STEREOTAXIS

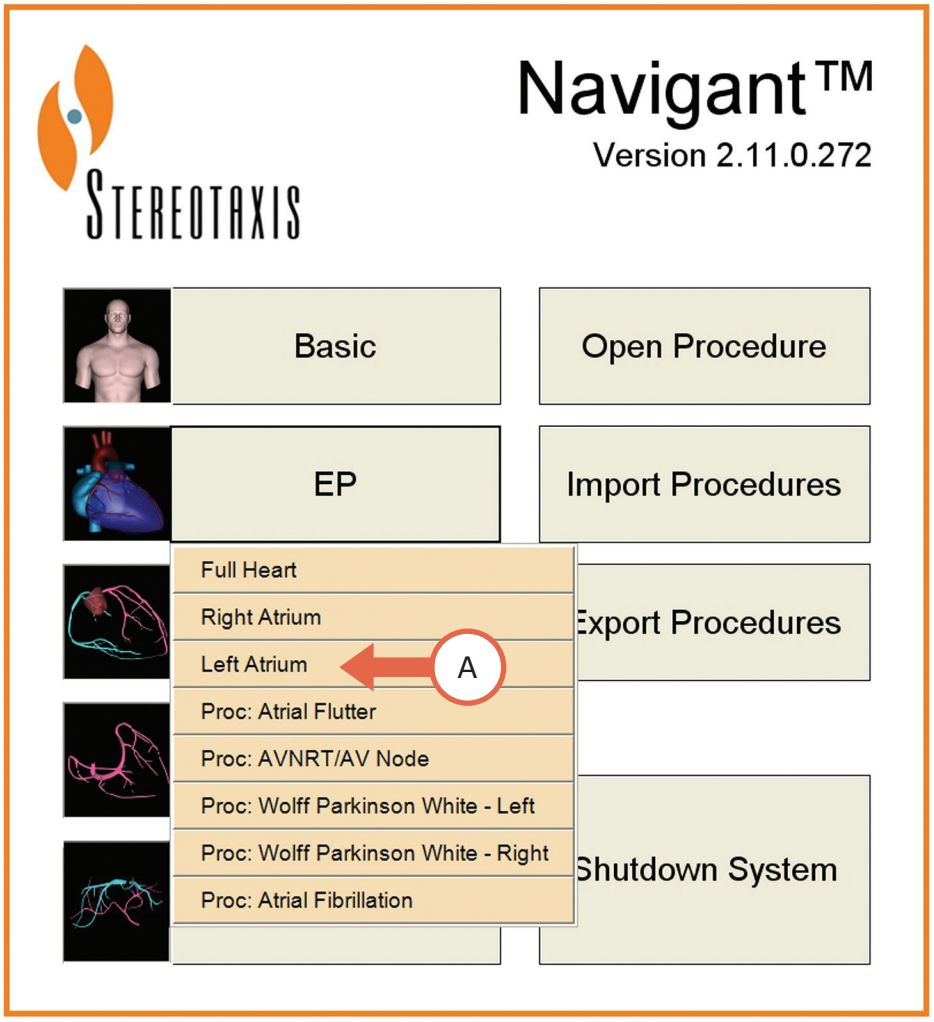
ELECTROPHYSIOLOGY NAVIGANT™ V2.11

LEFT ATRIAL MAPPING FOR SUPRA-VENTRICULAR TACHYCARDIA

Getting Started

The **Opening Screen** displays the application procedure selection menu. Choose an application (**EP** for electrophysiology).

Choose from the drop down menu to select the type of procedure (A).



