NAVIGANT™

Integration with CARTO 3

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MDSS
(Medical Device Safety Service GmbH)
Schiffgraben 41
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EC REP

Patents

Navigant
Manufactured under one or more of the following United States patents:
7,516,416; 7,537,570; 7,540,288; 7,540,866; 7,543,239; 7,627,361; 7,630,752; 7,657,075; 7,708,696; 7,751,867; 7,756,308; 7,761,133; 7,769,428; 7,831,294; 7,853,306; 8,024,024; 8,192,374; 8,369,934; 8,721,655; 9,314,222
Manufactured under the following European patents:
EP 1 682 024 issued in Germany, France, and the United Kingdom; EP 1 769 390, issued in Germany, France, and the United Kingdom

Niobe
Manufactured under one or more of the following United States patents:
6,975,197; 7,019,610; 7,161,453; 7,305,263; 7,313,429; 7,495,537; 7,772,950; 7,966,059
Manufactured under the following European patent:
EP 1 488 431 issued in Germany, France, and the United Kingdom

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

Other patents issued and pending.

Stereotaxis Trademarks

1) *Navigant, Niobe,* and *Cardiodrive* are trademarks of Stereotaxis, Inc., registered in the United States, European Community, the United Kingdom, and Japan.
2) *Genesis* and *GenesisX RMN* are trademarks of Stereotaxis, Inc., registered in the United States.
3) *Odyssey* is a trademark of Stereotaxis, Inc., registered in the United States, European Community, and the United Kingdom.
4) *iCONNECT* and *Synchrony* are trademarks of Stereotaxis, Inc.

Other Trademarks

1) *CARTO* 3 is a registered trademark of Biosense Webster.

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:	**Niobe:** IEC 60601-1-2:2007 EN55011, FCC Part 15.109(g), FCC Part 15.107(a) & ICES-003, EN61000-3-2:2006 +A1:2009 +A2:2009, EN61000-3-3:2013 **Genesis:** IEC 60601-1-2 ed 4.0 (2014-02) CISPR11 ed 6.1 (2016-06), Class A (Professional Healthcare Facility Environment)
Immunity:	**Niobe:** EN 60601-1-2:2015, EN61000-4-2:2009, EN61000-4-3:2006 +A1:2008 +A2:2010, EN61000-4-4:2012, EN61000-4-5:2006, EN61000-4-6:2009, EN61000-4-8:2010, EN61000-4-11:2004 **Genesis:** IEC 60601-1-2 ed 4.0 (2014-02), IEC 61000-4-2 ed 4.0 (2008-12), IEC 61000-4-3 ed 3.2 (2010-04), IEC 61000-4-4 ed 3.0 (2012-04), IEC 61000-4-5 ed 3.0 (2014-05) + AMD:2017, IEC 61000-4-6 ed 4.0 (2014 COR2015), IEC 61000-4-8 ed 2.0 (2009-09), IEC 61000-4-11 ed 2.0 (2004-03) + AMD1:2017

When operating this equipment, verify that other devices installed near it conform to the applicable EMC standards for that device. Navigant and the Stereotaxis RMNS are designed to be installed and operated in a Professional Healthcare Facility Environment.

Safety Standard Statement

Safety Standard Compliance	This equipment was tested and found to conform to the following IEC 60601-1 Medical Electrical Equipment General Requirements for basic safety and essential performance test specifications:
Standard:	*Niobe*: ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1 CAN/CSA-C22.2 No. 60601-1:14 *Genesis*: CAN/CSA-C22.2 No. 60601-1:14 ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1 IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)

Related documents

HDW-0312 Niobe User Guide
HDW-0367 iCONNECT User Guide
HDW-0358 Genesis RMN User Guide
HDW-0372 Navigant User Guide
HDW-0387 GenesisX User Guide
Respective documentation for compatible devices and /or systems.

Operating conditions

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

Storage and transport conditions

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

Stereotaxis Companion Systems

System	Part Number
Niobe	Siemens Reference number: 001-006000-1
	Philips Reference number: 001-006100-1
	Model S Reference number: 001-006200-1
Genesis RMN	Siemens Reference number: 001-011000-1
	Model S Reference number: 001-011000-3
GenesisX RMN	001-014000-1
Cardiodrive	001-004115-9
iCONNECT	001-009040-1

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

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

Disposal

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

Waste and Recycling

A contractor is responsible for the disposal and recycling of scrap metals and electronics found in *Navigant*.
Suggested Contractor: Walch Recycling & Eldelmentalle

Notice to the User and/or Patient

Any adverse event or malfunction that occurred in relation to the device should be reported to the manufacturer. Serious adverse events should be reported to the competent authority of the Member State in which the user and/or patient is established.

Cover art

CONTENTS

Overview

Introduction

The purpose of this document is to provide Navigant™ users with integration guidance for third-party systems. *Navigant* works in conjunction with a Stereotaxis Robotic Magnetic Navigation System (RMNS) to provide enhanced integration of catheterization and electrophysiology (EP) labs and improved automation during robotic magnetic navigation of medical devices.

Navigant communicates with mapping systems such as Biosense Webster CARTO® 3 to allow integrated mapping and navigation. This document includes instructions and troubleshooting for integration with *CARTO* 3; *Navigant* is not compatible (integrated) with *CARTO* 3 v7.

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

Indications

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

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

Intended Patient Population

The intended patient population for the MNS is patients undergoing diagnostic and interventional procedures in the following areas: right and left heart, and the coronary, peripheral, and neurovasculature.

Intended Users

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

Contraindications

There are no known contraindications.

Graphics and Symbols

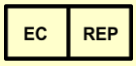
The following graphics and symbols are used in this guidance document:

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
	**AC Power**	Indicates the status of the AC power.
	**Catalog Number**	Catalog/part number.
	**Caution**	Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot be presented on the medical device.
	**CE Marking**	Product conforms to European Medical Directive 93/42/EEC and meets applicable healthy, safety, and environmental requirements. If the mark is accompanied by a number, conformity is valid.
	**Consult Instructions**	See the Operating Instructions for additional information or instruction.

Symbol	Name	Description
	**Date of Manufacture**	The date when the medical device was manufactured.
	**E-stop**	Indicates the E-stop button or the E-stop indicator light.
	**European Representative**	Name and address of the authorized representative in the European Community.
	**Importer**	Name and address of the entity importing the medical device into the locale.
	**Magnet Present**	Indicates a magnet is present in the equipment.
	**Manufacturer**	Name and address of the manufacturer of the product.
	**Medical Device**	Indicates the item is a medical device.
	**Power**	Indicates the power status.
	**Prescription Only**	Caution: Federal law restricts this device to sale by or on the order of a physician.
	**Recycle: Electronic Equipment**	Product that is subject to the European Union's Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC/EU Directive for recycling of electronic equipment.
	**Refer to Instruction Manual/Booklet**	The instruction manual or booklet must be read.

Symbol	Name	Description
SN	**Serial Number**	The manufacturer's serial number so a specific medical device can be identified.
UKRP	**UK Responsible Person**	A person established in the United Kingdom (UK) who acts on the behalf of a non-UK established manufacturer in relation to the manufacturer's obligations under UK regulations.

Glossary

The following terms appear in this document:

Term	Description
3D	Three-Dimensional.
AP	Anterior-Posterior.
AutoMap	An integrated feature between *Navigant* and the mapping system that enables the user to initiate a sequence of automatic, computer-controlled catheter movements throughout the cardiac chamber.
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* Catheter Advancement System (CAS)**	The Stereotaxis tool that provides the physician with the ability to advance and retract catheters from a Control Room. Commonly referred to as *Cardiodrive* or CAS.
***CARTO* 3 System**	Biosense Webster system that combines 3D mapping and navigation systems with the Stereotaxis RMNS.
Click & Go	An integrated feature between the *Navigant* 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.
Edit *NaviLine* Mode	Provides a toolbox with features to create and edit a *NaviLine* such as New Line, Remove Line, Open/Close, Color, and Measure; available for all surfaces and volumes.

Term	Description
EMC	Electromagnetic compatibility.
EP	Electrophysiology.
Fluoro	Fluoroscopic, or Fluoroscopy.
Fluoroscope	An X-ray image intensifier that produces live X-ray images displayed on a monitor. Also called X-ray or C-Arm.
Robotic Magnetic Navigation System (RMNS)	A medical platform that enables physicians to navigate catheters, guidewires and other magnetic interventional devices through the blood vessels and chambers of the heart to treatment sites and then to effect treatment; system consists of computer-controlled magnets that assist physicians in orienting and steering compatible, magnetically-adapted devices and works in conjunction with *Navigant* Workstation.
IC	Interventional, or Intracardiac, Cardiology.
Ideal registration	Instruction to the user for complementary fluoro images that will yield the best registration data.
Isocenter	In X-ray technology, isocenter is the point in space where from any angle (AP, LAO, RAO) the central ray of the radiation beams will pass.
LAO	Left Anterior Oblique.
Navigation volume	Spatial volume defined for RMNS, where the RMNS is capable of generating any magnetic field direction at the target magnetic field strength provided by the RMNS. This volume is aligned in the same location as defined by the x-ray isocenter.
***NaviLine* automated linear navigation**	An integrated feature between the Stereotaxis *Navigant* software and the mapping system that enables the user to automatically follow a predefined line along a 3D surface created by the mapping system. *NaviLine* navigation moves the catheter in prescribed increments forward and/or backward along the line.
***Odyssey Cinema* System**	The optional recording system for the *Odyssey Vision* System that provides remote viewing of live and recorded procedures.
***Odyssey Vision* System**	An 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 *Navigant* and mapping systems that have been tested to be compatible. These compatible mapping systems are referred to as OpenMapping systems.
RAO	Right Anterior Oblique.

