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GENESIS **RMN**

ROBOTIC MAGNETIC NAVIGATION

User Guide



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Genesis RMN
User Guide

HDW-0358, Rev. F Effective Date: 3/26/2021



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30175 Hannover, Germany



Patents

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

Genesis RMN

7,774,046

Navigant

7,516,416; 7,537,570; 7,540,288; 7,540,866; 7,543,239; 7,627,361;
7,630,752; 7,657,075; 7,708,696; 7,751,867; 7,756,308; 7,761,133;
7,769,428; 7,831,294; 7,853,306; 8,024,024; 8,192,374; 8,369,934;
8,721,655; 9,314,222

Manufactured under the following European patent:

Navigant

EP 1 682 024, issued in Germany, France, and Great Britain; EP 1 769 390,
issued in Germany, France, and Great Britain.

Other patents issued and pending.

Stereotaxis Trademarks

- *Genesis RMN* is a trademark of Stereotaxis, Inc., registered in the United States.
- *Cardiodrive* and *Navigant* are trademarks of Stereotaxis, Inc., registered in the United States, the European Community, and Japan.
- *Odyssey* is a trademark of Stereotaxis, Inc., registered in the United States and the European Community.
- *Odyssey Cinema* is a trademark of Stereotaxis, Inc., registered in the European Community.

- *Odyssey Vision, Bullseye, NaviLine, NaviView3, QuikCAS, and TargetNav* are trademarks of Stereotaxis, Inc.

Other Trademarks

- *CARTO3, Lasso, Pentaray, Soundstar, Navistar, Thermocool, Celsius, and Celsius Thermocool* are registered trademarks of Biosense Webster.
- *AcQMap* is a registered trademark of Acutus Medical.

All other brand names, product names, and/or trademarks found in this document are the property of their respective owners.

EMC Directive Statement

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

Emissions: IEC 60601-1-2 ed 4.0 (2014-02)
CISPR11 ed 6.1 (2016-06), Class A (Professional Healthcare Facility Environment)

Immunity: 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. The *Genesis RMN* System is designed to be installed and operated in a Professional Healthcare Facility Environment.

Safety Standard Statement

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

Standard: 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-0352 Genesis Preventive Maintenance and Service Guide
HDW-0356 Troubleshooting Guide for Genesis with Siemens
HDW-0357 Genesis Education and Magnet Safety Manual
HDW-0361 Genesis Automatic Positioner Centering
HDW-0362 Quick Reference for Genesis with Siemens
HDW-0364 Quick Reference for Genesis with Stereotaxis Imaging Model S
HDW-0366 Troubleshooting Guide for Genesis with Model S
PRO-1019 Genesis with Siemens Site Planning Guide
PRO-1024 Genesis with Stereotaxis Imaging Model S Site Planning 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

Equipment information

Model no.: 001-011000-1 (Siemens), 001-011000-3 (Model S)

Classification: Class I Medical Electrical equipment



Note: No class B applied parts. Class B limits used for patient leakage. No class BF applied parts.

Degree of protection: IPX0

Mode of operation: Continuous

Electrical ratings:

Voltage rating:	400/480 V $\overset{3N}{\sim}$
Current rating:	12/10 A
Frequency:	50 / 60 Hz

The hospital will provide a disconnect device that removes all power to the *Genesis RMN* System when activated.



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



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

Operator-accessible disconnect device

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



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

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

Waste and Recycling

A contractor is responsible for the disposal and recycling of magnetic materials, scrap metals and electronics found in the *Genesis RMN* System.

Suggested Contractor: Walch Recycling & Eldementalle

Accessories

Accessory	Part Number
Cardiodrive	001-004115-9

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.

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Cover art

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1. Overview

Introduction

The Stereotaxis Genesis Magnetic Navigation System (MNS) is a medical platform designed for electrophysiological and interventional procedures. Genesis MNS facilitates the control of the distal tip of compatible magnetic devices via magnetic fields. Genesis MNS includes the Stereotaxis *Genesis RMN*® System (*Genesis System*) with the *Navigant*® Workstation (NWS) System (*Navigant*) and the *Cardiodrive*® System. Genesis MNS is an interventional workstation for the intravascular navigation of appropriately equipped, magnetically-adapted devices (e.g., catheters or guidewires) through tissue to designated target sites.

Physicians use computer—controlled permanent magnets, found in the *Genesis RMN* System, to orient or steer the tips of compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart. The *Genesis RMN* System integrates with *Navigant* software which determines the direction the magnetic field should be applied and allows the physician to remotely advance and retract compatible, magnetically-adapted devices using *Cardiodrive*.

About This User Guide

The purpose of this user guide is to provide the Genesis MNS user with instructions for operating the equipment. The guide describes basic system information, specific functionality (*Genesis RMN*, *Navigant*, *Cardiodrive*, integration and automation EP, and intracardiac features), and emergency operations and troubleshooting. The manual does not address instructions for the use of associated magnetic disposables. This guide covers the following systems:

Genesis RMN Siemens Reference number 001-011000-1

Genesis RMN Model S Reference number 001-011000-3

Companion Systems

Genesis MNS may be used with the following magnetically-compatible devices:

- NAVISTAR® Catheter
- NAVISTAR® RMT THERMOCOOL® Catheter
- Celsius® RMT Catheter
- Celsius® Thermocool® RMT Catheter

Genesis MNS (specifically *Navigant*) communicates with:

- Biosense Webster® Stockert 70 RF Generator

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

Genesis MNS communicates with a variety of digital fluoroscopy systems:

- Siemens AXIOM™ Artis™ dFC MN
- Siemens AXIOM™ Artis™ dBC MN
- Stereotaxis Imaging Model S (powered by Omega Imaging)

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

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

Indications

In the United States, the following Indications are applicable for the *Genesis RMN* and *Cardiodrive* systems.

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

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

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

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

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

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




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

Contraindications

There are no known contraindications.



Graphics and Symbols






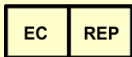

The following graphics and symbols are used in this User Guide:

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

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

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

Symbol	Name	Description
	Magnet Present	Indicates a magnet is present in the equipment.
	Consult Instructions	See the Operating Instructions for additional information or instruction.

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

Safety

Warnings

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



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



WARNING: The *Genesis RMN* System should be used only by qualified medical professionals who have been thoroughly trained in its use. The *Stereotaxis Cardiodrive* System should only be used by physicians trained in the use of these

systems, with a thorough understanding of angiography and percutaneous interventional procedures.



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

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

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



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



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



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



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



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



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



WARNING: When a graphical representation of the catheter tip and shaft on the Genesis MNS display screen, the graphical representation is a display of the calculated catheter shape, based on the initial location and orientation of the catheter base and distance of catheter shaft advancement (or retraction) by the *Cardiodrive* System.



WARNING: *Genesis RMN* does not track the location or orientation of the catheter. (If the user purchases a compatible mapping system, the location and orientation of the catheter tip can be displayed.)



WARNING: The graphical representation of the catheter on the Genesis MNS 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 Image" button.



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



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



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



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



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



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



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



WARNING: Ablation system foot pedal should not be connected to the RF

generator in the Procedure Room. It is intended for use only in the control room.



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



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

Precautions



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



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



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



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



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



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



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



CAUTION: If the physician believes the catheter may be in the wrong location, the physician should refresh the fluoroscopy image. If a discrepancy occurs, the physician should reregister the mapping system to *Navigant*, remark the catheter base, and recalibrate the *Cardiodrive* System.



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



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



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

Pressing the X-ray system E-stop will cause the *Genesis RMN* System to stop (via software).



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



CAUTION: If the *Genesis RMN* System is operated with interlocks overridden (as described in the Emergency Operations section), a collision between the *Genesis RMN* System and the X-ray system is possible. Closely monitor the magnet movement, and be ready to release the Move button if a collision is imminent. Failure to heed this caution may cause damage to the equipment.



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

- In the Navigate position, the field strength at the flat front surface of the magnet covers can be as high as 0.7T.
- In the Navigate position, the field strength is less than 0.2T five inches (13 centimeters), or more, in front of the front surface of the magnet cover.
- In the Pivoted and Stowed positions, the field strength is less than 0.2T one inch (3 centimeters), or more, in front of the front surface of the magnet cover.
- Field strengths above, below, behind, and to the sides of the magnets are always less than those on the front surface.



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



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

Technical Details and System Testing

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

Mechanical Performance Testing

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

Deflection Testing Positions

Pos A - Isocenter

Pos B – Posterior 2 inches (5 centimeters) from A

Pos C – Inferior 2 inches (5 centimeters) from A

Pos D – Patient right 2.5 inches (6 centimeters) from A

Pos E – Patient left 2 inches (5 centimeters) from A

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

In vivo testing

Navigation to predefined targets with compatible catheters was successfully performed with the following results (threshold < 2.85ma is considered good contact).

Target Anatomy	Navistar RMT		Navistar RMT Thermocool		Celsius RMT		Celsius Thermocool RMT	
	Target Achieved	Pacing Threshold	Target Achieved	Pacing Threshold	Target Achieved	Pacing Threshold	Target Achieved	Pacing Threshold
RA Lateral Wall	yes	0.6	yes	0.7	yes	0.8	yes	0.5
RA Posterior Wall	yes	1.0	yes	0.5	yes	0.2	yes	0.6

LA Pulmonary Vein	yes	n/a	yes	n/a	yes	n/a	yes	n/a
LA Appendage Wall	yes	0.3	yes	1.1	yes	0.4	yes	0.8
RV Lateral Wall	yes	0.3	yes	0.4	yes	0.8	yes	0.9
RV Septum Wall	yes	0.5	yes	1.3	yes	0.4	yes	1.6
LV Lateral Free Wall	yes	0.3	yes	0.4	yes	0.5	yes	1.1
LV Septum Wall	yes	0.4	yes	1.5	yes	0.6	yes	1.1

Fluoroscopy Exposure

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

Cybersecurity

Please note the following important information concerning cybersecurity:

- Genesis MNS cybersecurity controls operate in the background the with *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 call center.
- Only trusted users should be allowed physical access to the Genesis MNS.
- 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 Genesis MNS. 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 Genesis.
- Images acquired during C-Arm movement cannot be transferred to Genesis.
- Images acquired during table movement cannot be transferred to Genesis.

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

C-Arm collision with magnet considerations

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

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

The magnetic tube shield around the X-ray tube would stick to the magnet.

The C-Arm could sustain physical damage.

The cosmetic covers of the magnets could sustain physical damage.



CAUTION (Siemens): Siemens collision avoidance is disabled by design when not communicating with the *Genesis RMN* System unless the Siemens System sees that the *Genesis RMN* magnets are in the Stowed position (via hardware signal). When collision avoidance is disabled, the C-Arm will move very slowly, but it is still possible to hit the magnets at this slow speed.



CAUTION (Model S): Model S collision avoidance is disabled by design when not communicating with the *Genesis RMN* System unless the Model S System sees that the *Genesis RMN* magnets are in the Stowed position (via hardware signal). When collision avoidance is disabled, the C-Arm will allow movement to only the AP position and table height movement will be restricted.

Electromagnetic Compatibility Information



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



WARNING: The Genesis MNS should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Genesis MNS should be observed to verify normal operation in the configuration in which it will be used.



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



WARNING: This equipment has been tested for radiated radiofrequency (RF) immunity only at selected frequencies, and use of nearby emitters at other frequencies could result in improper operation. Improper operation may consist of (1) prevention of patient treatment, (2) uncontrolled motion of magnets, and (3) uncontrolled motion of the *Cardiodrive* System.

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

Emissions

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

The following table provides guidance and Stereotaxis' declaration on **electromagnetic emissions** for the *Genesis RMN* System:

Emissions	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The <i>Genesis RMN</i> System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Complies	

Emissions	Compliance	Electromagnetic environment—guidance
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 radio-frequency 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 *Genesis RMN* System:

Immunity test	IEC 60601 test level*	Compliance level*	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8 & 15 kV air	± 8 kV contact ± 2, 4, 8 & 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 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 <i>Genesis RMN System</i> requires continued operation during power mains interruptions, it is recommended that the <i>Genesis RMN System</i> be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Immunity—RF interference

The following table provides guidance and Stereotaxis' declaration on **electromagnetic immunity** regarding radiofrequency for the *Genesis RMN System*:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Conducted RF IEC 61000-4-6	3 Vrms	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the <i>Genesis RMN System</i> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	150 kHz to 80 MHz 3 V/m 80 mHz to 2.7 GHz	3 V/m	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Proximity Fields to RF Wireless Communications			$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
	27V/m		
	380-390Mhz		
	28V/m	27V/m	
	430-470Mhz		
	800-960Mhz	28V/m	
	1700-1990Mhz		
2400-2570Mhz			
	9V/m		
9V/m			
704-787Mhz			
5100-5800Mhz			

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b

Interference may occur in the vicinity of equipment marked with the following symbol:



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

Separation distances



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

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

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.



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

Glossary

The following terms appear in this document:

Term	Description
2D	Two-Dimensional.
3D	Three-Dimensional.
5 Gauss line	See Gauss.
AP	Anterior-Posterior.
AutoMap	An integrated feature between <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.
Cardiodrive System	The Stereotaxis tool that provides the physician with the ability to advance and retract catheters from a Control Room. The full name is <i>Cardiodrive</i> Catheter Advancement System (CAS).
CARTO 3 System	Biosense Webster system that combines 3D mapping and navigation systems with the Stereotaxis Genesis MNS.
CAS	<i>Cardiodrive</i> Catheter Advancement System. (See <i>Cardiodrive</i> System.)
Click & Go	An integrated feature between the <i>Navigant</i> software and the CARTO 3 System that enables the user to automatically target any location on the map surface by double-clicking a point on the map.
Clinical Workflow Manager (CWM)	A component of the NWS application software that executes scripts to guide medical procedures.
CRT	Cardiac Resynchronization Therapy.
DICOM	Digital Imaging and Communications in Medicine (standardized protocol for exchanging medical image and patient data).
EMC	Electromagnetic compatibility.
EP	Electrophysiology.
Fluoro	Fluoroscopic, or Fluoroscopy.

Term	Description
Fluoroscope	An X-ray image intensifier that produces live X-ray images displayed on a monitor. Also called X-ray or C-Arm.
Fully retracted	Magnet positioners are pivoted toward the patient and at the farthest distance from the patient.
Gauss (G)	The centimeter-gram-second (cgs) unit of magnetic flux density. A 5 Gauss line is marked on the floor of the Procedure Room. < 5 G of static magnetic field exposure for the general public is considered safe.
Genesis Magnetic Navigation System (MNS)	A medical platform that enables physicians to more effectively navigate catheters, guidewires and other magnetic interventional devices through the blood vessels and chambers of the heart to treatment sites and then to effect treatment. The Genesis MNS consists of the <i>Genesis RMN</i> , <i>Navigant</i> , and <i>Cardiodrive</i> systems and is available only in magnetic labs.
Genesis Robotic Magnetic Navigation (RMN) System	A Stereotaxis system consisting of computer-controlled magnets that assist physicians in orienting and steering compatible, magnetically-adapted devices.
IC	Interventional, or Intracardiac, Cardiology.
Isocenter	In X-ray technology, the isocenter is the point in space through which the central ray of the radiation beams pass.
LAO	Left Anterior Oblique
MNS	Magnetic Navigation System. (See <i>Genesis</i> Magnetic Navigation System.)
Move button	Upon selecting a magnet position on the UTSC, the user will hold down the Move button to move the magnets into the selected position.
Navigant software	A platform of software applications designed to simplify clinical workflows. The <i>Navigant</i> product (excluding the <i>Odyssey</i> add-on), provides enhanced integration of catheterization and electrophysiology labs and improved automation during magnetic navigation of medical devices. (Available only in magnetic labs.)
Navigation volume	Spatial volume defined for MNS, where the MNS is capable of generating any magnetic field direction at the target magnetic field strength provided by the MNS.

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.
NWS	“ <i>Navigant</i> Workstation.” See <i>Navigant</i> software.
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	An optional display and user interface package that enables the user to customize consolidation of the point of control for the entire interventional lab.
OpenMapping System	OpenMapping API feature allows communication between Genesis MNS and mapping systems that have been tested to be compatible. These compatible mapping systems are referred to as OpenMapping systems.
RAO	Right Anterior Oblique.
RF	Radiofrequency.
RMN	Robotic Magnetic Navigation (<i>e.g., Genesis is a RMN System</i>)
RMT	A remote magnetic technology. (RMT is often used to refer to the integrated CARTO 3 / Genesis MNS environment incorporating 3D mapping and navigation and magnetic maneuvering of compatible devices).
Tesla (T)	The standard unit of magnetic flux density.
USB	Universal Serial Bus. An interface-standard device that enables many peripheral devices to connect to a computer.
UTSC	Universal Tableside Controller. Touchscreen controller positioned on the side of the patient table in the Procedure Room.
W·s	Watt-second, the energy equivalent to the power of one watt sustained for one second.

2. Basic Information

Genesis RMN Magnet Information

The arrangement of the magnetic Procedure Room is fairly standard among institutions. This drawing describes the main components (**Figure 1**) with the X-ray system.

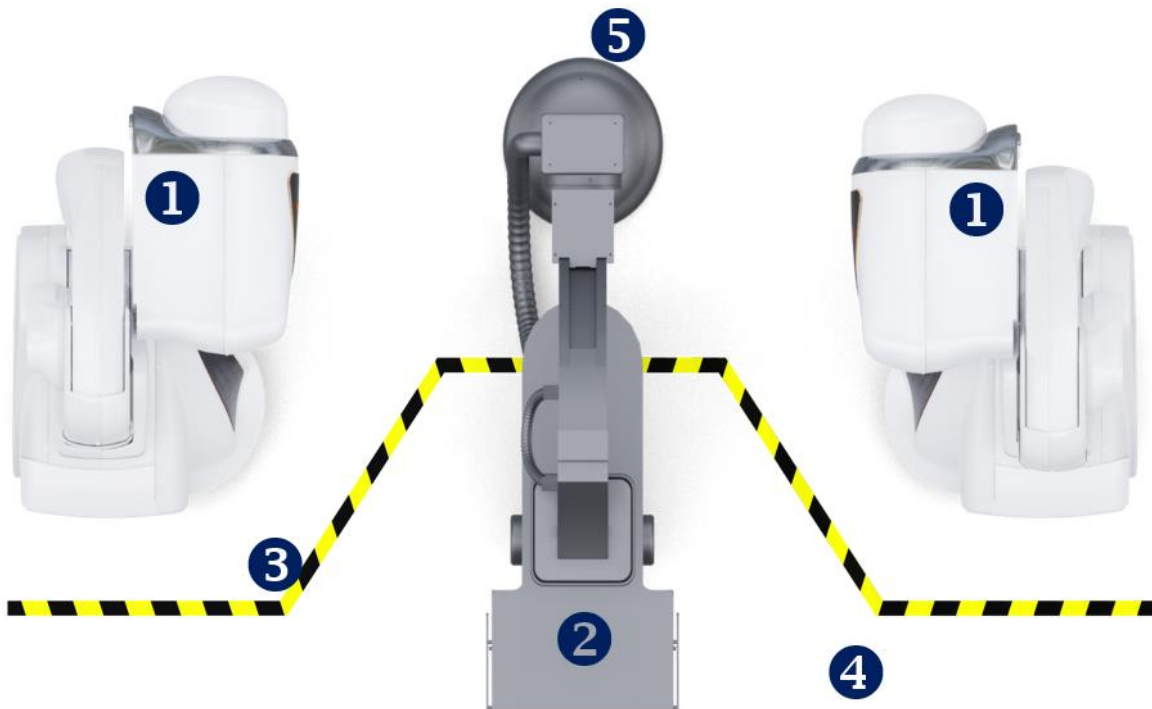


Figure 1. Procedure Room components

Procedure Room component guide (**Figure 1**)



- ① **Genesis RMN magnet positioners.** Magnet positioners or *pods* contain system magnets.
- ② **Patient table.**
- ③ **Five Gauss line.** The dividing line between the zones that are less than 5 G and more than 5 G when the magnets are stowed. Institutions indicate this division in various ways.
- ④ **Five Gauss zone.** The zone that is less than 5 G (the table side of the room) within which individuals should remain when magnets are stowed.
- ⑤ **X-ray system.** The compatible digital fluoroscopy system in use.



Genesis RMN Magnet Positions

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

System positions

At any given time, the magnets are in one of the following positions: Stowed, Pivoted, Retracted, or Navigate AP. The magnets are moved by pressing buttons on the Universal Tableside Controller (UTSC). The following table describes each of the positions and lists when the various positions are used in a procedure.

Position	Position description	When position is used
Stowed	 <p>Figure 2. Magnets in Stowed position</p>	<ul style="list-style-type: none"> • When no procedure is being performed • During non-magnetic procedure • To allow increased imaging angle flexibility • When greater patient access is needed • When field beyond Physician Access Line needs to be less than 5 G
Pivoted	 <p>Figure 3. Magnets in Pivoted position</p>	<ul style="list-style-type: none"> • When greater patient access is needed • To allow increased imaging angle flexibility
Retracted	<p>Magnets are pointed toward patient; cover-to-cover distance is larger than what is necessary to enable magnetic navigation. When magnets are retracted a maximum distance from patient while in fully Pivoted position, system is in Retracted position.</p>	<ul style="list-style-type: none"> • When field needs to be reduced • To allow increased imaging angle flexibility without having to wait for magnets to pivot away from patient • When greater patient access is needed

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

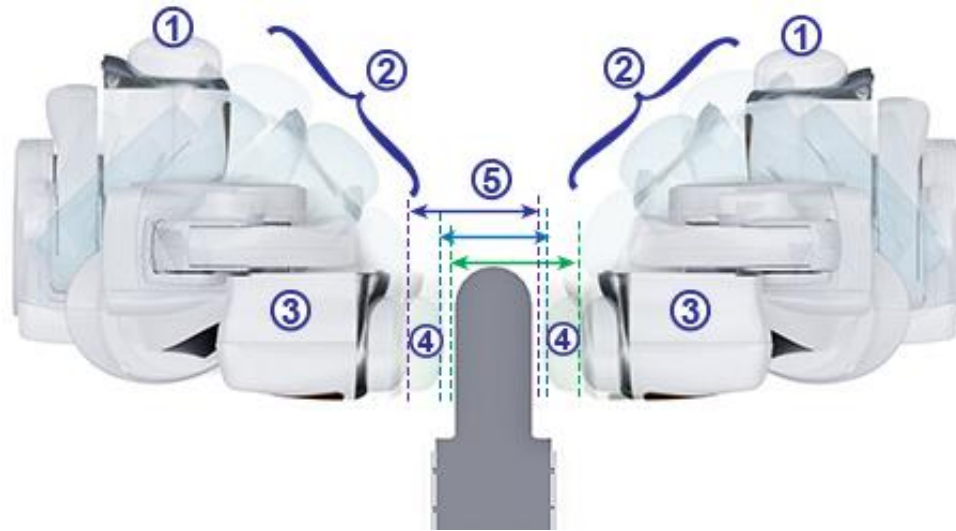


Figure 7. Magnet position options

Magnet positions guide (Figure 7)

- ① Stowed
- ② Pivoted
- ③ Retracted
- ④ Extended
- ⑤ Cover-to-cover distance

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



Figure 8. Stowed positions



Figure 9. Navigate AP position

The magnets move in close proximity to the patient table and the imaging system C-Arm. The user may move the patient table off center to optimize visualization of the desired anatomy for magnetic navigation. When the **Navigate AP** button is pressed on the bedside controller, the magnets will automatically calculate the table position and the cover-to-cover distance required. The user may also manually move each magnet independently to accommodate the change in table position. For example, if the right magnet is moved away from the patient, the left magnet needs to be moved toward the patient until the message “Magnets in Navigate Position” displays on the *Genesis RMN* screen.

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

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

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

Figure 10. Red shading indicates pinch hazard areas



Note: To prevent collision, all accessories and cables should be clear of magnet movement. The user should note areas labeled for potential pinch hazard as shown in **Figure 10**.



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

Universal Tableside Controller (UTSC)

The UTSC allows the user to physically move the magnets and controls various other system functions. In the Procedure Room, the user controls the *Genesis RMN* System magnets using the UTSC (**Figure 11**). Once the Genesis RMN icon is selected (**Figure 12**), more UTSC buttons display as well as a **Transfer Image** button.