Opening Dialogue Box

Choose a Clinical Workflow

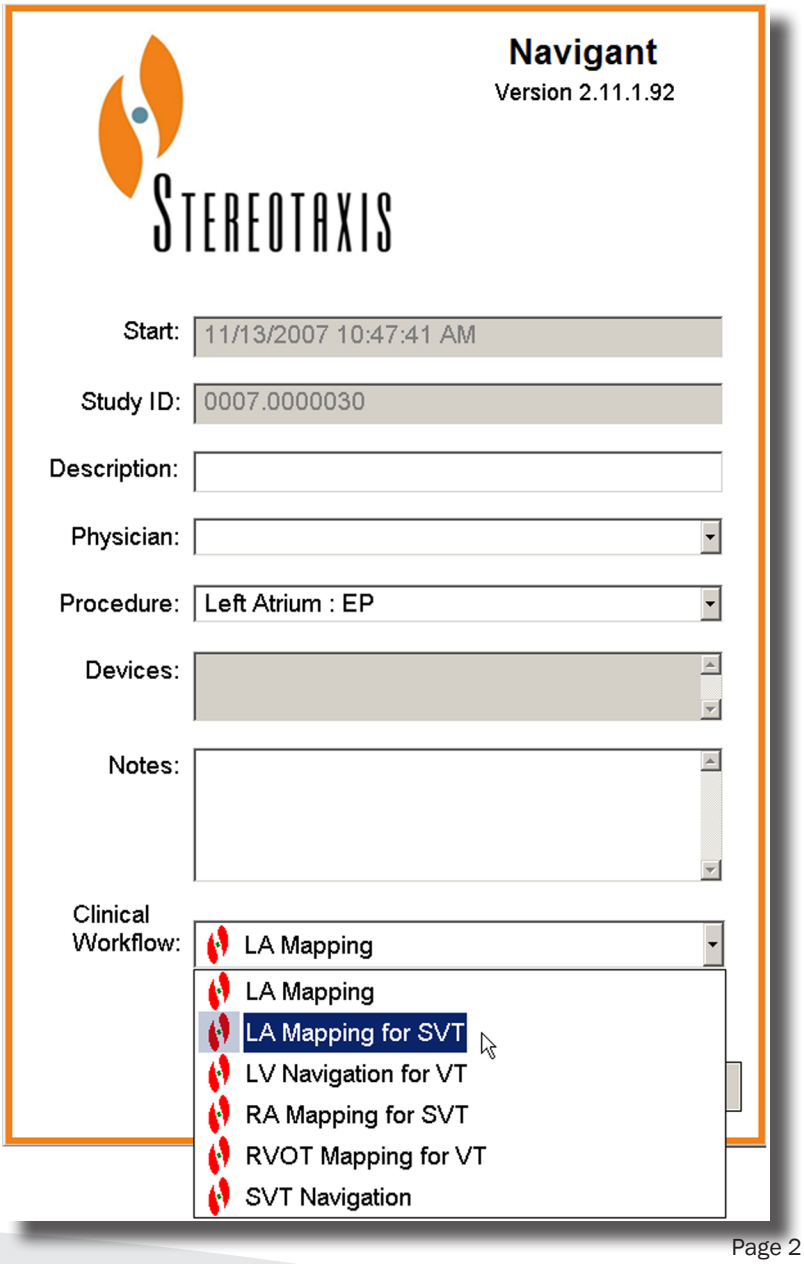
Once the procedure has been selected, the Procedure Information Window will appear. A start date, time, and a study ID are automatically assigned. Fill in the description and physician by typing or selecting from a drop-down list if available.

Click OK once the Clinical Workflow has been selected. The Navigant main screen will appear.

The devices window will be grayed out.

TIP

You must fill in the physician and description in order to save a physician layout.



Information Window

Clinical Workflow Manager

Clinical workflows are designed to facilitate case progression in the following ways:

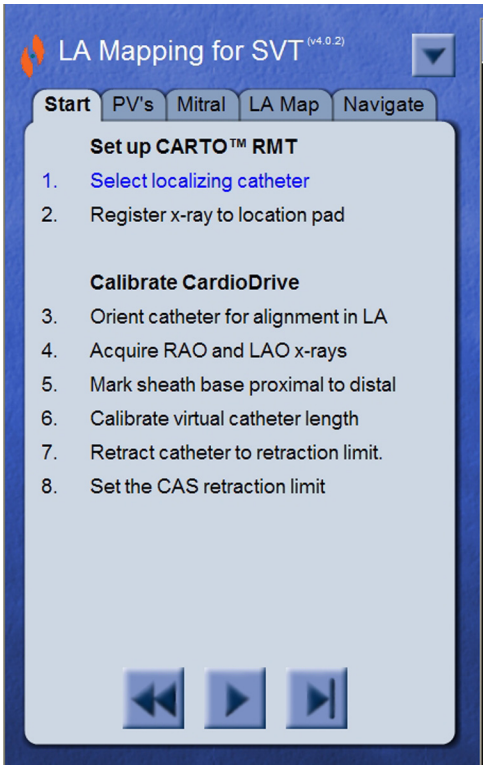
- By providing a simple step-by-step approach to automation and integration
- Keeping navigation and control options easily accessible throughout the case

The Clinical Workflow Manager menu will be on the left side of the monitor. Click Execute ▶ to advance to the next numbered step.

