NeuWave™

NEUWAVE™ ABLATE-IQ™ User Reference Manual

Software Version 3.2.X

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Johnson & Johnson SURGICAL TECHNOLOGIES

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 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.

Company Contact Information

Customer/Technical Service

Contact the Ethicon Customer Service Department or your local representative for any customer or technical support.

USA/Canada: +1-877-ETHICON (384-4266)
USA/Canada: +1-513-337-8901 (English)

NeuWave Medical, Inc.
3529 Anderson Street
Madison, WI 53704 USA

www.neuwave.com - click on “Contact Us”

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1 Introduction

Indications For Use

ABLATE-IQ assists physicians in identifying ablation targets, assessing proper ablation probe placement and visualizing treatment zones when used with the NEUWAVE Microwave Ablation System (NEUWAVE System). The software is not intended for diagnosis, to predict ablation volume, or to predict ablation success.

Device Description and System Overview

ABLATE-IQ is intended to assist physicians in identifying ablation targets, assessing proper ablation probe placement, and visualizing treatment zones.

ABLATE-IQ, is a Computed Tomography (CT) image processing software package available as an optional feature for use with the NEUWAVE System. ABLATE-IQ is resident on the NEUWAVE System and is accessible to physicians via a second, dedicated monitor with its own user interface, separate from the ablation user interface. ABLATE-IQ imports images from CT scanners and the facility's electronic Picture Archiving and Communication Systems (PACS) for display and processing during ablation procedures. ABLATE-IQ functions are controlled via a USB-connected mouse and receives CT images via a Digital Imaging and Communications in Medicine (DICOM) protocol over the Hospital network. 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 messages can be exchanged between two entities that can receive image and patient data in DICOM format. DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into an electronic PACS.

ABLATE-IQ 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)/target identification, segmentation, and measurement
- Image-based detection of ablation probes manually placed by the user (physician)
- Registration of multiple images into a single view

Prior to an ablation procedure, physicians can use ABLATE-IQ 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 ABLATE-IQ then uses segmentation algorithms to construct a 2D visualization of the selected target lesion. The physician can accept the initial segmentation results or use ABLATE-IQ 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 the *CT Scanner Configuration Guidance* Section 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 ABLATE-IQ 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, ABLATE-IQ automatically imports the scan, processes the images, and identifies up to three probes. ABLATE-IQ 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, ABLATE-IQ allows the physician to semi-automatically segment and visualize the treatment zone using the same process as that in the initial target segmentation. ABLATE-IQ then performs a registration of the initial CT scan that contains the identified target with the final CT scan that contains the segmented treatment zone. For more details, see the *CT Scanner Configuration Guidance* Section at the beginning of Chapter 3. The resulting image includes the treatment zone overlaid with the initial target lesion segmentation to help physicians determine the technical success of the ablation procedure.

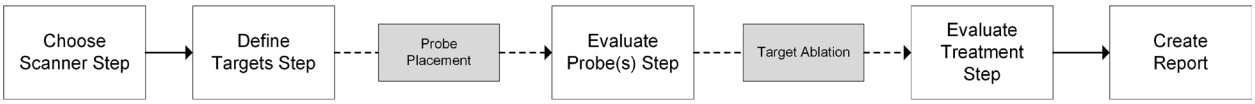


Figure 1-1. ABLATE-IQ Software User Steps

The software steps are summarized in Figure 1-1.

All ABLATE-IQ processing and viewing are accomplished with the NEUWAVE 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.

Patient Target Groups

ABLATE-IQ is intended to be used on adult populations (22 years of age and older) undergoing ablation of soft tissue in a percutaneous setting.

Intended Users

The NEUWAVE System should only be used by licensed physicians.

Expected Clinical Benefit

ABLATE-IQ Software provides important lesion- and procedure-related information to make better-informed decisions by interventional physicians.

Undesirable Side Effects and Residual Risks

Refer to the NEUWAVE System user manual and NeuWave Ablation Probe Instructions for Use.

Additional Information

For additional information regarding the system hardware such as Cleaning and Disinfection Instructions, Servicing, Device Lifetime, and System Disposal, please consult the accompanying NEUWAVE System user manual.

MRI Safety

Not Applicable. ABLATE-IQ is Medical Device Software. A previous MRI scan can be imported into ABLATE-IQ for comparison use.

Essential Performance

The essential performance of ABLATE-IQ is:

1. To accurately display patient data from diagnostic images on the user interface.
2. Allow users to effectively segment or otherwise identify target lesions.
3. Allow users to effectively segment treatment zones.
4. Allow users to effectively register and overlay different images in a series of scans.
5. Allow users to visualize the position of ablation probes relative to defined targets.

Serious Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation EU 2017/745); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

ABLATE-IQ Features

- 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.
- Measurement of anatomical structures in CT images.
- Profiles defined on the NEUWAVE System can be customized to change the appearance and behavior of the ABLATE-IQ Software.

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 the ***CT Scanner Configuration Guidance*** Section at the beginning of Chapter 3.

ABLATE-IQ Premium Features

The following features are available as optional features of ABLATE-IQ Premium:

- Probe Insertion Path Planning
- Proposed Ablation Zone Display on CT Images
- Case Detail Report (Report Creation Step)

Probe Insertion Path Planning is a feature that provides image-based probe-insertion visualization, to pre-plan the location and trajectory of the probe(s) relative to a pre-defined target(s). Proposed Ablation Zone Display allows the user to try different combinations of time and power derived from ex-vivo animal tissue data to help users visualize proposed ablation zones with targets (please see important information provided in Section 3.5.2.6.). Generation of an electronic report containing procedural information (e.g., ablation time and power used), data related to the target, and the treatment zone dimensions is also a new optional software feature available. The benefits of creating an electronic record of the target lesion and treatment zone measurements include the ability to retrieve patient-specific historical data from PACS and EMRs to monitor disease progression. Electronic reports and images stored in PACS and EMRs can also be used for educational, training, and clinical research purposes.

Using this Manual

This manual uses text formatting to identify different aspects of the product and its use.

Warnings and Cautions tell about the dangerous conditions that can occur if the instructions in the manual are not followed. Read and follow all warnings and cautions.

Refer to the NEUWAVE System user manual for operating instructions, warnings, and cautions associated with the NEUWAVE System.

WARNING	Warnings tell about a condition that can cause injury to the operator or the patient. In the manual, the word **WARNING** is in all caps and bold text with additional text indented. If more than one warning is listed in a row, the word **WARNINGS** is only printed once.
CAUTION	Cautions tell about a condition that can cause damage to the equipment. In the manual, the word *CAUTION* is presented in italics and in all caps. If more than one caution is listed in a row, the word *CAUTIONS* is only printed once.
Important	Important statements provide tips on device operation or settings. In the manual, the word *Important* is presented in italic text.
Device command	Device commands are written in bold typeface, for example **View Steps**.
Menu tab	Menu tabs on the system display are presented in bold, italic text. For example, ***Define***.
‘Message’	Messages that appear on the system display are presented in single quotation marks, for example, ‘Use the Target Tools to define the targets’.
Section and Heading	When referring to different sections or headings in this manual, the text is presented in the color green, for example, Navigating the ABLATE-IQ Software.

Symbols Used in Manual, Equipment and Packaging

Symbol	*Symbol Description*
	Manufacturer
	Date of manufacture
	Authorized representative in the European Community/ European Union
	Batch code
	Catalogue number
	Medical Device
	Unique Device Identifier
	Caution
	Consult instructions for use or consult electronic instructions for use. EU: Call paper on demand help desk to get paper copies free of charge within 7 days.
	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Keep dry
	Keep away from heat
	Packaging unit

2 Warnings and Cautions

You should be familiar with all warnings and cautions before using ABLATE-IQ. Refer to the NEUWAVE Microwave Ablation System user manual for operating instructions, warnings, and cautions associated with the NEUWAVE System.

WARNINGS

- ABLATE-IQ should only be used by physicians 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 ABLATE-IQ.
- 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 ABLATE-IQ for that procedure. Refer to the CT scans on your CT review station to evaluate the ablation procedure.
- Always use imaging to confirm desired ablation results for percutaneous applications. See the appropriate Instructions for Use of the NEUWAVE Microwave Ablation Probes for tables of ex-vivo ablation results.

WARNINGS

- User should not solely rely on the 3D rendering for planning, measurement, navigation, or guidance. Measurements or clinical decisions should be verified using CT.
- 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.
- 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 contrast prior to the setup scan may be helpful in target definition.

3 Using the ABLATE-IQ Software

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

Workflow during ABLATE-IQ may vary from case to case, or from site to site. In some ABLATE-IQ procedures, you will not need to acquire certain image series and might choose to skip screens in the typical sequence. In other cases, procedural steps must be repeated; for those cases, you have the option to navigate backward through the screen sequence as needed.

3.1 CT Scanner Configuration Guidance

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

Scan slice thickness of 2.0 to 2.5 mm is recommended for ABLATE-IQ. If you use slice thickness that is greater than 2.5 mm probes may not be detected and the registration accuracy will be reduced. NeuWave Medical discourages scanning at a coarser resolution and reformatting to achieve a finer slice thickness.

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 CT scans. For each CT scan, the breath hold should be initiated at the same point during the patient's breathing cycle (e.g., at full inspiration). Maintaining this consistency will improve registration accuracy and reduce registration time.

The scanner must be in helical (or spiral) mode. Series acquired in Sequential mode will be rejected by the ABLATE-IQ Software. The use of Fluoro images is not supported by the ABLATE-IQ Software; Some scanners will shut down DICOM while in Fluoro mode. In this case, an ABLATE-IQ user message indicating that the software has lost communication with the scanner will be displayed. Connectivity will be automatically reestablished when the Fluoro mode is turned off and the CT scanner is switched to helical mode.

Standard ABLATE-IQ installation automatically communicates with the CT scanner; however, in some instances, manual push of CT scans to the ABLATE-IQ Software is necessary. If the latter, select only the relevant series to be transferred.

ABLATE-IQ requires all series to be within the same DICOM study.

Recommendations for specific CT manufacturers are provided below.

GE Scanners: Select 'Repeat Series' between scans. DO NOT select 'Repeat Last Group'. ABLATE-IQ 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 ABLATE-IQ 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 contrast prior to the setup scan may be helpful in target definition.*

3.2 Select Profile and Tissue

Refer to the NEUWAVE System user manual for details on creating, selecting, and editing system profiles and tissue.

ABLATE-IQ Edit Profile

To configure ABLATE-IQ default settings, use the Edit Profiles button next to the Profile selection on the Select Profile and Tissue window. The ABLATE-IQ default settings do not control the NeuWave System nor probe output in any way. The Profiles window appears in Figure 3-1.

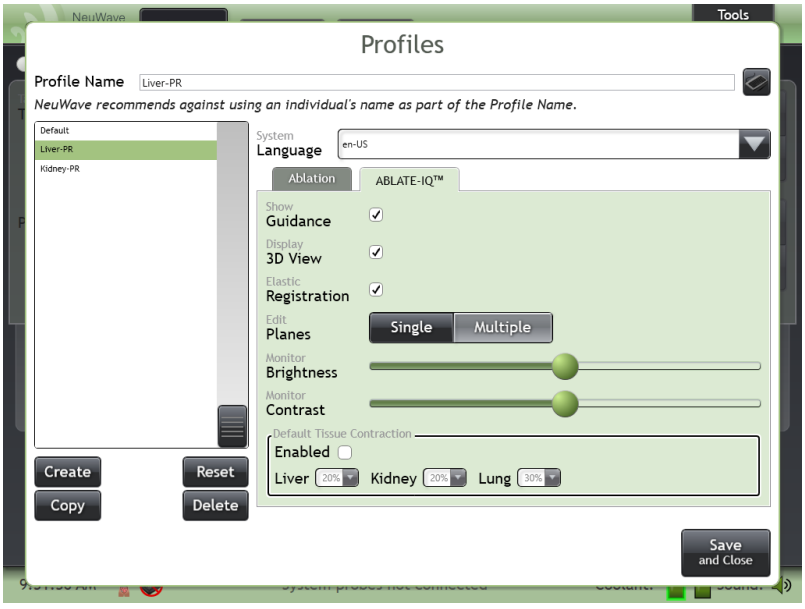


Figure 3-1: Profiles Window.

Important: Editing profile only edits selected Profile Name default settings; to select the Profile to be used for the procedure, the user must return to the Select Profile and Tissue window and select the desired Profile.

ABLATE-IQ Tab

The Edit Profiles window includes the following additional settings on the ABLATE-IQ tab:

- **Show Guidance** - If selected, display the guidance window when entering each screen.
- **Display 3D View** - If selected, display the 3D viewport for all steps.
- **Elastic Registration** - If selected, perform a deformable registration by default. Otherwise, perform a static registration.
- **Edit Planes** - Define the default behavior of the edit tools. 'Single' will edit a single slice 'Multiple' will affect the current slice and slices above and below the current slice.
- **Monitor Brightness** - Drag the slider to adjust the default brightness of the ABLATE-IQ user display.
- **Monitor Contrast** - Drag the slider to adjust the default contrast of the ABLATE-IQ user display.
- **Default Tissue Contraction**
    - **Enabled** - If selected, automatically apply the specified default contraction value when entering the **Post Ablation** screen.
    - **Liver, Kidney, Lung** - If enabled, specify the default contraction percentage to be applied to targets in each organ. The available % values are Liver (0, 10, 15, 20 and 30), Kidney (0, 10, 15, 20 and 30), Lung (0, 10, 20, 30, 40 and 50).

Press the **Save and Close** button to save the desired settings.

3.3 Starting the Procedure

The ABLATE-IQ Software is ready to use when the **Welcome** screen appears on the monitor, as shown in the left panel of Figure 3-2. If the system does not have a valid license, the **Welcome** screen will appear as shown in the right panel of Figure 3-2. No **Navigation Bar** or ***Admin*** tab are displayed if the application has not yet been registered with a valid license.

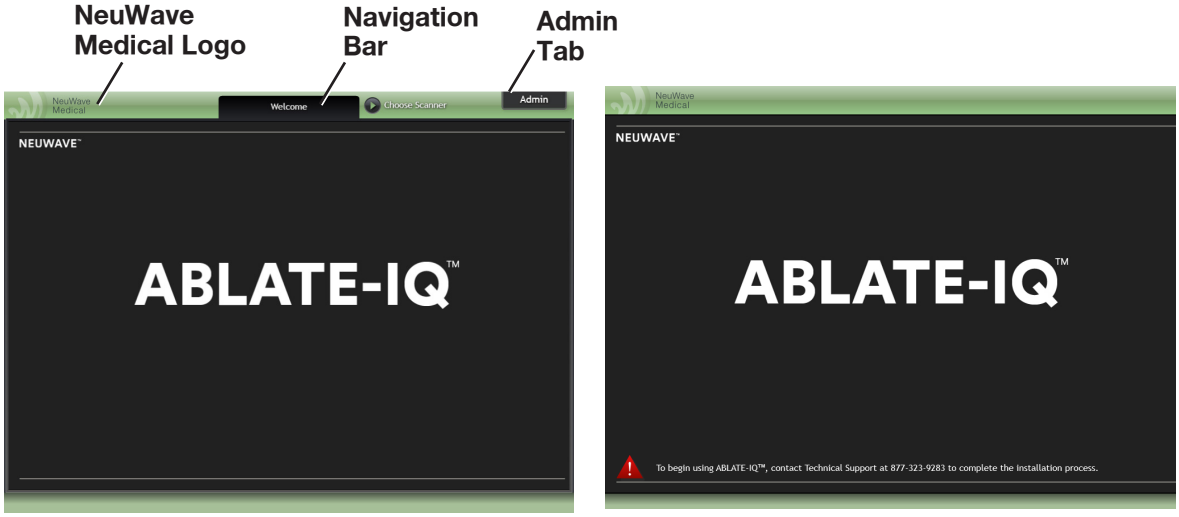


Figure 3-2: Welcome Screen of the ABLATE-IQ Software. Left Panel: Typical Welcome Screen. Right Panel: Welcome Screen when the system starts without a valid license.

If the system does not have a valid license, please refer to license information received when the product was purchased and enter the license numbers by accessing the Tools menu. For all other network connectivity problems, see the *Handling Network Connectivity Problems* Section at the end of *Appendix B* or contact Ethicon Customer Service.

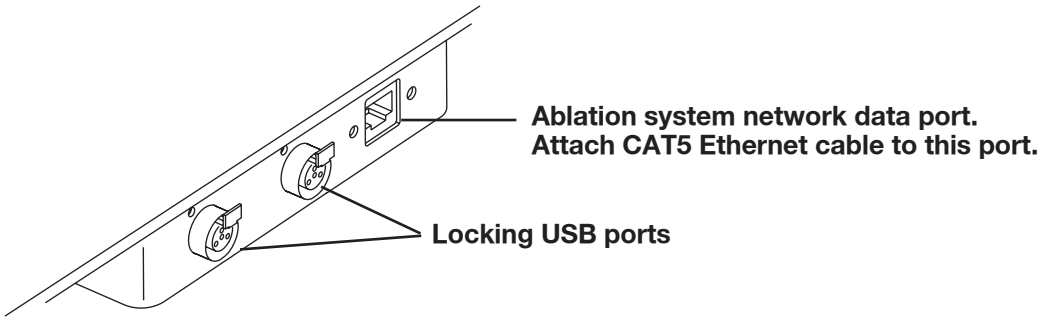


Figure 3-3: Ablation system network connection.

3.4 Navigating the ABLATE-IQ Software

The ABLATE-IQ Software is designed to guide you logically through the ABLATE-IQ 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 3-4). Clicking the screen names or the arrows next to them allows going to the next screen or return to the previous screen.

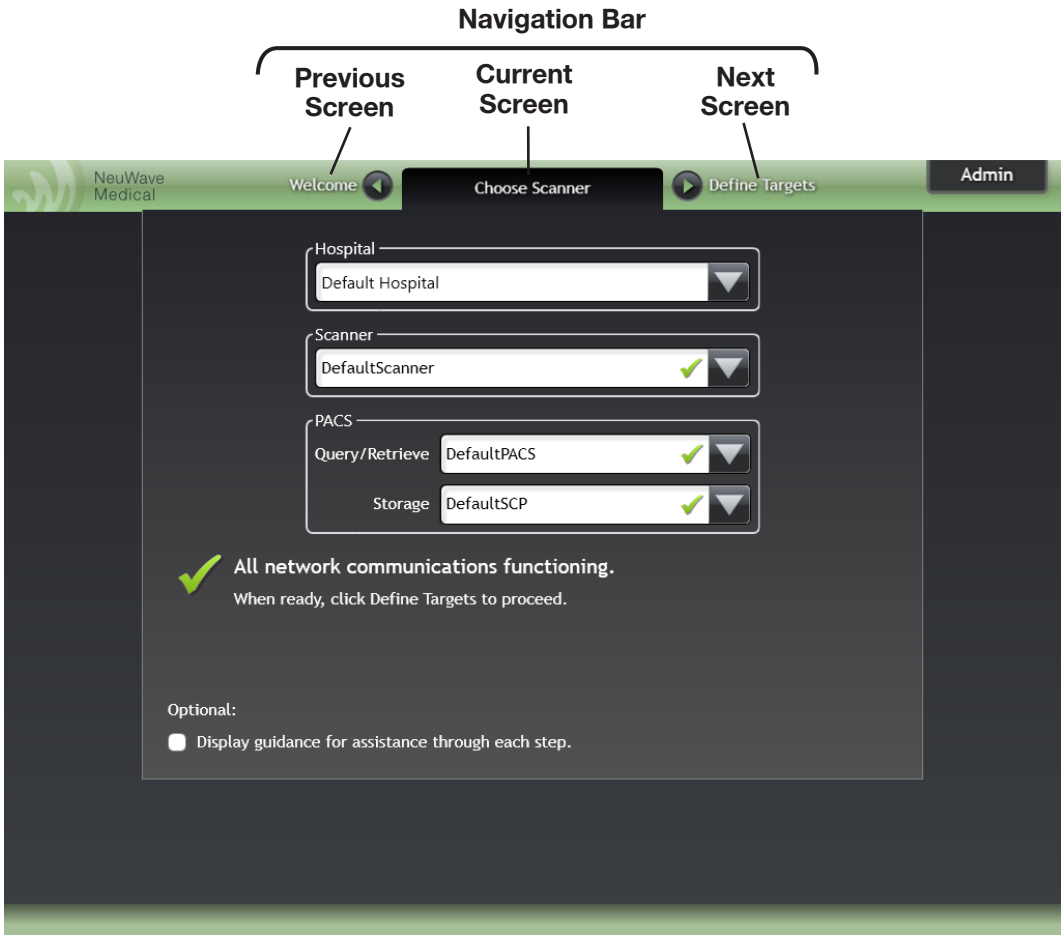


Figure 3-4: ABLATE-IQ Software Screen navigation and guidance.

Clicking the ***Admin*** tab in the upper right corner of the **Choose Scanner** screen prompts the user to enter an admin password to ensure that the cart's settings are properly protected (Figure 3-5). Selecting the keyboard icon will enable an on-screen keyboard allowing the user to type their password.

Figure 3-5: Admin Authorization screen to enter the Admin password.

3.4.1 Screen System Overview

Figure 3-6 shows how the ABLATE-IQ Software screens are organized. In the example shown for the **Define Targets** step, the screen is divided into panels containing clickable tools and options on the left side of the screen, and panels displaying the patient images on the right side. From top to bottom, the leftmost panels show:

- Patient-related information.
- Tools to manipulate images (e.g., Image Tools).
- CT Scan tabs (4 tabs).
- A Series Description listing the sets of images available to the user.

Figure 3-6: General organization of the ABLATE-IQ Software screen system.

Figure 3-7 depicts screenshots of the 4 tabs under the **Define Targets** step. A similar tab organization is followed under the **Evaluate Probe(s)** and the **Evaluate Treatment** steps. For the **Define Targets** step, these 4 tabs include tools that allow the user to select and download CT image series (***Select*** and ***PACS*** tabs), define target lesions (***Define*** tab), and plan ablations (***Plan*** tab) (see detailed description under the *Define Targets STEP* Section below).