Figure 11. UTSC buttons (*left*)

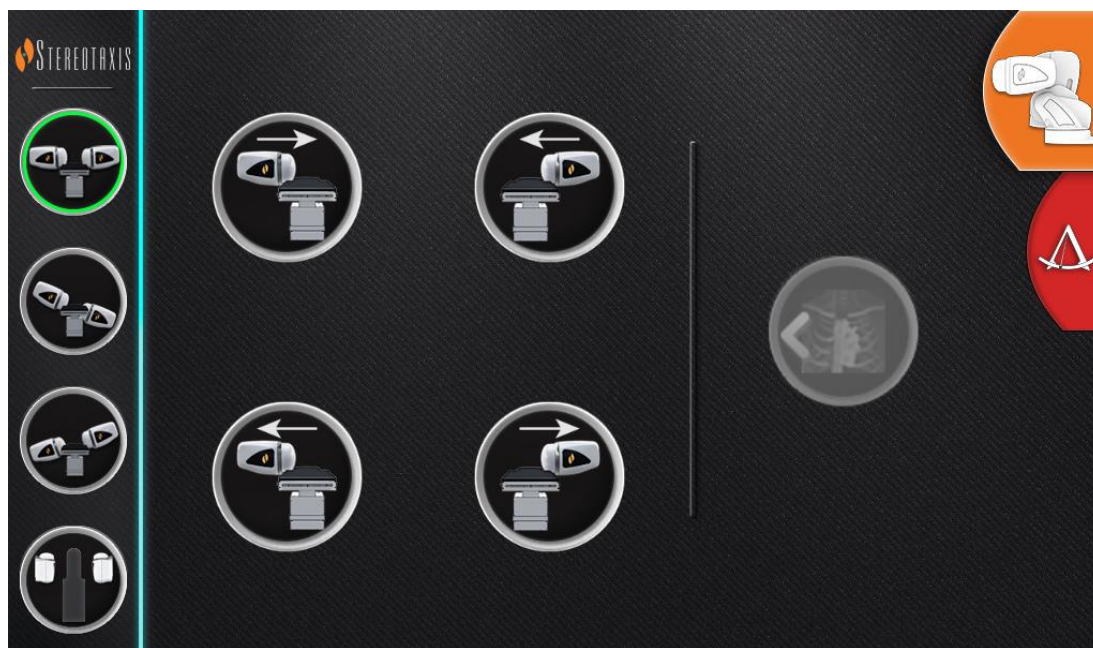










Figure 12. Genesis RMN icon selected, more UTSC buttons displayed

Table 1 details the magnet positions that correspond with the UTSC buttons (**Figure 11** and **Figure 12**). The user must select a magnet position on the UTSC and hold down the **Move** button (**Figure 16**) to move the magnets into the desired position.

Table 1. UTSC buttons and descriptions

	Navigate AP		Advance patient right side*
	Navigate LAO		Advance patient left side*
	Navigate RAO		Retract patient right side*
	Stowed		Retract patient left side*

* Applies to patients in head-first supine position.

System Power Up

Preparing for patient's entry

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

1. Ensure no ferrous objects (objects magnets could attract) are in the area.
2. Ensure objects magnets could damage are not in the area, such as credit cards, watches, floppy disks, cell phones, beepers, and hearing aids.
3. Power up the system. On the remote power panel (located in Control Room), hold the toggle switch in the **ON** ("I") position for approximately 1 second until the green power lamp illuminates (**Figure 13**).
4. If not already positioned, retract magnet positioners to Stow by pressing the **Stow** button on the UTSC **Error! Reference source not found.** and the **Move** button (**Figure 16**) to aid in patient loading.

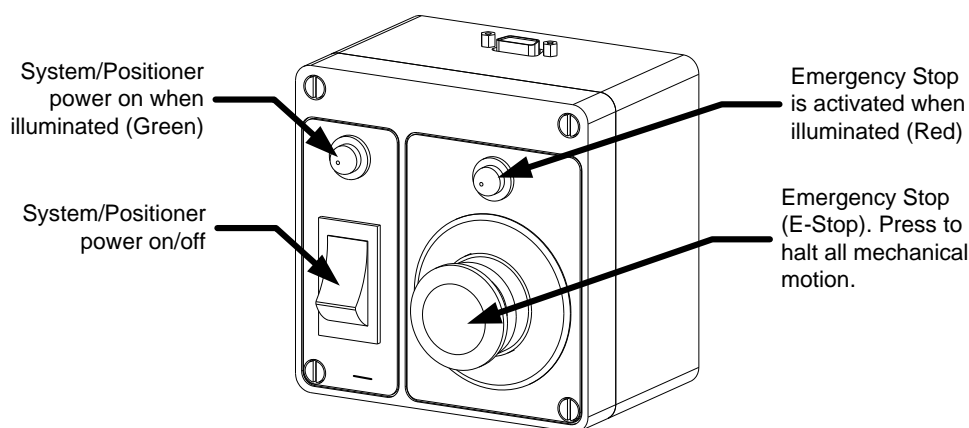


Figure 13. Power Box in Control Room



Note: In case of a voltage interruption, *Genesis* might shut down, requiring a system restart.

Recommended Patient Loading Procedure

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

Magnetic safety precautions

The intent of this procedure is to keep the patient and attending medical staff in a low magnetic field (less than 5 G) while the patient is transferred into and out of the Procedure Room. The 5 Gauss line is marked on the floor. The user should move the magnets into the Stowed position using the UTSC, and move the tabletop back, away from the X-ray system and magnets. Individuals should stay on the tableside of the 5 Gauss line when the magnets are stowed.



WARNING: The *Genesis RMN* System produces a strong magnetic field that is always on. Patients and operators with pacemakers, internal cardiac defibrillators (ICD), neurostimulators, or magnetic sensitive or ferromagnetic implants should contact the manufacturer of their respective implant **before** entering the Procedure Room. Serious injury may result if no precautions are taken.

Patient Table

The patient should be centered laterally on the table so the magnets on either side of the table can move toward the patient equally. The table can be moved vertically to adjust the height. See **Figure 105** and **Figure 106** for specifics about adjusting table height.

Positioning patient

The position of the patient on the table depends on the type of procedure performed. Patients should be in a head-first supine position (**Figure 14**) except when a femoral or tibial procedure is performed. For femoral and tibial cases, the patient should be feet-first supine (**Figure 15**).



Figure 14. Patient loaded in head-first supine position



Figure 15. Patient loaded in feet-first supine position

The patient is loaded feet first for femoral and tibial cases; however, the user must **register the patient “head-first, supine”** for some **Siemens X-ray systems** to ensure proper image transfer. Check the X-ray system user manual to see how the system handles feet-first cases.

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

Cover-Force Sensor

The magnet covers contain cover-force sensors that detect when the face of the cover is pressing against the patient or padding. When a cover-force sensor is activated, the magnet positioner pauses, then retracts slightly and stops.

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



Figure 16. Move button

If the second cover-force sensor is activated before the positioner reaches Navigate position, the Navigate Position Assistance dialog appears. If the second positioner has enough room to reach Navigate position, the *Genesis RMN* System adjusts the Navigate position center based on this new location and displays the status message, *“Magnets in Navigate Position.”*

Automatic positioner centering

The *Genesis RMN* System can automatically center the magnet positioners in the Navigate position, based on the patient table’s lateral and vertical positions. To understand this, it is important to first understand the Navigate position and cover-force sensor.

1. Using fluoroscope images, center the patient (region of interest) relative to the X-ray isocenter. (See *Common Registration Tasks* for more information about the isocenter.)

2. Press one of the **Navigate** buttons (the ring around the button will light) on the UTSC. Then press the **Move** button. The system calculates the target position based on the position of the patient table and begins moving to that position.
3. If motion stops and the message “*Magnets in Navigate Position*” displays in the bottom-left corner of the monitor, the automatic positioner centering has been successful. The system also emits an audio signal that the system is in Navigate position. (The user may adjust the volume in the Settings → System tab.)
4. If the cover contacts the patient and activates the cover sensor, the cover will stop and retract slightly. The other cover’s position will adjust to try to reach the Navigate position.
5. If motion stops before the system reaches the Navigate position, one of these conditions has occurred:

After selecting one of the **Navigate** buttons, the operator did not hold the **Move** button down until the system reached the Navigate Position. The operator may continue to the Navigate Position by pressing and holding the **Move** button.

Both cover-force sensors have activated. The system displays a message in the bottom-left corner of the monitor and emits an audio signal if the system does not reach Navigate position because of cover-force sensor activation.

The cover cannot achieve the position because of a potential collision with the table or X-ray system. Alternatively, the cover cannot achieve this position because the patient is not centered laterally on the table and one cover is fully extended.

Navigation Procedure Tasks

1. Place the patient on the table as described in *Recommended Patient Loading Procedure*.
2. Prepare the patient per hospital procedure and apply a sterile drape over the tableside user interface.
3. Insert the magnetic catheter or guidewire and advance it to the desired anatomy. The user can advance the device manually or with the *Cardiodrive* System (for approved catheters).
4. Place the X-ray system in the AP, head-side position.
5. Select one of the **Navigate** buttons on the UTSC. Then press and hold the **Move** button to move the magnets to the Navigate or Navigate AP position.
6. Perform the procedure.
7. When the procedure is complete, move the magnets to the Stowed position by pressing the **Stow** button on the UTSC. After which, press and hold the **Move** button until the

message “*Magnets in Stowed Position*” displays in the bottom-left corner of the window.



Notes:

- In case of a voltage interruption, the *Genesis RMN* System might shut down, necessitating a system restart.
- The system was designed with a safety feature that requires pressing the Navigate button multiple times to give the user an opportunity to double-check patient positioning and safety before moving the magnets.
- If the system is unable to reach Navigate position due to a possible collision with the X-ray system or table, a Navigate Position Assistance dialog will display indicating which system components are at risk for a collision.

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

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

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



CAUTION: The *Genesis RMN* System uses a magnetic field to orient the tip of the catheter to the desired intracardiac orientation.

Navigate Position Assistance

The position of equipment (e.g., the table and X-ray arm) in the Procedure Room may interfere with magnet movement. If the system detects a collision risk while the magnets are moving, a Navigate Position Assistance dialog will be displayed. Warning messages associated with the collision risks will be displayed in the dialog. These messages show the system component in red (table, X-ray arm) that needs to be adjusted. In the case of a cover sensor activation, either of the magnetic pods will be shown in red (**Figure 17**). After the appropriate adjustment is made to resolve the collision risk, the associated component will be shown in gray. In some cases, adjustments of multiple components may be required to resolve the collision.

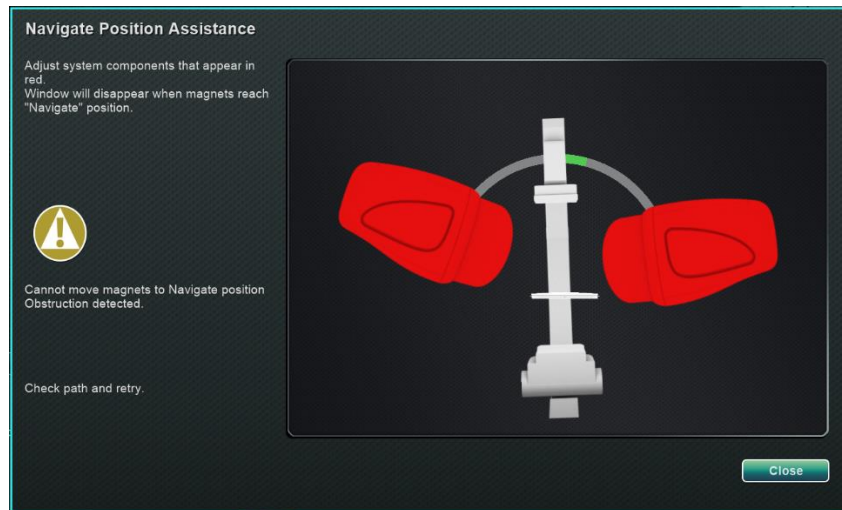


Figure 17. Magnet collision risk message

Once the collision risk has been eliminated, press and hold the **Navigate** button on the UTSC. The dialog automatically disappears after reaching Navigate position. The user is now able to proceed. If it is determined that there are no collision risks, the user may press the **Close** button to remove the dialog.

The green zones in the Navigate Position Assistance dialogs represent regions where the C-Arm or table should be positioned to eliminate the collision risks. In **Figure 18**, the C-Arm is shown in red and needs to be adjusted until it reaches the green zone. Until the C-Arm collision risk is eliminated, the magnets will not move. In **Figure 19**, the C-Arm has been adjusted into the green zone and is shown in gray. The user may now proceed as there is no collision risk.

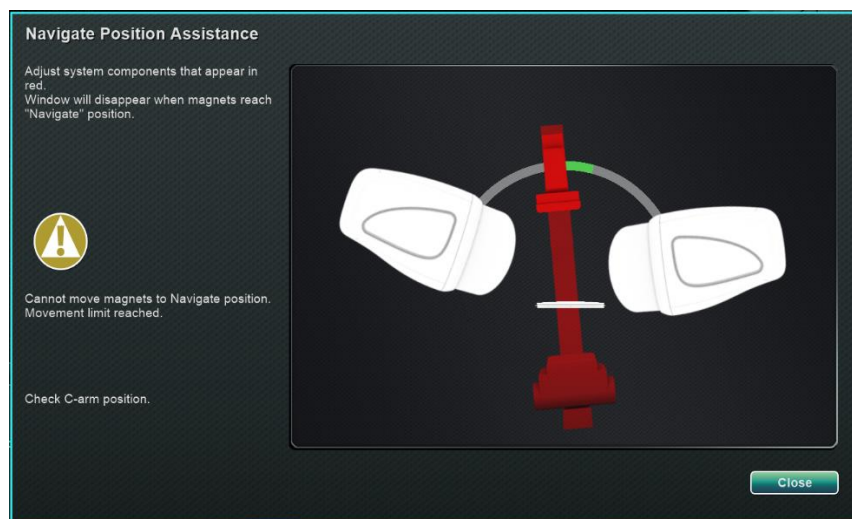


Figure 18. C-Arm collision risk message

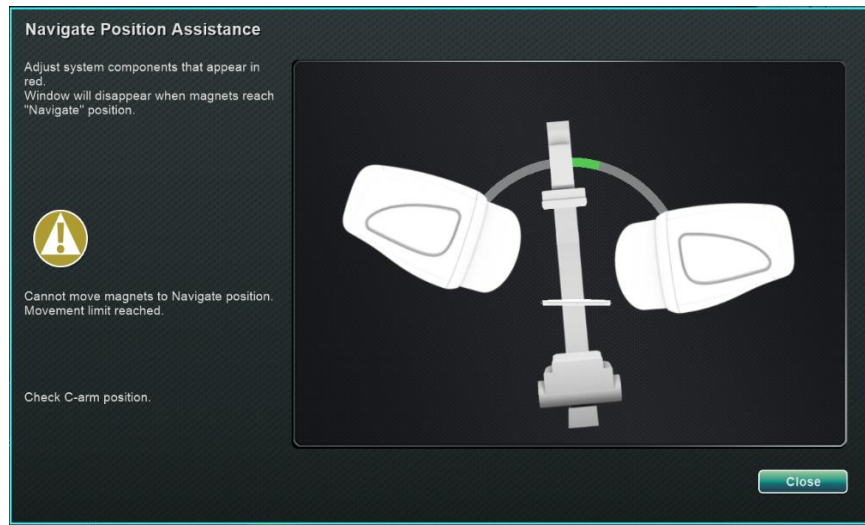


Figure 19. C-Arm graphic after C-Arm has been adjusted

In **Figure 20**, the table is shown in red. Before proceeding, adjust the table laterally until it is in the green zone and displays as gray. In **Figure 21**, the table is shown in gray after having been moved back into the green zone.

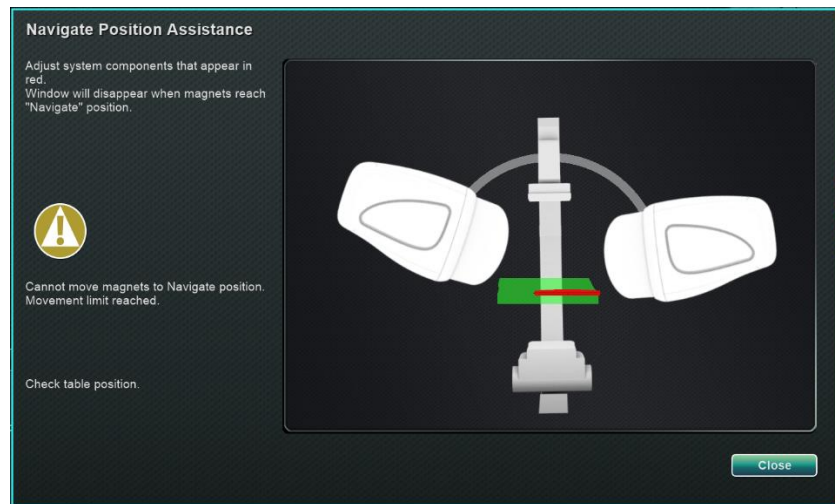


Figure 20. Table collision risk message

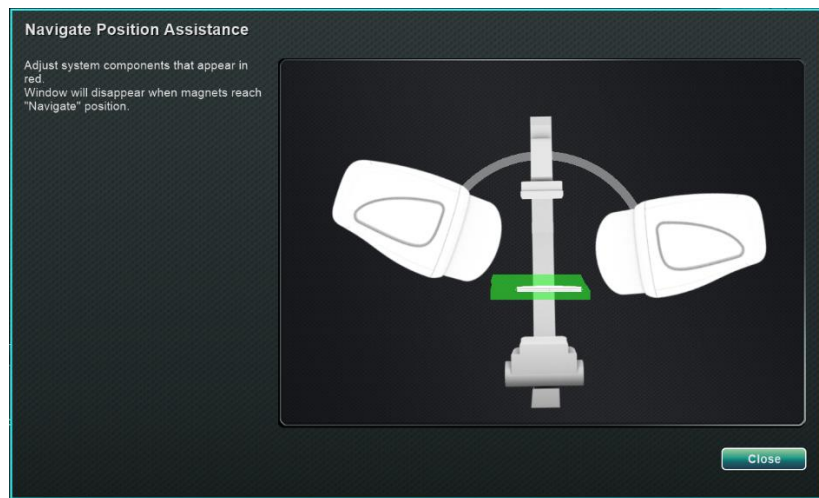


Figure 21. Table graphic after being adjusted

Software Basic Information

Start window



Figure 22. Start window

Start window

- **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**
 - o **Genesis RMN** icon – the icon displays *Genesis RMN* messages, warnings, or errors.
 - o **X-ray** icon – the icon displays X-ray system messages, warnings, or errors.
 - o **System info** icon – the icon displays *Genesis RMN* 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 23**). The top graphic displays a traditional *Odyssey*® user interface and the bottom graphic displays a QuadHD user interface.

Info 1 Start Time: 02-Jan-2020 14:36:17

Last Name First

2 Patient ID DOB

Sex Male Female Other Arrhythmia 3

4 Physician

5 Notes

Heart Chamber 6

7    

Right Atrium Left Atrium Right Ventricle Left Ventricle

8 Use Mapping: Use RMN

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


7    

Right Atrium Left Atrium Right Ventricle Left Ventricle

8 Use Mapping: Use RMN

Figure 23. 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 23** 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.



Help Dialog button. Displays Help DialogError! Reference source not found. for fields on this screen.

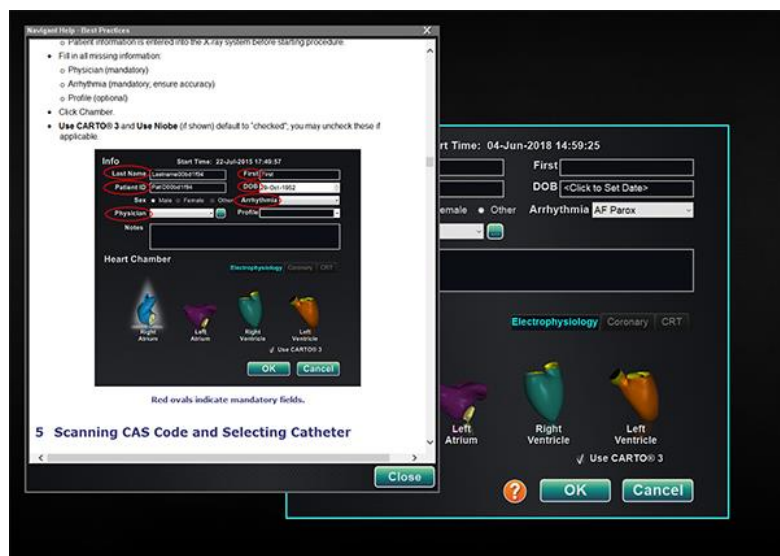


Figure 24. Help Dialog for new procedure information window



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 25**) lists all previously run 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.

Procedures

Start Time	Patient	Patient ID	Physician	Arrhythmia
17-Feb-2021 13:24:33	Ring, Julia	2468	Melinda	AF Redo
17-Feb-2021 13:23:28	Adams, Jeff	555	Genevieve	A Flutter
17-Feb-2021 13:17:18	Smith, Linda	321	Diane	SVT
17-Feb-2021 13:15:28	Jenkins, Debra	12345	Carla	A Flutter
17-Feb-2021 13:14:16	Jones, Steve	123	Alex	A Flutter

Start: 17-Feb-2021 13:23:28

Patient: Adams, Jeff

ID: 555

Sex: M Date of Birth: 01-Jan-1970

Physician: Genevieve

Notes:

Figure 25. 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 is able to **Delete** or **Rename** a physician name 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. 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. See **Figure 26** to explore the **Procedures** tab.



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 26. Utilities window – 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 27**) 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*

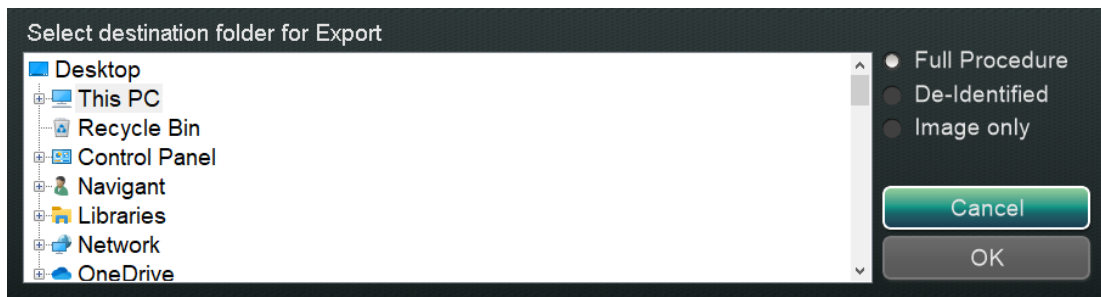


Figure 27. Select destination folder for Export window



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, a CD/DVD drive, the *Cardiodrive* user interface, and a barcode scanner.

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

Cardiodrive user interface

The *Cardiodrive* Catheter Advancement System (CAS) user interface (**Figure 28**) 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 28. *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 *Genesis RMN* 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).

i **Note:** The *Cardiodrive* CAS enables physicians to advance/retract compatible magnetic electrophysiology (EP) catheters from a control room. Before utilizing CAS, compatible catheters must be registered.

QuikCAS unit

The *QuikCAS*[™] Catheter Advancement System is used to remotely advance and retract catheters during magnetic navigation.

Scanning the activation code of each *QuikCAS* unit is necessary before use. 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 29**[Error! Reference source not found.](#)) is located on the CAS II disposable box in two places: the outer box label and the inner tray label. Scan either label to activate the *QuikCAS* device. Scan an activation code at any time **before** requesting a magnetic field direction.



Figure 29. 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 30**.

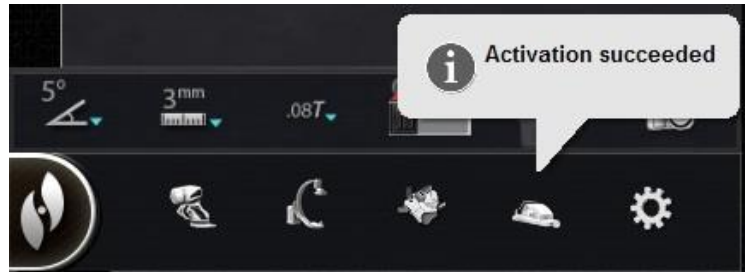


Figure 30. Activation succeeded

The activation code displays in the text field at the bottom of the Device Selection dialog (**Figure 31**). 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 32**) on the hardware status bar.



Figure 31. Device Selection dialog; Activation Code displayed

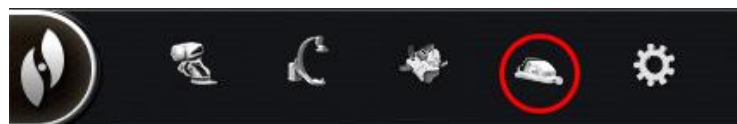


Figure 32. CAS procedure indicator

Keypad

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

Guide to Figure 33

- 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 33. Keypad – Top blue keys and orange keys

Guide to Figure 34

- 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 34. Keypad – Green keys

Guide to Figure 35

- 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 35. Keypad – Stop key and right blue keys

Logitech Mouse & Keyboard: Features and Troubleshooting

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.

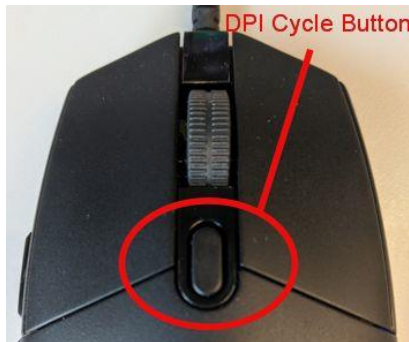


Figure 36. Logitech PRO Mouse- "DPI Cycle" button

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.
 - o To toggle Game Mode on/off, press the **FN** and **F8** keys at the same time.



Figure 37. 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 38)**.
- **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 38. 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 on it (**Figure 38**).

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 2. 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

Cleaning Instructions

Cleaning the lab

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

To clean the floor under the *Genesis RMN* magnets, pivot the system between the Stowed and Navigate positions using the UTSC.

Cleaning the *Genesis RMN* System

The following section details how to clean the Genesis RMN System. The *Genesis RMN* magnets can be wiped clean between cases. The cleaning solutions should be a pH neutral hospital-grade, EPA-registered germicidal solution (e.g., CIDEX® Activated Dialdehyde).

Drapes can be purchased to cover the *Genesis RMN* System and maintain a sterile field on the front of the pods to keep them clean throughout the procedure. Account Managers can assist in purchasing drapes as needed.