Term	Description
Registration set	3D models imported into *Navigant* as surfaces in VTK format; once imported, all surfaces are moved and manipulated as a group.
RF	Radiofrequency.
RMT	A remote magnetic technology. (RMT is often used to refer to the integrated *CARTO* 3 / RMNS environment incorporating 3D mapping and navigation and magnetic maneuvering of compatible devices.)
Synchrony	The *Synchrony* system is an optional display and user interface package designed to consolidate the point of control of a medical lab.
Target Navigation	Using field and CAS movements to automatically move the catheter to the user-indicated target.
W·s	Watt-second, the energy equivalent to the power of one watt sustained for one second.

Safety

Warnings

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

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

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

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

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

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

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

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

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

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

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

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

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

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

WARNING: If there is a cybersecurity breach during a procedure, press the E-stop button to stop all device activities. Contact the Hospital IT and TeleRobotic Support Team at Stereotaxis to report the suspicious activity prior to resumption of the procedure.

Precautions

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

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

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

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

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

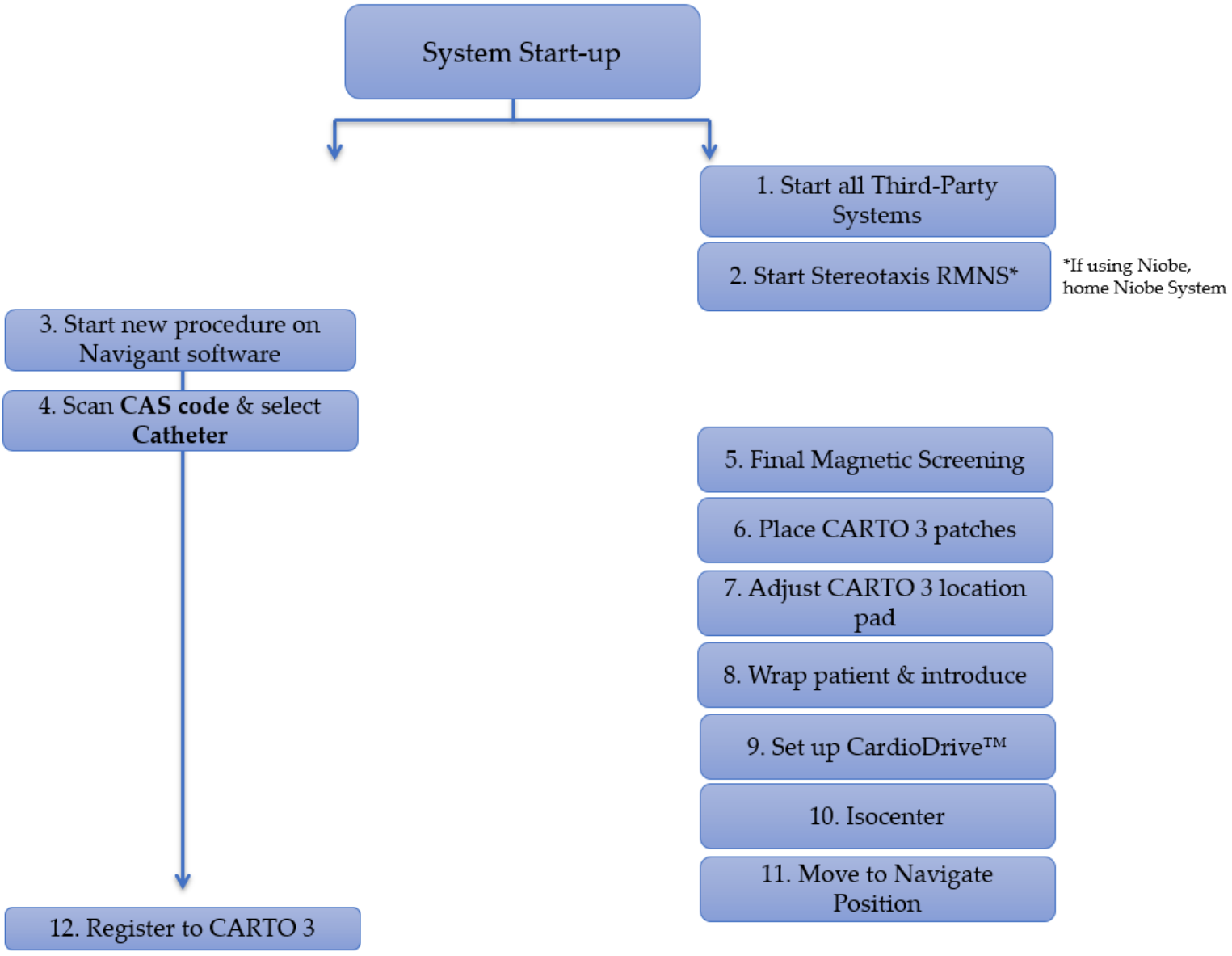
CAUTION: Do not set anything on the keypad or flip the keypad over. This will prevent a key from being held down causing unwanted repetitive motion.

General Notes

- Always verify the fluoroscopy images match the current patient.
- Images that are electronically zoomed and/or panned cannot be transferred to Stereotaxis RMNS.
- Images acquired during C-Arm movement or table movement cannot be transferred to Stereotaxis RMNS.
- Before ablation, verify the field is applied to ensure proper device functionality.
- The following features are only enabled at sites where the RMN is integrated with the fluoroscopy system:
    - Display of fluoroscopic system status in Navigant
    - C-Arm and table position for display and collision detection
    - ViewSync to the C-Arm angle
    - Transfer of fluoro images to Navigant
    - Nav Fluoro A, Nav Fluoro B, or Clockdial Sync C-ARM windows on Navigant desktop, or settings related to those windows
    - All features available with registration (see **Register to *CARTO* 3 RMT** section).
    - Any dialog that displays a Fluoro Window:
        - Catheter Calibration and Mapping System Registration
        - Manual Vessel Registration
        - Point Annotation on Fluoro
        - Surface Registration
        - Vessel Marking
        - Volume Guidance Dialog and all Volume support

CARTO 3 Integration

Procedural Setup Workflow Chart



System Start-up

1) Turn on all 3rd party systems: *CARTO* 3, Fluoro, ECG.
2) Turn on RMNS system with the rocker switch shown. Hold down until the green light illuminates.
   a) ON=I, OFF=0.
   b) If you have a Genesis system with an *Odyssey* solution, there is a single rocker switch and it will also turn on *Odyssey*.
3) If the site has a *Niobe* system with an *Odyssey* solution, there are two rocker switches. After the *Niobe* is powered on, wait 10 seconds and push the rocker switch on *Odyssey* to the ON position until the green light illuminates.
   a) If the site has a *Niobe* system, home the *Niobe* once the *Odyssey* solution has been turned on and is illuminated.

Start New Procedure on *Navigant* Software

Select **Start New Procedure**. Patient information previously entered in X-ray system is transferred from X-ray to *Navigant* software. Fill in all missing information:

- **Physician** (mandatory)
- **Arrhythmia** (mandatory, make sure to be accurate)
- **Profile** (optional)

Select specific Heart Chamber. If applicable, select **Use *CARTO* 3** and **Use RMN**.

Note: Ensure a new procedure is also opened on *CARTO*. If there is a procedure open in *Navigant* and "another (new/old)" procedure in *CARTO* is opened, there may be conflict map information being sent to *Navigant*.

Scan CAS Code and Select Catheter

Select catheter type in **Select Device** window.

1) Select catheter type in **Select Device** window.
2) Scan the QuikCAS™ Activation Code on the CardioDrive disposable packaging.
   a) If unable to scan barcode, manually enter barcode number on keyboard.
3) Press **Select**.

CARTO 3 RMT Patches

Correct placement of the ***CARTO* 3 RMT patches** is the most important part of RMT setup. Correct placement ensures:

- Ability to see all areas of chamber of interest despite limited viewing angle and table panning.
- Map accuracy.
- Ability to reach all areas of the chamber of interest with the RMT catheter.
- "Six dots" will be close enough to AP image to find when needed for registration.

The RMT window for patch placement is much smaller than the non-RMT window (**Figure 1**). Therefore, the area on the patient where the patches can be placed is much smaller and should be done with great accuracy.

