparison screen (the PACS screen on the left). Also, The predetermined Window/Level setting, using the drop down list next to the Window/Level tool, will only affect the Setup series, not the PACS series when using the side by side comparison view.

4. To return to the setup series in the multiple-view configuration, click the A/S/C/3D tab.



When you are satisfied that you have defined the targets over the lesion, you can move on to the next screen.

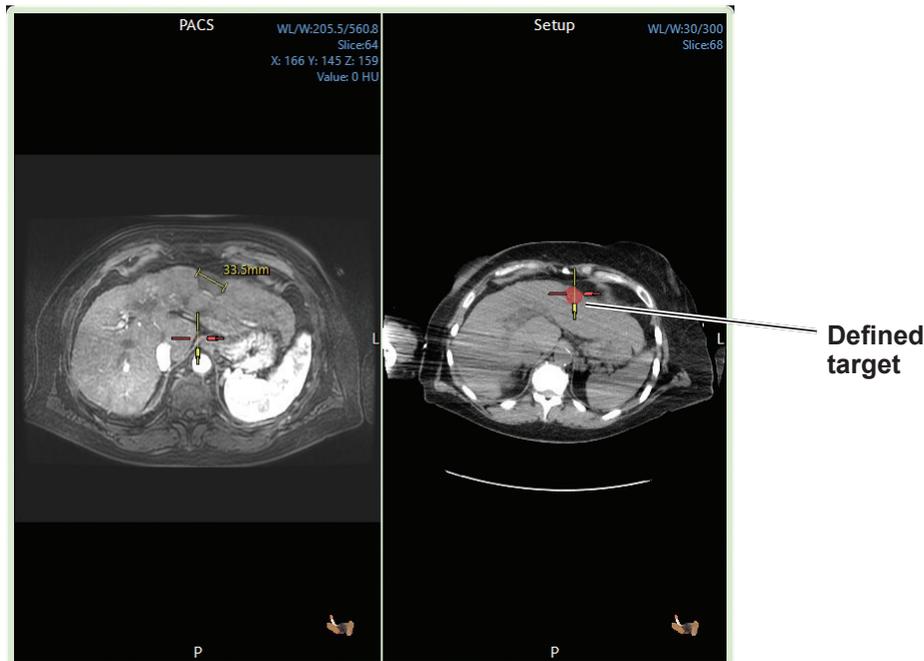


Figure 3-11: Using the comparison screens

Placing and Reviewing the Probes

The next step is to place the probes in the patient and perform the CT scan. The software detects each probe at the location it was placed in the patient. After the scan, review the image slices to ensure that the probes are placed correctly in the target areas. If necessary, you can edit the probe displays yourself, as explained in *Manually Editing Probe Displays* later in Chapter 3.

NOTE: Probes will not appear in AC until a lesion target has been defined and registration has been completed. (Registration is described in the next section.) If probes are present in the setup series, all the probes will be detected once the targets are defined.

1. Click the  button at the top of the screen to advance to the Place Probes screen. Place up to three patient probes at the site of the lesion(s) and then perform the CT scan.
2. Advance to the Select Probe(s) Series screen.
3. Select the newly acquired scan series in the lower-left corner, and then click the Pull Series button.

The application imports the series from the scanner and displays the series you selected from the list. The application only displays data for one patient at a time.

For the most part, the Select Probe(s) Series screen is very similar to the Select Setup Series screen, which you used earlier in this chapter.

4. View the image slices to ensure that the probes are placed correctly in the target areas. Move the mouse wheel to scroll through the slices in the 2D and 3D image views and locate the targets and probes.

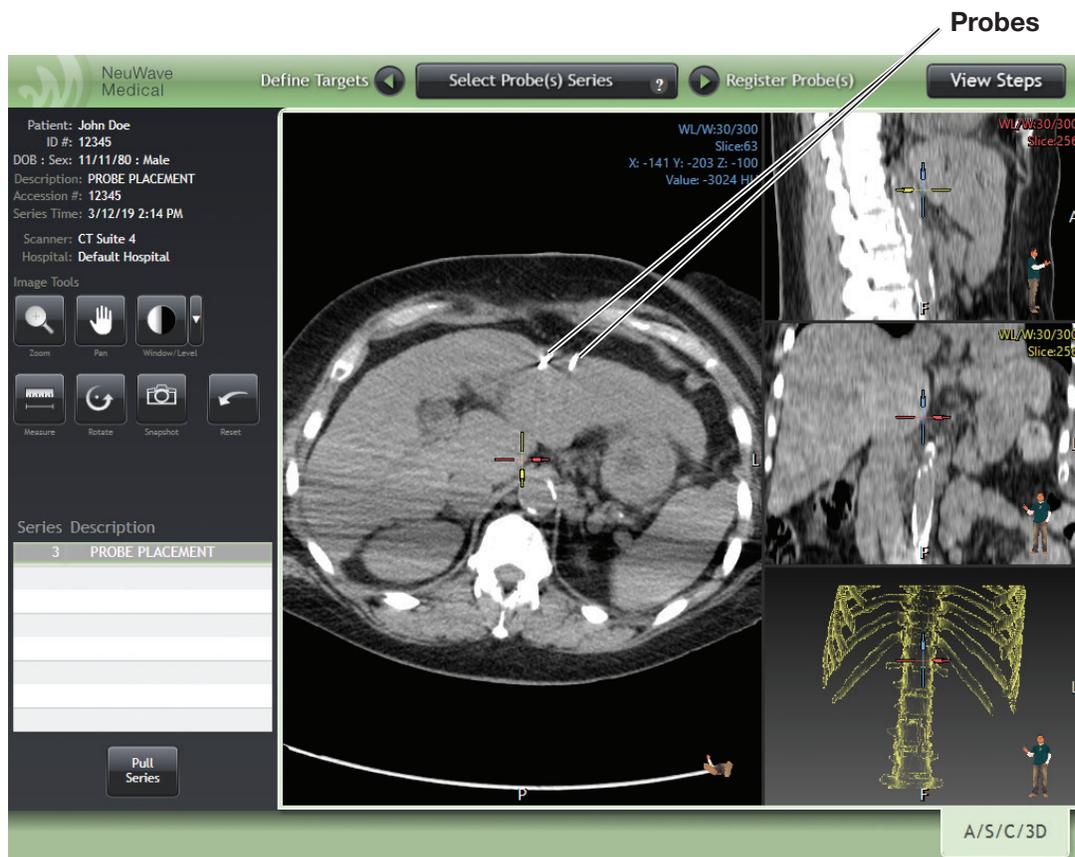


Figure 3-12: Locating the probes

Registering the Setup Images with Probe Placement Images

The next step is to register the setup image series with the probe placement series you have scanned. For example, the areas around the edges of organs need to be aligned in the two image scans as precisely as possible. The Register Probe(s) screen displays the setup series images with the probe placement images by superimposing one series upon the other.

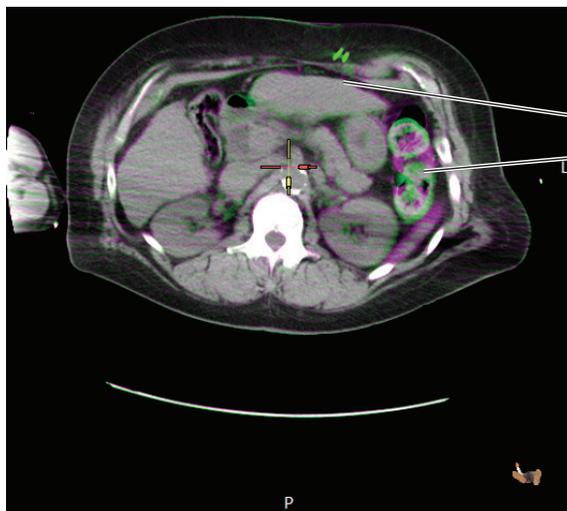
CAUTION The patient's position (for example, supine or decubitus) should remain consistent across all scans. Variations in patient position may result in the inability to properly register image sets.

Because of slight patient movement and the patient's breathing, the alignment or registration of different image series cannot be exact. However, you can use tools in the Register Probe(s) screen to manually refine the registration in the two series.

1. Click the  button at the top of the screen to advance to the Register Probe(s) screen. The registration process will start automatically using a deformable image registration algorithm. Activity will be indicated by a spinning wheel at the center of the screen.
2. After the registration has been completed, inspect the two image series (see Figure 3-13) and review the colored areas to evaluate how well the superimposed images are registered.

When slices from separate image series are superimposed within a view, areas displayed in gray tones are registered well. When areas are shaded in green and/or purple, a shift has occurred between the two image sets. Areas in purple are from the setup series, and areas in green are from the probe placement series, as indicated by the Series Displayed color key in the screen's lower-left corner.

If a large shift has occurred between two image sets, consider using the probe scan as the set-up scan and re-define the target.



When areas are shaded in green and/or purple, a shift has occurred between the two image sets.

Figure 3-13: Evaluating registration

WARNING When evaluating registration, note that if significant amounts of the image sets are shaded in green and/or purple, a large shift has occurred between the two image sets. In such cases, an additional CT scan should be performed and the registration process repeated. If re-registration does not improve the registration differences, stop using AC for this procedure. Refer to the CT scans on your CT review station to evaluate the ablation procedure.

3. If you are satisfied that the software’s registration algorithm improved alignment sufficiently, you can go to the next section.
4. If you are not satisfied with the software’s automatic image registration, adjustments can be made using the Refinement Tools (see Figure 3-14) as described below.