3. Navigant Features

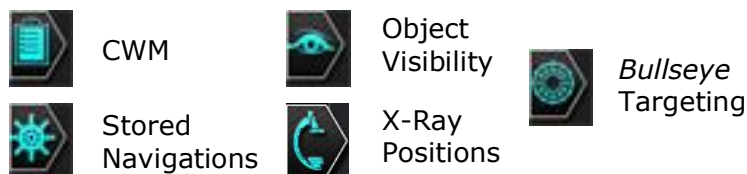
Clinical Workflow Manager

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 39).



Figure 39. 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 (**Figure 40**) from which to display **preset navigations**.



Figure 40. Navigations panel categories

Preset navigations

The list of preset navigations changes based on the workflow.

1. To display preset navigations, click the arrow next to the category name.
2. To select a preset navigation, click to highlight the preference. Once the preset navigation is highlighted, the **Apply** button becomes available (**Figure 41**).
3. Preset navigations represent commonly used *field directions*. The user may want to fine-tune these settings by moving the field vector slightly.
4. After the user selects **Apply**, the option to store the navigation then becomes available.



Figure 41. Preset navigations, Septum selected

Stored navigations

1. When the user has created a new field direction they want to store, click **Store Error! Reference source not found.** or press the **Store Navigation** button on the keypad (**Figure 42**).



Figure 42. Store navigation button

2. Stored navigations are displayed under a new heading, **Stored Navigations** and fields are sequentially named: Navigation #1, Navigation #2, etc., (**Figure 41, right**).



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

Currently applied navigation

In **Figure 43, left**, Navigation #1 is selected but not in **bold** as Navigation #1 has not yet been applied. Navigation #1 is **bold** in **Figure 43, 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 43. Left: "Navigation #1" selected but not applied;
Right: "Navigation #1" selected and applied

Rename stored navigations

1. To rename a stored navigation, right-click the name and select **Rename**.

2. Type a new name and click **Apply**. The stored navigation is renamed.

Delete stored navigations

1. To delete a stored navigation, right-click the name and select **Delete**.
2. 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 44).



Figure 44. 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 45**).

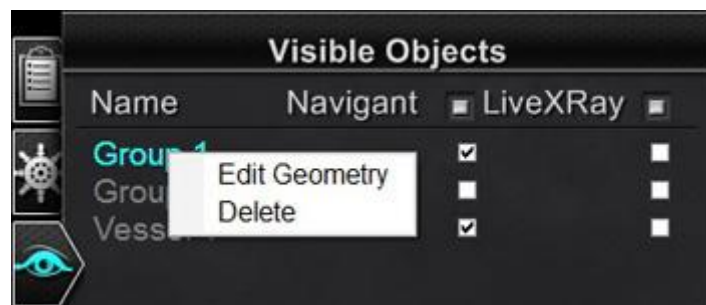


Figure 45. Visible Objects – Edit Geometry and Delete

Right-click menu for Vessels

Vessels are the only Visible Objects that display the **Properties** and **Manual Registration** commands on the right-click menu (**Figure 46**).

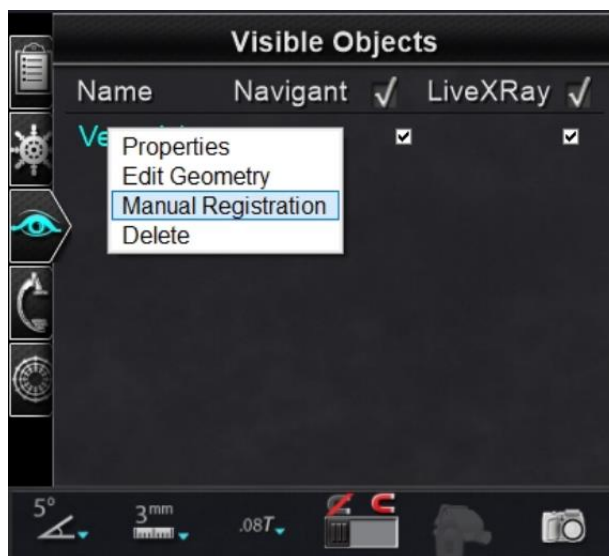


Figure 46. Right-click menu for Vessels

Vessel Properties

In the Visible Objects Vessel right-click menu., click **Properties**. The Vessel Properties dialog displays (Figure 47) 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.

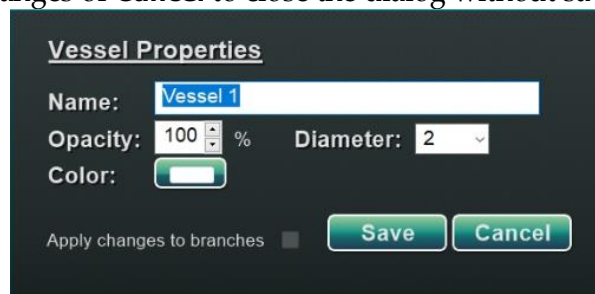


Figure 47. Vessel Properties dialog

Manual Vessel Registration

In the Visible Objects control panel, right-click **Vessel** and select **Manual Registration**. The Vessel Registration dialog displays (Figure 48). **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.

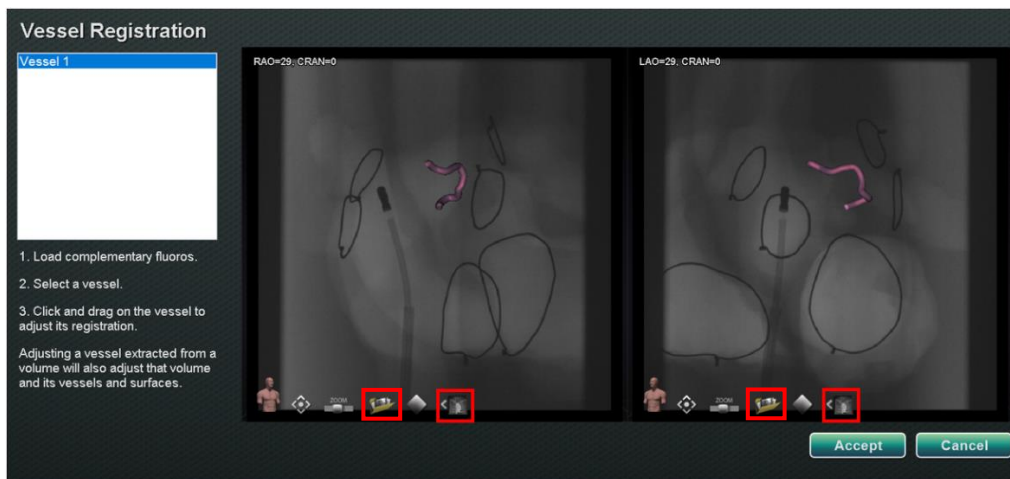


Figure 48. Vessel Registration dialog

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 48** and) but various display options are available.

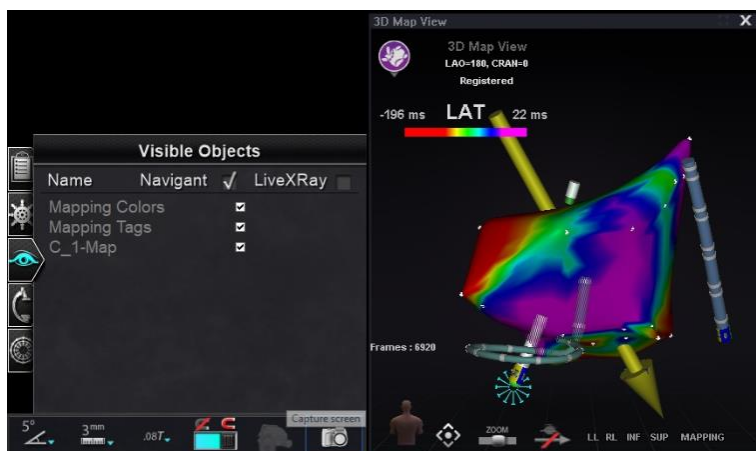


Figure 49. Mapping Colors and Mapping Tags

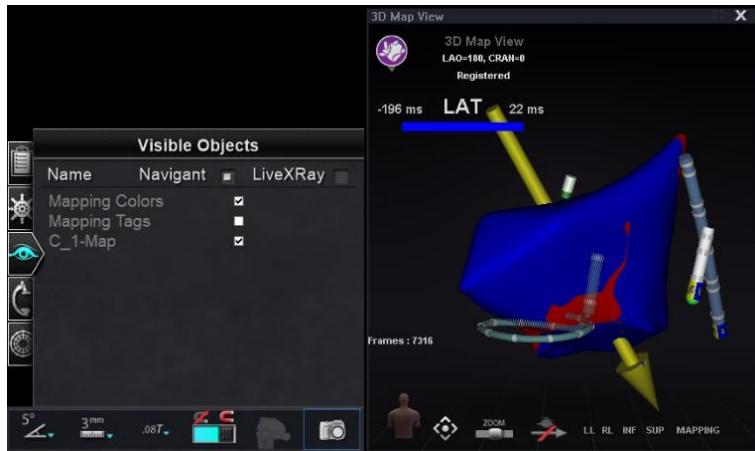


Figure 50. Mapping Colors without Mapping Tags

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 3. X-ray Positions control panel

System	X-ray positions
---------------	------------------------



Bullseye Targeting control panel

The *Bullseye*TM Targeting control panel (**Figure 51**) provides a simple interface for navigating the catheter around a central point. The Stereotaxis *Bullseye* uses the “bull’s eye” target concept to facilitate directional movement of the catheter relative to a central position. Movements around a central axis are made by double-clicking on the target surface or via automatic sequencing. *Bullseye* movement is simultaneously visible in two places on the screen: (1) within the *Bullseye* surface itself and (2) in the Ideal Anatomy view.

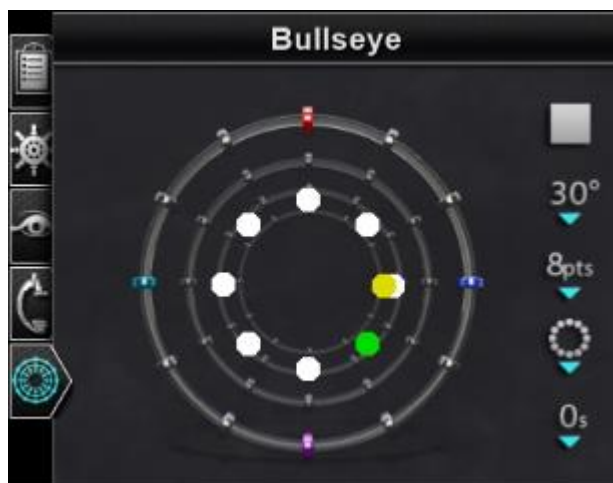


Figure 51. *Bullseye* Targeting control panel

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* surface 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 52**), 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 52. Bullseye Target and vector markers aid navigation


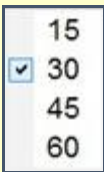
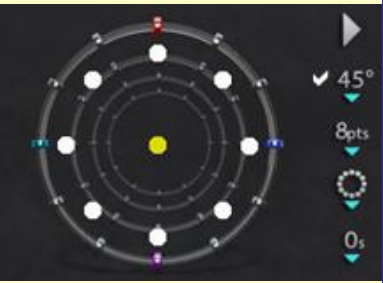


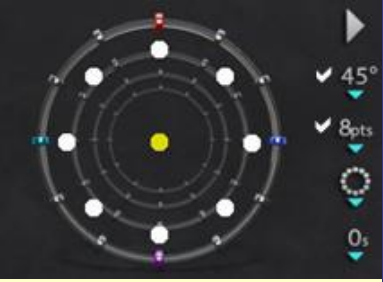

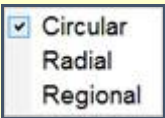


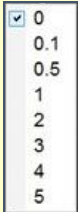

Altering Bullseye Targeting

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 4** 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 4. Bullseye Targeting Settings

Button	Icon	Default setting	Explanation
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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 to halt automation, either on the button in this dialog (**Figure 53**) or on the UTSC in the Procedure Room. 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 53** and **Figure 54**).



Figure 53. Automation dialog

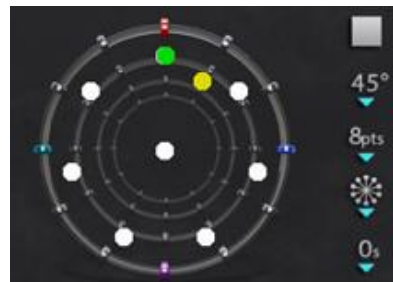


Figure 54. Radial pattern



Figure 55. 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 55**) 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 56**). The slide bars for adjusting the volume for the Procedure and Control rooms are just above the drop-down menu.



Figure 56. 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.

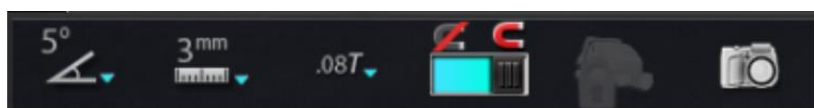
Control Toolbars – The “Dashboard”

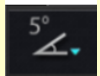
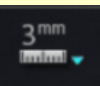
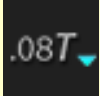
The two toolbars at the bottom-left corner of the main window are similar to the dashboard of a car. They display functional buttons and information about the system:





- Main toolbar
- Hardware status indicator bar

Main toolbar

The Main toolbar (**Figure 57**) is the first of two toolbars on the dashboard. **Table 5** details the settings and features found on the Main toolbar.

**Figure 57.** Main toolbar**Table 5.** Main toolbar settings

Button	Icon	Explanation
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.
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.

Button	Icon	Explanation
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 Genesis RMN System.
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 disabled. See Figure 102 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 58** when no device is selected. The buttons for Magnetic Field and Access Protection are disabled.



Figure 58. Main toolbar display— no device selected

Hardware status indicator bar

The hardware status indicator bar (**Figure 59**) 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 6** details the features found on the Hardware status indicator bar.

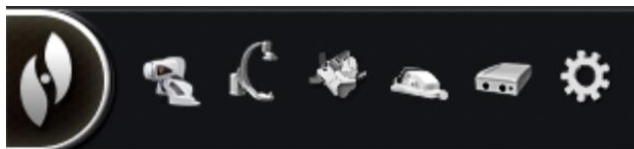

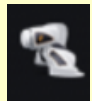







Figure 59. Hardware status indicator bar

Table 6. Hardware status indicator settings

Button	Icon	Explanation
Systems options		Displays the System options menu. See below for menu options.
Genesis status		Indicates connection status of Genesis RMN system.
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 Stockert 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 Stockert Generator.

Viewing messages

Following are the three ways to view hardware status messages:

ToolTips (Figure 60): Hold the cursor over the button to view the ToolTip status message summary.

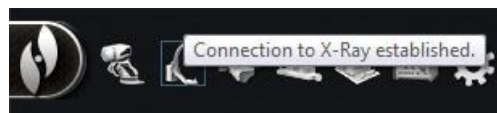


Figure 60. ToolTip displaying X-ray status message

Popup messages (Figure 61): *Navigant* displays messages when necessary. They pop up from the hardware icon that represents the affected system.

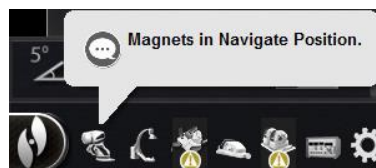


Figure 61. Popup window – *Genesis* message

Dialogs (Figure 62): 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 62. CARTO 3 dialog displaying messages

System options menu

Access the System options menu by clicking the **System options** button (far left) on the hardware status toolbar (Figure 59). Several options display (Figure 63).

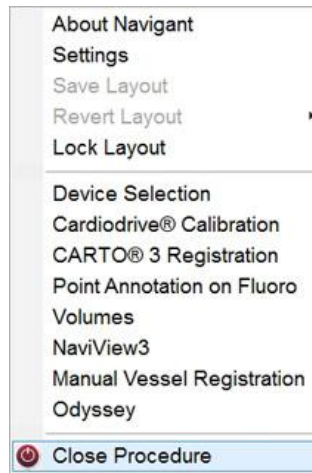


Figure 63. System options menu

About *Navigant*

The About *Navigant* dialog displays information about the software, such as name, company name, version number, and copyright (Figure 64). Access it from the **System options** button on the hardware status indicator toolbar.



Figure 64. About *Navigant* dialog

Layout Editor



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

The Layout Editor (**Figure 65**) allows the user to customize the procedure layout displayed.

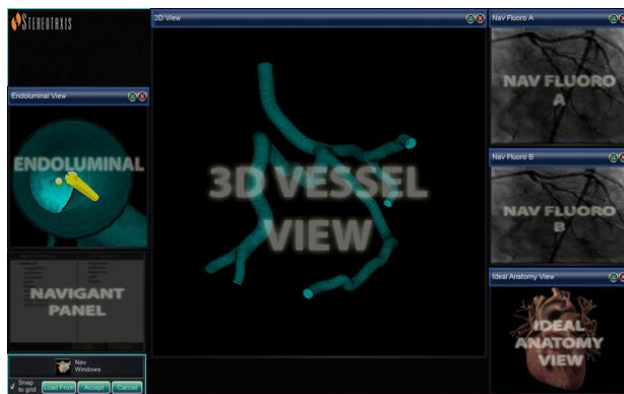


Figure 65. Layout Editor

Move, resize, and close control panels and windows

Move

Move a window or control panel Layout Editor by pressing and dragging anywhere in the element except the **X** in the red circle (upper-right corner). When 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 66**). A layout cannot be saved when elements overlap.



Figure 66. 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

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

The Settings dialog contains four tabs (plus an additional one or two tabs 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 67**) 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 as seen in **Figure 68**.

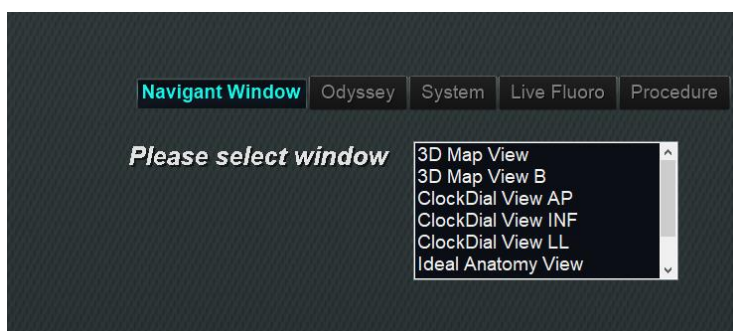


Figure 67. Settings windows – *Navigant* tab

In **Figure 68**, 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 (message outlined in **Figure 68**).

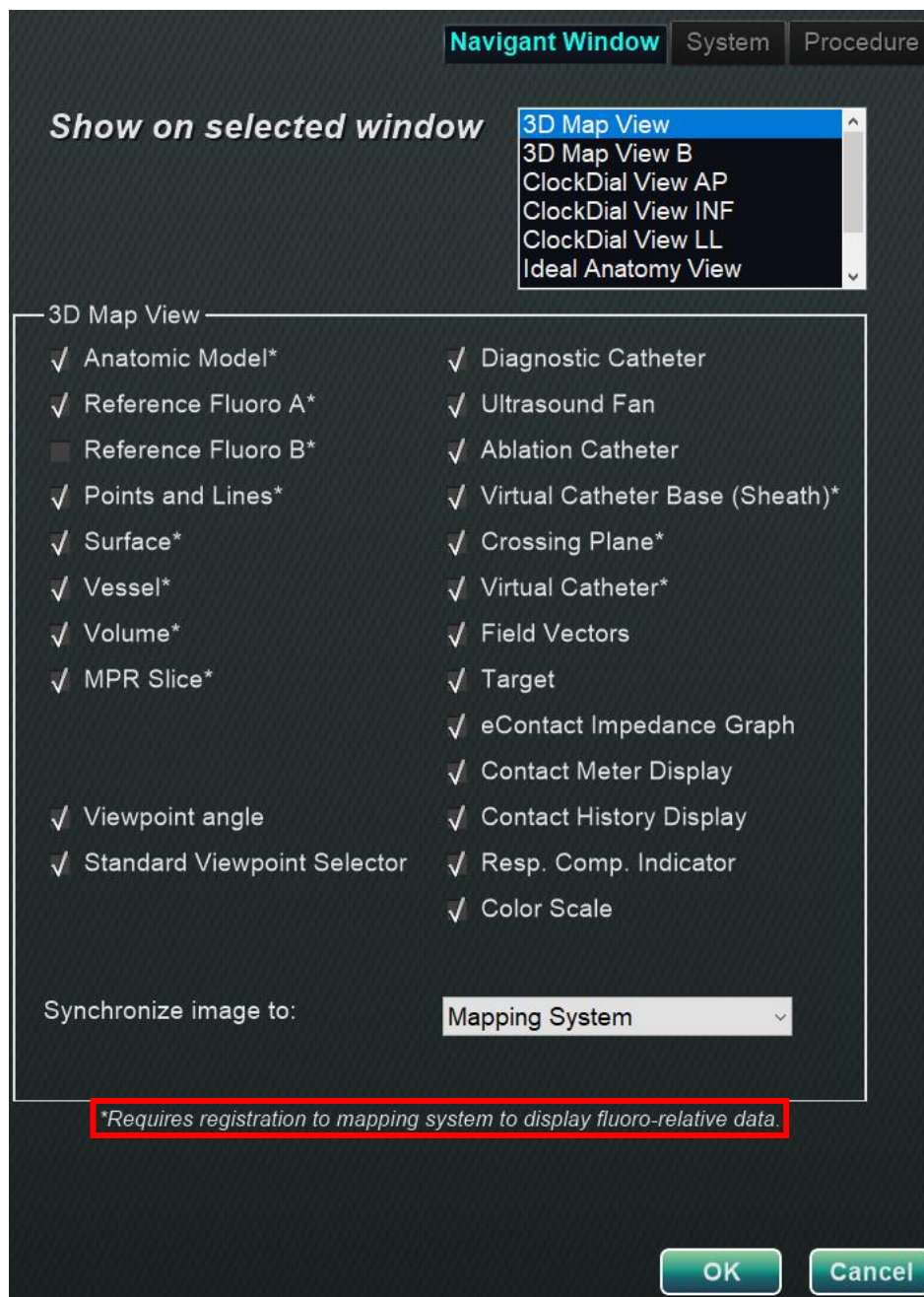


Figure 68. 3D Map View window selected

Alternatively, when any other window is selected such as Ideal Anatomy View in **Figure 69**, fluoro (X-ray) items will display. Upon registration to a mapping system, mapping system data will display (message outlined in **Figure 69**).

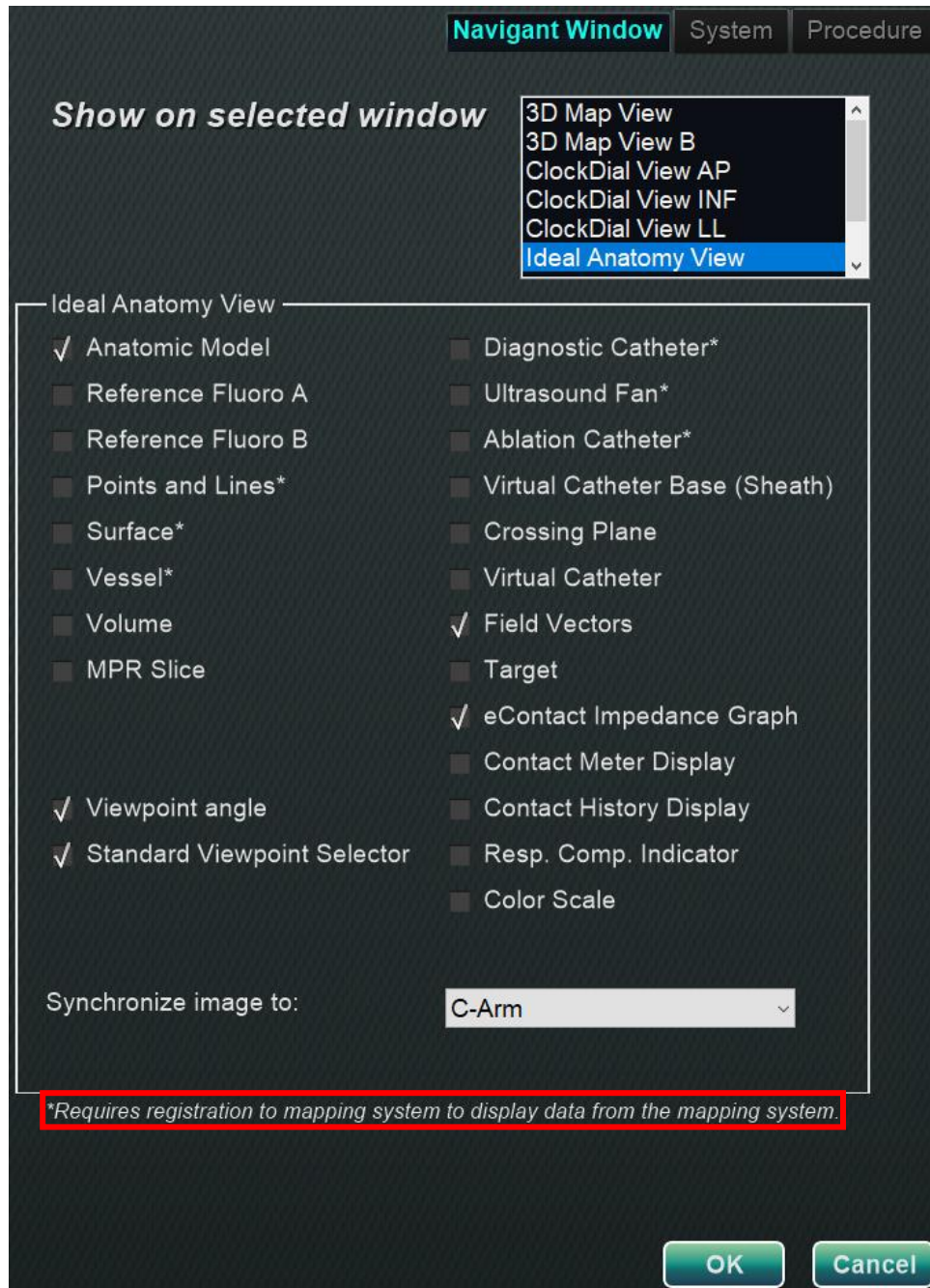


Figure 69. Ideal Anatomy View window Selected

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 68** shows typical selections for the 3D Map View window. For example, if the Nav Fluoro A window is selected, the Reference Fluoro A box typically would be checked.

