

NorthStar® Mapping System

Instructions for Use

Software Version: 1.4

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Symbols

Symbol	Description	Symbol	Description
	Manufacturer		Date of manufacture
	Package Unit		Caution: Federal law restricts this device to sale by or on the order of a physician
	Consult instructions for use		Medical device
	Caution	N/A	Intentionally left blank
	Catalog number		Serial number
	Unique device identifier		Fragile, handle with care
	Keep dry		Keep away from sunlight
	Atmospheric pressure limitation		Humidity limitation
	Temperature limit		This way up
	Waste electrical and electronic equipment, WEEE		Volume Icon – toggle button to view or hide volume thumbnails
	MR Status Icon - MR Scanner communication is not established		MR Status Icon - MR Scanner communication is established
	Advantage-MR Icon - Advantage-MR system communication is not established		Advantage-MR Icon - Advantage-MR system communication is established
	Patient Icon – Indicates patient information		Shell Icon – 3D segmentation shells (color is user selectable)
	Map Icon – Set of activation and voltage measurement points (color is user selectable)		Ablation Icon – Set of ablation points (color is user selectable)
	Device Icon – Interventional device (color is user selectable)		View Icon – toggle button to view or hide an object
	Stack Icon – toggle button to view or hide stack thumbnails		Cine Icon – toggle button to view or hide thumbnails

Device Information

Device Description

The NorthStar® Mapping System (NorthStar) is a 3D mapping and navigation system for use in interventional Cardiovascular Magnetic Resonance Imaging (iCMRI) procedures (interventional procedures using periprocedural MR imaging). NorthStar provides a 3D environment in which real-time MR images of the anatomy, 3D representations of the anatomy, and device(s) are displayed. In addition, during electrophysiological (EP) procedures, NorthStar can display electroanatomical maps (voltage or activation) and/or therapy delivery information. These capabilities allow for procedure planning and guidance, and procedural therapy assessment.

NorthStar operating modes include:

- Real-time MR images
- 3D representations of anatomical structures (shells, volumes, etc.)
- Interventional device location
- Electroanatomical maps (EA Maps)
- Ablation points

The NorthStar system consists of a computer and application software, along with a monitor, mouse, and keyboard located in the control room. This system communicates with a compatible MR scanner computer and, during EP procedures, the Advantage-MR EP Recorder/Stimulator System (Advantage-MR).

Intended Use/Indications for Use

The NorthStar® Mapping System is intended to aid interventional Cardiovascular Magnetic Resonance Imaging (iCMRI) procedures, including electrophysiology procedures, by providing a 3D environment in which MR images, devices, and procedure-related data are displayed.

Contraindications

The system has no specific contraindications.

Operating Modes

NorthStar creates a 3D environment for mapping and navigation using the imaging capabilities of a magnetic resonance imaging (MRI or MR) scanner. The information displayed by NorthStar includes real-time MR images, 3D representations of anatomical structures, interventional device location, electroanatomical maps, and ablation points.

For pediatric use cases, follow the compatible device IFU and manufacturer recommendations.

Real-time MR Images

NorthStar provides an interface for limited MR scanner control. For example, NorthStar can select the scan sequence, start/stop scanning, and change pulse sequence parameter settings. NorthStar

automatically receives MR images from the scanner in real time and displays them in the 3D environment as they are received.

3D Representations of Anatomical Structures

NorthStar displays 3D anatomical shells and/or volumes created from MR images. These 3D representations are static and represent the anatomical structure at the time of the scan. NorthStar allows 3D anatomical shells and/or volumes to be visualized alone or with MR images.

Interventional Device Location

NorthStar provides the location of interventional devices in relation to the 3D shells and/or MR images in the 3D environment. Interventional devices can be categorized in three ways which are not necessarily mutually exclusive.

- *Passively Tracked* devices are those which are visualized within the MR images.
- *Actively Imaged* devices are those that incorporate one or more active tracking coils which can be seen as bright spots in an MR image.
- *Actively Tracked* devices are those that incorporate one or more active tracking coils and for which NorthStar contains device geometry information. NorthStar calculates the location of each coil using the MR scanner's coordinate system and renders some relevant portion of the device in the 3D environment.

Refer to the compatible equipment section for compatible interventional devices with active tracking coils.

Electroanatomical Maps

NorthStar provides electroanatomical mapping (EAM) capabilities for interventional procedures that use EAM, such as diagnostic cardiac electrophysiological studies or cardiac ablation procedures. EAM points may be viewed as measurement points in the 3D environment with or without MR images. They may also be viewed as color-mapped measurement data projected onto a 3D anatomical shell.

Ablation Points

NorthStar displays ablation points at their locations in 3D space along with the information associated with each point, such as duration, power delivered, impedance drop and tip temperature. The location is determined by using the actively tracked device location at the time of ablation.

Warnings, Precautions, and Potential Adverse Events

The order of the following warnings, precautions, and potential adverse events does not give any indication of their relative importance.

Warnings

- Users must read the complete Instructions for Use (IFU) prior to operating NorthStar. NorthStar should only be used by qualified and trained professionals.
- NorthStar is intended for use with other medical devices in an iMRI laboratory. Other medical devices have indications, contraindications, and warnings or precautions that are specific to that device. Before using other devices with NorthStar, please refer to the specific device IFU to obtain information relevant to that device.

- Do not use NorthStar if any component appears damaged, or the computer appears to start up and/or function abnormally. Contact Imricor Medical Systems if system appears damaged or is functioning improperly.
- Do not modify this equipment without authorization from Imricor Medical Systems as this may void the warranty.
- Do not upload any files or install any software onto the NorthStar computer, except as part of the normal procedures described in the NorthStar documentation and training. These exceptions include importing MR images or anatomical shells or volumes.
- To avoid incorrect placement of the interventional device, the user should use multiple means of verifying interventional device positions within the anatomy, including:
    - MRI techniques, such as Passive Tracking, Active Catheter Imaging, Active Tracking, real-time imaging, and interleaved imaging.
    - Real-time intracardiac electrograms (for electrophysiology procedures) displayed on Advantage-MR.
- The anatomical shell(s) may become misaligned if the patient moves with respect to the bed. If anatomical shell(s) appear misaligned, it may be necessary to recreate or realign the shell(s) using the segmentation software. Please refer to the segmentation software instructions to either recreate or realign the shell(s). Previously acquired electroanatomical mapping points and/or ablation points may not align with the new or realigned shell(s).
- NorthStar is not intended to be connected to any network. It is intended to be connected to compatible equipment as described in the Compatible Equipment section.
- To prevent electrical shock hazards or impaired performance of NorthStar from incorrect installation, only representatives of Imricor Medical Systems or its authorized agents may carry out installation of NorthStar.
- To avoid the risk of electric shock, only connect NorthStar to a supply mains with protective earth. Do not use power strips or extension cords.
- Risks related to use of the device in an aircraft, and subsequent analysis of possible RF interference during air travel, are not assessed because it is beyond the intended use environment for the device.

Note: For MR scanner commands initiated from NorthStar, messages, including warnings from the MR scanner monitor are also displayed on the NorthStar monitor. Examples of these messages are also provided in this IFU in the Troubleshooting Guide > MR Scanner Messages section. Refer to the MR scanner computer IFU for details on the MR scanner messages.

Precautions

- Do not cover or block vent openings of the computer while it is functioning.
- When cleaning the system, do not spray or pour agents directly onto equipment and do not use acetone solvents. Do not submerge the cables.
- Do not connect additional devices to the workstation. Do not place wireless charging devices near the workstation. Do not use RF card readers near the workstation.

Potential Adverse Events

Potential clinical complications are in large part expected to be related to the interventional devices that are used with NorthStar, rather than NorthStar itself. To identify potential adverse events, the user is instructed to read pertinent instructions for use documents associated with the interventional devices and any other devices or systems used during the procedure.

As with other mapping systems, the NorthStar system can be incidentally associated with minor or major clinical complications intrinsic to intracardiac procedures. Potential adverse events associated with interventional cardiac procedures include, but are not limited to arrhythmias, unintended complete or incomplete AV, SA, or other heart block or damage, nerve injury, perforation, tamponade, bleeding/hemorrhage, and pericardial effusion. In addition, with any electrical system there is a potential risk of electrical shock to the user, patient, and service representative.

Installation and Setup

Initial Installation

Only personnel authorized by Imricor may install, set up, and test the NorthStar System. The system is ready for clinical use only after it has been installed and fully tested.

The NorthStar software application is provided on a dedicated computer. The NorthStar computer should not be used for any other purpose than that described in these instructions for use.

System Components

The following are the main components of the NorthStar® Mapping System. Do not use accessories or cables other than those specified.

- NorthStar computer with software installed
- Mouse
- Keyboard
- Monitor
- DisplayPort cable
- HDMI cable
- USB-A cables
- Ethernet cables
- Power cables

For information related to third party software notices applicable to NorthStar, please contact an Imricor Medical Systems representative.

Compatible External Devices/Equipment

The following devices and/or equipment are used with NorthStar but sold separately. Consult the manufacturer's instructions for use for the compatible devices and/or equipment.

Device/Equipment Type	Name(s)/Requirements
EP recording and stimulator system	Advantage-MR EP Recorder/Stimulator System
MR Scanners	Siemens Magnetom 1.5T MR Scanners enabled for use with Access-i v1 and Access-i v2

Device/Equipment Type	Name(s)/Requirements
	Philips scanners listed for use with software version R13 & R12.XX SP1 (e.g., Ingenia Ambition 1.5T S, Ingenia Ambition 1.5T X, Ingenia 1.5T Evolution, BlueSeal SE and BlueSeal XE)
Segmentation tools	ADAS 3D Medical Segmentation tool
	Medical Imaging Interaction Toolkit (MITK)
Interventional devices with active tracking coils	Vision-MR Ablation Catheters
	Vision-MR Diagnostic Catheter
	NavTrac-MR Dilator
MR room monitor	MR Conditional Must support 1920x1080 resolution Must support HDMI or DisplayPort interface

System Setup

The NorthStar System is installed in the Control Room. Refer to the figure below for the standard setup.

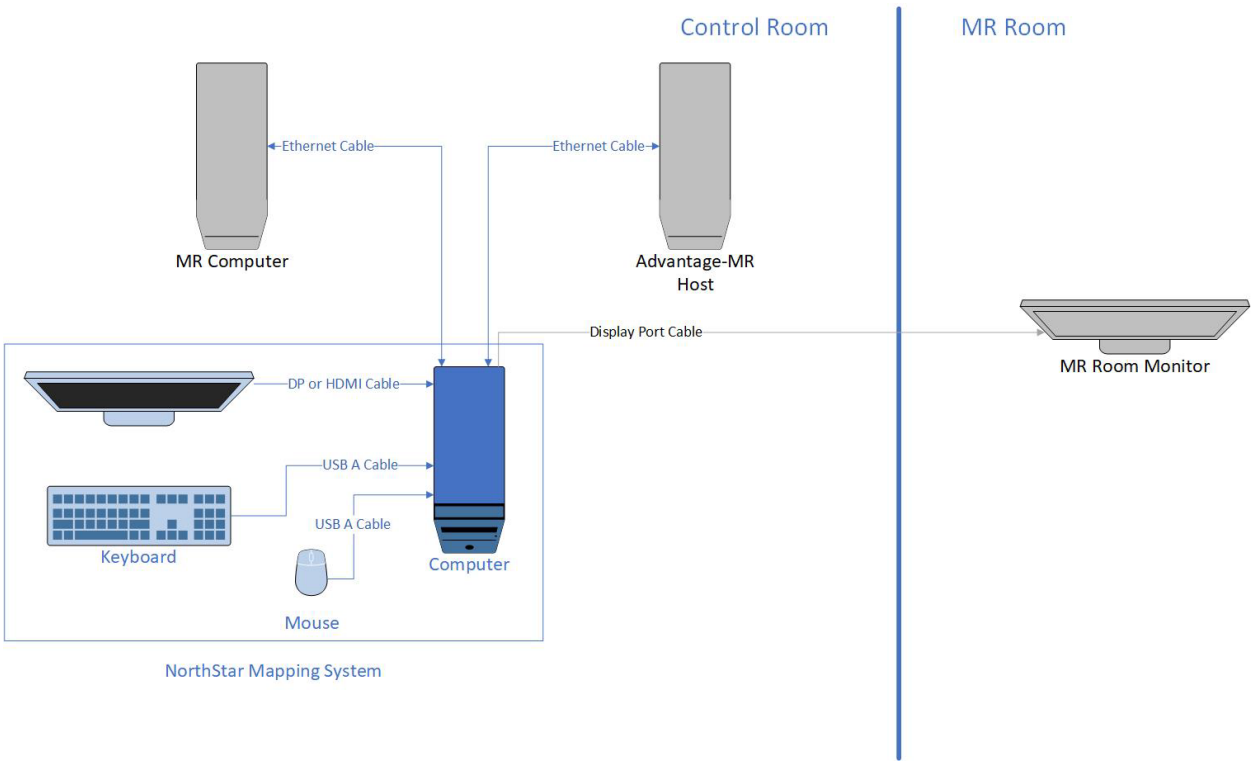


Figure 1. NorthStar Mapping System Setup

Network Characteristics and IT Security Measures

The user must have physical access to the NorthStar Mapping System computer where login credentials are required to access the system.

The NorthStar Mapping System is not designed to connect to a network. To ensure security and patient privacy, follow these recommendations:

- Use strong passwords
- Change passwords regularly
- Ensure that the NorthStar Mapping System is operated only by authorized users in a secured hospital environment

If a cybersecurity incident is suspected, discontinue the use of the NorthStar Mapping System and contact an Imricor Medical Systems representative.

NOTE: It is the shared responsibility of all stakeholders to ensure the safe and secure use of medical devices.
NOTE: Healthcare facilities must implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed as specified in 45 CFR §164.310(a)(1).

NOTE: Healthcare facilities must implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision as specified in 45 CFR §164.310(a)(2)(iii)

Connections and Information Exchange

The NorthStar Mapping System directly connects to the MR scanner computer and Advantage-MR using ethernet cables.

For the NorthStar Mapping System to communicate with the Siemens MRI scanner computer, the Access-i protocol must be enabled on the MR scanner computer and the Access-i router must be connected to both the MRI scanner and the NorthStar computers. An Imricor Service Representative will enter the Access-i license on the NorthStar Mapping System at installation and update license information prior to expiration.

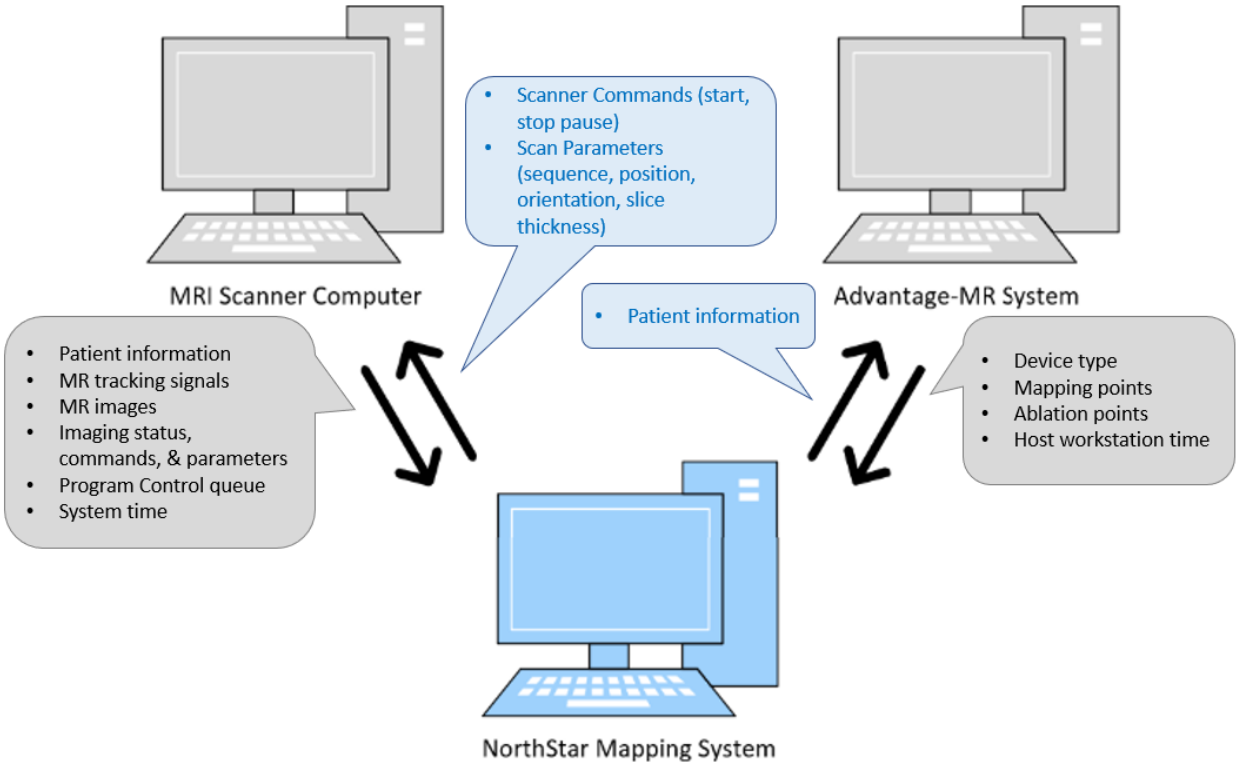


Figure 2. NorthStar Mapping System Information Exchange

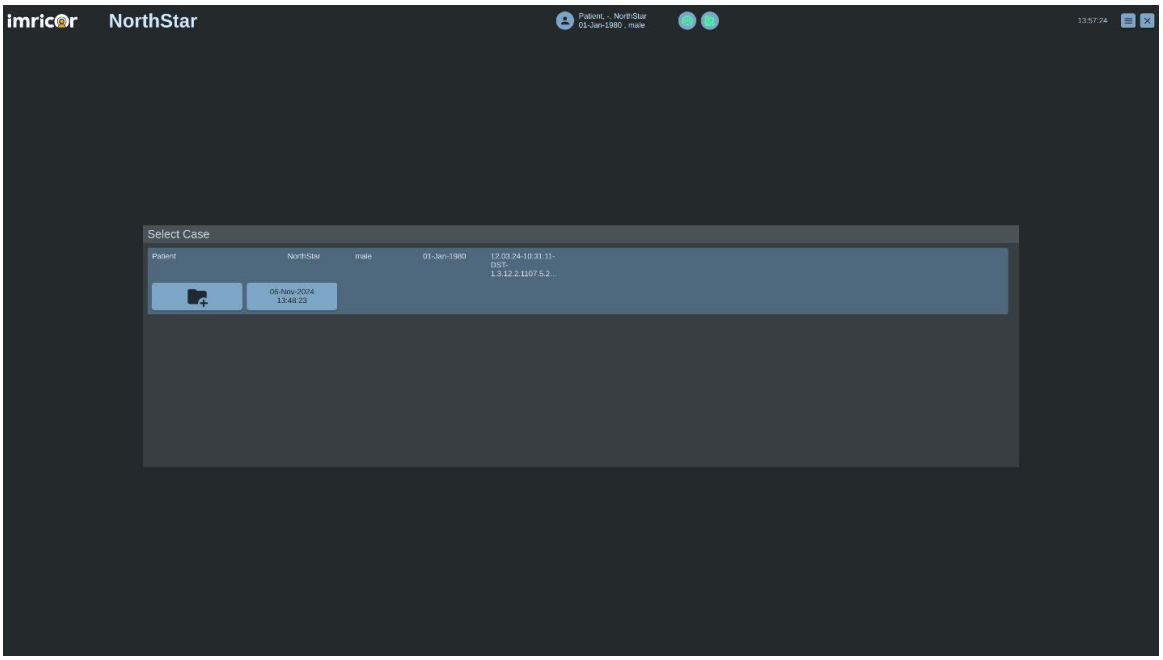
Qualified Users and Training

Physicians, medical staff, and Imricor representatives designated as NorthStar users must complete NorthStar training prior to using the system. For this purpose, please contact an Imricor Medical Systems representative.

Getting Started

System Start and Login

1. Power on the NorthStar Mapping System by pushing the power button (⏻) on the front of the computer.
2. Log into the NorthStar Mapping System using the login credentials provided by Imricor.
3. The Select Case screen is the first screen displayed in the NorthStar Mapping System.



Case Set Up

Siemens MR Scanner Connection

Establish communication between the NorthStar Mapping System and the Siemens MRI scanner computer by clicking the Remote Connection icon ( ) located in the bottom right corner of the MRI scanner computer (Siemens MAGNETOM 1.5T MRI Scanner with Access-i). For example:



Philips MR Scanner Connection

The Philips MRI scanner computer connects automatically. No additional setup or user action is required.

Once communication is enabled, the MRI connection status icon ( ) located in the NorthStar Mapping System Status Bar turns green.

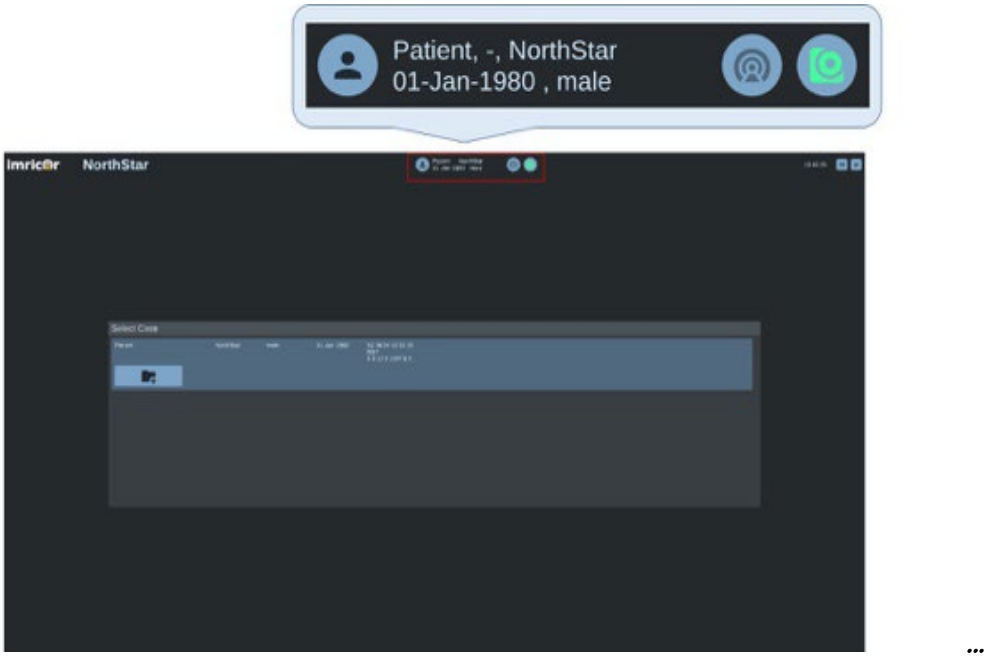


This allows the NorthStar Mapping System to display information about the registered patient on the MRI scanner, display MR images acquired by the MR scanner, and run scan sequences from the MRI scanner Program Control queue.