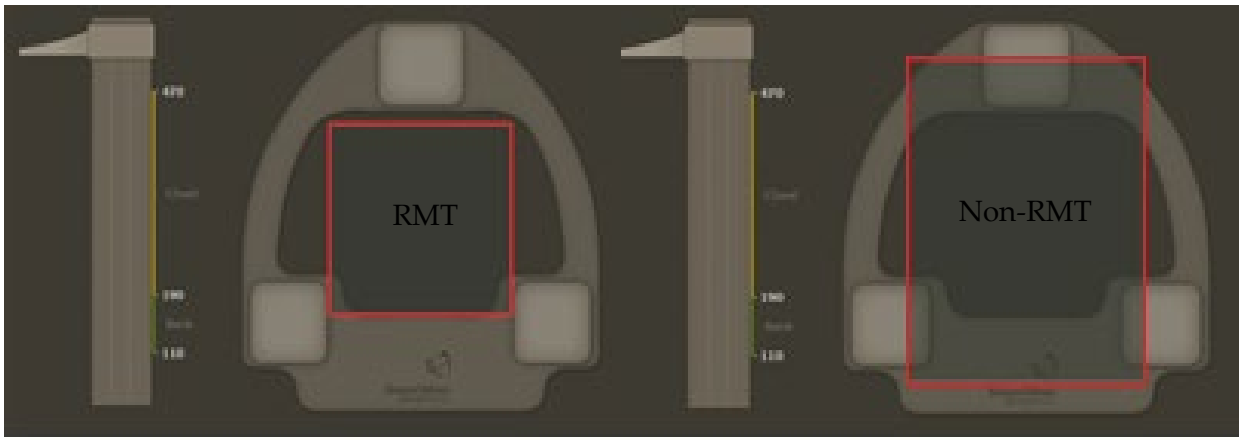


Figure 1. **RMT Patch Placement Window**

CARTO 3 RMT Patch Placement

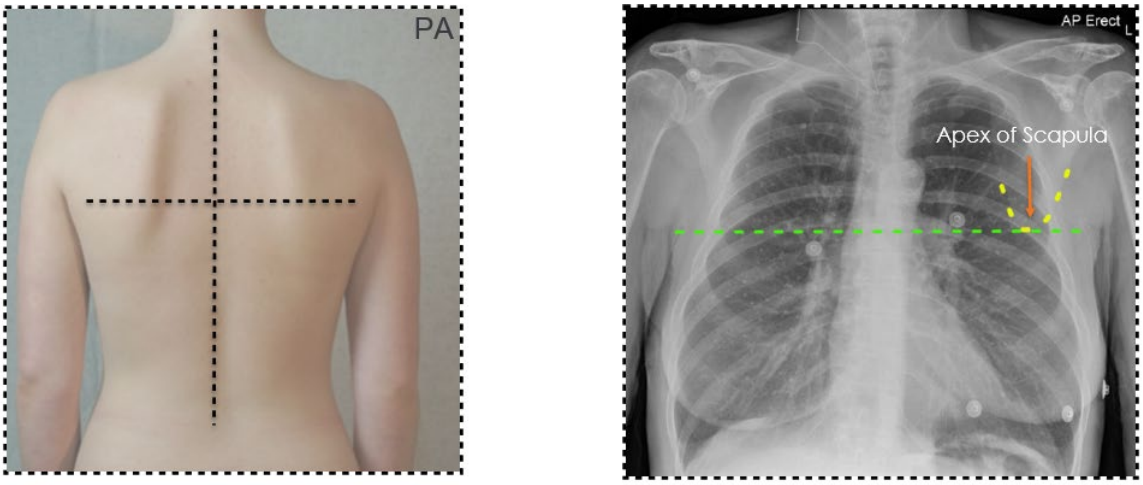


***Figure 2*. Apex of Scapula for Patch Placement.**

At the level of the apex of the scapula (**Figure 2**), place fist slightly to the left of the spine (**Figure 3**). This position is suitable for atrial and **Right/Left Ventricular Outflow Tract (R/LVOT)** procedures; patches will need to be slightly lower for **Ventricle Tachycardia (VT)** procedures.

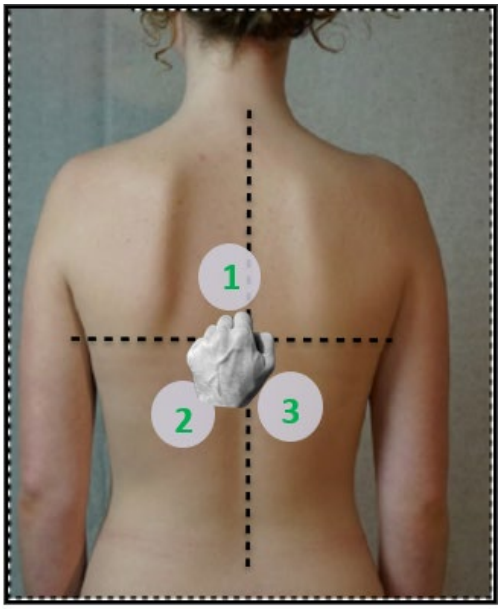


***Figure 3*. *CARTO* 3 RMT Patch Placement near the spine.**

Green and Yellow markers in *CARTO* 3 location setup screen (**Figure 4**) represent the sensors in the middle of each of the patches. These markers show up (**Figure 5**) once the patient is laying on the table.

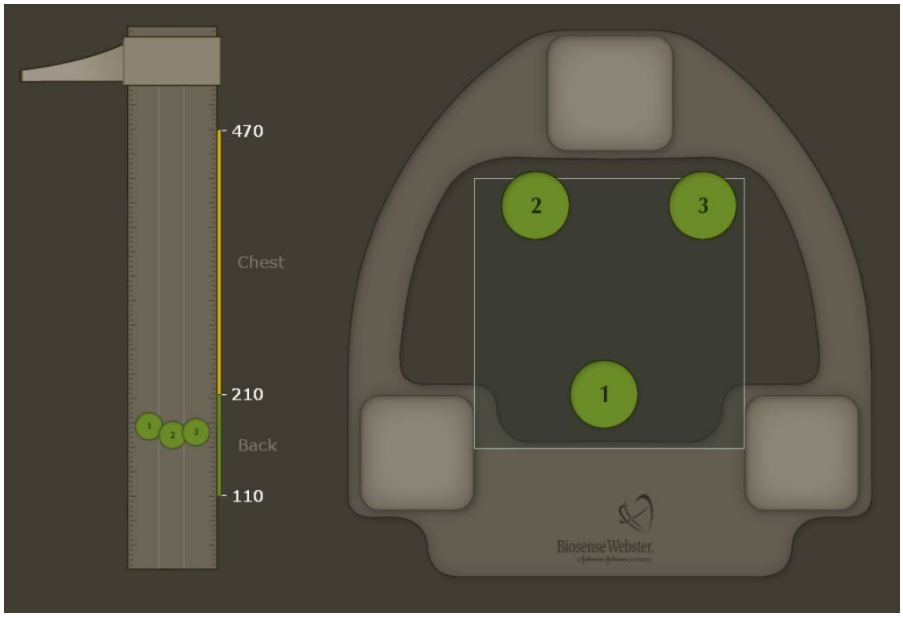


***Figure 4. CARTO* 3 Patch Sensors.**

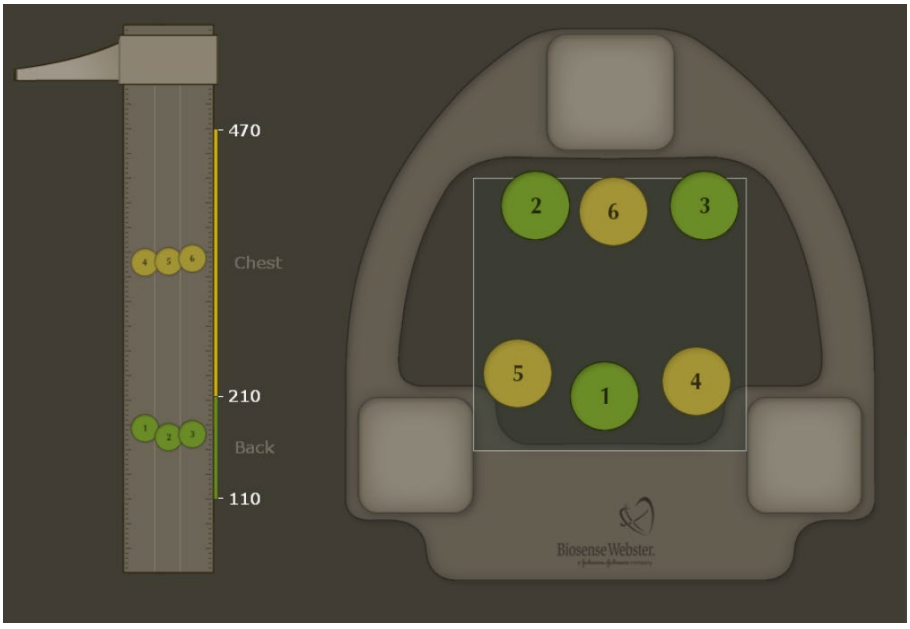


***Figure 5.* All Patches Sensors Placed.**

Place green back patches "around the fist" (**Figure 6**). There should be as much distance between patches as possible.

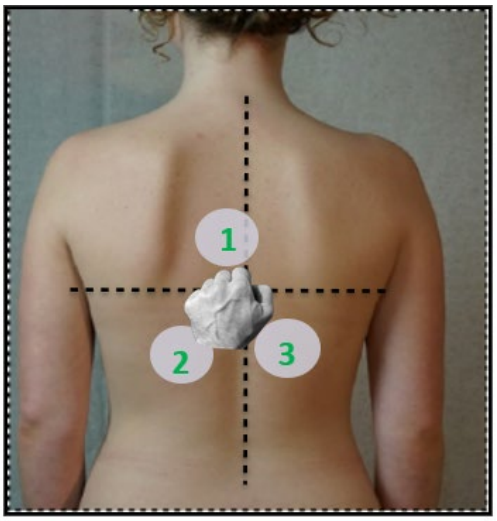


***Figure 6. CARTO* 3 Patch Placement around fist near spine.**

Similarly, place the yellow patches on the chest in opposite orientation (**Figure 7**).