General window options

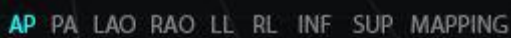
- **Viewpoint angle.** C-Arm angulation (**Figure 70**).



RAO=22, CRAN=5

Figure 70. Viewpoint angle

- **Standard Viewpoint Selector.** Selection bar for standard anatomic views (**Figure 71**).



AP PA LAO RAO LL RL INF SUP MAPPING

Figure 71. Standard Viewpoint Selector

“Synchronize image to” drop-down menu

The selection menu for image synchronization. In **Figure 72**, the image is synched to the CARTO 3 System. This may be changed to **C-Arm**, **Fluoro A**, **Fluoro B**, or **None**.

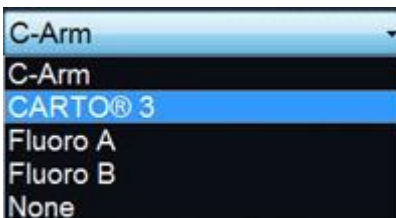


Figure 72. “Synchronize image to” drop-down menu

OK / Cancel

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

System tab

Settings on the System tab (**Figure 73**) are saved by the physician and can be manipulated. Below **Figure 73**, General, *NaviLine*, Audio, and Ablation History settings are further explained.

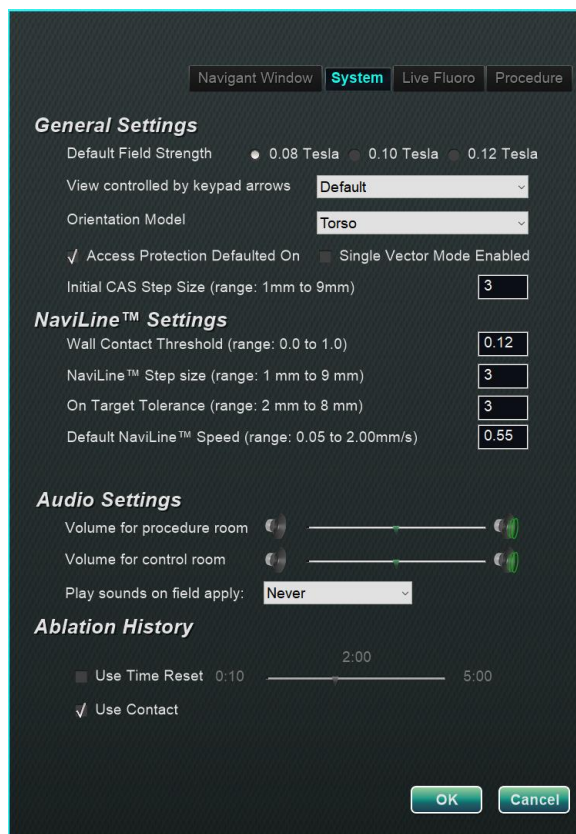


Figure 73. Settings windows – System tab

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 for the next procedure.
- **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: 0.10 to 2.00mm/s). The starting, or default, speed of the Slider tool used for several Window Controls and other icon options.

Audio Settings

- **Volume for procedure room.** 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 74**) the user can adjust the display of graphics on the Fluoro windows. Settings on the Live Fluoro tab are saved by the 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.

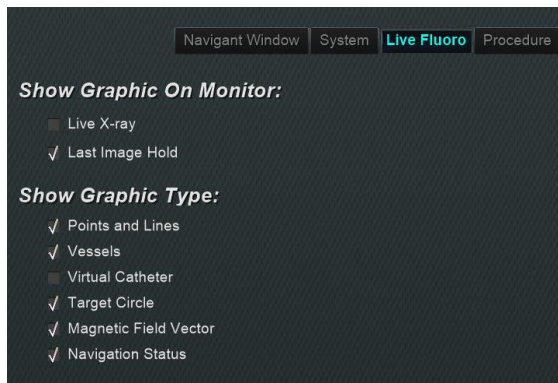


Figure 74. Settings windows – Live Fluoro tab

Procedure tab

The **Procedure** tab 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 (robotic magnetic navigation) 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.

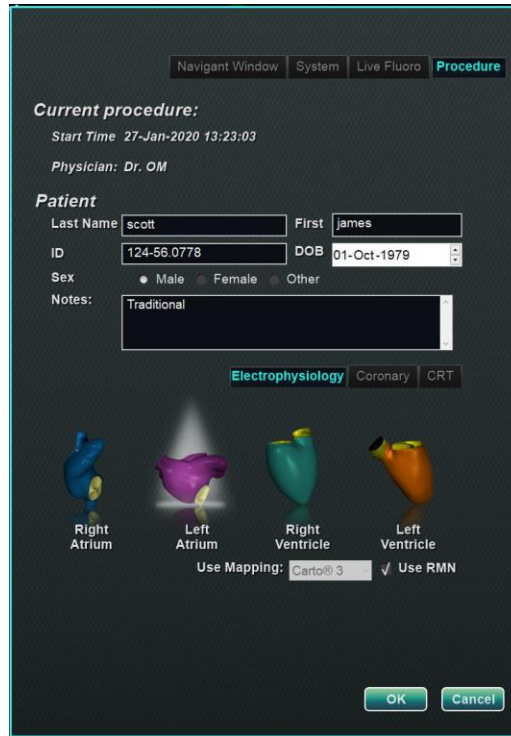


Figure 75. Settings windows – Procedure tab

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.

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




Window Controls buttons





The number of buttons the Window Controls (**Figure 76**) displays depends on the window type and the selected object.



Figure 76. Window Controls example from Fluoro window

Table 7. 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>	
Zoom control	Press and drag the slider right (+) to increase the window image’s size and left (-) to decrease the size. As long as the user continues to press the mouse, they can operate the control anywhere within the window.	
Transfer Fluoro	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.	
Load Fluoro	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).	
Brightness/contrast control	<p>Brightness: Press and drag up to increase the brightness of the window's image and down to decrease it.</p> <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>Any direction: Press and drag in any direction to make brightness and contrast adjustments. Continue to press the mouse button to operate the control anywhere within the window.</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>	
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 removed temporarily. 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>	

Window swap feature

Within the *Navigant* windows, displays may be swapped by using the drop-down menu from the window-identifier icon (**Figure 77**):



Figure 77. 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 78**). **Error! Reference source not found.** 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 78. 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 79**) 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.

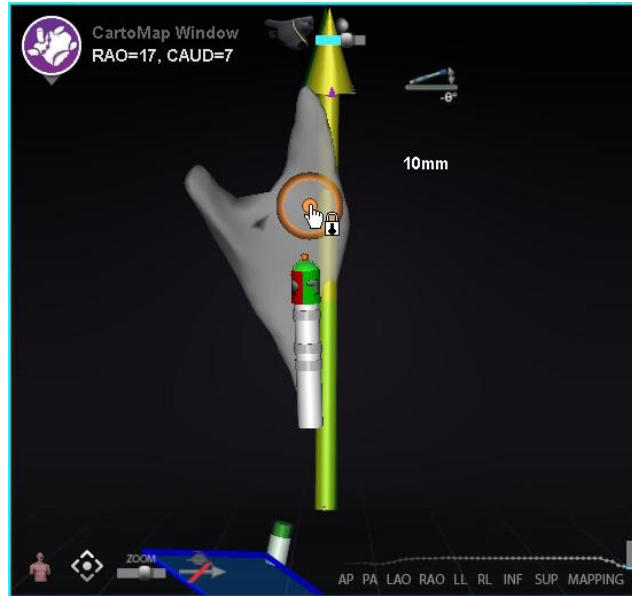


Figure 79. Target Lock (*lock icon is present*)

Magnetic Torque Meter

A Magnetic Torque Meter Trace (emphasized by a red rectangle) is pictured below (**Figure 80**). 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.

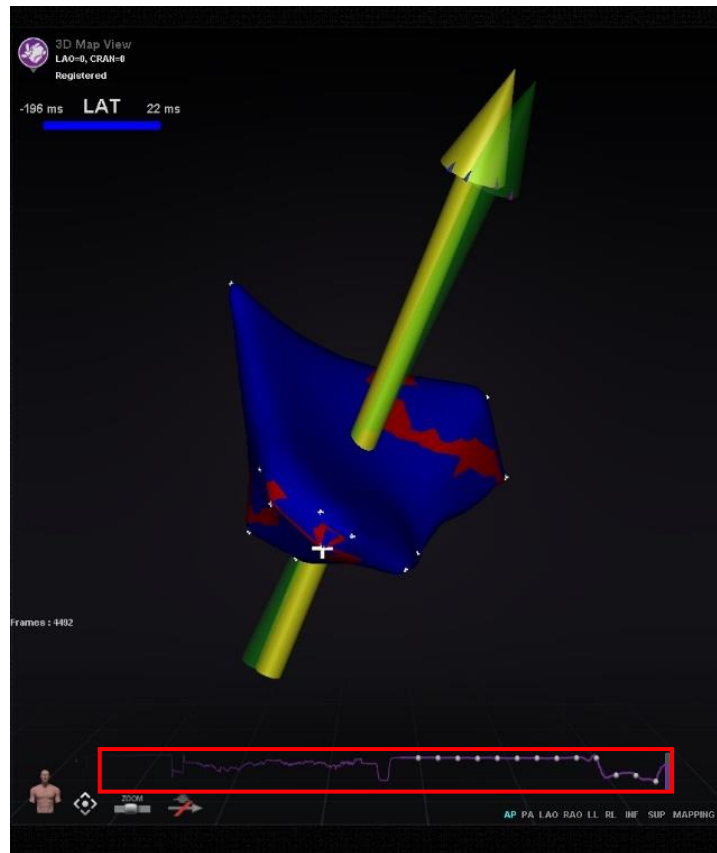


Figure 80. Magnetic Torque Meter Trace

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.

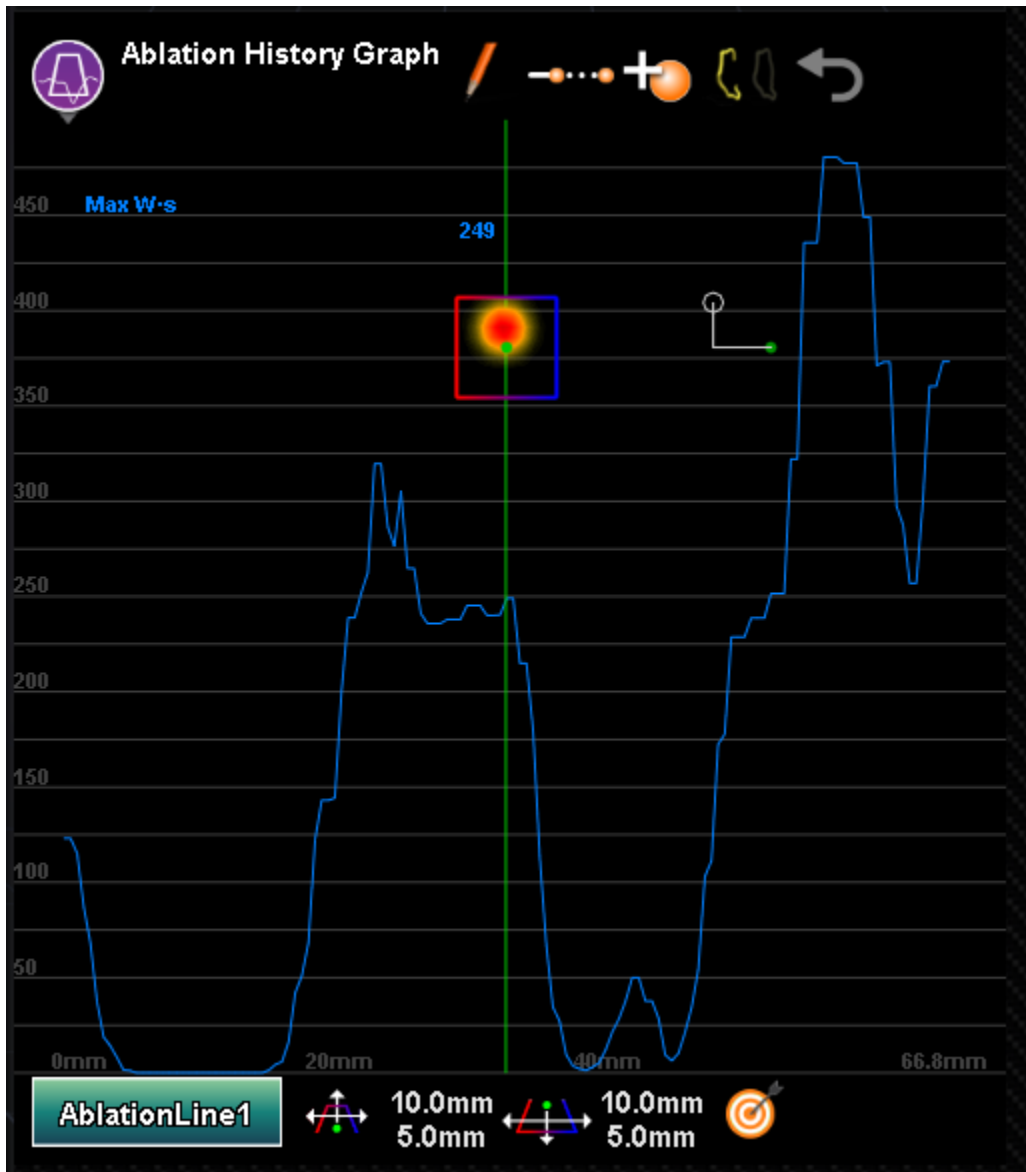




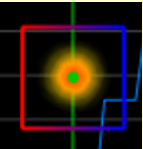
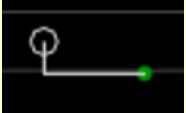





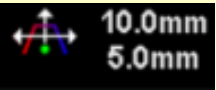
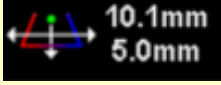




Figure 81. Ablation History Graph

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.

<p>Create <i>NaviLine</i></p>		<p>Creates a new empty <i>NaviLine</i>, named <i>AblationLine#</i> where # is the number of lines made in the AHG, and becomes the selected line for the AHGraph.</p>
<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</p>

		and top height.
Bottom Width, Bottom Height		Two-direction slider that controls the distance of the bottom of the trapezoid cursor from the line, and the width of the bottom of the cursor, followed by labels displaying the bottom width and bottom height.
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

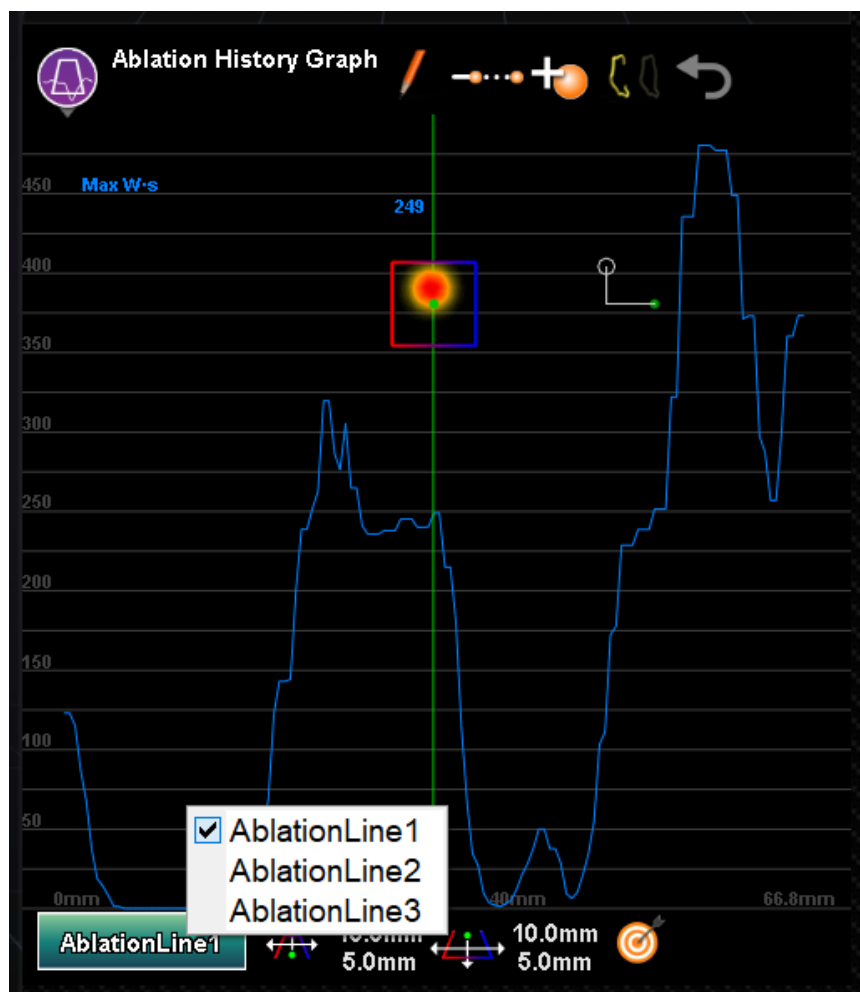
Access the AHG by pressing on the icon in the upper left corner and selecting “Ablation History Graph” (**Figure 82**). A green vertical line shows the position of the cross section along the *NaviLine*. To move the position indicator, click anywhere in the graph window and the indicator will jump to the position of the mouse. If the user holds the mouse down, the indicator will continue to follow the mouse's position.



Figure 82. Selecting the Ablation History Graph

As the indicator moves, two values are displayed next to the indicator (emphasized by a red rectangle in **Figure 83**). The blue number is 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 83**). A menu will display that shows a list of all available *NaviLines* to choose from.

**Figure 83.** 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 84**), use the window controls located at the bottom of the Ablation History Graph window.

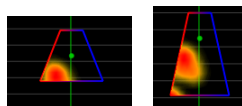


Figure 84. Changing Shape of Cross Section

The cross section location is seen in all windows displaying the selected *NaviLine* and Ablation History. The cross section (AHG window in **Figure 85**) 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 85**) 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 85. Cross Section Display (3D Map Window and AHG Window)

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, and after selecting the desired files, press **OK**.

Mark the checkboxes next to the desired surface objects or **Select All / Deselect All** to make selections. After a surface loads successfully, it displays in the preview area and a *Loaded* status

appears next to the surface item (**Figure 86**). Only actively selected surfaces are shown in the preview area. The status column will display **Error** if *Navigant* could not import the surface.

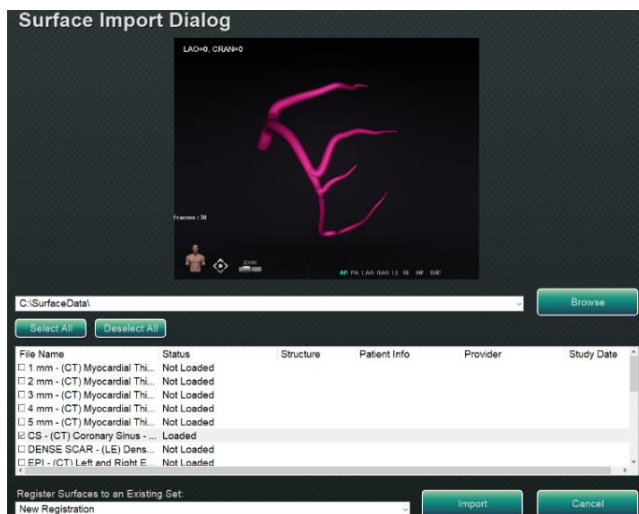


Figure 86. Imported Surface Shown in Preview Window

Using the dropdown menu (**Figure 87**), surfaces are imported as a new registration or to an already existing set of imported surfaces.

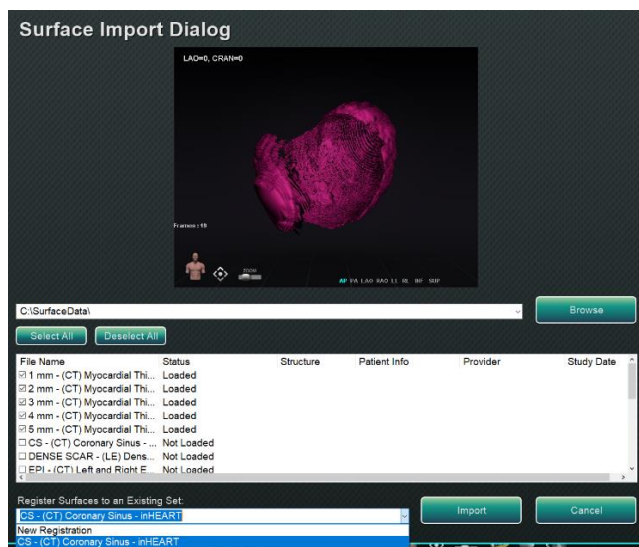


Figure 87. Register Surfaces

After surfaces are loaded, press **Import** to bring the surfaces into *Navigant* for use. Once imported, the 3D surface(s) can be rotated and panned to align with other objects in the 3D window. All objects imported together pan and rotate as a group. To display the position controls (the oval in **Figure 88**), click on a surface of the imported object. Once displayed, click the desired controls and then move the mouse to change the surface orientation and position. The rotate control rotates the 3D surface relative to the other objects in the 3D window. The pan

control moves the object laterally. These two controls bring the imported surface into alignment with other 3D objects.

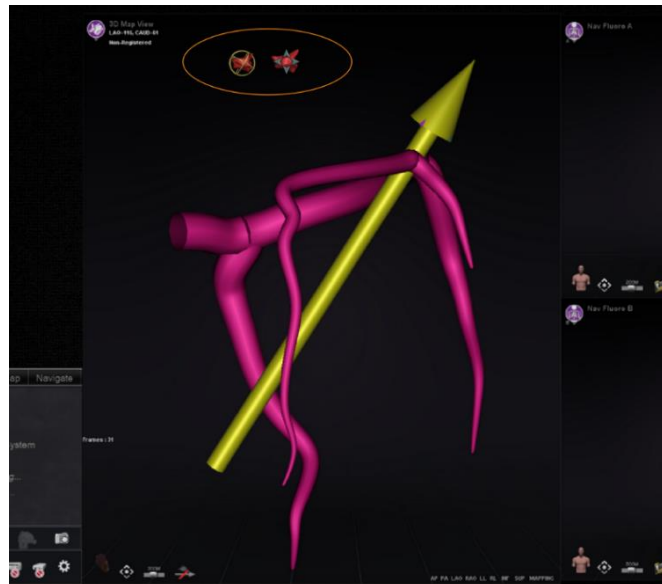


Figure 88. Controls for adjusting surfaces

4. Integration Features

Pre-Registration

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

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

Features such as Targeting, Automapping, *Bullseye*, *NaviLine*, X-ray overlays, and fluoroscopically localized objects will be unavailable until 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 CARTO3 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 89**). During an unregistered state, this label will read "Non-Registered."

Figure 89. Registered Label

Registering to CARTO 3

The *Genesis RMN* System supports the Biosense Webster CARTO 3 System and compatible catheter devices. Features include but are not limited to:

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

The CARTO 3 Registration dialog (**Figure 90**) is accessible by clicking **Register to Mapping System** (on the CWM) or **CARTO 3 Registration** (on the System options menu).



Figure 90. CARTO® 3 System registration dialog

CARTO 3 System registration

- **Directions.** Dialog displays directions for CARTO 3 Registration on the left-hand side.
- **Help.** Click the orange question mark icon for help with Step 1.
- **Transfer image.** Step 2 in the directions states, “**Transfer AP X-ray.**” Transfer the X-ray by clicking the transfer button at the bottom of the preview screen.

- **Preview screen.** If the six markers and the catheter tip are correctly located, the transferred image displays in the preview screen on the right-hand side.
- **Use Access Protection.** Retraction feature that prevents the catheter from retracting beyond a certain position.
- **Correct Height.** The blue dot in this image indicates the catheter location in conjunction with isocentering (see *Isocentering with Mapping* under *Common Registration Tasks* for more information).
- **Accept or Cancel.** A successful transfer results in the establishment of a connection to the CARTO 3 System, the six location pad markers being within acceptable tolerance, and enabling of the **Accept** button. Click **Cancel** to close the dialog.

Successful X-ray transfer

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

- Verify six green “plus” signs display, centered over the black registration dots.
- Move the six green plus signs **IF** they are *not* automatically centered by clicking and dragging them to the correct position over the black registration dots.
- Ensure the catheter shaft is properly positioned. (The CARTO 3 Registration dialog automatically registers the length of the catheter.)
- Verify the location of the tip of the sheath by clicking on the red sheath base and dragging it to the desired location on the fluoro image.
- Ensure the crossing plane is adjusted to the septum location for left atrium procedures. In **Figure 91**, the crossing plane is displayed in the registration dialog (pre-adjustment). Move the crossing plane to the location of the septum in the current fluoro image by clicking and dragging the yellow plane. Once properly adjusted, the crossing plane will display blue as seen in **Figure 92**.
- Click the **Accept** button once all the above conditions are met.