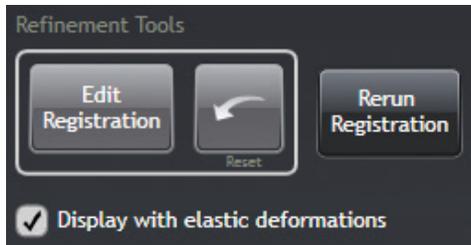


Figure 3-14: Refinement Tools

5. The registration is done in two parts, a rigid registration (translation, rotation, scaling, etc.) and an elastic registration (local alignment of one image to the other). The registration can be viewed using the rigid registration only by deselecting the “Display with elastic deformations” checkbox. This is recommended before making any manual adjustments.
6. Manual adjustments to the registration can be made using the Edit Registration tool. Once the Edit Registration tool is selected, vertical and horizontal axis lines and a circle will be drawn on the series images (see Figure 3-15). The circle will be centered around the current reference point.

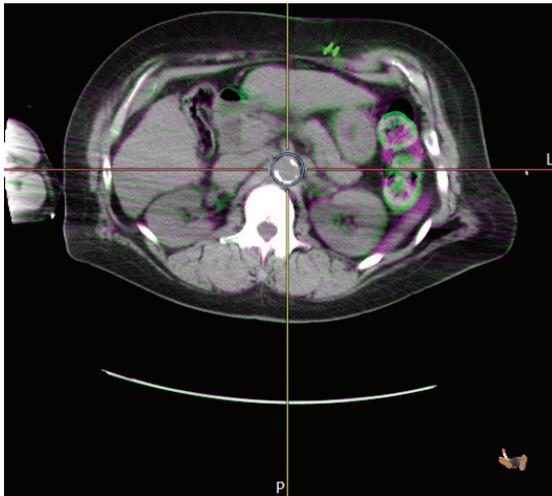


Figure 3-15: Edit registration

7. Left click and drag inside the circle to translate the Setup Series with respect to the Probe Placement Series. Left click and drag on one of the axis lines to rotate the Setup Series with respect to the Probe Placement Series. If, at any time, you wish to remove all manual changes made, use the Reset button immediately to the right of the Edit Registration button.

NOTE: Improvement of the registration alignment in one part of the image may cause a degradation of alignment in a different part of the series. Since the goal is improvement of the alignment in the area of the target, this may be acceptable.

8. If desired, the automatic registration may be rerun using the Rerun Registration tool.

NOTE: If the “Display with elastic deformations” checkbox is unchecked, the completed registration will not include elastic deformations.

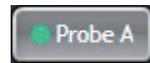
Evaluating Probe Placement

Use the next screen, Evaluate Probe(s), to make sure that the probes are well-placed in relation to the target areas you defined. Now that you have registered the setup image series with the probe placement series, the lesions and probes are in the same coordinate system.

NOTE: AC is designed to automatically identify up to three ablation probes placed in the CT image series. However, depending on the proximity of the probes to each other and image settings such as slice thickness, the software may not be able to distinguish the presence of multiple probes, and may display fewer probes than are present in the patient. If so, refer to the original CT image on the CT review station. See the next section if you need to define probes manually. If the incorrect number of probes is consistently detected, the scanner and cart time may not match. Cart time can be adjusted in the tools menu on the ablation interface.

1. Click the  button at the top of the screen to advance to the Evaluate Probe(s) screen.

Each probe detected by the software is color-coded with an associated button on the left side of the screen.



NOTE: Probes A, B, and C do not necessarily correlate with channels 1, 2, and 3 on the NEUWAVE™ Ablation System.

2. View the image slices to ensure that the probes are placed in the target areas.
 - Move the mouse wheel to scroll through the slices in the image view and locate the targets and probes. By default, all targets and probes are displayed, but you can temporarily hide them from view by clicking the appropriate Show Target boxes and Probes Detected buttons on the left side of the screen.
 - Click the Probe tabs in the lower-right corner of the screen to examine targets and probes in special views. If you click a Probe tab, the resulting Periscope view on the left side of the screen lets you look down the shaft of the probe (see Figure 3-17). The Needle view on the right provides a lengthwise look at the probe in tissue. Click the Axial/Sagittal/Coronal/3D tab to return to the usual view.

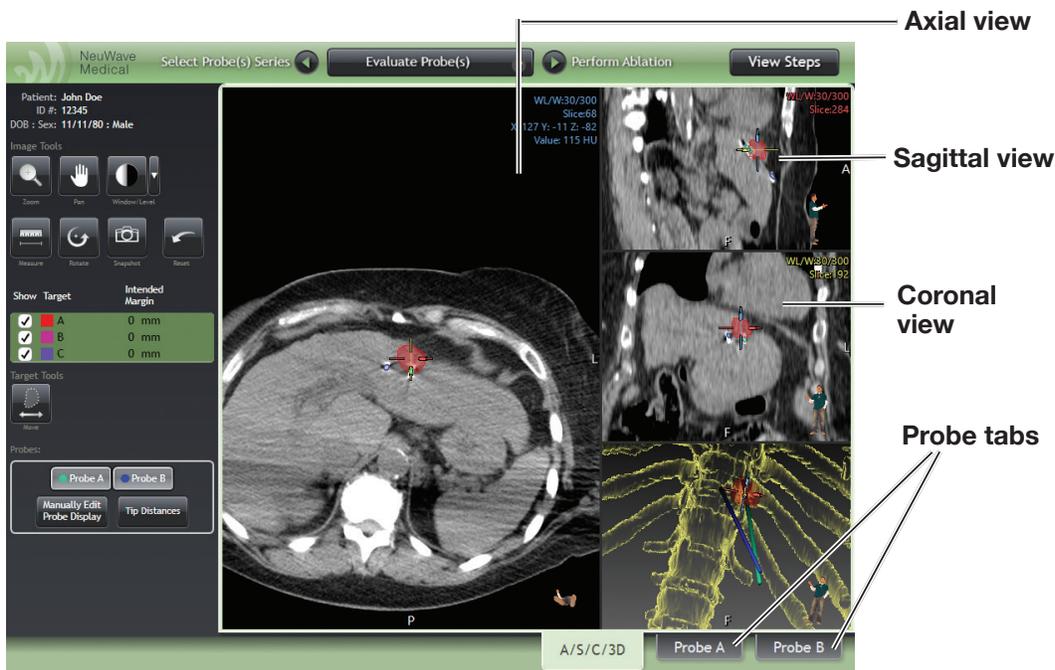
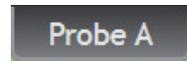


Figure 3-16: Evaluating probes

You can use all the Image tools in the Periscope and Needle views. The Zoom, Window Level, and Rotate tools operate synchronously in the two views. The Pan and Measure tools operate independently in the two views.



Figure 3-17: Using the Periscope and Needle views to examine probes

3. In some cases after registration, you might find that the insertion of the probe has pushed the lesion slightly and shifted its original position, although the lesion's shape has not changed. If necessary, click the Move tool on the left side of the screen and move the mouse pointer to a 2D image view.



Click the target and drag it to the correct position. Dragging in the axial view moves the target in the X/Y direction (see Figure 3-16), dragging in the sagittal view moves the target in the X/Z direction, and dragging in the coronal view moves the target in the Y/Z direction. The entire target is moved intact to the new position.

Manually Editing Probe Displays

If the software does not detect a probe or incorrectly detects a probe, you can click the Manually Edit Probe Display button in the lower-left corner of the screen and then create or delete probe displays yourself.

If the automatically generated probe displays appear accurate and well-placed in relation to the target areas you defined, you can skip this section.

1. If necessary, click the Manually Edit Probe Display button in the lower-left corner of the screen, as shown in Figure 3-18. In the figure, the system has automatically detected two probes (A and B). If no probes are connected to the NEUWAVE™ Microwave Ablation System, the manual probe button does not appear.



Figure 3-18: Manually editing probe displays

2. If you need to delete the display of a probe from the system, click the appropriate X button to remove the probe, shown in Figure 3-19.

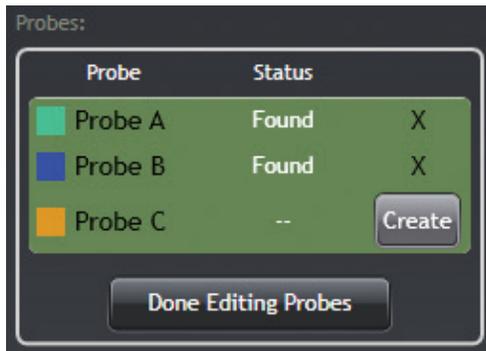


Figure 3-19: Deleting and creating probe displays

3. If you need to create the display of a probe, click the appropriate Create button, as shown in Figure 3-19. Scroll through the slices and find the location on the scan where the tip of the probe is displayed.
4. Click the scan where the tip of the probe is displayed. The clicked point shows a yellow box. If you need to delete the new probe display and start over, click the Cancel button.
5. Click on a second location along the probe. The system defines a line starting at the first point created through the second point.
6. After you click the second location on the probe, the Probe Creation Complete message will appear over the image for five seconds.
7. Click the Done Editing Probes button. The new probe display will look and function exactly like the probes identified automatically by the software.

Tip Distances

The distances between the detected or defined probe tips can be displayed by clicking the Tip Distances button. The distances between the tips of all detected or defined probes is displayed.

Performing the Ablation and Creating an Ablation Zone

The final series of screens in the software guide you through the process of performing the ablation with the NEUWAVE Ablation System, defining the ablated area, registering the ablation image series against the setup series, and evaluating the ablated area. Click the  button at the top of the screen to move through the screens.