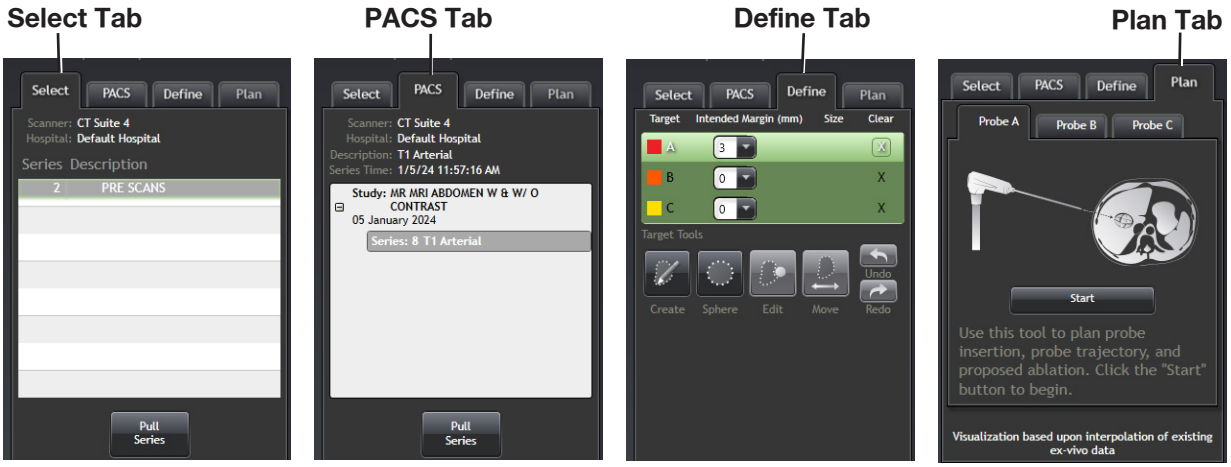


Figure 3-7: Tabs under the Define Targets Step.

3.4.2 Steps Menu

When working through the ablation procedure, 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 ***Steps*** menu, which you can open by clicking the **View Steps** button in the upper-right corner of the screen (Figure 3-8). Users will find the ***Steps*** menu useful when they need to return to any previous screen at any time to make quick adjustments.

To move directly to a screen listed in the menu, simply click the screen name. The screens are listed in the sequential order they appear in the software (Figure 3-8). The active screen is highlighted in the menu. Grayed out steps indicate that they have not been viewed and requirements have not been completed. The ***Steps*** menu becomes available when you reach the **Define Targets** screen. Until then, the ***Admin*** tab appears in the upper-right corner.

When a checkmark appears next to a screen name, requirements for that screen have been satisfied. If a snapshot has been taken on a screen, the screen name appears in the menu with a camera icon next to it (Figure 3-8).

Important: Note that some screens, such as the series registration screen, are not shown in the Steps menu, shown in Figure 3-8. The series registration screen is embedded as a tab under the Evaluate Probe(s) screen. You will learn how to register two sets of images at a later step in this chapter.

The ***Steps*** menu can be closed by left-clicking the mouse on the **Close Menu** option at the bottom of the ***Steps*** menu (Figure 3-8), or by clicking anywhere in the active screen outside the ***Steps*** menu.

Figure 3-8: Steps Menu next to the Navigation Bar.

3.4.3 Screen Guidance

The ABLATE-IQ Software Screen Guidance system briefly describes the function of each screen. To activate and display the system click on the question mark in the **Navigation Bar** at the top of the screen (Figure 3-9). Screen Guidance specific to the step shown is displayed.

All screens display an optional screen guidance step at the bottom. Checking the box activates the ABLATE-IQ Software Guidance to help the user through each step of the process (Figure 3-9).

To disable the guidance system in subsequent screens, click the minus/dash sign next to the **Hide** button in the upper-right corner of the guidance screen (Figure 3-9). If you have disabled/ hidden the guidance messages, you can still display single messages, one at a time, by clicking the question mark next to the active/current screen name (Figure 3-9).

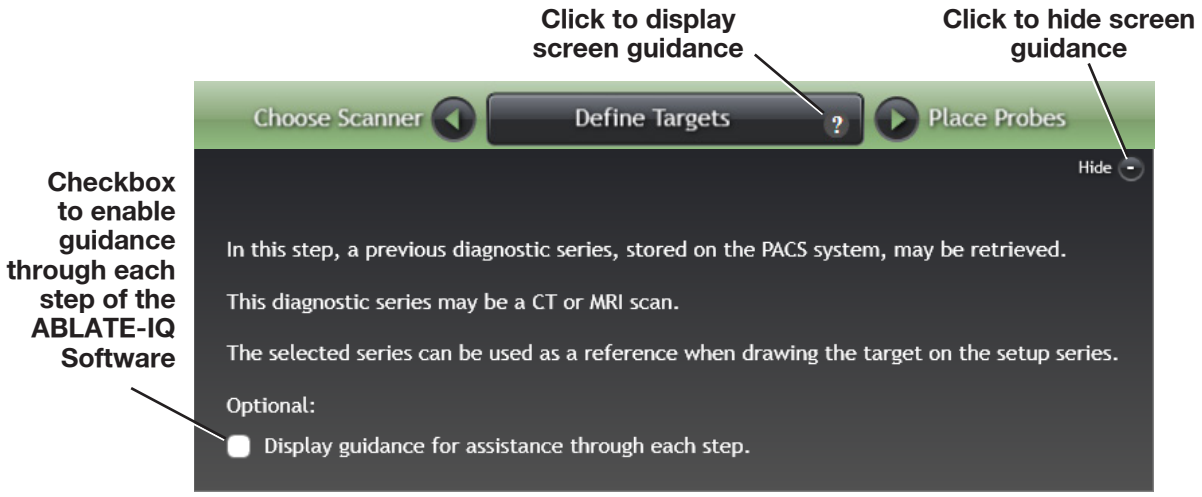
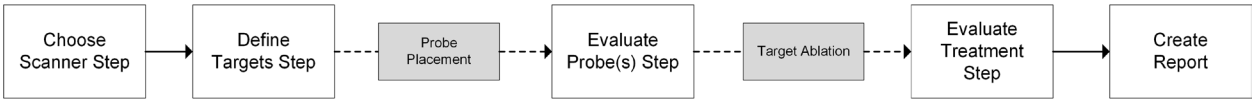


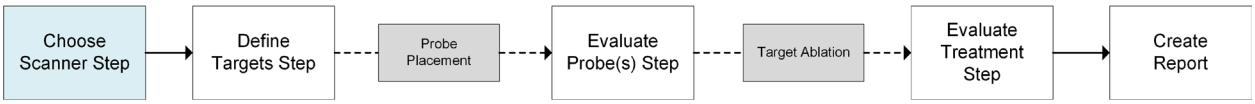
Figure 3-9: ABLATE-IQ Software Screen Guidance system.

3.5 ABLATE IQ Software STEPS

The software encompasses 5 major sequential steps to assist the user with detailed instructions for the entire ABLATE-IQ procedure, from choosing a scanner to defining targets, and evaluating probe placement and treatment. A Premium feature allows users to create a report of the procedure.

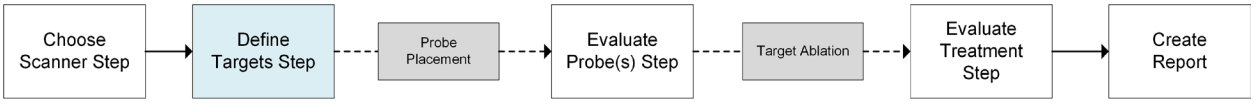


3.5.1 Choose Scanner STEP



1. Click the **Choose Scanner** name or the arrow button at the top of the **Welcome** screen (Figure 3-2) to advance to the **Choose Scanner** screen. This will displace the **Welcome** screen to the left side of the **Navigation Bar** and the **Define Targets** screen will appear on the right side of the bar.
2. 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 may have already been selected.

3.5.2 Define Targets STEP



1. Click the arrow button on the right side of the **Navigation Bar** in the **Choose Scanner** screen to advance to the **Define Targets** screen.
   a. The ***Admin*** tab is automatically replaced by a **View Steps** button and selection menu on the upper right corner of the screen.
   b. The ***Steps*** menu displays the primary screens of the ABLATE-IQ Software (Choose Scanner, PACS Images, Evaluate Probe(s), Evaluate Treatment, and Create Report (Figure 3-7).

2. Perform the scan. A CT image series, called the Setup CT Series, is acquired. To help limit computation time, it is best to limit the number of slices in the scan to 250 or fewer.

Important: 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.

3. Select the newly acquired series from the list in the lower left side of the screen (Figure 3-10).
   a. The list shows the scans taken for the selected patient in the current scanner in chronological order, with the most recent scan at the top of the list.
   b. The application displays data for only one patient at a time. If a new patient is scanned, the list will be replaced with the new patient's scans.
   c. If needed, use the scroll bar to view all series listed. Note that the description of the CT series is the same entered at the CT scanner console.
   d. After selecting the series, click the **Pull Series** button beneath the list (Figure 3-10). The application "pulls" (downloads) the series to the ABLATE-IQ Software for examination. A spinning wheel appears in the center of the screen while the series is being downloaded (click **Cancel** button if necessary). After downloading the selected series is completed, the software auto steps to the ***Define*** tab for the user to define the target(s), If you decide to change the CT series, you can go back to the ***Select*** tab and choose a different CT series.
   e. If the selected series is multiphasic (consisting of two or more phases), 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 the user wants to view a different phase, they may select the phase and then click the **Pull Series** button.

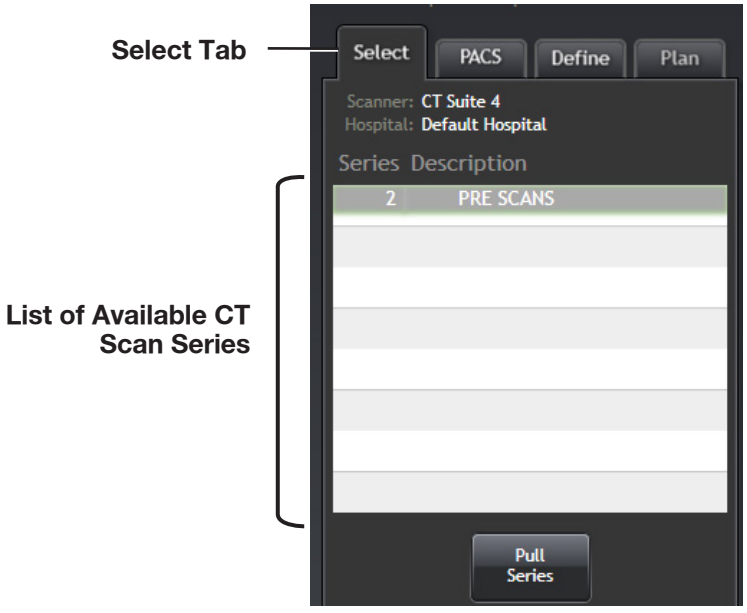


Figure 3-10: The Select Tab showing the CT Series Description list.

3.5.2.1 Examining the Image Setup Series

Take a moment to examine the selected CT Setup Series shown on the **Define Targets** screen. This screen displays how Image Views and Image Tools are organized in this and subsequent screens of the ABLATE-IQ Software (Figure 3-11). The **Define Targets** screen contains a set of tools on the left panel that help you examine the selected image series shown on 4 separate anatomical planes called Image Views displayed on the right side of the screen. These Image Views help you locate and define the lesion. Use the mouse wheel to explore the CT series images by scrolling up and down in any of the 4 Image View panels: Axial (A), Sagittal (S), Coronal (C) or three dimensional (3D).

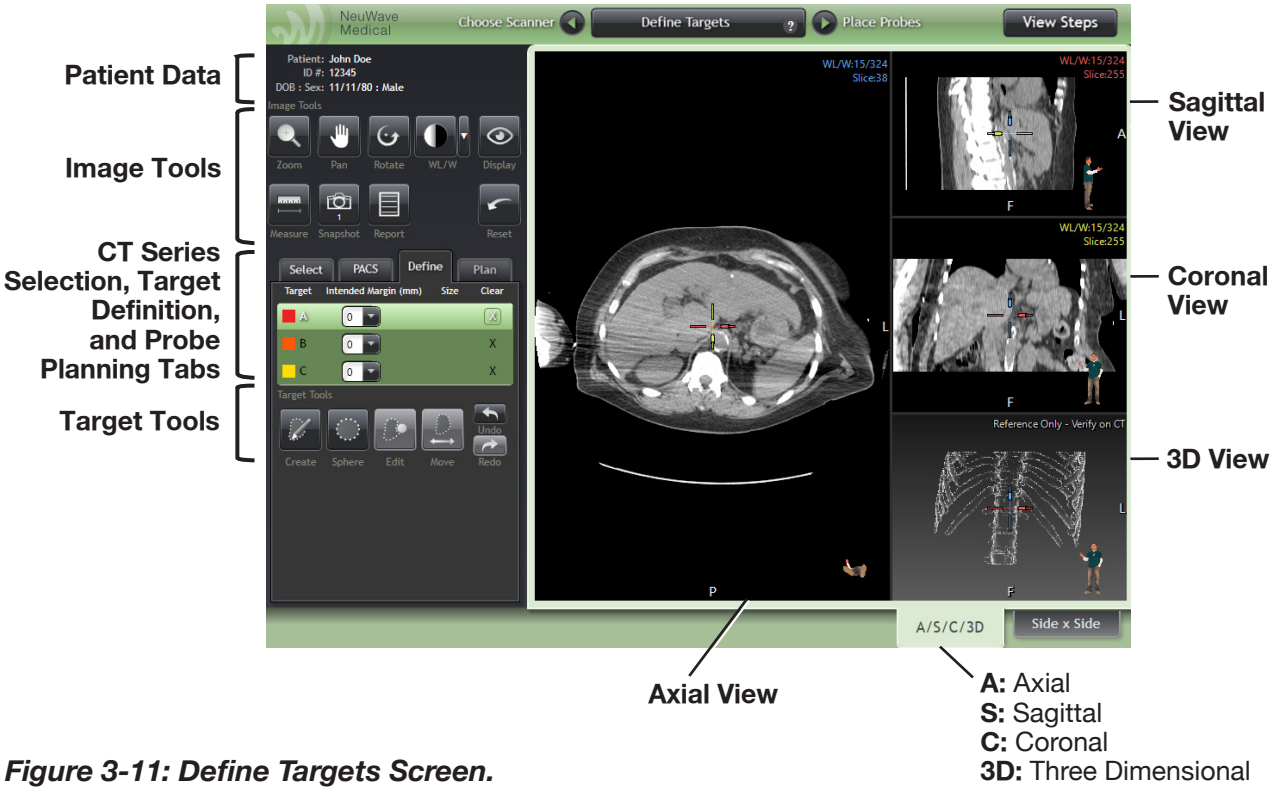


Figure 3-11: Define Targets Screen.

Using the Image Tools

The middle-left section in the **Define Targets** screen displays the Image Tools panel, which includes 8 Image Tools and a **Report** tool (also available as a **Create Report** selection in the ***Steps*** menu) (Figure 3-12).

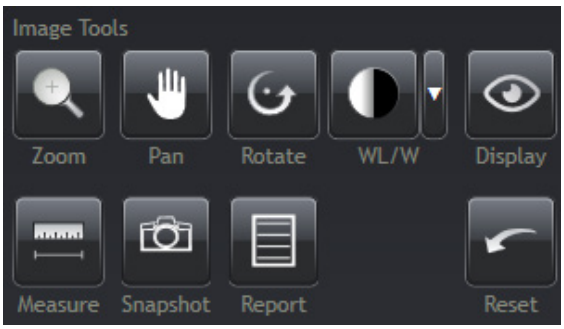


Figure 3-12: Image Tools panel.

The 8 Image Tools help the user scroll through, manipulate, and annotate the image slices in the selected image series. You cannot use these tools unless an image series is pulled, and image slices are shown in the Image Views panels on the right side of the screen.

The Image Tools panel displays icons for the following tools (Figure 3-12):

- 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 **Rotate** tool allows you to rotate a 2D or 3D image.
- The Window Level tools (**WL/W**) adjust an image's contrast and brightness, which helps splay features within an image more prominently.
- The **Zoom, Pan**, and **WL/W** 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 **Snapshot** tool acquires a screen shot of the displayed image data. You have the option of sending the screenshot to the storage PACS of the active study. All screenshots 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 in-depth descriptions on how to use the Image Tools, see *Appendix A*.

3.5.2.2 Using the Image Views

The right side of the selected CT Setup Series screen displays the Image Views (Figure 3-11).

- The Image Views panels include 4 views (anatomical planes), as described in Figure 3-11: Axial (A), Sagittal (S), Coronal (C), and 3D.
- The edges of each Image View contain letters that indicate the orientation of the patient (e.g., H: head, F: foot, A: anterior).
- Review these images to make sure the scan is sufficient for your needs.
- Roll the mouse wheel forward and backward to move through the CT slices and locate the lesion. You can also locate the lesion by clicking and dragging the mouse to move through the slices.
- Names and abbreviations for the 4 views/planes and the 6 patient orientations used in the software are shown in the Abbreviations for Image Views and Patient Orientations table below.
- The 3D view is for reference only. Please refer to the CT image for accuracy.

For more information on the mouse functions, see ***Mouse Functions*** in the ***Image Views*** Section in *Appendix A*.

Abbreviations for Image Views and Patient Orientations

Image Views (anatomical planes)
A: Axial (Transverse/Horizontal view)
S: Sagittal (Longitudinal/Vertical view; left or right)
C: Coronal (Longitudinal/Vertical view; front or back)
3D: Three-Dimensional (Reference only - Verify on CT)

Patient Orientations (anatomical directions)
A: Anterior (Ventral)
P: Posterior (Dorsal)
L: Left (Lateral)
R: Right (Lateral)
H: Head (Superior)
F: Foot (Inferior)

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 human 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 Reference Points displayed by default as crosshairs on each Image View can be easily displaced or removed by the user. A right click of the mouse away from the crosshairs will position the Reference Point at the same location in all Image Views. A right click over the crosshairs will remove the Reference Point from view, and a second click will display it back.

The colors of the crosshairs (Reference Points) and radiologic data correspond in all four views of the slices: Blue: Axial Image Plane; Red: Sagittal Image Plane, and Yellow: Coronal Image Plane.

3.5.2.3 Defining Targets

Use the **Define Targets** screen to draw ablation targets on areas to be treated in the patient. You can define up to three targets on an image slice in any 2D View each in a different color.

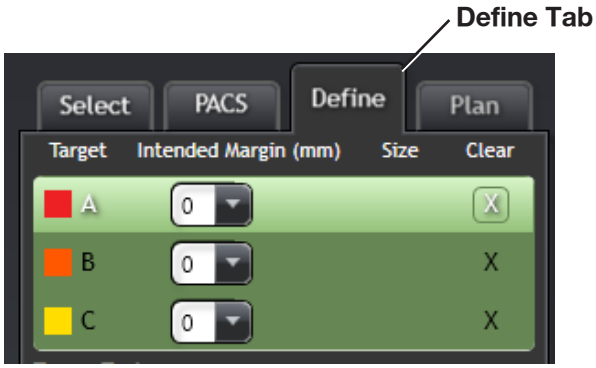


Figure 3-13: Target Selection Table.

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

1. Locate the lesion in the Image Views.
2. If you have trouble locating a lesion in the just-acquired scan, you can pull in an image from PACS for reference. See the *PACS Images Step* Section for details.
3. In the Target Selection Table on the left side of the **Define Targets** screen (Figure 3-11 and Figure 3-13), 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 (Figure 3-14), click the **Create** or **Sphere** tool to define your target.

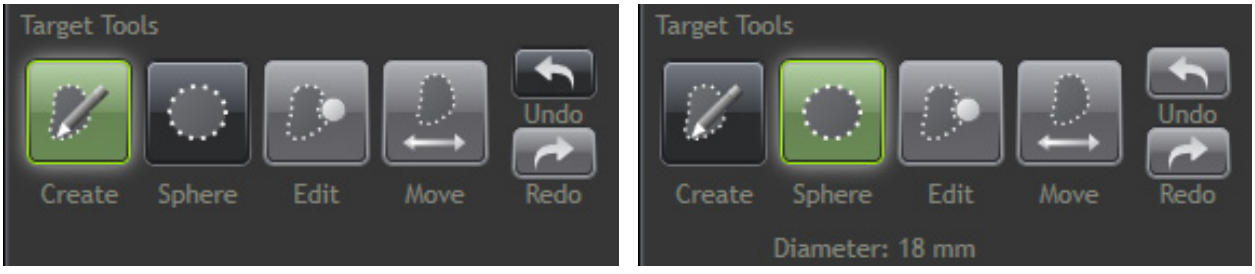


Figure 3-14: The Create or the Sphere Tool can be selected in the Target Tools panel.

Important: The Create tool is most effective when the target lesion is visible and well defined, whereas the Sphere tool is most useful when the target lesion is not clearly defined but the location and size are known by the user.

5. When the **Create** tool is selected (Figure 3-14) move the mouse pointer to a CT slice/image near the center of the targeted lesion; use the mouse scroll wheel to grow or reduce the segmented area. Once you are satisfied with the software-generated target, left-click to accept its shape and size.
6. The **Create** tool looks for tissue of similar CT radiodensity (measured in Hounsfield units) and automatically propagates the target through CT slices above and below the selected slice.
7. When the **Sphere** tool is selected (Figure 3-14) move the mouse pointer to a CT slice near the center of the targeted lesion. Use the mouse scroll wheel to grow or reduce the sphere diameter. Left click to accept the size of the target.
8. The default sphere diameter is 18 mm.

The target becomes the color assigned to the target letter in the Target Selection Table on the left side of the screen (A: red, B: orange, C: yellow). The red target created in Figure 3-15 corresponds to Target A.

