NIOBE ES

User Guide

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(Medical Device Safety Service GmbH)
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Patents

Manufactured under one or more of the following United States patents:

Niobe

6,014,580; 6,940,379; 6,975,197; 7,161,453; 7,286,034; 7,305,263;7,313,429; 7,495,537; 7,757,694, 7,771,415; 7,772,950; 7,774,046

Navigant

7,516,416; 7,537,570; 7,540,288; 7,540,866; 7,543,239; 7,627,361; 7,630,752; 7,657,075; 7,708,696; 7,751,867; 7,756,308; 7,761,133; 7,769,428; 7,831,294; 7,853,306

Manufactured under the following European patent:

Niobe: EP 1 488 431, issued in Germany, France, Great Britain, and Netherlands.

Other patents issued and pending.

Trademarks

- *Cardiodrive, Navigant,* and *Niobe* are trademarks of Stereotaxis, Inc., registered in the United States, the European Community, and Japan.
- *Odyssey* is a trademark of Stereotaxis, Inc., registered in the United States and the European Community.
- *Odyssey Cinema* is a trademark of Stereotaxis, Inc., registered in the European Community.
- *Epoch* and *Vdrive* are trademarks of Stereotaxis, Inc., registered in the United States.
- *Bullseye, NaviLine, NaviView, QuikCAS, TargetNav,* and *VascuCAS* are trademarks of Stereotaxis, Inc.

All other brand names, product names, or trademarks are the property of their respective owners.

EMC Directive Statement

EMC Directive Compliance

This equipment was tested and found to conform to the Medical Directive 93/42/EEC for electromagnetic compatibility. Compliance with this Directive is based upon compliance with the following harmonized standards:

Emissions: IEC 60601-1-2:2007
EN55011, FCC Part 15.109(g), FCC Part 15.107(a) & ICES-003, EN61000-3-2:2006 +A1:2009 +A2:2009, EN61000-3-3:2013

Immunity: EN 60601-1-2:2015, EN61000-4-2:2009, EN61000-4-3:2006 +A1:2008 +A2:2010, EN61000-4-4:2012, EN61000-4-5:2006, EN61000-4-6:2009, EN61000-4-8:2010, EN61000-4-11:2004

When operating this equipment, verify that other devices installed near it conform to the applicable EMC standards for that device. The *Niobe* ES system is designed to be installed and operated in a Professional Healthcare Facility Environment.

Safety Standard Statement

Safety Standard Compliance

This equipment was tested and found to conform to the following IEC 60601-1 Medical Electrical Equipment General Requirements for basic safety and essential performance test specifications:

Standard: ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1
CAN/CSA-C22.2 No. 60601-1:14

Related documents

Document	Relationship
HDW-0311 *Odyssey Vision* User Guide	Optional Stereotaxis system
HDW-0309 *Odyssey Vision* QHD User Guide	Optional Stereotaxis system
HDW-0295 *Vdrive* User Guide	Optional *Niobe* accessory (includes *Vdrive Duo* system)
HDW-0120 *Niobe* ES and *Niobe* II MNS Preventive Maintenance Manual	*Niobe* system maintenance manual
HDW-0137 *Niobe* Magnetic Navigation System Maintenance and Service Manual	*Niobe* system maintenance manual
HDW-0227 *Niobe* ES Mechanical Installation Manual	*Niobe* system installation manual
HDW-0228 *Niobe* ES Magnetic Alignment Procedure	*Niobe* magnet positioners installation and setup manual
985-008452 *Niobe* ES Magnetic Navigation System Installation Verification and Testing	*Niobe* ES system tests for pre- and post-magnet installation
HDW-0181 *Niobe* Troubleshooting Guide for Siemens	System troubleshooting for P/N 001-006000-1
HDW-0182 *Niobe* Troubleshooting Guide for Philips	System troubleshooting for P/N 001-006100-1
HDW-0061 Niobe ES MNS Education and Magnet Safety Manual	Safety and education for Stereotaxis magnetic navigation systems
HDW-0216 *Cardiodrive* Installation, Operation, and	Optional *Niobe* accessory

Document	Relationship
Service Manual	
HDW-0265 *VascuCAS* User Guide	Optional Stereotaxis guidewire and catheter advancement system
HDW-0331 *Niobe* ES *e-Contact* Module User Instructions[1]	Optional *Niobe* accessory
PRO-617 *Niobe* MNS Philips R7.7 Site Planning Guide	*Niobe* system site planning guide
PRO-690 *Niobe* ES MNS Siemens Site Planning Guide	*Niobe* system site planning guide
DSP-0210 *Niobe* Cover Drape IFU	*Niobe* magnet positioner cover drape unfolding instructions for use

Operating conditions

Temperature: 15°C to 30°C
Humidity: 20% to 75%, non-condensing
Atmospheric pressure: 70 kPa to 106 kPa

Storage and transport conditions

Temperature: –10°C to 50°C
Humidity: 20% to 95%
Atmospheric pressure: 70 kPa to 106 kPa

Equipment information

Model no.: 001-006000-1 (Siemens); 001-00-6100-1 (Philips); 001-011000-3 (Model S)
Classification: Class I Medical Electrical equipment
Degree of protection: IPX0
Mode of operation: Continuous
Electrical ratings:

Voltage rating:	400 V 3N~
Current rating:	20.0 A
Frequency:	50 / 60 Hz

The hospital will provide a disconnect device that removes all power to the *Niobe* ES system when activated.

WARNING: No modification of this equipment is allowed.

[1] e-Contact™ Module is not available in the US

Operator-accessible disconnect device

In accordance with NEC article 517-72(b), the equipment circuit breaker(s) must be located in a readily operable manner from within the equipment control area. If this is impossible or impractical, a shunt trip circuit breaker with an emergency off pushbutton mounted in the Control Room is acceptable to meet operability requirements.

Note: The hospital facility is responsible for installation of this disconnect device.

Pressing the Control Room Emergency Stop button removes power from the Stereotaxis equipment and activates the Siemens X-ray E-stop.

Accessories

Accessory	Part Number
Cardiodrive	001-004115-9
VascuCAS	001-004115-10
Vdrive	001-002307-1
Vdrive Duo	001-002307-2

Cover art

Contents

1. Overview

Introduction

The Stereotaxis *Niobe* ES magnetic navigation system (MNS) is a medical platform designed for electrophysiological and interventional procedures. *Niobe* ES MNS facilitates the control of the distal tip of compatible magnetic devices via magnetic fields.

About This User Guide

The purpose of this user guide is to provide the *Niobe* ES system user with instructions for operating the equipment. The guide describes basic system information, specific functionality (*Navigant*, integration and automation EP, and intracardiac features), and emergency operations and troubleshooting.

The guide also covers the following systems:

- *Niobe* II, Siemens Reference number 001-006000-1
- *Niobe* II, Philips Reference number 001-006100-1
- *Niobe* ES, Model S Reference number 001-006200-1

The manual does not address instructions for the use of associated magnetic disposables.

The documentation for the companion fluoroscopy system is provided by its manufacturer and is not duplicated here.

Companion Systems

The *Niobe* ES system may be used with the following magnetically-compatible devices:

- Biosense Webster Navistar RMT
- Biosense Webster Navistar RMT Thermocool
- Biosense Webster Celsius RMT
- Biosense Webster Celsius RMT Thermocool
- Stereotaxis Helios II
- Cronus family of magnetic guidewires
- Titan family of magnetic guidewires
- Pegasus family of magnetic guidewires
- PowerAssert magnetic guidewire

The *Niobe* ES system communicates with:

- Biosense Webster Stockert 70 RF Generator
- Biosense Webster SmartAblate RF Generator

The *Niobe* ES system communicates with a variety of digital fluoroscopy systems:

- Siemens AXIOM™ Artis™ *d*FC MN
- Siemens AXIOM™ Artis™ *d*BC MN
- Siemens Artis zee™ Floor MN
- Siemens Artis zee™ Biplane MN
- Philips Allura® Xper FD10C
- Stereotaxis Imaging Model S (powered by Omega Imaging)

The *Niobe* ES system communicates with the Stereotaxis *Cardiodrive* system found in the laboratory where the *Niobe* ES system is installed.

The *Niobe* ES system and CARTO® 3 mapping system communicate to allow integrated mapping and navigation. The OpenMapping API feature allows communication between the *Niobe* ES system and mapping systems that have been tested to be compatible such as the Acutus AcQMap® High Resolution Imaging and Mapping System.

The MNS integrates with a digital fluoroscopy system to provide real-time guidance to the physician during an interventional procedure. The fluoroscopy system must be able to operate in the high magnetic field environment produced by the MNS.

Indications

In Canada, the following Indications are applicable for the *Niobe* ES and *Cardiodrive* systems.

- The Niobe ES system is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart and coronary vasculature and peripheral vasculature by orienting the device tip in a desired direction.
- The Stereotaxis *Cardiodrive* automated catheter advancement system (CAS) is intended for automatically advancing and retracting only compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis MNS.

The *Cardiodrive* system is not intended to advance the EP mapping and ablation catheters through the coronary vasculature or the coronary sinus.

In the United States, the following Indication is applicable for the *Niobe* ES and Cardiodrive (Niobe System)

- The Niobe System is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart and coronary vasculature, neurovascular and peripheral vasculature by orienting the device tip in a desired direction.

- The Cardiodrive Catheter Advancement System (CAS) is intended to automatically advance and retract compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis MNS.

- The *Cardiodrive* system is not intended to advance the EP mapping and ablation catheters through the coronary vasculature or the coronary sinus.

- The Cardiodrive system is not intended to advance or retract non-compatible catheters and/or other non-compatible devices into the neurovasculature.

In all other geographies, the following Indications are applicable for the *Niobe* ES and *Cardiodrive* systems.

- The *Niobe* ES system is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart, pericardial space, coronary vasculature, and peripheral vasculature by orienting the device tip in a desired direction.

- The Stereotaxis *Cardiodrive* automated catheter advancement system (CAS) is intended for automatically advancing and retracting only compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart and pericardial space when used in conjunction with a Stereotaxis MNS.

Safety

Warnings

Although the *Niobe* ES system provides skill amplification and an automated means of steering the distal tip of catheters and guidewires, these features do not replace the physician's knowledge, expertise, or judgment.

WARNING: Federal (USA) law restricts this device to sale by or on the order of a physician

WARNING: The *Niobe* ES system should be used only by qualified medical professionals who have been thoroughly trained in its use. The Stereotaxis *Cardiodrive* remote advancement system should only be used by physicians trained in the use of these systems, with a thorough understanding of angiography and percutaneous interventional procedures.

WARNING: The MNS has permanent magnets that always produce a strong magnetic field. The field cannot be turned off. This field could cause metal objects in the Procedure Room to become airborne projectiles if not kept sufficiently isolated from the magnetic field. The magnetic field is present in the vicinity of the magnets at all times. Patients and operators with pacemakers, internal cardiac defibrillators (ICD), neurostimulators, or magnetic sensitive or ferromagnetic implants should contact the manufacturer of their respective implant before entering the Procedure Room. Serious injury may result.

Refer to the "Reference Manual for Magnetic Resonance Safety, Implants & Devices" published by Biomedical Research Publishing Group for details on the types of objects and medical implants compatible with magnetic environments.

Individuals near the magnet should remove from their person items that could be affected by magnetic fields, including items with magnetic stripes on them (credit cards, employee badges), wristwatches with mechanical movements, cell phones, and magnetic media such as floppy disks and ferrous materials.

WARNING: The *Niobe* ES system magnets produce a strong magnetic field, which is always on. Patients and operators with pacemakers, internal cardiac defibrillators (ICD), neurostimulators, or magnetic sensitive or ferromagnetic implants should contact the manufacturer of their respective implant before entering the Procedure Room. Serious injury may result.

WARNING: The user should not attempt to upgrade, configure, or run any other software programs on the *Niobe* ES computers, other than those specifically called out in the product documentation.

WARNING: There are no user serviceable parts inside the *Niobe* ES magnets. The user should not remove any covers (other than the hand crank covers) or guards, or attempt to disassemble any portion of these magnets.

WARNING: All equipment brought into the Procedure Room (for example, IV poles, patient monitoring equipment, oxygen tanks, etc.) must be safe in a magnetic environment. All equipment that is "MRI compatible" meets these criteria.

WARNING: The operator must not touch the Procedure Room monitor while also touching the patient.

WARNING: Target navigation is most effective in open chamber navigation. Target navigation does not directly account for patient anatomy and is not intended to predict navigation across a valve.

WARNING: When the *Niobe* ES system displays a graphical representation of the catheter tip and shaft on the *Niobe* ES display screen, the graphical representation is a display of the calculated catheter shape, based on the initial location and orientation of the catheter base and distance of catheter shaft

advancement (or retraction) by the *Cardiodrive* Catheter Advancement System.

WARNING: The *Niobe* ES system does not track the location or orientation of the catheter. (If the user purchases the Biosense Webster CARTO® 3 EP Navigation System and uses an appropriate Biosense Webster NAVISTAR® 3 catheter, the *Niobe* ES system can be instructed to display the location and orientation of the catheter tip.)

WARNING: The graphical representation of the catheter on the *Niobe* ES display represents an approximate location and orientation of the catheter inside the patient's heart after the user acquires a new fluoro image and subsequently transfers it from the X-ray to the *Niobe* ES MNS using the "Transfer Image" button.

WARNING: The Target Navigation mode is intended to serve as a tool to assist the physician in guiding the compatible magnetic device to the intended location inside the heart chambers. Because the navigation field is static, results may vary in the beating heart. Stereotaxis neither claims nor quantifies the accuracy of the device tip localization via Target Navigation. Physicians should monitor fluoroscopic visualization and ECG to correlate between the visual representation and final resulting device tip position.

WARNING: Exercise caution with moving parts of the system to prevent inadvertent contact or damage to the patient, operator, or equipment. Movable items include both magnet positioners, the accompanying fluoroscopy system's C-Arm, and the patient table.

WARNING: The magnetic navigation system should be used only with magnetic devices and accessories appropriately labeled as compatible with MNS navigation applications.

WARNING: Make sure the patient table pivot is in the central position (centered between the *Niobe* pods) before moving the *Niobe* pods out of the Stowed position toward the Navigate position.

WARNING: The operator should always confirm device location using a live fluoroscopic image.

WARNING: If the device is moved manually instead of using the *Cardiodrive* system, the *Cardiodrive* display and any previously stored position data may become invalid. The physician should remove all previously set markers after moving the device manually.

WARNING: Always verify catheter motion using live fluoroscopy images. Stop immediately if catheter motion can no longer be verified.

WARNING: Advancement of a guidewire is controlled manually by the physician. Always verify guidewire motion using live fluoroscopy images. Stop immediately if resistance is encountered.

WARNING: EP navigation features are only available for use in the EP software. Please refer to HDW-0158 for features available for Interventional Neuroradiology.

WARNING: Do not attempt to use a magnetically compatible guidewire with the Cardiodrive system as the guidewire diameter is too small to engage the drive mechanism.

WARNING: The tip of magnetically compatible guidewires and microwires should only be advanced and manipulated under direct fluoroscopic observation.

WARNING: Ablation system foot pedal should not be connected to the RF generator in the procedure room. It is intended for use only in the control room.

WARNING: If unexpected catheter motion occurs during ablation, stop RF energy delivery.

WARNING: If there is a cybersecurity breach during a procedure, press the Estop button to stop all device activities. Contact the Emergency call center to report the suspicious activity prior to resumption of the procedure

Precautions

CAUTION: If a patient is to receive a permanent pacemaker or internal cardiac defibrillator (ICD) *de novo* in the MNS room, the *Niobe* ES magnets must be moved and kept in the Stowed position. The magnets should stay in their Stowed positions during the entire period starting from the moment the ICD or pacemaker is brought inside the Procedure Room, and ending when the patient (with the ICD or pacemaker implanted) is moved out of the Procedure Room. Proper functioning of ICDs and pacemakers should be verified following the removal of the patient from the Procedure Room.

CAUTION: During patient loading and unloading, there is a collision risk for individuals in the vicinity of the magnet positioners and the X-ray system. All individuals should make sure they are not in this vicinity when the magnets are moving between the Stowed, Pivoted, and Navigate positions. An audio signal sounds when magnets have completed their movement. (You may adjust the volume in the Settings → System tab.)

CAUTION: Do not enter the area between the X-ray system and magnet positioner when the magnets are in the Pivoted position or between Pivoted and Stowed.

CAUTION: Due to space constraints in the Procedure Room in the low magnetic field (less than 5 Gauss) area, remove one patient before bringing in another.

CAUTION: The *Niobe* ES MNS uses a magnetic field to orient the tip of the catheter to the desired intracardiac orientation.

CAUTION: The points on the CARTO® 3 system screen are for reference only. Always confirm orientation of the catheter location with localization methods—fluoroscopy, for example—in addition to the electrograms.

CAUTION: The CARTO® 3 system points and catheter tip location displayed on the CARTO® 3 screen can be transferred to the *Navigant* screen. The catheter tip displayed on the *Navigant* screen is used only as a visual reference to aid navigation, not to identify the location of the catheter tip in the heart. Always confirm orientation of the catheter location with localization methods—fluoroscopy, for example—in addition to the electrograms.

CAUTION: If the physician believes the catheter may be in the wrong location, the physician should refresh the fluoroscopy image. If a discrepancy occurs, the physician should:

1. Re-register CARTO® 3 system to the *Navigant* platform.
2. Re-mark the catheter base.
3. Calibrate the *Cardiodrive* system.

CAUTION: While the magnet system is homing, varying magnetic fields will be applied in the vicinity of the magnets and the patient table.

CAUTION: Do not enter the area between the C-Arm and magnet when the magnets are in the pivoted position.

CAUTION (Siemens): The *Niobe* and the Siemens X-ray systems have different emergency stop buttons. Pressing the *Niobe* E-stop will activate the X-ray E-stop (via a hardware connection), causing the X-ray to stop. Pressing the X-ray system E-stop will cause the *Niobe* ES system to stop (via software).

CAUTION (Philips): With Philips, pressing the X-ray system E-stop will cause the *Niobe* ES system to stop.

CAUTION (Model S): With Model S, pressing the X-ray system E-stop will cause the *Niobe* ES system to stop.

CAUTION: If the *Niobe* ES system is operated with interlocks overridden (as described in the Emergency Operations section), a collision between the two systems is possible. Closely monitor the magnet movement, and be ready to release the movement buttons if a collision is imminent. Failure to heed this caution may cause damage to the equipment.

CAUTION: Although the magnetic field is 0.08 to 0.1T (Tesla) in the navigation volume at Isocenter, it is stronger than this in regions closer to the front of the magnets:

- In the Navigate position, the field strength at the flat front surface of the magnet covers can be as high as 0.7T.

- In the Navigate position, the field strength is less than 0.2T five inches (13 centimeters), or more, in front of the front surface of the magnet cover.
- In the Pivoted and Stowed positions, the field strength is less than 0.2T one inch (3 centimeters), or more, in front of the front surface of the magnet cover.
- Field strengths above, below, behind, and to the sides of the magnets are always less than those on the front surface.

CAUTION: Automated features are only available after activating the barcode on the QuikCAS packaging.

CAUTION: Do not set anything on the keypad, or flip the keypad over. This will prevent a key from being held down causing unwanted repetitive motion.

Clinical Information

SUMMARY OF CLINICAL INFORMATION

Data from four clinical studies involving 511 patients who underwent catheter ablation using the Stereotaxis Magnetic Navigation System (MNS) are summarized. The Magnetic Navigation System includes the Niobe System, the *Navigant* software, the Cardiodrive catheter advancement system (CAS) and either the Stereotaxis Helios Ablation catheter, or the BWI Navistar Thermocool RMT ablation catheter. Collectively, the data in these studies demonstrates the safety and effectiveness of the Magnetic Navigation System for catheter ablation.

Study Design:

All four studies were prospective in nature and included safety and efficacy endpoints. Data from all four studies were used to support regulatory approvals. Evaluation of 7 day major adverse events for safety, and acute procedural success was measured in all studies. Three studies reported long-term (90 day) success.

Study Results:

Acute procedural success was achieved in 473/498 (95.0%) subjects who underwent catheter ablation using the Stereotaxis Magnetic Navigation System.

Long-term success (90-day success) was achieved in 278/288 (96.5%) of subjects who completed the predefined follow-up visit.

Adverse Events:

The overall 7-day major complication rate for all four studies was 20/511 (3.9%) Major adverse that occurred within 7 days post procedure included:

- 1 cardiac tamponade related to right sided catheter

- 1 cardiac tamponade related to the transseptal puncture
- 1 new focal wall abnormality
- 1 change in LVEF (60% to 45-50%)
- 2 vena cava thrombi
- 1 groin complication
- 1 chest soreness
- 1 prolonged hospitalization for grogginess
- 1 pseudoaneurysm
- 1 bleeding
- 1 anemia
- 1 dementia
- 1 pericardial effusion
- 1 heart block requiring pacemaker
- 2 pulmonary embolisms
- 1 AV fistula
- 2 arrhythmia recurrence (per protocol requirement)

Conclusion

The data in this summary support the reasonable assurance of safety and effectiveness of the Stereotaxis Magnetic Navigation System for cardiac ablation procedures.

Technical Details

The Niobe system generates a directional 0.08T or 0.1T magnetic field within the patient's heart. The navigation volume is 6 inches (15 centimeters) in diameter centered at X-ray isocenter.

Mechanical Performance Testing

Mechanical performance testing of the compatible catheters included anatomical and deflection target testing. Deflection testing included six separate deflection directions and was performed at five separate positions around the navigation volume. Acceptable performance was reaching anatomical targets and all deflection targets.

Deflection Testing Positions

Pos A - Isocenter
Pos B – Posterior 2 inches (5 centimeters) from A
Pos C – Inferior 2 inches (5 centimeters) from A
Pos D – Patient right 2.5 inches (6 centimeters) from A
Pos E – Patient left 2 inches (5 centimeters) from A

Catheter	Anatomic	Pos A	Pos B	Pos C	Pos D	Pos E
Navistar RMT	Success	Success	Success	Success	Success	Success

Navistar Thermocool RMT	Success	Success	Success	Success	Success	Success
Celsius RMT	Success	Success	Success	Success	Success	Success
Celsius Thermocool RMT	Success	Success	Success	Success	Success	Success
Helios II	Success	Success	Success	Success	Success	Success

Fluoroscopy Exposure

Patients and operators will be exposed to fluoroscopy during procedures performed with the Niobe ES system. Operators may experience less exposure because they will be remotely performing the procedure in the control room. Clinical trials using previous versions of magnetic navigation systems reported mean fluoroscopy times ranging from 10.64 minutes to 16.91 minutes.

Cybersecurity

Please note the following important information concerning cybersecurity:

- Cybersecurity controls operate in the background in the Niobe MNS with *Navigant* Workstation (NWS). No user actions are required to maintain the security of the system, but any suspected cybersecurity incidents should be reported to Stereotaxis call center.
- Only trusted users should be allowed physical access to the Niobe system.
- Caution should be used when using removable media, e.g., CD, DVD, Blu-ray disks, flash drives, USB hard drives, with Niobe. Independent virus scanning is recommended before insertion or connection to the system.

Notes

Images that are electronically zoomed and/or panned cannot be transferred to the *Niobe* ES system.

Images acquired during C-Arm movement cannot be transferred to the *Niobe* ES system.

Images acquired during table movement cannot be transferred to the *Niobe* ES system.

Always verify the fluoroscopy images match the current patient.

Before Ablation, verify the field is applied to ensure proper device functionality.

Barcode activation of the QuikCAS only applies to EP functionality and does not affect the neurovascular or peripheral vascular applications.

C-Arm collision with magnet considerations

When both are powered up, the MNS and the X-ray system are "aware" of each other and their current location. The user will neither be able to move the magnet into an area where the C-Arm is located, nor move the C-Arm into an area where the magnets are located. If the user attempts to do this, a warning message will appear and the controls will be locked out.

The X-ray C-Arm and magnets must **never** physically contact each other, for several reasons:

- The magnetic tube shield around the X-ray tube would stick to the magnet.
- The C-Arm could sustain physical damage.
- The cosmetic covers could sustain physical damage.

CAUTION (Siemens): Siemens collision avoidance is disabled by design when not communicating to the *Niobe* ES system unless the systems see the *Niobe* ES magnet is in the Stowed position (via hardware signal). When collision avoidance is disabled, the C-Arm will only move very slowly, but it is possible to hit the magnets at this slow speed.

CAUTION (Model S): Model S collision avoidance is disabled by design when not communicating to the *Niobe* ES system unless the systems see the *Niobe* ES magnet is in the Stowed position (via hardware signal). When collision avoidance is disabled, the C-Arm will allow movement to only the AP position and table height movement will be restricted.

Note: What is referred to as the C-Arm in Siemen and Model S systems is referred to as the L-Arm in Philips systems. To eliminate confusion, this document will reference the device as *C-Arm*.

Electromagnetic Compatibility Information

WARNING: The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by Stereotaxis, Inc., may result in increased emissions or decreased immunity of the *Niobe* ES system.

WARNING: The *Niobe* ES system should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the *Niobe* ES system should be observed to verify normal operation in the configuration in which it will be used.

Note: In addition to the requirements of 7.9.3 of the general standard for Permanently Installed Large Medical Electrical (ME) Equipment and Large ME Systems for which the exemption specified in 8.6 from the testing requirements of IEC 61000-4-3 is used,

this technical description includes the following information:

WARNING: This equipment has been tested for radiated radiofrequency (RF) immunity only at selected frequencies, and use of nearby emitters at other frequencies could result in improper operation.

Following are the frequencies and modulations used to test the Immunity of the ME Equipment or ME System:

- 52.5Mhz
- 144Mhz
- 433MHz
- 467Mhz
- 2.4GHz

Emissions

The *Niobe* ES system is intended for use in the electromagnetic environment specified in the following tables. The customer or the user of the *Niobe* ES system should ensure that it is used in such an environment.

The following table provides guidance and Stereotaxis' declaration on **electromagnetic *emissions*** for the *Niobe* ES system:

Emissions	Compliance	Electromagnetic environment—guidance
EN55011 FCC Part 15.109(g) FCC Part 15.107 (a) ICES-003	Group 1	The *Niobe* ES system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
EN55011 FCC Part 15.109(g) FCC Part 15.107 (a) ICES-003	Class A Complies	
Harmonic emissions IEC 61000-3-2		
Voltage fluctuations/ flicker emissions IEC 61000-3-3		

Immunity—General electromagnetic effects

The following table provides guidance and Stereotaxis' declaration on **electromagnetic *immunity*** regarding general electromagnetic effects for the *Niobe* ES system:

Immunity test	IEC 60601 test level*	Compliance level*	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8 & 15 kV air	± 8 kV contact ± 2, 4, 8 & 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst I EC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (100 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (100 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *Niobe* ES system requires continued operation during power mains interruptions, it is recommended that the *Niobe* ES system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

* U_T is the a.c. mains voltage before application of the test level.

Immunity—RF interference

The following table provides guidance and Stereotaxis' declaration on **electromagnetic *immunity*** regarding radiofrequency for the *Niobe* ES system:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the *Niobe* ES system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. ***Recommended separation distance*** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol : 
Radiated RF IEC 61000-4-3	3 V/m 80 mHz to 2.7 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Niobe* ES system is used exceeds the applicable RF compliance level above, the *Niobe* ES system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Niobe* ES system.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Separation distances

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the *Niobe* ES system, including cables specified by Stereotaxis, Inc.

The *Niobe* ES system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Niobe* ES system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Niobe* ES system as recommended in the following table, according to the maximum output power of the communications equipment.

The table provides **recommended separation distances** between portable and mobile RF communications equipment and the *Niobe* ES system.

Rated maximum output power of transmitter* W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz t0 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

* For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Note: If there are Electromagnetic Compatibility (EMC) issues with the *Niobe* system, please contact Stereotaxis Service. Otherwise, there are no specific service requirements to maintain *Niobe* ES EMC integrity.

Graphics and Symbols

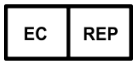
The following graphics and symbols are used in this User Guide:

	**WARNING**	**WARNING** indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	**CAUTION**	**CAUTION** indicates a potentially hazardous situation which, if not avoided, could result in injury to patient or operator or damage to the equipment.
	**NOTE**	**NOTE** identifies information that could affect the outcome or results of the procedure.

Warnings and Cautions precede the text and any procedure involving a clear risk to the operator(s), the patient, or the equipment. General warnings are listed in the Warnings and Precautions summary later in this section. Pay close attention to the instructions that accompany the warnings, notes, and symbols.

The following graphical symbols are used in this document and/or on the *Niobe* ES components:

Symbol	Name	Description
	Magnet Present	Indicates a magnet is present in the equipment.
	Consult Instructions	See the Operating Instructions for additional information or instruction.
	Power	Indicates the power status of the *Vdrive* or *Niobe* ES system.

Symbol	Name	Description
	E-stop	Indicates the E-stop button or the E-stop indicator light.
	AC Power	Indicates the status of the AC power.
	DC Power	Indicates the status of the internal DC power.
	Manufacturer	Name and address of the manufacturer of the product.
	European Representative	Name and address of the authorized representative in the European Community.
	Pinch Point	Indicates location of a pinch point.

Glossary

The following terms appear in this document:

Term	Description
2D	Two-Dimensional.
3D	Three-Dimensional.
5 Gauss line	*See* Gauss.
AP	Anterior-Posterior.
AutoMap	An integrated feature between the *Navigant* software and the mapping system that enables the user to initiate a sequence of automatic, computer-controlled catheter movements throughout the cardiac chamber.

Term	Description
***Bullseye* Targeting**	A navigation scheme that allows vector direction changes to be made on a polar map projected onto a plane.
C-Arm	An X-ray image intensifier that produces live X-ray images displayed on a monitor and named because of its configuration, with the top part of the C extending over the patient and the bottom extending under.
***Cardiodrive* system**	The Stereotaxis tool that provides the physician with the ability to advance and retract catheters from a Control Room. The full name is *Cardiodrive* catheter advancement system (CAS).
CARTO® 3 system	Biosense Webster system that combines 3D mapping and navigation systems with the Stereotaxis *Niobe* magnetic navigation system.
CAS	*Cardiodrive* catheter advancement system. (*See Cardiodrive* system.)
Cinema	The optional recording system for the *Odyssey Vision* system that provides remote viewing of live and recorded procedures.
Click & Go	An integrated feature between the *Navigant* software and the CARTO® 3 3D mapping system that enables the user to automatically target any location on the map surface by double-clicking a point on the map.
Clinical Workflow Manager (CWM)	A component of the NWS application software that executes scripts to guide medical procedures.
CRT	Cardiac Resynchronization Therapy.
DICOM	Digital Imaging and Communications in Medicine (standardized protocol for exchanging medical image and patient data).
EMC	Electromagnetic compatibility
EP	Electrophysiology.
Fluoro	Fluoroscopic, or Fluoroscopy.
Fluoroscope	An X-ray image intensifier that produces live X-ray images displayed on a monitor. Also called X-ray or C-Arm.
Fully retracted	Magnet positioners are pivoted toward the patient and at the farthest distance from the patient.
Gauss (G)	The centimeter-gram-second (cgs) unit of magnetic flux density. A 5 Gauss line is marked on the floor of the magnetic navigation system Procedure Room. The amounts of 5 G and lower are considered safe levels of static magnetic field exposure for the general public. (Named for Johann Carl Friedrich Gauss.)

Term	Description
IC	Interventional, or Intracardiac, Cardiology.
Isocenter	In X-ray technology, the Isocenter is the point in space through which the central ray of the radiation beams pass.
LAO	Left Anterior Oblique.
MNS	Magnetic navigation system. (See *Niobe* magnetic navigation system.)
***Navigant* software**	A platform of software applications designed to simplify clinical workflows. The *Navigant* product (excluding the *Odyssey* add-on), provides enhanced integration of catheterization and electrophysiology labs and improved automation during magnetic navigation of medical devices. (Available only in magnetic labs.)
Navigation volume	Spatial volume defined for MNS, where the MNS is capable of generating any magnetic field direction at the target magnetic field strength provided by the MNS.
***NaviLine* automated linear navigation**	An integrated feature between the Stereotaxis *Navigant* software and the mapping system that enables the user to automatically follow a predefined line along a 3D surface created by the mapping system. *NaviLine* navigation moves the catheter in prescribed increments forward and/or backward along the line.
***Niobe* magnetic navigation system**	A Stereotaxis system that enables physicians to more effectively navigate catheters, guidewires and other magnetic interventional devices through the blood vessels and chambers of the heart to treatment sites and then to effect treatment. (The *Niobe* system is available only in magnetic labs.)
NWS	"*Navigant* Workstation." *See Navigant* software.
***Odyssey Vision* system**	An optional display and user interface package that enables the user to customize consolidation of the point of control for the entire interventional lab.
OpenMapping System	OpenMapping API feature allows communication between *Niobe ES* and mapping systems that have been tested to be compatible. These compatible mapping systems are referred to as OpenMapping systems.
RAO	Right Anterior Oblique.
RF	Radiofrequency.
RMT	Remote magnetic technology. (RMT is often used to refer to the CARTO® 3 EP navigation system and the integrated CARTO® 3 / *Niobe* MNS environment).

Term	Description
Tableside Control	Touchscreen controller positioned on the side of the patient table in the Procedure Room.
Tesla (T)	The standard unit of magnetic flux density.
USB	Universal Serial Bus. An interface-standard device that enables many peripheral devices to connect to a computer.
W·s	Watt-second, the energy equivalent to the power of one watt sustained for one second.

2. Basic Information

Niobe System Magnet Information

The arrangement of the magnetic Procedure Room is fairly standard among institutions. The major difference is the X-ray system (Siemens, Philips, or Model S). This table describes the main components (**Figure 1**) without the X-ray system.

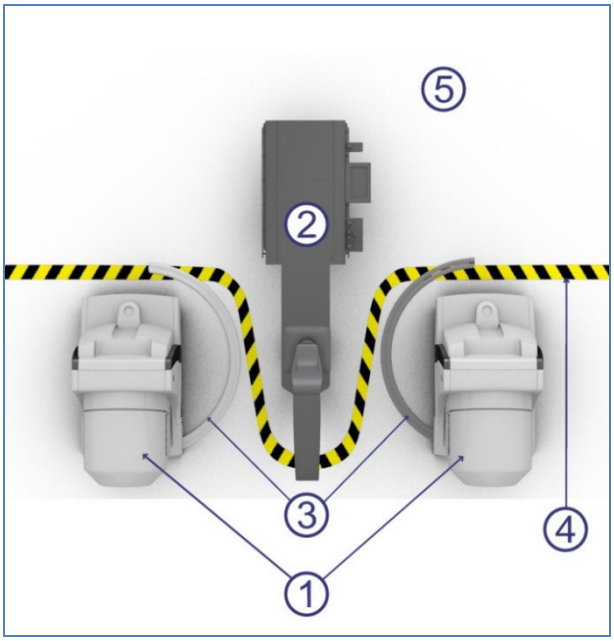


Figure 1. Drawing of Procedure Room components

Procedure Room component guide (Figure 1)

① ***Niobe* system magnet positioners.** Also called pods, the magnet positioners contain the *Niobe* system magnets.

② **Patient table.**

③ ***Niobe* system magnet positioner floor tracks.** The floor tracks support the magnet positioners as they swing in and out.

④ **Five Gauss line.** The dividing line between the zones that are less than 5 G and more than 5 G when the magnets are stowed. Institutions indicate this division in various ways.

⑤ **Five Gauss zone.** The zone that is less than 5 G (the table side of the room) within which individuals should remain when magnets are stowed.

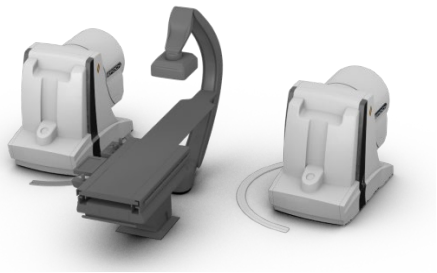
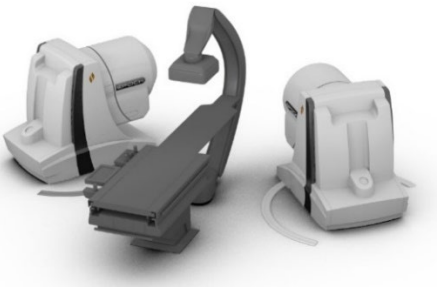
Niobe System Magnet Positions

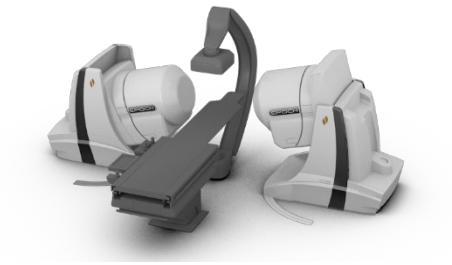
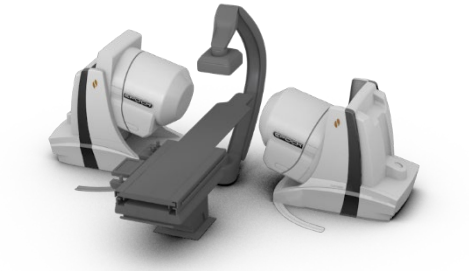
System positions define location of where the external surfaces of the magnet system can be located relative to the patient.

System positions

At any given time, the magnets are in one of the following positions: Stowed, Pivoted, Retracted, Navigate AP, Navigate RAO, or Navigate LAO. The magnets are moved by pressing buttons on the Tableside Controller. The following table and **Figure 2.** through **Figure 6** describe each of the positions and list when the various positions are used in a procedure.

Note: The user cannot navigate when the magnets are in any of these positions.

Position	Position description	When position is used
Stowed	 **Figure 2.** Magnets in Stowed position—pivoted as far as possible (90°) away from the patient	• When no procedure is being performed • During non-magnetic procedure • To allow increased imaging angle flexibility • When greater patient access is needed • When field beyond Physician Access Line needs to be less than 5 G
Pivoted	 **Figure 3.** Magnets in Pivoted position	• When greater patient access is needed • To allow increased imaging angle flexibility
Retracted	Magnets are pointed toward patient, but cover-to-cover distance is larger than what is necessary to enable magnetic navigation. Whenever magnets are retracted a maximum distance from patient while in fully Pivoted position near patient, system is considered to be in fully Retracted position.	• When field needs to be reduced • To allow increased imaging angle flexibility without having to wait for magnets to pivot away from patient • When greater patient access is needed

Position	Position description	When position is used
Navigate AP	 **Figure 4.** Magnets in Navigate AP	During magnetic navigation procedure with maximum C-Arm angulation centered with respect to patient
Navigate RAO	 **Figure 5.** Magnets in Navigate RAO	During magnetic navigation procedure with maximum C-Arm angulation on right side of patient
Navigate LAO	 **Figure 6.** Magnets in Navigate LAO	During magnetic navigation procedure with maximum C-Arm angulation on left side of patient

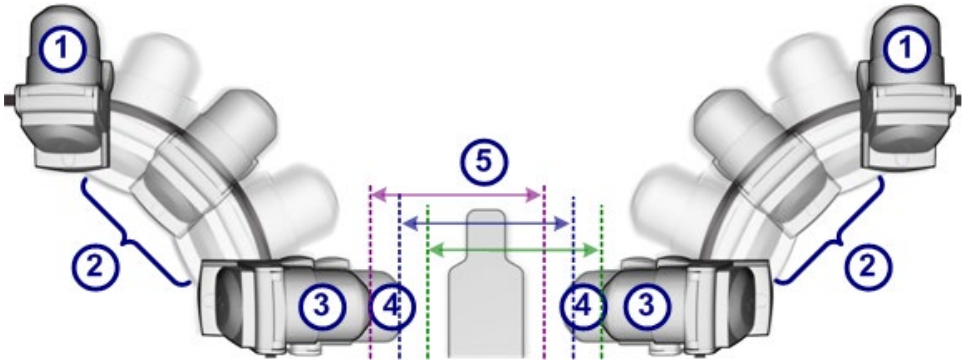


Figure 7. Magnet position options

Magnet positions guide (Figure 7. – Figure 9.)

① **Stowed**

② **Pivoted**

③ **Fully retracted**

④ **Fully extended**

⑤ **Cover-to-cover distance**
Magnetic field strength determines the cover-to-cover distance. A force of 0.1 Tesla requires a distance of 23.5 inches (60 centimeters), while 0.08 T requires 26.5 inches (67 centimeters). The offset is variable: If the table is not centered and one cover comes too close to the table, the cover will automatically retract and the opposite cover will extend to maintain the same cover-to-cover distance.

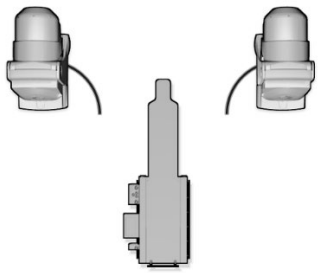


Figure 8. Stowed positions

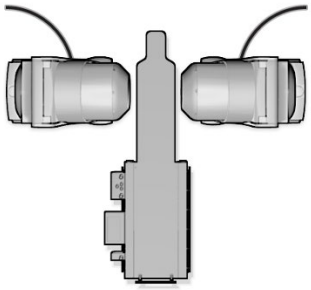


Figure 9. Navigate positions: Navigate AP, Navigate RAO, Navigate LAO

Before starting movement of a magnet to a Navigate position, the magnet is first moved to the Retracted position and then tilted.

Note: The magnets can be tilted **only** when the *Niobe* MNS is not in navigation mode.

The magnets move in close proximity to the patient table and the imaging system C-Arm.

The user may move the patient table off center to optimize visualization of the desired anatomy for magnetic navigation. When the Navigate AP, RAO, or LAO button is pressed on the bedside controller, the magnets will automatically calculate the table position and the cover-to-cover distance required. The user may also manually move each magnet independently to accommodate the change in table position. For example, if the right magnet is moved away from the patient, the left magnet needs to be moved toward the patient until the message "Magnets in Navigate Position" is displayed on the *Niobe* ES screen.

The cover positions for each of the last achieved positions (Navigate AP, Navigate RAO, and Navigate LAO) are stored by the system. Subsequent moves of the magnets to one of these positions will result in their movement to the stored position. The stored positions will be adjusted if the table is moved, or a new patient is started.

The approximate time the magnet takes to move between any two positions is listed below. Up to an additional 5 seconds' variation may occur in movements from the Navigate position depending on the magnet position inside the covers:

- Stowed to/from Retracted: 15 seconds
- Retracted to/from Navigate: 5 seconds
- Stowed to/from Navigate: 20 seconds
- Navigate RAO or LAO to/from Retracted: 7 seconds

Notes:

- All accessories should be clear of the magnet movement and all cables should be clear (not on the floor) of the magnet movement.
- Magnets pivot on tracks that are mounted in the floor. User should exercise caution when working in the floor track area due to risk of stumbling.
- User should note areas labeled for potential pinch hazard as shown in **Figure 10.**

Figure 10. Red shading indicates pinch hazard areas

CAUTION: Do **not** use the Tableside Controller to move magnets when hand crank cover is off. See Section 7. **Moving Magnets Manually** for manual hand crank operation.

Tableside Magnet Controller

The Tableside Magnet Controller allows the user to physically move the magnets and controls various other system functions.

Note: Keep accessories clear of the magnet movement zone to prevent collision with magnets.

In the Procedure Room, the *Niobe* ES magnets are controlled using the Tableside Controller. The configuration of the Controller varies based on the X-ray and *Niobe* ES systems (**Figure 11**).

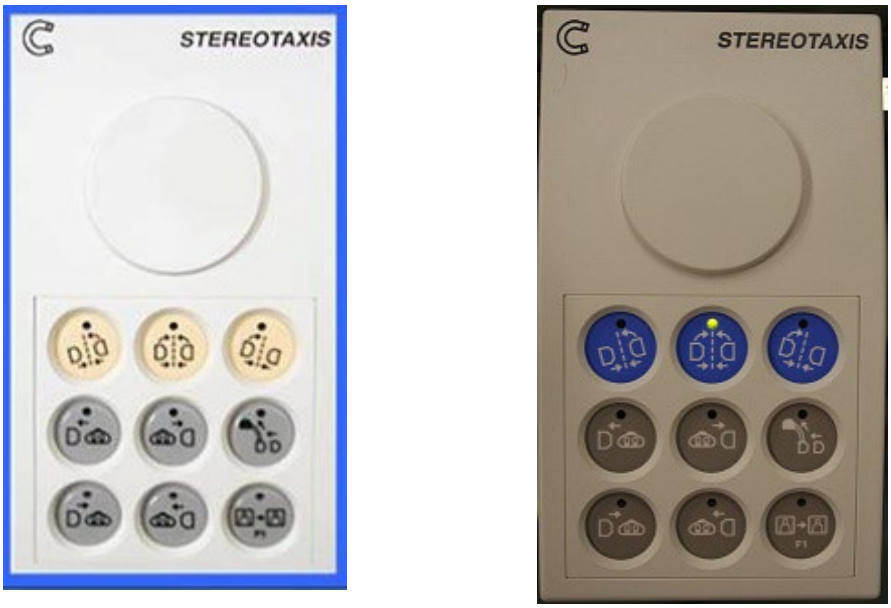


Figure 11. Top view of two Tableside Controllers:
Niobe ES – Philips and Model S (*left*) and *Niobe* ES – Siemens (*right*)

Niobe ES Tableside Controller buttons

Niobe ES buttons are dark yellow and light gray for the Philips and Model S X-ray systems, and blue and gray for the Siemens X-ray system. The button images (in Philips/Model S colors) are displayed in **Figure 12.**

Panel	Buttons and names		
	 **Navigate RAO**	 **Navigate AP (Also used for homing)**	 **Navigate LAO**
	 **Retract – Patient right side↑**	 **Retract – Patient left side↑**	 **Stowed**
	 **Advance – Patient right side↑**	 **Advance – Patient left side↑**	 **Image transfer (Also used for override moves**)**

Figure 12. Niobe ES Tableside Controller buttons and descriptions

↑ **Applies to patients in head-first supine position**.

** ***Niobe*** **ES Tableside Controller Override buttons:**

To perform a move in override mode, press and hold the Override move button (image transfer button), and then press the button you want to override. During an emergency or other exceptional situation, Override mode enables you to override the safety precaution restraints on individual controller buttons. For example, the mode enables you to immediately stow the magnets regardless of the X-ray C-Arm and table position.

WARNING: Use of the Override feature may result in a *Niobe* magnet collision with the C-Arm or table.

System Power Up

Preparing for patient's entry

Follow these steps before bringing the patient into the Procedure Room:

1. Ensure no ferrous objects (objects magnets could attract) are in the area.
2. Ensure objects magnets could damage are not in the area, such as credit cards, watches, floppy disks, cell phones, beepers, and hearing aids.
3. Clear and clean the magnet positioner floor tracks (see **Figure 1**).
4. Power up the system. On the remote power panel (located in Control Room), hold the toggle switch in the ON ("I") position for approximately 1 second until the green power lamp illuminates (**Figure 13.**).

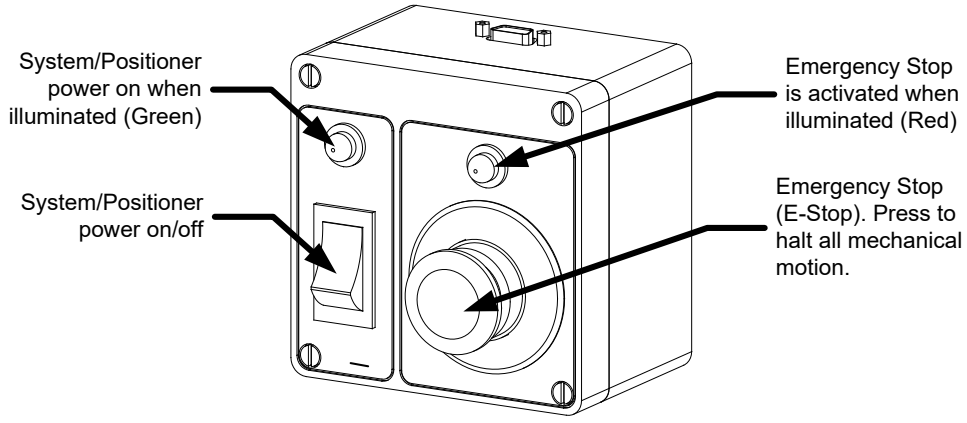


Figure 13. Power Box in Control Room

5. Home the system by pressing and holding the Navigate AP (**Figure 14**) button on the *Niobe* Tableside Controller. Hold the button until the "Homing Complete" message displays in the bottom-left corner of the *Niobe* ES screen. Homing takes up to 60 seconds.
6. Retract magnet positioners back to Stowed position (see **Figure 2.**) by pressing the Stow button on the Tableside Controller (**Figure 15)** to aid in patient loading.

Note: In case of a voltage interruption, the *Niobe* ES system might shut down, necessitating a system restart.

Niobe ES – Navigate AP button

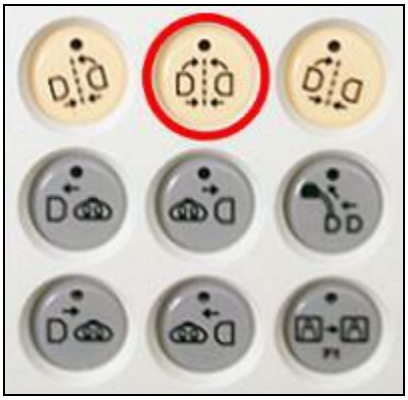


Figure 14. Navigate AP button is top-middle button on Tableside Controller (Philips/Model S colors displayed)

Remember: Button colors differ on Philips and Model S (dark yellow and gray) and Siemens (blue and gray) X-ray systems.

Niobe ES – Stow button

Figure 15. Stow button is on far right of second row of Tableside Controller (Siemens colors displayed)

Recommended Patient Loading Procedure

This section outlines the basic steps and precautions for generic and peripheral magnetic navigation procedures.

Magnetic safety precautions

The intent of this procedure is to keep the patient and attending medical staff in a low magnetic field (less than 5 G) while the patient is transferred into and out of the Procedure Room. The 5 Gauss line is marked on the floor. Individuals should stay on the table side of the 5 Gauss line when the magnets are stowed.

WARNING: The *Niobe* ES system produces a strong magnetic field that is always on. Patients and operators with pacemakers, internal cardiac defibrillators (ICD), neurostimulators, or magnetic sensitive or ferromagnetic implants should contact the manufacturer of their respective implant before entering the Procedure Room. Serious injury may result.

1. Move *Niobe* magnets into the Stowed position (**Figure 16.**) using the *Niobe* Tableside Controller.
2. Move the tabletop back completely, away from the X-ray system and magnets (**Figure 17.**).

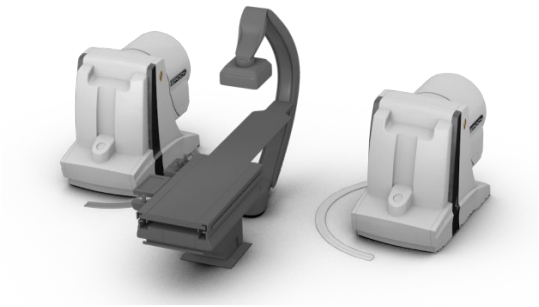


Figure 16. *Niobe* magnets in Stowed position with tabletop moved forward completely

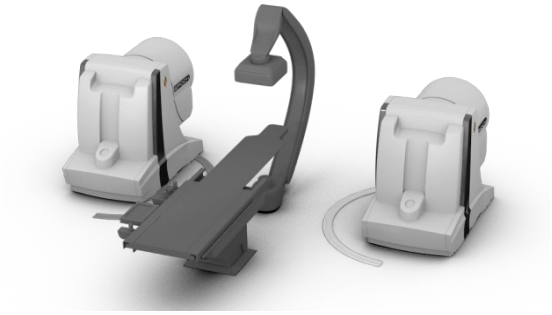


Figure 17. *Niobe* magnets in Stowed position with tabletop moved back completely

Positioning patient on table

The position of the patient on the table depends on the type of procedure performed. Patients should be in a head-first supine position (**Figure 18.**) except when you are performing a femoral or tibial procedure. For femoral and tibial cases, the patient should be feet-first supine (**Figure 19.**).

Head-first supine

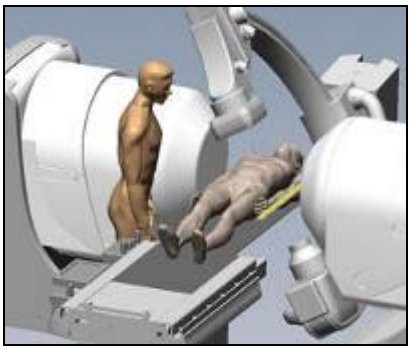


Figure 18. Patient loaded in head-first supine position (for all procedures except femoral and tibial)

Feet-first supine

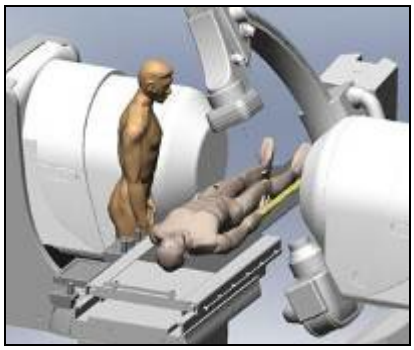


Figure 19. Patient loaded in feet-first supine position (only for femoral and tibial procedures)

Important: The patient is loaded feet first for femoral and tibial cases; however, you must register the patient "head-first, supine" for some Philips and Siemens X-ray systems to ensure proper image transfer. Check your X-ray system's manual if you are not sure how your system handles these feet-first cases.

1. Place the patient on the table in a supine position.
2. Center the patient on the tabletop laterally. Aligning the patient too far off center can interfere with successful automatic positioning of the *Niobe* magnet covers.
3. Secure the patient's legs.
4. Secure the patient's arms. Ensure no part of the arms is below the tabletop to avoid pinching when the magnet positioners move toward the table.
5. Make sure no excess table padding protrudes outside the edge of the tabletop.

Figure 20. *Niobe* ES magnet cover moves toward and away from patient table (see guide below for numbered references)

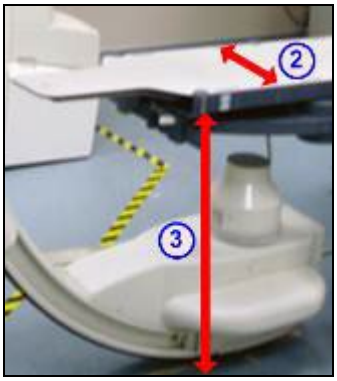


Figure 21. Lateral position on table and vertical height of table

Niobe magnet and table guide (Figure 20 and Figure 21.)

