EnSite™ X EP System Software

REF ENSITE-DWS-01, ENSITE-R-DWS-01

INSTRUCTIONS FOR USE

Abbott

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

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Contents

Description

The DWS consists of the workstation (computer), application software, video display monitors, and medical grade isolation transformer.

Figure 1. EnSite™ X EP System

System Components

The EnSite™ X EP System is comprised of two primary components: the EnSite™ X Amplifier with associated modules, and the Display Workstation (DWS) as described below.

NOTE:

- Cleaning is recommended after each use. All surfaces should be cleaned with a dry, lint free cloth, gently applied. Where necessary, alcohol can be applied on such a cloth to remove grease and stains. The monitor screens can be cleaned with an appropriate solution.
- Cleaning is recommended after each use. All surfaces should be cleaned with a lint free cloth, using one of the following cleaning solutions:
  - Isopropyl Alcohol
  - Cidex‡ Solution
  - Cidex OPA‡ Solution
  - Sani-Cloth† AF Germicidal Disposable Wipes

EnSite™ X Amplifier

- The EnSite™ X Amplifier accepts signals from SurfaceLink Module, 20 pin Catheter Input Modules, the EnSite™ X Field Frame, and four (4) Patient Reference Sensors. The devices accept signals from catheters and electrodes attached to the patient and pass these signals to the EnSite™ X Amplifier. The EnSite™ X Amplifier converts these signals to a digital format and sends them to the DWS for processing and display.
- EnSite™ X Field Frame Generator. The Field Frame generates the magnetic tracking field necessary for the VoXel catheter tracking and navigation mode of the EnSite™ X EP System.
- SurfaceLink™ Module. Connects the EnSite™ X surface electrodes, system reference surface electrode, and RL ECG electrode to the EnSite™ X Amplifier.
- Catheter Input Modules. 20 pin module allows for connection of standard diagnostic catheters to the EnSite™ X Amplifier.
- Four (4) Patient Reference Sensors, one anterior (PRS-A) and three posterior (PRS-P) sensors with cables.
- EnSite™ X ECG cable. Connects standard ECG electrodes to the EnSite™ X Amplifier.
- Medical Grade Isolation Transformer. When using the Amplifier Cart, the system components connected to line power through the isolation transformer. Only components on the Amplifier Cart should be connected to this isolation transformer.

EnSite™ X Display Workstation (DWS)

The DWS consists of the workstation (computer), monitors, medical grade isolation transformer, and optional printer.

- Workstation. The workstation contains the system software displaying data from the EnSite™ X Amplifier. Attached to the workstation are a keyboard and mouse for user input.
- Monitors. Monitors are used to display patient information. One monitor is placed near the workstation and keyboard for system operation.

- Medical Grade Isolation Transformer. All system components on the DWS cart are connected to line power through the isolation transformer. Only components of the DWS should be connected to this isolation transformer.

Required Components Not Included

The following components are required for EP studies but are not included with the EnSite™ X EP System:

- Standard and Sensor Enabled™ EP Catheters - These catheters are introduced into the cardiac chamber of interest and used in electrophysiology procedures.
- EnSite™ Surface Electrodes - Six surface electrodes are used for the EnSite™ X EP System.
- Patient Reference Sensor (PRS) Patches - Four patches used to place the four Patient Reference Sensors (PRS) used with the EnSite™ X EP System.
- ECG Electrodes - These industry-standard surface electrodes are placed in a standard 12-lead configuration.
- System Reference Electrode - The EnSite™ NavX System Reference.
- Right Leg ECG Electrode - Placed as right leg ECG electrode during EnSite™ X EP System procedure.

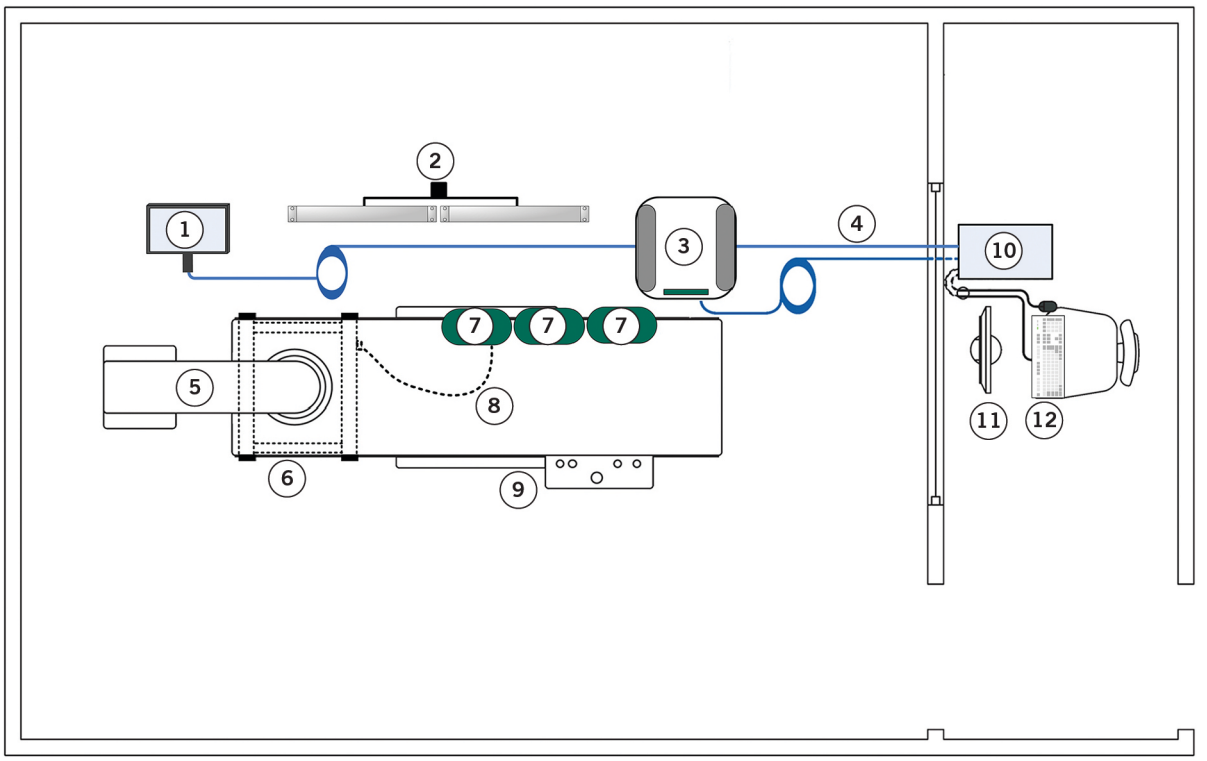
Optional Components Not Included

The following components are optional for EP studies and are not included with the EnSite™ X EP System:

- Ampere™ RF Generator - Radio Frequency Ablation Generator.
- CoolPoint™ Irrigation Pump - Provides irrigation to an Ablation catheter tip when used with Ampere™ RF generator.
- Workmate™ Claris™ Recording System Amplifier - ECG amplifier for the WorkMate™ Claris™ electrophysiology signal recording system.
- TactiSys™ Quartz Force Sensing Module - Calculates and displays force data for Force Sensing Catheters.
- Printer - An optional printer is available for printing images from the system.
- Video Extender - This device splits the video signal so that the same information appears on the local and remote EnSite™ X EP System monitors.
- Remote Monitor - A remote monitor can be placed near the patient table for use by the physician. The monitors display identical information from the same source.
- Display Workstation Cart - Optional cart to mount DWS, Monitor, isolation transformer, and printer.
- Amplifier Cart - Optional cart to mount, EnSite™ X Amplifier, Workmate™ Claris™ Recording System, Ampere™ RF Generator, TactiSys™ Quartz Force Sensing Module, and CoolPoint™ Irrigation Pump. The cart incorporates integrated locations for cable and EnSite™ X Field Frame storage and option for remote monitor.
- Remote Monitor Stand - Optional stand that supports from 1 to 3 video displays.

EnSite™ X EP System Layout

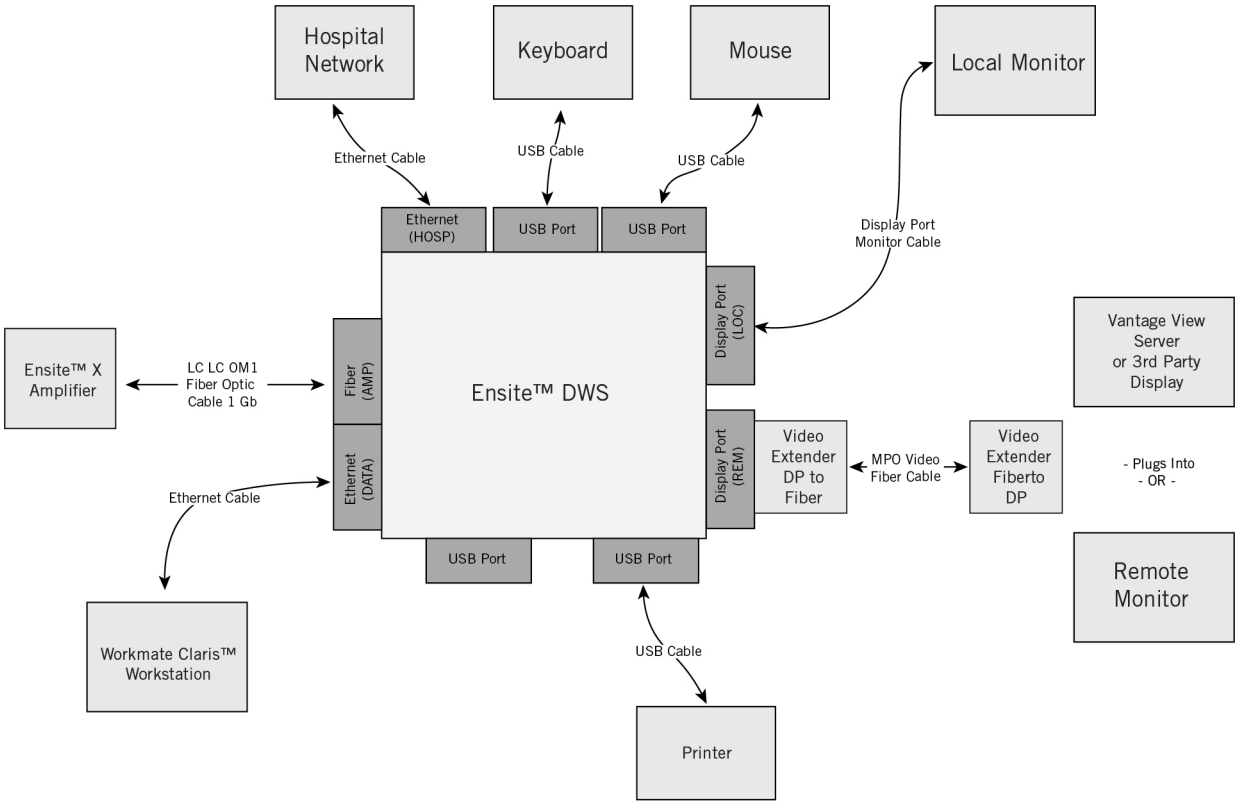
Figure 2. Typical Lab Setup



1. Remote Monitor Stand.
2. Monitor Boom (Patient Monitors).
3. EnSite™ X Amplifier.
4. Fiber Optic Cables.
5. C Arm.
6. EnSite™ X EP System Field Frame and bracket.
7. EnSite™ X SurfaceLink, Catheter Input Module (CIM) 20 pin.
8. EnSite™ Field Frame cable to the EnSite™ X Amplifier routed under the patient table.
9. Patient Table.
10. Display Workstation (DWS).
11. Monitor.
12. Keyboard and Mouse.

System Diagram

Figure 3. DWS Component Layout



Indications for Use

The EnSite™ X EP System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated.

The EnSite™ X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological (EP) procedures.

Clinical Benefit

The intended clinical benefit is to provide diagnostic information to the physician to aid in the treatment of arrhythmias.

Contraindications

There are no known contraindications.

Warnings

- AutoMarks are placed based on EnGuide location. Sudden impedance changes of the body or catheter electrodes caused by the connection of other devices (e.g., stimulator, defibrillator, and other devices), poor patch adhesion or patient movement may create a location shift. Use conventional EP techniques, such as fluoroscopy or inspection of intracardiac electrogram signals, to confirm catheter location.
- Use ONLY the EnSite™ X field frame cable (with ferrites) ENSITE-FF-3MC-01 or ENSITE-FF-4.5C-01. Other cables do not provide adequate protection against electromagnetic events
- Sudden impedance changes of the body or catheter electrodes caused by the connection of other devices (e.g., stimulator, defibrillator, and other devices) may create a location shift.
- Do not modify or make any additional connections to the EnSite™ X EP System, other than those described in this manual. Do not connect the system to multiple portable socket outlets or extension cords.
- The EnSite™ X EP System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, this product should be observed to verify normal operation in the configuration in which it will be used.
- If the workstation is powered off by the user, rather than shutdown by the operating system, data on the hard drive may become corrupted and the EnSite™ X EP System may cease to be operational.
- The EnSite™ X EP System model display should be used in conjunction with conventional EP techniques to confirm catheter location.
- Do not rely solely on the stability indicator information during ablation.
- Baseline drift of the force output may occur during the procedure. Operator should verify baseline integrity periodically during use. To check for baseline drift, position the catheter tip in a free-floating position away from the heart wall. In case of significant baseline drift (e.g. >5 g), a reset to zero should be applied by clicking the Reset Force button on the EnSite™ Contact Force Module screen (when not ablating).
- Make sure that the catheter is in a free-floating (non-contact) position before manually resetting the baseline. Contact can be identified by periodic changes (“bumps”) on the force graph or generally an uneven force graph.
- When the catheter is in a free-floating position, the force value will not be around zero if baseline drift has occurred. Resetting to zero while the catheter is in contact may cause differences between the value shown on the screen and the actual force applied to the tissue.

- When ablating on the posterior wall, all information available in the electrophysiology laboratory should be taken into consideration by the operator to determine the amount of RF energy delivered in order to avoid esophageal damage. The operator should not rely solely on LSI or FTI parameters during ablation on the posterior wall.
- The default display for AutoMarks is 4mm gray spheres. Adjustment to display thresholds is recommended to distinguish individual AutoMarks.
- The AutoMark feature does not indicate lesion effectiveness. AutoMarks are placed based on user-defined parameters for catheter stability and RF metrics only.
- Do not touch accessible connectors and the patient simultaneously.
- The ablation metrics display is not to be used as the primary/sole display of ablation information during an Electrophysiology study. Reference the ablation generator for ablation information.
- In the event of a suspected cybersecurity issue, discontinue use of the EnSite™ X System and contact Abbott Technical Support.
- To protect the privacy and security of sensitive information, including protected health information (PHI), the system should be located in a secured environment.
- Manage security settings, individual user logins, and passwords per the Administrators Guide for the EnSite™ X EP System.
- The site controlling the device should have policies in place prescribing the physical safety and security of the devices in the electrophysiology laboratory. For example, physically securing devices and information should include policies that limit physical access, securing equipment in locked rooms, managing access to secured rooms, and restricting the ability to remove devices from a secure area.
- The ECG display is not to be used as the primary/sole patient monitor during an Electrophysiology study. The EnSite™ X EP System contains no alarms for indicating inoperative conditions.
- Non-SE catheters cannot collect location data and should not be used for navigation in VoXel Mode because they do not have a magnetic sensor. However, they can be visualized and display intracardiac signals.
- Changing the distortion threshold over Level II allows 3D point collection with more metal distortion error in VoXel Mode.
- For patient safety, any connections that directly connect the patient to the EnSite™ X EP System must be routed through the appropriate modules: SurfaceLink Module, 20 pin Catheter Input Module, and Direct Connect Ports on the EnSite™ X Amplifier.
- When using the EnSite™ X full protection against the effects of cardiac defibrillator discharge and other leakage currents is dependent upon the use of appropriate cables.
- Only connect items that have been specified as part of the EnSite™ X EP System or compatible with the EnSite™ X EP System to the multiple socket-outlets.
- The use of this device in conjunction with radio frequency ablation, as a part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.

Precautions

- Make all connections between systems before validating the EnSite™ X EP System. Adding or removing connections after validation may affect navigation quality. Additionally, all patient connections to ancillary equipment (e.g. external defibrillators) should be made prior to validation. Connections between systems refers only to Abbott-supplied or approved devices.
- When the EnSite™ X Amplifier is turned off, it can affect ECG signals viewed on the recording system. When the EnSite™ X Amplifier is turned off and a recording system is in use, it is recommended that the cables to the EnSite™ X EP System be disconnected from the EnSite™ X Amplifier.
- EnSite™ X Nav X™ Navigation and Visualization Technology studies intending to use Field Scaling must not have electrodes in a sheath during point collection.
- For studies where Field Scaling is used, be sure that appropriate interelectrode spacing and size are specified for any catheter that is used for collecting points. Model points collected with catheters that are inappropriately described may yield unexpected Field Scaling results. This cannot be corrected by re-entering correct information after the fact. However, Field Scaling is an option which can be unapplied if unexpected results occur.
- When baselining the sheath filter, the catheter must be in the blood pool.
- Do not use Stabilize ABL in situations where electrodes 2, 3, or 4 on the ablation catheter are covered by a sheath.
- Do not immerse system components in liquid.
- Do not place the EnSite™ X EP Field Frame cable inside the measurement volume or wrap it around the Field Frame, as it may create a magnetic interference.
- Do not coil the EnSite™ X EP Field Frame cable. The cable carries enough electric current that a magnetic field will be created when the cable is placed in a circular formation. This magnetic field may disturb the Field Frame's magnetic field.
- Metallic equipment used in close proximity to the magnetic field during the procedure, such as a sterile drape holder, may cause metal distortion.
- Do not use the EnSite™ X EP System in the presence of other magnetic fields.
- Do not expose or immerse the EnSite™ X system to liquids or allow fluid to enter the equipment in any way. Exposing the EnSite™ X system to liquids may result in equipment damage, produce a fire or shock hazard, and result in possible personal injury.
- Snugly hand-tighten the screws with the hex wrench. Do not over-tighten, as the screw may break off inside the Frame.
- Discard Changes will delete all surfaces if the model has not been finished at least once.
- Patients with any implantable device might undergo the procedure provided that the implantable device complies with ANSI/AAMI PC69 and the implantable device manufacturer's recommendations regarding the type of invasive procedure and exposure to electromagnetic interference (EMI) are strictly followed. In addition, it is recommended to turn off the magnetic field generated by the EnSite™ X Field Frame during telemetry or communication between an external programmer and the implanted device.
- In any case of abnormal behavior of the implanted device, turn the system's magnetic field off. Whenever device programming has been performed before or during the procedure, it is recommended, following the procedure, to:
  - Program the device back to its original pre-procedure settings or other settings according to the patient's clinical indications.
  - Perform a routine device evaluation.
  - In any case of uncertainty regarding device programming, please consult with a relevant device expert.
- Do not place multiple socket-outlets on the floor.

- The multiple socket outlets provided with the EnSite™ X EP System should only be used for supplying power to EnSite™ X EP System components. Failure to do so may result in excessive leakage current. The maximum permitted loads for the multiple socket outlets are:

System Component	Input Current	Output Current
Power strip on carts	12A	N/A

System Component	Power (Max)	Output Current (Max)
Amplifier or DWS Isolation Transformer	US: 1000VA	US: 8.4A
	EU: 1000VA	EU: 4.17A
	JPN: 840VA	JPN: 8.4A
Remote Monitor Isolation Transformer	US/JPN: 720VA	US/JPN: 6A
	EU: 750VA	EU: 3.12A

- EnSite™ X EP System components should be connected to power through an isolation transformer or the multiple socket outlet supplied with the system carts. Connecting equipment directly to a wall outlet may result in excessive leakage current.
- Always respond to warning messages as soon as possible. Failure to do so may cause an inability to record data or to communicate properly with the EnSite™ X Amplifier.
- Model points, mapping points, and map tags (labels, lesions, shadows, etc.) placed at EnGuide within approximately 15 seconds prior to notification of dislodgement may not be based on the previous location of the positional reference catheter. The user should confirm whether these points are valid. After a dislodgement has been detected, the Positional Reference Tool gives users the option to take immediate action (click Adjust Now) or to take action later (click Adjust Later).
- If the Adjust Later button is selected, the user must be aware that any tasks that rely on the positional reference catheter's location may be affected. These tasks include collecting model points, collecting mapping points, placing labels, placing lesions, etc.
- The Positional Reference Tool will not monitor positional reference catheter dislodgements if Adjust Later is selected. To re-enable the Positional Reference Tool and accept the new location of the positional reference electrode after a dislodgement has been detected, click on Accept.
- In the event that the system notifies the user of both an EnSite™ X electrode error and a Positional Reference Tool dislodgement message, the EnSite™ X electrode error should be addressed first.
- In the event that the system notifies the user of both an EnSite™ X electrode error and a Positional Reference Tool dislodgement message, the user should verify that the positional reference catheter has physically moved.
- Periodic Inspection: The system components should be inspected by the customer monthly: Check the Torx security screws and discontinue use if there is visible evidence of tampering.
- EnSite™ X Amplifier is not intended to be used as a networked device. All remote network access protocols into the amplifier are disabled/not installed.
- Only a qualified service representative can perform maintenance or service the system.
- After moving the system, inspect all connections for damage, reconnect the system per instructions in this IFU as well as the EnSite™ X EP System IFU. Damaged cables or components must be replaced.
- This system contains the following security features: Whitelisting - Whitelisting technology prevents the execution of unauthorized software on this system to protect against malware. An indicator shows that the security software is running in the background. To check if the security software is running, observe the Cybersecurity software status icon in the bottom left corner of the Login Manager or Launcher screens. If the Cybersecurity status icon shows the security software is not running, discontinue use of the device and contact the local administrator of the facility the system is located in or Abbott Technical Services.
- Do not drop the EnSite™ X Field Frame or subject it to impact. Physical damage to the Field Frame may alter the Field Frame's factory calibration.
- Do not disconnect the EnSite™ X Field Frame from the system while tracking. Disconnecting the Field Frame while in tracking mode may result in sparks being generated.
- Non-Patient environment system components are not suitable for use within the patient environment where intentional or unintentional contact can occur between a patient and these components or between a patient and other person touching parts of these components.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Do not operate the EnSite™ X EP Field Frame within 10 m of another operating Field Frame.
- Do not place tool cables within 30 mm of the EnSite™ X Field Frame cable. If placed this close-particularly if the cables are parallel to each other-the tool cable may become subject to electromagnetic interference.
- Keep the EnSite™ X Field Frame approximately 75cm away from any exposed ground planes to prevent interference which may affect Sensor Enabled™ points and Sensor Enabled™ field scaling accuracy. 3D point collection stops when metal distortion is detected.
- Do not clean the system components with disinfectants that contain surfactants.
- Do not clean system components with bleach.
- Do not apply cleaners while the system is warm to the touch.
- Do not sterilize system components.
- Disconnect power to the EnSite™ X system before cleaning it.
- Do not use aerosol sprays near the equipment as these sprays can damage circuitry.
- Do not autoclave any EnSite™ X system component. Autoclaving may damage the system.
- Do not sterilize EnSite™ X interconnect cables.
- Do not leave cable connectors where they can be damaged, particularly on the floor, where they can easily be stepped on and damaged.
- Pull connections apart by gripping the connector. Do not pull them apart by tugging on the cable as this can damage the connecting cable. Never force a connection or a disconnection.

Limitations

Device(s) should connect directly to the EnSite™ X EP System, not through a third device.

Adverse Events

- Cardiac Perforation
  - Cardiac effusion/ tamponade
- Cardiovascular Injury, which might include but are not limited to:
  - Vascular injury
  - Damage to the coronary vasculature
  - Valvular damage
  - Cardiac effusion/ tamponade
- Organ Injury, which might include but are not limited to:
  - Esophageal lesion
  - AE fistula
  - Puncture of surrounding organs
  - Hemothorax
  - Pneumothorax
- Arrhythmias, which might include but are not limited to:
  - Recurrent arrhythmia
  - Non-sustained ventricular tachycardia
  - Recurrence of atrial fibrillation
- Peripheral Nerve Damage
  - Phrenic nerve (PN) palsy
- Superficial Tissue Injury
- Electric Shock
- Thermal Injury

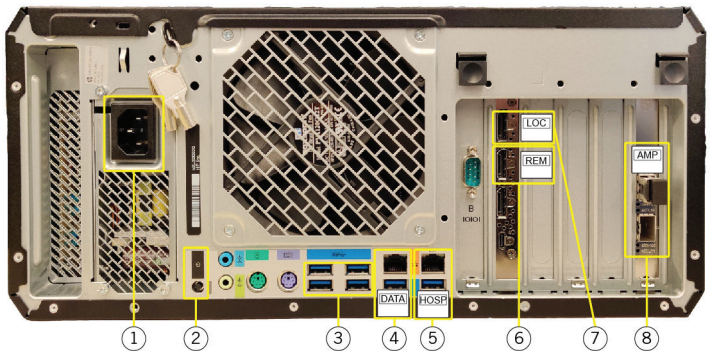
EnSite™ X Display Workstation Connections

EnSite™ X Display Workstation (DWS) Front and Back Panels

Figure 4. DWS Front Panel

1. Power On button
2. USB Drive Connections
3. CD/DVD Read/Write Drive

Figure 5. DWS Back Panel

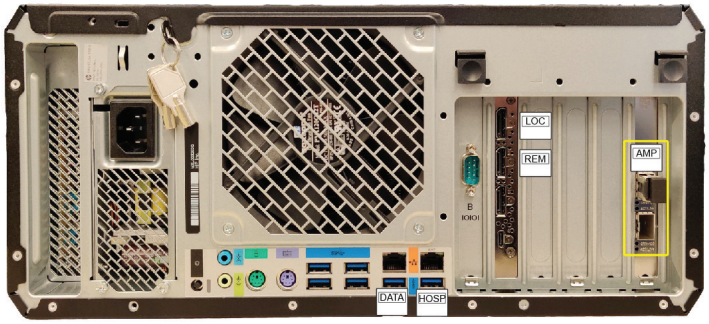


1. Power Connection
2. Secondary Power On/Off Switch
3. USB Ports for Keyboard, Mouse and Printer
4. WorkMate™ Claris™ Recording System Connection
5. Ethernet Connection for Hospital Network
6. Remote Monitor Connection
7. Local Monitor Connection
8. EnSite™ X Amplifier Connection

Connecting the EnSite™ X Amplifier to the EnSite™ X Display Workstation (DWS)

Connect a "LC to LC OM1, 1 Gb Fiber Optic Cable" from 1 Gb Data Port on the EnSite™ X Amplifier back panel to the AMP Port on the EnSite™ X Display Workstation (DWS) back panel.

Figure 6. Local Monitor Display Connection



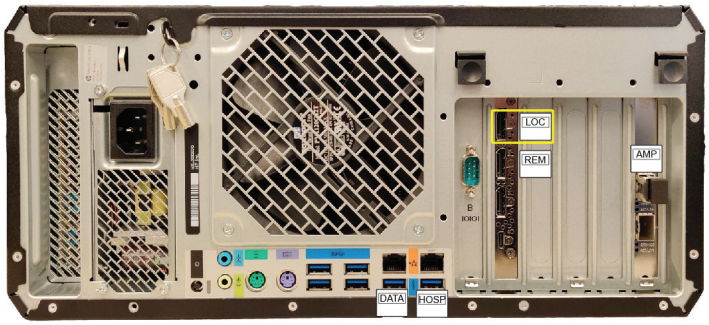
EnSite™ X DWS Back Panel, AMP (amplifier) port.

EnSite™ X Amplifier Back Panel.

Connecting to the Local Monitor

Connect a local monitor to the [LOC] display port connector as shown.

Figure 7. Local Monitor Display Connection.

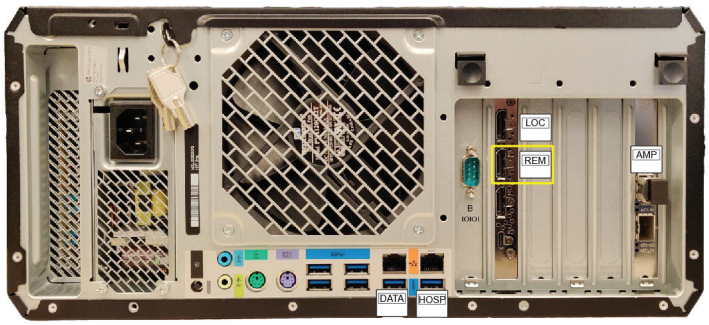


EnSite™ X DWS Back Panel, LOC (local monitor display) port.

Connecting to the Remote Monitor

Connect a remote monitor to the [REM] display port connector as shown.

Figure 8. Remote Monitor Display Connection

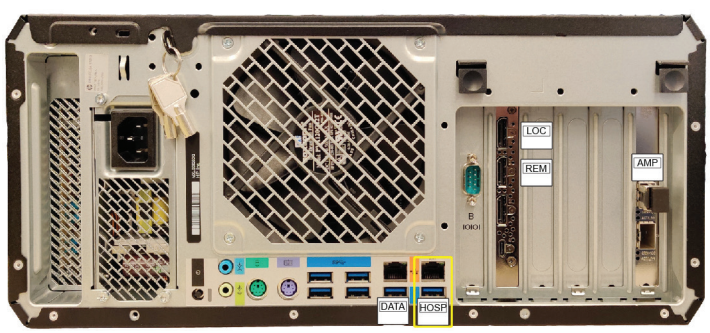


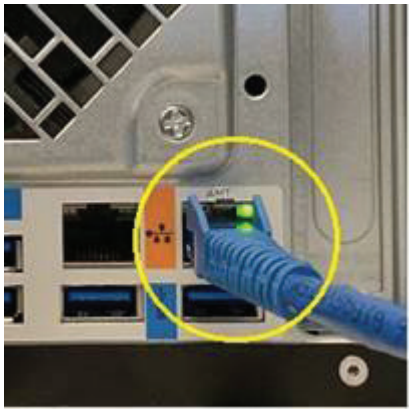
EnSite™ X DWS Back Panel, REM (remote monitor display) port.

Connecting to the Hospital Network

Connect a standard copper ethernet cable to the ethernet connection labeled [HOSP] as shown below.

Figure 9. Hospital Network Connection



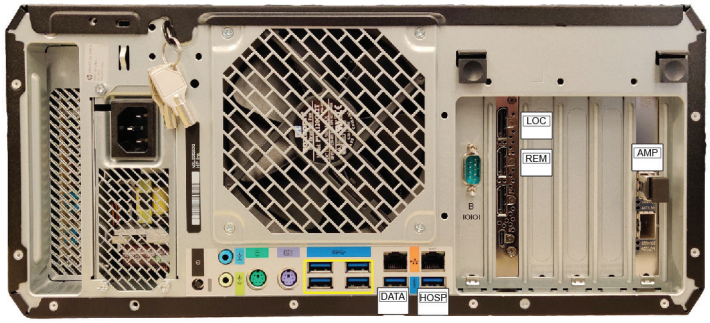


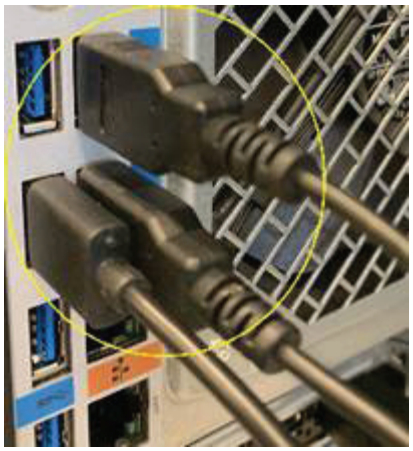
EnSite™ X DWS Back Panel, HOSP (hospital network) port.