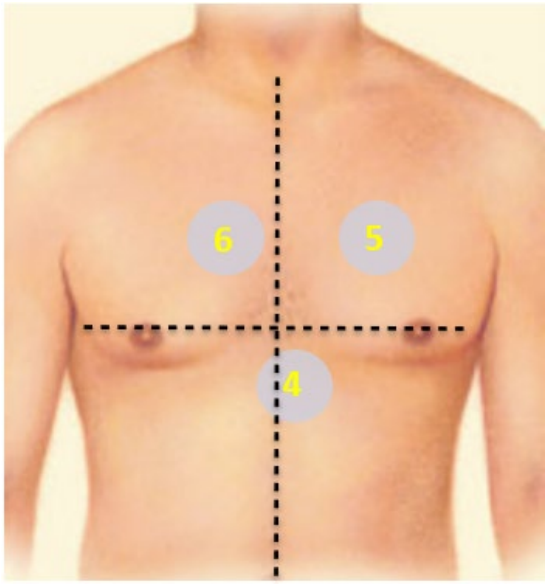


***Figure 7. CARTO* 3 Patches Placed Opposite on Chest.**

CARTO 3 RMT Patches for Ventricles

The fist shifts lower and to the left because the 6 dots must encompass the entire Ventricle, including the Apex (**Figure 8**).

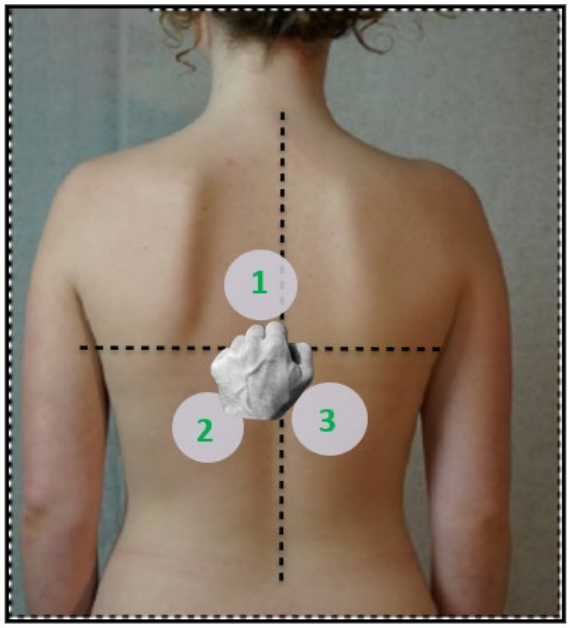


***Figure 8*. Placement encompasses entire Ventricle, along with the Apex.**

WARNING: If there isn't correct location patch and pad placement, then the catheter may not be visualized in the mapping and fluoro windows when the catheter is placed apical or lateral in the **Left Ventricle (LV)**.

CARTO 3 RMT Location Pad

To best optimize the use of the *CARTO* 3 RMT Location Pad (**Figure 9**), the patient needs to be centered on the table with their head at the top of the bed (**Figure 10**). *CARTO* 3 RMT Location Pad has "Six Dots" marker, shown in the red dotted circle. "Six Dots" are needed to complete *CARTO* 3 and *Navigant* software registration.

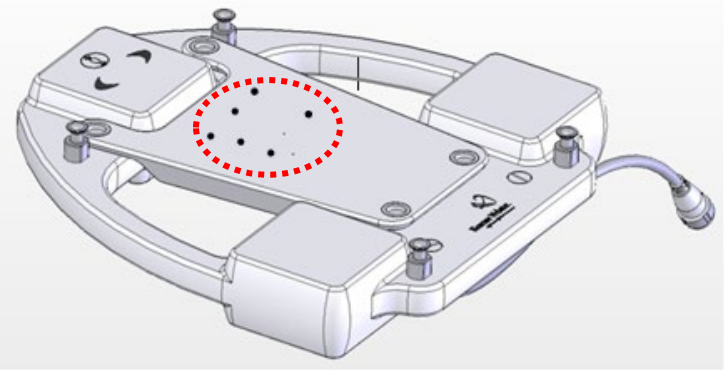


Figure 9. **RMT Location Pad with Its Six Dots.**

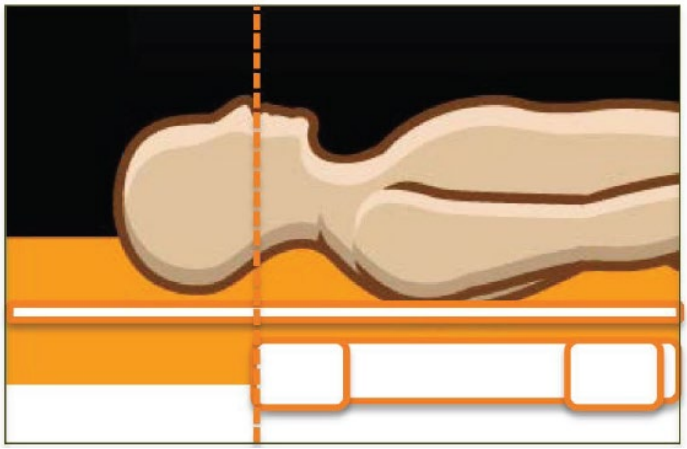


Figure 10. **Patient Head Centered at the Top of the Bed.**

Note: When CARTO patch setup looks fine, cross-check that CARTO Location Pad is aligned with patient ear lobe level.

CARTO 3 RMT Location Pad Placement

1) With patches on, center the patient on the table and position them at the very head of the table.
2) Verify the location pad is placed under the table and falls between ear and elbow level on the patient (**Figure 11**).

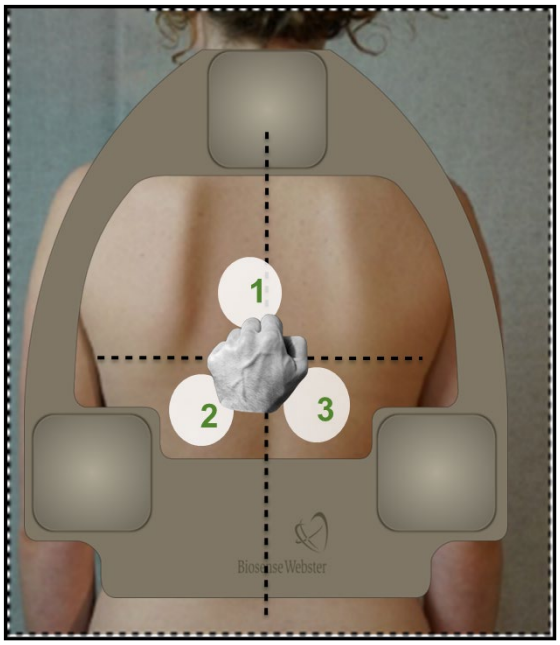


***Figure 11*. Where the Location Pad is Placed.**

3) All patches should now display on *CARTO* 3 location pad setup and be shown (**Figure 12**).

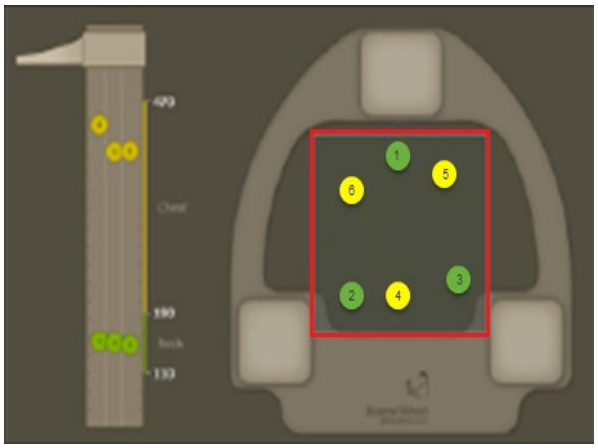


***Figure 12*. Location Pad Placed around Sensors.**

⚠ **CAUTION:** If patient is not centered, this may cause trouble when moving the magnets into the Navigate position later. Ensure patient centering is done properly the first time.

At this point:

- Patches placed
- Patient centered on the table with the patient head at the very end of the bed
- Location pad centered under patient
- Yellow and green patches displayed within CARTO 3 location setup inside of RMT location window

Capture AP "Six Dots" image (**Figure 13**). The six dots on the location pad under the table will be magnified in the fluoro image. The location pad under fluoro may need to be slightly adjusted until all six dots are in the fluoro image. With patches placed correctly and using the location setup on CARTO 3, only a small adjustment may be needed.

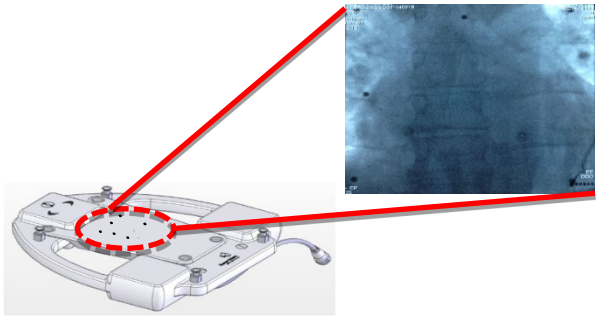


***Figure 13*. CARTO 3 RMT System**

The size of the fluoro image (**Figure 14**) is highly magnified. This will cause anatomical sizes to appear larger in X-ray. Their true, smaller size highlights the importance of accurate patch placement.