Once all steps have been completed, use the Execute ▶ button at the bottom of the tab window to advance to the next tab window.

Each tab on the CWM lists steps pertaining to a part of the procedure. By progressing through the appropriate steps, you can complete a portion of the study.

CWM Tab Controller buttons:
Start Over (left)
Execute Step (middle)
Next Section (right)



LA Mapping for SVT CWM with the Start Tab open

LA Mapping for SVT

Start Tab

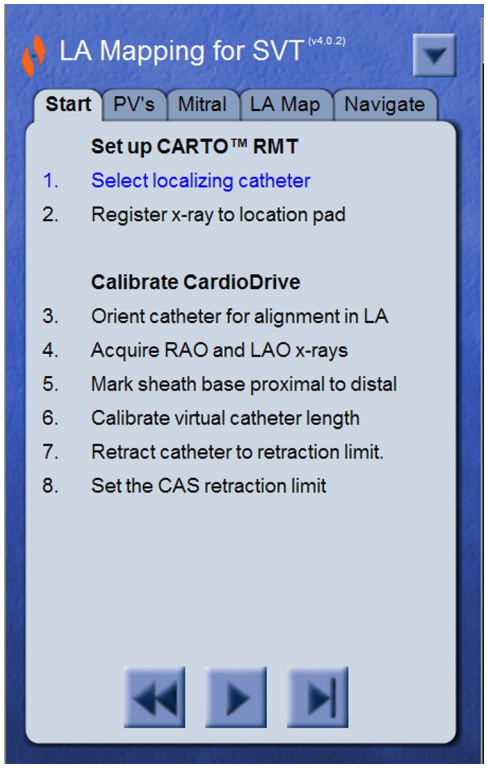
The Start tab is divided into two sections:

Set up Carto™ RMT

After completion of these steps Navigant and Carto RMT will be integrated.

Calibrate CardioDrive®

Automation is enabled after completion of these steps.

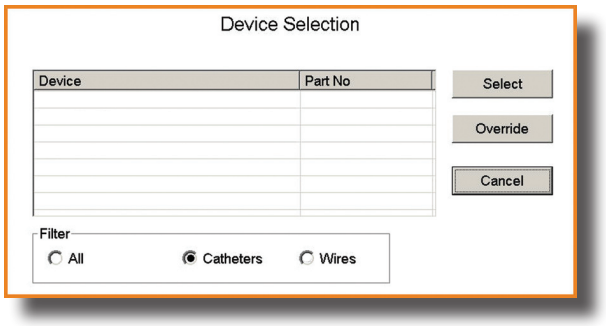


LA Mapping for SVT CWM with the Start Tab open

1. Select localizing catheter

The device selection window opens automatically. Click the Override button to view the menu of available catheters. Either double-click the option of choice or select one, then click **Add Device** to choose a device.