① The cover of the magnet positioner can move toward and away from the table. One of the movement methods is automatic positioning. Cover-force sensors detect force between the cover and patient or padding.

② The lateral table dimension. The patient should be centered laterally on the table so the magnet covers on either side of the table can move in equally toward the patient.

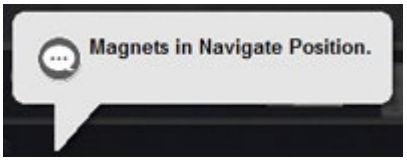
③ The vertical table dimension.

Cover-Force Sensor

The *Niobe* magnet covers contain cover-force sensors that detect when the face of the cover (**Figure 20**) is pressing against the patient. When a cover-force sensor is activated, the magnet positioner pauses, then retracts slightly and stops.

If a single cover-force sensor is activated, the operator may choose to continue holding the movement button. The *Niobe* ES system automatically retracts the individual cover that is contacting the patient slightly and advances the opposite cover to continue movement to the Navigate position.

If the second cover-force sensor is activated before the positioner reaches Navigate position, the Navigate Position Assistance dialog appears. If the second positioner has enough room to reach Navigate position, the *Niobe* ES system adjusts the Navigate position center based on this new location and displays the following status message:



Automatic positioner centering

The *Niobe* ES system can automatically center the magnet positioners in the Navigate position, based on the patient table's lateral and vertical positions (**Figure 21.**). To understand this, it is important to first understand the Navigate position and cover-force sensor.

1. Using the Tableside Controller and fluoroscope, center the patient relative to the X-ray isocenter.
2. Press one of the Navigate buttons on the *Niobe* controller and hold it down. The *Niobe* ES system calculates the target position, including an offset based on the lateral and vertical position of the patient table, and begins moving to that position.
3. If motion stops and the message "Magnets in Navigate Position" displays in the bottom-left corner of the monitor, the automatic positioner centering has been successful. The *Niobe* ES system also emits an audio signal that the system is in Navigate position. (You may adjust the volume in the Settings → System tab.)
4. If the cover contacts the patient and activates the cover sensor, the cover will stop and retract slightly. The other cover's position will adjust to try to reach the Navigate position.
5. If motion stops before the system reaches the Navigate position, one of these conditions has occurred:
   - The operator did not hold down the Navigate button until the system reached the Navigate Position. In this case, the operator may continue to the Navigate Position by pressing and holding one of the Navigate buttons on the Tableside Controller.
   - Both cover-force sensors have activated. The *Niobe* ES system displays a message in the bottom-left corner of the monitor and emits an audio signal if the system does not reach Navigate position because of cover-force sensor activation.
   - The cover cannot achieve the position because of a potential collision with the table or X-ray system**.**
   - The cover cannot achieve the position because the patient is not centered laterally on the table and one cover is fully extended.

Navigation Procedure Tasks

1. Place the patient on the table as described in "Recommended Patient Loading Procedure."
2. Prepare the patient per hospital procedure and apply a sterile drape over the tableside user interface.
3. Insert the magnetic catheter or guidewire and advance it to the desired anatomy. You can advance the device manually or with the *Cardiodrive* system (for approved catheters).
4. Place the X-ray system in the AP, head side position.

5. Press one of the Navigate (top row) buttons on the Tableside Controller. Release the button and press it again to move the magnets to the Navigate or Navigate AP position.

   Note: The system was designed with a safety feature that requires pressing the Navigate button multiple times to give the user an opportunity to double-check patient positioning and safety before moving the magnets.

   Note: If the system is unable to reach Navigate position when pressing the Navigate button due to a possible collision with the X-ray system or table, a Navigate Position Assistance dialog will display indicating which system components are at risk for a collision. See the Navigate Position Assistance section below for more details.

6. Perform the procedure.

7. When the procedure is complete, move the magnets to the Stowed position (see **Figure 2.**) by pressing the Stow button (**Figure 15**) on the Tableside Controller. Hold the button until the message "Magnets in Stowed Position" displays in the bottom-left corner of the window.

   CAUTION: The *Niobe* ES system uses a magnetic field to orient the tip of the catheter to the desired intracardiac orientation.

When the magnetic field direction is defined with the use of any single plane X-ray system, similar to the one employed with the MNS, the views are acquired simultaneously. However, when two X-ray views are employed, the views are not acquired simultaneously.

As a result, the overlay on the X-ray views is an approximate representation of the magnetic field direction relative to the heart's location. This is because the two X-ray views may have been acquired at different phases in the patient's respiratory and cardiac cycle.

When changes are made to the magnetic orientation of the device tip, confirm the orientation of the device tip with localization methods such as fluoroscopy and electrograms (if using a catheter). If the device tip is not at the desired orientation, update the magnetic field direction and repeat the magnetic navigation procedure if desired.

Navigate Position Assistance

The position of equipment (such as the table and X-ray arm) in the Procedure Room may interfere with magnet movement. If the system detects a collision risk while the magnets are moving, a Navigate Position Assistance dialog will be displayed. Warning messages associated with the collision risks will be displayed in the dialog. These messages show the system component in red (table, X-ray arm) that needs to be adjusted. In the case of a cover sensor activation, either of the magnetic pods will be shown in red (**Figure 22.**). After the appropriate adjustment is made to resolve the collision risk, the associated component will be shown in gray. In some cases, adjustments of multiple components may be required to resolve the collision.

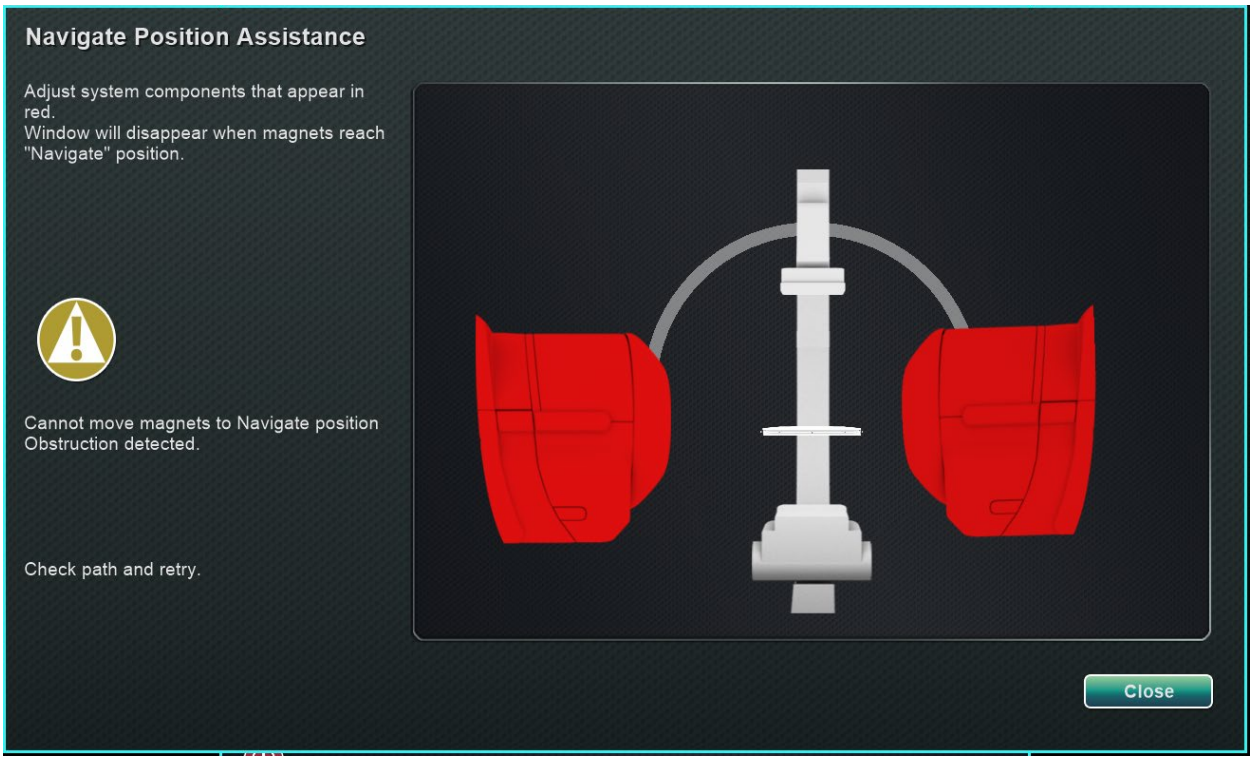


Figure 22. Magnet collision risk message

Once the collision risk has been eliminated, press and hold the Navigate button on the Tableside Controller. The dialog automatically disappears after reaching Navigate position. You are now able to proceed. If you have determined that no system component has a collision risk, you may press the **Close** button to remove the dialog.

The green zones in the Navigate Position Assistance dialogs represent regions where the C-Arm or table should be positioned to eliminate the collision risks. In **Figure 23**, the C-Arm is shown in red and needs to be adjusted until it reaches the green zone. Until the C-Arm collision risk is eliminated, the magnets will not move.

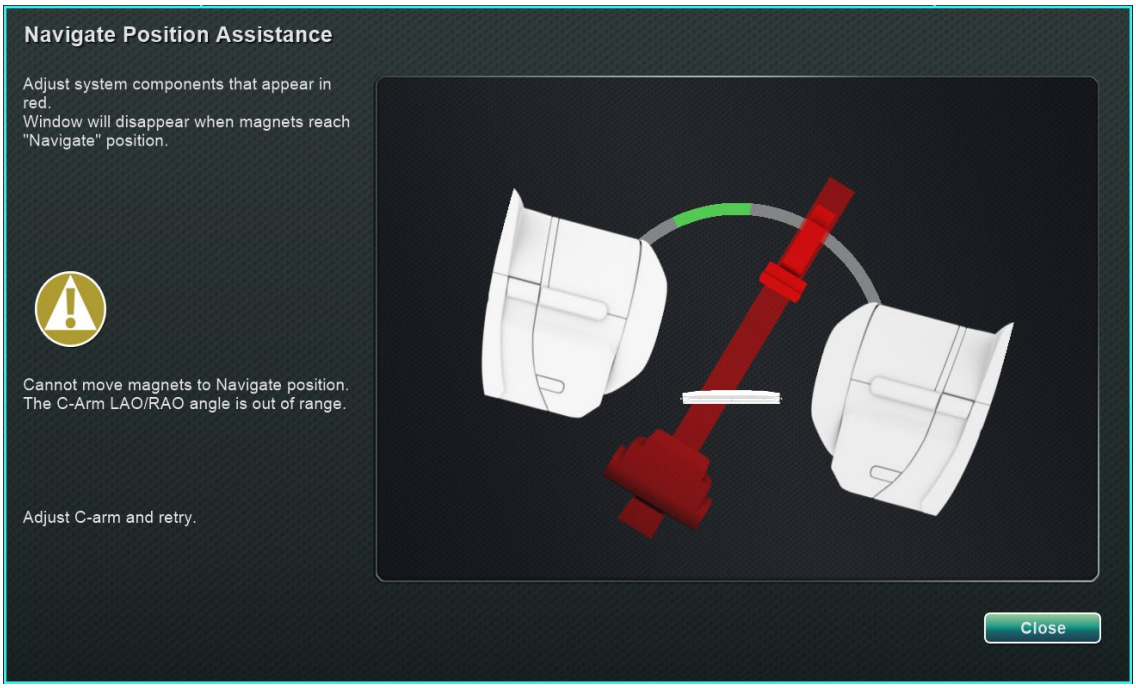


Figure 23. C-Arm collision risk message

In **Figure 24**, the C-Arm has been adjusted into the green zone and is shown in gray. You may now proceed as there is no collision risk.

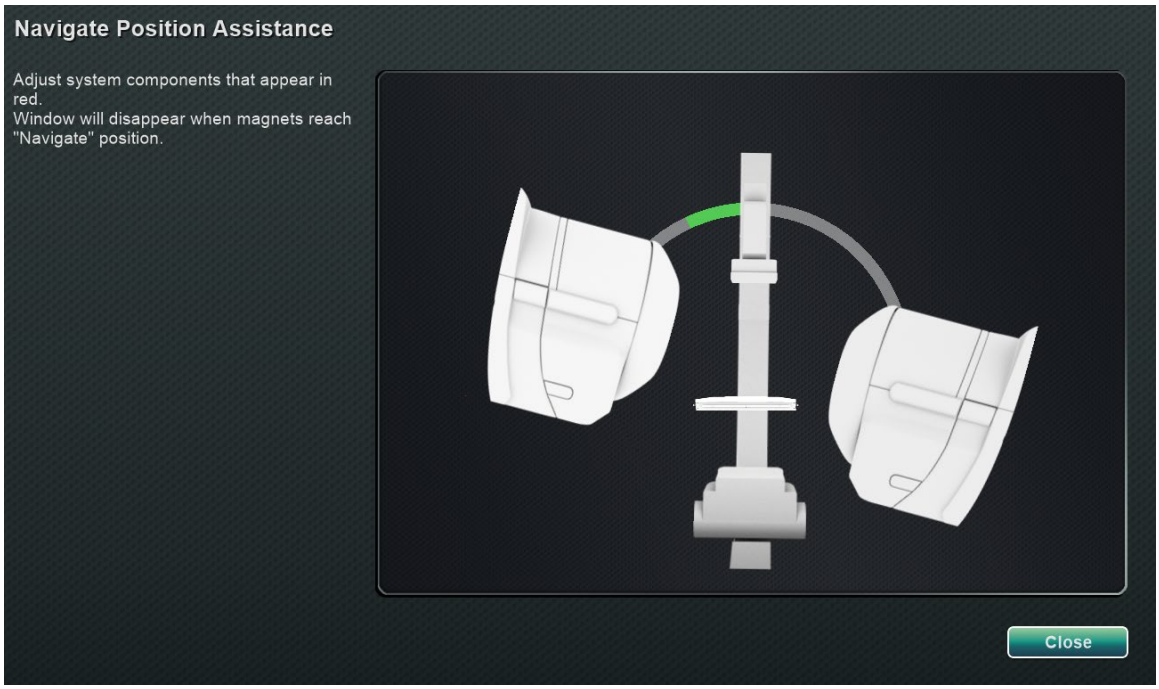


Figure 24. C-Arm graphic after C-Arm has been adjusted

In **Figure 25**, the table is shown in red. Before proceeding, adjust the table laterally until it is in the green zone and displays as gray. Once the table is shown in gray, it is safe to proceed as the collision risk has been eliminated.

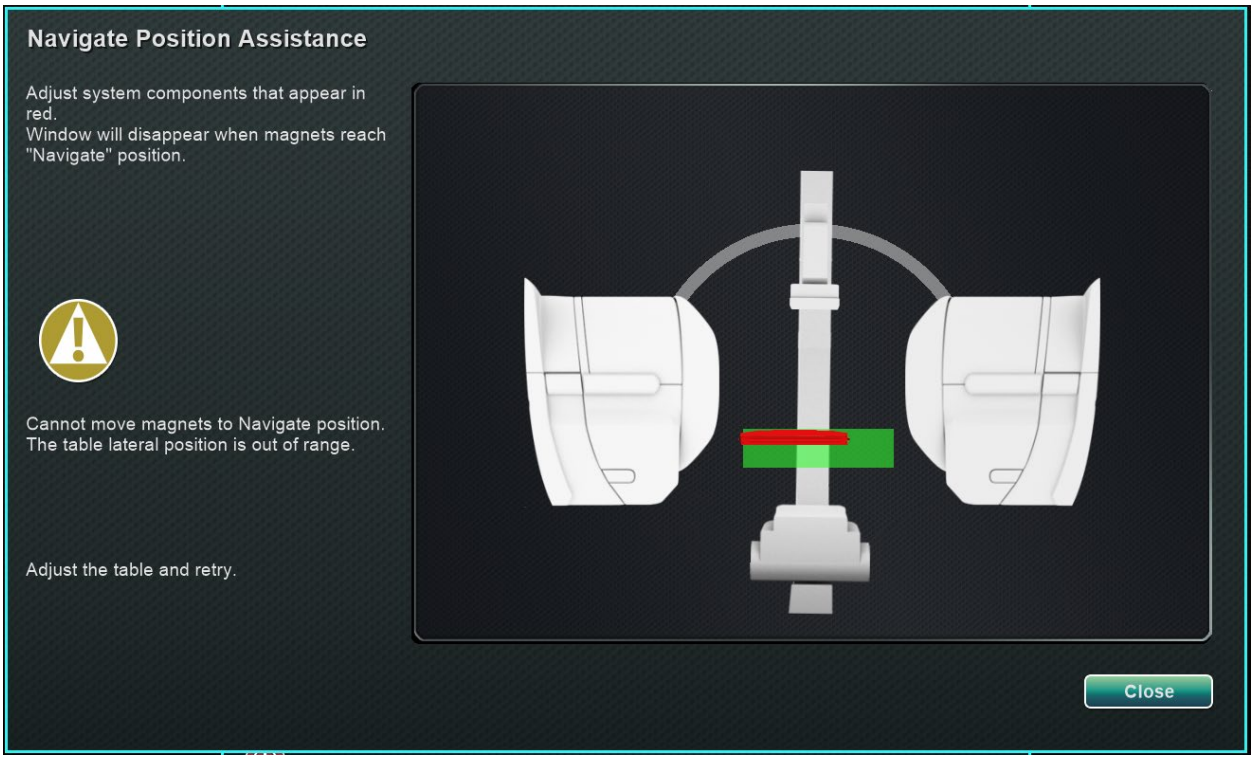


Figure 25. Table collision risk message

Software Basic Information

Start window

Figure 26. Start window

Start window guide (Figure 26.)

Functional buttons

① **Start New Procedure button.** Click this button to start a new procedure. A blank New Procedure Information window displays. Complete the information section, select a procedure type, click **OK**, and proceed to the main screen.

② **Open Existing Procedure button.** Click this button to restore a previously completed procedure. The Existing Procedure window displays a list of existing procedures. Select a procedure and the Procedure Information section populates for verification. Click **Open** to proceed to the main screen.

③ **Utilities button.** Click this button to access the Utilities window with three tabs: Physicians, Procedures, and Licenses. On the Physicians tab, you can rename or delete physician names. On the Procedures tab, you can view, import, export, and delete procedures. On the Licenses tab, you can view and install licenses. Click **Close** to return to the start screen.

④ **Help Guide button.** Click this button to display help documents onscreen. You may also click any question mark in an orange circle on any screen to display helpful information pertinent to the current topic.

⑤ **Shutdown System button.** Click this button to shut down the system. A confirmation dialog displays. Click **Yes** or **No**.

⑥ **System Indicators**

- ***Niobe* icon.** Click this icon (**Figure 27.**) to show the *Niobe* ES system messages, warnings, or errors.

Figure 27. *Niobe* icon

- **X-ray icon.** Click this icon (**Figure 28.**) to show the X-ray system messages, warnings, or errors.

Figure 28. X-ray icon

- **System info icon.** Click this icon (**Figure 29.**) to show *Niobe* ES system messages, warnings, or errors.

Figure 29. System info icon

Note: All system indicators may appear in three states:

- **Clear** – The system is ready.
- **"No" symbol** – The system is not ready for use.
- **Warning** – A warning message is available. Double-click the icon to display the message.

New procedure information window

Whether you are starting a new procedure or opening an existing one, the next display after the start window is the procedure information window (**Figure 30.**) The top graphic displays a traditional odyssey user interface and the bottom graphic displays a QuadHD user interface.

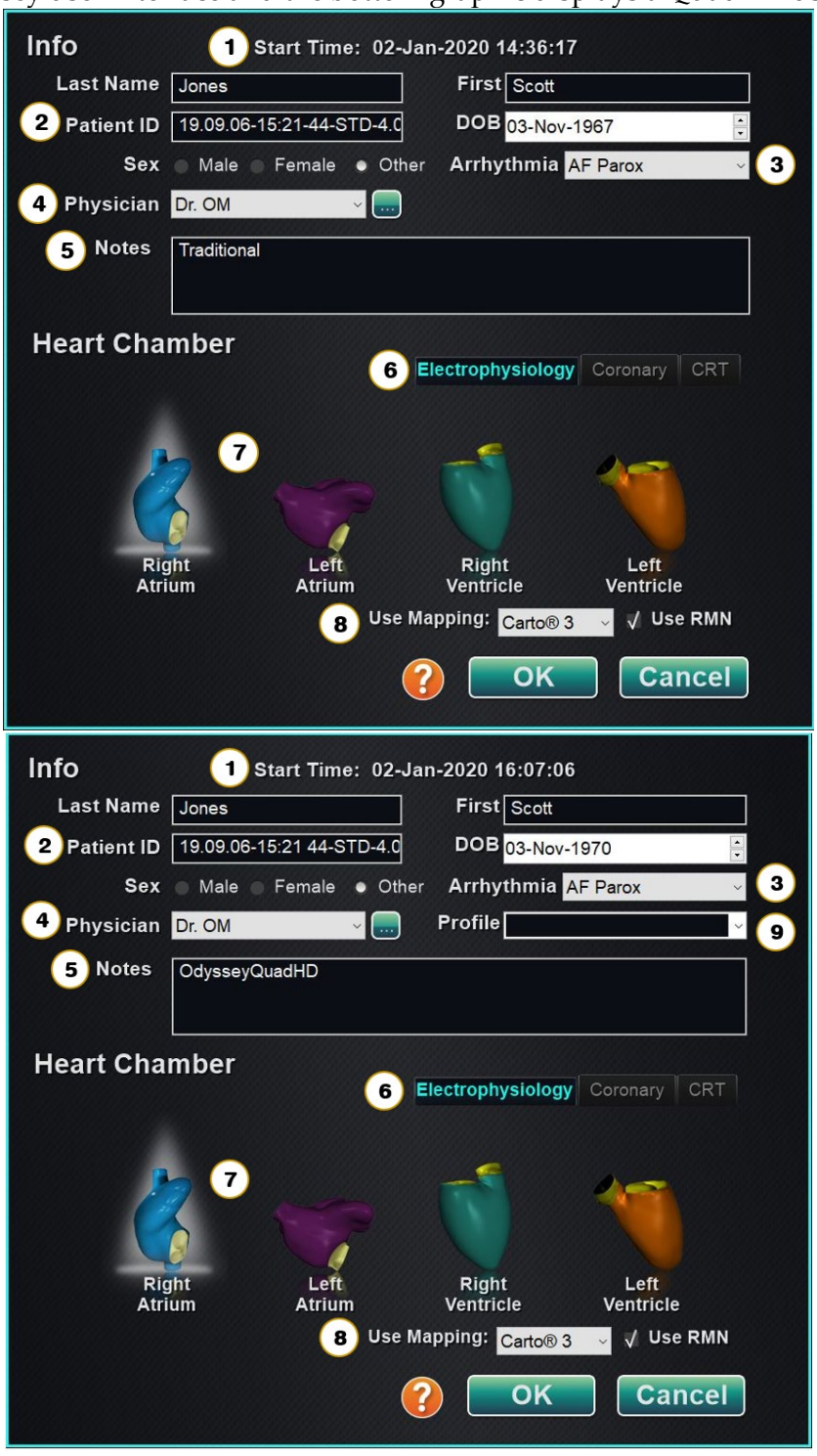


Figure 30. New procedure information window

New procedure information window guide (Figure 30)

① **Start Time field.** *Niobe* ES system automatically records the start date and time (to the second) of a new procedure.

② **Patient fields.** Supply the patient information (Last Name, First Name, Patient ID, Date of Birth, and Sex) in the appropriate fields.

③ **Arrhythmia field.** From the drop-down menu, select the type of arrhythmia involved.

④ **Physician field.** Click the down arrow to select a name, ***or*** click the  button to add a physician via the Utilities → Physicians tab (see "Utilities window" later in this section).

⑤ **Notes field.** Type any desired information about the case or procedure.

⑥ **Procedure Type tabs.** Procedures are divided by tabs into three types. Select the appropriate tab:

- Electrophysiology (EP)
- Coronary for Interventional Cardiology (IC)
- CRT (Cardiac Resynchronization Therapy)

⑦ **Heart Chamber panel.** Procedure types are further divided by heart chamber (when applicable). To choose the Heart Chamber, simply click on the appropriate anatomy icon. **Figure 30** shows an EP procedure with Right Atrium selected.

- EP: Right Atrium, Left Atrium, Right Ventricle, or Left Ventricle
- Coronary: Coronary arteries
- CRT: Coronary sinus

⑧ **Mapping System Selection.** (Displays only on the Electrophysiology tab.) The dropdown box provides the opportunity to select the mapping system for use with the procedure. All compatible mapping systems that are connected will be shown in the list.

⑨ **Profile field.** Click the down arrow to the right of the field to choose a procedure if working with previously entered information.

Help Dialog button. Displays Help Dialog (**Figure 31**) for fields on this screen.

Note: You may enter new information for the Physician and Profile fields to be stored for future procedures. The Physician and Profile fields are used to display the customized layouts that a physician has created.

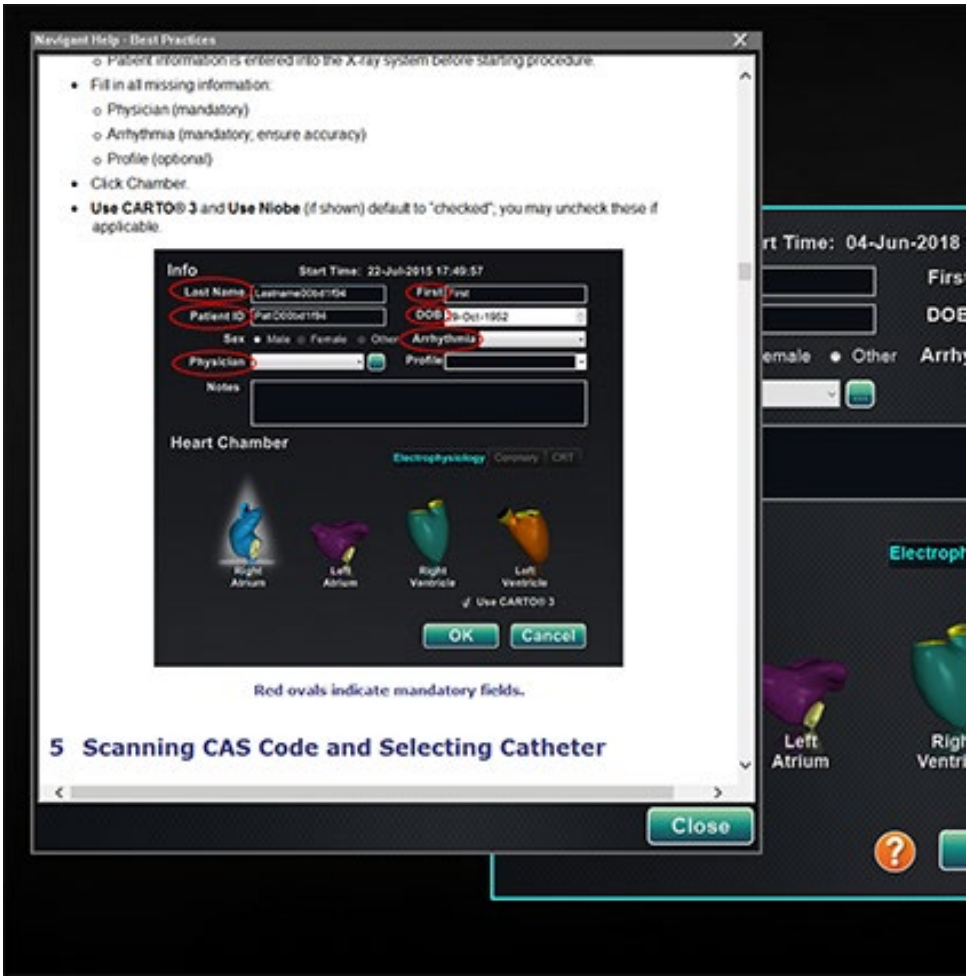


Figure 31. Help Dialog for new procedure information window

Figure 32. Existing procedure information window

Existing procedure information window guide (Figure 32)

① **Procedures list panel.** *Niobe* ES system lists all previously run procedures, with the most recent on top. Select a procedure.

② **Procedure Information panel.** The bottom panel displays the information the user typed at the start of the highlighted procedure:

- Start time and date
- Patient Information
- Physician name
- Notes

Note: Although you cannot edit information on this window, you can edit the Patient name and Notes after you open the procedure. Go to System options → Settings → Procedures.

Utilities window

The Utilities window features functions on three tabs: Physicians, Procedures, and Licenses (and a fourth, *Odyssey*, if this system is running). These tabs are used to configure aspects of the *Navigant* platform that are not procedure specific, such as licensing.

Physicians tab

(Figure 33. – Figure 36)

Figure 33. Utilities window – Physicians tab

① **Physician list.** When a physician starts a procedure, he or she must select *or add* a physician name. These names display on the Physicians tab. The list displays in alphabetic order. If present, select a physician name.

② **Delete button.** Click **Delete** to remove a physician's name (or right-click on the name and select **Delete**) (**Figure 34.**).

③ **Rename button.** Click **Rename** to edit a physician's name (or right-click on the name and select **Rename**) (**Figure 34.**). Edit the name in the edit field. Press **Enter** to save the change.

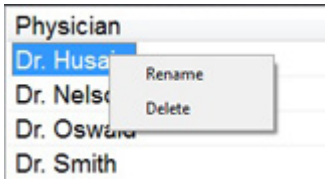


Figure 34. Right-click to rename or delete physician name ***or*** edit name in edit field

④ **Add button.** Click **Add** to add a physician's name. Type the name in the Physician Name field (**Figure 35**). Press **OK** to save the addition. The screen returns to your former display (e.g., New Procedure) with that physician selected.

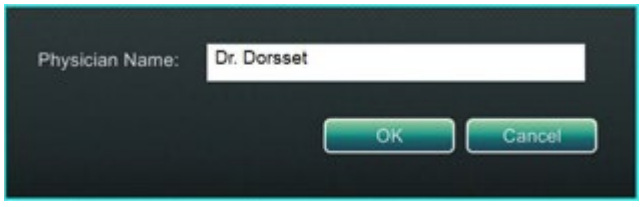


Figure 35. Physician Name add field

However, if the physician name "collides" with an existing entry, the message in **Figure 36** appears. You must edit the field to create a unique name and then click **OK** or click **Cancel** to return to the Physicians tab to modify entries as necessary.

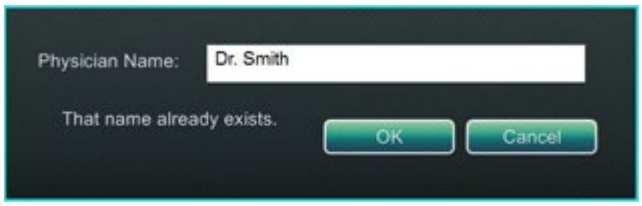


Figure 36. Physician Name duplication message

⑤ **Close button.** Click **Close** to close the window.

Procedures tab

Figure 37. Utilities window – Procedures tab with single selection

① **Procedures list.** The Procedures list displays saved procedures and can be sorted by clicking the column heading for:

- Start Time
- Patient
- Physician
- Procedure Type

② **Select a procedure.** Select one procedure or multiple procedures by holding the **Ctrl** key for non-sequential selections and the **Shift** key for sequential selections.

③ **Delete button.** Click to delete a procedure.

④ **Import button.** Click to display the Select source folder for Import window.

⑤ **Export button.** Select a procedure from the Procedures tab and click **Export**. The Select destination folder for Export window displays.

⑥ **Close button.** Click **Close** to close the window.

Import window

Import source folder guide (Figure 38)

① **Import window.** The Select source folder for Import window (**Figure 38**) is a Windows browser. Navigate to the drive or directory that contains the procedure folder to be imported. Typically, this is a USB flash drive (also called thumb drive, flash memory, multimedia drive, or travel drive).

② **Close buttons.** Click **OK** to import the procedure or **Cancel** to cancel the import.

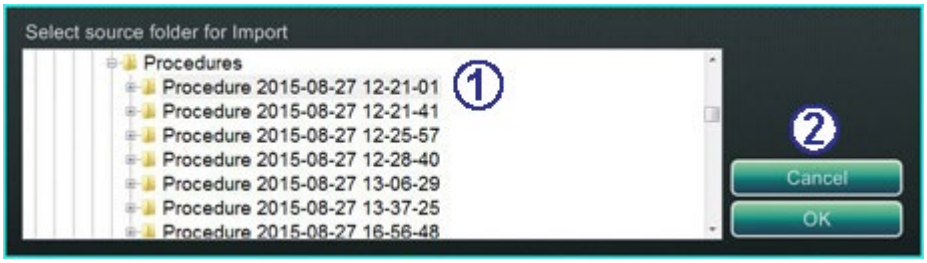


Figure 38. Select source folder for Import window

Export window

Export destination guide (Figure 39)

① **Export window.** The Select destination folder for the Export window (**Figure 39**) is a Windows browser. Navigate to the drive or directory where the exported procedure file is to be saved. The file may be saved to a flash drive or a CD.

② **Export level.** Select the level of export for your procedure:

- **Full Procedure**
- **De-Identified.** Procedure that contains no identifying patient data.
- **Image only.** Only the screen captures saved during the procedure.

③ **Close buttons.** Click **OK** to export or **Cancel** to cancel the export.

Note: You have sole responsibility to export data according to your own internal procedures. If no guidelines are on site, Stereotaxis recommends a full procedure backup every 3 months.

Figure 39. Select destination folder for Export window

Licenses tab

(Figure 40.)

The Licenses tab lists licenses acquired with the *Navigant* system. The columns show the following:

- Name
- Start date
- Expiration date
- Status (Active or Expired)

① **Install button.** Only Stereotaxis representatives should operate the **Install** button.

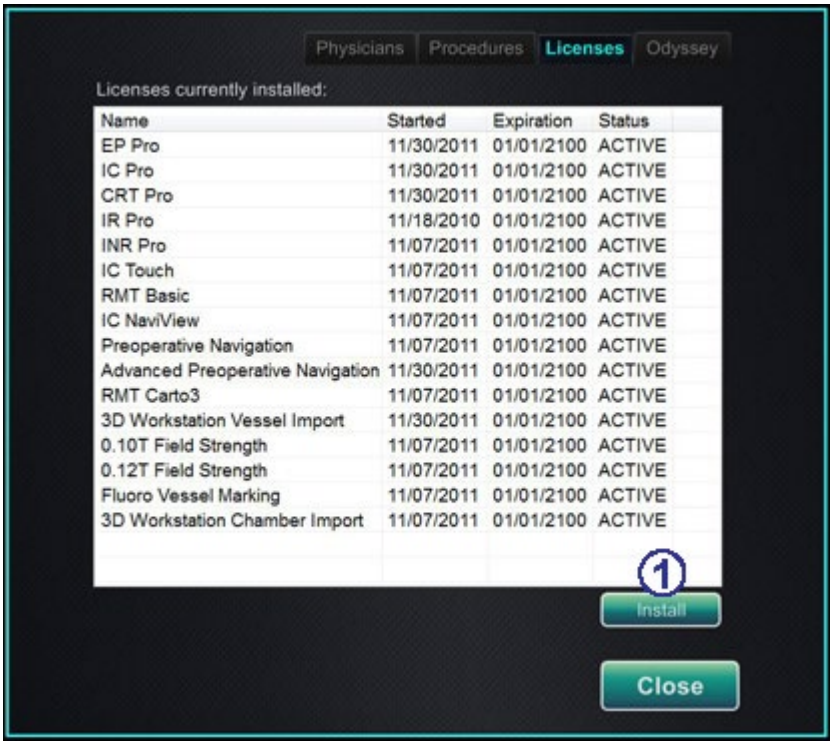


Figure 40. Utilities window – Licenses tab

Input Devices

The *Niobe* ES system provides these input devices in the Control Room: a standard wheel mouse, a standard keyboard, a keypad, a CD/DVD drive, the *Cardiodrive* user interface, and a barcode scanner.

A wheel mouse is provided in the Control Room and an optional second mouse is located on a small platform attached to the accessory rail in the Procedure Room. In addition to standard functions, the wheel mouse controls catheter advancement and retraction when the wheel is rolled forward or backward, respectively.

Cardiodrive user interface

The *Cardiodrive* catheter advancement system (CAS) user interface (**Figure 41**) provides CAS controls and alternate methods of navigation. The interface is one of three instruments for advancing and retracting the CAS catheter. The other two are the mouse wheel and specific buttons on the *Navigant* keypad in the Control Room.

Figure 41. *Cardiodrive* (CAS) user interface

Cardiodrive (CAS) user interface guide (Figure 41)

① **E-stop button.** Push the red button to quickly shut down power to the CAS interface. When the button is pressed, power is off, and the green light is off. To restore power, twist the button clockwise; the green light should turn on. (However, if the *Niobe* E-stop is on, the CAS E-stop green light will not turn on.)

② **Selection button.** Push this button to enable CAS. When CAS is enabled, the green light is on. Also use this button to take control from the Procedure or Control Room.

③ **Joystick button.** Press and hold this button to activate the joystick. The graphic shows a top view of the joystick with the button outlined by the dashed orange circle.

④ **Joystick.** Tilt the joystick forward (toward the +) to advance the catheter and back (toward the –) to retract it. The motion is slower as you approach the joystick's center and speeds up as you tilt the joystick farther in either direction.

⑤ **Step size controller.** This button controls the step size. Twist the button counterclockwise to point it to the 1 mm setting and clockwise for the 3 mm setting.

⑥ **Single step buttons.** Press these buttons to advance (+) or retract (–) CAS one step at a time (1 mm or 3 mm). Or double-press these buttons to advance twice the set distance (2 mm or 6 mm).

Note: The *Cardiodrive* CAS enables physicians to advance/retract compatible magnetic electrophysiology (EP) catheters from a control room. Before utilizing CAS, compatible catheters must be registered. See **Registering to CARTO® 3** or **Registering to OpenMapping** for more information about catheter registration.

QuikCAS unit

The *QuikCAS* catheter advancement system is used to remotely advance and retract catheters during magnetic navigation.

Scanning the activation code of each *QuikCAS* unit is necessary before use, when initiating a procedure. This procedure ensures that only authorized devices designed and tested with the Stereotaxis magnetic technology are used during magnetic navigation, and it prevents the unintentional use of expired sterile products.

Figure 42. *Above* – Barcode scanner *Right* – Example of *QuikCas* barcode (highlighted by red box)

The *Niobe* ES system includes a barcode scanner (**Figure 42.**) situated in the Control Room. The scanner must be used to scan a valid activation code to activate the *QuikCAS* device.

The *QuikCAS* activation code is located on the CAS II disposable box in two places: The outer box label and the inner tray label. Scan either label to activate the *QuikCAS* device. **Figure 42.** shows a sample of the activation code location outlined in red.

Note: Scan an activation code at any time before requesting a magnetic field direction.

To confirm whether the scan was successful, observe the appropriate status messages.

- Before the start of the procedure, status messages are displayed above the system indicators on the start window.
- The status message of a successful activation code scan is shown in **Figure 43**.

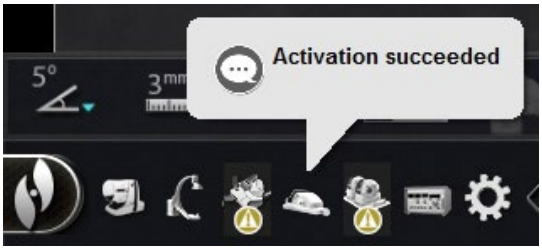


Figure 43. Activation succeeded

- The activation code displays in the text field at the bottom of the Device Selection dialog (**Figure 44**).

Figure 44. Device Selection dialog with Activation Code displayed

- If the scan is successful, the text field will be disabled. No user input is required.
- If the scan is not valid, the text field will be enabled and the user will be able to input (type) a valid scan code.

The CAS system status may be checked by clicking the CAS procedure indicator (icon in red circle in **Figure 45**) on the hardware status bar:

Figure 45. CAS procedure indicator

Keypad

The keypad augments the standard keyboard. Several *Navigant* system functions are available on this keypad and are described below.

Keypad keys

Guide to Figure 46.

1. Apply Field
2. Reduce Field
3. Transfer Image
4. Decrease device deflection
5. Increase device deflection
6. Counterclockwise device rotation (mimics torque)
7. Clockwise device rotation (mimics torque)

Note: The device deflection and rotation keys imitate the actions of a standard (non-magnetic) deflecting device. Use them for small adjustments.

Figure 46. Keypad – Top blue keys and orange keys

Guide to Figure 47

(8) Up arrow for magnetic field deflection

(9) Down arrow for magnetic field deflection

(10) Right arrow for magnetic field deflection

(11) Left arrow for magnetic field deflection

Note: These keys relate to the window selected from the Settings panel.

The left and right field deflections are executed in a rotational adjustment about the vertical axis.

To deflect magnetic fields, you must press and release the respective arrow key.

Figure 47. Keypad – Green keys

Guide to Figure 48.

(12) Store navigation

(13) Advance *Cardiodrive* (CAS) device one step

(14) Retract *Cardiodrive* device one step

(15) Stops automation for:

- Chamber targeting
- *Bullseye* Targeting pattern navigation
- Vessel sequencing
- Automapping

Figure 48. Keypad – Stop key and right blue keys

Cleaning Instructions

Cleaning the lab

Because the magnetic field in a Stereotaxis lab is always on, caution must be taken while cleaning the lab. MRI-compatible cleaning equipment is recommended, such as mops and brooms without ferrous material in their construction.

To clean the floor under the *Niobe* system, pivot the system between the Stowed and Navigate positions with the Tableside Controller.

Cleaning the *Niobe* system

The *Niobe* system can be wiped clean between each case. The cleaning solutions used are institution specific but should be a hospital-grade, EPA-registered germicidal solution (e.g., CIDEX® Activated Dialdehyde).

Niobe drapes can be purchased to cover the magnetic navigation system and maintain a sterile field on the front of the pods to keep them clean throughout the procedure. Please contact your Account Manager to purchase *Niobe* drapes as needed.

3. *Navigant* Features

Clinical Workflow Manager

The Clinical Workflow Manager (CWM) is your map through a clinical workflow. It displays on the left of the main window throughout a procedure. You may use it to work your way through an entire procedure, or ignore it and follow your own workflow. You may change workflows by selecting one of the workflows marked with an asterisk listed on the Start tab (**Figure 49**).

Figure 49. Clinical Workflow Manager (CWM)

The default layout shows the CWM as the first tab open when a procedure starts. The following are icons of all tabs. (The remaining tools are discussed next.)


CWM


Stored Navigations


Object Visibility


Bullseye Targeting

Control Panels

The tabs for the control panels in a default layout display on the left side of the dialog below that for the CWM.

Navigations control panel

The Navigations control panel displays categories (**Figure 50**) from which to display **preset navigations**.

Figure 50. Navigations panel categories

Preset navigations

The list of preset navigations changes based on the workflow and steps you are following.

1. To display preset navigations, click the arrow next to the category name.
2. To select a preset navigation - Left Atrium for **Figure 51**, *left* – click to highlight the preference. Once the preset navigation is highlighted, the **Apply** button becomes available (**Figure 51**, *right*).
3. Preset navigations represent commonly used **field directions**. You may want to fine-tune these settings by moving the field vector slightly.
4. After the user selects **Apply**, the option to store the navigation then becomes available (**Figure 52**, *left*).

Figure 51. Left: Stored navigations for Left Atrium; *Right:* **RS PV** selected and **Apply** button available

Figure 52. *Left:* **Store** button available; *Right:* "Navigation #1" example of stored navigation

Stored navigations

1. When you have created a new field direction you want to store, click **Store** (**Figure 52**, *left*) ***or*** press the store navigation button on the keypad (**Figure 53**).

Figure 53. Store navigation button on keypad

2. Stored navigations are displayed under a new heading, "**Stored Navigations**," and fields are sequentially named: Navigation #1, Navigation #2, etc., as shown in **Figure 52**, *right*.

Note: Stored navigations store field (vector) directions, **NOT** *positions*.

Currently applied navigation

The currently applied navigation, Navigation #4, is bold in **Figure 54**, *left*. If the user wants to explore other stored navigations, the stored navigations can be selected prior to being applied. In **Figure 54**, *right*, Navigation #3 is selected (and highlighted) but not in bold as Navigation #3 has not yet been applied.

Figure 54. Currently applied, stored navigation

Rename stored navigations

1. To rename a stored navigation, right-click the name and select **Rename** (**Figure 55,** *right*). The field opens for editing.
2. Type a new name and click **Apply**. The stored navigation is renamed.

Figure 55. Rename stored navigation—*Left:* Options dialog; *Right:* New name typed

Delete stored navigations

1. To delete a stored navigation, right-click the name and select **Delete** (**Figure 56**).
2. A confirmation message displays in the middle of the Navigations panel. Click **Yes** to confirm or **No** to cancel.

Figure 56. Delete stored navigation—*Left*: Options Dialog; *Right*: confirmation message

Visible Objects control panel

Visible Objects guide (Figure 57.)

① When you open a new procedure, the Visible Objects control panel is empty.

② The control panel field populates as you create vessel reconstructions, point groups, surface points, and maps (if you are using a mapping tool) (**Figure 57.**).

Following are the types of dialogs and the visible objects they create:

Dialog	Visible Objects
Fluoro Annotation	Groups
NaviView3	Vessels
Volume Marking	Vessels, Surfaces
CARTO® 3 Registration	Maps

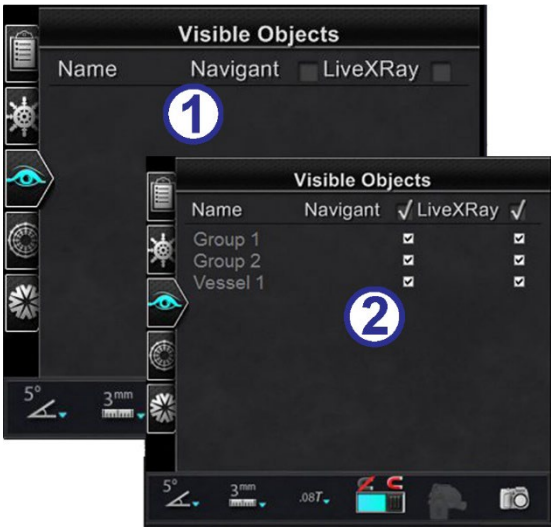


Figure 57. Visible Objects control panel

Note: During a procedure, catheters, vectors, and point groups are highlighted when the cursor is positioned over them. Clicking on the object selects it.

Visible Objects checkboxes

The checkboxes for **Navigant** and **LiveXRay** serve as filters. When they are checked, selected objects display on the *Navigant* and *LiveXRay* monitors. When they are cleared, objects do not display.

You can select or clear an entire column of checkboxes by clicking the checkbox next to a title in the menu bar: ***Navigant*** or **LiveXRay** (**Figure 58**).

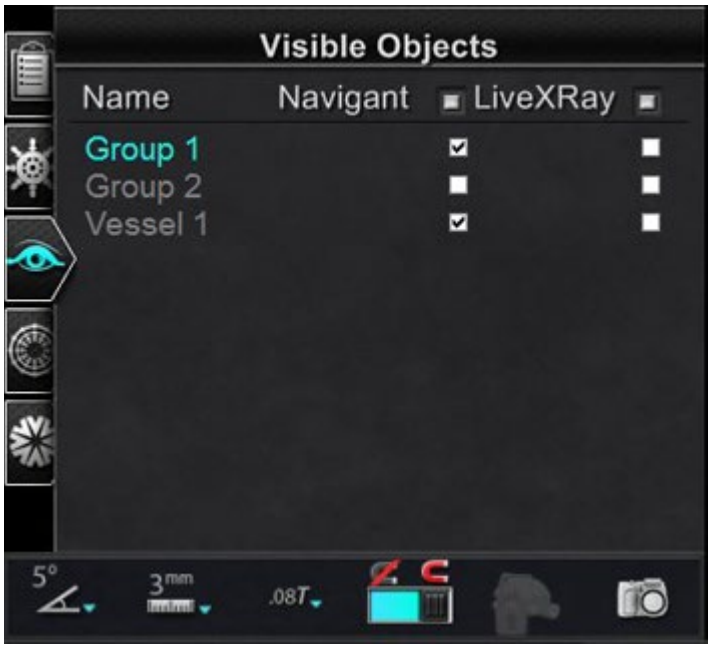


Figure 58. Display checkboxes for Visible Objects

Editing and deleting Visible Objects

Each visible object type has a different right-click menu. However, they all have a Delete command.

Delete

To delete an object, right-click its name in the objects list and select **Delete** (**Figure 59**).

Edit Geometry

To edit an object, double-click its name in the Visible Objects list, or right-click and select **Edit Geometry**. Its source guidance dialog opens for editing (**Figure 59**).

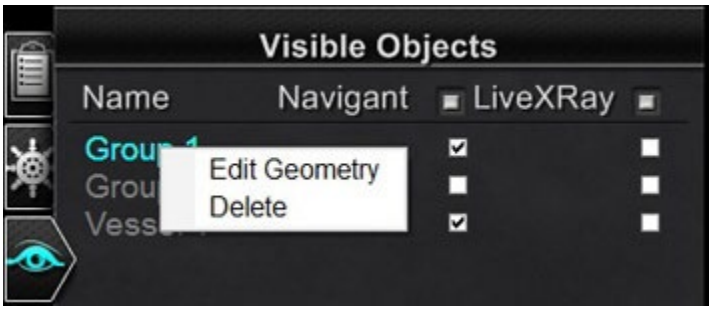


Figure 59. Right-click menu for Groups – Edit Geometry and Delete

Right-click menu for Vessels

Vessels are the only Visible Objects that display the **Properties** and **Manual Registration** commands on the right-click menu (**Figure 60**).

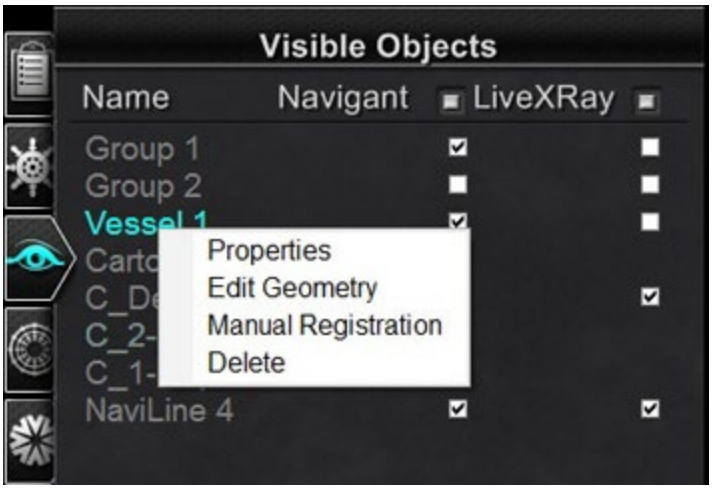


Figure 60. Right-click menu for Vessels –
Properties, Edit Geometry, Manual Registration, and Delete

Vessel Properties

Click **Properties** in the Visible Objects Vessel right-click menu.

The Vessel Properties dialog displays (**Figure 61**). In Vessel Properties, you can change the appearance of the vessel's 3D reconstruction:

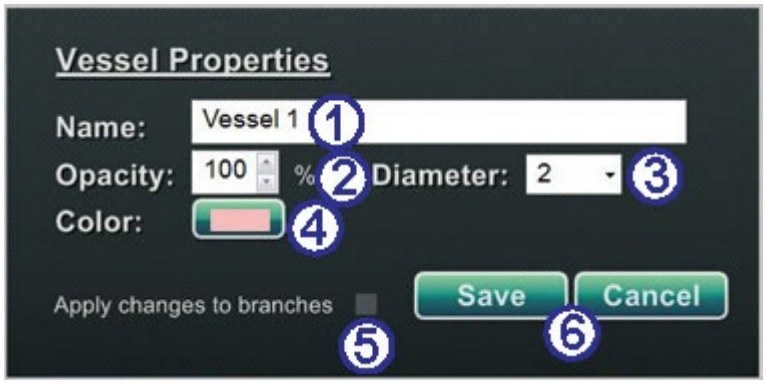


Figure 61. Vessel Properties dialog with Diameter drop-down menu and Color palette

Vessel Properties guide (Figure 61)

① **Name.** The existing name is highlighted by default. Type a new name.

② **Opacity** (transparency). The range is 0 to 100 percent. Click the up and down arrows to change the number.

③ **Diameter.** Click the drop-down arrow to display a selection box. The range is 1 to 12 mm. Click the preferred number to select it.

④ **Color.** Click the existing color to display a color palette. Click the preferred color to select it. If you have created vessel branches, you can apply all changes to the branches by clicking:

⑤ **Apply changes to branches** checkbox. To clear it, click the checkbox again. The checkbox is clickable only if branches exist.

⑥ Click **Save** to save the changes or **Cancel** to close the dialog without saving changes.

Manual Vessel Registration

Click **Manual Registration** in the Visible Objects Vessel right-click menu (**Figure 62**). The Vessel Registration dialog displays (**Figure 63**).

You can use this feature if you have extracted a vessel from a volume or marked a vessel that does not match your current fluoro images. This feature can move vessel images for viewing the position of a guidewire.