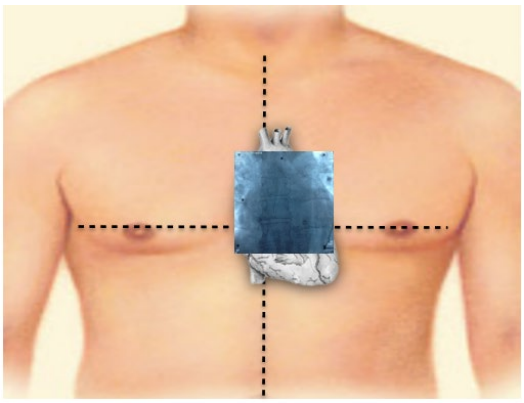


***Figure 14*. Fluoro of heart.**

Wrap the Patient and Introduce Catheter

Supporting patients' arms needs special attention. Arm board supports may prevent the RMNS system from reaching the Navigate position. It is advisable to wrap the patient (**Figure 15**) or place arm boards very low to support only hands.

***Figure 15*. Patient Arm Wrapping.**

Why Wrap the Patient?

Use of arm boards may result in the inability to fit the patient between the magnet positions. Wrapping the patient is the desired approach. Wrapping patient maximizes the chance the magnet positioners will come into the Navigate position without issues. Ensure the arms are not wrapped too tightly and periodically check patient status throughout the procedure.

Alternative to Wrapping the Patient

If wrapping the patient is not a desired option because of concerns such as wrapping a patient will block the view or access to the injection line and will not wrap the patient, there are thin and flexible arm rests that are made by Siemens (**Figure 16**) with thin, fatty gel cushioning. The thin cushioning and flexibility make it possible to bring the magnets into 0.1T Navigate position. (This is an alternative if the site chooses not to wrap the patient.)

***Figure 16*. Siemens Flexible Arm Rests.**

X-Ray Isocenter vs. CARTO 3 Registration

X-ray Isocenter: Defines the region of interest on fluoro (where the catheter will be located during the procedure).

Establishing isocenter defines the region of interest and allows visualization of the catheter. The associated magnetic navigational volume ensures the catheter can move within this space. Isocenter and magnetic navigational volume must be in the same physical space. Table panning is restricted due to the magnet location in the Navigate position; physician is remotely moving the catheter in the control room. The most that is possible to do is adjust the table height (**Figure 17**).

***CARTO* 3 Registration**: Establishes communications between *CARTO* 3 and *Navigant* software (magnetic volume).

There is limited area to pan the table and a limit on the angles for RAO and LAO. Proper isocenter ensures:

- The table will not need to be panned during the procedure.
- The ability to see the entire volume of the chamber of interest.
- Catheter can reach all areas of chamber with consistent highest magnetic strength.

Isocenter

At this point:

- Patches placed
- Location pad set
- Six dot image includes six dots surrounding chamber of interest

Capture another fluoro image to verify that the six dot AP image is still accurate. Movement may have occurred during patient wrapping and catheter placement. If necessary, pan the table in AP view to center the anatomical region of interest. The location pad should remain fixed in its present position (assuming it has not been moved since placement).

WARNING: Magnetic positioners navigate very close to the patient.

Once registered via the 6 dots, *CARTO* can notify *Navigant* what the height of the catheter is relative to isocenter/navigation volume.

Adjusting Table Height

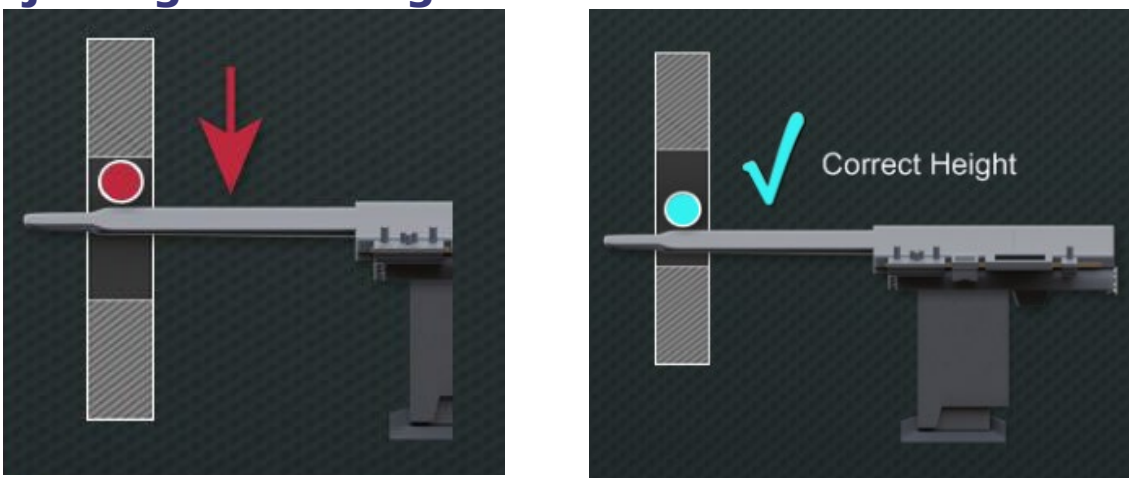


***Figure 17*. Left: Table Height Adjustment Needed; Right: Correct Table Height.**

Move the C-Arm to **Lateral** position. Because the magnet positioners are not yet in the Navigate position, moving the C-Arm to Lateral positions is still possible. All chambers of interest and the catheter should be seen.

If not, move only the table height_until all target anatomy is seen. This can be done with whatever table controller is in use: Siemens (**Figure 18**), Philips (**Figure 19**), or Stereotaxis Imaging Model S (**Figure 20**).

***Figure 18*. Siemens Controller.**

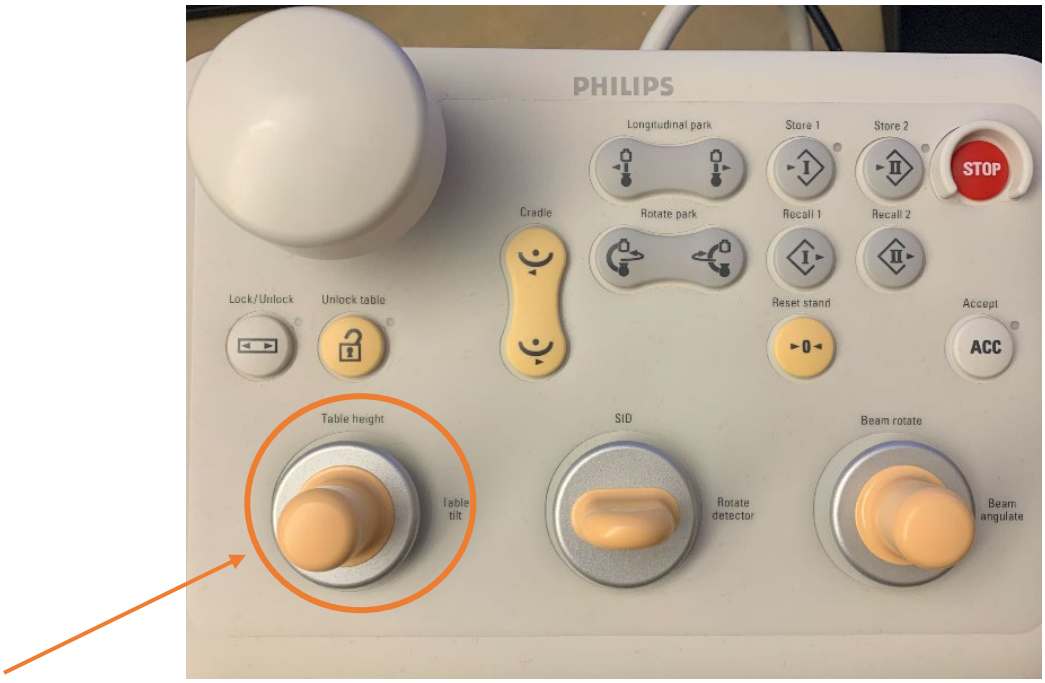


***Figure 19*. Philips Controller.**

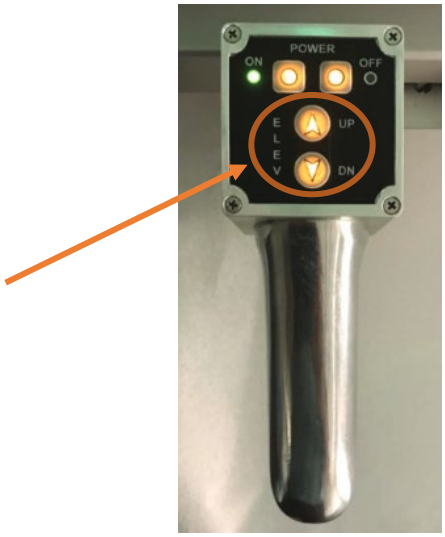


***Figure 20*. Stereotaxis Imaging Model-S Controller.**

Register to *CARTO* 3 RMT

Once the magnets are in the Navigate position, prior to registration, initialize *CARTO* 3.

1) Open the registration menu on *Navigant* software.
2) Transfer the AP fluoro image with the six dots visible (**Figure 21**).