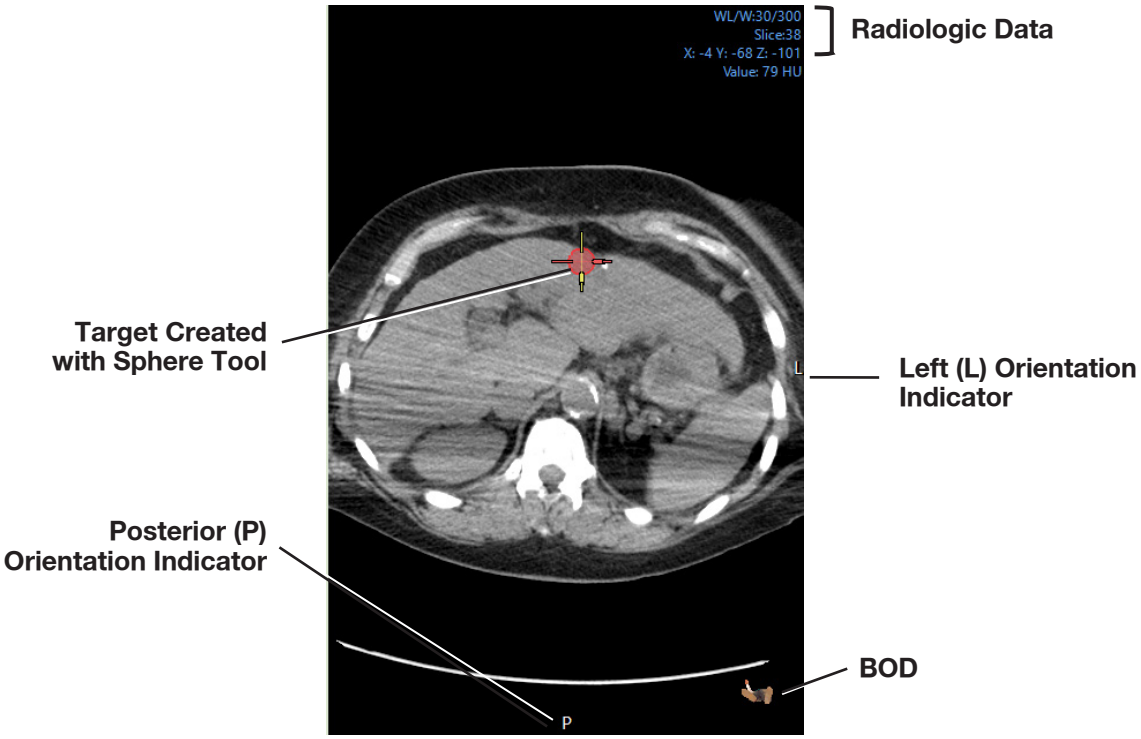


Figure 3-15: Target created (red outline) with the Sphere Tool. BOD: Body Orientation Diagram.

If you want to refine the target, click the **Edit** tool in the Target Tools panel (Figure 3-16) and then move the mouse pointer to the target you just defined.

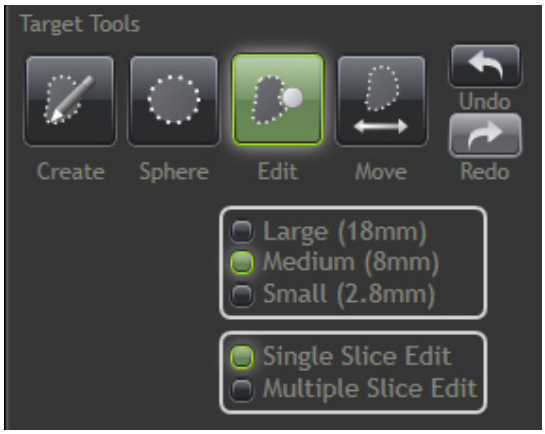


Figure 3-16: The Edit Tool.

9. Choose a Large, Medium, or Small diameter for refining the target. The Medium option is selected by default (Figure 3-16).
10. Choose the single- or multiple slice edit option for refining the target. The single slice option is selected by default. Selecting the multiple slice edit option will edit slices above and below the displayed slice using a sphere of the selected size.
11. To remove portions of the target, place the mouse pointer just outside the target's area; a red circle appears. Click and hold the mouse, using the pointer to guide the circle. Slowly drag the red circle along the target's border (Figure 3-16).
12. To expand portions of the target, place the mouse pointer just inside the target's area; a green circle appears. Click and hold the mouse, using the pointer to guide the circle. Slowly drag the green circle along the target's border (Figure 3-17).
13. Single slice manual editing of a target extending over several CT slices can be performed by systematically scrolling from one end of the target lesion to the other end. After the target is individually edited in a CT slice, the mouse wheel is used to scroll to the next slice to edit the target. This single slice editing process is repeated over several slices until the end of the target is reached.

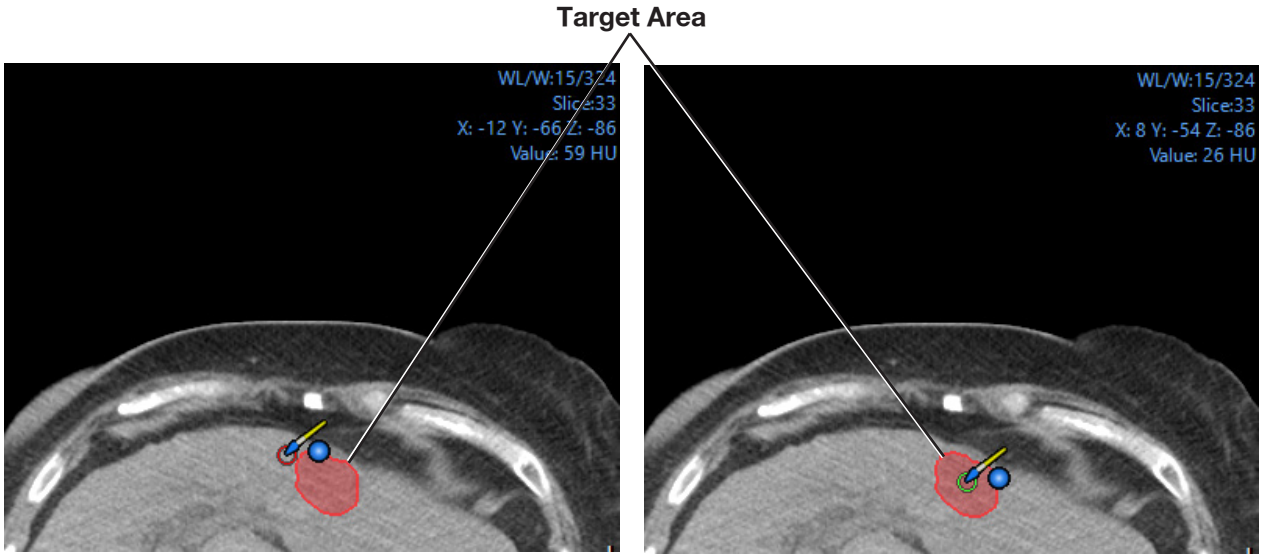


Figure 3-17: Using the Edit Tool to decrease (left panel) or increase (right panel) the size of the target area.

14. If necessary, repeat the preceding steps 1-7 to create two additional targets. Up to three targets can be created.
15. Use the **Undo** and **Redo** buttons (Figure 3-14) to modify steps taken in creating and defining an ablation target.
16. In the Target Selection Table, you can select the size of a margin to display around the target(s) (Figure 3-13). 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 setting size of the intended ablation margin ranges from 1 to 10 mm.
17. To see the size of a target area, click its **Size** arrow in the Target Selection Table. The size displays the target's length in millimeters along the X-, Y-, and Z-axes, and its total volume in cubic cm (cm^3).
18. To toggle between displaying and hiding targets and probes in the Image Views click the **Display** tool in the Image Tools panel and select or deselect the appropriate box (e.g., targets).

Important: 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.

19. To delete a target and start over, click the appropriate **X** icon under the Clear column (Figure 3-13).

3.5.2.4 PACS Images Tab

The ***PACS*** tab allows the user to select a previously acquired, historical image series from the current patient and compare it to the setup series just acquired to aid in defining the target lesion (s). The comparison scan can be a previously acquired CT series, magnetic resonance (MR) series, or fused PET image series.

Fused Positron Emission Tomography (PET) images must be created and stored (in PACS or other workstation) prior to comparison in the ABLATE-IQ Software. If fused PET images are used (see example in Figure 3-18), not all functionality, including measurement functionality, will be available.

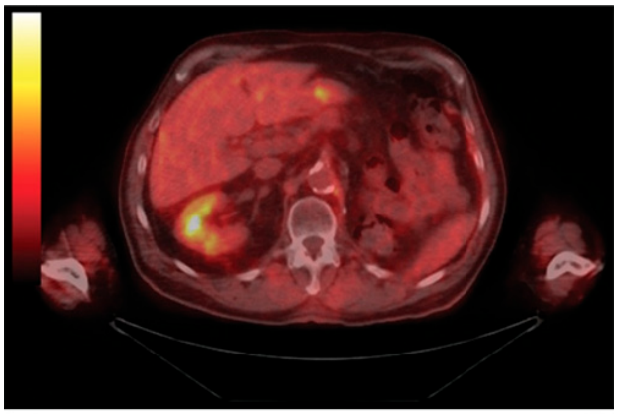


Figure 3-18: Example of a fused PET image.

Reference images retrieved from PACS can sometimes help the user locate a lesion in the just-acquired scan. If you have trouble locating or seeing a lesion in the current scan, the reference scan might help you find the lesion. For example, a contrast enhanced 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.

To select reference images from PACS:

1. Refer to the list of studies under the ***PACS*** tab on the left side of the **Define Targets** screen (Figure 3-19). The list shows studies that are available for the current patient within the last 6 months. A date and description are displayed for each study. Each study can be expanded to reveal the series associated with it. ABLATE-IQ does not import images older than six months and only CT, MR, or fused PET series are made 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.

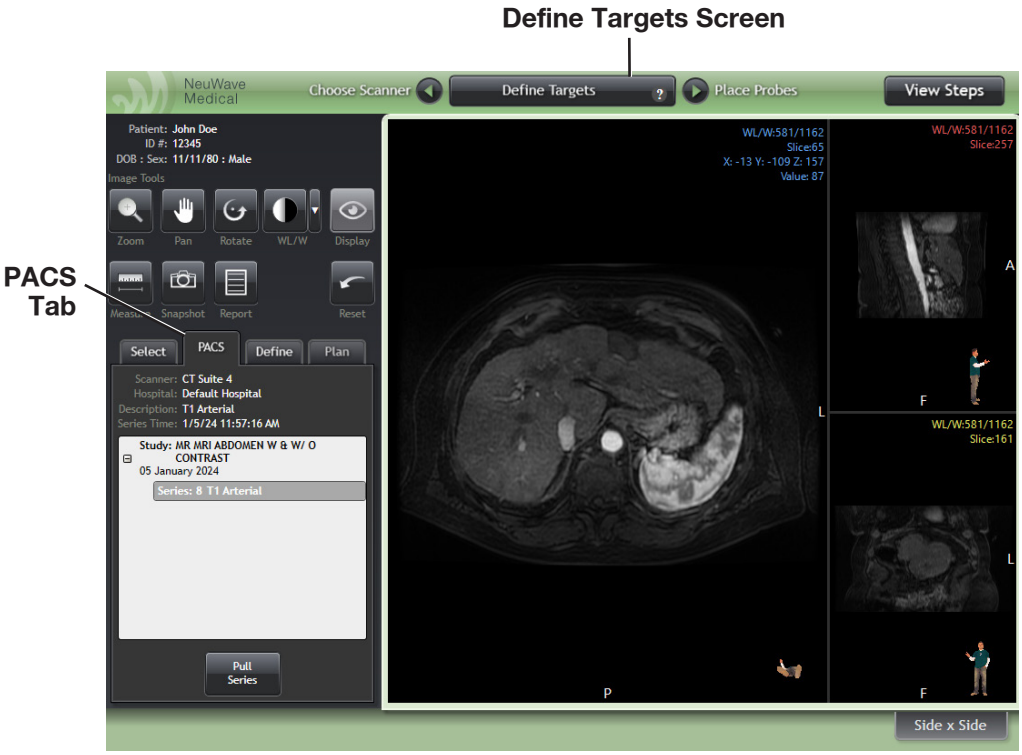


Figure 3-19: The PACS Tab under the Define Targets Screen. A historical MR Series is shown under the PACS Tab. The series was selected, and the images were downloaded ("pulled").

3. To select a series, click its name in the list (Figure 3-19).
4. Click the **Pull Series** button below the image series list or drag the series entry to the image display area to load the series into the system.
5. If the pulled series is multiphasic (consisting of two or more phases), 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**.
6. Notice that a new ***Side x Side*** tab appears in the lower right corner of the Image View panel in the **Define Targets** screen after downloading the PACS Series is completed, indicating that the system is ready to run a comparison between the the Setup CT Series and the historical PACS Series.
7. Click on the ***Side x Side*** tab to display both sets of images, the Setup Series and the Comparison Series retrieved from PACS. The screen changes to display side-by-side axial views of both sets of images, as shown in Figure 3-20.

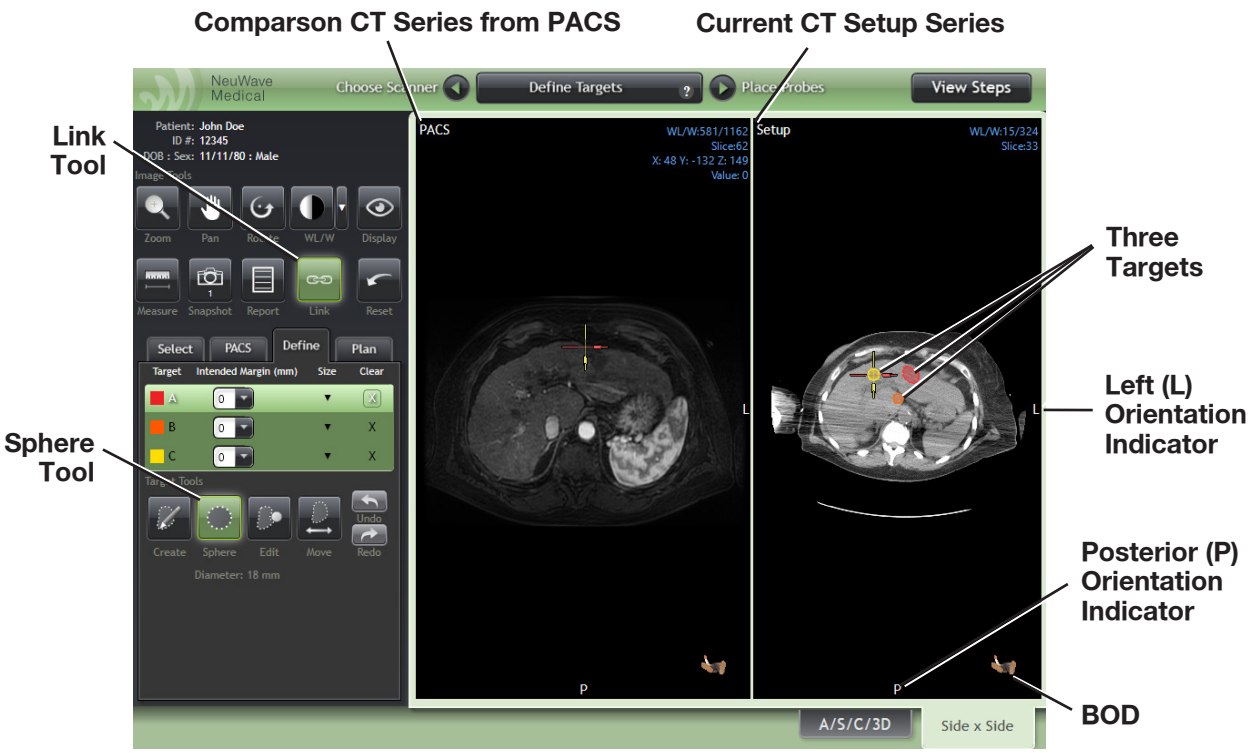


Figure 3-20: Side x Side Tab to compare the current Setup CT Series with a historical MR Series (Comparison MR Series) from the same patient. Three targets were created with the Sphere Tool as shown in the Target Selection Table.

8. The Comparison Series appears on the left under the PACS label and the Setup Series on the right labeled “Setup”. The border between the two Image Views cannot be moved and no 3D images can be viewed either.
9. Click the **Link** tool if you want your actions in one image view (e.g., **Zoom**, **Pan**) to affect both Image Views. The **Link** tool is available only when the ***Side x Side*** tab is selected, and both sets of axial images are viewed (Figure 3-20). When the **Link** tool is not selected, your actions only affect the selected Image View.

Important: 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.

10. Use the Image Tools and mouse actions to compare images. You can also define targets while using the ***Side x Side*** view but only in the Setup Series on the right side of the screen.
    a. For example, you might want to use the **Measure** tool in the Comparison Series 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.
    b. Measurements can also be useful when you are comparing images and you already know specific distances between features of interest in the comparison image.

Important: A target cannot be defined on the reference image (the PACS screen on the left side). Also, the predetermined Window/Level (WL) setting, using the drop-down list next to the WL/W tool, will only affect the Setup Series, when using the Side x Side comparison view. The PACS Series W/L can be adjusted on the PACS tab.

11. To return to the Setup Series in the multiple-view configuration, click the ***A/S/C/3D*** tab. When you are satisfied with the defined target(s), you can move on to the next step.

3.5.2.5 Probe Insertion Path Planning (Premium)

To plan the probe insertion path and display the proposed ablation zone using the ABLATE-IQ Software follow these steps:

1. Open the ***Plan*** tab on the **Define Targets** screen. Three tabs labeled Probe A, Probe B and Probe C appear indicating that up to three probe placement plans can be created. Each tab displays a diagram of a probe and an axial drawing of an abdominal plane (Figure 3-21).

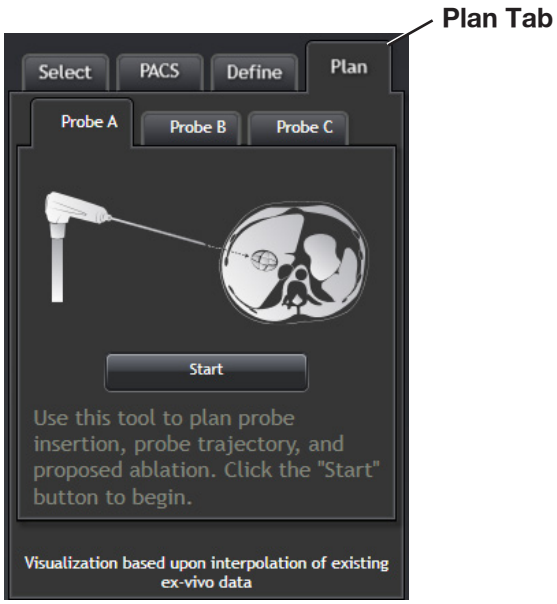


Figure 3-21: The Plan Tab in the Define Targets Step.

2. As indicated in the legend at the bottom of the diagram, click the **Start** button to begin planning placement of the first probe (Probe A).
3. The system is now ready for the user to select starting and ending points along a probe's pathway. A window prompts the user to select the starting point of the probe based on the targets previously created on the images (Figure 3-22).

Figure 3-22: Create a Probe display to indicate that the ABLATE-IQ Software is ready to select the probe's starting point.

4. Move the cursor to a 2D image on the right side of the screen where you would like to set the probe's starting point. Any 2D View can be used to create the probe's insertion pathway. A number "1" next to the cursor indicates that the starting point is to be selected next. Distance from the starting point to the patient's body surface is displayed in mm along the probe's line.
5. After selecting the starting point and clicking over the defined target, an orange line simulating the probe is created. The orange line can be rotated around the starting point by moving the mouse cursor over the image in the 2D View.

Important: Probe location is simultaneously shown in the 4 Image Views (Axial, Sagittal, Coronal, and 3D).

6. After selecting the planned starting point, a number "2" is displayed next to the cursor indicating that the system is ready to select an additional point. Follow the desired probe's trajectory and select the probe's ending point. This step defines the probe's position in the 2D View. At this stage, the probe's single line becomes a double purple line extending from outside of the patient's body to the target lesion (Figure 3-23).

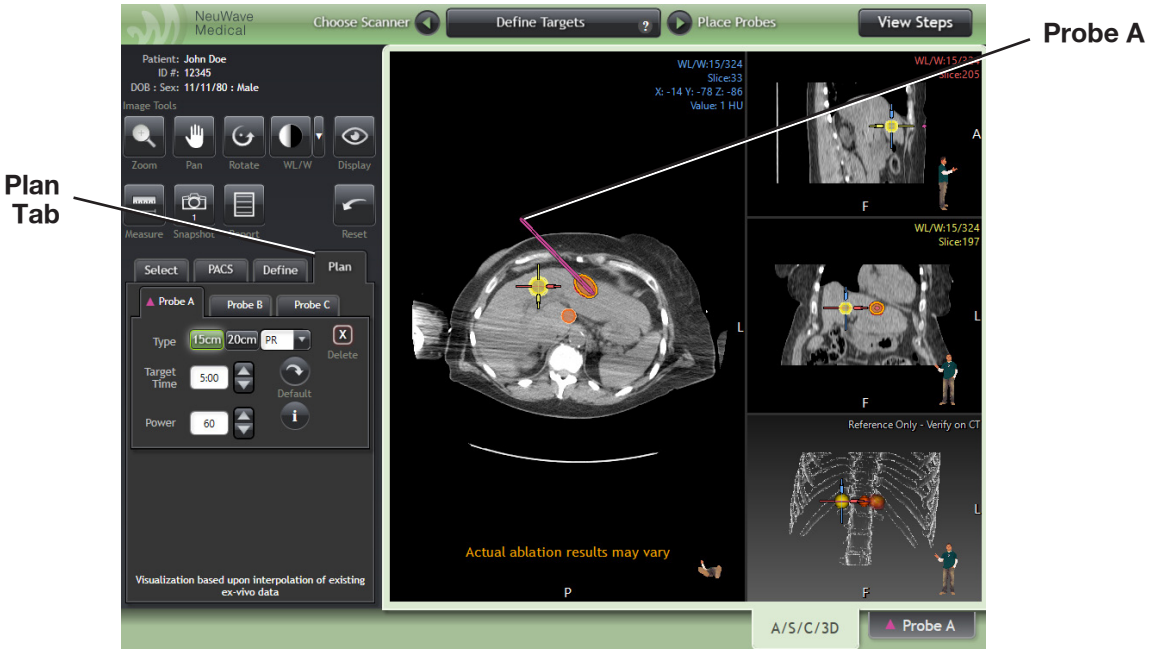


Figure 3-23: Creating an ablation probe in the Plan Tab. The probe (Probe A), probe's insertion, and trajectory are shown in the active 2D View (Axial View).

7. Out of plane probes can be created by selecting the starting point (point 1) in one slice and the ending point (point 2) in a different slice. Using the mouse wheel to scroll up or down the CT slices, a second slice can be displayed to select the second probe's point.

Important: As the probe is moved in a 2D image, intersections with bones are highlighted in red indicating that the probe cannot penetrate these structures and the probe's trajectory should be adjusted.

