

NAVIGANT™

User Guide



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Patents

Navigant

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

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; 8,024,024; 8,192,374; 8,369,934; 8,721,655; 9,314,222

Manufactured under the following European patents:

EP 1 682 024 issued in Germany, France, and the United Kingdom; EP 1 769 390, issued in Germany, France, and the United Kingdom

Niobe

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

6,975,197; 7,019,610; 7,161,453; 7,305,263; 7,313,429; 7,495,537; 7,772,950; 7,966,059

Manufactured under the following European patent:

EP 1 488 431 issued in Germany, France, and the United Kingdom

Genesis RMN

Manufactured under the following United States patent:
7,774,046

Other patents issued and pending.

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- *iConnect* is a trademark of Stereotaxis, Inc., registered in the United States.
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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: | Niobe: 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 Genesis: IEC 60601-1-2 ed 4.0 (2014-02) CISPR11 ed 6.1 (2016-06), Class A (Professional Healthcare Facility Environment) |
| Immunity: | Niobe: 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 Genesis: IEC 60601-1-2 ed 4.0 (2014-02), IEC 61000-4-2 ed 4.0 (2008-12), IEC 61000-4-3 ed 3.2 (2010-04), IEC 61000-4-4 ed 3.0 (2012-04), IEC 61000-4-5 ed 3.0 (2014-05) + AMD:2017, IEC 61000-4-6 ed 4.0 (2014 COR2015), IEC 61000-4-8 ed 2.0 (2009-09), IEC 61000-4-11 ed 2.0 (2004-03) + AMD1:2017 |

When operating this equipment, verify that other devices installed near it conform to the applicable EMC standards for that device. *Navigant* and the Stereotaxis RMNS are 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: | <i>Niobe</i> : ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1 CAN/CSA-C22.2 No. 60601-1:14 <i>Genesis</i> : CAN/CSA-C22.2 No. 60601-1:14 ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1 IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) |

Related documents

HDW-0312 Niobe User Guide
HDW-0331 e-Contact Module User Guide
HDW-0358 Genesis RMN User Guide
HDW-0367 iConnect User Guide
Respective documentation for compatible devices and /or systems.

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

Stereotaxis Companion Systems

| System | Part Number |
|-------------------------|--|
| <i>Niobe</i> | Siemens Reference number: 001-006000-1 |
| | Philips Reference number: 001-006100-1 |
| | Model S Reference number: 001-006200-1 |
| <i>Genesis RMN</i> | Reference number: 001-011000-1 |
| | Model S Reference number: 001-011000-3 |
| <i>Cardiodrive</i> | 001-004115-X |
| <i>e-Contact Module</i> | 001-003680-1 |
| <i>iConnect*</i> | 001-009040-1 |

*Only available in the EU.



WARNING: No modification of this equipment is allowed. No user-serviceable parts are inside *Navigant*. The user should not attempt to disassemble any portion of *Navigant*.



WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains that have a protective earth ground.

Disposal

This product should be recycled and not disposed of as general waste (subject to WEEE annex IV resp. EN 50419).

Waste and Recycling

A contractor is responsible for the disposal and recycling of scrap metals and electronics found in *Navigant*.

Suggested Contractor: Walch Recycling & Eldelmentalle



Notice to the User and/or Patient

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Cover art

Cover art © 2021, 2023 Stereotaxis, Inc.

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Introduction

Navigant™ Workstation (NWS) is a platform of software applications designed to simplify clinical workflows. *Navigant* works in conjunction with a Stereotaxis Robotic Magnetic Navigation System (RMNS) (e.g., Niobe™ or Genesis RMN™) to provide enhanced integration of catheterization and electrophysiology labs and improved automation during robotic magnetic navigation of medical devices. *Navigant* integrates with a compatible, digital fluoroscopy system to provide real-time guidance to the physician during an interventional procedure and communicates with mapping systems to allow integrated mapping and navigation. See the following section regarding companion systems for more information.



Note: The Niobe system includes *Niobe RMN*, *Navigant*, and *Cardiodrive™* systems. The Genesis system includes *Genesis RMN*, *Navigant*, and *Cardiodrive* systems. *Navigant* features may be specific to the Stereotaxis RMNS in use.

Companion Systems

To determine what magnetically-compatible devices, radiofrequency (RF) ablation generators, and digital fluoroscopy systems may be used with *Navigant* and the RMNS, see the *Niobe* or *Genesis RMN* system user guides.

Navigant communicates with the Biosense Webster CARTO® 3 System to allow integrated mapping and navigation; *Navigant* is not compatible (integrated) with CARTO 3 v7. The OpenMapping API feature allows communication between *Navigant* and mapping systems that have been tested to be compatible such as the Acutus AcQMap® High Resolution Imaging and Mapping System.

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

Indications

The *Navigant* Workstation Software is intended to be used with a Stereotaxis RMNS, *Cardiodrive*, *Odyssey Vision™*, and/or *Vdrive™* systems.

The Stereotaxis RMNS and *Navigant* Workstation Software, when used in combination with *Cardiodrive* or *Vdrive*, provides the means for the physician to steer, advance, and retract catheters from a control room.

Contraindications

There are no known contraindications.

Clinical Benefits for Patients

Fewer major and minor patient complications during MNS ablation procedure. Reduction of harmful radiation to patients during MNS ablation procedure due to shorter fluoroscopy times. Acute success, long-term success, and procedure times are similar between MNS and manual




procedures with no compromise to safety. Potential to treat more complex pathologies due to the precision, reach, and stability of the system.

Clinical Benefits for the Physician and Staff



Reduction of harmful radiation to clinical staff performing and/or participating in MNS ablation procedure due to shorter fluoroscopy times, and system console location outside the x-ray exposure zone. Reduction in orthopedic burden to clinical staff because heavy lead aprons do not have to be worn for the duration of an MNS ablation procedure as compared to manual ablation procedures for which the protective equipment is required. Reduction in posterior subcapsular changes (vision effects) from radiation.





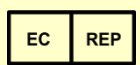






Graphics and Symbols



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, which can be found in the *Safety* section. Pay close attention to the instructions that accompany the warnings, notes, 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. |

The following graphical symbols are used in this document and/or on system components:

| Symbol | Name | Description |
|---|-----------------------|--|
|  | AC Power | Indicates the status of the AC power. |
| REF | Catalog Number | Catalog/part number. |
|  | Caution | Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot be presented on the medical device. |

| Symbol | Name | Description |
|---|--------------------------------|---|
|  | CE Marking | Product conforms to European Medical Directive 93/42/EEC and meets applicable healthy, safety, and environmental requirements. If the mark is accompanied by a number, conformity is valid. |
|  | Consult Instructions | See the Operating Instructions for additional information or instruction. |
|  | Date of Manufacture | The date when the medical device was manufactured. |
|  | E-stop | Indicates the E-stop button or the E-stop indicator light. |
|  | European Representative | Name and address of the authorized representative in the European Community. |
|  | Importer | Name and address of the entity importing the medical device into the locale. |
|  | Magnet Present | Indicates a magnet is present in the equipment. |
|  | Manufacturer | Name and address of the manufacturer of the product. |
|  | Medical Device | Indicates the item is a medical device. |
|  | Power | Indicates the power status. |
|  | Prescription Only | Caution: Federal law restricts this device to sale by or on the order of a physician. |

| Symbol | Name | Description |
|---|--|---|
|  | Recycle: Electronic Equipment | Product that is subject to the European Union's Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC/EU Directive for recycling of electronic equipment. |
|  | Refer to Instruction Manual/Booklet | The instruction manual or booklet must be read. |
| SN | Serial Number | The manufacturer's serial number so a specific medical device can be identified. |
| UKRP | UK Responsible Person | A person established in the United Kingdom (UK) who acts on the behalf of a non-UK established manufacturer in relation to the manufacturer's obligations under UK regulations. |

Glossary

The following terms appear in this document:

| Term | Description |
|---|---|
| 2D | Two-Dimensional. |
| 3D | Three-Dimensional. |
| AP | Anterior-Posterior. |
| AutoMap | An integrated feature between <i>Navigant</i> and the mapping system that enables the user to initiate a sequence of automatic, computer-controlled catheter movements throughout the cardiac chamber. |
| 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. |
| Cardidrive Catheter Advancement System (CAS) | The Stereotaxis tool that provides the physician with the ability to advance and retract catheters from a Control Room. Commonly referred to as <i>Cardidrive</i> or CAS. |

| Term | Description |
|--|---|
| CARTO 3 System | Biosense Webster system that combines 3D mapping and navigation systems with the Stereotaxis RMNS. |
| Click & Go | An integrated feature between the <i>Navigant</i> software and the <i>CARTO 3 System</i> 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 <i>Navigant</i> 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). |
| Edit <i>NaviLine</i> Mode | Provides a toolbox with features to create and edit a <i>NaviLine</i> such as New Line, Remove Line, Open/Close, Color, and Measure; available for all surfaces and volumes. |
| 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. |
| Robotic Magnetic Navigation System (RMNS) | A medical platform that enables physicians to 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; system consists of computer-controlled magnets that assist physicians in orienting and steering compatible, magnetically-adapted devices and works in conjunction with <i>Navigant</i> Workstation. |
| IC | Interventional or Intracardiac Cardiology. |
| Ideal registration | Instruction to the user for complementary fluoro images that will yield the best registration data. |
| Isocenter | In X-ray technology, the isocenter is the point in space where from any angle (AP, LAO, RAO) the central ray of the radiation beams will pass. |
| nLAO | Left Anterior Oblique. |
| Navigation volume | Spatial volume defined for RMNS, where the RMNS is capable of generating any magnetic field direction at the target magnetic field strength provided by the RMNS. This volume is aligned in the same location as defined by the x-ray isocenter. |

| Term | Description |
|---|--|
| NaviLine automated linear navigation | An integrated feature between the Stereotaxis <i>Navigant</i> software and the mapping system that enables the user to automatically follow a predefined line along a 3D surface created by the mapping system. <i>NaviLine</i> navigation moves the catheter in prescribed increments forward and/or backward along the line. |
| Odyssey Cinema System | The optional recording system for the <i>Odyssey Vision</i> System that provides remote viewing of live and recorded procedures. |
| Odyssey Vision System | A 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 <i>Navigant</i> and mapping systems that have been tested to be compatible. These compatible mapping systems are referred to as OpenMapping systems. |
| RAO | Right Anterior Oblique. |
| Registration set | 3D models imported into <i>Navigant</i> as surfaces in VTK format; once imported, all surfaces are moved and manipulated as a group. |
| RF | Radiofrequency. |
| RMT | A remote magnetic technology. (RMT is often used to refer to the integrated <i>CARTO 3</i> / <i>RMNS</i> environment incorporating 3D mapping and navigation and magnetic maneuvering of compatible devices.) |
| Target Navigation | Using field and CAS movements to automatically move the catheter to the user-indicated target. |
| W·s | Watt-second, the energy equivalent to the power of one watt sustained for one second. |



Note: Historical Stereotaxis documentation uses the term *Magnetic Navigation System* (e.g., Niobe MNS) instead of *Robotic Magnetic Navigation System* (e.g., Genesis RMN) though the two systems are comparable.

Safety












Warnings





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









WARNING: *Navigant* should be used only by qualified medical professionals who have been thoroughly trained in its use.

-  **WARNING:** The user should not attempt to upgrade, configure, or run any other software programs on the *Navigant* computers, other than those specifically mentioned in the product documentation.
-  **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 a graphical representation of the catheter tip and shaft display on the *Navigant* 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* System.
-  **WARNING:** The graphical representation of the catheter on the *Navigant* display screen 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 using the “Transfer Fluoro” 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:** 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, 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:** 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 E-stop button to stop all device activities. Contact the Emergency call center to report the suspicious activity prior to resumption of the procedure.

Precautions

-  **CAUTION:** The Stereotaxis RMNS 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 reregister the mapping system to *Navigant*, remark the catheter base, and recalibrate the *Cardiodrive* System.
-  **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.

Performance Characteristics

Navigant's Essential Performance Characteristics

Navigant provides multiple user interface features as described in this document to allow a physician to move and steer magnetically enabled devices. Each of these features supports one of the core performance characteristics of the software.

- 1) Provide graphical displays for the user so that the direction of the magnetic field created by the MNS with reference to the patient can be understood by the operator.
- 2) Allow the user to change the direction magnetic field created by the MNS to point in a direction that will move a magnetically enabled device as intended by the operator.

- 3) Give the operator the ability to insert and retract the magnetically enabled device in a controlled manner to allow positioning of the magnetically enabled device as intended by the operator.
- 4) When integrated mapping is used, to display the device position on the user interface and to provide an overlay of the mapping information on pre-acquired fluoroscopic images.

Testing of Performance Characteristics

Understand field direction by reference to patient:

| Functions that support performance characteristic | Tested by | Result | Report |
|---|--|--------------|--------------------|
| Main navigation window | TC1308 Basic Functionality – Window and Object Visibility TC689 – Desired and current field | Pass Pass | NWS-447 NWS-430 |
| Standard Viewpoint Selector and Synchronization options | TC1308 Basic Functionality – Window and Object Visibility | Pass | NWS-447 |
| ClockDial Navigation | TC 1316 Basic Functionality – Navigation Modes | Pass | NWS-397 |
| Vessel View Navigation | TC1345 General System Validation TC777 Vessel Navigation Basic | Pass | NWS-422 |
| DynaCT™ (licensed option) | TC1345 General System Validation TC722 DynaCT: Registration | Pass | NWS-430 |
| Volumes dialog box | TC1345 General System Validation | Pass | NWS-430 |

| Functions that support performance characteristic | Tested by | Result | Report |
|---|---|--------|---------|
| | TC931 Volume Guidance Dialog Basic | | |
| Fluoro Annotation dialog box | TC1345 General System Validation TC600 Fluoro Annotation (Point Group) Guidance Dialog | Pass | PM3-641 |

Allow the user to change the magnetic field direction:

| Functions that support performance characteristic | Tested by | Result | Report |
|---|---|--------|----------|
| Vector on main navigation window | TC689 – Desired and current field | Pass | NWS-430 |
| Vector set on clock dial screen | TC775 – Clockface function | Pass | NWS-396 |
| Incremental vector movement from keypad | TC2138 – Navigant Keypad | Pass | CWS-149 |
| Targeting | TC978 – Click and go targeting | Pass | NWS-452 |
| NaviLine | TC69 – NaviLine Start and Settings | Pass | NWS-447 |
| Bullseye | TC637 – Bullseye Control | Pass | NWS-447 |
| Vessel navigation | TC777 – Vessel Navigation Basic | Pass | NWS-416 |
| Navigant Assistant | TC108 – Displays on the Assistant | Pass | NWS-416 |
| Auto Mapping | TC1318 – Script Workflow Electrophysiology LA | Pass | PM10-032 |

| Functions that support performance characteristic | Tested by | Result | Report |
|---|---|--------|--------|
| | TC1321– Script Workflow Electrophysiology RA | | |

Allow the user to advance and retract the catheter:

| Functions that support performance characteristic | Tested by | Result | Report |
|---|---|--------|----------|
| Mouse wheel CAS interface | TC984 – Mouse Wheel Functionality TC110 – Cardiodrive Connection & CAS Mouse Wheel | Pass | CWS-149 |
| Keypad incremental CAS Step | TC2138 – Navigant Keypad – Common Keys | Pass | CWS-149 |
| Targeting | TC978 – Click and go targeting | Pass | NWS-452 |
| Joystick | TC2307 CardioDrive firmware/hardware UI | Pass | PM10-041 |
| Auto Mapping | TC1318 – Script Workflow Electrophysiology LA TC1321– Script Workflow Electrophysiology RA | Pass | PM10-032 |

Allow the user to see device position and fluoroscopic overlay with mapping system integration

| Functions that support performance characteristic | Tested by | Result | Report |
|---|--|--------|-------------------------------|
| Main Navigant window | TC28 Ablation Catheter Graphic Object | Pass | NWS-452 |
| Visibility panel | TC194 Visible Objects Control Panel | Pass | NWS-452 |
| Mapping Registration | TC65 Carto Registration Dialog TC66 Carto Registration Marker Placement | Pass | NWS-430 NWS-447 NWS-447 |

| Functions that support performance characteristic | Tested by | Result | Report |
|---|--|--------|---------|
| | TC114 CAS Calibration/Catheter Registration Dialog | | |
| Fluoro Overlay Screen | TC2262 Mapping System Registration Free Workflow | Pass | NWS-452 |



Cybersecurity

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

General Notes

- Always verify the fluoroscopy images match the current patient.
- Images that are electronically zoomed and/or panned cannot be transferred to Stereotaxis RMNS.
- Images acquired during C-Arm movement or table movement cannot be transferred to Stereotaxis RMNS.
- Before ablation, verify the field is applied to ensure proper device functionality.

Electromagnetic Compatibility 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. Improper operation may consist of (1) prevention of patient treatment, (2) uncontrolled motion of magnets, and (3) uncontrolled motion of the <i>Cardiodrive</i> System. |
|  | 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 preceding information from the above warning. |

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

- 52.5Mhz
- 144Mhz
- 433Mhz
- 448Mhz
- 452Mhz
- 467Mhz
- 470Mhz
- 1.2Ghz
- 2.4Ghz
- 5.0Ghz

Impedance Measures When Using iCONNECT

When used with the optional iCONNECT system, the impedance readings from the catheter can be displayed if the operator chooses. Cardiac impedance values are a useful means to help understand contact with the tissue and assess changes over time.

With impedance values, there is significant variability between patients as to baseline impedance values for blood and heart tissues. Because of this, it is not an actual numerical impedance value that is of significance but rather the measured changes that occur between these tissues and blood as the catheter is moved and over time as therapies are delivered. The iCONNECT measures of impedance are designed to be of sufficient accuracy and precision for assessing these changes.

The iCONNECT system when used with Genesis is designed to provide an impedance measure as follows:

| | |
|-------------------------|---------------------|
| Channels | 2 (E1-E3 and E2-E4) |
| Calibrated Range | 120 to 340 ohms |
| Accuracy | <2.5% |
| Precision | ≤1 ohm |

Emissions

The **equipment** is intended for use in the electromagnetic environment specified in the following tables. The user of the **equipment** should ensure it is used in such an environment. The following

table provides guidance and Stereotaxis' declaration on **electromagnetic emissions** for the **equipment**:

| Emissions | Compliance | Electromagnetic environment—guidance |
|---|---------------------|--|
| RF emissions CISPR 11 | Group 1 | The equipment 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. |
| RF emissions CISPR 11 | Class A Complies | |
| Harmonic emissions IEC 61000-3-2 | | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | | |



WARNING: The EMISSIONS characteristics of this equipment make it suitable for use in industrial and hospital (CISPR 11 class A) settings. If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Immunity—General Electromagnetic Effects

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

| 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. |


| Immunity test | IEC 60601 test level* | Compliance level* | Electromagnetic environment—guidance |
|--|---|---|--|
| 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 equipment requires continued operation during power mains interruptions, it is recommended that the equipment 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 (RF) for the equipment:

| 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 equipment, 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 |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 mHz to 2.7 GHz | 3 V/m | |
| Proximity Fields to RF Wireless Communications | 27V/m 380-390Mhz | 27V/m | |

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment—guidance |
|---------------|---|------------------|--|
| | 28V/m 430-470Mhz 800-960Mhz 1700-1990Mhz 2400-2570Mhz | 28V/m | 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 |
| | 9V/m 704-787Mhz 5100-5800Mhz | 9V/m | Interference may occur in the vicinity of equipment marked with the following symbol:  |

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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment or needing to contact the TeleRobotic Support Team.
- b** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Separation Distances

The equipment is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment 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 affected equipment.

| 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 to 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.



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 equipment, including cables specified by Stereotaxis, Inc.



Note: If there are Electromagnetic Compatibility (EMC) issues with the equipment, please contact Stereotaxis TeleRobotic Support Team. Otherwise, there are no specific service requirements to maintain EMC integrity.

Basic Information

Start Window



Figure 1. Start window

Start Window Guide

- **Start New Procedure.** Click this button to start a new procedure. A blank New Procedure Information window displays. Complete the information section, and select a procedure type, click **OK** and proceed to the main screen.
- **Open Existing Procedure.** 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.
- **Utilities.** Click this button to access the Utilities window with three tabs: Physicians, Procedures, and Licenses. On the Physicians tab, the user can rename or delete physician names. On the Procedures tab, the user can view, import, export, and delete procedures. On the Licenses tab, the user can view and install licenses. Click **Close** to return to the start screen.

- **Help Guide.** Click this button to display help documents onscreen. The user may also click any question mark in an orange circle on any screen to display helpful information pertinent to the current topic.
- **Shutdown System.** Click this button to shut down the system. A confirmation dialog displays. Click **Yes** or **No**.
- **System Indicators**
 - **Stereotaxis RMNS** icon – the icon displays Stereotaxis RMNS messages, warnings, or errors.
 - **X-ray** icon – the icon displays X-ray system messages, warnings, or errors.
 - **System info** icon – the icon displays Stereotaxis RMNS messages, warnings, or errors.



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 starting a new procedure or opening an existing one, the next display after the start window is the procedure information window (**Figure 2**). The figure below displays a QuadHD *Odyssey* user interface. (The traditional *Odyssey* user interface does not have the **Profile** field but contains all other fields.)

Info 1 Start Time: 02-Jan-2020 16:07:06

Last Name First

2 Patient ID DOB

Sex Male Female Other Arrhythmia 3

4 Physician Profile 9

5 Notes

Heart Chamber


6 Electrophysiology Coronary CRT

7 Right Atrium Left Atrium Right Ventricle Left Ventricle

8 Use Mapping: Use RMN

Figure 2. New procedure information window

New Procedure Information Window Guide

- ① **Start Time** field. The start date and time of a new procedure is automatically recorded.
- ② **Patient information** 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.
- 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), or 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 2** 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**. 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. Only displays on the EP tab.
- ⑨ **Profile** field. Click the down arrow to the right of the field to choose a procedure if working with previously entered information. If not working with previously entered information, this field will not be available.



Help Dialog button. Displays Help Dialog for fields on this screen.



Note: The user 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.

Existing Procedure Information Window

The top **Procedures** panel (**Figure 3**) lists all previous procedures, the most recent procedure listed first. The user must select a procedure. The bottom panel displays information the user typed at the start of the highlighted procedure: start time and date, patient information, physician name, and notes.



Note: The user can edit the Patient name and Notes after the procedure is opened. Go to System options → Settings → Procedures.

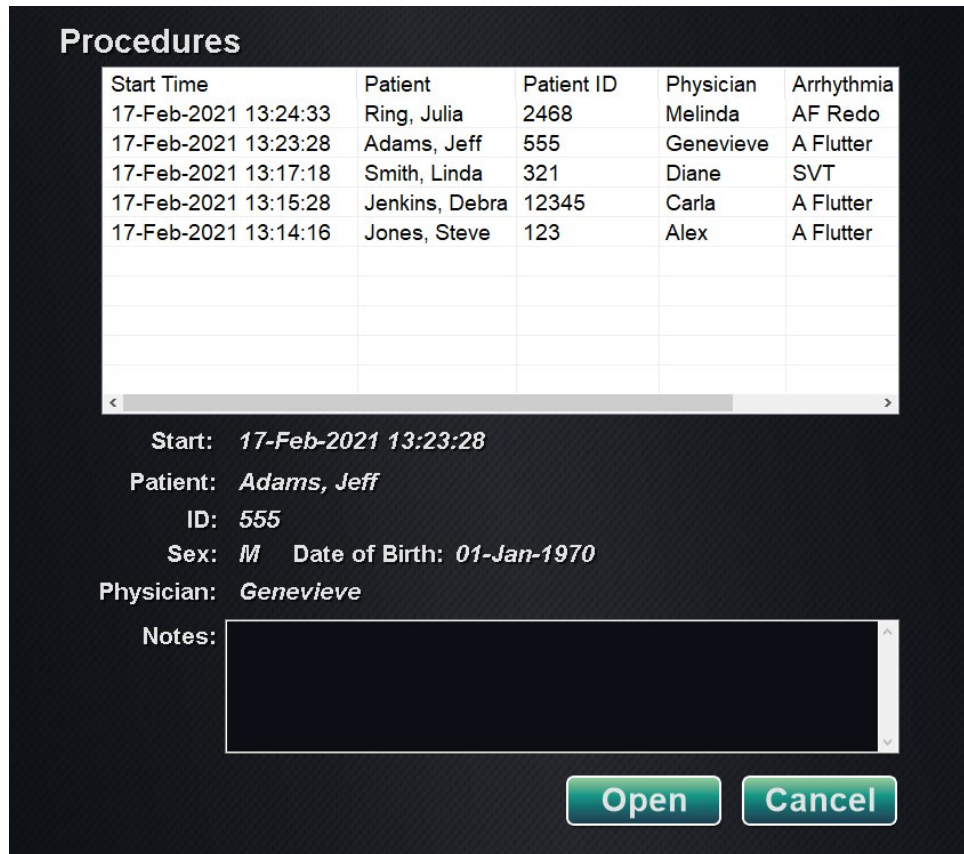


Figure 3. Existing procedure information window

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

On the **Physicians** tab, a list of physicians is displayed in alphabetic order. When a user starts a procedure, they must select or **Add** a physician name. The user can **Delete** or **Rename** a physician by right-clicking on the name and selecting **Delete / Rename**, or by using the functional buttons at the bottom of the tab.