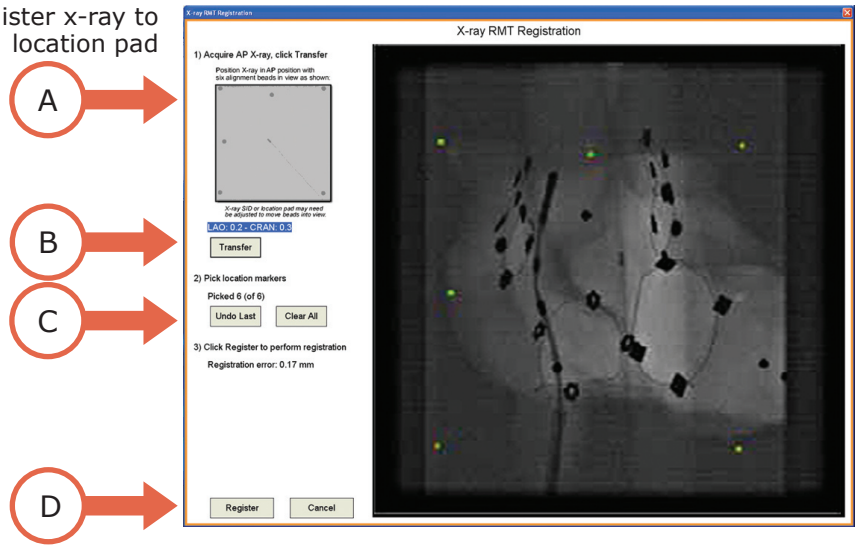
Device Selection Dialogue Box



2. Register x-ray to Carto location pad

- The registration screen will automatically appear.
- Ensure all six radiopaque markers are visualized on fluoro as seen on the reference template (A).
- Transfer an AP image by clicking the **transfer** button on the registration screen (B). Select all six markers with mouse clicks. At this time, a registration error will be displayed on step 3 of the registration screen (C).
- The registration error must be below 1.0 mm. If greater than 1, select clear all and remark
- Select **register** (D).

Step 2: Register x-ray to location pad



Section 2: Cardiodrive

Calibrate Cardiodrive

3. Orient catheter for alignment

Position the catheter, so the tip is located in the center of the chamber. Selecting this step will apply the initial magnetic field.

4. Acquire RAO and LAO x-rays

Acquire and transfer RAO and LAO images (they must be a minimum of 40° apart).

5. Mark sheath base proximal to distal

This step identifies the anatomical location of the catheter's entry point.

a. Position the mouse over one of the transferred fluoro images where the catheter enters the chamber
b. Left click and drag the mouse over the catheter shaft from proximal to distal (a short segment)
c. A red line will appear indicating the path
d. Repeat steps a and b on the second fluoro image using the yellow dotted line as a position reference. A pop-up will appear asking that you accept or reject the identified sheath base.
e. Once accepted, the sheath base will appear

6. Calibrate CAS length

The calibrate window will pop-up and the yellow virtual catheter will appear.
Click advance or retract to set the length of the virtual catheter equal to the length of the actual catheter.

TIP

Do not move the Cardiodrive during the calibration of the CAS length.

7. Retract catheter to the retraction limit

Using Cardiodrive micro-navigation tools retract the catheter until the middle magnet of the catheter tip is in the transeptal region.

8. Set the CAS retraction limit

By clicking this step, Navigant stores the retraction limit, and will prevent the catheter from moving past this point during automated movements.
Click **Execute ▶** to advance to the next tab.

PV Tab

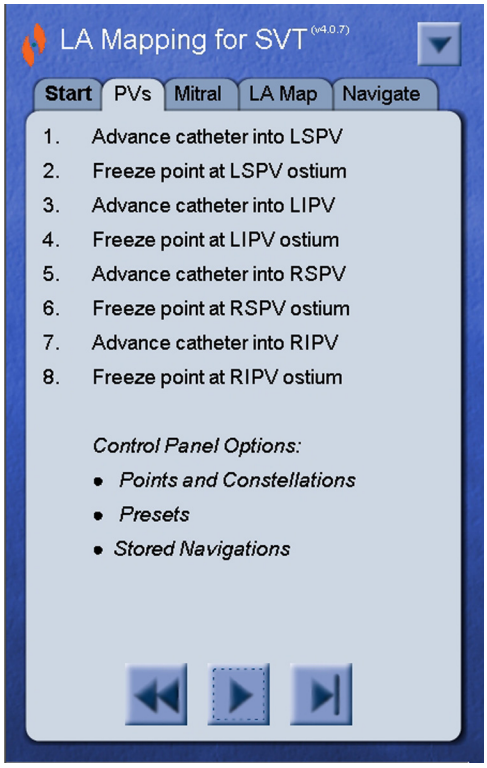
The PV Tab assists the user in localizing and marking the pulmonary veins.

Advance catheter into LSPV
When step one is activated the field direction will direct the catheter to the Left Superior Pulmonary Vein. Using the Cardiodrive, advance the catheter into the vein.

When the catheter is sufficiently advanced into the vein the user enables the vessel tag tool on Carto. The user withdraws the catheter using micro-navigation movements until the tip of the catheter is at the os of the pulmonary vein creating a tube.

By activating the next step a point is acquired at the os of the vein.