1. In the Perform Ablation screen, you are prompted to select the proper power and time settings on the ablation system screen and then perform the ablation.
2. When the ablation is complete, perform a scan to acquire a new CT image series into AC that displays the treated areas of the patient.
3. Advance to the next AC screen, which is the Select Ablation Series screen. It is identical in function to the Select Setup Series screen, which you used earlier in this chapter.
4. Click the description of the newly acquired series in the lower-left corner of the screen, and then click the Pull Series button to display the post-ablation series in the image views.

Verify that you can see the ablation and any probes that remain, and that the extent of the scan is correct.

If the pulled series is multiphasic (i.e., if it consists of more than one phase), the first phase will be displayed and entries for each of the phases will be added to the list of available series. The series description for each phase will be preceded by the number of the phase. If you want to view a different phase, select the phase and then click Pull Series.

5. Advance to the Define Ablation screen so you can define a zone around the lesion that has been ablated. You can define up to three ablation zones in an image series.
6. On the left side of the screen, make sure that the correct Ablation Zone box is checked. In other words, Ablation Zone A must cover Target A that you defined earlier, Ablation Zone B must cover Target B, and so on.

If the Ablation Zone box is not checked, you will see only the outline of the ablation zone in 2D views after you create it.

7. On the left side of the screen, click the Create tool in the Ablation Tools panel and then move the mouse pointer to a 2D image view to begin creating the ablation zone.



In the active image view, try to move to a slice near the center of the ablation and try to center the mouse over the area that has been ablated. The tool previews the area by creating a green outline where you first placed the tool pointer. Based on where the preview area is displayed, the tool outlines the area of similar tissue.

NOTE: Using the Create tool becomes more challenging when the edges of ablation zones are not well delineated. As an alternative, you can use the Sphere tool to quickly define a perfectly spherical ablation zone. For details, see Using the Sphere Tool in the next chapter.

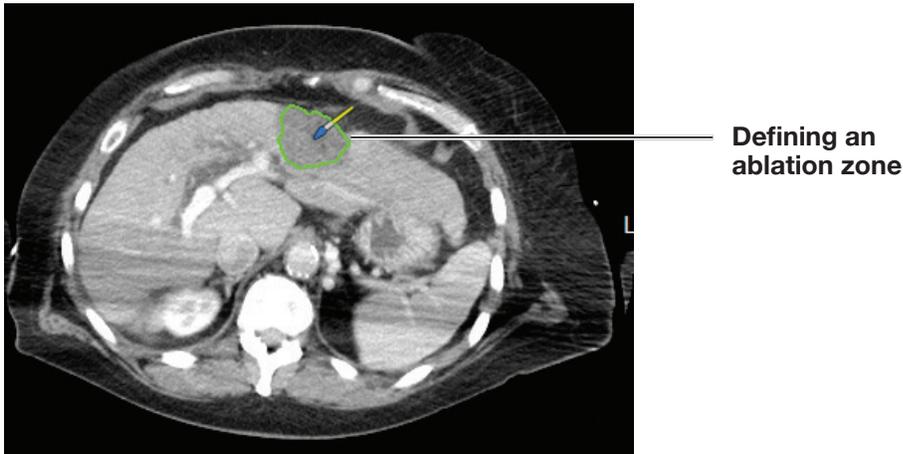


Figure 3-20: Defining an ablation zone

8. Expand the outline to encompass the ablation zone. Roll the mouse wheel forward and let the tool expand the zone radius as it identifies tissue of like density. Roll the wheel backward to reduce the radius. Left-click when the desired ablation zone is encompassed by the green preview outline.

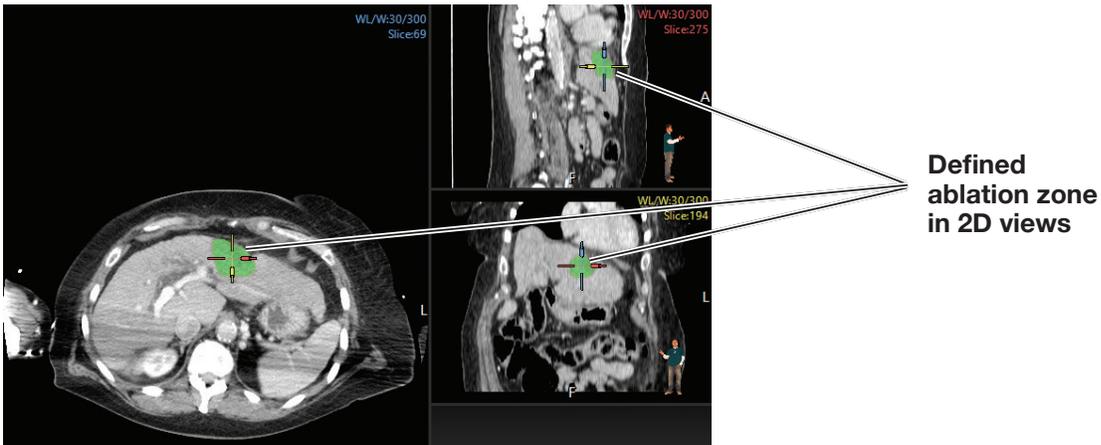


Figure 3-21: Defined ablation zone

9. If you want to refine the ablation zone, click the Edit tool in the Ablation Tools panel and then move the mouse pointer to the zone you just defined.
 - Choose a large, medium, or small diameter for refining the ablation zone. The Medium option is selected by default, but you can select a smaller or larger diameter.
 - Choose single or multiple slice edit for refining the ablation zone. The single slice option edits only the current slice. The multiple slice edit option will edit slices above and below the displayed slice using a sphere of the selected size.
 - To remove portions of the ablation zone, place the mouse pointer just outside the zone; a red sphere appears. Click and hold the mouse, using the pointer to guide the sphere. Slowly drag the red sphere along the ablation zone's border.
 - To expand portions of the ablation zone, place the mouse pointer just inside the zone; a green sphere appears. Click and hold the mouse, using the pointer to guide the sphere. Slowly drag the green sphere along the ablation zone's border.



10. If necessary, you can create one or two more ablation zones.
11. The Undo and Redo buttons can be used to undo or redo creation of an ablation zone or changes to an ablation zone.
12. To see statistics for an ablation zone, click its Stats arrow above the Ablation Tools panel. The statistics show the ablation zone's length in millimeters along the X-, Y-, and Z-axes, and its total volume in cubic centimeters.
13. To temporarily hide the ablation zone from view and display only its outline in the 2D views, click its Show button just above the Ablation Tools panel. To delete the ablation zone and start over, click the X in the Clear column.

Registering the Ablation Series and Evaluating the Ablation

After creating the ablation zone, you can register the ablation series and then complete your evaluation of the procedure.

1. Advance to the next screen, Register Ablation, and use the refinement tools to align or register the ablation series against the previous image series you scanned. The use of these tools is described in the section Registering the Setup Images with Probe Placement Images earlier in this chapter.

The areas around features of interest need to be aligned in the image scans as precisely as possible. The function of this screen is very similar to that of the Register Probe(s) screen; for more details, see *Registering the Setup Images with Probe Placement Images* earlier in this chapter.

CAUTION The patient's position (for example, supine or decubitus) should remain consistent across all scans. Variations in patient position may result in the inability to properly register image sets.

2. Insertion and removal of the probes can cause slight shifts in the position of lesions you have targeted. If you used the Move tool in the Evaluate Probe(s) screen to move a target earlier in the procedure, you have the option in the Register Ablation screen to return the targets to the original positions you assigned. To use the target positions you determined using the Move tool, click the Show Moved Targets check box. To return the targets to the original positions you assigned, click the Show Moved Targets check box again to remove the check mark.
3. Advance to the final screen, Evaluate Ablation, and scroll through the image slices to locate the ablated area.

A side by side view of the Setup and Post Ablation scans can be displayed by clicking the Comparison tab in the lower right corner.

4. Evaluate the results of the ablation. The screen displays targets, probes if they were present in the post-ablation scan, and the ablated area together. You need to ensure that the ablated area and the defined margins cover the lesion.

If the ablation zone does not cover the lesion, a message on the left side of the screen informs you that the target exceeds the ablation (see Figure 3-22).

If the ablation zone does cover the lesion, a message displays the minimum and maximum margins, in millimeters, between the lesion's edge and the edge of the ablation zone.

If you used the Move tool in the Evaluate Probe(s) screen to move a target earlier in the procedure, you have the option in the Evaluation Ablation screen to return the targets to the original positions you assigned. See Step 2 of this procedure for more details.

If the software does not detect a probe or incorrectly detects a probe, you can click the Manually Edit Probe Display button in the lower-left corner of the screen and then delete or create probe displays yourself. For more information, see *Manually Editing Probe Displays* earlier in Chapter 3.

5. Soft tissue generally contracts during thermal ablation procedures. If tissue contraction is not accounted for, the assessment of the technical success of a thermal ablation procedure can be impacted.

The Target Contraction % field allows you the option to approximate the tissue contraction effect. From the menu that appears, select the contraction percentage you wish to apply to the target(s) intersecting the defined ablation zone(s) and select the Contract button. Note that the contraction values offered depend on the tissue selected on the ablation system at the start of the procedure.

The “area of effect” is where the contraction algorithm is applied. The area of effect includes the entire region of the defined ablation zone plus additional areas outside of the defined ablation zone. This is because the tissue defined as the ablation zone has contracted during the application of microwave energy.

When the Contract button is selected, the defined ablation zone remains unchanged on the display. Only the target(s) are shown as contracted on the display, and only those portions of the target that intersect the area of effect are contracted. If you check the Show Moved Targets check box, the system will contract and display the moved targets. If the box is unchecked, the system will contract and display the original targets.