Patient Information

Ensure the patient is registered on the MR scanner computer and that the following minimum information has been entered:

- First name (required for Advantage-MR System)
- Last name
- Patient ID
- Date of birth
- Gender

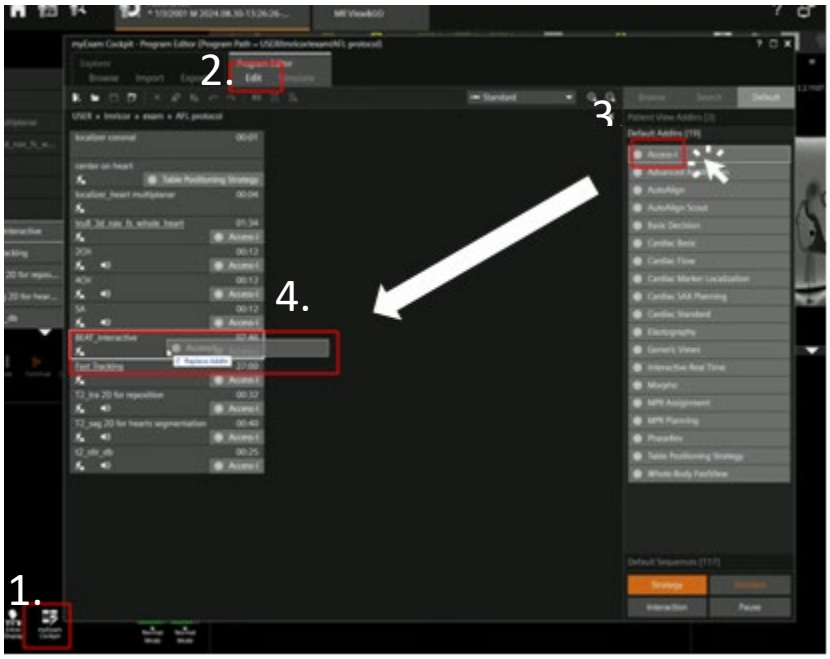


With connection established, once the patient information is entered on the MR scanner computer, the patient information is transferred to NorthStar and shown as the first patient on the Case Select screen.

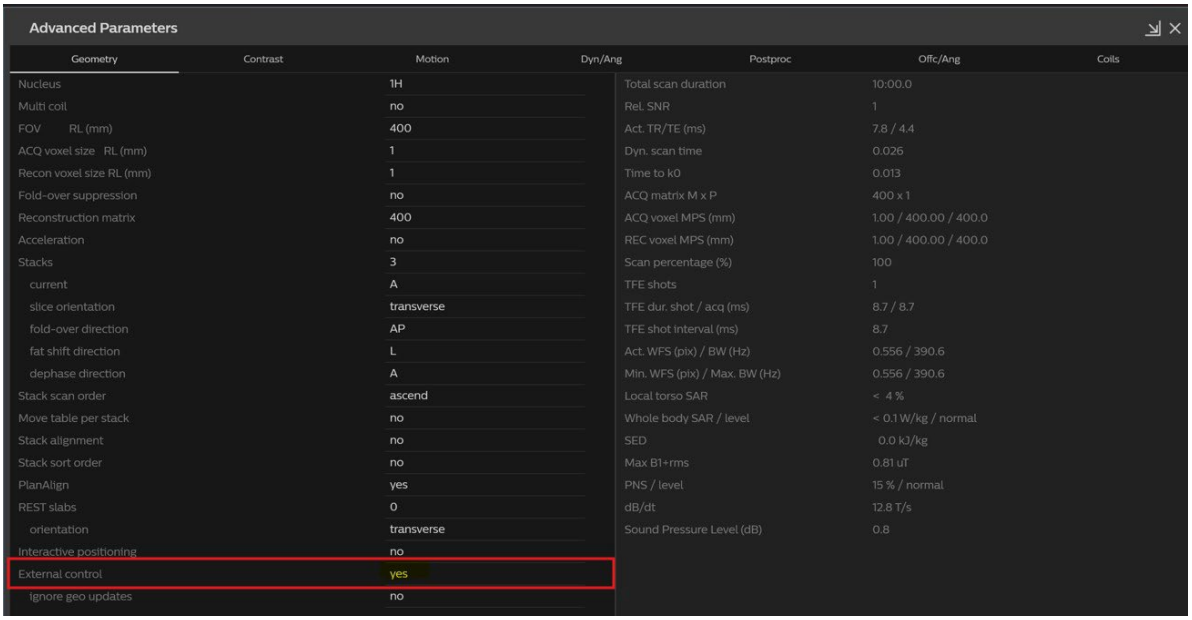
Scan Sequences

Ensure the planned MRI scan sequences are placed in the Program Control queue on the MR scanner computer.

All scans to be initiated from NorthStar must be linked to the Access-i ADDIN. Additional MRI scan sequences can be added at any time during the procedure and will automatically be added to the NorthStar Scan list if the Access-I ADDIN is linked to it.

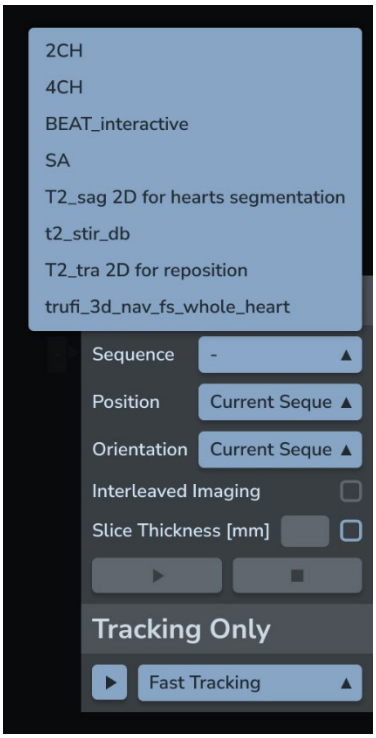


For the Philips scanner, make sure the External Control with Geometry menu is set to “yes” for the sequence to populate in the sequence list in NorthStar.



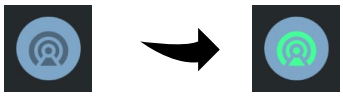
NOTE: To identify a tracking only sequence and for that scan to appear in the Tracking scan list, the name of the scan sequence must include the text “Tracking”.

Scan sequences identified in the Program Control queue are available on the NorthStar Imaging and Tracking menu.



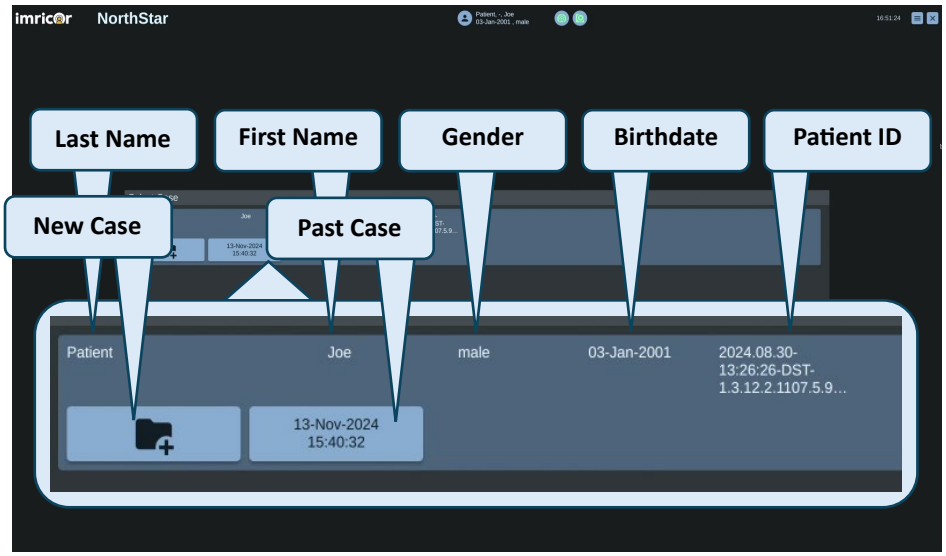
Advantage-MR Connection

Establish communication between the NorthStar Mapping System and the Advantage-MR System. Ensure that interventional devices are connected to the Advantage-MR System and that the Advantage-MR System is connected to the MRI scanner. For additional information on the system set up, refer to the Advantage-MR System IFU. Once communication is established, the Advantage-MR System status icon ( ) located in the NorthStar Mapping System Status Bar turns green.



Start a Case

The Select Case screen is the first screen displayed in the NorthStar Mapping System. It allows the user to create a new case, resume a previous case, or review a previous case. This screen shows previous cases available for review and will allow the user to create a new case for the patient registered in the MR scanner.



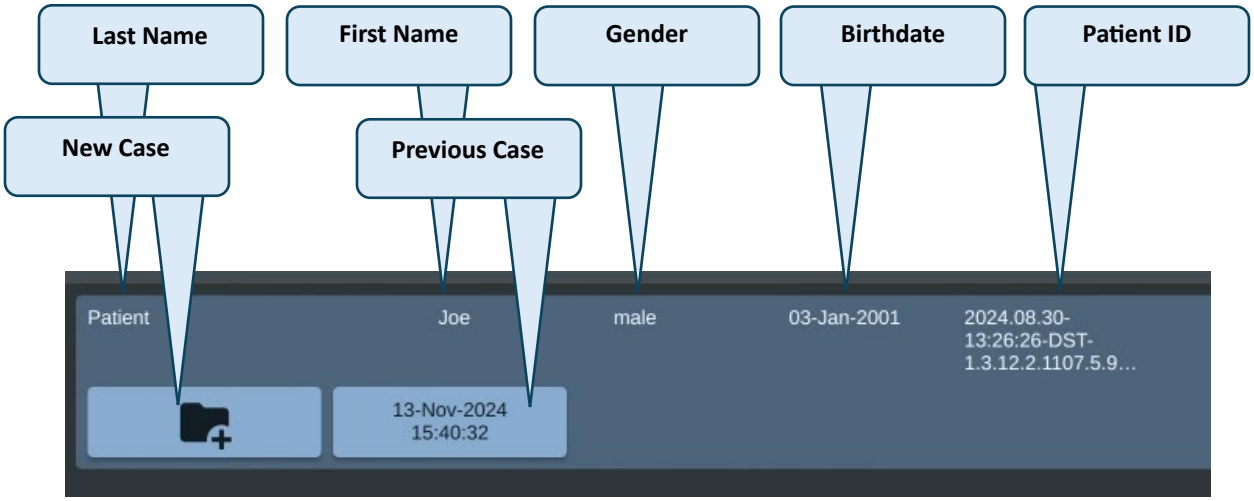
Start a New Case

To start a new case, register the patient in the MR computer and click on the NorthStar New Case folder ( ). This will send the registered patient information to the Advantage-MR System. For additional information on operating Advantage refer to the Advantage-MR System IFU.

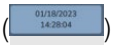


Resume a Previous Case

To resume a previous case, the patient must be registered on the MRI scanner. Click on the Previous Case folder for the case to be resumed and the data for the selected previous case will be displayed. The user will have access to the Scanning Menu and the Scanner Status as the patient is registered on the MRI scanner.



Review a Previous Case

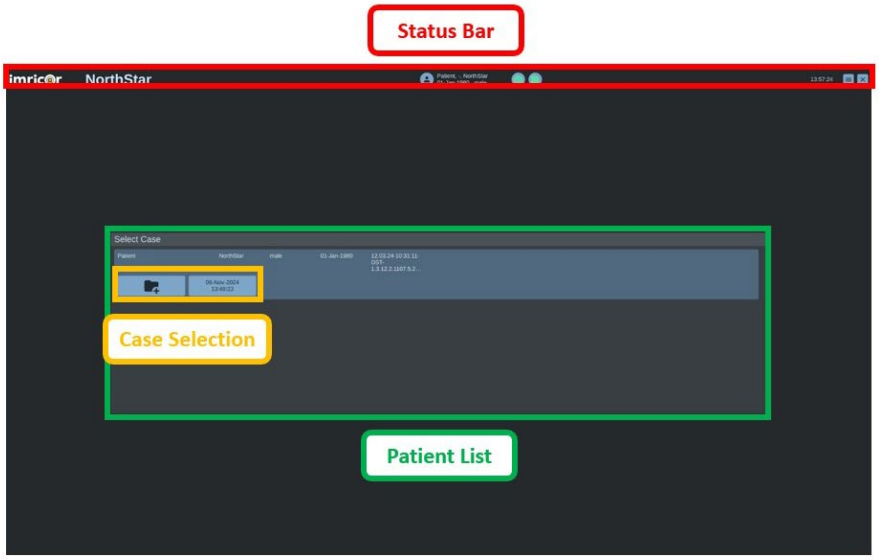
To review a previous case for a patient that is not currently registered on the MR computer, click on a Previous Case folder () that contains the applicable date and time. The data for the selected case is displayed. The user does not have access to the Scanning Menu and the Scanner Status when that patient is not actively registered on the MRI scanner.

Operating Modes

General Operation

Select Case Screen Elements

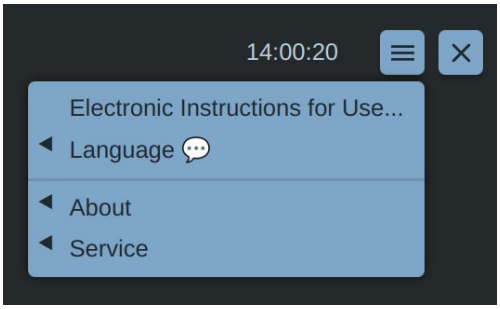
The Select Case screen allows the user to create a new case, resume a previous case, or review a previous case.



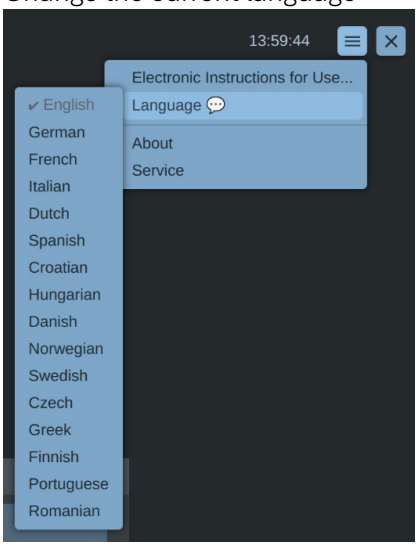
Select Case Screen Menu Options

The Status Bar Menu on the Select Case Screen allows the user to do the following:

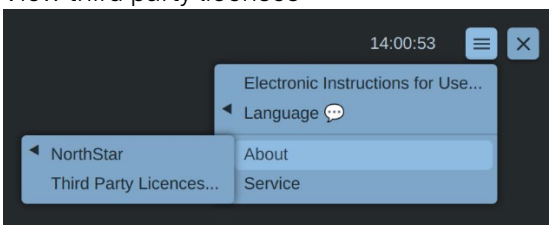
- View the Electronic IFU



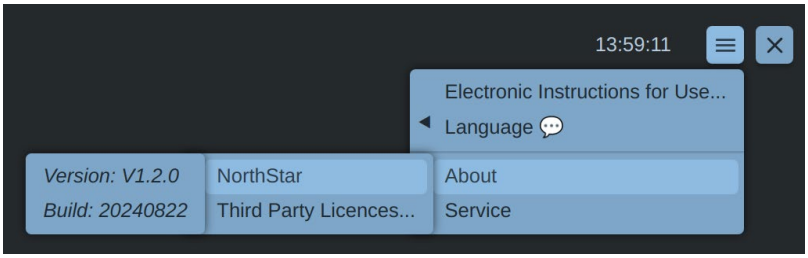
➢ Change the current language



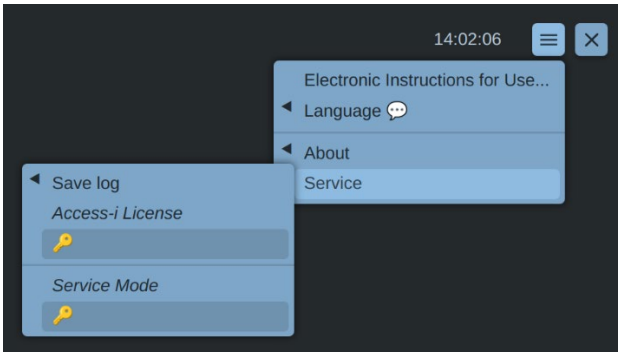
➢ View third party licenses



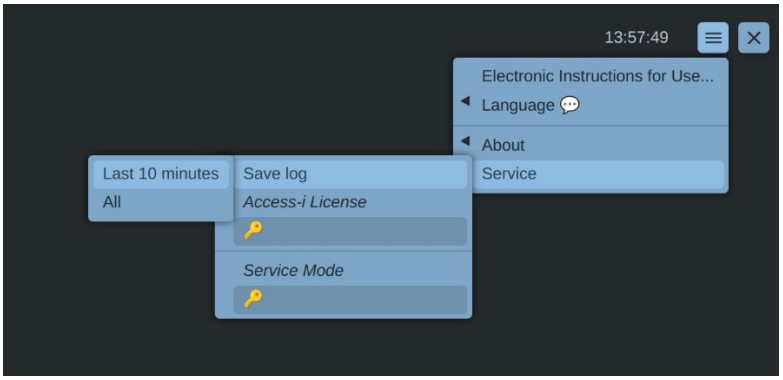
➢ View the current NorthStar version



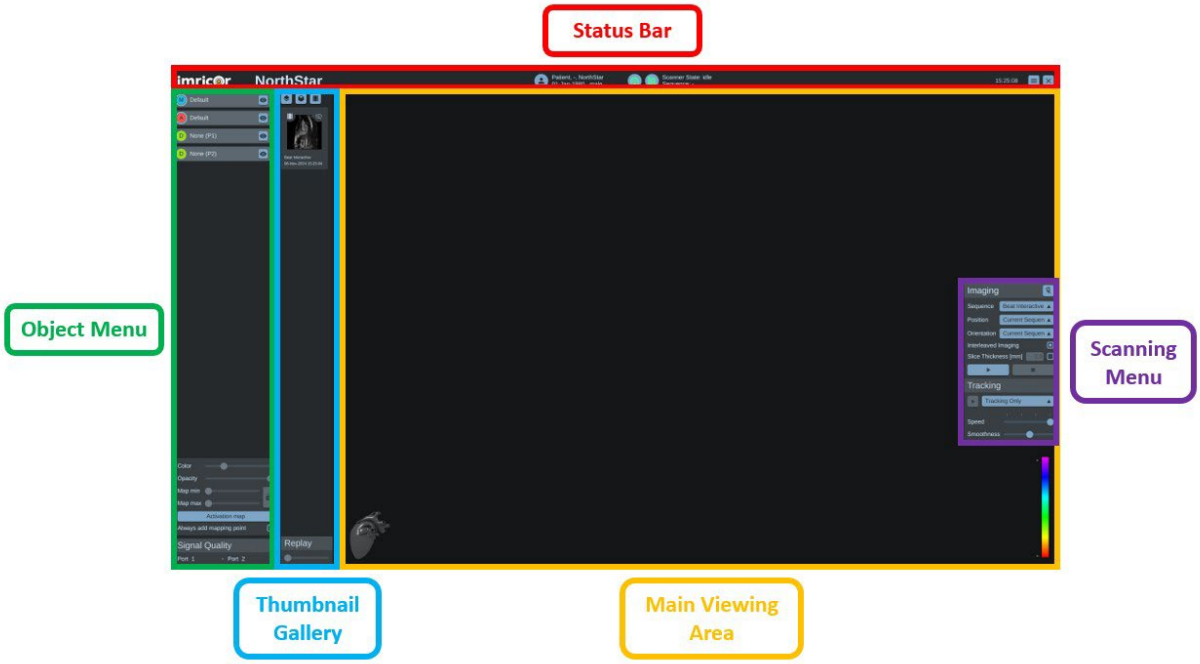
➢ Input the Access-i license to connect to the Siemens scanner and input the password to enter service mode (Imricor personnel only).



➢ Save all available log files or just the log files from the last 10 minutes



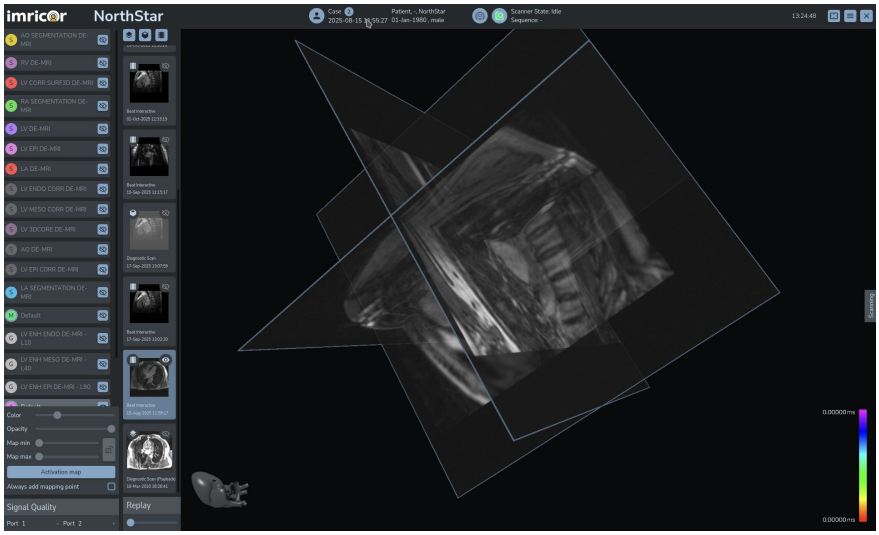
Main Screen Elements



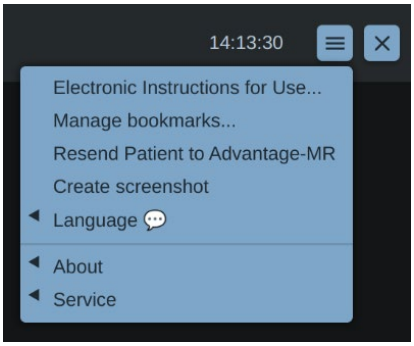
Main Screen Menu Options

The Status Bar Menu, on the Main Screen, allows the user to do the following:

- Show the case information by hovering over the patient Name.