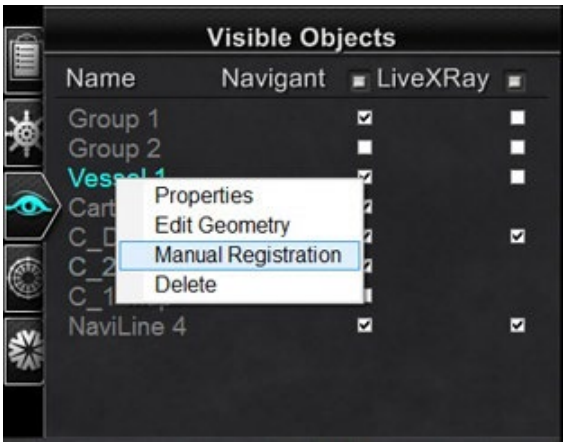


Figure 62. Manual Registration command on Vessel Visible Objects right-click menu

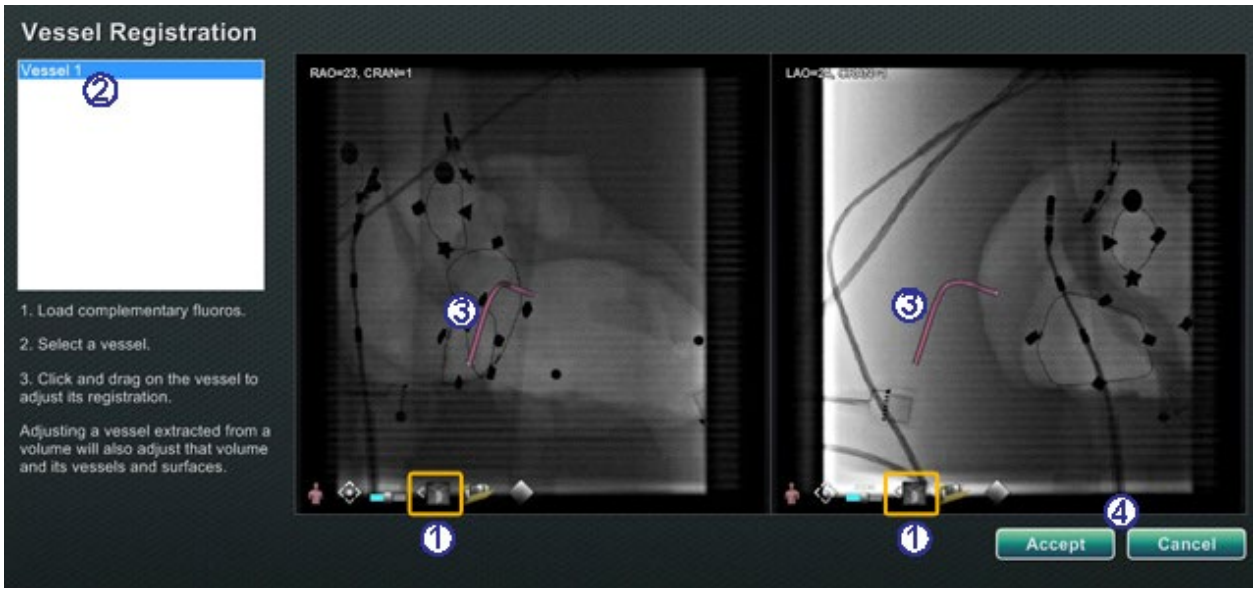


Figure 63. Vessel Registration dialog

Vessel Registration guide (Figure 63)

① Load fluoro images A and B (if not already loaded).

② Select a vessel.

③ Click and drag the vessel in any direction (except rotational). Dragging the image in one fluoro view causes the image in the second view to move in tandem.

④ Click **Accept** or **Cancel** to close the dialog.

Note: Adjusting a vessel extracted from a volume also adjusts the volume and its vessels and surfaces.

Carto Colors and Carto Tags

The items **Carto Colors** and **Carto Tags** may be checked or unchecked in the *Navigant* column on the Visible Objects panel once you have set up CARTO® registration. **Figure 64.** through **Figure 67** indicate the various display options.

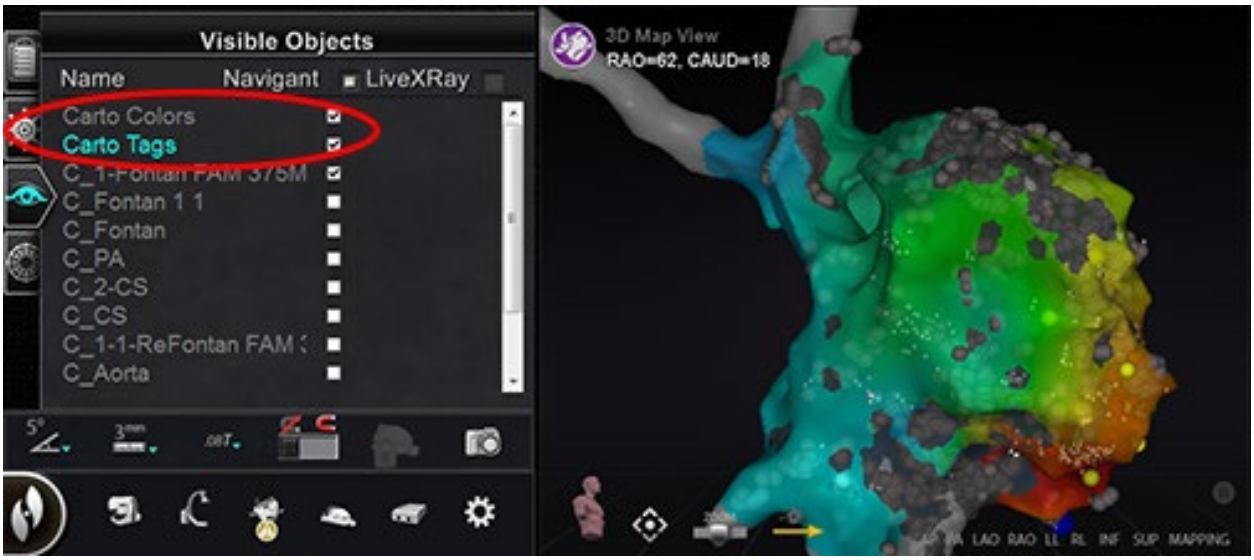


Figure 64. Carto Colors and Carto Tags mapped

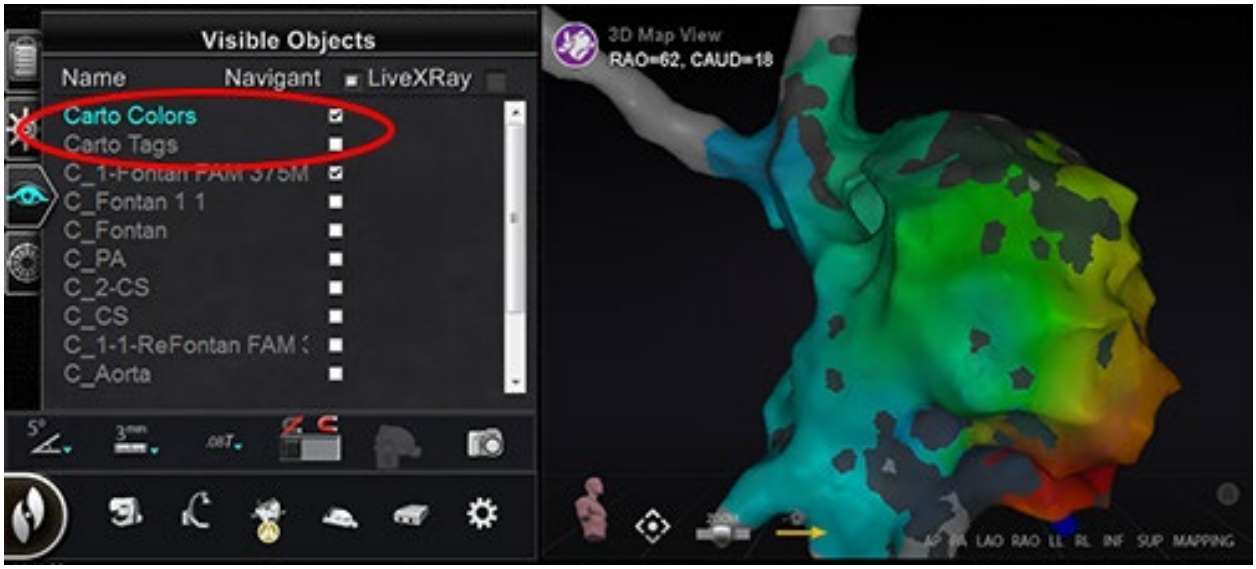


Figure 65. Carto Colors without Carto Tags

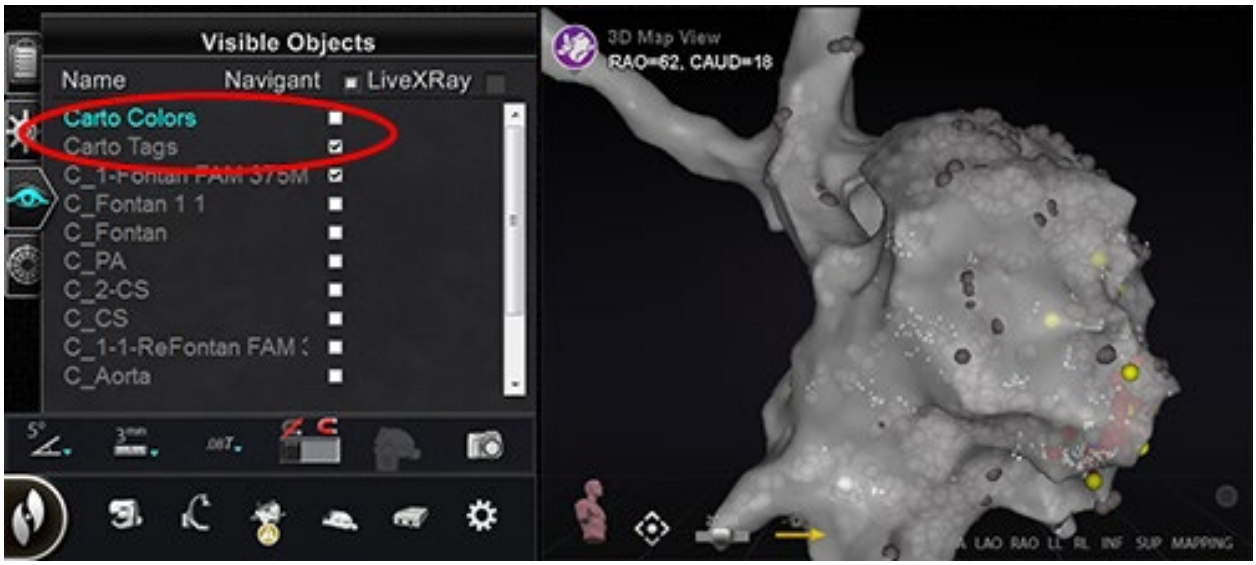


Figure 66. Carto Tags without Carto Colors

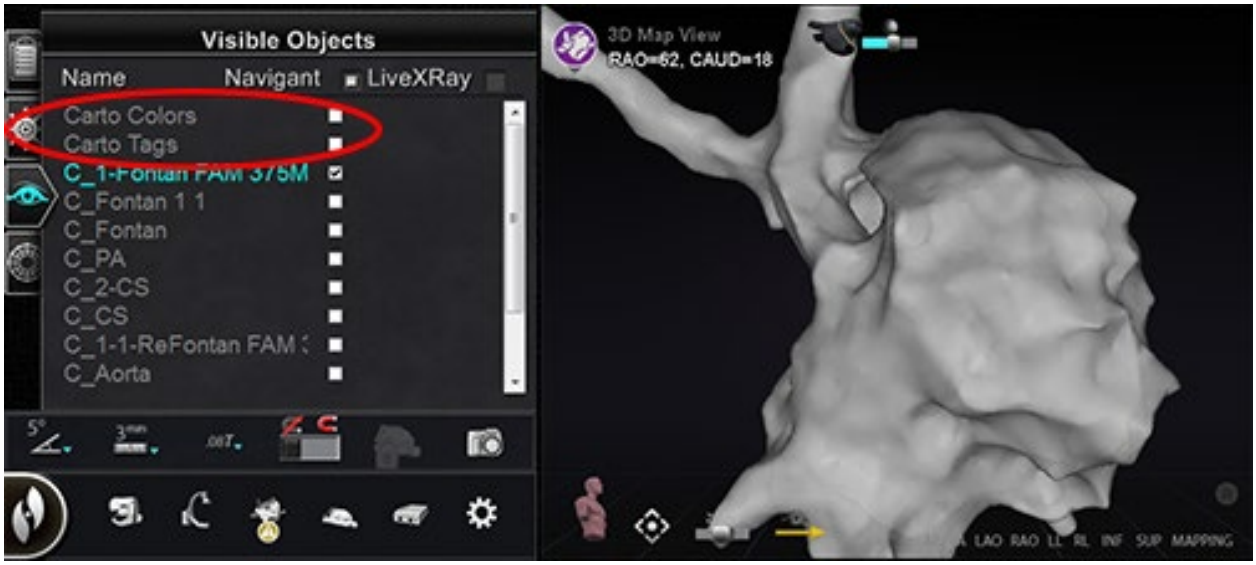


Figure 67. Carto Colors and Carto Tags hidden

Bullseye Targeting control panel

The *Bullseye* Targeting control panel (**Figure 68**) provides a simple interface for navigating the catheter around a central point.

Figure 68. *Bullseye* Targeting control panel

A dartboard "bull's eye" target has a central axis surrounded by concentric rings. The Stereotaxis *Bullseye* uses the target concept (**Figure 69**) to facilitate directional movement of the catheter relative to a central position. Movements around a central axis are made by double-clicking on the target surface or via automatic sequencing.

Bullseye movement is simultaneously visible in two places on the solution screen: (1) within the *Bullseye* surface itself and (2) in the Ideal Anatomy view.

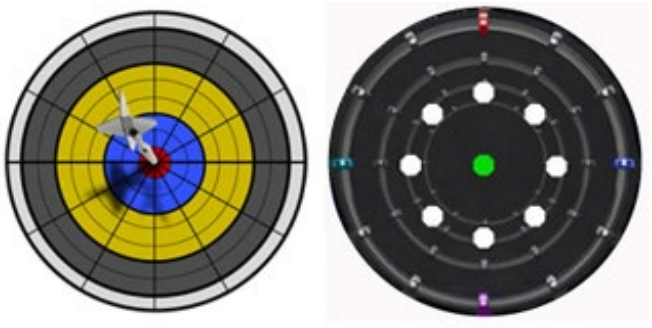


Figure 69. Typical "bull's eye" target (*left*) and *Bullseye* Targeting (*right*)

The *Bullseye* Targeting tool may be used with magnetically enabled catheters in EP or guidewires in vascular procedures:

- In EP, *Bullseye* Targeting enables the circumferential evaluation of electrical signals within the great vessels of the heart, such as pulmonary veins, or systematic regional mapping of a cardiac wall to identify a signal of interest, such as conduction gap and CFAE.
- In vascular procedures, *Bullseye* Targeting can locate a particular branch opening or a channel through a diseased vessel.

Bullseye Target colors

The *Bullseye* Target has four colored markers that correspond with the four markers on both ends of the field direction vectors (**Figure 69**): red, blue, purple, and turquoise. As previously noted, you can navigate with *Bullseye* Targeting in two ways:

- Double-click on the *Bullseye* surface to indicate where you want the location of the vector. Double-clicking on any point within the *Bullseye* field will move the vector in that direction.
- Click the automatic play button, and the vectors will move according to the selected configuration.

With the colored markers, if you double-click the *Bullseye* red marker, the vectors will move in the direction of the red marker. If you double-click between colors, the vectors move toward the position that is between those two colors.

With automatic play, you can better visualize the position, angle, rotation, and direction of the vectors by watching where the vector goes in relationship to the markers on the *Bullseye* surface and the vectors (**Figure 70**).

Figure 70. *Bullseye* Target and vector markers aid navigation

Bullseye Target and vector color guide (Figure 70)

① ***Bullseye* Target:** In this radial configuration, the vector is moving to the center.

② **Vectors:** The vectors follow the *Bullseye* guidance by moving to a point between the red and blue markers.

Note: Automation is currently running. The Automation dialog is outlined by a red rectangle in **Figure 70**. For more information about the Automation dialog, see **Automation Features.**

Bullseye Targeting guide (Figure 71. and Figure 72.)

① ***Bullseye* Targeting.** The *Bullseye* Target itself is the canvas where the center axis and points are depicted (**Figure 71.**).

The buttons on the right control variations in point appearance and movements on the *Bullseye* Target.

② **Play/Stop button (Figure 72.).** Starts and stops automatic catheter movement in a defined pattern. This button is a toggle that displays future action, not the current activity.

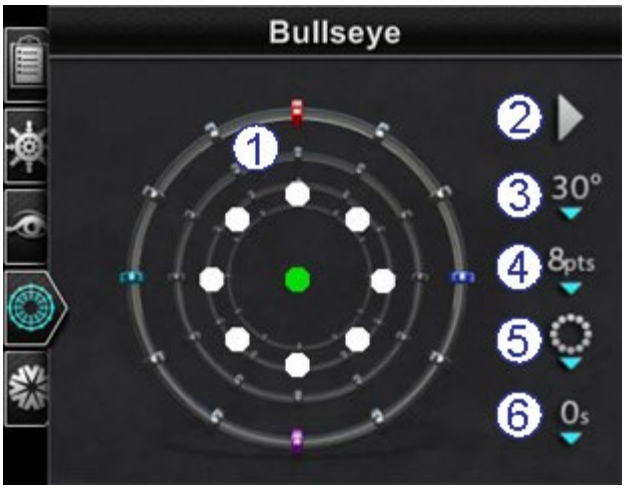


Figure 71. *Bullseye* Targeting control panel with default settings

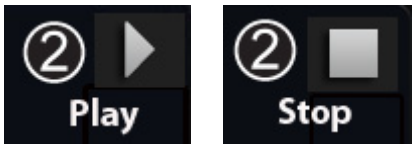


Figure 72. The Play / Stop button toggles

③ **Angle.** Controls the angle of deviation from the center axis. Increasing the angle extends the deviation; decreasing the angle reduces the deviation from the center axis.

④ **Points.** Controls the number of points displayed.

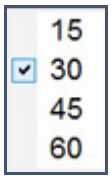
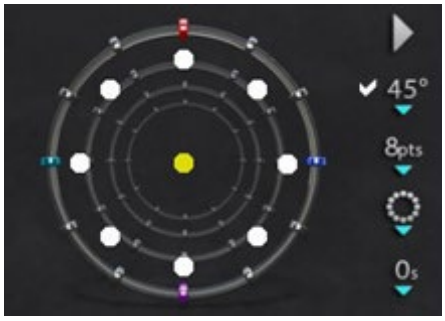
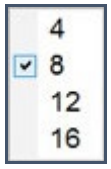
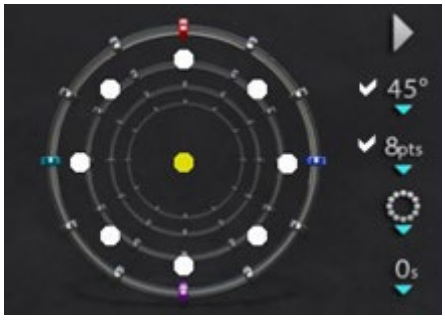
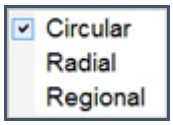
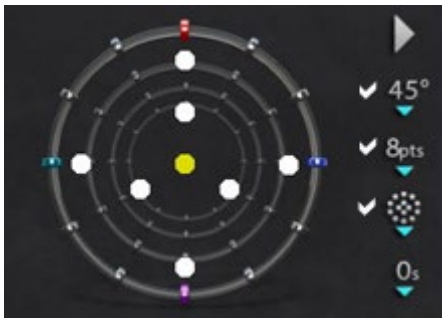
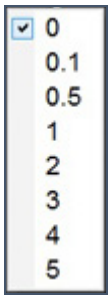
⑤ **Pattern.** Controls the pattern of points: circular, radial, or regional.

⑥ **Time Delay.** Controls the duration of pauses between catheter movement during automation.

Note: The example in Figure 71. shows the default buttons for *Bullseye* Targeting settings.

Altering *Bullseye* Targeting

The following table shows the popup menus from the *Bullseye* buttons that have a green down arrow. The figures also show changes in *Bullseye* Targeting as menu options are applied. The white checkmark(s) have been added to show what feature(s) changed on each image.

Name	Button icon	Menu with default setting	Alternate pattern examples
Angle button			 **Figure 73.** *Bullseye* Targeting changed to 45 degrees
Points button			 **Figure 74.** *Bullseye* Targeting changed to 45 degrees and 8 points
Pattern button			 **Figure 75.** *Bullseye* Targeting changed to 45 degrees, 8 points, and regional pattern
Pause length button			**No image displayed** because the *Bullseye* image does not change when you change the pause length.

Note: The *Bullseye* Targeting automation is performed in continuous motion mode by retaining "0" for the pause length.

Bullseye Targeting automation

After specifying your settings, click the play button (which toggles between play/stop) to start automatic navigation. The automation indicator displays with a "spinner." You can click **Stop** at any time to halt automation, either on the button in this dialog (see **Figure 76**), or on the OBUI (Odyssey Bedside User Interface) button in the Procedure Room.

Note: Selecting "**Stop**" on the automation dialog or on the OBUI will stop **all automation**, not just *Bullseye* Targeting automaton.

Green and yellow dots indicate magnetic direction in *Bullseye* Targeting. As with vectors, green represents the target direction and yellow represents the current direction. The green dot moves first, indicating the next targeted direction, and the yellow dot follows to the target (**Figure 76** and **Figure 77.**).

Figure 76. *Bullseye* Targeting circular pattern with Automation dialog and **Stop** button displayed (lower left)

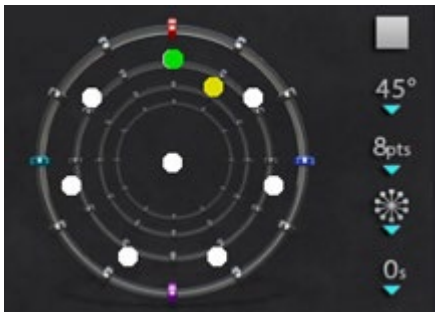


Figure 77. *Bullseye* Targeting radial pattern

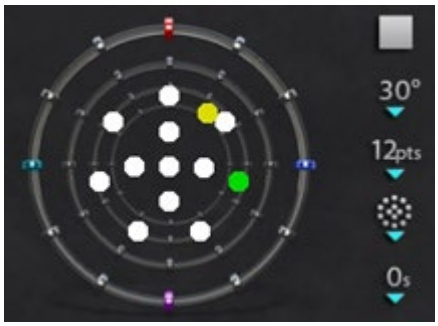


Figure 78. *Bullseye* Targeting regional pattern

Movements vary according to the pattern you have selected:

- If you accepted the default circular pattern, the dots move clockwise in a circle.
- If you selected the radial pattern (**Figure 77**), the dots move from the center to the circumference, back to the center, then on to the next point on the circumference.
- With the regional pattern (**Figure 78**), the dots tend to move around an outer circle first, followed by an inner circle. If you are going to select the regional pattern, you should increase the number of points displayed to get a more consistent pattern.

Bullseye Targeting audio

If you have the audio turned on, you will hear a *ping* each time the yellow dot reaches the target (green dot). This ping is an auditory prompt to select a point in mapping or move the guidewire. You can turn off the sound by going to **System options icon → Settings → System → Audio Settings → Play sounds on field apply** and selecting *Never* from the drop-down menu (**Figure 79**). The slide bars for adjusting the volume for the Procedure and Control rooms are just above the drop-down menu.

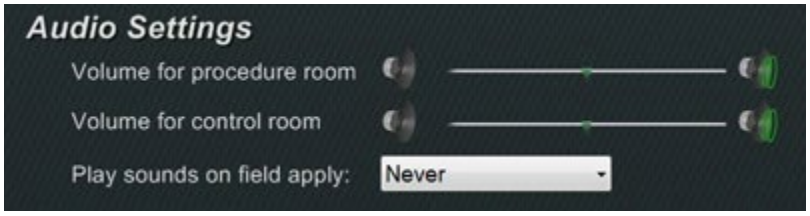


Figure 79. Audio Settings

Storing points in *Bullseye* Targeting

In addition, when the yellow dot reaches a target, the **Store** button is enabled on the Navigations panel (**Figure 80**). Click it if you want to store the current field direction – or press the Store Navigation button on the keypad (see **Figure 53**).

Figure 80. Store Navigation button is enabled (*left*) when *Bullseye* Targeting hits target (*right*)

You may want to adjust the speed of movement, so you have more time to click the **Store** button while it is enabled. (As soon as the green dot moves again, **Store** is disabled.)

Control Toolbars — The "Dashboard"

The two toolbars at the bottom-left corner of the main window are similar to the dashboard of a car. They display functional buttons and information about the system:

- Main toolbar
- Hardware status indicator bar

Main toolbar

The Main toolbar (**Figure 81**) is the first of two toolbars on the dashboard.

Figure 81. Main toolbar

Main toolbar guide

① **Global angular step size (Figure 82.).** Displays a menu of angles by degree: 1, 3, 5, 10, 15, and 30. The default is 5 degrees. The step size applies to the 2D anatomic control windows, the anatomic direction adjustment keys, and the rotation deflection keys.

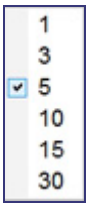


Figure 82. Global angular step size menu

② **Global step size (Figure 83).** Displays a menu of step size parameters from 1 to 9 mm for the *Cardiodrive* device. The default is 3 mm.

Figure 83. Global step size menu

③ **Magnetic field strength** (**Figure 84.**). Displays the magnetic field strength for current procedure. Clicking this button allows you to change the magnetic field strength (**Figure 87**).

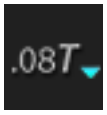


Figure 84. Magnetic field strength example

④ **Apply magnetic field** (**Figure 85**). Click if you have reduced the magnetic field and want to restore it to its previous strength. The button is disabled if the software is not connected to the

Niobe ES system.

Reduce magnetic field (**Figure 86**). Click if you want to decrease the magnetic pull on the catheter or guidewire (**Figure 87**). Following are instances where you might want to reduce the magnetic field:

- Inserting catheters to keep them from dragging in the sheath
- Moving the sheath position to keep the catheter relaxed
- Moving a catheter up the inferior vena cava without a sheath
- Exchanging the wire
- Pulling any wire out of the body

Figure 85. Apply Magnetic Field

Figure 86. Reduce Magnetic Field

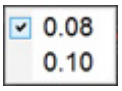


Figure 87. Magnetic field strength menu

⑤ **Access Protection.** This icon indicates the status of the Access Protection, Enabled (Locked) or Disabled (Unlocked).

⑥ **Screen capture.** This button captures the entire screen and stores it in the directory on the computer's hard drive. A system message displays the date and time of the capture. The screen capture is saved with all 6 numbers plus a system identifier: workstation or assistant.

Note: The main toolbar appears as shown in **Figure 88** when ***no device is selected***. The buttons for Magnetic Field and Access Protection are disabled.

Figure 88. Main toolbar display when no device is selected

Hardware status indicator bar

The hardware status indicator bar (**Figure 89**) can display several icons, depending on the number of connected devices. Each icon functions as a status indicator and a button. Each indicates one of three states: good (clear icon), information (icon plus gold triangle), and not connected (icon plus the "no" symbol).

Figure 89. Hardware status indicator bar

Hardware status indicator bar guide (Figure 89)

① System options. This button displays the System Options menu (**Figure 90**):

- The options above the gray line display general dialog boxes.
- The lower options display guidance dialog boxes.

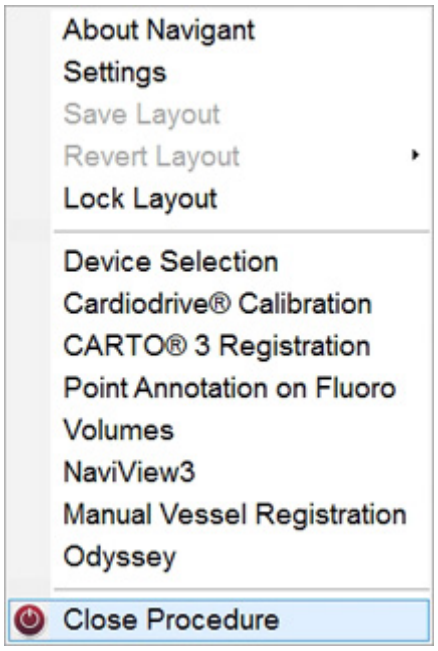


Figure 90. System Options menu example

Note: For systems with Layout Editor, this option replaces the three "Layout" options visible in the Figure 90 example.

② *Niobe* status indicator and button 

③ X-ray / fluoro status indicator and button 

④ Connection to mapping system-status indicator and button 

⑤ *Cardiodrive* status indicator and button 

⑥ *Vdrive* status indicator and button (if available) 

⑦ Stockert generator status indicator and button 

⑧ System status indicator and button 

Note: The system status button also serves as an anchor for popup system messages.

Viewing messages

Following are the three ways to view hardware status messages:

- **ToolTips** (**Figure 91.**): Hold the cursor over the button to view the ToolTip status message summary.

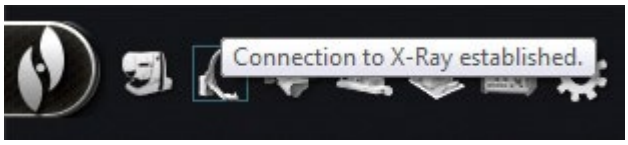


Figure 91. ToolTip displaying X-ray status message summary

- **Popup messages** (**Figure 92.**): The *Navigant* software displays messages when necessary. They pop up from the hardware icon that represents the affected system.

Figure 92. Popup window displaying *Niobe* message

- **Dialogs** (**Figure 93.**): Double-click a button to open a dialog with information about that hardware system.

The three message types are distinguished by icons:

Information

Warning

Error

Figure 93. CARTO® 3 dialog displaying all three types of messages – Information, Warning, and Error

System Options Menu

Access the System Options menu by clicking the system options button on the hardware status toolbar (**Figure 94**). Several options display (see also Figure 90).

Figure 94. System options button (far left) on hardware status toolbar

- About *Navigant*
- Device Selection
- Point Annotation on Fluoro
- Manual Vessel Registration
- Settings
- Catheter Registration
- Volumes
- *Odyssey* (if available)
- Layout options
- CARTO® 3 Registration
- *NaviView3*
- Close Procedure

About *Navigant*

The About *Navigant* dialog displays information about the software, such as name, company name, patents, version number, and copyright (**Figure 95**). Access it from the System Options menu (system options button) on the hardware status indicator toolbar (see Figure 94).

Figure 95. About *Navigant* dialog

Layout Editor

The Layout Editor (**Figure 96**) allows you to customize the procedure layout displayed.

The Layout Editor is available in **Traditional** or **Magnetic HD** systems. For directions to alter layouts in **Magnetic Quad** systems, refer to the *Odyssey Vision* User Guide or *Odyssey Vision* QHD User Guide.

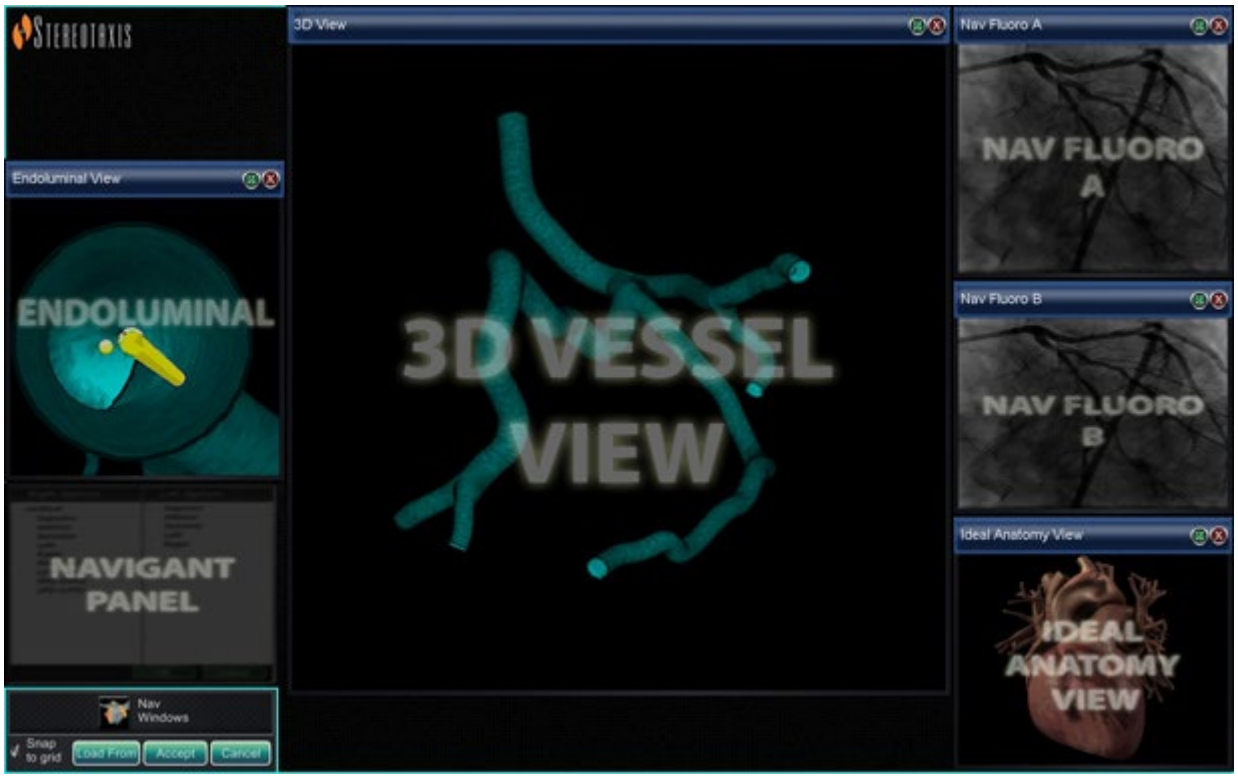


Figure 96. Layout Editor

Move, resize, and close control panels and windows

Move

Move a window or control panel Layout Editor by pressing and dragging anywhere in the element except the **X** in the red circle (upper-right corner). When you select an element, a bright blue border displays around it (**Figure 97**). When you drag it to a position where it overlaps another element, the border of both the selected element and the overlapped element turn bright red. You cannot save a layout when elements overlap.

Figure 97. Control panel on left has a bright blue border because it is selected. Two control panels at right have red borders because they overlap each other.

Note: Because Clinical Workflow Manager is in a static position in the *Navigant* system, you cannot move, close, or resize it in Layout Editor.

Resize

To resize a window or control panel, hold the cursor over any part of the edge. The cursor changes from a pointer to a double arrow (**Figure 98**). Press and drag the edge as desired. If you resize the element so it overlaps another, the border turns red. You cannot save a layout when elements overlap.

Figure 98. When resizing elements in Layout Editor, cursor turns to double arrow

Close

Close an element in Layout Editor by clicking the red circle **X** ( ) in the upper right corner.

Figure 99. Layout Editor Control Panel

Layout Editor Control Panel guide (Figure 99 and Figure 100)

Nav Windows menu button. Displays a list of available and displayed *Navigant* windows.

Nav Controls menu button. Displays available and displayed *Navigant* control panels.

Accept button. Saves the designated layout.

Cancel button. Rejects layout edits and returns to previous screen.

Load From button. Allows the user to copy a layout from another user for the same layout.

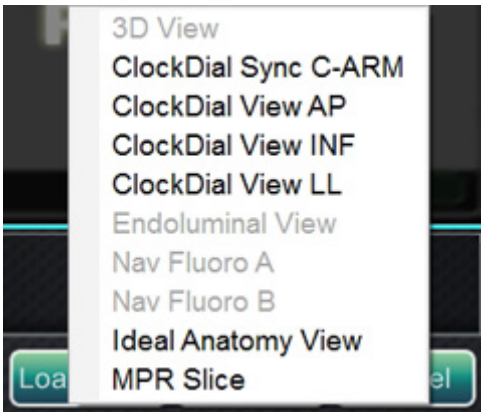


Figure 100. Example of *Navigant* Windows menu in Layout Editor – Siemens system

Notes:

- A window or control panel cannot be repeated within a layout.
- Only one instance of Live Fluoro A may exist in any given layout.

Select a window or control from the menu to add it to the layout. Move or resize other elements in the layout if necessary so none are overlapping. (Overlapping elements are indicated by a red border.) If you would prefer to use an existing layout, you may use the **Load From** button.

Figure 101. Load From dialog in Layout Editor

Load From dialog guide (Figure 101)

- To import this layout from a different physician, use the Load From dialog (**Figure 101**). Select a physician name (and/or profile for the layout), and then click **OK**.
- To use the *Odyssey* default layout, leave the Physician Name and Procedure Type fields blank and then click **OK**.

When the layout is satisfactory, click the **Accept** button from the Layout Editor Control Panel. (The **Accept** and **Cancel** buttons are available only after a layout is changed.) After clicking the **Accept** button, the save dialog (**Figure 102**) displays.

- Click the **For This Procedure Only** button to use the layout for *only* the current procedure.
- Click the **As My New Default** button if you want the layout to be available for *all future* procedures for this *physician and procedure type*.

Figure 102. Save dialog in Layout Editor

Settings

The Settings dialog contains four tabs (and an additional one or two tabs if a *Vdrive* robotic navigation system and/or *Odyssey Vision* system is connected):

- *Navigant* Window
- System
- Live Fluoro
- Procedure

Each allows you to control various *Navigant* system elements.

Navigant Window tab

Settings in the *Navigant* Window tab (**Figure 103**) are saved by Physician and Procedure Type. For example, Dr. Nestor may have several different default settings saved per procedure type. Each settings tab allows you to control various *Navigant* system elements.

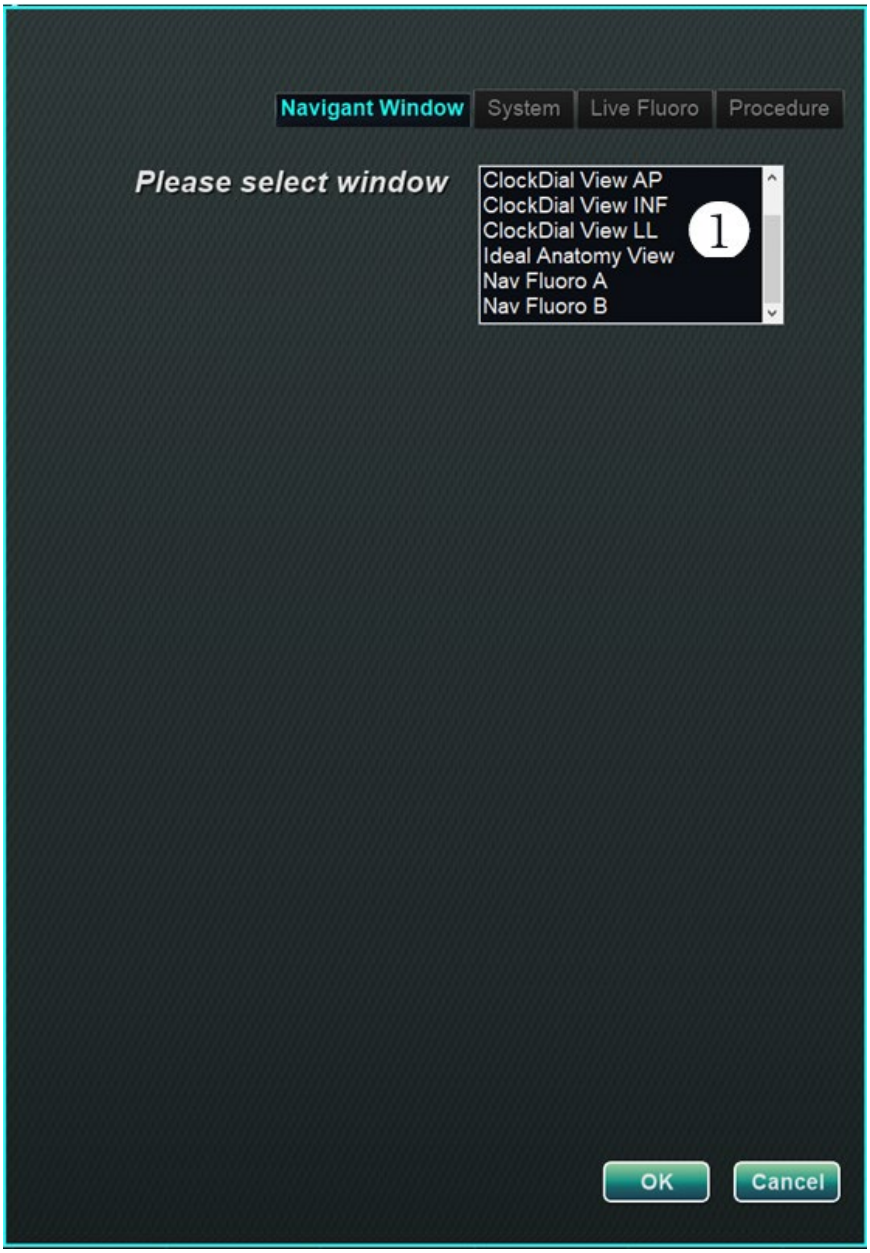


Figure 103. Settings windows – *Navigant* tab before window selection

① **Please select window.** Select the desired window from the selections displayed and adjust settings as seen in **Figure 104**. (*3D Map View* and *3D Map View B* are also window options, found at the top of the window selection scrollbar.)

In **Figure 104**, 3D Map View has been selected. 3D Map View and 3D Map View B will display mapping system items. Upon registration to a mapping system, fluoro (x-ray) data will display (see the message emphasized by a yellow rectangle in **Figure 104**).

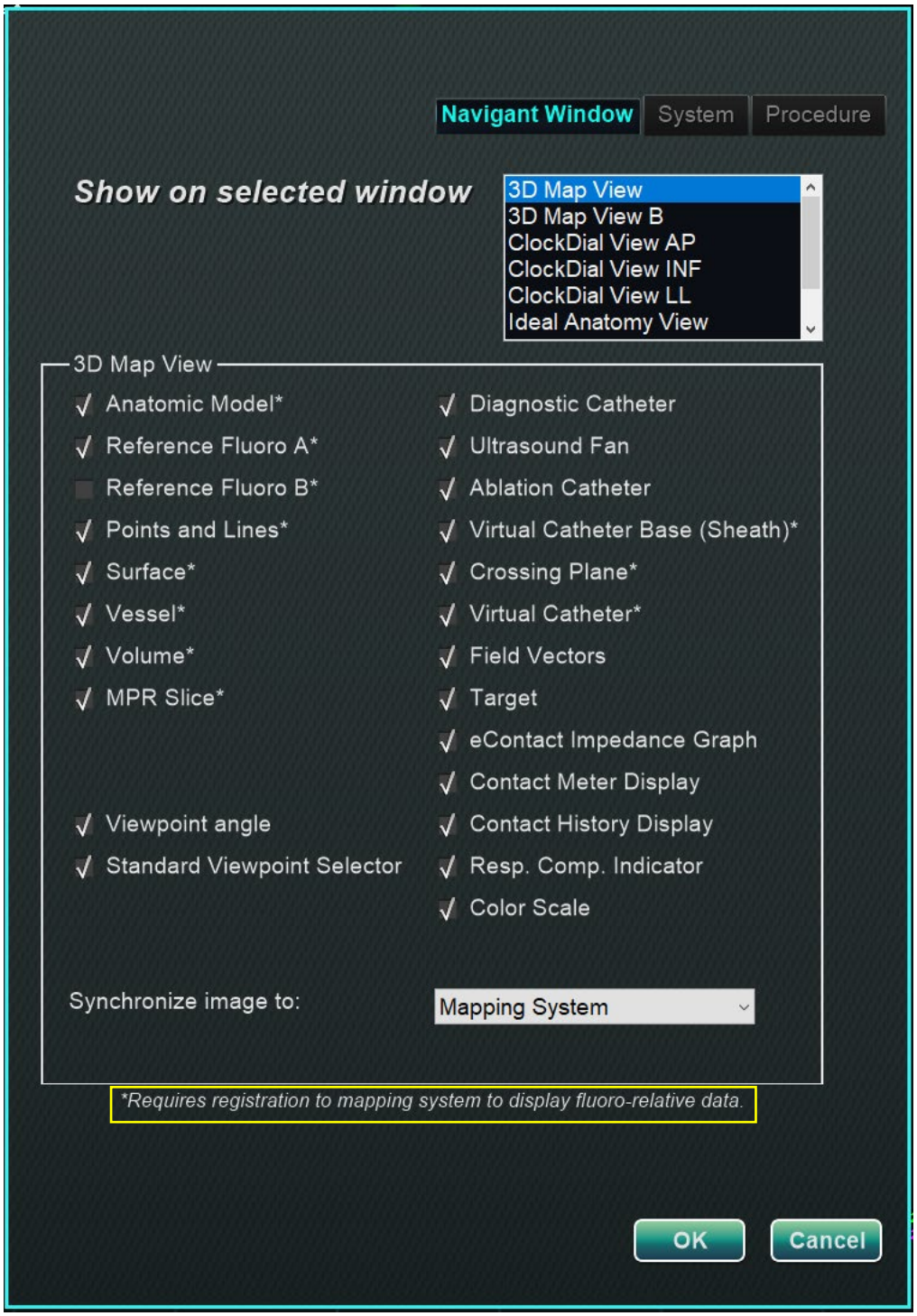


Figure 104. Settings windows – *Navigant* tab with 3D Map View window selected

Alternatively, when any other window is selected such as Ideal Anatomy View in **Figure 105**, fluoro (x-ray) items will display. Upon registration to a mapping system, mapping system data will display (see the message emphasized by a yellow rectangle in **Figure 105**).

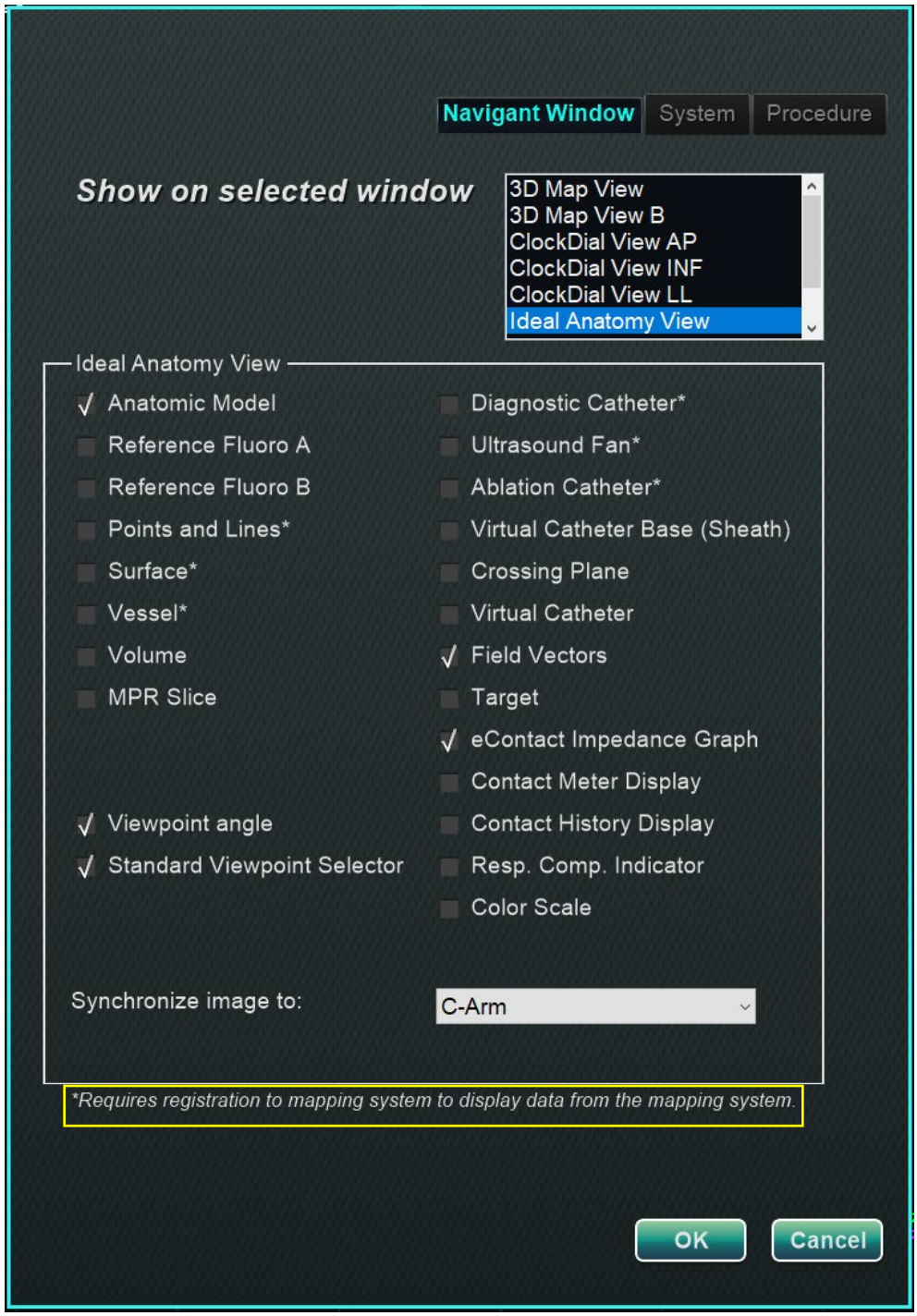


Figure 105. Settings windows — *Navigant* tab with Ideal Anatomy View window selected

Navigant Window tab guide (Figure 106 – Figure 108)

Selected window viewing options

Click on the box to the left of the items (selected items will display a √) you wish to view. The 3D Map View window example in **Figure 104** shows typical selections for the 3D Map View window. If, for example, the Fluoro A window is selected, the Reference Fluoro A box would typically be checked.

General window options

- **Viewpoint angle.** The C-Arm angulation (**Figure 106**).

Figure 106. Viewpoint angle

- **Standard Viewpoint Selector.** The selection bar for standard anatomic views (**Figure 107**).

Figure 107. Standard Viewpoint Selector

"Synchronize image to" drop-down menu

The selection menu for image synchronization. For example, in **Figure 108**, the image is synched to the CARTO® 3 system. This may be changed to C-Arm, Fluoro A, Fluoro B, or no synchronization ("None").

Figure 108. "Synchronize image to" drop-down menu

OK / Cancel

Click **OK** to accept the changes or **Cancel** to close the window without saving changes.

System tab

Control the following settings on the System tab (**Figure 109**).

- General
- *NaviLine*
- Audio
- Ablation History

Settings on the System tab are saved by the physician. See the following guide for explanations.

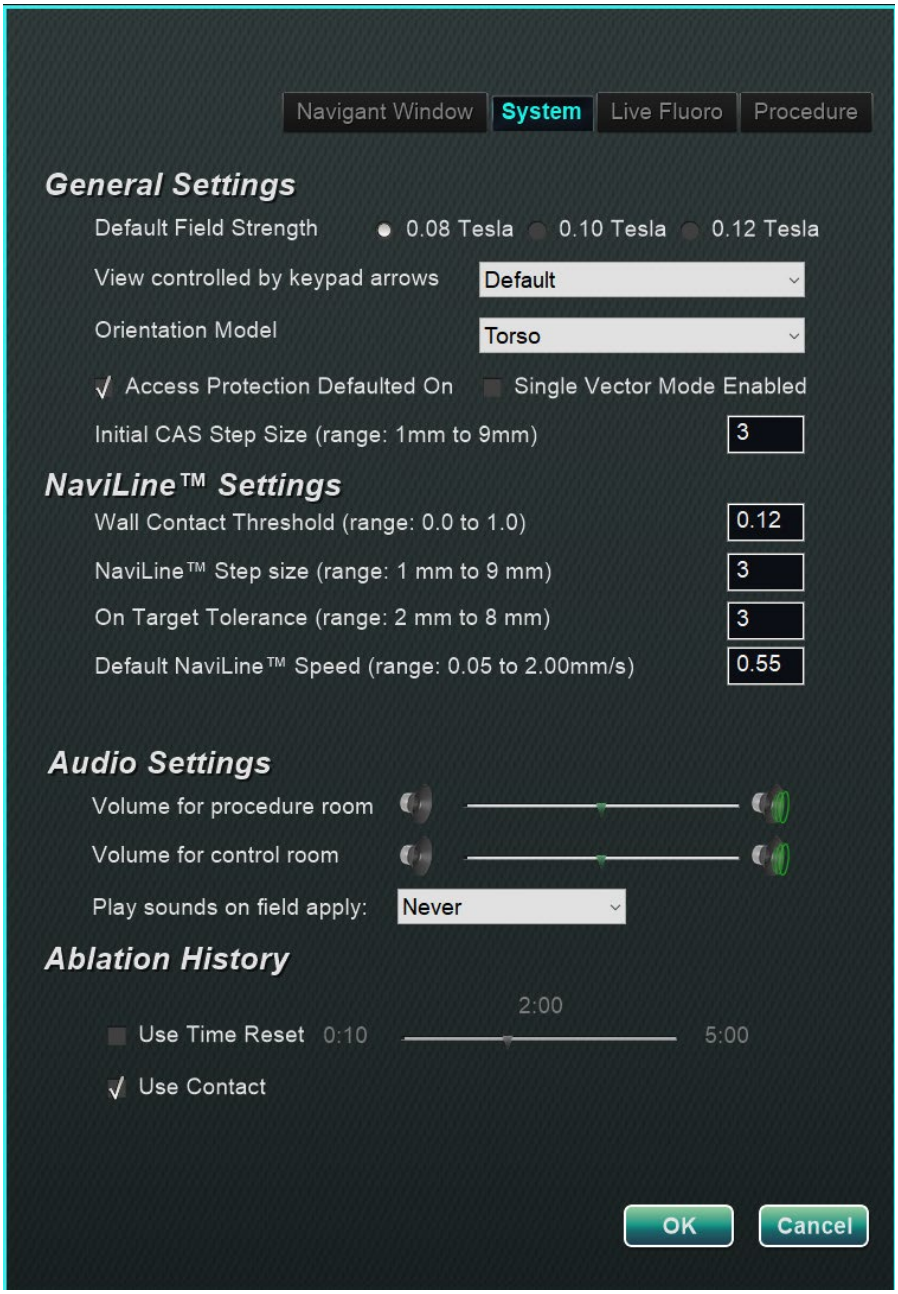


Figure 109. Settings windows – System tab

System tab guide (Figure 109)

General Settings

Default Field Strength. The magnetic field (measured in Tesla) in the navigation volume at isocenter. Depending on system licensing, various magnetic field strengths may be displayed. When multiple choices display, the user can change the default setting by selecting the preferred field strength. Changing the default magnetic strength setting will *not* change the field strength for the current procedure, but the next procedure to be performed.

View controlled by keypad arrows. Select the window that can be controlled by the *Navigant* keypad arrows: up, down, left, right. Choices vary by workflow.

Orientation Model. The drop-down menu offers three options for the icon that displays among the Window Controls icons: Torso, Heart, and Chamber. The choice represents the desired anatomic model for the specific workflow and remains the default until changed in this dialog.