The contraction effect is greater at the center of the ablated area and decreases as the distance from the center of the ablated area increases. The total effect of the contraction at the edge of the defined ablation zone(s) is the user-selected percentage and decreases to zero outside the ablation zone as a function of the distance from the center.

If contraction is enabled by default in the Admin tab (see Figure 5-1), the target(s) will be contracted upon entering the Evaluate Ablation screen. The contraction percent used will be based on the selected tissue and the Admin tab settings. Even if contraction is enabled by default, the user may change the contraction percent or remove contraction altogether.

Weighing factors such as applied power, time and number of probes used, use your clinical judgement to select which, if any, contraction percentage to apply. Note that the post-ablation tissue contraction accuracy has not been fully evaluated.

The contraction effect, and the range of selectable contraction values, is based on the following peer-reviewed scientific journal references:

Brace CL, Diaz TA, Hinshaw JL, Lee FT, Jr. Tissue contraction caused by radiofrequency and microwave ablation: A laboratory study in liver and lung. *J Vasc Interv Radiol* 2010;21:1280-1286.

Farina L, et al. Characterisation of tissue shrinkage during microwave thermal ablation. *International Journal of Hyperthermia* 2014.

Liu D, Brace CL. CT imaging during microwave ablation: Analysis of spatial and temporal tissue contraction. *Med Phys* 2014;41:113303.

Moreland AJ, Ziemelewick TJ, Best SL, et al. High-Powered Microwave Ablation of T1a Renal Cell Carcinoma: Safety and Initial Clinical Evaluation. *J Endourol* 2014;28:1046-1052.

Sommer CM, et al. Quantification of Tissue Shrinkage and Dehydration Caused by Microwave Ablation: Experimental Study in Kidneys for the Estimation of Effective Coagulation Volume. *J Vasc Interv Radiol* 2013; 24: 1241–1248.

Ziemelewick TJ, Wells SA, Lubner MA, Musat AI, Hinshaw JL, Cohn AR, Lee FT, Jr. Microwave Ablation of Giant Hepatic Cavernous Hemangiomas. *Cardiovasc Intervent Radiol* 2014;37:1299-1305.

When the contraction is complete the contracted target(s) will be displayed and a label describing the contraction percentage will be displayed in the image display area. To remove the contraction effect, deselect the contract button.

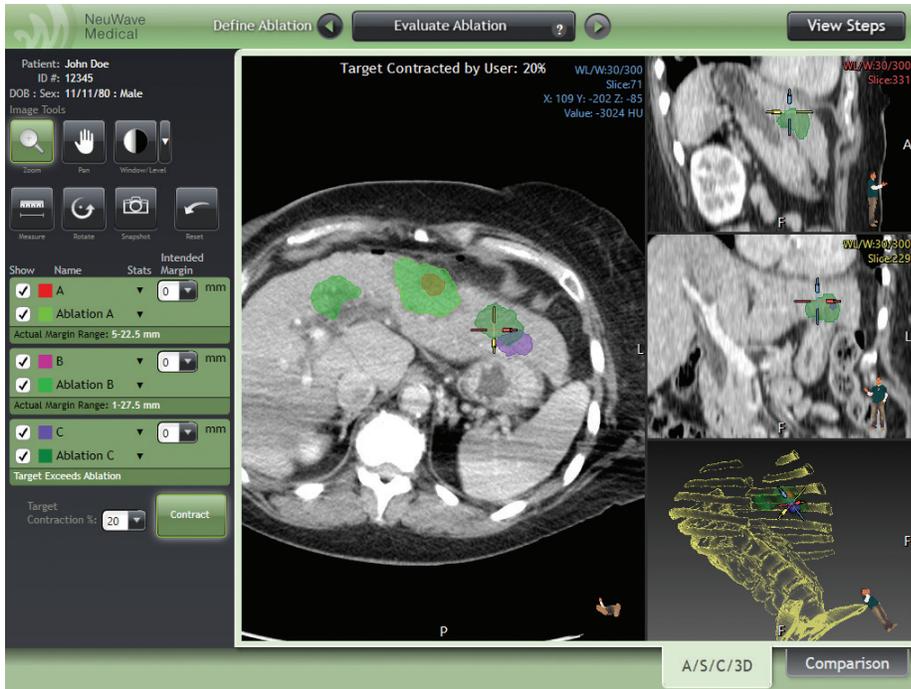


Figure 3-22: Evaluating the ablation

If you are not satisfied with the results, you have the option of continuing the ablation. To return to a previous screen and make adjustments to your procedure, use the View Steps menu (see Figure 3-23), which you can open by clicking the View Steps button in the upper-right corner of the screen. To move immediately to a screen listed in the menu, simply click the screen name. The screens are listed in order as they appear in the software.

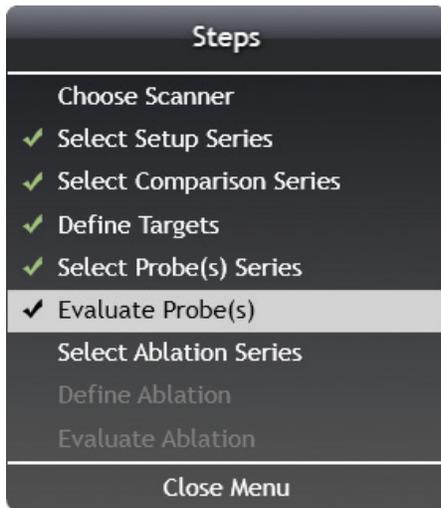


Figure 3-23: View Steps menu

The active screen is highlighted in the menu. Note that some screens, such as the registration screen, are not shown in the menu. If a screen is not currently available for selection, its screen name is shown in grey in the menu.

If a check mark appears next to a screen name, requirements have been satisfied for that screen. If a snapshot has been taken on a screen, the screen name appears in the menu with a camera icon next to it.

Click Close Menu to dismiss the View Steps menu.

You can also click the Previous Screen button (see Figure 3-24) to move back through the workflow until you reach the necessary screen, and then load new scans and continue the ablation.

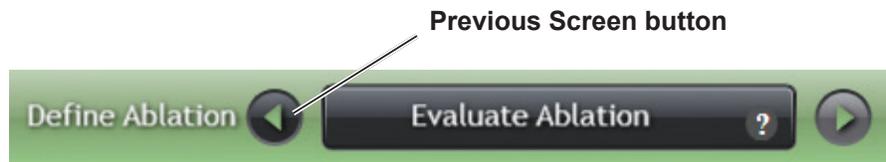


Figure 3-24: Previous Screen button

6. When you are satisfied with the results of the scans, close the procedure on the ablation system. Before you close the procedure, NeuWave recommends that you use the Snapshot tool to capture the final results to the patient record on the PACS.

The software will reset for the next patient when a new procedure is started.

4

Using Image Views and Tools

The previous chapter provided a step-by-step guide for using AC. Use this chapter for more information about image views, using the mouse in image views, and the following Image tools:

- The Zoom tool
- The Pan tool
- The Window Level tools
- The Measure tool
- The Rotate tool
- The Snapshot tool
- The Reset tool

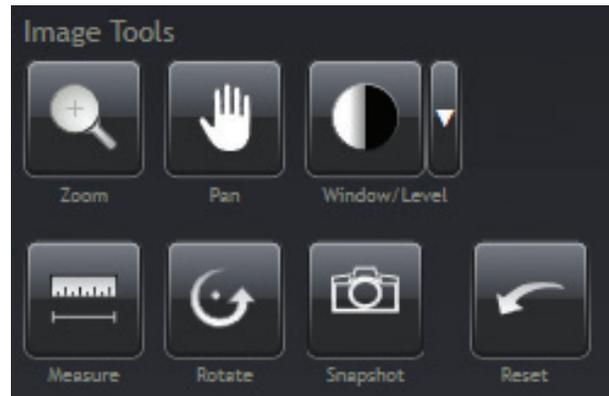


Figure 4-1: Image Tools panel

This chapter also describes how to use the following tools, which allow you to define ablation targets and other features of interest:

- The Create tool for ablation targets
- The Sphere tool
- The Edit tool
- The Move tool
- The Edit Region tool to improve registration
- The Create tool for ablation zones

Using the Image Views

AC offers multiple views of an image series. Four views appear by default, as shown in Figure 4-2, and the edges of each view contain letters that indicate the orientation of the patient:

- Axial (horizontal view)
- Sagittal (vertical, left/right view)
- Coronal (vertical, front/back view)
- 3D view
- A, P Anterior, posterior
- L, R Left, right
- H, F Head, foot

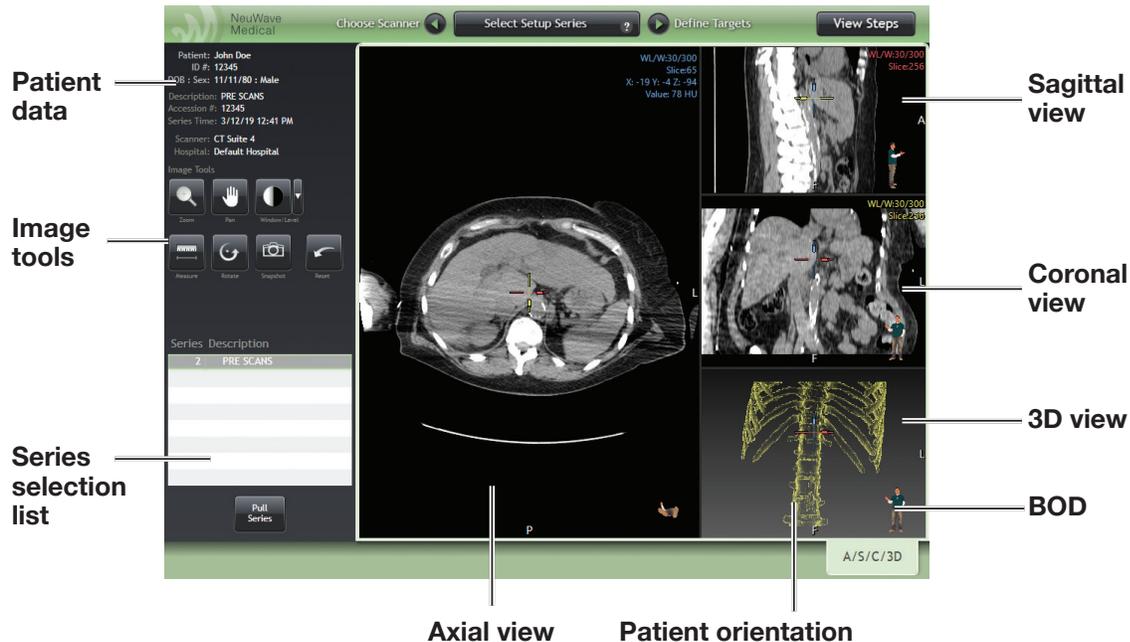


Figure 4-2: Select Setup Series screen

The lower-right corner of each image view displays a body orientation diagram (BOD), which shows the position of the patient’s body with respect to the image slice shown. In the 3D view, the BOD shows the position of the patient’s body with respect to the constructed image.