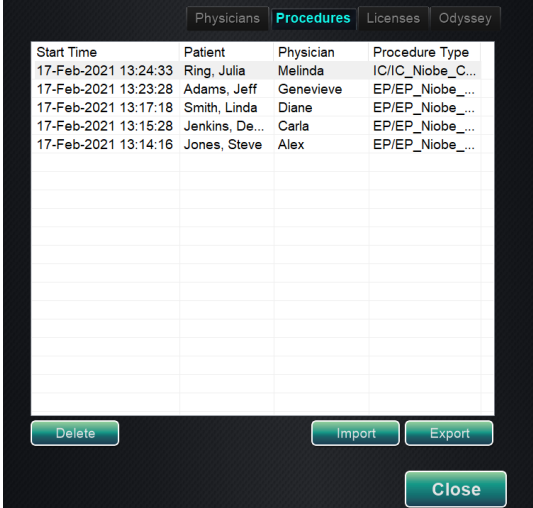
After selecting **Rename** the Edit field will allow the user to edit the name. Press **Enter** to save the change. When adding a physician name, click **Add** and type the name in the Physician Name field. Press **OK** to save the addition. The screen returns to the former display with that physician selected. However, if the physician name is a duplicate of an existing entry, the message, "**That**

name already exists” will appear. The user must edit the field to create a unique name and then click **OK** or click **Cancel** to return to the Physicians tab. After all edits, select **Close** to close the window.

Procedures Tab

Procedures list (Figure 4). The user must select a procedure. To select multiple procedures, hold the **Ctrl** key for non-sequential selections or the **Shift** key for sequential selections. The Procedures list displays saved procedures and can be sorted by clicking the column heading for Start Time, Patient, Physician, or Procedure Type.

The user can **Delete**, **Import**, or **Export** procedures by selecting the functional buttons at the bottom of the tab. Click **Import** to display the window **Select source folder for Import** where the user can select what folders to import. To export a procedure, select a procedure and click **Export**. The window **Select destination folder for Export** displays. Once all edits have been made, click **Close** to close the window.



| Start Time | Patient | Physician | Procedure Type |
|----------------------|----------------|-----------|------------------|
| 17-Feb-2021 13:24:33 | Ring, Julia | Melinda | IC/IC_Niobe_C... |
| 17-Feb-2021 13:23:28 | Adams, Jeff | Genevieve | EP/EP_Niobe_... |
| 17-Feb-2021 13:17:18 | Smith, Linda | Diane | EP/EP_Niobe_... |
| 17-Feb-2021 13:15:28 | Jenkins, De... | Carla | EP/EP_Niobe_... |
| 17-Feb-2021 13:14:16 | Jones, Steve | Alex | EP/EP_Niobe_... |

Figure 4. Procedures tab

Licenses Tab

The Licenses tab lists licenses acquired with *Navigant*. Each entry includes name, start date, expiration date, and status (**Active** or **Expired**). Only Stereotaxis representatives should operate the **Install** button.

Import Window

The **Select source folder for Import** window allows the user to navigate to the drive or directory that contains the procedure folder to be imported. Once selections are made, click **OK** to import the procedure or **Cancel** to cancel the import.

Export Window

The **Select destination folder for the Export** window (Figure 5) allows the user to navigate to the drive or directory where the exported procedure file is to be saved. This tool should be used to perform backups as *Navigant* does not perform backups automatically. The file may be saved

to a flash drive or a CD. The user must select the level of export for the procedure. After all selections are made, click **OK** to export or **Cancel** to cancel the export.

Level of Export

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

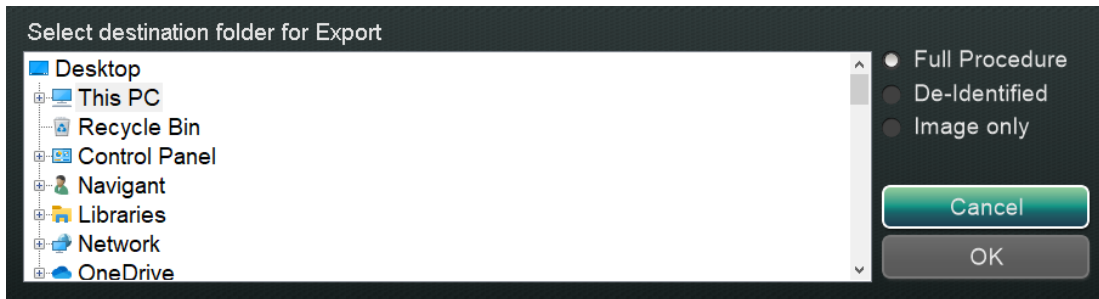


Figure 5. Select destination folder for Export window



Note: The user has the sole responsibility to export data according to internal procedures. If no guidelines are on site, Stereotaxis recommends a full procedure backup every 3 months.

Input Devices

The following input devices are provided in the Control Room: a standard wheel mouse, a standard keyboard, a keypad, (some sites include) the *Cardiodrive* user interface, and a *QuikCAS* barcode scanner. In addition to standard functions, the wheel mouse controls catheter advancement and retraction when the wheel is rolled forward or backward, respectively.

If a Logitech PRO mouse is installed at a site, it replaces the existing wheel mouse and has the same functions. See *Logitech PRO Mouse* below for more information.

Cardiodrive User Interface (If Present)

For the sites that have one, the *Cardiodrive* Catheter Advancement System (CAS) user interface (**Figure 6**) 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 6. *Cardiodrive* (CAS) user interface

***Cardiodrive* (CAS) user interface guide**

- ① **E-stop** button. Push the red button to 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. (If the Stereotaxis RMNS 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 +) to advance the catheter and backward (toward -) to retract it. The motion is slower as the joystick approaches its center and speeds up as the joystick is tilted 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, a compatible catheter must be registered.

***QuikCAS* barcode scanner**

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. This procedure ensures that only authorized devices are used during magnetic navigation and prevents the

unintentional use of expired sterile products. A barcode scanner is 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 (**Figure 7**) is located on the CAS II disposable box at the outer box label. Scan the label to activate the *QuikCAS* device. Scan an activation code at any time **before** requesting a magnetic field direction.

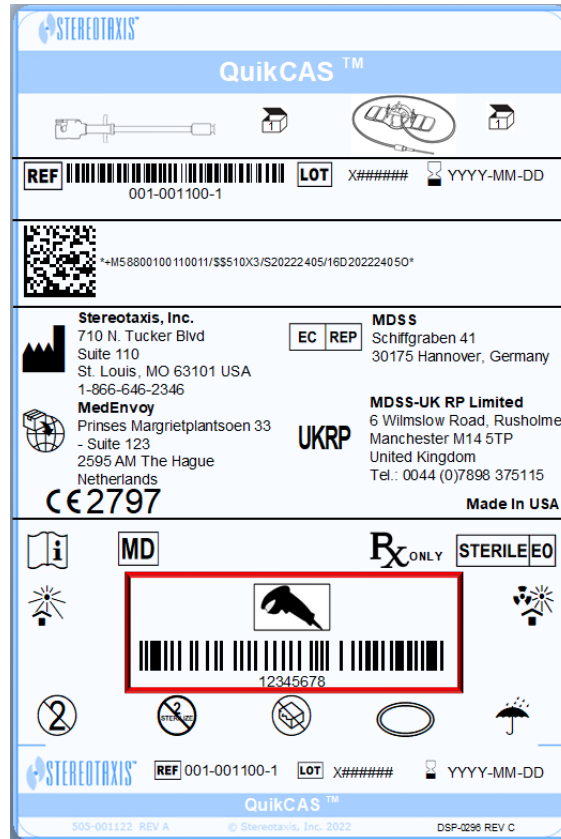


Figure 7. *QuikCAS* Activation code

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 8**.

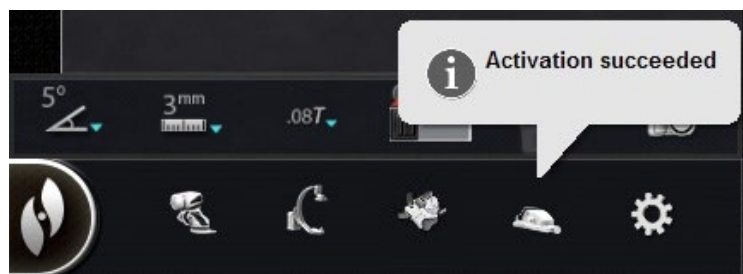


Figure 8. Activation succeeded

The activation code displays in the text field at the bottom of the Device Selection dialog (**Figure 9**). If the scan was 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 a valid scan code. The CAS status may be checked by clicking the CAS icon (encircled in **Figure 10**) on the hardware status bar.



Figure 9. Device Selection dialog; Activation Code displayed

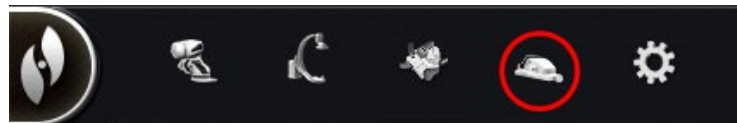


Figure 10. CAS procedure indicator

Keypad

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

Guide to Figure 11

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



Figure 11. Top blue keys and orange keys

Guide to Figure 12

- 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

- i** **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, press and release the respective arrow key.



Figure 12. Green keys


Guide to Figure 13

- ⑫ Store navigation
- ⑬ Advance *Cardiodrive* device one step
- ⑭ Retract *Cardiodrive* device one step
- ⑮ Stops automation for:
 - Chamber targeting
 - *Bullseye* Targeting pattern navigation
 - Vessel sequencing
 - Automapping



Figure 13. Stop key and right blue keys

Logitech Mouse & Keyboard: Features and Troubleshooting

 **Note:** This is applicable only to Genesis RMNS.

Logitech PRO Mouse

The Logitech PRO Mouse has a **DPI Cycle** button located adjacent to the scroll wheel. Each time the button is pressed, the speed of the mouse (how quickly it travels on screen compared to how the device moves) cycles through 4 settings.

Troubleshooting

- If the user finds the mouse too fast or too slow, they are advised to click the **DPI Cycle** button until a satisfactory speed is found.
- If the mouse has unexpectedly changed speed, the user might have accidentally clicked the **DPI Cycle** button. Click the button to adjust the speed.

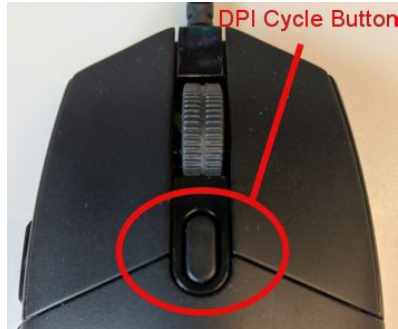


Figure 14. Logitech PRO Mouse- "DPI Cycle" button

Logitech G512 Keyboard - Special FN keys

The Logitech G512 keyboard has FN keys that when pressed, provide special features to the user when troubleshooting. The user should **NOT** press any FN keys unless trying to troubleshoot. Review the section below for more details.

- **If the Windows key stopped working**, check the indicator lights on the keyboard above the number pad. If the right-hand light is illuminated, the keyboard is in *Game Mode*, and in that mode, the Windows key is disabled.
 - To toggle Game Mode on/off, press the **FN** and **F8** keys at the same time.



Figure 15. Keyboard indicator lights

- **If the keyboard is dim or dark** while the mouse is showing colors, check the keyboard's brightness setting.
 - Press the **FN** and **F7** keys at the same time cycles the brightness through settings that vary between 0% and 100%.
- **If the keyboard is dark while the mouse is showing colors AND the previous suggestion (FN+F7) does not work**, try the following suggestion:
 - Press the **FN** and **F5** keys at the same time.
 - Ensure the **Keyboard has been plugged in correctly (Figure 16)**.
- **If the keyboard is displaying color patterns not in keeping with the mouse (including no colors)**, the user probably pressed the **FN** and **F5** keys at the same time, which cycles the keyboard pattern mode.
 - To fix the keyboard colors, move the magnet so that the color effect on the mouse changes, and the keyboard colors will update.



Figure 16. Logitech G512 Keyboard Cable

Note: The Logitech G512 keyboard has a cord with 2USB plugs. When plugging the keyboard into the UIC, use the cord that has a keyboard graphic (**Figure 16**).

Keyboard and Magnet Communication

During normal operation when *Navigant* can talk to the magnets, the keyboard and mouse are a steady light blue color. When the magnets are moving or in certain positions, the keyboard and mouse will be colored differently. See the table below that details the relationship between magnet status and keyboard/mouse color.

Table 1. Magnet status and Keyboard/Mouse Color

| Magnet Status | Keyboard and Mouse Color |
|----------------------------------|---|
| Magnets are moving | Keyboard and mouse pulse a light blue color |
| Magnets are in Stowed position | Keyboard and mouse are a steady dark blue color |
| Magnets are in Navigate position | Keyboard and mouse are a steady Stereotaxis orange color |

Clinical Workflow Manager

The Clinical Workflow Manager (CWM) is the user's map through a clinical workflow. It displays on the left of the main window throughout a procedure. The user may use the CWM to work through an entire procedure or ignore it and follow an individualized workflow. The user may change workflows by selecting one of the workflows marked with an asterisk listed on the Start tab (**Figure 17**).



Figure 17. Clinical Workflow Manager (CWM)

The default layout shows the CWM as the first tab open when a procedure starts. The following are icons of tabs:



Control Panels

Navigations Control Panel

The Navigations control panel displays categories from which to display **preset navigations**. The list of preset navigations changes based on the workflow.

To display preset navigations, click the arrow next to the category name. To select a preset navigation, click to highlight the preference. Once the preset navigation is highlighted, the **Apply** button becomes available (Figure 18). Preset navigations represent commonly used *field directions*. The user may want to fine-tune these settings by moving the field vector slightly. After the user selects **Apply**, the option to store the navigation then becomes available.



Figure 18. Preset navigations, Septum selected

Stored Navigations

To store a new field direction, click **Store** or press the **Store Navigation** button on the keypad (Figure 19). Stored navigations are displayed under a new heading, **Stored Navigations** and fields are sequentially named: Navigation #1, Navigation #2, etc. Stored navigations store field (vector) directions, **not** positions.



Figure 19. Store navigation button

Currently Applied Navigation

In Figure 20, left, Navigation #1 is selected but not in **bold** as Navigation #1 has not yet been applied. Navigation #1 is **bold** in Figure 20, right as it is now the currently applied navigation. If the user wants to explore other stored navigations, the stored navigations can be selected (and highlighted) prior to being applied.



Figure 20. Left: Navigation selected but not applied;
Right: Navigation selected and applied

Rename Stored Navigations

To rename a stored navigation, right-click the name and select **Rename**. Type a new name and click **Apply**. The stored navigation is renamed.

Delete Stored Navigations

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

Visible Objects Control Panel

When the user opens a new procedure, the Visible Objects control panel is empty. The control panel field populates as the user creates vessel reconstructions, point groups, surface points, and maps (if using a mapping tool). Following are the types of dialogs and the visible objects they create:

| Dialog | Visible Objects |
|----------------------|-------------------|
| Fluoro Annotation | Groups |
| <i>NaviView3</i> | Vessels |
| Volume Marking | Vessels, Surfaces |
| CARTO 3 Registration | Maps |



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. The user 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 21).



Figure 21. 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. To delete an object, right-click its name in the Visible Objects list and select **Delete**. 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 22**). Vessels are the only Visible Objects that display the **Properties** and **Manual Registration** commands on the right-click menu (**Figure 23**).

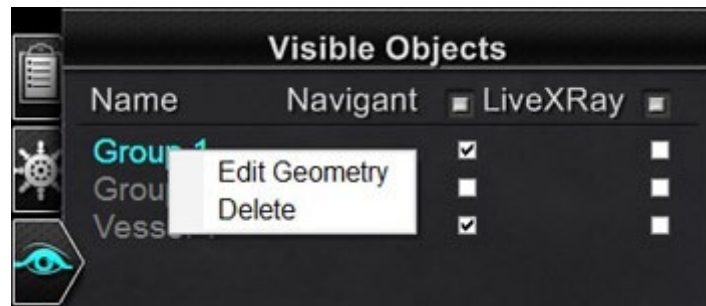


Figure 22. Edit Geometry and Delete

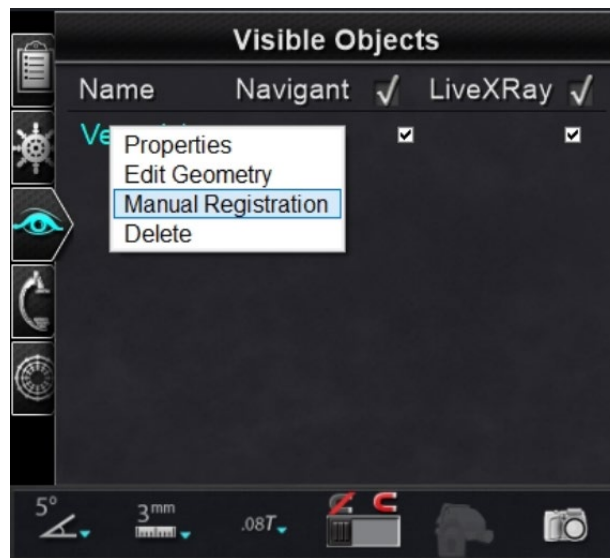


Figure 23. Right-click menu for Vessels

Vessel Properties

In the Visible Objects Vessel right-click menu., click **Properties**. The Vessel Properties dialog displays (**Figure 24**) where **Name**, **Opacity**, **Diameter**, and **Color** can be changed. The existing name is highlighted by default, but the user can type a new name. The opacity falls within a range of 0 to 100 percent, use the arrows to find the desired number. The diameter range is 1 to 12mm, click the drop-down arrow to select the preferred number. Click the existing color to display a color palette where the preferred color can be selected. The **Apply changes to branches** checkbox is only clickable if vessel branches exist. Once all selections have been made, click **Save** to save the changes or **Cancel** to close the dialog without saving changes.

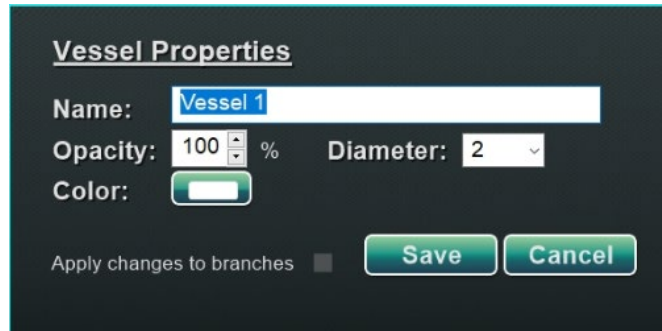


Figure 24. Vessel Properties dialog

Manual Vessel Registration

In the Visible Objects control panel, right-click **Vessel** and select **Manual Registration**. The Vessel Registration dialog displays (Figure 25). **Load Fluoro** or **Transfer Fluoro** images A and B into the respective windows. (The icons are emphasized by red rectangles in the figure below.)

Select a vessel. Click and drag the vessel in any direction (except rotational). Dragging the image in one fluoro causes the image in the second fluoro to move in tandem. After manipulating the vessel, click **Accept** to save changes, or **Cancel** to close the dialog.

This feature can be used if the user has extracted a vessel from a volume or marked a vessel that does not match the current fluoro images. This feature can move vessel images for viewing the position of a guidewire.



Figure 25. Vessel Registration dialog



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

Mapping Colors and Mapping Tags

The items **Mapping Colors** and **Mapping Tags** may be checked or unchecked in the *Navigant* column on the Visible Objects panel once mapping registration is set up. Two display options can be seen below (**Figure 26** and **Figure 27**) but various display options are available.



Figure 26. Mapping Colors and Mapping Tags

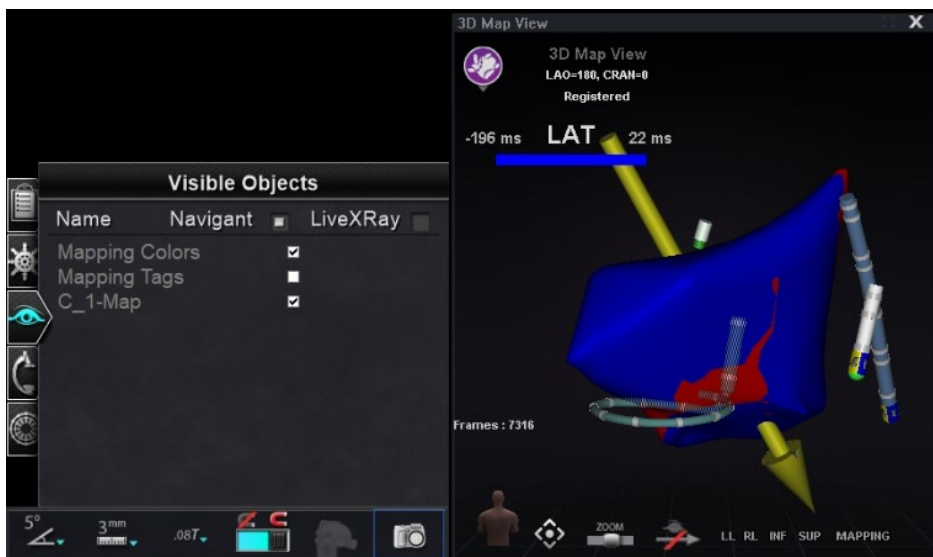


Figure 27. Mapping Colors without Mapping Tags

X-Ray Positions Control Panel

On this control panel, the user can see X-ray positions once the connection to an X-ray system has been established. The X-ray systems may not display all positions. See the table below for system specifics.

Table 2. X-ray Positions control panel

| System | X-ray positions |
|-----------------------|--|
| <p>Model S</p> |  |
| <p>Siemens</p> |  |
| <p>Philips</p> |  <p>Note: Philips X-ray systems are only available in labs with <i>Niobe</i>.</p> |

Bullseye Targeting Control Panel

The Bullseye™ Targeting control panel (Figure 28) provides a simple interface for navigating the catheter around a central point. The Stereotaxis *Bullseye* uses the “bull’s eye” targeting control panel to facilitate and display directional movement of the vector relative to the currently applied vector (or central axis). Movements around the central axis are made by using the play button within the *Bullseye* control panel. You may also double-click directly within the *Bullseye* field to move the vector to a desired location. *Bullseye* movement is visible within the *Bullseye* targeting control panel or by observing the vector movement in the Ideal Anatomy window or 3D Map window.



Figure 28. *Bullseye* Targeting control panel

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: red, blue, purple, and turquoise. As previously noted, navigation with *Bullseye* Targeting can occur in two ways:

- Double-click on the *Bullseye* field to indicate the desired 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 the user double-clicks the *Bullseye* red marker, the vectors will move in the direction of the red marker. Double-clicking between colors allows the vectors to move toward the position that is between those two colors. With automatic play, the user 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.

In this radial configuration (**Figure 29**), the yellow vector is moving toward the green vector pointed toward the bottom right. The vectors follow the *Bullseye* guidance by moving to a point between the blue and purple markers.

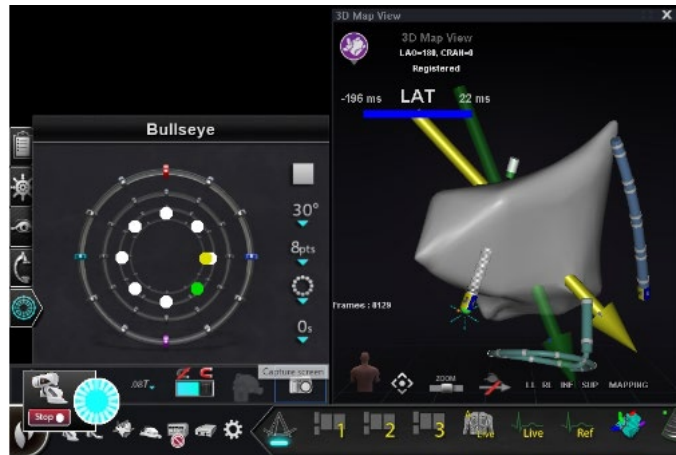



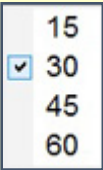
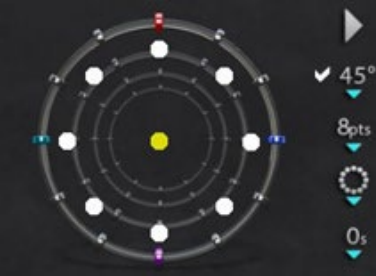

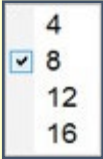
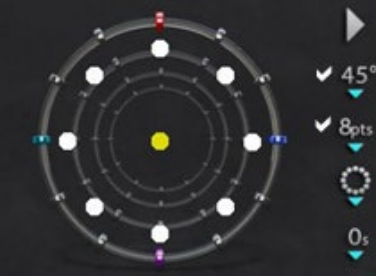

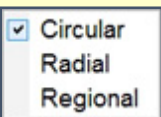
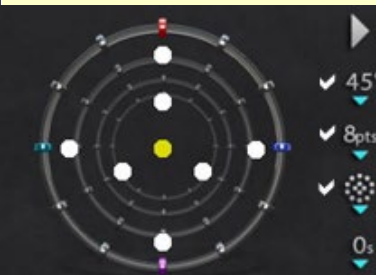

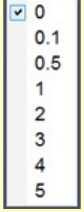

Figure 29. Bullseye Target and vector markers aid navigation

Altering *Bullseye* Targeting

The *Bullseye* Target is the canvas where the center axis and points are depicted. The buttons on the right control variations in point appearance and movements on the target. **Table 3** details the default settings and shows changes as menu options are applied. White checkmark(s) have been added to show what feature(s) changed on each image.

Note: The **Play/Stop** button starts and stops automatic catheter movement in a defined pattern. This button is a toggle that displays future action, not current activity.

Table 3. Bullseye Targeting Settings

| Button | Icon | Default setting | Explanation |
|--------------|---|---|---|
| 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. |
| Points |  |  |  Controls the number of points displayed. |
| Pattern |  |  |  Controls the pattern of points: circular, radial, or regional. |
| Pause length |  |  | Controls the duration of pauses between catheter movement during automation.  Note: The <i>Bullseye</i> Targeting automation is performed in continuous motion mode by retaining "0" for the pause length. |

Bullseye Targeting Automation

After specifying the desired settings, click the **Play** button to start automatic navigation. The automation indicator displays with a “spinner.” The user can click **Stop** at any time the button in this dialog to halt automation (**Figure 30**). Selecting **Stop** will stop **all automation**, not just *Bullseye* Targeting automation.