Connecting the Keyboard, Mouse and Printer

Connect the USB mouse, keyboard, and optional printer to any of the USB ports on the rear panel as shown below.

Figure 10. Mouse, Keyboard and Printer Connections



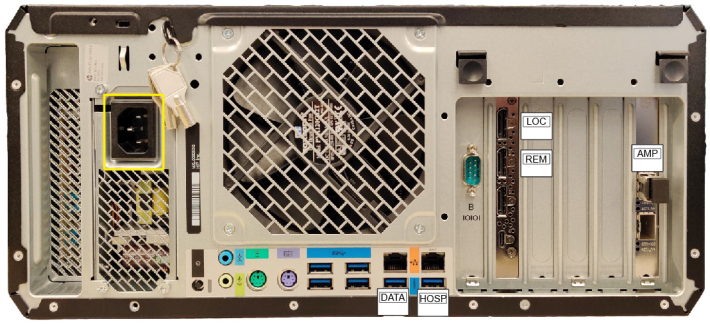


EnSite™ X DWS Back Panel; Keyboard, Mouse and Printer USB ports.

Connecting the Power Cable

Connect an IEC power cable to the DWS as shown below. Connect the power cable to the isolation transformer.

Figure 11. Power Connection



EnSite™ X DWS Back Panel, Power Connection.

EnSite™ X EP System Setup

Starting the System

Before starting the system, verify the following:

- All cable connections to the EnSite™ X Amplifier are secure.
- The fiber-optic cable connection between the DWS and the EnSite™ X Amplifier is secure. Use the following procedure to start the system:

  NOTE: If the system will only be used to review previously recorded data in Offline Review Mode, the EnSite™ X Amplifier does not need to be powered on.
  NOTE: If the EnSite™ X Amplifier is already powered on when setting up the system for a new study, power cycle the EnSite™ X Amplifier before starting a new study. The EnSite™ X Amplifier self-test provides important information about the status of the EnSite™ X Amplifier components that may not be available unless the EnSite™ X Amplifier is power cycled.

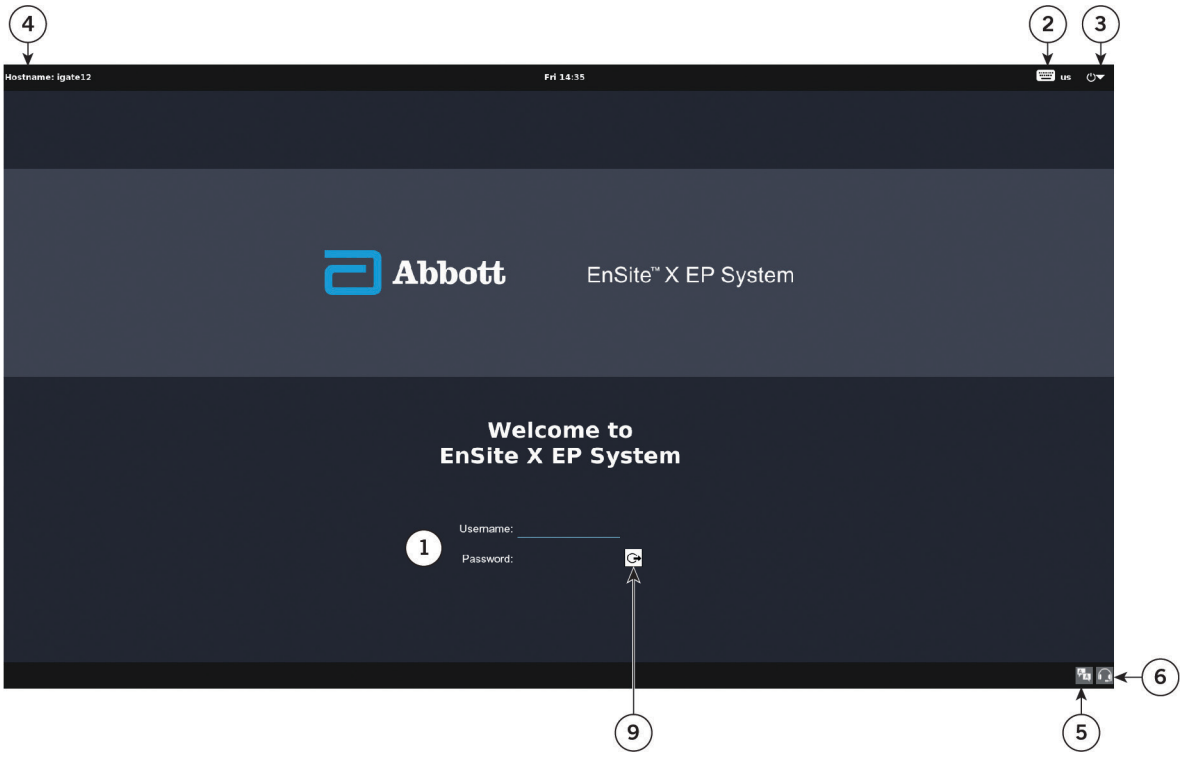
1. Power on the isolation transformer.
2. Press and release the workstation power switch (located on the front of the workstation) to power on the workstation. When powered on, the workstation begins automated self-testing. When self-testing is complete, the system login screen appears on the monitor.
3. Press the EnSite™ X Amplifier power button in to the ON position.
4. When the system is powered on, the status lights may change state for approximately two minutes while the system performs self-testing. After two minutes, check the EnSite™ X Amplifier status lights. The green light should illuminate and remain lit. If the amber light flashes or is steadily illuminated, there is a problem.

Login to System

Login to the system with username and password.

NOTE: Refer to the EnSite™ X System Admin Guide for initial login and setup instructions. The instructions below are for the configured system.

Figure 12. Login Screen

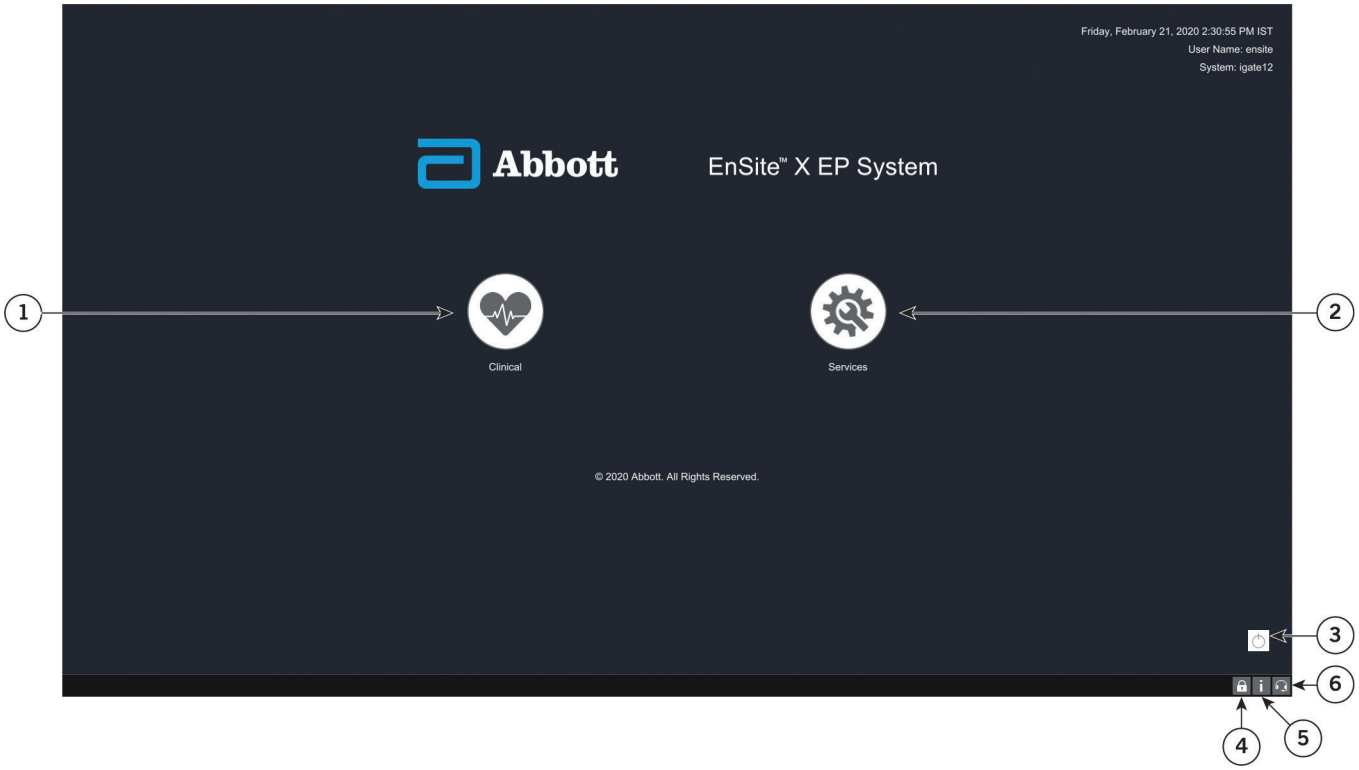


1.	Hostname	The hostname of the system.
2.	Change Keyboard Language	Select to access available languages.
3.	Power dropdown menu	Open to Power Off or Restart system.
4.	Username	Enter username to log into system.
5.	Password	Enter password to log into system.
6.	Logon Button	Select this button to logon.
7.	Change Language	Select to access available languages.
8.	SJM™ Connect icon	Select to access SJM™ Connect.

Launcher Main Screen

Upon successful login, the Launcher screen will be displayed.

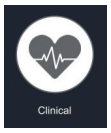
Figure 13. Launcher Main Screen



1.	Clinical	Select to start or review a study.
2.	Services	Select to access System Log files, Licenses, and additional functions.
3.	Exit icon	Exit application.
4.	Change Password icon	Select to access change password screens.
5.	About the System	Select to access the About system dialog box.
6.	SJM™ Connect icon	Select to access SJM™ Connect.

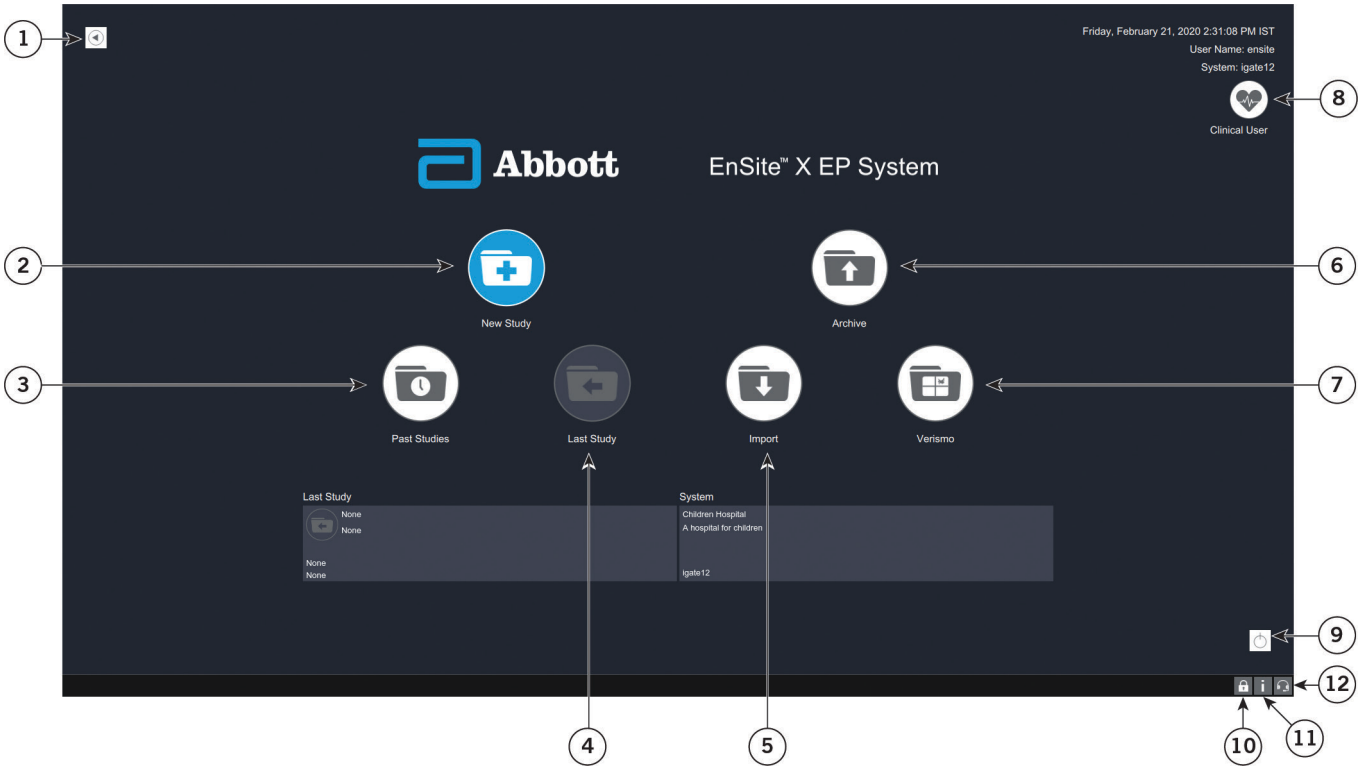
NOTE: The options seen on the Launcher Main Screen will be displayed based on the assigned User Role(s). User Roles include: Administrator, Clinical, Service, and Training and are described in the EnSite™ X System Administration Guide.

Clinical Menu



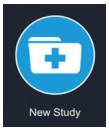
After selecting the Clinical icon, the Clinical Menu screen will be shown. Select an action from the Clinical Menu Screen.

Figure 14. Clinical Menu Screen



1.	Back icon	Go back one screen.
2.	New Study	Starts a new study.
3.	Past Study	Open a previously recorded study (Opens in Review Mode).
4.	Last Study	Open the last study (Opens in Review Mode).
5.	Import	Import files onto the system hard drive from a storage device.
6.	Archive	Archive files on the system hard drive to another storage source.
7.	Verismo	Opens the EnSite Verismo™ Segmentation Tool.
8.	User	Clinical user.
9.	Exit icon	Exit application.
10.	Change Password icon	Select to access change password screens.
11.	About the System	Select to access the About system dialog box.
12.	SJM™ Connect icon	Select to access SJM™ Connect.

Start a New Study/New Patient



After selecting the "New Study" icon, The Study Setup screen will be shown. Perform the following steps for a New Patient.

Figure 15. New Study/New Patient Screen

1. Select New Patient button. (selected by default)
2. Enter patient information into the fields, required information is noted.

   NOTE: Patient ID and weight cannot be changed after leaving this screen.
3. Select the Navigation Mode.

   NOTE: Navigation mode cannot be changed after leaving this screen.
4. Select the Lab.

   NOTE: Lab cannot be changed after leaving this screen.
5. Select Begin Study button once all patient and system information has been entered. The EnSite™ X Setup Screen will appear.
6. Select the Exit button to leave the Study without saving.

   NOTE: Use the mouse to hover the pointer over the to show informational text about a selection for entry field.

Navigation Mode Description

The EnSite™ X EP System provides users with two distinct navigation modes; EnSite NavX™ mode and EnSite™ VoXel mode. Selection of a navigation mode is required before beginning a study and cannot be changed after leaving the setup screen.

The EnSite™ VoXel model should be selected when only Sensor Enabled™ catheters will be used for location data collection. In this mode, catheter locations are mainly based on the magnetic signals generated by Sensor Enabled™ catheters in conjunction with the Field Frame. Standard catheters (that is, without a sensor) can only be visualized in this mode and only after enough magnetic information has been collected near the catheter location.

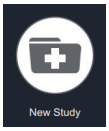
The EnSite NavX™ mode should be selected when the use of standard electrophysiological (EP) (that is, without a sensor) catheters to collect location data is desired. In this mode, catheter locations are calculated based on impedance signals generated using the EnSite™ Surface Electrodes attached to the patient. Optionally, a Sensor Enabled™ catheter(s) in conjunction with the EnSite™ X Field Frame can be used in this mode to collect magnetic information. The system will use the collected magnetic information for EnGuide Stability Monitor, and during the optional EnSite NavX™ SE field scaling calculation.

Lab Description

During installation, service personnel will perform a Lab characterization procedure in each room the system is planned to be used. This procedure will measure the magnetic field of the room. Selection of a lab is required before beginning a study and cannot be changed after leaving the setup screen. A "Non-Characterized Lab" is an option, but not the default. Selecting a non-characterized lab may limit C-Arm movement and may cause false detections of metal distortion.

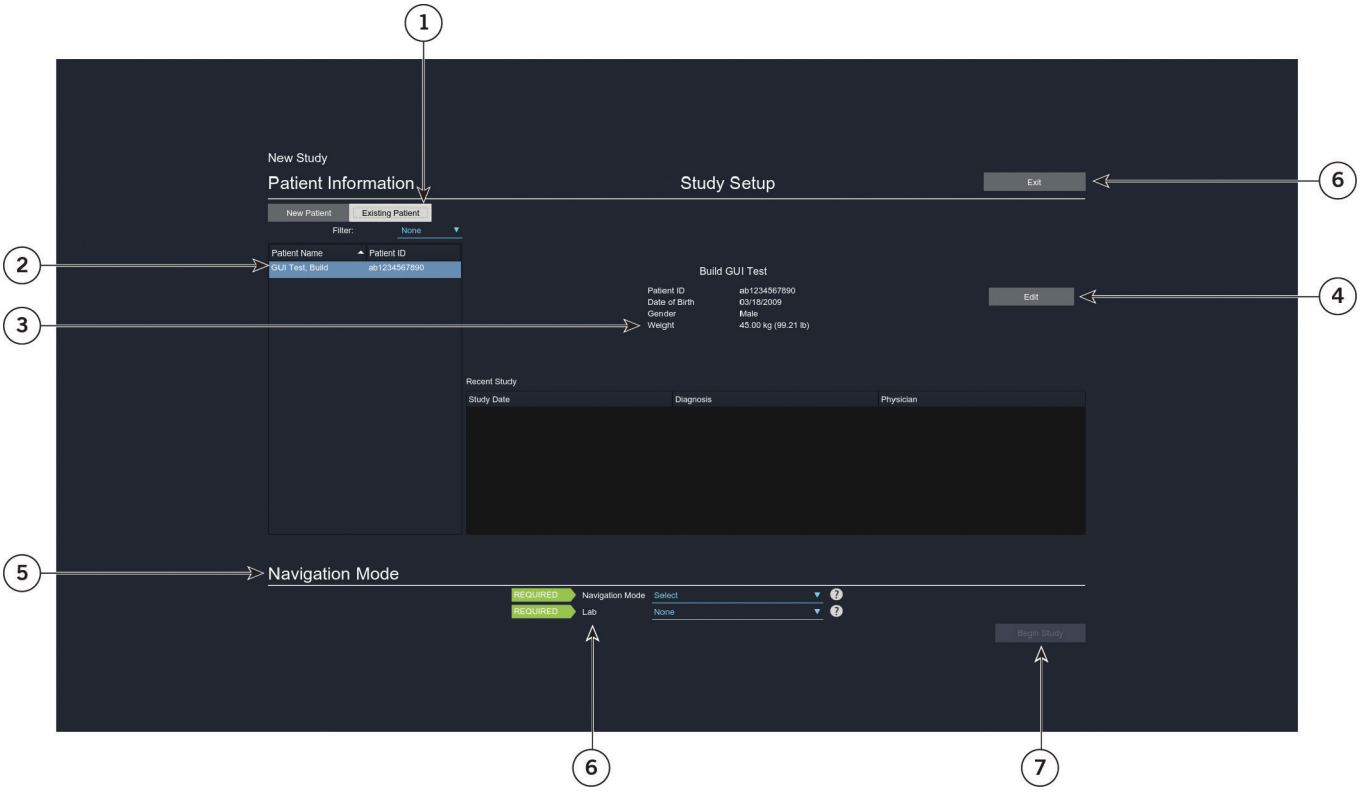
The Lab characterization information for the selected lab will be used to correct magnetic positions due to metal distortion and prevent inaccurate data collection. If the metal environment in the lab changes (e.g. new fluoroscopy system) the lab must be re-characterized as the original data may no longer be accurate.

Start a New Study/Existing Patient



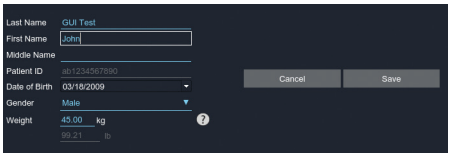
To begin a new study with an existing patient, select the "Existing Patient" icon. Perform the following steps for a new study with an existing patient.

Figure 16. New Study/Existing Patient Screen



1. Select the Existing Patient button.
2. Select a patient from the list.
3. Review patient information.
4. If changes to the patient information are desired, select Edit button. The Edit dialog box will open. Make changes to the patient information as needed and select the Save button to save changes or the Cancel button to discard changes to the patient information.

Figure 17. Edit dialog box



5. Select the Navigation Mode.

   NOTE: Navigation mode cannot be changed after leaving this screen.

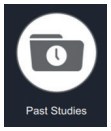
6. Select the Lab.

   NOTE: Lab cannot be changed after leaving this screen.

7. Select Begin Study once all patient and system information has been entered. The EnSite™ X EP System - Setup screen will appear.
8. Select the Exit button to leave the Study without saving.

   NOTE: Use the mouse to hover the pointer over the Help icon to show informational text about a selection or entry field.

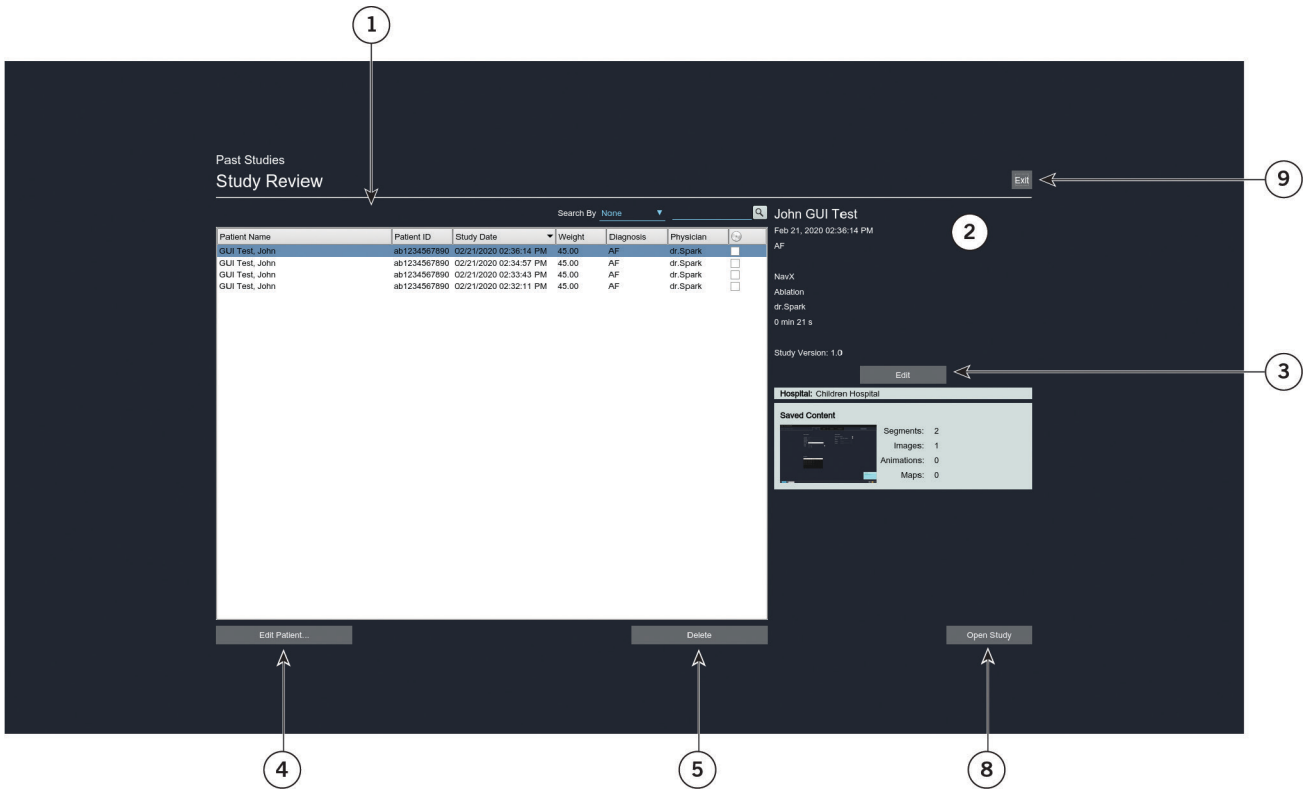
Past Studies



After selecting thePast studies icon, the Study Review screen will be shown. Perform the following steps for a past study.

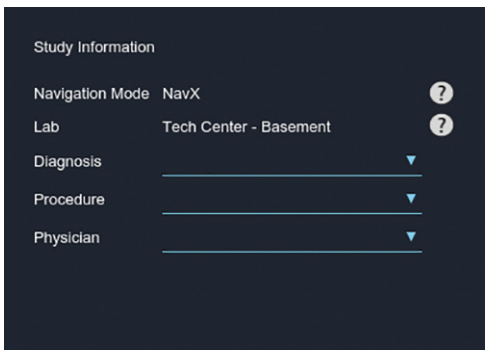
NOTE: To open the last study, select Last Study on the Study Launchpad Screen.

Figure 18. Past Studies Screen



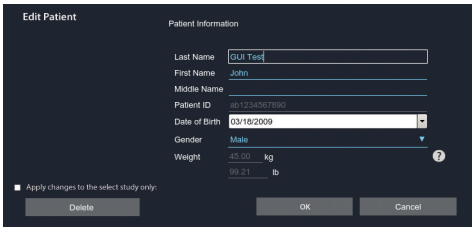
1. Select a study from the list.
2. Review study information on the right side of screen.
3. If changes to the study information are desired, select Edit button. The Edit Studies dialog box below will open. Make changes to the study information as needed and select the Save button to save changes or the Cancel button to discard changes to the study information.

Figure 19. Edit Studies dialog box



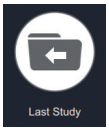
4. If changes to the patient information are desired, select Edit Patient button. The Edit Patient dialog box below will open. Make changes to the patient information as needed and select the Save button to save changes or the Cancel button to discard changes to the patient information.

Figure 20. Edit Patient dialog box



5. Select the Delete button to delete the study.
6. Select the "Apply changes to the selected study only" checkbox to apply the changes to only this study.
7. Select OK button to accept changes. Select the Cancel button to discard changes. The dialog will close.
8. Select Open Study button in the lower right corner of screen. The Workspace screen will open with the study in Review.
9. Select the Exit button to leave study without saving.

Last Study



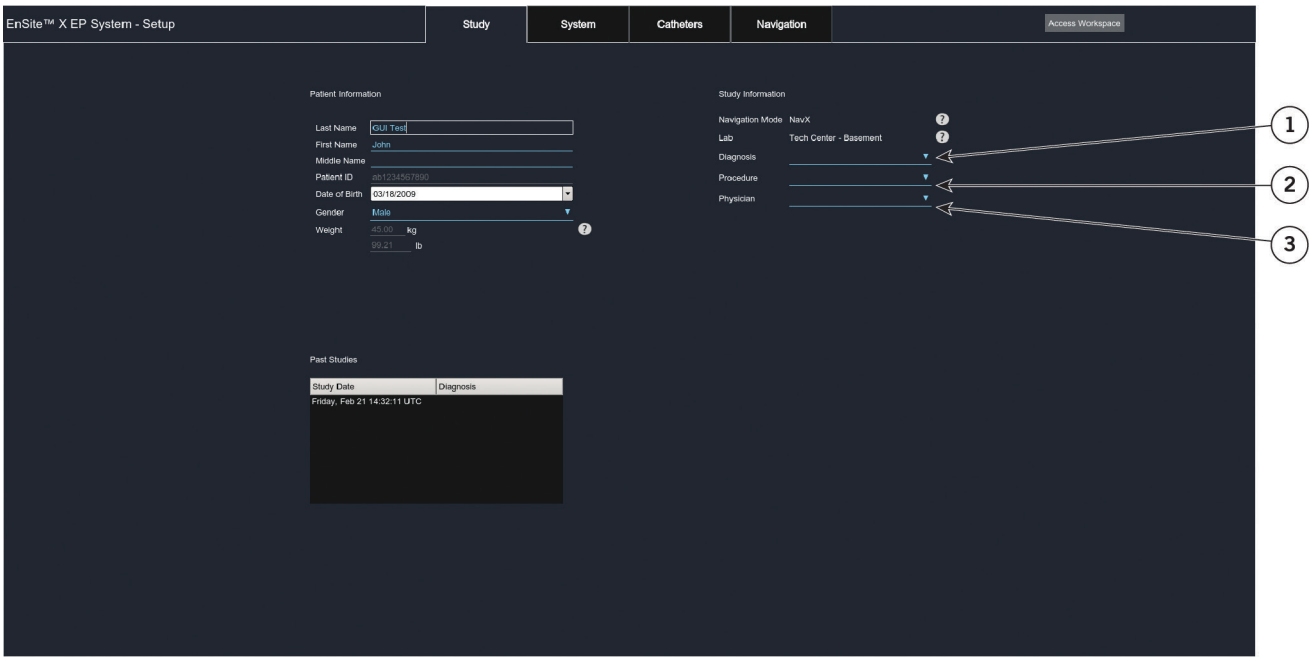
On the Study Launchpad screen, press the last study icon. The Workspace will open with the Last Study view in Review mode.

EnSite™ X EP System Setup Screen

EnSite™ X EP System Setup, Study Tab

The System Setup screens open when the study and patient information has been completed.

Figure 21. Setup - Study Tab



1. Select patient's Diagnosis.
2. Select Procedure type.
3. Select name of Physician.

   NOTE: If items 1 through 3 above are required to save and exit a study.
   NOTE: For each field, select a pre-set value from the drop-down menu or freely type a new value. This new value will be available for future studies. Anything typed cannot be deleted.