Radiologic data appears in the upper-right corner of each 2D view. When you use a program tool within the image and inside the bore of the CT scanner, four lines of radiologic data are shown:

- The window level (WL) and the window width (W) in Hounsfield Units (HU); this data refers to the image’s contrast and brightness
- The slice number within the selected image series
- The coordinates for the active tool’s position on the X-, Y-, and Z-axes
- The value in Hounsfield Units for the point where the active tool is positioned

The colors of the crosshairs (reference points) and radiologic data correspond in all four views of the slices:

- Blue Axial image view
- Red Sagittal image view
- Yellow Coronal image view

Double-click an image to make it full size. Double-click it again to return to the previous display.

To resize an image view, move the mouse to a view’s border until a “grab” handle appears. Click and drag the grab handle to change a border’s horizontal or vertical placement. Release the handle when you are satisfied with the size of the image view. Note that the adjacent views are resized as well.

Using the Mouse in Image Views

This section provides an overview for how to use the various mouse functions in the 2D image views. For more details on using the mouse in the 3D image view, see *Using the Rotate Tool in 3D Views* later in this chapter.

- **Mouse wheel**—The mouse wheel can be used to scroll and as a “click and hold” button. To scroll through image slices in a series, place the mouse within a 2D image view and roll the wheel. The crosshairs change positions in synchrony within all four views, and the active view’s radiologic data changes accordingly.

If you click and hold the mouse wheel like a regular mouse button, it takes on the function of the Window Level tool. For details, see *Using the Window Level Tools* later in this chapter.

- **Left mouse button**—When you left-click and drag the mouse within a 2D image view without selecting a tool first, you scroll through the image slices in the series. The slice in view updates, as does the associated radiologic data.

In the other 2D image views, the slices in view do not change, but the crosshairs within the slices in view move to indicate the image plane of the active view.

- **Mouse movement**—When you move the mouse within a 2D image view without clicking a mouse button, the X- and Y-axes values update in the upper-right corner of all three 2D image views and the HU value displays the image density according to the mouse position. If the Window Level tool is used, the mapping of HU density values to grayscale pixels is modified to enhance image features.

- **Right mouse button (for crosshair movement)**—The crosshairs in each image view serve as a reference point. Clicking the right mouse button within a 2D image view moves the reference point where you right-clicked. Right-clicking on the crosshairs hides them from view. The crosshairs can be shown again by right-clicking on the image.

The reference points in adjacent image views, including the 3D view, move in synchrony so that they mark the same patient coordinates relative to their image view. The reference point’s thicker lines indicate that the coordinate value for that axis increases in the direction of the thicker end of the reference point’s associated line.

You can also right-click to move the reference point in the 3D image view when using the Zoom, Pan, or Rotate tool.

Using the Zoom Tool

Use the Zoom tool to increase or decrease the size of an image within a view. The Zoom tool is useful for locating the lesion or another feature of interest within an image slice. The zoom operation is centered around the reference point.

1. In the Image Tools panel on the left side of the screen, click the Zoom tool and then move the mouse pointer to a 2D or 3D image view.
2. Left-click and drag the mouse upward within the active image to zoom in on the slice in view. The associated radiologic data changes accordingly.
3. Left-click and drag the mouse downward within the active image to zoom out from the slice in view. Again, the associated radiologic data changes accordingly.



Within adjacent 2D image view, the images resize to correspond with the change in the active view.

4. You can also use the Zoom tool in the 3D view. The Zoom tool looks and works the same in the 3D view as it does in the 2D views, but changing the size of the 3D image does not change the 2D image sizes.

Using the Pan Tool

Use the Pan tool to move an image within the active image view.

1. In the Image Tools panel on the left side of the screen, click the Pan tool and then move the mouse pointer to a 2D or 3D image view.
2. In the active view, left-click and drag the mouse. Image movement tracks with the movement of the mouse pointer.



Within the adjacent 2D and 3D image views, nothing happens. In other words, the Pan tool affects only the active view.

Using the Window Level Tools

Use the Window Level tools to display features within an image more prominently. Tissue densities are associated with particular grayscale colors; changing the window level alters the grayscale range within an image slice so that certain types of tissue become more visible. For example, you can adjust the window level to the lowest density (black) to view only air, or you can change to the highest density (white) to view bone. You can also select a predetermined window level setting that makes the abdomen, bone, lung, or liver appear more prominently within an image.

1. In the Image Tools panel on the left side of the screen, click the Window Level tool and then move the mouse pointer to a 2D image view.



The X- and Y-axes values update in all three 2D image views and the mapping of HU density values to grayscale pixels is modified to enhance image features.

The Window Level tools have no function within the 3D image view.

2. In the active 2D view, adjust the image by clicking and dragging the mouse.
 - Drag to the left to increase the image contrast.
 - Drag to the right to reduce the contrast.
 - Drag the mouse up to increase the image brightness.
 - Drag the mouse down to reduce the brightness.

When you adjust the contrast, the associated radiologic data changes accordingly in the upper-right corner of each 2D image view. Within adjacent 2D image views, the changes correspond with those in the active view.

3. Use the drop-down list beside the Window Level tool to select a predetermined window level setting that makes the abdomen, bone, lung, or liver appear more prominently within a 2D image view.



You can make a selection from this list without selecting the Window Level tool. For example, selecting Bone from the list highlights bone in the image by showing denser areas that are predominantly white.

NOTE: The predetermined window level settings do not affect the comparison series when displayed in the side by side view on the Define Targets screen.

4. Roll the mouse wheel over a 2D image to scroll through image slices in the series after changing the window level. The reference points change positions in synchrony within all four image views, and the active view's radiologic data changes accordingly.

If you click and hold the mouse wheel like a regular mouse button, the mouse takes on the function of the left mouse button, as described in Steps 2 and 3.

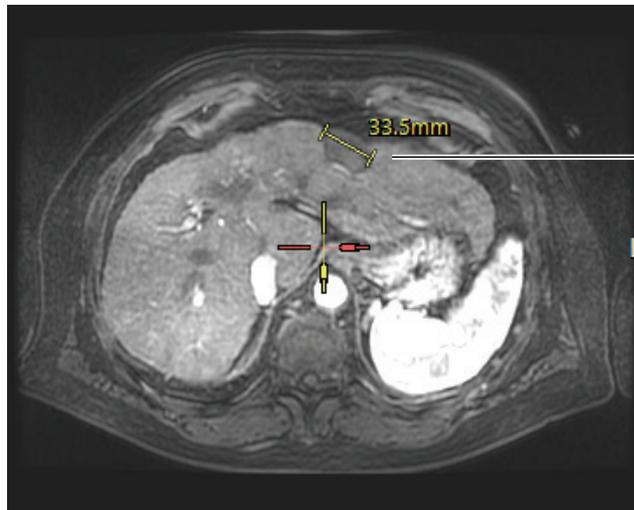
Using the Measure Tool

The Measure tool allows you to measure the length of one or more lines you draw on an image slice. For example, you might want to measure the width of a lesion, or you might want to measure the distance from the edge of a lesion to the edge of an organ or other known fiducial. Measurements can also be useful when you are comparing images and you already know the distances between features of interest in the comparison image.

The Measure tool works only in the active image view, and measurements appear only on the image slice on which you draw the lines. Measurements are shown in millimeters next to each line you draw.

NOTE: The Measure Tool will not be available on Fused PET images.

1. In the Image Tools panel on the left side of the screen, click the Measure tool and then move the mouse pointer to a 2D or 3D image view.
2. To draw a measuring line, place the Measure tool pointer at the desired starting point of the measurement, then click and hold down the left mouse button at that point.
3. Drag the tool pointer to the desired endpoint and release the mouse button.
The line appears with the measurement shown in millimeters (see Figure 4-3).



Using the Measure tool

Figure 4-3: Using the Measure tool

4. To draw another line, repeat steps 1-3. You must select the Measure tool from the Image Tools panel for every additional line you want to draw.
5. To move a measurement line, place the mouse pointer on the *middle* of the line, left-click and drag the line to the desired position, and then release the mouse button.
6. To change the length or angle of a measurement line, place the mouse pointer on the end of the line, as indicated by the small crossbar. Click and hold the left mouse button, drag the line to the desired length or angle, and then release the mouse button.
7. To delete a measurement line, place the mouse pointer over the line and right-click it when the line icon is displayed. Right-click the Delete option that appears.