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 targeted direction, and the yellow dot follows (**Figure 30** and **Figure 31**).



Figure 30. Automation dialog

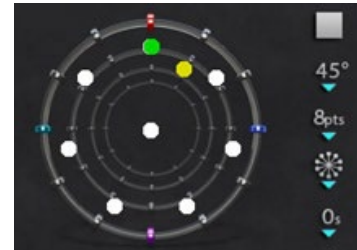


Figure 31. Radial pattern

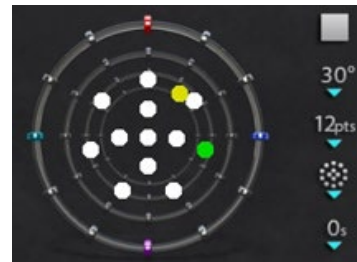


Figure 32. Regional pattern

Movements vary according to the selected pattern:

- If the user accepts the default circular pattern, the dots move clockwise in a circle.
- If the user selects the radial pattern, 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 32**) the dots tend to move around an outer circle first, followed by an inner circle. When selecting the regional pattern, increase the number of points displayed to get a more consistent pattern.

Bullseye Targeting Audio

If the audio is turned on, the user will hear a *ping* each time the yellow dot reaches the target (green dot). The user can turn off the sound by going to System options icon → Settings → System → Audio Settings → Play sounds on field apply: *Never* (**Figure 33**). The slide bars for adjusting the volume for the Procedure and Control rooms are just above the drop-down menu.

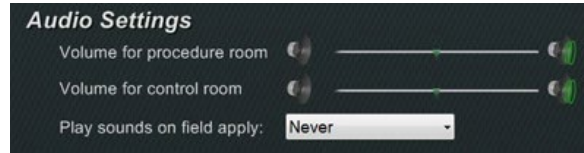


Figure 33. Audio Settings

Storing Points in Bullseye Targeting

In addition, when the yellow dot reaches a target, the **Store** button is enabled on the Navigations panel. Click it to store the current field direction – or press the **Store Navigation** button on the keypad. By adjusting the speed of movement, the user has more time to click the **Store** button while it is enabled. This is helpful because 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 display functional buttons and information about the system.

Main Toolbar

The Main toolbar (**Figure 34**) is the first of two toolbars on the dashboard. **Table 4** details the settings and features found on the Main toolbar.

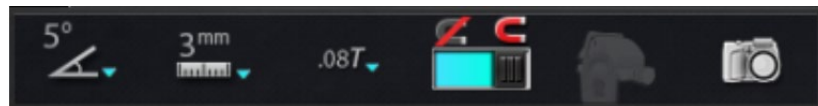
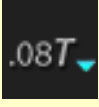






Figure 34. Main toolbar

Table 4. Main toolbar settings

| Setting | Icon | Function |
|---------------------------------|------|---|
| Global Angular Step Size | | Displays a menu of angles by degree. 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. |
| Global Step Size | | Displays a menu of step size parameters from 1 to 9 mm for the <i>Cardiodrive</i> device. The default is 3 mm. |

| Setting | Icon | Function |
|--------------------------------|---|--|
| Magnetic field strength |  | Displays the magnetic field strength for the current procedure and allows users to change the magnetic field strength. The default is 0.08T. |
| Apply magnetic field |  | Allows user to restore the magnetic field strength to the previous strength. The button is disabled if the software is not connected to the Stereotaxis RMNS. |
| Reduce magnetic field |  | Allows user to decrease the magnetic pull on the catheter or guidewire. Following are instances where the user might want to reduce the magnetic field: <ul style="list-style-type: none"> • 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 |
| Access protection |  | Indicates the status of Access protection as <i>disabled</i> , <i>locked</i> , and <i>unlocked</i> . The icon in this example is unlocked. See Figure 78 for more details about this feature. |
| Screen capture |  | Allows user to capture the entire screen and store it in 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. |

The main toolbar appears as shown in **Figure 35** when no device is selected. The buttons for Magnetic Field and Access Protection are disabled.



Figure 35. Main toolbar display— no device selected


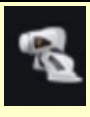

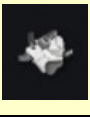



Hardware Status Toolbar

The hardware status toolbar (**Figure 36**) displays several icons, depending on connected devices. Each icon functions as a button and status indicator. The icons indicate one of three states: **good** (*clear icon*), **information** (*icon plus gold triangle*), and **not connected** (*icon plus the “no” symbol*). **Table 5** details the features found on the Hardware status toolbar.



Figure 36. Hardware status toolbar

Table 5. Hardware status toolbar settings

| Setting | Icon | Function |
|------------------------------|---|--|
| Systems options |  | Displays the System options menu. See “Systems Options” section several pages below for menu options. |
| RMNS |  | Indicates connection status of Stereotaxis RMNS. |
| X-ray status |  | Indicates connection status of X-ray / fluoro system. |
| Mapping system status |  | Indicates connection status of mapping system. |
| Cardiodrive status |  | Indicates connection status of <i>Cardiodrive</i> system. |
| Stockert generator |  | Indicates connection status of the ablation generator. |
| System status |  | Indicates the status of <i>Navigant</i> . If outside a procedure, this icon offers connection status messages regarding the mapping system, <i>Cardiodrive</i> , and ablationstockert generator. |

Status Messages

Following are the three ways to view hardware status messages:

ToolTips (Figure 37): Hold the cursor over the button to view the ToolTip status message summary.

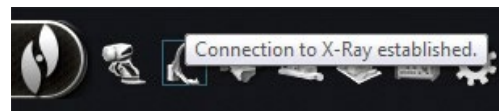


Figure 37. ToolTip status message

Popup messages (Figure 38): *Navigant* displays messages when necessary. They pop up from the hardware icon that represents the affected system.



Figure 38. Popup window message

Dialogs (Figure 39): 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 39. CARTO 3 dialog messages

System Options Menu

Access the System options menu by clicking the **System options** button (far left) on the hardware status toolbar. Several options display (Figure 40).

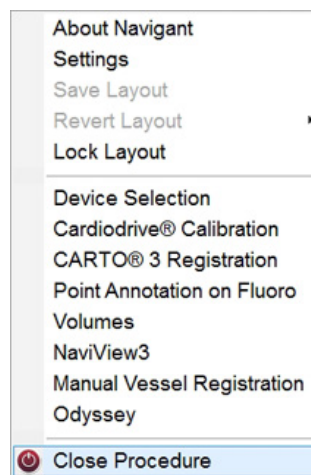


Figure 40. System options menu

The *About Navigant* dialog (Figure 41) displays information about the software, such as name, company name, version number, and copyright. Access it from the **System options** button on the hardware status toolbar.



Figure 41. About *Navigant* dialog

Layout Editor

The Layout Editor (**Figure 42**) allows the user to customize the procedure layout displayed. The following section details how to manipulate layouts.



Figure 42. Layout Editor



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

Move

Move a window or control panel by pressing and dragging anywhere in the element except the **X** in the red circle (upper-right corner). When the user selects an element, a bright blue border displays around it. When the element is dragged to a position where it overlaps another element, the border of both the selected element and the overlapped element turn bright red (**Figure 43**). A layout cannot be saved when elements overlap.




Figure 43. Left: Control panel selected; Right: Overlapping control panels

Note: Because Clinical Workflow Manager is in a static position in *Navigant*, the user 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. Press and drag the edge as desired. If the user resizes the element so it overlaps another, the border turns red. A layout cannot be saved when elements overlap.

Close

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

Layout Editor Control Panel

Layout Editor Settings

- **Nav Windows** button. Displays a list of available and displayed *Navigant* windows.
- **Nav Controls** 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 user to copy a layout from another user for the same layout.

Notes:

- A window or control panel (e.g., Live Fluoro A) may not be repeated within a 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. (Overlapping elements are indicated by a red border.) If an existing layout is preferred, click the **Load From** button.

Load From Dialog

To import this layout from a different physician, use the Load From dialog. 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**.
- Once 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 displays.
- Click **For This Procedure Only** to use the layout for *only* the current procedure.
- Click **As My New Default** to use the layout for *future* procedures (saved for specific *physician* and *procedure type*).

Settings Dialog

The Settings dialog contains four tabs (an additional one or two tabs will display if an *Odyssey Vision* system is connected). Each tab allows the user to control various *Navigant* elements:

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

Navigant Window Tab

Settings in the *Navigant* Window tab (**Figure 44**) 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 the user to control various *Navigant* elements. In the **Please select window**, the user can select the desired window from those displayed. After which, the user can adjust settings (**Figure 44**).

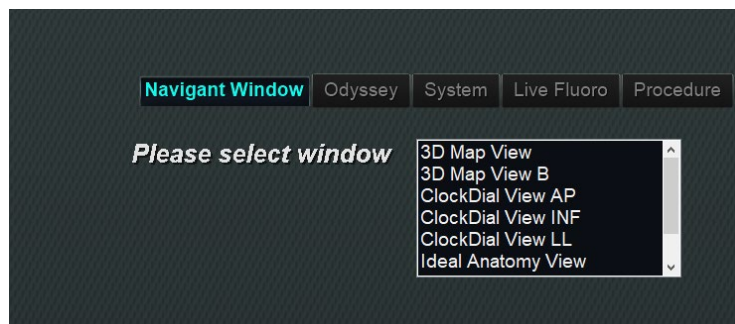


Figure 44. Settings windows – *Navigant* tab

In **Figure 45** , 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. Alternatively, when any other window is selected such as Ideal Anatomy View, fluoro (X-ray) items will display. Upon registration to a mapping system, mapping system data will display.

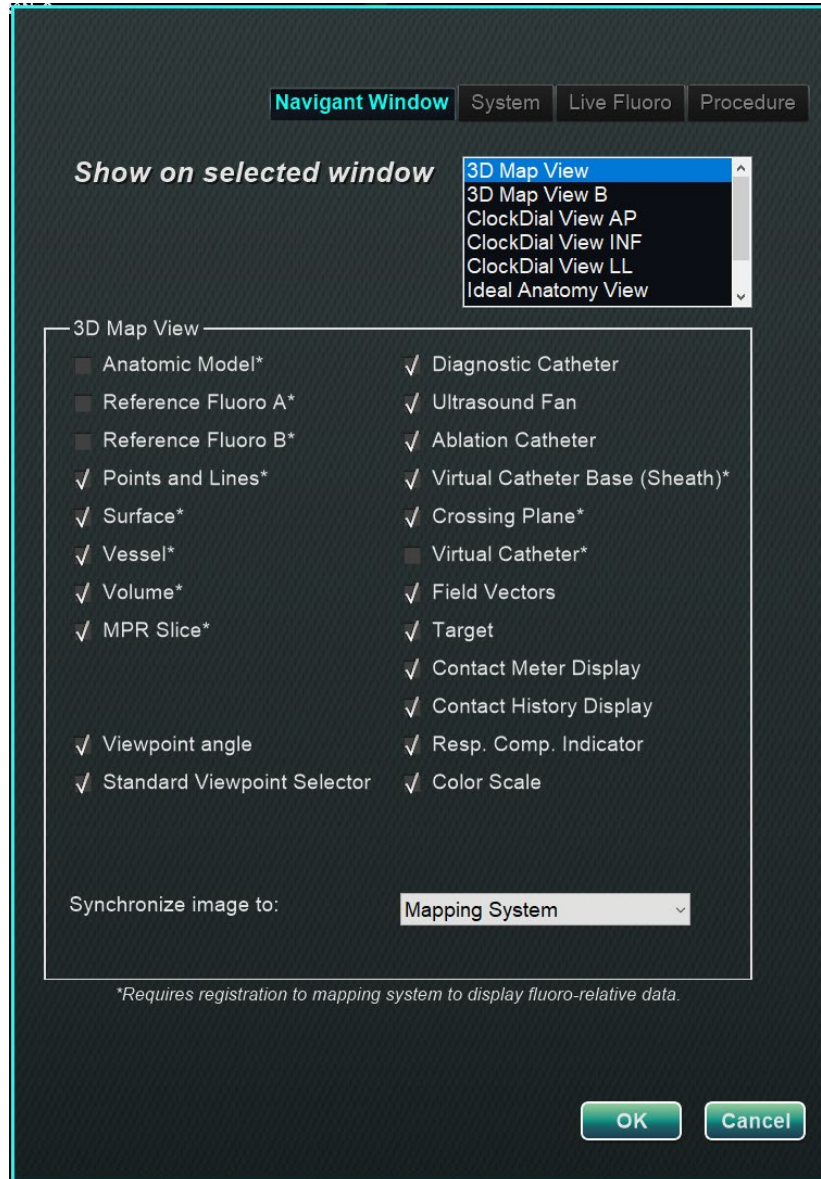


Figure 45. Navigant Window Settings

Navigant Window Tab Guide

Selected Window Viewing Options

Users can select items they wish to view; selected items display a ✓. The 3D Map View window example in **Figure 45** shows typical selections for the 3D Map View window.

“Synchronize image to” Drop-Down Menu

The selection menu for image synchronization. Options include **C-Arm**, **Fluoro A**, **Fluoro B**, **Mapping System**, **System**, or **None**.

OK / Cancel

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

System Tab

Settings on the System tab (**Figure 46**) are saved by the physician and can be manipulated. Below **Figure 46**, General, NaviLine™, Audio, and Ablation History settings are further explained.

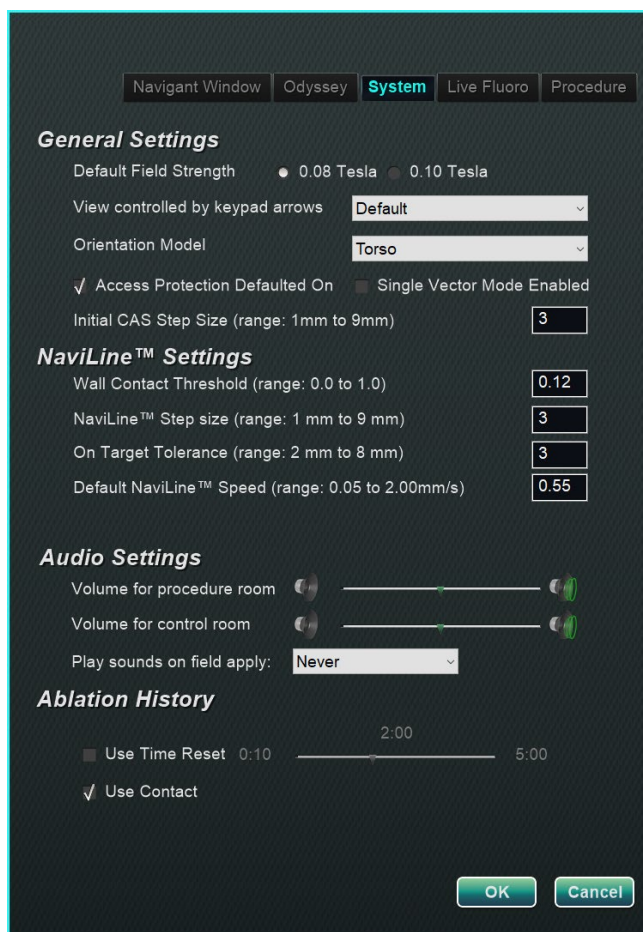


Figure 46. Settings windows – System tab

General Settings

- **Default Field Strength.** Magnetic field 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 options that display among the Window Controls icons: Torso, Heart, and Chamber. The selection represents the desired anatomic model for the specific workflow; remains the default until changed.
- **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 to turn off Access Protection for the next procedure.
- **Single Vector Mode Enabled.** The default is unchecked, or *disabled*. Check the box to use Single Vector Mode which will enable for the current procedure and save the setting for future procedures until it is unchecked.
- **Initial CAS Step Size** (range: 1mm to 9mm). The default is 3mm. 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 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: 0.05 to 2.00mm/s). The starting, or default, speed is the speed of the automated movement along a *NaviLine*.

Audio Settings

- **Volume for procedure room.** Volume level for *Navigant* sounds in procedure room.
- **Volume for control room.** Volume level for *Navigant* sounds in 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 the area has rested for time specified.



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

Live Fluoro Tab

On the **Live Fluoro** tab (Figure 47) the user can adjust the display of graphics on the Fluoro windows. Settings on the Live Fluoro tab are saved by physician.

Live Fluoro Settings

- **Show Graphic On Monitor.** This item refers to the X-ray live monitor. Select to display graphics on Live X-ray, the Last Image Hold, or both.
- **Show Graphic Type.** This item also refers to the X-ray live monitor. Select the graphic images to display on the X-ray screen. Choices are Points and Lines, Vessels, Virtual Catheter, Target Circle, Magnetic Field Vector, and Navigation Status.
- **OK/Cancel.** Click **OK** to accept the changes or **Cancel** to close the window without saving changes.

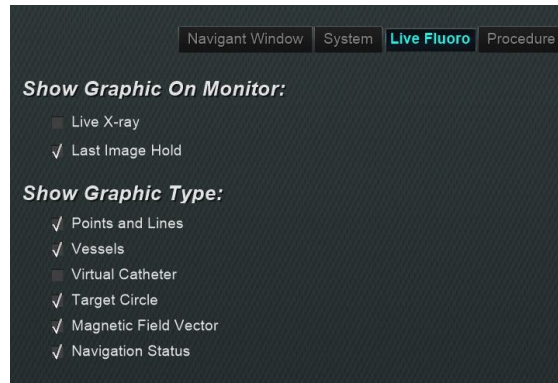


Figure 47. Settings windows – Live Fluoro tab

Procedure Tab

The **Procedure** tab (Figure 48) displays procedure information and reflects information previously entered. The following may be edited here: patient name and notes, procedure type and anatomy, the selection of a mapping system, and the use of RMN if the procedure utilizes a compatible magnet system. Start time or Physician name cannot be changed on the Procedure tab.

Procedure Settings

- Patient name.
- **Notes.** Special information about the case or procedure.
- **Procedure type and anatomy.** Click the desired tab and select anatomy.
- **Electrophysiology, Coronary, or CRT.** To select anatomy type, click the desired icon.
- **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.

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

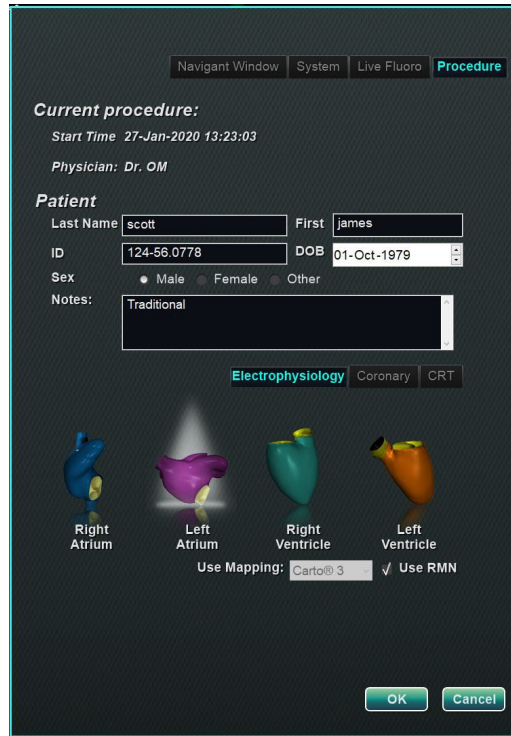


Figure 48. Settings windows – Procedure tab

Navigant Windows

The number, type, and layout of windows changes by procedure type and workflow step. Each procedure opens to a default layout that can be changed. Following are available windows:

| Electrophysiology: Left and Right Atrium & Left and Right Ventricle | Interventional Cardiology: Coronary |
|--|--|
| 3D Map View 3D Map View B ClockDial View AP ClockDial View INF ClockDial View LL Fluoro A View Fluoro B View Ideal Anatomy View Ablation History Graph | 3D Vessel View 3D Vessel View B ClockDial Sync C-ARM ClockDial View AP ClockDial View INF ClockDial View LL Endoluminal View MPR Slice 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 is present at the bottom of the window and displays controls for that window. The number of buttons the Window Controls (Figure 49) displays depends on the window type.



Figure 49. Window Controls example from Fluoro window

Table 6. Window Controls buttons

| Button | Description | Icon |
|------------------------------------|---|------|
| Anatomic orientation model | <p>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.</p> <p>Dynamic model: The dynamic anatomic model on the Window Controls displays the anatomic position of the window’s image and is rotatable.</p> | |
| Pan/Fit to view control | <p>Press and drag anywhere on the pan control to move the window’s image anywhere on the screen.</p> <p>Double-click the control to center the image in the window and restore it to its default size.</p> | |
| Zoom control | <p>Single-click on the right or left side of the slider to increase or decrease the zoom level accordingly or click-an-drag to the right or left to continuously change zoom level.</p> | |
| Transfer Fluoro | <p>Click to transfer a fluoro image to the Fluoro Image windows A and B. This icon flashes (between the current state and a negative of the image) as the fluoro image is being transferred.</p> | |
| Load Fluoro | <p>Click 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).</p> | |
| Brightness/contrast control | <p>Brightness: Press and drag up to increase the brightness of the window’s image and down to decrease it.</p> | |

| Button | Description | Icon |
|------------------------------|---|---|
| | <p>Contrast: Press and drag to the left to decrease the contrast of the window's image and to the right to increase it.</p> <p>Double-click to reset to the original brightness and contrast.</p> | |
| Vector Show/Hide mode | <p>Click to show or hide the vector(s) on the screen. If the solid yellow arrow is showing, the vector(s) have been hidden. If the gray arrow crossed by a red line is showing, the vectors are displayed. These buttons are available only in 3D Map and Fluoro windows.</p> |  |

 **Note:** The ClockDial windows in IC procedures do not have Window Controls.

Window Swap Feature

Within the *Navigant* windows, displays may be swapped by using the drop-down menu from the window-identifier icon (**Figure 50**):



3D Map



Ideal Anatomy




Nav Fluoro A



Nav Fluoro B

Figure 50. Window-identifier icon samples

 **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 represent current and target directions. Mouse control of the target vector causes the current vector to follow. When the current vector (yellow) catches up to the target vector (green), the green vector disappears. The vectors' visibility and behavior are the same in both the *Navigant* and mapping systems. **Single-vector mode** shows only the target field vector and colors it yellow while hiding the current vector (except for a few instances).

Vector Lock

While working in a procedure, the user may enable **Vector Lock** mode by selecting the desired, or target field vector (green) and locking it to the mouse movements (**Figure 51**). To enable this mode, press and hold the **Ctrl** button and left mouse click 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, left-click anywhere in the window other than on the target vector or model or move the mouse out of the window and left-click. This feature has an automatic timeout that occurs after 10 seconds of not moving the vector or the *Cardiodrive* device using the mouse.

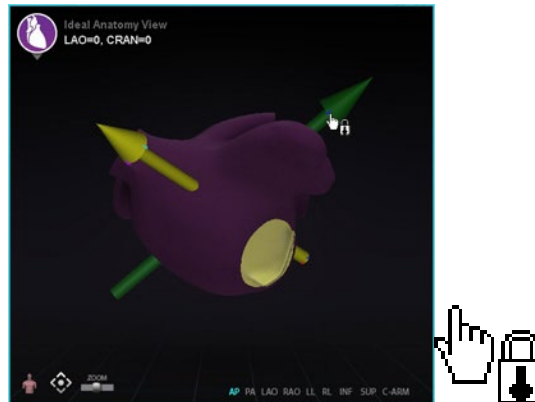


Figure 51. Left: Vector Lock enabled; Right: Vector Lock icon

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 52) and the target moves whenever the mouse moves and intersects with the volume.

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

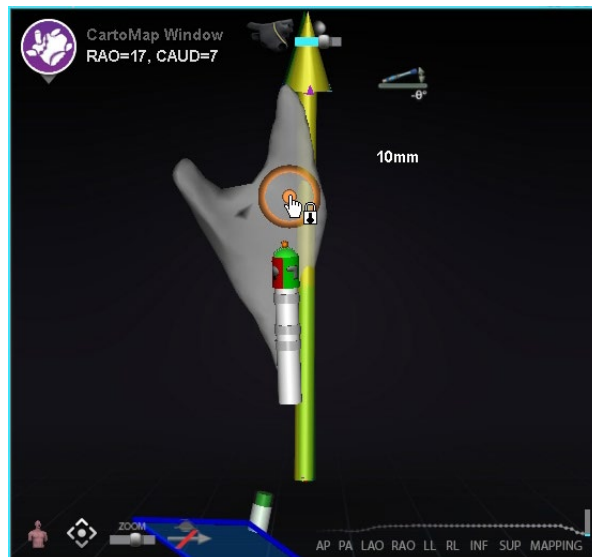


Figure 52. Target Lock (*lock icon is present*)

Magnetic Torque Meter

A Magnetic Torque Meter Trace (emphasized by a red rectangle) is pictured below (**Figure 53**). 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.

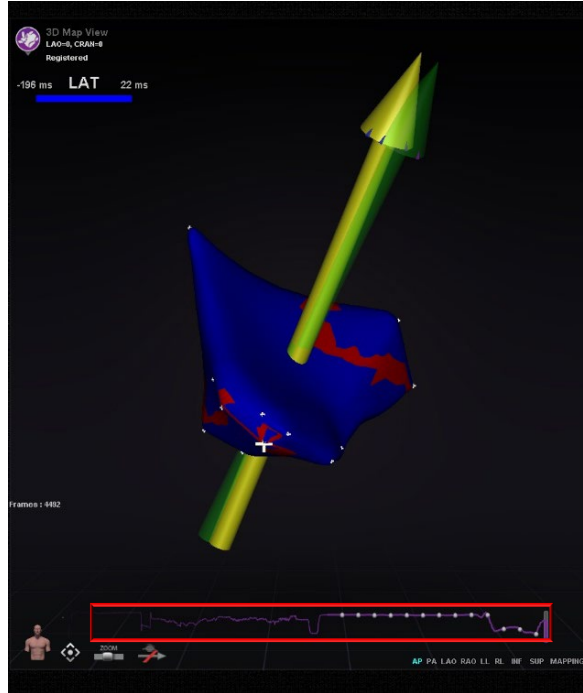


Figure 53. Magnetic Torque Meter Trace

Import Surface Object

3D models created by other programs can be imported into *Navigant* as surfaces and must be in VTK format. To import a 3D surface, click on the **Navigant Start Menu** button and select **Import Surface Objects**. Press **Browse** to navigate to the directory containing the surface data. The available VTK files will be listed on the right. Press **OK**.