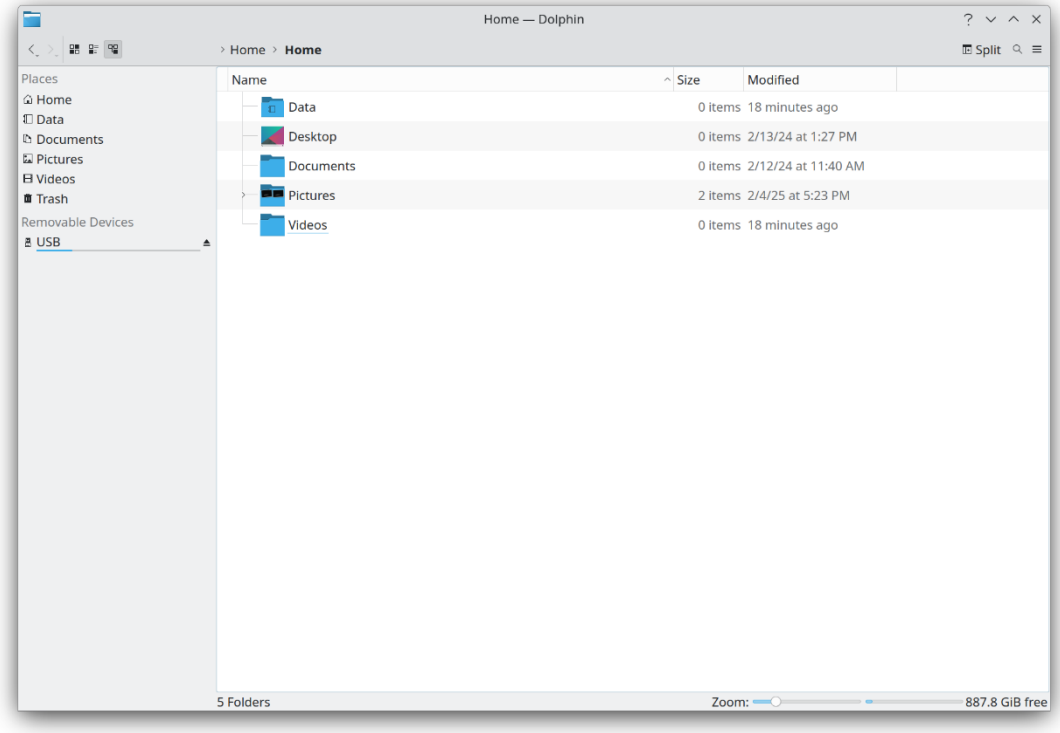
- View the Electronic IFU, Manage Bookmarks, Resend Patient to Advantage-MR System, and Create Screenshots of 3D Environment.



Exporting Screenshots:

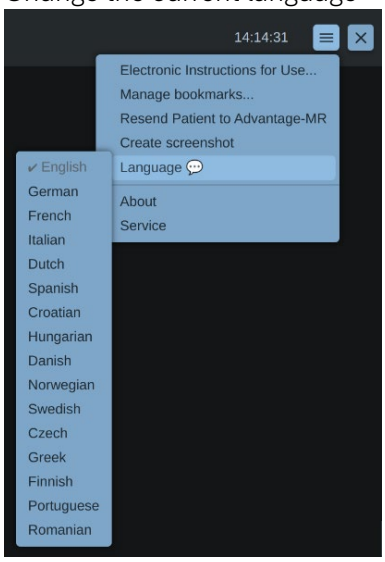
- Insert a USB storage device into one of the USB ports
- Open a file manager window by pressing <Alt> + <Spacebar> and entering “Files”

- Navigate to directory ~/Pictures by clicking on the Pictures entry in the sidebar

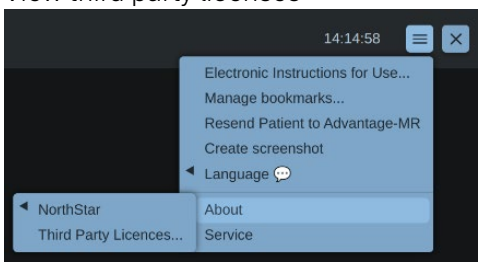


- Copy the screenshot file(s) to the USB storage device
- Close the file manager

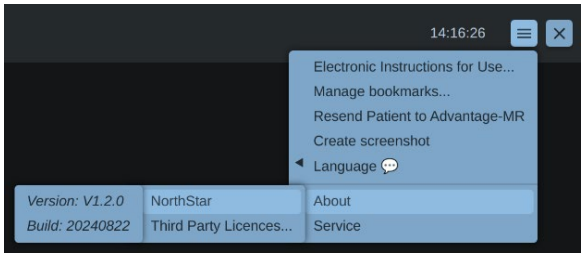
➢ Change the current language



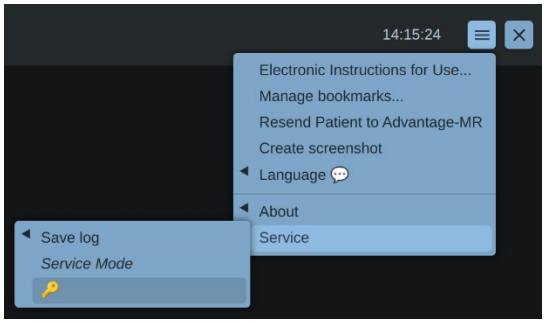
- View third party licenses



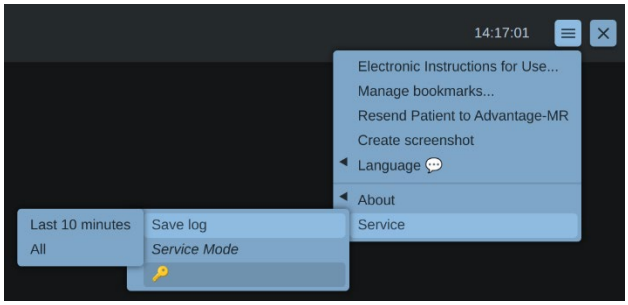
- View the current NorthStar version



- Input the password to enter service mode (Imricor personnel only).

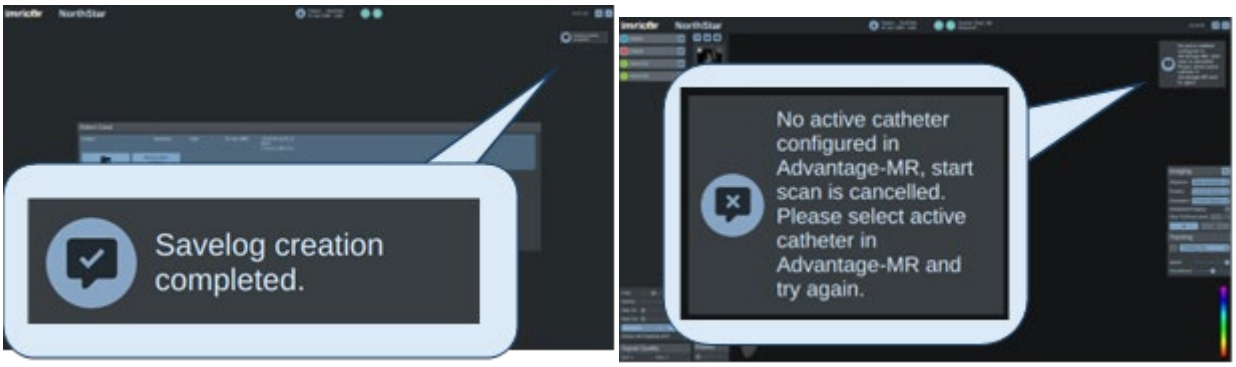


- Save all available log files or just the log files from the last 10 minutes



NorthStar Notifications

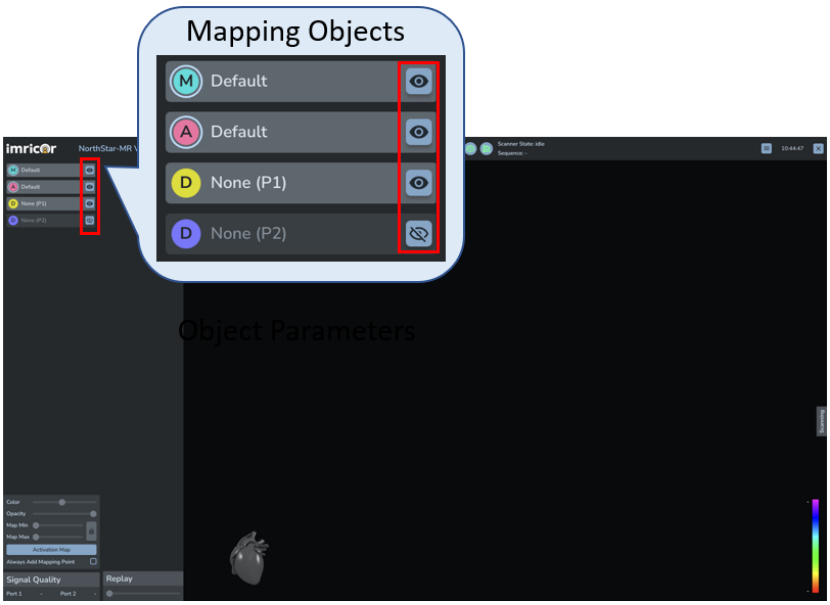
Notifications relevant to the current task will appear in the upper right of NorthStar on both the Select Case Screen and Main Screen.



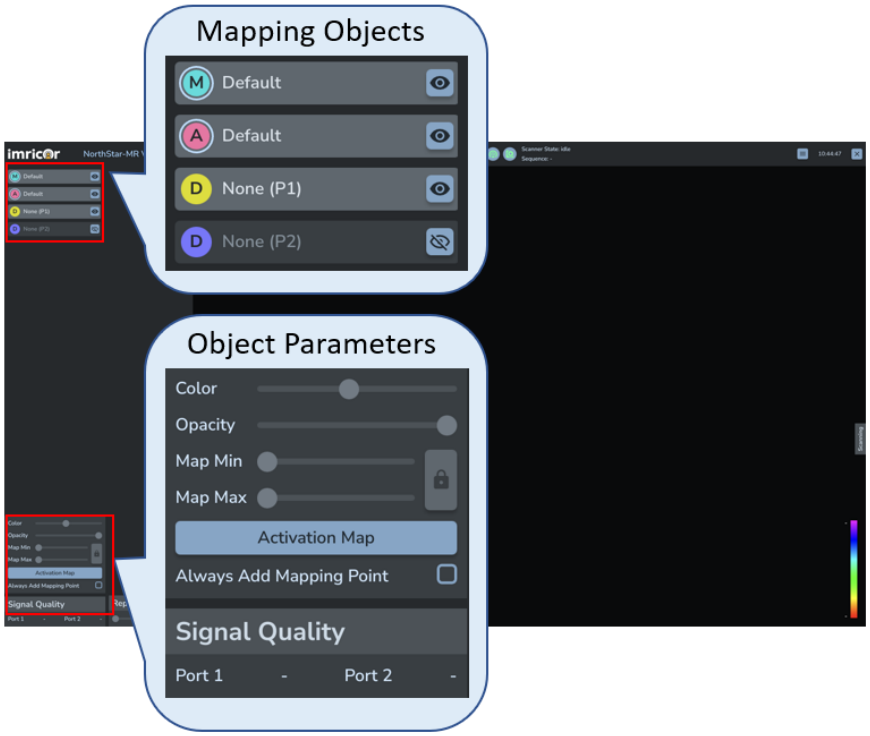
For a full list of possible notifications see | Troubleshooting Guide > NorthStar Notifications |

Customize Display Objects

➢ Select the View Icon ( ) to display a Mapping Object in the 3D environment.



➢ The Mapping Objects and Object Parameters can be modified by the user to meet their desired preference.



Mapping Object	Description
	Electroanatomical Map (Activation or Voltage)
	Set of Ablation Points
	Anatomical 3D Shell
	Interventional device with receive coils connected to Advantage-MR Port 1 [P1], labeled as ABL CATH on the Advantage-MR PDI
	Interventional device with receive coils connected to Advantage-MR Port 2 [P2], labeled as CATH 2 on the Advantage-MR PDI

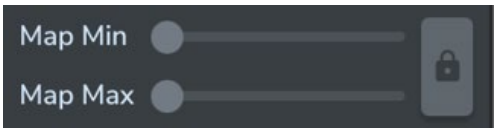
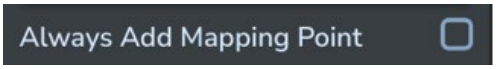
- A new Mapping Object can be created by right clicking in the Object Menu or on a shell and selecting New > Mapping.



- To modify a Mapping Object, ensure the object is visible ( ) and left click the label or icon to select it.



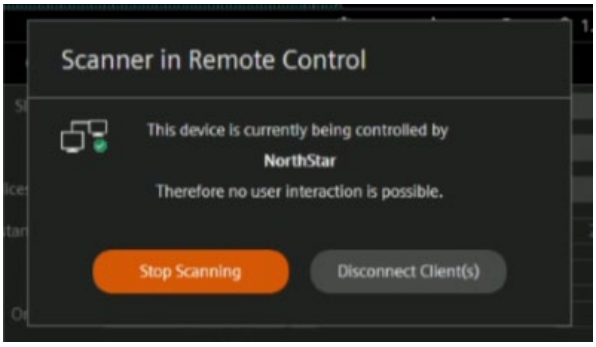
- The following Object Parameters can then be modified:

Object Parameter	Description
	Sets the color of selected object.
	Sets the color gradient scale distribution for the Electroanatomical Map (Voltage or Activation)
	Selects the type of Electroanatomical Map to display (Voltage or Activation)
	Selecting the check box automatically places mapping points on the 3D shell so the Advantage-MR user does not need to click the Map button. The mapping point will appear as soon as the second caliper is positioned.

Real-Time MR Images

NorthStar displays MR images from the MR scanner during an active case. The MRI scans can be initiated from the MR scanner computer or NorthStar. Before any imaging scans can be run from NorthStar or the MR scanner a scout scan or localizer should be run on the MR scanner computer.

NOTE: In older versions of the Siemens scanner software, i.e. before Numaris X, If the user starts a scan from NorthStar then stops the scan using the MR scanner computer, the MR scanner computer terminates the connection to all connected devices, including NorthStar. To reconnect, click the Remote Connection () icon again. In Numaris X there are two options, selecting 'Stop Scanning' will not disconnect NorthStar but selecting Disconnect Client(s) will.



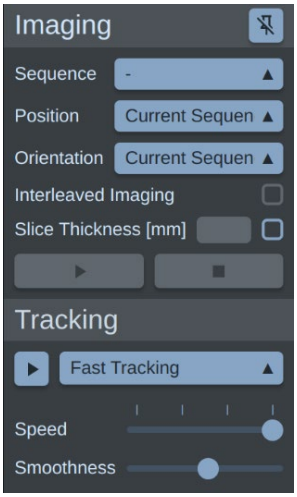
Scanning Methods

This section describes how to control scanning. MR scans that have been configured on the MR scanner computer can be initiated from either the MR scanning computer or from within NorthStar. The MR images can be automatically displayed in real time on NorthStar.

There are two methods to run an MRI imaging scan:

Method 1 - From NorthStar

Click the Imaging and Tracking Menu (right-side of screen), select the appropriate Sequence from the dropdown, and click the Play button ().



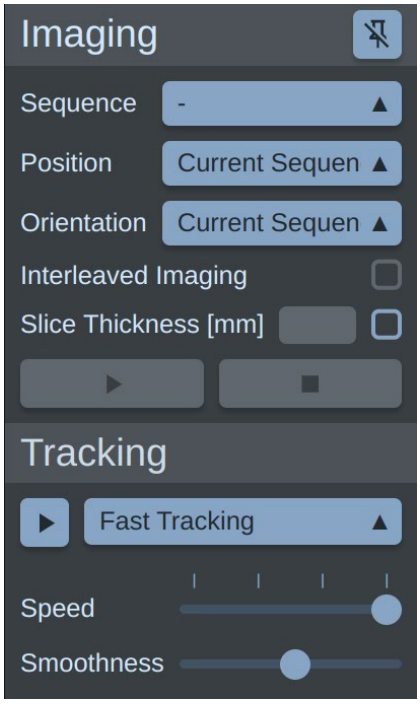
Method 2 - From the MR scanner computer

Ensure the target sequence has the text [Template] which indicates the Access-i ADDIN was added. Then click Copy and Go, after the scan starts all incoming images will appear in NorthStar as they appear on the MR scanner computer.

NOTE: MR scanner messages, including warnings, are displayed on NorthStar when the MR scanner commands are initiated from NorthStar. Refer to the MR scanner IFU for details on the MR scanner messages.

Imaging and Tracking Menu

The imaging and tracking menu can be accessed on the right side of the screen.



The scan controls are defined as follows:

- **Sequence** – Scan sequence imported from the MR scanner Program Control queue
- **Position** – Location in 3D space where the scan is taken
- **Orientation** – Orientation of the scan plane
- **Interleaved Imaging** (Siemens Only)– When checked, images from interactive scans (e.g. Beat_Interactive) are shown and the device is tracked. When unchecked, images from interactive scans are not shown, only the tracking sequence is executed.
- **Slice Thickness** – Sets the slice thickness of the scan. If an invalid value is entered, the scanner selects the nearest valid value and returns that value to NorthStar. That value is displayed as the actual slice thickness set.
- **Tracking Only sequence** – Scan sequence defined to display the interventional device(s) with no imaging associated. This scan sequence is faster and quieter than scans where images are captured. Sequences named with the string “Tracking” are placed in this selection box.
- **Tracking Speed** – Determines the scan time between scan pauses. Set high when navigating for smoothness and low when the catheter is stationary for best signal quality.
- **Tracking Smoothness** – Controls the amount of averaging of the catheter movement. Set high for the smoother catheter movement and low for more response.
- **Upper Play Button** – Starts the scan sequence selected in the Sequence field
- **Stop Button** – Stops the currently running scan sequence
- **Pause Button** – Pauses the currently running scan sequence
- **Lower Play Button** – Starts the selected Tracking Only Sequence
- **Menu Pin** – Keeps the Scanning Menu visible after losing focus. Otherwise, the Scanning Menu is hidden after one second.

Within the Imaging and Tracking Menu, there are dropdown menus for the Position and Orientation options. The options for the Position and Orientation are defined as follows:

Position and Orientation Options	Definition
Current Sequence Setting	Position and Orientation defined by the selected sequence in the Sequence field[1,2]
[Catheter Type] [(P1) or (P2)] e.g. Ablation Catheter (P1)	Position defined by the Catheter Tip for two coil devices[1] Position defined by the Catheter Coil for single coil devices[1] Note: P stands for port, as in which port on the PDI the device is plugged into. P1 = ABL, P2 = Cath 2
Bookmark	Position and Orientation (if applicable) defined by the user created Bookmark[1,2]
Series	Position and Orientation defined by the selected thumbnail series
Activation	Position defined by the selected activation measurement point
Voltage	Position defined by the selected voltage measurement point
Ablation	Position defined by the selected ablation point
Selected Points	Position and Orientation defined by the selected measurement or ablation points (calculated mean if more than three points are selected)
Image	Position and Orientation defined by the selected MR image

1. Available Position parameter option for all types of Mapping Objects or MR images.
2. Available Orientation parameter option for all types of Mapping Objects or MR images.

To make use of the above option, right click the object (Mapping Object, Image or Image Thumbnail) and select “Use for scanning”. Depending on the object selected, the position and orientation options vary. Some apply to all objects, and each object has unique options.

Position and Orientation options common to all objects:

Position Options	Orientation Options
Current Sequence Catheter(s) connected to Port 1 and Port 2 Bookmarks	Current Sequence Bookmarks

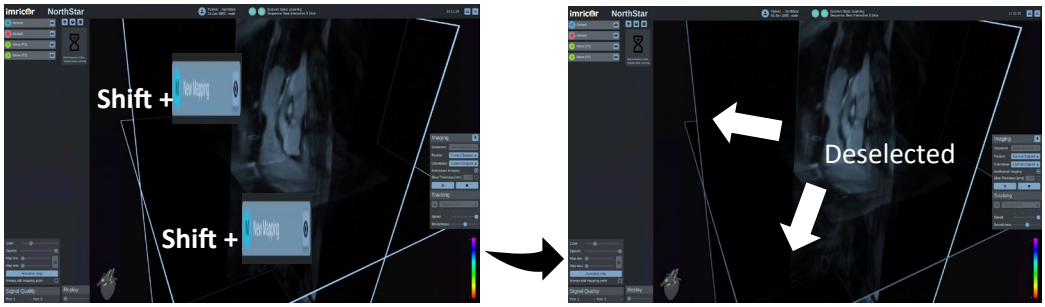
In addition to the above options, there are unique Positions and Orientation Menu options depending on the object selected. The unique position and orientation settings by object selected are described in the table below. The unique options are the default values for the respective object selected.

Object Selected	Unique Position Options	Unique Orientation Options
Image Thumbnail	Series (the median image)	Series
Single Activation Point	Activation	None
Single Voltage Point	Voltage	None
Single Ablation Point	Ablation	None
Multiple Measurement or Ablation Points Note: to select multiple points hold Shift and left click on 3 or more points.	Selected Points (the center of the point group)	Selected Points (the plane closest to passing through all points in the point group)
Image in the 3D space	Image	Image

Real-Time Scan Plane Manipulation

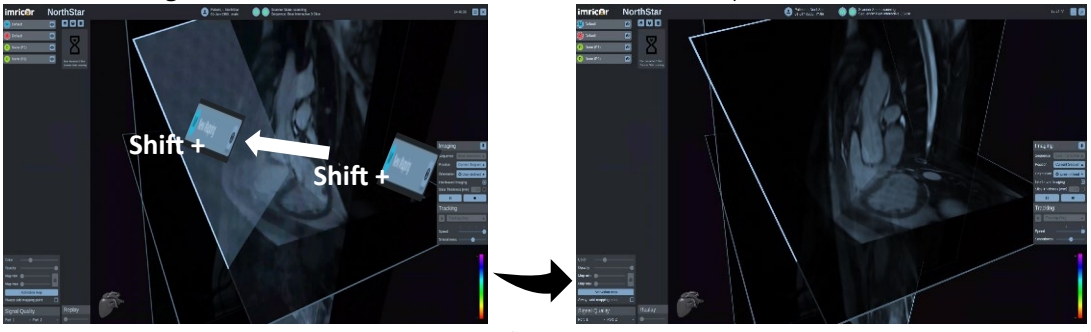
When using interactive scan sequences started from NorthStar, the scan planes can be manipulated on NorthStar in real time.

During the scan, select the live scan image in the main viewing area. If there is more than one scan plane, select and deselect one or more scan planes by holding shift and clicking on individual scan planes.