NOTE: You cannot right-click and drag the reference point when the Measure tool is active.

Using the Rotate Tool in 2D Views

You can use the Rotate tool to rotate a 2D image on the axis marked by the reference point. For example, you could rotate a previously acquired supine scan to roughly align with a decubitus scan.

For details on using the Rotate tool on a 3D image, see the next section.

1. In the Image Tools panel on the left side of the screen, click the Rotate tool and then move the mouse pointer to a 2D image view.
2. In the image view, left-click and drag the mouse. The following occurs:
 - The image slice moves around the image view's axis. The view's reference point defines the axis pivot point.
 - The BOD moves synchronously to reflect how the patient's body would be oriented with respect to the movement of the image slice.
 - The view's orientation letters (A, P, L, R, H, F) change as necessary to reflect the image slice's positioning.
 - Images, BODs, and orientation letters in each adjacent 2D view change synchronously with movement in the active view.
3. Roll the mouse wheel over a 2D image to scroll through image slices in the series and view the rotated slices. The reference points change positions in synchrony within all four image views, and the active view's radiologic data changes accordingly.



If you click and hold the mouse wheel like a regular mouse button, the mouse takes on the function of the Window Level tool, as described earlier in this chapter.

Using the Rotate Tool in 3D Views

You can also rotate the 3D image in its view, either by using the Rotate tool or simply by clicking and dragging the mouse within the 3D image view without selecting a system tool. The behavior of the 3D image varies depending on the mouse's position in the view.

For details on using the Rotate tool on a 2D image, see the previous section.

1. In the Image Tools panel on the left side of the screen, click the Rotate tool and then move the mouse pointer to the 3D image view. As an alternative, simply move the mouse to the 3D image view without selecting a system tool.
2. Left-click and drag the mouse over the 3D image. Depending on where the mouse is positioned in the image view, the following occurs:
 - When the mouse is positioned within the 3D image, the image rotates around its center in all three directions.
 - When the mouse is positioned within the corner areas of the image view, the image rotates two-dimensionally around the Z-axis.
 - When the mouse is positioned within the upper or lower area of the image view, the image rotates around the Y-axis.
 - When the mouse is positioned within the right or left area of the image view, the image rotates around the X-axis.



The BOD moves synchronously to reflect how the patient's body would be oriented with respect to the movement of the image slice.

Using the Snapshot Tool

Click the Snapshot tool to acquire a screen shot of the displayed image data. If snapshots are enabled in the software, a new series will be created for the snapshots and stored as part of the active study. The snapshot data will be transmitted to the configured storage PACS.



The number of snapshots taken of the active screen appears below the Snapshot tool. Also, in the View Steps menu, a camera icon appears next to any screen of which you have taken a snapshot.

To enable snapshots in AC, click the Admin button in the upper-right corner of the screen while on the Choose Scanner screen. At the bottom of the Administration screen that appears, make sure the Snapshots Enabled box is checked.

Using the Reset Tool

Click the Reset tool to return all four image views to their default zoom, pan, and rotation settings.

NOTE: The Reset tool does not affect window level settings or measurement lines.



Using the Create Tool to Define an Ablation Target

Use the Create tool in the Define Targets screen to draw an ablation target in a 2D image view. You can create up to three targets on an image, each in a different color. For complete details on using the Create tool to define a target, see *Defining Targets* in Chapter 3.



Using the Sphere Tool

In some cases, lesions and ablation zones cannot be well defined on CT images. For example, image quality or lesion characteristics might make it difficult to distinguish the lesion from surrounding tissue. In these situations, the software allows you to manually place a sphere on the image to represent the target. When placing the spherical target, you rely on lesion location information from other imaging modalities, such as MR or ultrasound. Once the target is placed and confirmed, the AC software processes it exactly as the software would process a target segmented from a CT scan.



Use the Sphere tool to quickly create an ablation target that is perfectly spherical, instead of segmenting a target using the Create tool. You can also use the Sphere tool to define an area that has been ablated.

NOTE: If the target cannot be identified on the non-contrast, pre-procedure planning CT scan but is detectable on prior diagnostic imaging studies (CT, MRI, or contrast-enhanced CT scans), you can use the Sphere tool to approximate the target location on the planning CT images using well-defined landmarks. When determining where to place the sphere on the CT image and how large to make it, be sure to account for the following factors:

- The patient's orientation and phase of respiration during both the pre-procedure planning CT scan and the prior diagnostic imaging study
- The location of the target in relation to relatively fixed anatomical landmarks, such as blood vessels, bile ducts, and gallbladder in the liver and airways, blood vessels, and fissures in the lungs
- The size of the target on the prior diagnostic scan, which can be used to determine the size of the sphere needed; the size can be adjusted by moving the mouse wheel up or down
- The time interval between the prior diagnostic imaging study and the pre-procedure planning CT, as the target may have grown in the interim

1. If you do not already know the diameter of the target area you need to define, click the Measure tool, move the mouse pointer to a 2D or 3D image view, and locate the lesion in the image slices. 
2. When you locate the lesion, measure it. Place the Measure tool pointer at the desired starting point of the measurement, then left-click and drag from that point. Drag the tool pointer to the desired endpoint and release the mouse button.
3. In the target selection table on the left side of the screen, click a row to associate the target with the lesion you will identify. By default, the top row is selected in the table.
4. In the Target Tools panel, click the Sphere tool and then move the mouse pointer to a 2D image view. 
5. Begin to create the target.

In the active image view, try to center the mouse over tissue that you want to target. The tool previews the area by creating a green, spherical outline where you first placed the tool pointer, as shown in Figure 4-4.

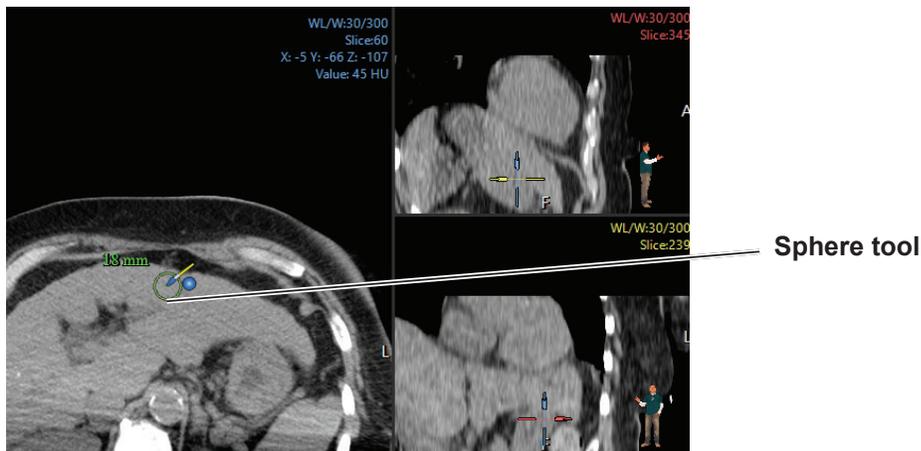


Figure 4-4: Defining a target with the Sphere tool

6. Roll the mouse wheel forward to let the tool expand the target's diameter and propagate the target through the other slices. Roll the wheel backward to reduce the diameter. The diameter of the spherical target is shown both next to the drawn sphere as well as the Sphere tool button. Left-click when the desired target area is encompassed by the green preview outline. When you finish, the target becomes the color assigned in the target selection table on the left side of the screen.
7. If you want to refine the target, click the Edit tool in the Target Tools panel and then move the mouse pointer to the target you just defined. 
 - Choose a large, medium, or small diameter for refining the ablation target or ablation zone. The Medium option is selected by default, but you can select a smaller or larger diameter.
 - Choose single or multiple slice edit for refining the ablation zone. The single slice option edits only the current slice. The multiple slice edit option will edit slices above and below the displayed slice using a sphere of the selected size.
 - To remove portions of the target, place the mouse pointer just outside the target's area; a red sphere appears. Click and hold the mouse, using the pointer to guide the sphere. Slowly drag the red sphere along the target's border.
 - To expand portions of the target, place the mouse pointer just inside the target's area; a green sphere appears. Click and hold the mouse, using the pointer to guide the sphere. Slowly drag the green sphere along the target's border.

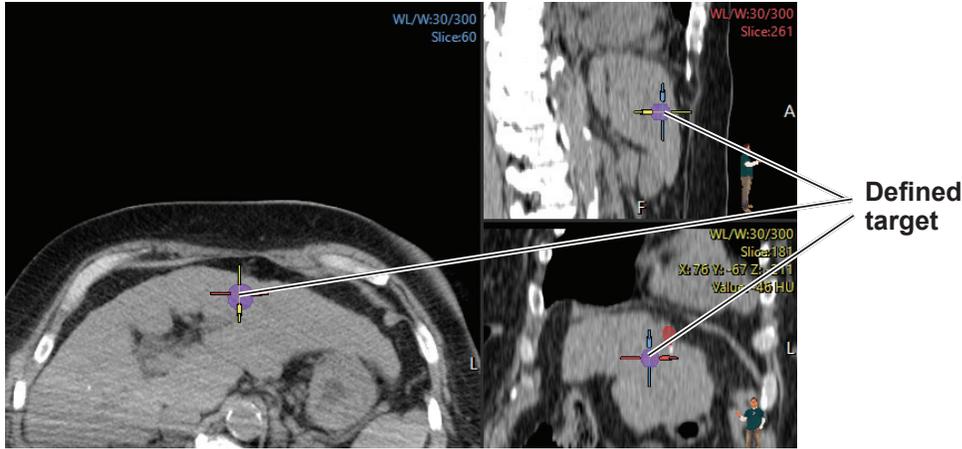


Figure 4-5: Target defined with the Sphere tool

8. If necessary, repeat the preceding steps to create two more targets.
9. The Undo and Redo buttons can be used to undo or redo creation of a target or changes to a target.
10. In the target selection table, you can select the size of a margin to display around the target. The margin display allows you to visualize the ablation zone with or without the margin to help identify the desired area. The margin area is shown in a different shade from the rest of the target area. The size of the margin ranges from 1 to 10 millimeters.
11. To see statistics for a target area, click its Stats arrow in the target selection table. The statistics show the target's length in millimeters along the X-, Y-, and Z-axes, and its total volume in cubic centimeters.
12. To temporarily hide a target from view and display only its outline in the 2D views, click its Show button in the target selection table. To delete a target from the image slices and start over, click the appropriate X in the Clear column.