4. To exit the study, select the Abbott Menu icon and select End Study.

Training Menu

The Training menu allows the user to access the training mode for the EnSite™ X EP System. When a user enters the Training Menu, the same options will appear as the Clinical Menu: New study, Past Study, Last Study, Archive, Import, Verismo. Although the Training Menu looks similar to the Clinical Menu the Training Mode is designed for Training Use only; the Training mode is not intended for Human Use studies. The following items are unique features of the Training Mode:

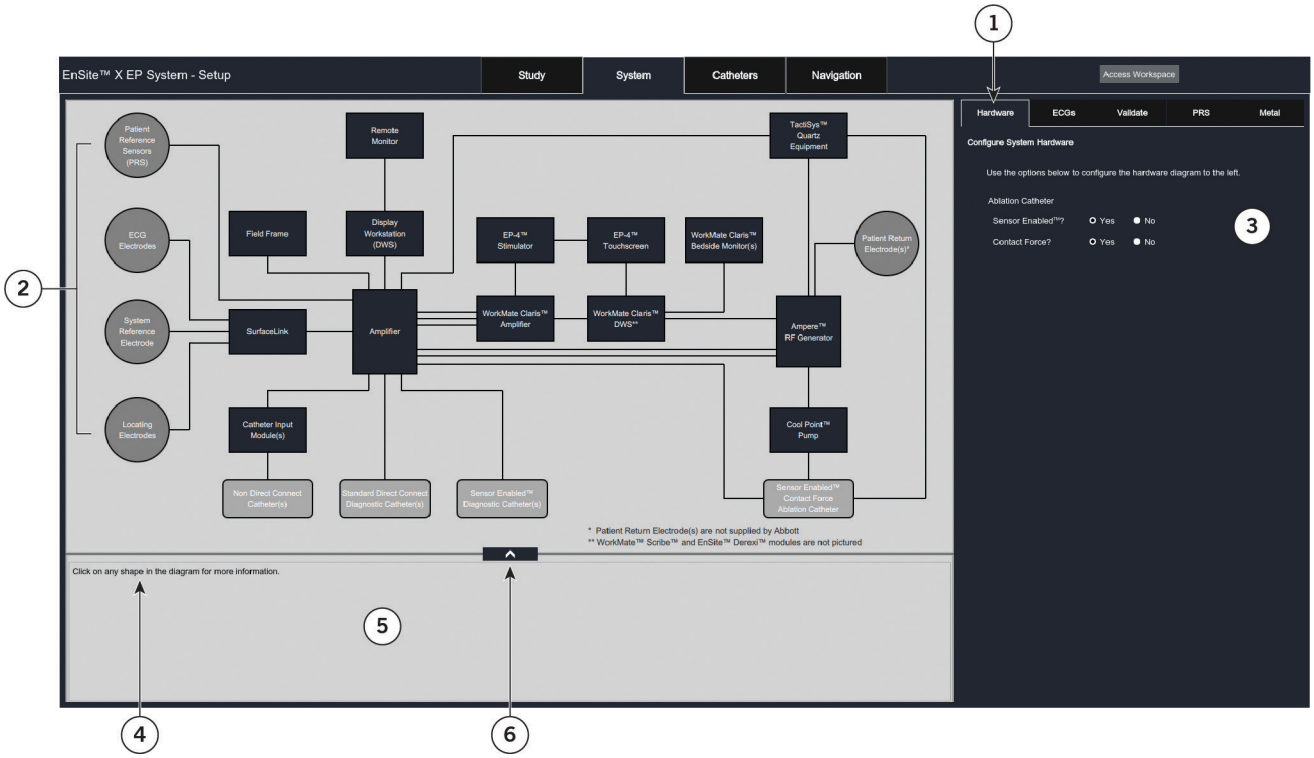
- The Training mode does NOT permanently save any information to the system. Every time a user logs into the system, the Training Menu is refreshed and all previous changes are discarded.
- Selecting "New Study" provides a simulation of a study. The system will NOT connect to the EnSite™ X Amplifier when using the Training Menu.
- Selecting "Past Study" provides the ability to review studies that are imported or provided by Abbott as a Training Database.

  NOTE: Any study that is imported by the user can only be used during the current log-in session. All changes, including study imports, are discarded upon user log-in.
- When reviewing a "Past Study" the "Edit Model" functionality is available to allow training on the model creation process.

EnSite™ X EP System Setup, System Tab

Select the Hardware Sub-tab to configure the system hardware.

Figure 22. Setup – System Tab – Hardware Sub-tab



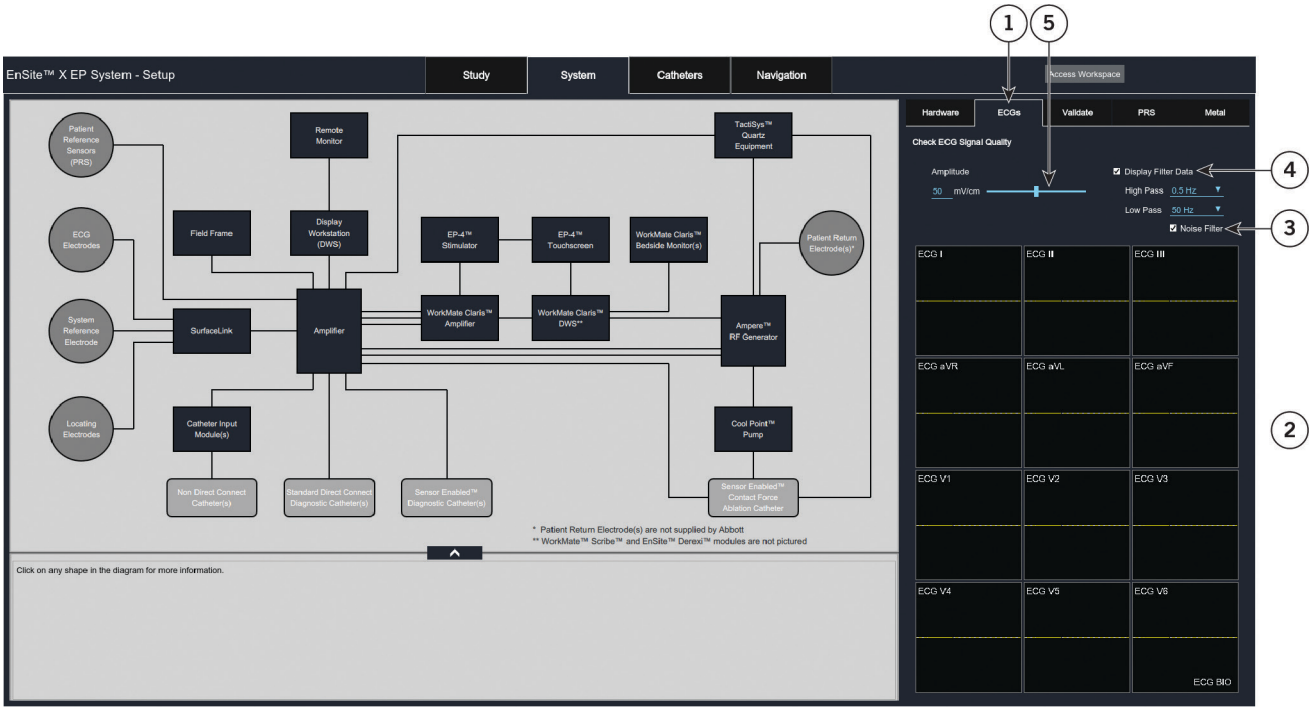
1. Select Hardware Sub-tab.
2. Review necessary connections in hardware diagram.
3. Configure ablation catheter types in hardware diagram as necessary. The ablation catheter types control the system components displayed on the system diagram screen.
4. Troubleshoot system connections if needed (user may select individual system components in the diagram, these will highlight). Setup and troubleshooting instructions will appear in the screen below the diagram.
5. The window at the bottom of the screen will display:
   - Selected Component. Any component in the hardware diagram can be clicked on, to bring up help content. A selected component is highlighted, indicated by a glow around the shape, and help content related to the selection appears in the section below. Clicking on a selected component deselects it. The highlighting disappears from around the shape, the help content below disappears, and the default instructional statement and legend reappear.
   - Label. Name of the selected component or connection. When a component is selected, its name appears here.
   - Hyperlinks. Clicking on a link (Description, Install, Troubleshoot) jumps/scrolls the help content to that subsection.
6. Expand/Collapse. Expands and collapses the size of the section where help content appears.

   NOTE: If the help section is expanded, then clicking the Exit buttion collapses the section size back down to the default size. Regardless of whether the help section is expanded or collapsed, clicking the Exit button also deselects the component. The highlighting disappears from around the shape, the help content below disappears, and the default instructional statement and legend reappear.

EnSite™ X EP System Setup, System Tab - ECG Sub-tab

The ECG Sub-tab assumes the following pre-requisites: the ECG surface electrodes are properly positioned on the patient and connected to the SurfaceLink™ Module which is in turn connected to the EnSite™ X Amplifier.

Figure 23. Setup – System Tab – ECG Sub-tab



1. Select ECG Sub-tab.
2. Visually examine signals to verify ECG signal quality. Signals should be visible for each of the 12 leads, free of high-frequency sine waves and free of excessive noise. If traces contain excessive noise, check all electrode and cable connections between the patient and the EnSite™ X Amplifier.
3. Enable/disable the Noise Filter checkbox.
4. Enable/disable Display Filter Data checkbox. If signal filtering is desired, verify that the Display Filter Data checkbox has the High Pass and Low Pass filters set accordingly. Refer to Filters and Settings Options Table below for a description of the filters and setting options. Use dropdown menus to set the low pass and high pass filters to desired values.
5. Use Amplitude slider to adjust size of the ECG signals.

The ECG Sub-tab assumes the following pre-requisites: the ECG surface electrodes are properly positioned on the patient and connected to the SurfaceLink™ Module which is in turn connected to the EnSite™ X Amplifier.

Table 1. Filters and Settings Options Table

Filter	Descriptions	Settings	Default Setting		
			ECG	EP Catheter	
				Bipolar	Unipolar
Noise	Noise filters are 50-60 Hz notch filters that reduce powerline noise. Available settings are ON/OFF. To adjust the powerline frequency and filter.	OFF, ON	OFF	OFF	OFF
High pass	High pass filters reduce low-frequency signals (i.e., repolarization signals) and baseline drift.	0.05, 0.5, 1, 2, 5, 10, 20, 30, 40 Hz	0.5 Hz	30 Hz	2 Hz
Low pass	Low pass filters reduce high-frequency signals commonly caused by electronic interference.	500, 400, 300, 200,100,60, 50, 40, 30, 20, 10 Hz	50 Hz	300 Hz	300 Hz

EnSite™ X EP System Setup, System Tab - Validate Sub-tab

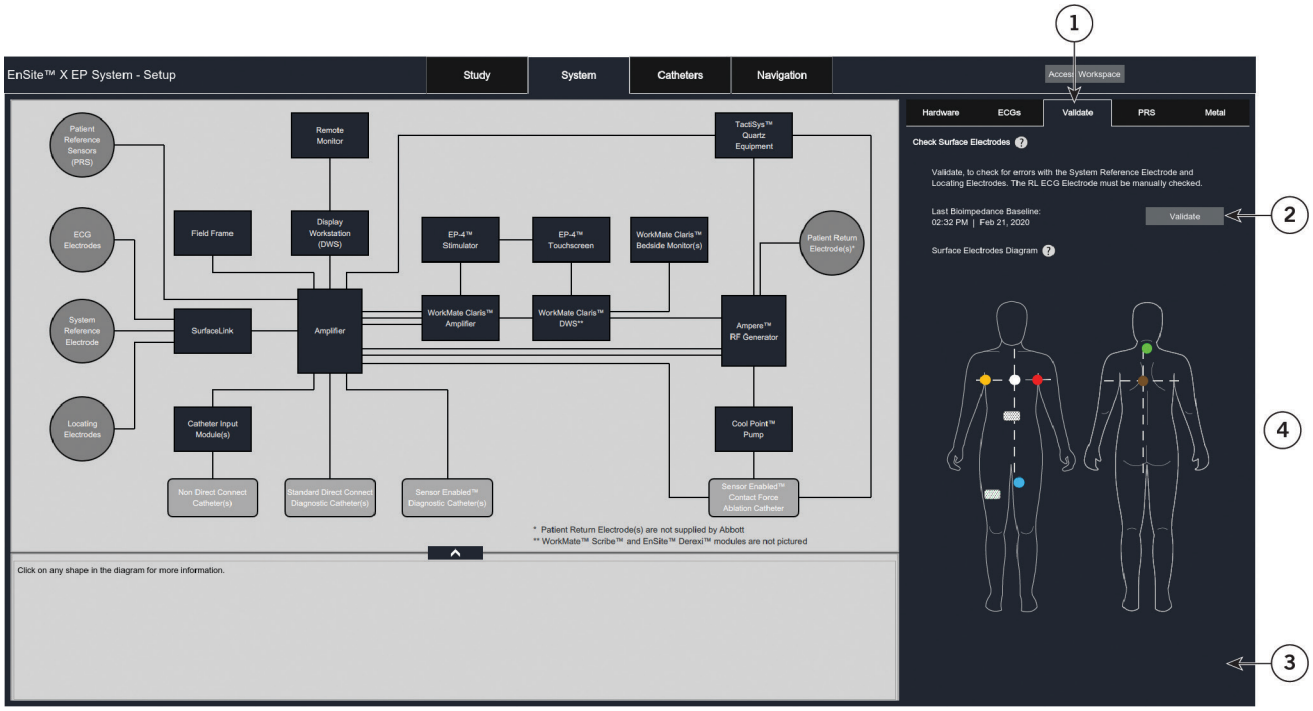
The Validate Sub-tab assumes the following pre-requisites: System Reference Electrode and the EnSite™ X Surface Electrodes are properly positioned on the patient and connected to the SurfaceLink™ Module which in turn is connected to the EnSite™ X Amplifier.

The EnSite™ X Surface Electrodes are single-use components. The surface electrodes must be validated before catheters can be visualized. Validation sets an 18-hour time-period during which the electrodes may be used during a study.

NOTE: Re-validation will delete all 3D objects, manually placed lesions, AutoMarks, shadows, and labels from the study. Validation or re-validation should be performed as close as possible to creating the first model, map or 3D point.
NOTE: All controls for 3D operations are unavailable until the EnSite™ X Surface Electrodes are validated.

CAUTION: EnSite™ X Surface Electrodes are intended for single-use only. Device integrity will be compromised by any reuse, which may compromise patient safety and system performance.

Figure 24. Setup – System Tab – Validate Sub-tab



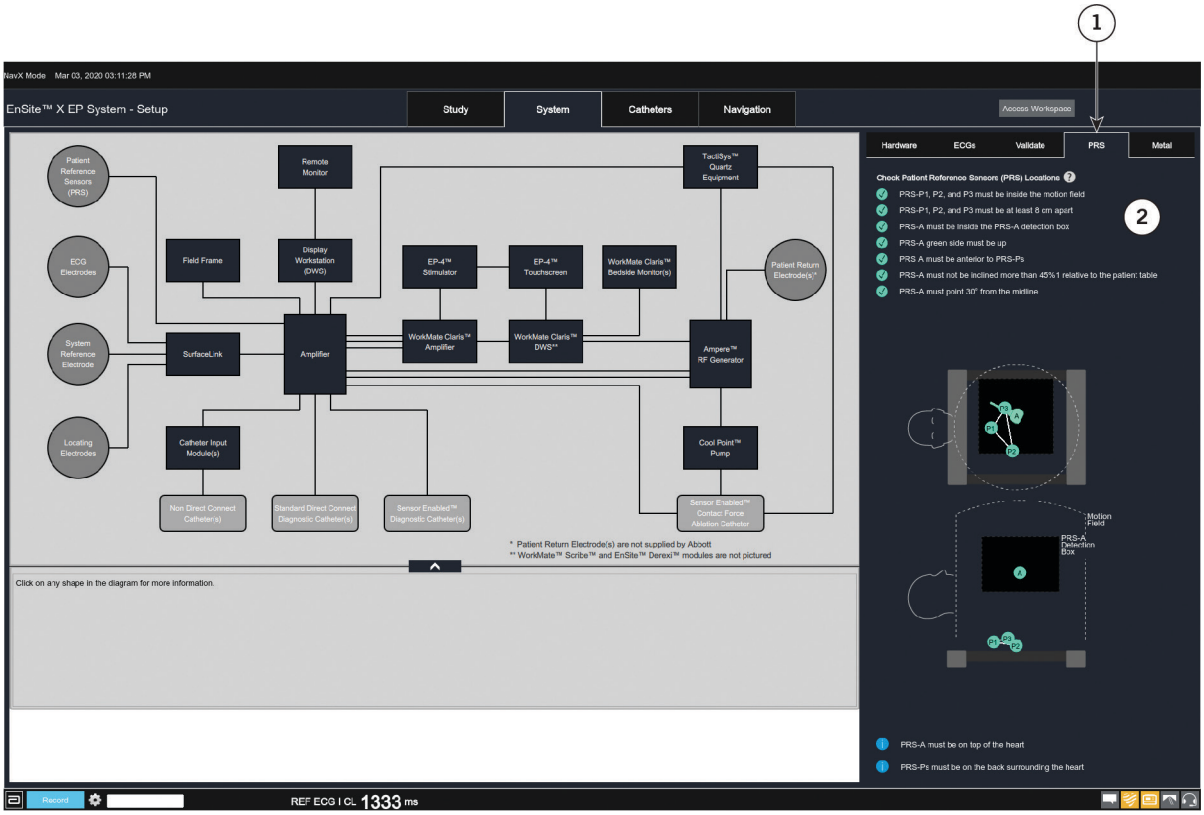
1. Select Validate Sub-tab.
2. Select Validate button.

   NOTE: Validation lasts for 18-hours.
   NOTE: The screen image does not necessarily represent surface electrode placement on the patient. It is not an indicator of actual surface electrode placement.
3. Message in the bottom right corner of display will confirm validation outcome.
4. If validation fails, troubleshoot surface electrode placement and/or EnSite™ X Amplifier connections.
5. To troubleshoot EnSite™ X Surface Electrodes placement refer to the EnSite™ X Surface Electrodes Kit Instructions for Use for preparation and placement. Other troubleshooting sources are the EnSite™ X Amplifier Instructions for Use and the online help under the System Setup tab.

EnSite™ X EP System Setup, System Tab - PRS Sub-tab

The Patient Reference Sensors (PRS) are used in the EnSite™ VoXel™ and EnSite NavX™ modes when using sensor enabled catheters. A total of four (4) PRS sensors are applied when using Sensor Enabled catheters; one (1) PRS-A (anterior) sensor and three (3) PRS-P (posterior) sensors. The PRS-A sensor is used to detect and compensate metal distortion. The three PRS-P sensors are used to establish the magnetic system reference. The PRS Sensors are positioned on the patient and are connected to the Amplifier using two PRS cables, PRS-A cable and PRS-P cable. Position the Field Frame generator and PRS patches as needed to facilitate getting all PRS sensors to a valid state. Refer to EnSite™ X Electrode Kit Instructions for Use for more information on how to place PRS patches and sensors.

Figure 25. Setup – System Tab – PRS Sub-tab



1. Select PRS Sub-tab.
2. Confirm that all PRS placement conditions are satisfied.

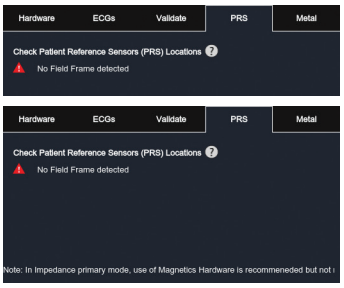
EnSite™ VoXel Mode and EnSite NavX™ Mode

If the field frame is not connected these messages will appear.

NOTE: In EnSite NavX™ mode, the user may ignore this message if they do not intend to use EnSite NavX™ SE field scaling with a Sensor Enabled™ catheter.

EnSite™ X EP System will detect and notify the user if the incorrect field frame model is connected. The only compatible model is ENSITE-FF-01. Verify the correct field frame is connected by reviewing the label on the field frame generator.

Figure 26. Field Frame Detection Errors



EnSite™ VoXel Mode

Indicates that no Field Frame has been detected.

EnSite NavX™ Mode

Indicates that no Field Frame has been detected.

Confirm PRS Placement

Refer to EnSite™ X Surface Electrode Kit Instructions for Use for more information on how to place PRS patches and sensors.

1. Confirm that PRS-P1, -P2, and -P3 are within motion field.
2. Confirm that PRS-P1, -P2, and -P3 spacing is at least 8 cm.

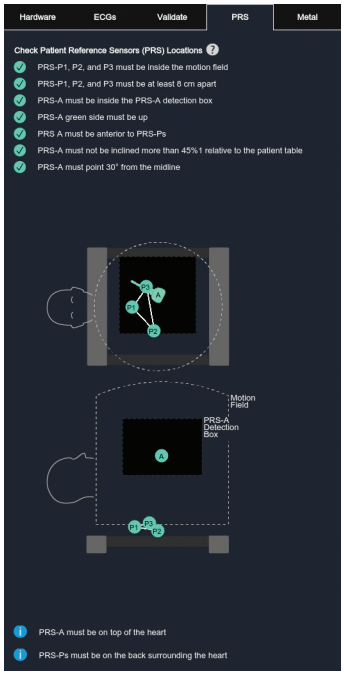
   NOTE: The center of the PRS-P triangle determines the magnetic positional reference of the magnetic coordinate system. This is used to compensate for patient movement within the magnetic field. The system will monitor that the distances between PRS-P sensors do not change to ensure that the system is able to compensate for patient movement.
3. In EnSite NavX™ mode, the distance between PRS-P pairs must not change after the first EnSite™ NavX SE point is collected.
4. In EnSite™ VoXel mode, the distance between PRS-P pairs must not change after the first Sensor Enabled™ catheter enters the motion box.
5. Confirm that PRS-A is within the PRS-A detection box.

6. Confirm that PRS-A green side is up.
7. Confirm that PRS-A is anterior to PRS-P1, -P2, and -P3.

Confirm that PRS-A is not inclined more than 45° relative to the patient table.

1. Confirm that PRS-A is pointing 30° from the midline towards the left shoulder.
2. Troubleshoot PRS placement issues as needed.

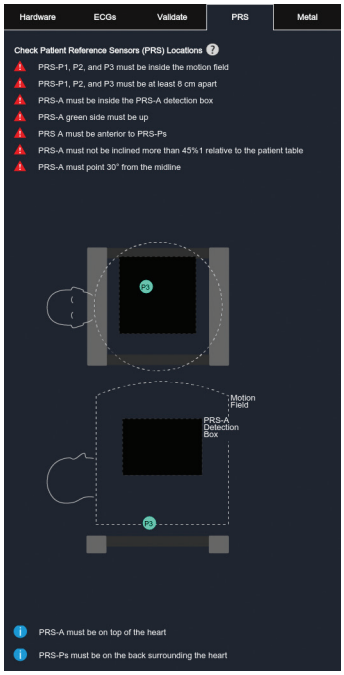
Figure 27. Patient Reference Sensors (PRS) Placement Examples

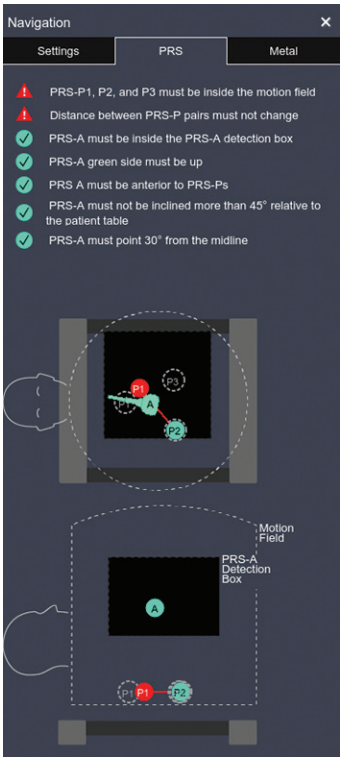


Field Frame connected, and all conditions satisfied.

Before the magnetic positional reference has been established or the first EnSite™ NavX SE point is collected in EnSite NavX™ mode or the first Sensor Enabled™ catheter enters the motion box in VoXel mode.

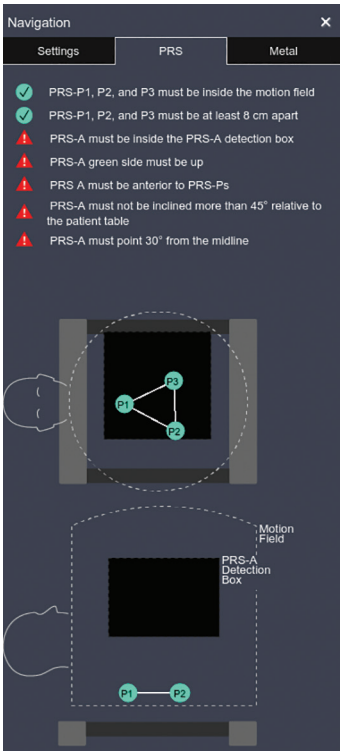
After the magnetic positional reference has been established or the first EnSite™ NavX SE point is collected in EnSite NavX™ mode or the first Sensor Enabled™ catheter enters the motion box in VoXel mode.





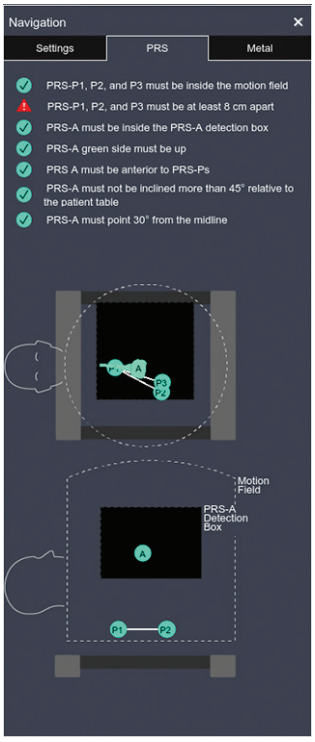
Two PRS-P (posterior) are out of the motion field.

Any PRS outside the motion field will not be shown. To resolve this condition, move the PRS into the motion field or adjust the field frame.



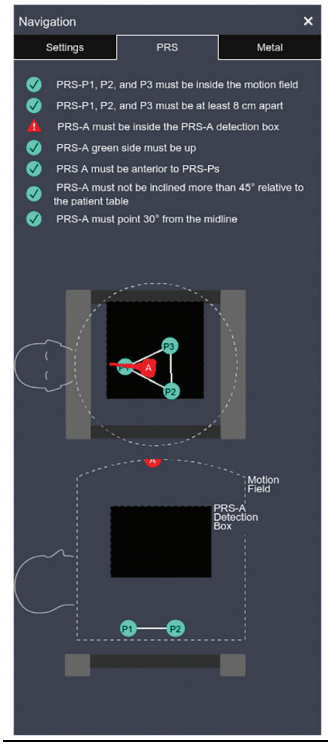
PRS-A (anterior) is out of the PRS-A detection box.

When PRS-A is out of the PRS-A detection box but inside the motion field, it will appear red. To resolve this condition, move the PRS-A or the field frame so that PRS-A is inside the PRS-A detection box while keeping PRS-A on top of the heart.



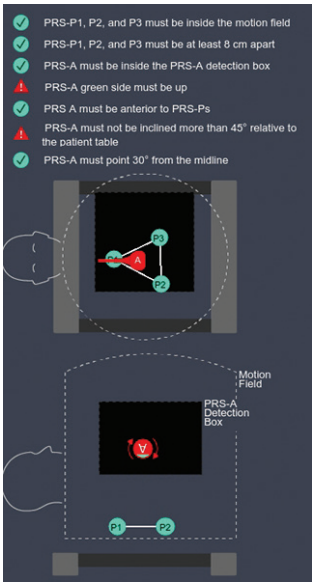
Distance between two PRS-P (posterior) is below 8 cm before the magnetic positional reference has been established.

To resolve this condition, move the PRS sensors further apart (8 cm minimum).



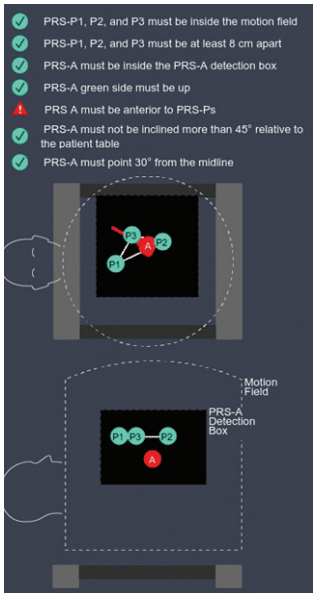
PRS-A (anterior) is out of the motion field.

Any PRS outside the motion field will not be shown. To resolve this condition, make sure PRS-A is connected and move the PRS-A into the PRS-A detection box or adjust the field frame while keeping PRS-A on top of the heart.



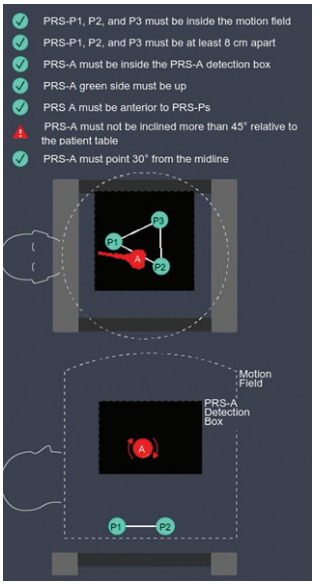
PRS-A (anterior) is upside down.

To resolve this condition, flip PRS-A so that the green side is up.



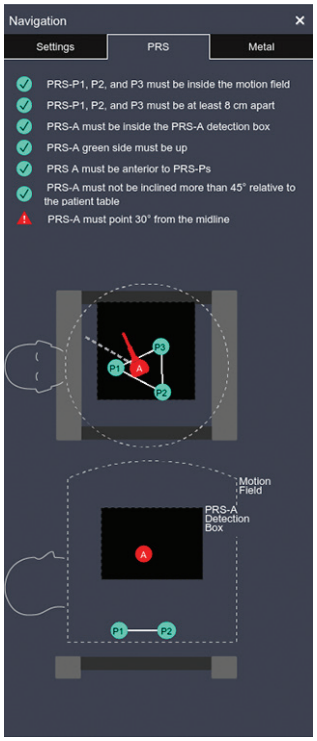
PRS-A (anterior) is not anterior to PRS-P1, -P2, and -P3.

To resolve this condition, place PRS-A on top of the heart and all PRS-P1, -P2, and -P3 on the back.



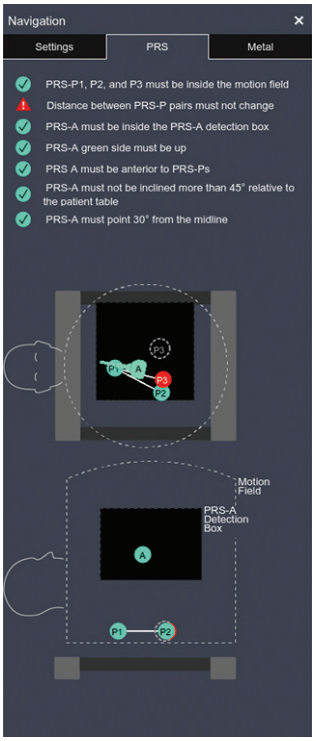
PRS-A (anterior) is inclined more than 45°.

To resolve this condition, place PRS-A on a flatter surface on top of the heart.



PRS-A is not pointing 30° from the midline towards the left shoulder.

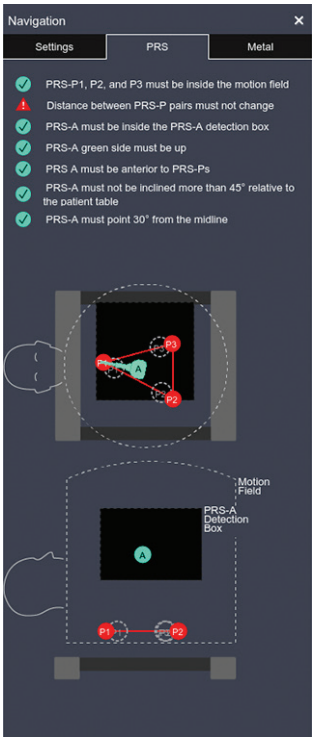
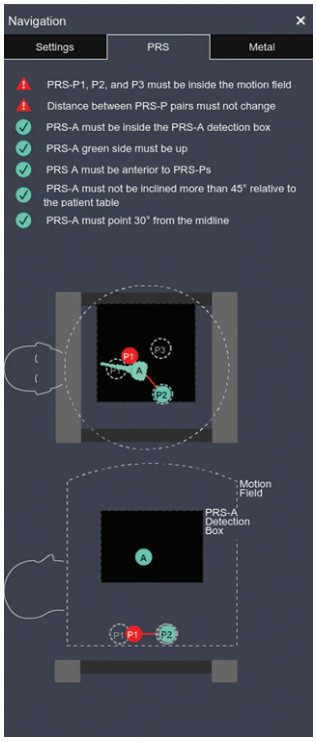
To resolve this condition, rotate PRS-A so that it points as shown in the dotted line.



One PRS-P has moved after the magnetic positional reference has been established. The distance between pairs of PRS-P has changed.