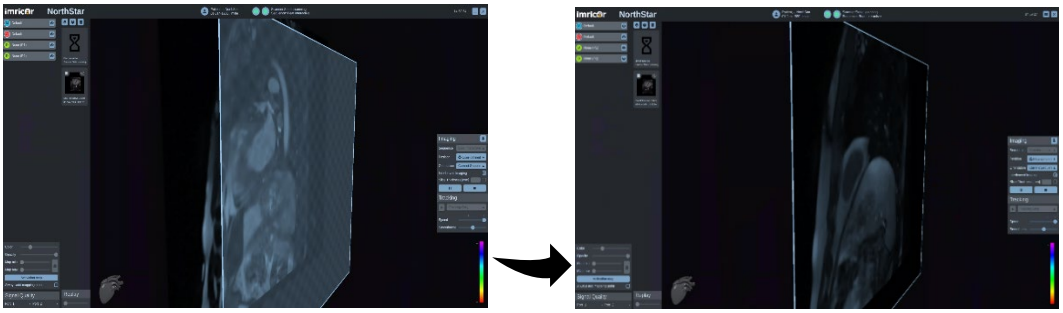
While pressing and holding the Shift key on the keyboard, the following actions manipulate the scan plane:

- Click and drag with the left mouse button to rotate the scan plane around its center

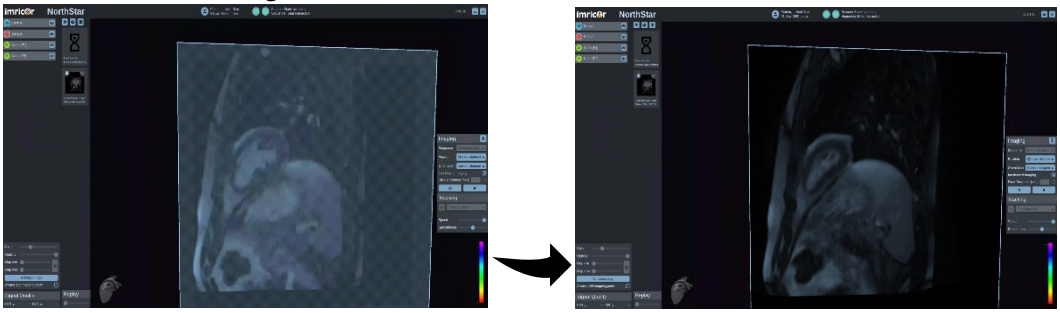


NOTE: Only 1 of the three planes moved since the other two were deselected

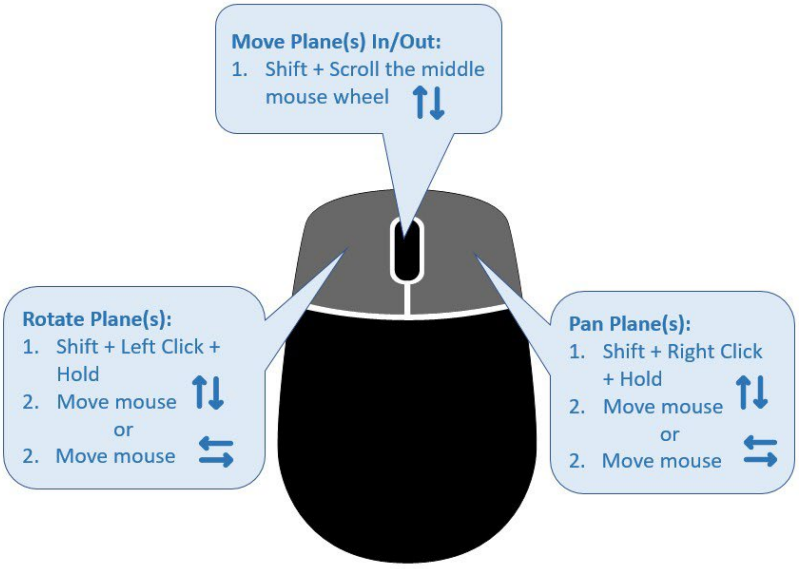
- Click and drag with the right mouse button to move the plane maintaining its current orientation



- Roll the middle mouse button up and down to push the plane away from and pull it closer to the viewer maintaining its current orientation



Summarized Controls:

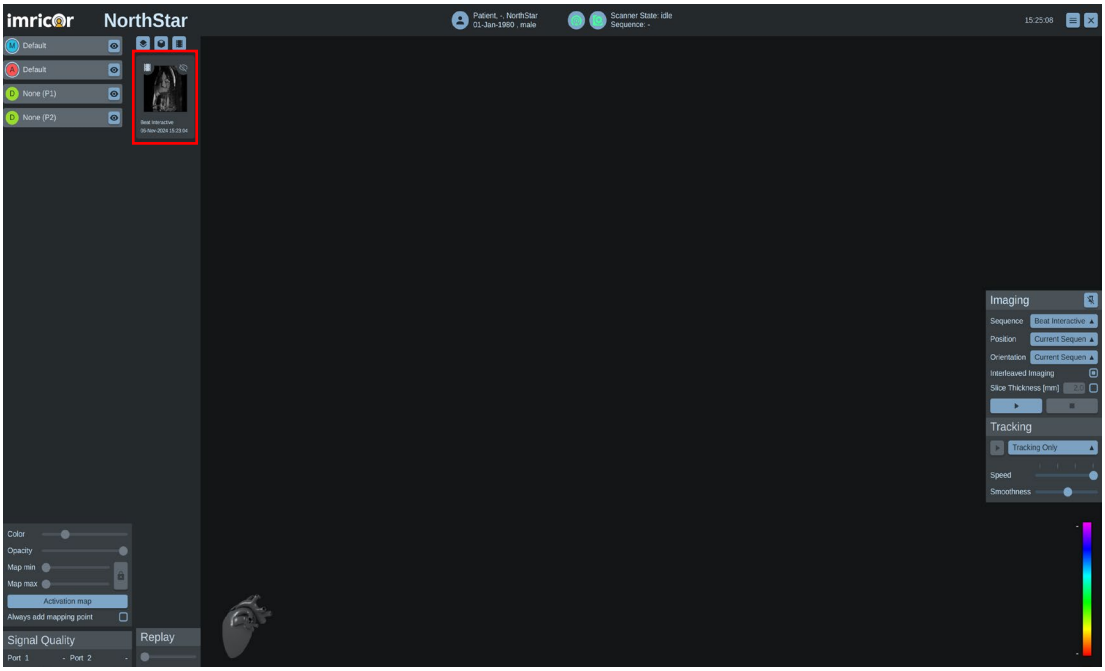


The scan plane can also be rotated using the numpad of a standard keyboard.

- Pressing the number 2 or down arrow will rotate the scan down.
- Pressing the number 4 or left arrow will rotate the scan left.
- Pressing the number 6 or right arrow will rotate the scan right.
- Pressing the number 8 or up arrow will rotate the scan up.
- Pressing the + button will zoom into the scan plane.
- Pressing the – button will zoom out of the scan plane.

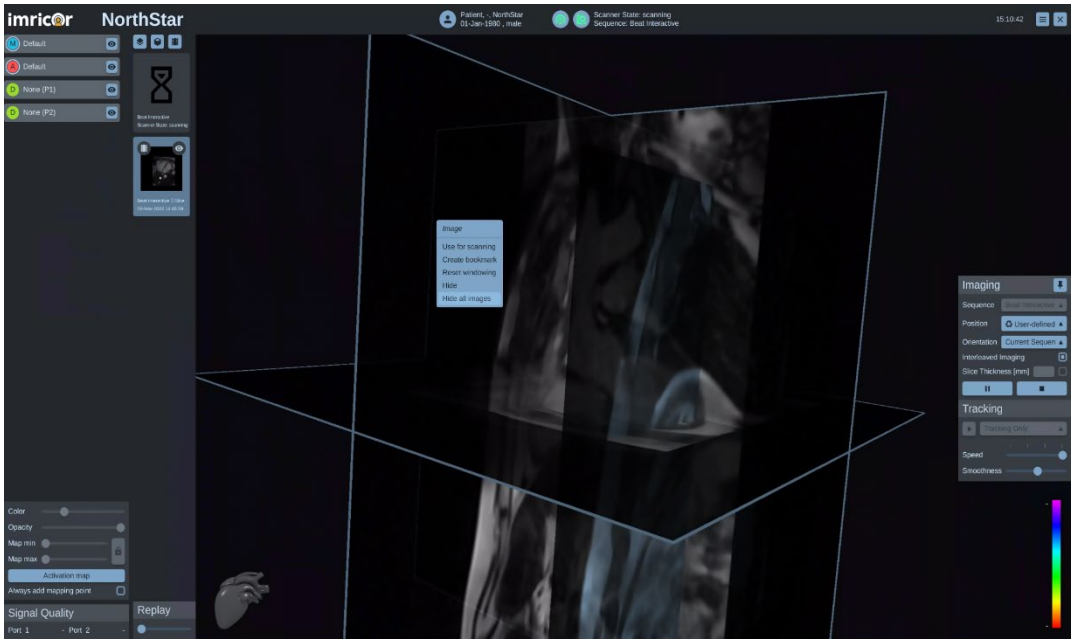
Viewing MR Images

Once the MR scan is stopped the MR image can be viewed in the main viewing area by clicking on the thumbnail.

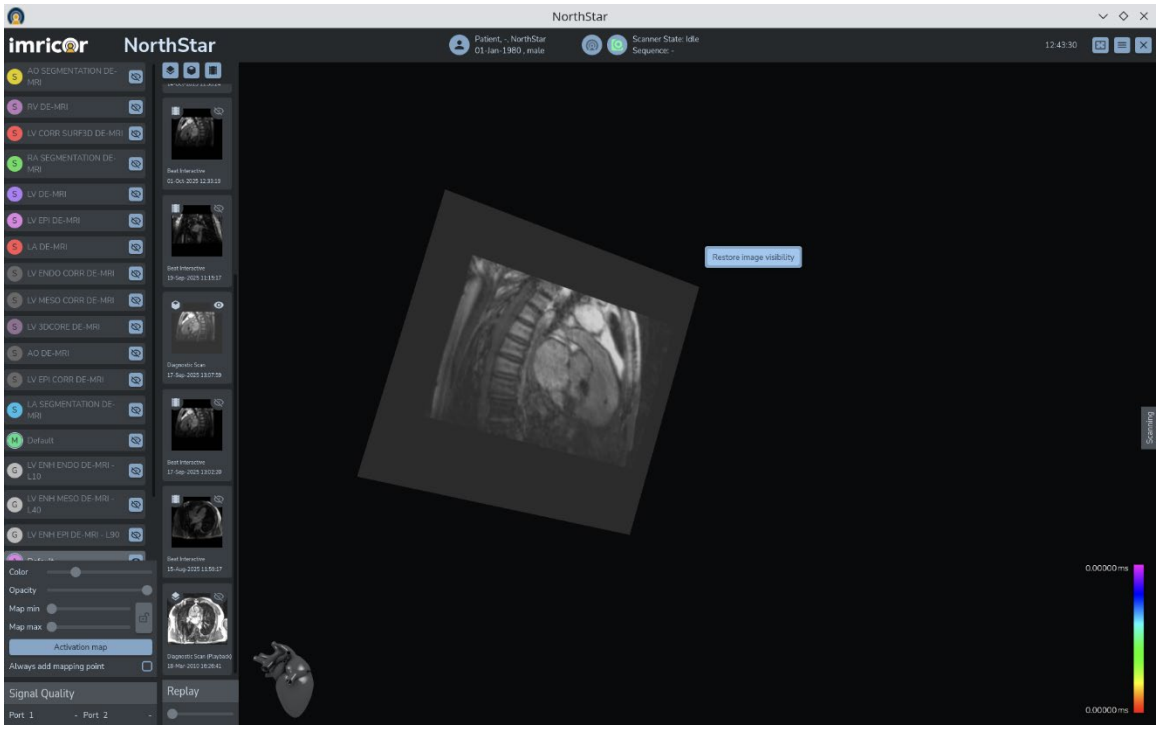


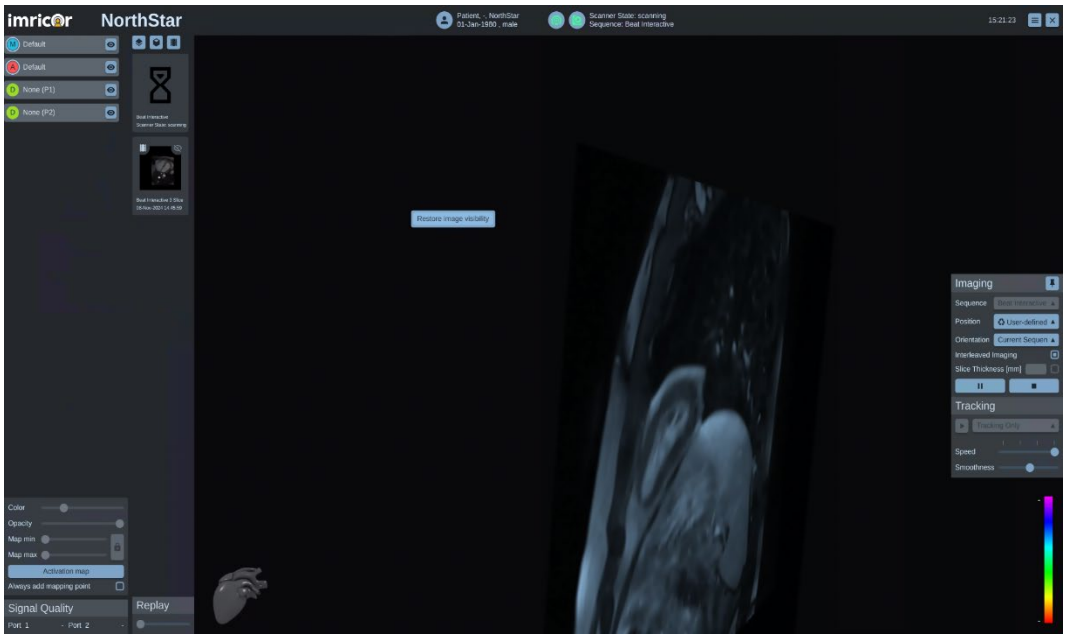
- Left-click a selected thumbnail (highlighted in blue) to hide that MR image in the main viewing area.
- Double-click on a thumbnail to hide all MR images except for the MR image that was double-clicked.
- Each thumbnail has an icon that identifies the type of series it represents (stack, cine or volume). Toggling the stack, cine and volume icons above the thumbnails will hide or show all of series of the corresponding type.

- Right click an MR image in the main viewing area and select Hide or Hide all images to hide MR images



- The Hide all images selection saves the set of hidden images. Right click in 3D space while not hovering over an object and select Restore image visibility to unhide that set of images again.

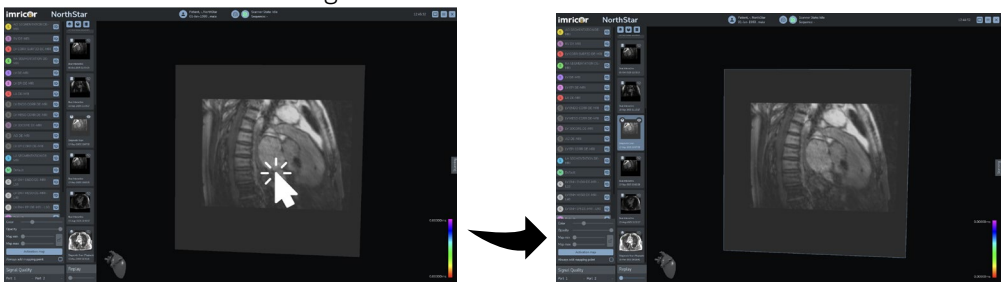




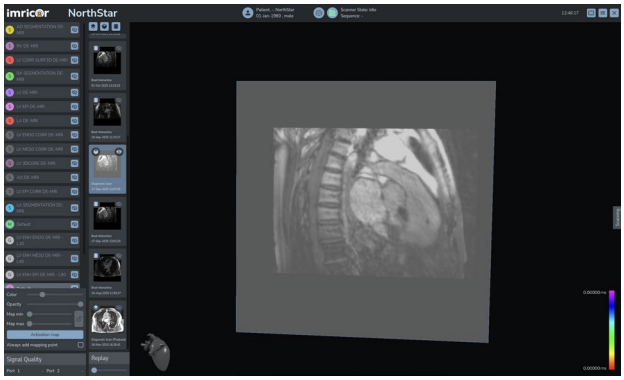
NOTE: The Hide/Restore all images function can be used in conjunction with Hide/Restore all shells function to quickly switch between viewing a specific set of images and shells.

Adjust the brightness and contrast (Windowing Parameters) of the MR image using the mouse.

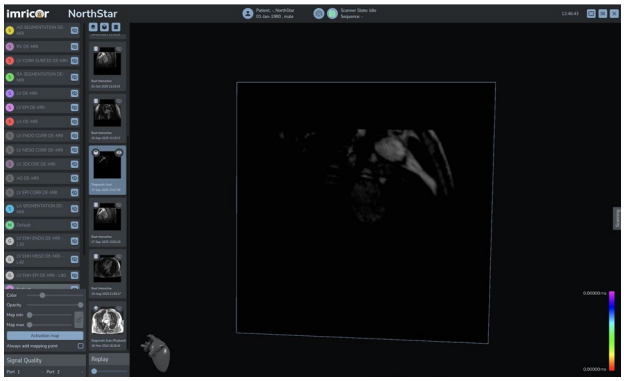
- Left click to select the image



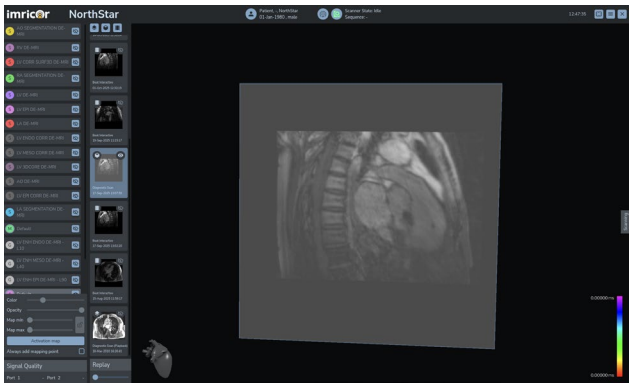
- Click and hold the middle mouse button, and then move the mouse down to increase brightness



- Click and hold the middle mouse button, and then move the mouse up to decrease brightness



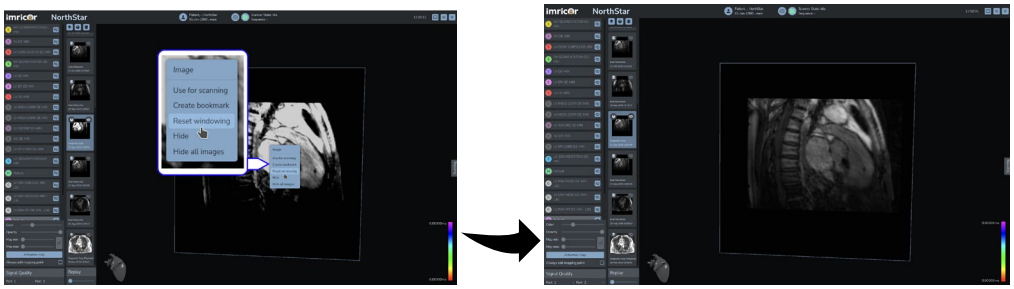
- Click and hold the middle mouse button, and then move the mouse right to decrease contrast



➢ Click and hold the middle mouse button, and then move the mouse left to increase contrast

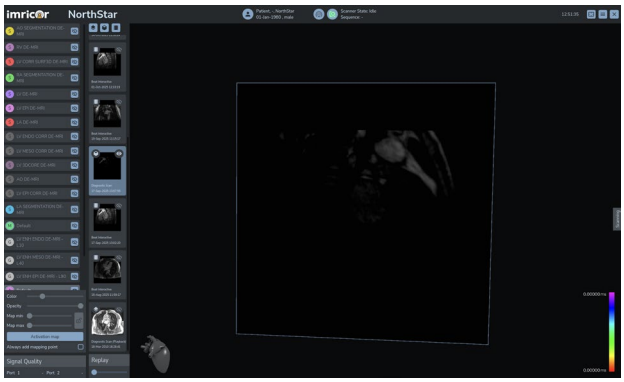


➢ To restore the original Windowing Parameters, right-click and select Reset Windowing.

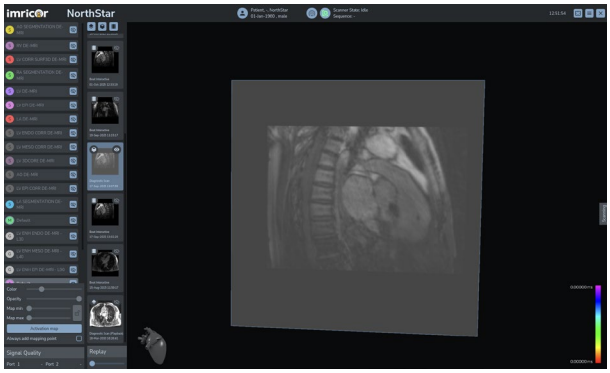


Adjust the opacity of the MR image using the mouse.

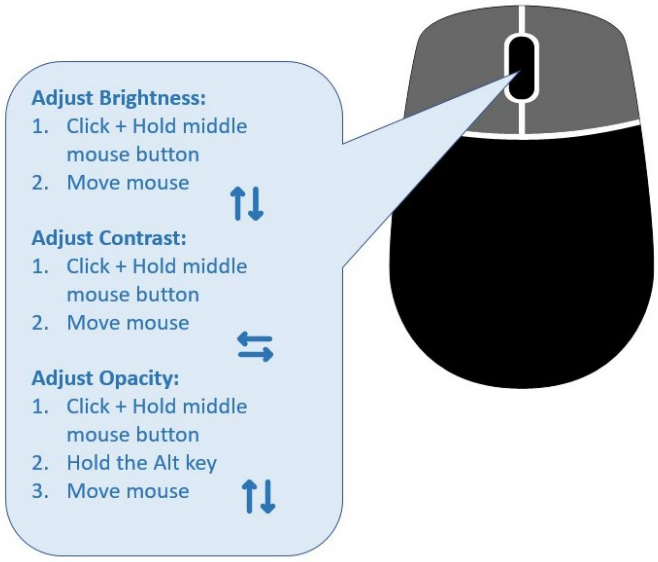
- Click and hold the middle mouse button, hold down the Alt key, and then move the mouse down to decrease opacity



- Click and hold the middle mouse button, hold down the Alt key, and then move the mouse up to increase opacity



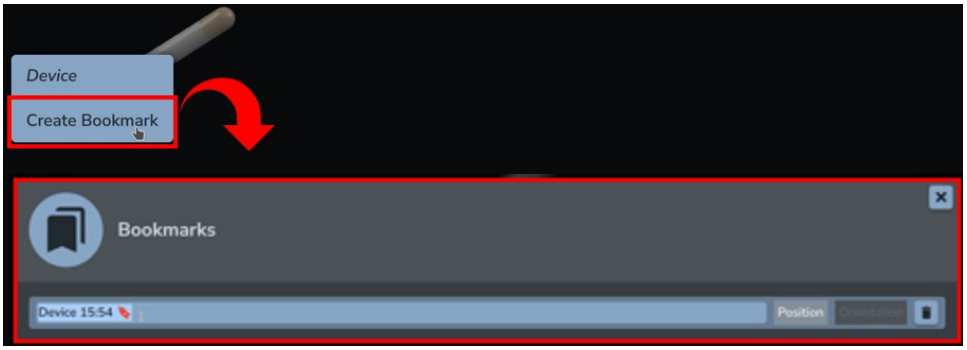
Summarized controls:



Create and Manage Bookmarks

Bookmarks provide user-configurable convenient access to scan locations and orientations of interest. When a desired scan location and/or orientation is achieved, they can be saved and used as parameters for future scans.

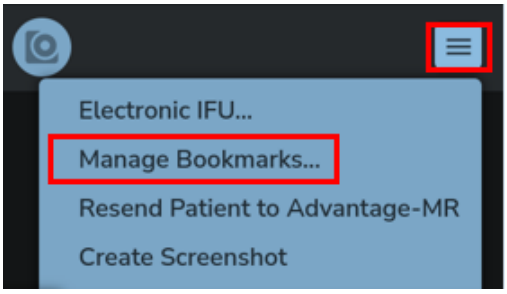
To create a Bookmark, right-click on the desired object either in the main viewing area or in the Mapping Objects List and select Create Bookmark. A dialog box appears for the user to customize the bookmark name. The user can enter the name of the bookmark or the default name can be accepted.



For example, once the left anterior oblique (LAO) and right anterior oblique (RAO) orientations are scanned, bookmarks can be created from those scans and named as LAO and RAO for easy reference to those orientations. This allows the same scan positions and/or orientations to be repeated later during the procedure.