Using the Edit Tool

Use the Edit tool to revise an ablation target or ablation zone you defined previously. For example, you can use the Edit tool to increase or reduce the size of the target area. For complete details on using the Edit tool, see any of the following sections:



- The previous section, *Using the Sphere Tool*
- *Defining Targets* in Chapter 3
- *Performing the Ablation and Creating an Ablation Zone* in Chapter 3

Using the Move Tool

In some cases after registration, you might find that the insertion of the probe has pushed the lesion slightly and shifted its original position, although the lesion's shape has not changed. If necessary, you can use the Move tool to return a target to the correct position over a lesion.



The best screen in which to use the Move tool is the Evaluate Probe(s) screen.

1. If you need to reposition a target, click the Move tool on the left side of the screen and move the mouse pointer to a 2D image view.
2. Click the target and drag it to the correct position. Dragging in the axial view moves the target in the X/Y direction, dragging in the sagittal view moves the target in the X/Z direction, and dragging in the coronal view moves the target in the Y/Z direction.

The entire target is moved intact to the new position.

Using the Refinement Tools to Improve Registration

Use the Edit Registration, Reset (for registration edits) and Rerun Registration tools to improve the alignment (or registration) of the displayed series'. For example, the areas around the edges of organs need to be aligned as precisely as possible.

Because of slight patient movement and the patient's breathing, the alignment or registration of different image series cannot be exact. However, you can use the Refinement Tools to more closely match or refine the registration in the two series.

For complete details on using the Refinement Tools, see *Registering the Setup Images with Probe Placement Images* in Chapter 3.

Using the Create Tool to Define an Ablation Zone

Use the Create tool in the Define Ablation screen to draw a zone around an area that has been ablated. You can then compare the ablated area to the area where the lesion was present before the procedure. You can define up to three ablation zones in an image series. For complete details on using the Create tool, see *Performing the Ablation and Creating an Ablation Zone* in Chapter 3.



5

System Setup and Configuration

To allow AC to communicate correctly with hospital DICOM devices, an authorized hospital representative or NeuWave representative enters appropriate configured network addresses, DICOM addresses, CT scanner names, and hospital names into the software.

WARNING If you are not authorized to set up or configure the system, *do not* change settings in the Administration screen. The screen is password-protected to prevent unauthorized access.



Figure 5-1: Administration screen

Admin Tab Functions

To configure the system parameters, click the Admin button in the upper-right corner of the screen, enter your password in the resulting window, and click OK. The following screen appears.

- Use the Hospital section at the top of the Administration screen to configure the names of all hospitals that will be connected to AC.
- Use the Cart Settings tab to configure the DICOM entity names that uniquely identify the NeuWave cart on the hospital's DICOM network. DICOM is based on two-way communication; one device sends information and one receives it. The service class provider (SCP) receives information and the service class user (SCU) sends the information.

The Cart Settings tab includes several additional settings:

Brightness and Contrast—Drag the sliders to adjust the brightness and contrast of the AC user display.

Snapshots Enabled—Check this box to allow “snapshots” of image views in AC using the Snapshot tool. When the tool is enabled and clicked, a new series will be created for the snapshots and stored as part of the active study.

Send Anonymous Data—All procedure and system data is sent to NeuWave to support system maintenance and optimization. To allow for transfer of anonymized image data to NeuWave along with the other system parameters, check this box.

Display 3D View—Uncheck this box if you do not want to use the 3D view in AC.

Show Guidance—Automatically show Guidance when entering a new screen

Display Contracted Targets by Default - Check this box to contract targets automatically when entering the Evaluate Post Ablation page.

Default contraction % in liver - Select the default contraction percent to use if Display Contracted Targets by Default is checked and the selected tissue is liver. The available values are 0, 10, 15, 20 and 30.

Default contraction % in kidney - Select the default contraction percent to use if Display Contracted Targets by Default is checked and the selected tissue is kidney. The available values are 0, 10, 15, 20 and 30.

Default contraction % in lung - Select the default contraction percent to use if Display Contracted Targets by Default is checked and the selected tissue is lung. The available values are 0, 10, 20, 30, 40 and 50.

Password—If you want to change the password needed to access the Administration screen, enter the new password in this field.

- Use the Cart Network tab to configure the TCP/IP network address for AC. IPv4 and IPv6 settings are both supported. The network address can be configured as a dynamic or static address for either the IPv4 or IPv6 setting.
- Use the CT Scanners tab to configure the user-defined names and DICOM entity names for each of the hospital's CT scanners that will be connected to AC. CT scanner names are configured per hospital and must be unique.
- Use the Query PACS tab to configure PACS devices that can be queried for retrieving comparison series. Configure the user-defined names and DICOM entity names for each of the hospital's PACS that will be connected to AC. The Query PACS are the systems from which previously acquired image series will be acquired for comparison with the setup series. Query PACS names are configured per hospital and must be unique.

In the CT Scanners tab and Query PACS tab, you can click the Config Query button and configure specific DICOM data attributes as needed for the study and series. Click the appropriate check boxes to include data attributes. Note that some attributes are required and cannot be disabled.

WARNING If you are not authorized to set up or configure the system, *do not* click the Config Query button and configure DICOM data attributes. Incorrect configuration can disrupt or disable communication with scanners and PACS devices.

- Use the Storage PACS tab to configure PACS devices that can store snapshots. Configure the user-defined names and DICOM entity names for each of the hospital's PACS that will be connected to AC. Acquired snapshot data will be sent to the Storage PACS. Storage PACS names are configured per hospital and must be unique. In many hospitals, the DICOM information for Query PACS and Storage PACS will be the same.

Click the Save and Close button to save the data entered in the Administration screen.

Handling Network Connectivity Problems

The Ablation Confirmation system includes communication monitoring to ensure that the software can communicate with the facility PACS and CT scanner. Some network problems are easy to fix yourself—for example, you might have forgotten to connect an Ethernet cable to the system. Other problems might require assistance from your IT department to troubleshoot and resolve. This section lists the network connectivity problems you might encounter and explains how to resolve the problems.

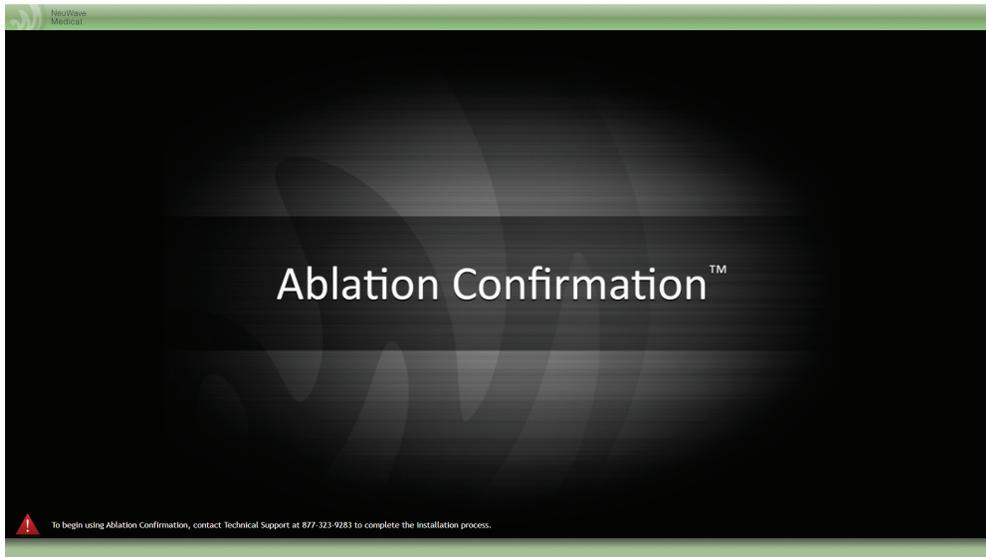


Figure 5-2: Welcome screen if system starts without a valid license

For example, the system's Welcome screen looks like Figure 5-2 if the system starts without a valid license. Note the message shown at the bottom of the screen. If you see this message, contact a member of your technical support staff to enable the software to work on your system.

The Welcome screen might also display another error message:

- **No network connection detected**—The software cannot detect a valid Ethernet connection. If you see this message, connect the Ethernet cable at the cart or the hospital wall connector. You might also see this error message if the hospital deactivated the connection for the wall at its network switch. In this case, your IT department must activate the desired network connection jack.

Connectivity Problems at the Choose Scanner Screen

Network problems might also produce the following error messages when you move to the Choose Scanner screen, which is the first screen after the Welcome screen. If there are no problems, the Choose Scanner screen reports “All network communications functioning.”