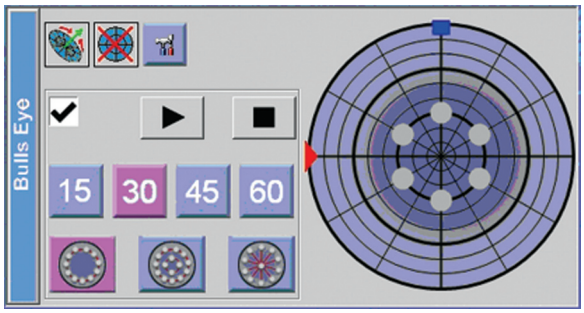
Continue this procedure for each vein–LIPV, RSPV, and RIPV–until all four have been mapped.



CWM with LA Mapping for SVT PVs Tab

Options

If the physician prefers to map the pulmonary veins this can be accomplished utilizing the Bulls Eye tool instead of the vessel tag on Carto.



Bulls Eye Panel

The Bulls Eye tool can be enabled from the Navigate Tab.

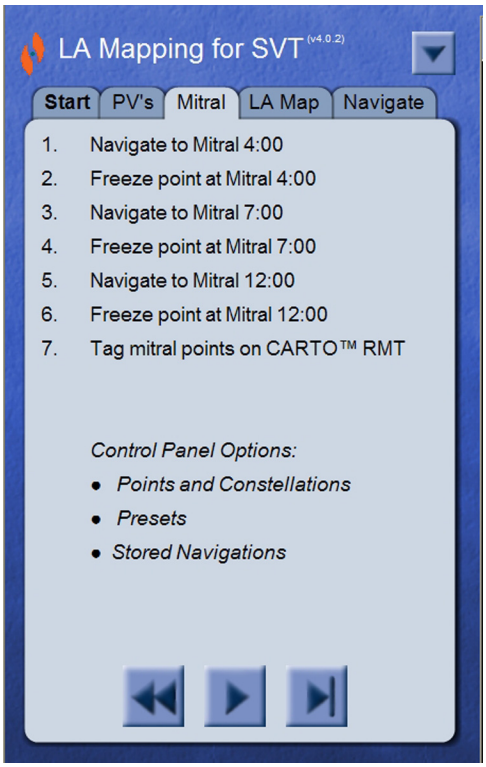
Click Execute ▶ to advance to the Mitral tab.

The Mitral Tab

The Mitral Valve Tab provides 3 preset field directions to orient the catheter tip. The first step, Navigate to Mitral 4:00, applies a preset field direction. Advance the catheter onto the Mitral annulus while observing electrogram signals.
The second step will freeze that point on Carto RMT.

Continue this process until all three points have been obtained.

REMINDER: Step 7 is performed on Carto RMT.



CWM with LA Mapping for SVT Mitral Tab

The LA Map Tab

The LA map is an automatic progression throughout the regions of the left atrium. It will collect 80 to 100 points in approximately 8 minutes.

Prior to pressing the Auto key on the Navigant keyboard set the RMT Acq to none or auto accept on the Carto RMT Monitor.

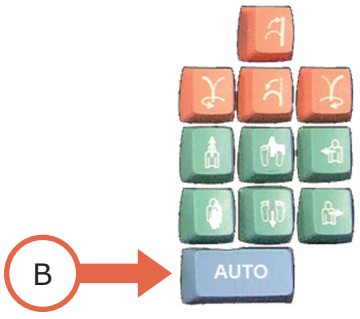
Select the first step on the tab (A), then hold down the **Auto** key (B) on the keyboard and the Navigant system will initiate the auto mapping sequence, changing the field direction and advancing or retracting the catheter as needed.

With the Carto RMT in "auto accept" mode the Navigant MNS will manipulate the catheter and acquire points into the map without any additional action required by the user.

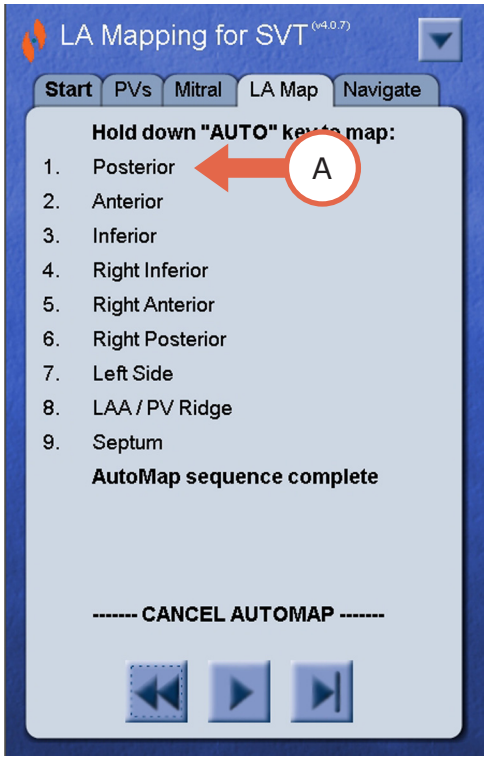
If the Carto RMT is in the "none" mode the Navigant MNS will manipulate the catheter but the user must manually "Freeze" and "Accept" the points on the Carto RMT system. The Auto map sequence will place the catheter at a location and wait for the user to "freeze" a point prior to advancing to the next location.