Bookmarked MR images record the Position and Orientation of the MR image while Bookmarked Points record only the Position of the point.

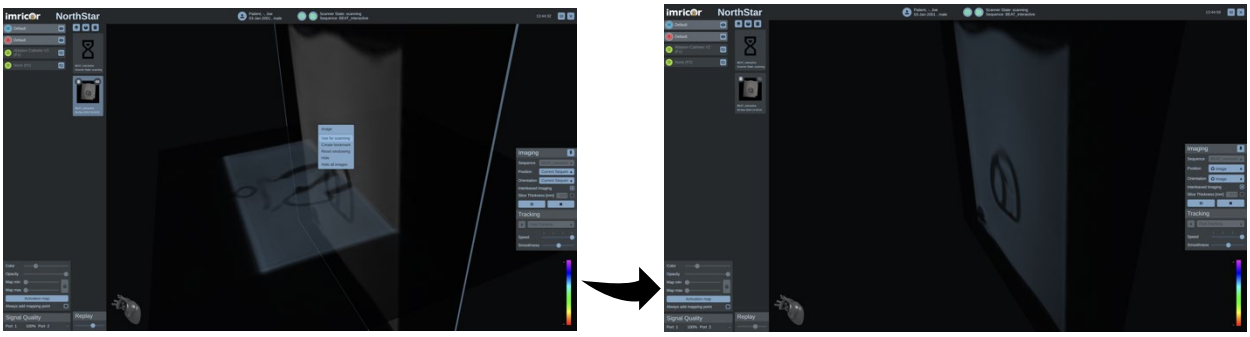
To rename or delete a Bookmark, select the Status Bar Menu and click on Manage Bookmarks. The list of bookmarks is displayed. Clicking the delete icon will delete the bookmark. Clicking the name of the bookmark will allow the user to rename the bookmark.



Use for Scanning

The Use for Scanning functionality allows the user to set the current or upcoming scan to locations and orientations of interest without requiring a bookmark.

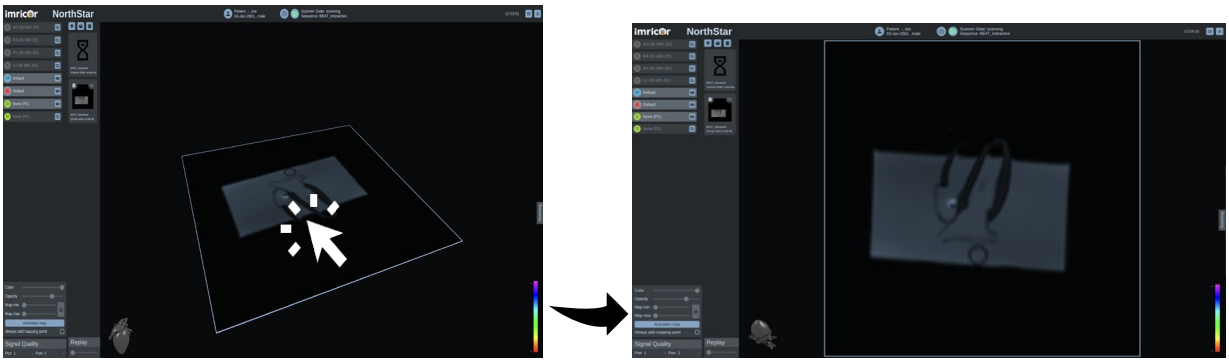
To use an object for scanning, right-click on the desired object either in the main viewing area or in the Mapping Objects List and select Use for Scanning. The position and orientation dropdowns in the scanning menu will be automatically populated with the selected object. If an interactive scan is currently running the position and orientation will be set to that of the selected object. Otherwise, the scan will still need to be started by pressing the play button.



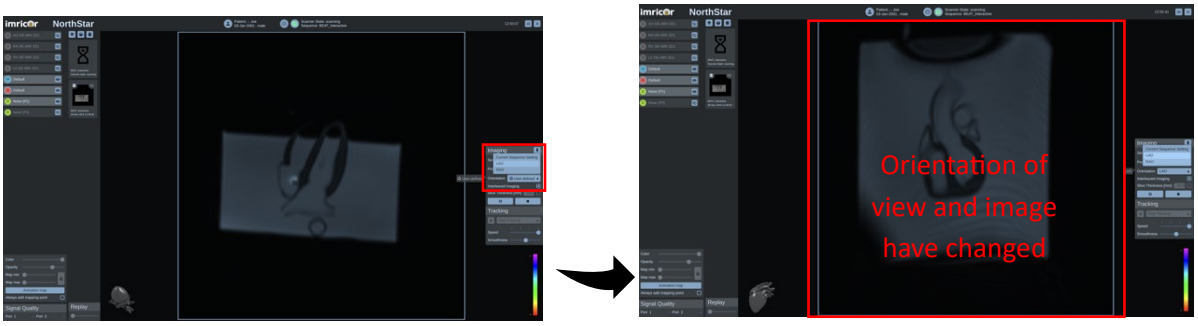
The resulting position and orientation in the scanning menu dropdowns are temporary. If a different object is used for scanning or the study is ended, the previous position and orientation in the scanning menu dropdown is no longer available.

2D Mode

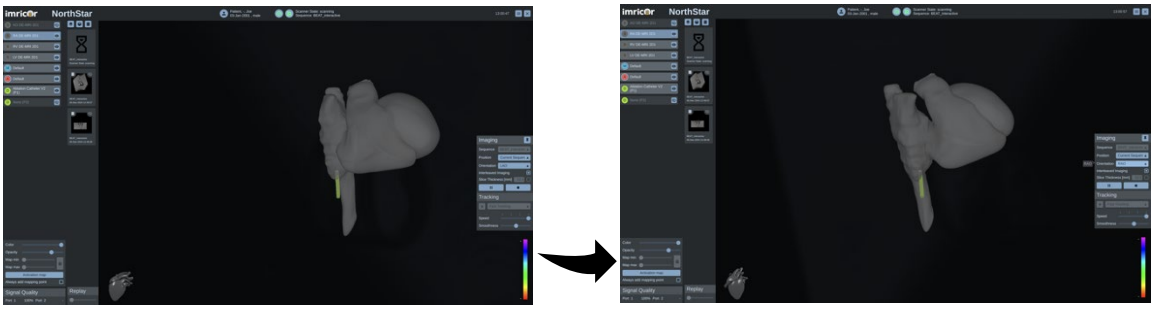
To snap any visible scan plane into a 2D mode where the main view is locked onto the scan plane and 3D rotation is disabled, double click the plane in the 3D view. In this mode the scan plane can still pan, zoom, and rotate with slice manipulation.



This can be used in conjunction with preset bookmarks to quickly switch between views. To do this, start an interactive scan and double click the image that appears to go into 2D Mode. Switch between views by selecting the bookmarks in the orientation dropdown of the scanning menu,



This can also be done with shells, but the scan must still be running with imaging enabled. The opacity of the image can be turned down to make the shells and catheter more visible.

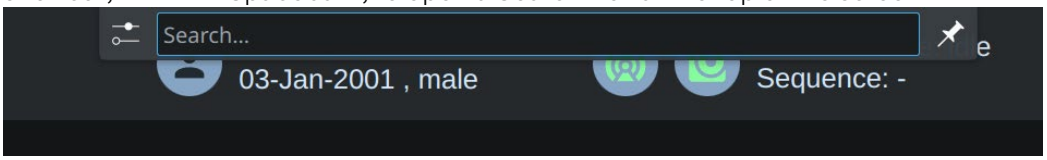


Display 3D Representations of Anatomical Structures

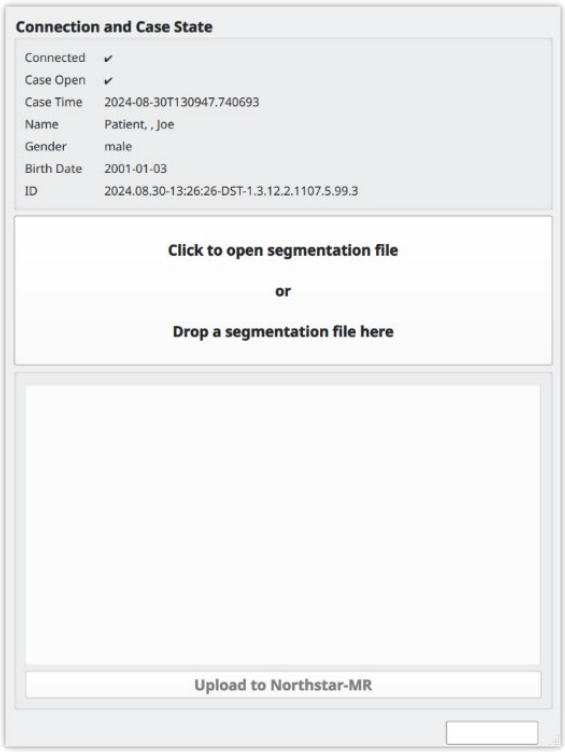
Anatomical 3D shells and/or volumes of the anatomy can be imported into the NorthStar Mapping System from compatible segmentation software, such as ADAS 3D (ADAS3D Medical S.L.) and Medical Imaging Interaction Toolkit (MITK). For information on how the segmentation software creates the 3D shells or volumes refer to the manufacturer's IFU.

Import 3D shell or Volume

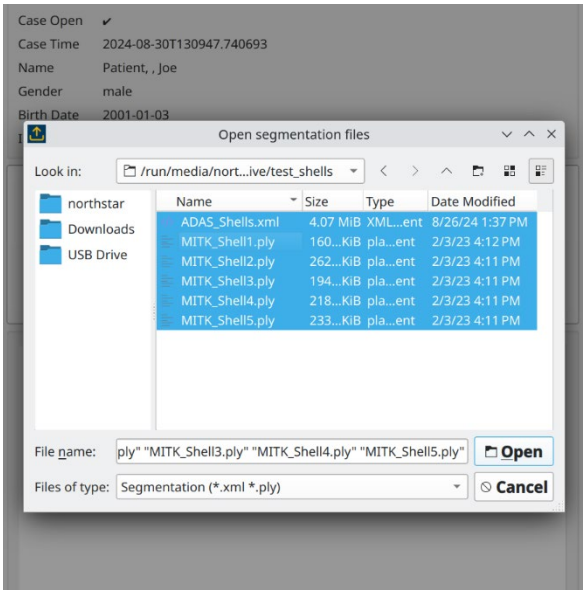
- To import the 3D shell or volume into the NorthStar Mapping System, use the keyboard shortcut, <Alt> + <Spacebar>, to open a Search Box at the top of the screen.



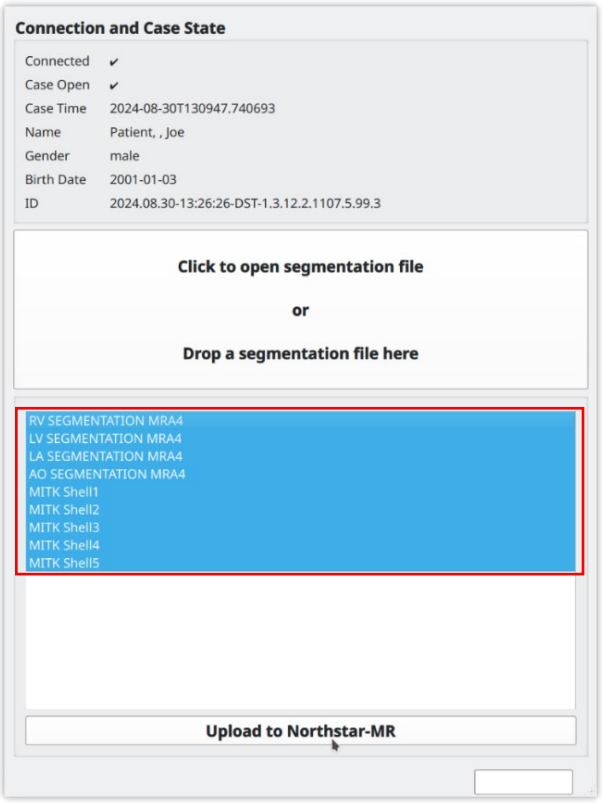
- Enter the term: “Uploader” in the text field to open the uploader software and select Click to Open Segmentation File.



- Select the USB drive in the left pane, then select the segmentation file(s) to be imported in the right pane and click Open.

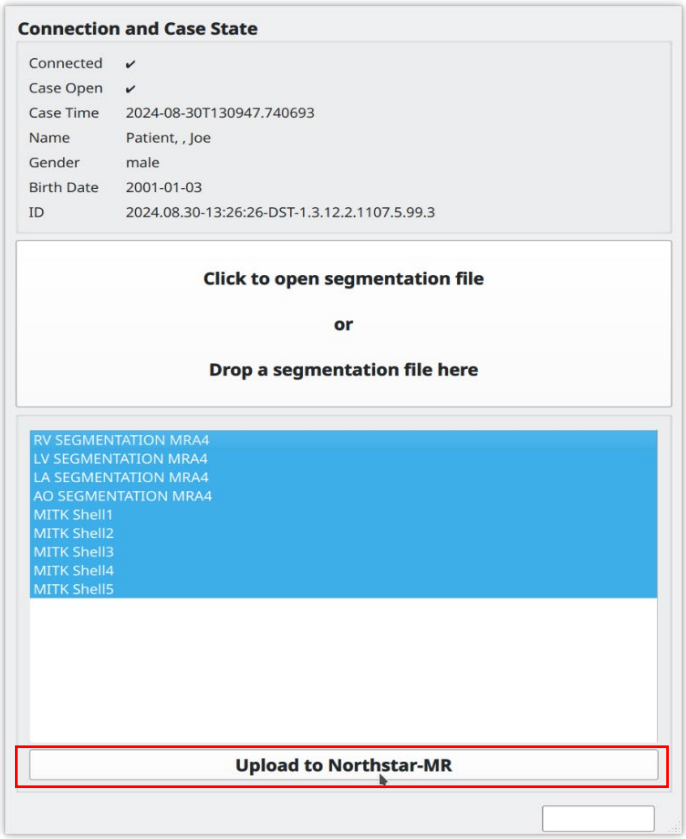


- The available segmentations are displayed in the bottom pane. Select the segmentations to be imported by clicking to highlight.

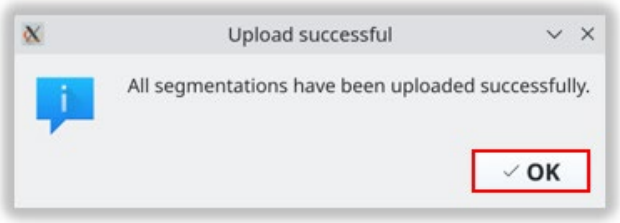


Note: to select all segmentations available select one item, hold down left click, and drag the mouse over all the other elements

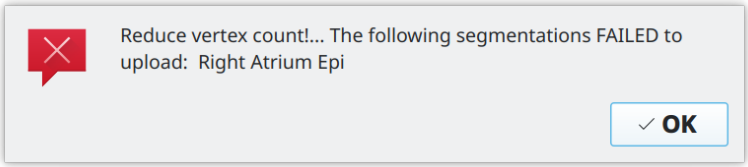
- Click Upload to NorthStar-MR.



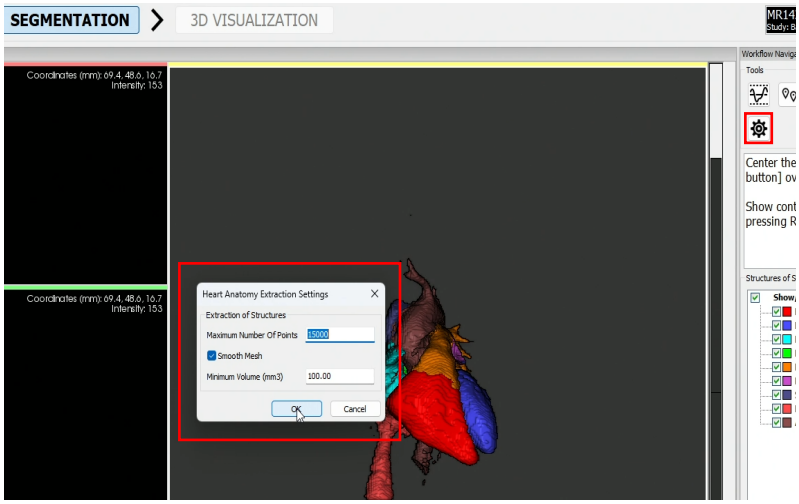
- Wait for upload success prompt and click OK.



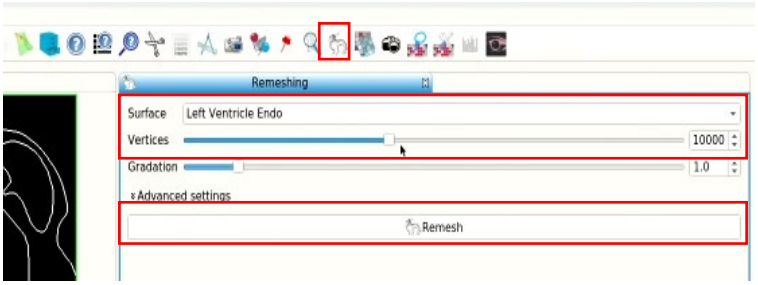
Note: If presented with the following error message use the remeshing tool in MITK to reduce the vertex count to under 19999 for each of the listed segmentation



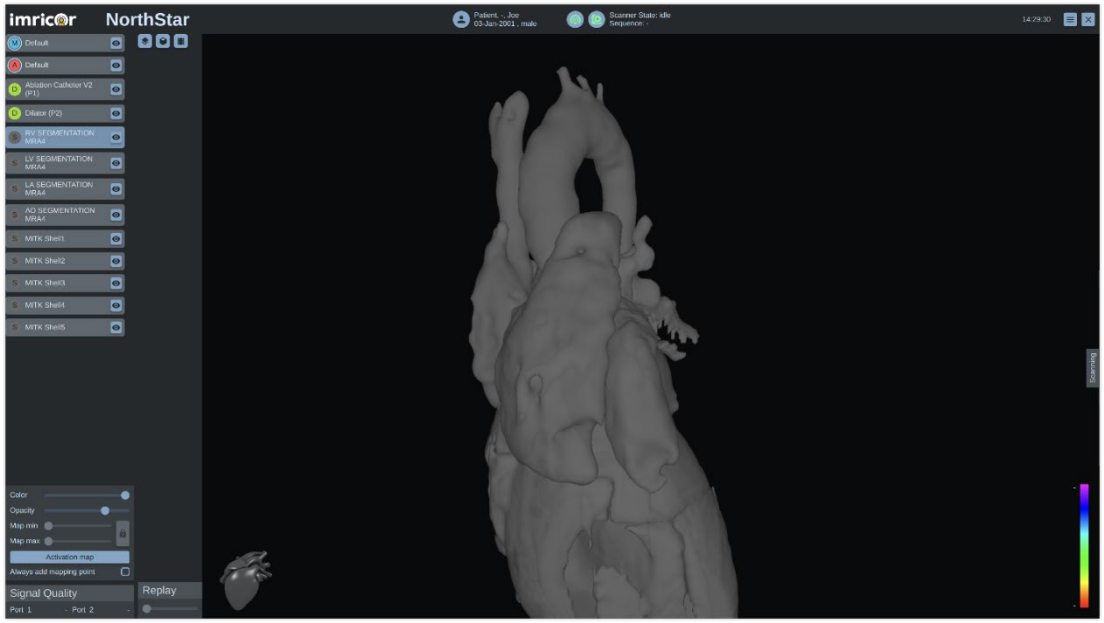
Setting the vertex count in ADAS:



Setting the vertex count in MITK:

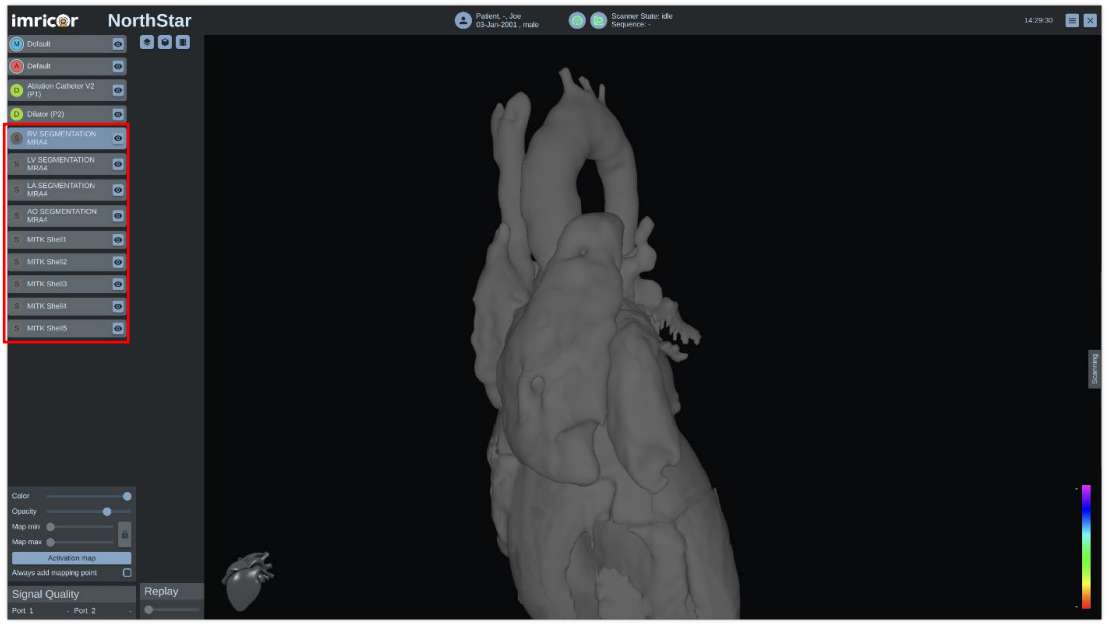


- Press <Alt> + <Tab> to get back to the Main Screen.