8. After being created, the probe's location and trajectory can be modified by the user. Left clicking on the probe tip and holding the mouse button allows to rotate the probe while keeping its end fixed in place. Conversely, left clicking on the end of the probe and holding the mouse button allows rotating the probe around its end to change the planned insertion point and probe trajectory while keeping the probe tip fixed in the same place. Additionally there are 2 views available for each planned probe, Periscope and Needle Views. The Periscope View lets you look down the shaft of the probe. The Needle View provides a lengthwise look at the probe in tissue. See the *Evaluating Probe Placement* Section for more details.

9. Clicking and holding the mouse cursor anywhere between the probe's ends allows displacing the probe parallel to the original location.
10. Probe Type (PR, PRXT, LK, LKXT, and LN), Target Time and Power can all be selected for each planned probe (Figure 3-24). Changes in ablation power (W) and time (min) is reflected in the displayed size of the planned ablation (orange ellipse) (Figure 3-23).

Important: Displayed proposed ablation zone may vary and does not account for multi-probe synchrony. Ablating with multiple probes simultaneously results in more rounded and confluent ablation zone compared to repositioning a single probe or multiple antennas from a single generator system.

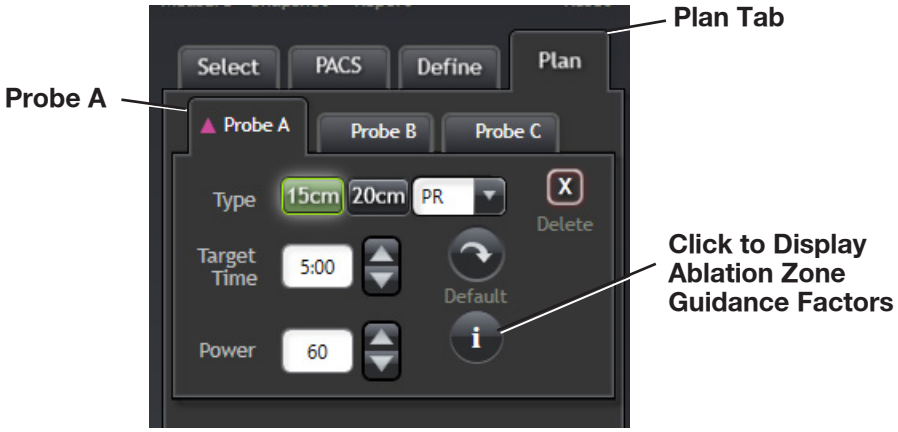


Figure 3-24: Settings for Probe A (probe type, ablation time, ablation power) are displayed under the Plan Tab.

11. The ⓘ at the bottom right of the ***Plan*** tab will provide the Ablation Zone Guidance Factors described in the next section that may impact the size of the ablation zone (Figure 3-24).
12. Planned probes in the **Define Targets** screen are designated with purple triangles and capital letters A-C (Probe A, Probe B, and Probe C). Information for up to three probes is displayed under probe-specific tabs (Figure 3-25). Once ablation probes are placed in the patient, the ABLATE-IQ Software designates these actual probes with circles.

To summarize, images of 3 defined targets and one planned ablation probe are shown in Figure 3-25. Color-coded targets defined in the active Axial Image View under the ***Define*** tab are labeled with capital letters A, B and C, and can be easily moved and redrawn by the user aided by the Target Tools. Targets were created with margins of 1, 2 and 4 mm (Panel A). Planned ablation Probes A, B and C depicted in panel C are also color-coded by 3 distinguishable shades of purple. The type of probe, ablation time, and power are set by the user (Panel C). The location and trajectory of Probe A is shown in the Axial Image View shown in panel D of Figure 3-25. The size of the planned ablation (orange ellipse around the probe's tip) changes according to the ablation time and power chosen.

The proposed ablation zone shown on a planned probe is a 3D representation with an assumption of an ellipsoid of the power and time data found in the probe Instructions for Use and in the Ablation Visualization Window of the NEUWAVE Microwave Ablation System. The visualization is based on interpolation of existing ex-vivo data. This data is based on 4 measurements taken from cross-sections of each ablation performed on ex-vivo animal tissue.

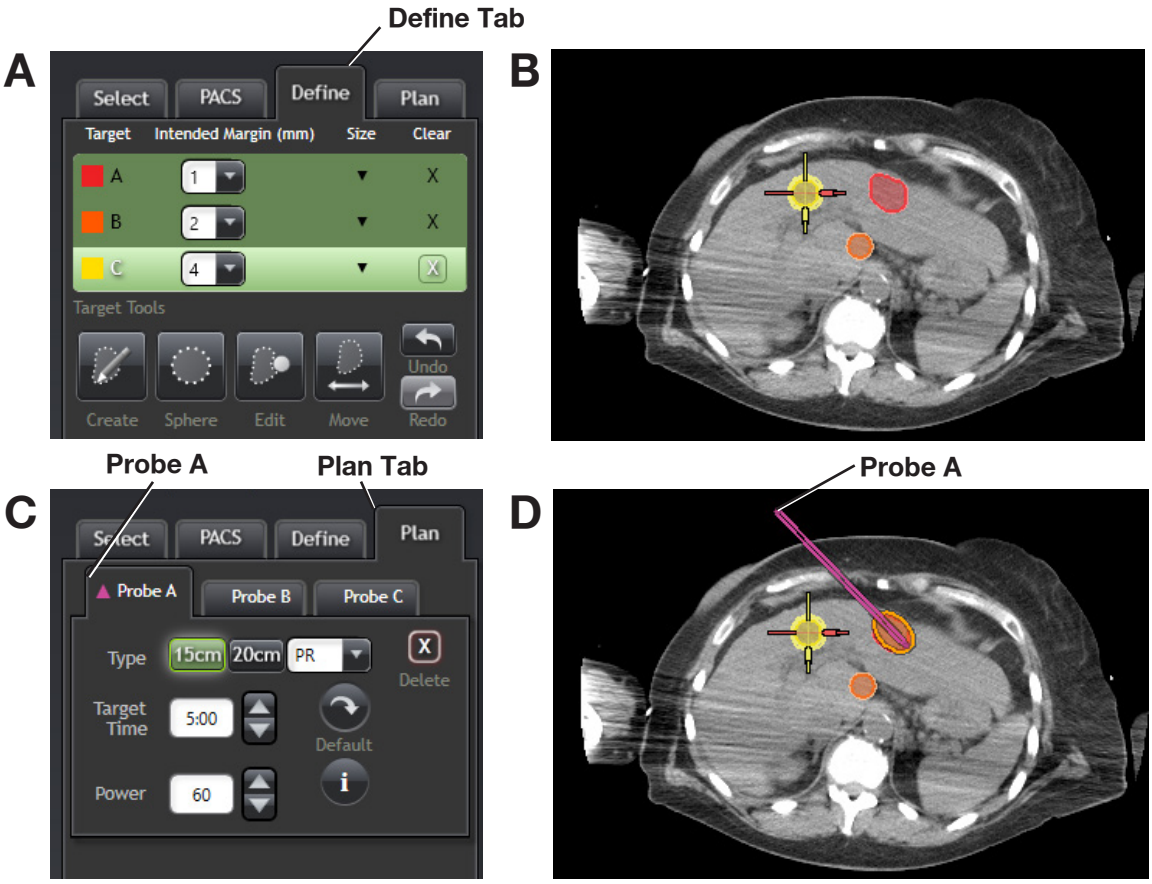


Figure 3-25: Summary of steps taken to define ablation targets (A and B) and plan the insertion and trajectory of probes (C and D). The probe's tip changes according to the ablation time and power chosen.

Important: The ablation zone sizes shown in the planning feature are representative of the data found in the probe Instructions for Use. The measurement data is based on ablations performed in ex-vivo animal tissue. There are many factors that may impact the ablation zone.

3.5.2.6 Ablation Zone Guidance Factors

Important: The ablation zone data provided is derived from ex-vivo animal tissue and does not provide a clinical representation of tissue to be ablated. This guidance factor information is also available onscreen by selecting the i *button at the bottom right of the Plan tab.*

The ablation zone data provided onscreen and in the instructions for use are from ablations performed in ex-vivo animal tissue and do not account for the cooling effects of blood flow.

Blood flow will generally result in a smaller ablation.

Lower power ablations are more impacted by the cooling effects of blood flow.

Additional factors that may impact the final ablation zone include but are not limited to:

Factors that may result in a smaller ablation	*Factors that may result in a larger ablation*
Increased/high level of vascularity	Decreased/low level of vascularity
Proximity to large blood vessels	Prior treatments such as TACE or embolization

Displayed ablation zone does not account for multi-probe synchrony.

Physicians should consider all factors when determining the appropriate ablation parameters for each case.

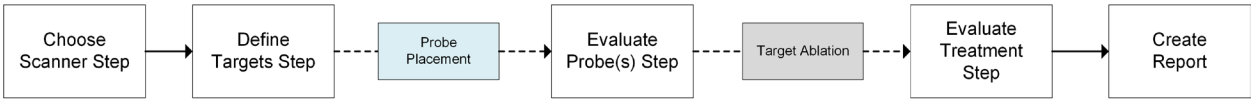
3.5.3 Placing the Ablation Probes

The next step in the ABLATE-IQ process is to place the ablation probes in the patient and perform a CT scan (Probe Placement CT Series). The Probe Placement CT Series is required to document and assess the ablation probe location in relation to the target(s) defined in the Setup CT Series.

See specific instructions on ablation probe placement and ablation modes of use (e.g., ablation vs. surgical mode, planar coagulation technique) in the user manual of the NeuWave Microwave Ablation System.

Important: Probes will not be detected in the ABLATE-IQ Software until a target has been defined and registration of the Setup CT Series and the Probe Placement CT Series has been completed. If probes are present in the setup series, all the probes will be detected once the targets are defined.

3.5.3.1 Ablation Probe Placement



Advance to the **Place Probes** screen (Figure 3-26). Place up to three patient probes at the site of the lesion(s) and then perform a CT scan (the Probe Placement CT Series).

Important: Performing all CT scans at the same point during the patient's breathing cycle, keeping the patient still during a CT session, and maintaining the patient's position (e.g., supine, lateral decubitus) consistent across the Setup CT Series and the Probe Placement CT Series will help ensure accurate registration of images. Image registration is a key step to achieving successful ablation and ABLATE-IQ procedures

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.*

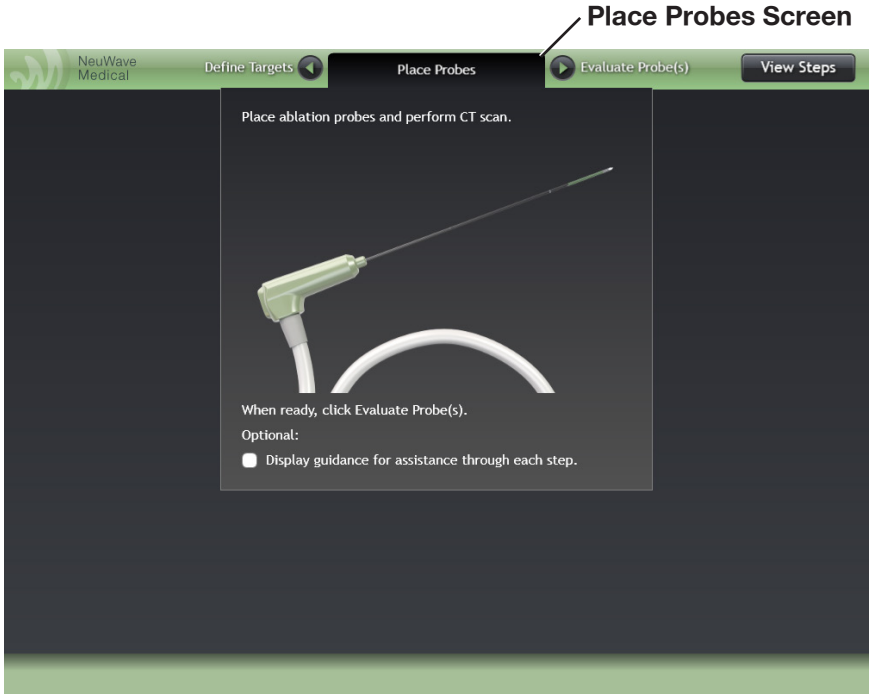
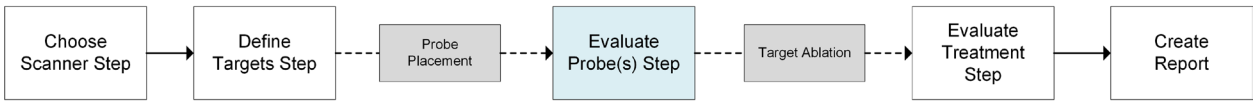


Figure 3-26: Ablation Probe Placement.

3.5.4 Evaluate Probe(s) STEP



The layout of the CT Scan tabs in the left panel of the **Evaluation Probe(s)** screen is very similar to the **Define Targets** screen layout, which you used earlier in this chapter. There are 4 tabs (***Select***, ***Register***, ***Evaluate***, and ***Plan***) (Figure 3-27). To evaluate the placement of the inserted probe(s), select a CT series and click the **Pull Series** button. The ABLATE-IQ Software auto steps to the register tab and automatically performs the registration process.

Figure 3-27: Tabs under the Evaluate Probe(s) Step.

Ensure you are in the **Evaluate Probe(s)** screen by clicking the right arrow or the screen name in the **Navigation Bar**.

3.5.4.1 Selecting the Probe Placement CT Series

Under the ***Select*** tab, select the newly acquired scan series from the Series Description list, and then click the **Pull Series** button. The application imports the series from the scanner and auto steps to the ***Register*** tab and automatically performs the registration of the Setup CT Series with the Probe Placement CT Series.

3.5.4.2 Registration of the Probe Placement CT Series

1. Registration superimposes the Setup Series images where the target(s) were defined with images from the Probe Placement Series. This new set of registered images allow the user to evaluate the current probe location in relation to the target for confirmation or adjustment before performing the ablation.
2. While registration is taking place, a 'Registration is in Progress' message and a spinning wheel are displayed in the Image View used to place the probe(s).
3. If the incorrect CT Image Series was pulled, you can manually select an alternative CT series by clicking the ***Select*** tab and choosing another series. You can do this while the registration is in progress.
4. View the image slices to ensure that the probes are placed correctly with respect to 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 3-28).

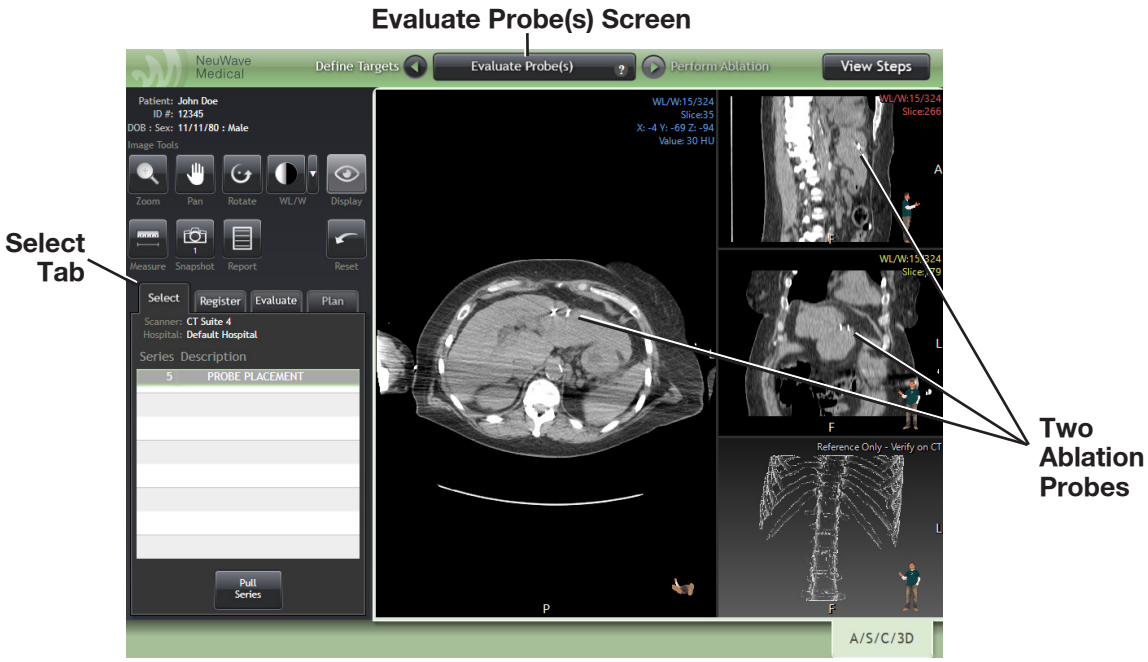


Figure 3-28: Locating the ablation probes. Full screen of the Evaluate Probe(s) Step under the Select Tab to verify probe's location.

3.5.4.3 Adjusting and Refining Image Registration

During registration (the superimposition of images from the Setup CT Series and the Probe Placement CT Series), areas around the edges of organs (e.g., kidney, liver) and other anatomical structures (e.g., vertebrae) should be aligned in the two image scans. The ***Register*** tab in the **Evaluate Probe(s)** screen displays the Setup Series images superimposed with the Probe Placement images (Figure 3-29).

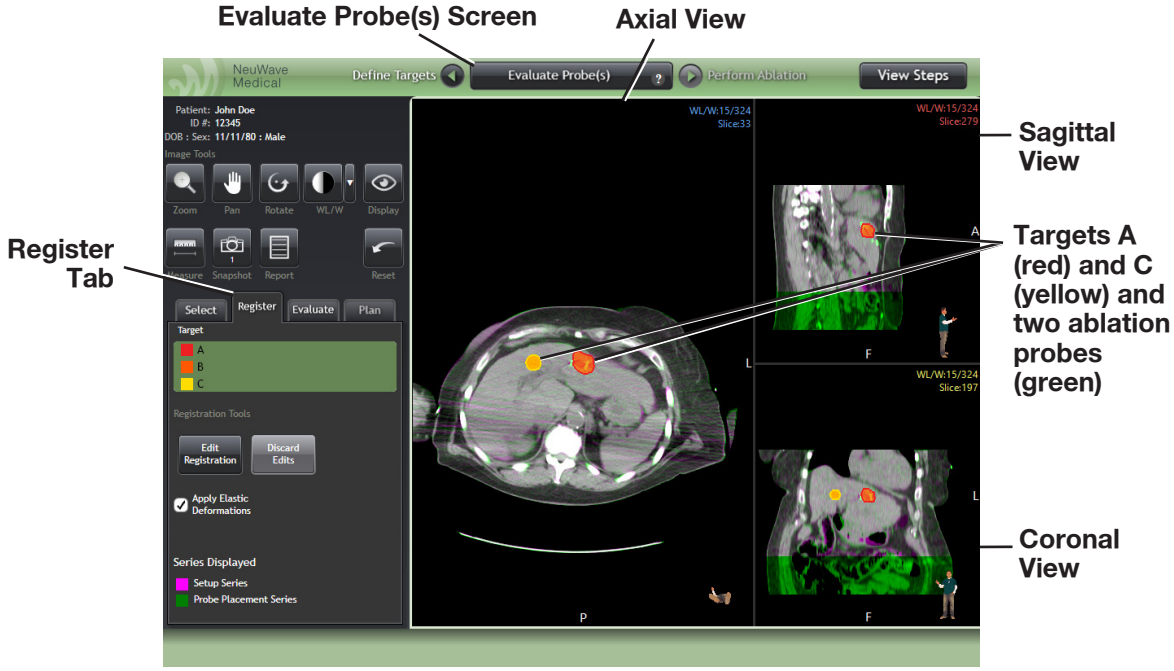


Figure 3-29: Image Registration. Registered (superimposed) images of the Setup CT Series (purple) and the Probe Placement CT Series (green) in the Evaluate Probe(s) screen under the Register Tab to verify probe's location in relation to the target.

Because of slight patient movement and the patient's breathing during CT scanning, the alignment of the same structures and organs in different image series from the same patient is not entirely exact. However, the registration of the two sets of images can be improved using the editing tools of the ***Register*** tab to manually refine the registration process.

After the auto-registration process has been completed, inspect the two image series (see Figure 3-29) paying particular attention to the purple- and green-colored areas to evaluate how well the superimposed images are registered. Figure 3-29 displays two planned targets as red (A) and orange (B) filled circles. Two probes are displayed in Figure 3-29 in yellow color (due to the superimposing of green and purple images) in the 2D Image Views (Axial, Sagittal, and Coronal).

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.

When slices from separate image series are superimposed within an image view, areas displayed in gray tones are registered well. When areas are shaded in green and/or purple, a shift has occurred between features in the two image sets (Figure 3-30).

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 ABLATE-IQ for this procedure. Refer to the CT scans on your CT review station to evaluate the ablation procedure.

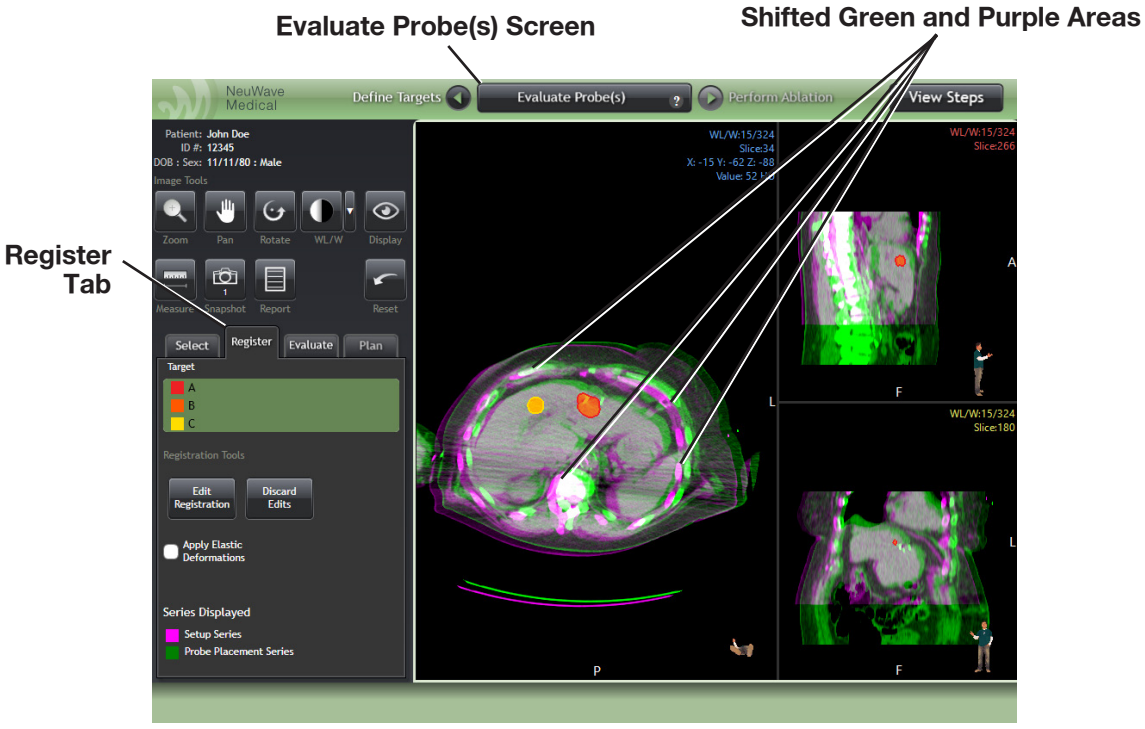


Figure 3-30: Evaluating Registration. Large areas in green and/or purple indicate that a significant shift has occurred between the Setup CT Series and the Probe Placement CT Series.