Access Protection Defaulted On. The default is checked. Access Protection is a retraction feature in left atrium procedures that prevents the catheter from retracting beyond a certain position. Uncheck the box if you wish to turn off Access Protection for the next procedure.

Single Vector Mode Enabled. The default is unchecked, or "disabled." Check the box if you wish to use Single Vector Mode for the next procedure.

Initial CAS Step Size (range: 1mm to 9mm). The default is 3 mm. The physician has the option to choose the initial CAS Step Size, or the distance to initially advance/retract the catheter. The physician can change the step size at any time during the procedure using the ruler found on the main toolbar.

NaviLine™ Settings

Wall Contact Threshold (range: 0.0 to 1.0). The maximum catheter-wall contact allowed. The value (0.12 in the image) represents a percentage; for example: 1 = 100%, 0.5 = 50%.

NaviLine Step size (range: 1 mm to 9 mm). The length of incremental steps along *NaviLine*.

On Target Tolerance (range: 2 mm to 8 mm). The amount of variance allowed for accessing the target.

Default NaviLine™ Speed (range: 0.10 to 2.00mm/s). The starting, or default, speed of the Slider tool used for several Window Controls and other icon options.

Audio Settings

Volume for procedure room. The volume level for the *Navigant* system sounds in the Procedure Room.

Volume for control room. The volume level for the *Navigant* system sounds in the Control Room.

Play sounds on field apply. The occurrence of system sounds playing when a field is applied. Choices are Always, *Bullseye* only, and Never.

Ablation History

Use Time Reset. The default is unchecked. Check the box so Ablation History resets after that area has rested for the amount of time you specify.
Use Contact. The default is checked if e-Contact (an optional feature) is enabled for the system. Use Contact indicates the accumulation of Ablation History data when the catheter is in contact.

Note: Field Strength, CAS Step Size, NaviLine Speed, and Access Protection are all settings that can be changed elsewhere in Navigant without modifying the physician preferences.

Live Fluoro tab

On the Live Fluoro tab (**Figure 110**) you can adjust the display of graphics on the Fluoro windows. Settings on the Live Fluoro tab are saved by the physician.

Live Fluoro tab guide

① **Show Graphic On Monitor.** This item refers to the X-ray live monitor. Select whether you want to display graphics on Live X-ray, the Last Image Hold, or both.

② **Show Graphic Type.** This item also refers to the X-ray live monitor. Select the graphic images you want to display on the X-ray screen. Choices are Points and Lines, Vessels, Virtual Catheter, Target Circle, Magnetic Field Vector, and Navigation Status.

③ **OK / Cancel**. Click **OK** to accept the changes or **Cancel** to close the window without saving changes.

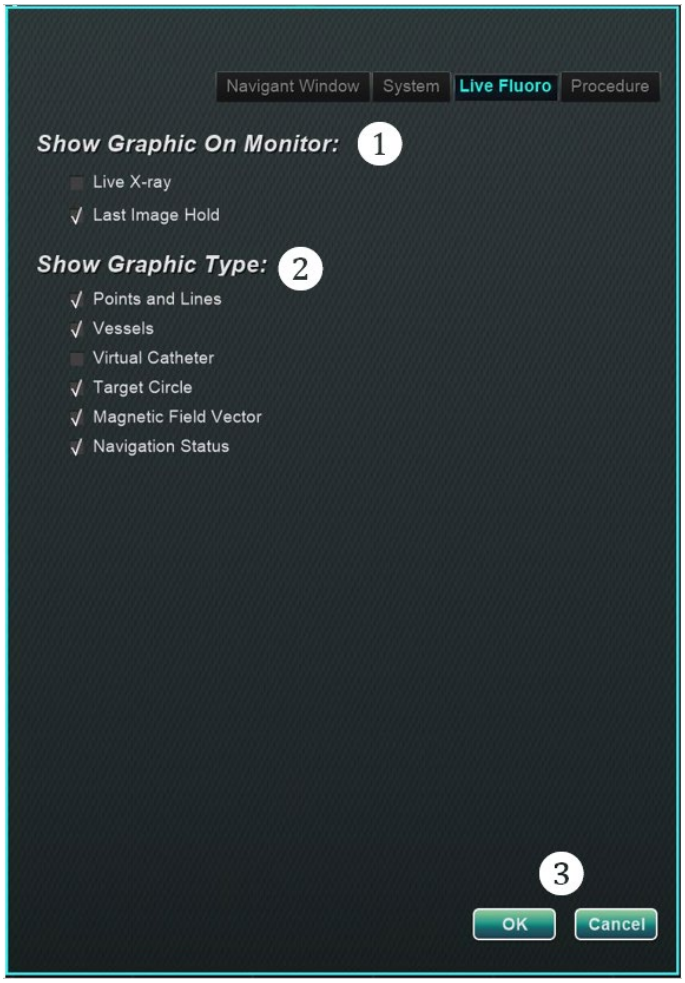


Figure 110. Settings windows – Live Fluoro tab

Procedure tab

The Procedure tab (**Figure 111**) displays procedure information and reflects the information previously entered on the Procedure window. The following may be edited here: patient name and notes, procedure and anatomy type, the selection of a Mapping system, and the use of RMN (robotic magnetic navigation, used synonymously with MNS).

Procedure tab guide

You cannot change the Start Time or Physician name on the Procedure tab.

Dynamic information

You can edit or change the following features:

① **Patient name.**

② **Notes.** Special information about the case or procedure.

③ **Procedure type and anatomy type.** To select procedure type, click the desired tab. To select anatomy type, click the desired icon. In Figure 111, Electrophysiology and Left Atrium are selected.

④ **Use Mapping** (displays only on the EP tab) and **Use RMN. Use Mapping** allows the user to select any compatible mapping system (and catheter) that is connected. Selecting **Use RMN** indicates that the procedure is a magnetic procedure (or employs a compatible magnet system).

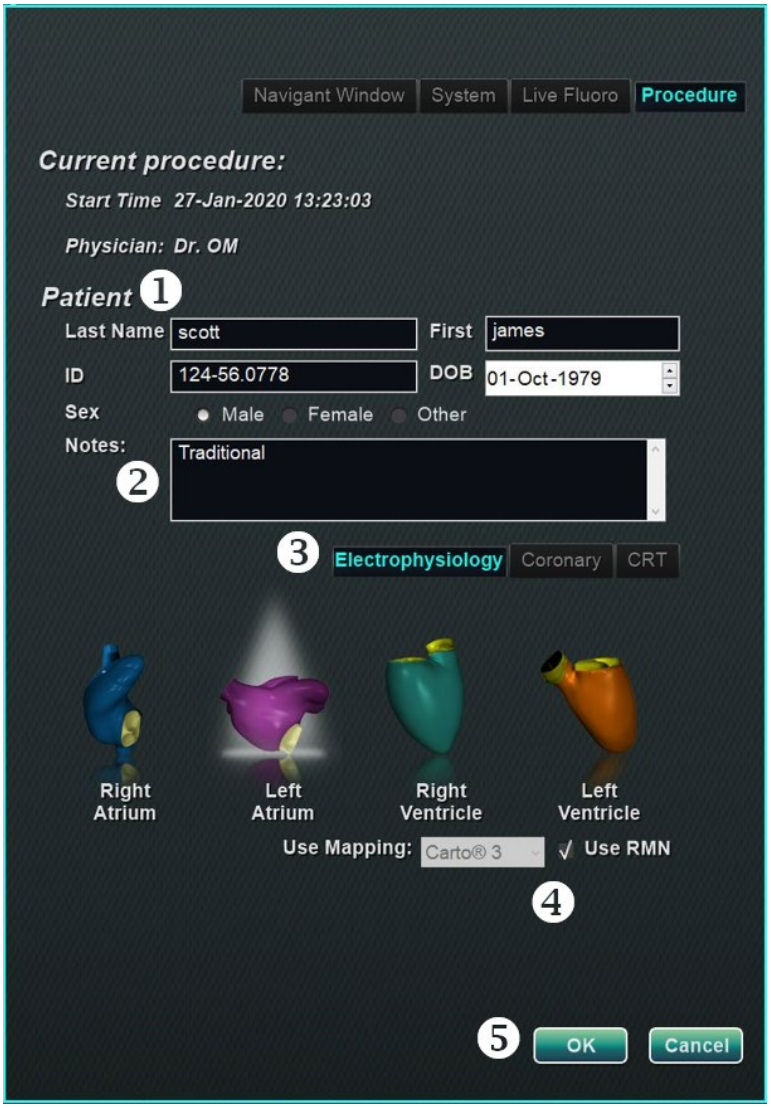


Figure 111. Settings windows – Procedure tab

⑤ **OK / Cancel.** Click **OK** to accept the changes, **Cancel** to close the window without saving changes.

Navigant Windows

The number, type, and layout of windows changes by procedure type and workflow step. Each procedure opens to a default layout; you may change the layout. The following are available windows:

Electrophysiology	Interventional Cardiology
Left and Right Atrium and Left and Right Ventricle	**Coronary**
3D Map View	3D Vessel View
3D Map View B	3D Vessel View B
ClockDial View AP	ClockDial Sync C-ARM
ClockDial View INF	ClockDial View AP
ClockDial View LL	ClockDial View INF
Fluoro A View	ClockDial View LL
Fluoro B View	Endoluminal View
Ideal Anatomy View	MPR Slice
Ablation History Graph	MPR Slice B
	Ideal Anatomy View
	Fluoro A View
	Fluoro B View

Window Controls

Most windows have a semi-transparent toolbar called "Window Controls." This toolbar (**Figure 112**) is present at the bottom of the window and displays controls for that window such as transfer image, rotate, pan, zoom, and brightness/contrast.

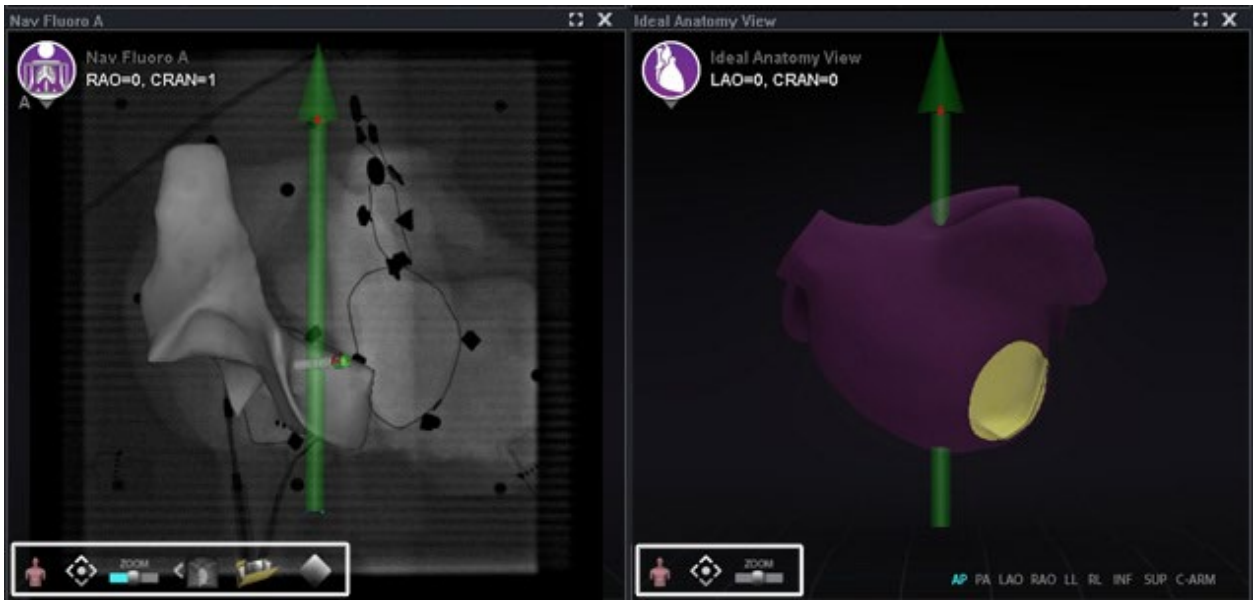


Figure 112. Two examples of displays with Window Controls – Nav Fluoro A *(left)* and Ideal Anatomy View *(right)*

Note: The ClockDial windows in Interventional Cardiology procedures do not have Window Controls.

Window Controls buttons

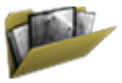
The number of buttons the Window Controls (**Figure 113**) displays depends on the window type and the selected object.

Figure 113. Window Controls example from Fluoro window

Window Controls buttons

Name	Description	Icon
Anatomic orientation model	**Static model:** The static anatomic model on the Window Controls displays the anatomic position of the window's image. This model ("Torso") is used in the Fluoro windows and is not rotatable. **Dynamic model:** The dynamic anatomic model on the Window Controls displays the anatomic position of the window's image and is rotatable.	
Pan/Fit to view control	• Press and drag anywhere on the pan control to move the window's image anywhere on the screen. • Double-click the control to center the image in the window and restore it to its default size (see Zoom control, which follows).	
Zoom control	Press and drag the zoom control's slider right (+) to increase the window image's size and left (–) to decrease the size. **Note:** As long as you continue to press the mouse button, you can operate the control anywhere within the window.	
Transfer X-ray / fluoro	Click this button to transfer a fluoro image to the Fluoro Image windows A and B. (The Register CARTO® 3 dialog uses the same icon for image transfer.) **Note:** This icon flashes (between the current state and a negative of the image) as the fluoro image is being transferred.	

Window Controls buttons

Name	Description	Icon
Load Fluoro	Click this button to open the Load Fluoro dialog, which contains all fluoro images of interest (thumbnails of the images from the Fluoro A or Fluoro B windows).	
Brightness/ contrast control	**Brightness:** Press and drag the control up to increase the brightness of the window's image and down to decrease it. **Contrast:** Press and drag the control to the left to decrease the contrast of the window's image and to the right to increase it. **Any direction:** Press and drag the control in any direction to create a combination of brightness and contrast adjustments. **Note:** As long as you continue to press the mouse button, you can operate the control anywhere within the window.	
Vector Show/ Hide mode	Click this button to eliminate or return display of the vector(s) on the screen. If the solid yellow arrow is showing, the vector(s) have been removed temporarily. If the grayed arrow crossed by a red line is showing, the vectors are displayed. These buttons are available only in 3D Map and Fluoro windows.	 

Note: To *cancel* an automated move, use the **STOP** button in the Automation dialog, as shown in **Figure 76** and **Figure 150.**

Window swap feature

Within the *Navigant* windows, displays may be swapped by using the drop-down menu from the window-identifier icon (**Figure 114** and **Figure 115**):

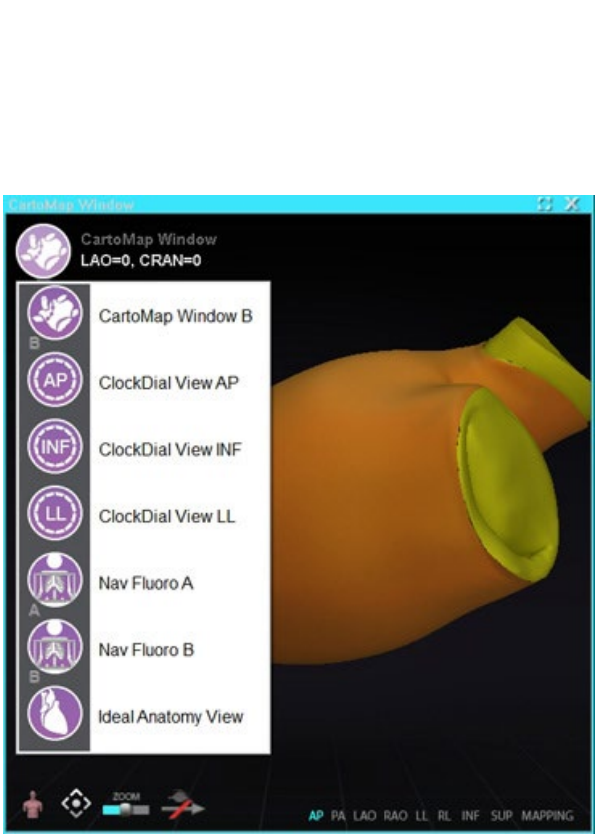

3D Map


Ideal Anatomy


Nav Fluoro A


Nav Fluoro B

Figure 114. Window-identifier icon samples



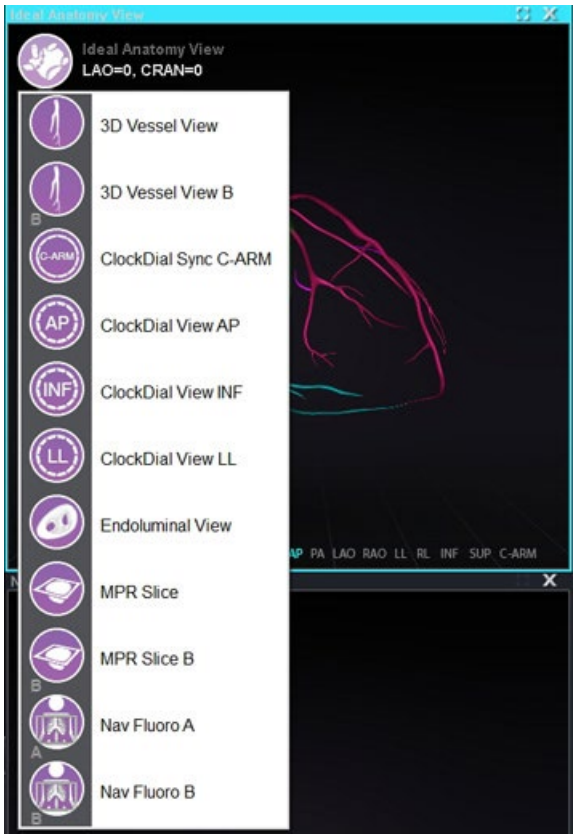


Figure 115. Two *Navigant* window examples with drop-down menus for selection: CartoMap Window–EP procedure, *left*, and Ideal Anatomy View–Coronary procedure, *right*

Note: When one *Navigant* window is swapped for another, the original window disappears from the *Navigant* screen display.

Vector orientation basics

The magnetic field vectors, yellow and green, represent current and target directions, respectively. Mouse control of the target vector causes the current vector to follow. The vectors' visibility and behavior are the same in both the *Navigant* and mapping systems.

Note: When the current vector (yellow) catches up to the target vector (green), the green vector disappears.

Single-vector mode shows only the target (desired) field vector and colors it yellow while hiding the current vector (except for a few instances in which it is shown).

Vector Lock

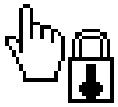


Figure 116. Vector Lock

***Above* –** Lock icon

***Left* –** Example of Vector Lock enabled

While you work in a procedure, you may select the desired, or target, field vector (green) and lock it to the mouse movements (**Figure 116**).

- To enable this mode, press and hold the **Ctrl** button and left-click with the mouse on the green vector. The mouse cursor will change to indicate the mode is active. Moving the mouse around the window in this mode will adjust the target vector in the direction of the mouse movement.
- To disable the Vector Lock mode, simply left-click anywhere in the window other than on the target vector or model, or move the mouse out of the window that was in Vector Lock mode.

This feature has an automatic timeout that occurs after 10 seconds of not moving the vector or the *Cardiodrive* device using the mouse wheel.

Target Lock

The Target Lock feature allows the user to lock the target to the cursor by holding down the **Ctrl** key and clicking the target. Once the target is locked to the cursor, the lock icon appears (**Figure 117**) and the target moves whenever the mouse moves and intersects with the volume.

The Target Lock automatically disengages if (1) moving off the vessel, (2) moving outside the window, (3) clicking the mouse, or (4) not moving the mouse for 10 seconds.

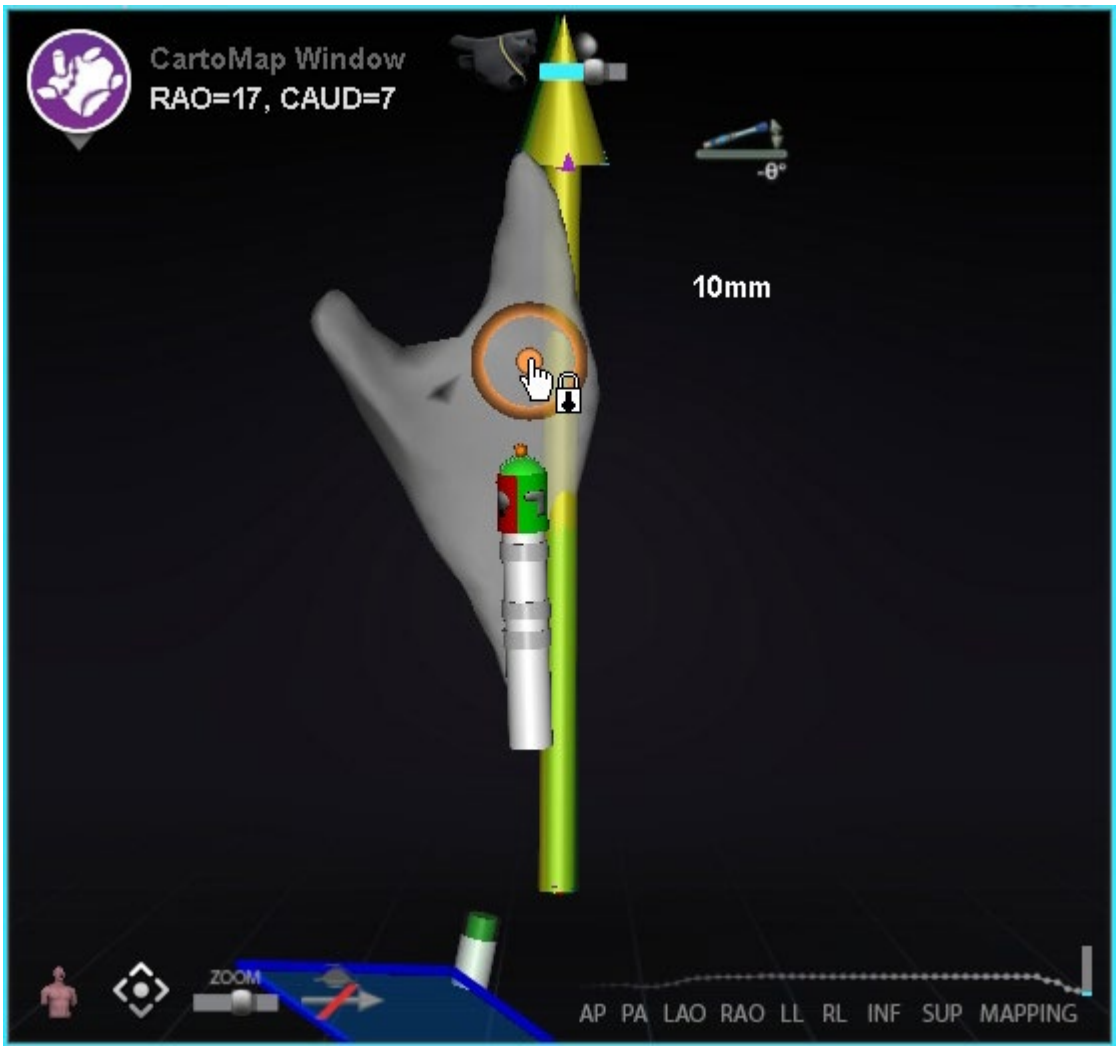


Figure 117. Target Lock *(cursor's lock icon is showing with finger point at center of target)*

Magnetic Torque Meter

A Magnetic Torque Meter Trace (emphasized by a red rectangle) is pictured below (**Figure 118**). The magnetic torque meter trace shows the last 120 seconds of history. The trace provides the ability to see how magnetic torque changes over time with the right side displaying the most recent data. The white dots on the torque meter trace are known as gated points. The mapping system generates a dot once per heartbeat.

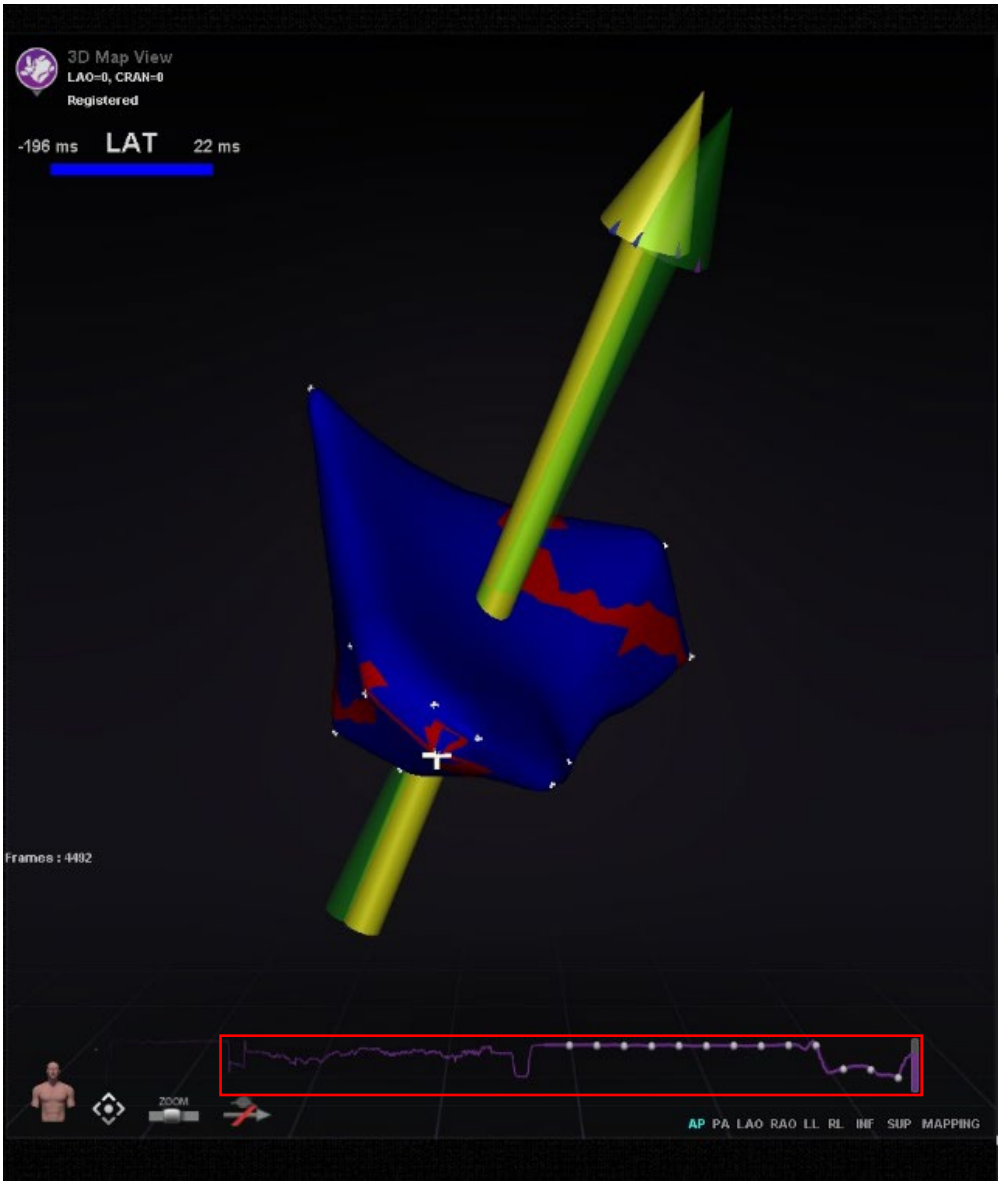


Figure 118. Magnetic Torque Meter Trace

The color scheme of the Magnetic Torque Meter Trace (emphasized by a red rectangle in **Figure 119**) will change if e-Contact (an optional feature) is present. This is because different types of contact can be observed on the Magnetic Torque Meter Trace if a system has e-Contact. A blue line signifies that *Navigant* is connected to e-Contact and there is strong contact. A gray line signifies that *Navigant* is connected to e-Contact but there is no contact. A dashed line signifies that there is intermittent contact.

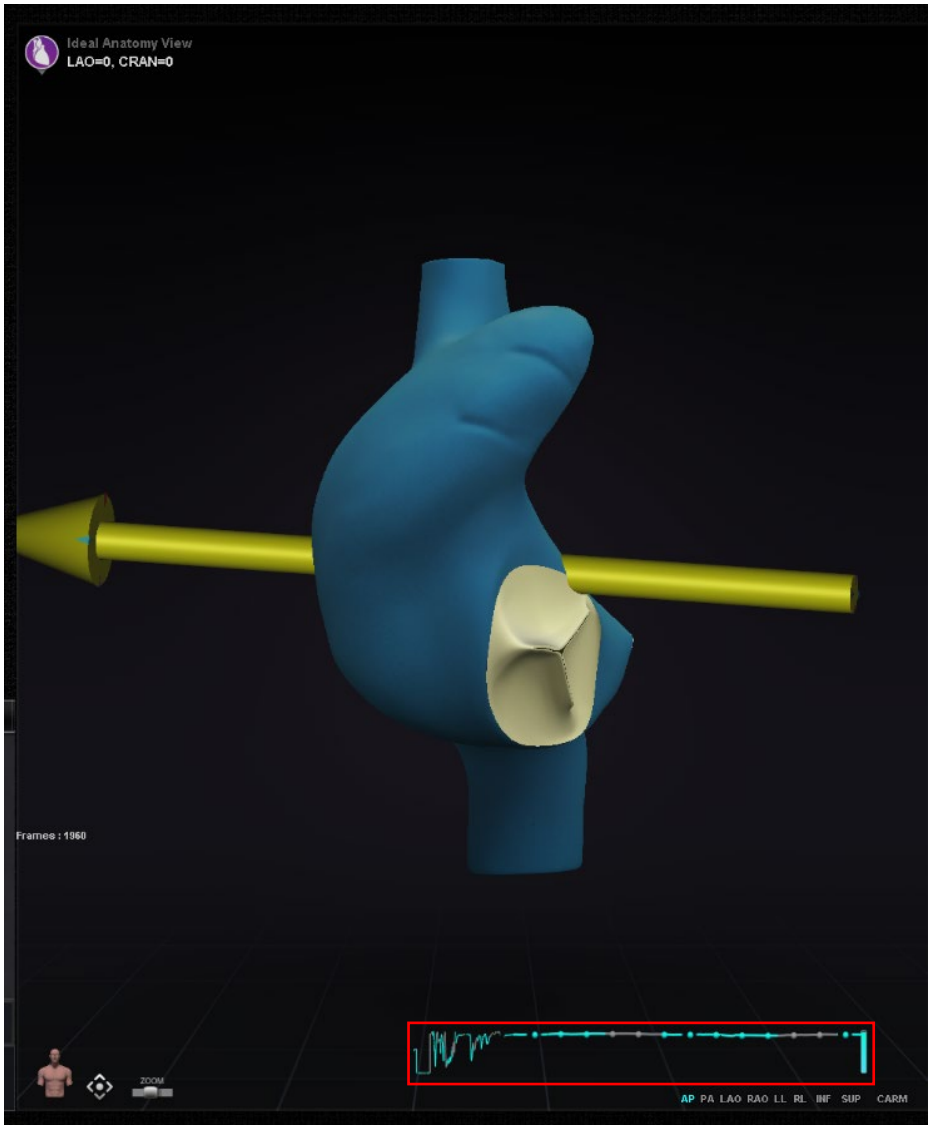
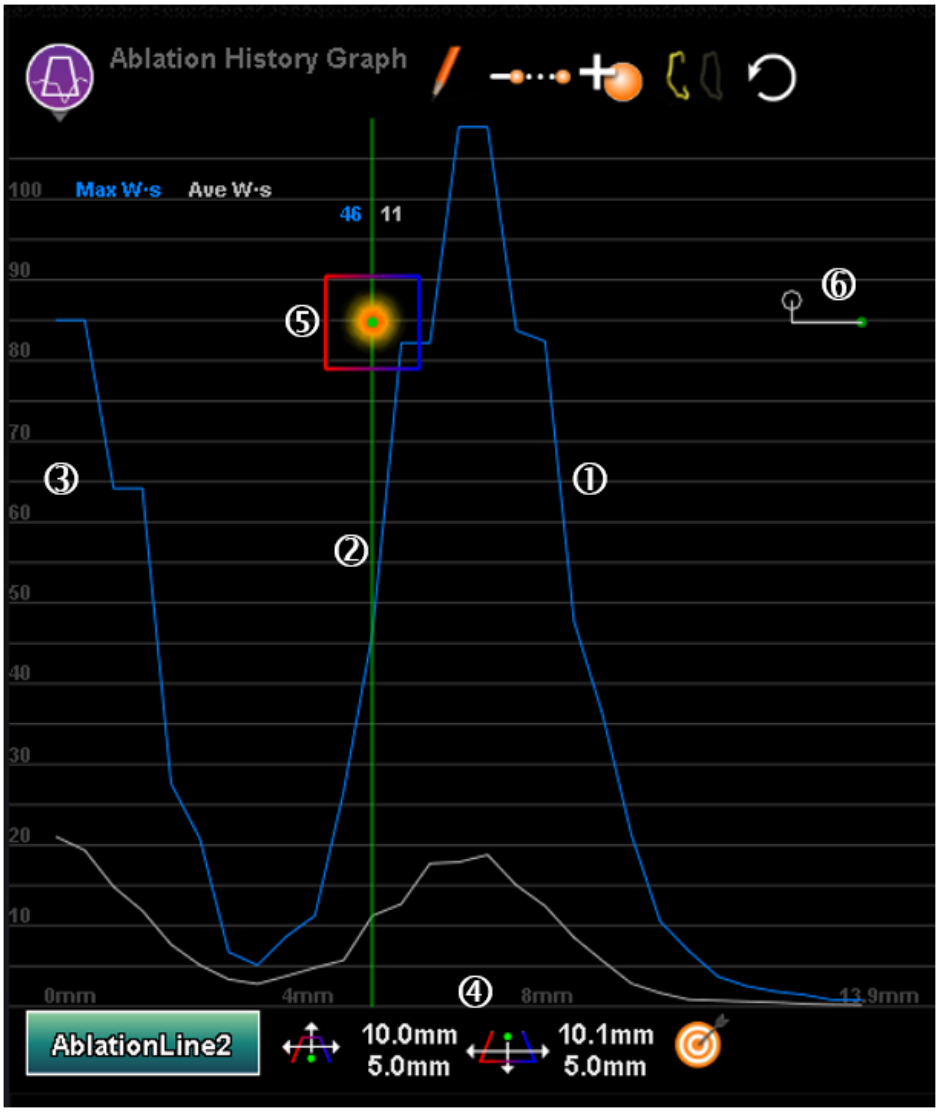


Figure 119. Magnetic Torque Meter Trace (with e-Contact)

Ablation History Graph

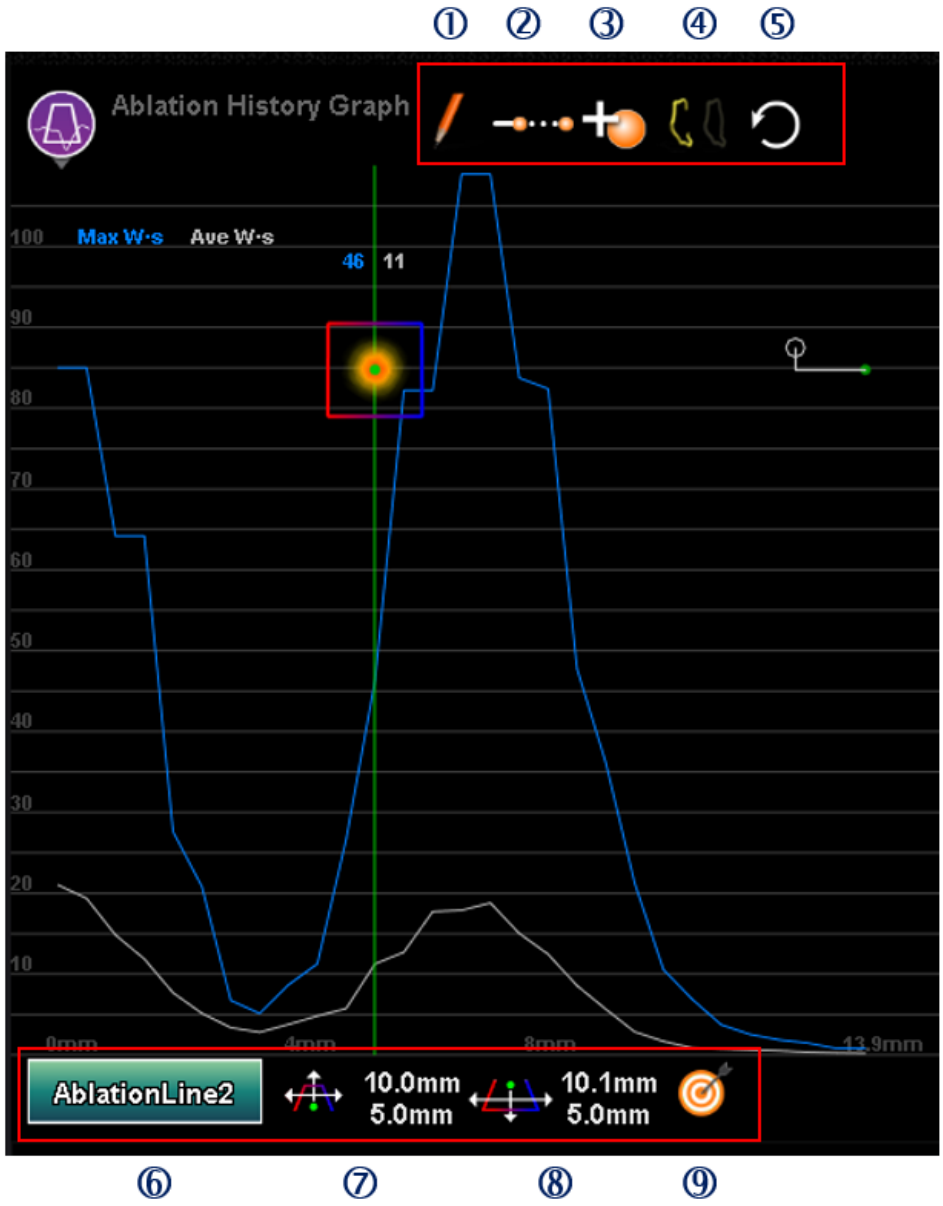
Description

Navigant's Ablation History Graph (AHG) feature shows the amount of ablation energy in Watt-seconds delivered along an entire NaviLine. The graph shows the average and maximum energy delivered from a cross section of the Ablation History volume along the selected NaviLine. The shape of the 2D cross section is configurable by the user to allow the cross section to be adjusted to optimize the position of the cross section in the Ablation History volume.



Description of Ablation History Graph Components

Item	Name	Function
1	**Graph Tracing**	The graph tracing displays the maximum and average Ablation History values found in the cross section along the NaviLine.
2	**Position Indicator**	A green line that indicates the position of the cross section along the NaviLine. As the line is moved in the graph, the position of the cross section will be updated in the 3D windows.
3	**Vertical Scale**	The vertical scale shows delivered energy. It is measured in Watt-seconds.
4	**Horizontal Scale**	The horizontal scale shows the position around the NaviLine at which a cross section is taken. It is measured in millimeters.
5	**Cross section**	The cross section is a two-dimensional slice into the ablation history volume showing a cross section of the delivered energy. **Note:** In the tooltips, the cross section is referred to as the "cursor."
6	**Catheter Position Indicator**	The green circle represents the closest point on the line to the catheter tip, the vertical and horizontal lines are the distance from line to the tip relative to the cursor orientation at the position, and the white circle is the tip position. Its position and appearance of course depend upon the shape of the line and position of the catheter.


①
②
③
④
⑤
Ablation History Graph
100
Max W·s
Ave W·s
46
11
90
80
70
60
50
40
30
20
10
0mm
4mm
8mm
13.9mm
AblationLine2
10.0mm
5.0mm
10.1mm
5.0mm
⑥
⑦
⑧
⑨

Description of Ablation History Graph Functional Buttons

Item	Name	Function
1	**Create NaviLine**	Creates a new empty NaviLine, named "**AblationLine#**" where # is the number of lines made in the AHG, and becomes the selected line for the AHGraph. (This NaviLine is **not** the system selected object highlighted in the Visibility Pane and showing context-sensitive controls in the 3D/Fluoro windows.)
2	**Auto-Extend NaviLine**	A "sticky" toggle-able button. When enabled, adds the current catheter position to the AHG-selected line when catheter is far enough from existing control points (6mm), ablation is on, **AND** the local maximum Ablation History value is more than 50 Watt-seconds. (The added position is the location of the highest AH value within 3mm of the catheter tip so it is ideal to keep the NaviLine centered within the ablation.)
3	**Add Catheter tip to NaviLine**	Adds the current catheter tip position to the AHG selected line. The user can also use the keyboard shortcut CTRL-A if *Navigant* has focus, which is also in the tooltip. Feature is disabled if current line is not editable in AHG (i.e., it came from the mapping system or was drawn on fluoros).
4	**Click to open/close the NaviLine**	Shows current state of the line. The tooltip says **what clicking will do**: toggling between an open and a closed line. Feature is disabled if current line is not editable in AHG (i.e., it came from the mapping system or was drawn on fluoros).
5	**Undo**	Undoes the latest change to the current AHG line. Undo history is lost when the procedure is closed or if the line is edited elsewhere (like Edit NaviLine Mode). Feature is disabled if there is no undo-able history for selected line.
6	**NaviLine selection**	Displays a menu of lines to use for AHG.
7	**Top Width, Top Height**	Two-direction slider button that controls the distance of the top of the trapezoid cursor from the line, and

		the width of the top of the cursor, followed by labels displaying the top width and top height.
8	**Bottom Width, Bottom Height**	Two-direction slider button that controls the distance of the bottom of the trapezoid cursor from the line, and the width of the bottom of the cursor, followed by labels displaying the bottom width and bottom height.
9	**Set Target at Cursor**	When using this tooltip, the cross section is referred to as the "cursor" as seen in the image below.  This feature tries to set a target at the position of the trapezoid cursor (cross section) on the current line. Setting a target will fail if *Navigant* is not registered to a mapping system, not getting catheter data, not connected to magnets, etc.

Ablation History Graph Usage

Access the AHG by pressing on the icon in the upper left corner and selecting "Ablation History Graph" (**Figure 120**).

Figure 120. Selecting the Ablation History Graph

A green vertical line shows the position of the cross section along the NaviLine. To move the position indicator, click anywhere in the graph window and the indicator will jump to the

position of the mouse. If the user holds the mouse down, the indicator will continue to follow the mouse's position.

As the indicator moves, two values are displayed next to the indicator (emphasized by a red rectangle in **Figure 121**). The blue number is the maximum value of the delivered energy present in the cross-sectional window at that position around the NaviLine. The white number is the average energy delivered in the collection window.

The data displayed in the graph depicts the energy delivered in the immediate region surrounding a NaviLine. To change the active NaviLine, click on the button in the lower left corner of the graphing window which has the name of the active NaviLine (**Figure 121**). A menu will display that shows a list of all available NaviLines to choose from.

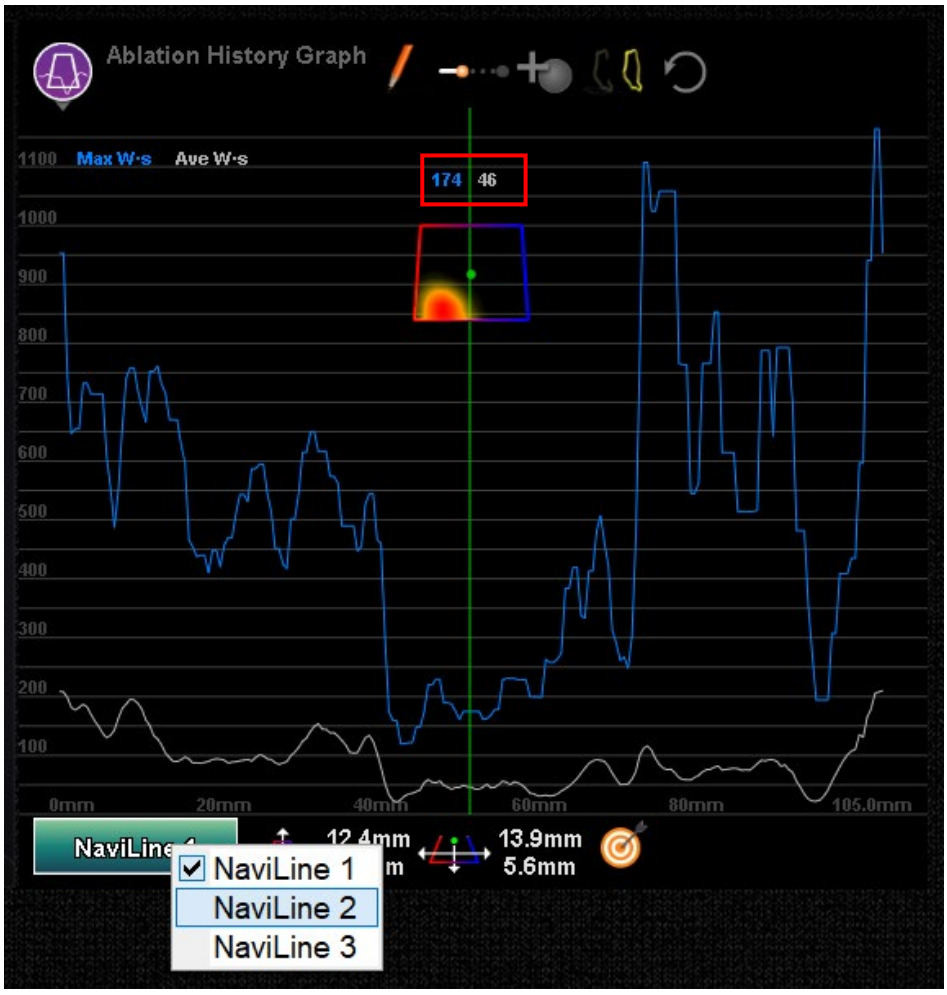


Figure 121. Selecting the NaviLine

The graph displays the maximum and average total energy delivered through ablation in the immediate volume around a NaviLine. To change the shape and position of the cross section

analyzed by the graph (surrounded by yellow circles in **Figure 122**), use the window controls located at the bottom of the Ablation History Graph window.

Figure 122. Changing Shape of Cross Section

The cross section location is seen in all windows displaying the selected NaviLine and Ablation History. The cross section (AHG window in **Figure 123**) presents a 2D slice into the ablation history volume showing a cross section of delivered energy. The cross section overlay (3D Map

Window in **Figure 123**) shows the location around a NaviLine from which the graph data was gathered.

When the green position indicator line is moved on the AHG, the cross section follows the path of the NaviLine and the cross section overlay displays the area that corresponds to the updated position indicator location.

Figure 123. Cross Section Display (3D Map Window and AHG Window)

Import Surface Object

Navigant can import 3D models created by other programs. These 3D models are imported into *Navigant* as surfaces and must be in the VTK file format. To import a 3D surface, click on the *Navigant* Start Menu Button. Select the "Import Surface Objects" menu item (**Figure 124**).

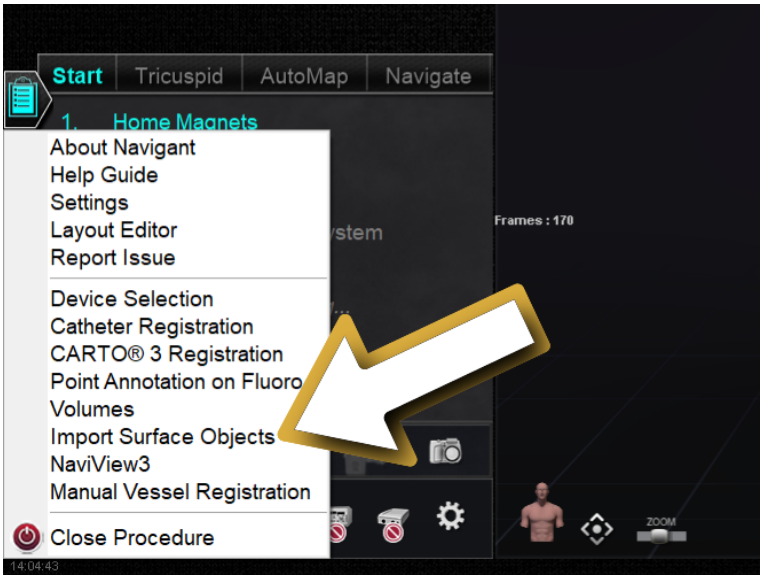


Figure 124. Selecting Import Surface Objects Function

Press browse (1) to navigate to the directory containing the surface data, and after selecting the desired files or folders (2) press **OK** (**Figure 125**).

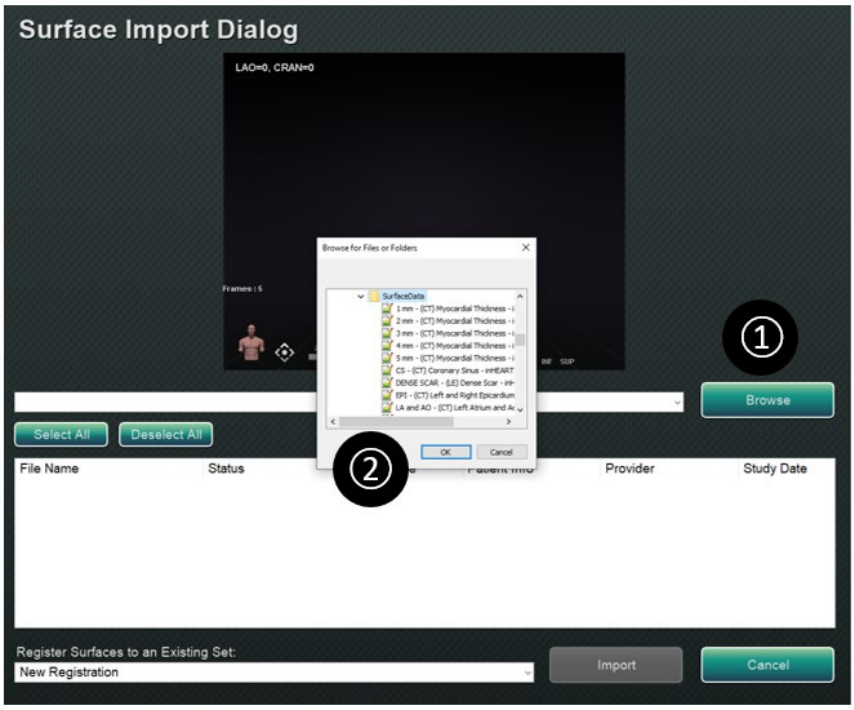


Figure 125. Selecting Object to Import

Mark the checkboxes next to the surface objects you want to load, or “Select All” or “Deselect All” to make selections. It may take several moments to load the surface information and a *loading* status will appear next to that surface item.

After a surface loads successfully, it will display in the preview area and a "Loaded" status will appear next to that surface item (**Figure 126**). Only the actively selected surfaces are shown in the preview area. The status column will display "Error" if *Navigant* could not import the indicated surface.

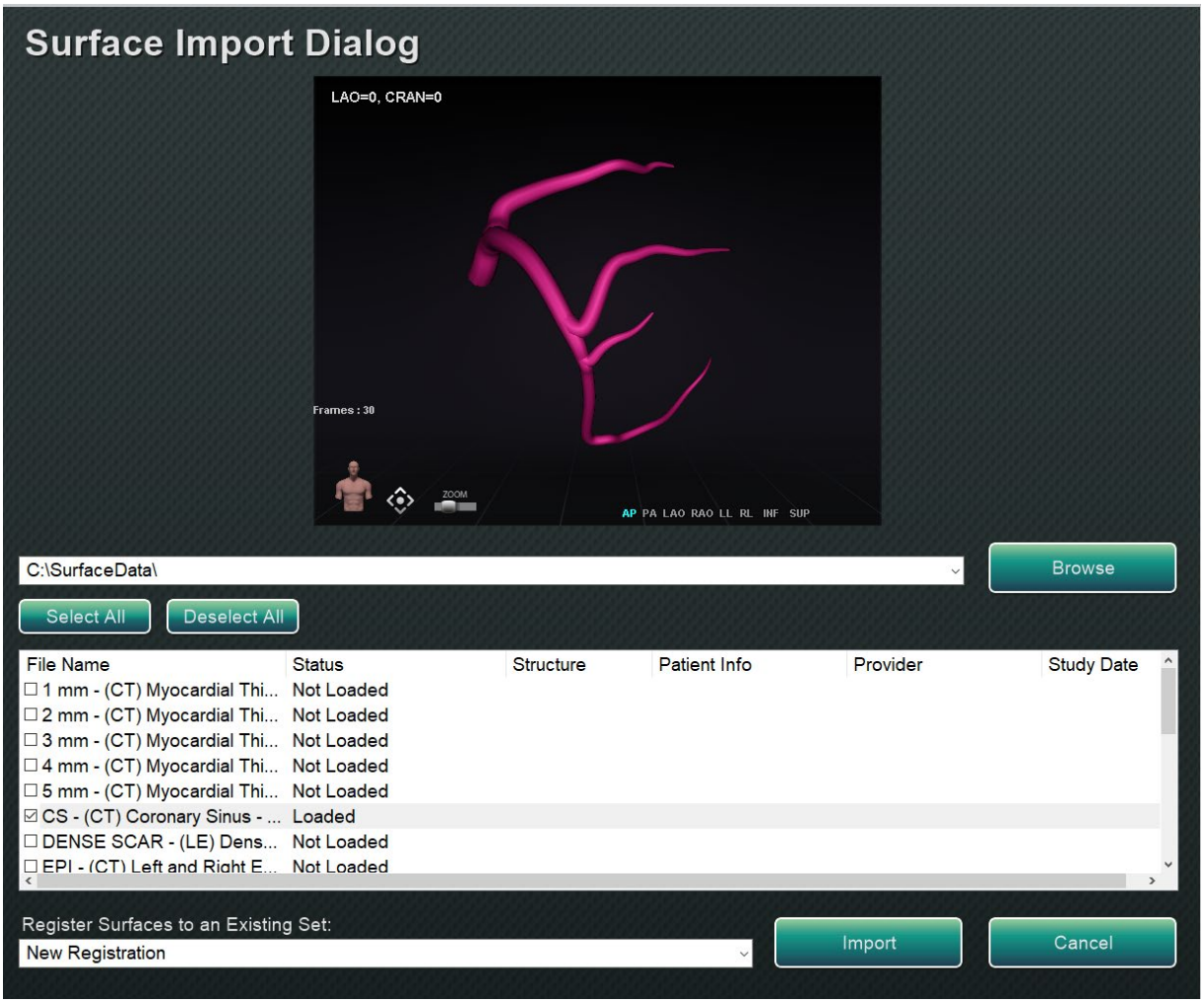


Figure 126. Imported Surface Shown in Preview Window

Using the dropdown menu (emphasized by a red rectangle in **Figure 127**), surfaces are imported as a new registration or to an already existing set of imported surfaces.