To resolve this condition, adjust PRS-P position so that it returns to the dotted circle position.

Alternatively, if you cannot return the PRS-P to its valid position you may reset magnetic positional reference by resetting the metal baseline or revalidating.

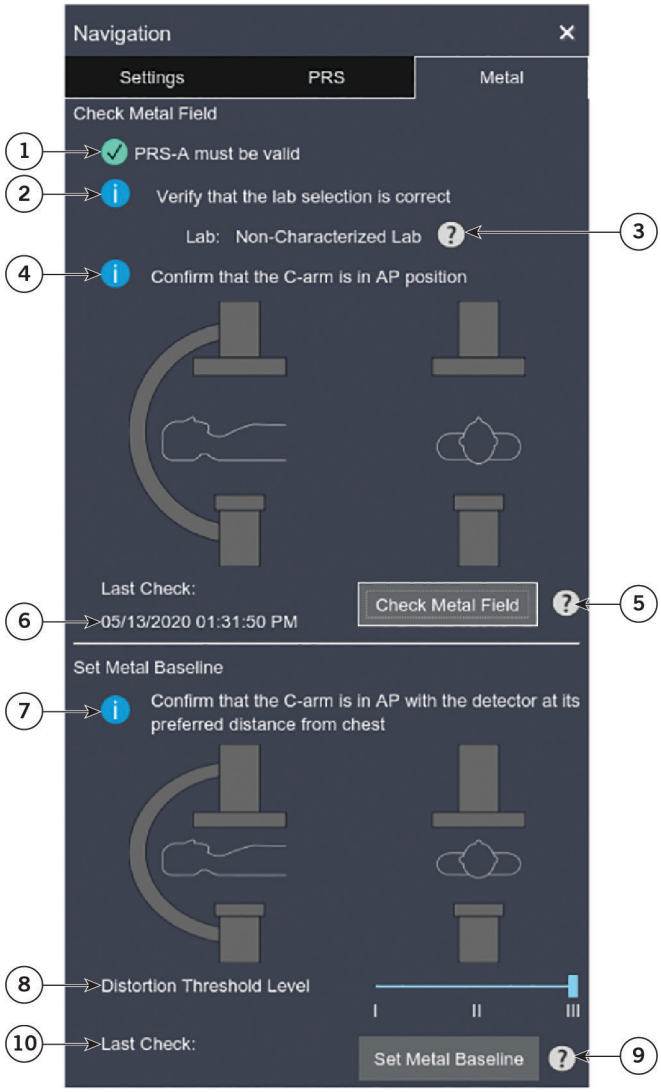
	Two or more PRS-P have moved after the magnetic positional reference has been established. The distance between pairs of PRS-P has changed. To resolve this condition, adjust PRS-P position so that sensors return to the dotted circle position. Alternatively, if you cannot return the PRS-P to its valid position you may reset magnetic positional reference by resetting the metal baseline or revalidating.		Two PRS-P are not detected in the motion field. Field Frame may have moved. To resolve this condition, adjust Feld Frame position so that sensors return the motion Field.

EnSite™ X EP System Setup, System Tab - Metal Sub-tab

The Check Metal Field and Set Metal Baseline must be performed to initiate the algorithm that corrects magnetic positions and simultaneously estimates the error due to metal distortion. Check Metal Field verifies that the metal field values match those collected during characterization when the C-arm was in AP on its highest position. Set Metal Baseline verifies that that the metal distortion error is less than the threshold and optimizes detection algorithm for the preferred C-arm height in AP. Both Check Metal Field and Set Metal Baseline must succeed prior to EnSite™ NavX SE point collection in EnSite NavX™ mode, or any 3D point collection in EnSite™ VoXel mode.

1. Check Metal Field
    a. Confirm the PRS-A location is valid.
    b. Confirm that the selected lab matches the current room.
    c. Confirm that the C-arm is placed in AP on its highest position.
    d. Click "Check Metal Field" button.
2. Set Metal Baseline
    a. Confirm that the C-arm is placed in AP on the preferred height.
    b. (Optional) Adjust metal distortion threshold level.
    c. Click "Set Metal Baseline" button.

Figure 28. Setup – System Tab – Metal Sub-tab



1. Indicates that the PRS-A location is valid. If the PRS-A location is not valid, return to PRS sub-tab to diagnose and fix the error. Check Metal Field and Set Metal Baseline will fail if the PRS-A location is not valid.
2. Reminds to verify lab selection.
3. Indicates the selected lab.
4. Reminds to confirm that the C-arm position is in AP on its highest position.
5. Check Metal Field button.
6. Indicates the time at which the last "Check Metal Field" succeeded.
7. Reminds to confirm that the C-arm position is in AP at its preferred distance from chest.
8. Distortion Threshold slider. Click and drag on the slider to adjust the metal distortion threshold.

   NOTE: The metal distortion threshold can also be adjusted from the metal distortion meter.
9. Set Metal Baseline button.
10. Indicates the time at which the last "Set Metal Baseline" succeeded.

    NOTE: The metal distortion meter will automatically show up in the modeling and map display after "Set Metal Baseline" succeeds.

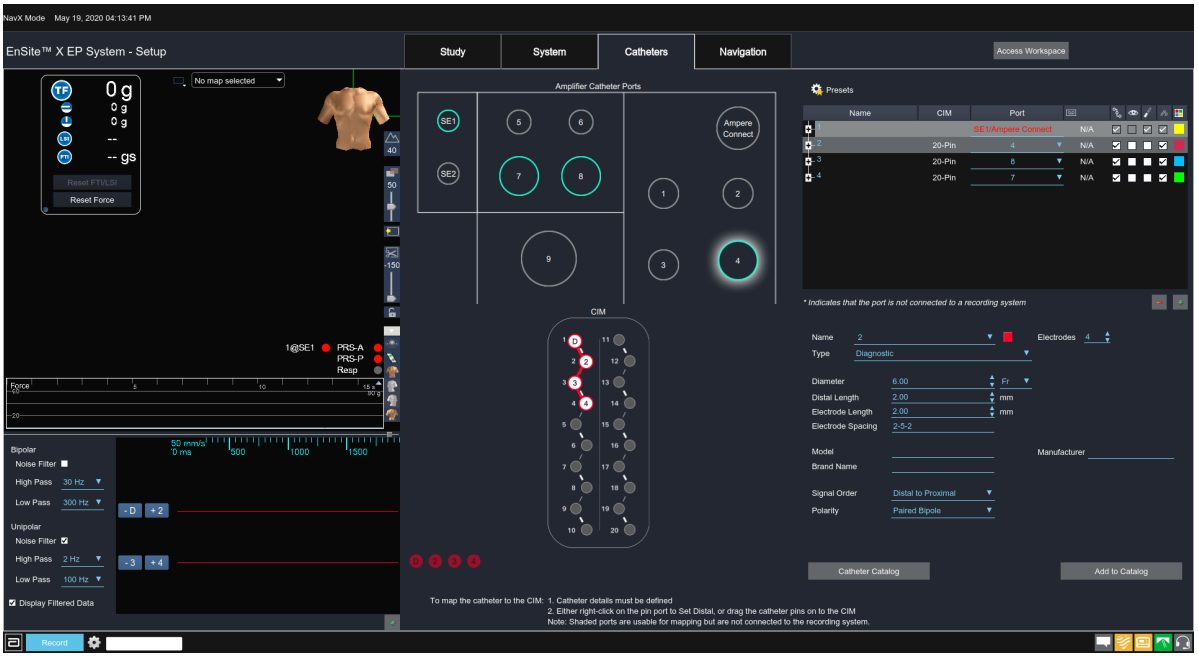
Distortion Threshold Level

When the distortion threshold level is exceeded, the collection of EnSite™ NavX SE points in EnSite NavX™ mode or any 3D points in EnSite™ VoXel mode will be suspended. In EnSite NavX™ mode, the default is Level III. In EnSite™ Voxel mode, the default and recommended threshold is Level II.

EnSite™ X EP System Setup, Catheter Tab

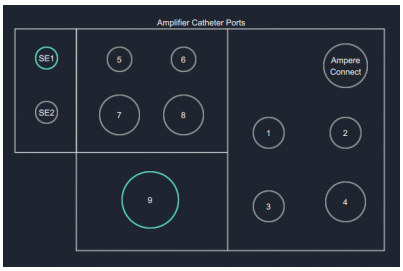
The figure below shows the full catheter setup screen. The following sections will describe the function of each area of the interface.

Figure 29. Setup - Catheters Tab



EnSite™ X EP System Setup, Catheter Tab - Amplifier Catheter Ports

Figure 30. Setup - Catheters Tab - Amplifier Catheter Ports



The following icons indicate the state of a port on the amplifier. They can be active (when a catheter extension cable or CIM is plugged in), inactive when nothing plugged in, highlighted when a row on the Catheter List associated with that port is selected, and red (with a triangle) which indicates that the catheter isn't fully defined.

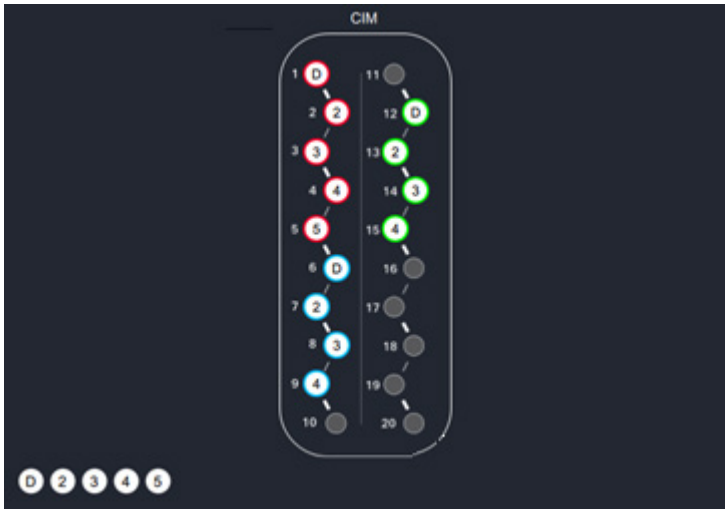
	Grey	Inactive when there no is connection detected at the port.
	Green	Active when there is a catheter extension cable or CIM connected to the port that is fully set up. NOTE: only active ports are selectable. Selecting results in highlighting the associated row on the Catheter List (which also then causes the port to be highlighted with a halo). If a selected port has a CIM connected, and the CIM has more than one catheter connected to it, the first catheter on the list is highlighted.
	Haloed	Indicates the port associated with the row that is currently selected on the Catheter List.
	Red	The red outline and triangle indicate that a CIM or catheter is connected, but the catheter is not fully defined. NOTE: this can appear on both active ports (shown) and haloed ports (not shown).
	Green/Grey	Indicates the recording system channels that are connected to the port. This can be green or grey depending if the recording system is connected or not. The numbers do not change colors. The numbers appear if the recording cable is connected and blank when not connected. If the image in the last row is there, then all the ports in that section should have numbers, regardless of if catheters are active or not.
		Indicates which block of ports are connected to the recording system on the amplifier's rear panel (catheter bank 1, 2A or 2B). Image shows connections at bank 1 (AmpereConnect and ports 1-4) and 2A (port 9). Bank 2B is the box containing port 9 for future use.

EnSite™ X EP System Setup, Catheter Tab - Catheter Input Module (CIM) Display

A graphic representation of the Catheter Input Module (CIM) will appear on the display when the CIM is connected to the Amplifier.

WARNING: Do not connect ablation catheters to CIM modules. The CIMs are low voltage components and ablation catheters are high voltage. Equipment damage may occur.

Figure 31. Setup - Catheters Tab - Catheter Input Modules (CIM) Display



1. Catheter – Red, Green, and Blue (represents the catheter color selected by user).
2. Catheter is selected – White fill and solid lines between pins.
3. Not used (available) ports.

Catheter Input Settings

Right click an electrode input channel in the CIM to display the options for the catheter representation.

Figure 32. Catheter Input Modules Settings

1. Visible checkbox
2. Connected checkbox
3. Set Positional Reference checkbox
4. Set Distal checkbox

1. Visible checkbox - Shows/hides the selected electrode.

   NOTE:

   - Making an electrode not visible will cause the system to not use the electrode's location information for EnGuide related functions such as collecting model points, making map tags, or 3D mapping information. Electrograms from the electrode will be available for viewing and measurement with calipers, but the electrograms will have "No Location" if displayed in Mapping Acquisition Waveforms. Mapping points will not be taken from electrodes with "No Location."
   - The visibility of non-functional electrodes on any catheter should be turned off.

2. Connected checkbox - Connects/disconnects the selected electrode. When an electrode is disconnected, its channel becomes available. To reconnect a disconnected electrode, select the electrode on the catheter image below the CIM representation.

3. Set Positional Reference checkbox - Allows the user to select an electrode that will remain stable during the study to be the positional reference. The displayed position of all electrodes is relative to the location of the positional reference.

   NOTE: Set positional reference is only available in EnSite NavX™ mode.

4. Set Distal checkbox - Moves all electrodes on a selected catheter to new input channels. To move the electrodes, select the catheter in the Catheter List, position the mouse over the new distal input channel of choice, right- click and select Set Distal. The input channel positions can also be manually moved by selecting and dragging the displayed electrodes.

Assign or Reassign CIM Pins

System automatically assigns the distal electrode to the first available channel and other electrodes in sequence. Connection to Ampere Generator using the AmpereConnect port is permanently pinned out to recording channels 53-56.

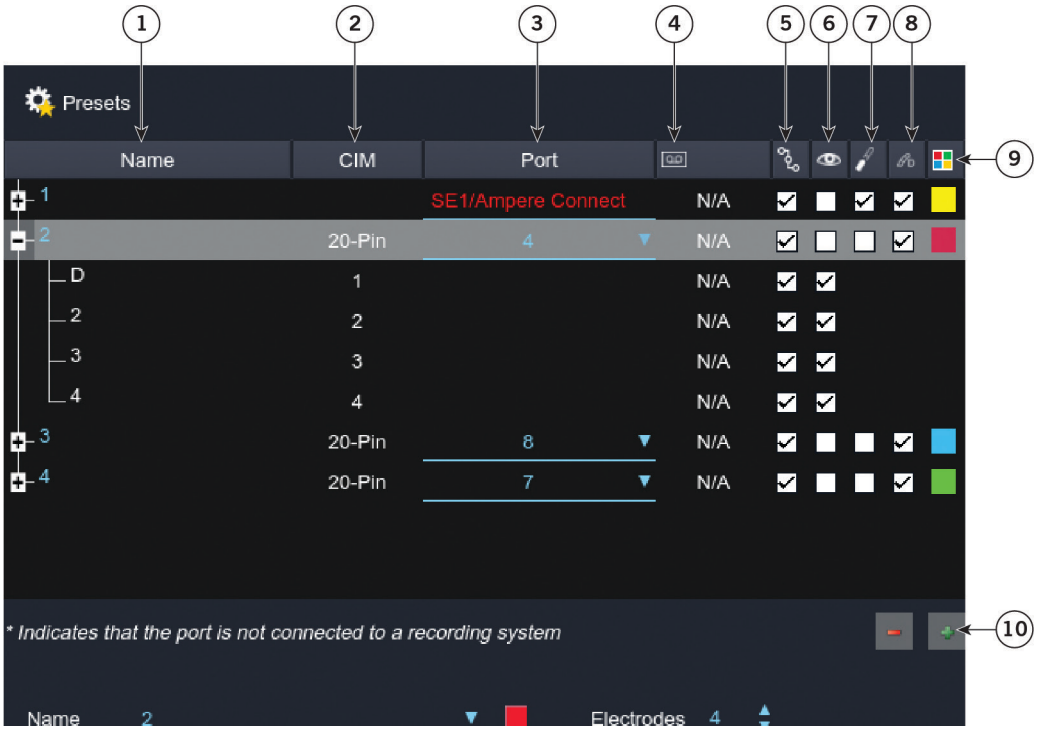
1. Select a row in the catheter list.
2. Right-click on the desired pin channel on the CIM diagram and select Set Distal.

or

1. Select and drag a catheter electrode to a pin channel.

EnSite™ X EP System Setup, Catheter Tab - Catheter List

Figure 33. Setup - Catheters Tab - Catheter List



The following describes the Catheter List Table:

1.	Individual Catheter Recording Channels The catheter name defaults to a number and the user can then define the name of the catheter.	The List displays with expandable/collapsible tree for each catheter. User may scroll up and down the list. Double clicking allows the user to change the name.
2.	CIM (Catheter Input Module)	Displays the CIM type, 20 pins. When the tree is expanded for a catheter connected to a CIM the CIM column displays the CIM port.
3.	Port (Amplifier Port)	Displays the amplifier port in which the catheter is plugged into. The port drop-downs lists: ports 1-9. Once a Sensor Enabled™ catheter is connected to the port, the dropdown feature is removed and if a Sensor Enabled™ catheter is on the list but not yet plugged in, the "-" option is inactive. Red text is used to indicate (1) ports that are specified but do not have anything connected (for example after a preset is applied but before a catheter is connected), and (2) indicating that a port has something connected but it is unidentified.
4.	Recording Channels	This column indicates which recording channels are being used by the recording system. In the case of a CIM where the ports are not pinned sequentially, the field lists the lowest number channel being used followed by an ellipsis point (that is, "...").
5.	Connected	Allows the user to connect or disconnect individual electrodes on the catheter.
6.	Visible	Show or hide a catheter in the navigation area.
7.	Sheath Filter	Turn on or off sheath filter for the selected catheter.
8.	Show Electrode Numbers	Show or hide the electrode numbers on the catheter being displayed. Requires Show Electrode Numbers to also be selected from the Display Settings panel.
9.	Color	Select the color the catheter is displayed as.
10.	Add/Remove a catheter from the Catheter List	Select + (plus) button to add a catheter to list. Select – (minus) button to remove a catheter from the list: Select and press OK to confirm. Unplug catheter cable from the Amplifier port.

Adding and Deleting Catheters to a Study

Catheters may be added to a study using four methods:

1. Auto-recognition when using magnetic catheters (Sensor Enabled™ tools).
2. Utilizing the Catheter Catalog.
3. Manually defining Catheter parameters.
4. Selecting a catheter preset.

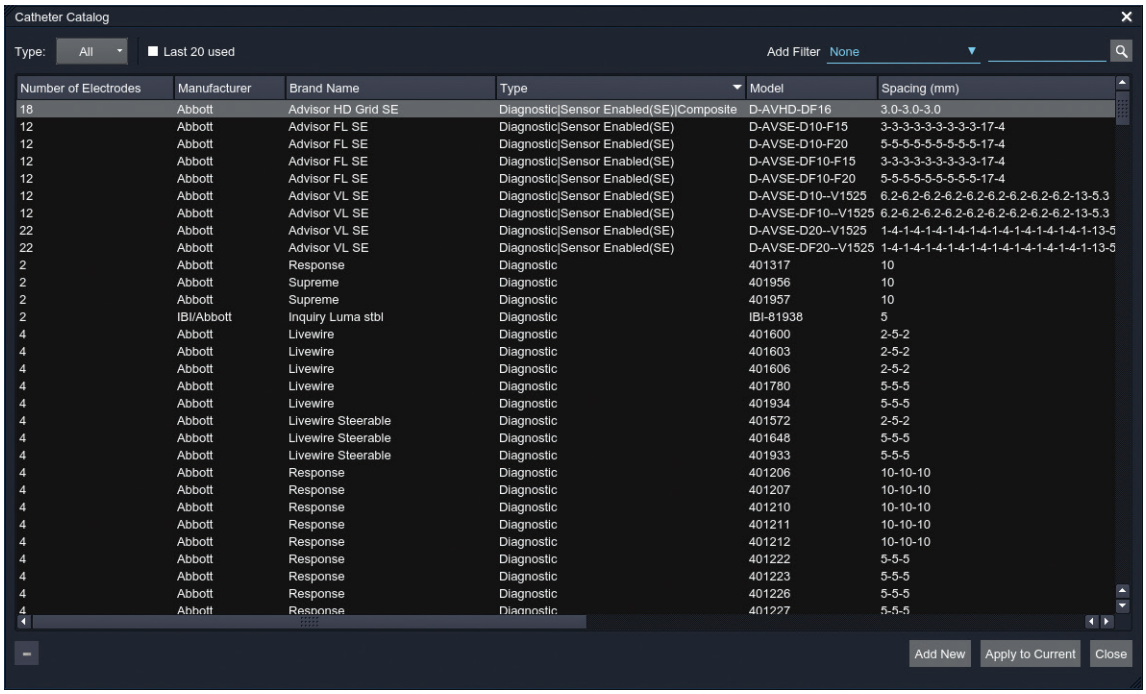
Auto-recognition of Sensor Enabled™ Catheters

When a Sensor Enabled™ catheter is connected, the system automatically adds its attributes.

Catheter Catalog

The catheter catalog contains many pre-defined Abbott catheters typically used in electrophysiological (EP) studies. Users may also define their own catheters and add them to the catalog for future use.

Figure 34. Setup - Catheters Tab - Catheter Catalog



To add a catheter to the Catheter List from the Catheter Catalog:

1. Select the Catheter Catalog button. The catalog screen opens.
2. Choose the desired catheter from the catalog list.
3. Select the Add New at the lower right of the catalog screen.
4. Choose more catheters or close the catalog screen with the Close button at the lower right corner of the catalog screen.

To redefine a catheter already in the Catheter List using the Catheter Catalog:

1. Highlight the catheter to be redefined in the Catheter List.
2. Select the Catheter Catalog button. The catalog screen opens.
3. Select the desired catheter in the catalog list.
4. Select Apply to Current at the lower right corner of the catalog screen. "Apply to Current" takes the currently selected catheter in the Catheter Catalog and copies its settings to the currently selected catheter in the Catheter List.
5. Choose more catheters or close the catalog screen with the Close button at the lower right corner of the catalog screen.

The selected catheter's attributes will populate the applicable property setting fields, and the catheter's distal electrode will be automatically assigned to the first available input. Subsequent electrodes will be placed in consecutive inputs, if available.

- The catheter name can be modified by double selecting on the name in the Catheter List or in the Name field (four-character limit). The name can also be modified by selecting a system default name from the drop-down list in the Name field.
- Modify any editable properties, if necessary.

  NOTE: Only diagnostic catheters added using the catalog can be modified.

Reassign any input channels, if necessary.

Filtering and Sorting the Catheter Catalog List

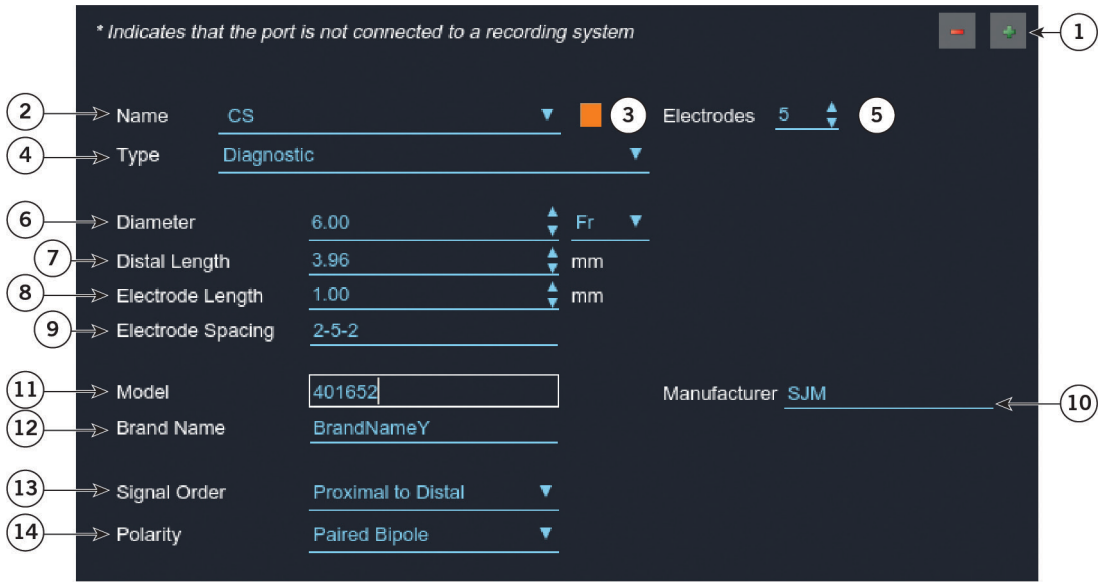
Users may scroll up and down the catheter list and select the appropriate catheter for the procedure. The catalog may contain many catheters. Several tools have been provided to aid in the selection of a catheter.

- Filter by Type: Select the pull-down menu to choose catheters by Type.
- To sort the catalog by a column heading alphabetically/numerically, select the column heading.
- To search for specific catheter, select the column heading type from Add Filter drop-down menu then type the desired search text in the text box.

When the desired catheter is located, select the Add New button and it will be added to the Catheter List and the catheter parameters will be automatically populated.

Manually adding a Catheter to the Catheter Catalog

Figure 35. Setup - Catheters Tab - Manually Adding a Catheter to the Catalog



1. Select the + button beneath the Catheter List.
2. Enter a catheter name (up to four alphanumeric characters) or choose a system default from the drop-down menu.
3. Select a color for the catheter body. The color of the waveforms for the catheter defaults to the color selected for the catheter body.
4. Select the Type.
5. Specify the number of electrodes. When specifying the number of electrodes, the electrodes will be assigned to consecutive input channels starting with the distal electrode assigned to the first available channel.
6. Specify the Diameter.
7. Specify the Distal Length.
8. Specify the Electrode Length.
9. Specify the Electrode Spacing.
10. Specify the Manufacturer.
11. Specify the Model.
12. Specify the Brand Name.
13. From the Signal Order drop down menu, specify the order.
14. From the Polarity drop-down menu, specify whether signals should be collected from paired bipoles, all possible bipoles, or all possible unipoles.

    NOTE:

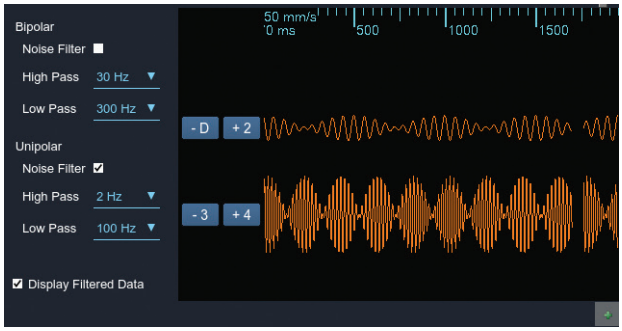
    - Electrode spacing is calculated from the edges of the electrodes.
    - If a catheter is to be used to collect Model points, and Field Scaling is to be applied, the electrode size and spacing information entered the catheter description must match the information provided by the catheter manufacturer.
    - Model points collected with catheters that are inappropriately described may yield unexpected EnSite™ NavX™ Field Scaling results. This cannot be corrected by re-entering correct information after the fact. However, EnSite™ NavX™ Field Scaling is an option which can be unapplied if unexpected results occur.

Catheter Signal Settings

Signals from the selected catheters in the Catheter List appear in the waveform display. Next to each trace are the electrodes that comprise the signal. In the instance of a bipolar signal, two numbers will appear. The number in the left column is the negative pole, and the right column is the positive pole. A trace can be configured as unipolar by setting the left electrode to the dash. The unipolar reference is the System Reference by default, but can be set to the Auxiliary Reference in the System Menu [References] Menu.

One or more waveforms can be selected for trace height adjustment. Traces should be smooth lines that are free of excessive noise. If traces contain excessive noise, check all electrode and cable connections between the patient and the EnSite™ X Amplifier.

Figure 36. Setup - Catheters Tab - Catheter Waveforms Display



Add/Remove a Trace to a Catheter

1. Select a catheter in the Catheter List.
2. Select "+" (plus) button (on the lower left) will add a trace. By default, it will be a unipolar electrogram configured with the distal electrode set as positive (right column), with the reference set as the System Reference (or Aux Ref, if chosen) (left column).
3. You can also configure this trace as a bipole by changing the electrode configuration to any combination of electrodes on the same catheter.
4. To remove a trace, left-click a trace and drag it out of the screen to the left, to remove it.

Set Catheter Polarity

1. Select a catheter in the catheter list.
2. Select polarity from the "Polarity" drop-down menu (on the lower left) (Paired Bipole, All Bipole, Unipole).
3. Select the "Negative Pole" icon and set it to "---" to change signal to unipolar.
4. Select the "Negative Pole" icon and select the electrode to assign as the negative pole.
5. Select the "Positive Pole" icon and select the electrode to assign as the positive pole.

Manually Setting up a Bipolar and Unipolar Filters

1. Select a catheter in the catheter list.
2. Enable/Disable noise filter (checkbox) (on the lower left).
3. Set High Pass filter (drop-down list).
4. Set Low Pass Filter (drop -down list).

Configure Miscellaneous Signal Settings

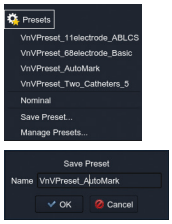
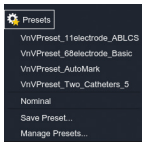
1. Enable/Disable display of filtered data (checkbox).
2. Select signal order (distal-proximal or primal-distal) (radio buttons).
3. Select signal trace and adjusting height/amplitude by clicking the middle mouse button and drag up/down to adjust trace height. A regular click and drag will just move the signal (change the order).

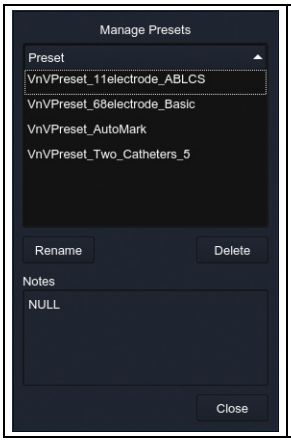
Deleting a Catheter from the Catheter Catalog

Choose the catheter to delete from the Catheter Catalog, select the [-] button.

NOTE: Only user-defined catheters can be deleted. The user cannot delete pre-populated Abbott catheters.

EnSite™ X EP System Setup, Catheter Tab - Catheter Presets

	To Save a Preset: To save the current catheter setup as a preset, open the Preset menu in the upper- left corner of the control panel and select Save Preset. In the Save Preset window, type a name for the preset, and then select OK.
	To Load a Preset: To load a preset for the current physician, open the Preset menu in the upper-right corner of the control panel and select a preset from the list. The menu lists the presets for the current physician followed by presets from other physicians. Select the desired preset and then select OK. NOTE: Loading a preset is equivalent to: - Deleting all the current catheters. - Defining the catheters in the preset, and then updating that list with connection status from the amplifier. - Loading a catheter preset will clear the intracardiac system reference and then set it to the value in the preset. To Use Default or Factory Settings Presets: Select Nominal from the Preset drop-down menu.



To Manage Presets: Select "Manage Presets" from Preset drop-down menu.

Rename a Preset: To rename the preset, double-click on the name then enter the new name, or select the preset to be renamed then select Rename.