1. If you are satisfied that the ABLATE-IQ Software's registration algorithm improved alignment sufficiently, you can move to the next section. If not, manual adjustments can be made using the Registration Tools (Figure 3-30).
2. 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 default registration is the deformable registration, which is automatically performed upon selection of the CT series. Clicking the **Edit Registration** button in the ***Register*** tab automatically unchecks the **Elastic Deformation** checkbox. The **Elastic Deformation** option can be recomputed by clicking the checkbox after the manual registration was performed.
3. 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 (Figure 3-31). The circle will be centered around the current Reference Point.

Figure 3-31: Edit Registration.

4. 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. The center of rotation can be changed by right clicking the mouse at the new location. Manual changes can be executed in any Image View.
5. If, at any time, you wish to discard all manual changes made, use the **Discard Edits** button immediately to the right of the **Edit Registration** button.
6. Each Image View also displays four arrowheads and two clockwise and counterclockwise rotating arrows in the upper left corner of each image that can be used to adjust the alignment of the two sets of images (Figure 3-31).

Important: 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 the improvement of the alignment in the target area, this may be acceptable.

3.5.4.4 Evaluating Probe Placement

Use the ***Evaluate*** tab 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.

Important: ABLATE-IQ 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.

If the number of probes found by the ABLATE-IQ Software does not correspond to the number of probes present in the patient, the user can define the missing probes manually. The section "Deleting and Creating Probe Displays" guides you on how to define probes manually. To evaluate the probes found by the ABLATE-IQ Software displayed in the Probes Table (Figure 3-31) follow these steps:

1. Click the ***Evaluate*** tab in the **Evaluate Probe(s)** screen. A Probes Table appears at the bottom left of the screen. Each probe detected by the ABLATE-IQ Software is color-coded with shaded tones of blue.

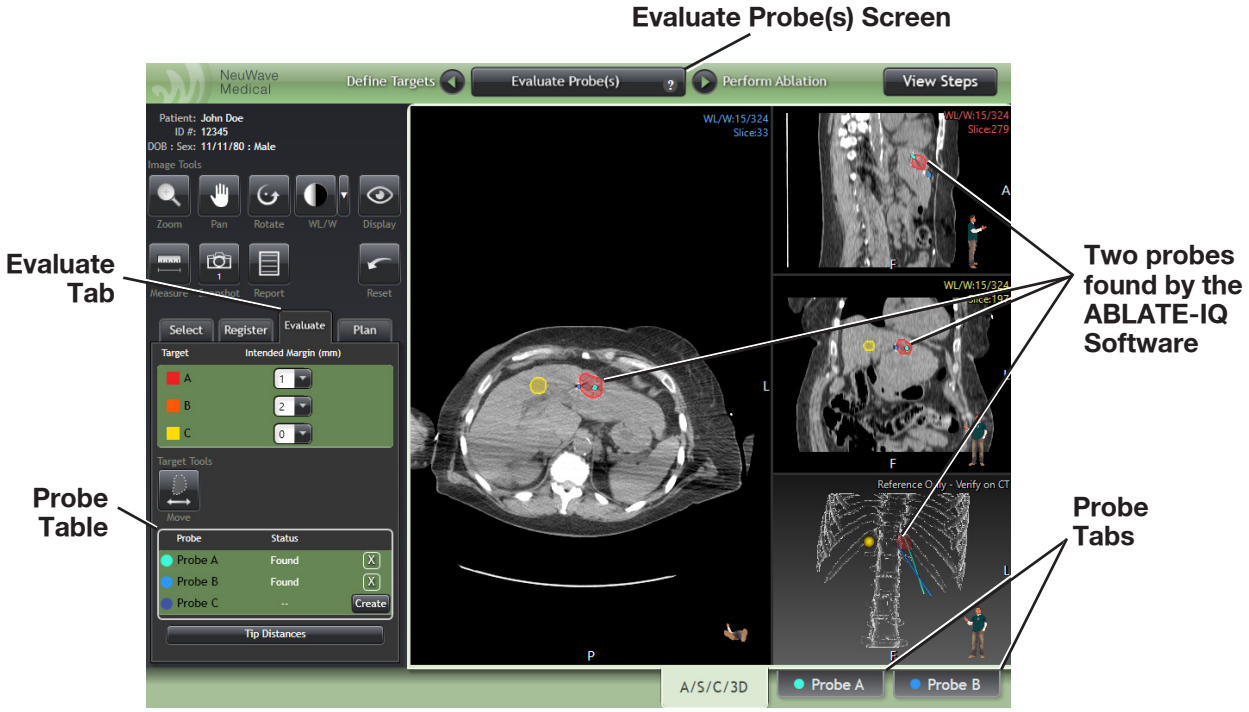


Figure 3-32: Probes Table under the Evaluate Tab in the Evaluate Probe(s) screen. Two probes, Probe A and Probe B, were found by the ABLATE-IQ Software. Clicking the Create button allows the user to manually draw the location and trajectory of a probe already placed in the patient.

Important: Probes A, B, and C do not necessarily correspond to channels 1, 2, and 3 on the NEUWAVE System.

2. View the image slices to ensure that the probes found 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.
3. Targets and probes can be displayed or hidden by checking the appropriate boxes under the **Display** tool in the Image Tools panel.

4. Click the ***Probe*** tabs in the lower-right corner of the Image Views to examine targets and probes in special views. The resulting Periscope View on the left side of the Image Views screen lets you look down the shaft of the probe (see Figure 3-33). The Needle View on the right provides a lengthwise look at the probe in tissue. Click the ***A/S/C/3D*** tab to return to the regular 4-image view.

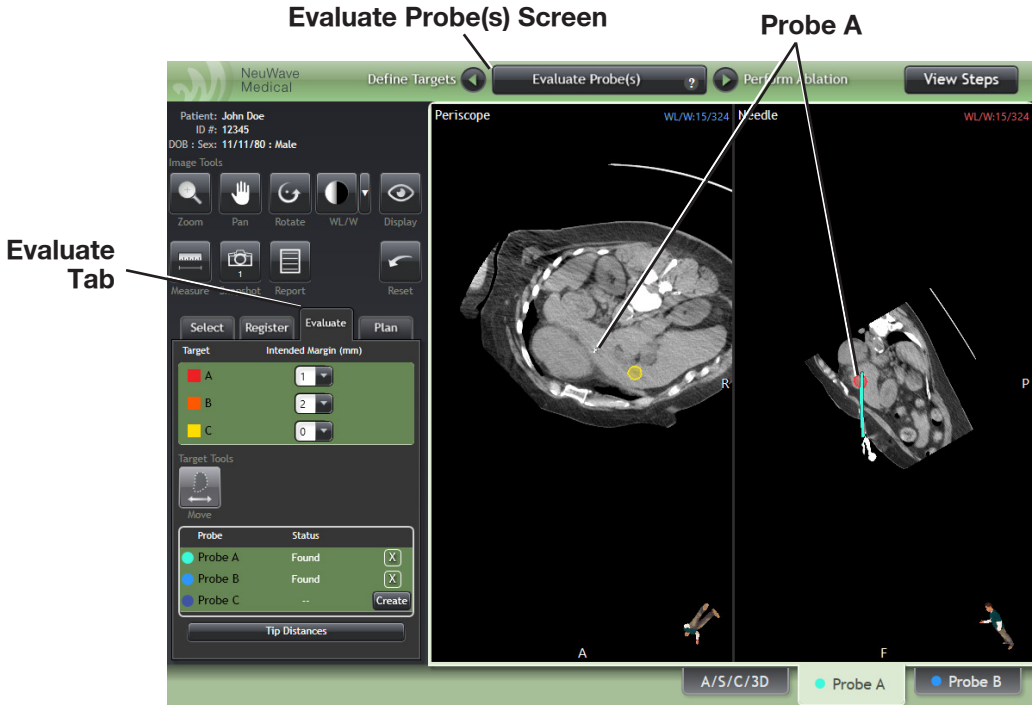


Figure 3-33: Periscope and Needle Views.

You can use all the Image Tools in the Periscope and Needle Views. The **Zoom**, **WL/W**, and **Rotate** tools operate synchronously in the two views. The **Pan** and **Measure** tools operate independently in the two views.

After registration, you might find in some cases that the insertion of the probe has displaced the lesion slightly, shifting its original position without changing the lesion's shape. If necessary, you can adjust the position of the target as follows:

1. Click the **Move** tool on the Target Tools panel on the left side of the screen and move the mouse pointer to a 2D Image View showing the target (the **Move** tool is the only tool displayed in the Target Tools when under the ***Evaluate*** tab).
2. Click the target and drag it to the correct position. Dragging the target in the Axial View moves the target in the X/Y direction, dragging it in the Sagittal View moves the target in the X/Z direction, and dragging it in the Coronal View moves the target in the Y/Z direction. The whole target is moved intact to the new position.

3.5.4.4.1 Deleting and Creating Probe Displays

If the software does not detect a probe already placed in the patient, or if it incorrectly detects a non-existent probe, you can manually correct the status of all probes placed in the patient for them to be correctly displayed in the Probes Table in the lower-left corner of the **Evaluate Probe(s)** screen (Figure 3-34). If a probe was incorrectly detected, it can be deleted by clicking the **X** next to the probe status; the probe can then be defined manually.

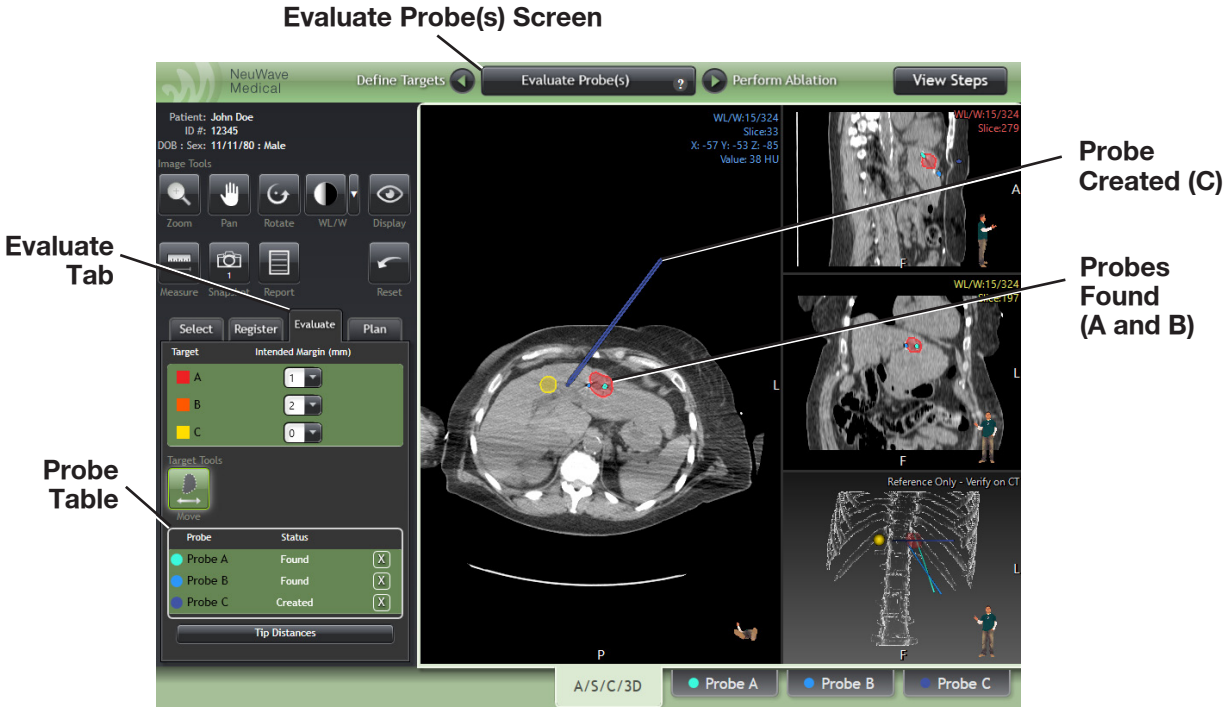


Figure 3-34: Creating probes in the Probes Table. For the case shown, two probes (A and B) were found by the ABLATE-IQ Software, but three probes were present in the patient.

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

1. Figure 3-32 shows that two probes, Probe A and Probe B, were automatically detected by the ABLATE-IQ Software. If the probe location is incorrectly displayed in the Image Views, the probe can be deleted from the system by clicking the appropriate **X** button in the Probe Table.
2. To create a probe that is placed in the patient but was not detected by the software, click the **Create** button in the lower-left corner of the screen, as shown in Figure 3-34. Scroll through the slices and find the location on the scan where the tip of the probe is displayed.
    a. If no probes are connected to the NEUWAVE System, the ABLATE-IQ Software does not detect any probe and the Status column in the Probe Table shows two dashes.
3. 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.
4. Click on a second location along the probe. The system defines a line starting at the first point and finishing at the second point. If the probe crosses multiple CT slices, the first and second points can be defined in two different slices/planes. After choosing the first point, scroll up or down slices using the mouse wheel and select a second CT slice for the second probe's point.
5. After you click the second location on the probe, the Probe Table is automatically updated with the new probe display.

3.5.4.4.2 Tip Distances

The distances between the detected or defined probe tips can be displayed by clicking the **Tip Distances** bar at the bottom of the left panel (Figure 3-35). The distances between the tips of all detected or defined probes is displayed. Measurements shown in mm are determined at the probe's tip not at the probe's energy emitting point.

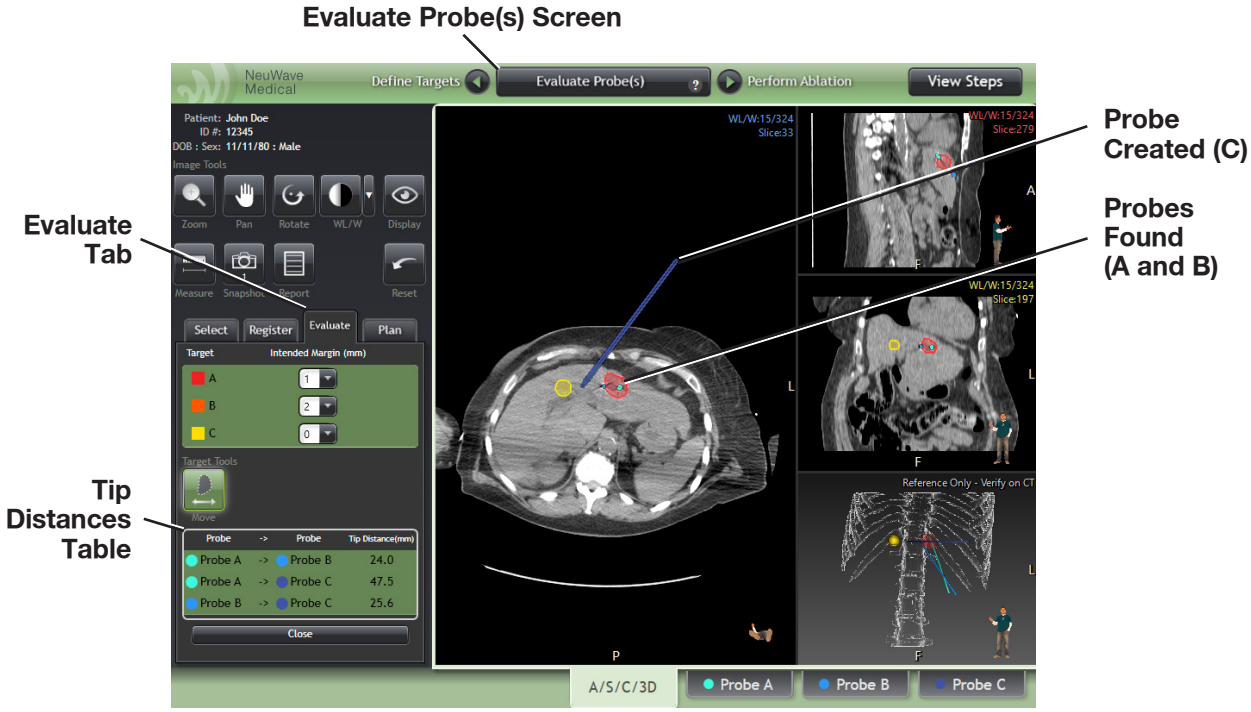


Figure 3-35: Probe Tip Distances Table.

3.5.4.4.3 Matching of Planned Probes with Actual Probes

Following the detection of the ablation probes placed by the physician in the patient, the ABLATE-IQ Software evaluates whether the planned probes match the actual probes inserted in the patient. Under the ***Plan*** tab of the **Evaluate Probe(s)** screen, ABLATE-IQ represents each of up to three planned probes as triangles with varying shades of purple color. Actual, physical probes detected by the software are represented as circles with varying shades of blue (Figure 3-36). If a planned probe matches the location of an actual probe, both geometric figures, a triangle and a circle, are displayed next to each other under each probe tab. Planned probes without an actual counterpart display only a triangle and actual probes without a planned counterpart only a circle (see ***Probe C*** tab, Figure 3-36).

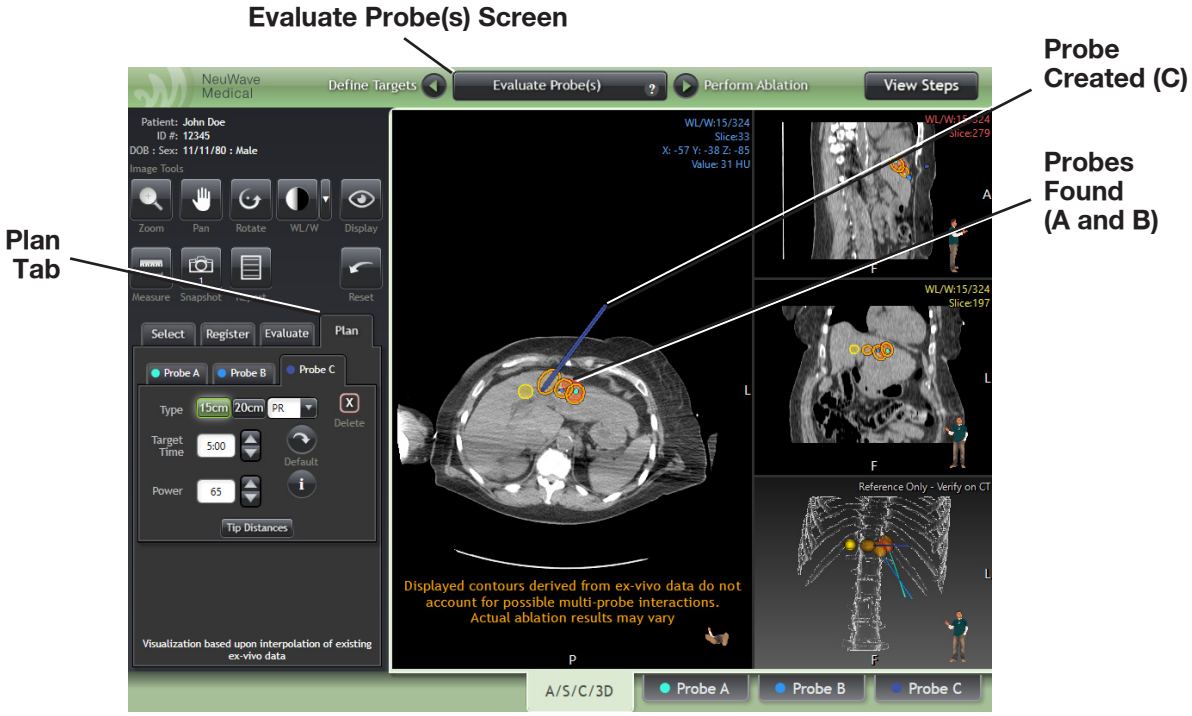
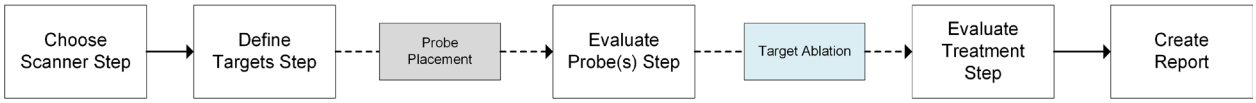


Figure 3-36: Matching of Planned Probes to Actual Probes.

3.5.5 Performing The Ablation



The final series of screens in the software will guide you through the process of a) performing the ablation with the NEUWAVE System, b) defining the treated area (treatment zone), c) registering the Post-Ablation Image Series against the Setup Series, and d) evaluating the treated area. Click the arrow button on the right of the **Navigation Bar** to move through the next screen.

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 (Figure 3-37).
2. When the ablation is complete, perform a CT scan to acquire a new image series into the ABLATE-IQ Software that displays the treated areas of the patient (Post-Ablation CT Series). The **Evaluate Treatment** step will not be available until after an ablation is performed in the patient.