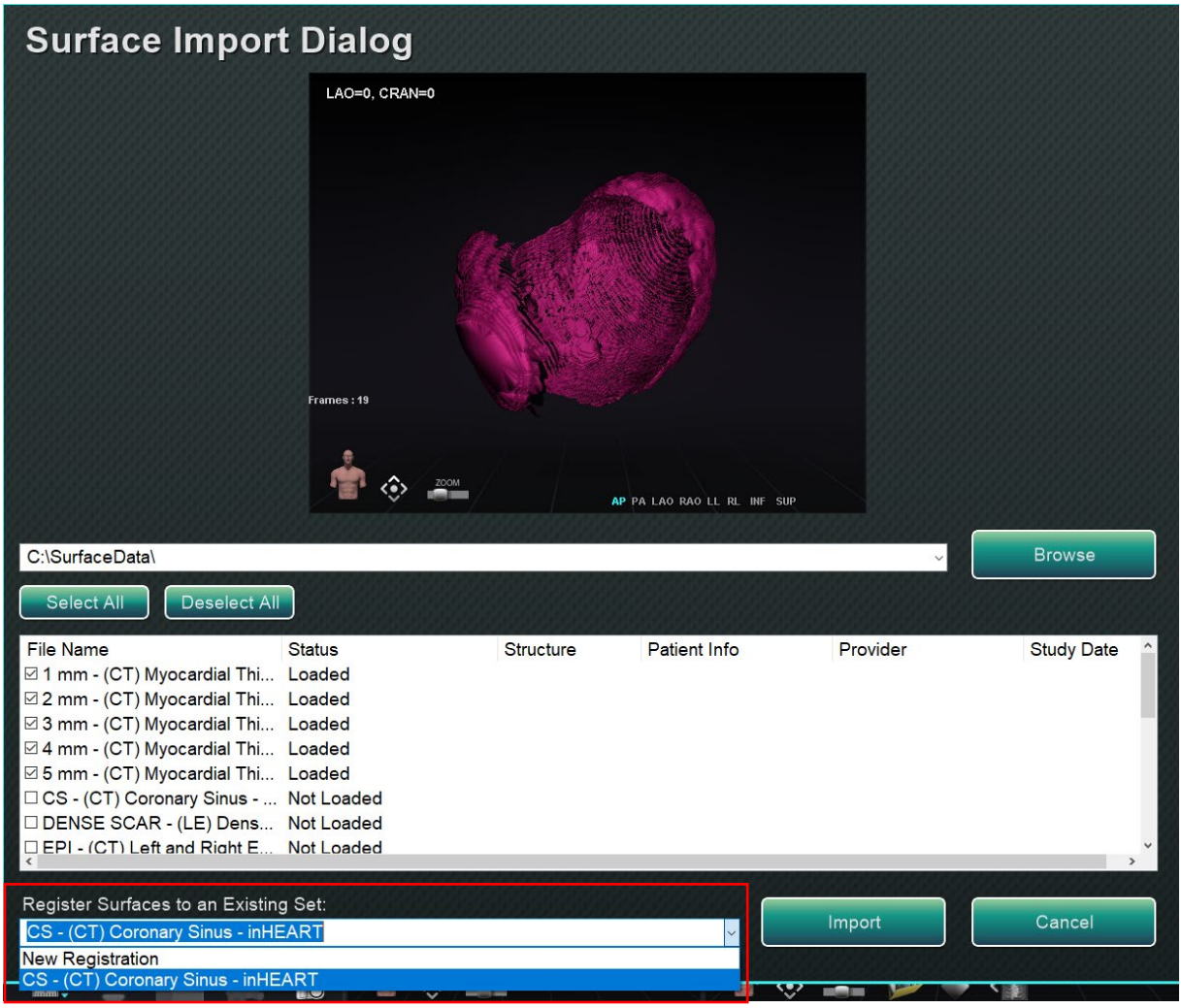


Figure 127. Register Surfaces

After all surfaces are loaded, press the import button to bring the surfaces into *Navigant* for use (**Figure 128**).

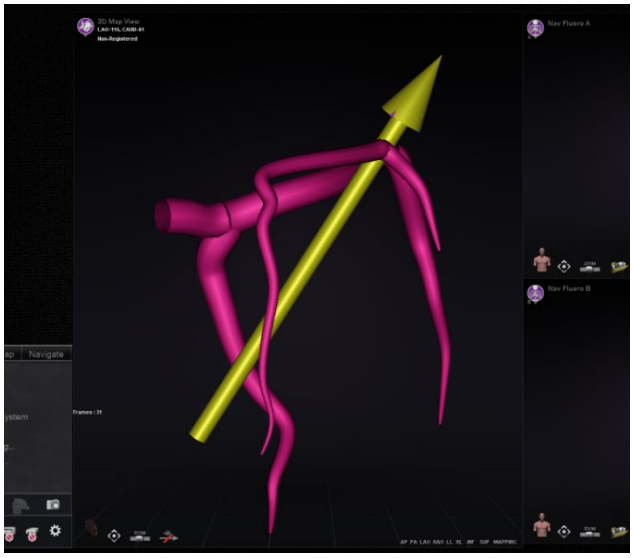


Figure 128. Imported Surface in 3D Window

Once imported, the 3D surface(s) can be rotated and panned to align with other objects in the 3D window. All objects imported together pan and rotate as a group. To display the position controls (see the oval in **Figure 129**), click on a surface of the imported object. Once displayed, click on the desired control and then move the mouse to change the surface orientation and position. The rotate control rotates the 3D surface relative to the other objects in the 3D window. The pan control moves the object laterally. These two controls bring the imported surface into alignment with other 3D objects.

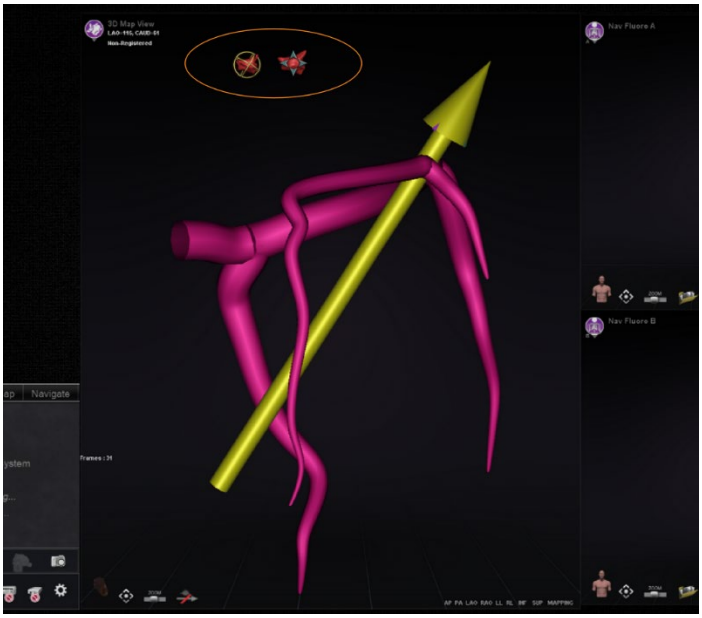


Figure 129. Rotate and Pan Controls for Adjusting Surface Position

Customer Satisfaction Feedback

A feedback form (**Figure 130**) displays when the user closes a procedure. Any feedback given will automatically be sent to the Remote Support Center, provided that a functioning VPN is present. All feedback helps with our continuous improvement efforts.

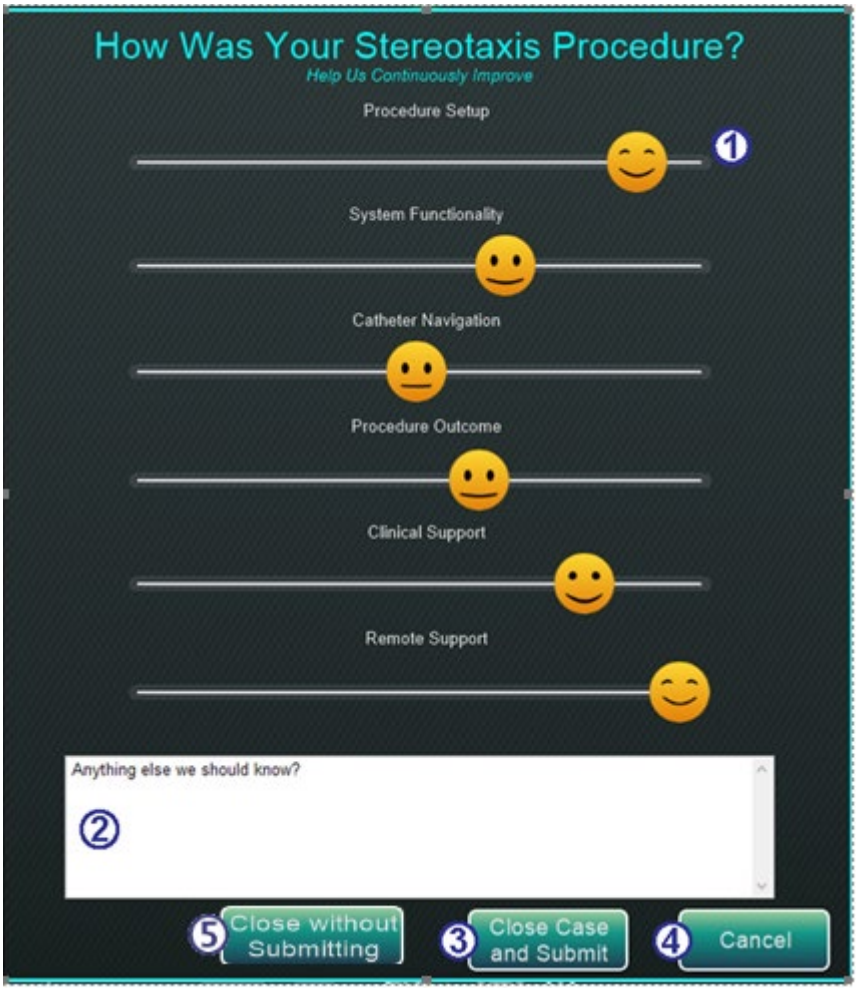


Figure 130. Customer Satisfaction Feedback form

Customer Satisfaction Feedback form (Figure 130)

① **Smiley face.** Slide each smiley face icon to indicate your satisfaction in that category. The face will change according to its position on the slider bar.

② **Notes area.** Type any notes you wish to leave about your Stereotaxis procedure.

③ **Close Case and Submit.** Click this button when you are finished.

④ **Cancel.** Click **Cancel** if you wish to return to the procedure.

⑤ **Close without Submitting.** Use this option if you wish to close the procedure without leaving feedback.

4. Integration Features

Pre-Registration

After creating a new procedure, *Navigant* is in an unregistered state and the mapping system's data is displayed in a default position until the user completes the registration task. While unregistered, a limited number of *Navigant* features are available and include:

- Viewing mapping system data (catheters, surfaces and their points/tags, lines, and vessels) in the 3D Map windows.
- Viewing Fluoro-localized data (lines drawn on fluoros, imported DICOM volumes and vessels/surfaces from those volumes) in the Fluoro A/B windows.
- Viewing and controlling field vectors in all windows.
- Creation and viewing of Ablation History in 3D Map windows.
- Viewing of imported third party surfaces (in VTK file format) in the 3D Map windows, not Fluoro.

Features such as Targeting, Automapping, Bullseye, NaviLine, X-ray overlays, and fluoroscopically localized objects will be unavailable until a registration occurs.

Registration

Upon registering, no work completed in an unregistered state is lost. Data appears in any window according to usual per-window settings and visible objects panel checkboxes. Registration allows *Navigant* to align spatial information from the mapping and fluoroscopy systems. Features not previously available become available after registering to a mapping system. *Navigant* is capable of registering to CARTO®3 and OpenMapping systems.

When a saved procedure is loaded into Navigant, the previous registration data is also loaded. The displayed information is based on stored data and presumed to be correct. The user must re-register if the location pad has moved since the previous registration. After registration, the 3D Map windows display a label that reads "Registered" (**Figure 131**). During an unregistered state, this label will read "Non-Registered."

Figure 131. Registered Label

Registering to CARTO® 3

The *Niobe* ES magnetic navigation system supports the Biosense Webster CARTO® 3 EP navigation system and compatible catheter devices. Features include but are not limited to:

- Real-time catheter location displayed in *Navigant* screen
- Target point and design-line data exchange
- Control of magnetic field from CARTO® 3
- Control of catheter advancement from CARTO® 3
- Presets for CARTO® 3
- Full color three-dimensional map generation
- CARTO® 3 Color Scale legend displayed in *Navigant* screen
- View synchronization
- Preoperative image export
- Vessel data exchange

You can access the CARTO® 3 Registration dialog from either the Clinical Workflow Manager (CWM) or the System Options menu on the toolbar. Click **Register to Mapping System** (on the CWM) or **CARTO® 3 Registration** (from the System Options menu) to display the CARTO®3 Registration dialog (**Figure 132**).

Figure 132. CARTO® 3 system registration dialog

CARTO® 3 system registration guide (Figure 132)

① **Directions.** The dialog displays directions for CARTO® 3 Registration.

② **Help.** Click the respective question mark icon if you need help with Step 1.

③ **Transfer image.** Step 2 in the directions states, "Transfer AP X-ray." Transfer the X-ray by clicking the transfer button at the bottom of the preview screen.

④ **Preview screen.** If the six markers and the catheter tip are correctly located, the transferred image displays in the preview screen.

⑤ **Use Access Protection.** Retraction feature that prevents the catheter from retracting beyond a certain position.

⑥ **Correct Height.** The blue dot in this image indicates the catheter location in conjunction with isocentering (see Isocentering with Mapping under Common Registration Tasks for more information).

⑦ **Accept** or **Cancel.** A successful transfer results in the establishment of a connection to the CARTO® 3 system, the six location pad markers being within acceptable tolerance, and enabling of the **Accept** button. Click **Cancel** if you simply want to close the dialog.

Successful X-ray transfer

When an X-ray image is successfully transferred and an appropriate device has been selected:

- Verify six green "plus" signs display, centered over the black registration dots.
- Move the six green plus signs **IF** they are *not* automatically centered by clicking and dragging them to the correct position over the black registration dots.
- Ensure the catheter shaft is properly positioned. (The CARTO® 3 Registration dialog automatically registers the length of the catheter.)
- Verify the location of the tip of the sheath by clicking on the red sheath base and dragging it to the desired location on the fluoro image.
- Ensure the crossing plane is adjusted to the septum location for left atrium procedures. In **Figure 133**, the crossing plane is displayed in the registration dialog (pre-adjustment). Move the crossing plane to the location of the septum in the current fluoro image by clicking and dragging the yellow plane. Once properly adjusted, the crossing plane will display blue as seen in **Figure 134.**
- The **Accept** button is green once all of the above conditions are met (see **Figure 134**).

Click **Accept** to return to the main window.

Figure 133. Crossing Plane Needs Adjustment

Figure 134. CARTO® 3 system registration is complete

When Accept button doesn't enable

Sometimes a perfectly good X-ray is transferred, but the **Accept** button does not enable. In this case, the registration cannot be completed. Several possible reasons are listed below.

- **Non-CARTO® 3 system device selected**

  You may have selected a device that is not compatible with the CARTO® 3 system. If so, a message displays with the "no" symbol in the bottom-left corner of the dialog and reads, "A CARTO® 3 compatible device is not selected" (**Figure 135**).

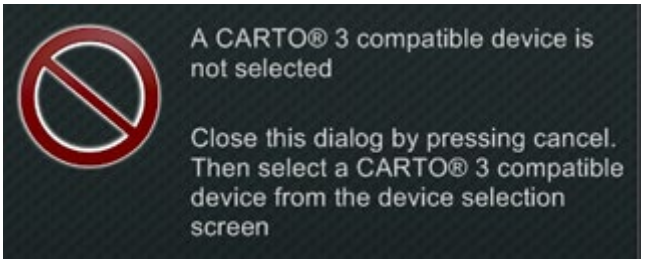


Figure 135. Message – "A CARTO® 3 compatible device is not selected"

  Close the dialog by clicking **Cancel**. On the Hardware status indicator bar, select the System Options icon (**see Figure 89**). Click **Device Selection** (see **Figure 90**) and select an appropriate device.

- **X-ray C-Arm not correctly positioned**

  The X-ray C-Arm may not be positioned correctly. It should be within 15 degrees of the anterior-posterior (AP) position. If it is not, a gold caution symbol displays with the message, "X-ray is not within 15.0° of AP" (**Figure 136**). Adjust the C-Arm so it is within 15° of the AP position.

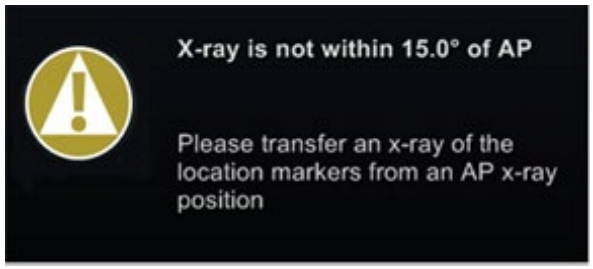


Figure 136. Message – "X-ray is not within 15.0° of AP"

- **CARTO® 3 system not licensed or connected**
  - If you do not have a license for the CARTO® 3 system or it is disconnected, you can open the CARTO® 3 Registration dialog and load a fluoro image, but you will not be able to register it.

- If you do not have a CARTO® 3 system, the CARTO® 3 icon will not display in the hardware status indicator bar on the “dashboard.”
- If the CARTO® 3 system is not connected, the "no symbol" displays over the CARTO® 3 icon.

CARTO® 3 system registration help window

Pressing the **Help** button for Step 1 displays the following window (**Figure 137**):

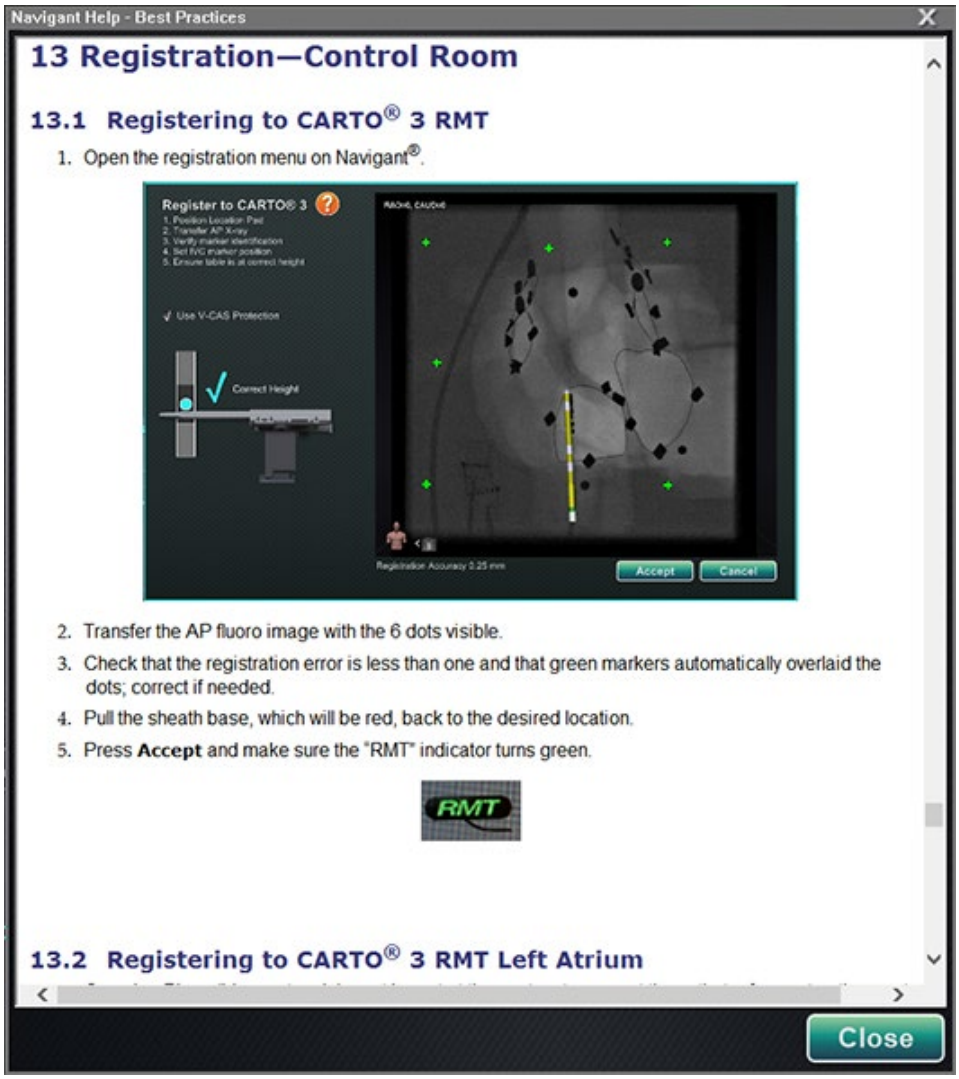
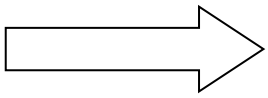


Figure 137. CARTO® 3 system help

Uncompensated Move After Registration

Upon registering, if an uncompensated move occurs (the most common being the electrodes on the patient moving), visible objects in the current window are marked "OLD_(*name of visible object*)." This is true for an ablation history, line, volume, surface, vessel, etc. If an additional uncompensated move occurs, that visible object will be marked "OLD2_(*name of visible object*), and the marking will continue for each uncompensated move. Consider the following example:

Line A is created
Uncompensated move occurs
Line A is marked "**OLD_Line A**"
Line B is created
Uncompensated move occurs
Line B is marked "**OLD2_Line B**"
Line C is created



The user will see
OLD_Line A
OLD2_Line B
Line C

The user will see all visible objects marked *old* as well as the newly created visible object. It is important to note that the user will **not** have to reregister after an uncompensated move occurs.

Registering to OpenMapping

Because of the OpenMapping API feature, the *Niobe* ES magnetic navigation system is able to support compatible navigation systems and catheter devices. Features of OpenMapping systems include but are not limited to:

- Real-time catheter location displayed in *Navigant* screen
- Full color three-dimensional map generation
- Target point and design-line data exchange*
- Control of magnetic field from the mapping system*
- Control of catheter advancement from the mapping system*
- View synchronization*

Note: Items with an asterisk are optional features and their usage will vary.

OpenMapping Registration (**Figure 138**) can be accessed from either the Clinical Workflow Manager (CWM) or the System Options menu. The magnets should first be homed and the patient setup. Upon selecting Steps 1. *Home Magnets* or 2. *Patient Setup* on the CWM, a document displays that has helpful instructions for homing the magnets and positioning the patient correctly.

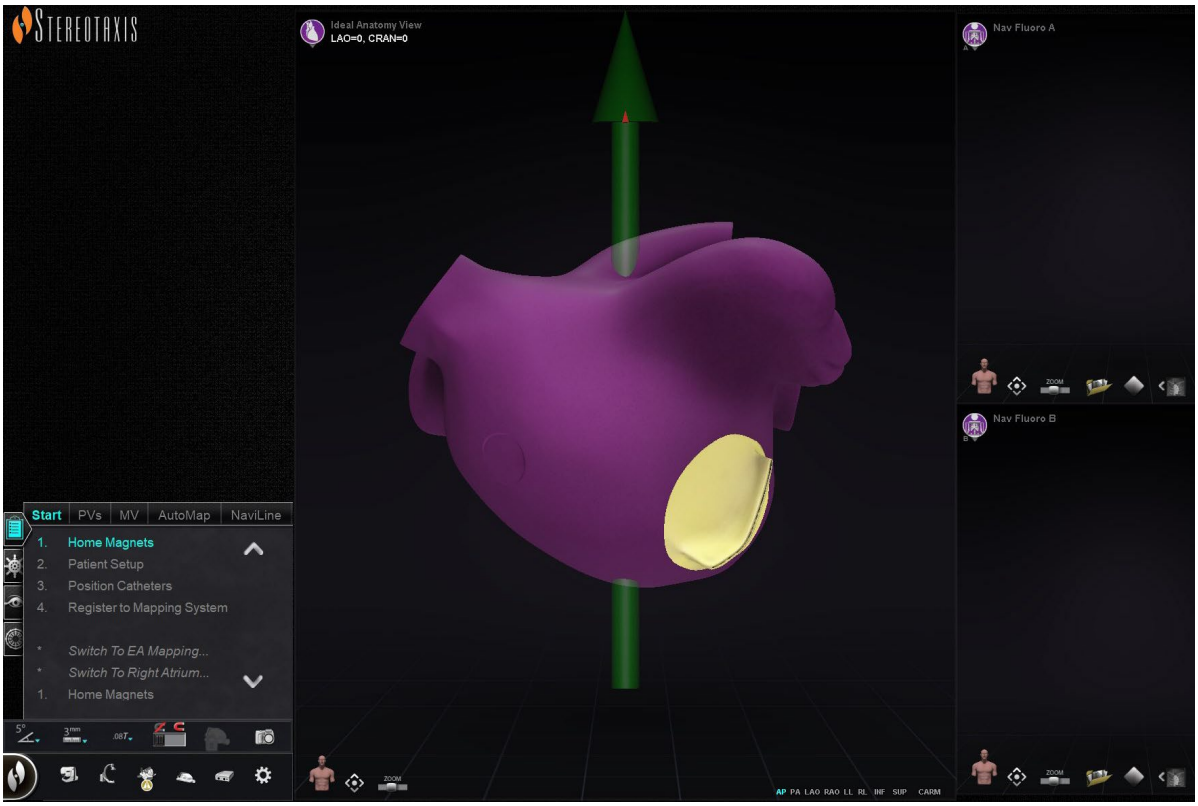


Figure 138. OpenMapping Registration

Successful X-ray Transfer

The Catheter Registration dialog can be used to tell the *Navigant* system how far the catheter is outside the sheath. When an OpenMapping system is used, the Catheter Registration dialog must be used to perform registration.

Catheter Registration is the third step on the CWM which reads *Position Catheters*. Selecting the **System Options** menu on the hardware status toolbar and then *Catheter Registration* is an alternative route for Catheter Registration. *Navigant* must be receiving real time catheter data or an error message (outlined by a red rectangle in **Figure 139**) will display. Before registration can continue, the user must ensure *Navigant* is receiving catheter data from the mapping system.

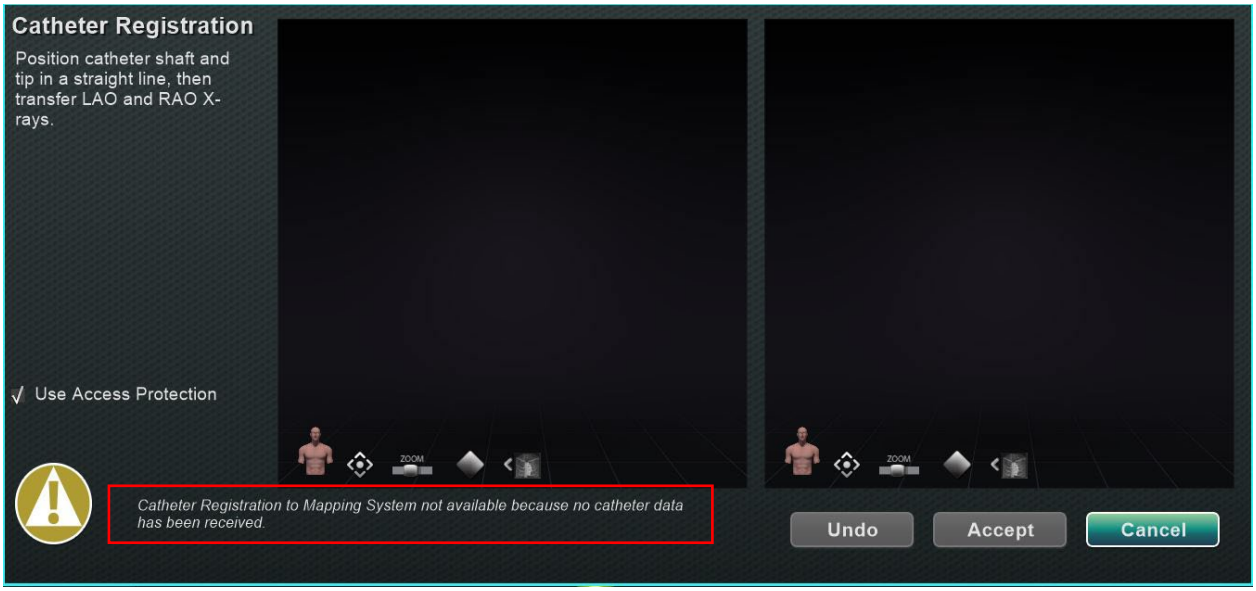


Figure 139. Catheter Registration- no data received

Once *Navigant* is receiving real time catheter data, registration can continue. Upload LAO and RAO X-ray images by clicking the transfer X-ray/fluoro button (emphasized by yellow rectangles in **Figure 140**). (During transfer, the button flashes between the regular image and a negative of the image.) See the Window Controls section for help with the other controls: pan, reset, zoom, and brightness/contrast. If the fluoros uploaded do not have at least 40 degrees of separation, an error message will display (**Figure 140**).

Figure 140. X-ray images have less than 40 degrees of separation

After acceptable X-ray images have been uploaded, the Catheter Registration dialog will instruct the user to draw the catheter tip and sheath base distal to proximal on each X-ray image. Once the catheter tip and sheath base are drawn, the crossing plane (yellow in **Figure 141**) will display.

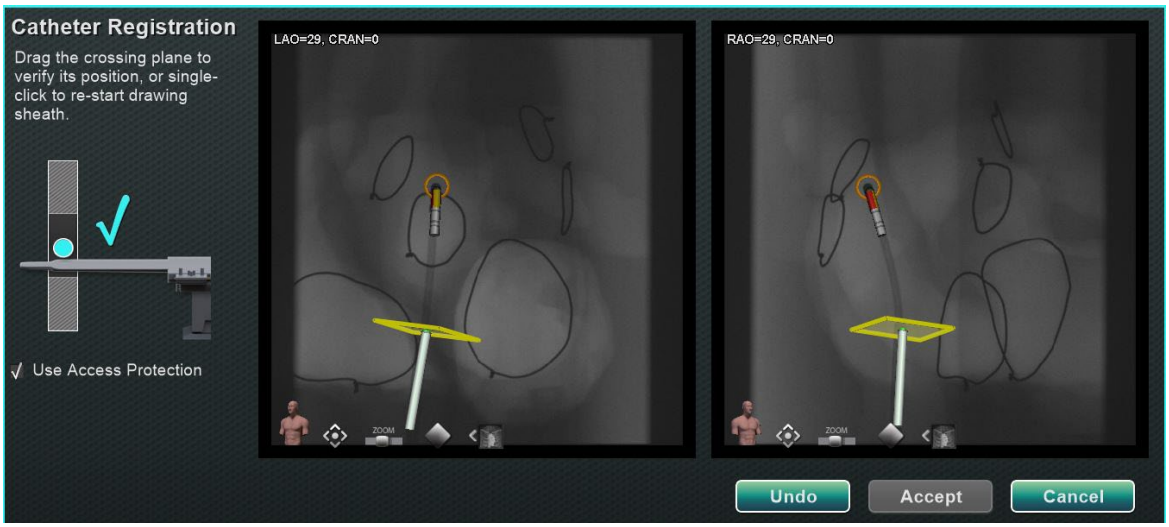


Figure 141. Catheter Registration- crossing plane not yet positioned

In Left Atrium procedures, the crossing plane must be adjusted to the location of the septum. By clicking and dragging, the crossing plane can be adjusted along the direction of the sheath. When the crossing plane is moved in one flouro window, it will automatically move in the other flouro window. Once adjusted, the crossing plane will display blue (**Figure 142**). The **Accept** button will be green once the catheter shaft and crossing plane are correctly positioned and can be selected to accept changes. Click **Cancel** to close without accepting the changes or **Undo** to undo any previous action. Upon selecting **Accept**, the main window will display (**Figure 143**).

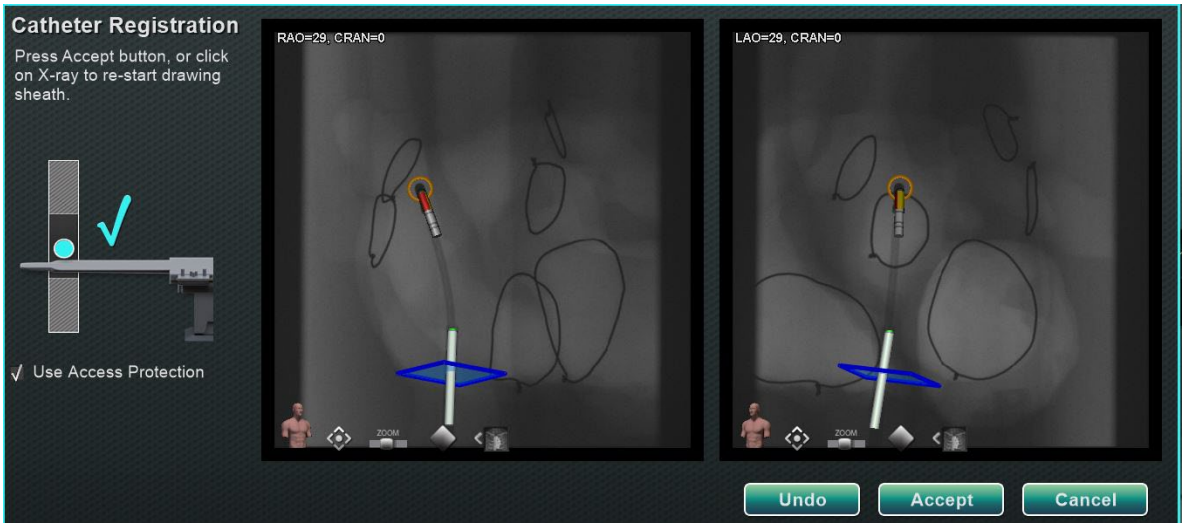


Figure 142. Catheter Registration- crossing plane positioned

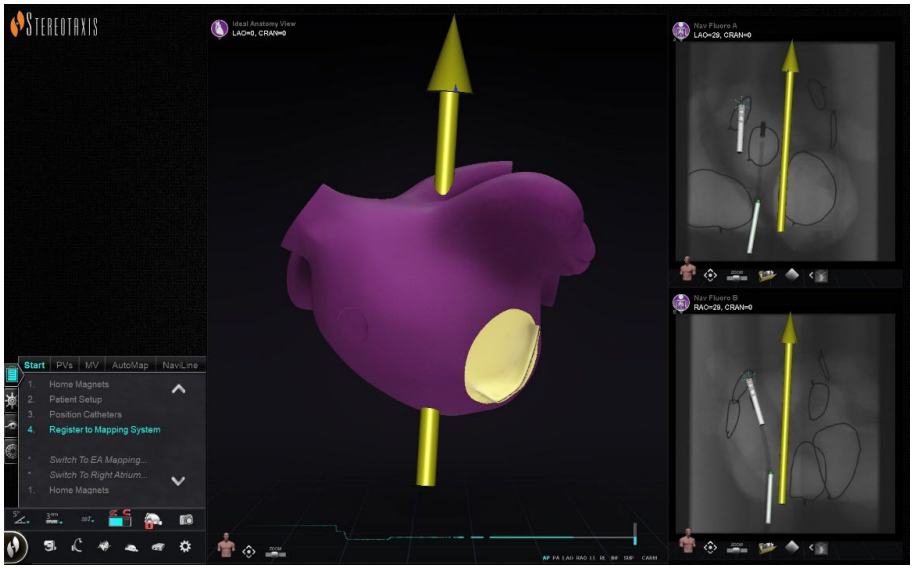


Figure 143. OpenMapping Registration Completed

Common Registration Tasks

Use Access Protection

Navigant includes a feature called Use Access Protection that prevents accidental retraction of the catheter from the left atrium into the right atrium and thus, is only available for magnetic left atrium (LA) procedures. This feature is automatically enabled in the software, but can be disabled by de-selecting the Use Access Protection checkbox in the CARTO® 3 Registration dialog or the OpenMapping Registration dialog. The registration dialog will tell the user what adjustments are needed (i.e. positioning the sheath base or crossing plane) before proceeding.

Access Protection Icon

The final crossing plane location represents the limit to which the catheter can be retracted and still remain in the left atrium (see limit indicators in **Figure 146**). The Access Protection icon on the Navigation toolbar changes to a Locked status when the checkbox has been selected and the crossing plane location has been defined.

Clicking on the Access Protection icon will toggle its state from Locked (ON) to Unlocked (OFF) and vice versa. The Access Protection status is represented by changes in the Access Protection icon (**Figure 144**). The icon is located on the *Navigant* toolbar, emphasized by a red rectangle in **Figure 145.**

Figure 144. Access Protection states- Disabled (left), Locked (middle), and Unlocked (right)

Figure 145. Access Protection status icon on toolbar

Crossing plane

The crossing plane graphic is a three-dimensional rectangle displayed in perspective on the X-ray. The rectangle shows the position in space that the *Navigant* software models as the anchor point of the catheter. It is calculated from the real-time position of the catheter reported by the CARTO® 3 or OpenMapping system. In left atrial procedures, adjust the position of the catheter until the crossing plane is at the septum location. (See CARTO® 3 or OpenMapping registration sections for more information about crossing plane adjustment.) Do not press the **Accept** button until the catheter is in the correct position. Some motion of the graphic will always be seen because of patient respiration and heartbeat.

Note: If the crossing plane is not positioned correctly, the targeting and automapping software performance will be compromised, and the software may inadvertently retract the catheter out of the chamber of interest (see the next section for indications). Ensure the crossing plane is in the correct position before pressing the **Accept** button.

Retraction limit indications

When the catheter retraction limit is reached during post-registration catheter usage, the crossing plane and the Access Protection limit icon both flash red, as indicated in **Figure 146**.

Figure 146. Crossing plane (1) and Access Protection limit icon (2) flashing red

Isocentering with Mapping

The region of interest should be centered and the catheter positioned in the center of the chamber of interest (no bend on distal catheter).

After which, the region of interest height should be adjusted to match the isocenter height. This is done by modifying the table height to move the dot (indicating catheter location) to the center of the range on the scale.

If the table is not at the appropriate height, the dot (indicating catheter location) will be red and an arrow will point in the direction that the table should be adjusted (**Figure 147**). Once the table is at the correct height, the dot will display blue (**Figure 148**). Table height adjustment can be made at any time by selecting the *Registration to Mapping* step on the CWM.

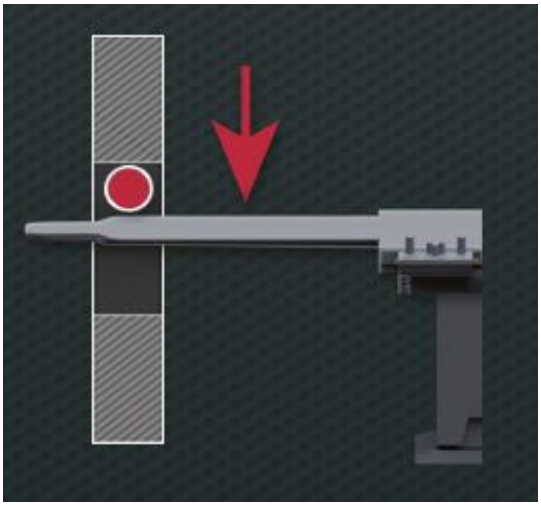


Figure 147. Adjust table height

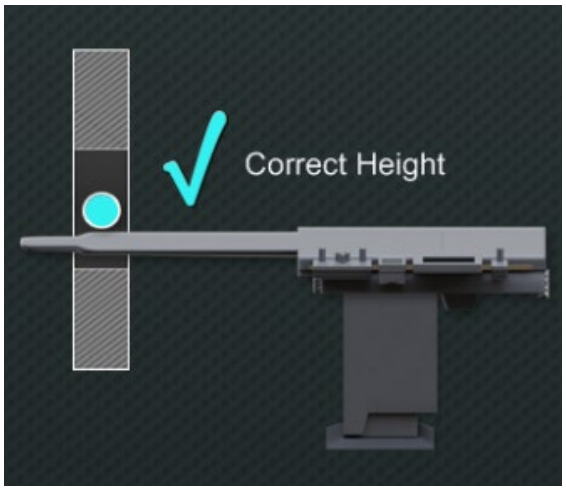


Figure 148. Correct table height

5. Automation Features

AutoMap

In the same procedure, clicking any step on the AutoMap tab (**Figure 149**) launches automatic CARTO® 3 or compatible OpenMapping system mapping.

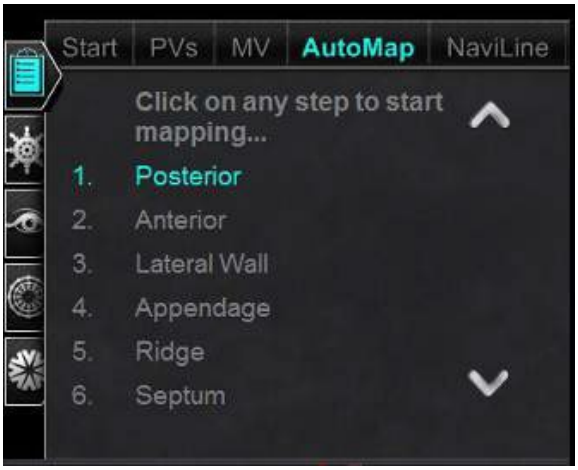


Figure 149. CWM Left Atrium AutoMap tab

Notes for CARTO® 3 EA (electroanatomical) mapping:

- The CARTO® 3 system is set to automatically freeze points.
- To view points before freezing, select **Manual** on the CARTO® 3 system.
- The *Navigant* system allows you to take points by clicking on the space bar when not in a data entry field. However, the CARTO® 3 system must be set for remote acquisition and must be enabled for each procedure.

Observe the generated map. In some circumstances, you may want to adjust the field direction or catheter length to:

- Avoid internal points
- Avoid excess points in one region
- Move the catheter if it encounters an obstruction
- Accommodate large chambers by adjusting catheter length

Stop AutoMap

At any time during the procedure, automapping and automatic moves may be stopped. The Automation dialog displays with a **Stop** button to stop automapping (**Figure 150**). It is important to note that selecting "**Stop**" on the automation dialog will stop all automation.

Figure 150. Automation dialog with **Stop** button during automapping

Navigation and Line Creation

Instructions for *NaviLine* Automated Linear Navigation are on the *NaviLine* tab of the CWM. These steps can be followed after a line has been created **(Figure 151).**

Lines can be created in *Navigant* (called NaviLines), CARTO® 3 (called Design Lines), or OpenMapping systems. If a line is created in Navigant, the first step of the CWM does not apply. If a line is created in the CARTO® 3 system "**Accept**" and "**Send**" the line to Navigant. If the function is supported in an OpenMapping system, line transfer will be specific to the system. After transfer, the line will then display in the 3D Map View Window.

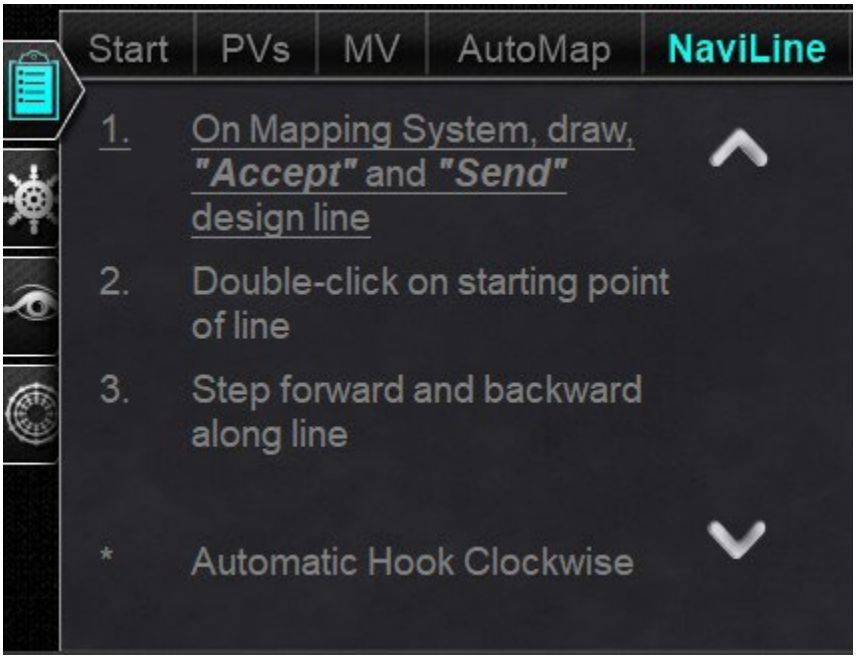


Figure 151. NaviLine Tab on CWM

Edit NaviLine Mode

To create a NaviLine in Navigant, click on the map surface in the 3D Map View Window. Select the "Edit NaviLine Mode" button (see the mouse cursor in **Figure 152**) to display the *NaviLine* toolbox. The toolbox (emphasized by a red rectangle in **Figure 153**) includes features such as New Line, Remove Line, Open/Close, Color, and Measure. These features aid in creating and editing a NaviLine.

Figure 152. Selecting Edit NaviLine Mode Button

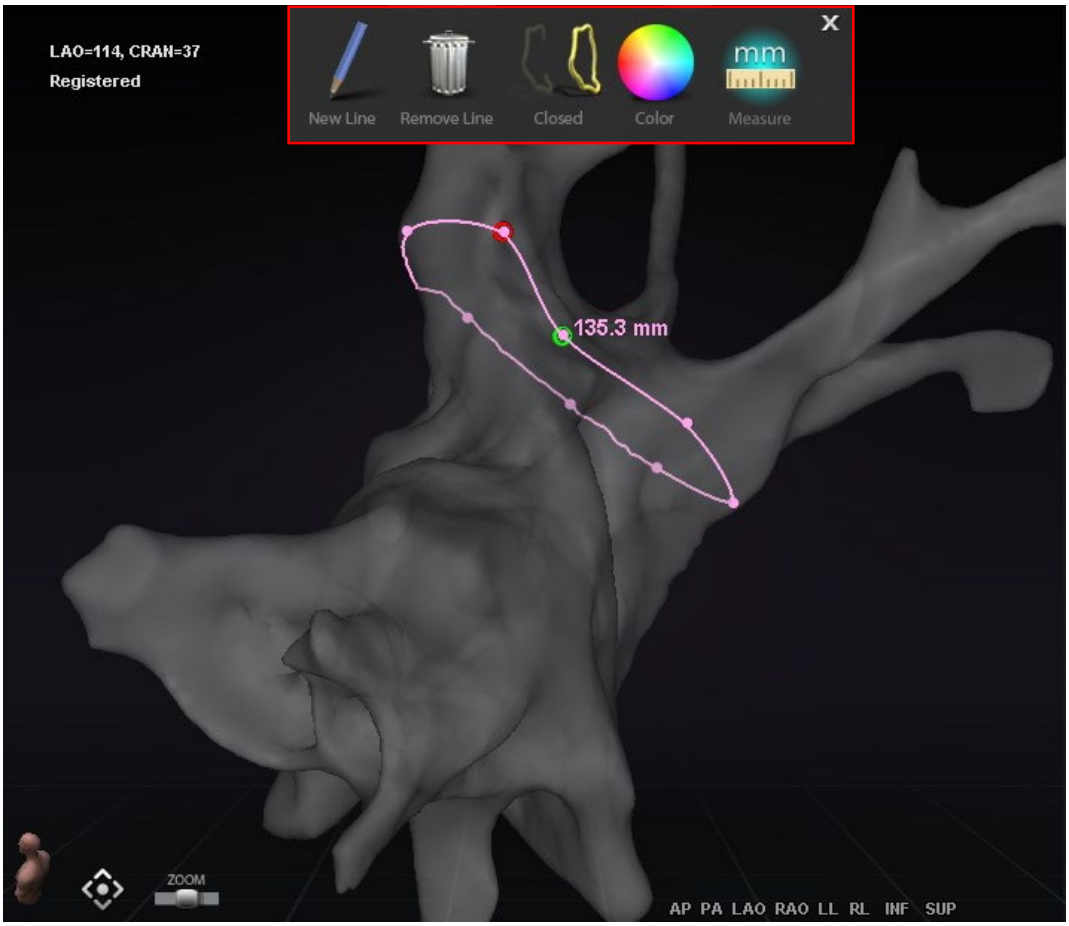


Figure 153. Edit NaviLine Mode- *NaviLine* toolbox (emphasized by a red rectangle)

The Edit Naviline Mode is also available for Ablation Histories. The user must first select the Ablation History from the Visible Objects pane (**Figure 154**). There can be multiple Ablation Histories, so the message "select an Ablation History" will display. Upon choosing an Ablation History, select the "Edit Naviline Mode" button to display the *NaviLine* toolbox and edit the Ablation History (**Figure 155**).

Figure 154. Visible Objects pane- Ablation History Selection

Figure 155. Ablation History- *Naviline* toolbox (emphasized by red rectangle)

Note: While in Edit NaviLine Mode, changes made simultaneously in Ablation History Graph will not appear. Conversely, changes while in Edit Naviline Mode will not appear in other windows- AHG, fluoro, etc. Further, it is not advised that the user performs these actions at the same time.

The images in **Figure 156** display closed lines. In the top image, the first point of the line is green and the last point is red. The selected point is white and a right-click menu option is displayed reading, “Delete Point” and “Delete Line.” In the bottom image, the cursor is too far from any one point to select, so the right-click menu reads “Insert Point” and “Delete Line.”

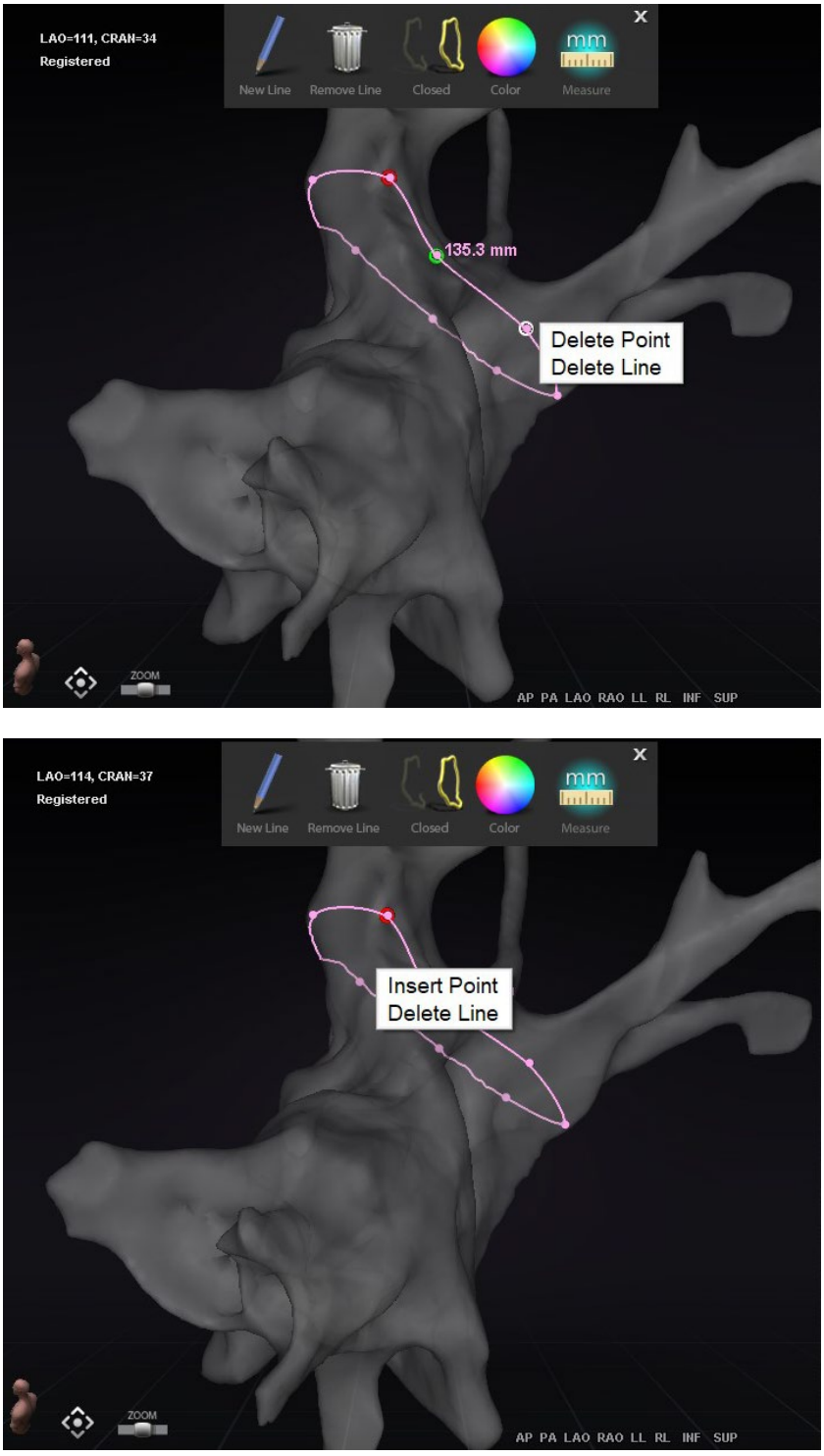


Figure 156. Edit *NaviLine* Mode; Right-Click Menu Options

After creating a NaviLine, the user can edit it by clicking the "Edit NaviLine Mode" button (see the mouse cursor in **Figure 157**). In the figure below, the Edit NaviLine Mode has been selected for a line surface. It is important to note that the option for Edit NaviLine Mode is only available in 3D windows, not fluoro windows.

Figure 157. Edit NaviLine Mode on Surface

The Edit NaviLine Mode is also available for already existing Ablation History lines. After creating a line, the user can reenter the edit mode by selecting the "Edit NaviLine Mode" button (see the mouse cursor in **Figure 158**).