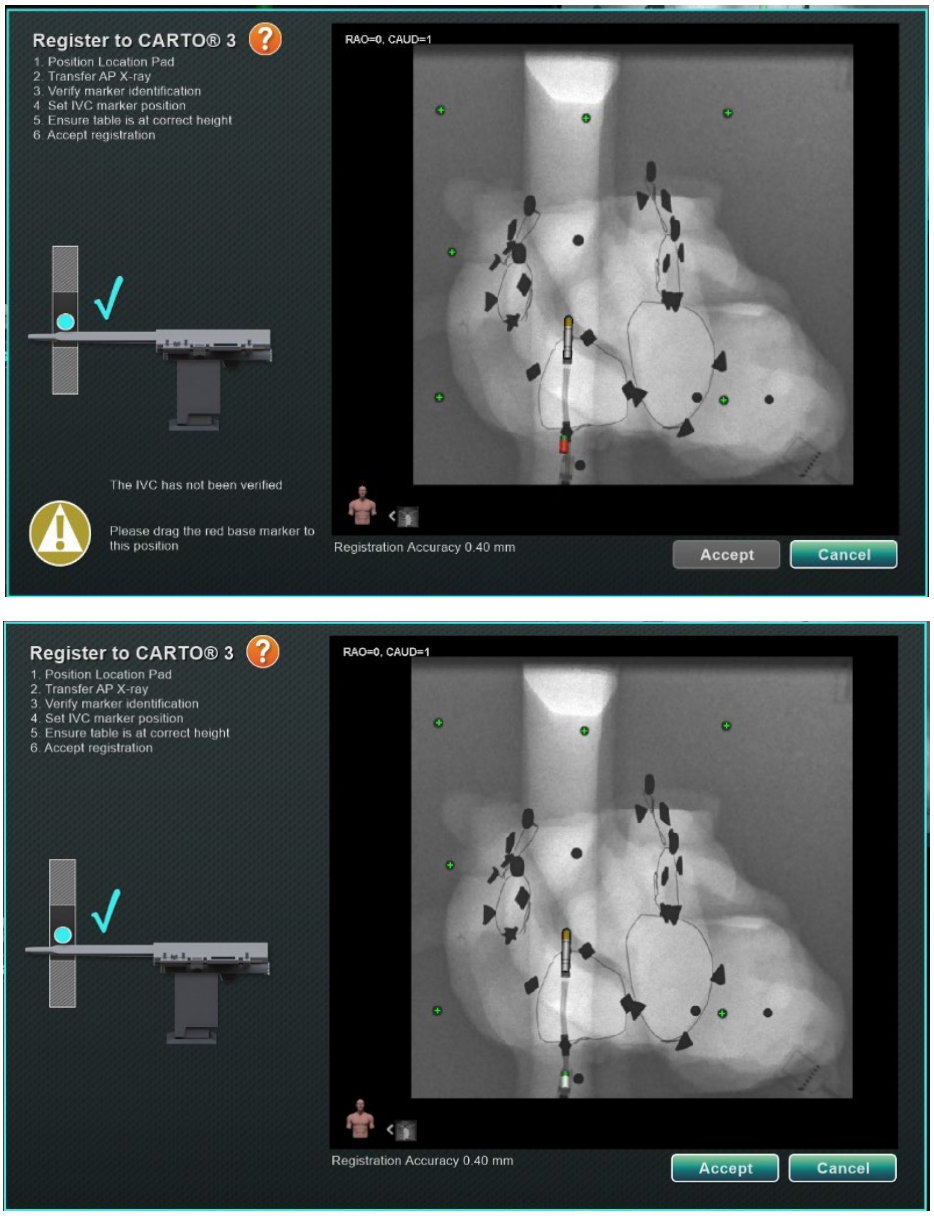


***Figure 21. CARTO* 3 Registration Menu. (Top initial transfer, bottom after steps)**

3) Check that **Registration Accuracy** is less than 1mm, and that green markers are projected over the six dots. Click and drag the green markers to the dots if necessary.
4) Select and drag the red base of the virtual catheter back to the actual sheath tip location in X-ray.
5) Press **Accept**.

Register to *CARTO* 3 RMT LA (Left Atrium)

The Retraction Limit sets the access protection (the rectangle shown in **Figure 22.**) This must be set at the septum to prevent the catheter from retracting beyond this plane. This helps prevent transseptal access from being lost. The Retraction Limit will turn blue once moved.

Retraction Limit feature is only available when choosing a Left Atrial workflow in *Navigant* software.

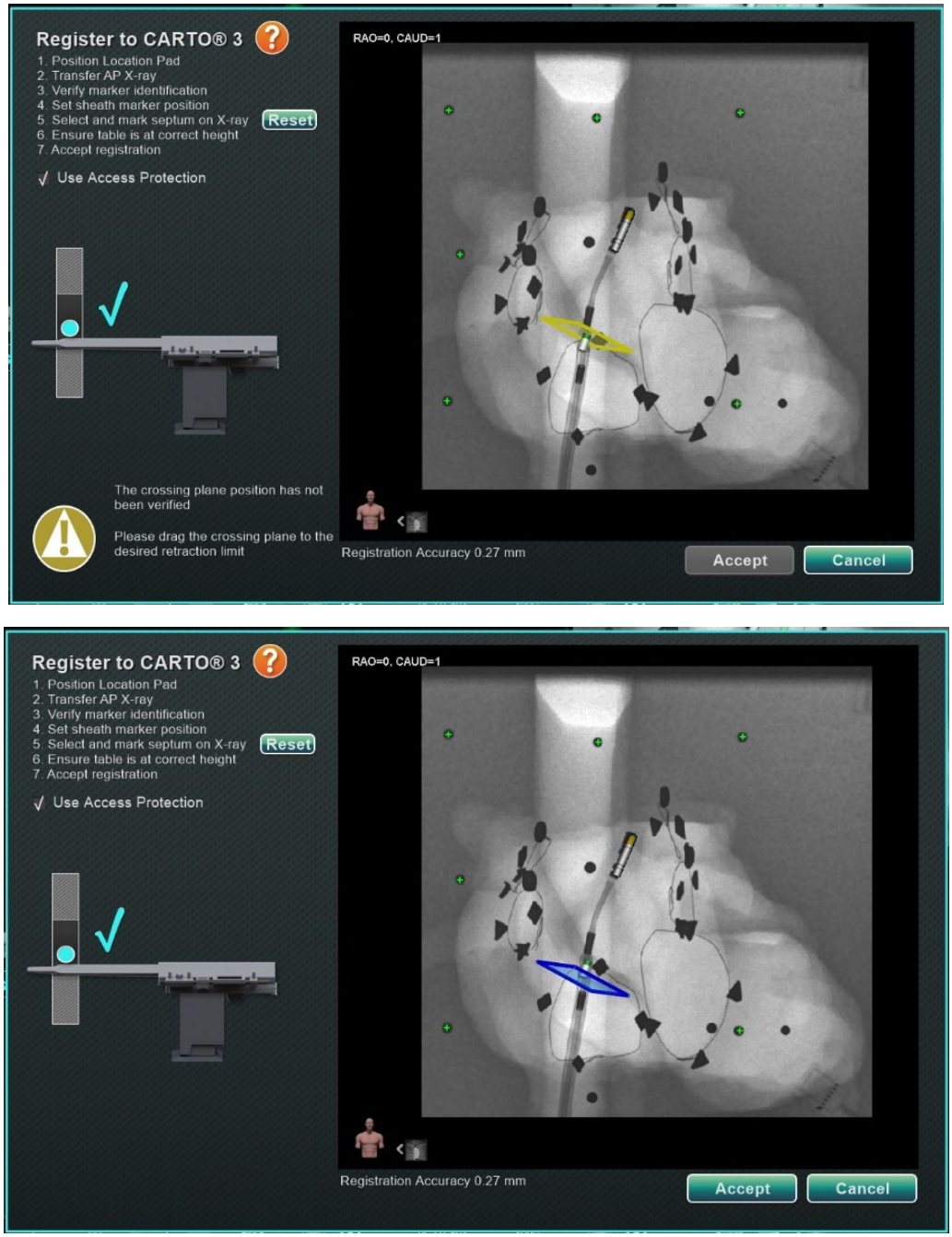


Figure 22. ***Retraction Limit in* CARTO *3 for the Catheter Registration (Top before setting crossing plane, bottom after setting crossing plane).***

Retrograde LV Registration to *CARTO* 3 (Figure 23)

Sheath Recommendations:

1) Use a recommended long sheath that will go around the aortic arch and reach into the ascending aorta and point the catheter tip toward the aortic valve.
   a) This provides for enhanced catheter stability while navigating in the LV.