Figure 91. Crossing Plane Needs Adjustment



Figure 92. CARTO 3 System registration complete

Errors After Successful X-ray Transfer

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

- **Non-CARTO 3 System device selected**

A device that is not compatible with the CARTO 3 System may have been selected. If so, a message displays with the “no” symbol in the bottom-left corner of the dialog and reads, “A CARTO 3 compatible device is not selected” (**Figure 93**). Close the dialog by clicking **Cancel**. On the Hardware status indicator bar, select the System options icon. Click **Device Selection** and select an appropriate device.

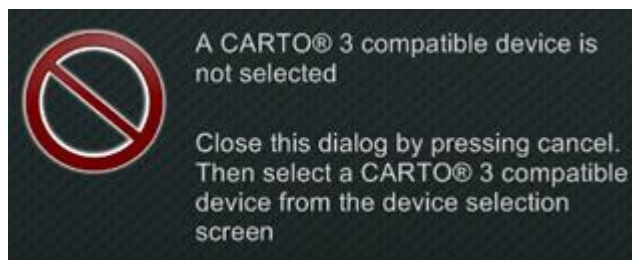


Figure 93. CARTO 3 compatible device is not selected

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

The X-ray C-Arm may not be positioned correctly. It should be within 15 degrees of the anterior-posterior (AP) position. Otherwise, a gold caution symbol displays with the

message, “*X-ray is not within 15.0° of AP*” (Figure 94). Adjust the C-Arm so it is within 15° of the AP position.

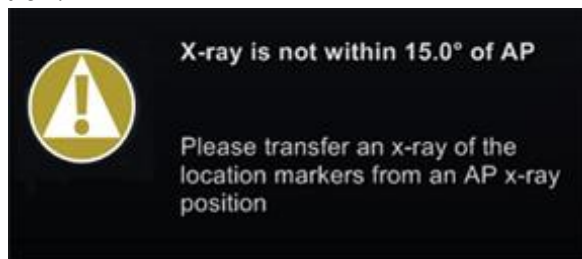


Figure 94. X-ray is not within 15.0° of AP

- **CARTO3 System not licensed or connected**
 - If the CARTO3 System is not licensed or connected, the user can open the CARTO3 Registration dialog and load a fluoro image, but will not be able to register it.
 - If the CARTO 3 System is disconnected, “no” symbol displays over the CARTO 3 icon.
 - If the user does not have a CARTO 3 System, the CARTO 3 icon will not display in the hardware status indicator bar on the “dashboard.”

CARTO 3 System registration help window

Pressing the **Help** button for Step 1 displays the following window (Figure 95):

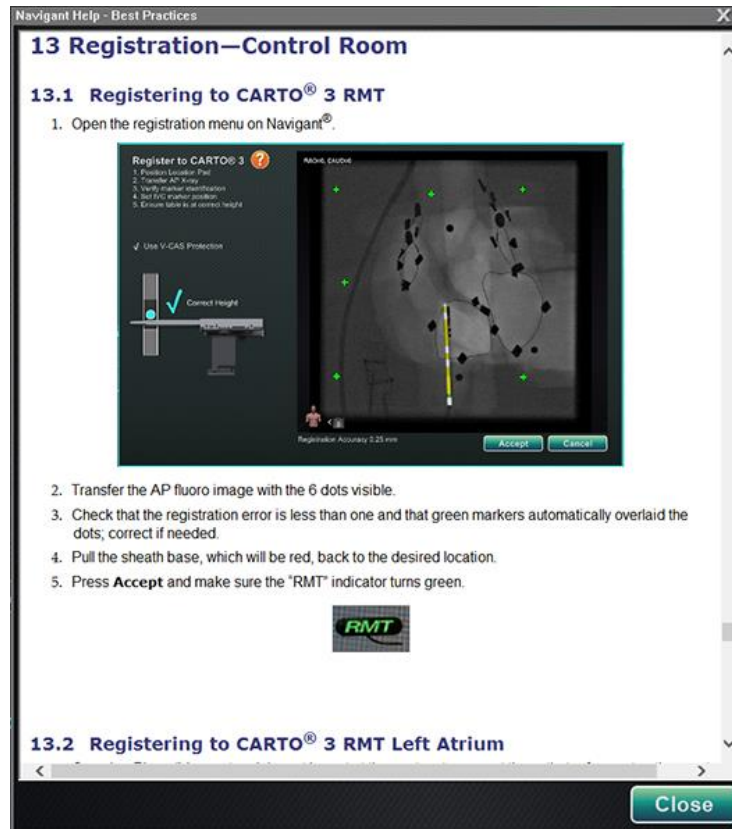


Figure 95. CARTO 3 System help

Uncompensated Move After Registration

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

Action	The user will see
Line A is created Uncompensated move occurs Line A is marked “OLD_Line A”	OLD_Line A
Line B is created Uncompensated move occurs Line B is marked “OLD2_Line B”	OLD2_Line B
Line C is created	Line C

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

Registering to OpenMapping

Because of the OpenMapping API feature, the *Genesis RMN* System is able to support compatible navigation systems and catheter devices. Features of OpenMapping systems include but are not limited to:

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

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

OpenMapping Registration (**Figure 96**) can be accessed from either the Clinical Workflow Manager (CWM) or the System options menu. The magnets should first be homed and the patient setup. Upon selecting Steps **1. Home Magnets** or **2. Patient Setup** on the CWM, a document displays that has helpful instructions for homing the magnets and positioning the patient correctly.

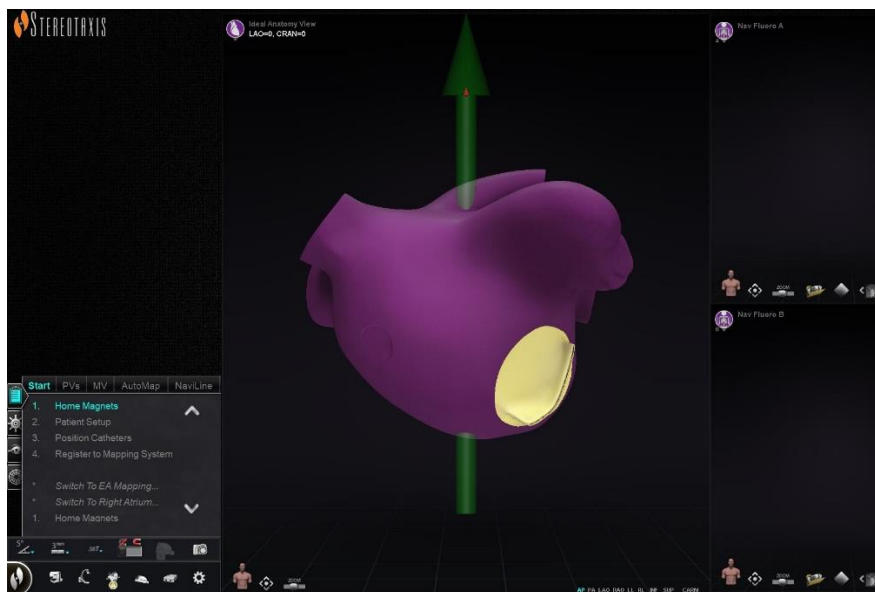


Figure 96. OpenMapping Registration

Successful X-ray Transfer

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

Catheter Registration is the third step on the CWM which reads *Position Catheters*. Selecting the **System options** menu on the hardware status toolbar and then **Catheter Registration** is an alternative route for catheter registration. *Navigant* must be receiving real time catheter data or an error message (outlined in **Figure 97**) will display. Before registration can continue, the user must ensure *Navigant* is receiving catheter data from the mapping system.

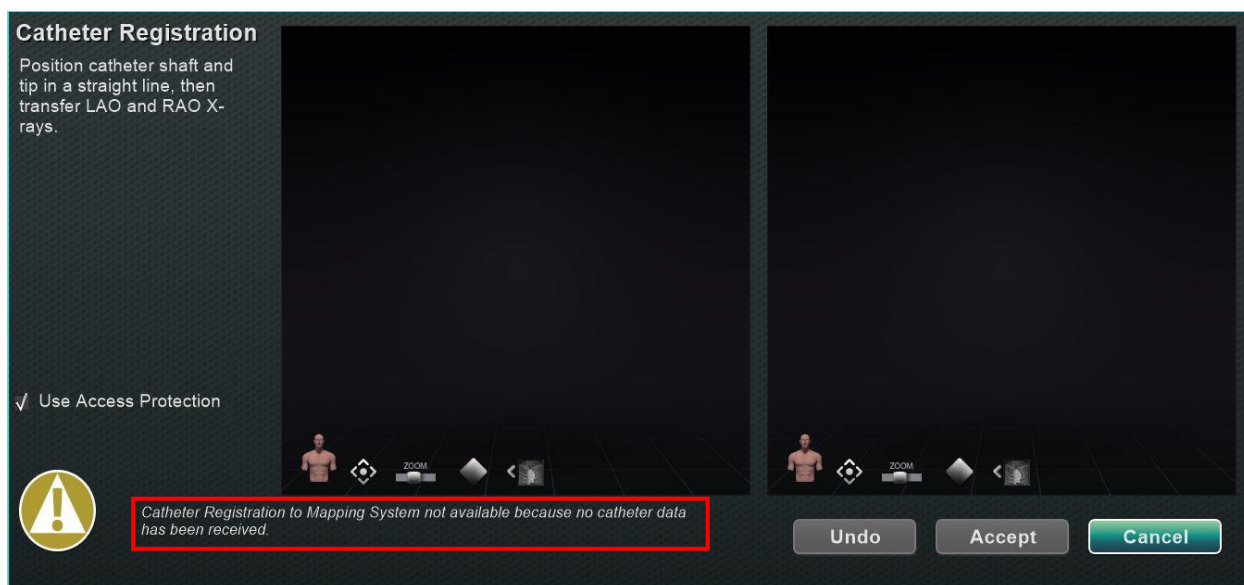


Figure 97. Catheter Registration- no data received

Once *Navigant* is receiving real time catheter data, registration can continue. Upload LAO and RAO X-ray images by clicking the **Transfer Fluoro** button (emphasized by yellow rectangles in **Figure 98**). (During transfer, the button flashes between the regular image and a negative of the image.) See the *Window Controls* section for help with the other controls: pan, reset, zoom, and brightness/contrast. If the fluoros uploaded do not have at least 40 degrees of separation, an error message will display (outlined in **Figure 98**).



Figure 98. X-ray images have less than 40 degrees of separation

After acceptable X-ray images have been uploaded, the Catheter Registration dialog will instruct the user to draw the catheter tip and sheath base distal to proximal on each X-ray image. Once the catheter tip and sheath base are drawn, the crossing plane (yellow in **Figure 99**) will display.

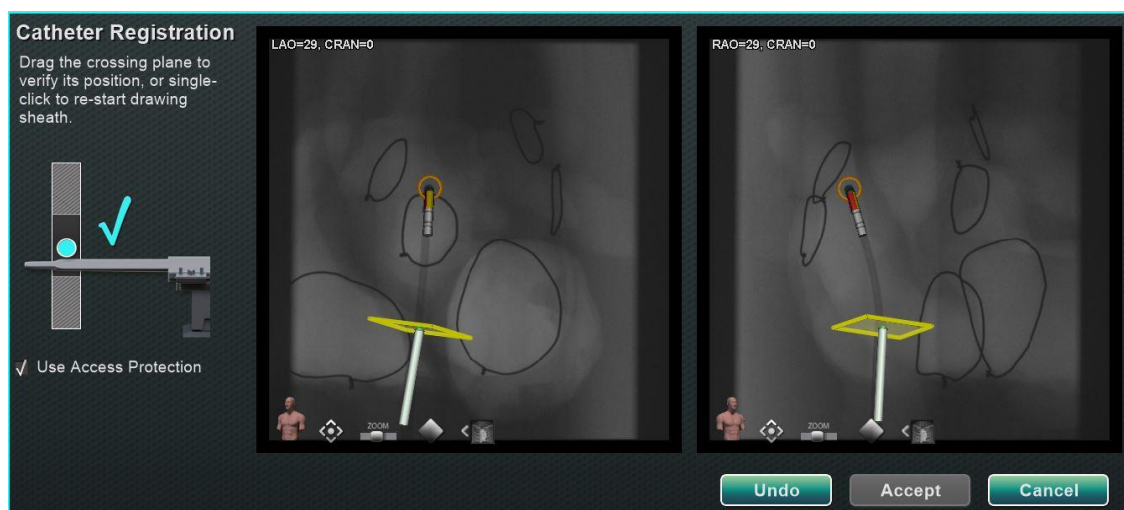


Figure 99. Catheter Registration- crossing plane not positioned

In Left Atrium procedures, the crossing plane must be adjusted to the location of the septum. By clicking and dragging, the crossing plane can be adjusted along the direction of the sheath. When the crossing plane is moved in one fluoro window, it will automatically move in the other fluoro window. Once adjusted, the crossing plane will display blue (**Figure 100**). The **Accept**

button will be green once the catheter shaft and crossing plane are correctly positioned and can be selected to accept changes. Click **Cancel** to close without accepting the changes or **Undo** to undo any previous action. Upon selecting **Accept**, the main window will display (**Figure 101**).

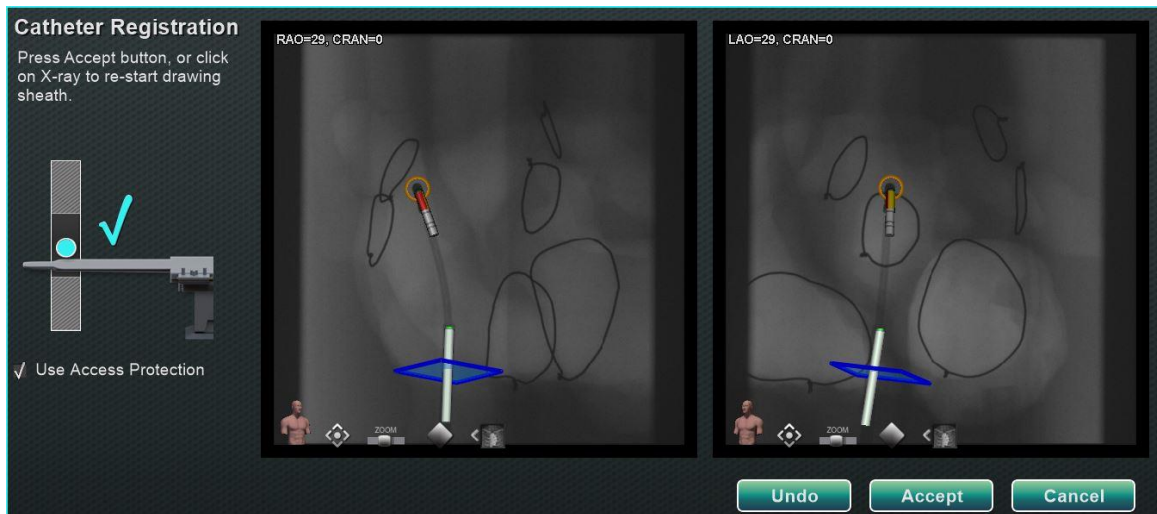


Figure 100. Catheter Registration- crossing plane positioned

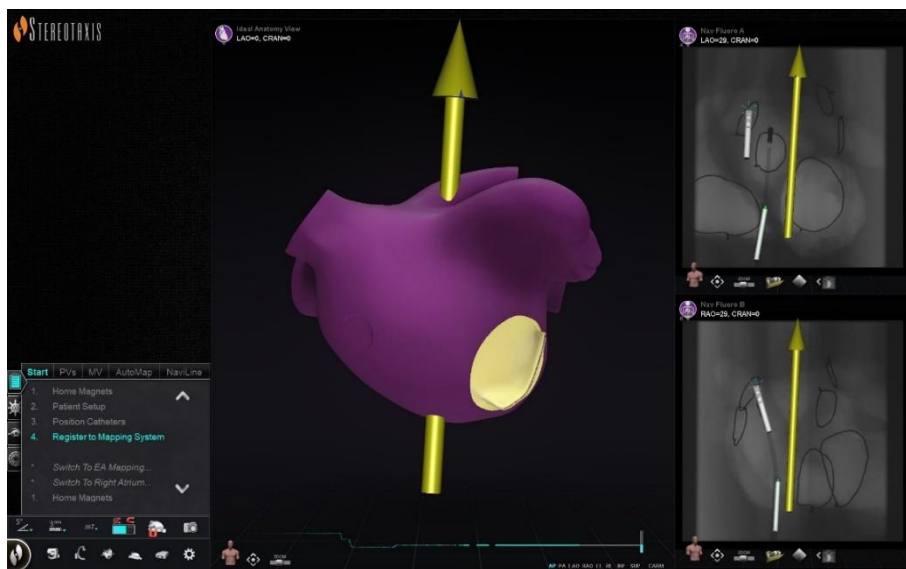


Figure 101. OpenMapping Registration Completed

Common Registration Tasks

Use Access Protection

Navigant includes a feature called Use Access Protection that prevents accidental retraction of the catheter from the left atrium into the right atrium and thus, is only available for magnetic left atrium (LA) procedures. This feature is automatically enabled in the software, but can be

disabled by de-selecting the Use Access Protection checkbox in the CARTO 3 Registration dialog or the OpenMapping Registration dialog. The registration dialog will tell the user what adjustments are needed (i.e. positioning the sheath base or crossing plane) before proceeding.

Access Protection Icon

The final crossing plane location represents the limit to which the catheter can be retracted and still remain in the left atrium (see limit indicators in **Figure 104**). 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 102**). The icon is located on the *Navigant* toolbar (**Figure 103**).



Figure 102. Access Protection states: Disabled (*left*), Locked (*middle*), and Unlocked (*right*)



Figure 103. 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.

i **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 both flash red (emphasized in **Figure 104**).

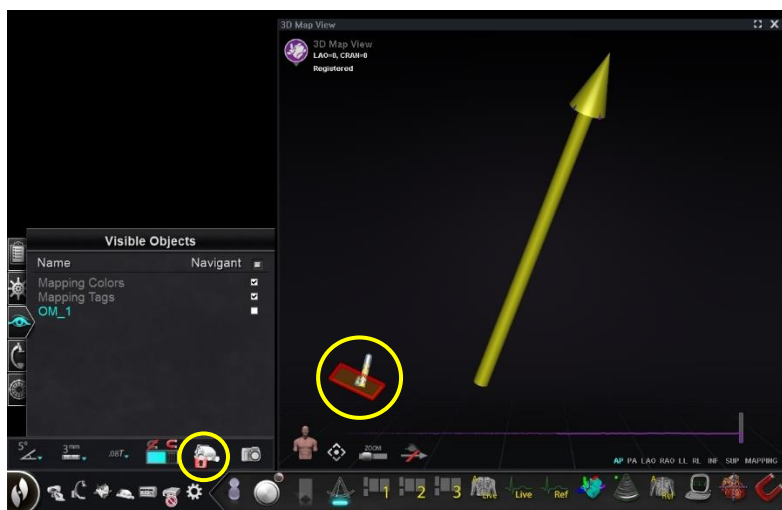


Figure 104. Retraction limit indicators

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 (**Figure 105**). Once the table is at the correct height, the dot will display blue (**Figure 106**). Table height adjustment can be made at any time by selecting the *Registration to Mapping* step on the CWM.

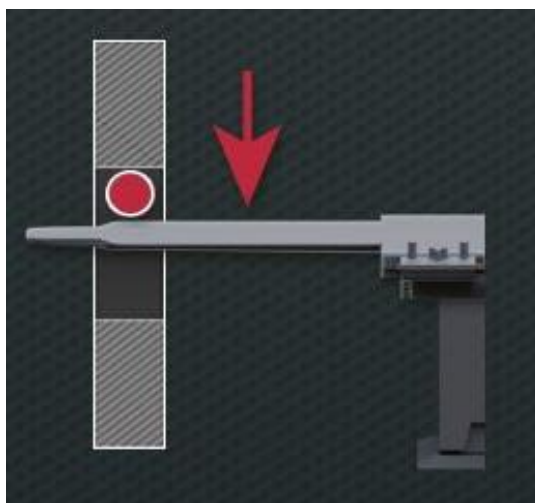


Figure 105. Adjust table height

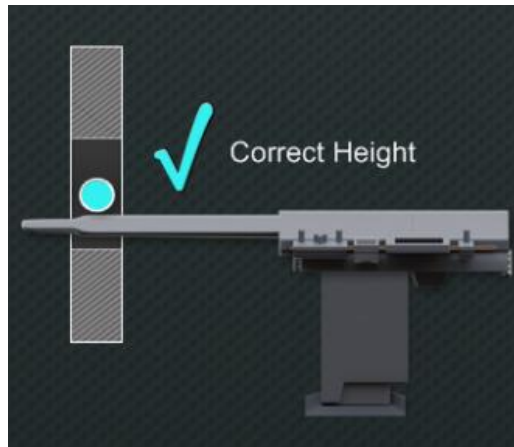


Figure 106. Correct table height

5. Automation Features

AutoMap

Clicking any step on the AutoMap tab (**Figure 107**) launches automatic CARTO 3 or compatible OpenMapping System mapping.



Figure 107. Automap tab on CWM



Notes for CARTO3 Electroanatomical (EA) System mapping:

- The CARTO 3 System is set to automatically freeze points.
- To view points before freezing, select **Manual** on the CARTO 3 System.
- *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. Selecting **Stop** on the automation dialog will stop *all automation*.



Figure 108. 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 109). Lines can be created in *Navigant* (called *NaviLines*), CARTO3 (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 CARTO3 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.

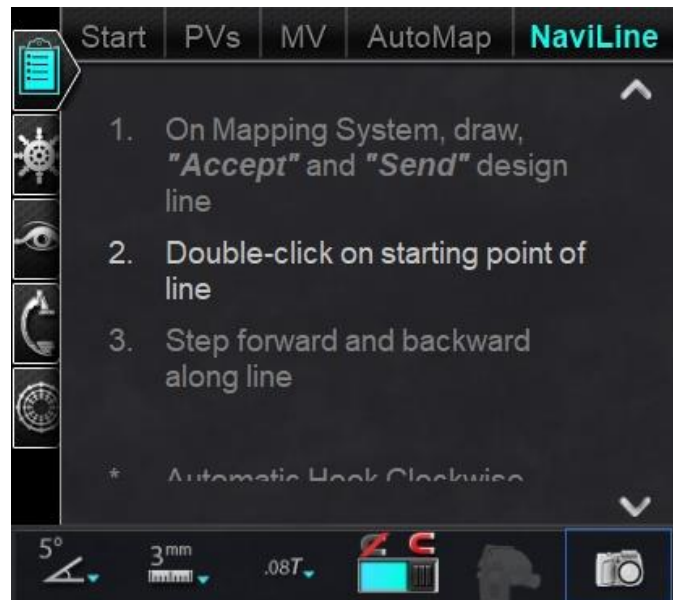


Figure 109. NaviLine tab on CWM

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 110**) to display the *NaviLine* toolbox. The toolbox (**Figure 111**) includes features such as New Line, Remove Line, Open/Close, Color, and Measure. These features aid in creating and editing a *NaviLine*.



Figure 110. Selecting Edit *NaviLine* Mode Button

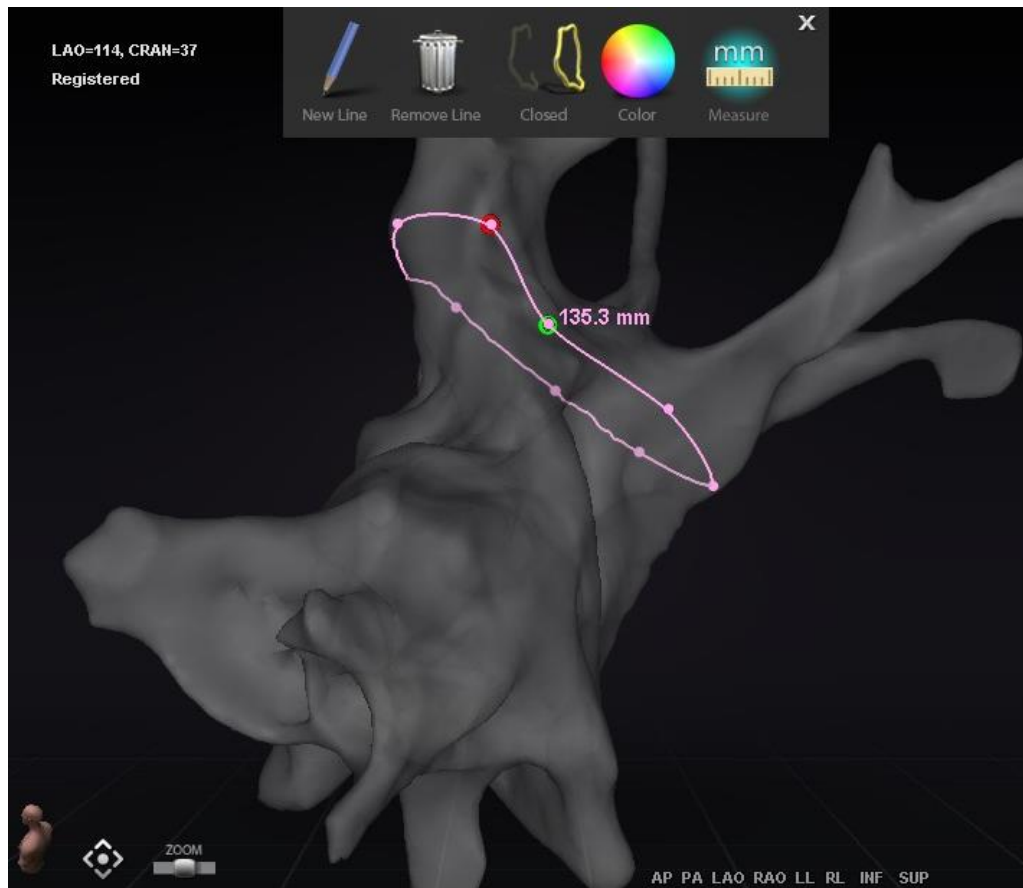


Figure 111. Edit *NaviLine* Mode- *NaviLine* toolbox


Edit NaviLine Mode is also available for Ablation Histories. The user must first select the Ablation History from the Visible Objects pane (**Figure 112**). 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 113**).