Mark the checkboxes next to the desired surface objects or **Select All** / **Deselect All** to make selections. After successfully loading, the surface(s) displays in the preview area and a **Loaded** status appears next to each surface (**Figure 54**). Only actively selected surfaces are shown in the preview area. The status column will display **Error** if *Navigant* could not import the surface.

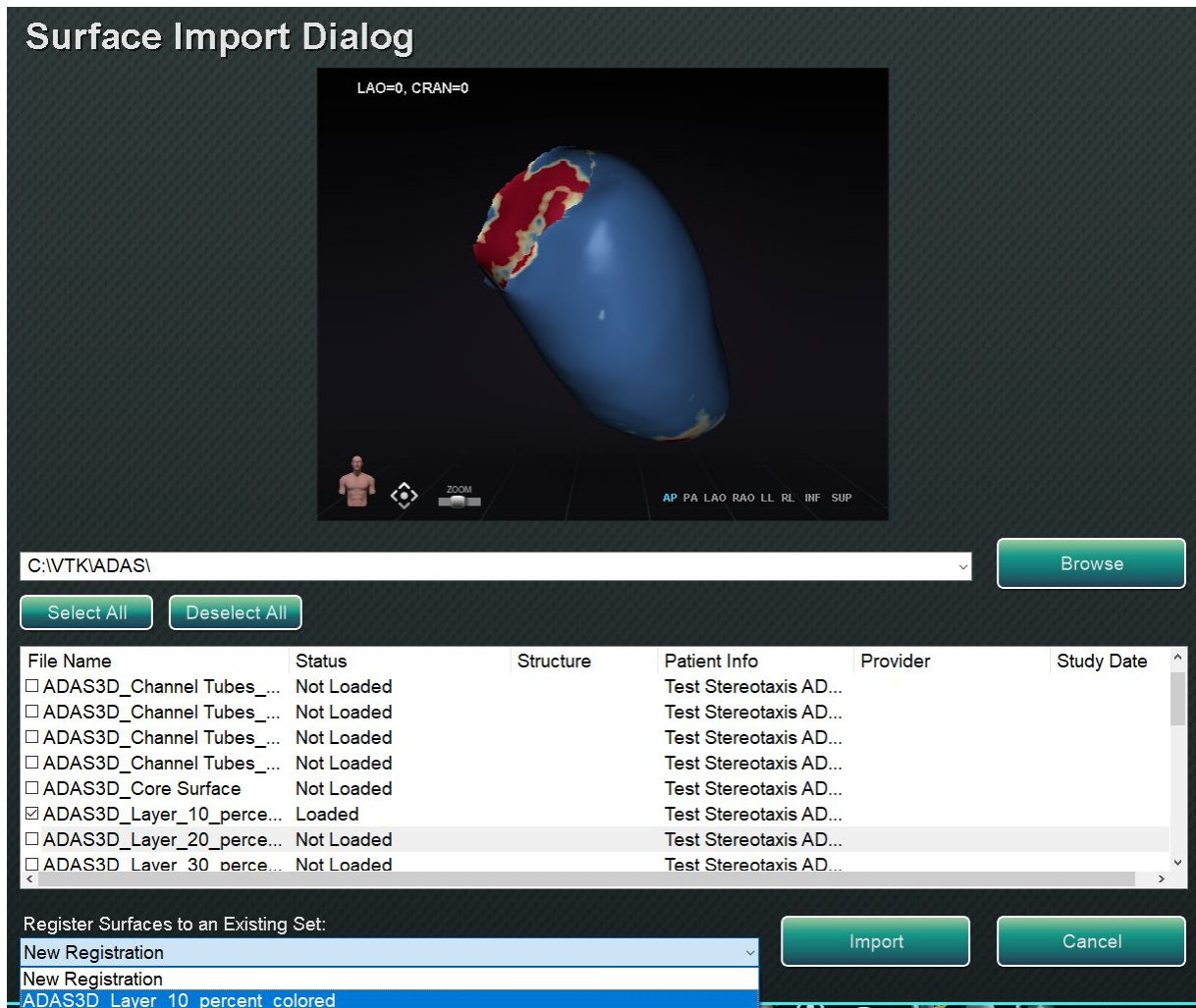


Figure 54. Imported Surface Shown in Preview Window

Using the dropdown menu (**Figure 55**), surfaces are imported as a new *registration set* or are added to an already existing set of imported surfaces.

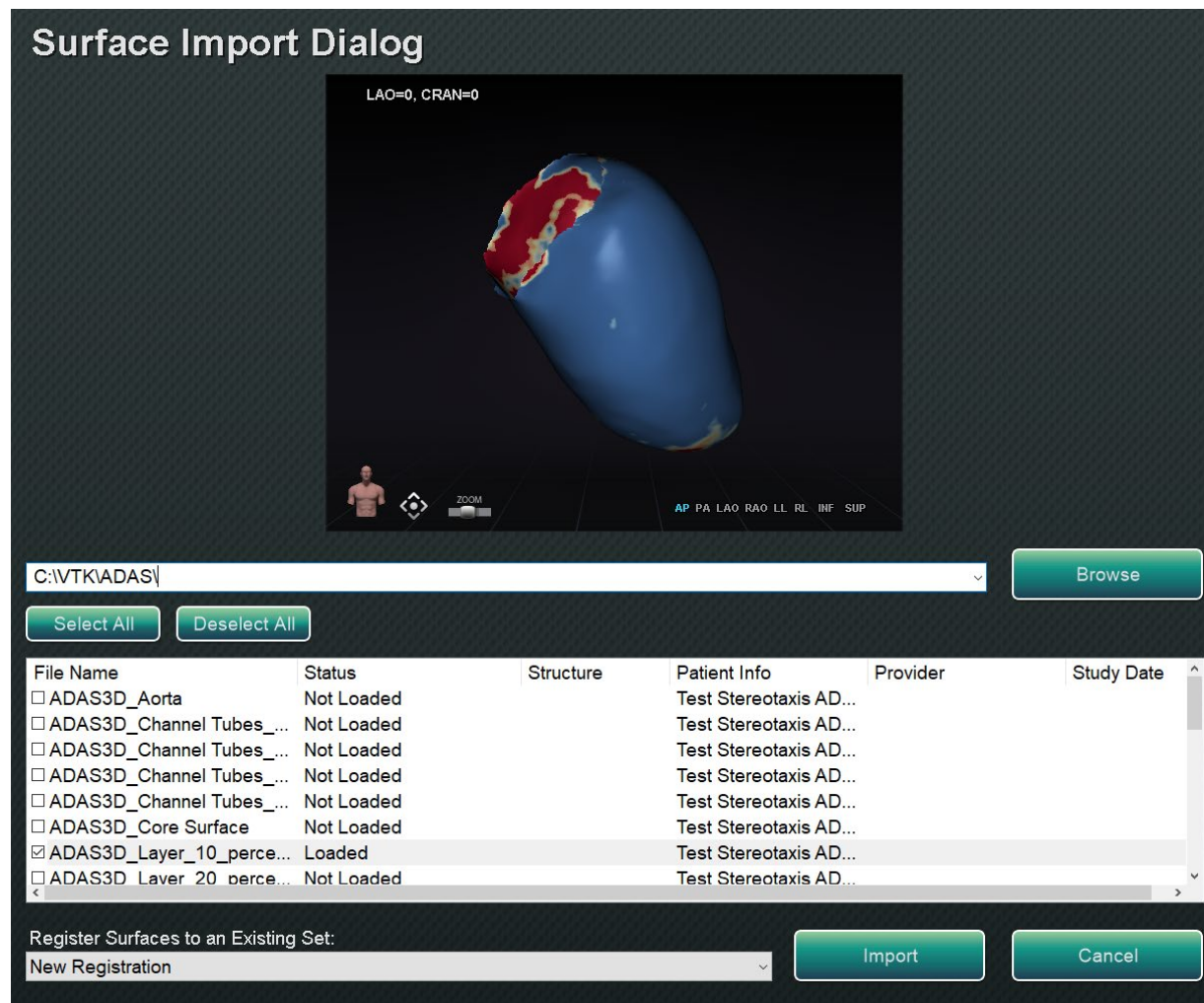


Figure 55. Register Surfaces

After surfaces are loaded, press **Import** to bring the surfaces into *Navigant* for use. Once imported, the 3D surface(s) can be adjusted to align with other objects in the 3D window. All objects imported together are manipulated as a group or *registration set*. To display the position controls (emphasized in **Figure 56**), click on a surface of the imported object(s).

Once displayed, click the desired controls, and move the mouse to change the surface orientation and position. The surface controls are **Edit NaviLine Mode**, **Surface Transparency**, **Pan**, and **Rotate**. These controls offer usability features and assist the user in aligning the imported surface(s) with other 3D objects. See **Table 7** below for more details.

Table 7. Surface Controls

| Control | Function |
|----------------------------------|---|
| Edit <i>NaviLine</i> Mode | Provides a toolbox with features to create and edit a <i>NaviLine</i> such as New Line, Remove Line, Open/Close, Color, and Measure |
| Surface Transparency | Adjusts transparency of the imported surface(s) |
| Pan | Moves the object laterally |
| Rotate | Rotates the 3D surface relative to the other objects in the 3D window |

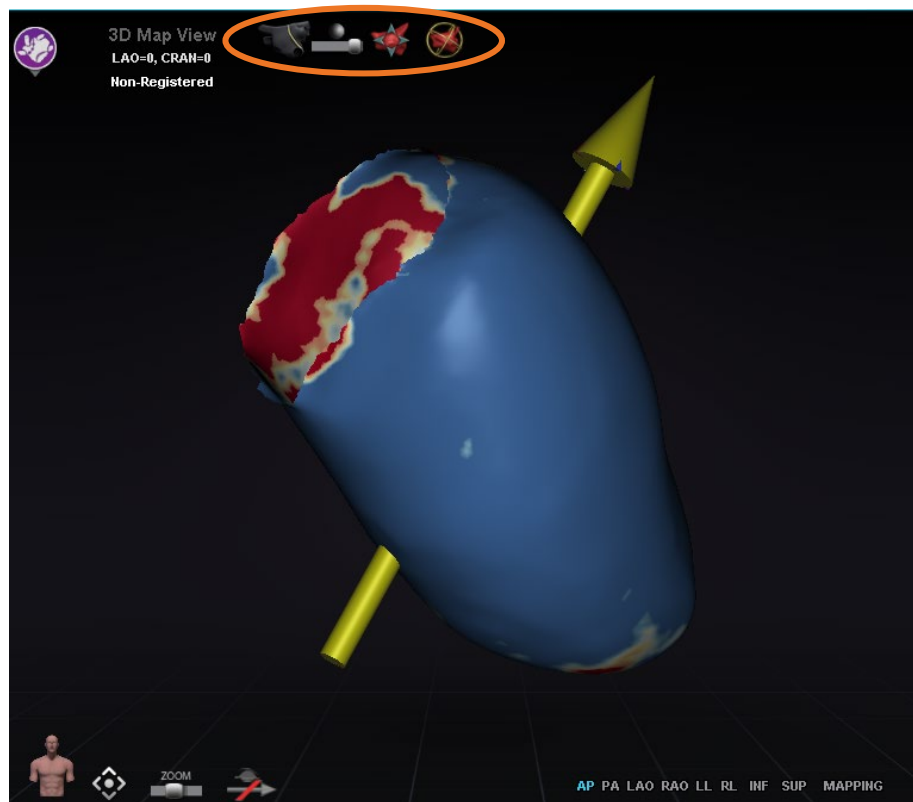


Figure 56. Controls for adjusting surfaces

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, NaviLine, mapping data overlaid in Fluoro A/B windows, and fluoroscopically localized objects in 3D map windows will be unavailable until 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* can register 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 57). During an unregistered state, this label will read **Non-Registered**.

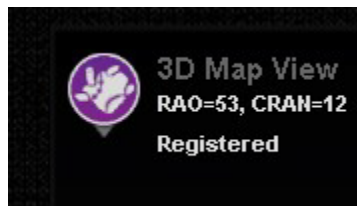


Figure 57. Registered Label

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.

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 60**). 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 58**). The icon is located on the *Navigant* toolbar (**Figure 59**).




Figure 58. Access Protection states



Figure 59. Access Protection status icon on toolbar

Crossing Plane

The crossing plane graphic is a 3D rectangle displayed 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. The software may 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 (emphasized in **Figure 60**) both flash red.



Figure 60. Retraction limit indicators

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; once the table is at the correct height, the dot will display blue (Figure 61). Table height adjustment can be made at any time by selecting the *Registration to Mapping* step on the CWM.

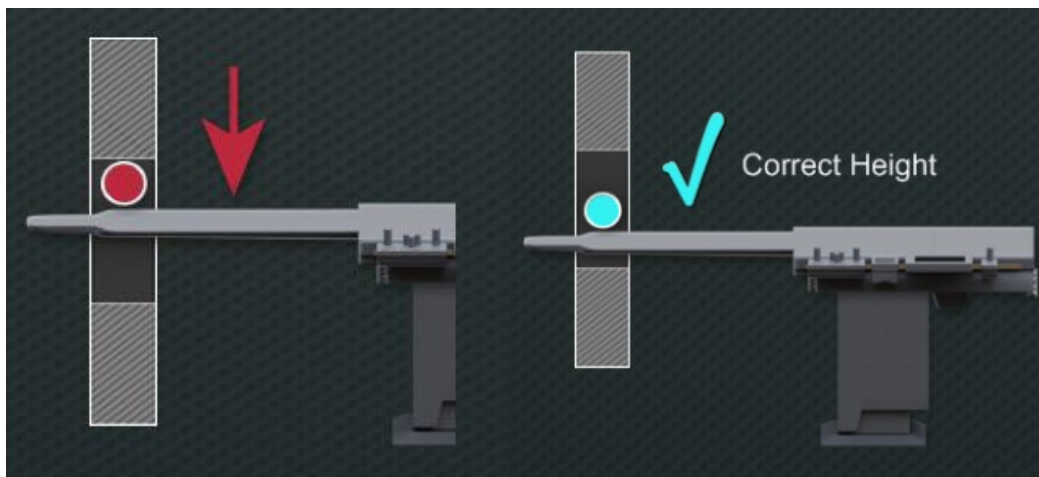


Figure 61. Left: Table Height Adjustment Needed; Right: Correct Table Height

Isocentering without Integrated Mapping

Without mapping integration, the software does not know where the region of interest is in relation to isocenter. It will be necessary to isocenter manually if using a non-integrated mapping system.

1. Pan the table to get the region of interest in the center of the AP fluoro view.
2. Move the C-arm to LAO or RAO position; you may also use a lateral view.
3. Move **only** the **table height** up to down to bring the region of interest into the fluoro view.

This will ensure that the region of interest is within the fluoro view at all times. The table will not need to be panned during the procedure, and the catheter will navigate with consistent maximum magnetic strength as the magnet isocenter is in the same space as the fluoro isocenter.

Automation Features

AutoMap

Clicking any step on the AutoMap tab (**Figure 62**) launches automatic *CARTO 3* or compatible OpenMapping System mapping.

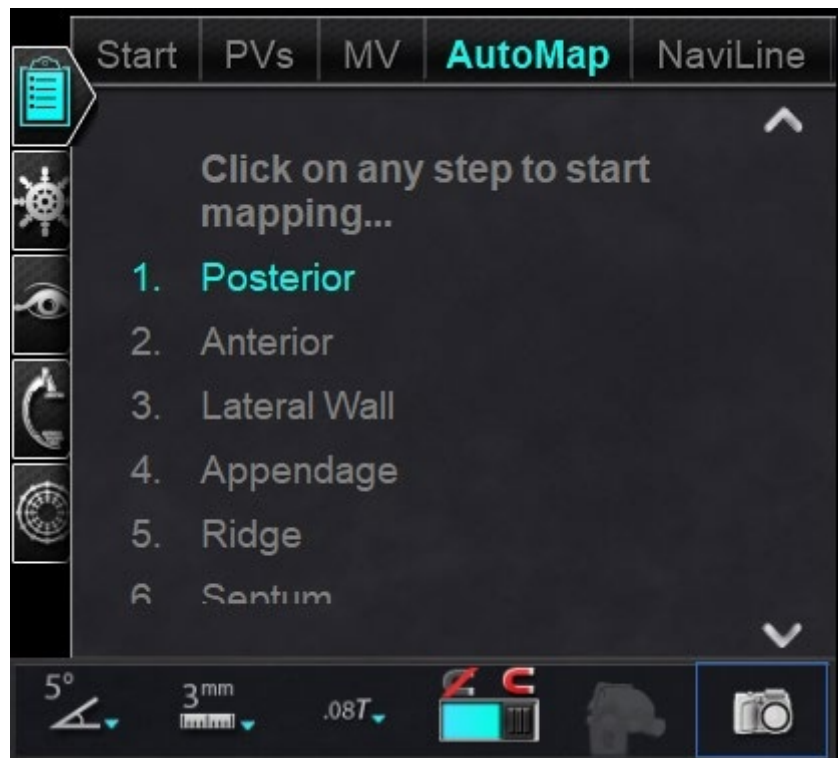


Figure 62. Automap tab on CWM



Notes for *CARTO 3* Electroanatomical (EA) System mapping:

- The *CARTO 3* System is set to automatically freeze points.
- Select **Manual** on the *CARTO 3* System to view points before freezing.
- *Navigant* allows the user 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, the user 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, and/or 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 63**). Selecting **Stop** on the automation dialog will stop *all automation*.



Figure 63. Automation dialog- Stop button

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 64**). 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.

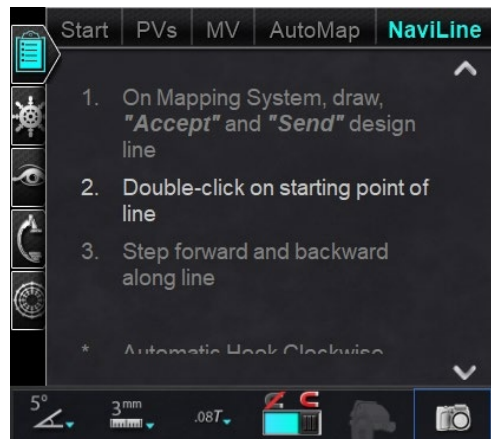


Figure 64. *NaviLine* tab on CWM

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 mouse cursor in **Figure 65**) to display the *NaviLine* toolbox. The toolbox (**Figure 66**) includes features such as New Line, Remove Line, Open/Close, Color, and Measure. These features aid in creating and editing a *NaviLine*.



Figure 65. Selecting Edit *NaviLine* Mode Button

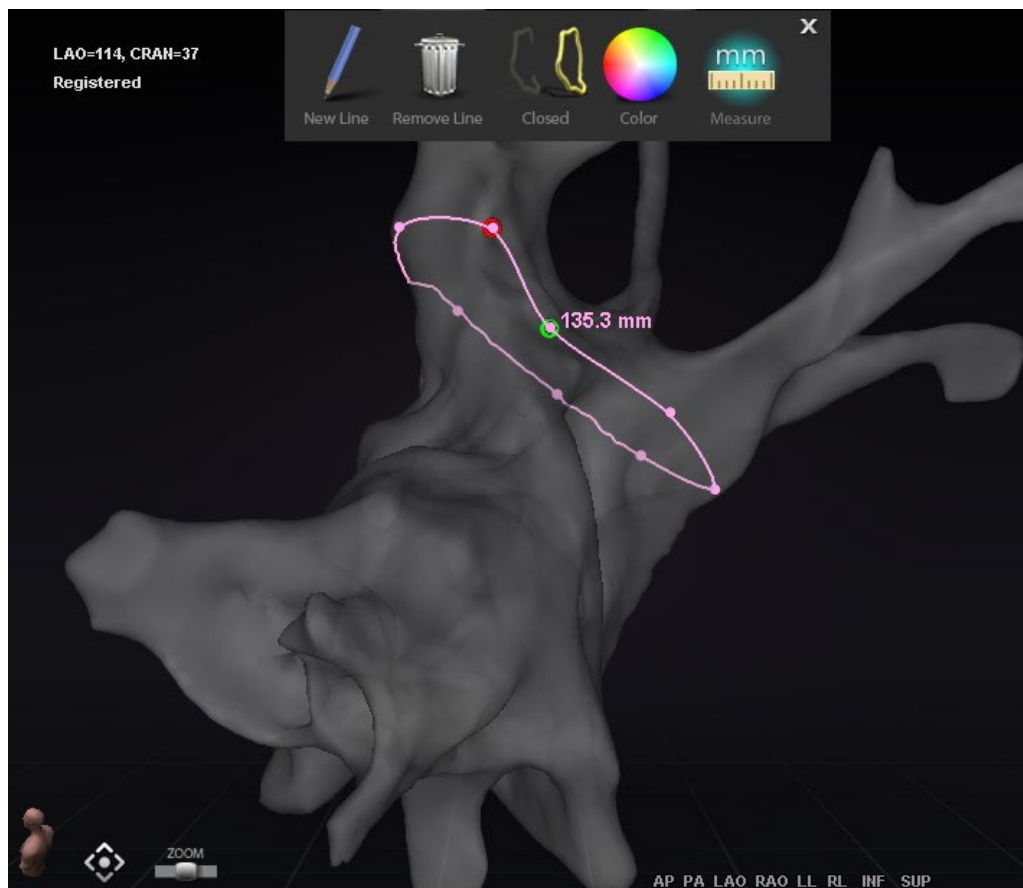


Figure 66. Edit *NaviLine* Mode- *NaviLine* toolbox

Edit NaviLine Mode is also available for Ablation Histories. The user must first select the Ablation History from the Visible Objects pane (**Figure 67**). There can be multiple Ablation Histories, so the desired Ablation History should be selected. Upon choosing an Ablation History, the user

must select **Edit NaviLine Mode** to display the *NaviLine* toolbox. A *NaviLine* can then be drawn on the selected Ablation History (**Figure 68**).



Figure 67. Visible Objects pane- Ablation History Section



Figure 68. Ablation History- NaviLine toolbox



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 69** display closed lines. In the left 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 right image, the cursor is too far from any one point to select, so the right-click menu reads **Insert Point** and **Delete Line**.

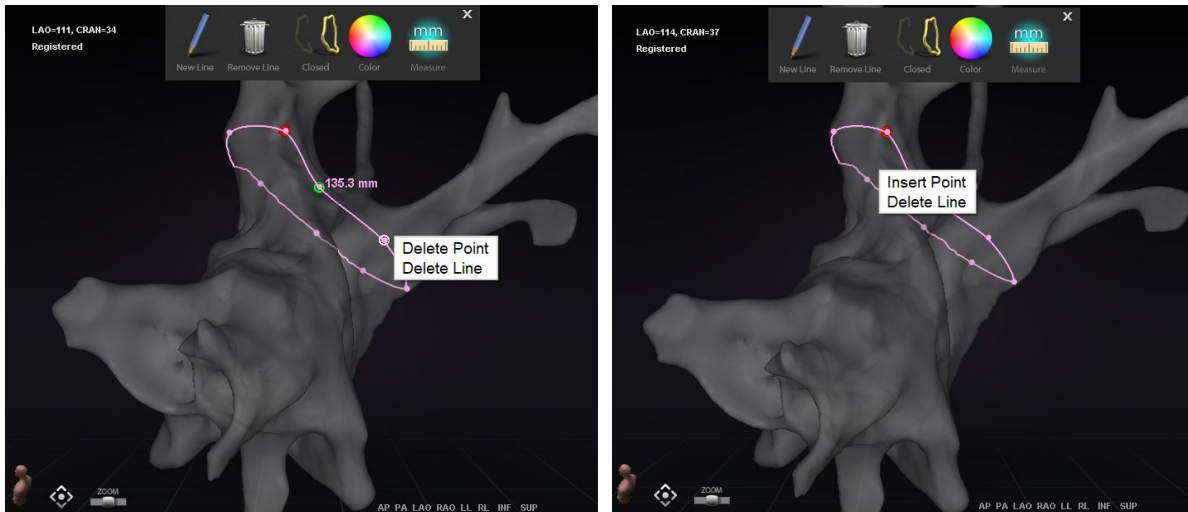


Figure 69. Edit NaviLine Mode; Right-Click Menu Options

After creating a *NaviLine*, the user can edit it by clicking the **Edit NaviLine Mode** button (Figure 70). In the figure below, the button has been selected for a line surface. The button is only available in 3D windows, not fluoro windows.

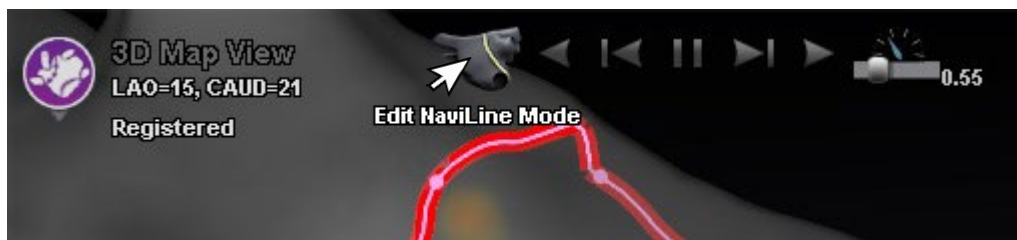


Figure 70. Edit NaviLine Mode on Surface

The **Edit NaviLine Mode** button is available for already existing Ablation History lines. After creating a line, the user can reenter the edit mode by selecting the button (Figure 71).