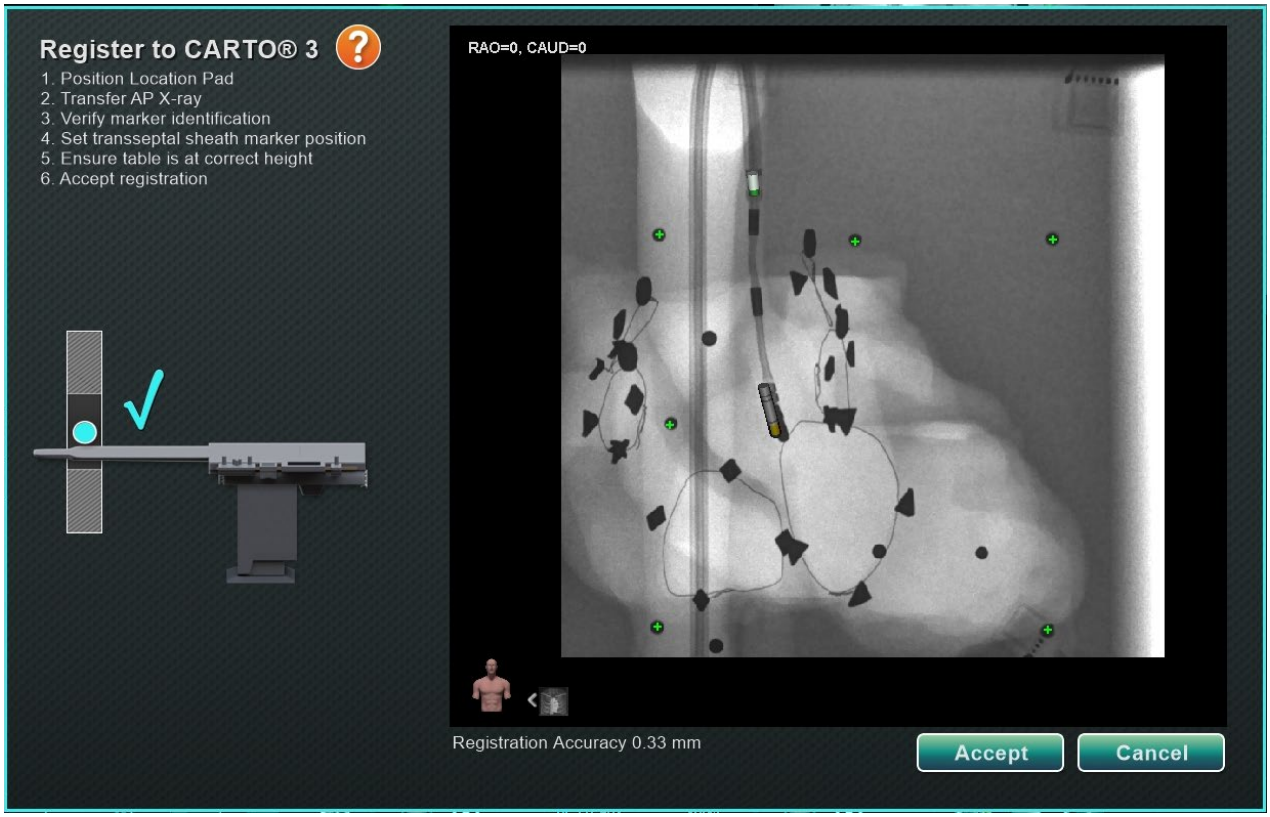


***Figure 23*. Fluoro image is center for base of the LV.**

Transeptal Registration to *CARTO* 3 (Figure 24)

Sheath Recommendations:

1) Use a long sheath with a primary curve long enough to terminate at the mitral valve.
   a) A steerable sheath may also be used.
2) This helps advance an RMT catheter into the LV and supports keep it in the LV during treatment.

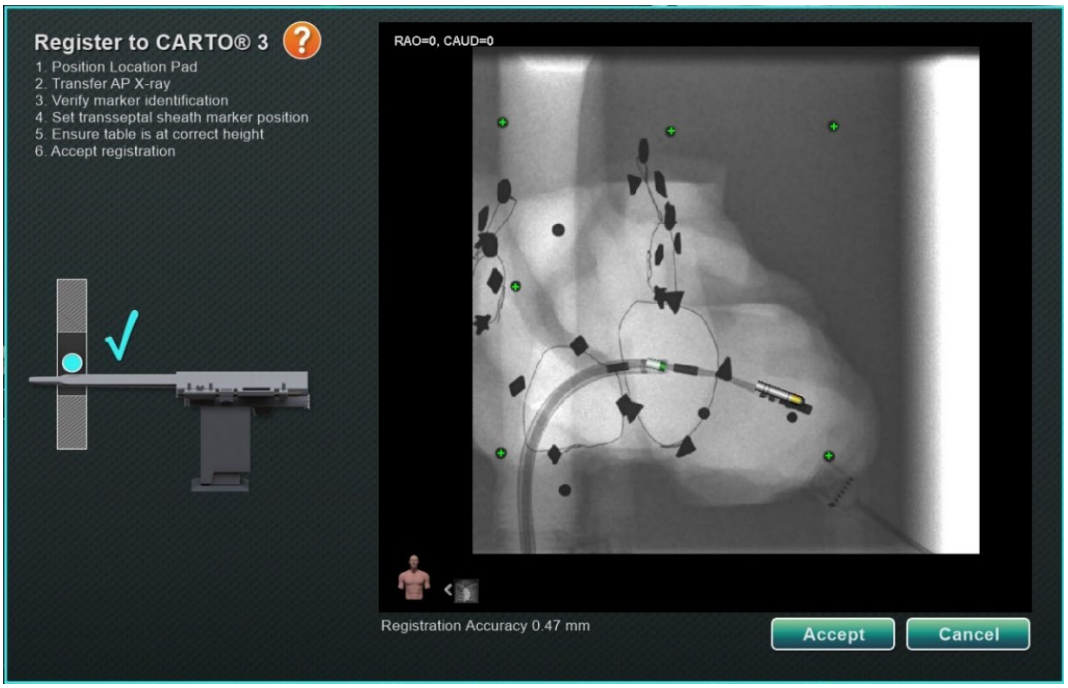


***Figure 24**. **CARTO** 3 Transeptal Registration.*

Good Registration vs. Bad Registration

Good (**Figure 25**):

1) Catheter appears straight in chamber.
2) Virtual catheter overlays catheter on fluoro.

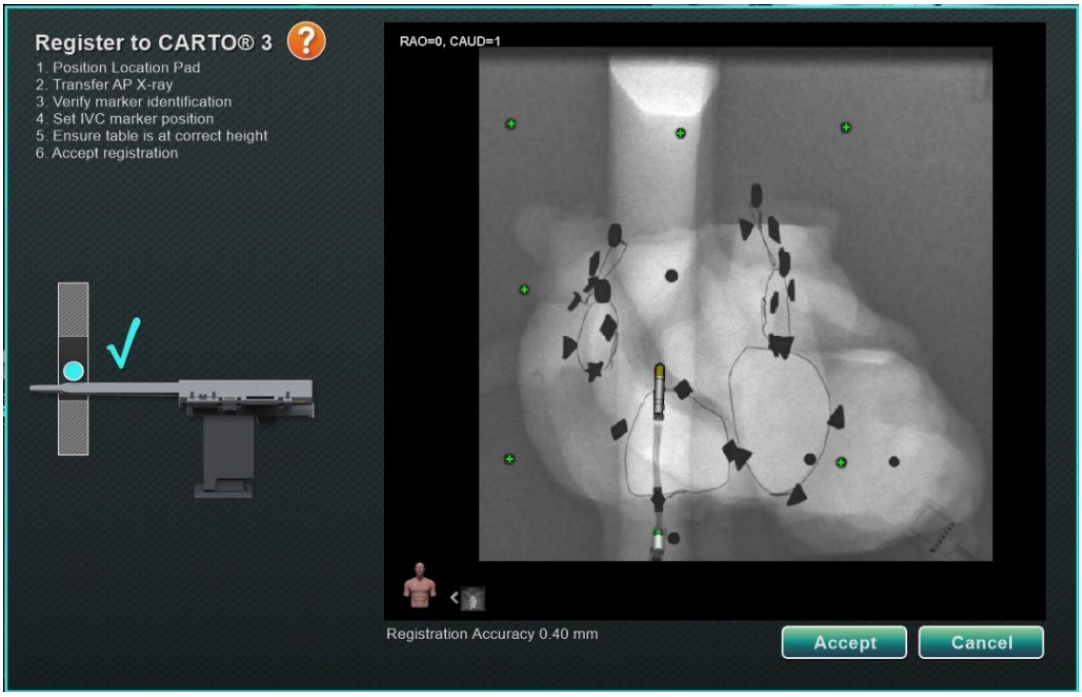


Figure 25*. Good* CARTO *3 Registration.*

Bad (**Figure 26**):

1) Catheter appears bent in chamber.
2) Virtual catheter does not overlay catheter on fluoro.