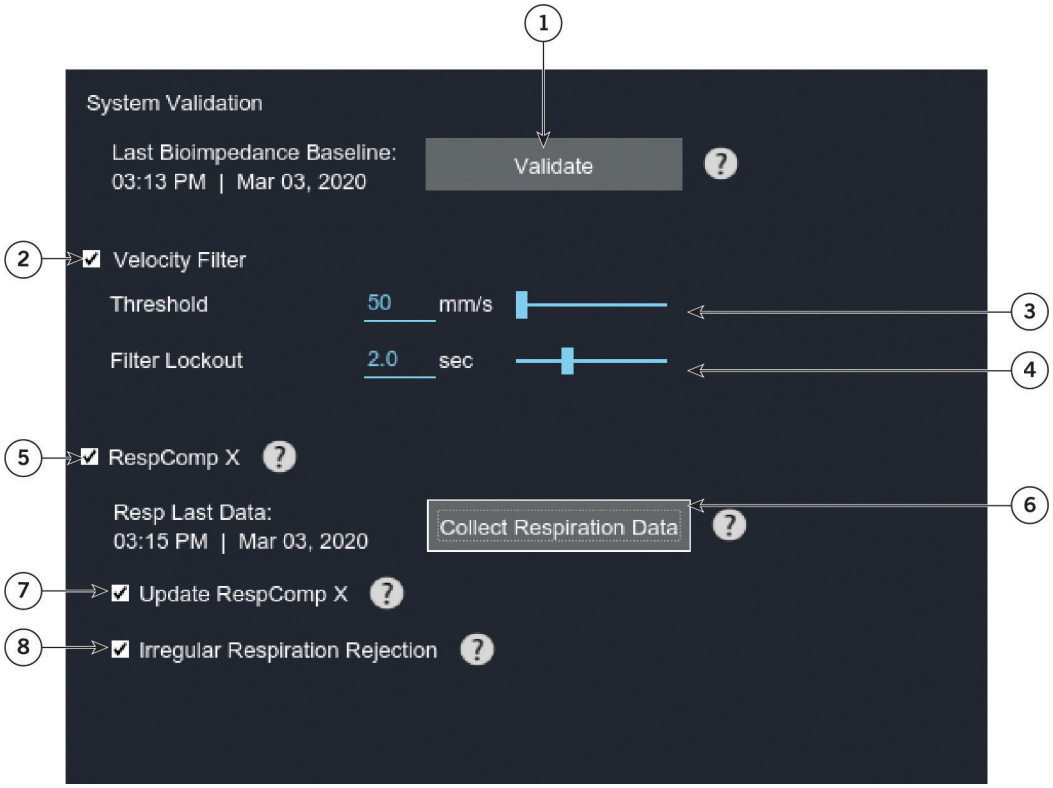
Delete a Preset: To delete a preset for the current physician, select a preset from the list in the Manage Presets window. To delete the preset, select Delete.

Add a Note to a Preset: To add a note for the preset, type in the Note text area. When the note is complete, select Close.

EnSite™ X EP System Setup, Navigation Tab

The navigation tab contains Setup controls that effect catheter navigation.

Figure 37. Setup - Navigation Tab - EnSite™ VoXel Mode



1. Validate button – Select to validate the surface electrodes and set the baseline for impedance measurements.
2. Velocity Filter checkbox – Turn on/off the velocity filter.
3. Threshold slider – Set the threshold of the velocity filter in mm/sec.
4. Filter lockout slider. Set the time (sec) when the system will collect model points after the Velocity filter returns to below threshold.
5. RespComp X checkbox – Select to enable respiration compensation.
6. Collect Respiration Data – Collect RespComp X data.
7. Update RespComp X checkbox – Select to continuously update respiration compensation.
8. Irregular Respiration rejection checkbox – Select to suspend data collection during irregular respiration events.

System Validation

The EnSite™ X Surface Electrodes are a single use device. The surface electrodes must be validated before system usage. Validation sets an 18-hour time period the electrodes may be used during a study. Validation also sets the baseline for impedance measurements.

A Validation should be performed as close as possible to creating the first model, map or 3D point.

NOTE: Validation may be performed earlier to verify electrode connections; in which case it is recommended to perform a second Validation just prior to creating the first model, map or 3D point.

Velocity Meter and Velocity Filter

The Velocity Meter shows the relative velocity of the fastest unsheathed enabled electrode of the Active EnGuide (white bar) and the velocity threshold (the transition between the black and grey backgrounds). The meter's border, normally white, flashes red if the velocity exceeds the velocity threshold. Enable the Velocity Meter from the Meters and Display Options Setting Panel. The Velocity meter can be moved within the Model/Map display area.

The Velocity Filter prevents model point collection during rapid catheter movements. When the velocity of any electrode used to collect model points exceeds a user-specified rate (threshold), the meter will highlight with a red border, the catheter electrodes will turn yellow, and model point collection is suspended only for those electrodes exceeding the threshold for a user-specified period of time (Filter Lockout).

Model point collection resumes after the lockout period only if the velocity of all electrodes has returned to a value below the velocity threshold. Velocity Filter settings are active only during model creation.

To display the Velocity Filter controls:

1. Select Navigation Settings Panel or through the Navigation Tab of the Setup Panel.
2. Select Velocity Filter checkbox to turn it on, uncheck to turn the filter off.
3. The Velocity threshold can be set by moving the slider.
4. Use the Filter Lockout in Seconds slider to set the collection lockout period.
5. The velocity threshold can also be adjusted using the meter display.
6. When the cursor hovers over the boundary line, a vertical blue line appears and can be used to adjust the threshold with the mouse.

Figure 38. Velocity Meter

Velocity Meter - The Velocity Meter shows the relative velocity of the fastest unsheathed enabled electrode of the Active EnGuide Active Electrode.

Velocity Threshold change indicator – The threshold line turns blue when the user hovers close to the threshold. When the line is blue a left-mouse click will adjust the Velocity Threshold. If the line is not blue, a left-mouse click will move the entire meter.

RespComp X

The RespComp X feature is used to compensate for catheter movement caused by a patient's breathing. The Irregular RespComp X feature is used enhance 3D point collection by suspending 3D point collection and labeling functions during unstable events. It may facilitate more consistent model creation and improve navigation stability while mapping and placing lesion markers.

Before RespComp X can be used, the system needs to briefly monitor the patient's respiration to collect respiration data and calculate a respiration range.

During respiration data collection, all catheters must be in stable positions; then, over a period of 12 seconds, the system collects the x-y-z coordinate of all located electrodes and the impedance values of all EnSite™ X surface electrodes. The system identifies respiration by a gradual rise in intrathoracic impedance of the EnSite™ X surface electrodes. The lowest and highest impedance values sampled during data collection define the respiration range. This range is referred to as the RespComp X range.

When respiration data collection is complete, an automatic segment is recorded, and RespComp X monitors the EnSite™ X surface electrodes for the impedance pattern of respiration; when respiration occurs, navigation on each electrode is gradually compensated in correlation with the degree of the impedance change.

When RespComp X is applied, the system will continually monitor the respiration motion of the catheters; the system gradually updates the compensation values throughout the study when the individual catheters are in a stable position and compensates to the end phase of respiration.

NOTE:

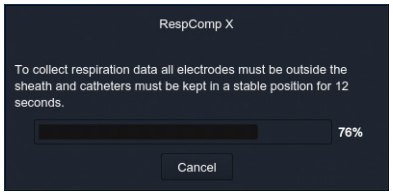
- If a new electrode is defined or catheter is introduced after respiration data collection completes, the user should recollect RespComp X data for the system to apply compensation to the newly added components.
- Visibility of bad electrodes on a catheter should be turned off so RespComp X can successfully be applied to a catheter.
- RespComp X is not applied to the Positional Reference electrode in EnSite NavX™ Mode.
- RespComp X data can be collected at any time during a study.

Collecting Respiration Data

Be sure the patient is in a stable respiration pattern and that all catheters are in stable positions.

1. Select Collect Respiration Data. Data collection takes approximately 12 seconds. During this time, a progress box is displayed. When data collection is complete, RespComp X is applied, and Update RespComp X and Irregular Respiration Rejection are turned on.
2. To disable RespComp X turn off the RespComp X checkbox. The most recent compensation values are saved and can be re-applied at any time.

Figure 39. RespComp X Progress Bar



To cancel RespComp X Data collection. select the Cancel button on the progress box. When RespComp X Data collection is canceled, Update RespComp X and Irregular Respiration Rejection are turned off.

NOTE: If desired, a respiratory waveform computed from surface electrode impedances can be displayed in the Waveform Display and the Respiration Meter.

Respiration data can be re-collected at any time during a study. The re-computed RespComp X values replace all previous RespComp X values.

Re-collecting respiration data is recommended for any of the following situations:

- Adding a catheter or electrodes not present during initial Respiration data collection.
- Significant movement of the catheter within the heart (for example, left atrium to right atrium).

- Significant changes in respiration, such as moving the patient onto or off a ventilator.
- Any time undesired respiratory motion is visible during catheter navigation.
- After the user resolves any EnSite™ X surface electrode errors.

Update RespComp X

Update RespComp X continuously monitors respiration and adapts the compensation applied to any slow changes in the respiratory pattern. When Update RespComp X is turned off, the system will use the most recently collected data as the RespComp X baseline. Update RespComp X begins again approximately 12 seconds after being turned back on.

Irregular RespComp X

The Irregular RespComp X feature is used to suspend model point collection and labeling functions when the patient's respiration falls outside of a percentage of the RespComp X range.

When Irregular RespComp X is enabled, and irregular respiration is detected, the Respiration Meter outline flashes red, and all displayed electrodes flash yellow, and the following functions are suspended.

- Model point collection.
- Map labels at the Active Electrode.
- Lesion markers at the Active Electrode.
- Shadow at selected EnGuide.
- Map point collection.
- VoXels (in EnSite™ VoXel mode).

Normal system functionality returns approximately 12 seconds after stable respiration returns.

Uncheck the Irregular Respiration Rejection checkbox to turn off.

Respiration Meter

The Respiration Meter displays the respiration waveform and provides visual indication of respiration compensation. The respiration meter controls are in the Meter & Display Options Settings Panel. The Respiration Meter will display by default when Respiration Data has been collected. Once the Respiration Meter is displayed the user can right select the meter and a right select menu will appear. The options are to turn off or change the time length of the respiration meter display. When irregular respiration is detected the meter will highlight in red color and the portion of the waveform that is irregular will change to a red dashed line.

Figure 40. Respiration Meter and Options

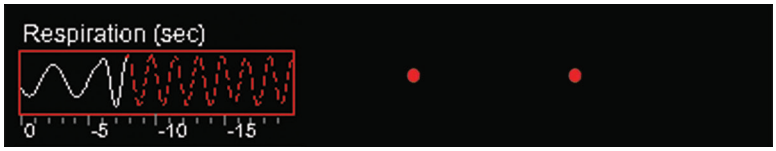
1. Respiration Meter – displays the respiration waveform and provides visual indication of respiration compensation.
2. Right-click Respiration menu – right-click on the respiration meter to see the Respiration menu.
3. 10-sec & 20-sec screen radio buttons – select a radio button to set the total viewable area of the Respiration meter.

Respiration Data Indicator

Figure 41. Respiration Data Quality Indicator

The Respiration Data Quality Indicator shows respiration compensation status and is in the lower right corner of the model display workspace panel.

The table below shows the relationship of the irregular respiration rejection setting to the respiration indicators based on the respiration pattern.

Irregular Respiration Rejection	Respiration Pattern	Respiration Meter	Respiration Data Indicator
ON	Regular		
ON	Irregular		
OFF	Regular		

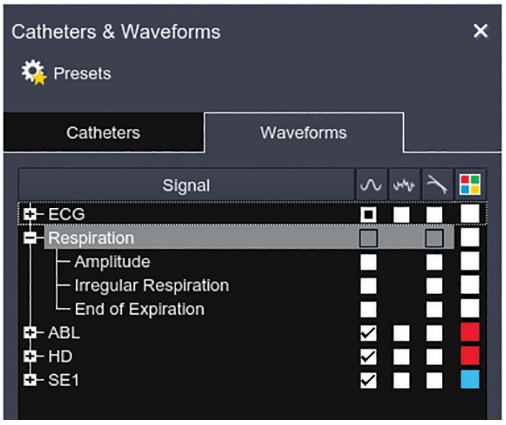
OFF	Irregular	

NOTE: Complete patient apnea will trigger irregular respiration approximately 10 seconds after detection of the respiration change.

Respiration Waveforms

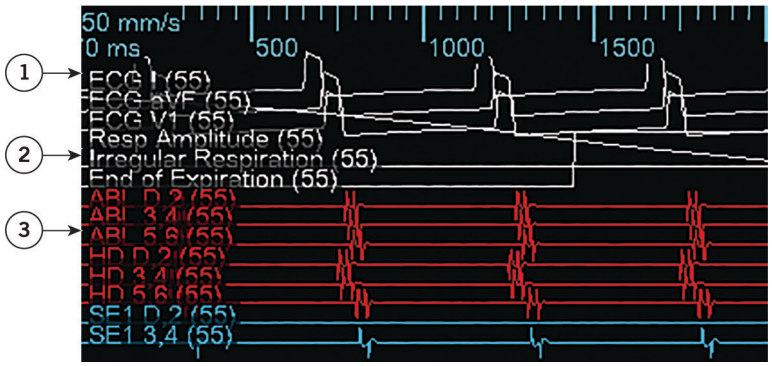
Select the waveforms to display from the waveforms list.

Figure 42. Respiration Waveforms list



1. The respiration waveforms can be enabled using the waveform list.

Figure 43. Respiration Waveforms Display screen



1. Respiration Amplitude Waveform: the same data as displayed in the respiration meter.
2. Irregular Respiration Waveform: "1" high state indicates respiration is irregular. "0" or low state indicates respiration is regular.
3. End of Expiration Waveform: "1" or high state indicates end-phase of respiration. "0" or low state indicates respiration is all other cases.

NOTE: Line turns purple if there is no data to calculate the respiration waveform.

EnSite™ X EP System Setup, Navigation Tab - EnSite NavX™ Mode

The images below show the options within the Navigation tab when operating in EnSite NavX™ Mode.

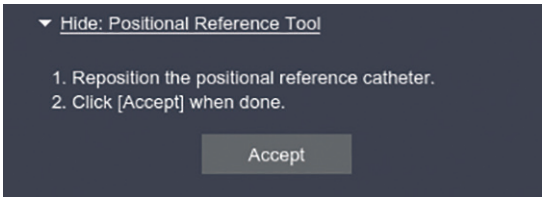
Figure 44. Setup - Navigation Tab - EnSite NavX™ Mode

1. EnGuide Stability Monitor checkbox – Enable/Disable EnGuide Stability Monitor.

2. Distance Threshold slider – Controls the distance at which the EnGuide Stability Monitor triggers an alert to the user.
3. Electrode drop-down menu – Select the System Reference (default) or intracardiac electrode for the Positional Reference Tool.
4. Catheter in desired location checkbox – Enable to confirm that the catheter chosen for the Positional Reference Tool is in the desired location.
5. Enable Positional Reference Tool checkbox – Enable to turn on Positional Reference Tool monitoring.

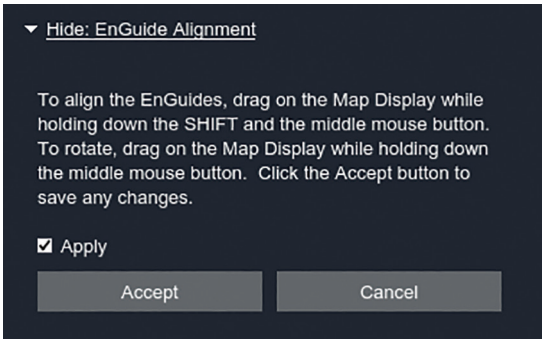
Figure 45. EnSite NavX™ Navigation Methods

EnSite NavX™ Mode, Positional Reference Tool



1. Show: Positional Reference Tool drop-down menu – Instructions and options to correct a Positional Reference Tool Catheter Dislodgement warning.
2. Accept button – Select Accept when the positional reference catheter is in the desired location.

EnSite NavX™ Mode, EnGuide Alignment



1. Show: EnGuide Alignment drop-down menu – Instructions and options to use the EnGuide Alignment feature.
2. Apply checkbox – Enable to apply the desired EnGuide Alignment.
3. Accept button – Select to Accept user changes to EnGuide Alignment.
4. Cancel button – Select to Cancel user changes to EnGuide Alignment.

EnGuide Stability Monitor (EnSite NavX™ Mode Only)

The EnSite™ X EP System can check for unexpected changes in Sensor Enabled™ EnGuide locations. If the system provides a message that instability has been detected, check for rate or rhythm changes, respiratory changes, or patient movement. If required, use EnGuide Alignment to adjust the alignment of EnGuides relative to the model. Also, check the status of the Metal Distortion Meter. If the distortion threshold is exceeded, there could potentially be a shift in the magnetic sensor positions caused by the presence of metal in the EnSite™ X EP System magnetic Field.

NOTE: The EnGuide Stability Monitor only works when actively tracking Sensor Enabled™ EnGuide locations. A Sensor Enabled™ catheter is required to be in the body, with EnSite™ NavX SE Field Scaling applied.

Show Positional Reference Tool (EnSite NavX™ Mode Only)

The Positional Reference Tool is a software feature available when operating in EnSite NavX™ mode procedures with an intracardiac positional reference selected. This feature alerts the user when there has been acute movement of the positional reference catheter. It is designed to detect sudden movement of the positional reference catheter along its long axis that exceeds a preset distance threshold of 4mm.

This feature requires that the positional reference catheter be in a stable location throughout the procedure. It is recommended that the coronary sinus (CS) catheter be used for this purpose. The Positional Reference Tool is intended to be used with a multi- electrode positional reference catheter and requires that the positional reference catheter consist of at least 4 electrodes. The Positional Reference Tool detects positional reference catheter movement by comparing the current position of the positional reference electrode to its past position. The Positional Reference Tool examines all the electrodes on the positional reference catheter to confirm that the detected movement is due to actual physical catheter dislodgement.

By default, this feature is not enabled; however, the user can enable or disable this feature at any time during the procedure. If positional reference catheter movement is detected, the user is provided with several methods to manage the repositioning of the catheter.

NOTE: The Positional Reference Tool can only be enabled if the positional reference catheter has at least 4 electrodes. If fewer than 4 visible electrodes are defined, the Positional Reference Tool will not activate, even if the user attempts to set up and enable the feature.

Setting Up the Positional Reference Tool (EnSite NavX™ Mode Only)

NOTE: The Positional Reference Tool requires that the positional reference catheter be in a stable location. It is recommended that the coronary sinus (CS) catheter be used for this purpose.

The Positional Reference Tool requires a minimum of 4 visible electrodes on the positional reference catheter. The visibility of bad electrodes on the positional reference catheter should be turned off.

Follow these steps to set up the Positional Reference Tool:

1. Select the positional reference catheter and positional reference electrode from the Positional Reference drop-down menu.
2. When the catheter is in the desired position select the Catheter Desired Location checkbox.
3. Select the Enable Positional Reference Tool checkbox.

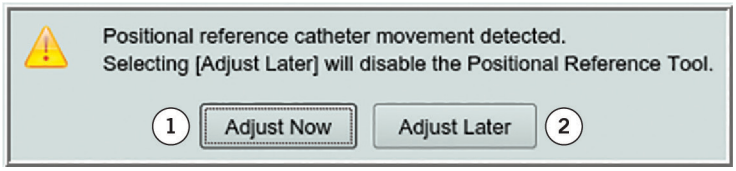
The system will display a progress bar while the Positional Reference Tool is being enabled. The catheter must be kept in a stable position and not disturbed for the duration of the Positional Reference Tool's initialization.

NOTE: Initializing the Positional Reference Tool takes approximately 10 seconds from the time that the Enable Positional Reference Tool checkbox is selected

Positional Reference Catheter Dislodgement (EnSite NavX™ Mode Only)

When the Positional Reference Tool detects that the positional reference catheter has moved at least 4mm from its previous location, a message will be displayed. The Positional Reference Tool message gives users the option to take immediate action (select Adjust Now) or to act later (select Adjust Later).

Figure 46. Positional Reference Catheter Movement Error Message



1. Adjust Now button – select to take immediate action
2. Adjust Later button – select to defer action to a later time

CAUTION:

- **Model points, mapping points, and map tags (labels, lesions, shadows, etc.) placed at EnGuide within approximately 15 seconds prior to notification of dislodgement may not be based on the previous location of the positional reference catheter. The user should confirm whether these points are valid.**
- **If the Adjust Later button is selected, the user must be aware that any tasks that rely on the positional reference catheter's location may be affected. These tasks include collecting model points, collecting mapping points, placing labels, placing lesions, etc.**
- **The Positional Reference Tool will not monitor positional reference catheter dislodgements if Adjust Later is selected.**
- **If the system notifies the user of both a surface electrode error and a Positional Reference Tool dislodgement message, the surface electrode error should be addressed first.**
- **If the system notifies the user of both a surface electrode error and a Positional Reference Tool dislodgement message, the user should verify that the positional reference catheter has physically moved after addressing the surface electrode error.**
- **Sudden impedance changes of the body or catheter electrodes caused by the connection of other devices (for example, stimulator, defibrillator, and other devices) may trigger the Positional Reference Tool. The user should verify the movement before accepting the adjustment.**

Managing Positional Reference Catheter Dislodgement

Managing the dislodgement of the positional reference catheter is done in the Navigation Setup Sub-tab or the Navigations Settings Panel.

- If Adjust Now was selected at the time of dislodgement notification, the system will immediately enter the Navigation Setup Sub-tab.
- If Adjust Later was selected at the time of dislodgement notification, the user will need to manually enter the Navigation Setup Sub-tab or the Navigations Settings Panel.

When the Navigation Setup is entered (either by selecting Adjust Now or manually selecting the Navigation sub-tab ask in the Setup workflow) the display will show the current location of the positional reference catheter as well as a preview of where the other catheters will be located if the adjustment is accepted. A yellow sphere will surround the previous location of the selected electrode on the positional reference catheter and a dashed line will connect the current location of the selected electrode with the previous location of that same electrode.

The user should assess the validity of the positional reference catheter dislodgement prior to selecting the Accept button in the Positional Reference Tool screen. The steps below discuss how to assess the validity of the dislodgement prior to accepting the new positional reference electrode location. With the Positional Reference Tool screen open:

- Assess the position of all the catheters within the field relative to the created geometry and other known landmarks.

Validate Against Fluoroscopy (if needed)

If the user does not think the catheters are shown in the appropriate locations, the user can disable and then re- enable the Positional Reference Tool by using the check box. This will disregard the notification and will not update the position of the catheters.

If the user does think the catheter are shown in the appropriate locations, the user has two options based on the perceived future stability of the positional reference catheter:

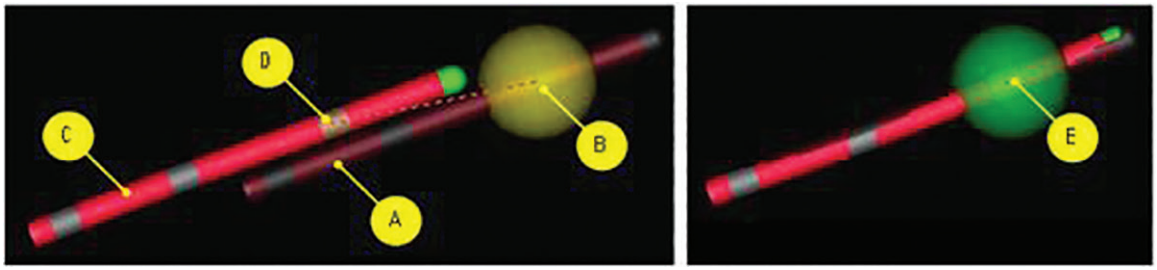
1. Manually reposition the catheter until the positional reference electrode is back to the original electrode location.

OR

2. Accept the new positional reference catheter location without manually repositioning the positional reference catheter.

If the user chooses option manually reposition the positional reference catheter, the user can use the yellow sphere and dashed line as a guide (catheter movement will appear damped). To return the positional reference electrode to its previous position, move the positional reference catheter until the positional reference electrode moves into the yellow sphere and the sphere turns green. The yellow sphere will turn green once the selected electrode is within 4mm of the previous location. When satisfied with the readjusted position, select Accept. This will reset the Positional Reference Tool with the new coordinates of the selected electrode. When the user selects Accept the new location of the positional reference catheter is set. All other catheters will be displayed relative to this new position.

Figure 47. Adjusting Positional Reference



1. A and B show the previous position of the positional reference catheter and electrode.
2. C and D show the current position of the positional reference catheter and electrode.
3. To return the positional reference electrode to its previous position, move catheter C until electrode D is within the yellow sphere, in which case the yellow sphere will turn green.
4. E shows the positional reference electrode properly adjusted.

If the user chooses to accept the new positional reference catheter location without manually repositioning the positional reference catheter the user selects Accept and the system will reset the Positional Reference Tool with the new coordinates of the selected electrode. When the user selects Accept the new location of the positional reference catheter is set. All other catheters will be displayed relative to this new position. The user should ensure that the positional reference catheter is in a clinically appropriate, stable location before selecting Accept.

A progress bar (beneath the control panel) can be seen while the re- initialization is in progress. When complete, the system will be ready for continued operation. During that time, some catheters may temporarily appear to have shifted.

Re-initializing the Positional Reference Tool takes approximately 10 seconds from the time that the Accept button is selected.

NOTE: Whenever the user selects Accept, the positional reference must be kept in a stable position and not be disturbed for the duration of the Positional Reference Tool's re-initialization.

Show EnGuide Alignment (EnSite NavX™ Mode Only)

In the Navigation Setup Sub-tab, select Show EnGuide Alignment to initiate EnGuide Alignment. If there are changes in catheter location that cannot be adapted by navigating the positional reference electrode, EnGuide Alignment allows for visually realigning the catheter to the model along the x-y-z-axes.

EnGuide Alignment is used to visually adjust the alignment of EnGuides relative to the model. To align the EnGuides in the workspace, hold down the <Shift> key and the middle mouse button, and drag the mouse. While dragging the mouse, the EnGuides will move, but the model remains stationary. Use the middle mouse button to rotate the model. Use the Apply checkbox to switch between the aligned (checkbox on) and unaligned (checkbox off) states. When satisfied with the alignment, select Accept.

Sheath Filter

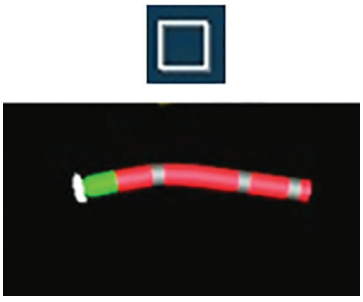
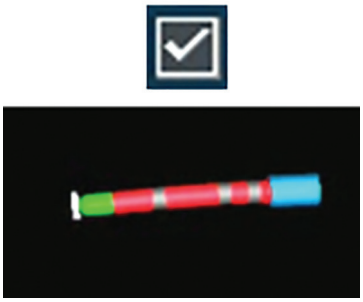
The Sheath Filter detects and provides visual feedback when all or part of a catheter is in the sheath. When an electrode is detected to be within the sheath, both visibility and data collection from the electrode will suspend.

A sheath graphic is drawn around the proximal catheter shaft to indicate that the sheath filter is active. The EnSite™ X EP System contains initial baseline setting for the Sheath Filter. The user may re-baseline the Sheath Filter to optimize performance.

NOTE: The Sheath Filter is compatible with the following 8.5F sheaths:

- Braided Swartz Transseptal Introducer
- Agilis NXT Introducer
- Baylis TorFlex
- BiosenseWebster MOBICATH

Figure 48. Sheath Filter States

Disabled	Enabled
	
Inactive	Blue colored sheath graphic. Sheath Filter is active

Sheath Filter for a Sensor Enabled™ Catheter

Sheath filter is automatically enabled for Sensor Enabled™ catheters. In EnSite™ VoXel mode, sheath filter cannot be disabled for Sensor Enabled catheters.

A Sensor Enabled catheter may be baselined to optimize performance at any time in a procedure. See rebaseline steps below.

Sheath Filter for a Standard Catheter

Sheath filter for standard catheters can be enabled or disabled in both EnSite™ VoXel and EnSite NavX™ Modes and is defaulted to "Disabled". When enabled, Sheath Filter will use initial system default settings for operation.

A standard catheter maybe rebaselined to optimize performance at any time in a procedure. See rebaseline steps below.

Enable/Disable Sheath Filter (not Available for Sensor Enabled™ Catheters in EnSite™ VoXel Mode)

1. Enabling/disabling the sheath filter for a standard catheter in the catheter list (checkbox).

OR

1. Right select the study workspace display.
2. Select "Sheath Filter".
3. Select catheter.
4. Then select Disable/Enable.

Figure 49. Set Baseline: from right-select Display menu (left) or Catheter Setup (right)

NOTE: Sheath Filter set baseline function is different from the Contact Force reset force button. Sheath Filter set baseline does not require a contact vs. non-contact position as when using a TactiCath™ ablation catheter, but rather requires that all electrodes be out of the sheath. Refer to the EnSite™ Contact Force Module Instructions for Use for additional information.

Re-Baseline Sheath Filter (Sensor Enabled™ and standard catheters, EnSite™ VoXel and EnSite NavX™ modes)

1. Perform the baseline procedure by first positioning the catheter with all electrodes out of the sheath when the catheter is not touching tissue or placed within the veins.
2. Begin the baselining procedure by selecting Set Baseline from the right-select Display Menu in the study workspace display.

OR

1. Right-selecting on the Sheath Filter icon in the catheter list item and selecting Set Baseline.
2. During the baselining process, a progress bar display in the lower-right area of the window.

   NOTE: The baselining procedure may fail if the system determines that electrodes are in the sheath. If baseline fails, the system will provide the option to revert to the default baseline settings or collect a new baseline.

Figure 50. Baseline Fail Message

NOTE: If the Sheath Filter is falsely triggering, a new baseline may be required.

Workspace

Realtime Mode vs Offline Mode

The EnSite™ X EP System can display data in two modes: Realtime and Offline Review. The display mode determines which system functions are available and are independent from navigation aids.

Realtime Mode allows data to be gathered, displayed, and recorded simultaneously while a patient is being studied. Patient connections to the EnSite™ X Amplifier are required, and the EnSite™ X Amplifier must be powered on.

Offline Review Mode allows data from a previous study to be viewed and edited. The EnSite™ X Amplifier does not need to be connected or powered on.

The functions available in Offline Review Mode are more limited than those available in Realtime Mode. The table below describes the functions that are available in each Mode.

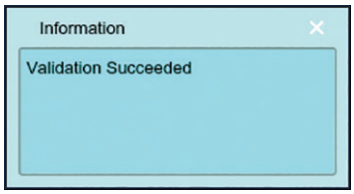
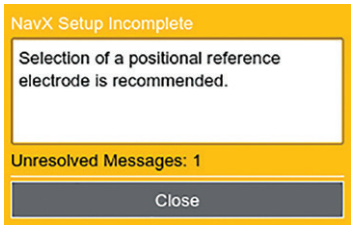
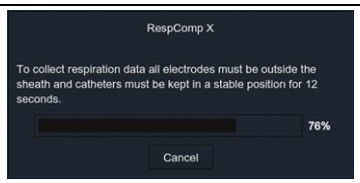
Table 2. Functions available in Realtime Mode and Offline Review Mode.

Task	Realtime	Offline Review
Setup	All	Shows a historical view of the study setup which is primarily read-only If viewing a segment or bookmark, shows the setup at the time of capture. If viewing the static items (Model, Model View, Images, or Animations), shows the final state of the setup. Review the ECG signals and adjust the controls. Shows the catheters and traces used during the study. Select which catheters are visible.
Collect: Model Sub-tab	All	Change surface colors, names, and visibility. Surface editing functions are not available.
Collect: Mapping Sub-tab	Primary & Secondary View: Left Primary pane shows the realtime study. Right Secondary pane shows either Realtime or RealReview. (When Split Screen is active.)	Open maps. Review map points. Collect points from the recorded catheter signals and locations. Switching to Split Screen view allows side-by-side comparison of the Review items.
Lesions	All	Review therapy data. Modify lesion markers NOTE: Lesion markers added in offline review will be given a brown background in the list.
Review	All	All
Split Screen	In Realtime Mode, the Split Screen	In Offline Review Mode, the Review task allows recorded data from a past study

	option allows recorded data from the study to be viewed. Primary View: Left Primary pane shows the realtime study. Secondary View: Right Secondary pane can show the realtime study or be switched to view recorded information (RealReview).	to be viewed and edited. Primary View: Left pane shows recorded data from the past study selected in the Title screen. Secondary View: Right pane shows a different view of the recorded data from the same past study.
Status Bar	Blue	Brown

System Messages

System messages appear near the status tray or on the desktop. The appearance and behavior of each message depends on the severity of the situation. System messages are logged to the system for troubleshooting purposes. There are four types of messages, as shown below.