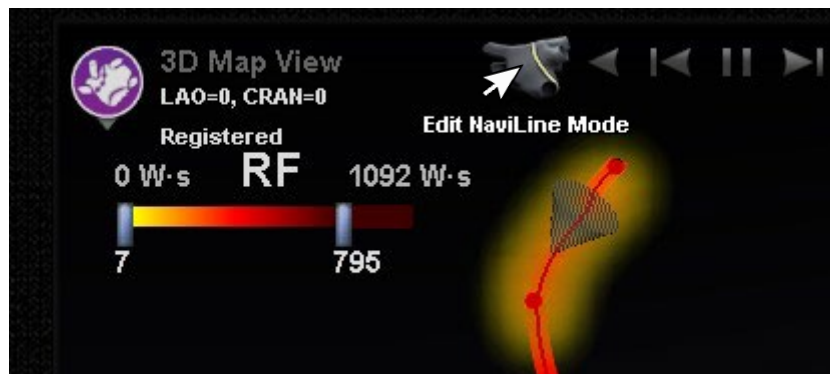


Figure 71. Edit NaviLine Mode on Ablation History line

Auto-NaviLine Feature

When the user selects a completed *NaviLine* design line, as in **Figure 72**, they will see context-sensitive controls at the top of the window. In addition, only if the system is set up so that *Auto-NaviLine* is enabled will buttons ① and ⑦ appear as shown in the following figures.

Because the target cone (**Figure 72, 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 72, right**, as the target indicator is at the end of the line and the **Forward** buttons are disabled.



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

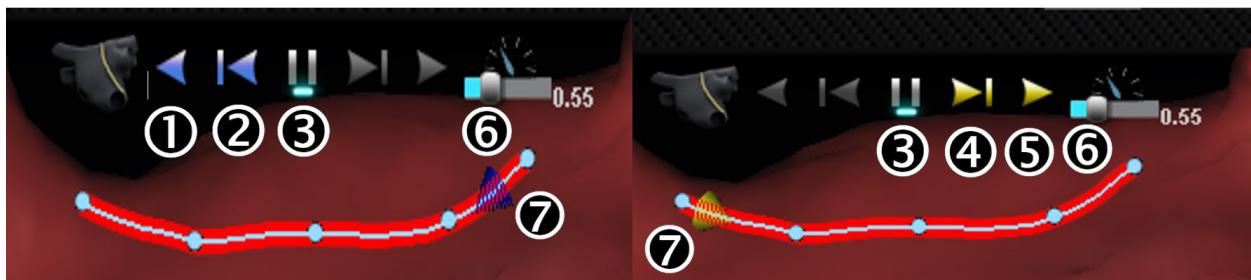


Figure 72. Target cones on NaviLine

Auto-NaviLine Tools Guide

- ① **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.
- ② **Step Backward.** Sets the target Step Size millimeters in the indicated direction.
- ③ **Pause Targeting.** Cancels current targeting automation in the same way as the **Stop** button on the Automation dialog.
- ④ **Step Forward.** Sets the target Step Size millimeters in the indicated direction.
- ⑤ **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.
- ⑥ **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.
- ⑦ **Cone.** Target indicator on NaviLine. Operates in the same manner as Step Backward and Step Forward when clicked.

In **Figure 73**, 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*. In the closed line, the Play function loops until it is canceled.

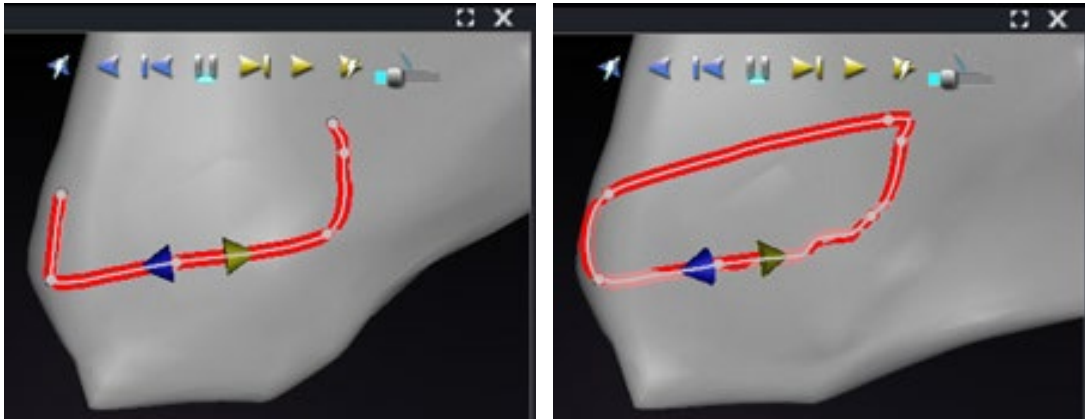


Figure 73. Auto-NaviLine cones in the middle of a line

Forward and *Backward* are set when the line is created: they are not window relative. In **Figure 74**, the camera has been rotated 180° around the line until the yellow cone is pointing left, but the direction is still “Forward.”

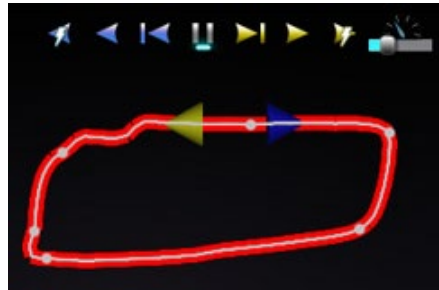


Figure 74. Auto-NaviLine cones according to camera rotation

Notice the highlighted **Play Forward on Ablate** button in **Figure 75**. It now has the blue line under it instead of the **Pause** button, indicating automated ablating at the target location.

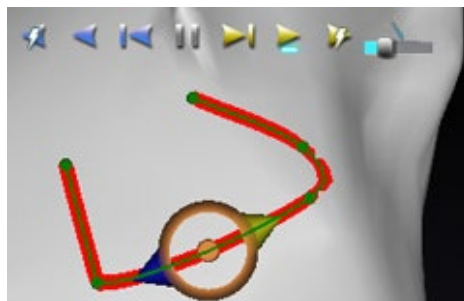


Figure 75. NaviLine with Auto-NaviLine target during Play Forward

Diagnostic Catheter Display

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

- **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 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 3* System.
- **Mapping catheters** – May be shown in different colors. While being used for ablation during an ablative procedure, the tip of the mapping catheter will be red. It is important to note that a mapping catheter cannot be stored or targeted.

Catheter Properties Dialog

During a procedure, positioning the cursor over a catheter highlights that catheter. To store a catheter, click the highlighted catheter and then select the lasso icon (+) (emphasized in **Figure 76**). On the left side of the *Navigant* display, the catheter will appear in the Visible Objects field.

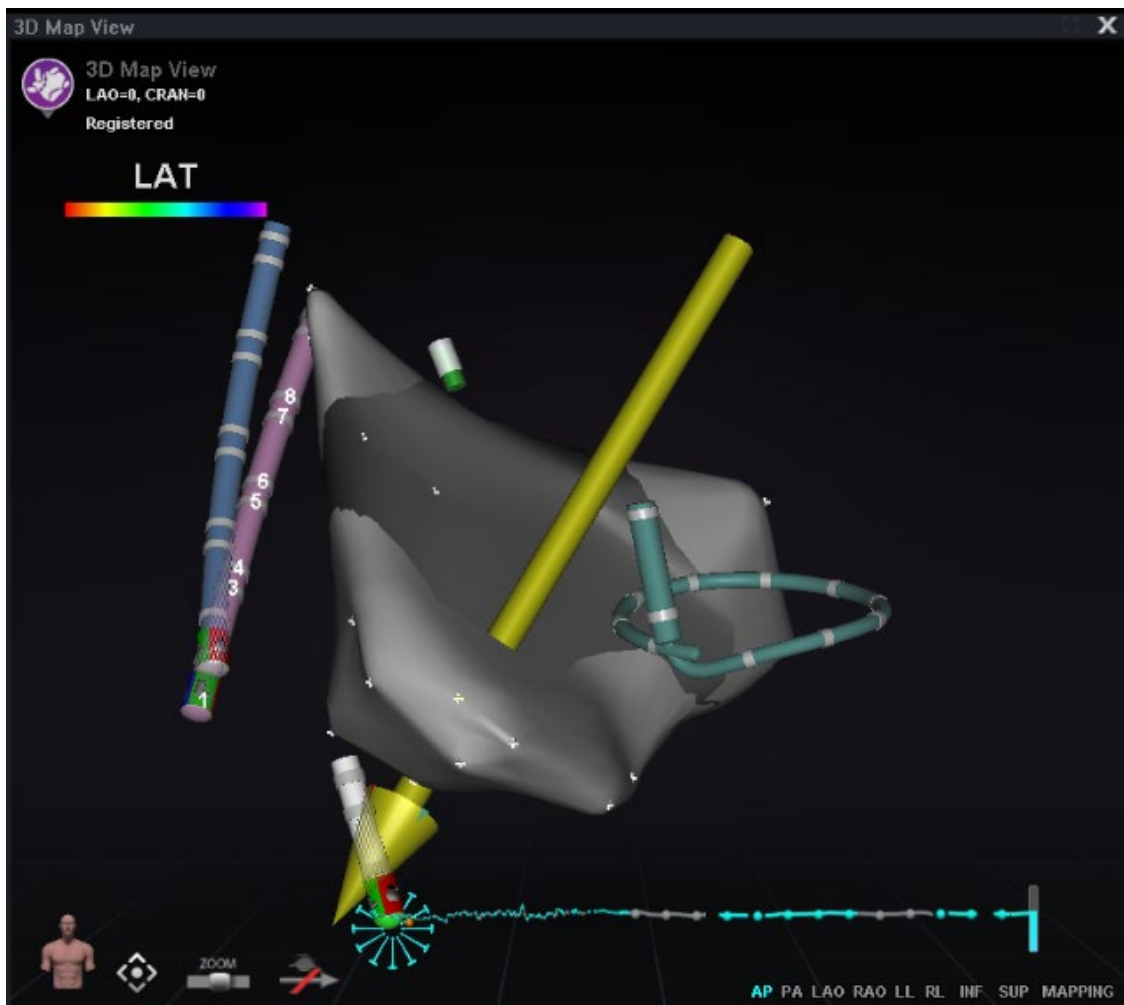


Figure 76. Lasso icon to store catheters

Right-clicking on the stored catheter opens a dialog (**Figure 77**) in which **Name**, **Opacity**, **Electrode Numbering**, and **Color** may be adjusted. The user can revise the catheter name by typing in the name field. The opacity may be entered as a numerical percentage value, or by clicking and dragging the sliding bar displayed on the right. **Electrode Numbering** is used when targeting by electrode number. The drop-down menu includes several choices: **No Numbers**, **All**, and **Even** or **Odd**. An example of electrode numbering is shown in **Figure 78** where electrode targeting can be seen in the main *Navigant* window (top left) and from a different view in Fluoro Image A (top right). Double-clicking on the **Color** box displays a choice of colors. Clicking on the desired color displays the catheter in that color. After all selections, click **OK** to save changes or **Cancel** to close the dialog.



Figure 77. Catheter Properties dialog



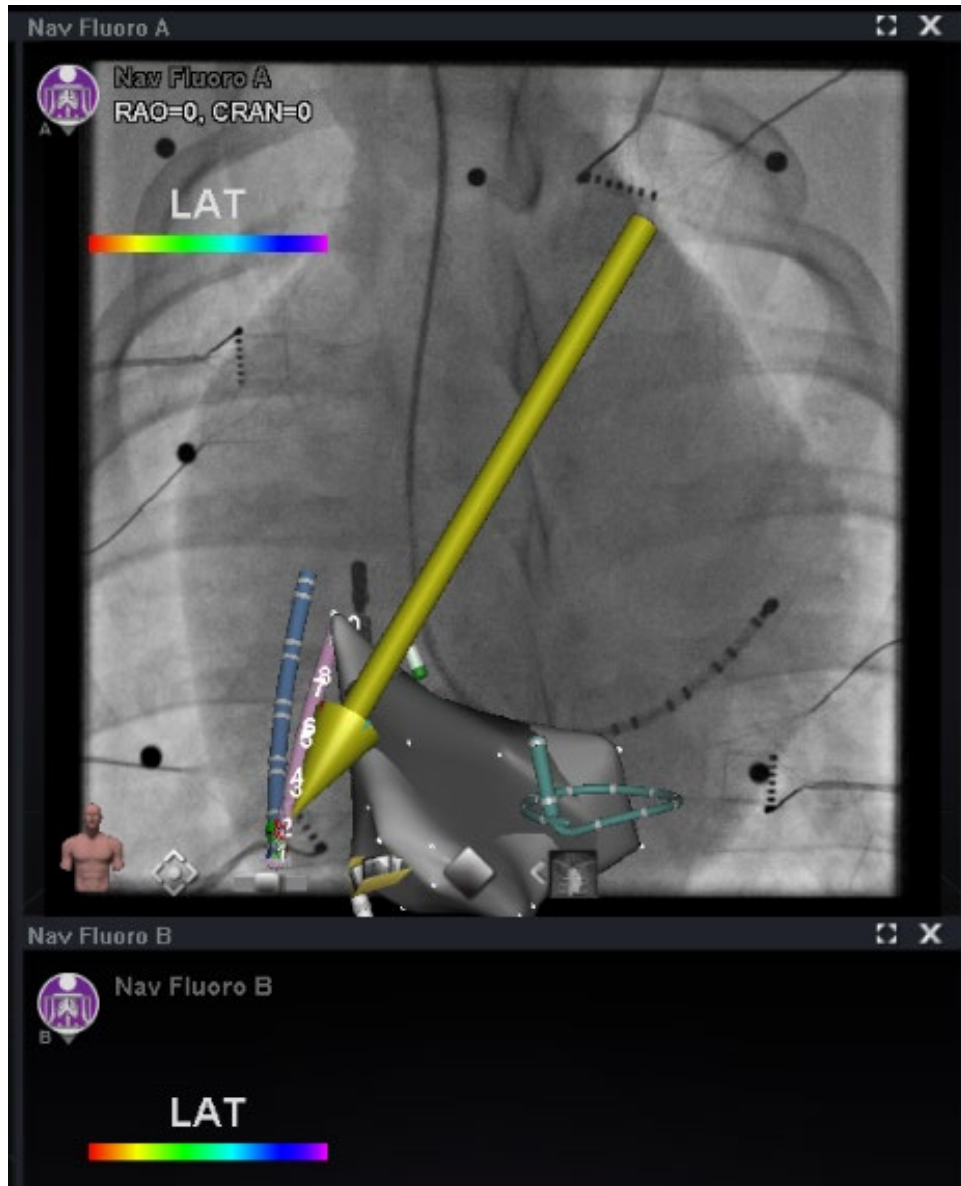


Figure 78. Electrode Numbering

***TargetNav* Feature**

The TargetNav™ feature is integrated between *Navigant* and compatible mapping 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 (emphasized by red rectangles in the figures below), click and drag the target freely. The user may move the target multiple times and the catheter automatically follows until it has reached the target. See **Figure 79** and **Figure 80** below. If no vector is showing, the gold-arrow icon (**Figure 81**) can be selected to show the vector. If the vector is displayed, the gray arrow icon (**Figure 82**) can be selected to hide the vector.



Figure 79. TargetNav targeting



Figure 80. Target reached



Figure 81. Vector (field) show icon



Figure 82. Vector (field) hide icon

Click & Go

Click & Go is a feature between *Navigant* and *CARTO 3* 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**. The catheter is directed to the target automatically. Targets created in *CARTO 3* appear in *Navigant* and targets created in *Navigant* appear in *CARTO 3*.

Electrode Targeting

Electrode targeting is available in *CARTO 3* and *OpenMapping* systems, allowing the user to set a target e.g., double-click on a coronary sinus catheter electrode to set a target. The mapping catheter is directed to that target. Electrode targeting by electrode number is also an option.



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

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*

When the network transfer is complete, *Navigant* 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, *Navigant* displays a small message in the lower-left corner of the screen indicating the completion of the import process. The newly imported surface will display in the mapping and fluoro windows of *Navigant* (**Figure 83**). Click the *NaviLine* icon to display the *NaviLine* toolbox (**Figure 84**).

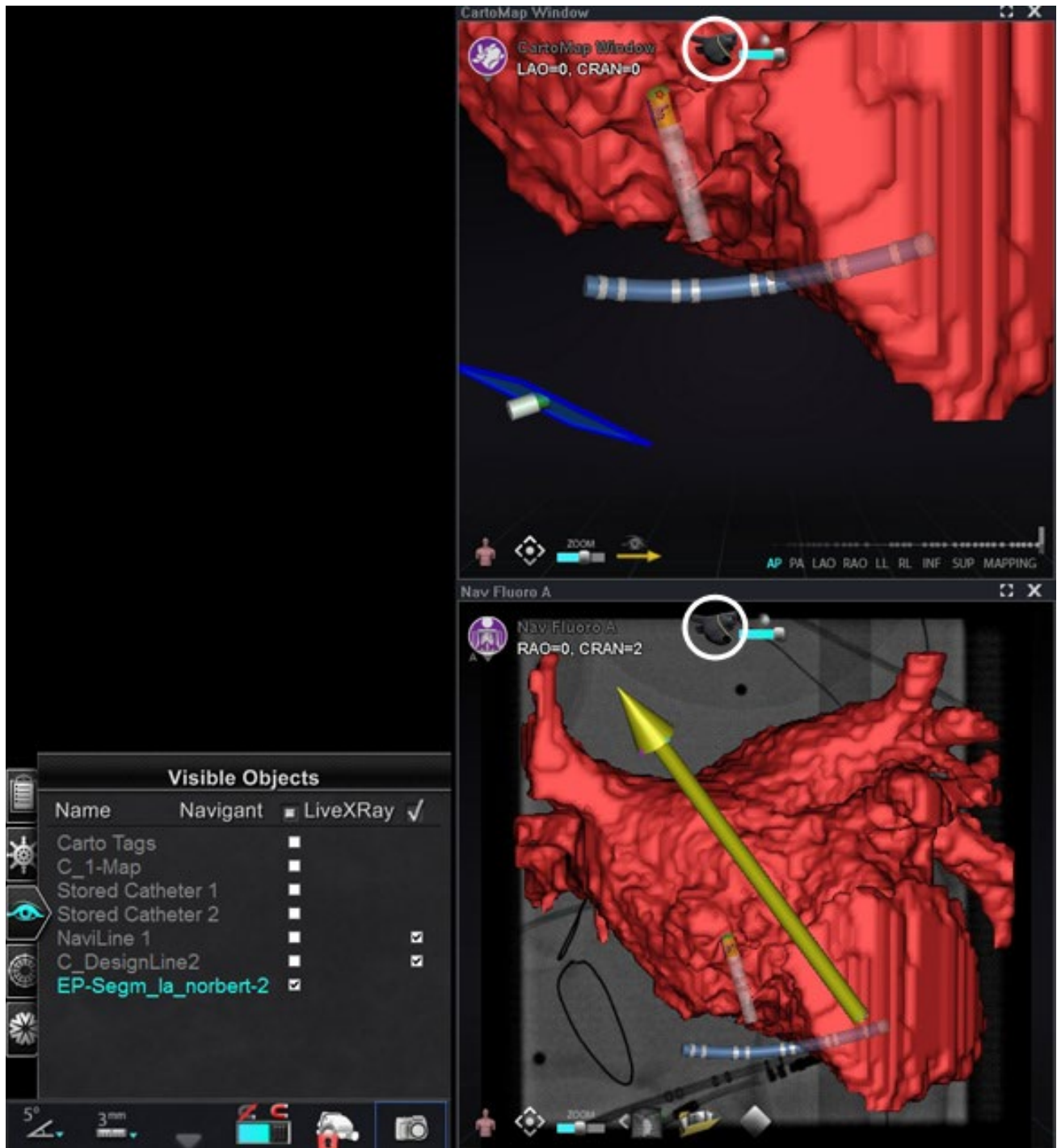


Figure 83. Imported surface with *NaviLine* icon (circled)

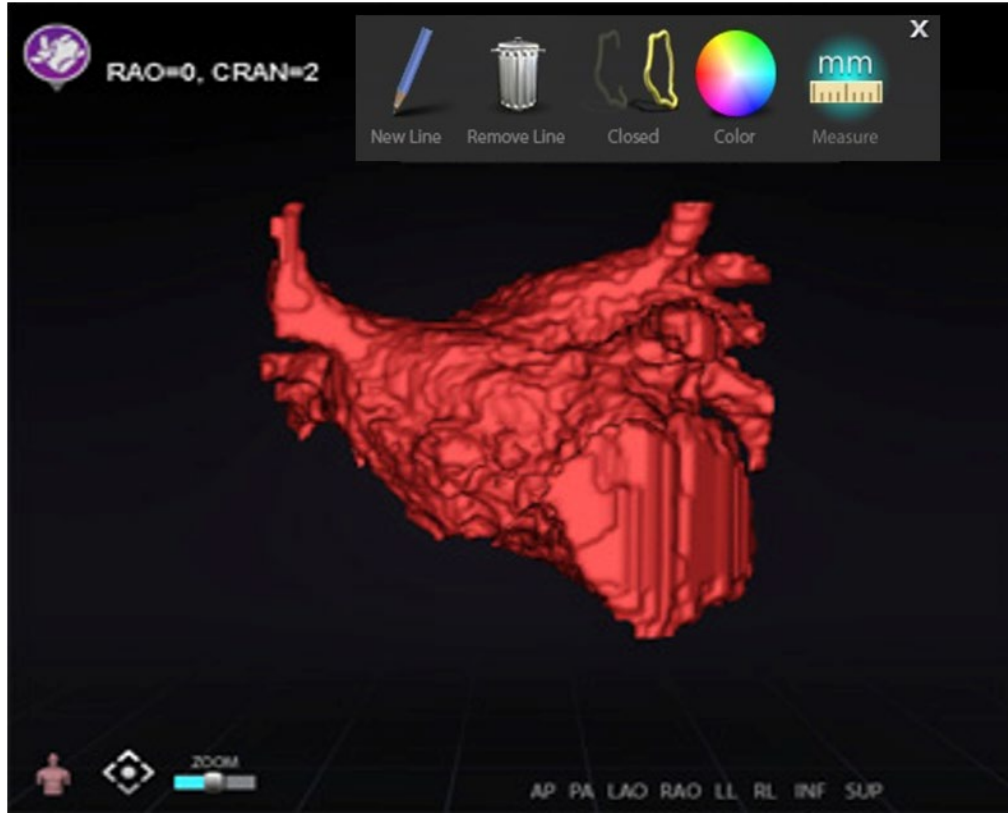


Figure 84. Imported surface with *NaviLine* toolbox displayed

Use the tools to create the new line on the imported surface (Figure 85). To delete an entire *NaviLine* design line, click the **Remove Line** (“trashcan”) icon in the *NaviLine* toolbox.

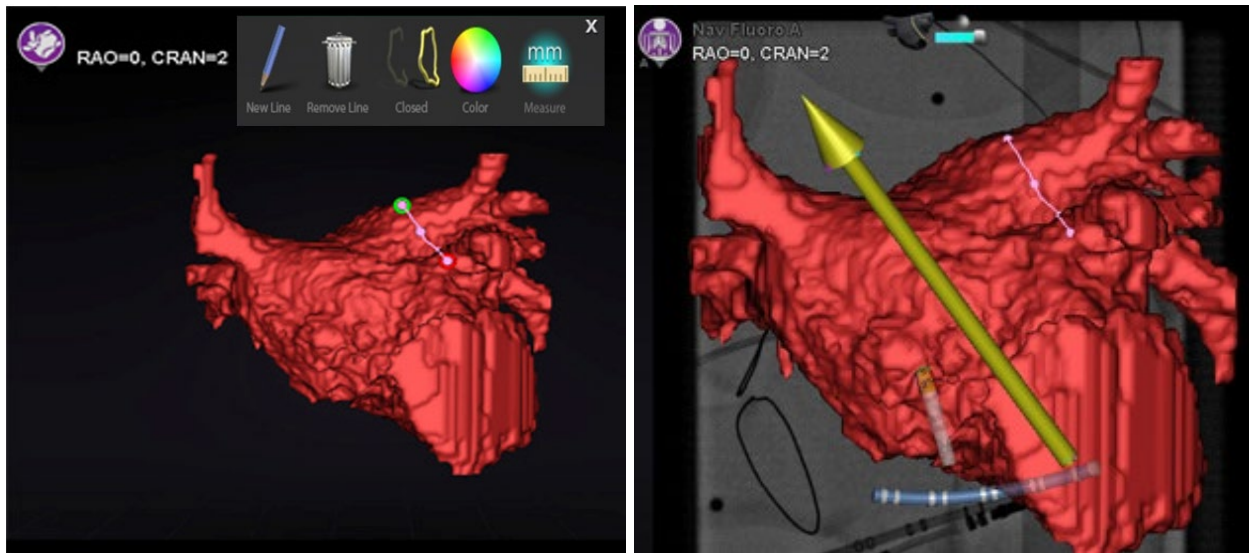


Figure 85. Left: *NaviLine* being drawn; Right: Completed drawing

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.

The 3DMap and Fluoro views display the selected surface and any other objects that are set as visible on the Visible Objects panel. The dialog allows the user to adjust the selected surface relative to other objects in the view.