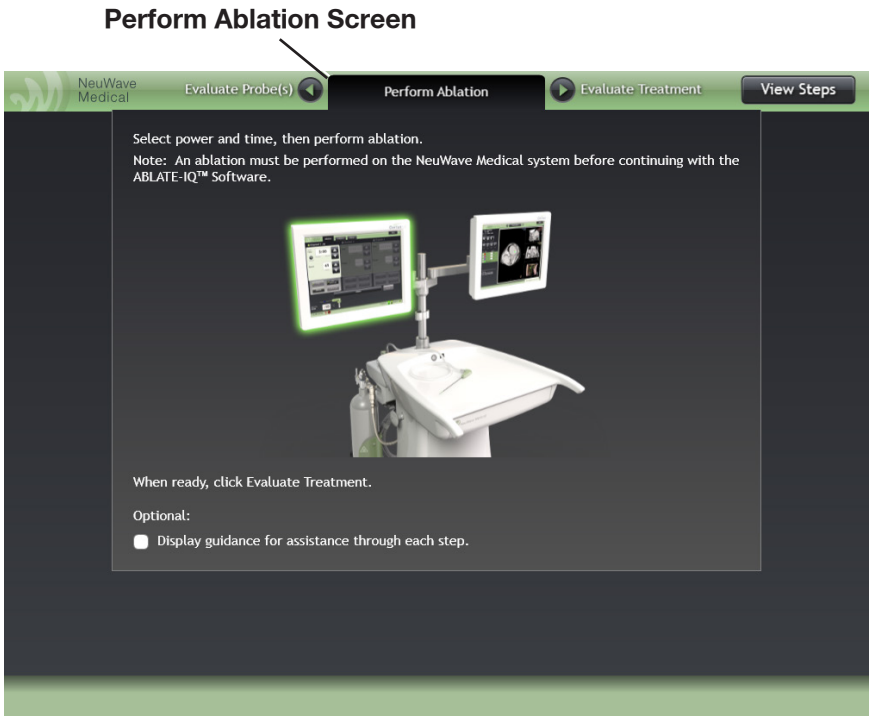
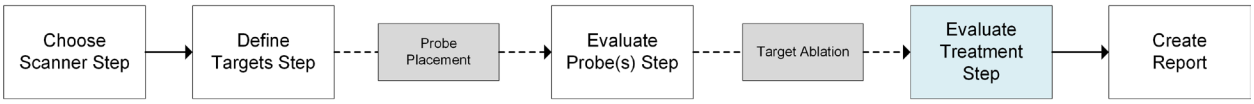


Figure 3-37: Perform Ablation screen.

3.5.6 Evaluate Treatment STEP



In the next steps, the performed ablation will be evaluated using two sets of tools, the Image Tools and the Treatment Definition Tools. Note that the set of Treatment Definition Tools is very similar to the Target Tools in the **Define Targets** screen used to define the lesion targets in the **Define Targets** step.

In the **Evaluate Treatment** step the user will perform the following:

a. Define the treatment zone in the Post-Ablation CT Series to obtain volumetric measurements of the treated target

b. Register the Post-Ablation CT Series containing the defined treatment zone to the Setup CT Series containing the defined targets, and

c. Evaluate the accuracy of the defined treatment zone to the defined target.

3.5.6.1 Selecting the Post-Ablation CT Series

1. Using the **Navigation Bar**, advance to the next ABLATE-IQ Software step, the **Evaluate Treatment** screen. The ***Select*** tab under the **Evaluate Treatment** screen is similar in function to the ***Select*** tab in the **Define Targets** and **Evaluate Probe(s)** steps, which you used earlier in this chapter. The Series Description panel on the left side of the screen lists the CT Series available for downloading to the ABLATE-IQ Software.
2. If the post-ablation pulled series is multiphasic (consisting of two or more phases), the first phase will be displayed in the Image View area 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 the **Pull Series** button.

3. Click the description of the newly acquired post-ablation series in the lower-left corner of the screen, and then click the **Pull Series** button to display the Post-Ablation CT Series in the Image Views. After downloading the selected series is completed, the software auto steps to the ***Define*** tab. Verify that you can see the treatment zone and any probes that remain in the patient, and that the extent of the scan is correct. If you decide to download a different CT series, you can go back to the ***Select*** tab and choose a different CT series.

3.5.6.2 Defining the Treatment Zone

1. Click on the ***Define*** tab so that you can define the treatment zone around the lesion created by the delivered microwave energy. You can define up to three treatment zones in an image series. Treatment zones are named Treatment A, B and C under the ***Define*** tab (Figure 3-38).

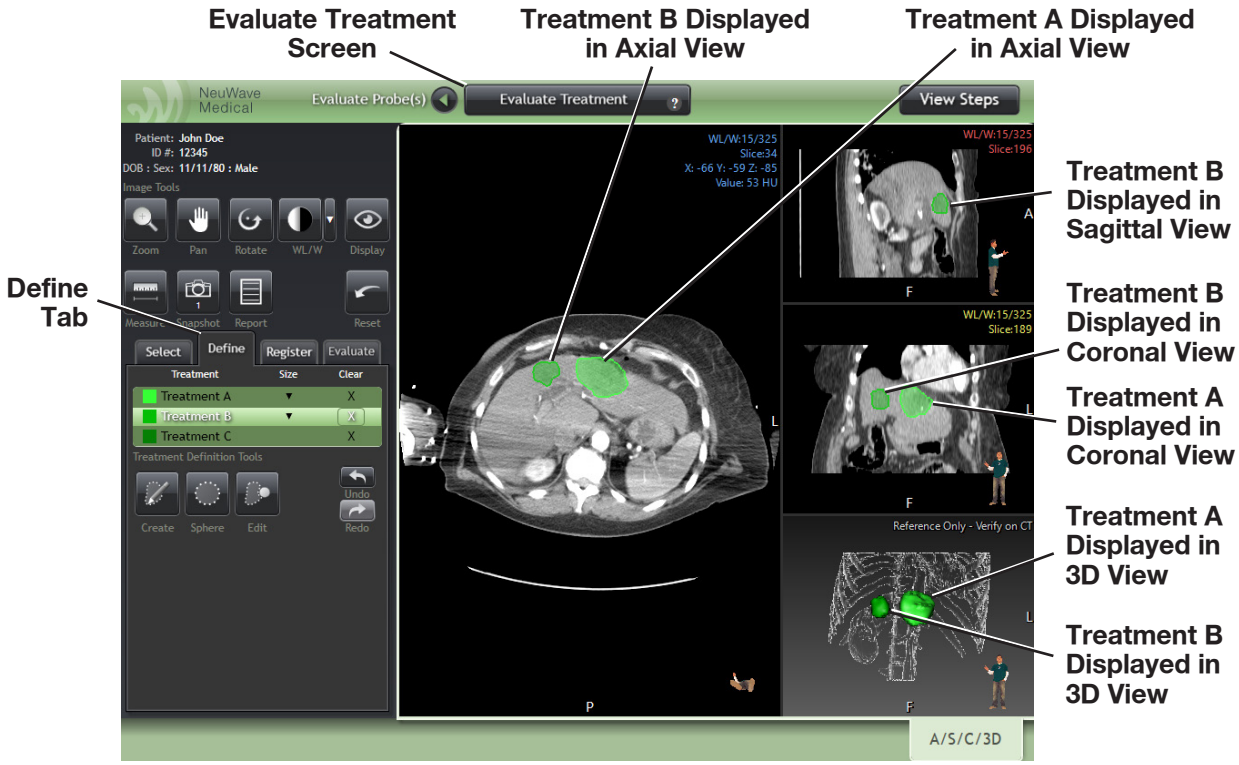


Figure 3-38: Defining the Treatment Zone.

2. On the left side of the screen, ensure that the correct treatment zone letter is selected. By default, Treatment A is the active zone. Treatment zones A, B, and C must cover previously defined Targets A, B, and C, respectively.
3. On the left side of the screen, click **Create** or **Sphere** in the Treatment Definition Tools panel and then move the mouse pointer to a 2D Image View to begin creating the treatment zone. Using the **Create** tool, in the active 2D Image View, move to a slice near the center of the treatment zone using the **Zoom** tool. Try to center the mouse over the area that has been treated. The **Create** tool previews the area by creating a green outline where the tool pointer is placed. Based on where the preview area is displayed, the tool outlines adjacent tissue areas of similar density (Figure 3-38).
4. If a large enough area was not achieved after the first use of the **Create** tool, the tool can be used a second time. Move to the area that was not detected the first time and click the left mouse button to redefine the larger treatment area. The two areas defined in this manner must intersect for the software to join them and expand the treatment zone.

Important: Using the Create tool becomes more challenging when the edges of the treatment zone are not well delineated. As an alternative, you can use the Sphere tool to quickly define a perfectly spherical treatment zone. For details on how to use the Image Tools, including the Sphere tool, see Appendix A.

5. Expand the outline to encompass the treatment 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 the mouse button when the desired treatment zone is encompassed by the green preview outline.

3.5.6.3 Refining the Treatment Zone

If you want to refine the treatment zone, click the **Edit** tool in the Treatment Definition Tools panel (Figure 3-38) and then move the mouse pointer to the zone you just defined. The process of removing or expanding the treatment zone using the **Edit** tool is no different from the process of removing or expanding the size of target areas in the ***Define*** tab of the **Define Targets** screen (Figure 3-16 and Figure 3-17). The only difference is that the Treatment Definition Tools do not include a **Move** tool (Figure 3-39).

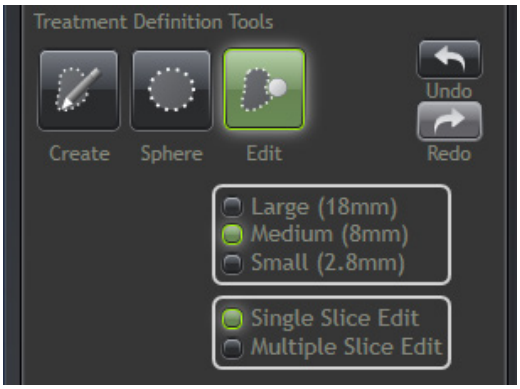


Figure 3-39: Treatment Definition Tools Panel under the Define Tab of the Evaluate Treatment Screen.

Unlike a target lesion defined in the planning stages of the ablation procedure (***Plan*** tab in **Define Targets** step), an treatment zone in the **Evaluate Treatment** step is an image of a physical structure within tissue created by delivery of microwave energy. Therefore, the resulting treatment zone cannot be moved with a software tool.

1. Choose a Large, Medium, or Small diameter for refining the treatment zone. The Medium option is selected by default, but you can select a smaller or larger diameter.
2. Choose **Single** or **Multiple Slice Edit** for refining the treatment zone. The **Single Slice Edit** 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.
3. To remove portions of the treatment 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 treatment zone's border.
4. To expand portions of the treatment 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 treatment zone's border.

5. Single slice manual editing of an treatment zone extending over several CT slices can be performed by systematically scrolling from one end of the target treatment zone to the other end. After the treatment zone is individually edited in a CT slice, the mouse wheel is used to scroll to the next slice to edit the next section of the treatment zone. This single slice editing process is repeated over several slices until the end of the treatment zone is reached and the entire three-dimensional extent of the treatment zone is defined.

If necessary, you can create one or two additional treatment zones.

The **Undo** and **Redo** buttons can be used to undo or redo steps in the creation of a treatment zone or changes to a treatment zone.

To see the measurements of a treatment zone, click the arrow under the Size column of the Treatment Table, right above the Treatment Definition Tools panel. The Size window shows the treatment zone's length in mm along the X-, Y-, and Z-axes, and its total volume in cm^3.

To temporarily hide the treatment zone from view and display only its outline in the 2D views, click the **Display** button in the Image Tools panel and deselect the **Treatments** checkbox.

To delete the treatment zone and start over, click the **X** in the Clear column of the Treatment Table.

3.5.6.4 Registration of the Post-Ablation CT Series

After creating the treatment zone, you can register the Post-Ablation CT Series and then complete your evaluation of the procedure.

1. Advance to the ***Register*** tab in the **Evaluate Treatment** screen.
2. After the auto-registration process has been completed, inspect the two image series paying particular attention to the purple- and green-colored areas to evaluate how well the superimposed images are registered. Areas in purple are from the Setup CT Series, and areas in green are from the Post-Ablation CT Series, as indicated by the Series Displayed color key in the screen's lower-left corner.
3. When slices from separate image series are superimposed within a registered image 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 (see Figure 3-30).
4. If you are not satisfied with the registration results, you have the option to adjust the superimposing image sets by clicking the **Edit Registration** button under the ***Register*** tab. Please refer to section "Adjusting and Refining Image Registration" under **Evaluate Probe(s)** step.

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

3.5.6.5 Evaluating the Treatment Zone

1. Advance to the ***Evaluate*** tab in the **Evaluate Treatment** screen and scroll through the image slices to locate the treated area (Figure 3-41).
2. Evaluate the results of the treatment. The screen displays ablation targets, ablation probes (if they were present during the post-ablation scan), and the treated area together. Axial, Sagittal, Coronal and 3D Views of the Post-Ablation CT Series are utilized to evaluate and confirm that the treated area and the defined margins cover the lesion three-dimensionally.
3. If no ablation probes were present during the post-ablation scanning, the ablation targets and the treatment zone would be displayed as shown in Figure 3-40.

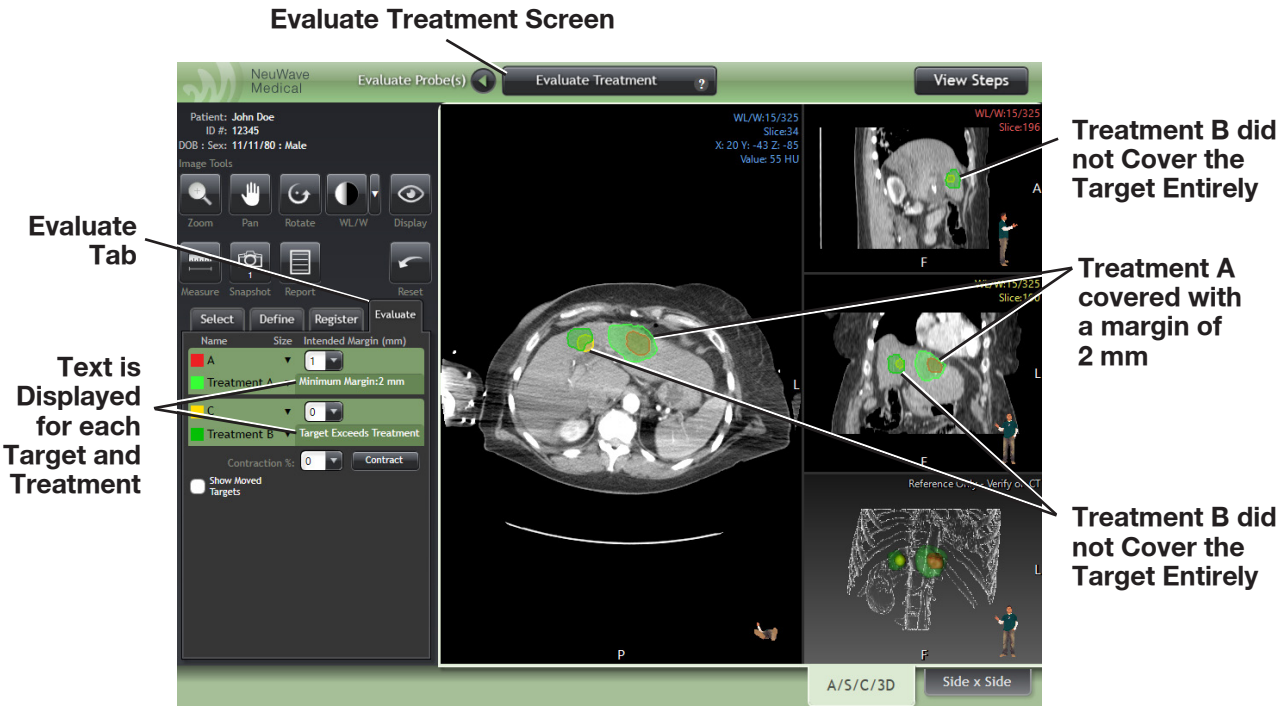


Figure 3-40: Treatment Evaluation Tab and Table.

4. If the treatment zone does not cover the lesion, a message on the left side of the screen informs you that the target is larger than the treatment zone: 'Target Exceeds Treatment' (Figure 3-40).
5. If the treatment zone does cover the lesion, a message displays the minimum margins (in mm) between the lesion's edge and the edge of the treatment zone (Figure 3-40).
6. A side-by-side view of the Setup CT Series where the targets were defined, and the Post-Ablation CT Series where the treatment zone was defined, can be displayed by clicking the ***Side x Side*** tab in the lower right corner of the Image Views screen panel.

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 ***Evaluate* tab** of the **Evaluate Treatment** screen to return the targets to the original positions you assigned.

a. To use the target positions determined previously in the **Evaluate Probe(s)** screen using the **Move** tool, check the **Show Moved Targets** checkbox.

b. To return the targets to the original positions you assigned, remove the checkmark in the **Show Moved Targets** checkbox.

3.5.6.5.1 Tissue Contraction Effect

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

1. The **Contraction %** field in the ***Evaluate*** tab allows the user to specify the tissue contraction effect (Figure 3-41, left panel).
2. Enter a contraction percentage appropriate for the treatment zone size in the **Contraction %** field at the bottom of the left pane. The ABLATE-IQ Software allows a contraction range from 10 to 30% in 5% increments. Contraction values depend on the tissue selected on the ablation system (e.g., NEUWAVE) at the start of the procedure.

3. Click the **Contract** button and review the changes in the minimum margin displayed for each treatment zone (Figure 3-41, left panel).
4. When the **Contract** button is selected, the defined treatment zone remains unchanged on the display. Only the target(s) are shown as contracted, and only those portions of the target that intersect the area of effect are contracted.
5. If you check the **Show Moved Targets** checkbox, the system will contract and display the moved targets. If the box is unchecked, the system will contract and display the original targets.
6. When the contraction process is completed, the contracted target(s) will be displayed and a label describing the contraction percentage will be displayed in the image display area.
7. Target lengths along their three axes and volume measurements for each treatment can be displayed by clicking the **Size** triangle button under the ***Evaluate*** tab.
8. To remove the contraction effect, deselect the **Contract** button.
9. For further scientific information on the rationale to determine the contraction effect please refer to *Appendix C*, Tissue Contraction Effect.

Targets defined in the Setup CT series are shown in Figure 3-41 as red (Target A) and orange (Target B) circles (central panel), whereas targets and treatment zones are shown as green areas in the Post-Ablation CT images (right panel). A target lesion contraction of 10% was applied to both treatments. A minimum margin of 2 mm without contraction (as displayed in Figure 3-38) increased to 7 mm for Treatment A, whereas Treatment B remained insufficient to fully cover the target. The minimum margin is the distance between the edges of the target and the treatment zone.

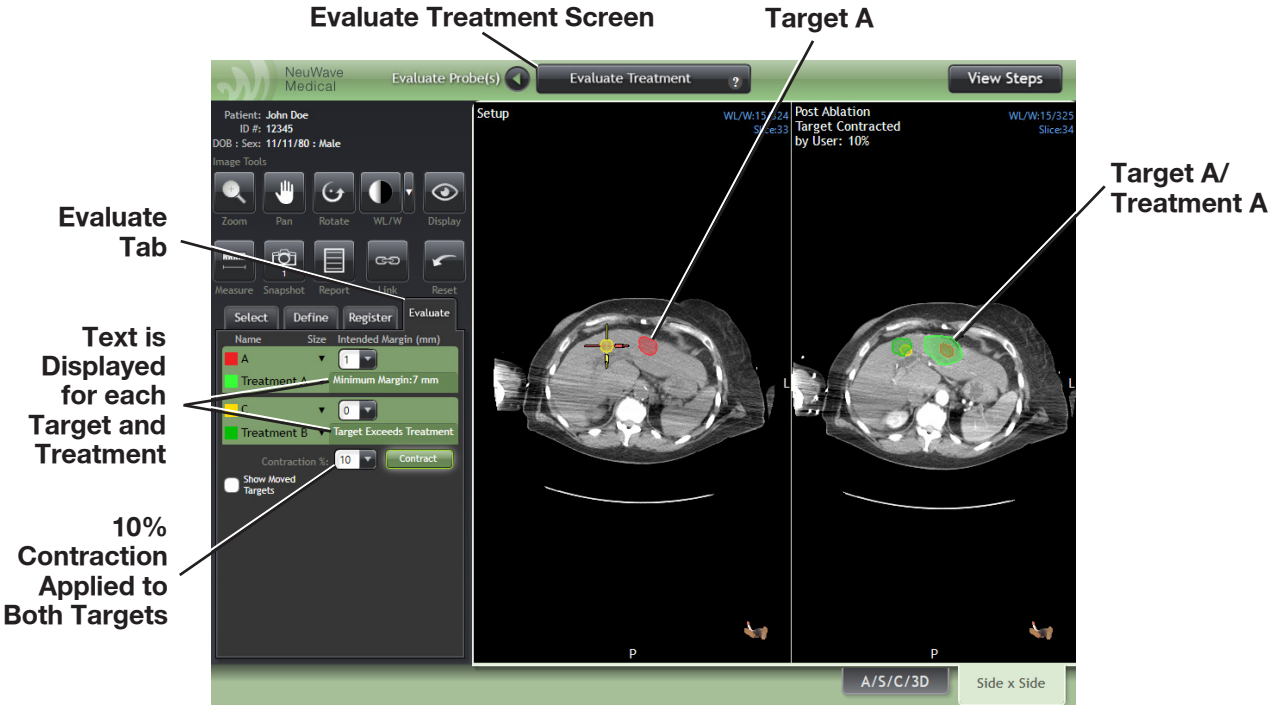


Figure 3-41: Side x Side Axial View comparison of the Setup CT Series (10% contraction not applied) and the Post-Ablation CT Series (10% contraction applied)

3.5.7 Final Review of the ABLATE-IQ Procedure

If you are satisfied with the results, the ABLATE-IQ procedure has now been completed. If the Report Creation feature is available, you can proceed to generate and submit a report to your facility's PACS (see the ***Create Report*** Section below).

If the results of the ABLATE-IQ procedure are not satisfactory, you have the option to review your steps and make appropriate adjustments to the procedure as follows:

a. To return to a previous screen to review and make adjustments, use the ***Steps*** menu (Figure 3-7). To move directly to a screen listed in the menu, you can bypass the **Navigation Bar** and simply click the step name in the ***Steps*** menu. The screens are listed in order, as they appear in the software.

b. If you would like to review additional CT series stored in PACS, you may go back to the **PACS Images** step to select and download a new CT Series to review the ABLATE-IQ procedure.