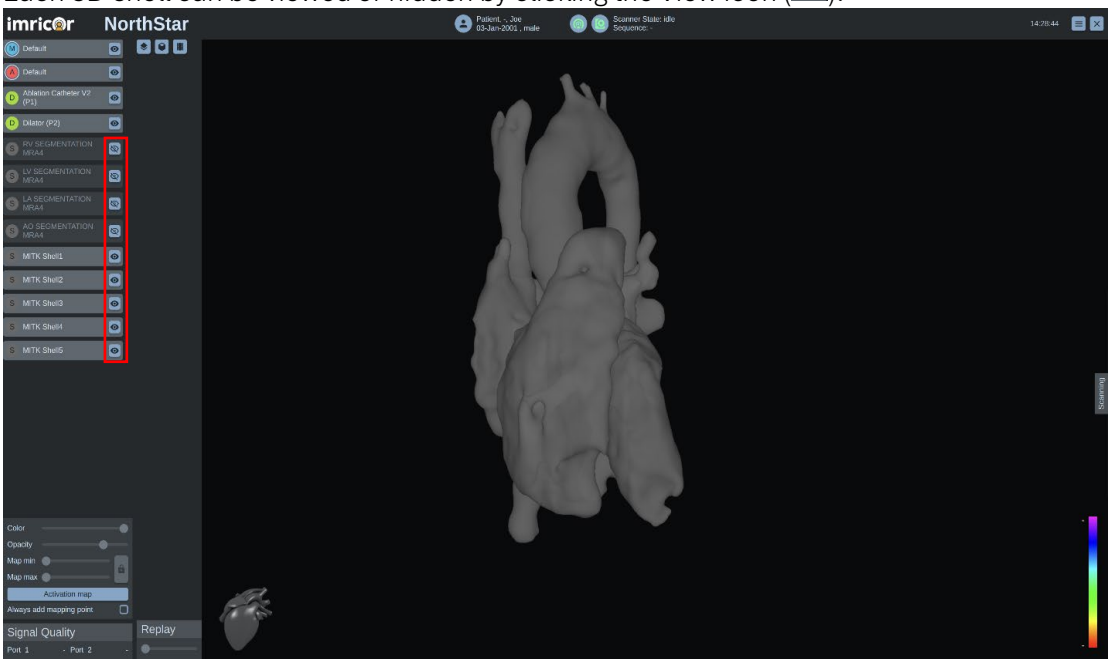


Display 3D Representations of Anatomical Structures

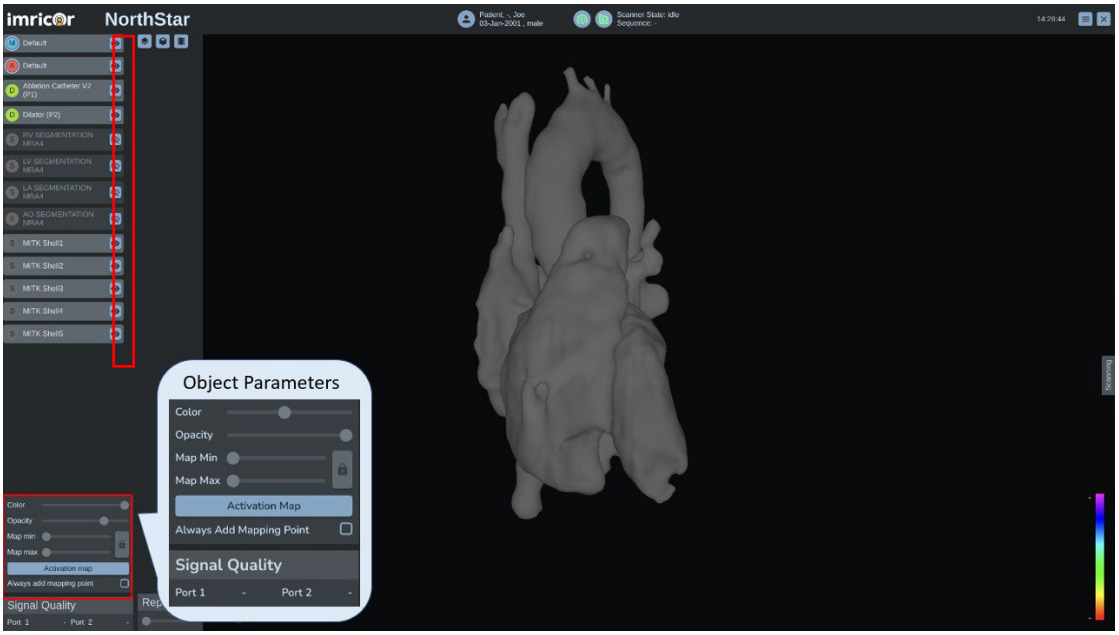
- The 3D shells and volumes are displayed in the Mapping Objects List in the NorthStar Mapping System.



- Each 3D shell can be viewed or hidden by clicking the View icon ( ).



- To modify the Color and Opacity of the segmentation, ensure the object is visible (), click on the object icon or label to select the segmentation, and adjust using the Color or Opacity slider in the Object Parameters Control Menu.

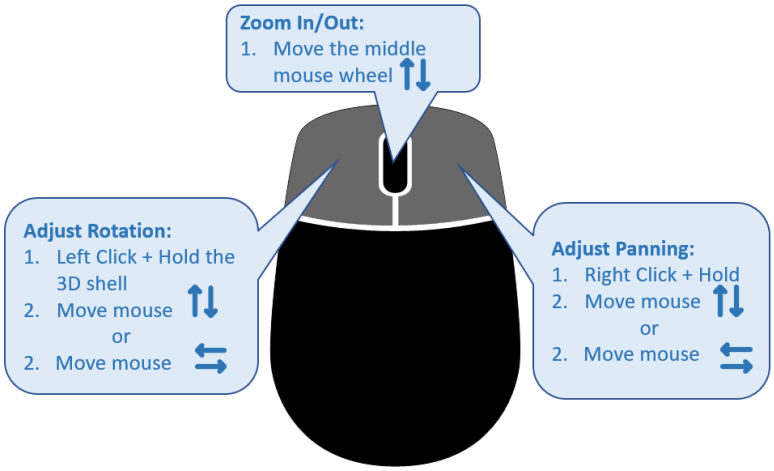


Object Parameter	Description
Color	Selects the color of the 3D shell/Segmentation
Opacity	Selects the opacity of the 3D shell/Segmentation

- A reference orientation of the 3D shell is displayed via the heart icon at the bottom left corner of the screen.



- The orientation of the 3D shell can be manipulated using the mouse.



WARNING: The anatomical shell(s) may become misaligned if the patient moves with respect to the bed. If anatomical shell(s) appear misaligned, it may be necessary to recreate or realign the shell(s) using the segmentation software. Please refer to the segmentation software instructions to either recreate or realign the shell(s). Previously acquired electroanatomical mapping points and/or ablation points may not align with the new or realigned shell(s).

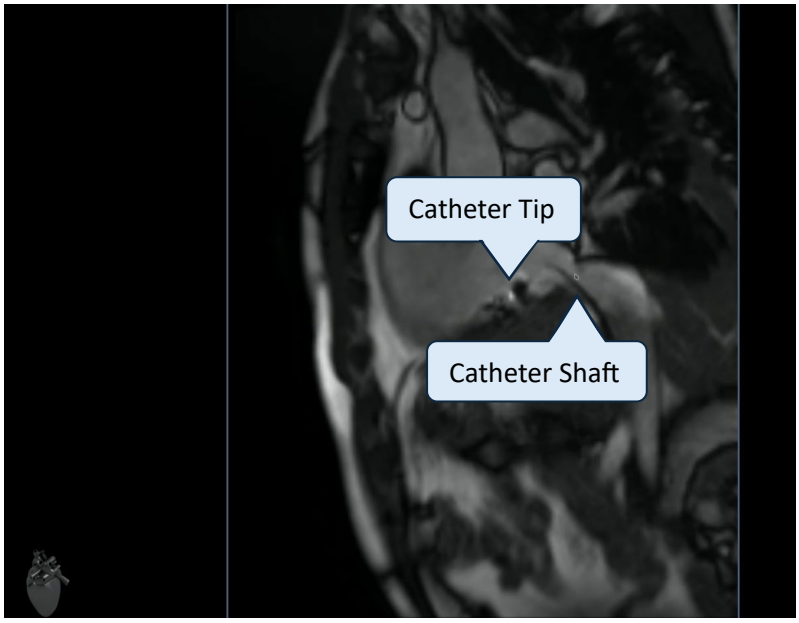
Interventional Device Location

NorthStar can display interventional device location using at least one of the three different methods: Passive Tracking, Active Catheter Imaging, or Active Tracking. To use Active Catheter Imaging or Active Tracking, the device must incorporate at least one miniature MR receive coil (coil). Any device with or without coil(s) can be located using Passive Tracking.

Passive Tracking

The catheter can also be visualized using standard MR imaging techniques by selecting an imaging plane that intersects with or is parallel to a subsection of the catheter shaft. Visualizing the catheter by either voids or local areas of enhancement it creates in MR images is referred to as Passive Tracking or visualization. Passive Tracking does not use active electronics or communication with the MR scanner to determine the catheter position. It relies solely on identifying the catheter in MR images of the cardiovascular anatomy.

If the interventional device includes receive coils, disable the coils in the scan sequence on the MR scanner computer. The receive coils will be less visible in the MR image, allowing the device to be seen more clearly.



NOTE: When passively tracking, the scan plane will not follow the location of the interventional device because tracking is not active.

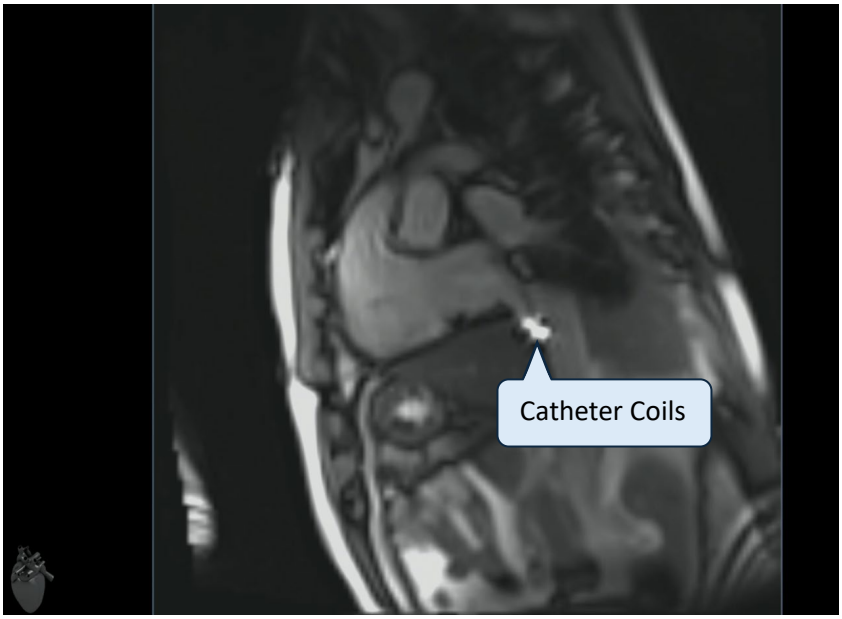
Active Catheter Imaging

Active Catheter Imaging refers to the process of using MRI signals received by miniature MR receive coils on a medical device to visualize the position of the device in real-time. During Active Catheter Imaging, the coils appear as bright spots in the MR image. The imaging plane can be either manually or automatically interactively manipulated during imaging to keep the coils in the imaging plane. To facilitate Active Catheter Imaging,

To facilitate Active Catheter Imaging, Imricor interventional devices integrate at least one coil into the device. When used for Active Catheter Imaging, each coil in the catheter is connected to a receive channel of the MRI via Advantage-MR and the MR scanner interface. This allows the MR scanner to receive signals from the coil(s) in the device.

On NorthStar, the device can be visualized using Active Catheter Imaging by making the device rendering invisible via the eye icon for that device. Set the scan plane position to the trackable interventional device to automatically update the live image position to the device's location as the device moves.

Refer to the Compatible Equipment section of this IFU for compatible interventional devices with active tracking coils.



Active Tracking

Active tracking refers to the process of using MRI signals received by miniature MR receive coils on a medical device to track the position of the device in real-time. It is an automated and continuous process of determining the device position and visualizing the device in MR images or segmented shells representing relevant anatomic structures.

To facilitate active tracking, Imricor interventional devices integrate at least one coil into the distal end of the device. When used for active tracking, each coil in the device is connected to a receive channel

of the MRI via Advantage-MR and the MR scanner interface. This allows the MR scanner to receive signals from coils in the device.

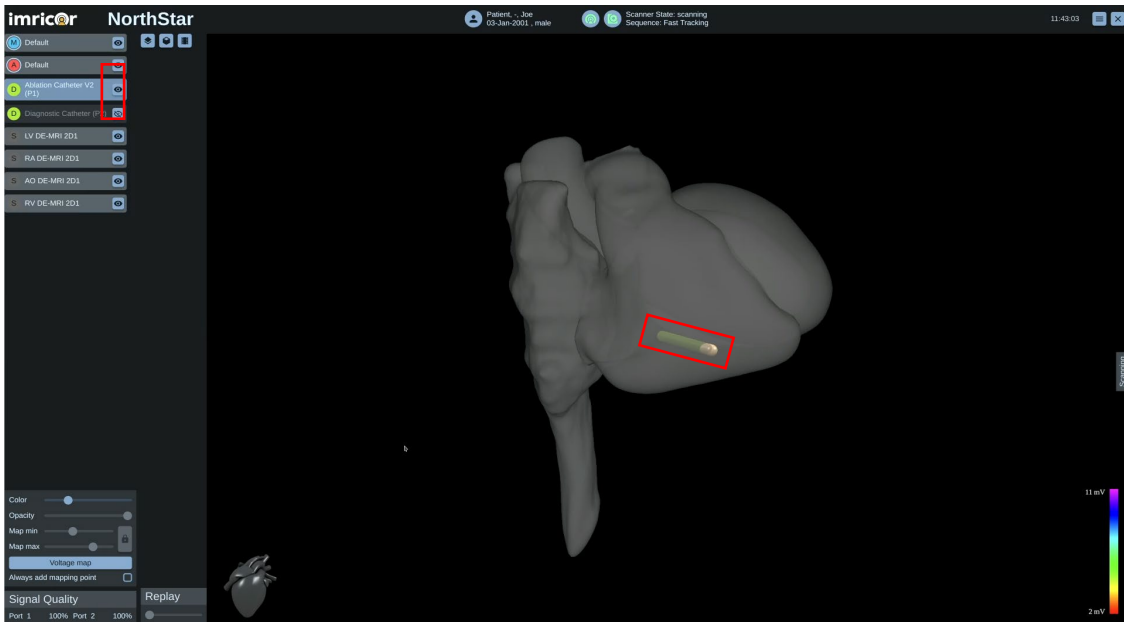
Refer to the Compatible Equipment section of this IFU for compatible interventional devices with active tracking coils.

Device Selection and Display

To actively track an interventional device, select the interventional device on Advantage-MR by right clicking on the EGM label for each device and selecting the device from the dropdown.

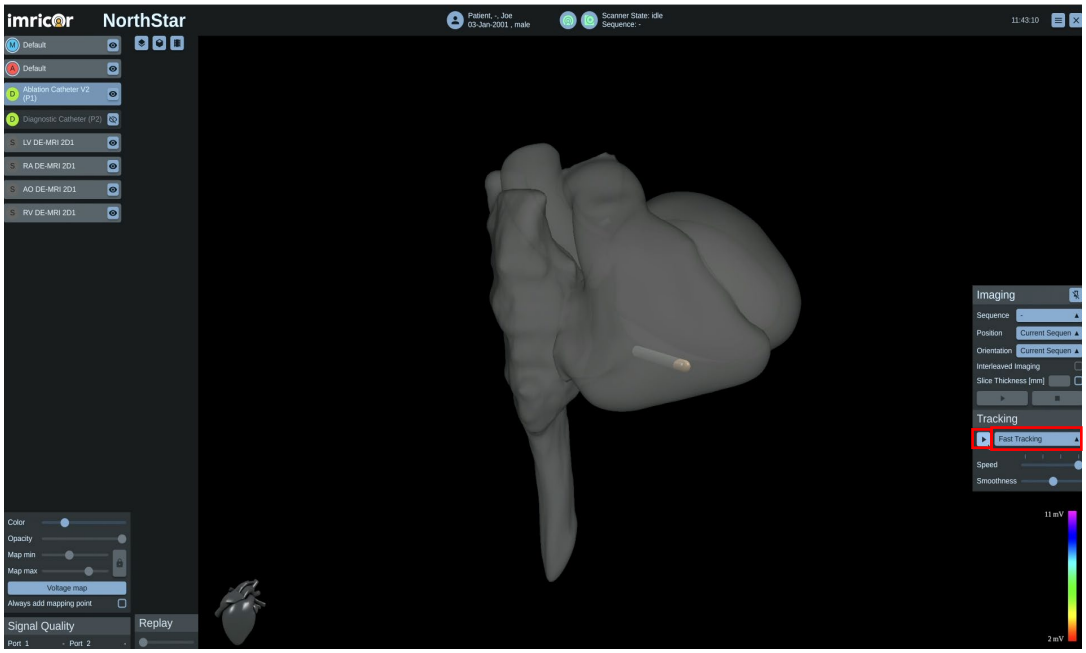


To display a compatible interventional device that is connected to the Advantage-MR System click the View icon ( ) for the device in the Objects Menu.

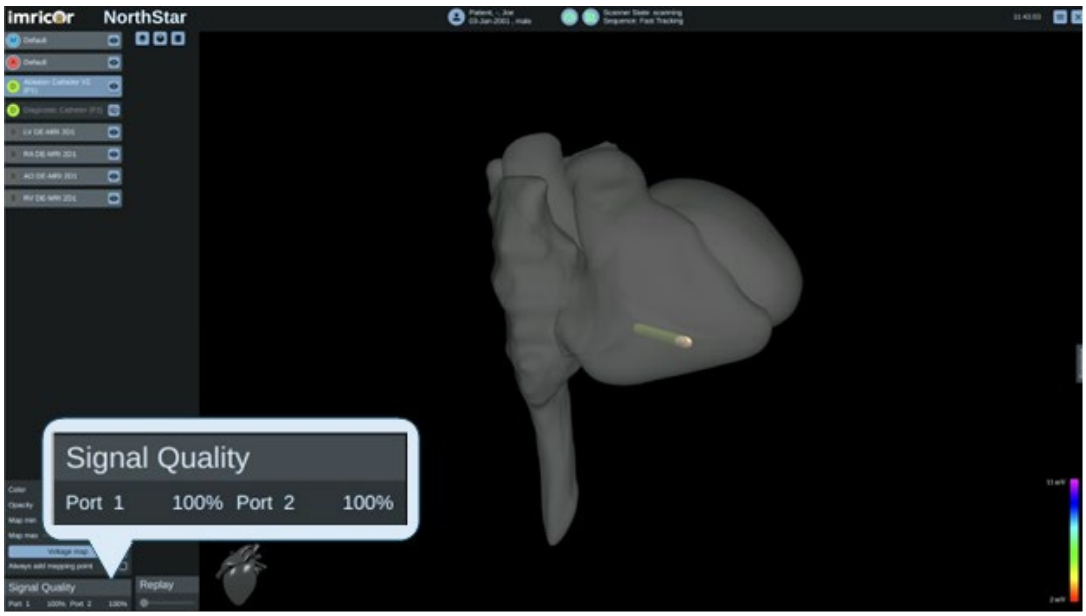


Device Tracking

To track the compatible interventional device, initiate a tracking MR scan, as described in the Display MR Images section. Select the Tracking Sequence and click the Play button ( ).



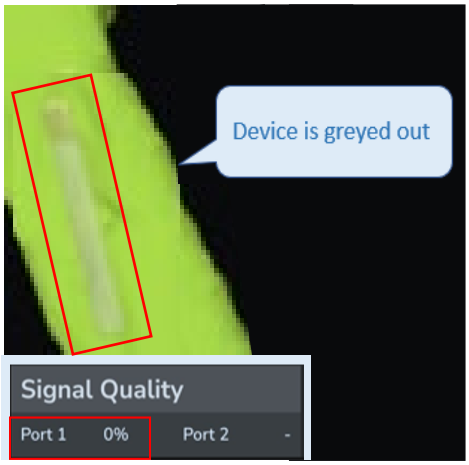
The reliability of the location of the interventional device rendering is dependent on the tracking signal quality. The Signal Quality is displayed in the lower left corner of the screen.



The Signal Quality of the interventional device must be greater than 50% to render the device in the user selected color. If the Signal Quality of the interventional device is below 50% the device will be rendered as grey to indicate the poor signal quality to the user.



High Signal Quality



Low Signal Quality

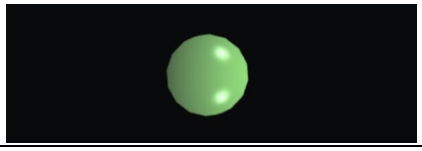
WARNING: To avoid incorrect placement of the interventional device, the user should use multiple means of verifying interventional device positions within the anatomy, including:

- MRI techniques, such as Passive Tracking, Active Catheter Imaging, Active Tracking, real-time imaging, and interleaved imaging.
- Real-time intracardiac electrograms (for electrophysiology procedures) displayed on Advantage-MR.

Device Rendering

The interventional device rendering location is determined based on the receive coils. A compatible interventional device with two or more receive coils is displayed as a rendered tip with orientation. An interventional device with only one receive coil is displayed as a rendered point at the receive coil location. The table below shows examples of how compatible interventional devices with tracking coils are rendered in the NorthStar Mapping System:

Interventional Device	Number of coils	Interventional Device Rendering (color of rendering is selectable)
Vision-MR Ablation Catheter 2.0	2	Rendering of location and orientation of tip: 
Vision-MR Diagnostic Catheter	1	Rendering of the coil (located approximately 10mm proximal to the tip of the catheter):

Location Accuracy

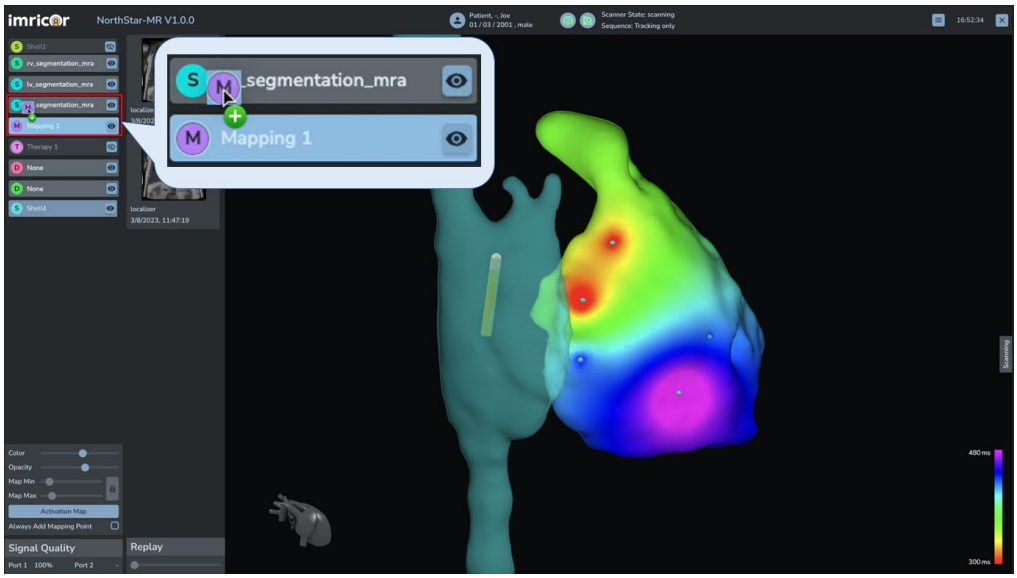
A device rendered in NorthStar is displayed on average within 5mm of the actual device's location.