Surface Registration Dialogs

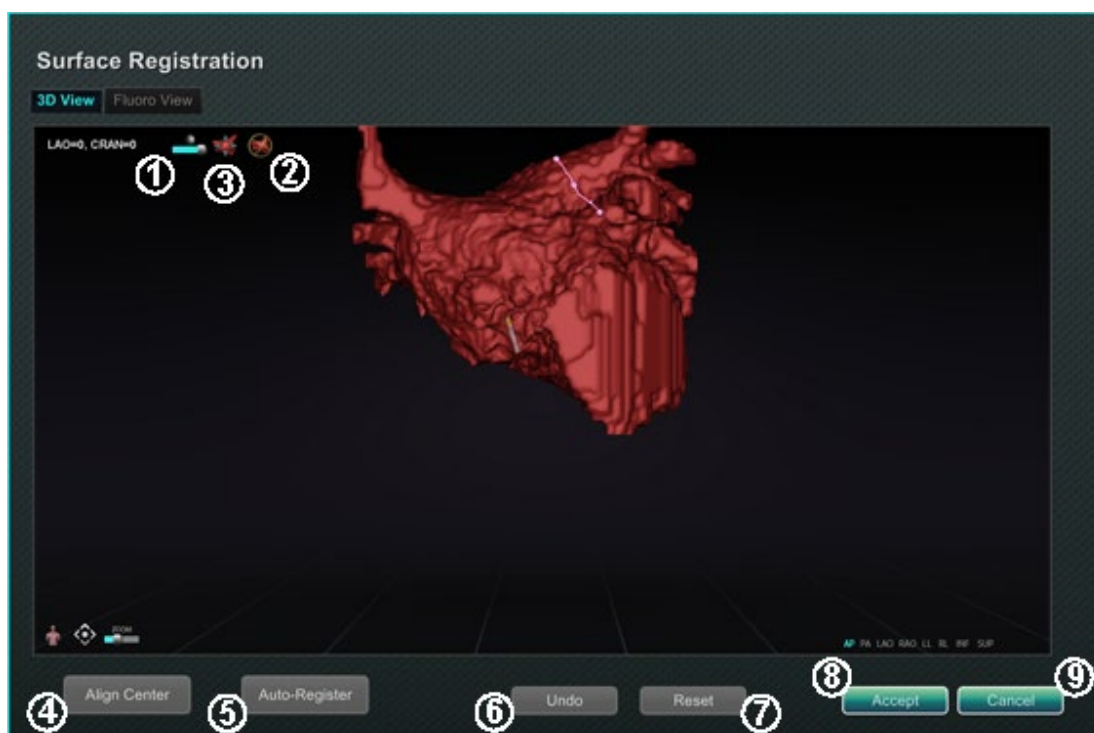


Figure 86. Surface Registration – 3D View



Figure 87. Surface Registration – Fluoro View

Surface Registration guide (Figure 86 and Figure 87)

- 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 or click **Cancel** (⑨) to close the window without saving changes.

Ablation History

The Ablation History feature indicates where the catheter has been while the radiofrequency (RF) generator is running. An interactive color scale allows manipulation of the gradient and power levels. 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

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 the user 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 (e.g., compatible generator) must be connected to use 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 seen in **Figure 88, left**. When not connected, the generator icon indicates an error, as seen in **Figure 88, 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 may show an error symbol if *Navigant* received an “*Ablation on*” message from the mapping system but did not receive the same message from the generator.



Figure 88. Ablation Generator connection status

Making Ablation History Visible

The *Navigant* Visible Objects control panel displays *Ablation History 1* (Figure 89) after the first ablation is performed post registration. Checking and unchecking Ablation History boxes displays or hides the 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) does not show in 3D Map Windows.



Figure 89. Ablation History viewing enabled

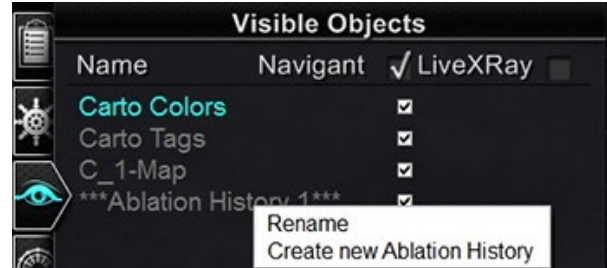


Figure 90. Ablation History Menu Options

Right-click on an Ablation History to either rename that Ablation History or create a new Ablation History (Figure 90). If **Create new Ablation History** is selected, *Ablation History 2* is added to the list of visible objects (Figure 91, left). Right-clicking the new ablation history and selecting **Rename** allows the user to edit the History's name (Figure 91, right).

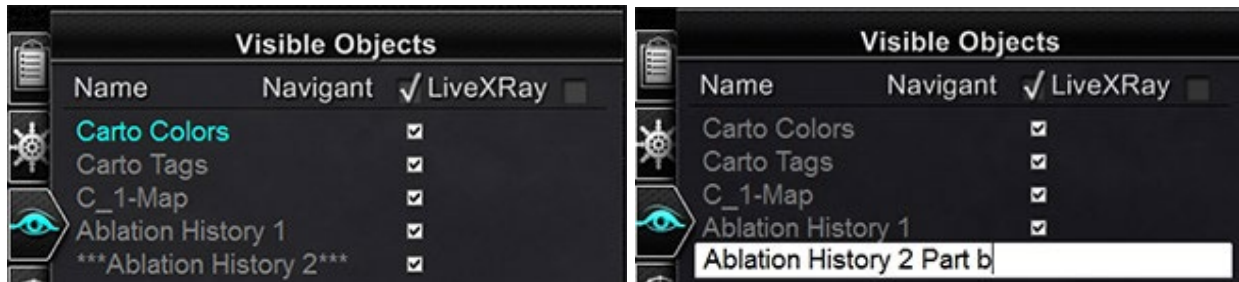


Figure 91. Left: Creation of New Ablation History; Right: Renaming New Ablation History

To activate an Ablation History after working with another history, right-click its name. A menu appears where the user can select **Activate**, with the result shown below (Figure 92).



Figure 92. "Ablation History 1" is activated



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.

Demonstrating Overlapping Ablation Histories

The images in Figure 93 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.

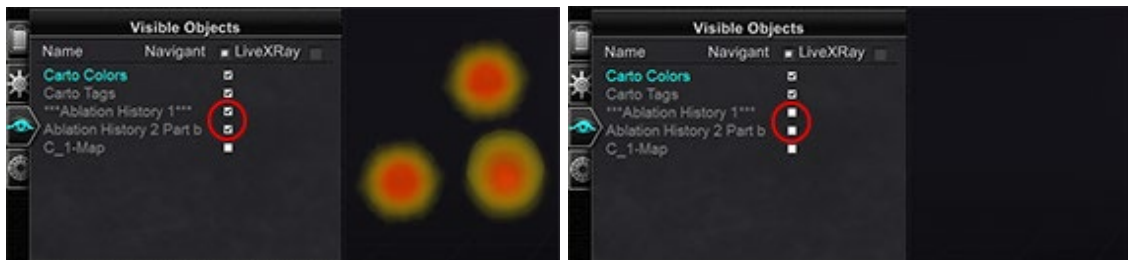


Figure 93. Left: Ablation Histories displayed; Right: Ablation Histories displayed

Ensuring Visibility Settings are Correct

From the hardware status indicator toolbar, click the **System options** button. From the System options menu, click **Settings**. The *Navigant Window* tab appears. In the *Navigant Window* tab, ensure the following settings are selected:

- 3D Map View or 3D Map View B
- Volume
- Color Scale

When the RF generator is running and *Navigant* is receiving real-time catheter position information from the mapping system, Ablation History is automatically created based on the system settings (**Figure 94**).

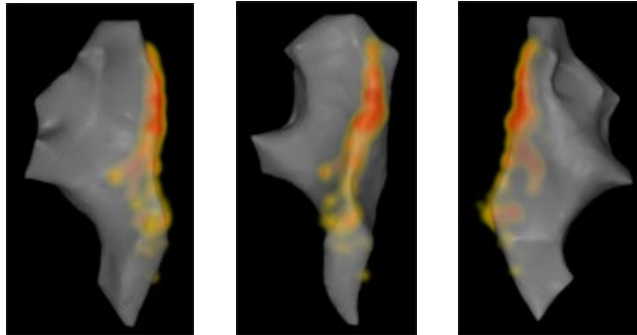


Figure 94. Ablation History viewed from various orientations

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 (**Figure 46**). 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 has expired. Once the time 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 95** shows a representative Ablation History screen with executed Ablation History, Color Scale, and Windows Controls visible.

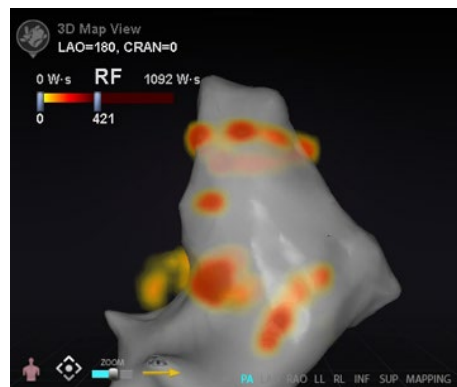


Figure 95. Example of Ablation History map

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 96** shows three examples of differing display ranges and color gradients.

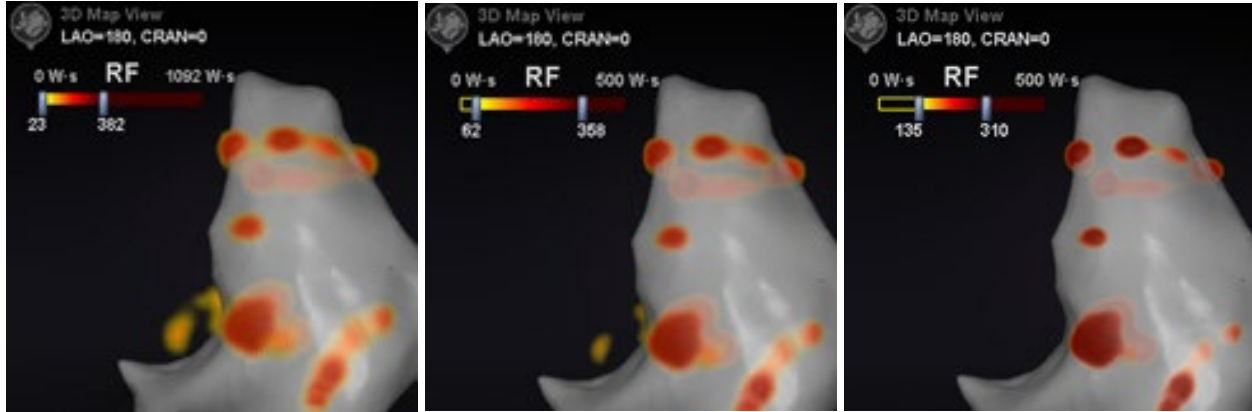


Figure 96. Differing areas of drawing intensity, or gradient fields

Maximum Ablation Value

Pressing the **Alt** key while using the mouse to hover over an area of shading shows a popup of the Ablation History value at that point (**Figure 97**). 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.

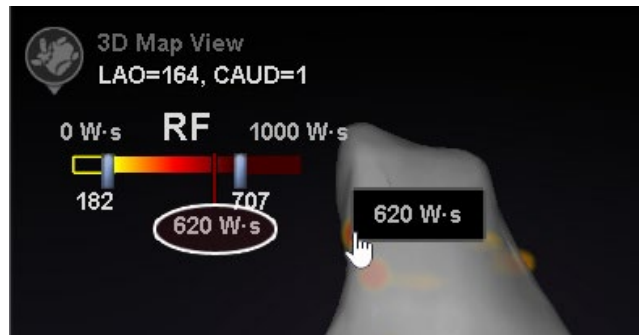


Figure 97. Maximum ablation value (620 W·s) shown in popup and on Color Scale

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. Manually edit the values (**Figure 98**) following the *rules* below:
 - Can't exceed lower number of bar.
 - May go as high as upper limit of 4,369 W·s.
 - Color range min \leq Color gradient min \leq Color gradient max \leq Color range max.



Figure 98. Edited W-s values indicated by red rectangles

Color Gradient

In addition to manually editing the range display, the user may also drag the bar at either end of the gradient display to change the color gradient within the defined range. Like in **Figure 98**, the user may select and slide the bar at **182** or the bar at **707** to a lower or higher number.

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 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.

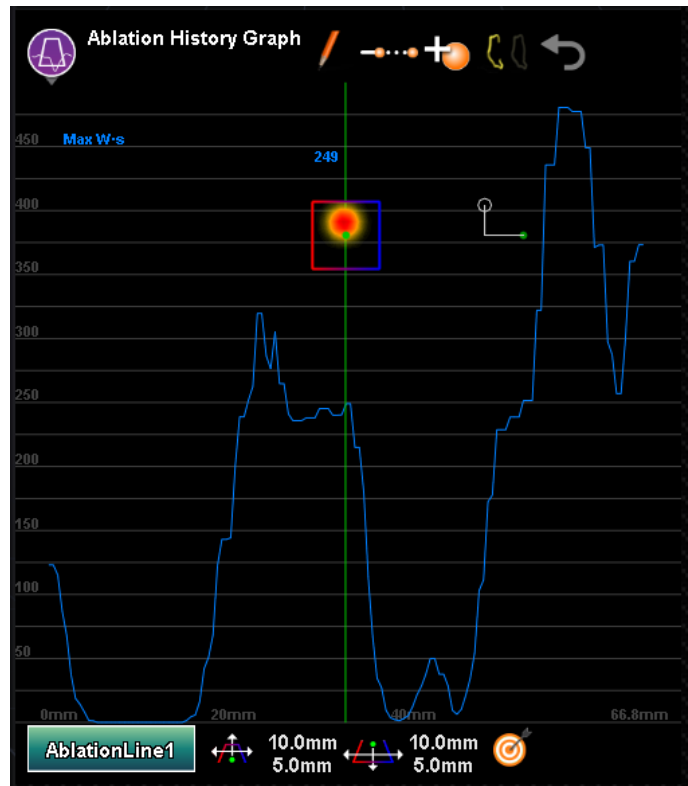

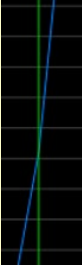

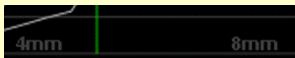



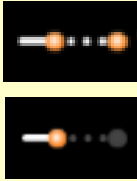
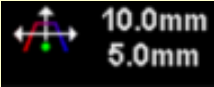




Figure 99. Ablation History Graph

Table 8. Ablation History Graph Components and Settings

| Component / Setting | Icon | Function |
|------------------------------------|---|---|
| Graph Tracing |  | Displays the maximum Ablation History value found in the cross section along the <i>NaviLine</i> . |
| Position Indicator |  | Green line that indicates position of the cross section along the <i>NaviLine</i> . As the line is moved in the graph, the position of the cross-section updates in the 3D windows. |
| Vertical Scale |  | The vertical scale, measured in Watt-seconds, shows delivered energy. |
| Horizontal Scale |  | The horizontal scale, measured in millimeters, shows the position around the <i>NaviLine</i> at which a cross section is taken. |
| Cross section |  | A 2D slice into the ablation history volume showing a cross section of the delivered energy. In the tooltips, the cross section is referred to as the cursor . |
| 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. The white circle is the tip position. Position and appearance depend upon the shape of the line and position of the catheter. |
| Create <i>NaviLine</i> |  | Creates a new empty <i>NaviLine</i> , named AblationLine# where # is the number of lines made in the AHG, and becomes the selected line for the AHGraph. |

| Component / Setting | Icon | Function |
|---|---|---|
| <p>Auto-Extend <i>NaviLine</i></p> |  | <p>Button that toggles. 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.</p> <p>The added position is the location of the highest AH value within 3mm of the catheter tip so it is ideal to keep the <i>NaviLine</i> centered within the ablation.</p> |
| <p>Add Catheter tip to <i>NaviLine</i></p> |  | <p>Adds the current catheter tip position to the AHG selected line. The user can also use the keyboard shortcut CTRL-A if <i>Navigant</i> 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).</p> |
| <p>Click to open / close the <i>NaviLine</i></p> |  | <p>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).</p> |
| <p>Undo</p> |  | <p>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 <i>NaviLine</i> Mode). Feature is disabled if there is no undo-able history for selected line.</p> |
| <p><i>NaviLine</i> Selection</p> |  | <p>Displays a menu of lines to use for AHG.</p> |
| <p>Top Width, Top Height</p> |  | <p>Two-direction slider 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.</p> |
| <p>Bottom Width, Bottom Height</p> |  | <p>Two-direction slider that controls the distance of the bottom of the trapezoid cursor from the line, and the width of the bottom of</p> |

| Component / Setting | Icon | Function |
|----------------------|---|--|
| | | the cursor, followed by labels displaying the bottom width and bottom height. |
| Set Target at Cursor |  | <p>When using this tooltip, the cross section is referred to as the “cursor” as seen in the image below.</p>  <p>This feature sets a target at the position of the trapezoid cursor (cross section) on the current line. Setting a target will fail if <i>Navigant</i> is not registered to a mapping system, not getting catheter data, not connected to magnets, etc.</p> |

Ablation History Graph Usage

Access the AHG by pressing on the icon in the upper left corner and selecting “Ablation History Graph” (Figure 100). 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.



Figure 100. Selecting the Ablation History Graph

As the indicator moves, a blue number displays which represents the maximum value of the delivered energy present in the cross-sectional window at the position around the *NaviLine*.

The data displayed in the graph depicts the max 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 101**). A menu will display that shows a list of all available *NaviLines* to choose from.

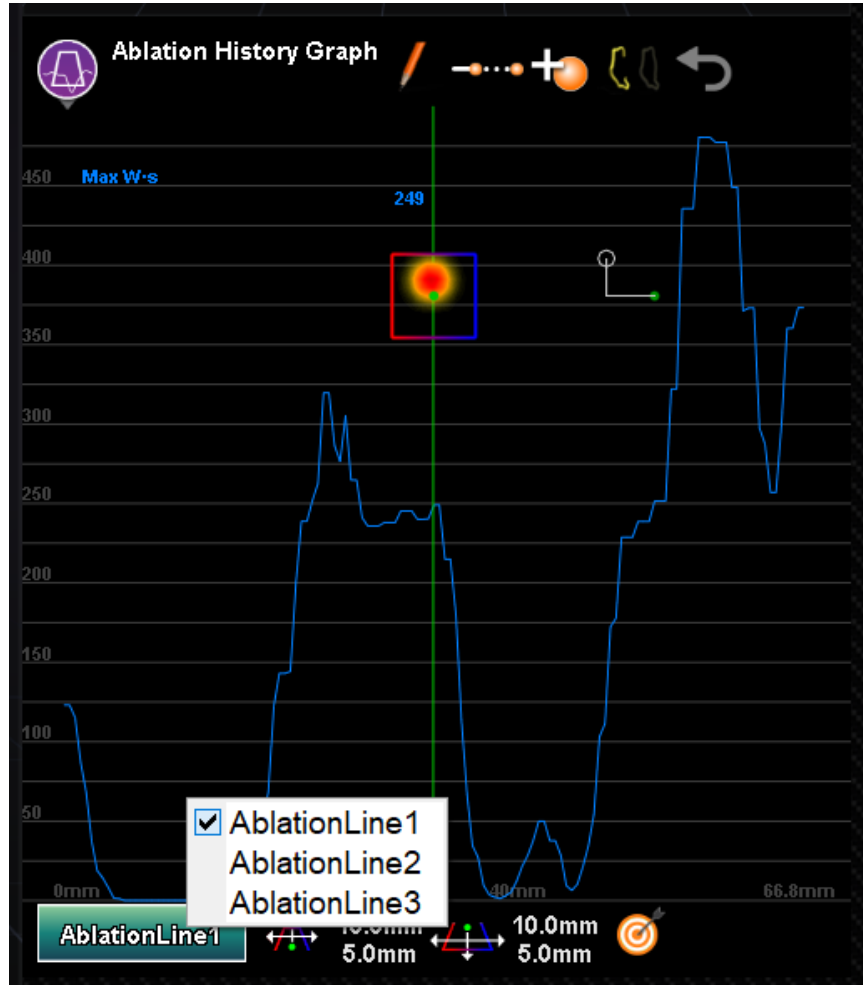


Figure 101. Selecting the *NaviLine*

The graph displays the maximum ablation energy delivered in the immediate volume around a *NaviLine*. To change the shape and position of the cross section analyzed by the graph (**Figure 102**), use the window controls located at the bottom of the Ablation History Graph window.

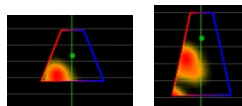


Figure 102. Changing Shape of Cross Section

The cross-section location is seen in all windows displaying the selected *NaviLine* and Ablation History. The cross-section (AHG window in **Figure 103**) 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 103**) 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 103. Cross-Section Display (3D Map Window and AHG Window)

Impedance Graph

Description

Navigant's Impedance Graph (IG) feature shows traces for impedance and ablation temperature measure with the catheter. The graph displays Channel 1 (R1) impedance, Channel 2 (R2) impedance and Channel 1 (R1) Baseline. While ablating, the graph shows traces for Ablation Temperature and Unipolar Impedance. The graph's ohms scale and time scale are configurable by the user to allow full control over how the traces are displayed.

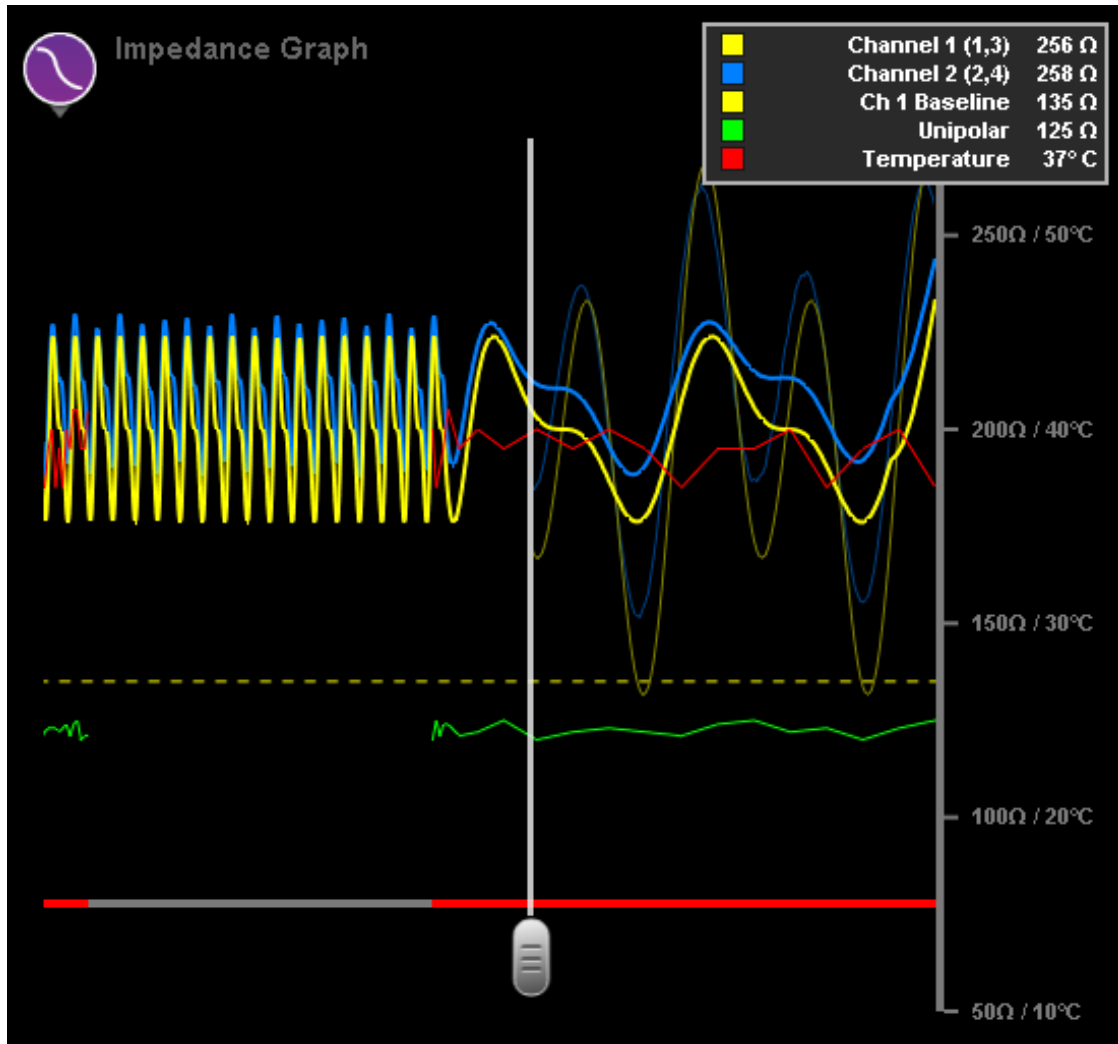
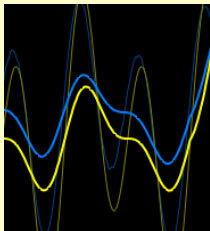

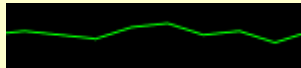
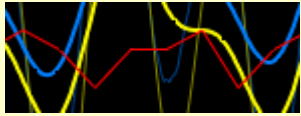
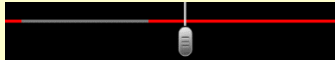


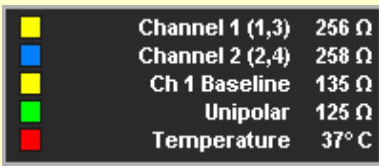


Figure 104. Impedance Graph

Table 9. Impedance Graph Components and Settings

| Component/Setting | Icon | Function |
|--------------------------------|---|---|
| Channel 1 and Channel 2 Traces |  | Displays the measured resistances across Channel 1 and Channel 2. The thin traces are the actual measured value. The wider traces are the 1 second moving averages of the measurements. |
| Channel 1 Baseline |  | The Channel 1 Baseline is indicated by a dashed line. |

| Component/Setting | Icon | Function |
|-----------------------------|---|---|
| Unipolar Trace |  | The unipolar resistance trace is only displayed while ablating. |
| Ablation Temperature |  | The ablation temperature trace (marked in red) is only displayed while ablating. |
| Ablation Meter |  | The ablation meter, at the bottom of the graph, shows a history of ablation. Red sections of the ablation meter indicate portions of the graph where ablating occurred. |
| Transition Indicator |  | A slider control that indicates where the graph transitions from fast (right side) to slow (left side). The transition point can be moved by clicking and dragging on the indicator's handle. |
| Vertical Scale |  | The vertical scale is shared between ohms and Celsius. Channel 1, Channel 2, Channel 1 Baseline, and Unipolar are measured with the ohms portion of the scale. Ablation Temperature will be measured with the Celsius portion of the scale. |
| Labels |  | The label area shows the most recent value for each trace. If the trace does not have a reading, it will display “—” for the value. Clicking on the colored squares will allow a user to change the color of the trace. |

Impedance Graph Usage

Access the Impedance Graph by pressing on the icon in the upper left corner of a window and selecting “Impedance Graph” (**Figure 105**). The graph traces will be scrolling from right to left, with the right side of the graph being the most recent values. If there is a Channel 1 baseline impedance set, the baseline will display with a dashed line. Channel 1 and Channel 2 impedance traces display their real-time impedance values (thin line) as well as their 1 second moving averages (thick line).