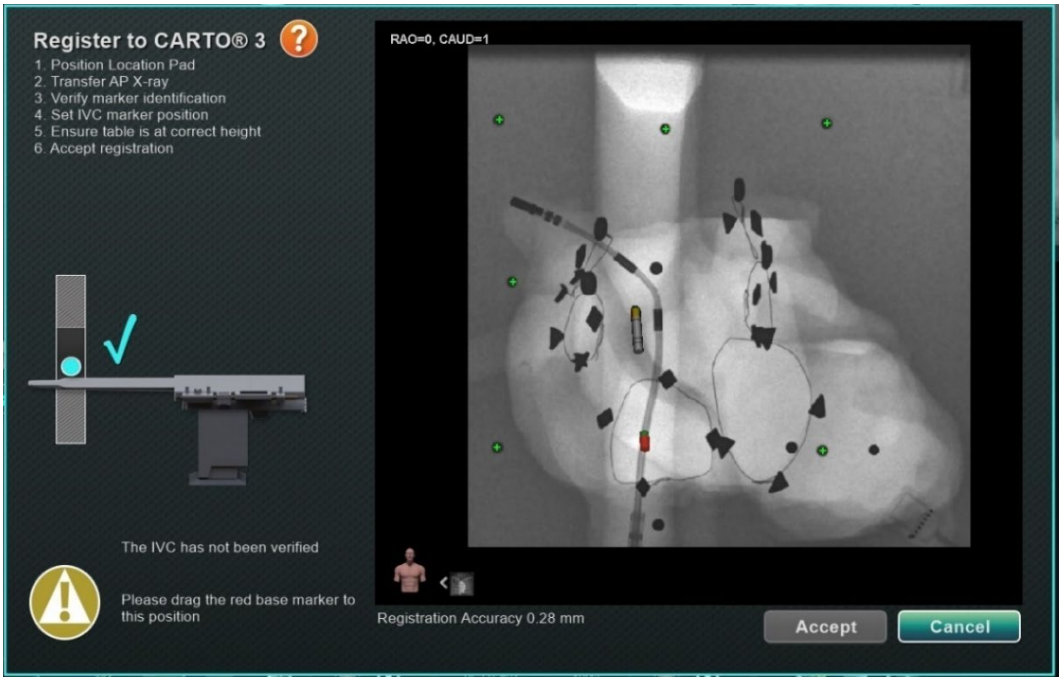


Figure 26. *Bad* CARTO *3 Registration.*

Registration FAQ

Why do we register to *CARTO* 3?

1) Registration allows *Navigant* software and *CARTO* 3 to share key information, maximizing the *Navigant* software's utility. After registration all integration features are available.

Can I use *CARTO* 3 and *Navigant* software without registering?

2) Yes. However, some *Navigant* software features will not be available.
   a) Automation features (ex: Automap, *NaviLine, Click and go/Target Navigation*)
   b) Nav Fluoro overlay features (ex: catheter tip overlay, 3D Map overlay)
   c) Retraction Limit

Troubleshooting

Errors After Successful X-ray Transfer

Sometimes a 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 27**). 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.

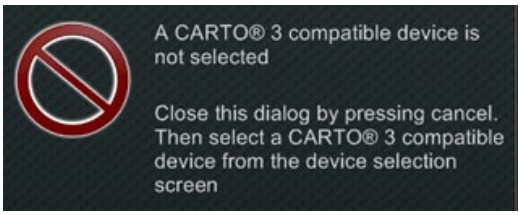


***Figure 27. CARTO* 3 compatible device is not selected.**

- **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 28**). Adjust the C-Arm so it is within 15° of the AP position.

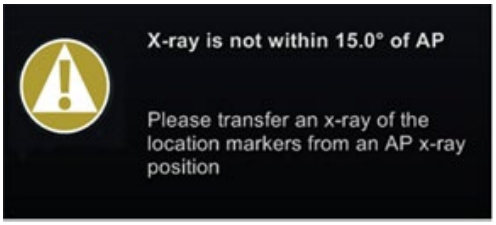


***Figure 28*. X-ray is not within 15.0° of AP.**

- ***CARTO* 3 System not licensed or connected**
  - If the *CARTO* 3 System is not licensed or connected, the user can open the *CARTO* 3 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."
- ***Navigant* unable to 'AutoMark' the six *CARTO* 3 location pad markers**

An obstruction in x-ray image causes *Navigant* to misidentify a location pad marker or the location pad is not properly mounted to the patient table, so *Navigant* cannot automatically

locate the six location pad marker positions. If so, a gold caution symbol displays with the message "Registration error exceeds 1.00 mm."

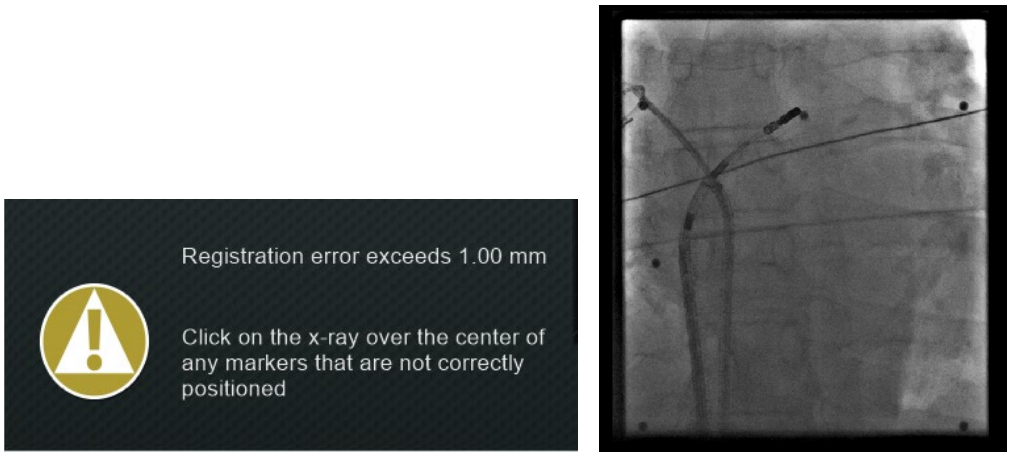


***Figure 29*. Location pad markers fail to 'AutoMark.'**

A location pad marker is misidentified when there's an obstruction in the x-ray image; an obstruction can be the distal end of a catheter or an ECG lead near one of the six location markers.

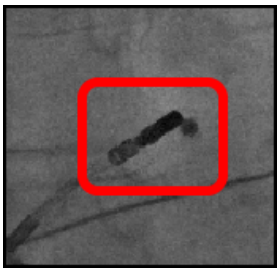


***Figure 30*. Example of obstruction in x-ray image.**

The location pad not being properly mounted can cause a problem by the pad becoming tilted from the surface of the patient table or rotated/skewed from the edges of the patient table.

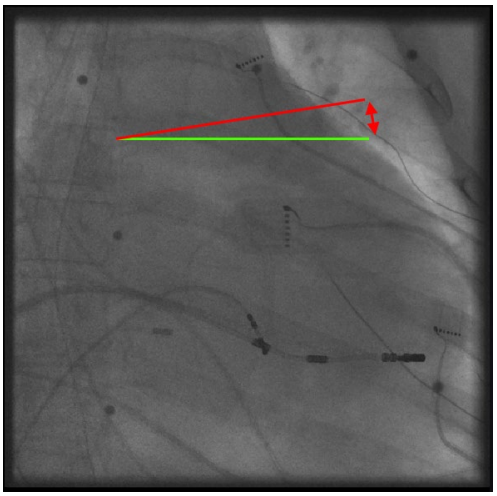


***Figure 31*. Improperly mounted location pad moved.**

When *Navigant* cannot 'AutoMark' the location pad markers, one of the following corrective actions can be taken:

- Click on the x-ray over the center of any markers that are not correctly positioned.
- Move any potential obstructions, acquire a new x-ray image, and transfer it to *Navigant*.
- Check the mounting of the *CARTO* 3 location pad to the bottom of the patient table. Ensure it is parallel/level with the surface of the patient table and square with the edges of the patient table. Once completed, acquire a new x-ray image, and transfer it to *Navigant*.

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.

When Non-RMT Mapping is Employed

To ensure that the patient and patches will not be shifted after non-RMT mapping with system (**Figure 29**), move magnets into Navigate position prior to registering.

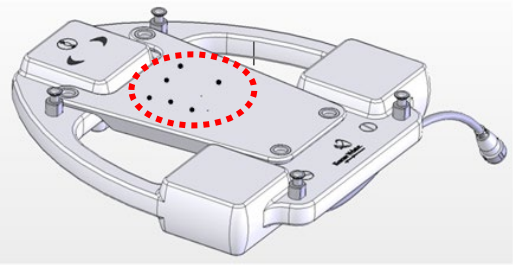


Figure 32. CARTO *3 RMT System is also used for non-RMT mapping.*

Can No Longer See Six Dots

It's possible (after patient wrapping and introducing catheters) that the patient shifted**,** and the six dots can no longer be seen (**Figure 30**).

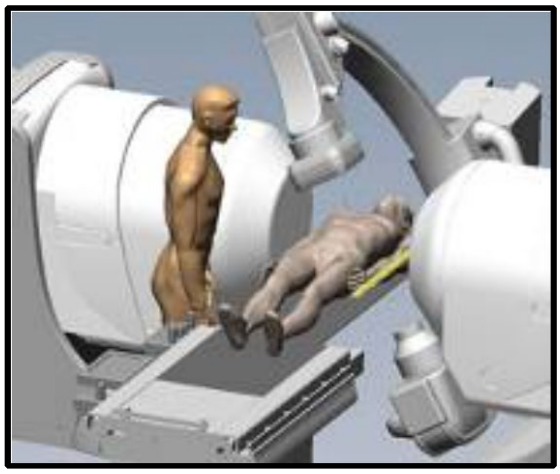


***Figure 33*. Patient Shifted, No Six Dots.**

1) You may be able to find the six dots without panning the table by moving the C-arm LAO or RAO up to 10 degrees. If this does not work, move onto Step 2.
2) In the AP view, pan the table to relocate the six dots.
3) Use this new six dot image for registration, ensuring anatomy is still in the center of the AP image.

⚠ **CAUTION:** Do not move the patient, patches, or location pad.