Electroanatomical Mapping

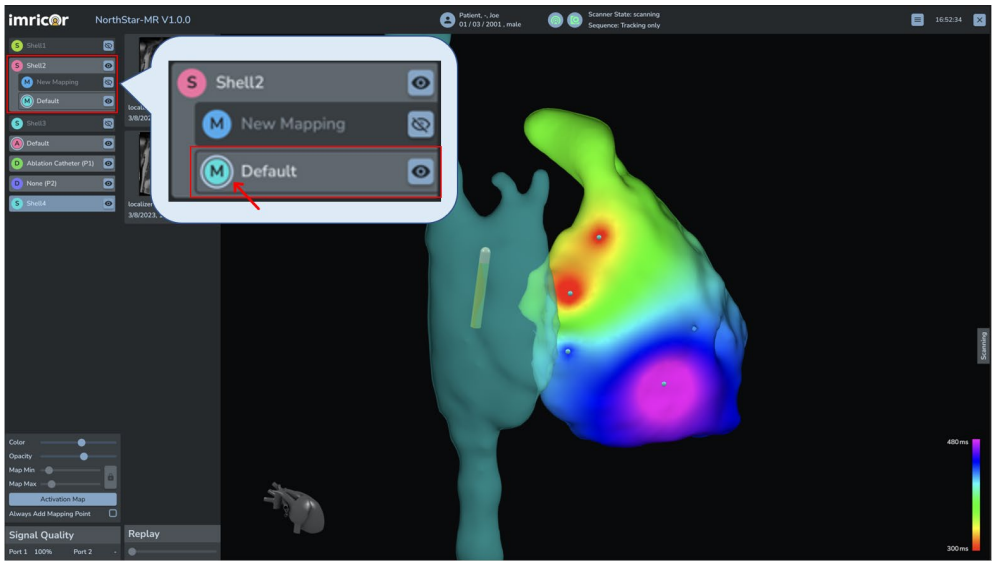
Electroanatomical Maps (EA maps) are continuous color gradient maps showing areas of higher and lower activation or voltage measurements. The electroanatomical map can be shown on the 3D shell displayed in the NorthStar Mapping System. The Advantage-MR System measures activation times and voltages which can be transferred to the NorthStar Mapping System. NorthStar can then combine those measurements with the tracked device location to place the measurement on the 3D shell.

Creating and Activating a Mapping Point Set

To create an electroanatomical map associate a Mapping Object to a 3D shell by clicking and dragging that Map Object onto the desired 3D shell Object in the Mapping Objects List.



The active Map Object is indicated by a white outline located around the Map Object icon. This is the map where new measurements will be placed.

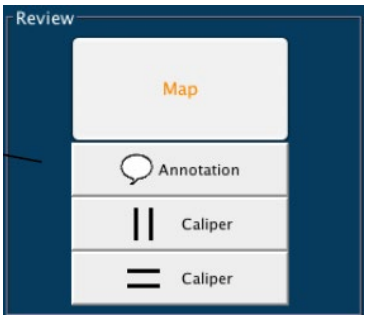


The Map Object may be dissociated from the 3D shell Object by right-clicking on the Map Object and selecting Unlink from Shell.

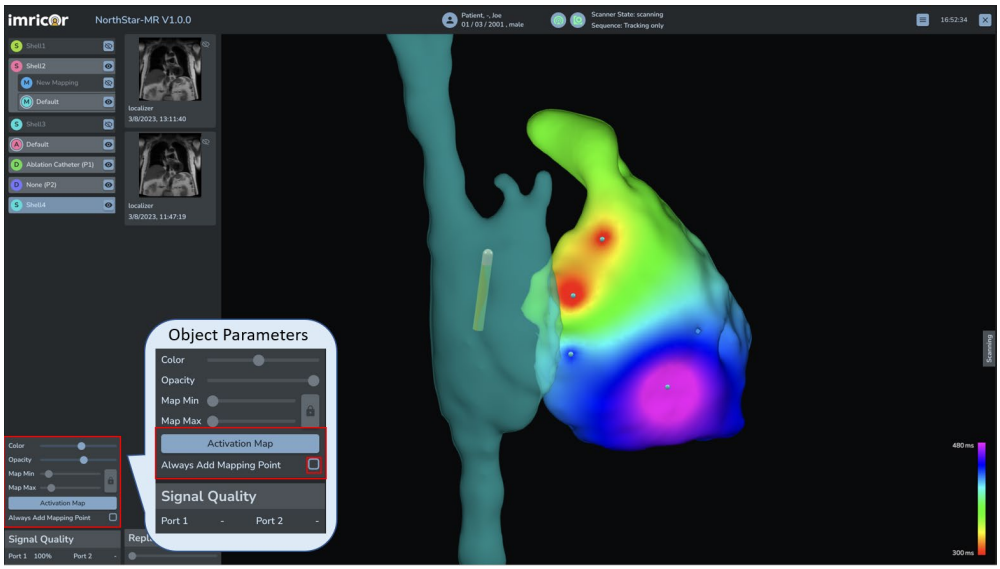
Adding Measurement Points to a Mapping Point Set

There are two methods to add an activation or voltage measurements on the 3D shell:

Method 1 - Initiate from Advantage-MR): Click on the Map button in Advantage-MR System. This will explicitly send a mapping point measuring point to NorthStar.



Method 2 - Always Add Mapping Point¿Select the Always Add Mapping Point checkbox from the Object Parameters Menu to automatically add mapping points to the 3D shell when the second caliper is placed on Advantage-MR System.

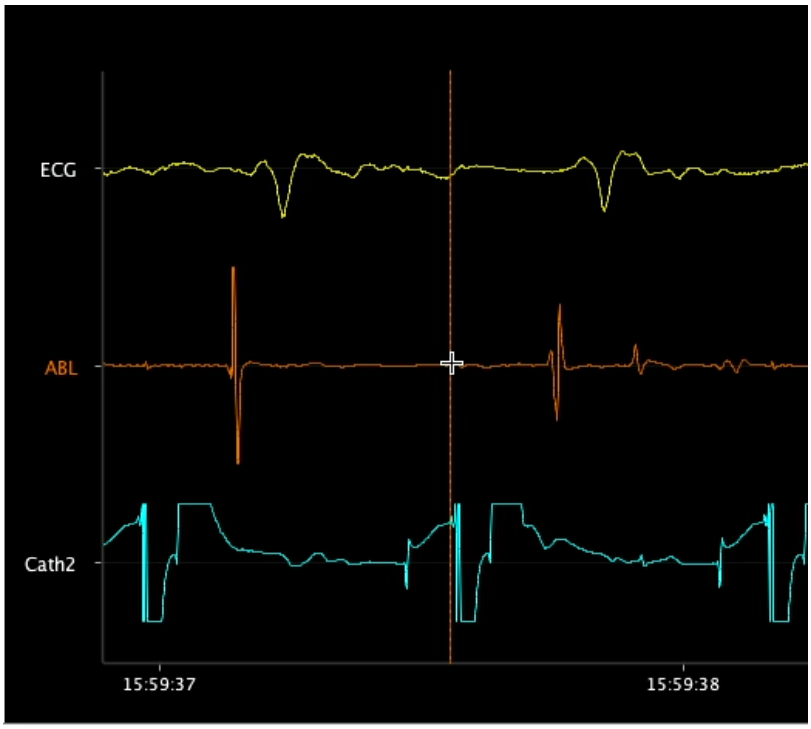


To send a mapping point from Advantage-MR to NorthStar, perform the following steps:

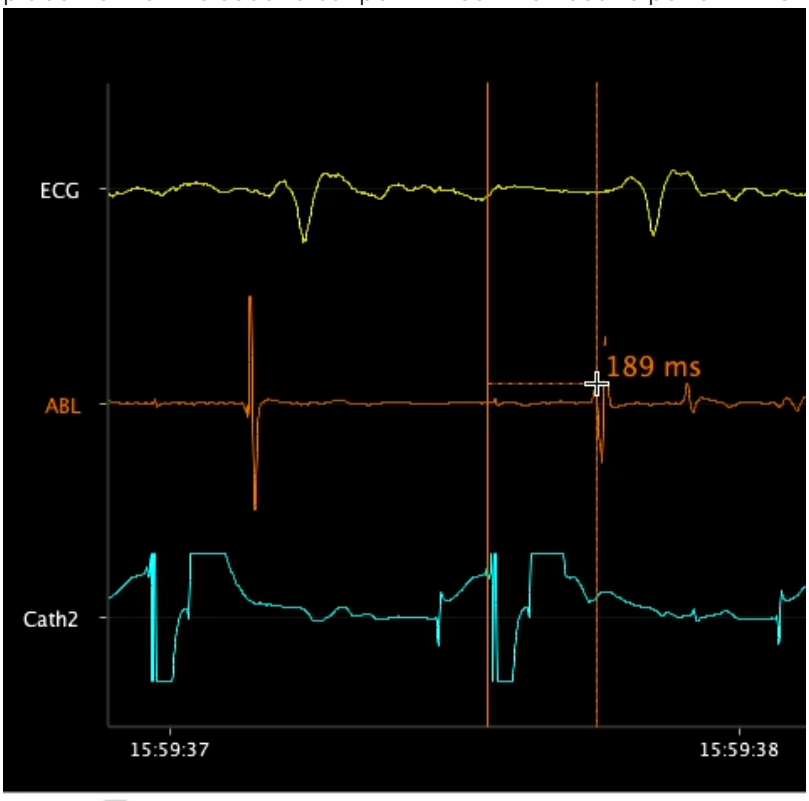
1. Select caliper (vertical calipers will create activation points and horizontal calipers will create voltage points)



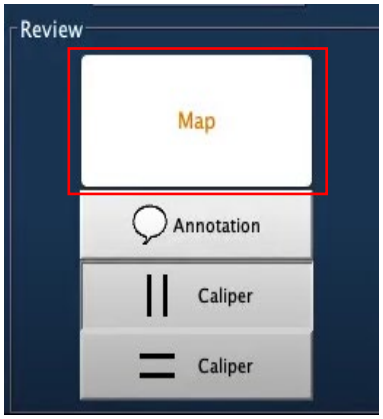
2. Make the waveform to measure visible in the Review Pane
3. Hover the mouse over the EGM associated with the device where the measurement point is to be placed so that the waveform is highlighted in orange. The highlighted EGM signal when you place the first caliper will determine which catheter in NorthStar the point is assigned to. The (P1) device in NorthStar corresponds to the ABL EGM channel in Advantage-MR and the (P2) device corresponds to the Cath2 EGM channel in Advantage-MR.



4. Place the calipers. The active waveform at the time of the placement of the first caliper determines which catheter the point will be placed at in NorthStar.
   Note: If Always add Mapping Point is checked, the point will be added automatically on the placement of the second caliper without the need to perform the next step.

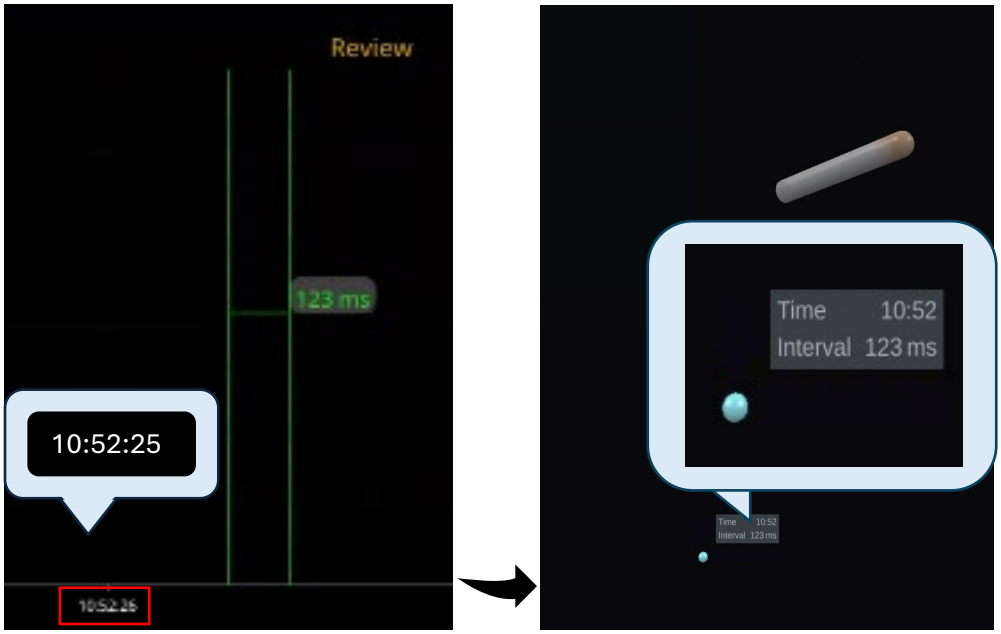


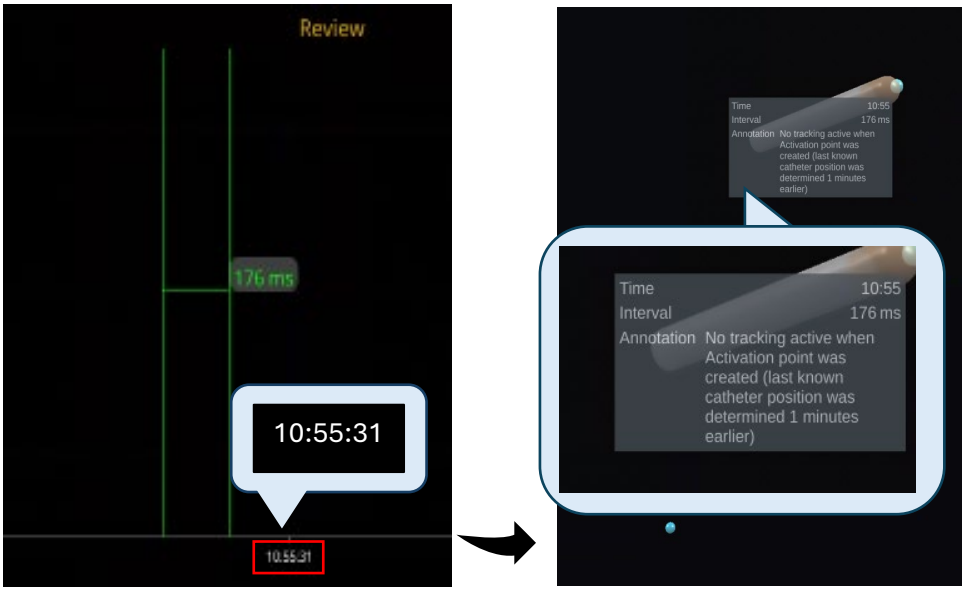
5. Click Map to send Mapping Point to NorthStar
   Note: If Always add Mapping Point is checked, the point will be added automatically without the need to perform this step.



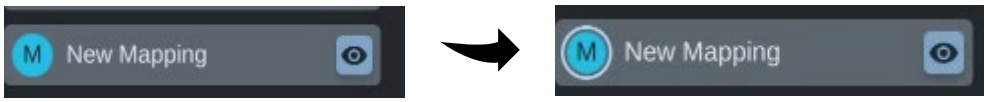
After receiving a caliper measurement from Advantage, a new Mapping Point will be placed at the location of the catheter tip corresponding to the point in the timeline on Advantage where the caliper measurement was taken.

E.g. If the caliper is placed 1 minute behind the latest data in the timeline on Advantage, then the mapping point will be placed where the catheter was 1 minute ago.





By default, Mapping Points will be placed in the Default Mapping Object. To change which Mapping Object new points are assigned to double click the 'M' icon, so that a white ring appears around the target Mapping Object.

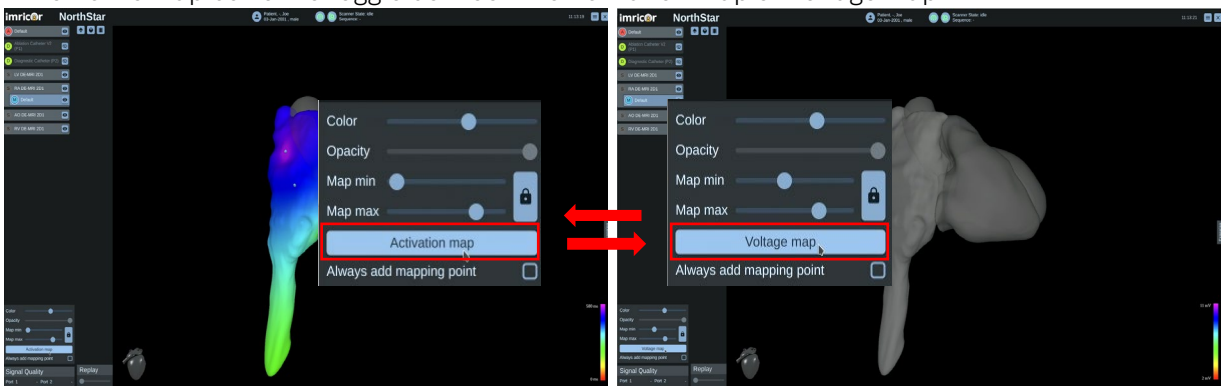


Viewing Measurement Points and Electroanatomical Maps

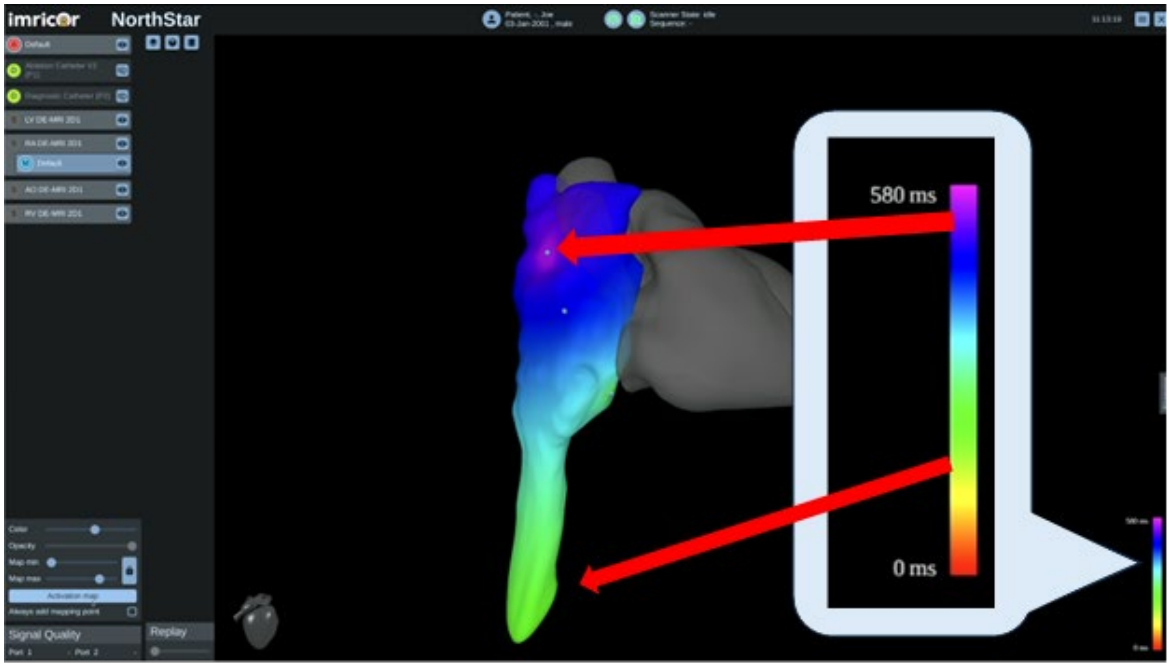
The mapping points are associated to the active Map Object and placed on the 3D shell at the location of the interventional catheter tip at the time of the measurement. Each mapping point is labeled with the timestamp, value recorded, and an optional annotation which can be used to record specific information relating to that mapping point.

Voltage Point with Annotation	Activation Point with Annotation
	

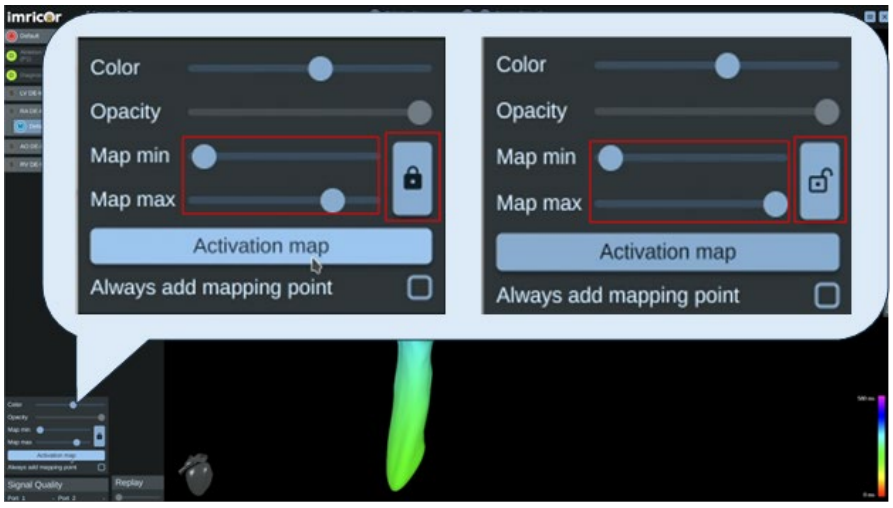
Click the Active Map button to toggle between the Activation Map or Voltage Map.



The map color gradients go from the lowest to highest measurement values according to the color scale located at the bottom right corner.



The minimum and maximum limits of the scale can be set automatically as the mapping measurements are taken or can be manually set by using the Map Min and Map Max slides. If the Lock symbol ( ) appears locked it indicates that the user has manually set limits of the scale. If Lock symbol appears unlocked, it indicates that the limits of the scale are set automatically. The user may unlock the limits and allow NorthStar to resume automatic scaling.