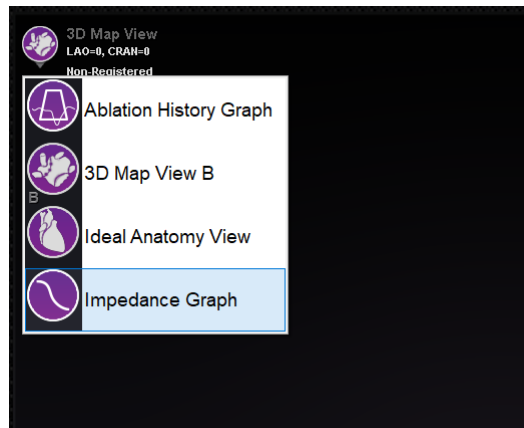


Figure 105. Selecting the Impedance Graph

The gray vertical line in the middle of the graph is the transition indicator. This line marks the point where the traces slow down to maintain a longer visible history. The transition indicator can be moved horizontally to adjust how much history is shown by clicking and dragging the handle on the bottom of the indicator (red square in **Figure 106**).

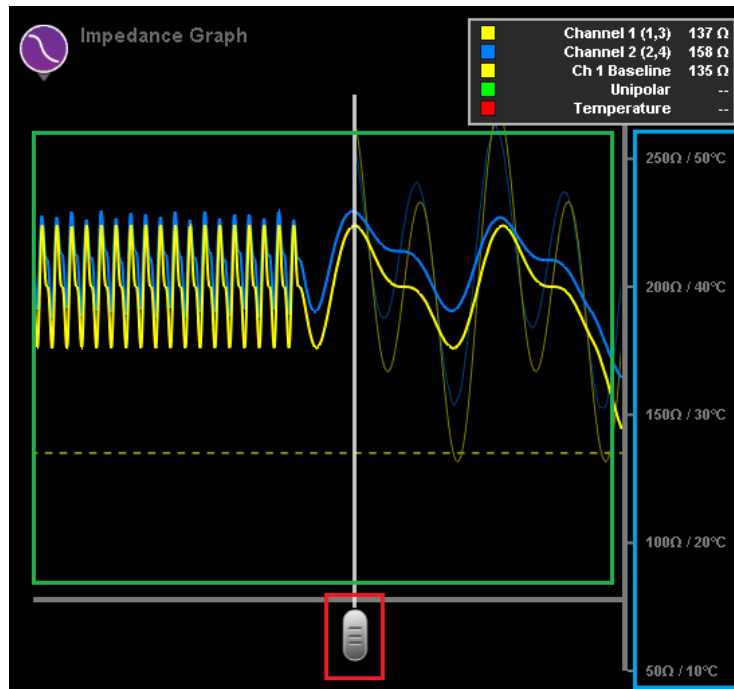


Figure 106. Transition indicator handle (red), graph scale (blue), graph offset (green)

The scale of the graph can be adjusted by clicking and dragging on the vertical axis (blue square in **Figure 106**). Dragging upward will zoom the scale in and dragging downward will zoom the scale out. Clicking and dragging vertically on the graph portion of the window (green square in **Figure 106**) will allow a user to move the graph up and down. Double-clicking the vertical axis will reset the graph to default.

While ablating, the unipolar impedance and ablation temperature traces will appear on the graph. The ablation meter on the bottom of the graph will highlight in red to indicate an ablation was occurring (**Figure 107**).

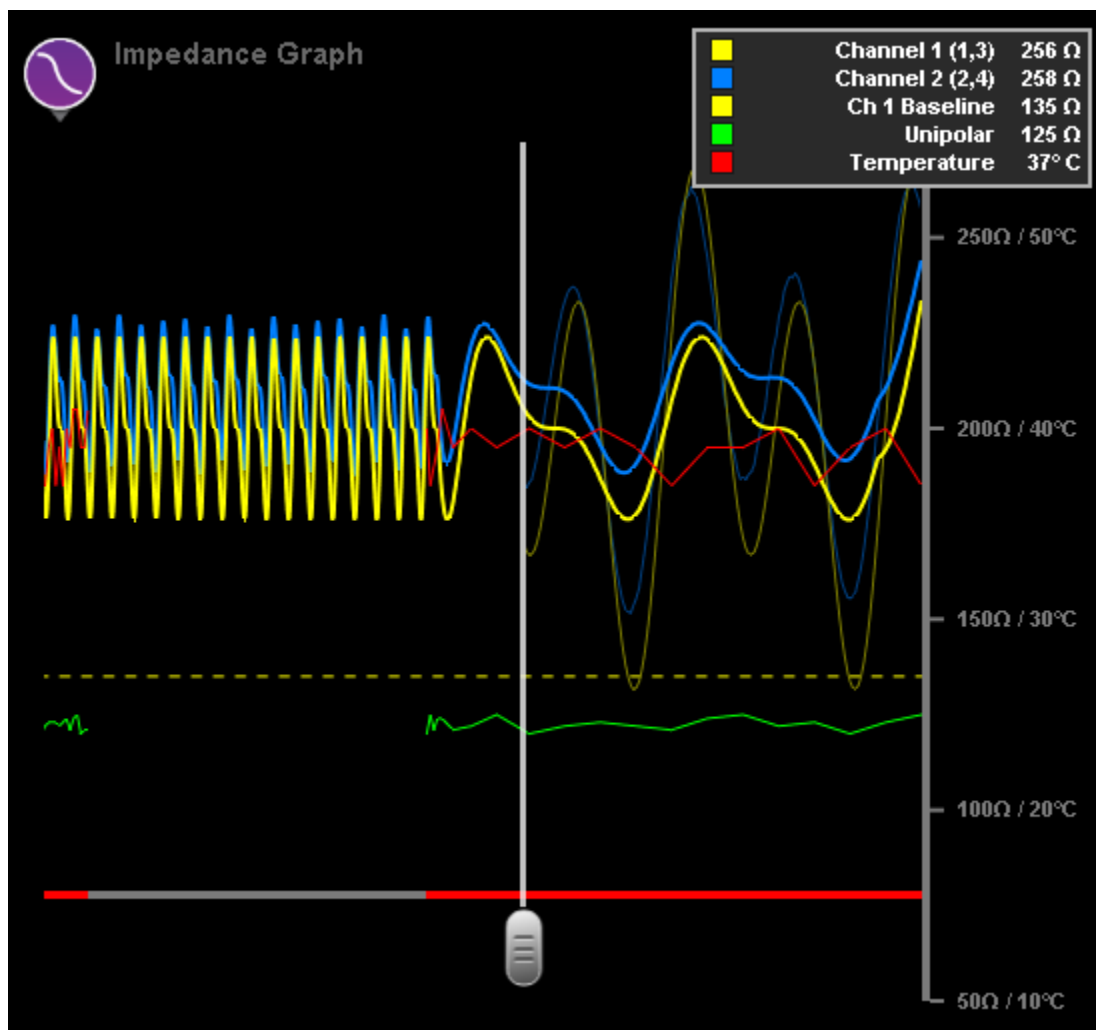


Figure 107. The ablation meter (gray line on the bottom of the graph) will highlight in red during ablation.

Ultrasound Fan

When *Navigant* receives Ultrasound Fan data from the *CARTO 3* System (while using the *SOUNDSTAR* catheter), the screen displays the fan as in **Figure 108**. It is important to note that the option **Ultrasound Fan** must be checked 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 108. Ultrasound Fan in **CARTO** Window

Intracardiac (IC) Features

Vessel Navigation

NaviView3 feature

The Stereotaxis NaviView™3 feature defines vessels in 3D space using complementary fluoro views. When the user draws the centerline of the desired vessel on the two fluoro images (separated by at least 40°), *Navigant* 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 the user clicks **NaviView3** without the appropriate license, the message “*Unable to open VesselView due to inactive license*” displays.

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 <i>Navigant</i> . |

| | |
|------------------------------|--|
| Trunk | The segment with the proximal end. |
| Vessel or Vessel Tree | A segment or set of segments where one end is proximal, and the others are distal. |

Point Annotation on Fluoro dialog

The Point Annotation on Fluoro dialog (**Figure 109**) 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.

Initial steps

After opening the dialog, transfer an RAO image to Fluoro Image A and an LAO image to Fluoro Image B by selecting **Transfer Fluoro** (emphasized in **Figure 109**). Once the images have transferred, click **Add Group**.

Notes:

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

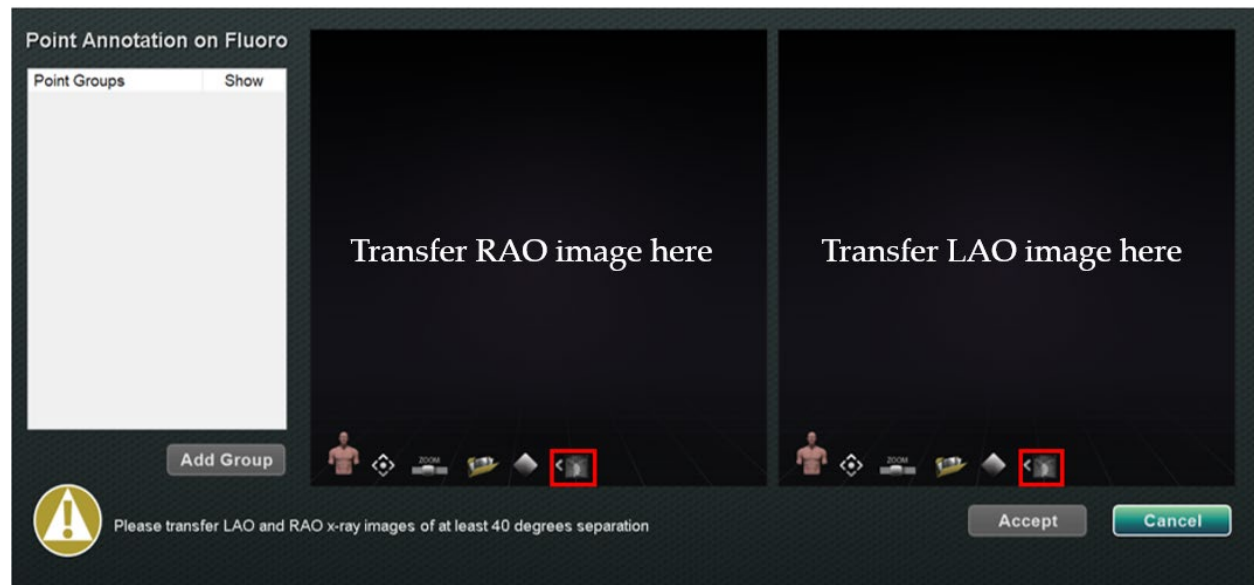


Figure 109. Point Annotation on Fluoro dialog

Group Properties

Right-click the group name to open the Group property menu and:

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

Rename Point Group

To rename the group, right-click on the group name and select **Rename**. A text editing field displays. Type a new group name. Click anywhere off the text editor to close the editor and accept the change. If **Show** has a checkmark, this 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

Change the Line Type to *Open* before marking Fluoro A. The default line type is *Closed*.

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

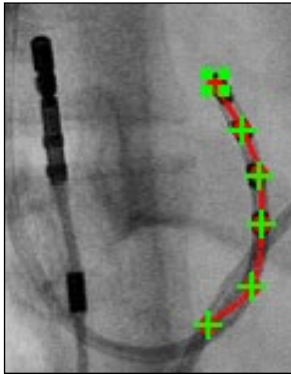


Figure 110.
Open line

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

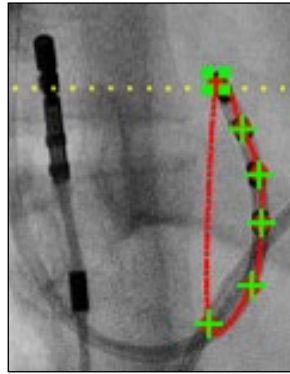


Figure 111.
Closed line

Closed creates a line that circles back to the beginning point and is useful when the user marks LASSO catheters.

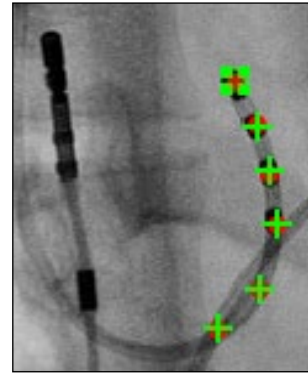


Figure 112.
Points Only

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

To change line thickness of point group, right-click on the group name and select **Line Thickness**. A list of thickness levels displays. Select a thickness and then click **Accept**.

Change Color of Point Group

To change a group's color, right-click on the group name and select **Color**. A color palette displays. Select a color and then click **Accept**. The color change feature is useful for visual distinction when creating more than one group.

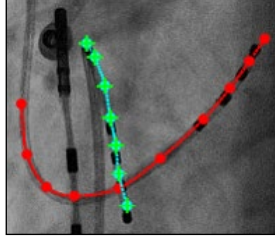


Figure 113. Colored Point groups

Delete Point Group

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

Marking Fluoro A

The user should mark the vessel starting at the proximal point **(1)** and continue marking individual points until the distal point is reached **(2)**. Fluoro Image A or B can be marked first. Fluoro A is marked first in **Figure 114** below.

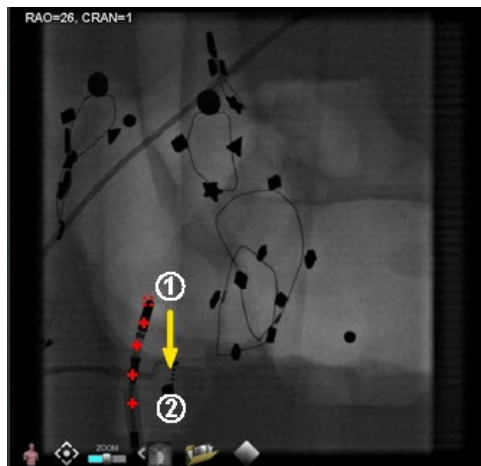


Figure 114. Marking Fluoro Image A

Marking Fluoro B

When the cursor is moved to Fluoro Image B, a yellow dotted line displays to guide the user to the proximal point on Fluoro B **(1)**. The yellow dotted line is the longitude of the proximal point marked on Fluoro A. The user should mark the proximal point on Fluoro B at the intersection of the yellow line and the catheter **(2)**. See **Figure 116** below. The marker turns green when it is in the correct location otherwise it is red. As soon as a point is marked, the yellow line moves to the longitude for the next point.

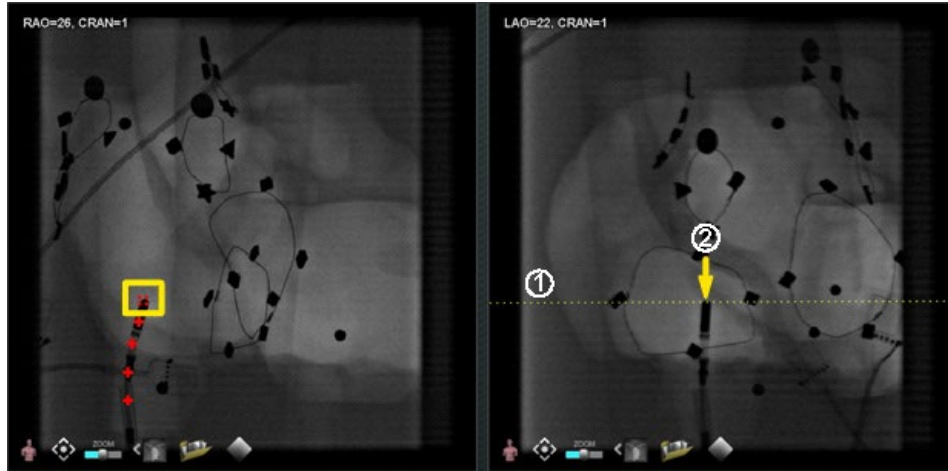


Figure 115. Marking Fluoro Image B

Continue marking points as the epipolar line moves. The objective is to match the points on Fluoro B with the points on Fluoro A. The points on Fluoro A turn green as corresponding points on B are selected (1). When all points have been marked correctly, the **Accept** button turns green (Figure 116). Click **Accept** to display the vessel(s) in the Fluoro Images A and B windows (2).

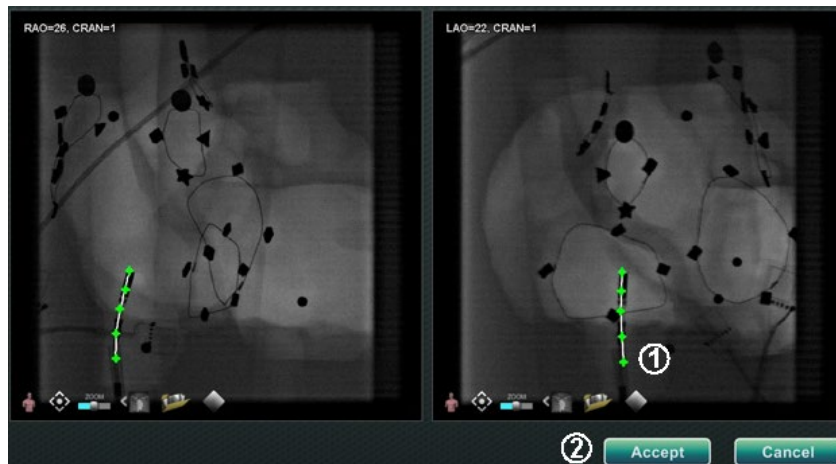


Figure 116. Fluoro annotation– Fluoro images A and B

Editing a Point Group

After creating a point group, the user can edit it by clicking **Point Annotation on Fluoro** (see mouse cursor in Figure 117). Features such as line type, color, and thickness become available.

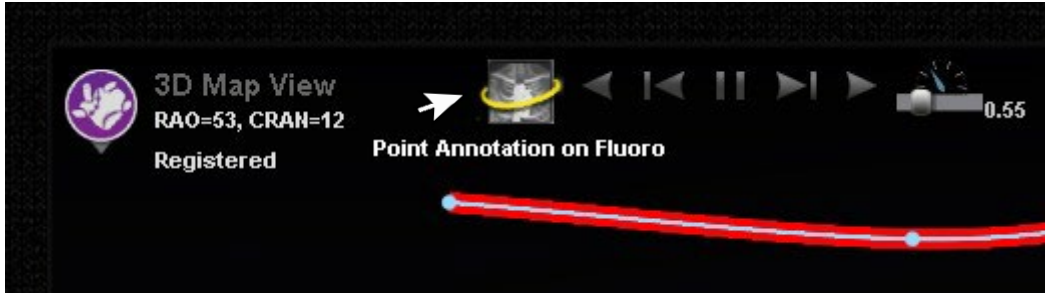


Figure 117. Accessing editing features

Volumes Dialog

Import Tab

With the Volumes dialog, the user can import and register preoperative data sets. Click **Browse** to find an image on a portable drive or CD or click **Scan Directory**. Select a record listed in the **Available Volumes** section and click **Import**.

The **Confirm Differing Patient Information** dialog displays (Figure 118). Click **Accept** to confirm, or click **Cancel** to close. If the user has clicked **Accept**, the Importing progress bar displays (Figure 119). The Data Set Attributes dialog displays with detailed attributes. Click **OK** to close it.

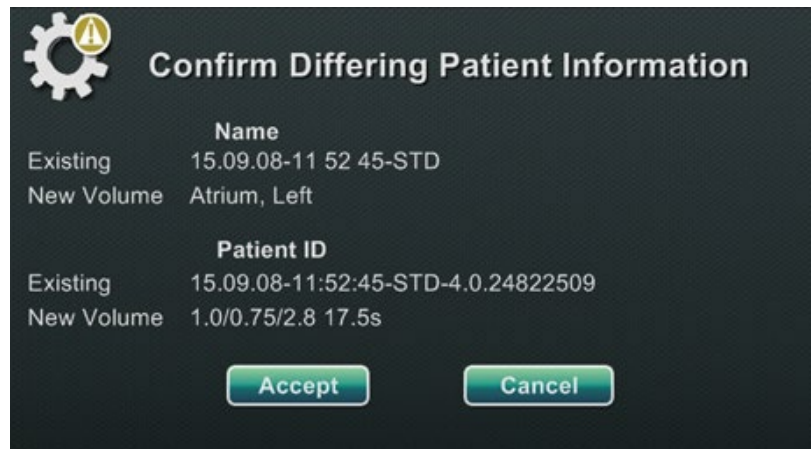


Figure 118. Confirm Differing Patient Information



Figure 119. Importing progress bar

Edit Tab

On the Edit tab the user can manipulate the data set's graphic display using standard transfer function attributes. The bottom buttons (Window controls) on the screen are standard for most windows. The top buttons, however, are unique to the Volumes Edit tab.

Edit Tab Buttons

- **Opacity**
- **Punch tool**
- Keep data inside the punch tool **selection range—available only when data is selected**
- Keep data outside the punch tool **selection range—available only when data is selected**
- **Undo last step**
- **Reset**

Vessel Tab

With Volumes Vessel Extraction, the user can extract a vessel from the data set. A multi-planar reconstruction (MPR) view (*slice*) can also be created.

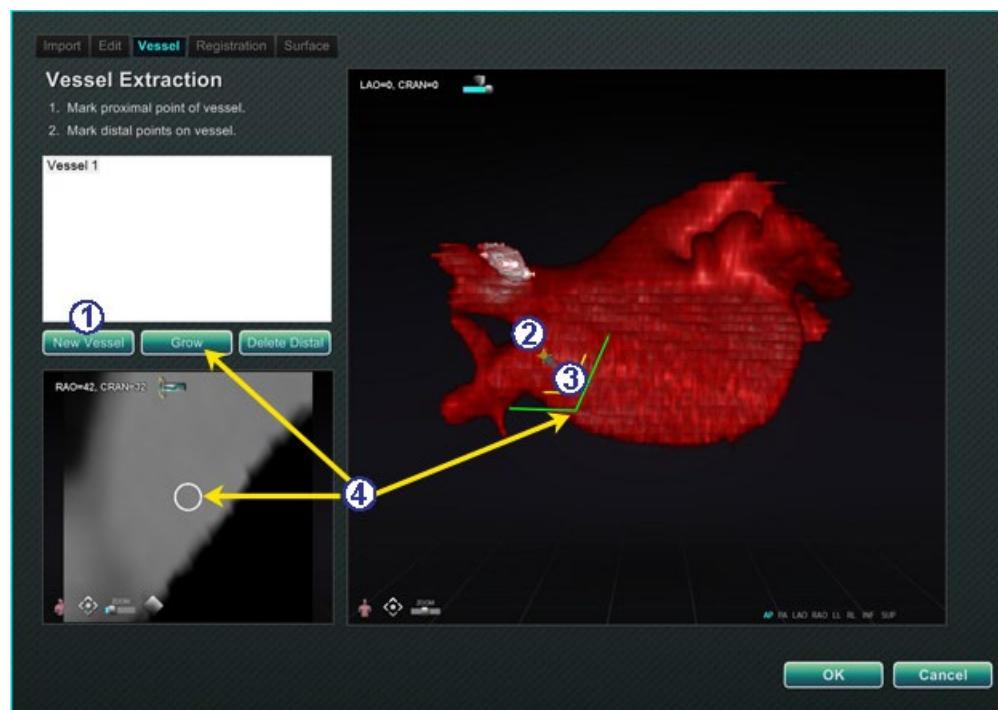


Figure 120. Vessel tab – Vessel Extraction and MPR slice

Vessel Tab Guide (Figure 120)

- ① Click **New Vessel**.
- ② Mark the vessel's proximal point.

- ③ Mark the vessel's distal point. If the message: *"Vessel not found. Add marked distal point?"* displays, the user can click **OK**. If that solution is not satisfactory, mark points extending from the proximal point until reaching the distal point.
- ④ The **Grow** button displays the MPR slice at the distal point.

Registration Tab

With the Volumes Registration tab, the user can register 3D objects by selecting corollary points on the volume and on the two Fluoro images. Select **Calculate Registration** to align anchor points before selecting **OK** and accepting changes.



Figure 121. Registration tab

Surface Tab

When **Extract Surface** on the Surface tab is selected, the **Calculating isosurface...** progress bar displays (Figure 122). **Extract Surface** displays a surface. After following the steps on the screen, click **OK** to transfer the images to the main windows of *Navigant*.

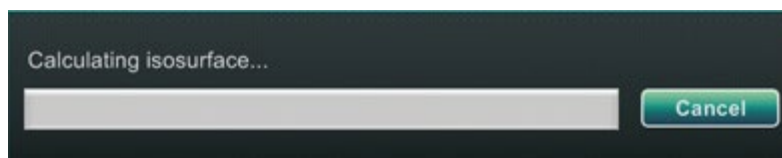


Figure 122. Calculating isosurface progress bar

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 opening a vessel, the user may notice that the original points changed. When the *NaviView3* dialog was closed, *Navigant* used the points to create a 3D reconstruction and discarded the 2D points. When reopening the dialog, *Navigant* recreated the 2D points based on the 3D image and spaced points evenly.