Type of Message	Example	Description
Information Message		Information messages are non-critical messages that appear temporarily in a blue screen above the status tray. They persist for 3 seconds and then fade away. NOTE: Access a list of Information and Advisory messages displayed during the study by clicking on the Message Log icon in the status tray in the lower right portion of the screen of Realtime and live studies only.
Advisory Message		Advisory messages appear above the status tray and persist until the user closes the message. NOTE: Access a list of Information and Advisory messages displayed during the study by clicking on the Message Log icon in the status tray in the lower right portion of the screen of Realtime and live studies only.
System Busy Message		System Busy Messages display when the system is collecting data; during this time the system will be non-responsive to user actions.
Warning Message		Warning messages alert the user of an action that is going to occur and asks the user to verify the action. The message must be acted upon before any other action can be taken on the system. NOTE: Some warning messages can be disabled by checking the "Do not show this message again" box; once this box is checked and the user clicks OK, the message will no longer display for the remainder of the study session.

Using the Mouse

EnSite™ X Specific Mouse Actions.

Right-click – Move the mouse pointer over a specified feature and press the right mouse button once and release to display any context-sensitive menus.

Rotating, Panning, and Zooming

- Use the mouse to rotate, pan, and zoom a model/map.
- To rotate the model/map in any direction, use the middle mouse button to click and drag in any direction.
- To rotate the model/map clockwise or counterclockwise, hold down <Ctrl> or <Alt> and middle-click and drag clockwise or counterclockwise.
- To pan (move vertically and horizontally) the model/map, hold <Shift>, middle-click, and drag. In Dual View, panning works independently for each model/map.
- To zoom the model/map in and out at the center of the map display, rotate the mouse middle wheel. In Dual View, zooming works independently for each model/map, unless synced/F3 is active.
- To zoom the model/map in and out at the mouse pointer position, hold down <Shift> and rotate the mouse middle wheel. In Dual View, zooming works independently for each model/map, unless synced/F3 is active.

Selecting and Adjusting Waveforms

Use the mouse to select and adjust waveforms:

- To add a temporary isoelectric line, left-click and hold on the waveform.
- To add a permanent isoelectric line to a waveform, select the waveform, hold down <Shift> and left-select the waveform.
- To move a waveform, left-select the waveform and drag up or down.
- To remove a waveform from the waveform display, left-select the waveform and drag it off the left edge of the screen. This functionality does not work in the Acquisition Waveform Display. To remove a waveform in the Acquisition Waveform Display, unselect the checkbox in the Signals tab of the Mapping Settings Panel.

- To adjust the amplitude of all waveforms, middle-select the waveform and drag up or down to increase or decrease the amplitude. Waveforms of a specific signal type are ganged so the amplitude for all will be adjusted.
- To adjust the amplitude of a single waveform, hold down <Ctrl> then middle-click and drag the waveform up or down.
- To pan a waveform in the Acquisition Waveform Display, hold <Shift>, middle-click, and drag left or right.
- Right click in the black background for waveform options menu:
  - Sweep Speed – Adjusts the number of mm/sec. in the waveform display (time scale).
  - Reset Offsets – Evenly spaces all visible waveforms vertically in the waveform display, without changing the order of the display.
  - Reorder Waveforms – Rearranges the waveforms according to the trace number and types as defined by the order in the Waveforms Tab of the Catheters and Waveforms Settings Panel.
  - Font Size – Used to select a font size for the label text in the waveform display.
  - Thickness – Used to adjust the thickness of all waveforms in the waveform display.
  - High/Low Lines – Used to display the peak-to-peak values of the roving signal. Options include displaying the High/Low Lines on all roving in signals, only on the distal roving signal, or not displaying the High/Low Lines. Only available in the Acquisition Waveform Display.

Adjusting the Torso View Using the Keyboard

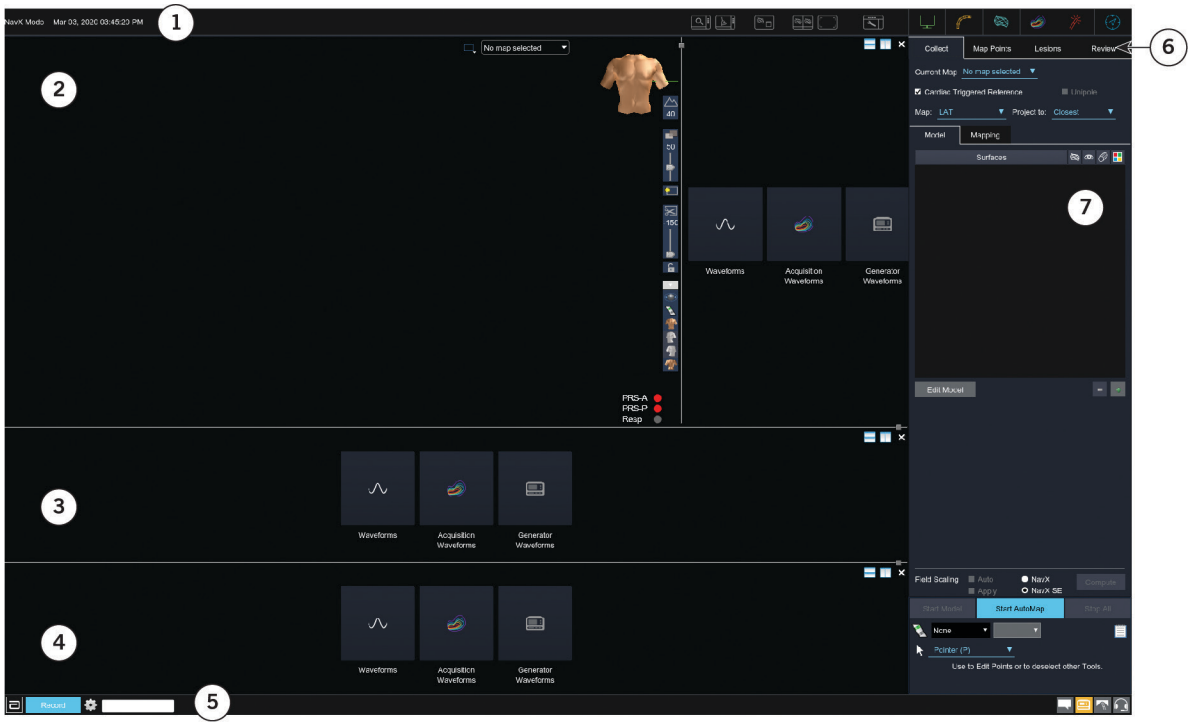
"A" and "D" rotate the view about the torso's vertical axis.

"W" and "S" tip the view forward and backward about the torso's horizontal axis (through its left and right sides).

Workspace Orientation

Organization of the application Workspace provides a Model/Map display, Waveform display areas, a Control Panel, Top bar, and Bottom bars.

Figure 51. Workspace Orientation

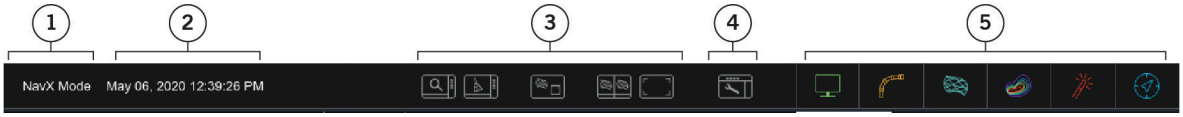


1. Top bar — The top bar presents the mode type, date/time information, display options, links back to setup screens, and provides access to the Settings Panels.
2. Model/Map Display — The area where catheters, three-dimensional models, and/or maps are displayed.
3. Waveform Display — A waveform display area.
4. Waveform Display — A waveform display area.
5. Bottom bar — The bottom bar contains the application menu as well as icons that indicate the status of various system components, system information and access to controls for recording segments.
6. Control Panel — The Control Panel provides access to the Work Panels:
   - Collect
   - Map Points
   - Lesions
   - Review
7. Waveform Display — A waveform display area.

Top Bar

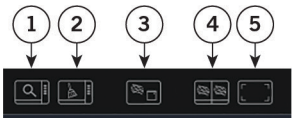
The top bar presents the Navigation mode type (VoXeL or NavX), date/time information, display options, links back to setup screens, and provides access to the Settings Panels.

Figure 52. Top bar



1. Study mode Type — Displays the current mode Type (EnSite NavX™ or EnSite™ VoXel).
2. Date/Time Stamp — Displays the current Date and Time.
3. Display Options — Provides the user with the ability to change the model/map display.
4. Access to Setup Link — Provides access to setup screens (Patient/Study Details, Hardware Map, etc.)
5. Settings Panel Access Icons — Provides access to the configuration settings/options for each panel.
   - Meter & Display Options
   - Catheter & Waveforms
   - Model, DIF & Fusion Options
   - Map Settings
   - AutoMark & Contact Force
   - Navigation

Figure 53. Display Options

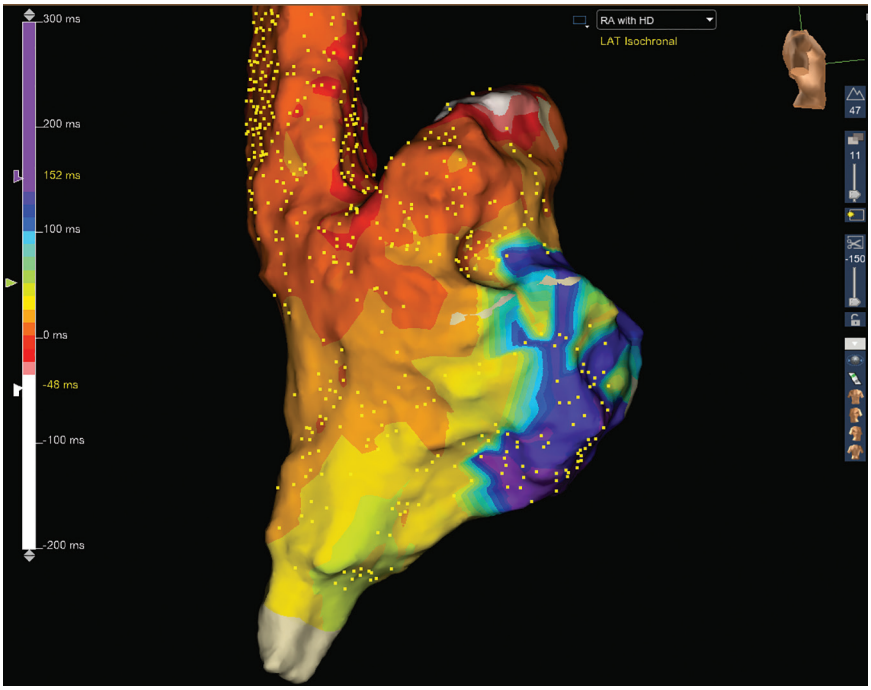


1. Auto Correct Model Visibility - Centers the model back into view, and resets display settings.
2. Clean Up Display - Temporarily hides meters, metrics, and orientation options. When in Full-screen mode also hides the Points and Tools panel.
3. Mobile Work Panel - Shows or hides the Mobile Work Panel.
4. Single View / Split View Toggle - Switches between single and split screen views.
5. Full Screen Toggle - Hides the Work Panel and displays the Model/Map area in full screen mode.

Model and Map Display Window

The area where catheters, three-dimensional models, and/or maps are displayed. The following sections will review each item displayed within the Model/Map display screen.

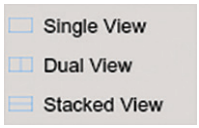
Figure 54. Map and Model Display Window



Mapping and Model Window Control: Single, Dual, and Stacked Views.

Dual View & Stacked View allow the user to display two views of the same map.

Figure 55. Mapping and Model Window Dropdown Menu



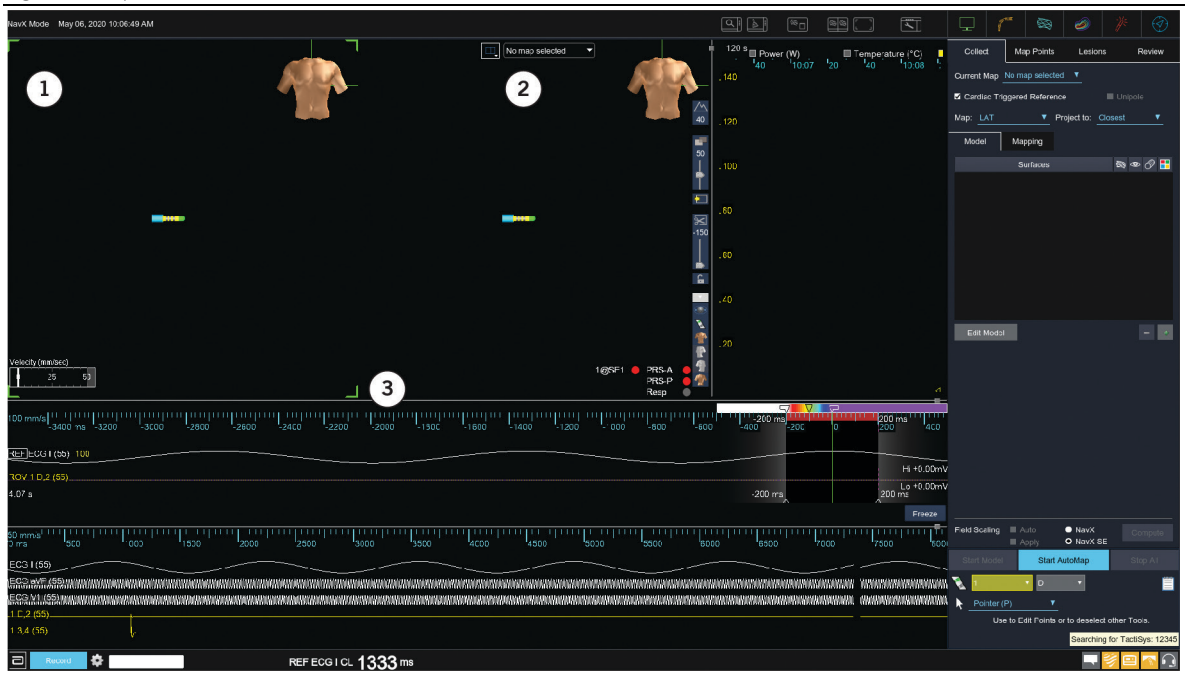
In Dual or Stacked View, the active view is highlighted by green corners, Dual View shown below. To make the other view active, click once on the black background of the non-highlighted view.

The following functions are available only for the highlighted, active view:

- Using the mouse to rotate the model.
- Adjusting the clipping plane.
- Adjusting the view scale.
- Saving or loading a model/map View.

  NOTE: Using the mouse to delete surface points or place map labels, lesion markers, anatomic markers, or tape measures can only be done in the highlighted view; however, the result of these actions appears in both model/map display areas.

Figure 56. Map and Model Dual View



1. Primary model/map display area
2. Secondary model/map display area
3. Active model/map display area

The left side of the model/map display when dual view is selected.

The right side of the model/map display when dual view is selected.

Framed with green brackets.

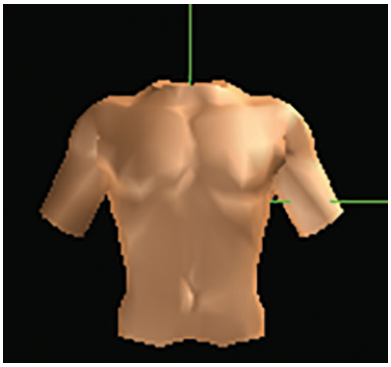
Views and the Orientation Reference

The current rotation of the display is indicated by the orientation reference icon in the upper right of the model or map display. A view is a saved orientation of a model or map (rotation and panning) that is accessible by clicking a button.

Four predefined views and up to three custom views are available. The predefined views are AP, LAO, RAO, and PA. The three custom views are user-named.

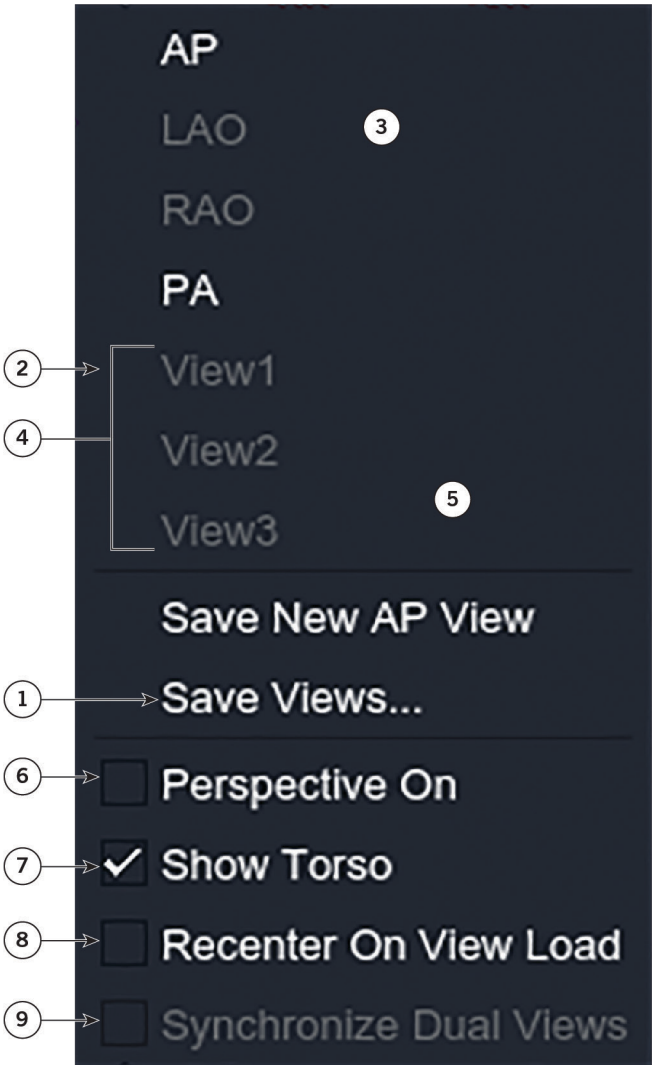
To access the view controls and the orientation reference settings, right-select the orientation reference icon.

Figure 57. Orientation Reference Icon



Right-select the orientation reference icon to open the views and orientation reference settings right-click menu

Figure 58. The Views and Orientation Reference Right-click Menu



1. To save the current view and settings as a custom view, select Save Views from the right-click menu.
2. In the Save View screen, select View1, View2, or View3, and then rename the view if desired.
3. The custom view name will be added to the right-click menu.
4. Up to three custom views can be created.
5. The custom views are independent and do not compute automatically.
6. Perspective On - Perspective View displays distant objects appearing smaller than close objects, thereby enabling improved visualization of the 3D image with a clearer representation of the catheter positions. When Perspective On is selected, zooming in on the map view transforms a view of the outside surface to that of the inside surface of a chamber. When zooming out, the view of the inside surface, likewise, changes back to a view of the outside surface of the chamber. In Dual View, Perspective On works independently for each model/map display.
7. Show Torso - Shows/hides the orientation reference icon.
8. Recenter on View Load – When switching between views; AP, PA, LAO, RAO, the image is recentered.
9. Synchronize Dual-views - When in Dual View, turn this checkbox on to synchronize the orientation of the two views and allow both models or maps to be rotated at the same time.

Creating and Saving Map Views

NOTE: If a DIF model is highlighted, map views cannot be saved unless registration has been applied using the EnSite™ X Fusion Registration Module.

Figure 59. Save View/View Angles screen

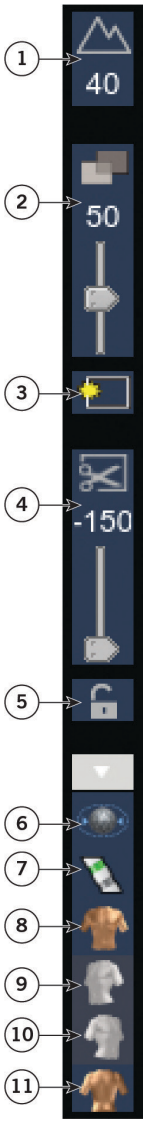
To save the current view and set as the AP view, select Save New AP View from the right- click menu. Saving the AP view automatically saves the LAO, RAO, and PA views. In the default settings, LAO is set at -45 degrees from AP, and RAO is set at 30 degrees from AP. These angles can be adjusted using the LAO Angle Setting and RAO Angle Setting slider bars under the "View Angles" tab, or the up and down arrows on the keyboard or by manual text entry.

For EnSite™ X studies, the orientation reference and AP view are automatically established at the time of system validation. If a model is created, and LAO and RAO are undefined, the LAO and RAO views are automatically established when the model is completed. Saving AP, LAO, RAO, or PA views also adjusts the orientation reference. The system does not overwrite custom views.

Orientation Toolbar

The Orientation Toolbar provides one-click access to several model/map views.

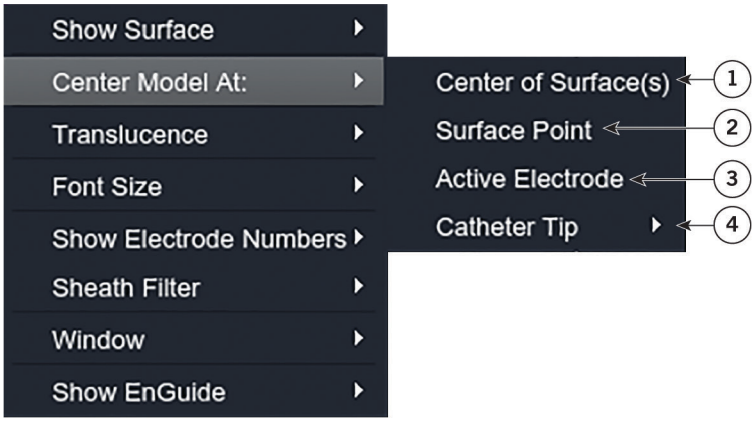
Figure 60. Orientation Toolbar



1. Zoom Level – Adjust the zoom level of the surfaces.
2. Surface Translucency – Adjust the translucency of the image for optimal visualization of objects behind other surfaces.
3. Edge Enhancement – When enabled, provides a rendering of the model where the body can be translucent, but the edge remains distinctly defined.
4. Clipping Plane – Clipping planes allow for a view of the interior and rear of the closed model by cutting a plane away from the viewing space. The slider provides a smooth, controlled way of adjusting the clipping plane. Unlocking the Clipping Plane deletes it.
5. Lock Clipping Plane – Clipping planes can be locked in the model/map display window. When locked, the orientation remains fixed relative to the model. When unlocked, the orientation is parallel to the screen. To change the orientation of a locked clipping plane, unlock it, rotate, and lock it again.
6. Center of Surface – Select to center the model/map display at the center of the surfaces being displayed.
7. Center on Active Electrode – Select to center the model/map display on the active electrode.
8. AP View – Anterior Posterior view shortcut.
9. LAO View – Left Anterior Oblique view shortcut.
10. RAO View – Right Anterior Oblique view shortcut.
11. PA View – Posterior Anterior view shortcut.

Right-click Menus for Mapping/Model Window

Figure 61. Center Model At Sub-menu.

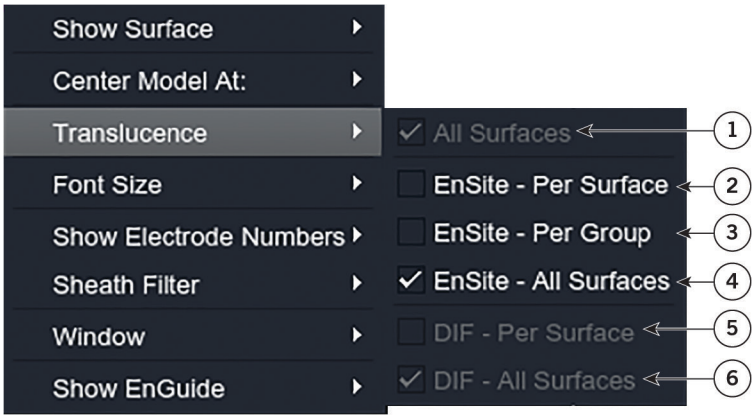


1. Center of Surface(s) – Centers the model within the view. In Dual View, it works independently for each model.
2. Surface Point – Centers the model at a selected point. When Surface Point is selected, the cursor changes to a red box with a dot in the center. With a left mouse click, select the point of interest on the model. The view is re-centered to this point, and a small marker appears at this point. Exit this mode by selecting off the model surface.
3. Active Electrode – Centers the map display to the active electrode.
4. Catheter Tip – Centers the model on the desired EnGuide.

The translucence sub-menu supports the image integration of co-located models, surface translucency can be applied independently to each surface or group. Translucency is applied to All Surfaces (both EnSite and DIF) as the default setting.

Select the Translucence menu item, then select one or more options.

Figure 62. Translucence Sub-menu.

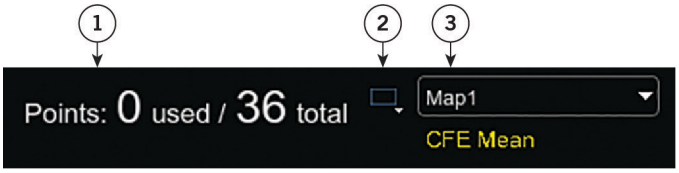


1. All Surfaces – Enable to apply translucence to all surfaces (EnSite and DIF) equally.
2. Per EnSite Surface – Enable to apply translucence to each EnSite surface independently.
3. Per EnSite Group – Enable to apply translucence to each EnSite Group (Right, Left, Other) independently.
4. All EnSite Surfaces – Enable to apply translucence to all EnSite surfaces equally.
5. Per DIF Surface – Enable to apply translucence to each DIF surface independently.
6. All DIF Surfaces – Enable to apply translucence to all DIF surfaces equally.

NOTE: When one of these modes is selected, adjustment of the translucency slider in the map display will apply to the surface, DIF, or Group currently selected within the Model or DIF list.

Map Point Count Display

Figure 63. Map Point Count Display

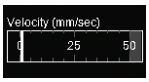


1. Displays in the Map and Model Window showing the points used and total points in the current map creation.
2. Name of the Map, drop-down menu.
3. Screen change drop-down: dual view, single view, stacked view.

Display Meters

The following meters display in the Model/Map area. Visibility controls are located in the Meters and Display Options Settings Panel. Refer to the Meters and Display Options Settings panel for more information.

Figure 64. Velocity, Respiration and Distortion Meters



Velocity (mm/s) meter – A meter that shows the relative velocity of the Active Electrode and the velocity threshold.

Respiration meter – A meter that shows the current respiration pattern.

Distortion (mm) meter – Indicates the level of possible interference of the magnetic field due to the proximity of a metal object.

Display Views

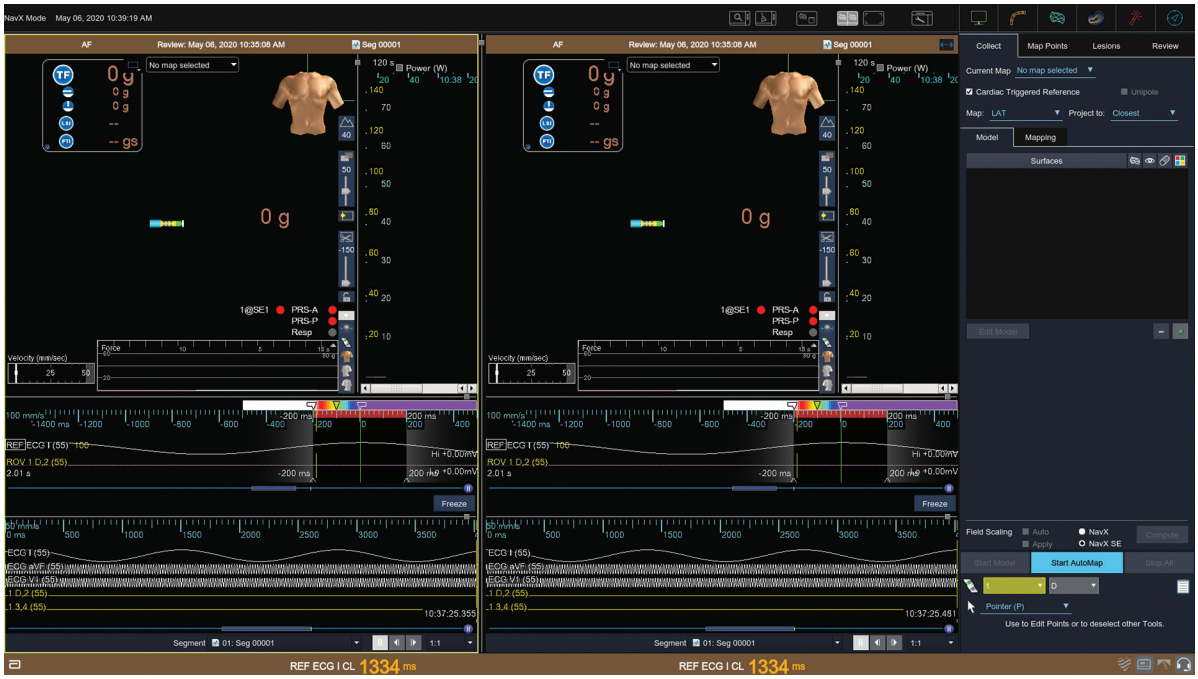
Figure 65. Split and Full Screen Views.

The Split View toggle allows the user to display combinations of Realtime and Review maps, generated with the same or different mapping points. The user can:

- Display the same map side-by-side in Realtime and Review workflows.
- Display two different maps, each generated with the same or different mapping points.
- Display one Realtime map (primary display) and one Realtime or Review map (secondary display).

NOTE: To visualize different screen arrangements, try a different screen layout preset.

Figure 66. Split Screen View



1. Primary Display: Click in this display to make it active.
2. Secondary Display: Click in this display to make it active.
3. Adjustment Bar: Click and drag to resize the display areas.
4. Yellow highlight around the active display. The Control Panel works with the active display.
5. Mapping waveform display.
6. Realtime/Review: Switch between Realtime or Review Mode.

Mobile Panel

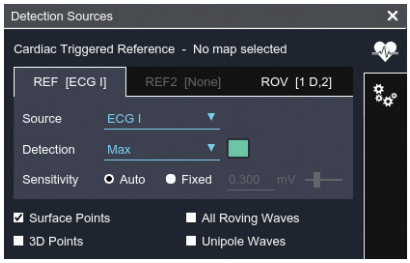
Provides access to Detection Sources and AutoMap Thresholds to support simultaneous workflow of mapping, therapy tasks, and full screen view.

To display the panel, the user selects the Mobile Work Panel button in the Display Options.

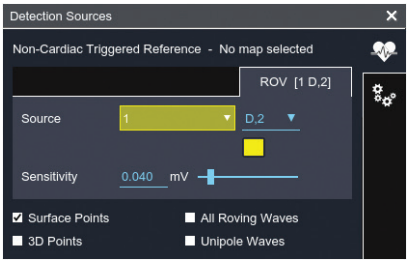
The Mobile Panel can be displayed on the screen in either Standard, Split-screen or Full Screen mode and can be positioned within the model space as desired. It is dismissed from view using the close icon in the top right corner of the panel or re-clicking the mobile work panel button within the Display Options area.