The **Auto** key (B) must be depressed by the user for the duration of the automap sequence. If it is released the sequence will pause until the **Auto** key is again depressed. The sequence resumes where it was interrupted.

Once the sequence is completed the **Auto** key can be released and the execute button pressed to advance to the next tab.



Auto Key on Navigant Keyboard



CWM with LA Map for SVT Tab

AutoMap Interaction

Interaction with AutoMap is possible. Observe the generated map as points are collected during the automapping process. In some circumstances it may be necessary to interact with the AutoMap.

Circumstances for Interaction:

- To avoid internal points
- To avoid excess pile-up of points in one region
- To manipulate the CAS if an obstruction is encountered
- To ensure even distribution of points
- To accommodate enlarged chambers by adjusting the length of the catheter

Interaction during the AutoMap process will not interrupt the mapping sequence.

The automap feature can be cancelled by activating the Cancel AutoMap feature at any point in the sequence.

TIP

An even distribution will maximize the accuracy and efficiency of the integrated navigation tools.

The Navigate Tab

The navigate tab allows customizing of the images, palettes, and tools on the Navigant™ screen.

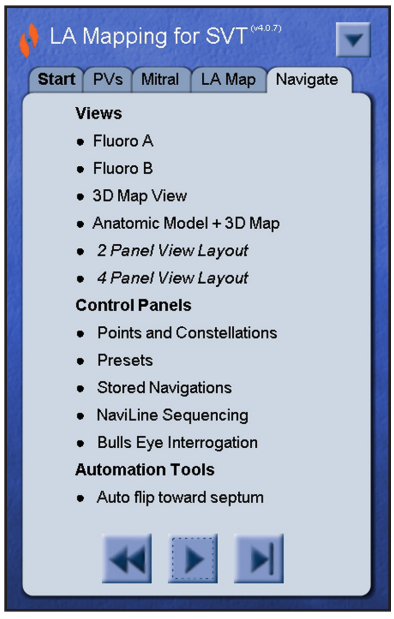
The Views section of the tab allows the display of:

- Fluoro (A and B)
- 3D Map View
- Anatomic Model and 3D Map
- Layout Views (2 or 4 panel)

The Control Panels section allows the display of the different tools to assist in the procedure. The panels are displayed above the image windows.

- Points and Constellations
- Presets
- Stored Navigations
- NaviLine Sequencing
- Bulls Eye Interrogation

The Automation Tools section has the **Auto flip toward septum** tool. This is a shortcut to enable the auto flip feature to direct the catheter towards the septum.