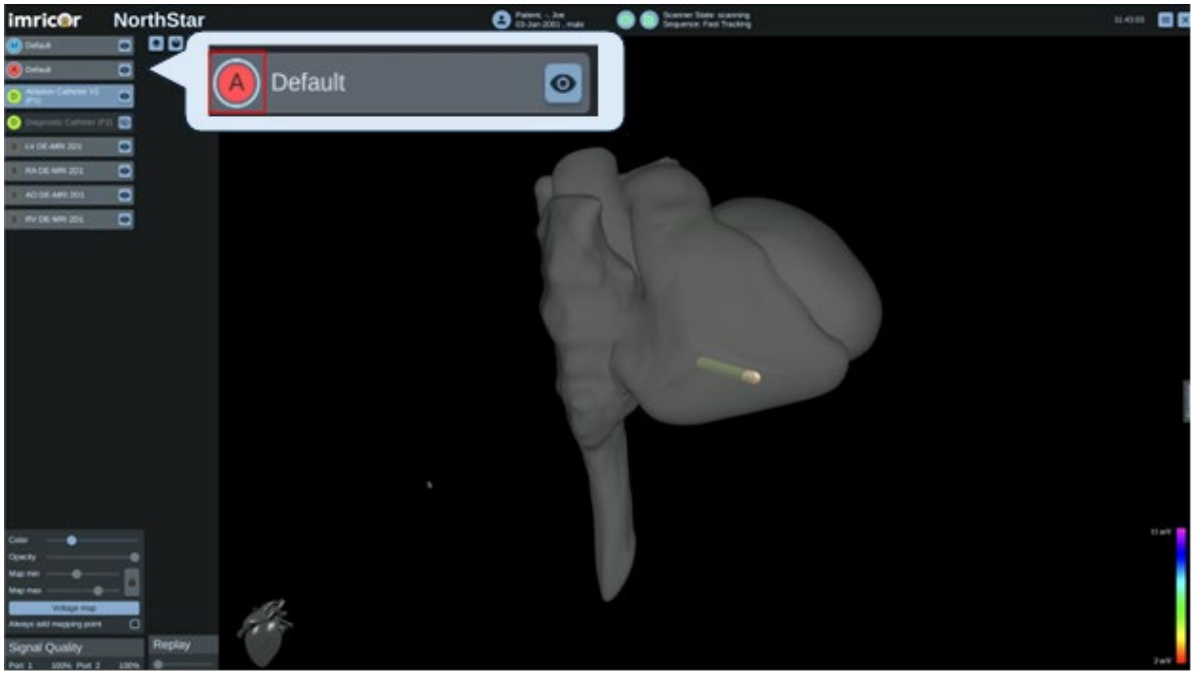


Display Ablation Points

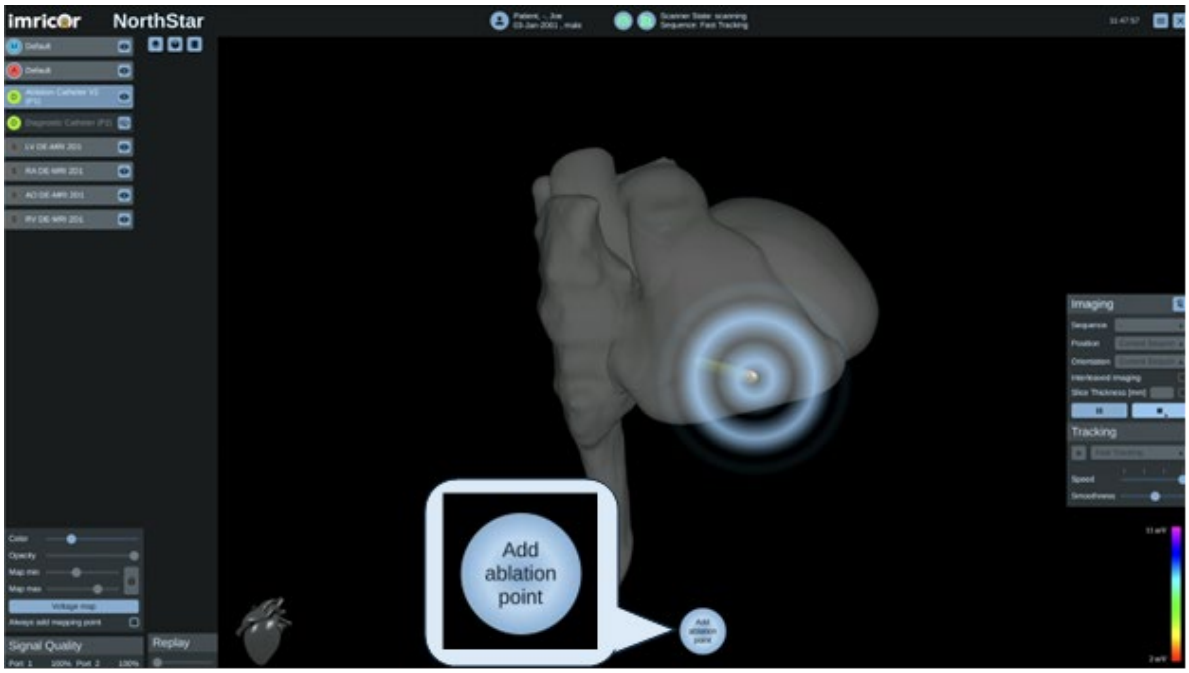
The NorthStar Mapping System can display ablation points on the 3D shell. When the NorthStar Mapping System is notified by the Advantage-MR System that an ablation is taking place, it displays a

pulsating animation and a button to manually add an ablation point. After an ablation is complete, the ablation point can display the ablation information when the cursor is hovered over the point.

- Ablation points are assigned to the active ablation point set when the ablation takes place. To assign an ablation point to a different point set, double click on the ablation point set object to which the point should be assigned.
- To create a new ablation point set, right-click in the Mapping Objects List and select New>Ablation. A new Ablation Object is created and can be associated to a 3D shell by clicking and dragging that Ablation Object onto the desired 3D shell Object.



- The Ablation Object may be dissociated from the 3D shell by right-clicking on the Ablation Object and selecting Unlink from Shell.
- Unlike associating a mapping point set with a shell (which determines which shell a colormap will be generated on), associating an ablation point set with a shell is for organizational purposes only.
- To manually add an ablation point, click the Add Ablation Point button which will immediately place an ablation point at the interventional catheter tip location. If the user does not click the Add Ablation Point button, the ablation point will be placed at the catheter tip location when the ablation stops. If another ablation is done at the same location, that ablation point data is added to the existing ablation point and another point is not created.



- Each ablation point displays the data collected during the ablation including the time stamp, duration, median power, maximum tip temperature, impedance drop, and an optional annotation. If the interventional device tracking is not active during an ablation, the Add Ablation Point button is not available, and the ablation point will be placed at interventional catheter tip's last known location. An annotation is automatically added to the point stating that tracking was not active.



- Ablation points can be deleted by right-clicking on the point and selecting Delete.

WARNING: To avoid incorrect placement of the interventional device, the user should use multiple means of verifying interventional device positions within the anatomy, including:

- MRI techniques, such as Passive Tracking, Active Imaging, Active Tracking, real-time imaging, and interleaved imaging.
- Real-time intracardiac electrograms (for electrophysiology procedures) displayed on Advantage-MR.

End Case

Close Current Case

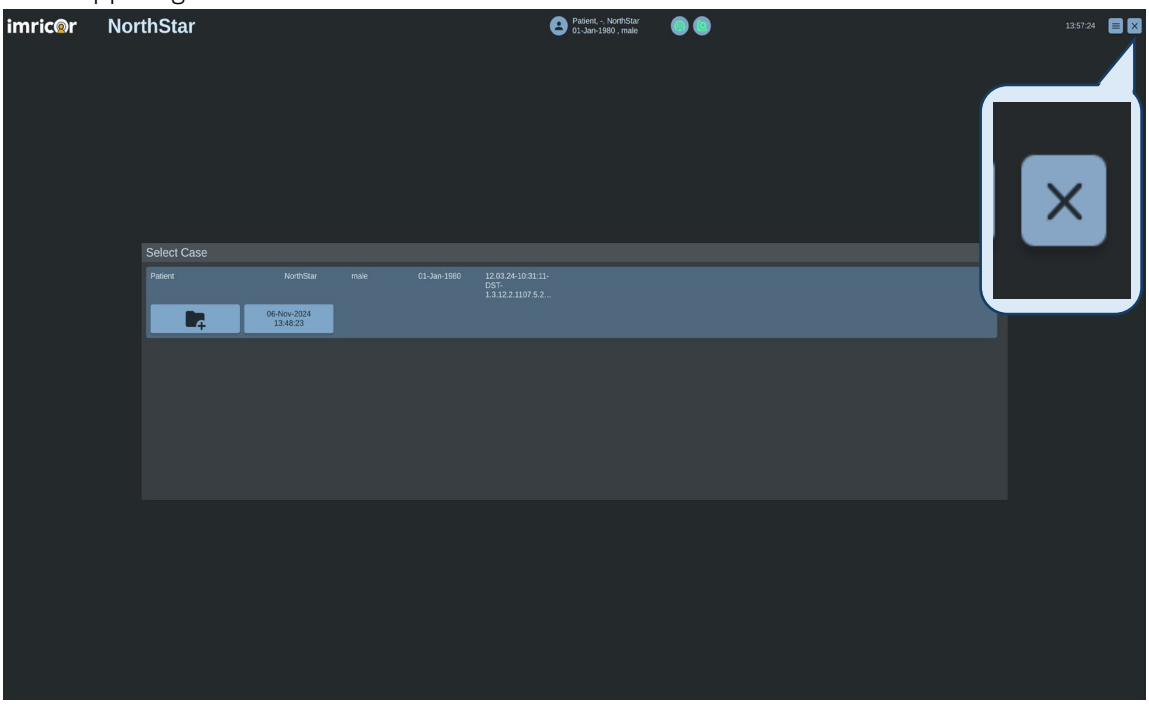
Once the study is complete and no scans are running, and shells are not being uploaded. The current case can be closed by clicking the ‘X’ button in the upper right-hand corner of the screen.



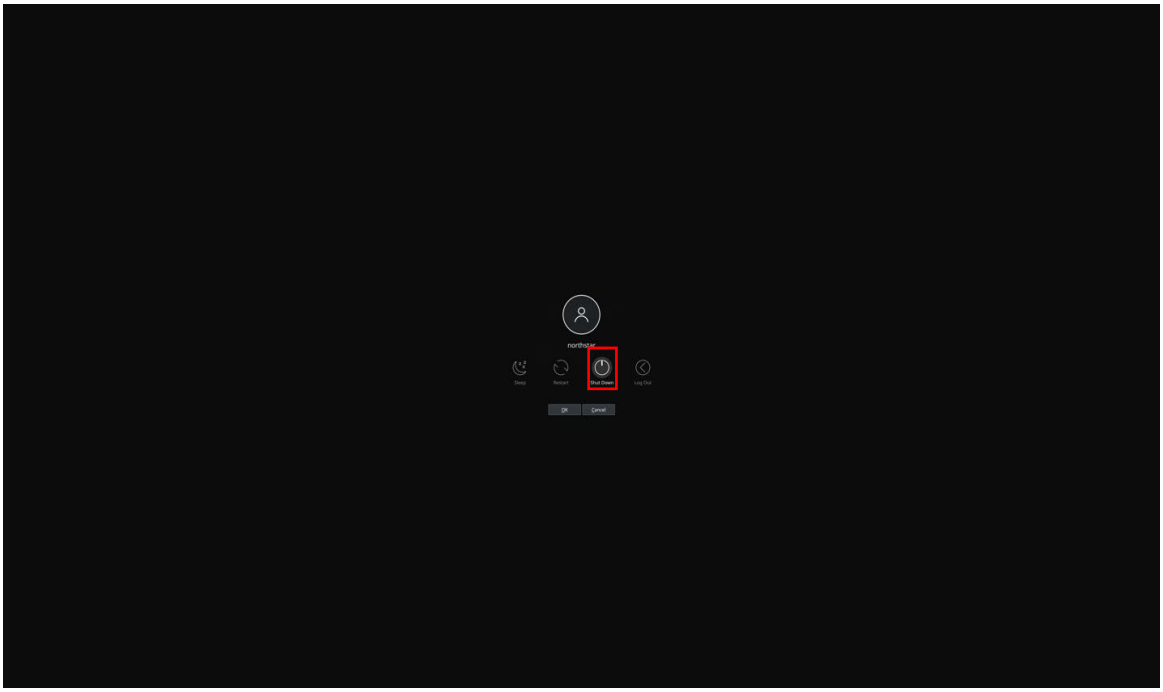
- Study data is automatically saved as the case progresses, so failing to close the case does not mean any study data will be lost.

Stop the Application and Shutdown

After use of the NorthStar Mapping System is complete stop the application by pressing the ‘X’ button in the upper right-hand corner of Case Select Screen.



Then, shutdown the computer by pressing the power button on the front panel of the computer and selecting Shutdown from the options that appear on screen.



Troubleshooting Guide

General Troubleshooting

Issue	Recommended Action
Unresponsive System	• Verify power cables are connected (computer and monitor) • Verify computer is powered on • Verify keyboard and mouse are plugged into the computer If all the above are verified and still unresponsive, restart the computer.
Monitor is not receiving video signal	• Verify monitor cables are connected (monitor and computer) • Verify monitor is powered on
Keyboard and/or mouse is unresponsive	• Verify the keyboard is plugged into a USB port on the computer • Verify the mouse is plugged into a USB port on the computer
Unable to login to the computer	• Verify that the correct username and password for the system has been entered • Verify that the CAPS LOCK is not on • Note: the password is case sensitive
NorthStar Mapping System does not start properly	• Restart the computer • Start the NorthStar program using the following steps: 1. Press <Alt> + <Spacebar> 2. Type “Northstar”, then press <Enter>

Functional Troubleshooting

If NorthStar performs irregularly, consult the table below. If the issue is not corrected by following the recommended action or if the symptom is not addressed, contact Imricor before further use.

Issue	Action
Device does not appear on NorthStar	• Verify catheter has been selected in Advantage-MR System • Verify Device Object is visible ()
Device does not change from grey	• Verify physical catheter connection to Advantage-MR System • Verify physical connection of the Advantage-MR PDI to the MRI scanner • Verify appropriate scan sequence for tracking • Verify the device is in the field of view • Take steps to improve signal quality
Cannot start a scan	• Verify Apply checkmark on MRI scanner has been selected • Verify the scanner is connected () • Verify MRI scanner table has been advanced into the MRI scanner bore
Scanning Menu is not available	• Verify the patient registered on the MRI scanner computer matches the patient info for the current case.
Patient registered on MRI does not show up on NorthStar	• Verify the scanner is connected ()
Cannot start a new case	• Verify a patient is registered correctly in the MRI scanner computer • Verify the scanner is connected ()
Advantage-MR shows an error about missing required information at the start of a case	• Verify all required patient information fields have been entered: ✓ First Name ✓ Last Name ✓ Patient ID ✓ Date of Birth ✓ Gender
Mapping points do not appear	• Verify the active Mapping Object is visible () • Verify Advantage-MR System is connected () • Verify opacity of 3D shell Object allows visibility • Verify opacity of the scan plane is set so that they should be visible • Verify the selected Activation/Voltage Mapping is set to the appropriate measurement being taken (i.e., select Voltage Map when taking voltage measurements).
Mapping points appear when they are not expected	• Verify Always Add Mapping Point is not checked
Ablation points do not appear	• Verify the Ablation Object is visible () • Verify the visible Ablation mapping is set to receive incoming ablation points
Electroanatomical (EA) Map does not appear	• Verify the EA Map Object is visible () • Verify the EA Map Object is associated to the 3D shell Object and that the 3D shell Object is visible () • Verify the limits of the map are set correctly

Issue	Action
Scan sequences do not show up in the scanning list	• Verify the Access-i ADDIN has been attached to the sequence
Tracking only sequence does not show up in Tracking Only section	• Verify “Tracking” has been included in the sequence name
MR images are distorted	• Verify the correct imaging coils are enabled in the sequence parameters on the scanner. The coils within the current scanning area of interest should be turned on • Verify the scan plane is in the correct location in NorthStar by comparing its location to other objects, e.g. shells, past scans, etc. • Verify the image is in the correct location on the scanner by running an imaging scan using the last scan sequence’s settings

NorthStar Messages

NorthStar may display messages throughout a case to provide information to the user.

Message	Action
Patient successfully sent to Advantage-MR.	• No action necessary.
Savelog creation completed.	• No action necessary.
Sending patient to Advantage-MR failed.	• Verify a patient is registered correctly in the MRI scanner computer • Verify the scanner is connected () • Verify Advantage-MR is connected ()
No connection to Advantage-MR, sending patient to Advantage-MR failed.	• Verify Advantage-MR is connected ()

Calculating slice orientation failed	• Scan and do one of the following:
	  • Use a different orientation for the scan sequence
	  OR
	  • Start the scan from the MR computer
	• Click the notification to dismiss the message.

Tracking sequence was started from MRI, tracking data won’t be forwarded.	• To actively track a device, start the tracking sequence from NorthStar • Click the notification to dismiss the message.
No active catheter in Advantage-MR, start scan is cancelled. Please select active catheter in Advantage-MR and try again.	• Select the interventional device on Advantage-MR by right clicking on the EGM label for each device and selecting the device from the dropdown
No Access-i authentication key for MRI connection configured. No connection MRI possible.	• Contact Imricor. An Imricor representative must enter the Access-i license. • Click the notification to dismiss the message.
Position could not be determined	• Follow the troubleshooting steps for a device that does not change from grey. • Click the notification to dismiss the message.
Time difference between NorthStar and MR is more than one day, clocks must be aligned.	• Align clocks on the NorthStar and MR scanner computers. • Click the notification to dismiss the message.

Message	Action
Time difference between NorthStar and Advantage-MR is more than one day, clocks must be aligned.	• Align clocks on the NorthStar and Advantage-MR computers. • Click the notification to dismiss the message.

MR Scanner Messages

The following MR scanner messages may be displayed on NorthStar when the MR scan sequences are initiated from NorthStar. For more information on these messages and appropriate actions consult the MR scanner manufacturer's Operator Manual.

Example MR Scanner Messages:

- SAR Limit(s) Exceeded
- Stimulation Warning
- Repositioning of Patient Required
- Sequence Boost
- Reference Amplitude Manipulated
- Automatic Table Movement
- Patient Information Correct?
- Stimulation Limits Exceeded
- Charge Balance Model Limit(s) exceeded
- SED Limits Exceeded

Maintenance

Operating and Cleaning Guidelines

- Keep the computer away from excessive moisture, direct sunlight, and extreme heat and cold.
- Keep liquids away from the computer and keyboard.
- Operate the computer on a sturdy, level surface.
- **Do not cover or block vent openings of the computer while it is functioning.**
- Turn off the computer and unplug the power cord before the following tasks:
  - Inspect all cables for damage, such as excessive pinching or crushing. Contact an authorized Imricor Service Representative if damaged cables are discovered.
  - While wearing disposable gloves, wipe the exterior of the system components with a soft cloth dampened with standard hospital equipment cleaning agents such as isopropyl alcohol or Cidex®, and dry with a clean cloth**. Do not spray or pour agents directly onto equipment and do not use acetone solvents. Do not submerge the cables.**
  - Clean the air vents on all vented sides of the computer. Lint, dust, and other foreign matter can block the vents and limit the airflow.
  - Use an antistatic screen cleaner to clean the monitors. Place the cleaner on a cloth and wipe the screen. Do not apply the cleaner directly to the screen and do not use window or glass cleaner on the monitors.
  - Be sure that surfaces have completely air-dried before turning the device on after cleaning.
  - After each hand washing or system cleaning, discard used disposable gloves.

System Service

Installation and service must be performed by an Imricor Service Representative.

Serviceable Life and Disposal

The NorthStar Mapping System has an expected service life of three years. Upon decommissioning of the NorthStar Mapping System, all components and cabling must be properly disposed of in accordance with the WEEE Directive 2012/19/EU and local regulations. Contact an authorized Imricor Service Representative to request system decommission and for guidance about appropriate disposal.

Specifications

Environmental Parameters			
Factor	Temperature (°C)	Humidity (non-condensing) (%)	Atmospheric Pressure (kPa)
Transport	-29-60	10–90	80-106
Storage	-20-45	10–90	80-106
Operating	10-35	10-80	80-106
AC Power Input			
Input voltage	100 to 240 VAC		
Input frequency	50/60 Hz		

Safety and Electromagnetic Compatibility (EMC)

The NorthStar Mapping System is comprised of components which are compliant to IEC 62368-1 Audio/video, information, and communication technology equipment – Safety requirements. The components have been individually evaluated for EMC. Refer to the accompanying documents for details and compliance information.

EMC Guidance

To help ensure safe performance:

- The NorthStar Mapping System shall be installed and put into service according to the EMC information provided. NorthStar is intended to be installed in an MR control room. Do not connect additional devices to the workstation as this can negatively affect the electromagnetic emissions and immunity of the workstation.
- Avoid placing NorthStar components adjacent to or stacked with other equipment as this can result in improper operation. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation.
- Portable RF communications equipment should be used no closer than 30 cm to any NorthStar equipment or cable to avoid potential degradation in NorthStar performance.

The following information helps ensure expected performance:

- Losses in communication between equipment will automatically recover within 30 seconds. If frequent loss of communication occurs, the environment should be assessed for potential interference. Contact an Imricor Medical System representative for assistance.
- During interruptions of power, the workstation may shut down. If this should occur, power the equipment on if necessary and resume work. The process of turning on the computer power and resuming a case may take up to 90 seconds. An uninterruptible power supply (UPS) may be used to prevent interruptions of power.

Essential Performance

The accuracy of an actively tracked device location is an essential visual aid for efficiently and effectively treating patients with NorthStar. The device location accuracy may become degraded beyond the specification. A Signal Quality value is provided to indicate the accuracy performance. Signal Quality below 50% results in the device becoming grey, indicating that the location of the device may not be within specification. The user should not solely rely upon the depicted device location

when the device rendering is grey and/or the Signal Quality is less than 50%. Device location should be confirmed with MRI techniques such as real-time imaging, interleaved imaging, and Passive Tracking and/or real-time intracardiac electrograms (for electrophysiology procedures) when this occurs. Refer to the troubleshooting section for potential ways to improve Signal Quality.

EMC Testing and Compliance

The NorthStar workstation complies with EN 55032 (CISPR 32) Class B for emissions and EN55035 (CISPR 35) for immunity. The following table summarizes the testing:

Emissions Test	Compliance Test	Observed Performance
Radiated Emissions	EN 55032:2015+A11:2020 AS/NZS CISPR 32:2015+A1:2020	Within Class B limits
Conducted Emissions	EN 55032:2015+A11:2020 AS/NZS CISPR 32:2015+A1:2020	Within Class B limits
Harmonic Current Emissions	EN IEC 61000-3-2:2019+A1:2021	Within limits
Voltage Fluctuations and Flicker	EN IEC 61000-3-3:2013+A1:2019	Within limits

Immunity Test	Immunity Test Level	Observed Performance
ESD (IEC 61000-4-2)	Air: up to ± 8 kV Contact: up to ± 4 kV	Criteria A, performance unaffected
Radiated RF EM Field (IEC 61000-4-3)	- 3V/m radiated sweep (80MHz – 1.0GHz) - 3V/m radiated sweep (1.0GHz – 6.0GHz) 3V/m radiated spot (1.8GHz, 2.6GHz, 3.5GHz, 5.0GHz)	Criteria A, performance unaffected
Electrical Fast Transients (EFT) and Bursts (IEC 61000-4-4)	±1kV	Criteria A, performance unaffected
Surge Line to Line (IEC 61000-4-5)	AC Main: - L/N to Gnd up to ±2kV - L to N up to ±1kV	Criteria A and B, performance automatically recovers
Conducted RF (IEC 61000-4-6)	3V-1V at 10-30MHz 1V at 30-80MHz	Criteria A, performance unaffected
Power Frequency Magnetic Fields (IEC 61000-4-8)	1 A/m, 50/60Hz	Criteria A, performance unaffected
Voltage, Dips, Interrupts, and Variations (IEC 61000-4-11)	Dips Class 2 - 100% reduction, 0.5 cycle - 30% reduction for 0.5 sec Interrupts Class 2 100% reduction for 5 sec	Dips Class 2, performance unaffected Criteria A Interrupts Class 2 Criteria C, computer experiences power cycle

Additionally, NorthStar has been tested to the following:

Immunity Test	Immunity Test Level	Observed Performance
RF Readers AIM 7351731	AIM 7351731	Criteria A, performance unaffected
Cellular 5G (61000-4-3)	5G Frequency Range 1 (FR1)	Criteria A, performance unaffected
Proximity Fields (61000-4-3)	Table 9 of IEC 60601-1-2	Criteria A, performance unaffected
Wireless Power Transfer	127.75kHz, 413 A/m	Criteria A, performance unaffected

The NorthStar Mapping System was tested according to the recommendations of IEC TS 60601-4-2, Medical electrical equipment – Part 4-2: Guidance and Interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems. The testing and immunity levels evaluated are the same as those outlined in the tables above.



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