- **No network connection detected**—The software cannot detect a valid Ethernet connection. If you see this message, connect the Ethernet cable at the cart or the hospital wall connector. You might also see this error message if the hospital deactivated the connection for the wall at its network switch. In this case, your IT department must activate the desired network connection jack.
- **Communication with scanner not functioning**—There is not a valid connection to the selected CT scanner. Before you can continue working with the software, your IT department must troubleshoot and repair the connection to the selected scanner or you must select a different scanner.
- **Communication with all PACS systems not functioning**—The software can communicate with the selected CT scanner, but communications have failed with the Query/Retrieve PACS and the Storage PACS. You can continue using the software in this state, but you will not be able to pull a comparison scan or store snapshots from the case. Before you can pull scans and store snapshots, your IT department must troubleshoot and repair the connection to the selected PACS or you must select a different PACS.
- **Communication with Query/Retrieve PACS not functioning**—The software can communicate with the selected CT scanner and Storage PACs, but communications have failed with the Query/Retrieve PACS. You can continue using the software in this state, but you will not be able to pull a comparison scan. To be able to pull a scan, you must either have the connection repaired or select a different Query/Retrieve PACS.
- **Communication with Storage PACS not functioning**—The software can communicate with the selected CT scanner and Query/Retrieve PACs, but communications have failed with the Storage PACS. You can continue using the software in this state, but you will not be able to store snapshots. If you want to store snapshots, you must either have the connection repaired or select a different Storage PACS.
- **Checking communication with remote systems**—This is not an error message, but a notification that the software is waiting for TCP/IP Ping messages and DICOM echo messages to return from other parts of the network.

Cybersecurity Information

The NEUWAVE™ Ablation System was designed with the cybersecurity needs of the Hospitals, Medical Centers, and Healthcare Providers that are marketed to by NeuWave. This includes the ability to support the network and connectivity preferences of Hospitals and Healthcare Providers. The NeuWave System supports network connectivity to enable importing images from CT Scanners and the Hospital PACS (Picture Archiving and Communication System) and export of snapshots obtained during the procedures to the Hospital PACS via the DICOM (Digital Imaging and Communications in Medicine) protocol. Customers that prefer the device is not connected to their network can still use the NeuWave device to perform ablation procedures but will not be able to use the imaging capabilities of the Ablation Confirmation software.

Key security features of the NeuWave device include:

- Secure communications
- Application whitelisting
- Digitally signed code
- Software upgrades
- Independent vulnerability and penetration testing has been performed on the NeuWave device to verify security features.

Below are the recommended cybersecurity best practices to follow when setting up and using the NeuWave device:

- Control and monitor physical access to the NeuWave device and other medical devices. Proper physical security is necessary to prevent tampering of the device.
- Ensure regular anti-malware practices are followed for the hospital device(s), to which the NeuWave device may be connected, as these may be a source of malware transmission.
- The network topology should be utilized to limit access to the NeuWave device, CT Scanners, and PACS. This will ensure that interruptions to connectivity are minimized as well as protect the devices from malware.
- If you believe you have identified a potential security vulnerability that you would like to report, please access <http://productsecurity.jnj.com> to review our disclosure and response processes.

This Page Intentionally Left Blank

6

Appendix A

Physician Lesion/Ablation Segmentation Measurement Variability Assessment

Ablation Confirmation is a software tool designed to assist physicians in identifying targets and ablation zones on CT images during ablation procedures. The information in this appendix is provided to users to help characterize potential measurement variability that may be observed when using the Ablation Confirmation software.

Studies were performed to gather data concerning the segmentation of lesions and ablation zones on image sets using the Ablation Confirmation software. Two separate studies were performed. All the studies were executed by three radiologists who are experienced in ablation procedures and familiar with the Ablation Confirmation software.

The overall goal of the studies was twofold:

- Verify that the Ablation Confirmation software provided adequate tools for a physician to create an acceptable target in a reasonable amount of time with an acceptable amount of measurement variability.
- Verify that the Ablation Confirmation software provided adequate tools for a physician to segment an acceptable ablation zone in a reasonable amount of time with an acceptable amount of measurement variability.

Six data sets were used. These data sets were comprised of actual, anonymized patient CT scans. The data included two liver, two lung, and two kidney cases. All data sets included both pre-ablation (target) images and images containing ablation zones. The ablation zone images were comprised of contrast-enhanced and non-contrasted enhanced images. A variety of image quality inputs were included in the data sets. Notably, Series 5 (Lung 1) and Series 6 (Lung 2) included the “ground glass” effect that occurs during a lung ablation. Images with this effect are considered by radiologists to be the most difficult to visually assess.

<i>Series ID</i>	<i>Tissue Type</i>
1 (Kidney 1)	Kidney
2 (Kidney 2)	Kidney
3 (Liver 1)	Liver
4 (Liver 2)	Liver
5 (Lung 1)	Lung
6 (Lung 2)	Lung

Overall Study Summary

The results indicate that all three physicians determined that AC functioned at a clinically acceptable level in terms of target and ablation zone segmentation.

Lesion/Ablation Segmentation Detailed Data

Segmentation accuracy was not specifically assessed by these studies, and analysis of the created targets and segmented ablation zones was not based on “Ground Truth” of the size of the ROI on each image set. NeuWave did perform an analysis of the ROI sizes obtained by the three physicians for each of the six data sets for both the target and ablation zone definition in an attempt to characterize expected measurement variability.

Measurement Error

The X, Y, and Z dimensions were defined as the longest diameter measurement in each plane. A bounding box was constructed around the ROI segmentation and the dimensions of that bounding box were used as the longest X, Y, and Z dimension.

Several peer-reviewed studies have been published that indicate approximately a 15% measurement error when physicians use commercially available CT image processing systems to evaluate the size of lesions. X and Y measurements are subject to this 15% expected error rate.

Z-axis measurement has the greatest measurement error, due to the expected 15% plus the inherent error that occurs when measuring across preset CT slice thicknesses. Differences between physician measurements of one slice on each end of the Z-axis would create an inherent potential variability of ± 2 slice thicknesses. Targets used in the study averaged between 9 and 34 mm. Slice thicknesses of 2.5 or 5 mm are very common. A slice thickness of 2.5 mm could cause measurement variability of up to ± 1.25 mm. A slice thickness of 5 mm could cause a measurement variability of up to ± 2.5 mm. Based on the ROI size, either of these values would contribute significant additional potential measurement error to the already expected 15% error. As such, some Z-axis measurements are expected to fall outside the nominal 15% measurement error bounds.

Volume measurements are affected even more by the error in all three dimensions, having a multiplying effect. Due to the greater expected measurement variability, the volumes and Z-axis values are not included in this analysis.

Software Segmentation Results

Target Creation/Segmentation

All six of the X and Y dimensions for the target segmentation values (all 36 measurements) fell within the expected 15% error rate (obtained by averaging the three values and then applying $\pm 15\%$ to determine the upper and lower bounds). All X and Y values listed are in millimeters.

<i>Study 1 Kidney</i>	<i>Average Value</i>	<i>Min. % of Avg.</i>	<i>Max. % of Avg.</i>
X	26.2	85.1	114.9
Y	29.8	87.8	114.0
<i>Study 2 Kidney</i>			
X	37.9	93.9	106.9
Y	33.0	93.2	107.8
<i>Study 3 Liver</i>			
X	16.2	87.7	114.2
Y	17.3	86.7	111.6
<i>Study 4 Liver</i>			
X	11.5	89.6	113.0
Y	12.1	92.6	107.4
<i>Study 5 Lung</i>			
X	16.4	89.8	114.3
Y	22.1	93.7	107.7
<i>Study 6 Lung</i>			
X	13.7	94.9	105.1
Y	13.5	96.5	101.7
Total X Avg.	N/A	90.2	111.4
Total Y Avg.	N/A	91.8	108.4

Ablation Zone Segmentation

Five of the six X and Y dimensions for the ablation zone segmentation values (32 of 36 measurements) fell within the expected 15% error rate (obtained by averaging the three values and then applying $\pm 15\%$ to determine the upper and lower bounds). All X and Y values listed are in millimeters.

<i>Study 1 Kidney</i>	<i>Average Value</i>	<i>Min. % of Avg.</i>	<i>Max. % of Avg.</i>
X	27.7	94.5	105.6
Y	25.7	92.7	105.2
<i>Study 2 Kidney</i>			
X	36.1	90.7	107.0
Y	32.4	92.1	110.0
<i>Study 3 Liver</i>			
X	37.0	91.2	107.1
Y	32.7	94.1	103.0
<i>Study 4 Liver</i>			
X	53.5	93.3	110.0
Y	46.6	97.4	103.2
<i>Study 5 Lung</i>			
X	36.9	83.4	130.8
Y	45.4	80.6	119.4
<i>Study 6 Lung</i>			
X	24.3	91.1	105.9
Y	31.3	93.3	106.7
Total X Avg.	N/A	90.7	111.1
Total Y Avg.	N/A	91.7	107.9

This Page Intentionally Left Blank



NeuWave Medical
3529 Anderson Street
Madison, WI 53704 USA
+1-877-ETHICON (384-4266)
+1-513-337-8901
www.neuwavemedical.com



Johnson & Johnson Medical GmbH
Robert-Koch-Strasse 1
22851 Norderstedt
Germany



DR-000551, DR-000616, DR-000783,
DR-000784, NWC1US1N, NWC1CA1N,
NWC2IT1N, NWC2KR1N, NWC2HK1N,
NWC2SG1N, NWC2FR1N, NWC2NL1N,
NWC2DE1N, NWC1BA2N, NWC2CB2N
ACUGUS, NWACINT

ETHICON
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

©2020 NeuWave Medical, Inc. All Rights Reserved.
Ablation Confirmation User Reference Manual
Translated From English Version PL-000429-B
Version 3.1.X Software
PL-000429 2020-11 Rev B