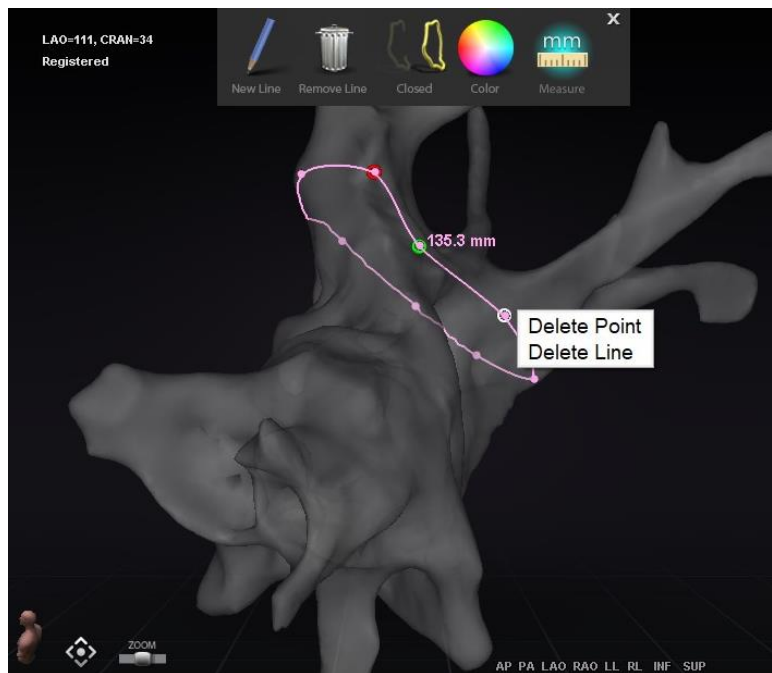
Figure 112. Visible Objects pane- Ablation History Section



Figure 113. Ablation History- *NaviLine* toolbox

 **Note:** While in **Edit NavLine Mode**, changes made simultaneously in Ablation History Graph will not appear. Conversely, changes while in **Edit NavLine 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 114** display closed lines. In the top image, the first point of the line is green, and the last point is red. The selected point is white, and a right-click menu option is displayed reading, **Delete Point** and **Delete Line**. In the bottom image, the cursor is too far from any one point to select, so the right-click menu reads **Insert Point** and **Delete Line**.



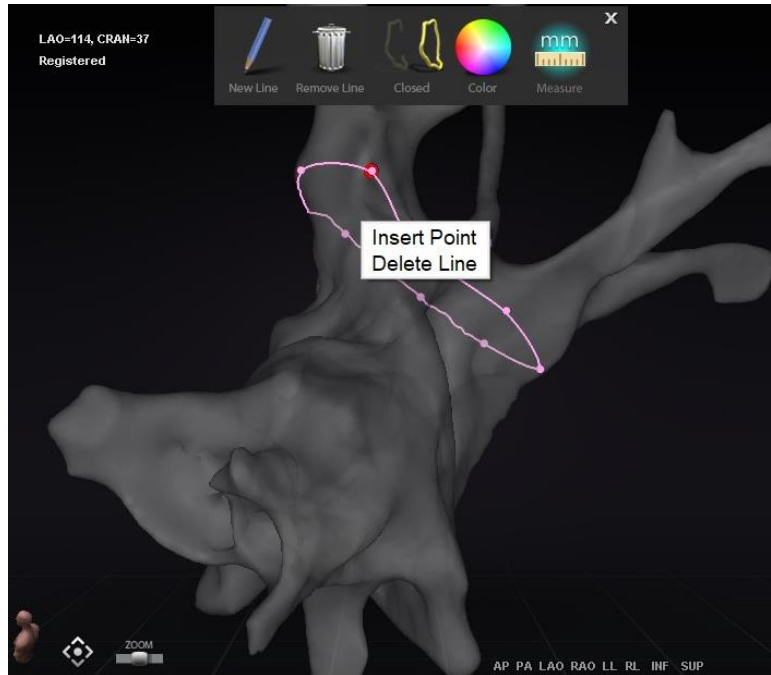


Figure 114. Edit *NaviLine* Mode; Right-Click Menu Options

After creating a *NaviLine*, the user can edit it by clicking the **Edit *NaviLine* Mode** button (Figure 115). 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 115. 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 116).

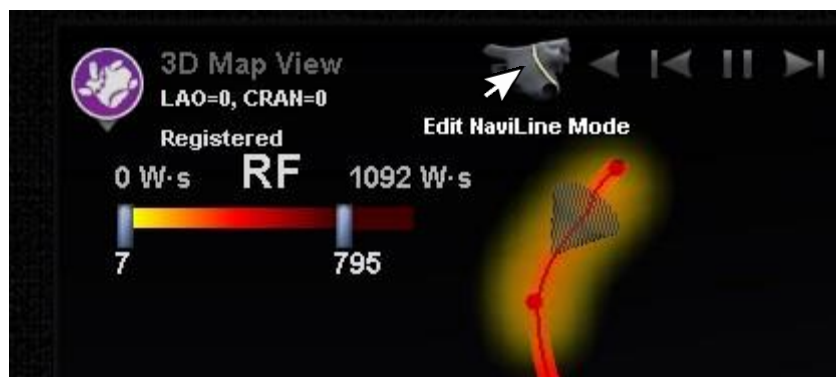


Figure 116. Edit *NaviLine* Mode on Ablation History line

Auto-*NaviLine* feature

When the user selects a completed *NaviLine* design line, as in **Figure 117**, 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 117, 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 117, 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*.

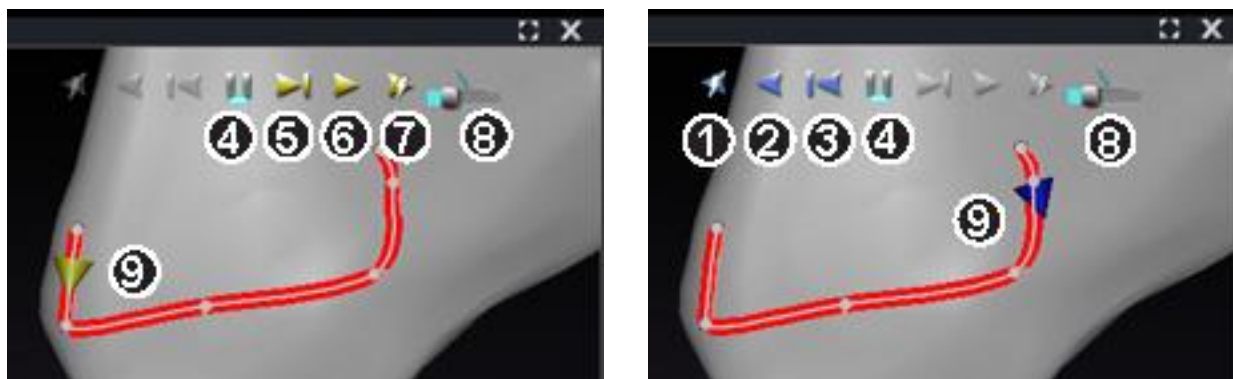


Figure 117. Target cones on *NaviLine*

Auto-*NaviLine* tools guide (**Figure 117**)

- ① **Play Backward on Ablate.** Same as Play Backward, but the target advances only when the mapping system indicates the Stockert generator is ablating.
- ② **Play Backward.** Targets the current position. Once the catheter reaches the target, the target goes backward along the line at a speed controlled by the Target Movement Speed slider.
- ③ **Step Backward.** Sets the target Step Size millimeters in the indicated direction.
- ④ **Pause Targeting.** Cancels current targeting automation in the same way as the **Stop** button on the Automation dialog.
- ⑤ **Step Forward.** Sets the target Step Size millimeters in the indicated direction.
- ⑥ **Play Forward.** Targets the current position. Once the catheter reaches the target, the target goes forward along the line at a speed controlled by the Target Movement Speed slider.
- ⑦ **Play Forward on Ablate.** Same as Play Forward, but the target advances only when the mapping system indicates the Stockert generator is ablating.
- ⑧ **Target Movement Speed.** Controls the speed at which the target moves when playing. Left is slower; right is faster. The exact speed is not displayed.
- ⑨ **Cone.** Target indicator on *NaviLine*. Operates in the same manner as Step Backward and Step Forward when clicked.

In **Figure 118**, all buttons are active because the *Auto-NaviLine* cones are in the middle of the *NaviLine* on the *left* and on a closed line on the *right*.



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

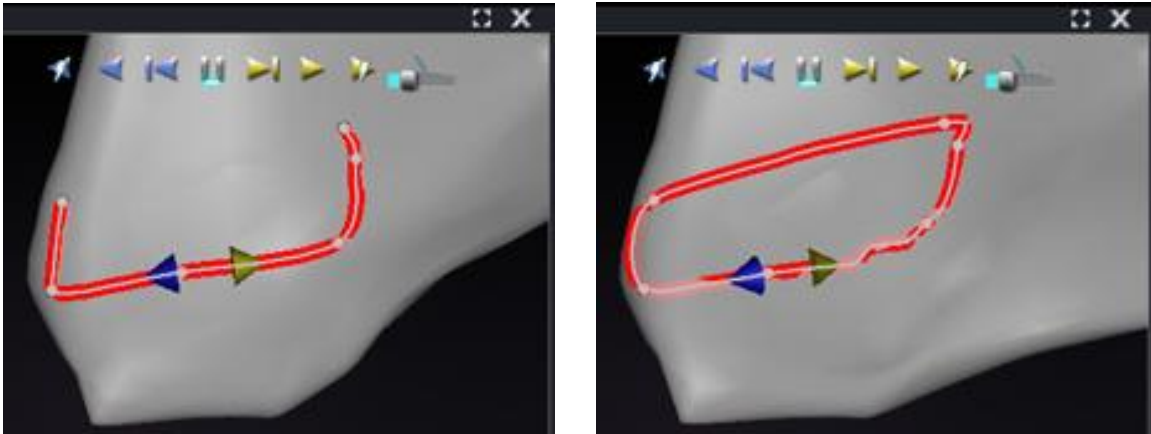


Figure 118. Auto-NaviLine cones in the middle of a line

Forward and *Backward* are set when the line is created: they are not window relative. In **Figure 119**, the camera has been rotated 180° around the line until the yellow cone is pointing left, but the direction is still “Forward.”

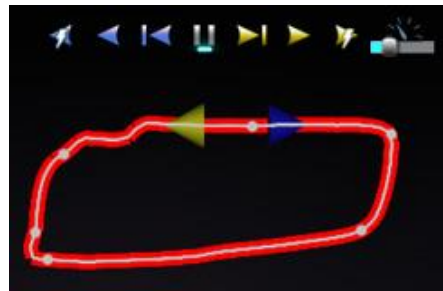


Figure 119. Auto-NaviLine cones according to camera rotation

Notice the highlighted **Play Forward on Ablate** button in **Figure 120**. It now has the blue line under it instead of the **Pause** button, indicating automated ablating at the target location.

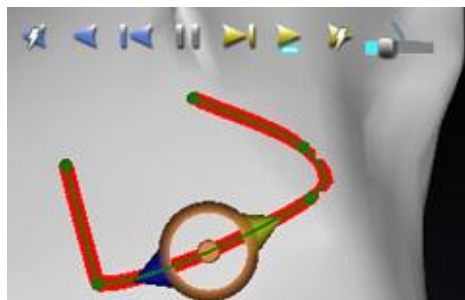


Figure 120. NaviLine with Auto-NaviLine target during Play Forward

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 121**). On the left side of the *Navigant* display, the catheter will appear in the Visible Objects field.



Figure 121. Lasso icon to store catheters

Right-clicking on the stored catheter opens a dialog (**Figure 122**) 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 123** 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.

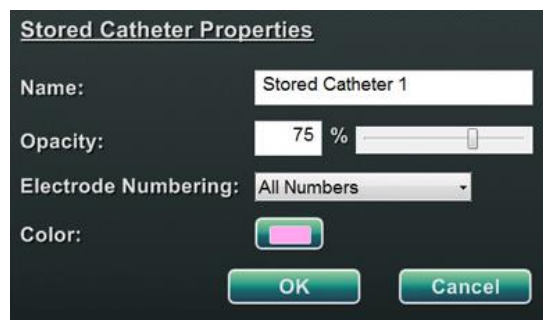


Figure 122. Catheter Properties dialog

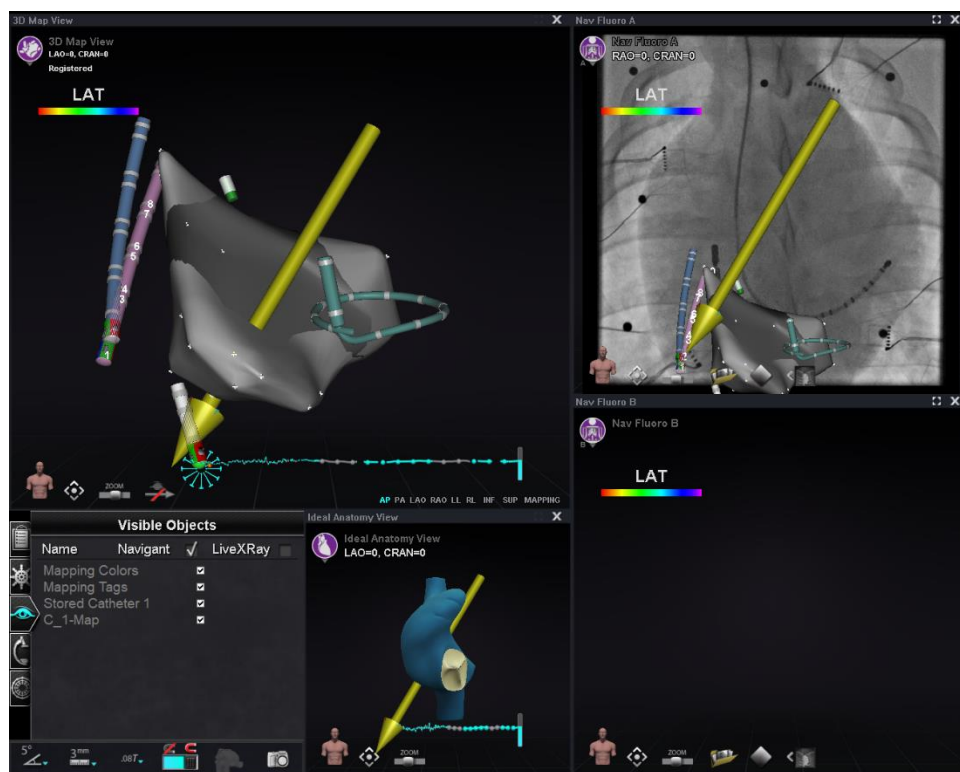


Figure 123. Electrode Numbering

TargetNav Feature

The *TargetNav*TM feature is integrated between *Navigant* and the compatible mapping system. 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 124** and **Figure 125** below. If no vector is showing, the gold-arrow icon (**Figure 126**) can be selected to show the vector. If the vector is displayed, the gray arrow icon (**Figure 127**) can be selected to hide the vector.

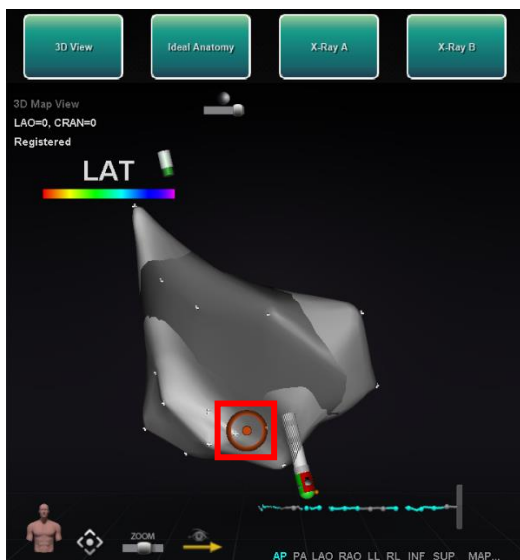


Figure 124. TargetNav targeting

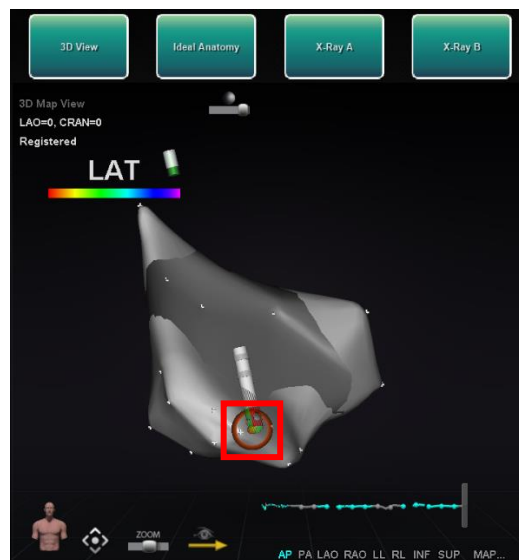


Figure 125. Target reached



Figure 126. Vector (field) show icon



Figure 127. 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 CARTO3 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 128**).

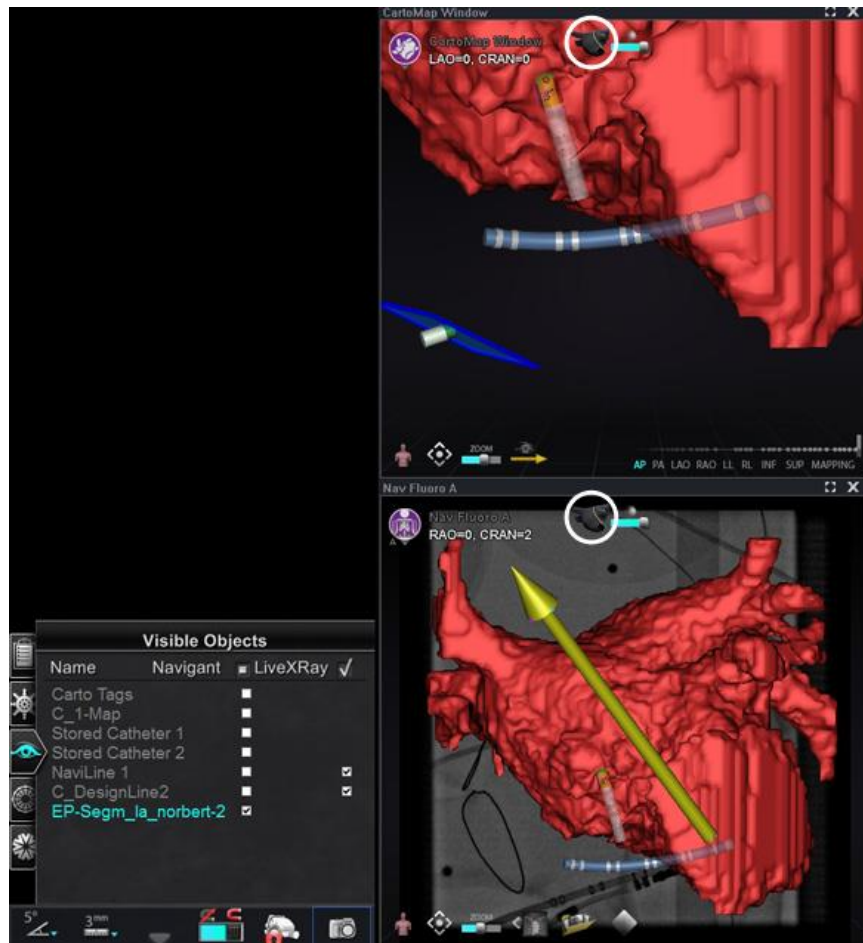


Figure 128. Imported surface with *NaviLine* icon (circled)

Click the *NaviLine* icon (**Figure 129** or **Figure 130**) to display the *NaviLine* toolbox (**Figure 131**).



Figure 129. *NaviLine* icon on red surface background



Figure 130. *NaviLine* icon on gray surface background

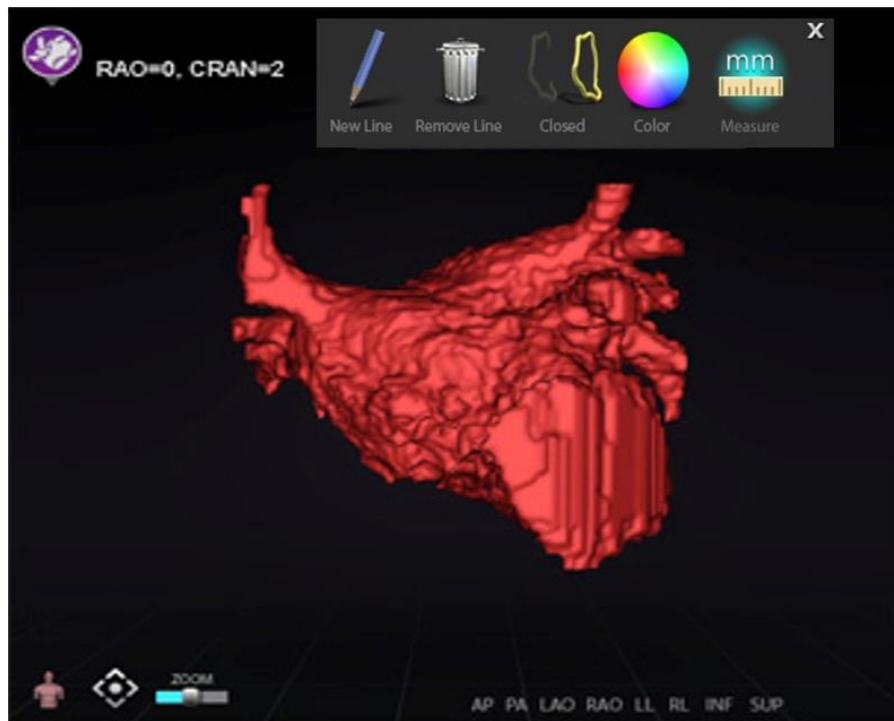


Figure 131. Imported surface with *NaviLine* toolbox displayed

Use the tools to create the new line on the imported surface (**Figure 132**). To delete an entire *NaviLine* design line, click the **Remove Line** (“trashcan”) icon in the *NaviLine* toolbox.