Figure 67. Mobile Panel – Detection Sources Tab

Cardiac Triggered Reference



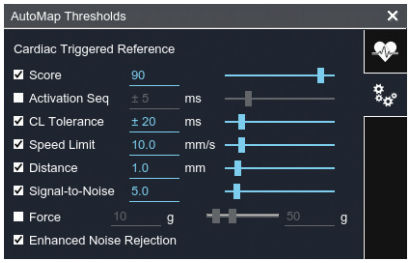
Non Cardiac Triggered Reference



Reference the Collect Tab Mapping Sub-tab for description of functionality.

Figure 68. Mobile Panel - AutoMap Thresholds Tab

Cardiac Triggered Reference



Non Cardiac Triggered Reference

Reference the Collect Tab Mapping Sub-tab for description of functionality.

Waveform Displays Window Control

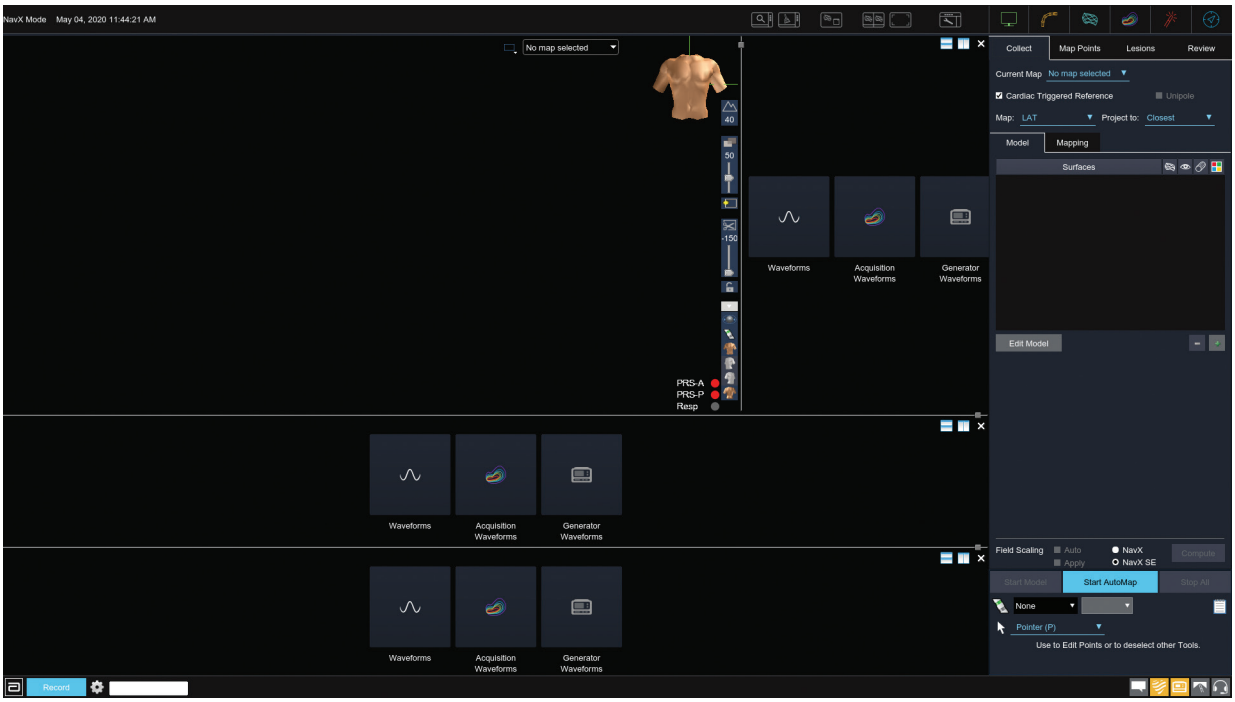
Only one waveform type can be displayed in any given screen at a time.

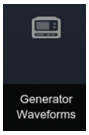
Example: If Acquisition Waveforms are displayed in the top right screen, then waveforms and generator waveforms can only be shown in the other open screens.

A different right-click sub menu opens for each of the waveform types.

> NOTE: Only one Realtime Waveforms display can be shown at a time, even when in Split Screen mode. The second Waveforms display will revert to a blank screen showing that the Waveforms content has been selected, and it will fill the screen when it can (if the display group is changed to show review data, or the Waveforms display from the other realtime display group is closed).

Figure 69. Waveform Display Controls

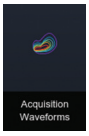


1 

Generator Waveforms: Displays Force and Ablation Generator waveforms

2 

Waveforms: Displays the active electrode signals and respiration waveforms

3 

Acquisition Waveforms: Displays the acquisition waveform

4 
The two Split Screen buttons open a second horizontal or vertical display group to the right of the original displays. The layout and content choices will be copied from original displays into the second display group.

5 
Select the "X" at the upper-right corner of the screen to close the screen.

Bottom Bar

The bottom bar contains icons that indicate the status of various system components, system information and access to controls for recording segments.

Figure 70. Bottom bar

1. Application Menu — Provides access to system level controls.
2. Segment Recording — Enables Segment Recording start/stop toggle, AutoMap and AutoMark Sessions checkboxes, and segment naming.
3. REF ECG info — Display of REF ECG info.
4. System Components — Displays the active system components.

Component Status

Figure 71. Component Status icons

1. Messages icon – Accesses messages in the system.
2. EnSite Derexi icon – Software features that uniquely integrate the WorkMate™ Claris™ Recording System with the EnSite™ X EP System.
3. Ampere icon – Ampere Generator.
4. TactiSys Quartz icon – Shows the measurements of the contact force sensor.
5. SJM™ Connect icon – Provides access to the SJM™ Connect configuration dialogue.

EnSite™ X Application Menu


The menu bar provides access to system-level controls. All active menu bar and menu options for the current operating environment (Realtime/Offline) are displayed in white lettering. Options not available for the current operating mode are shown in gray lettering. Selecting a menu will display a column of additional options. Menu options followed by three periods "..." will display a window when selected.

Menu Option	Sub-menu Option	Function
Study and Patient Information		Displays the Study and Patient Information Screen
Save Bookmark ...		Create and save a bookmark to the notebook
Save Image …		Capture and save still images
Save Event ...		Create and save a timestamped comment to the notebook
Load DIF …		Import a three-dimensional model created from digital images sources such as CT or MRI for display in the EnSite™ X EP System
Eject External Media		Eject a CD/DVD from the DWS

Menu Option	Sub-menu Option	Function
Amplifier		Access EnSite™ X Amplifier controls
	Power Line	Power line frequency; 50 or 60 Hz
	Log	Access the EnSite™ X Amplifier log
	Reconnect	Initiate communication between DWS and EnSite™ X Amplifier
	Reset Amplifier	Reset and self-test the EnSite™ X Amplifier
	Magnetic Field Enabled	Turn on or off the EnSite™ X Field Frame
Validate		Validate the EnSite™ X surface electrodes for use
Reference		
	Unipolar Reference	Select the unipolar reference for a study
Hotkeys		
	Synchronize Split Screen	Synchronizes the two screens so that both models pan, zoom, rotate, spin, and change perspective together.
	Record	Record/Stop recording.
	Collect Respiration Data	Collect RespComp X
	Add Lesion at EnGuide	Add a lesion at the Active Electrode.
	Add 3d Lesion at EnGuide	Add a 3D lesion at the Active Electrode.
	Stop All Collection	Stop all data collection
	AutoMap Start/Stop	Start/Stop AutoMap feature
	Freeze	Freeze and save a mapping point
	Cancel	Discard the collect point
	Step Forward	Moves the cursor to the right (forward)
	Step Backward	Moves the cursor to the left (backward)
Help		
	Quick Help	Display a list of quick actions and shortcuts.
	About	Display hardware and software version information, copyright information.
End Study		End the current study and Logout.

Control Panel

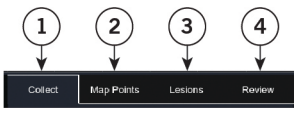
The Control Panel provides access to the Work Panels, Point Collection functions, the Active EnGuide options and the Points and Tools Panel.

The controls most often used during the work flow of a study are in the "Work Panel". Tasks are arranged from left to right in the order of typical work flow. Panel content displays below each workpanel.

The controls and settings less often modified during a case, (typically those configured with presets,) are grouped into the Settings Panels. The contents of a Settings Panel temporarily replaces the Work Panel when an individual control is accessed. Panels are minimized using the 'Close' icon, or when another panel icon is selected. Once Settings Panels are closed, the Work Panel returns to view.

Work Panels Description/Navigation

Figure 72. Work Panels Tabs



1. Collect Work Panel — The Collect Work Panel provides access to the features and activities associated with creating geometry models and maps.
2. Map Points Work Panel — The Map Points Work Panel provides access to the features and activities associated with the Points list and point display options.
3. Lesions Work Panel — The Lesions Work Panel provides access to the features and activities associated Lesion lists, lesion properties, and AutoMark metrics options.
4. Review Work Panel — The Review Work Panel provides access to the features and activities associated Recorded notebook entries.

Settings Panels Description/Navigation

The Settings Panels contain controls and settings less often modified during a case. Presets can be managed from the settings panels and are context sensitive. When the user is within any specific Settings Panel, the user may manage the presets for that Settings Panel only.

Figure 73. Settings Panel Icons

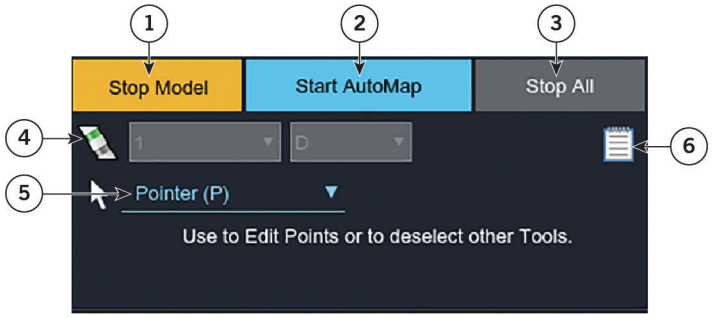
Panel	Sub-Menus or Controls
1. Meters and Display Options	Layout options - size, location and content of waveforms and map display. Display options for meters, filters, model and map display settings, Contact Force display, EnGuide display options, zoom and color contour.
2. Catheter and Waveforms	- Specifications - Attributes - Setup - Signal Settings - Waveform Attributes
3. Model Surface Properties, DIF and Fusion options.	- Model - DIF - Fusion
4. Mapping and Signals	- Settings - Map Appearance - Map Display - Points/Labels - Detection Settings - AutoMap Thresholds - Signals
5. AutoMark & Contact Force	- Metrics - Placement Settings - Visible Thresholds - CF Display - CF Stability
6. Navigation Setup options	- Metal Distortion - Velocity Filter - Respiration Compensation

Points and Tools Panel

The Points and Tools Panel provides access to the Point Collection buttons; the Active EnGuide option menu; a link to the Tools Tag list; the Tool selection menu and options.

- Points and Tools Panel is available in Full-screen mode, it can be located by dragging to desired position but cannot be dismissed.
- The Cursor display is mapped to the selected Tool.

Figure 74. Points and Tools Panel



1. Start/Stop Model button – Select to begin anatomic model point collection – select again to stop anatomic model point collection.
2. Start/Stop AutoMap button – Select to begin automatic mapping point collection — select again to stop automatic mapping point collection. The user can also start/stop the AutoMap feature by using <shift> + <F11>.
3. Stop All button – Select to stop automatic mapping point collection AND stop anatomic model point collection.
4. Active EnGuide Option – Select the drop-down list to choose the Active EnGuide and Electrode.
5. Tools Menu – Displays the currently selected tool and tool options. Select the drop-down list to select a different tool or use the following keyboard shortcuts for Tool selection:
   a. <P> - Pointer
   b. <R> - Rotate/Pan
   c. <H> - Shadow
   d. <M> - Marker
   e. <T> - Tape Measure
   f. <C> - Caliper
   g. <B> - Label
   h. <L> - Lesion
6. Tools Tag list – Displays a list of items associated with the currently selected tool. The Tools Tag list can also be accessed by the hotkey <O>.

Tools Description

Tools Menu

The Tools menu displays the currently selected tool and tool options. Select the drop-down list to select a different tool or use keyboard shortcuts for Tool selection. For each tool the menu will show the relevant tool options as summarized in the Tool descriptions below.

Tools Tag List

The Tools Tag List are independent of the current Work Panel and is accessed by clicking the Tools Tag List icon in the Points and Tools Panel or by using the hotkey <O>. By default, the list displays above the palette but can be repositioned within the Model and Waveform space. Lists are associated and displayed based on the currently selected tool. When a different tool is selected with the option menu, or with a keyboard shortcut, the list responds to the new selection and displays the related list.

Helpful tips for the Tools Tag List include:

- Lists can be relocated and dismissed in either standard mode or full screen mode.
- Right-click options are provided and accessed from the lists.
- Row selection is not retained when Tool is changed, or list is dismissed from view.
- List permits name changes for individual rows.

Tools Description

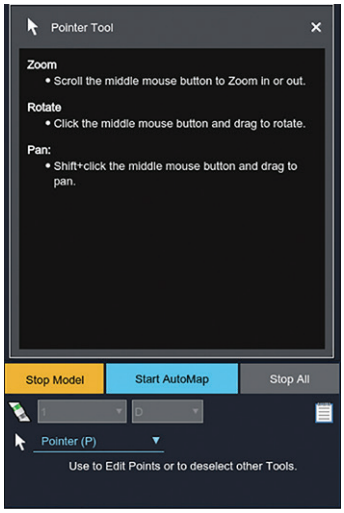
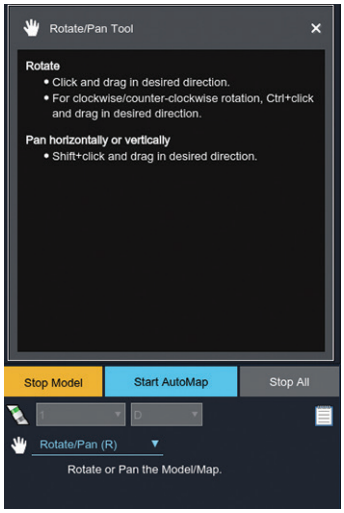
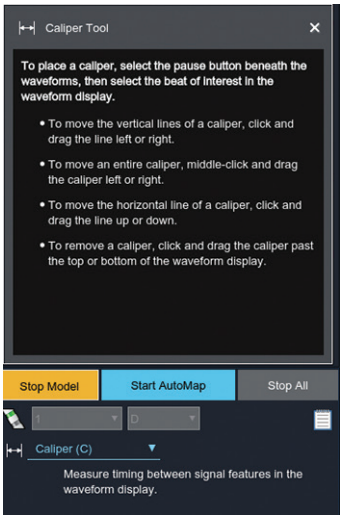
This section will review the Tool function, Tools List, and Tools Menu for each of the Tools within the Points and Tools Panel. The tools are split into two categories:

1. Tools that have an associated Tools List.
2. Tools that do not have an associated Tools List.

Tools that do not have an associated Tools List will be described first.

Pointer, Rotate/Pan, and Caliper Tools Overview

The Pointer, Rotate/Pan, and Caliper Tools do not have associated lists; the list box displays instructional text related to the tool use.

Tool Name	Pointer Tool	Rotate/Pan Tool	Caliper Tool
Hotkey	<P>	<R>	<C>
Tool Cursor display			
Tools List and Tool Menu			
Tools List Instructional Text	Zoom Scroll the middle mouse wheel/button to zoom in or out. Rotate Select the middle mouse wheel/button and drag the mouse to rotate. Pan <Shift> + <click> the middle mouse button and drag mouse to pan.	To Rotate Left click and drag mouse in desired direction For clockwise/counter-clockwise rotation, <Ctrl> + <click> and drag mouse in desired direction. To Pan Horizontally or Vertically <Shift> + <click> and drag mouse in desired direction.	To place a caliper, select the pause button beneath the waveform, then select the beat of interest in the waveform display. To move the vertical lines of a caliper, left-click and drag the line left or right. To move the entire caliper, middle-click and drag the caliper left or right. To move the horizontal line of a caliper, left-click and drag the line up or down. To remove a caliper, left-click and drag the caliper past the top or the bottom of the waveform display.

Pointer and Rotate/Pan Tools Details

The Pointer and Rotate/Pan tools are basic tools that allow the user to rotate, pan, and zoom the surfaces within the Map/Model Display Window.

Caliper Tool Details

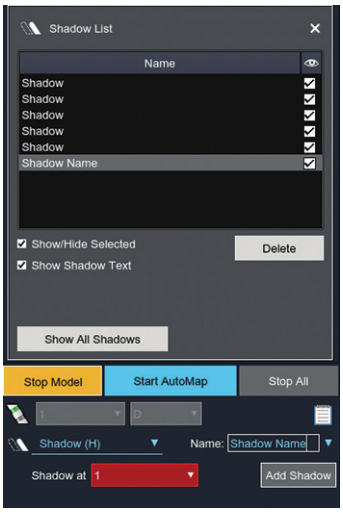
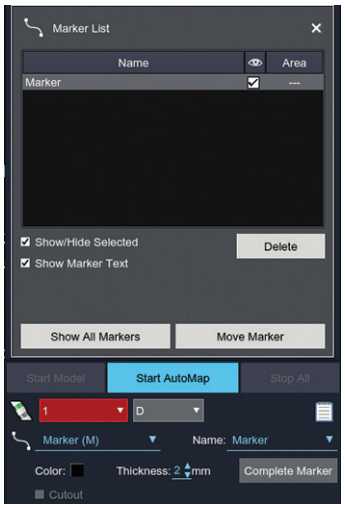
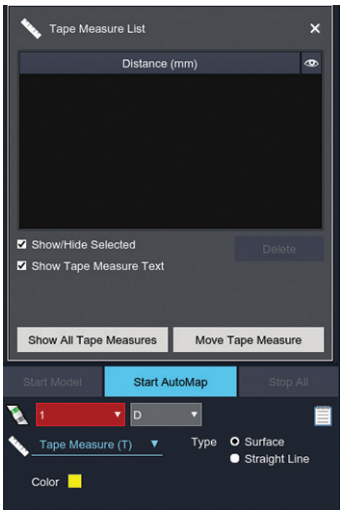
A caliper is a set of two vertical lines with a horizontal line between them. The time between the vertical lines is displayed above the horizontal line in milliseconds (ms). The frequency is displayed beneath the caliper measurement in Hertz (Hz).

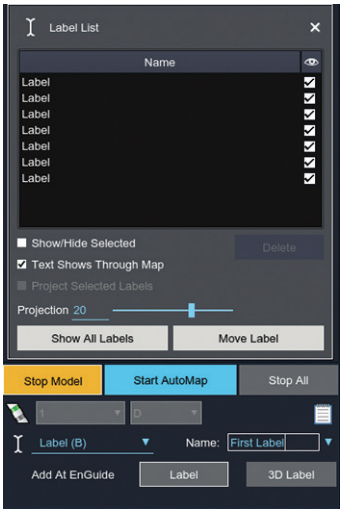
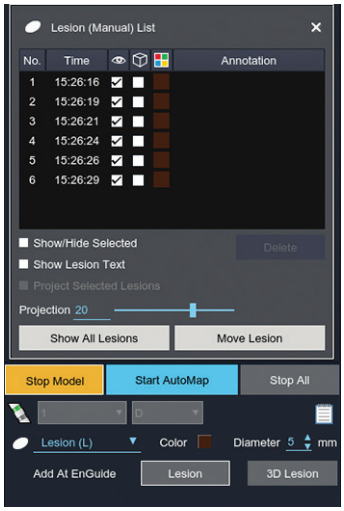
Ten calipers can be placed in a recorded segment, and ten per mapping point in the Mapping Acquisition Window. The calipers in the Mapping Acquisition Window are saved with the points. Calipers placed in a recorded segment are not saved.

Calipers move with the waveform display. When a vertical line or caliper moves outside of the display area, a small arrow appears at the edge of the screen. This arrow can be left-clicked to select the vertical caliper line then dragged to bring the caliper back into the waveform display. The relative caliper position also appears in the segment overview.

Shadow, Marker, Tape Measure, Label, and Lesion Tools (Map Tags) Overview

Map Tags is a general name to describe 3D annotation types which include EnGuide shadows, anatomic markers, tape measures, labels, and lesion markers. The properties of Map Tags are similar therefore the descriptions will be grouped with the unique tool features highlighted below.

Tool Name	Shadow Tool	Marker Tool	Tape Measure Tool
Hotkey	<H>	<M>	<T>
Right-click Menu	To use the right-click menu in the display area, select the tool from the Tools drop-down list on the Points and Tools panel (or use the HotKey combination), right-click in the display area to display the tools menu, and then select one of the tool functions.		
Tool Cursor display			
Tools List and Tool Menu			

Tool Name	Label Tool	Lesion Tool
Hotkey	<H>	<M>
Right-click Menu	To use the right-click menu in the display area, select the tool from the Tools drop-down list on the Points and Tools panel (or use the HotKey combination), right-click in the display area to display the tools menu, and then select one of the tool functions.	
Tool Cursor display		
Tools List and Tool Menu		

1. Name (list column) – Map Tag Name.
2. Visibility (list column) – Use the visibility checkbox to show/hide the item. When the checkbox is selected, the Map Tag is visible. To hide the Map Tag, deselect the checkbox. Hiding an item does not delete the item.
3. Show/Hide Selected checkbox (list column) – Shows/hides the selected Map Tag. The Map Tags are only hidden, not deleted.
4. Show [Map Tag] Text checkbox – Shows/hides the text associated with the selected Map Tag.
5. Show All [Map Tags] button – shows all instances of the selected Map Tag.
6. Delete button – Deletes the selected Map Tag(s) from the map and the Tools List.
7. Shadow at Drop-down selection – Use the dropdown to select to shadow at a single EnGuide from the list or All EnGuides.
8. Name – Select from dropdown list or enter manually.
9. Add Shadow Button – Select to place the Shadow(s) based on the user selection.
10. Area – Calculated Area of the Marker Tool. See the Marker Details section for additional information.
11. Move [Map Tag] Button – Use this button to modify the location of the selected Map Tag. Only Map Tags placed at mouse can be moved.

1. Color selection – Choose the desired color for the selected Map Tag.
2. Cutout checkbox – Show/hide the center of a closed Marker.
3. Thickness value – Adjust the thickness of the Marker line.
4. Complete Marker Button – Select to automatically finish the current Marker creation.
5. Distance (mm) (list column) – Displays the measured distance (in mm) between points on the model of the endocardial surface. See Tape Measure Details for additional information.
6. Type – Select the type of Tape Measure. Surface radio button – connects two selected points on the map with the shortest possible line along the endocardial surface.
7. Straight Line radio button – connects two selected points on the map with a straight line.
8. 3D icon (list column) – Use the 3D checkbox to show a Map Tag as 3D Map Tag or project the Map Tag to the model surface. When the checkbox is selected, the Map Tag will be shown as a 3D Map Tag in space.
9. Project Selected [Map Tag] checkbox – Changes a Map Tag's Projection. A Map Tag placed with the [Map Tag] at EnGuide button is already projected. To move the Map Tag to the original 3D location where the Map Tag was placed, deselect Project Selected [Map Tag]. A Map Tag placed with the 3D [Map Tag] at EnGuide button is placed at the Active Electrode. To project the Map Tag onto the closest surface, select Project Selected [Map Tag].

1. Text Shows Through Map checkbox – Makes label visible regardless of the map/model orientation.
2. Projection slider – Sets the maximum distance for automatic projection to surface of a Map Tag placed at EnGuide. Map Tags beyond this distance from the model surface will be shown at the 3D location. The projection slider applies to all applicable Map Tags.
3. Add at EnGuide Buttons – Select button to add a Map Tag at the model surface or 3D Map Tag at EnGuide.
4. [Map Tag] button – Select to add Map Tag at EnGuide. This option projects the Map Tag based on the projection slider value.
5. [3D Map Tag] button – Select to add 3D Label at EnGuide.
6. No. (list column) – Numeric name of a Lesion Marker based on order of Lesion placement.
7. Color selection (list column) – Choose the desired color for the selected Map Tag.
8. Annotation (list column) – Select field to manually enter annotation text for individual Lesions.
9. Diameter value – Adjust the diameter of the lesion.

Selecting and Modifying Map Tags

To select Map Tags in the Model/Map Display:

- To select a single Map Tag, select the tool from the Points and Tools Panel or via the hotkey, hold down <Shift>, and then select the Map Tag's name.
- To select multiple Map Tags of the same type, select the tool from the Points and Tools Panel or via the hotkey, hold down <Ctrl>, and then select each Map Tag. Alternatively, after selecting the tool, hold down <Shift> or <Ctrl>, hold down the left mouse button, and drag a box around the Map Tags.

To deselect a Map Tag(s) in the Model/Map Display:

- Hold down <Shift> and click away from the Map Tag's name.

  NOTE:

  - When a Map Tag is selected, the color of its name changes to white or red in the model/map display area.
  - Multiple Map Tags can only be selected if they are of the same type (such as labels, anatomic markers, tape measures lesion markers, and EnGuide shadows).

To select Map Tags in a Tools list:

- To select a single Map Tag in the list, select the Map Tag in the list.
- To select multiple Map Tags in the list, hold down <Ctrl> and select each Map Tag.
- To select multiple consecutive Map Tags in the list, hold down <Shift>, select a Map Tag, and then select another Map Tag. Alternatively, select a Map Tag and drag to select additional consecutive Map Tags.

  NOTE: When a Map Tag is selected, the color of its name changes to white in the model/map display area.

To modify a Map Tag(s):

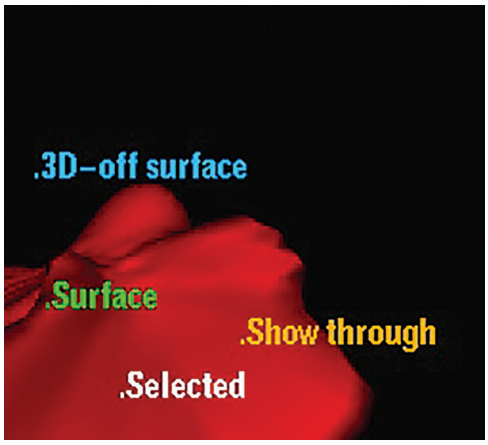
- Select the Tools List icon to open the Tools List.
- Select a Map Tag(s) using one of the selection methods above.

- Use the options in the Tools List screen to modify available options.

Map Tag Colors

The color of a Map Tag indicates the type of Map Tag and/or relationship to the surface.

Figure 75. Map Tag colors



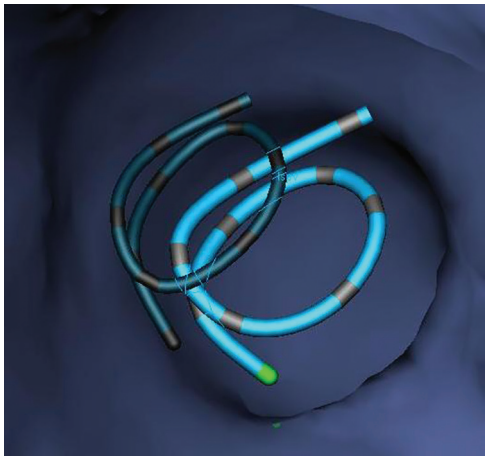
- Green indicates that the Map Tag is on the nearest surface.
- Amber indicates that the Map Tag is on the surface, but something is obstructing the Map Tag. This could indicate that the Map Tag is on the far side of the model or behind an object such as an EnGuide electrode.
- Blue indicates that the Map Tag is not tied to the surface (such as 3D labels, 3D Lesions and EnGuide Shadows).
- White indicates that the Map Tag is selected. AutoMark annotations are also displayed in White.
- Yellow indicates a Map point annotation. The Map point annotation flashed between yellow and red when the Map point is selected.

EnGuide Shadow Tool Details

EnGuide Shadows display a three-dimensional historic image of an EnGuide catheter position. EnGuide Shadows can be useful in returning a catheter to a previous position or for confirming that a catheter has remained in position. Up to 256 EnGuide Shadows can be placed in the map display.

NOTE: In EnSite™ VoXel mode, Shadows can only be placed with Sensor Enabled™ catheters that are in a high confidence state.

Figure 76. An EnGuide Shadow (at arrow)



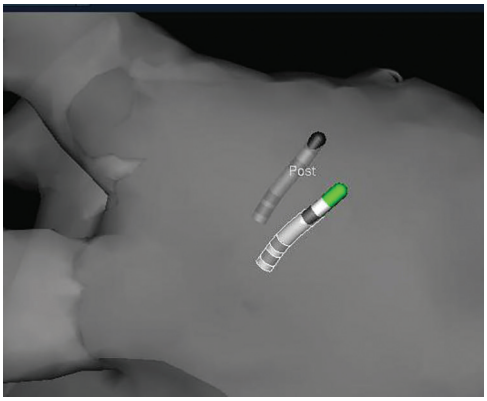
The stability of diagnostic catheters can be verified using EnGuide Shadows.

1. Display one or more electrodes on a stable catheter.
2. Early in the study, place an EnGuide Shadow on the stable catheter electrodes.
3. If the catheter moves away from the Shadows, suspect catheter movement.

   NOTE: In EnSite NavX™ mode, a shadow placed on an intracardiac positional reference does not move away from the positional reference electrode. In the event of a positional reference dislodgement, all other electrodes move from previous shadows.

Below is a n example of a catheter that has moved in an EnSite NavX™ study. The arrow points to the EnGuide Shadow.

Figure 77. An example of a catheter in an EnSite NavX™ study



Placing EnGuide Shadows

1. Select the EnGuide Shadows tool on the Points and Tools Panel.
2. Select a catheter from the Shadow at drop-down menu. Or select All EnGuides to place an EnGuide Shadow at the locations of all catheters.

   NOTE: EnGuide Shadow keeps the color of the displayed catheter.
3. Select Add Shadow to place an EnGuide Shadow(s) at the location of the selected catheter(s).
4. Type a name for the EnGuide shadow in the Name text area or select a name from the drop-down menu. Names appear at the middle of the EnGuide Shadow display.

   NOTE: When a shadow is placed on the map, it also appears in the EnGuide Shadow Tools List.

Anatomic Marker Tool Details

Anatomic markers connect points on the surface of the model with lines. Closed anatomic markers are useful for drawing valve or vessel openings on the model; these circular markers can be cut out of the map to show these openings. Up to 256 anatomic markers can be placed on the map.

The Marker value is displayed next to the Marker in the Model/Map Display and in the Tools List. The Marker display value is dependent upon the surfaces that it crosses.

- If a surface that the marker crosses is deleted, the marker is deleted.
- If a surface that the marker crosses is not included, the marker is hidden.

  NOTE: In EnSite NavX™ Mode, Field Scaling must be applied for values to be displayed.

The method of calculating the area differs depending on whether the marker is cut out.

- For markers that have not been cut out, the area is calculated for the entire surface encompassed by the marker.
- For markers that have been cut out, the area is calculated for an averaged plane across the open marker.

To place an anatomic marker:

1. Select the Marker tool on the Points and Tools Panel.
2. Create the marker by clicking at desired locations on the surface. The marker will be formed by connecting consecutive points.
3. Complete the marker.
4. For closed markers, click near the first point in the marker to close and complete the marker. To remove the center of the closed marker, turn on the Cutout checkbox.

   NOTE: If the marker encompasses the center of the model, the wrong portion of the model may be cut out.
5. For open markers, right-click in the display area to display the Marker menu, and then select Complete Open Marker or deselect the Marker tool or select Complete Open Marker from the Tools List.
6. Set the marker's color and thickness with the Color and Thickness controls on the Points and Tools Panel.
7. Type a name for the marker in the Name text area or select a name from the drop-down list.