Transfer Images and New Vessel

- **Transfer image** – Transfer two images into the Fluoro windows by clicking the **Transfer Image** button for each window; the images must be *at least* 40 degrees apart.
- **New Vessel** – Click **New Vessel** before marking points.



Note: Click the **New Vessel** button before 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

The user can rename the vessel immediately by right-clicking the name, selecting **Properties**, and editing the name in the Vessel Properties dialog. Vessel properties can also be changed later in the procedure.

To create a new vessel or change properties, click the **New Vessel** button. The default vessel name, *Vessel #*, displays. Right-click the vessel name to display the Vessel Properties dialog, where the properties below may be changed for 3D reconstruction. After all changes, click **Save** to save or **Cancel** to exit the dialog.

Vessel Properties

- **Name.** The default name is *Vessel #*; but the user can change this.
- **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. Decimal numbers can be typed in the field.
- **Color.** The color button displays the current selection. Click the button to display a palette of 16 available colors. Every time a new vessel is created, a new color is applied; however, the user can change it. Every branch associated with a vessel acquires the current color unless changed.
- **Apply changes to branches.** If selected, the user makes the selected properties the default for all distal branches.

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 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 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

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.

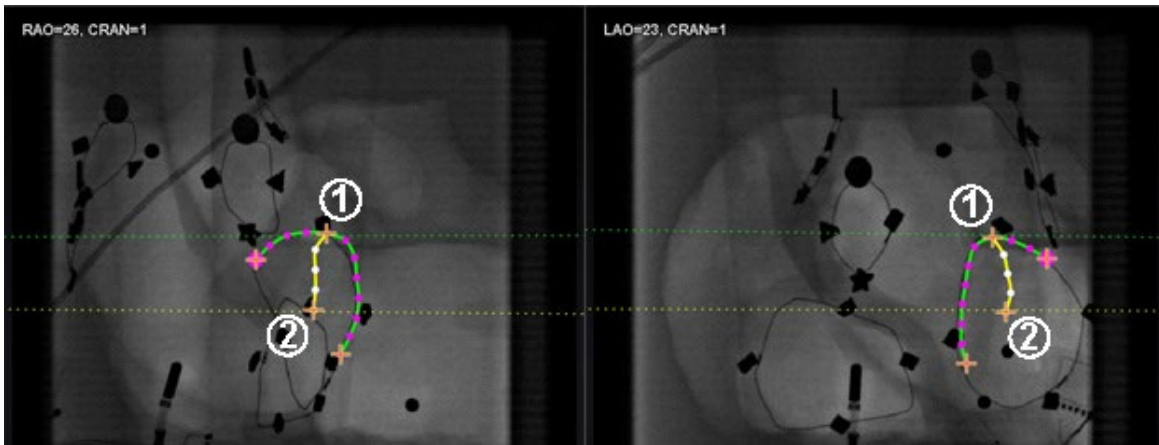


Figure 123. Vessel marking - Epipolar lines

Epipolar Line Colors Guide (Figure 123)

- 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 the user draws on the active image.

Drawing Simple Vessel Marking

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. End the drawing by double-clicking to create the distal point at the cursor location, or right-clicking to make the last drawn point the distal point.

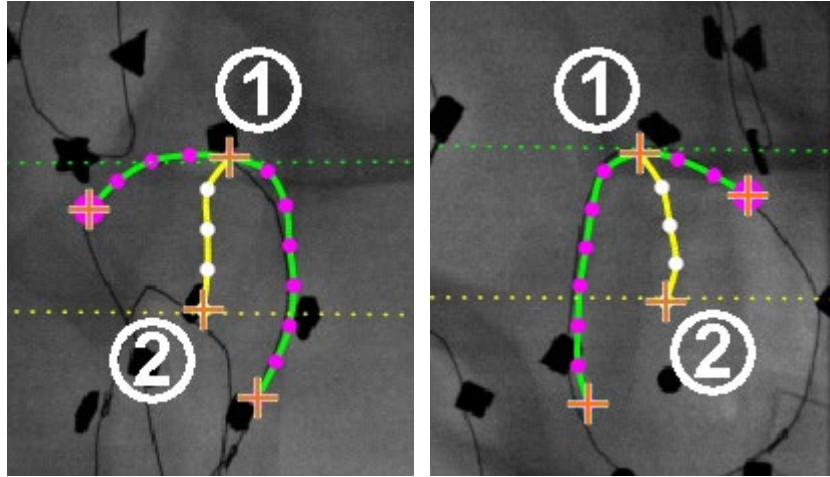


Figure 124. Simple vessel drawing – RAO (left) and LAO (right)

Drawing Simple Vessel Marking Guide (Figure 124)

- ① The green dotted line indicates the epipolar line of the proximal point. In **Figure 125**, 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.

i Notes:

- Because the fluoros are not always acquired at the same instance, the mathematical projection of the epipolar line may not line up exactly with the fluoro features.
- Alignment of anchor points across the fluoro images depends on the physician's judgement. The user should strive to match features in the two fluoro images. Having a small offset between a start — or endpoint in one fluoro and the epipolar line of its corresponding point is acceptable. However, a large offset is not acceptable.

Selected Point

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

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

In the image below (**Figure 121**), the proximal anchor point (**1**), selected point (**2**), and (**3**) distal anchor point are all shown. To cancel the selection, click elsewhere on the image.

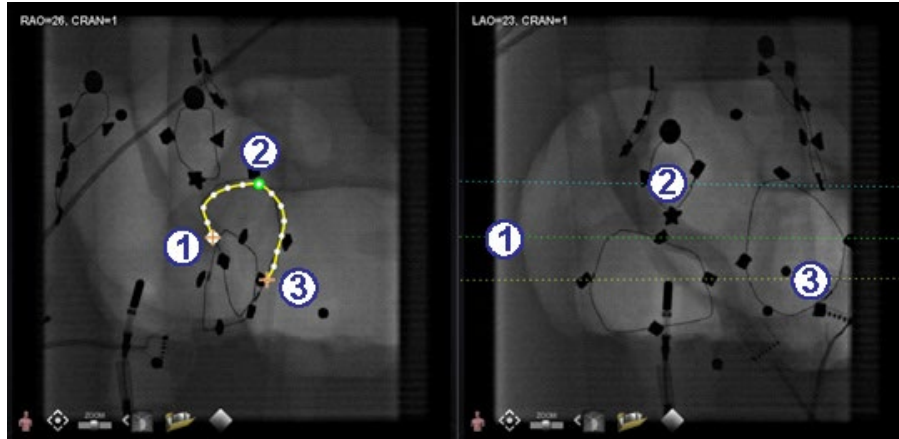


Figure 125. Proximal, selected, and distal points

Distal Point in Progress

As the user marks a vessel on a complementary fluoro (as on the LAO fluoro in **Figure 126**), the last point drawn is the distal point. The yellow dotted line in the original fluoro (RAO below) indicates the distal point of the complementary fluoro.

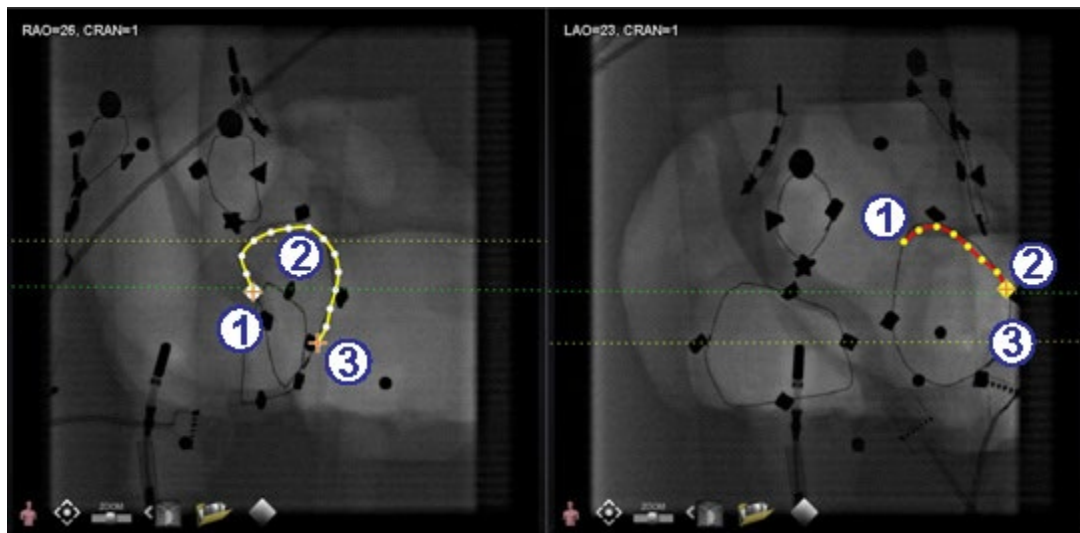


Figure 126. On complementary image, last point drawn is distal point

Distal Point in Progress Guide (Figure 126)

- ① Proximal anchor point
- ② Distal point of the active drawing (LAO in **Figure 126**)
- ③ Distal anchor point of the original drawing (RAO in **Figure 126**)

Moving Points

Click and drag a single point to move it. A green circle indicates a selected point (**Figure 127**).

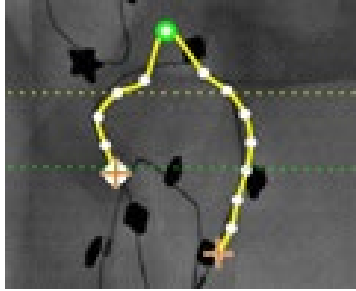


Figure 127. Click and drag single point to move it

Simple Vessel

A simple vessel is one that has only two anchor points on each of the two fluoro images. To create a simple vessel, follow the instructions below. Once all steps have been completed, a simple 3D vessel displays on Fluoro A and B on the main screen.

Creating a Simple Vessel

- Mark a vessel in one Fluoro window.
- Mark a matching vessel in the other Fluoro window, matching distal and proximal points along the green and yellow epipolar lines.
- Click **Accept**.
- Click **Yes** in the query dialog: “{Vessel #} contains only 2 anchor pairs. Continue without marking additional pair(s)?”
 - For a more precise drawing, click **No** and add more anchor points.
 - *Convert to anchor* point in the following section.

Vessel Point Menu

Right-click a point to view the point menu. 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.

Delete Point

To delete a point, right-click on the point and select **Delete point** (Figure 128). A confirmation dialog will appear, and the point disappears and cannot be restored. However, the user can click to add a new point.

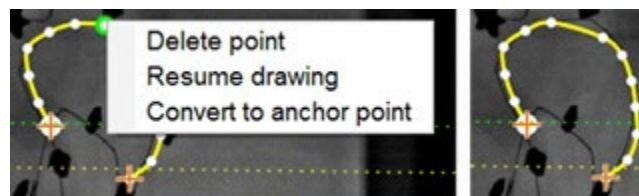


Figure 128. Delete point option

i **Note:** The user cannot delete a proximal point. **Delete point** will not display as a menu option when a proximal point is selected. If the user deletes a point that is also the starting point for a branch, the branch will also be deleted.

Resume Drawing

To extend a line, right-click any point on the line and select **Resume drawing**. A red, unanchored line extension displays. The user can drag the tip anywhere on the fluoro to position it. Click to set the next point. Continue to add points with single clicks or 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

The user may want to add anchor points to a vessel tree to make the 3D reconstruction more accurate. To convert a point to an anchor point, right-click and select **Convert to anchor point**. The new anchor point displays in addition to any existing anchor points.

i **Note:** The user must ensure there are matching anchor points on both images for 3D reconstruction. If a point is converted an anchor on one image, it must match on the other.

Add Branches



Figure 129. Adding branches – Start with matching trunks

Step 1 (Figure 129)

- ① To add branches, start with a pair of complementary trunks.
- ② Click **Add Branch**.

Step 2 (Figure 130)

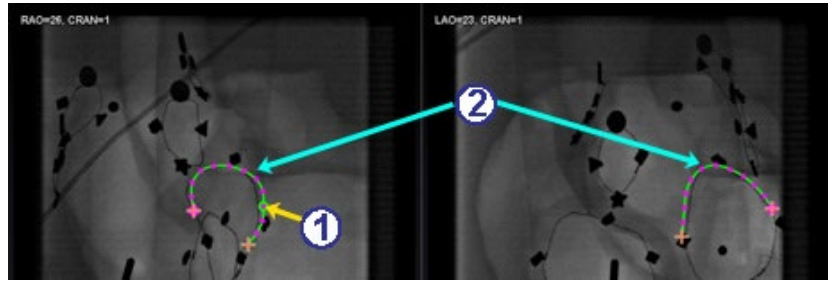


Figure 130. Select branching point on one trunk

- ① The user should select the point on the trunk where they wish to start the branch (**Figure 130**). 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.
- 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 about to be drawn.

- i** **Note:** If the user starts on the curve and wants to change the starting point, right-click and the point disappears. This is only true for a branch or trunk. If the user starts on an existing point, they must right-click elsewhere to deselect that point.
- i** **Note:** If the user selects a point and starts to draw before clicking **Add Branch**, drag the point back, click **Add branch**, and try again.

Step 3 (Figure 131 and Figure 132)



Figure 131. Branch name displays after selecting branching point

- ① A default branch name {Branch #} displays in the directory window after clicking a starting point (**Figure 131**). (The user can rename branches and trunks the same way.) The branch being drawn is in drawing mode (red and yellow).
- ② If the user starts on the curve and changes their mind about the starting point, right-click, and the point disappears. This is only true when starting a branch or trunk. If starting on an

existing point, simply right-click elsewhere to deselect that point. Complete the drawing by double-clicking the distal point, and the branch will display in the selected mode, yellow and white, **Figure 132**.

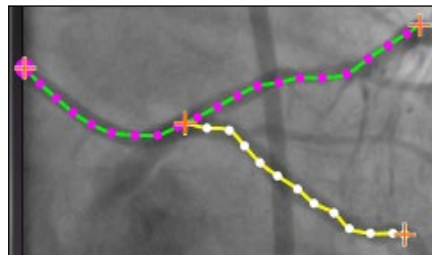


Figure 132. Completed branch in selected mode

Step 4 (Figure 133)

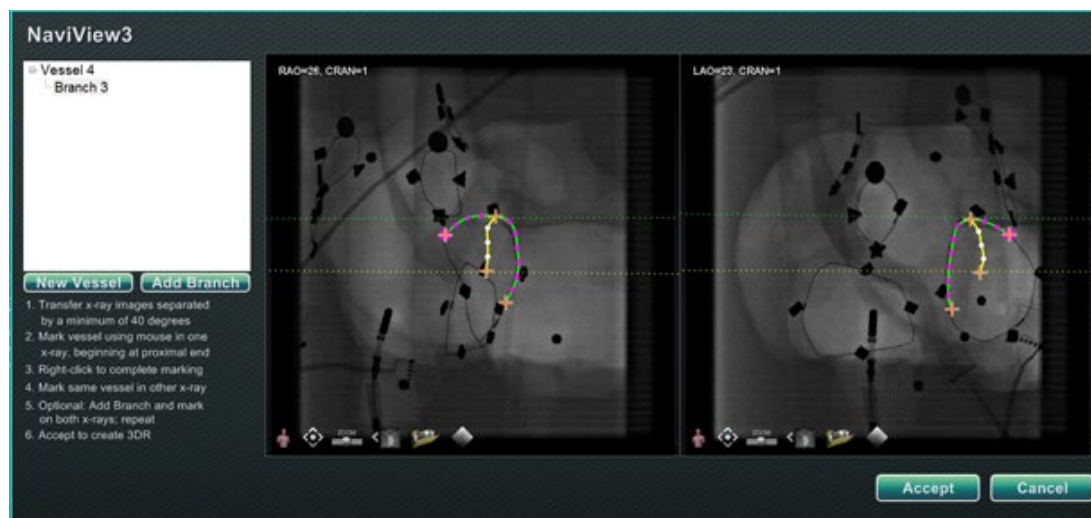


Figure 133. Draw complementary branch and click Accept

- ① Draw and complete the complementary branch.
- ② Click **Accept**.

i Note: There must be matching branches on both images for 3D reconstruction. If a branch is added on one image, it must match on the other.

Add More Branches

Following the process outlined above, the user can create more branches off existing branches and trunks (**Figure 134**). The user can create as many vessels and branches as desired.

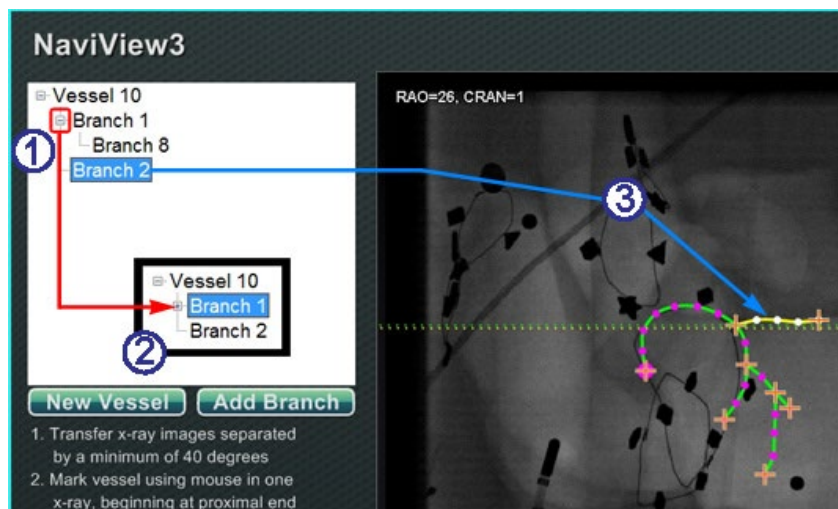


Figure 134. Directory tree tracks vessels and branches

Add More Branches Guide (Figure 134)

- ① As the user adds 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 The user can expand and collapse the vessel and branch names as branches are added beneath them. For example, to collapse Vessel 1 in **Figure 134**, click the minus (-) sign. Only the name Vessel 1 will display. The user can also collapse Branch 1. The user 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

The following section details numbering vessels and branches. Vessels and branches number consecutively. Deleted vessels and branches maintain their numbers. For example, if five branches are drawn and Branch 5 is deleted, the next branch drawn will be **Branch 6** (**Figure 135**).

- Numbering is only consecutive and does not relate to placement. For example, if three branches are drawn (Branch 1, 2, and 3) off Vessel 1; two branches (Branch 4 and 5) off Vessel 2; and then the user returns to Vessel 1 to draw another branch, the new branch will be **Branch 6**.
- If a new procedure is started AND *Navigant* has not been restarted, the vessel and branch numbering will continue from the previous procedure.

- Vessel / Branch name can be revised in the name field by right-clicking the vessel or branch and selecting **Properties**.
- When the directory tree window reaches capacity, scrollbars display.

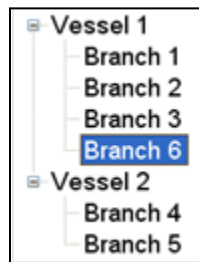


Figure 135. Vessel and Branch Numbering

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)

ClockDial Navigation offers users another way to navigate in three dimensions. To begin, click inside the Clock face. Clicking here provides the user with ClockDial Control. This feature expands the window to fit the frame, and four arrows appear (**Figure 136**).

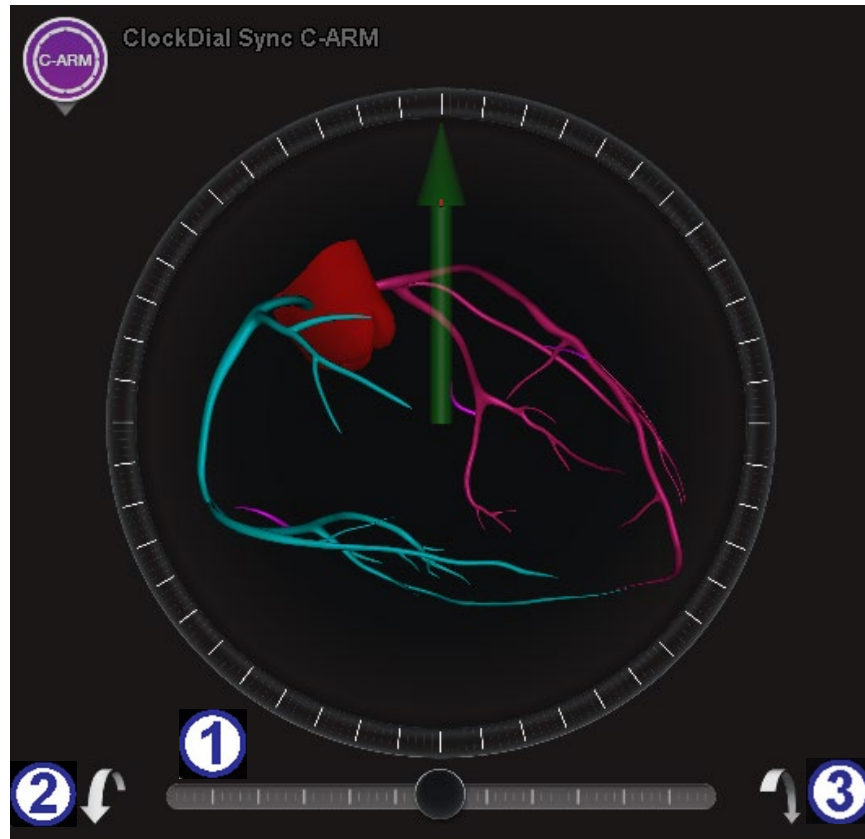



Figure 136. Synch C-Arm ClockDial View

ClockDial Guide (Figure 136)

- ① Adjusts rotation toward or away from the user. The center of the slider is in-plane with the clock dial.
- ② Rotates toward user by 5°.
- ③ Rotates away from user by 5°.
-  **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.

Navigation Assistant

The *Navigant* Assistant feature is only available for *Niobe* systems. It is the “touchscreen” in the Procedure Room, similar to the *Navigant* system in the Control Room. The user touches buttons on the screen to control views and manipulations and can select any of the green buttons at the top of the screen for the desired view (**Figure 137**). With the *Navigant* Assistant option, the user can guide the tip of the guidewire from within the Procedure Room.

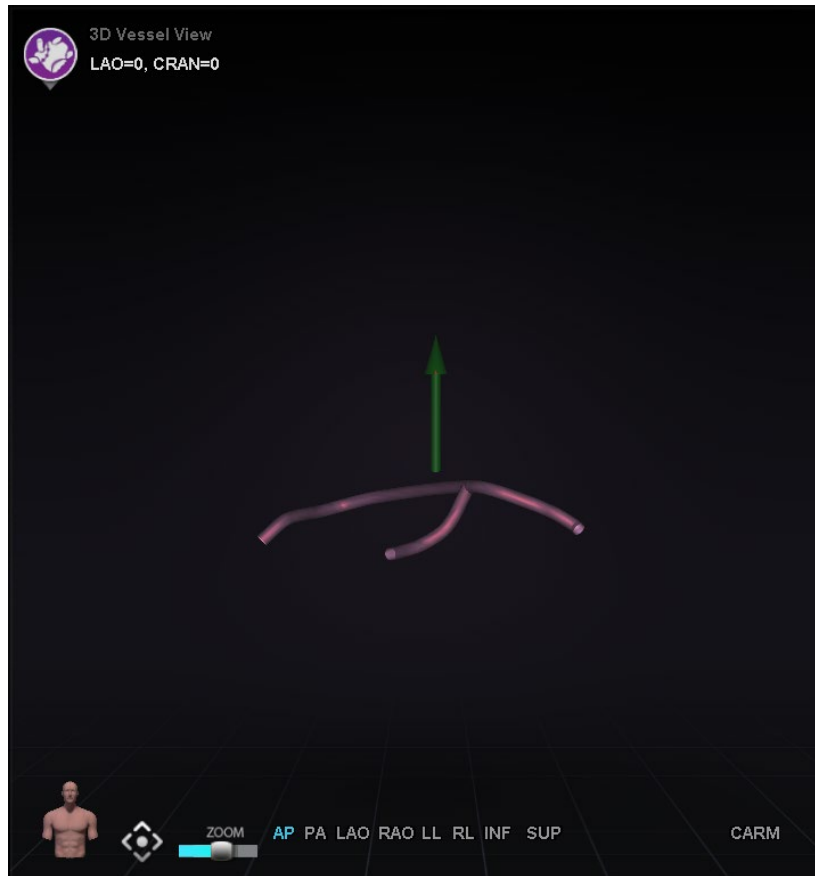


Figure 137. Navigant Assistant feature – Vessels view

Customer Satisfaction Feedback

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

Troubleshooting

If assistance is needed with any of the solutions below, call the TeleRobotic Support Team (TST) at 1-314-678-6200 or 1-866-269-5268.

Error Handling

| Problem | Solution |
|---|--|
| Attachment to USB Controller failed. | Click OK to shut down the system; restart. If the problem persists, call the TST. |
| Cannot connect to the Video Controller. | Click OK to shut down the system; restart. If the problem persists, call the TST. |

| Problem | Solution |
|---|--|
| Connection to the <i>Navigant</i> 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 TST. |
| Error opening Odyssey.xml file. | Click OK to shut down the system; restart. If the problem persists, call the TST. |
| 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 TST. |
| Hourglass displays on the <i>Odyssey</i> System main menu window for more than 2 minutes. | Call the TST. |
| Non- <i>Navigant</i> window displays improper color or a shifted image. | Reload the parameters for that device: <ul style="list-style-type: none"> • Click Configure Video. • Select the problem device. • Click Load Video Parameters. If the problem persists, call the TST. |
| Received a message that " <i>Only one instance can run at a time.</i> " | Shut down the system; restart. If the problem persists, call the TST. |
| Unable to use the <i>Odyssey</i> System mouse in the <i>Navigant</i> 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 TST. |
| 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 TST. |

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