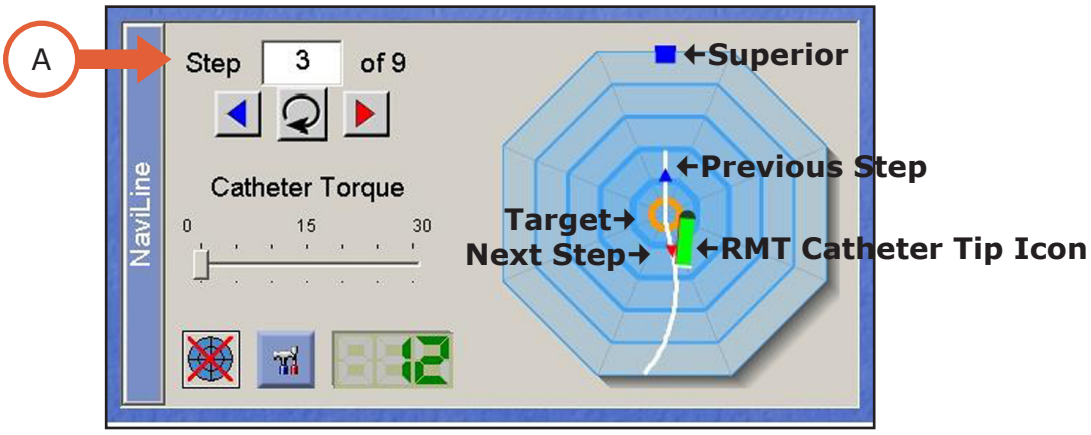
CWM showing the Navigate Tab

NaviLine Sequencing

About NaviLine

NaviLine Sequencing is the tool designed to follow a Design Line created in Carto RMT. When NaviLine Automated Navigation is selected, the Navigation mode will change to Target navigation (indicated by the icon in the upper left corner of Navigant).

Navigant calculates the length of a Design Line and translates that into evenly distributed steps in NaviLine. The number of steps are displayed in the NaviLine panel (A) as well as a 2D graphic representation of the steps.



NaviLine Panel

Interpreting the NaviLine Surface Graphic

The NaviLine will be displayed on this surface graphic. The surface is viewed from the top.

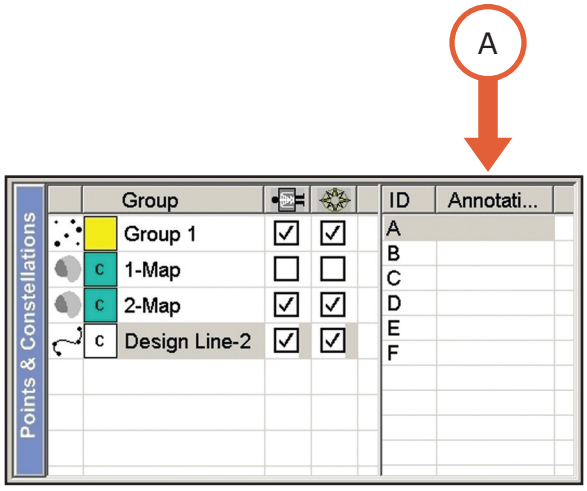
- The blue square at the top represents **superior**.
- The **gold ring** in the center identifies the CURRENT target.
- The **red triangle** identifies the NEXT target.
- The **blue triangle** indicates the PREVIOUS target.
- A **solid line** indicates something above the surface.
- A **dotted line** indicates something below the surface.

Setting Up NaviLine

Select the NaviLine panel from the Navigate Tab.

- Create Design Line on Carto RMT
- Send to Navigant from Carto RMT
- Design Line will appear in the Points and Constellation Panel
- NaviLine will appear in the Navigant windows on 3D Map

A series of points will appear under the ID column in the Annotation section (A) correlating to the points selected on Carto RMT.



Points & Constellations Panel

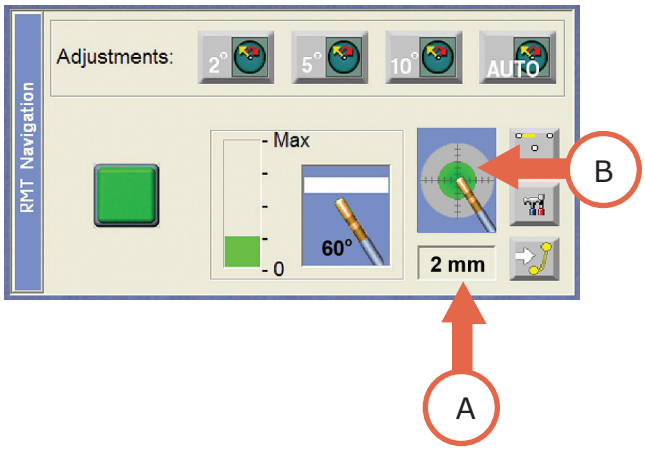
To activate the NaviLine **double-click** the desired starting location on the line **while holding down the AUTO key**.

This action will set the initial target as identified by the gold ring on the 3D map.

Using NaviLine

During this process, monitor the distance to target (A) on the RMT panel, as well as the target icon (B).