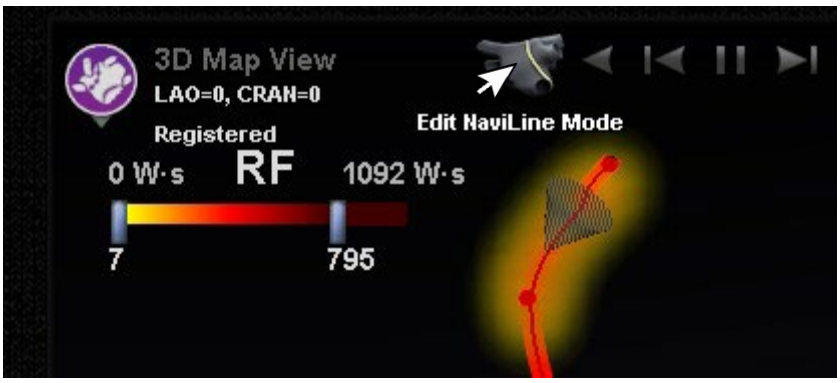


Figure 158. Edit NaviLine Mode on Ablation History line

Auto-*NaviLine* feature

You will see context-sensitive controls at the top of the window when you select a completed line, as in **Figure 159**. In addition, only if your system is set up so that Auto-*NaviLine* is enabled will buttons ① and ⑦ appear as shown in the following figures.

Note: The Auto-*NaviLine* controls, or buttons, match the cones in color: Forward is *yellow*, backward is *blue*.

Because the target cone in **Figure 159** *left* is currently at the beginning of the line, the "Backward" buttons are disabled. The Pause button is highlighted (blue underline) because no targeting is active. The opposite is true in **Figure 159** *right*, where the target indicator is at the end of the line and the "Forward" buttons are disabled.

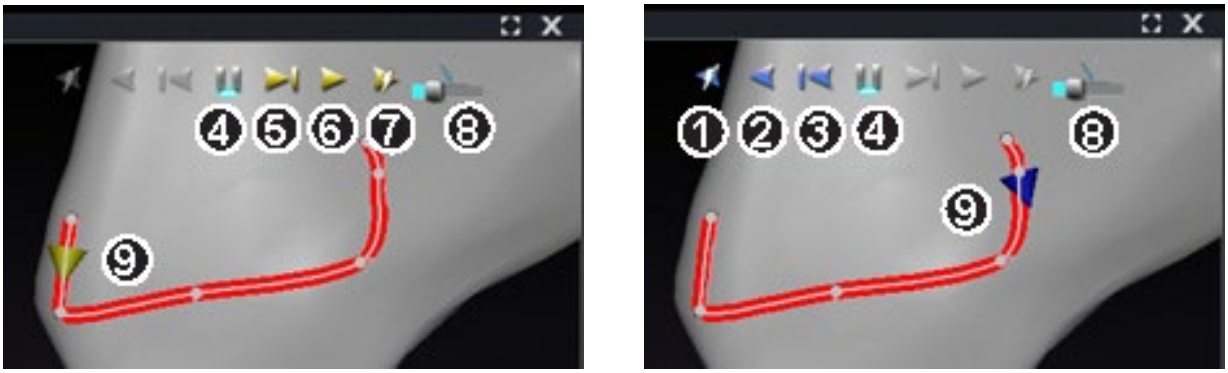


Figure 159. Auto-NaviLine at beginning (*left*) and end (*right*) of NaviLine design line

Auto-*NaviLine* tools guide (Figure 159)

① **Play Backward on Ablate.** Same as Play Backward, but the target advances only when the mapping system indicates the Stockert generator is ablating.

② **Play Backward.** Targets the current position. Once the catheter reaches the target, the target goes backward along the line at a speed controlled by the Target Movement Speed slider.

③ **Step Backward.** Sets the target Step Size millimeters in the indicated direction.

④ **Pause Targeting.** Cancels current targeting automation in the same way as the **STOP** button on the Automation dialog.

⑤ **Step Forward.** Sets the target Step Size millimeters in the indicated direction.

⑥ **Play Forward.** Targets the current position. Once the catheter reaches the target, the target goes forward along the line at a speed controlled by the Target Movement Speed slider.

⑦ **Play Forward on Ablate.** Same as Play Forward, but the target advances only when the mapping system indicates the Stockert generator is ablating.

⑧ **Target Movement Speed.** Controls the speed at which the target moves when playing. Left is slower; right is faster. The exact speed is not displayed.

⑨ **Cone.** Target indicator on *NaviLine*. Operates in the same manner as Step Backward and Step Forward when clicked.

In **Figure 160**, all buttons are active because the Auto-*NaviLine* cones are in the middle of the *NaviLine* on the *left* and on a closed line on the *right*.

Note: In the closed line on the right, the Play function loops until it is canceled.

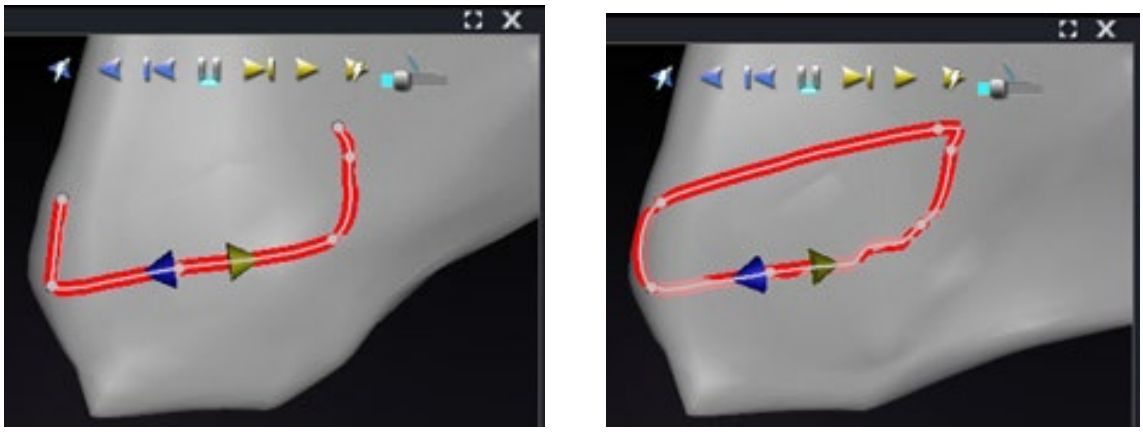


Figure 160. Auto-*NaviLine* cones are in the middle of a line *(left)* and on a closed line *(right)*

"Forward" and "Backward" are set when the line is created; they are not window relative. In **Figure 161**, the camera has been rotated 180° around the line until the yellow cone is pointing left, but the direction is still "Forward."

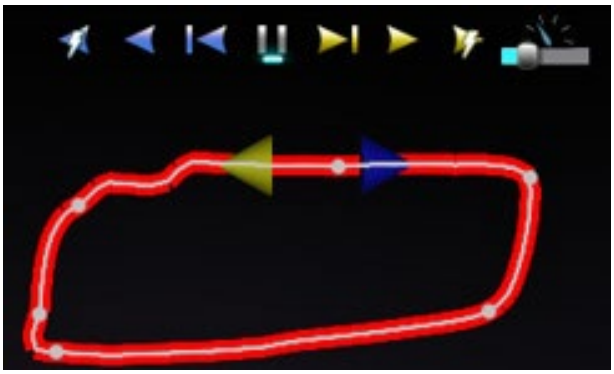


Figure 161. Auto-*NaviLine* cones pointing according to camera rotation

Notice the highlighted "Play Forward" on Ablate button in **Figure 162**. It now has the blue line under it instead of the Pause button, indicating automated ablating at the target location.

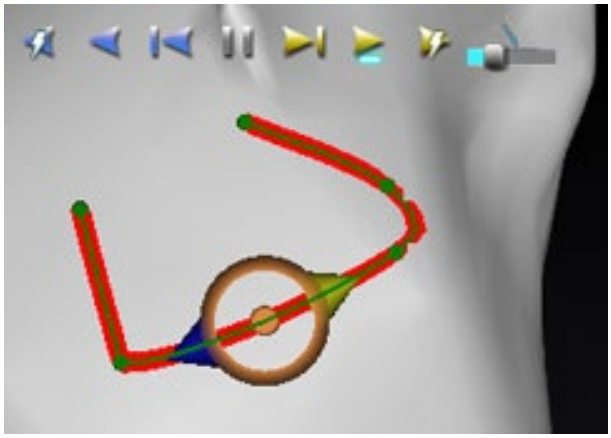


Figure 162. *NaviLine* design line with Auto-*NaviLine* target on it during Play Forward

Diagnostic Catheter Display

Diagnostic catheters used during a procedure will be displayed in the *Navigant* window. Types include:

- **Coronary sinus catheters**

  Also known as reference catheters, coronary sinus catheters have several electrodes that may be numbered.

- **Biosense Webster LASSO® catheters**

  LASSO® catheters have a variable loop with several electrodes that may be numbered.

- **Biosense Webster PENTARAY® catheters**

  PENTARAY® catheters have five, soft flexible branches (for better coverage) with several electrodes that may be numbered.

- **Biosense Webster SOUNDSTAR® catheters**

  SOUNDSTAR® catheters map cardiac anatomy and interpret ultrasound in the CARTO® system.

- **Mapping catheters**

  May be shown in different colors. The tip of the mapping catheter will become red while being used for ablation in an ablative procedure. A mapping catheter cannot be stored or targeted.

Catheter Properties dialog

During a procedure, positioning the cursor over a catheter highlights that catheter. The highlighted catheter will be selected if clicked.

Catheter information (such as location) may be stored. To store a catheter, double-click on the desired catheter. On the left side of the *Navigant* display, the catheter will appear in the Visible Objects field (**Figure 163**). The default name of the catheter (such as "Stored Catheter 1") may be changed, if desired.

Figure 163. Storing a catheter

Right-clicking on the stored catheter opens a dialog (**Figure 164**) in which you may change or adjust the following catheter properties:

- **Name**

  May be edited by typing in the name field.

- **Opacity**

  May be entered as a numerical (percentage) value, or by clicking and dragging the sliding bar displayed on the right.

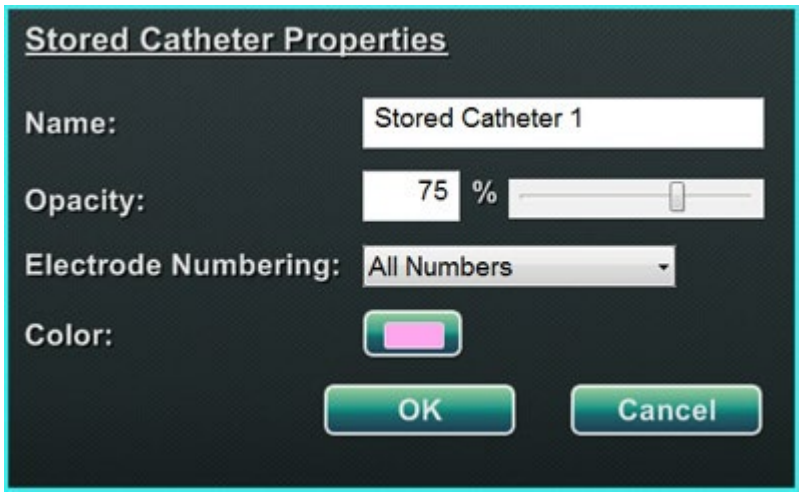


Figure 164. Catheter Properties dialog

- **Electrode Numbering**

  Used when targeting by electrode number. The drop-down menu includes several choices: *No Numbers*, *All*, and *Even or Odd*. Examples of Electrode Numbering on a coronary sinus catheter are shown in **Figure 165** and **Figure 166.**

- **Color**

  Double-clicking on the Color box outlined in green displays a choice of 16 colors. Clicking on the desired color displays the catheter in that color.

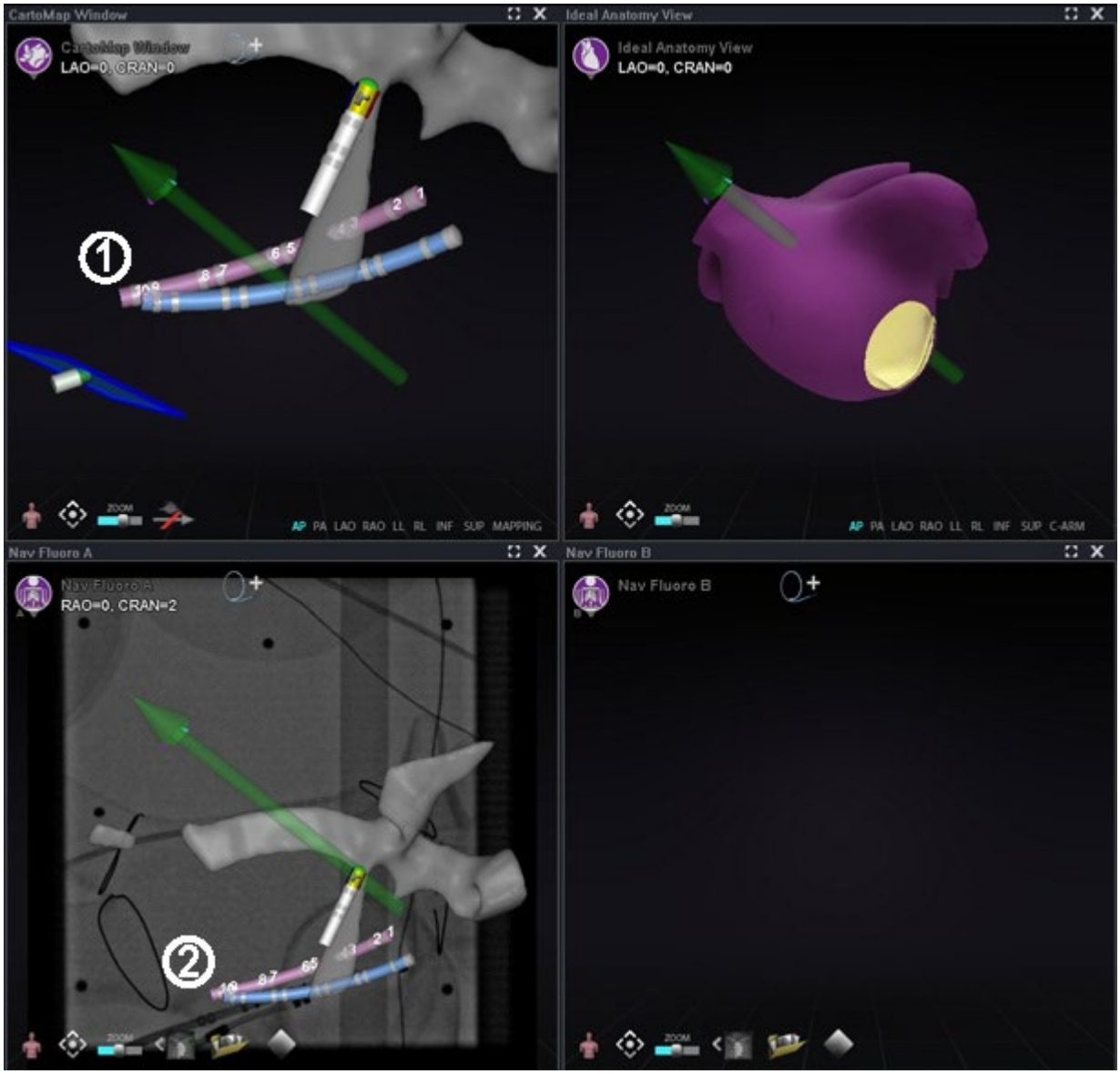


Figure 165. Electrode Numbering

① Electrode Targeting shown in main *Navigant* windows

② Same catheter, different view, in Fluoro Image A

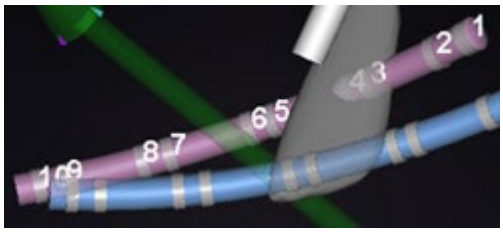


Figure 166. Electrode Numbering, enlarged

TargetNav Feature

The *TargetNav* feature is integrated between the *Navigant* system and the CARTO® 3 3D and OpenMapping systems. This feature enables the user to automatically target any location on the map surface. To create a target, double-click the desired point on the surface.

To move the target to the desired point, simply click it (**Figure 167**). While in this mode, you may move the target multiple times.

TargetNav guide (Figure 167 — Figure 170)

① **Vector Show/Hide mode.** Click the gray arrow icon with the diagonal red line across it (**Figure 170**) to hide the vector from display, or click the gold arrow (**Figure 169**) to return it to display. For example, if no vector is showing, as in **Figure 167** and **Figure 168**, the gold-arrow icon can be selected to show the vector. If the vector is displayed, the gray arrow with the red line can be selected to hide the vector.

② **Target.** Use the cursor to drag the target freely. The catheter automatically follows until it has reached the target (**Figure 168**).

Note: The target in **Figure 168** was moved slightly from its position in **Figure 167**.

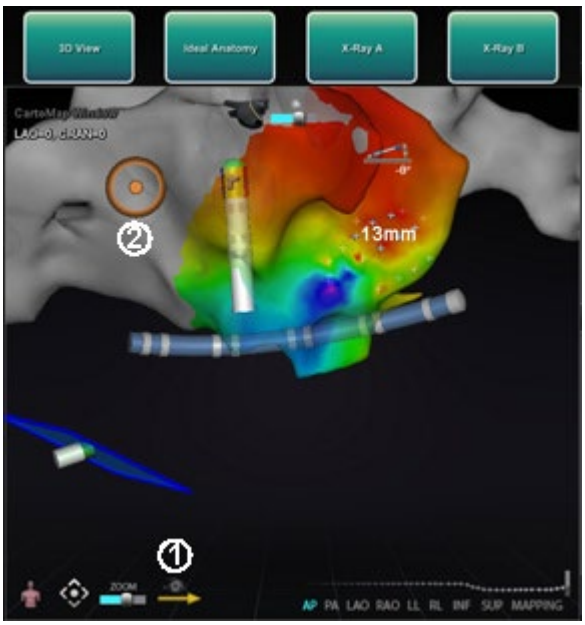


Figure 167. *TargetNav* targeting

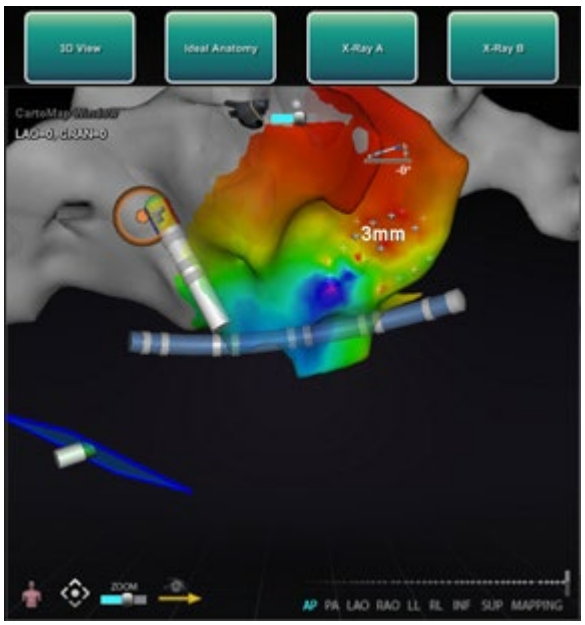


Figure 168. Target reached

Figure 169. Vector (field) show icon

Figure 170. Vector (field) hide icon

Click & Go

Click & Go is a feature integrated between the *Navigant* system and the CARTO® 3 3D mapping system that enables the user to automatically target any location on the map surface by double-clicking a point on the map. In the CARTO® 3 window's **RMT** tab, select **Click & Go** (**Figure 171**). The catheter is directed to the target automatically.

Note: Targets created in the CARTO® 3 system appear in the *Navigant* system and vice versa.

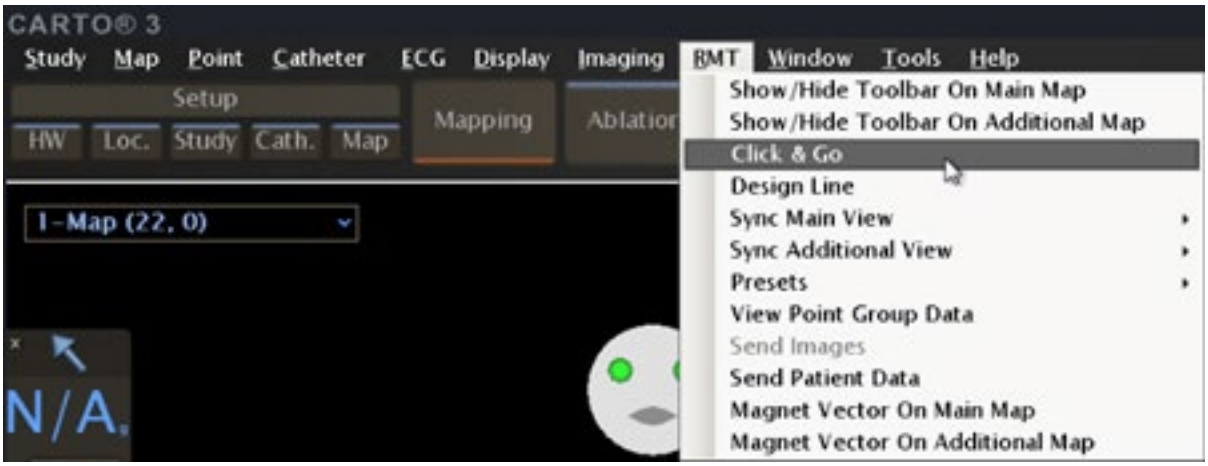


Figure 171. Click & Go CARTO® 3 RMT menu selection

Electrode Targeting

The *Niobe* ES MNS includes an electrode targeting feature (**Figure 172**) available in both CARTO® 3 and OpenMapping systems, which allows the user (in this example) to double-click on a coronary sinus catheter electrode to set a target. The mapping catheter is directed to that target automatically. The *Niobe* ES system also allows electrode targeting by electrode number.

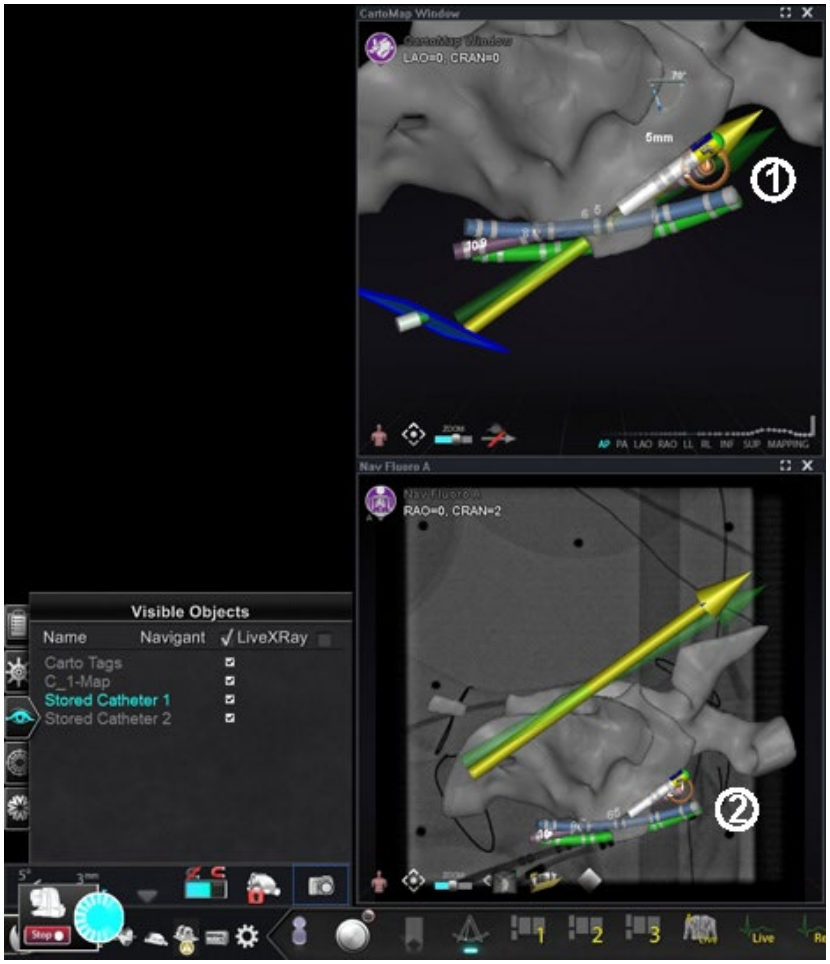


Figure 172. Electrode targeting

① Target shown in main *Navigant* window

② Same electrode pair targeted, shown in Fluoro Image A

Note: To enable electrode targeting in CARTO 3, go to the ECG graph window of CARTO 3 and right-click on the pair of electrodes desired.

DynaCT™

The Siemens syngo® DynaCT™ software option provides three features to support importation of DynaCT™ surface reconstructions segmented by the Siemens syngo® InSpace EP 3D segmentation software.

1. Import a surface via DICOM network transfer.
2. Draw *NaviLine* design lines on the imported surface.
3. Adjust registration of the imported surface.

Import via DICOM network transfer

Start the import by transmitting segmentation results from a Siemens Leonardo® workstation via DICOM transfer.

WARNING: If the patient table has been moved since the segmentation data was acquired, the imported data will not be registered to the X-ray system or the catheter location. The imported data will be offset by the amount of table movement.

Initiate a transfer

To initiate a DICOM transfer:

1. Open the patient browser on the Siemens Leonardo® workstation.
2. Select the appropriate patient data.
3. From the menu, click **Transfer\Send…**.
4. Select the *Navigant* node from the list of DICOM nodes.

View transfer results in *Navigant* system

When the network transfer is complete, the *Navigant* system displays a small message in the lower-left corner of the screen notifying the user that the import process has started. The importation and conversion to a displayable surface can take up to about 2 minutes.

At the end of the import process, the *Navigant* system displays a small message in the lower-left corner of the screen that it has completed the import process. The newly imported surface will display in the *Navigant* system's Mapping and Fluoro windows (**Figure 173**).

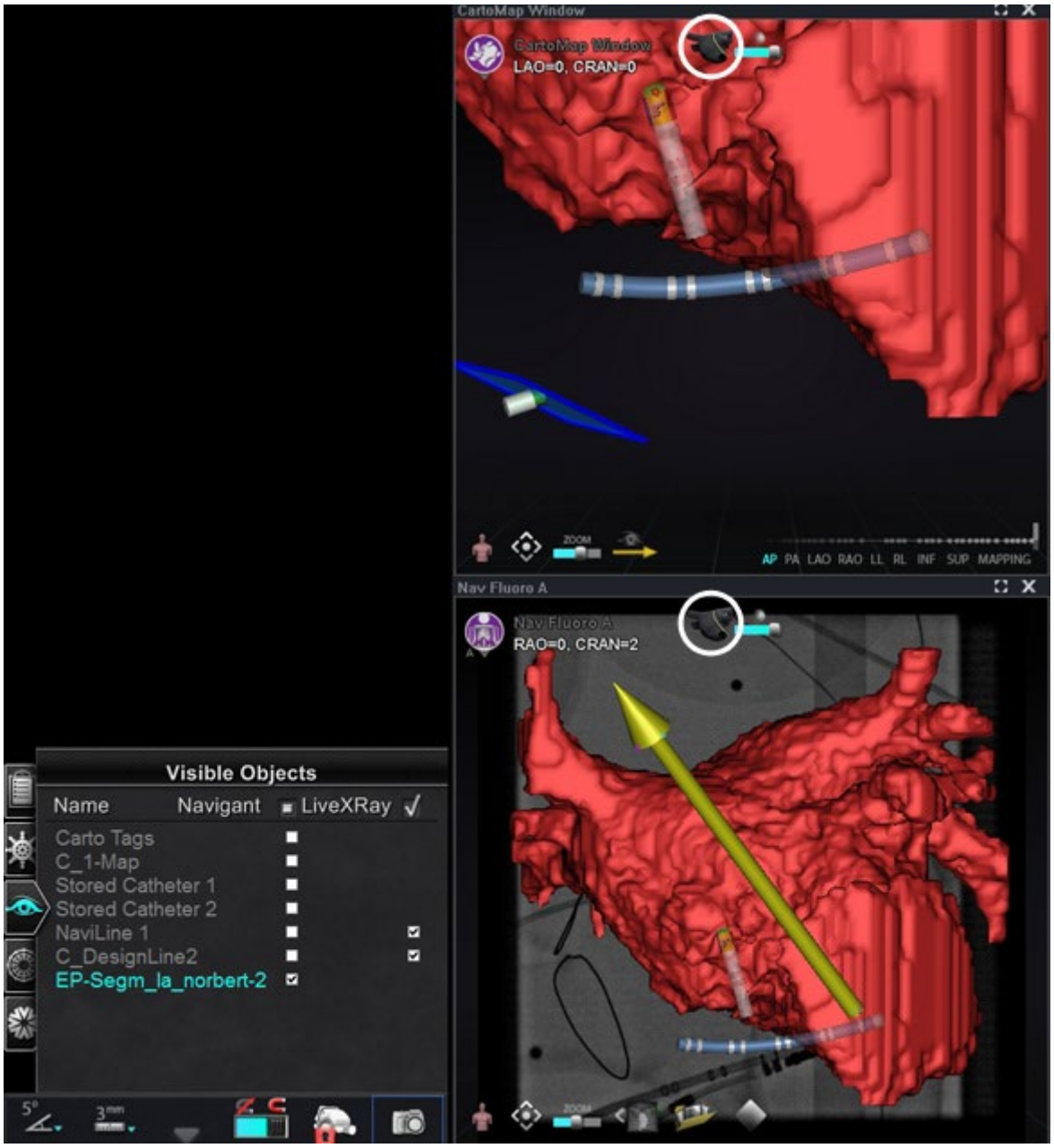


Figure 173. Imported surface with *NaviLine* icon *(circled)*

Click the *NaviLine* icon (**Figure 174** or **Figure 175**) to display the *NaviLine* toolbox (**Figure 176**).

Figure 174. Appearance of *NaviLine* icon on red surface background

Figure 175. Appearance of *NaviLine* icon on gray surface background

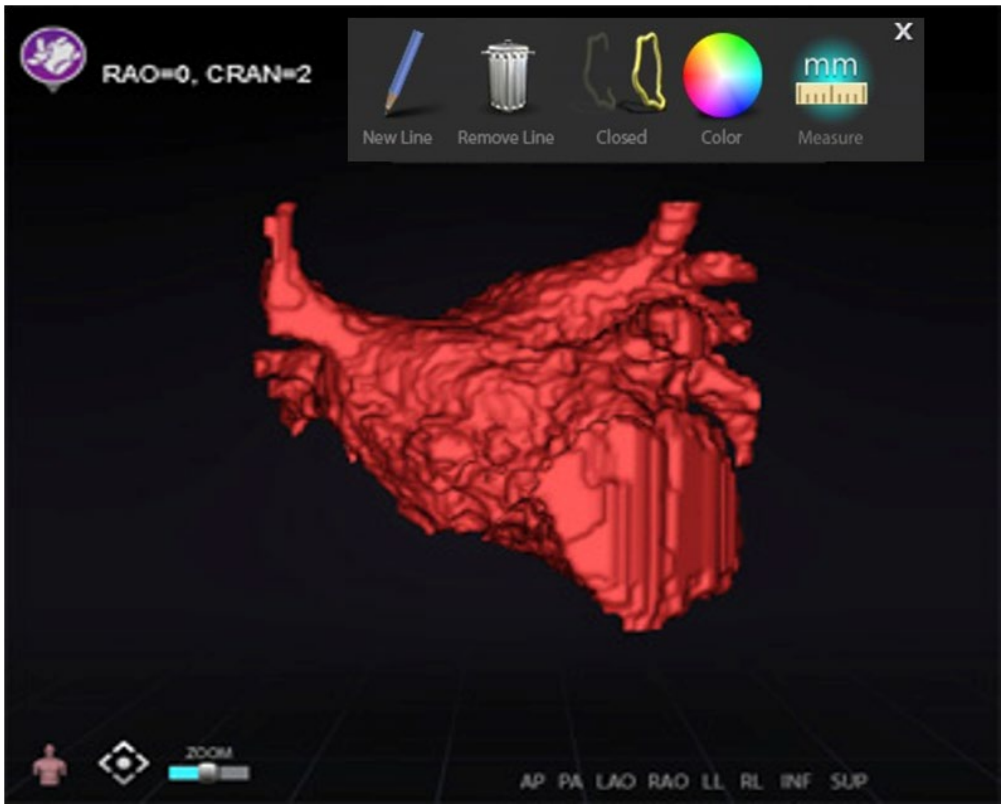


Figure 176. Imported surface with *NaviLine* toolbox displayed

Use the tools to create the new line on the imported surface (**Figure 177**). To delete an entire *NaviLine* design line, click the **Remove Line** ("trashcan") icon in the *NaviLine* toolbox.

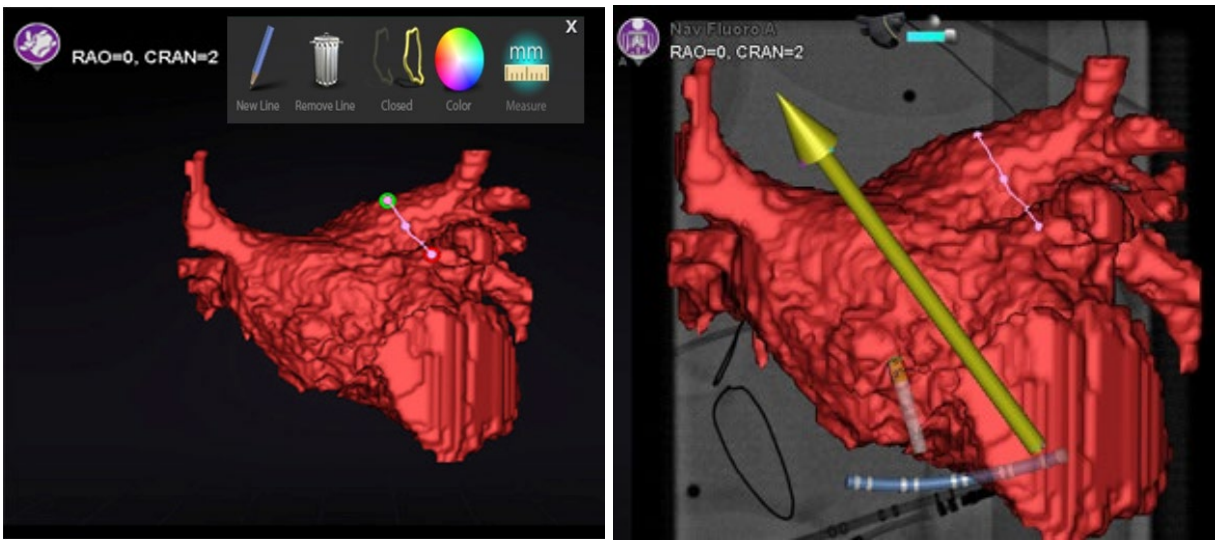


Figure 177. Imported surface with *NaviLine* being drawn *(left)* and drawn *(right)*

Register imported surface

An imported surface can be adjusted relative to existing mapping information by following these steps:

1. Right-click the surface in the Visible Objects panel.
2. Select **Surface Registration** from the popup menu (**Figure 178).**

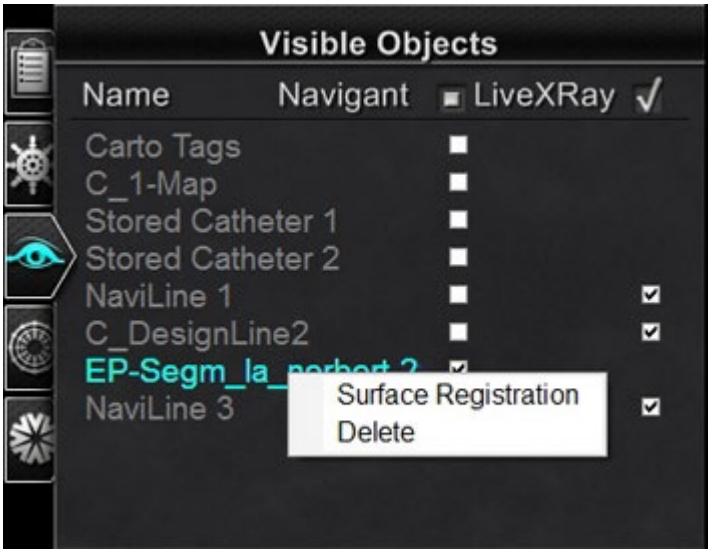


Figure 178. Accessing the Surface Registration dialog

In the image above, the 3DMap and Fluoro views display the selected surface and any other objects that are set as visible on the Visible Objects panel. The CARTO® 3 catheter tip also displays if the CARTO® 3 system is transmitting locations. The dialog allows the user to adjust the selected surface relative to other objects in the view.

Surface Registration dialogs

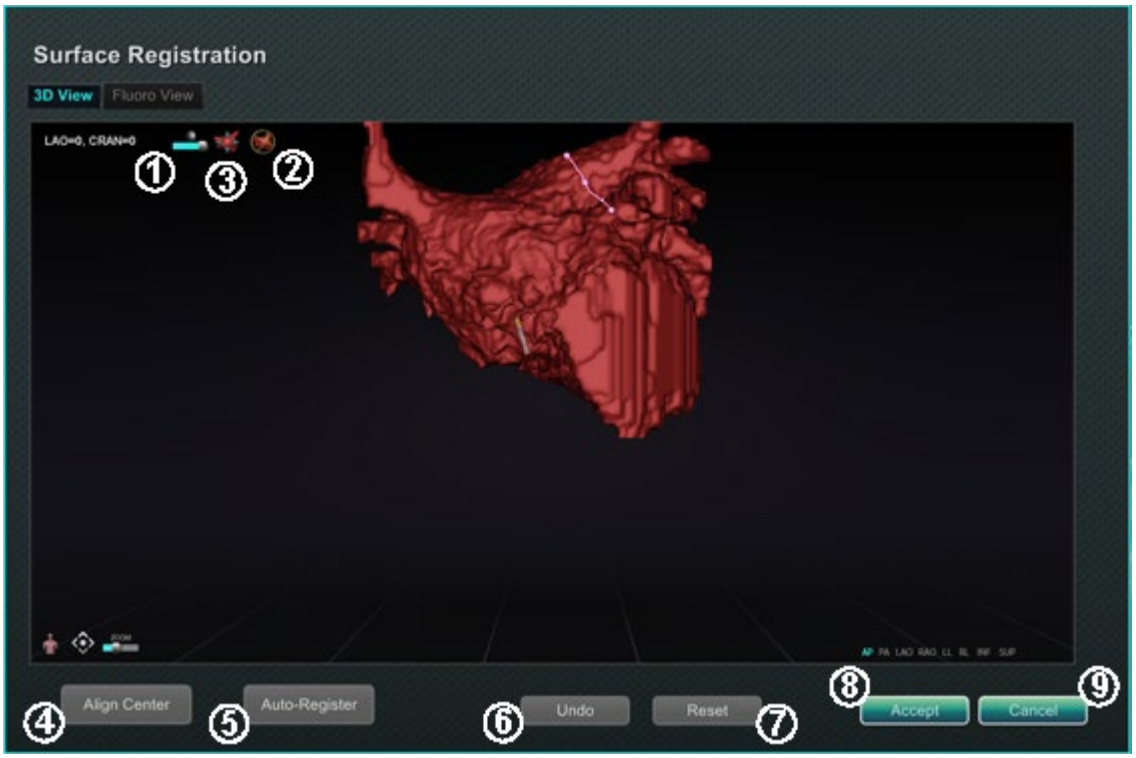


Figure 179. Surface Registration – 3D View

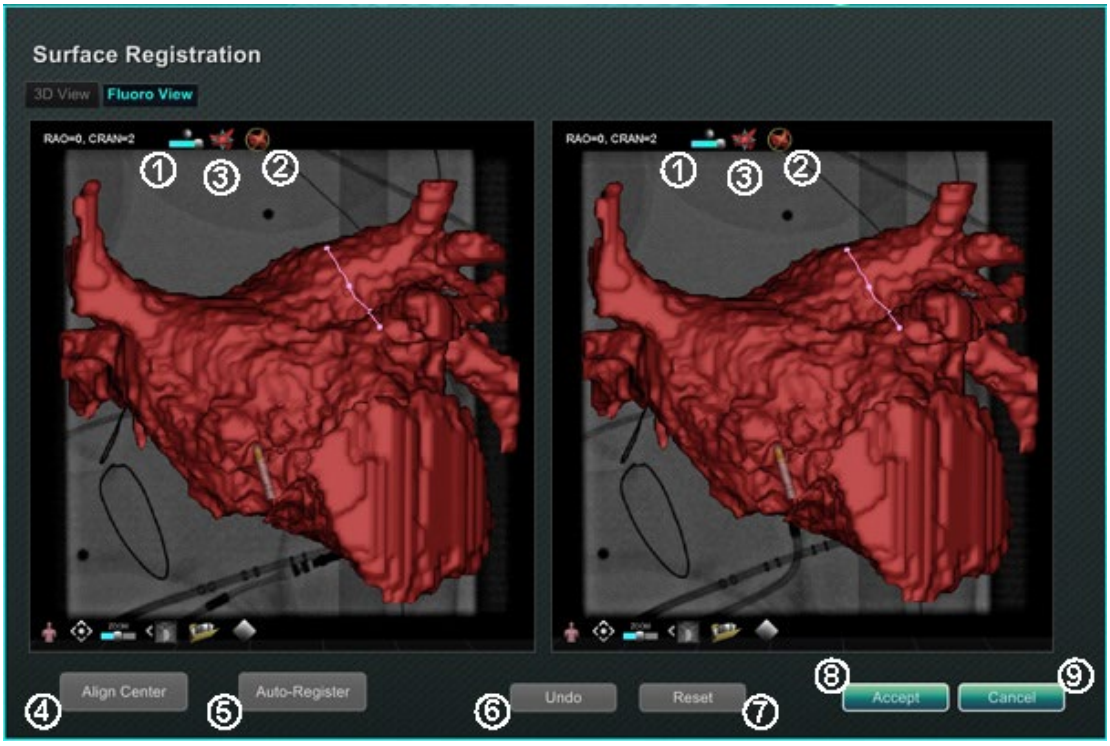


Figure 180. Surface Registration — Fluoro View

Surface Registration guide (Figure 179 and Figure 180)

① ***Toolbar icons.*** Make manual adjustments to the surface by either rotating or translating the surface by dragging the cursor on the appropriate control on the toolbar.

② ***Relative rotation.*** Rotates the surface relative to the map.

③ ***Relative translation.*** Translates surface relative to map.

④ **Align Center.** Computes the center of the map and surface and translates the surface so the two centers coincide.

⑤ **Auto-Register.** Attempts to minimize the distance between the map and the imported surface. It is more effective when all the boundaries of the heart chamber of interest have been mapped.

⑥ **Undo.** Undoes the most recent adjustment. Each click on the button backs up one step.

⑦ **Reset.** Restores the relative position of the selected imported surface to its position at first import.

⑧ ***Closing the dialog.*** Click **Accept** to save changes and close the window; click **Cancel** (⑨) to close the window without saving changes.

Ablation History

The *Niobe* ES Ablation History feature indicates where the catheter has been while the radiofrequency (RF) generator is running.

When the RF generator is running, Ablation History provides the following two indications:

- The location of the catheter during the time that the generator was on
- An increase in coloration and size of display depending on amount of time in a given position multiplied by the amount of power used

In addition, an interactive color scale allows manipulation of the gradient and power levels.

Multiple Ablation Histories

Multiple Ablation Histories can be created to segment ablations by time; for example, different Histories may be used for when the catheter ablates in different chambers. Only one Ablation History can be active at a time, and new ablations will be added to that History. However, multiple Ablation Histories can overlap, and it is up to you to activate their preferred History if the catheter is in the location of a previous Ablation History. When an overlap occurs, the power used in previous ablations in that location will also become visible in the current Ablation History. This may cause the sudden appearance of more intense coloration.

Setup

RF generator

The RF generator (Biosense Webster® Stockert 70 RF generator or SmartAblate™ RF generator) must be connected for the Ablation History feature. When a procedure is opened and the Ablation History feature is enabled, the generator icon on the *Navigant* hardware status indicator bar shows connection, as on **Figure 181,** *left*.

Figure 181. Ablation History generator status icon indicating, *left*, connection and, *right*, non-connection

When not connected, the generator icon indicates an error, as on **Figure 181**, *right*. Non-connection may occur when the generator is inactive or if the system is unable to open the communication port to the generator.

Note: The status icon also may show an error symbol if the *Navigant* system received an "Ablation on" message from the mapping system but did not receive the same message from the generator.

Navigant system

Making Ablation History visible

1. The *Navigant* system Visible Objects control panel displays "Ablation History 1" (oval in **Figure 182**) when the first ablation is performed after registration. Checking and unchecking Ablation History boxes displays or hides display of Ablation Histories.

   Note: The asterisks around a name indicate an active Ablation History volume. If no Ablation Histories are visible, the Color Scale (found in the subsequent section, *Color Scale*) does not show in 3D Map Windows.

Figure 182. Visible Objects panel with Ablation History viewing enabled (checkmark)

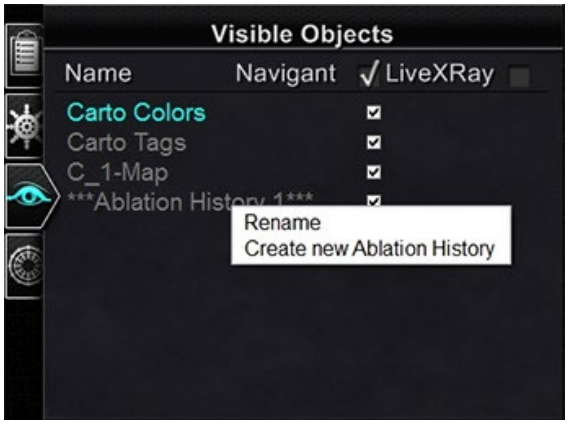


Figure 183. Rename/Create new Ablation History options

2. Right-click on an Ablation History to either rename that Ablation History or create a new Ablation History (**Figure 183**). If "Create new Ablation History" is chosen, "Ablation History 2" is added to the list (**Figure 184**, *left*). Right-clicking on "Ablation History 2" and choosing "Rename" allows that History's name to be edited (**Figure 184**, *right*), as an example.

Note: For CARTO® 3 systems **only** — if an ablation history has been marked as "OLD_(*name of ablation history*)", the user is unable to create a new ablation history using the marked ablation history.

Figure 184. Sample results of "Rename/Create new Ablation History" selections

3. To activate an Ablation History after working with another history, right-click its name. A 3-item menu appears as shown in **Figure 185**, with the result shown on the right.

Figure 185. "Activate" menu selection *(left)* and result *(right)* when "Ablation History 1" is activated

Demonstrating overlapping Ablation Histories

The images in **Figure 186** and **Figure 187** demonstrate how an area can belong to multiple Ablation Histories. The ball on the lower right was created by an ablation when "Ablation History 1" was active **and** an ablation in the same location when "Ablation History 2 Part b" was active, so it remains visible when **either** History is visible.

Figure 186. Encircled checkboxes show number of Ablation Histories displayed at right of each example: *Left*, Both Ablation Histories; *Right*, Only "Ablation History 1"

Figure 187. Encircled checkboxes show number of Ablation Histories displayed at right of each example: *Left*, Only "Ablation History 2 Part b"; *Right*, Neither Ablation History

Ensuring visibility settings are correct

1. From the hardware status indicator toolbar, click the system options button to display the System Options menu.
2. From the System Options menu, click **Settings**. The screen for the *Navigant* Window tab appears (**Figure 188**).
3. In the *Navigant* Window tab, ensure the settings shown in **Figure 188** are checked or selected.

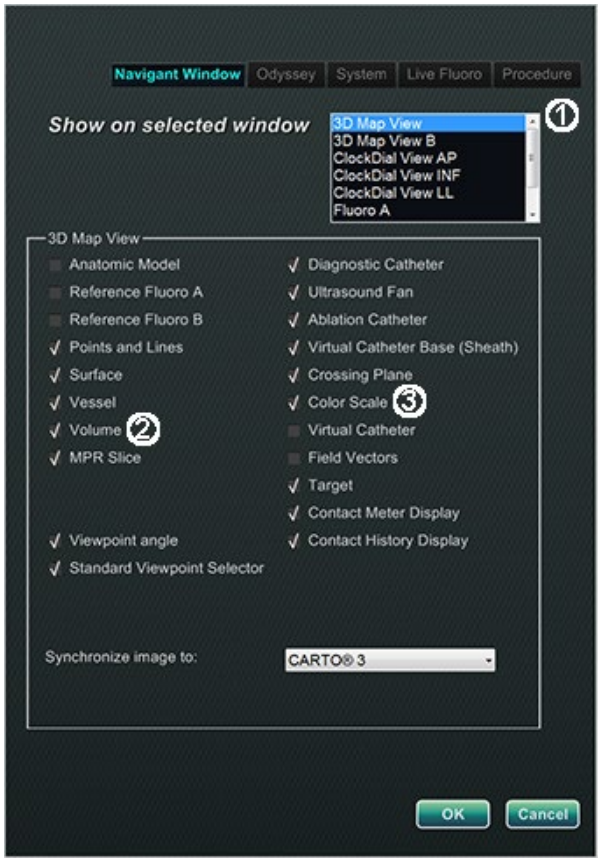


Figure 188. *Navigant* Window settings for Ablation History:

① 3D Map View *or* 3D Map View B ② Volume ③ Color Scale

When the RF generator is running and the *Navigant* system is receiving real-time catheter position information from the mapping system, Ablation History is automatically created based on the system settings (**Figure 189**).

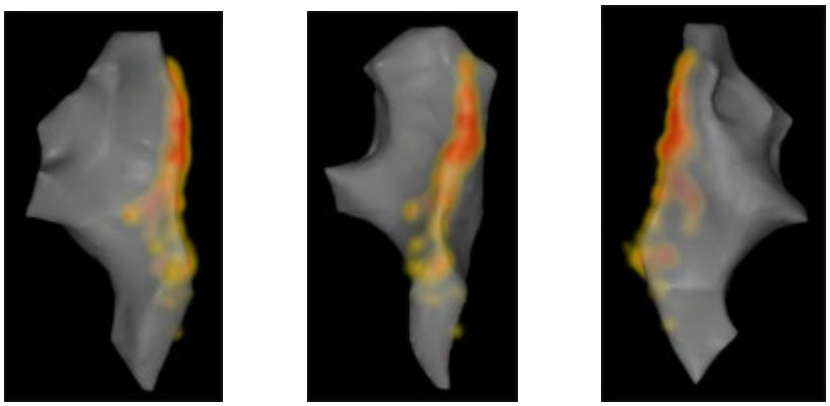


Figure 189. Ablation History viewed from various orientations

Creation

The Ablation History function operates by displaying an area around the catheter position that grows in size and deepens in coloration over time. The physician using the Color Scale is able to determine the manner in which these display changes occur.

The physician may also elect to reset the accumulation of history after a specified amount of time has passed. The amount of time is indicated with the "Use time reset" setting in the **Settings System** panel (see **Figure 109**) **.** When this setting is used, the Ablation History accumulation resets after the selected time interval. This reset results in the need to re-accumulate the Ablation History when returning to areas previously documented with an Ablation History after the time period has expired. Once the time period has expired, the level of accumulated Ablation History must reach the previously recorded level before the history display continues to grow in size or deepen in coloration.

Figure 190 shows a representative Ablation History screen with executed Ablation History, Color Scale, and Windows Controls visible.

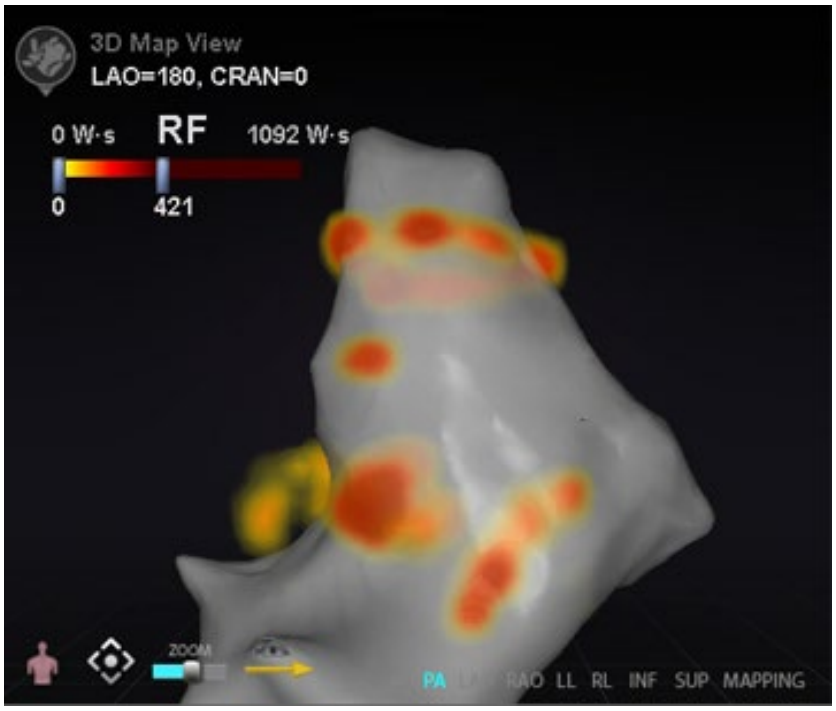


Figure 190. Example of Ablation History map

Color Scale

The Color Scale appears above the mapping area and displays the range of numbers (indicating watt-seconds, or W·s) and colors that form the current view of Ablation History intensity. **Figure 191** shows three examples of differing display ranges and color gradients.