Figure 132. *Left:* Imported surface with *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

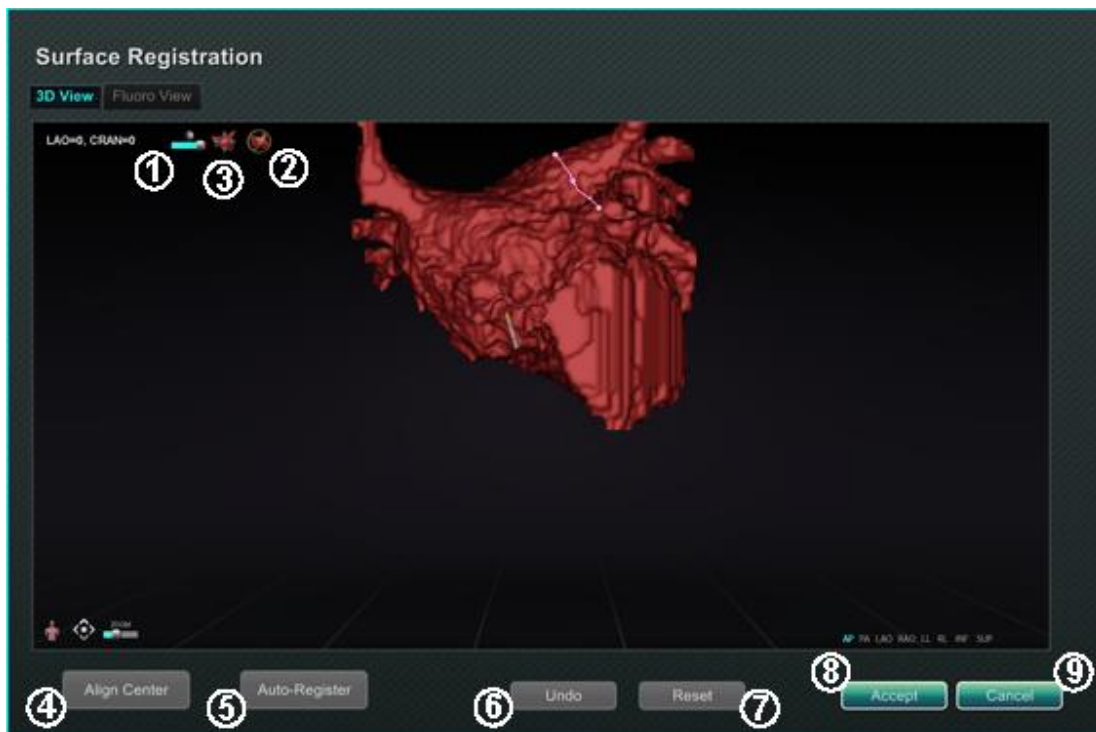


Figure 133. Surface Registration – 3D View

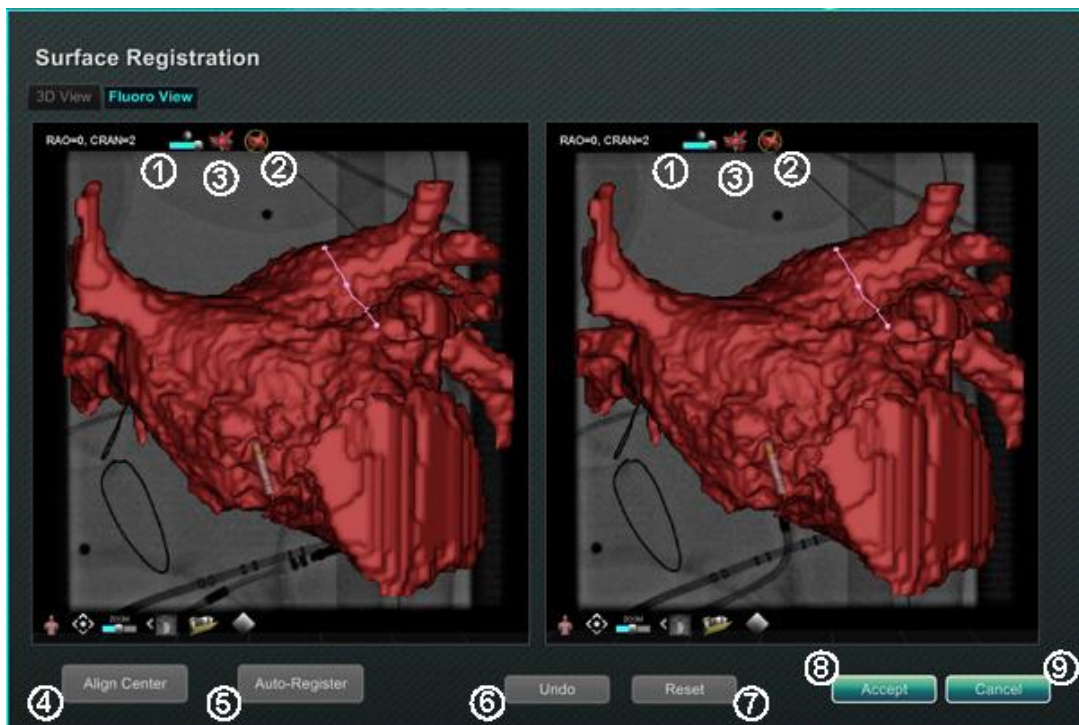


Figure 134. Surface Registration — Fluoro View

Surface Registration guide (Figure 133 and Figure 134)

- 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., Biosense Webster Stockert 70) 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 135, left**. When not connected, the generator icon indicates an error, as seen in **Figure 135, 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 135. Ablation Generator connection status

Navigant

Making Ablation History visible

- The *Navigant* Visible Objects control panel displays **Ablation History 1** (**Figure 136**) 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, *Color Scale*) does not show in 3D Map Windows.

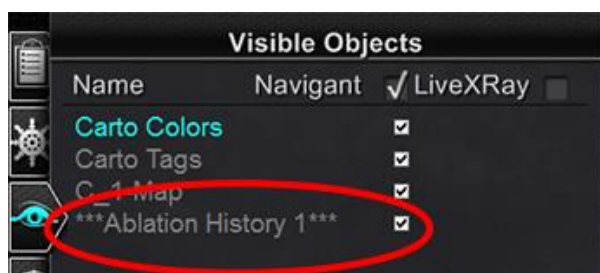


Figure 136. Visible Objects panel- Ablation History viewing enabled

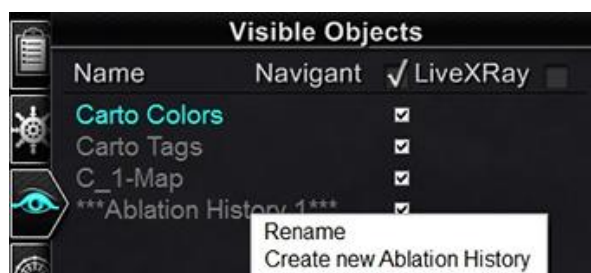


Figure 137. Ablation History Menu Options

Right-click on an Ablation History to either rename that Ablation History or create a new Ablation History (**Figure 137**). If **Create new Ablation History** is selected, **Ablation History 2** is added to the list of visible objects (**Figure 138, left**). Right-clicking the new ablation history and selecting **Rename** allows the user to edit the History's name (**Figure 138, right**).

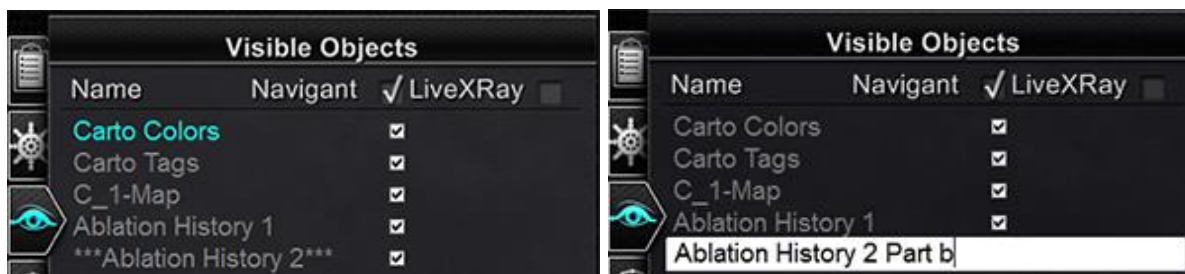


Figure 138. Left: Creation of New Ablation History; Right: Renaming New Ablation History

- To activate an Ablation History after working with another history, right-click its name. A 3-item menu appears where the user can select **Activate**, with the result shown below (**Figure 139**).

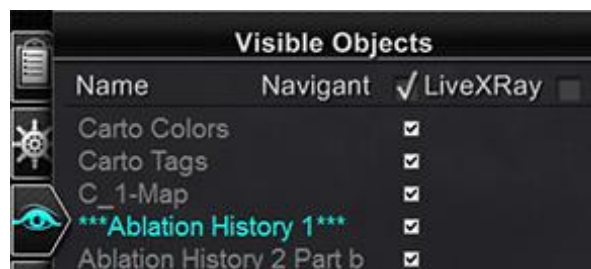


Figure 139. Result when “Ablation History 1” is activated

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 140** and Error! Reference source not found. 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 140. Left: Both Ablation Histories displayed; Right: No Ablation Histories displayed

Ensuring visibility settings are correct

1. From the hardware status indicator toolbar, click the **System options** button.
2. From the System options menu, click **Settings**. The *Navigant* Window tab appears.
3. 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 141**).

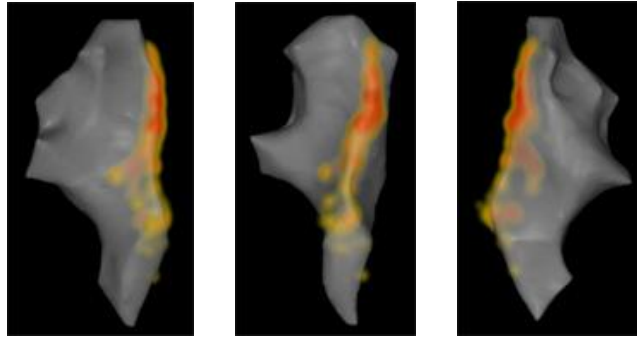


Figure 141. Ablation History viewed from various orientations

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 73**). When this setting is used, the Ablation History accumulation resets after the selected time interval. This reset results in the need to re-accumulate the Ablation History when returning to areas previously documented with an Ablation History after the time period has expired. Once the time period has expired, the level of accumulated Ablation History must reach the previously recorded level before the history display continues to grow in size or deepen in coloration. **Figure 142** shows a representative Ablation History screen with executed Ablation History, Color Scale, and Windows Controls visible.

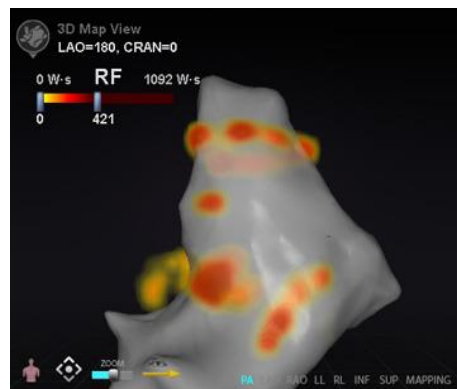
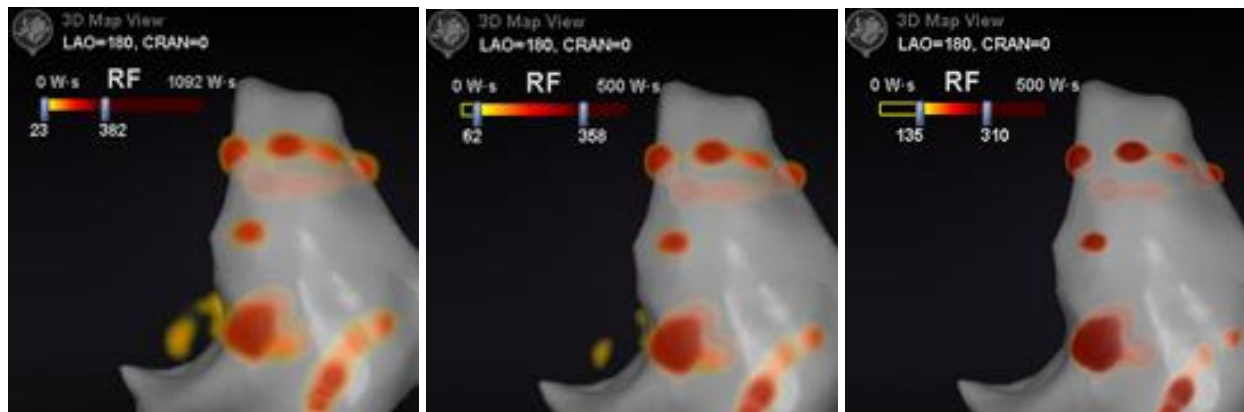


Figure 142. Example of Ablation History map

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 143 shows three examples of differing display ranges and color gradients.

**Figure 143.** Differing areas of drawing intensity, or gradient fields

Maximum ablation value

Pressing the **Alt** key while using the mouse to hover over an area of shading allows popup of the Ablation History value at that point (**Figure 144**). 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 144.** 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. Type a new value allowing for the following “rules”:
 - Can’t exceed lower number of bar.
 - May go as high as upper limit of 4,369 W·s.
 - Color range min ≤ Color gradient min ≤ Color gradient max ≤ Color range max.
3. See **Figure 145** for an example of manual editing.

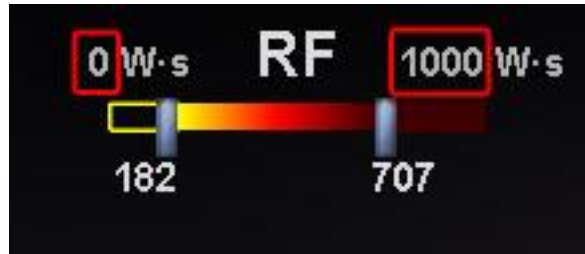


Figure 145. Edited W-s values indicated by red rectangles

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 145**, the user may select and slide the bar at **182** or the bar at **707** to a lower or higher number.

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 146**. It is important to note that the option “Ultrasound Fan” must be checked (**Figure 68**) 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.

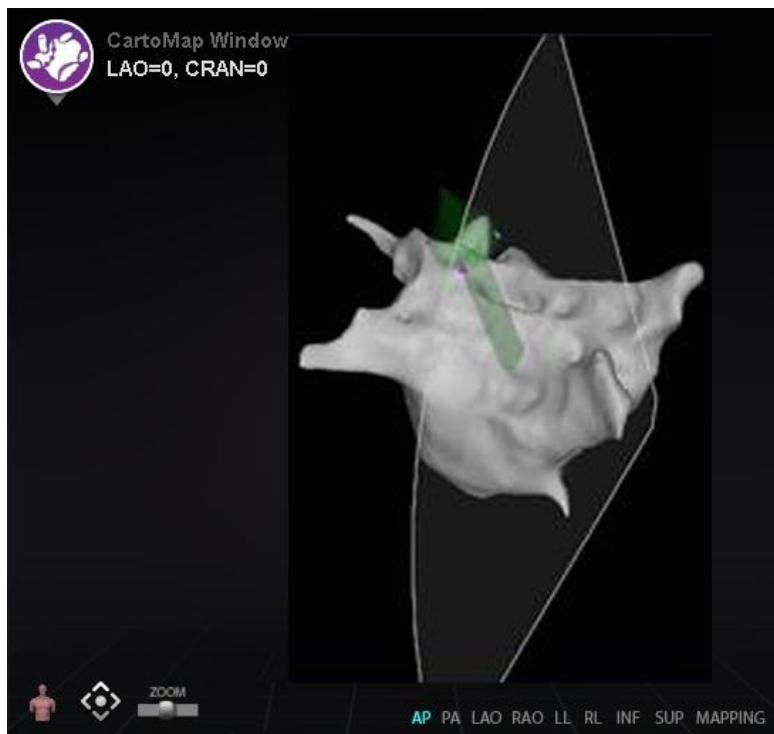


Figure 146. Ultrasound Fan display in CARTO 3DMap Window

6. Intracardiac (IC) Features

Vessel Navigation

NaviView3 feature

The Stereotaxis *NaviView*^{TM3} 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.

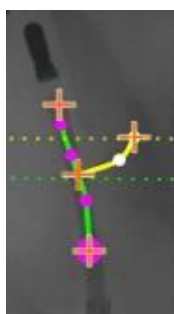


Figure 147. Vessel tree showing trunk (green) and branch (yellow)

Point Annotation on Fluoro dialog

The Point Annotation on Fluoro dialog (**Figure 148**) 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 148**.) 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.

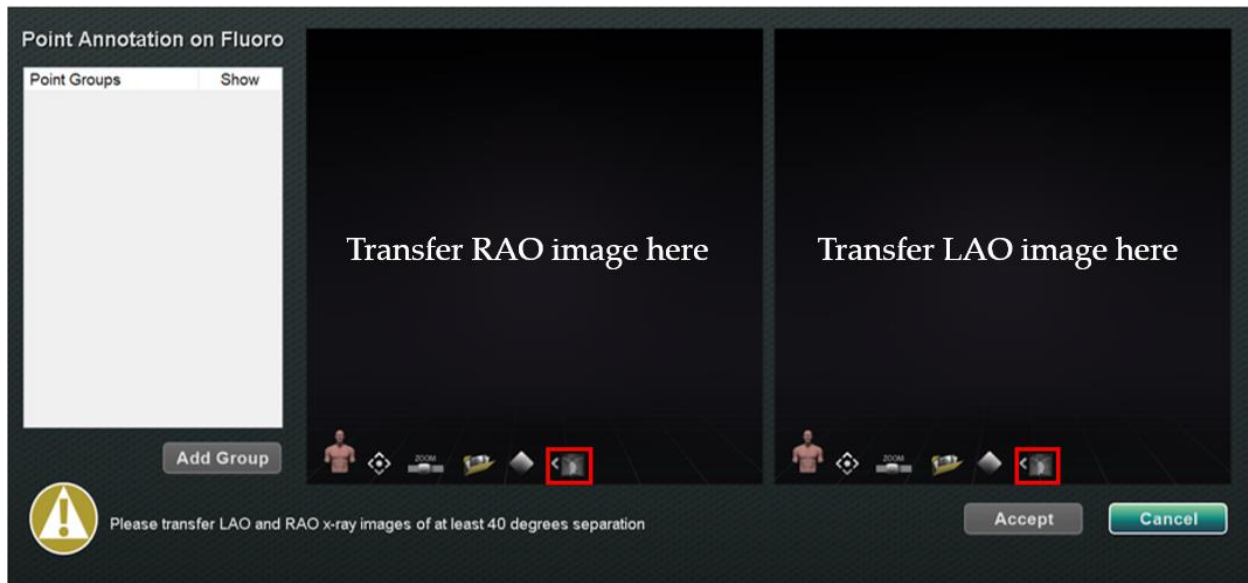


Figure 148. Point Annotation on Fluoro dialog

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 of 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**.

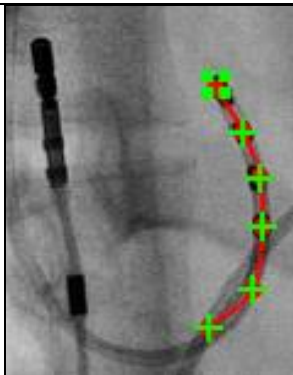


Figure 149.
Open line

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

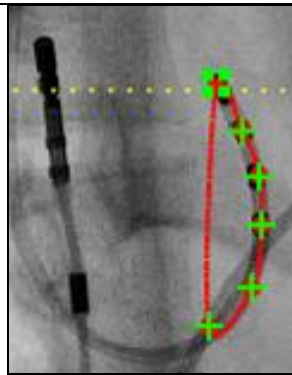


Figure 150.
Closed line

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

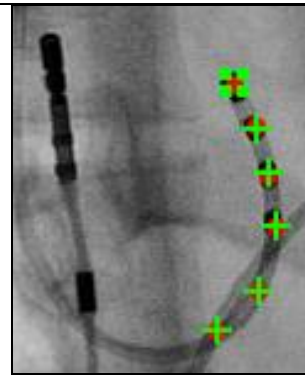


Figure 151.
Points Only

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.

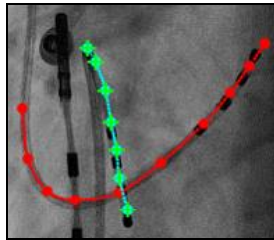


Figure 152. Colored Point groups

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 153** below.

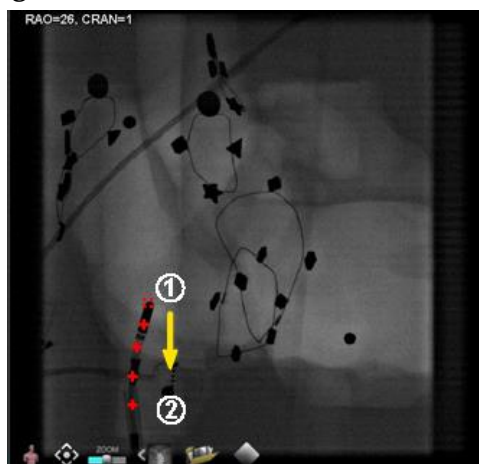
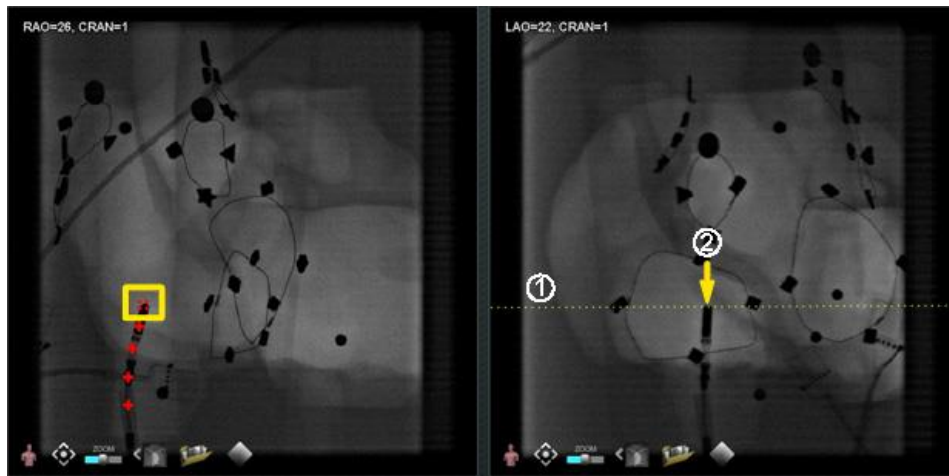


Figure 153. Marking Fluoro Image A

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 155** 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 154.** 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 155**). Click **Accept** to display the vessel(s) in the Fluoro Images A and B windows **(2)**.

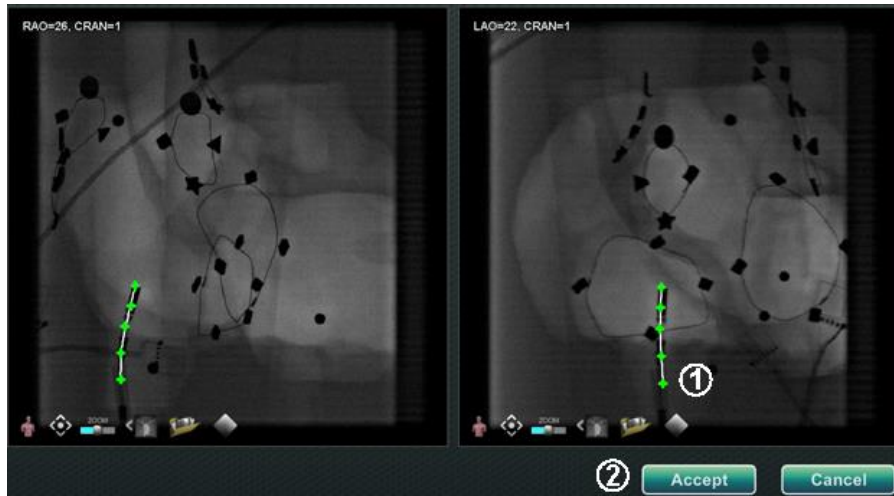


Figure 155. Fluoro annotation– Fluoro images A and B

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 156**). Features such as line type, color, and thickness become available.



Figure 156. 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**.

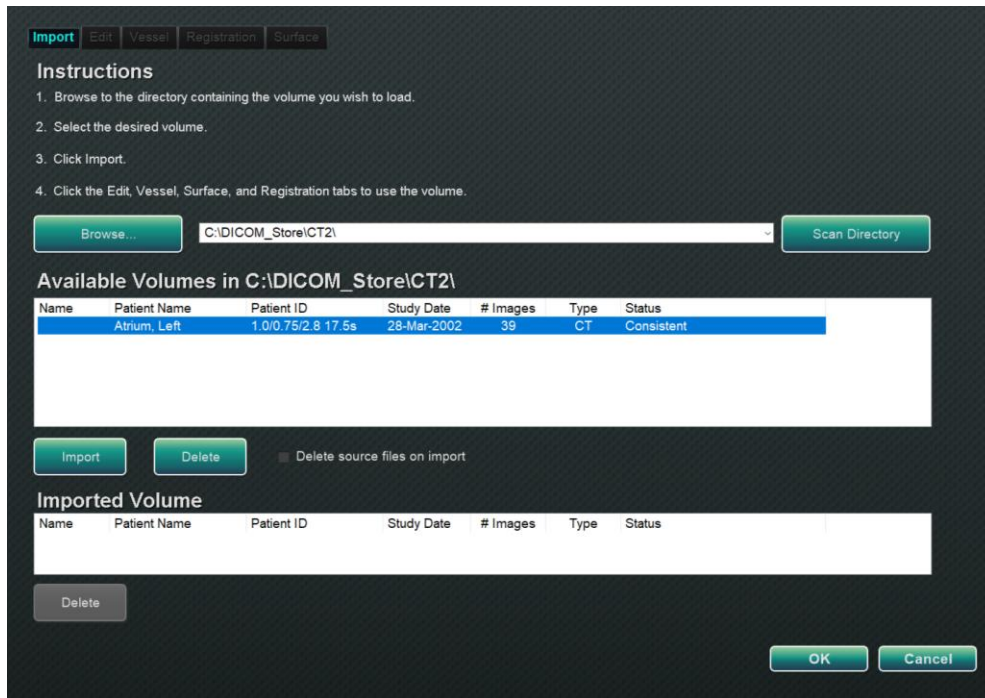


Figure 157. Import patient information

The Confirm Differing Patient Information dialog displays (Figure 158). Click **Accept** to confirm, or click **Cancel** to close.



Figure 158. Confirm Differing Patient Information

If the user has clicked **Accept**, the Importing progress bar displays (Figure 159). The Data Set Attributes dialog displays with detailed attributes. Click **OK** to close it.