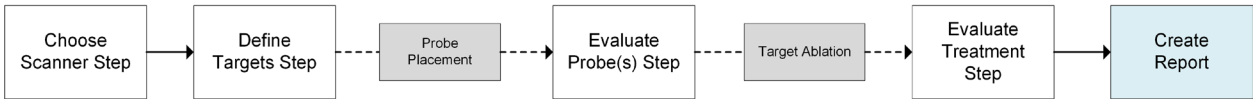
c. Note that some procedures in the ABLATE-IQ Software, including the two image registrations of the Setup CT Series with the Probe(s) Placement CT Series and the Post-Ablation CT Series, are not shown in the ***Steps*** menu; these key procedural steps are integrated as specific tabs in the **Evaluate Probe(s)** and **Evaluate Treatment** steps, respectively.

d. Note also that you may use the **Snapshot** tool to capture images and save them to the patient record on the facility's server using PACS.

e. When you are satisfied with the results, close the procedure on the NEUWAVE System.

f. The ABLATE-IQ Software will reset for the next patient when a new procedure is started.

3.5.8 Report Creation STEP (Premium)



The ABLATE-IQ Report can be generated as follows:

1. Click the **View Steps** button and select **Create Report** from the selection menu options. Alternatively, the report can also be created by clicking the **Report** icon button in the Image Tools panel.
2. The **Create Report** option automatically generates a report that includes patient information (e.g., name, birth date), target and treatment data, and procedural details (Figures Figure 3-42 A and Figure 3-42 B). Snapshots taken during the ABLATE-IQ procedure are also included with the report (Figure Figure 3-42 C). A preview of the report will be shown and available for review prior to submitting for storage in the PACS.
3. Click the **Submit** button for the document to be submitted to PACS.

Ablation, of the Liver, performed on 2/15/24.

Patient Information

Name: C41 UW
Sex: M
Birth Date: 11/11/80
MRN: C41-C41-C41

Energy Delivery Details

Channel 1: PR 15 cm probe.

Delivery #	Power (Watts)	Elapsed Time (Min:Sec)	Total Time (Min:Sec)	Average Temp (°C)	Maximum Temp (°C)
1	65	05:00	05:00	95.0	100.0
2	65	03:00	08:00	100.0	100.0

Channel 2: PR 15 cm probe.

Delivery #	Power (Watts)	Elapsed Time (Min:Sec)	Total Time (Min:Sec)	Average Temp (°C)	Maximum Temp (°C)
1	65	05:00	05:00	95.1	100.0
2	65	03:00	08:00	100.0	100.0

Figure 3-42: A. ABLATE-IQ Software Report. Patient information, and delivery information are displayed for the user review.

Treatment Evaluation

Target A

		Sizes (mm)				
Target	Color	X	Y	Z	Vol (cm^3)	Initial Margin (mm)
A		16.6	17.5	16.5	3.1	0.0

		Sizes (mm)			
Treated Area	Color	X	Y	Z	Vol (cm^3)
Treatment A		42.7	42.7	43.5	41.7

Figure 3-42: B. ABLATE-IQ Software Report (continuation). Target and treatment area measurements.

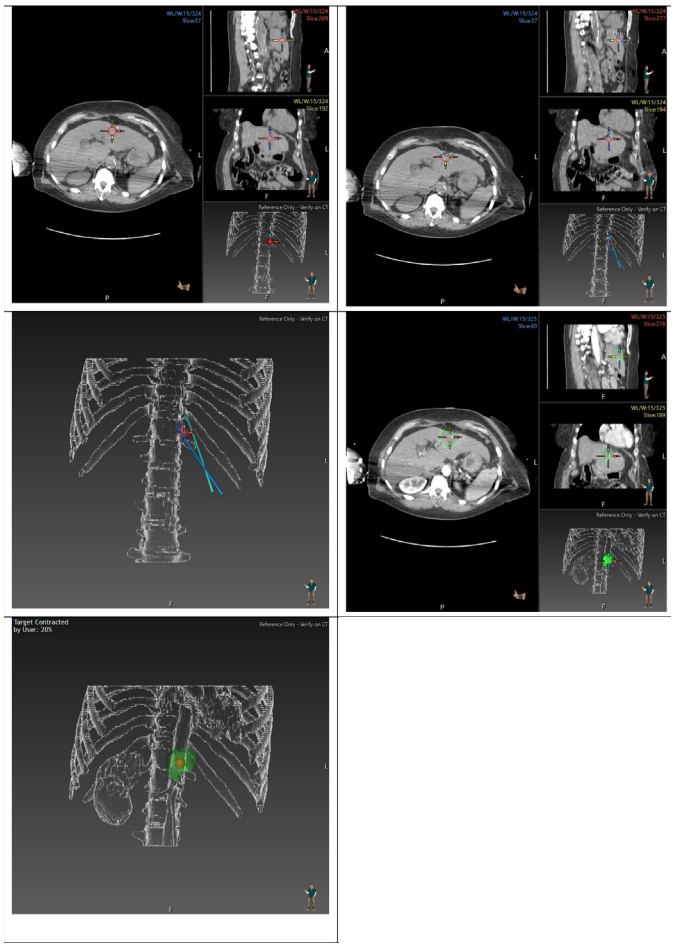


Figure 3-42: C. ABLATE-IQ Software Report (continuation). Snapshots taken during the ABLATE-IQ procedure.

3.5.9 ABLATE-IQ Software User Flow Diagram

The software steps, actions, procedures performed by the physician on the patient (e.g., probe placement, CT scans), and the interactions between PACS, DICOM and ABLATE -IQ are summarized in Figure Figure 3-43. Reference images can be retrieved from PACS to compare with the current procedural CT scan.

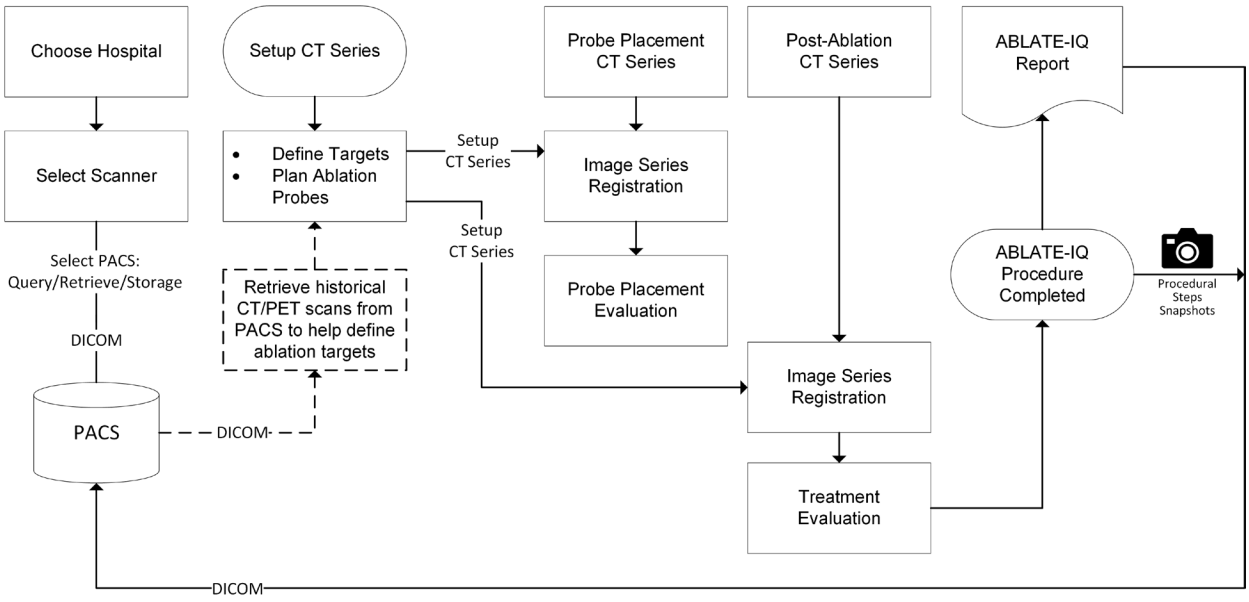


Figure 3-43: ABLATE-IQ Software User Flow Diagram.

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Appendix A
Using the Views and Tools

A.1 Image Views

A.1.1 Image Views (Planes) and Image Orientations

ABLATE-IQ offers multiple anatomical views of an image series. Four views appear by default, and the edges of each view display letters that indicate the orientation of the patient. **Image Views** (planes) and **Orientations** are labeled as follows throughout the **ABLATE-IQ Software** (Figure A-1).

Image Views (anatomical planes)
A: Axial (Transverse/Horizontal view)
S: Sagittal (Longitudinal/Vertical view; left or right)
C: Coronal (Longitudinal/Vertical view; front or back)
3D: Three-Dimensional (Reference only - Verify on CT)

Patient Orientations (anatomical directions)
A: Anterior (Ventral)
P: Posterior (Dorsal)
L: Left (Lateral)
R: Right (Lateral)
H: Head (Superior)
F: Foot (Inferior)

The lower-right corner of each of the 4 image views displays a human 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 (Figure A-1).

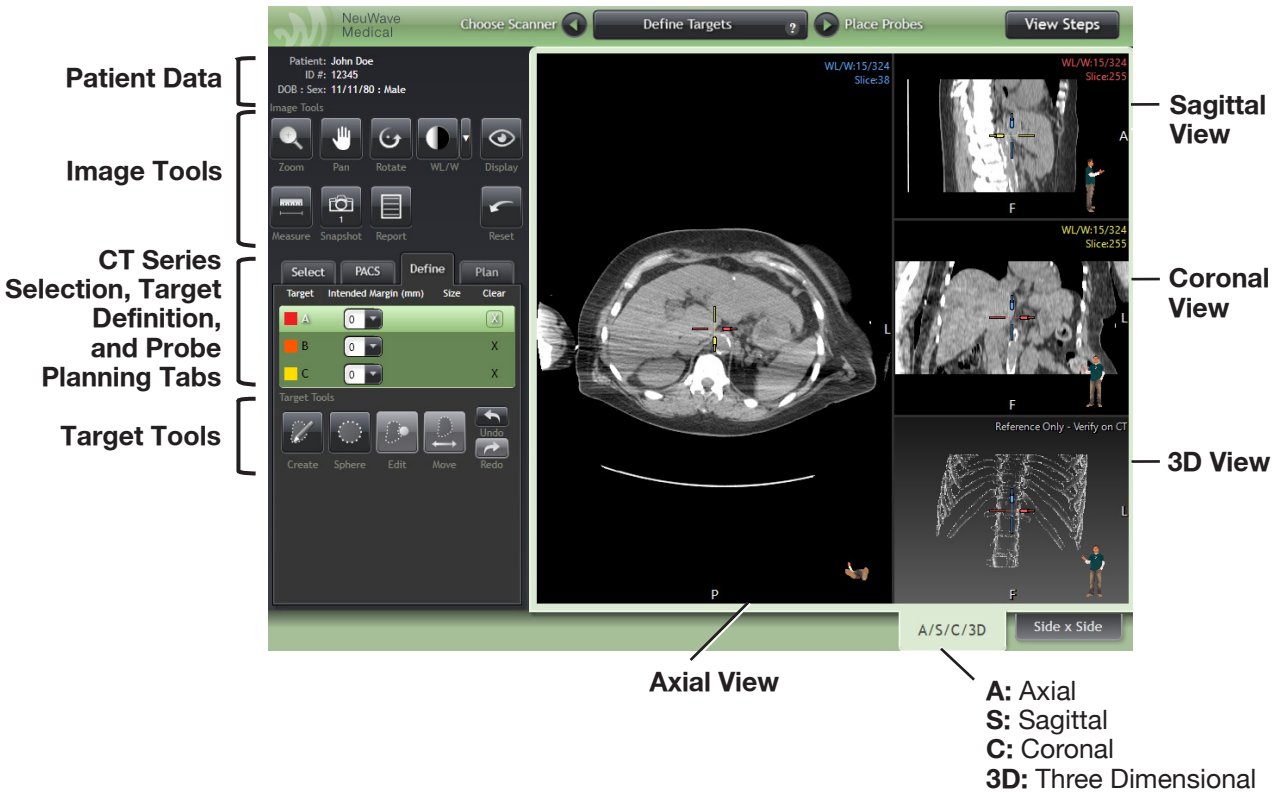

Figure A-1: Define Targets screen displaying Image Views panels on the right side of the screen, and Image Tools and Target Tools panels on the left side.

A.1.2 Radiologic Data

Radiologic data appears in the upper-right corner of each 2D View (Figure A-1). 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 information 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 HU for the point where the active tool is positioned.

A.1.3 Image Resizing

- 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.

A.1.4 Mouse Functions

This section provides an overview on how to use the multiple mouse functions in the 2D Image Views. For more details on using the mouse in the 3D Image View, see ***The Rotate Tool in 3D Views*** in the ***Image Tools*** Section later in this appendix.

A.1.4.1 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 **WL/L** tool. For details, see ***The Window Level (WL/L) Tool*** in the ***Image Tools*** Section later in this appendix.

A.1.4.2 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 (A, S, and C) and the HU value displays the image density according to the mouse position. If the **WL/W** tool is used, the mapping of HU density values to grayscale pixels is modified to enhance image features.

A.1.4.3 Left Mouse Button

When you left click and drag the mouse within the active 2D Image View without selecting a tool first, you scroll through the image slices in the series. The slice in view updates with this action, 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.

A.1.4.4. Right Mouse Button

Most functions of the right mouse button are related to the Reference Point as described in the section below.

A.1.4.5 The Reference Point (Crosshairs)

Colors displayed by the crosshairs and radiologic data correspond in the 2D Image Views as follows: Blue: Axial (A); Red: Sagittal (S); Yellow: Coronal (C).

The crosshairs displayed in each Image View serve as the Reference Point for that view. Moving the Reference Point on an Image View is performed with the right mouse button as follows:

- Right clicking the mouse within a 2D Image View moves the Reference Point where you right clicked and displays a cross (a set of 4 white lines) to indicate that the Reference Point has been moved.
- The small blue arrow at the cursor tip points at the exact new location of the Reference Point.
- Right clicking on the crosshairs hides them from view. The crosshairs can be shown again by right clicking anywhere on the image.
- The crosshairs also serve as Reference Points in adjacent Image Views, including the 3D Image View, and 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.
- The user can also right-click the mouse over an anatomical structure or a target to move the Reference Point in the 3D Image View when using the **Zoom**, **Pan**, or **Rotate** tools.

A.1.4.6 Cursor Icons and Associated Functions

The cursor uses two different displays depending on where in the ABLATE-IQ Software screen is located. A standard white cursor arrow is used to select functions on the screen's left panel, whereas a small blue arrowhead with a tool-specific icon behind it is shown when the cursor is moved to the Image Views panels on the right-hand side.

- The standard white cursor arrow is displayed when the cursor hovers over the set of panels located on the left side of the screen of the **Define Targets**, **Evaluate Probe(s)**, and **Evaluate Treatment** screens.
- When the cursor is moved to the 2D Image Views panels (A, S and C), the cursor's white arrow becomes a small blue arrowhead with an icon displaying 3 staggered squares and a double-headed arrow across the upper right corner of the 3 squares (Figure A-2). This icon represents CT slices above and below the slice being viewed, and it indicates that the mouse wheel can be used to scroll through image slices located above and below the current image, as described in the **Mouse Wheel** section above.

Figure A-2: Cursor display when moved to 2D Image Views.

- For the 3D Image View, the blue arrow and cursor icon format is similar, except that the representation of CT slices are replaced by two convexly curved, double-headed, intersecting arrows to indicate that the 3D Image View can be rotated in different directions as described in detail in the **Rotate Tool in 3D Views** section below.
- Left clicking any of the Image Tools is performed by the standard cursor's white arrow. When the cursor is displaced to the Image Views panels, the cursor display changes to the blue arrowhead and a tool-specific icon behind it. For example, the **Zoom** tool will display a magnifying glass, the **Pan** tool displays four arrows to signify that the entire image can be moved in any direction. The **Rotate** tool displays a rotating double-headed arrow, and the **Measure** tool displays a ruler.
- In general, the blue arrow cursor displays tool-specific icons when a tool is selected from the tool panels on the left side of the **Define Targets**, **Evaluate Probe(s)** and **Evaluate Treatment** screens and the cursor is moved to the Image Views area on the right side of those screens.

A.2 Image Tools

The Image Tools panel is located in the left mid panel and includes a series of tools to manipulate the size, position and luminosity of image slices displayed in the Image Views panels (Figure A-1 and Figure A-3). **Report** and **Reset** buttons are also located in this panel.

A.2.1 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.

In the Image Tools panel on the left side of the screen (Figure A-3), click the **Zoom** tool and then move the mouse pointer to a 2D or 3D Image View.

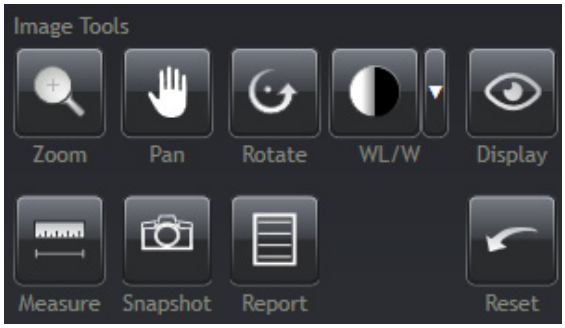

Figure A-3: Image Tools panel.

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.

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 Views, the images resize to correspond with the change in the active view.

You can also use the **Zoom** tool in the 3D Image 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.

A.2.2 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 (Figure A-1), 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. The **Pan** tool affects only the active view. Within the adjacent 2D and 3D image views, nothing happens.

A.2.3 The Rotate Tool

A.2.3.1 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 scan in a supine orientation to roughly align with a scan taken in decubitus.

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. As you drag the mouse, the following occurs:
    - The image slice moves around the Image View's axis. The Image 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 image orientation letters (A, P, L, R, H, F) change to reflect the changes in the patient's orientation with respect to the scan slices.
    - Images, BODs, and image 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 also changes accordingly.

A.2.3.2 The Rotate Tool in 3D Views

You can also rotate the 3D Image 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.

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 3D Image View, the image rotates two-dimensionally around the Z-axis.
- When the mouse is positioned within the upper or lower area of the 3D Image View, the image rotates around the Y-axis.
- When the mouse is positioned within the right or left area of the 3D 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.

A.2.4 The Window Level Tool (WL/L)

Use the **WL/W** tool to display features within an image more prominently in 2D Image Views. The **WL/W** tool has no function within the 3D Image View.

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, adjusting the window level to the lowest density (black) displays only air, whereas changing the level to the highest density (white) displays bone tissue. 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 (Figure A-1), click the **WL/W** tool (Figure A-3) 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.
2. In the active 2D view, adjust the image by left-clicking and holding (or clicking the mouse wheel and holding), and dragging the mouse as follows:
    - 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 image 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 **WL/W** tool to select a predetermined window level setting that makes the abdomen, bone, lung, or liver appear more prominently within a 2D Image View (Figure A-4).

Figure A-4: The WL/W Tool displaying a series of predefined window level settings for different organs.

4. You can select from this list without selecting the **WL/W** tool. For example, selecting **Bone** from the list highlights bone in the image by showing denser areas that are predominantly white.
5. The predetermined window level settings affect only the active window when displayed in the Side-by-Side view on the **Define Targets** screen.
6. 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.

A.2.5 The Display Tool

The **Display** tool allows you to show objects that have been manually or automatically created (e.g., targets, probes, ablations). Objects can be displayed independently or simultaneously. Just click the **Display** tool once and check any of the options displayed (Figure A-5).

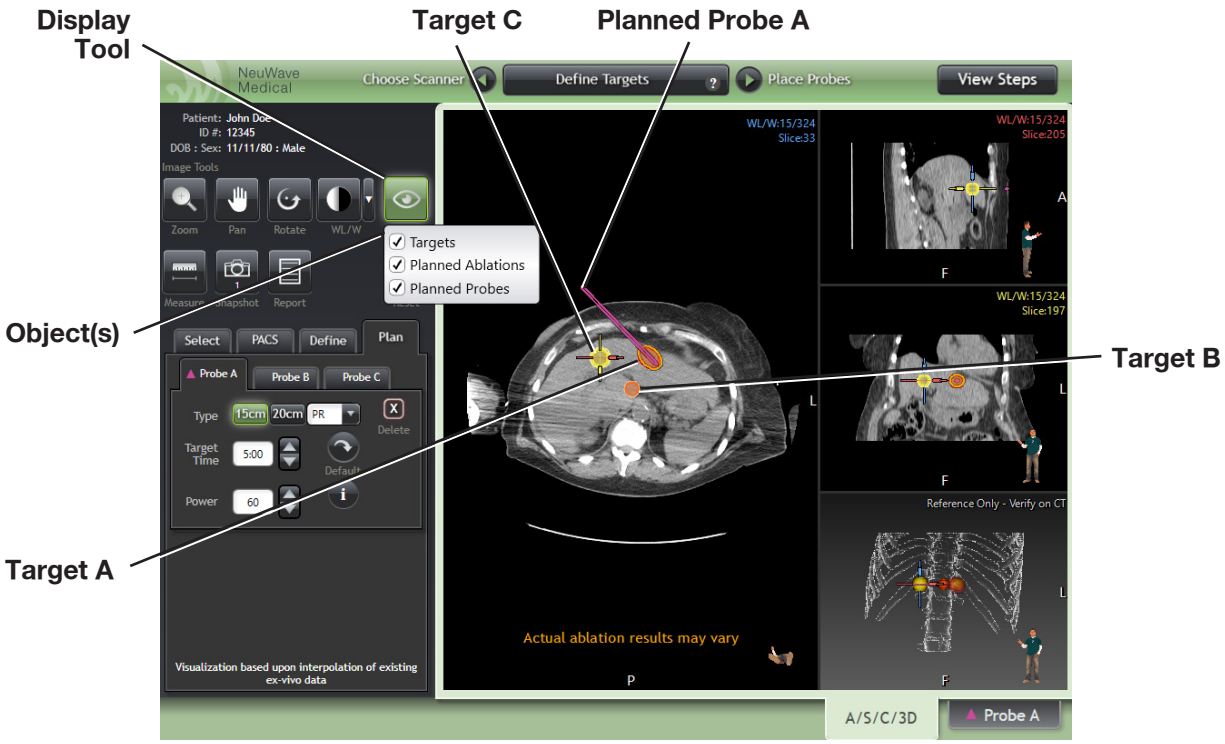

Figure A-5: The Display Tool.