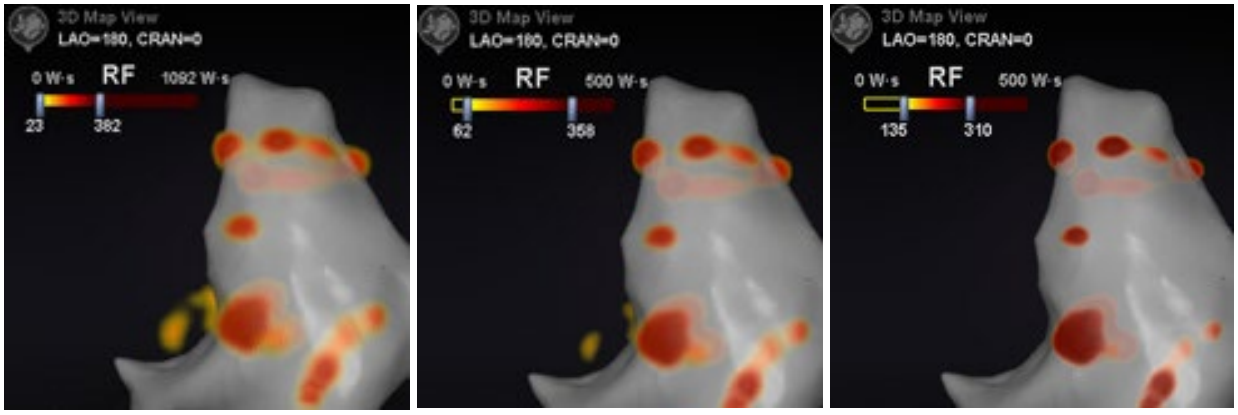


Figure 191. Differing areas of drawing intensity, or gradient fields

Maximum ablation value

Pressing the **Alt** key while using the mouse to hover over an area of shading allows popup of the Ablation History value at that point, as shown in **Figure 192**. The value shown is the highest value accumulated under the pointer to a maximum depth of 1 cm. This maximum value also displays on the Color Scale.

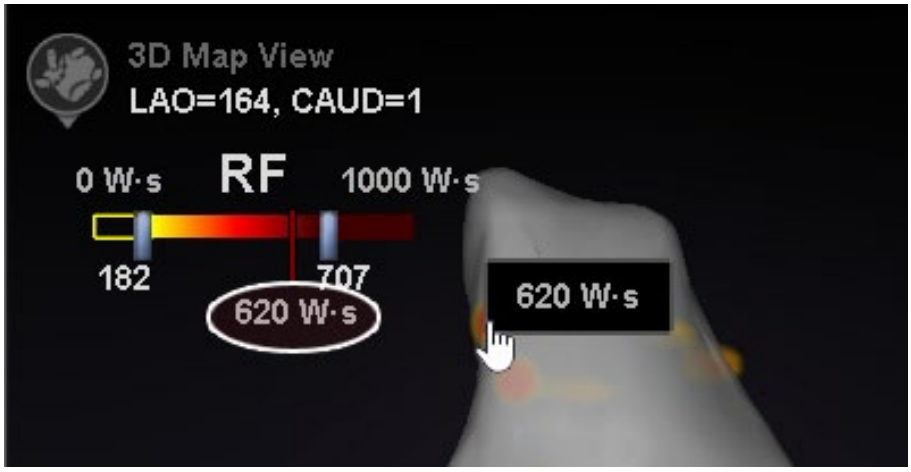


Figure 192. Maximum ablation value (**620 W·s**) shown in popup and on Color Scale (by vertical red line and numeric label, highlighted by white oval here)

Accumulation range

The range of watt-seconds may be manually edited to allow zooming in on a desired location:

1. Double-click on the numeral to the left of the **W·s** label.
2. Type a new value allowing for the following "rules":
   - Cannot exceed lower number of bar.
   - May go as high as upper limit of 4,369 W·s.
   - Color range min ≤ Color gradient min ≤ Color gradient max ≤ Color range max.
3. See **Figure 193** for an example of manual editing.

Figure 193. Edited W-s values indicated by red rectangles

Color gradient

In addition to manually editing the range display, you may also drag the bar at either end of the gradient display to change the color gradient within the defined range. Like in **Figure 193**, the user may select and slide the bar at **182** or the bar at **707** to a lower or higher number.

Ultrasound Fan

When the *Navigant* system receives Ultrasound Fan data from the CARTO® system (while using the SOUNDSTAR® catheter), the screen displays the fan as in **Figure 194**. It is important to note that the option "Ultrasound Fan" must be checked (**Figure 104**) in the *Navigant* Window settings for data transfer to occur.

The system highlights the intersection of the ultrasound plane with the mapping catheter as a green line on the catheter. This indication helps identify the catheter's location on the ultrasound image.

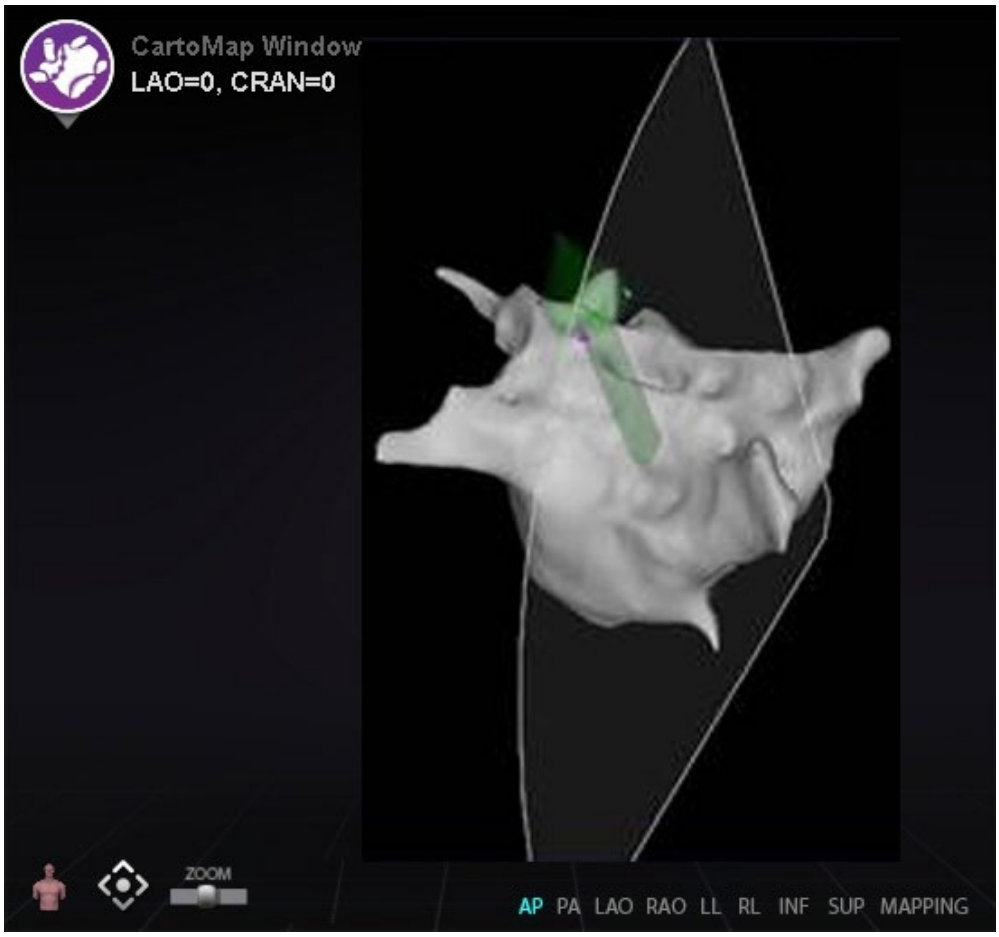


Figure 194. Ultrasound Fan display in CartoMap Window example

6. Intracardiac (IC) and Features

Vessel Navigation

NaviView3 feature

The Stereotaxis *NaviView3* feature defines vessels in 3D space using complementary fluoro views. When you draw the centerline of the desired vessel on the two fluoro images (separated by at least 40°), the *Navigant* system has enough information to mathematically construct a three-dimensional software vessel navigation and X-ray roadmaps.

The *NaviView3* on Fluoro option is a licensed feature; access it from the System Options menu on the hardware status indicator toolbar. If you click ***NaviView3*** and do not have a license for it, the *Navigant* system displays the message "Unable to open VesselView due to inactive license."

NaviView3 terms

Anchor point All proximal, distal, and branch points (the branch's starting point on the trunk), and all user-designated anchor points (added to make the 3D reconstruction more accurate). Anchor points are marked with an orange cross.

Branch A segment that stems from a trunk or another branch.

Epipolar The projection of one fluoro source into the space of the other fluoro within the three-dimensional space maintained by the *Navigant* system.

Trunk The segment with the proximal end.

Vessel A segment or set of segments where one end is proximal and the others are distal. (Also called vessel tree [**Figure 195**].)

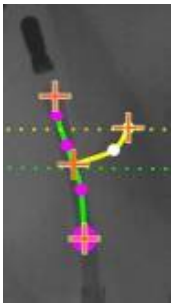


Figure 195. Vessel tree example showing trunk (green) and branch (yellow)

Point Annotation on Fluoro dialog

The Point Annotation on Fluoro dialog (**Figure 196**) can be used to annotate fluoroscopic images to create a frame of reference for certain objects. Common uses are marking and annotating catheters, probes, and other significant or unusual anatomic landmarks.

Opening steps

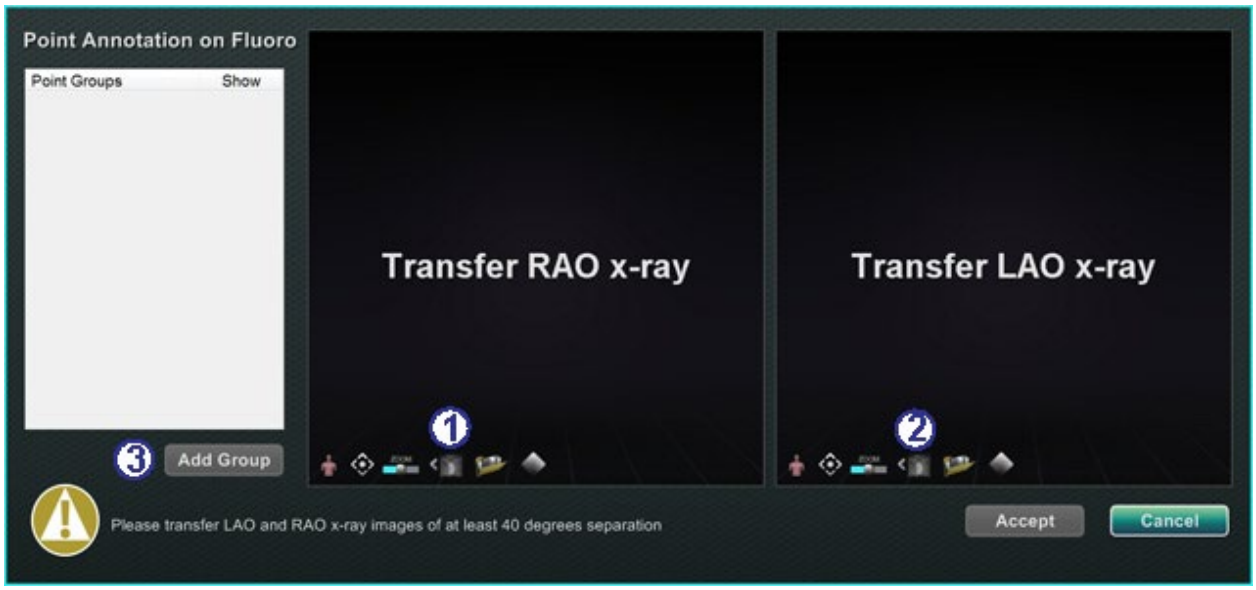


Figure 196. Point Annotation on Fluoro dialog

Point Annotation on Fluoro dialog guide (Figure 196)

After you open the dialog:

① Transfer an RAO image to Fluoro Image A.

② Transfer an LAO to Fluoro Image B.

Notes:

- The X-ray system images must be at least 40° of separation, as noted in the message area of the dialog.
- The fluoro icon flashes (between the current state and a negative of the image) as the fluoro image is being transferred.

③ Click **Add Group**.

Group properties

Right-click the group name (Group 1 in **Figure 197**) to open the Group property menu. On the property menu, you can:

- Rename the group
- Change the color
- Change the line type / thickness
- Delete the group

Rename point group

To rename the group, right-click on the group name and select **Rename** (**Figure 197**). A text editing field displays. Type a new group name.

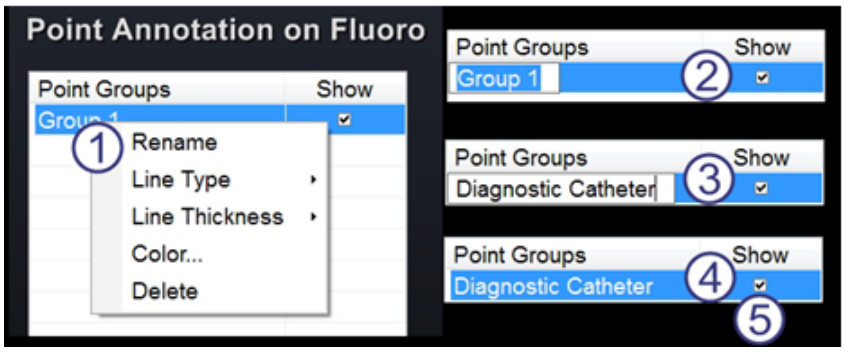


Figure 197. Rename point group

Rename point group guide (Figure 197)

To rename a group:

① Right-click on the group name and select **Rename**.

② The text editor displays in brackets.

③ Type the new name.

④ Click anywhere off of the text editor to close the editor and accept the change.

⑤ **Show:** A checkmark means the point group displays on the fluoro in the dialog; no checkmark means the group does not display.

Change line type of point group (Figure 198- Figure 201)

For purpose of illustration, before you start marking Fluoro A, change the Line Type to Open.

1. Right-click the group name.
2. Select **Line Type → Open**.

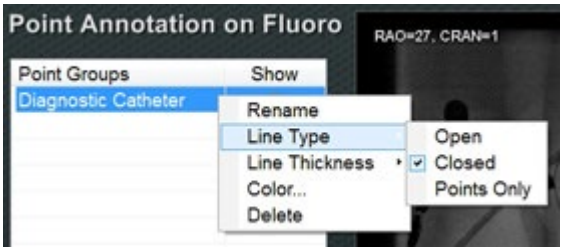


Figure 198.
Change Line Type (default is Closed)

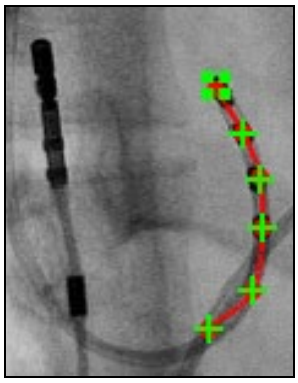


Figure 199.
Open line

Open line creates an open-ended line that connects the points you mark.

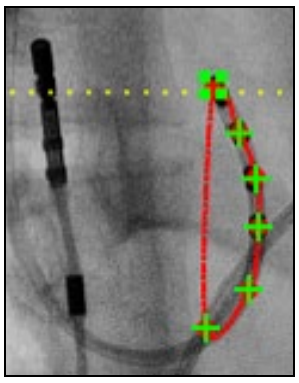


Figure 200.
Closed line

Closed creates a line that circles back to the beginning point and is useful when you mark LASSO® catheters.

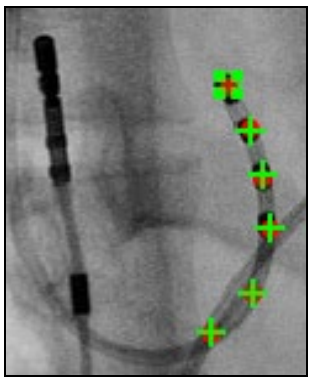


Figure 201.
Points Only

Points Only creates a series of points with no connecting line and is useful for marking significant points – not necessarily along a catheter.

Change line thickness of point group

Change line thickness of point group guide (Figure 202)

To change a group's color:

① Right-click on the group name and select **Line Thickness**. A list of thickness levels displays.

② Select a thickness, and then click **Accept**.

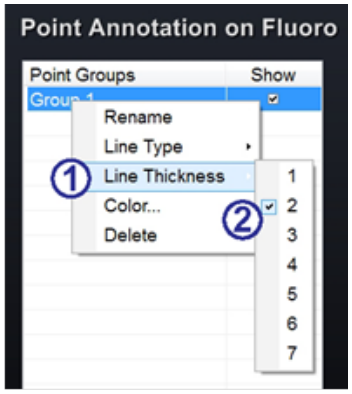


Figure 202. Change line thickness of point group

Change color of point group

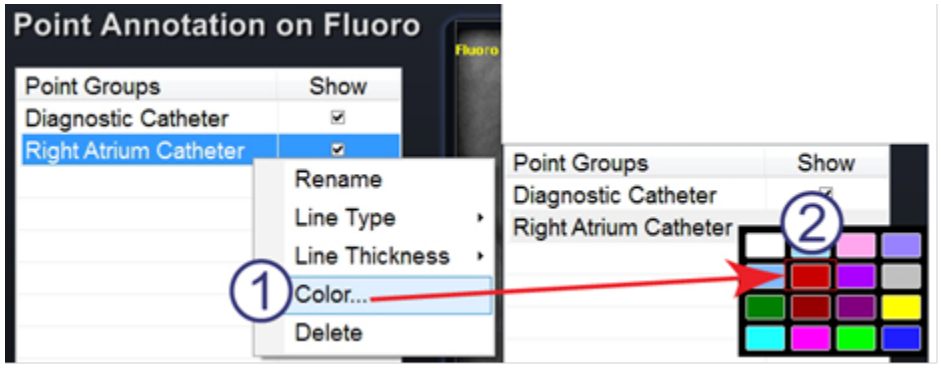


Figure 203. Change color of point group

Change color of point group guide (Figure 203)

To change a group's color:

① Right-click on the group name and select **Color**. A Windows color palette displays.

② Select a color, and then click **Accept**.

The color change feature is useful for visual distinction when you are creating more than one group (**Figure 204**).

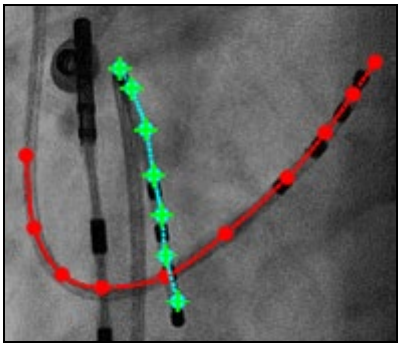


Figure 204. Point groups in two different colors

Delete point group

To delete a point group, right-click the group name and then select **Delete** (**Figure 205**).

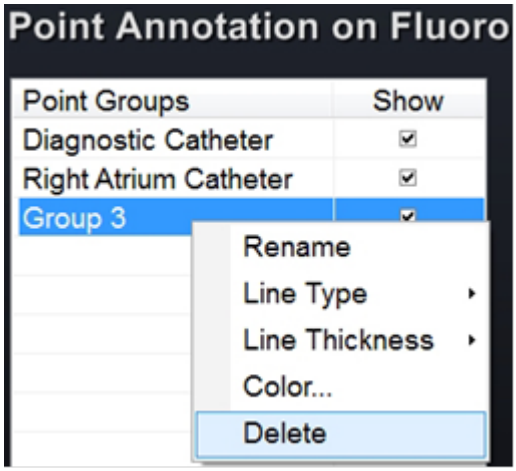


Figure 205.
Delete point group

Marking Fluoro A

Note: You can mark either Fluoro Image A or B first. In this example, Fluoro A is marked first.

Marking Fluoro A guide (Figure 206)

Mark the vessel starting at the proximal point and marking individual points until you reach the distal point:

① Proximal point

② Distal point

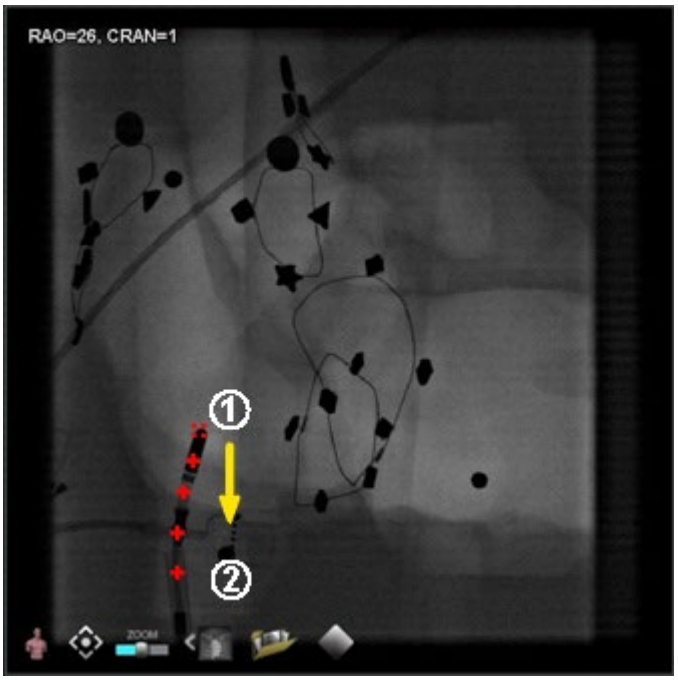


Figure 206.
Marking Fluoro Image A on *Navigant* screen

Marking Fluoro B

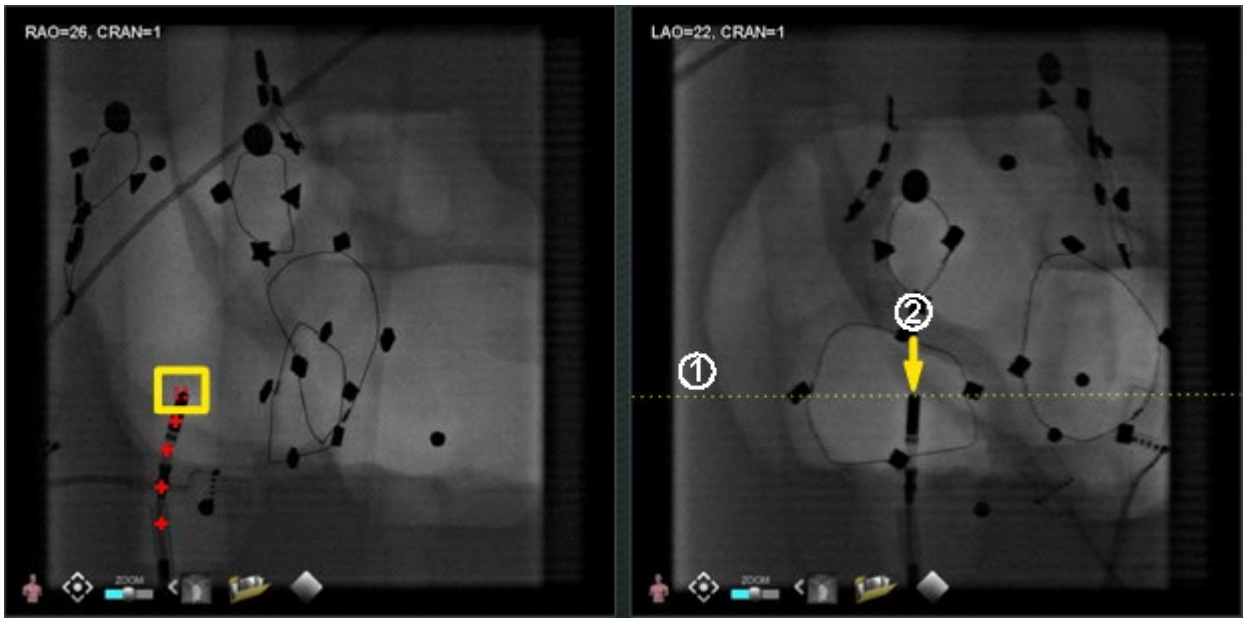


Figure 207. Marking Fluoro Image B on *Navigant* screen

Marking Fluoro B guide (Figure 207)

① When you move the cursor to Fluoro Image B, a yellow dotted line displays to guide you to the proximal point on Fluoro B (at the longitude of the proximal point you marked on Fluoro A).

② Mark the proximal point on Fluoro B at the intersection of the yellow line and the catheter. The marker turns green when it is in the correct location (**Figure 208**) (otherwise it is red).

As soon as you mark a point, the yellow line moves to the longitude for the next point.

Note: These steps assume the user has already marked Fluoro A.

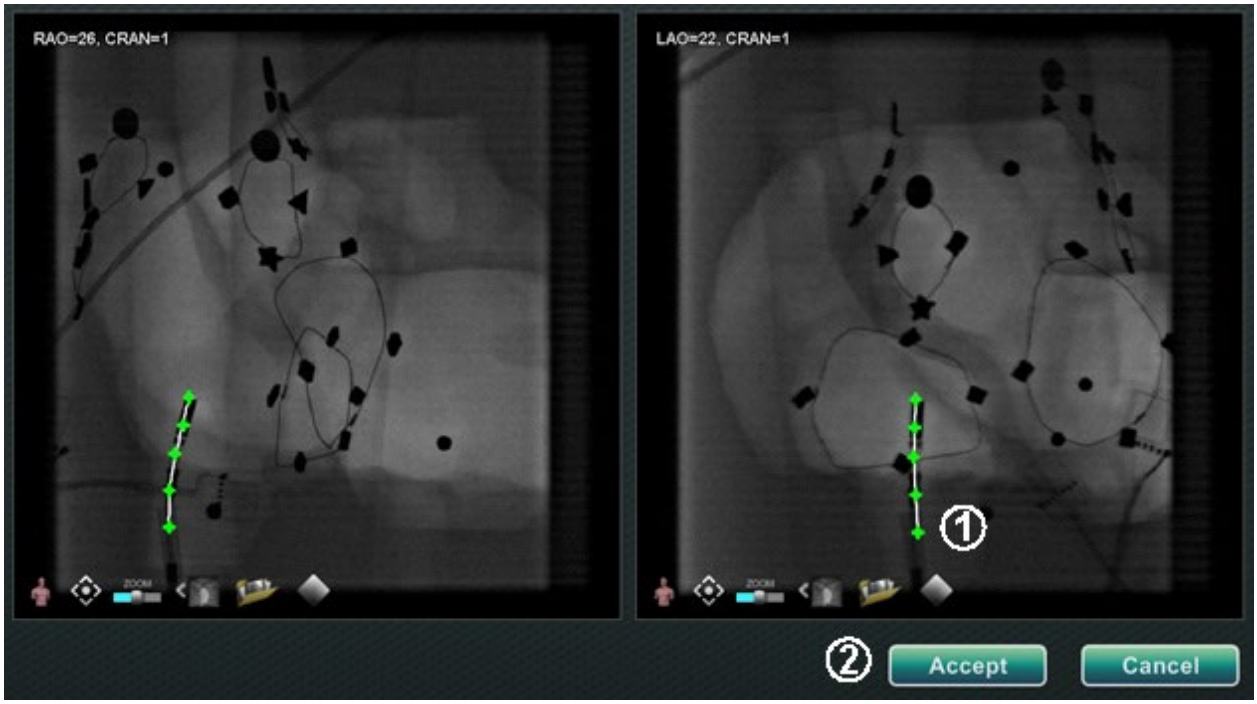


Figure 208. Fluoro annotation on *Navigant* screen – Fluoro images A and B

① Continue marking points as the epipolar line moves. Your objective is to match the points on Fluoro B with the points on Fluoro A. The points on Fluoro A turn green as you select corresponding points on B.

② When you have marked all points correctly, the **Accept** button turns green (**Figure 208**). Click **Accept** to display the vessel(s) in the Fluoro Images A and B windows.

Editing a point group

After creating a point group, the user can edit it by clicking the "Point Annotation on Fluoro" button (see the mouse cursor in **Figure 209**). Features such as line type, color, and thickness will become available.

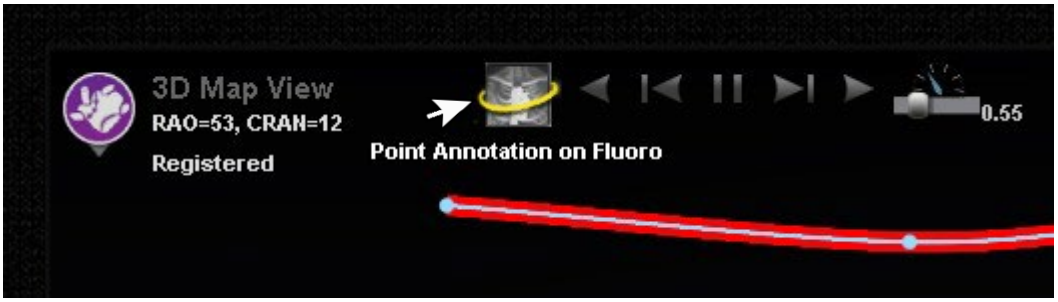


Figure 209. How to access editing features

Volumes dialog

With the Volumes dialog, you can import and register preoperative data sets.

Import tab

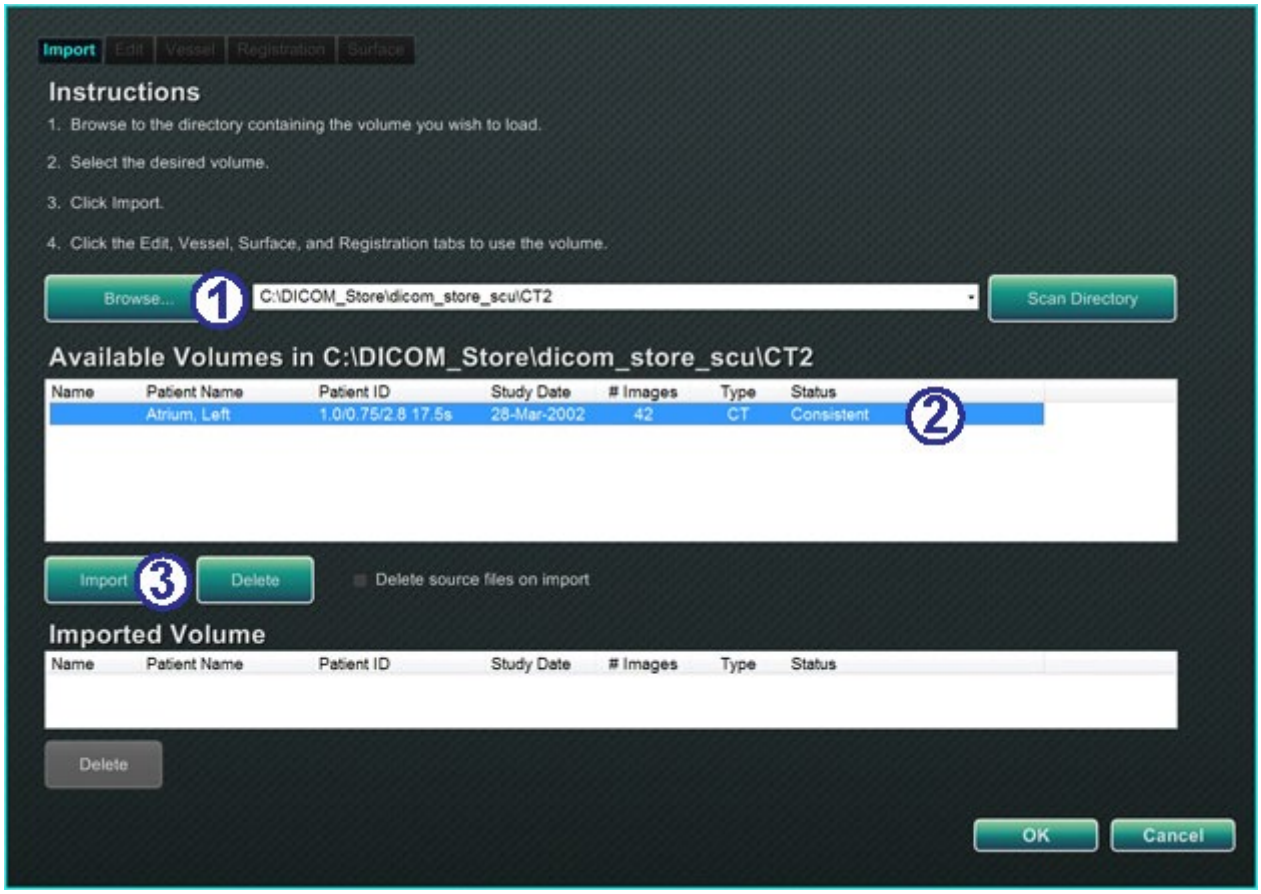


Figure 210. Import tab – Import patient information

Import tab guide (Figure 210)

① Click **Browse** to find an image on portable drive or CD or click **Scan Directory**.

② Select a record listed in the Available Volumes section.

③ Click **Import**.

The Confirm Differing Patient Information dialog displays (**Figure 211**). Click **Accept** to confirm, or click **Cancel** to close.

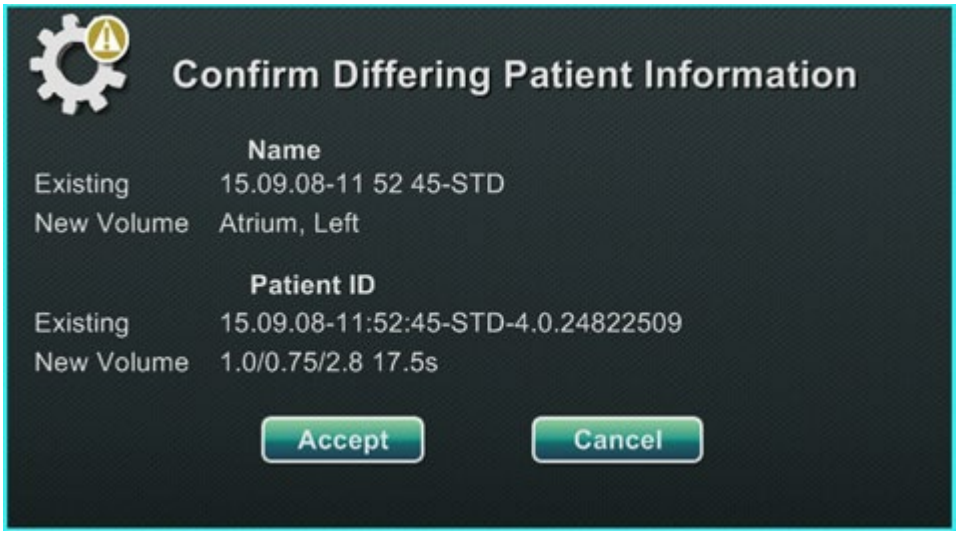


Figure 211. Volumes dialog – Confirm Differing Patient Information dialog

If you click **Accept**, the Importing progress bar displays (**Figure 212**).

Figure 212. Volumes dialog – Importing progress bar

The Data Set Attributes dialog displays with detailed attributes. Click **OK** to close it.

Edit tab

On the Edit tab you can manipulate the data set's graphic display using standard transfer function attributes.

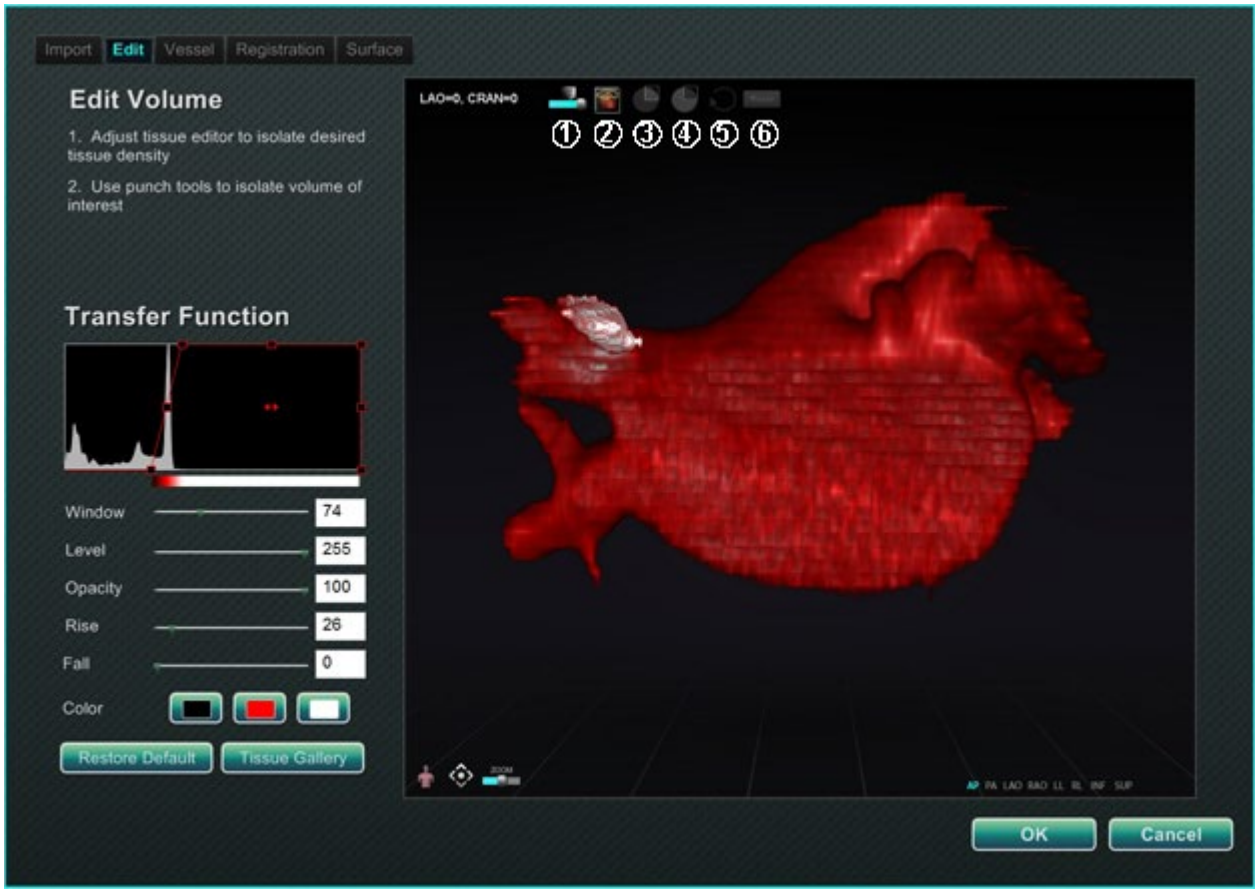


Figure 213. Edit tab

Edit tab guide (Figure 213)

The bottom three buttons (Window controls) on the screen are standard for most windows. The top six, however, are unique to the Volumes Edit tab:

① Opacity

② Punch tool

③ Keep the data inside the punch tool selection range—available (green and black) only when data is selected

④ Keep the data outside the punch tool selection range—available (green and black) only when data is selected

⑤ Undo last step

⑥ Reset

Vessel tab

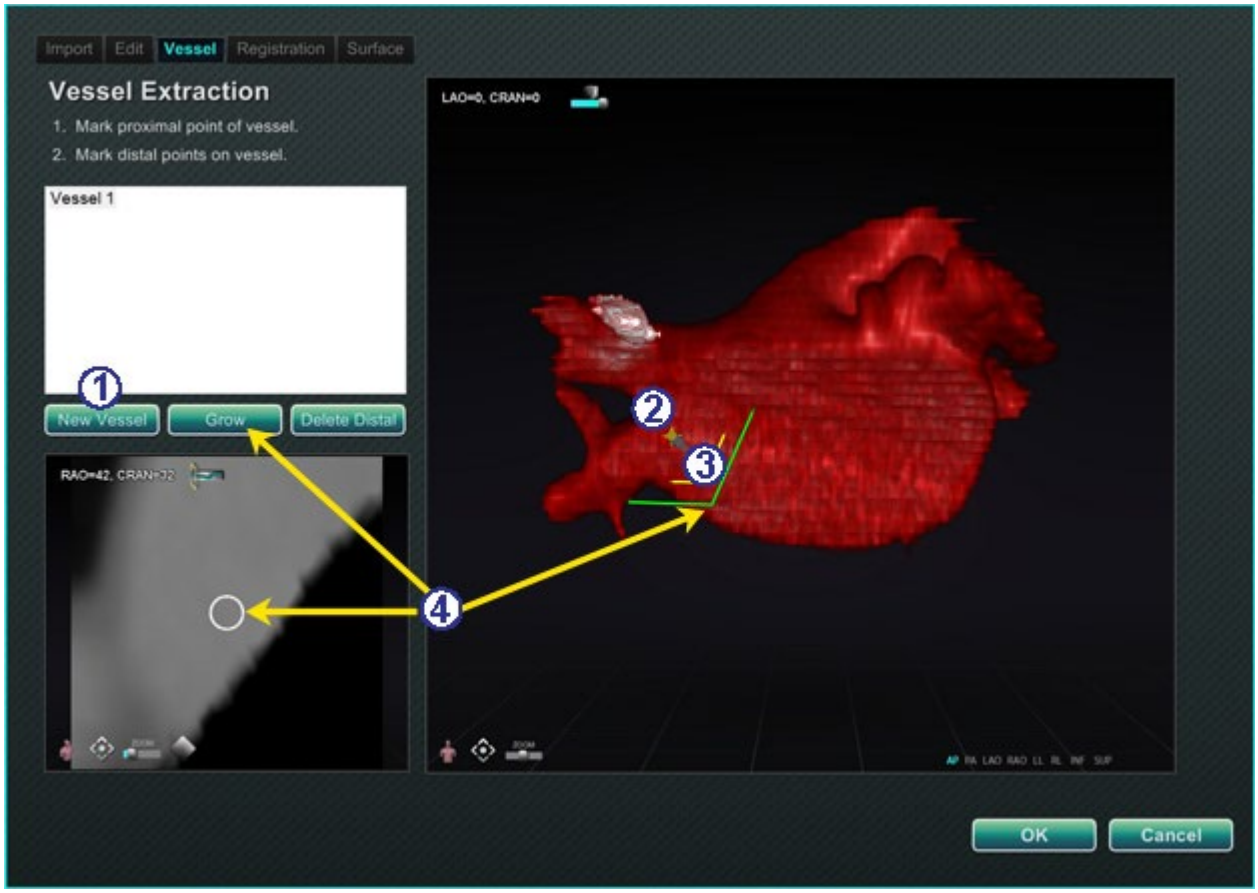


Figure 214. Vessel tab – Vessel Extraction and MPR slice

Vessel tab guide (Figure 214)

With Volumes Vessel Extraction, you can extract a vessel from the data set. You also can create a multi-planar reconstruction (MPR) view (slice).

① Click **New Vessel**.

② Mark the vessel's proximal point.

③ Mark the vessel's distal point. If you get the message: "Vessel not found. Add marked distal point?" you can click **OK**. If that solution is not satisfactory, you can mark points extending from the proximal point until you reach the distal point.

④ The **Grow** button displays the MPR slice at the distal point.

Registration tab

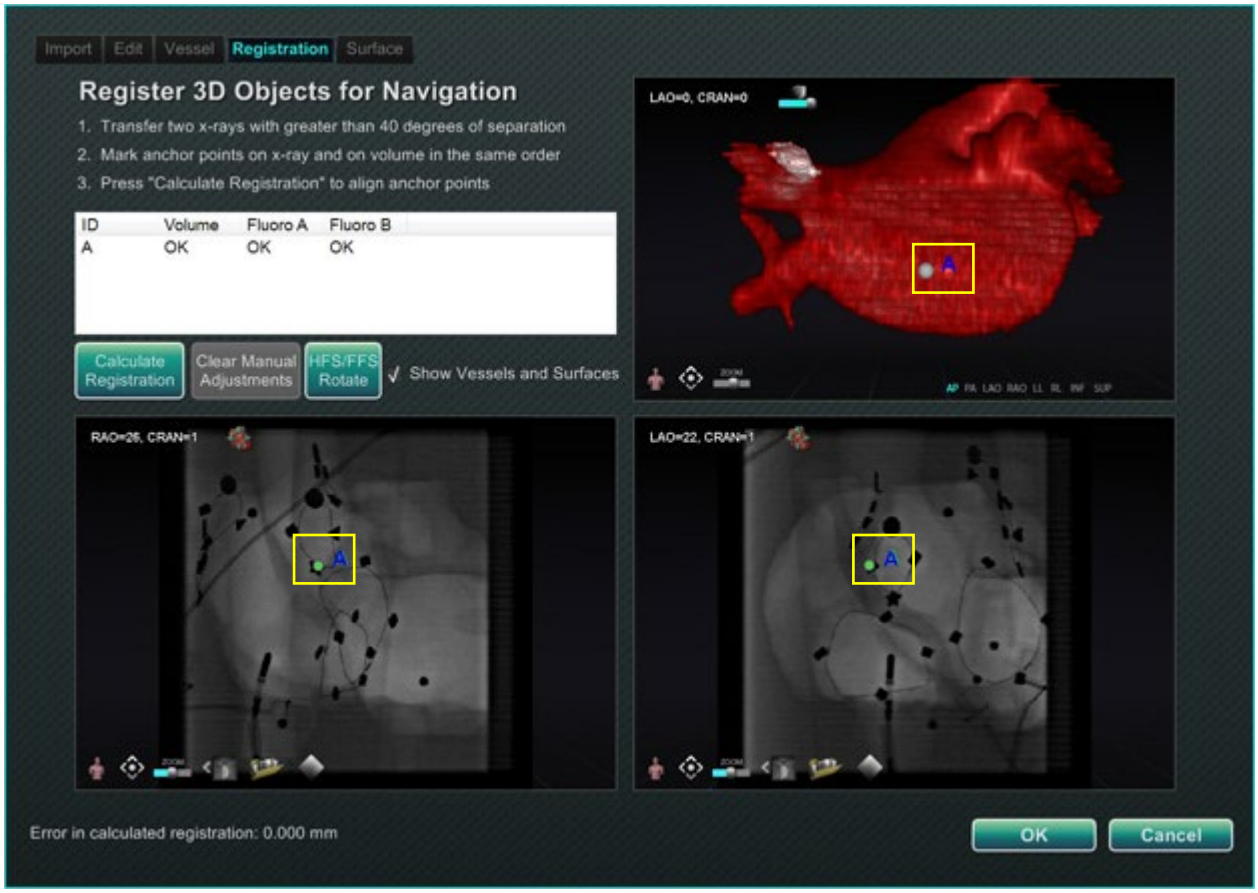


Figure 215. Registration tab

With the Volumes Registration tab, you can register 3D objects by selecting corollary points (see the yellow rectangles in **Figure 215**) on the volume and on the two Fluoro images. Select "Calculate Registration" to align anchor points before selecting **OK** and accepting changes.

Surface tab

When you click **Extract Surface** on the Surface tab, the **Calculating isosurface…** progress bar displays (**Figure 216**):

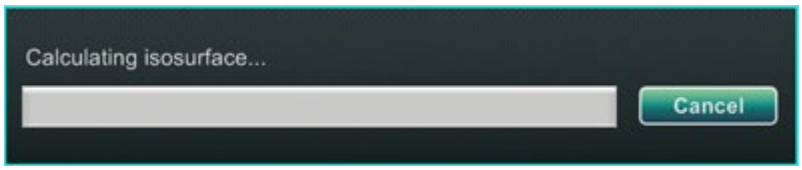


Figure 216. Surface tab – Calculating isosurface progress bar

Extract Surface displays a surface rendering (**Figure 217**):

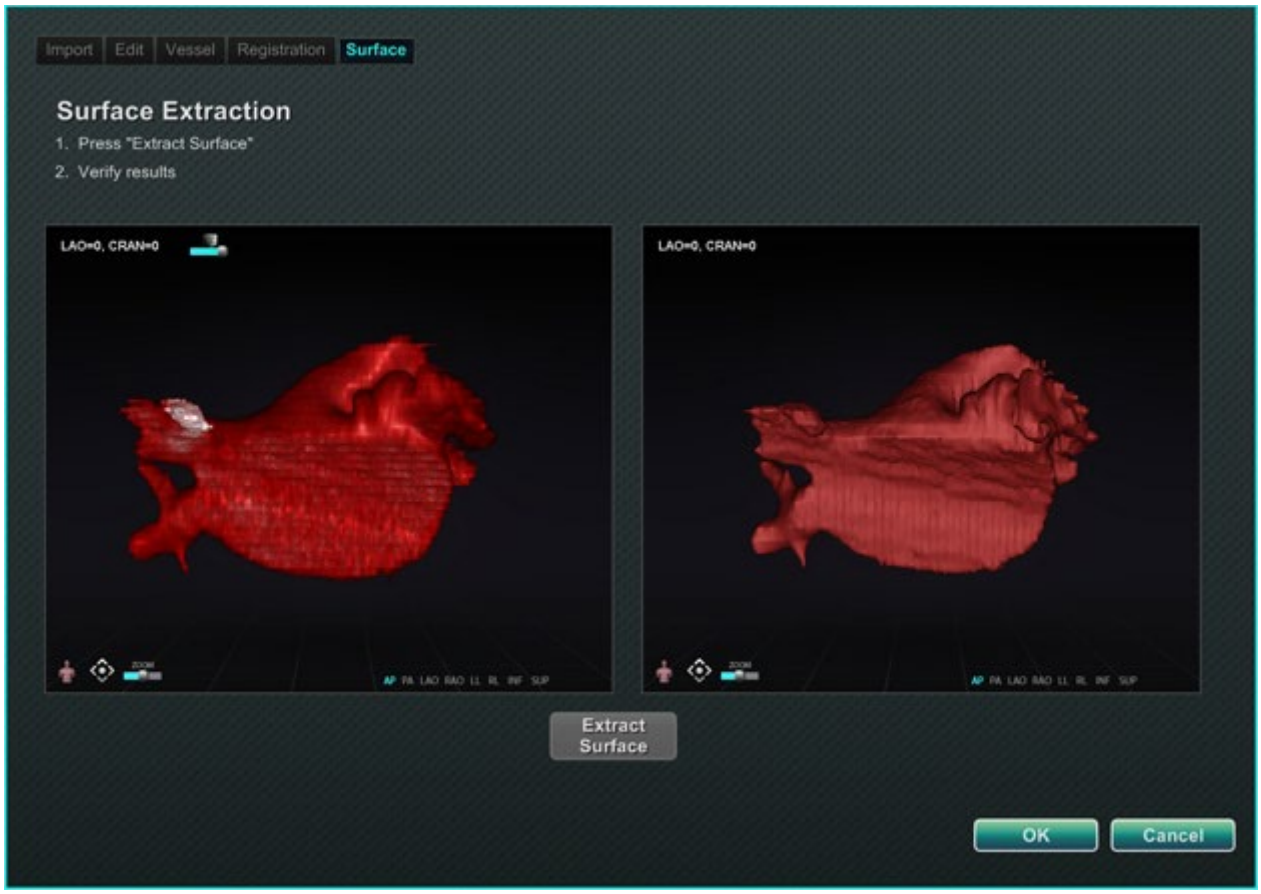


Figure 217. Surface tab – Surface Extraction

After following Steps 1 and 2 on the screen, click **OK** to transfer the images to the *Navigant* system's main windows **(Figure 218** and **Figure 219**).