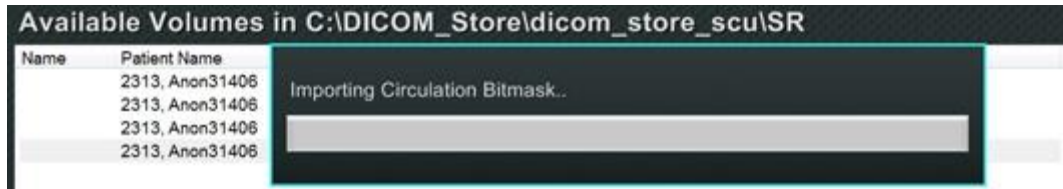


Figure 159. Importing progress bar

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

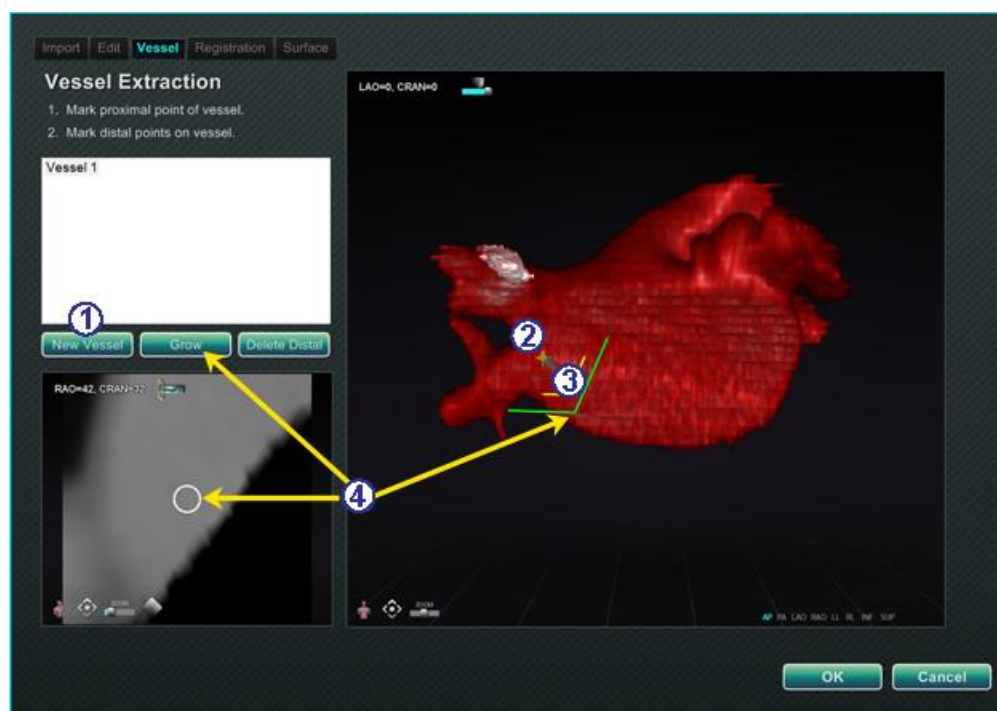


Figure 160. Vessel tab – Vessel Extraction and MPR slice

Vessel tab guide (Figure 160)

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.

- 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 161. Registration tab

Surface tab

When **Extract Surface** on the Surface tab is selected, the **Calculating isosurface...** progress bar displays (**Figure 162**). **Extract Surface** displays a surface. After following the steps on the screen, click **OK** to transfer the images to the main windows of *Navigant*.

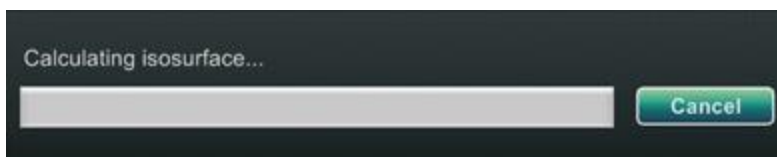


Figure 162. Calculating isosurface progress bar

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.

i **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.

i **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.

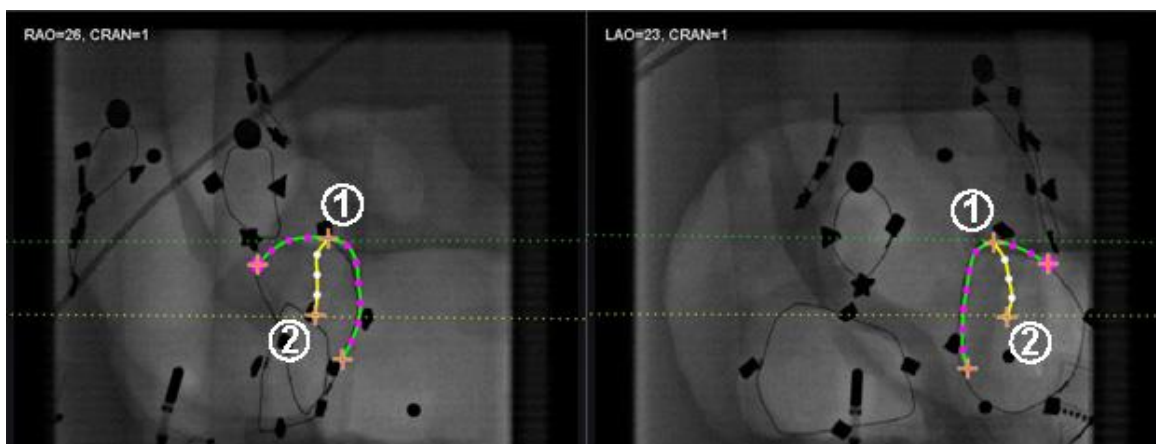


Figure 163. Vessel marking - Epipolar lines

Epipolar line colors guide (Figure 163)

- 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.

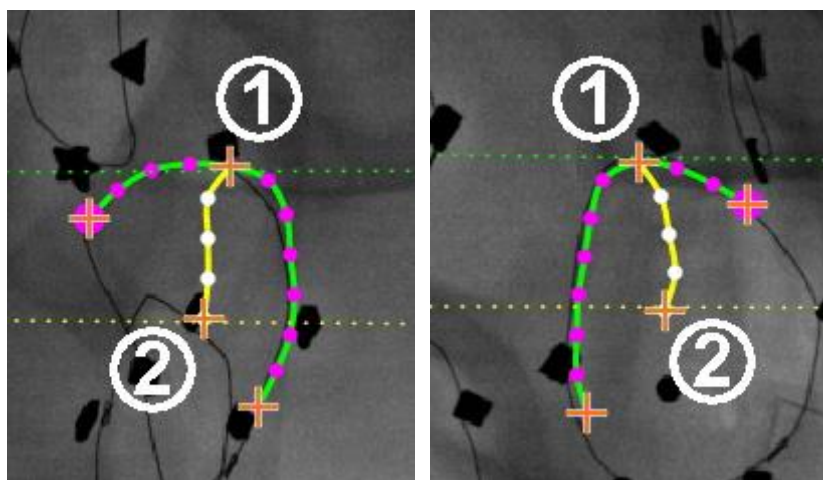


Figure 164. Simple vessel drawing – RAO (left) and LAO (right)

Drawing simple vessel marking guide (Figure 164)

- ① The green dotted line indicates the epipolar line of the proximal point. In **Figure 165**, the proximal anchor point has a solid circle behind the orange cross.
- ② The yellow dotted line indicates the epipolar line of the distal point.

Notes:

- Because the fluoros are not 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 end — point 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 165**), the proximal anchor point **(1)**, selected point **(2)**, and **(3)** distal anchor point are shown. To cancel the selection, click elsewhere on the image.

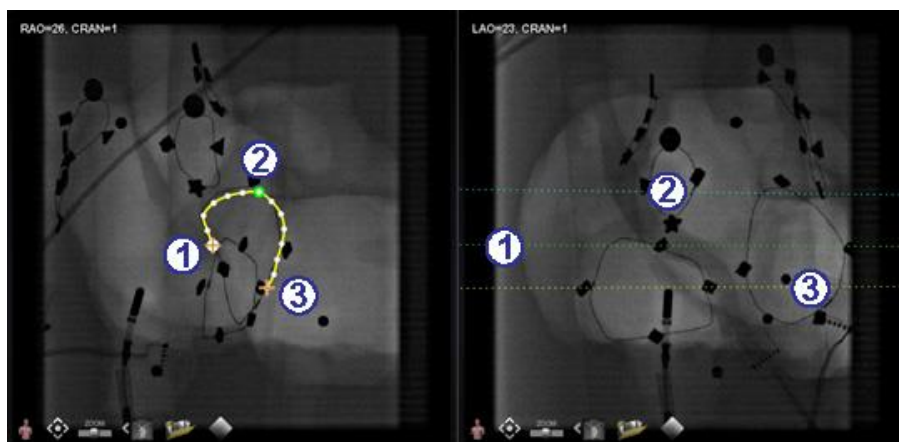


Figure 165. Proximal, selected, and distal points

Distal point in progress

As the user marks a vessel on a complementary fluoro (as on the LAO fluoro in **Figure 166**), 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.

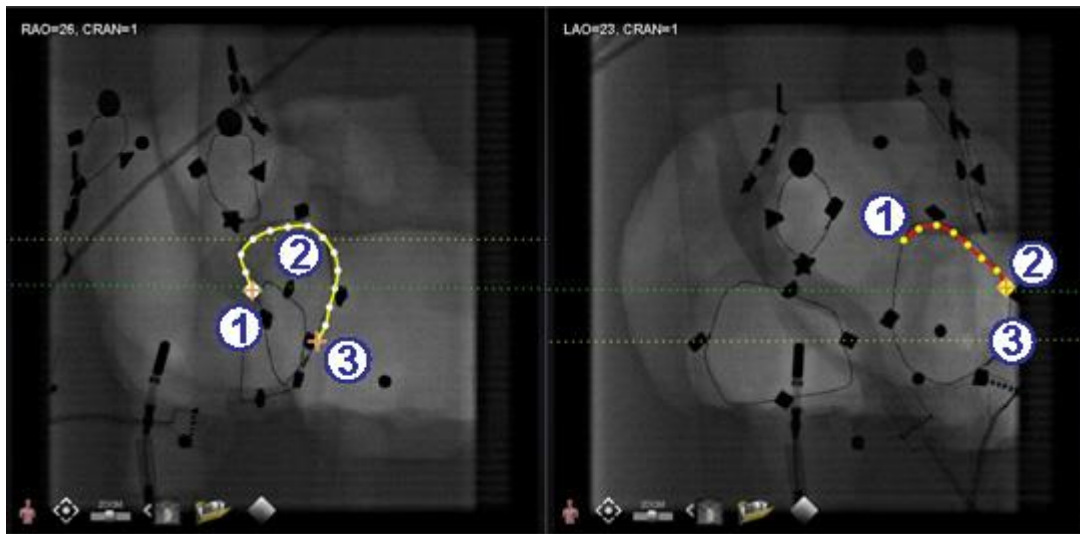


Figure 166. On complementary image, last point drawn is distal point

Distal point in progress guide (Figure 166)

- ① Proximal anchor point
- ② Distal point of the active drawing (LAO in **Figure 166**)
- ③ Distal anchor point of the original drawing (RAO in **Figure 166**)

Moving points

Click and drag a single point to move it. A green circle indicates a selected point (**Figure 167**).

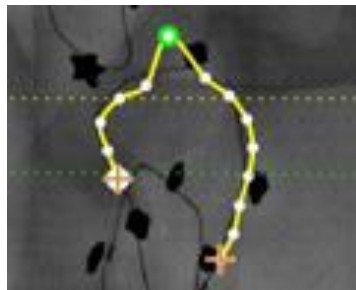


Figure 167. Click and drag single point to move it

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. See *Convert to anchor point* in the following section.

Vessel point menu

Right-click a point to view the point menu (**Figure 168** and **Figure 169**). The menu varies depending on whether the point is an anchor. The difference is with the last menu item: **Convert to anchor point** vs. *no option* for converting to a non-anchor point.

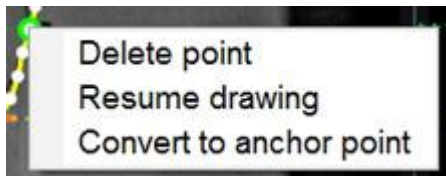


Figure 168. Vessel point properties menu for point

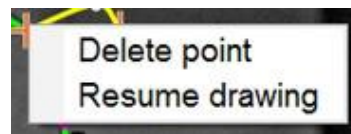


Figure 169. Vessel point properties menu for anchor point

Delete point

To delete a point, right-click on the point and select **Delete point** (**Figure 170**). A confirmation dialog will appear, and the point disappears and cannot be restored. However, the user can click to add a new point.

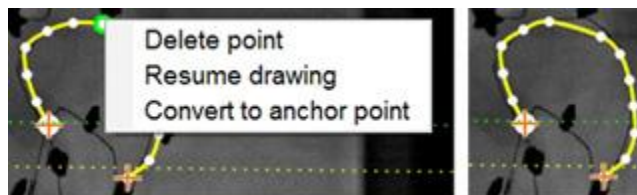



Figure 170. Delete point option

 **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).

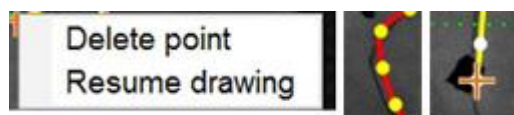


Figure 171. Resume drawing option

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.

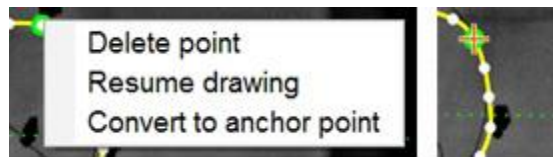



Figure 172. Convert to anchor point option

 **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 173. Adding branches – Start with matching trunks

Step 1 (Figure 173)

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

Step 2 (Figure 174)

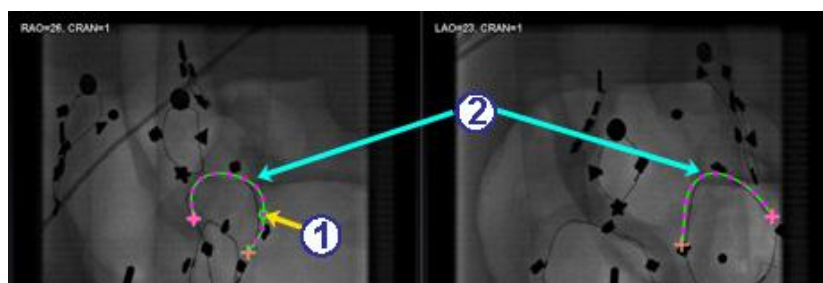


Figure 174. Select branching point on one trunk

- ① The user should select the point on the trunk where they wish to start the branch (**Figure 174**). 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 175 and Figure 176Error! Reference source not found.)

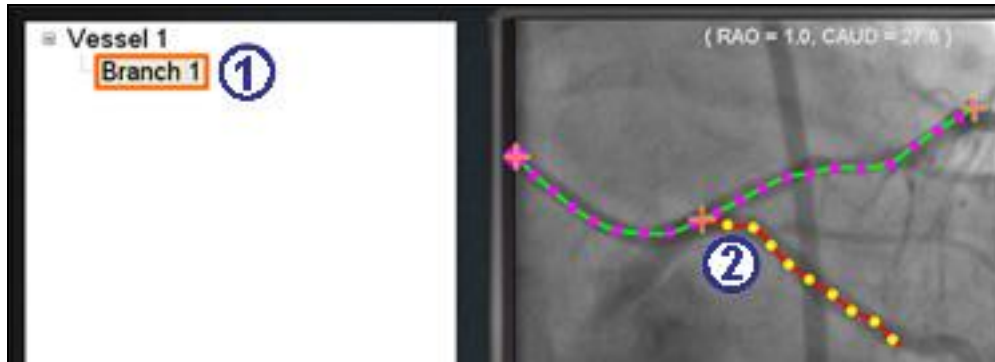


Figure 175. Branch name displays after selecting branching point

- ① A default branch name {Branch #} displays in the directory window after clicking a starting point (**Figure 175**). (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 176**.

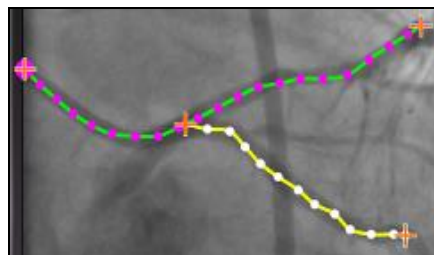


Figure 176. Completed branch in selected mode

Step 4 (Figure 177)

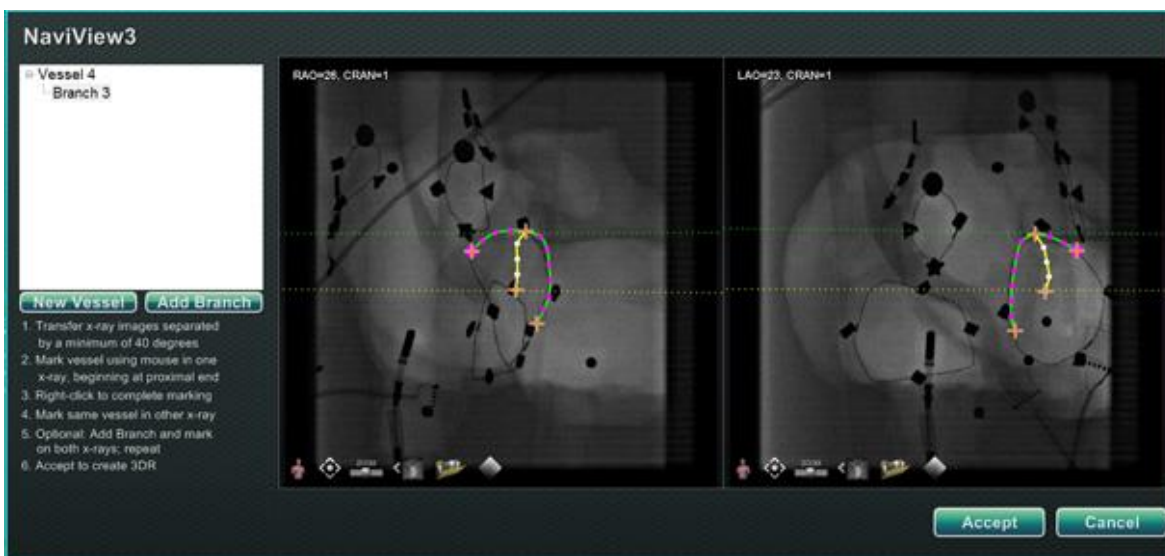



Figure 177. Draw complementary branch and click Accept

① Draw and complete the complementary branch.

② Click **Accept**.

 **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 178**). The user can create as many vessels and branches as desired.

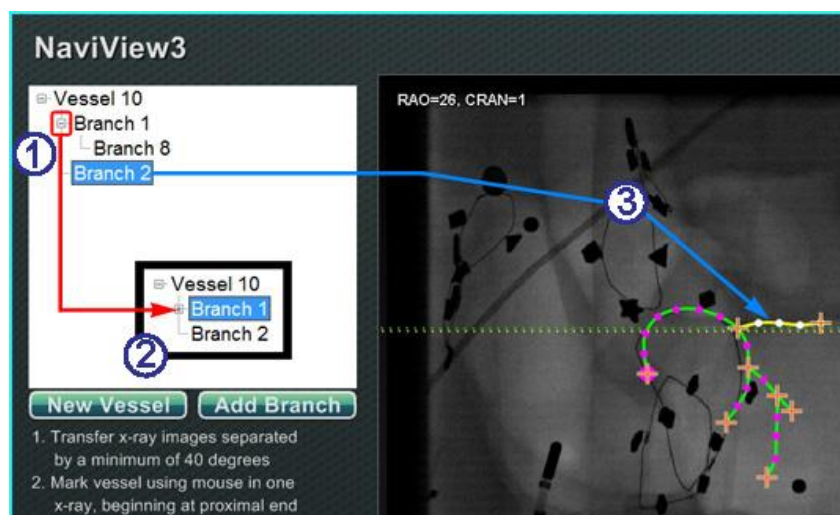


Figure 178. Directory tree tracks vessels and branches

Add more branches guide (Figure 178)

- 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 178**, 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 consecutivelyError! Reference source not found..
- 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 179)**.
- 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 displayError! Reference source not found..

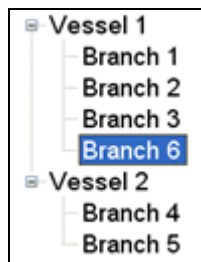


Figure 179. Vessel and Branch Numbering

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 180**).

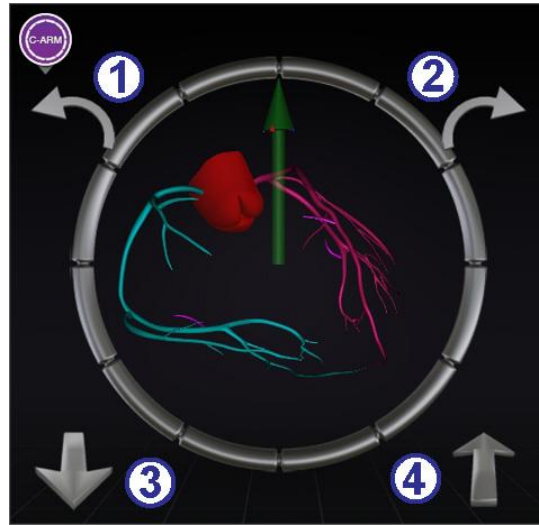


Figure 180. Synch C-Arm ClockDial View

ClockDial guide (Figure 180)

- ① Rotates counterclockwise within the plane of the view chosen.
- ② Rotates clockwise within the plane of the view chosen.
- ③ Rotates toward user.
- ④ Rotates away from user.

i **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.

7. 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.

8. Emergency Operations

Emergency Patient Retraction

To move the magnets out of the way for an emergency patient retraction, press the **Stowed Position** button on the UTSC and press and hold the **Move** button. Note that the magnets do not have to swing to the full 90° and lock in the Stowed position. The user can release the **Move** button whenever the magnets are sufficiently out of the way. If a power or other failure occurs that keeps the magnets from moving, see **Figure 182** for manual movement of the magnets.

Overriding Magnet Interlocks

System software interlocks prevent the magnet from moving into and colliding with the X-ray system components. The user can override this interlock and move the magnets by simultaneously pressing the **Stow Position** button on the UTSC and pressing and holding the **Move** button. While the **Move** button is held, the magnets are moving and the UTSC will display the message seen in **Figure 181**.



Figure 181. Interlock Override UTSC Message



WARNING: When using the interlock override, visually ensure magnet and X-ray system components will not physically collide. Closely monitor the magnet movement and be ready to release the **Move** button if a collision is imminent. Failure to heed these warnings may cause damage to equipment.

Moving Magnets Manually

A manual hand crank allows the user to manually move the magnets in the event of a facility power failure, or if a mechanical or electrical failure renders the system unable to move normally.



WARNING: When using the manual hand crank, **EXTREME CAUTION** must be taken to ensure proper patient table, C-Arm, and magnet positioning clearance. Also ensure that no one attempts to use the UTSC while manually moving the magnets. Failure to heed these warnings may cause an unsafe condition resulting in personal injury and/or damage to equipment.

To move the magnets manually, follow the steps outlined below that correspond with **Figure 182**. When power is restored and the UTSC is again used, the interlocks will automatically re-engage.

- ① Remove the side cover and set it aside.
- ② Remove hand crank bar from clip.
- ③ Insert bar into the hand crank hole. Make sure hand crank bar is *fully* inserted.
- ④ Turn hand crank bar to pivot magnet.

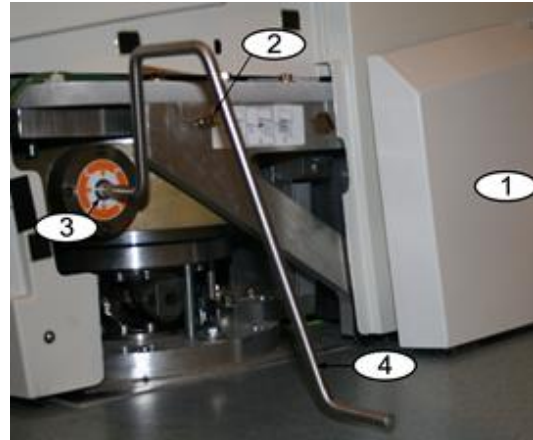


Figure 182. Manual hand crank for *Genesis RMN* magnets

Removing Item Stuck to Magnet

If all safety precautions are followed, ferrous items should never be near the magnet. An incident of something being attracted to and becoming stuck to a magnet should never occur.

However, if an item does become stuck to a magnet, please review the following before attempting removal.

1. The permanent magnets are always “on” and cannot be turned “off.”
2. The larger the mass of the item stuck to the magnet, the harder it will be to remove.
3. Use work gloves or other protective equipment around hands to prevent injury (e.g., skinned or scraped knuckles) when removing large items from a magnet.
4. The magnetic forces are strongest at the front (flat) face of the magnet.
5. The force decays rapidly with increased distance from the front face of the magnet.
6. If the item is sharp, consider potential damage to oneself or others if the user or the item slips, or is re-attracted to the magnet during removal.
7. The general strategy should be to **slide** the item (on the surface of the cosmetic cover) away from the front face of the magnet, and then **quickly and firmly** pull the item away **without hesitation**.
8. Sliding an item toward an outside corner of the cosmetic cover before making the “pull off” attempt over the edge of the cover is most effective.
9. Be aware that the forces around the magnet change. If an item becomes stuck to the magnet and one attempts to move the magnet from the Navigate to the Retracted or Stowed position, the field will change and the item could fall on its own (or become stuck even firmer).
10. **DO NOT** remove cosmetic magnet covers in an attempt to remove a stuck item. If contacted, the magnet (which the covers protect) could be irreversibly damaged.
11. Contact Stereotaxis personnel for assistance if unable to easily, or safely remove an item stuck to a magnet.

9. Messages

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.
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.

Problem	Solution
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.

Facility Breakers

If the *Genesis RMN* facility breakers have switched or turned off, contact one of the following:

- The hospital in-house Facilities Department
- Stereotaxis main number
 - o 314-678-6100
- Stereotaxis TeleRobotic Support Team:
 - o 314-678-6200
 - o 1-866-269-5268 (US only)

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