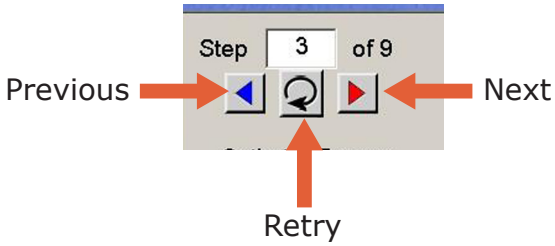
This information combined with the ongoing assessment of the contact meter level will assure the most accurate catheter tip placement.



During this ongoing assessment, if a closer proximity to the target is desired, the Retry button can be utilized.

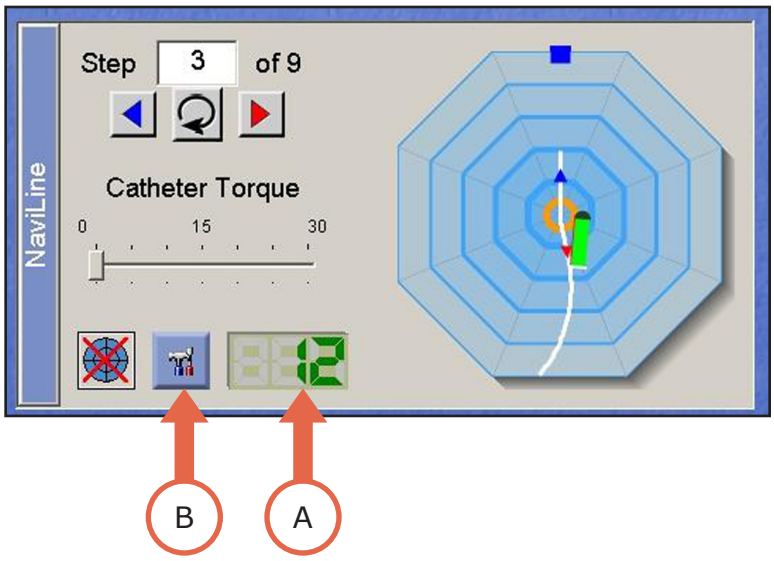
The NaviLine, based on this input as well as the catheter tip location, will adjust the field direction and/or the CAS by making small incremental movements towards the target. This can be repeated if desired.

The Next step button will advance the catheter to the next incremental target location. The Previous button will return the catheter to a previous target location.



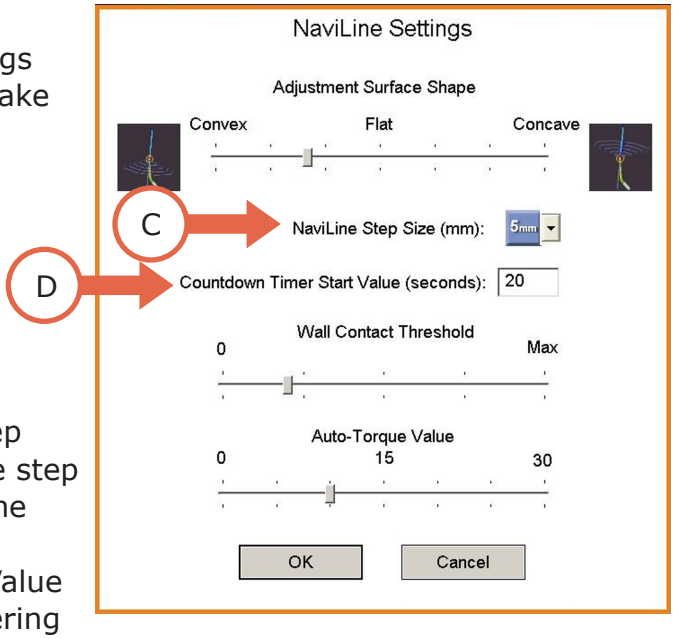
Naviline Settings

In the Naviline Panel there is a counter (A) that begins a second-by-second countdown when the auto sequence for the catheter has finished positioning.



NaviLine Panel.

Click the Naviline Settings toolbox button (B) to make adjustments.



The default NaviLine step size is 5 mm. Adjust the step size by selecting from the drop down menu (C).
The Countdown Timer Value can be adjusted by entering a new value in seconds (D).
The Wall Contact and Auto-Torque controls are utilized during the NaviLine sequencing process. They set the parameters for magnetic torque adjustments based on tip location information as well as contact meter input received from the RMT panel.
The default Auto-Torque Value is 10 (indicated by the second marker on the horizontal bar). Adjust the step size by dragging the slider along the bar.