Volumes transferred to main window

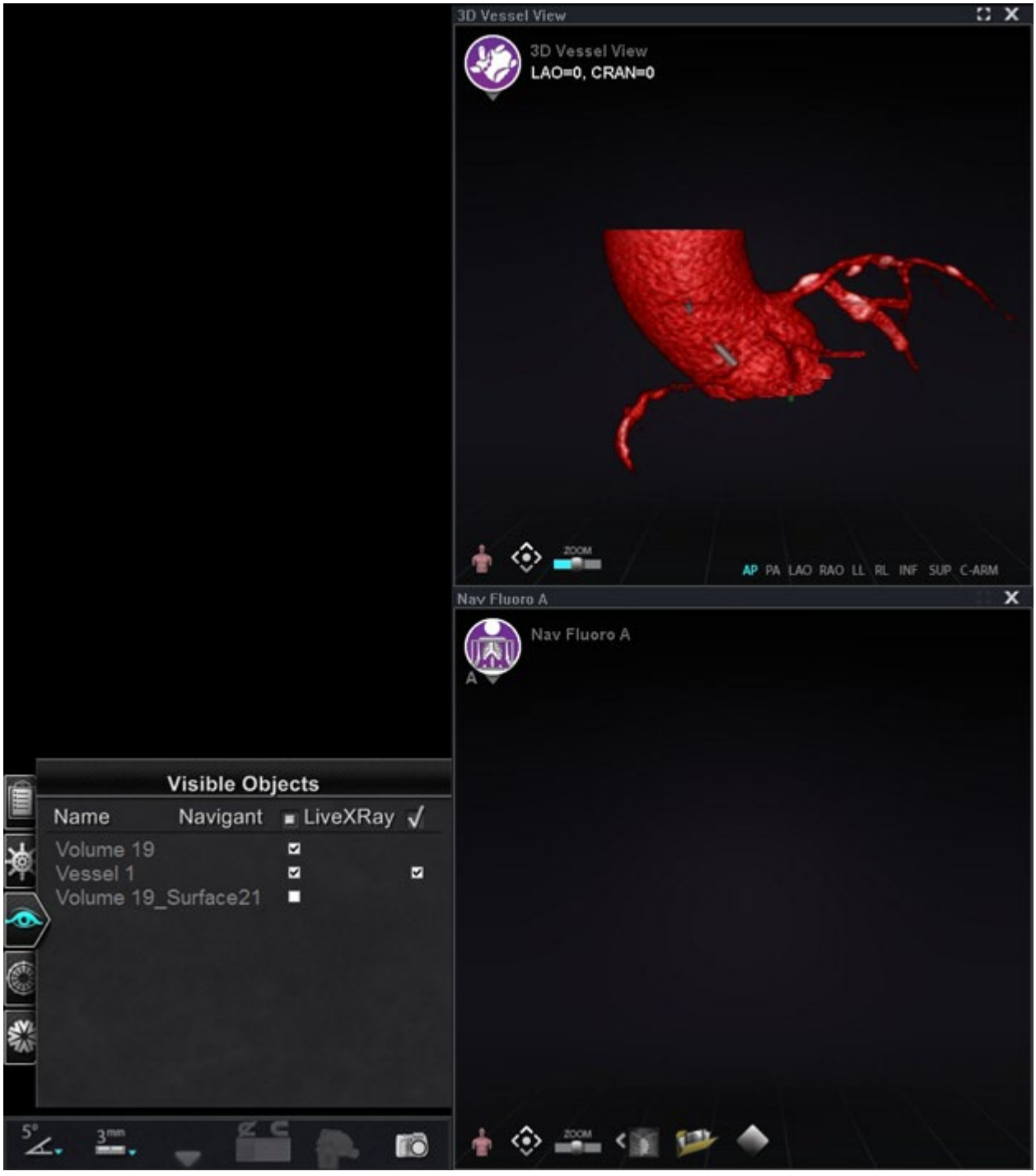


Figure 218. Volume imported into 3D vessel navigation window

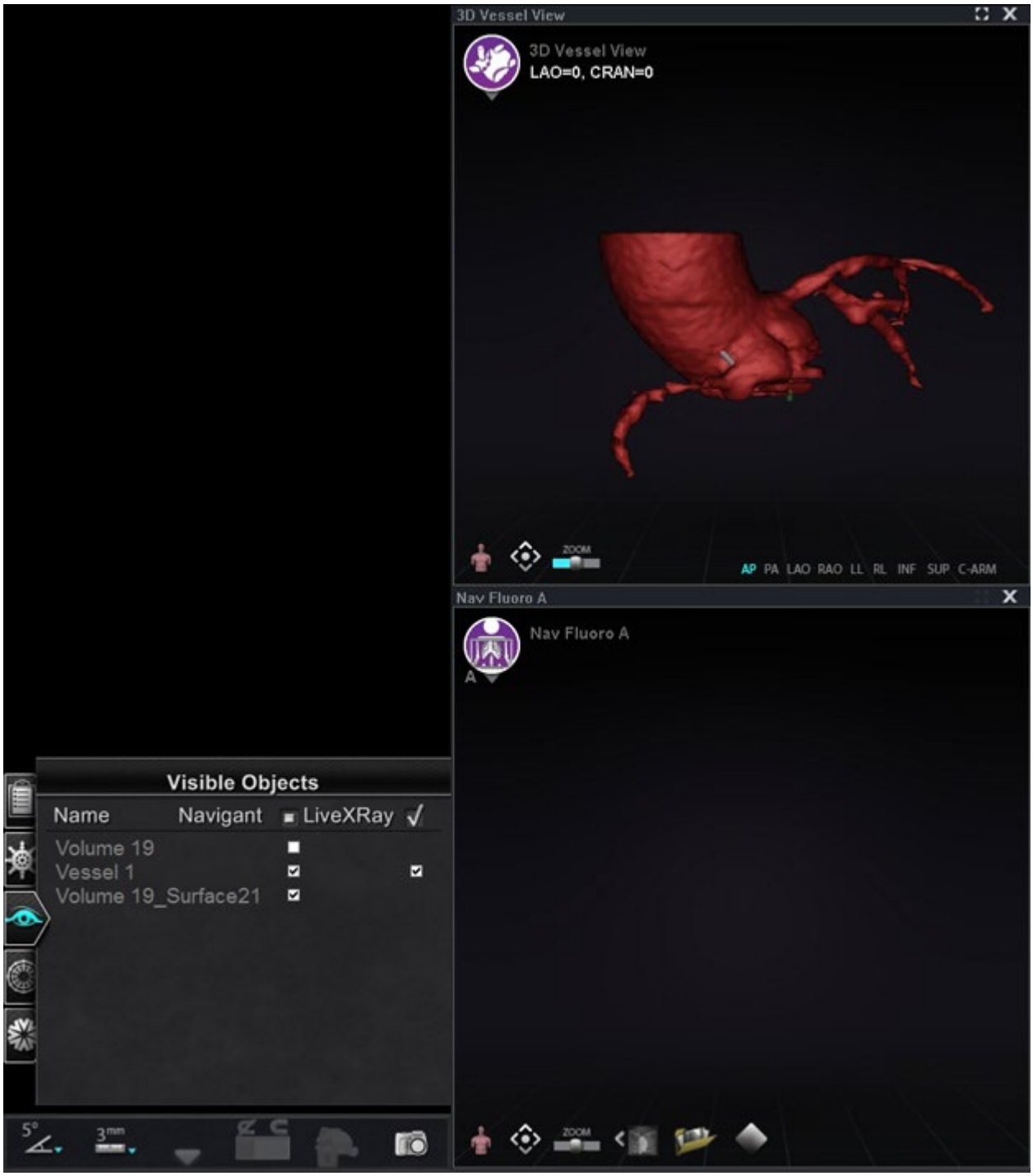


Figure 219. Volume surface imported into 3D vessel navigation window (note checkmark on Visible Objects panel)

NaviView3 dialog

To create a new vessel, access the *NaviView3* dialog from the system options button on the hardware status indicator toolbar. To edit an existing vessel, double-click a vessel name in the Visible Objects dialog *or* right-click and select **Edit Geometry,** if the vessel was created in the *NaviView3* dialog.

Note: When you open a vessel from the Visible Objects dialog, you may notice your original points have changed. When you closed the *NaviView3* dialog, the *Navigant* system used the points to create a 3D reconstruction and discarded the 2D points you created. When you reopened the dialog, the *Navigant* system recreated the 2D points based on the 3D image and spaced points evenly. Additionally, vessels may be created in the Volume Marking guidance dialog. The vessel opens in the guidance dialog where it was created.

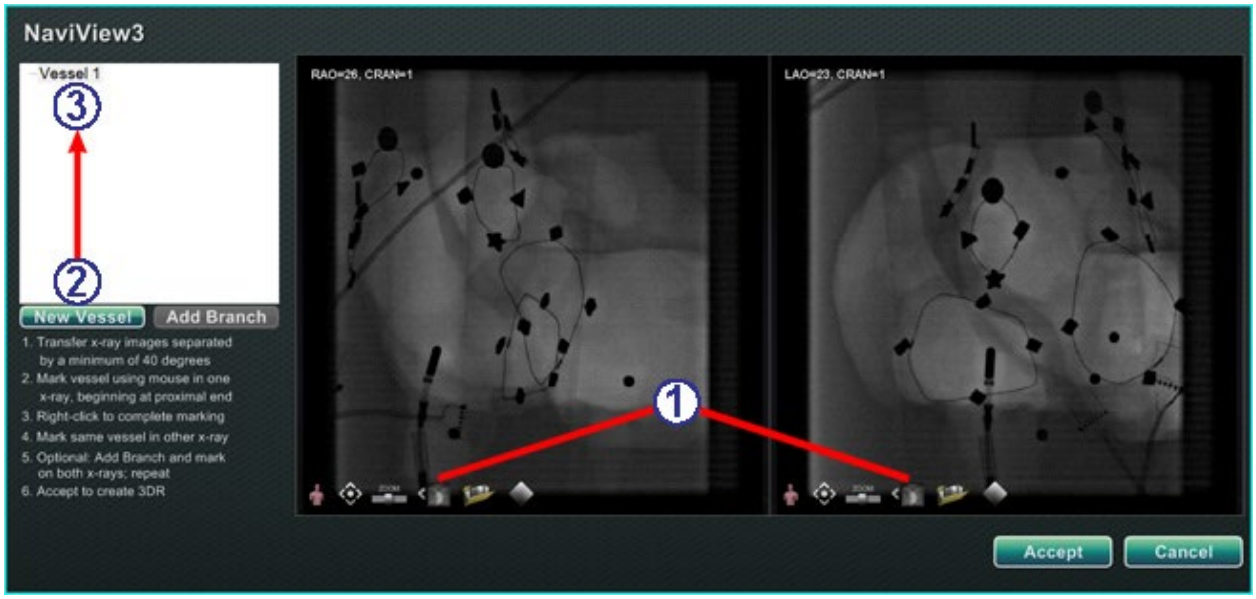


Figure 220. Transfer image and New Vessel button

Transfer images and New Vessel guide (Figure 220)

① **Transfer image button** – Transfer two images (Fluoro A and B) into the Fluoro windows by clicking the transfer button for each window. The images must be at least 40 degrees apart.

② **New Vessel button** – Click **New Vessel** before you start marking points.

③ **New Vessel** populates the vessel list with the first vessel name, Vessel 1.

Notes:

- For a description of other buttons on the Fluoro windows, see Window controls.
- Click the **New Vessel** button before you start drawing the first vessel. "Vessel 1" will display in the dialog window. Subsequent vessels will overwrite "Vessel 1" if **New Vessel** is not clicked before starting subsequent vessel drawings.

Vessel Properties dialog

You can rename the vessel immediately by right-clicking the name, selecting **Properties**, and editing the name in the Vessel Properties dialog (**Figure 221**). You also can change vessel properties later in the procedure.

Create new vessel and change properties guide (Figure 221)

① Click the **New Vessel** button.

② The default vessel name, *Vessel #*, displays.

③ Right-click the vessel name to display the Vessel Properties dialog, where the following properties may be changed for 3D reconstruction:

- **Name.** The default name is *Vessel #*; however, you can change it to a more descriptive name.
- **Opacity.** Level of solid color: 100% is solid and 0% is clear.
- **Diameter.** The length of a straight line through the center of a vessel. The range is 0.1 to 12 millimeters. The drop-down menu displays integer choices. You can type decimal number in the field.

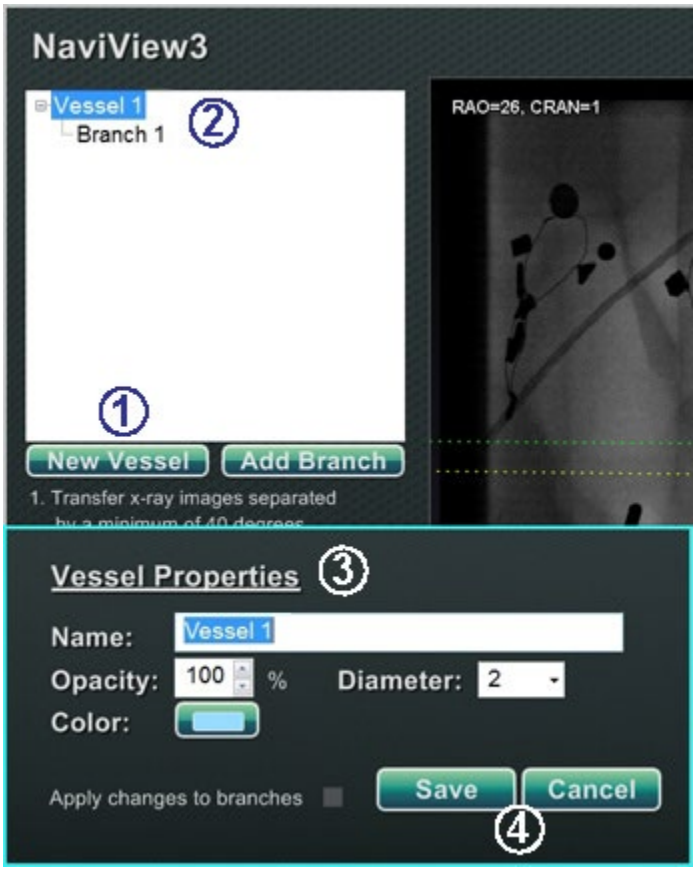


Figure 221. Vessel properties dialog

- **Color.** The color button displays the current selection. When you click the button, it displays a palette of 16 available colors. Every time you create a new vessel, a new color is applied but can be changed. Every branch associated with a vessel acquires the current color unless/until you change it.
- **Apply changes to branches.** If you select this checkbox, you make your selected properties the default for all distal branches.

④ Click **Save** or **Cancel**.

Vessel marking colors

The *NaviView3* dialog has three color schemes for vessel marking. (Do not confuse this with the color palette for 3D vessel reconstruction which is completely separate from this particular function.)

A vessel marking is a series of points connected by a curve. The user controls the location of the points and the curve is automatically calculated from those points. When you are drawing, the colors are yellow and red; when a trunk or branch is selected, the colors are white and yellow; when a trunk or branch is not selected, the colors are purple and green.

Marking mode	Point color	Curve color
Draw	Yellow	Red
Selected	White	Yellow
Unselected	Purple	Green

Epipolar line colors

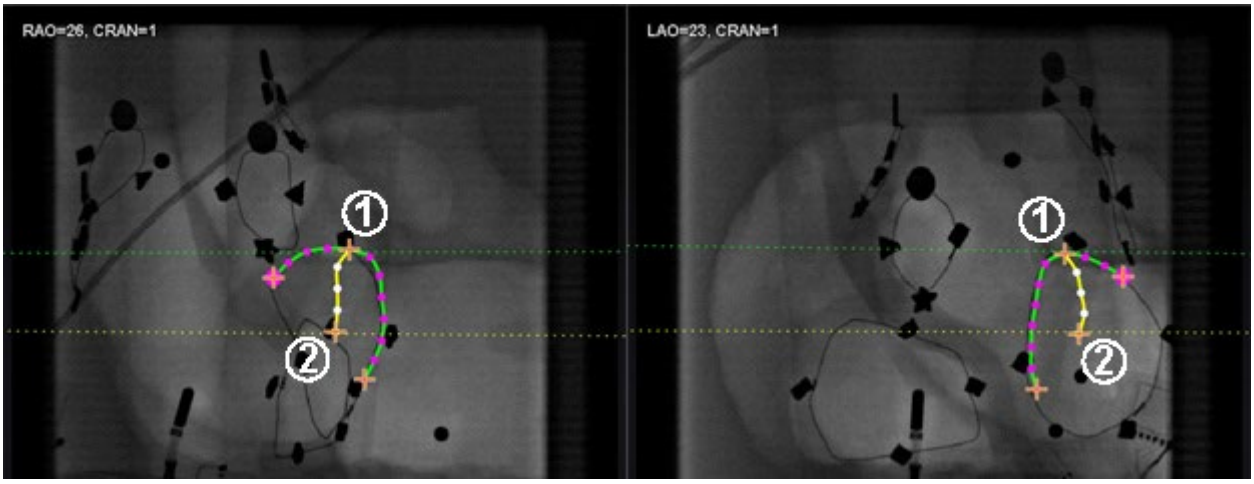


Figure 222. Dotted lines display in up to four colors in vessel marking. Epipolar lines coincide with specific points.

Epipolar line colors guide (Figure 222)

White is the default color for epipolar lines, which are based mainly on anchor points. However, under certain conditions, epipolar lines are green, yellow, or blue. **Blue** represents the projected position of a selected point on the opposite fluoro image—when selected, the point has a green circle behind it.

① **Green:** Proximal points.

② **Yellow:** Distal points: This is the final distal point for each vessel. It also tracks the distal point on the opposite image as you draw on the active image.

Drawing simple vessel marking

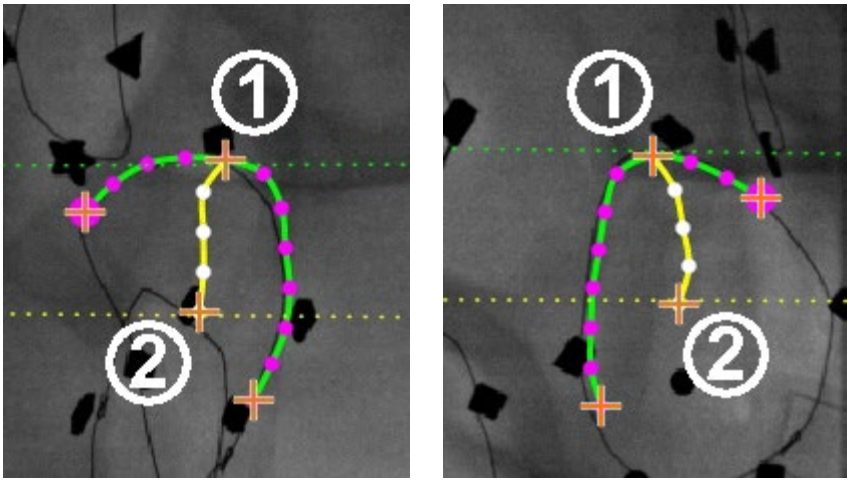


Figure 223. Simple vessel drawing – RAO *(left)* and LAO *(right)*

Drawing simple vessel marking guide (Figure 223)

Create a vessel by clicking each individual point or clicking and dragging the cursor to mark a continuous line with intermittent points. An orange cross indicates an anchor point. The start point is proximal; the endpoint is distal.

You can end the drawing two ways:

- Double-click to create the distal point at the cursor location.
- Right-click to make the last drawn point the distal point.

① The green dotted line indicates the epipolar line of the proximal point. In **Figure 223**, the proximal anchor point has a solid circle behind the orange cross.

② The yellow dotted line indicates the epipolar line of the distal point.

Notes:

Because the fluoros are not necessarily acquired at the same instant, the mathematical projection of the epipolar line may not line up exactly with the fluoro features.

The alignment of anchor points across the two fluoro images depends on the judgment of the physician. Strive to match features in the two fluoro images. Having a small offset between a start—or end—point in one fluoro and the epipolar line of its corresponding point is acceptable. A large offset is not acceptable.

Selected point

The selected point in the *NaviView3* dialog is indicated in two ways:

- **Green circle:** Surrounds point you have clicked and displays only in selected fluoro image.
- **Blue dotted line:** Indicates position of selected point on opposite fluoro image.

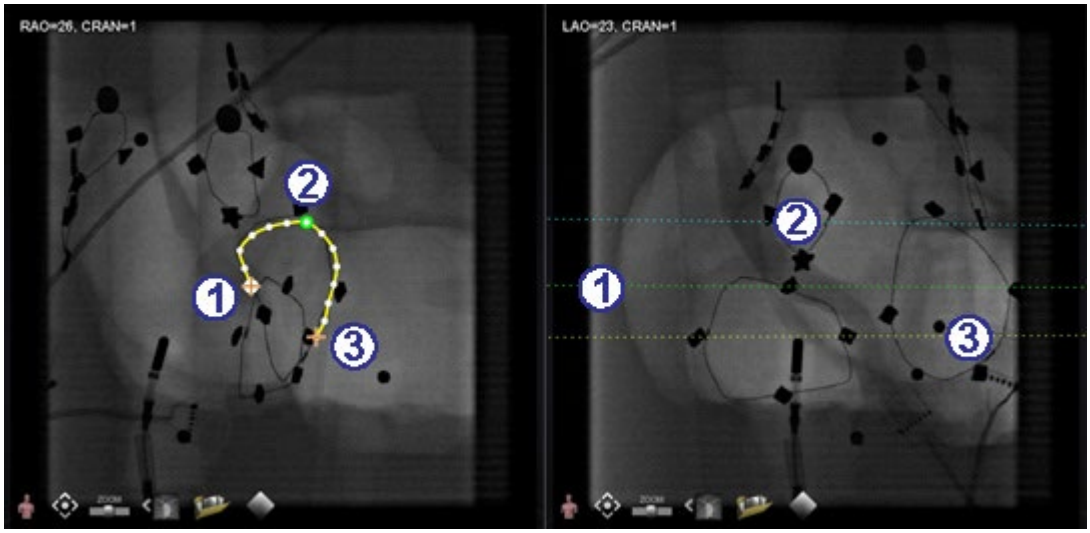


Figure 224. Proximal, selected, and distal points

Selected point guide (Figure 224)

① Proximal anchor point

② Selected point

③ Distal anchor point

Note: To cancel the selection, click somewhere else on the image.

Distal point in progress

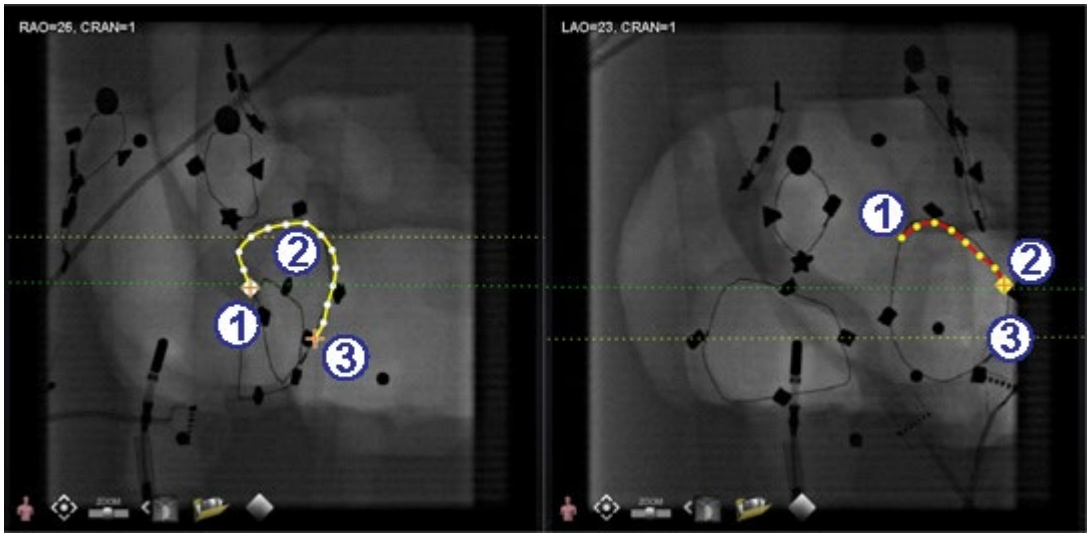


Figure 225. On complementary image, last point drawn is distal point

Distal point in progress guide (Figure 225)

As you mark a vessel on a complementary fluoro (as on the LAO fluoro in **Figure 225**), your last point drawn is the distal point. The yellow dotted line in the original fluoro (RAO in **Figure 225**) indicates the distal point of the complementary fluoro.

① Proximal anchor point

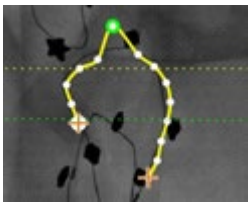
② Distal point of the active drawing (LAO in **Figure 225**)

③ Distal anchor point of the original drawing (RAO in **Figure 225**)

Moving points

Click and drag a single point to move it (**Figure 226**). A green circle indicates a selected point.

Figure 226. Click and drag single point to move it



Accepting simple drawing

A simple drawing is one that has only two anchor points on each of the two fluoro images (**Figure 227**).

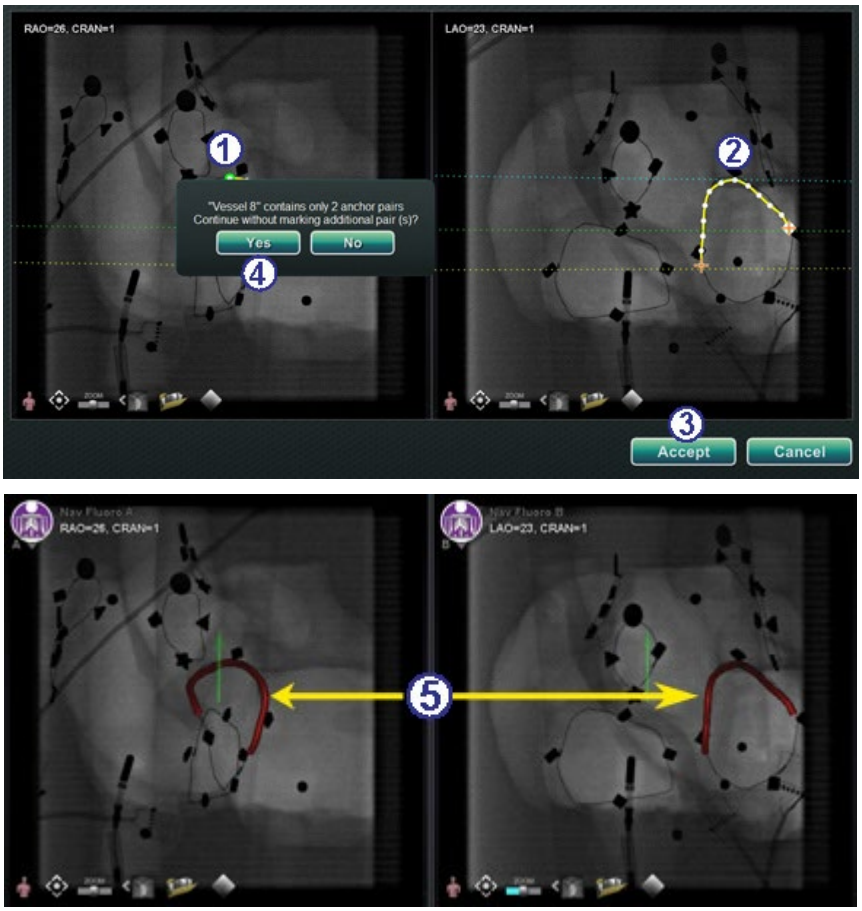


Figure 227. Creating simple vessel

Create simple drawing guide (Figure 227)

You can create a simple vessel with these steps:

① Mark a vessel in one Fluoro window.

② Mark a matching vessel in the other Fluoro window, matching distal and proximal points along the green and yellow epipolar lines.

③ Click **Accept**.

④ Click **Yes** in the query dialog: "{Vessel #} contains only 2 anchor pairs. Continue without marking additional pair(s)?" (If you wanted a more precise drawing, you would click **No** and add more anchor points. See Convert to anchor point.

⑤ A simple three-dimensional vessel displays on Fluoro A and B on the main screen.

Vessel point menu

Right-click a point to view the point menu (**Figure 228.** and **Figure 229.**). The menu varies depending on whether the point is an anchor. The difference is with the last menu item: **Convert to anchor point** vs. *no option* for converting to a non-anchor point.

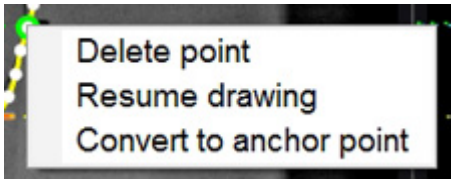


Figure 228. Vessel point properties menu for point

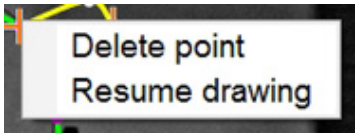


Figure 229. Vessel point properties menu for anchor point

Delete point

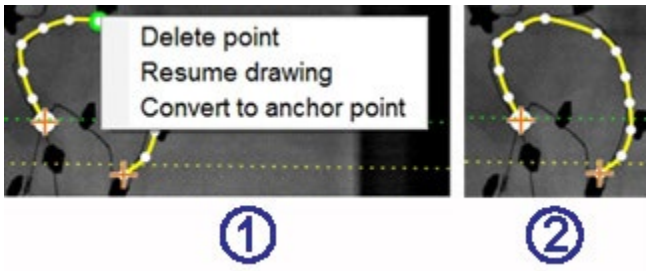


Figure 230. Delete point option

Delete point guide (Figure 230)

① To delete a point, right-click on the point and select **Delete point** (**Figure 230.**). You will not get a confirmation dialog and you cannot restore that exact point.

② The point is gone. (Click to add a new point.)

Notes:

You cannot delete a proximal point. Delete point will not display as a menu option

when you have selected a proximal point. If you delete a point that is also the starting point for a branch, the branch will also be deleted.

Resume drawing

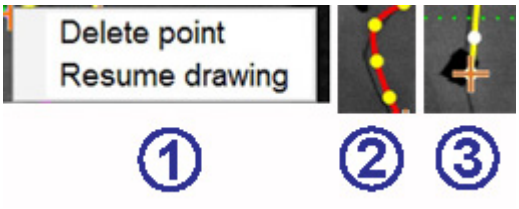


Figure 231. Resume drawing option

Resume drawing guide (Figure 231)

① To extend a line, right-click any point on the line and select **Resume drawing**.

② A red, unanchored line extension displays. You can drag the tip anywhere on the fluoro to position it.

③ Click to set the next point. You can continue to add points with single clicks, or you can click and drag the cursor to add a series of points. Double-click to create the distal point at the cursor location (or right-click to make the last drawn point the distal point).

Convert to anchor point

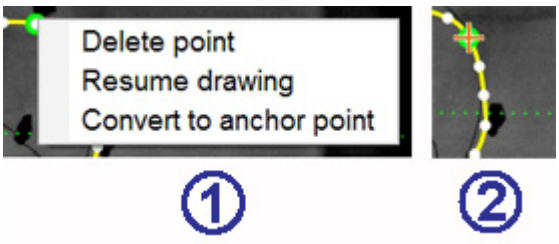


Figure 232. Convert to anchor point option

Convert non-anchor point to anchor point guide (Figure 232)

You may want to add anchor points to a vessel tree to make the 3D reconstruction more accurate.

① To convert a point to an anchor point, right-click and select **Convert to anchor point**.

② The new anchor point displays in addition to any existing anchor points.

Note: You must have matching anchor points on both images for 3D reconstruction. If you convert a point to an anchor on one image, you must match it on the other.

Add branches

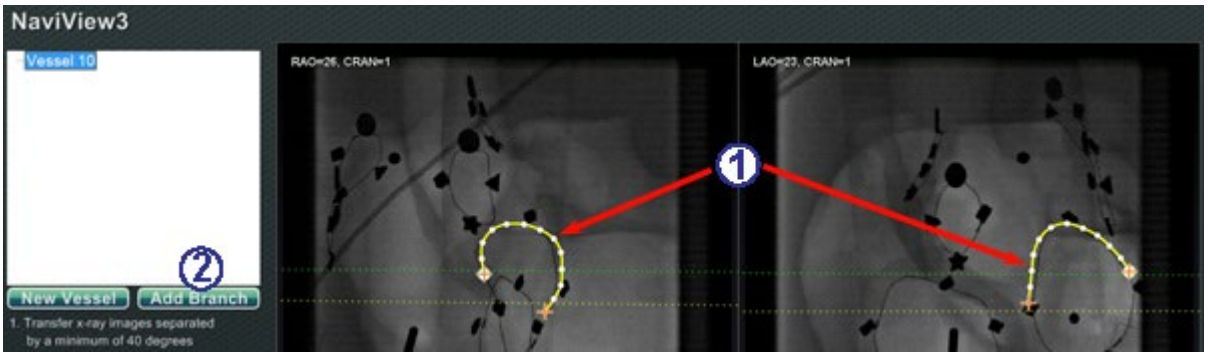


Figure 233. Adding branches – Start with matching trunks

Add branches guide (Figure 233– Figure 237)

Step 1 (Figure 233)

① To add branches, you have to start with a pair of complementary trunks.

② Click **Add Branch**.

Step 2 (Figure 234 and Figure 235)

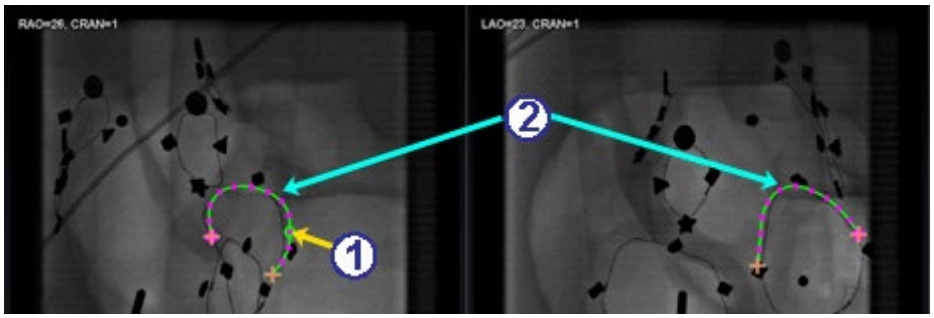


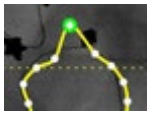
Figure 234. Select branching point on one trunk

① Select the point on the trunk where you want to start the trunk (**Figure 234**). The point can be existing or somewhere on the curve. If it's on the curve, a new point is created. The selected point is indicated by a green circle.

Notes: If you start on the curve and you change your mind about the starting point, right-click, and the point disappears. This is only true when you start a branch or trunk. If you start on an existing point, simply right-click elsewhere to deselect that point.

If you select a point and start to draw before clicking **Add Branch**, simply drag the point back, click **Add Branch**, and try again (**Figure 235**).

Figure 235. Starting to draw branch before clicking Add Branch



② Notice the trunks are now in the unselected mode, as evident by the green and purple (magenta) colors. The focus has changed to the branch you are about to draw.

Step 3 (Figure 236 and Figure 237)

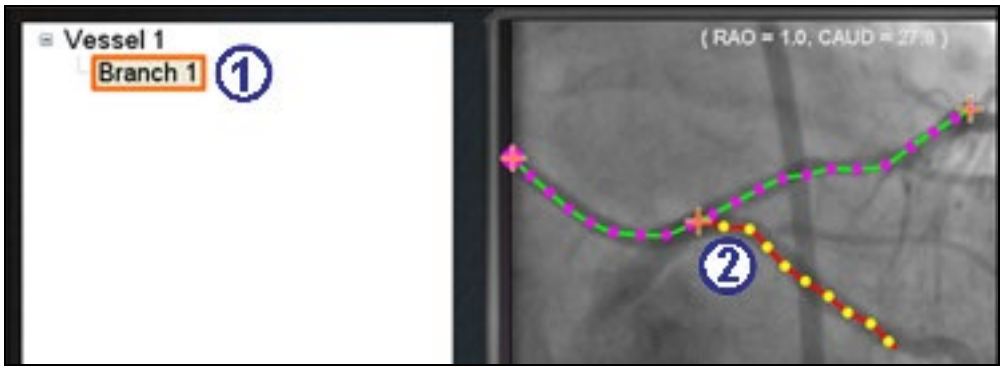


Figure 236. Branch name displays as soon as you select branching point

① A default branch name {Branch #} displays in the directory window as soon as you click a starting point (**Figure 236**). (You can rename it the same way you rename trunks.)

② Notice the branch you are drawing is in the drawing mode (red and yellow).

If you start on the curve and change your mind about the starting point, right-click, and the point disappears. This is only true when you start a branch or trunk. If you start on an existing point, simply right-click elsewhere to deselect that point.

Note: When you complete the drawing by double-clicking the distal point, the branch displays in the selected mode (yellow and white) (**Figure 237**).

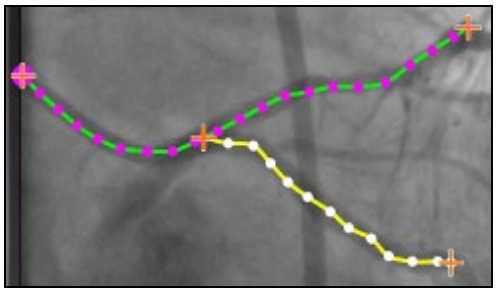


Figure 237. Completed branch displays in selected mode

Step 4 (Figure 238)

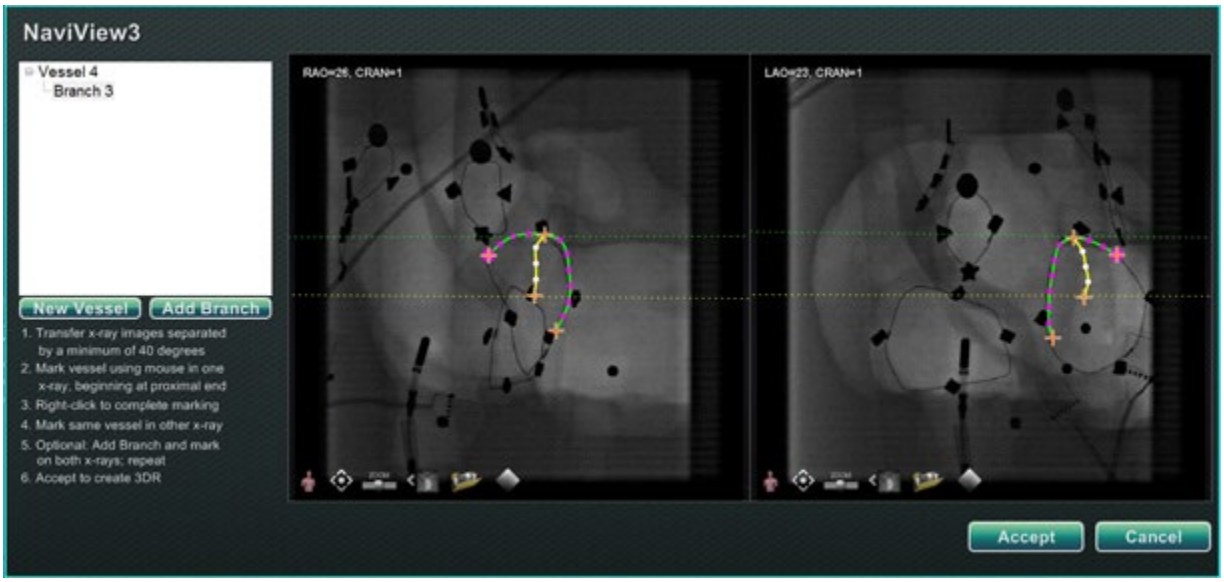


Figure 238. Draw complementary branch and click **Accept**

① Draw and complete the complementary branch.

② Click **Accept**.

Note: You must have matching branches on both images for 3D reconstruction. If you add a branch on one image, you must match it on the other.

Add more branches

Following the process outlined above, you can create more branches off existing branches and trunks (**Figure 239**). You can create as many vessels and branches as you want.

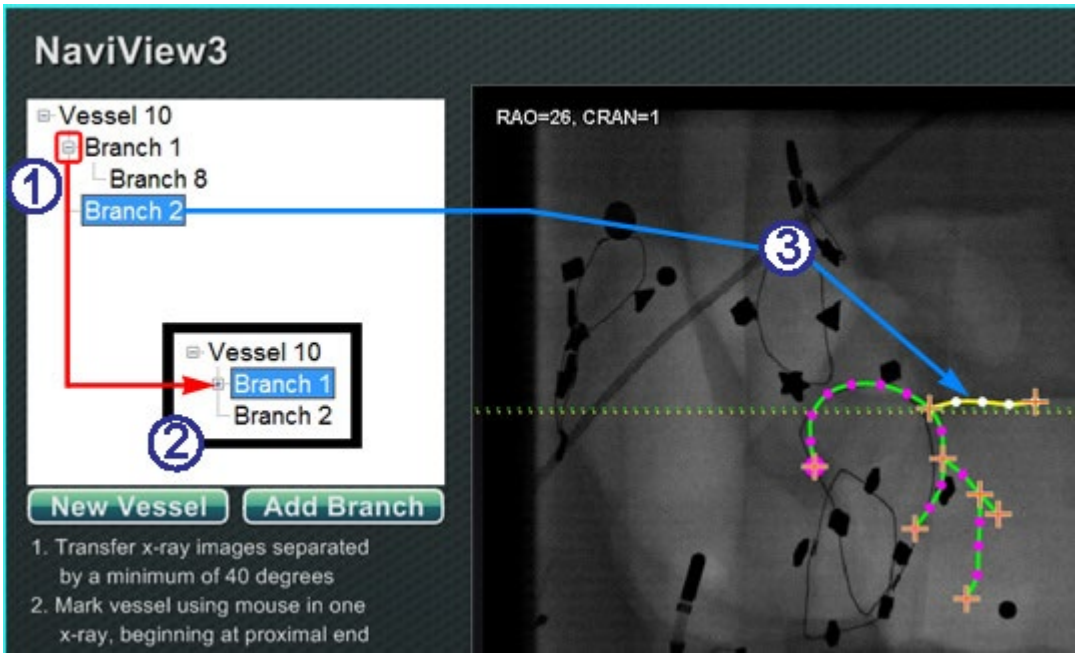


Figure 239. Directory tree tracks vessels and branches

Add more branches guide (Figure 239)

① As you add vessels and branches, the directory tree grows. The indentation of each branch name indicates the branch level. So, a branch name indented twice is the branch of a branch.

② You can expand and collapse the vessel and branch names as branches are added beneath them. For example, you can collapse Vessel 1 in **Figure 239** by clicking the minus (–) sign. Only the name Vessel 1 will display. You also can collapse Branch 1. You can expand either group by clicking the plus (+) sign.

③ Click a vessel or branch name to select that vessel or branch. The name is highlighted with a bright blue rectangle, and the drawing is highlighted in the selected mode colors: yellow and white.

Numbering vessels and branches

Following are some of the rules related to numbering vessels and branches:

- The vessels number consecutively and the branches number consecutively (**Figure 240**).
- Deleted vessels and branches maintain their numbers so, for example, if you draw five branches and delete Branch 5, the next branch you draw will be Branch 6.
- The numbering is only consecutive and does not relate to placement. So, for example, if you draw three branches (Branch 1, 2, and 3) off Vessel 1; two branches (Branch 4 and 5) off Vessel 2; and then return to Vessel 1 to draw another branch, the new branch will be Branch 6.

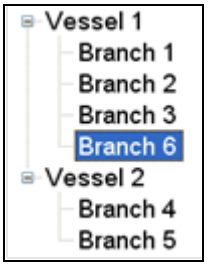


Figure 240. Numbering is consecutive, no matter where you place next vessel or branch

- If you start a new procedure, and you have not restarted the *Navigant* system, the vessel and branch numbering will continue from the previous procedure. So, you might find yourself creating a new vessel called Vessel 146 and adding a branch off 146 called Branch 78.
- By right-clicking the vessel or branch name and selecting Properties, you can edit the name in the name field.
- When the directory tree window reaches capacity, scrollbars display (**Figure 241**).

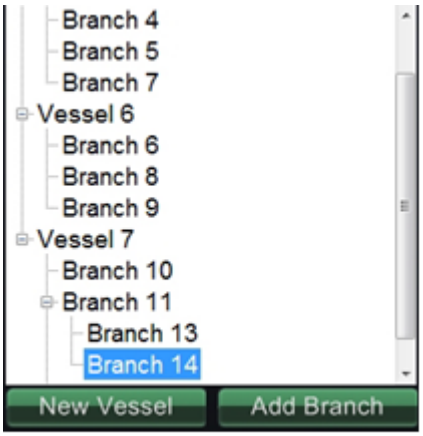


Figure 241. Scrollbars display when necessary to view more vessels and branches

ClockDial Navigation

For Electrophysiology studies, ClockDial Navigation views include:

- **AP** — Anterior-Posterior
- **INF** — Inferior
- **LL** — Left Lateral

For Interventional Cardiology studies, ClockDial Navigation views include:

- **AP** — Anterior-Posterior
- **INF** — Inferior
- **LL** — Left Lateral
- **C-ARM** — Synch to C-Arm (Live Fluoro View)

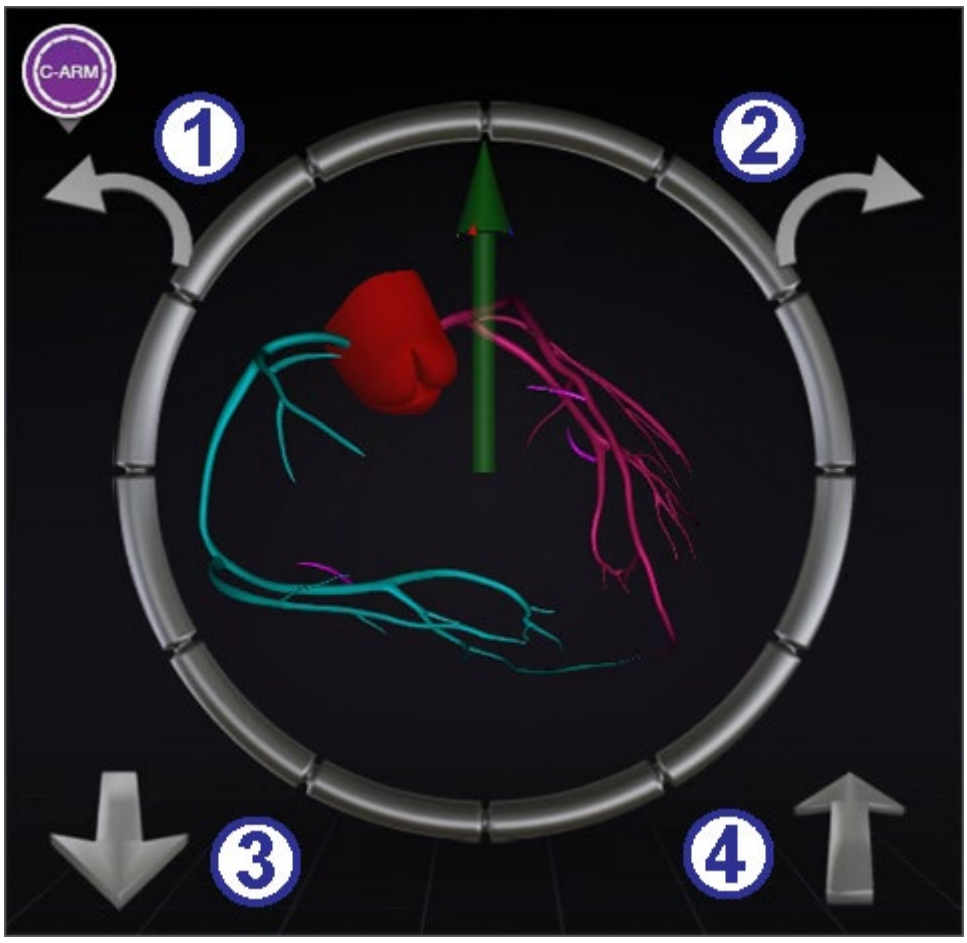


Figure 242. Synch C-Arm ClockDial View

ClockDial guide (Figure 242)

ClockDial Navigation offers users another way to navigate in three dimensions. To begin, click inside the Clock face. Clicking here gives you ClockDial Control. This feature expands the window to fit the frame, and four arrows appear (**Figure 232**).

① Rotates counterclockwise within the plane of the view chosen.

② Rotates clockwise within the plane of the view chosen.

③ Rotates toward you.

④ Rotates away from you.

Note: The default when using the arrows within the ClockDial window is 5° of rotation per click. The default may be changed if increments greater or less than 5° are desired.

Navigant Assistant

The *Navigant* Assistant feature is the "touchscreen" in the Procedure Room. It is similar to the *Navigant* system in the Control Room, but you touch the buttons on the screen to control views and manipulations. Select any of the green buttons at the top of the screen for your desired view (**Figure 243**). With the *Navigant* Assistant option, you can guide the tip of the guidewire from within the Procedure Room.

Vessels view

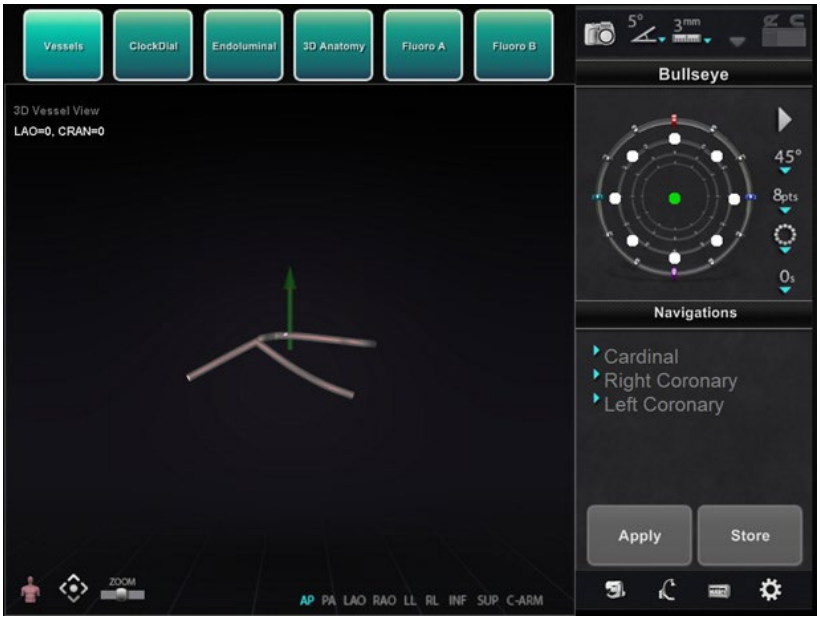


Figure 243. *Navigant* Assistant feature – Vessels view

7. Emergency Operations

Emergency Patient Retraction

To move the magnets out of the way for an emergency patient retraction, press the Stowed Position button on the Tableside Control. Note that the magnets do not have to swing to the full 90° and lock in the Stowed position. The user can release the button whenever the magnets are sufficiently out of the way. If a power or other failure occurs that keeps the magnets from moving, see **Figure 245** for manual movement of the magnets.

Overriding Magnet Interlocks

System software interlocks prevent the magnet from moving into and colliding with the X-ray system components. The user can override this interlock by simultaneously pressing and holding the Transfer Image and Stowed Position button on the Tableside Controller illustrated in **Figure 12** and then pressing and holding one of the movement buttons (Stowed, Retracted, or Navigate) to move the magnet.

WARNING: When using the interlock override, visually ensure magnet and X-ray system components will not physically collide. Closely monitor the magnet movement, and be ready to release the movement buttons if a collision is imminent. Failure to heed these warnings may cause damage to equipment.

Moving Magnets Manually

A manual hand crank allows the user to manually move the magnets in the event of a facility power failure, or if a mechanical or electrical failure renders the system unable to move normally.

WARNING: When using the manual hand crank, **EXTREME CAUTION** must be taken to ensure proper patient table, C-Arm, and magnet positioning clearance. Also, ensure that no one attempts to use the Tableside Control while manually moving the magnets. Failure to heed these warnings may cause an unsafe condition resulting in personal injury and/or damage to equipment.

To move the magnets first remove the side cover by pushing on the button and pulling off the cover (**Figure 244**). Next, follow the steps outlined in **Figure 245**. When power is restored and the Tableside Control is again used, the interlocks will automatically re-engage.

Figure 244. *Niobe* ES cover for emergency manual pod movement

① Set side cover aside.

② Remove hand crank bar from clip.

③ Insert bar in to hand crank hole. Make sure hand crank bar is ***fully*** inserted.

④ Turn hand crank to pivot magnet on curved floor track.

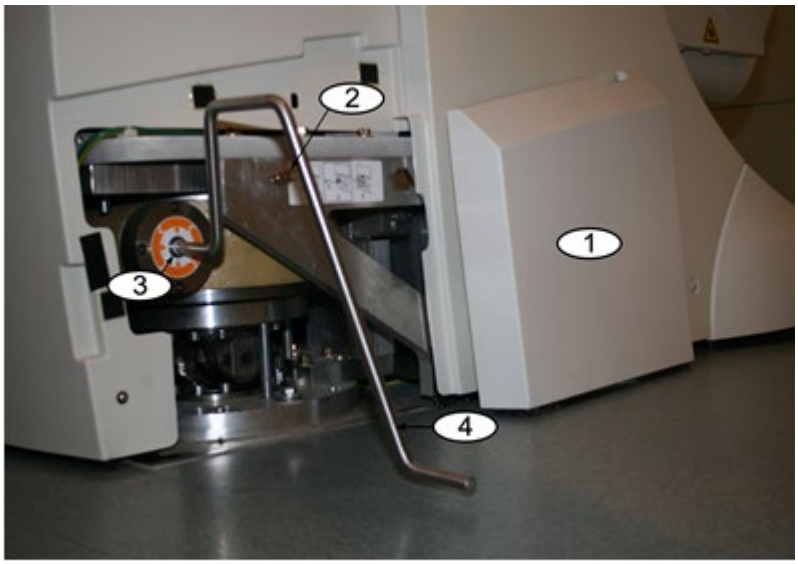


Figure 245. *Niobe* ES manual hand crank

Removing Item Stuck to Magnet

If all safety precautions are followed, ferrous items should never be near the magnet. An incident of something being attracted to and becoming stuck to a magnet should never occur.

However, if an item does become stuck to a magnet, please review the following before attempting removal.

1. The permanent magnets are always “on” and cannot be turned “off.”
2. The larger the mass of the item stuck to the magnet, the harder it will be to remove.

3. Use work gloves or other protective equipment around hands to prevent injury (e.g., skinned or scraped knuckles) when removing large items from a magnet.
4. The magnetic forces are strongest at the front (flat) face of the magnet.
5. The force decays rapidly with increased distance from the front face of the magnet.
6. If the item is sharp, consider potential damage to oneself or others if the user or the item slips, or is re-attracted to the magnet during removal.
7. The general strategy should be to **slide** the item (on the surface of the cosmetic cover) away from the front face of the magnet, and then **quickly and firmly** pull the item away **without hesitation**.
8. Sliding an item toward an outside corner of the cosmetic cover before making the "pull off" attempt over the edge of the cover is most effective.
9. Be aware that the forces around the magnet change. If an item becomes stuck to the magnet and one attempts to move the magnet from the Navigate to the Retracted or Stowed position, the field will change and the item could fall on its own (or become stuck even firmer).
10. **DO NOT** remove cosmetic magnet covers in an attempt to remove a stuck item. If contacted, the magnet (which the covers protect) could be irreversibly damaged.
11. Contact MNS service personnel for assistance if unable to easily, or safely remove an item stuck to a magnet.

8. Messages

Troubleshooting

If you need assistance with any of the solutions below, call Technical Support at 866-269-5268 or 314-678-6200.

If you do not have a support contract, call the Customer Care Center at 866-NIOBE-GO (866-646-2346) for assistance.

Error Handling

Problem	Solution
Attachment to USB Controller failed.	Click **OK** to shut down the system; restart. If the problem persists, call the Customer Care Center or Technical Support.
Cannot connect to the Video Controller.	Click **OK** to shut down the system; restart. If the problem persists, call the Customer Care Center.
Connection to the *Navigant* computer was lost.	Wait 2 minutes for the connection to automatically restore. If the connection is not restored, shut down the system; restart. If the problem persists, call the Customer Care Center or Technical Support.
Error Opening Odyssey.xml file.	Click **OK** to shut down the system; restart. If the problem persists, call the Customer Care Center.
Failed to initialize Layout Manager.	The layout directory is missing or a layout file is corrupted. Click **OK** to shut down the system; restart. If the problem persists, call the Customer Care Center.
Hourglass displays on the *Odyssey* system main menu window for more than 2 minutes.	Call the Customer Care Center or Technical Support.

Problem	Solution
Non-*Navigant* window displays improper color or a shifted image.	Reload the parameters for that device: • Click the **Configure Video** button. • Select the problem device. • Click the **Load Video Parameters** button. If the problem persists, call the Customer Care Center or Technical Support.
Received a message that "Only one instance can run at a time."	Shut down the system; restart. If the problem persists, call the Customer Care Center or Technical Support.
Unable to use the *Odyssey* system mouse in the *Navigant* window.	Reset the USB Controller. Click the **About** button, then the **Reset USB Controller** button. If that doesn't work, restart the system. If the problem persists, call the Customer Care Center.
Unexpected error occurred in opening required layout file.	A layout file is corrupt or has been removed. Shut down the system; restart. If the problem persists, call the Customer Care Center.

Facility Breakers

If for some reason the MNS facility breakers have switched or turned off, contact one of the following areas:

- The hospital in-house Facilities Department
- The Stereotaxis Customer Care Center: 1-866-269-5268 (from the US)
- The Stereotaxis main number: 314-678-6200

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