Hiding an object (e.g., target, probe) in a 2D view helps removing the overlaying color outline or fill of the object that may be affecting the subtlety of grayscale variations and shading of a CT scan that help identify features of interest (e.g., lesions and lesion margins). Targets and treatment zones cannot be hidden in the 3D view.

A.2.6 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 mm next to each line you draw.

Important: The Measure tool will not be available on Fused PET images.

1. In the Image Tools panel on the left side of the screen (Figure A-1), click the **Measure** tool and then move the mouse pointer to any 2D View. The **Measure** tool is not available in the 3D 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 mm (see Figure A-6).

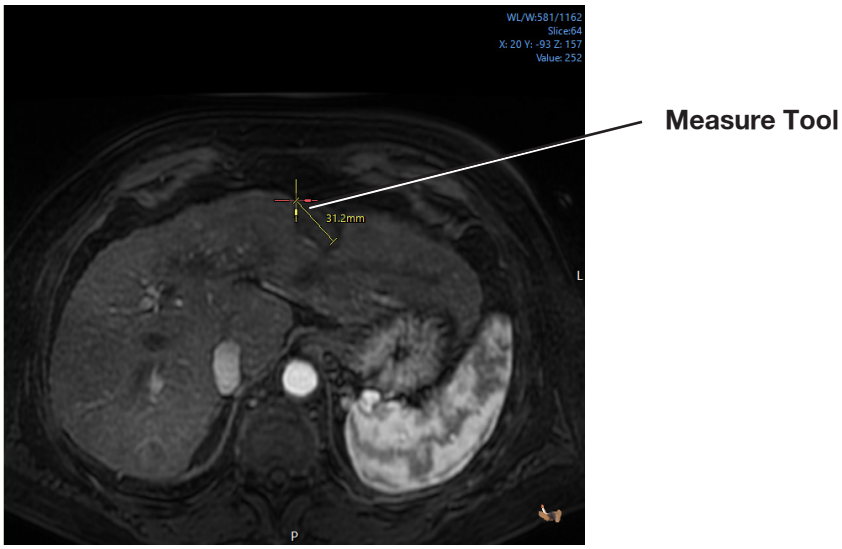

Figure A-6: Using the Measure Tool.

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 or left click the **Delete** option that appears.

Important: You cannot right click and drag the Reference Point when the Measure tool is active. Measurements cannot be taken when displaying a PET/CT merged image.

A.2.7 The Snapshot Tool

Click the **Snapshot** tool in the Image Tools panel (Figure A-2) to acquire a screenshot of the displayed image data. If snapshots are enabled in the ABLATE-IQ Software, a new series will be created for the snapshots and stored as part of the active study. (The series number for the snapshots in the PACS will be 53704.) 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 ***Steps*** menu, a camera icon appears next to any screen of which you have taken a snapshot.

A.2.8 The Report Tool (Premium)

The **Report** tool can be accessed from the Image Tools panel (Figure A-3) and the ***Steps*** menu (upper-right corner of Figure A-1). Clicking on the **Report** tool displays a NEUWAVE System procedure report containing all information related to the procedure performed (see the *Detailed Report Information (Premium)* Section in *Appendix C*). Clicking the **Submit** button sends the report to the storage PACS. (The series number for the report in the PACS will be 53705.)

A.2.9 The Reset Tool

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

Important: The Reset tool does not affect measurement lines.

A.3 Target Tools

The Target Tools are used to create, edit, and move up to three ablation targets. Four Target Tools are available in a single row at the bottom of the left side panel of the **Define Targets** screen: **Create**, **Sphere**, **Edit**, and **Move**. **Undo** and **Redo** features are functional with the 4 Target Tools.

A.3.1 The Create Tool

Use the **Create** tool in the **Define Targets** screen to draw an ablation target in a 2D Image View. Prior to creating or editing a target, it must be selected from the target table. You can create up to three targets on an image, each in a different color.

In the active Image View, locate a slice near the center of the targeted lesion and 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.

When the target edges are not well defined, the **Sphere** tool (see below) can be used instead to draw a spherical target over a lesion. Dimensions of targets delineated with the **Create** and **Sphere** tools can be adjusted with the **Edit** tool and the **Undo** and **Redo** functions.

A.3.2 The Sphere Tool

In some cases, lesions and tretament zones are not clearly visible 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 ABLATE-IQ Software allows you to manually place a circle on a 2D View using the **Sphere** tool to represent the 3D target. When placing the spherical target, you rely on lesion location information from other imaging modalities, such as MR. Once the target is placed and confirmed, the ABLATE-IQ 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 (Figure A-7). You can also use the **Sphere** tool to define an area that has been treated.

Important: 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 A-7.
6. Roll the mouse wheel forward to let the tool expand the sphere's diameter. 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 (Figure A-7).
7. Two targets were created with the sphere tool in the Axial View of the example shown in Figure A-7: a 20 mm diameter (B, orange outline), and a 23 mm diameter (C, yellow) target. The Reference Point (crosshairs) is located at the center of Target C so that Target C could be seen in the Sagittal View, and Targets A and C in the Coronal View. The Target Selection Table in the left panel displays the defined Targets A, B, and C with intended margins set at 1, 2 and 4 mm, respectively.

Figure A-7: The Sphere Tool. Define Targets screen showing the Sphere Tool active (green background) on the lower left side panel.

A.3.3 The Edit Tool

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.

1. Choose a Large (18 mm), Medium (8 mm), or Small (2.8 mm) diameter for refining the ablation target or treatment zone. The Medium option is selected by default.
2. Choose the single- or multiple slice edit option for refining the treatment 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.
3. 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 (Figure 3-17).
4. 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 3-17).
5. Single slice manual editing of an treatment zone target extending over several CT slices can be performed by systematically scrolling from one end of the target treatment zone to the other end. After the treatment zone target is individually edited in a CT slice, the mouse wheel is used to scroll to the next slice to edit the next section of the treatment zone target section. This single slice editing process is repeated over several slices until the end of the treatment zone target is reached and the entire three-dimensional extent representation of the treatment zone target is defined.
6. The **Edit** tool is usually utilized to define targets and treatment zones (see the *Treatment Definition Tools* Section below).

A.3.4 The Move Tool

After registration, you might find that in some cases the insertion of the probe has pushed the lesion slightly and shifted its original position, although the lesion's shape has not changed. In these cases, you have the option to use the **Move** tool to return a target to the correct position over a lesion.

The Move Tool is usually utilized in the ***Evaluate*** tab of 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.

A.4 Registration Tools

The Registration Tools (**Edit Registration** and **Discard Edits**) are used in two key steps of the ABLATE-IQ procedure, the **Evaluate Probe(s)** and **Evaluate Treatment** steps. In both cases, the functionality of the **Edit Registration** and the **Discard Edits** tools is identical.

1. Two sets of images are registered in the ***Register*** tab of the **Evaluate Probe(s)**: the Setup CT Series and the Probe Placement CT Series.
2. The Setup CT Series and the Post-Ablation CT Series are registered in the ***Register*** tab of the **Evaluate Treatment step**.

A.4.1 The Edit Registration Tool

Use the **Edit Registration** tool to improve the alignment (registration) of the displayed series. For example, the areas around the edges of organs need to be aligned as precisely as possible in both sets of images.

When **Edit Registration** is selected the Elastic Deformations will be discarded and only static registration results will be displayed. Manual registrations are all static. The goal is to align the structures in the region of the target. Other areas of the series will no longer be aligned. Once **Edit Registration** is completed, a new set of deformations may be computed by selecting **Apply Elastic Deformations**. This will compute new deformations based on the new manual static registration.

A.4.2 The Discard Edits Tool

Use the **Discard Edits** tool to discard the edits performed with the **Edit Registration** tool. Discarding the edits simply resets the overlapping images to their original location as determined by the auto-registration feature of the ABLATE-IQ Software. You may repeat the editing and discarding steps as many times as needed.

Important: Because of slight patient movement and the patient's breathing during CT scanning, the alignment or registration of different image series cannot be exact in all areas within an image. However, you can use the Registration Tools to more closely match or refine the registration in the two CT series.

A.5 Treatment Definition Tools

After completing the ablation procedure in the patient, a CT scan is performed, and the treatment zone is defined in the Post-Ablation CT Series. Since drawing the borders of lesion targets and treatment zones involves segmenting areas of interest in CT images, the tools used to define a lesion target are similar to those used to define a treatment zone.

A.5.1 The Create, Sphere, and Edit Tools to Define the Treatment Zone

The Treatment Definition Tools include **Create**, **Sphere**, and **Edit** tools to aid in delimiting the borders of the treatment zone. **Undo** and **Redo** tools in the Treatment Definition Tools panel (***Define*** tab of the **Evaluate Treatment** screen) are also identical to the tools used to define lesion targets (in the ***Define*** tab of the **Define Targets** screen).

Unlike defining lesion targets that can be repositioned in a CT image, treatment zones are physical structures within tissues that result from delivering microwave ablation energy. Treatment zones can be delimited with precision and their borders adjusted with editing tools but they cannot be moved to other regions of the image. Therefore, a **Move** tool is not included in the Treatment Definition Tools panel.

Use the **Create** tool in the ***Define*** tab of the **Evaluate Treatment** screen to draw a zone around an area that has been treated. You can then compare the treated area to the area where the lesion was present before the procedure. You can define up to three treatment zones in an image series. For additional details on using the **Create** tool and **Sphere** tool, see the *Defining the Treatment Zone* Section in Chapter 3.

A.5.2 The Registration Tools to Evaluate the Treatment Zone

The Registration Tools used to evaluate the treatment zone include the **Edit Registration** and the **Discard Edits** tools. Both tools have functions similar to those utilized to evaluate probe placement after registration of the Setup CT Series and the Probe Placement CT Series. Details on how to use these tools can be found in the **Evaluate Probe(s)** step, under the Adjusting and Refining Image Registration Section.

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Appendix B System Setup and Configuration

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 ABLATE-IQ and possible network connectivity problems, reference this appendix.

Network Connectivity

The NEUWAVE System, with the ABLATE-IQ 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 B-1.

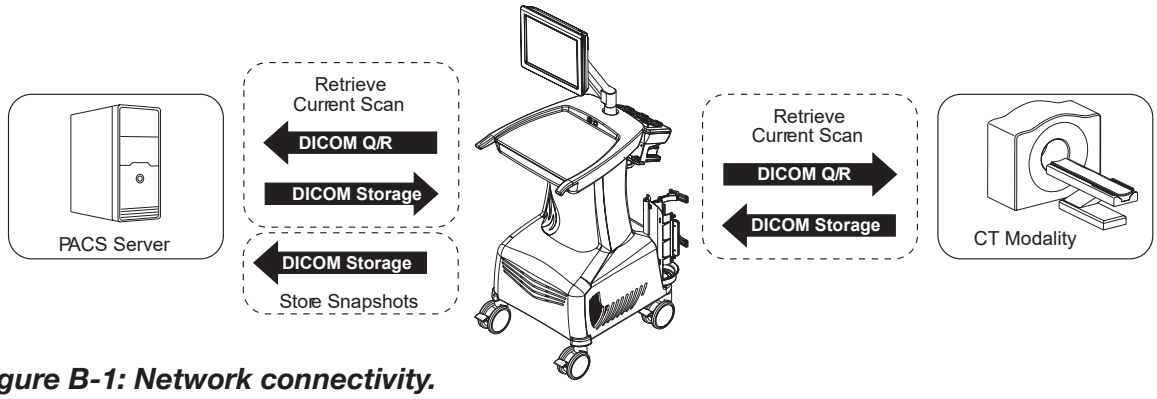

Figure B-1: Network connectivity.

The Hospital network must support the TCP/IP networking protocol. NeuWave does not impose a minimum network transmission speed requirement on network.

To allow ABLATE-IQ 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.

Admin Tab Functions

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

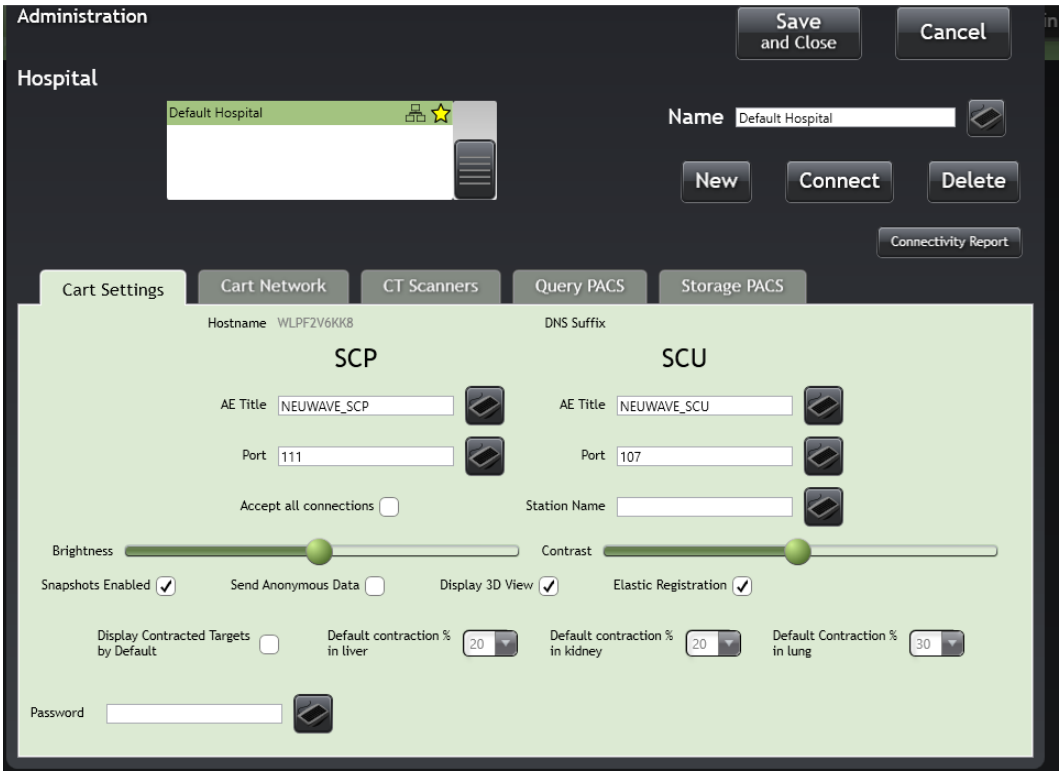

Figure B-2: Administration screen.

- Use the Hospital section at the top of the **Administration** screen to configure the names of all hospitals that will be connected to ABLATE-IQ.
- 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:
    - **Snapshots Enabled** - Check this box to allow “snapshots” of image views in ABLATE-IQ 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.
    - **Password** - If you want to change the password needed to access the **Administration** screen, enter the new password in this field.

Important: Default Brightness, Contrast, Display 3D View, Elastic Registration and Default Tissue Contraction selections are available but are overridden by ABLATE-IQ user profiles if and when selected.

- Use the ***Cart Network*** tab to configure the TCP/IP network address for ABLATE-IQ. 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 ABLATE-IQ. 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 ABLATE-IQ. 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 and reports. Configure the user-defined names and DICOM entity names for each of the hospital’s PACS that will be connected to ABLATE-IQ. 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 ABLATE-IQ 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. This section lists the network connectivity problems you might encounter and explains how to resolve the problems. If the networking issues cannot be resolved, the ablation procedure may be performed using alternate imaging sources.

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

For example, the system's **Welcome** screen looks like Figure B-3 if the system starts without a valid license. Note the message shown at the bottom of the screen. If you see this message, please refer to license information received when the product was purchased and enter the license numbers by accessing the Tools menu or contact Ethicon Customer Service.

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 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 ABLATE-IQ 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.
- Users are not allowed access to the Operating system, the only open ports are those required to communicate with Hospital PACS and CT Scanners, the firewalls are in place in the system.
- No storage of patient information after case.

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.
- ABLATE-IQ uses the DICOM Protocol for communication with radiological equipment as defined in the DICOM PS3 standard. DICOM PS3 conformance and data attribute information is available upon request. Company Contact Information can be found on page ii of this manual.

Additional Information

Connection of the NEUWAVE System, with the ABLATE-IQ Software, to an IT-NETWORK that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties. The Hospital/clinician should identify, analyze, evaluate and control these RISKS. subsequent changes to the IT-NETWORK could introduce new RISKS and require additional analysis. changes to the IT-NETWORK include:

- changes in the IT-network configuration;
- connection of additional items to the IT-NETWORK;
- disconnecting items from the IT-NETWORK;
- update of equipment connected to the IT-NETWORK; and
- upgrade of equipment connected to the IT-NETWORK.

System Security

The cart should be stored in a locked/secured area.

Appendix C
Physician Lesion/Treatment Segmentation Measurement Variability Assessment

ABLATE-IQ is a software tool designed to assist physicians in identifying targets and treatment 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 ABLATE-IQ Software.

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

The overall goal of the studies was twofold:

- Verify that the ABLATE-IQ 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 ABLATE-IQ Software provided adequate tools for a physician to segment an acceptable treatment 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 treatment zones. The treatment 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.

Series ID	*Tissue Type*
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 ABLATE-IQ functioned at a clinically acceptable level in terms of target and treatment zone segmentation.

Lesion/Treatment Segmentation Detailed Data

Segmentation accuracy was not specifically assessed by these studies, and analysis of the created targets and segmented treatment 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 treatment 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±15% to determine the upper and lower bounds). All X and Y values listed are in millimeters.

Study 1 Kidney	*Average Value*	*Min. % of Avg.*	*Max. % of Avg.*
X	26.2	85.1	114.9
Y	29.8	87.8	114.0
Study 2 Kidney			
X	37.9	93.9	106.9
Y	33.0	93.2	107.8

Study 3 Liver			
X	16.2	87.7	114.2
Y	17.3	86.7	111.6
Study 4 Liver			
X	11.5	89.6	113.0
Y	12.1	92.6	107.4
Study 5 Lung			
X	16.4	89.8	114.3
Y	22.1	93.7	107.7
Study 6 Lung			
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

Treatment Zone Segmentation

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

Study 1 Kidney	*Average Value*	*Min. % of Avg.*	*Max. % of Avg.*
X	27.7	94.5	105.6
Y	25.7	92.7	105.2
Study 2 Kidney			
X	36.1	90.7	107.0
Y	32.4	92.1	110.0
Study 3 Liver			
X	37.0	91.2	107.1
Y	32.7	94.1	103.0
Study 4 Liver			
X	53.5	93.3	110.0
Y	46.6	97.4	103.2
Study 5 Lung			
X	36.9	83.4	130.8
Y	45.4	80.6	119.4

Study 6 Lung			
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

Tissue Contraction Effect

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 treatment zone(s) and select the **Contract** button. Note that the contraction values offered depend on the tissue selected for 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 treatment zone plus additional areas outside of the defined treament zone. This is because the tissue defined as the treatment zone has contracted during the application of microwave energy.

When the **Contract** button is selected, the defined treatment 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** checkbox, the system will contract and display the moved targets. If the box is unchecked, the system will contract and display the original targets.

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.

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

If contraction is enabled by default in the ***Admin*** tab (see Figure 3-5), the target(s) will be contracted upon entering the **Evaluate Treatment** screen. The contraction percentage 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 percentage or remove contraction altogether.

Weighing factors such as applied power, time, and number of probes used, use your clinical judgment 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 publications:

1. 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(8):1280-1286.
2. Farina L, Weiss N, Nissenbaum Y, et al. Characterisation of tissue shrinkage during microwave thermal ablation. Int J Hyperthermia. 2014;30(7):419-428.
3. Liu D, Brace CL. CT imaging during microwave ablation: analysis of spatial and temporal tissue contraction. Med Phys. 2014;41(11):113303.

4. Moreland AJ, Ziemlewicz TJ, Best SL, et al. High-powered microwave ablation of t1a renal cell carcinoma: safety and initial clinical evaluation. J Endourol. 2014;28(9):1046-1052.
5. Sommer CM, Sommer SA, Mokry T, 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(8):1241-1248.
6. Vasiniotis Kamarinos N, Gonen M, Sotirchos V, et al. 3D margin assessment predicts local tumor progression after ablation of colorectal cancer liver metastases. International Journal of Hyperthermia. 2022;39(1):880-887.
7. Ziemlewicz TJ, Wells SA, Lubner MA, et al. Microwave ablation of giant hepatic cavernous hemangiomas. Cardiovasc Intervent Radiol. 2014;37(5):1299-1305.

Detailed Report Information (Premium)

The **Create Report** option automatically generates a report that includes patient and procedural information, target and treatment data, as well as the screenshots taken by the user (see ***Report Creation Step*** Section). All parameters contained in a procedural report are described below.

Information contained in the ABLATE-IQ Report

Patient Information	*Channel / Probe*	*Energy Delivery*
Procedure Date	Channel Number	Delivery Number
Organ treated	Probe Type	Target Power
Name	Probe Length	Elapsed Time
Sex		Total Time
Birthdate		Average Temperature
Medical Record Number		Maximum Temperature
Target(s) Defined	*Treated Area(s) Defined*	*Evaluation of Target-Treatment*
Name	Name	Target Name
Displayed Color	Displayed Color	Target Displayed Color
Max X Dimension	Max X Dimension	Target Maximum X dimension
Max Y Dimension	Max Y Dimension	Target Maximum Y dimension
Max Z Dimension	Max Z Dimension	Target Maximum Z dimension
Total Volume	Total Volume	Target Volume
Specified Margin	Contraction Amount (%)	Treated Area Name
		Treated Area Displayed Color
		Treated Area Maximum X dimension
		Treated Area Maximum Y dimension
		Treated Area Maximum Z dimension
		Treated Area Volume
Photographs		
A table of snapshots taken during the ABLATE-IQ procedure		

Scientific References

The following peer-reviewed scientific publications were cited throughout the ABLATE- IQ Software manual:

1. 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(8):1280-1286.
2. Farina L, Weiss N, Nissenbaum Y, et al. Characterisation of tissue shrinkage during microwave thermal ablation. Int J Hyperthermia. 2014;30(7):419-428.
3. Liu D, Brace CL. CT imaging during microwave ablation: analysis of spatial and temporal tissue contraction. Med Phys. 2014;41(11):113303.
4. Lyons GR, Pua BB. Ablation Planning Software for Optimizing Treatment: Challenges, Techniques, and Applications. Tech Vasc Interv Radiol. 2019;22(1):21-25.
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NeuWave™

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

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ABLATE-IQ™ User Reference Manual
Translated From English Version 501086631-B
Version 3.2.X Software
501086631 Rev B 2024-04-30