   NOTE: When an anatomic marker is placed on the map, it is also added to the Tools List.

Tape Measure Tool Details

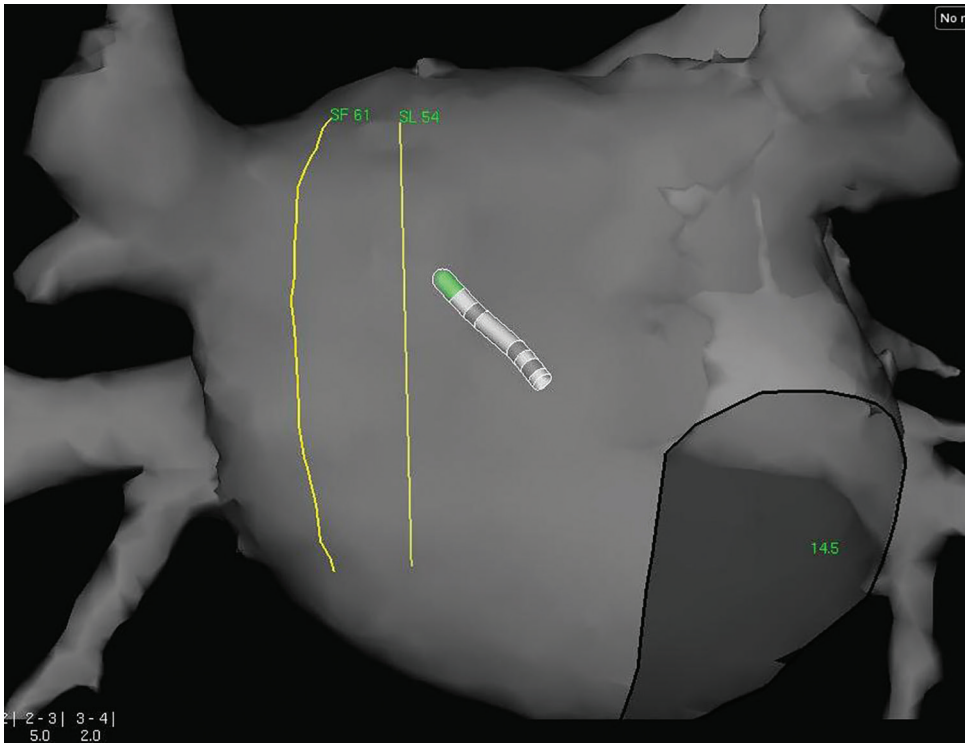
Tape measures are used to measure the distance (in mm) between points on the model of the endocardial surface. The Tape Measure feature may be used with DIF models. Up to 12 tape measures can be placed on the map.

NOTE:

- Tape measure values can only be as accurate as the contoured chamber model that they measure.
- In EnSite NavX™ Mode, Field Scaling must be applied for values to be displayed.

The example below shows a map with two tape measure lines, one across the model surface and one straight line between two model surface locations.

Figure 78. An example of the Tape Measure Tool



Placing a Tape Measure

Select the Tape Measure tool on the Points and Tools Panel.

1. Set the tape measure's color with the Color control on the Points and Tools Panel.
2. Select the desired Type button:
   - Surface radio button – connects two selected points on the map with the shortest possible line along the endocardial surface.
   - Straight Line radio button – connects two selected points on the map with a straight line.
3. Place the tape measure:
   - Select on the map at the point to begin measuring, and then drag the mouse to position the other end of the tape measure.

The tape measure appears on the map as a colored line. The tape measure's type and the distance between the points in mm, appear at the beginning of the tape measure. Up to 12 tape measures (yellow, green, cyan, orange, red, and magenta) can be used.

NOTE: In EnSite NavX™ mode, measurements will not be shown if Field Scaling is not enabled (the line will still show through).

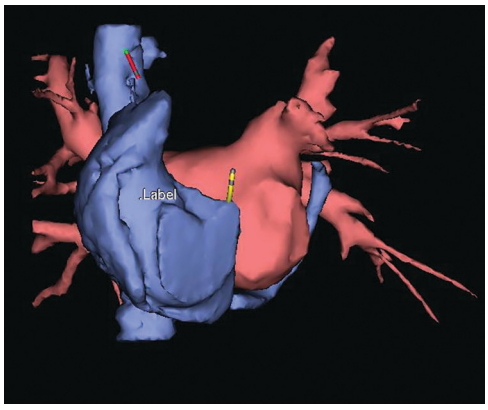
Label Tool Details

Labels are used to identify points on the model. Up to 1024 labels can be placed during a study.

NOTE:

- The labels have no intrinsic meaning to the EnSite™ X EP System. Users can assign their own meaning to labels.
- In EnSite™ VoXel mode, Label at EnGuide(s) can only be placed with Sensor Enabled™ catheter electrodes that are in a high confidence state.

Figure 79. A model with a label displayed



Placing a Label

Select the Label tool on the Points and Tools Panel.

1. Type the label's name in the Name text area on the Points and Tools Panel or select a name from the drop-down menu. By selecting the drop-down menu after a name appears in the text area, commonly used names can be added or removed from the drop-down menu.

   NOTE:

   - Once a label name is automatically added to the list, it cannot be manually removed.
   - The list in the drop down is cleared at the end of each study.

1. Use the Projection slider (text entry box) to set the projection distance if the label is to be projected.

2. Place the label using one of the following methods:

   - Select on the map or DIF surface to place the label at the pointer location. Clicking repeatedly places multiple labels.

   NOTE: When placing labels with the mouse, labels can be placed on either the DIF model or the created model surface. For multiple-surface models, the label appears on the surface beneath the pointer.

   - Select [Label] button to place a label at a point on the surface nearest to the Active Electrode. For multiple-surface models, the label appears on the nearest included surface. Label location is projected from the 3D center of the Active Electrode to the nearest surface. If the surface is edited and the projection distance is exceeded, the label re-projects from the original 3D catheter location, because the original 3D catheter location is preserved.
   - Select [3D Label] button to place a 3D label at the Active Electrode location. This label is not connected to the surface of the map but rotates with the model. This function is useful for labeling the location of catheters outside of the chamber.

   NOTE: When a label is placed, it is also added to the Tools List.

Lesion (Manual) Marker Tool Details

Lesion markers are used to identify ablation lesion marker sites. Up to 1024 lesions can be placed in the map display. Lesion markers are projected from the 3D center of the Active Electrode to the nearest surface. The original 3D catheter location is preserved. If the surface is edited, the lesion is re-projected from the original 3D catheter location.

When using the Lesion Marker tool, the user can place lesion markers with the mouse or use the tool bar to place surface and 3D lesions at the Active Electrode.

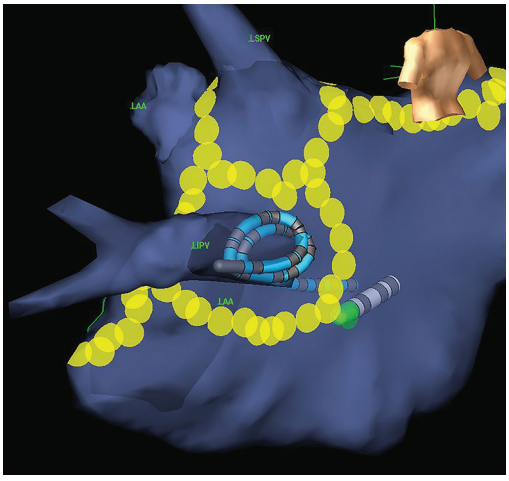
An adjustable distance control allows the user to edit the distance allowed for projection. Lesion markers that are present and do not meet the 3D distance requirement are displayed as 3D objects (without being tied to a surface).

The user has the option to project, or not to project the lesion.

Each lesion marker has a numeric name that is displayed in a list. This number increments each time a lesion marker is placed on the map. If a lesion marker is deleted, the numeric list is updated to keep numbers consecutive.

NOTE: In EnSite™ VoXel mode, Lesion markers can only be placed with Sensor Enabled™ catheter electrodes that are in a high confidence state.

Figure 80. A map with lesion markers on the surface



Placing Lesion Markers

Place the lesion marker using one of the following methods:

1. Click on the map to place the lesion marker at the mouse pointer. For multiple-surface models, the lesion marker appears on the surface beneath the pointer.

2. Click the Lesion button to place the lesion marker on the point on the endocardial surface that is highlighted by the EnGuide proximity indicator. For multiple-surface models, the lesion marker appears on the nearest included surface. A lesion marker placed with the Lesion button is already projected. To move the lesion marker to the Active Electrode, turn off the Project Selected Lesions checkbox.

   - Hot key: <F6> places a lesion marker at the Active Electrode.

3. Click the 3D Lesion button to place the lesion marker at the Active Electrode. This lesion marker appears as a sphere and is not connected to the surface of the map but rotates with the model. To project the lesion marker onto the closest surface, turn on the Project Selected Lesions checkbox.

   - Hot key: <Shift>+<F6> places a 3D lesion marker at the Active Electrode.

NOTE:

- The last lesion marker placed is outlined in yellow. If this lesion marker is deleted, the next to last lesion marker is outlined.
- When a lesion marker is placed on the map, it is added to the Lesion List.
- The diameter control also adjusts the maximum diameter of the proximity indicator on the EnGuide electrode.

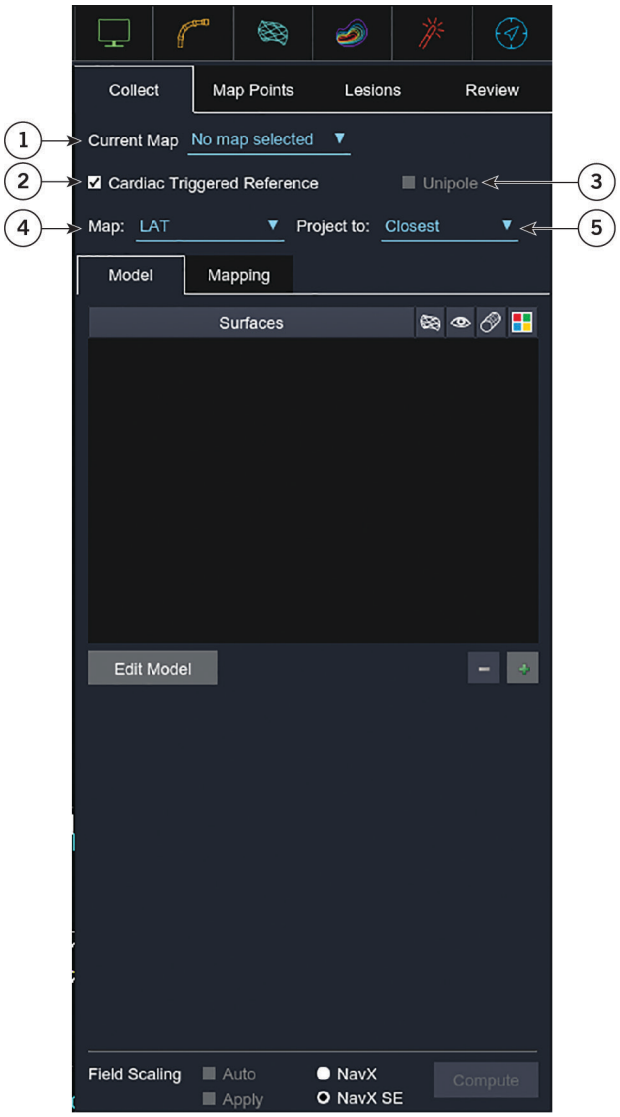
Work Panels

The Work Panels contain the controls most often used during the work flow of a study. Tasks are arranged from left to right in the order of typical work flow. Panel content displays below each subtab. Each of the Work Panel Tabs are described in the following section.

Collect Panel

The Collect Work Panel provides access to the features and activities associated with creating anatomic models and maps. The Collect Work Panel contains two sub-tabs: Model Sub-tab and Mapping Sub-tab. The top portion of the Collect Work Panel contains selections that are independent on the sub-tab selection.

Figure 81. Collect Work Panel



1. Current Map drop-down list – Use the drop-down menu to select the desired map to display in the Model/Map display.
2. Cardiac Triggered checkbox – Select the checkbox to create a map using a cardiac triggered reference (ECG or IEGM) or deselect to create a map using a non-cardiac triggered reference (segment length).
3. Unipole checkbox – Select the checkbox to view the unipolar map for the selected Peak-Peak or Peak-Negative Map. Note: Bipolar and unipolar data are simultaneously collected for all cardiac triggered maps.
4. Map drop-down list – Use the drop-down to select the map type. Refer to the mapping section for further information on Map options.
5. Project to drop-down list – Use the drop-down to select projection location: Closest [surface], Right Group, Left Group, Other Group.

Model Sub-tab

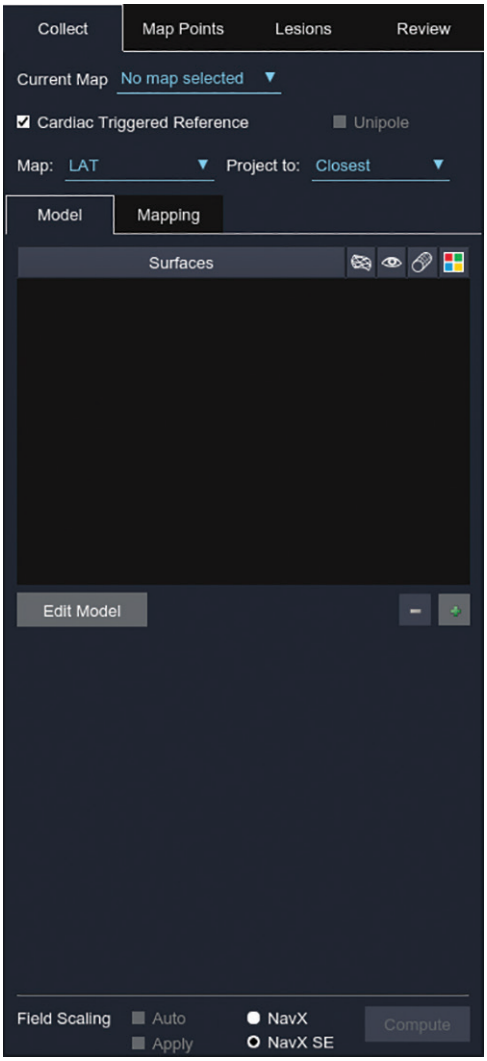
The Model Sub-tab in the Collect Panel displays the settings and options for creating anatomic models. The Model Sub-tab has two different states:

- Finish Model state.
- Edit Model state.

The state seen is controlled by the Finish Model/Edit Model toggle button. If Edit Model is showing, then the user is in the Finish Model state. Both states are described in the following section.

NOTE: Field Scaling and associated controls are not visible in EnSite NavX™ mode. All other Model functionality is the same in EnSite NavX™ and EnSite™ VoXel modes.

Figure 82. Collect Work Panel – Model Sub-tab – Edit Model state



1. Surfaces list (list column) – After creating a model the name of each available surface appears in the surfaces list. The list can contain one model with up to 16 created surfaces; surfaces may be edited and adjusted independently from one another.
2. Included icon (list column) – This checkbox controls whether a surface is displayed in the model. When the checkbox is checked, the surface is displayed for labeling, intersecting, and overlapping surfaces. When the checkbox is unchecked, the entire surface is excluded from view. See the Field Scaling section for more information on how surface inclusion/exclusion impacts the Field Scaling algorithm.
3. Visibility icon (list column) – Use the visibility checkbox to show/hide the item. When the checkbox is selected, the surface is visible. To hide the surface, click on the checkbox. Hiding a surface does not delete the surface and the surface is still available for intersecting and overlapping other surfaces.
4. Grid Control icon (list column) – The number of selects (1, 2, or 3) on cylinder will determine where a surface grid is placed on the model. Selecting once, places the grid on the interior of the model, selecting twice, places the grid on the exterior of the surface. Selecting a third time turns the grid off.
5. Color icon (list column) – Use the color chart to select a color for the item. Select on the colored square to open the color chart, and then select on the desired color. The color can be changed for entire group of surfaces together or for each individual surface.
6. Edit Model – Select Edit Model button to bring up the modeling controls (the display in this area will change to the Edit Model state and the Edit Model button becomes the Finish Model button).
7. Add/remove Surface buttons – Selecting the "+" Add Surface button will bring up the modeling controls (the display in this area will change to the Edit Model state and the Edit Model button becomes the Finish Model button). The Remove Surface button "-" becomes active when a surface is selected on the list.

Figure 83. Collect Work Panel – Model Sub-tab – Finish Model state

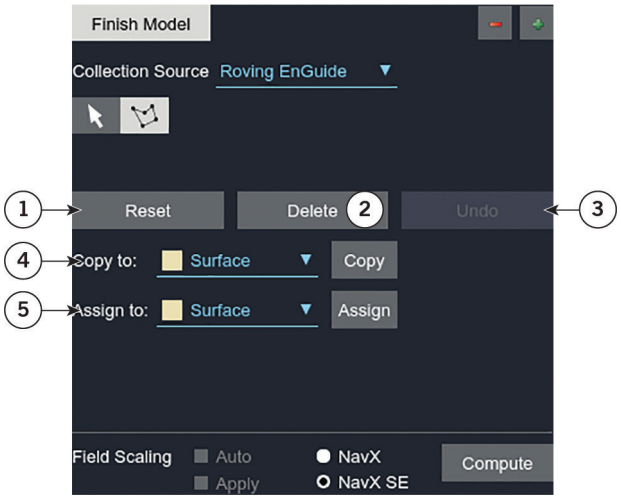
1. Collection Source drop-down list – Model points can be collected using the Roving Electrode, all electrodes on the Roving EnGuide, or all electrodes on all EnGuides. Default is all electrodes on the Roving EnGuide.
2. Edit Surface - When highlighted, the currently selected surface can be edited.
3. Select Points – When selected, point editing is active.
4. Name drop-down list – The name of the surface. Select a name from the drop-down menu or type a name.
5. Group drop-down list – Allows surfaces to be associated to one another typically in terms of blood pool. Selections are Left, Right and Other. Overlapping surfaces from the same group are automatically cut away. Overlapping surfaces from different groups are not cut away.
6. Color – Use the color chart to select a color for the item. Select on the colored square to open the color chart, and then select on the desired color.
7. Type drop-down list – Drop down list controls the level of surface detail. Selections are OneModel, High and Low. Default is OneModel.
8. Fill slider – Controls the level of surface detail. Surface detail smooths as the slider is moved to the right.
9. Force checkbox/slider – Controls the high and low force values that can be used in model point collection when using a force sensing catheter. These controls are grayed out if Contact Force Software license and/or Force Sensing catheter are not present.
10. Points drop-down list – Use the drop-down list to select which points are shown: None, Used (based on Force criteria), or All. Hiding points is useful if the point cloud begins to obscure navigation. Showing points is useful for evaluating areas requiring further collection.
11. NavX SE checkbox (EnSite NavX™ mode only) – Allows visualization of EnSite™ NavX SE points collected from Sensor Enabled™ catheters in EnSite NavX™ mode.
12. Delete Points button – Enabled when Edit Surface button is highlighted. This function allows the user to erase selected points from the model using the mouse.
13. Undo Delete button – Select this button to undo the delete operation.
14. Discard Changes button – Discards model point editing on the selected surface except for reassigned or copied points.

CAUTION: Discard Changes will delete all surfaces if the model has not been finished at least once.

Field Scaling (EnSite NavX™ mode only)

15. Auto checkbox – Enables automatic Field Scaling updates. When sufficient new EnSite™ NavX or EnSite™ NavX SE points are collected, the navigation field is automatically updated.
16. Apply checkbox – Applies Field Scaling to the surfaces that are included in the surface list.
17. NavX radio button – Field scaling is computed based upon defined catheter electrode size and spacing.
18. NavX SE radio button – Field scaling is computed based on known offsets between position and orientation of the magnetic sensor(s) and electrodes.
19. Compute button – Select to begin field scaling operation. Select at any time to update the field scaling computation.

Figure 84. Collect Tab – Model Sub-tab – Edit Model/Select Points mode



Select Points Mode

When the Select Points button is selected, point editing is active. To select points in the selected surface, sequentially click to create a closed loop around the desired points. Once the loop is closed the selected points will be highlighted. These points can then be deleted, assigned to another surface, or copied to another surface.

1. Reset button – Select to reset the point selection in the Model/Map Display.
2. Delete Points button – Enabled once the point selection loop is closed. When enabled, select the Delete Points button to delete the selected points.
3. Undo Delete button – Select this button to undo the delete operation.
4. Copy to drop-down list & Copy Button – Use the drop-down list to choose the desired existing or new surface to copy the selected points. Then select the Copy Button to Copy the selected points to the selected surface. The selected points now appear in the original surface and the newly selected surface.
5. Assign to drop-down list & Assign Button – Use the drop-down list to choose the desired existing or new surface to assign the selected points. Then select the Assign Button to move the selected points from the current surface to the selected surface.

The EnSite™ X EP System Navigation Modes

The EnGuide navigation system is used to display catheters and electrodes. The EnSite™ X EP System provides two primary ways to locate and navigate catheters. The EnSite™ VoXel Mode and the EnSite NavX™ mode.

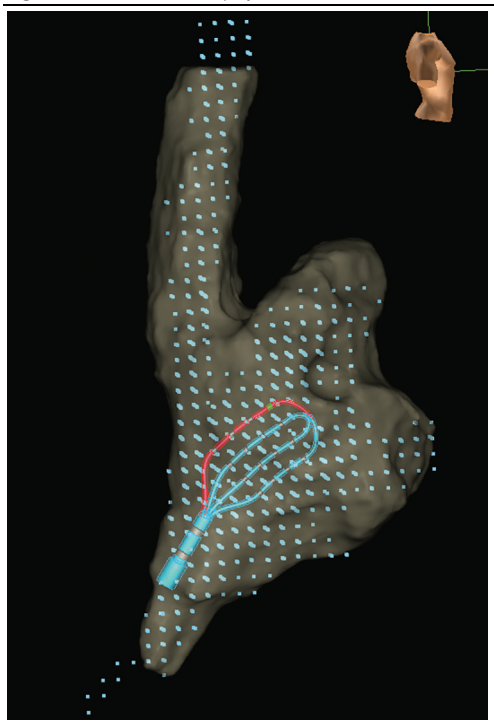
In both navigation modes the maximum number of catheters that can be used simultaneously is 8. The maximum number of electrodes that can be located is 200, and the maximum number of electrodes per catheter is 80. Catheter setup is typically done as a part of the Setup task at the beginning of a study.

EnSite™ VoXel Mode

The EnSite™ VoXel mode can be used to locate, navigate, and collect data from one or more Sensor Enabled™ catheters; standard catheters will be visualized but cannot be used to collect 3D data. In EnSite™ VoXel mode the locations of the catheters are primarily based on the signals generated by Sensor Enabled™ catheters in conjunction with the Field Frame. EnSite™ X Surface Electrode data is used to aid in catheter visualization. Only Sensor Enabled™ catheters may be selected as the Active EnGuide or Roving Source in EnSite™ VoXel mode.

NOTE: The maximum catheter navigation accuracy error is 2.0 mm in EnSite™ VoXel mode.

Figure 85. VoXel Cloud Display



EnSite™ VoXel Mode

VoXels are not limited to the model creation process, rather VoXels are collected at all times. The user may turn visualization of the VoXel cloud on or off at any time. Visualization of the point cloud can aide in showing areas that may require more attention to obtain high confidence catheter visualization.

To enable display of the VoXel cloud, enable the checkbox located in the Map and Display Settings Panel.

If RespComp X is enabled, VoXels are collected continuously.

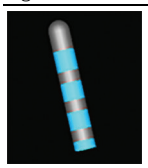
If RespComp X is not enabled, or turned off, collection of VoXels is gated to the end expiration phase.

Sensor Enabled™ Catheter Visualization

VoXels are links between the magnetic and impedance data which allow non-rigid portions of Sensor Enabled™ tools to be visualized and used for data collection. VoXels are automatically created by moving a Sensor Enabled™ catheter within the cardiac anatomy and appear as blue squares in 3D space when turned on by the user. The catheter visualization changes depending on the density of VoXels surrounding each catheter. When the density of VoXels is low, the catheter will show in a low confidence state. When the density of VoXels is high, the catheter will show in a high confidence state. 3D data can be collected from any electrode that is shown which changes based on the confidence state.

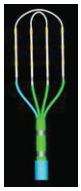
NOTE: VoXels are collected at all times as long as the magnetic and impedance data of the catheter shaft is valid and RespComp X is enabled. VoXel collection is not tied to the Edit Model state or a specific model surface.

Figure 86. Sensor Enabled™ visualization for confidence states



High confidence example: Ablation catheter

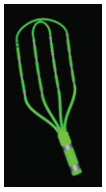
Sensor Enabled™ Ablation catheters are always high confidence and will be visualized showing all electrodes and color as selected by the user.



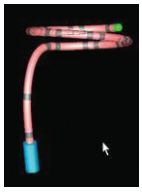
LOW Confidence Example: Advisor™ HD Grid Catheter, Sensor Enabled™

LOW Confidence example: Advisor™ FL and Advisor™ VL Catheters, Sensor Enabled™

Sensor Enabled™ diagnostic catheters have low and high confidence states. If the density of VoXels surrounding a Sensor Enabled™ diagnostic catheter is too low, the Sensor Enabled™ diagnostic catheter will display in the low confidence state. In the low confidence state the electrodes near the magnetic sensor location (on the shaft) will appear as well as the proximal row of electrodes on the Advisor HD Grid catheter. The rest of the electrode will be replaced by a ghost-like shape as seen here. In the low confidence state, 3D data can only be collected from the visible silver electrodes.



HIGH Confidence example: Advisor™ HD Grid Catheter, Sensor Enabled™



HIGH Confidence example: Advisor™ FL and Advisor™ VL Catheters, Sensor Enabled™

Once the density of VoXels surrounding a Sensor Enabled™ diagnostic catheter is sufficient, the Sensor Enabled™ diagnostic catheter will display in the high confidence state. In the high confidence state ALL electrodes on the catheter are visible and 3D data can be collected from all electrodes.

NOTE: If a catheter confidence is low in a region, move the catheter to that area until enough VoXels are collected to obtain high confidence.

Standard Catheter Visualization

Standard Catheters are any catheters that are not Sensor Enabled™. Standard catheters will be visualized but cannot be used to collect 3D data. IEGM data can always be visualized for Standard Catheters. Standard catheters will not be displayed in a region without VoXels. When the density of VoXels is low, the catheter will show in low confidence. When the density of VoXels is high, the catheter will show in high confidence.

NOTE: 3D locations of low confidence Standard catheters are shown for information purposes only. 3D locations should be visualized with an alternate 3D imaging technique.

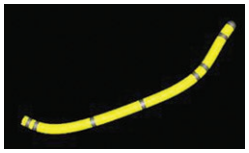
Figure 87. Standard Catheter visualization for confidence states

No catheter shown.

Standard catheters will not be displayed if VoXels have not been collected.

LOW Confidence example: Standard Catheter

Standard catheters have low and high confidence states once VoXels have been collected. If the density of VoXels surrounding a Standard catheter is too low, the catheter will display in the low confidence state. In the low confidence state, Standard catheter electrodes will be replaced by a ghost-like shape as seen here.



HIGH Confidence example: Standard Catheter

Once the density of VoXels surrounding Standard catheter is sufficient, the Standard catheter will display in the high confidence state. In the high confidence state ALL electrodes on the catheter are visible. Although the electrodes are visible, Standard catheters will be visualized but cannot be used to collect 3D data.

Impedance Shift

When an impedance shift is detected in VoXel mode the VoXel collection is suspended. Catheters go into low confidence (shaft electrodes are still in high confidence). A message appears stating that a shift has been detected and VoXel collection will be stopped with the option to 'Close" or "Delete VoXels".

If the user presses "Close" the message will be dismissed for 5 seconds.

If the user presses "Delete VoXels" a new message appears asking: Are you sure you want to delete all VoXels? Model Map Lesions and AutoMarks will not be deleted.

Press the Delete VoXels button for VoXel collection to resume, the catheters go into low/high confidence according to the available VoXels. A message will appear stating that the impedance shift has resolved and VoXel collection has resumed.

EnSite NavX™ Mode

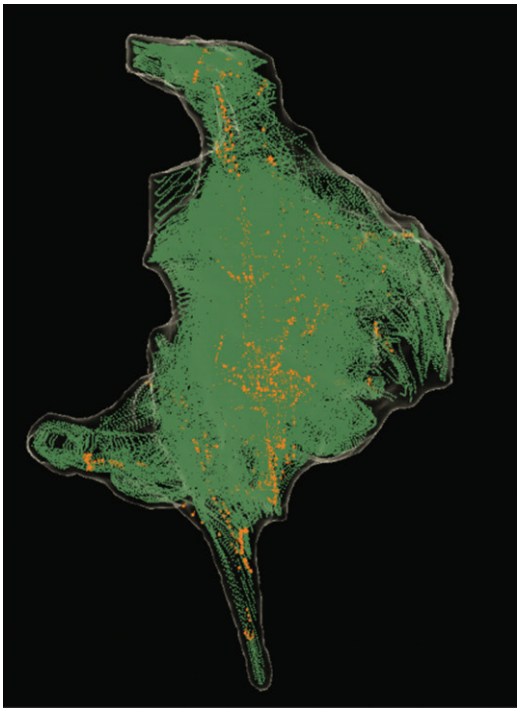
The EnSite NavX™ mode can be used to locate one or more standard EP catheters; Sensor Enabled™ catheters may also be used. In EnSite NavX™ mode the locations of the catheters are primarily based on the signals generated from the impedance measurements of NavX surface electrodes. When using Sensor Enabled™ catheters in EnSite NavX™ Mode, the EnSite™ X EP System collects both impedance-based (NavX) points and magnetic-based (NavX SE) points. Field Scaling can then be applied using either data set to optimize the model.

When using EnSite NavX™ Mode, accurate distance measurements are dependent on application of NavX Sensor Enabled™ Field Scaling. Prior to EnSite™ NavX™ SE Field Scaling being applied, distance measurements are either not shown or are estimated based on the impedance measurements and the user-supplied patient weight. Measurements that become dimensionally accurate with the application of EnSite™ NavX™ SE Field Scaling include:

- Interior Projection
- Exterior Projection
- Interpolation
- Speed Limit
- Distance (AutoMap Threshold)
- Lesion Marker & AutoMark - Diameter
- Lesion Marker & AutoMark - Project on Surface
- Label Tool & Lesion Tool – Projection
- Marker Tools List – Area (Area measurement will not be displayed until Field Scaling is applied)
- Tape Measure – Name (Tape Measure measurement will not be displayed until Field Scaling is applied)

NOTE: The maximum catheter navigation accuracy error is 2 mm in an EnSite NavX™ mode in a Sensor Enabled™ field scaled model.
NOTE: The maximum allowable Tracking Accuracy error in an EnSite NavX™ SE field scaled model is 10%.

Figure 88. Points Display



Example of Edge Enhancement and EnSite NavX™ SE points

1. EnSite NavX™ Mode
2. In EnSite™ NavX™ Sensor Enabled™ points, orange points, are collected from Sensor Enabled™ catheters during model creation. EnSite NavX™ SE points represent the magnetic data within the impedance field. Select the NavX Sensor Enabled™ checkbox to display these points in addition to the green model points.
3. Collect EnSite NavX™ SE points globally throughout the model to ensure an accurate distribution of sensor data within the field.

Looking closely at the EnSite NavX™ SE point pairs, the points are made up of two components:

- The orange sphere, which corresponds to the location of the electrode located within the EnSite™ NavX™ impedance field.
- The tail of the point pair, which points toward the corresponding sensor location.

NOTE: EnSite NavX™ SE points are always gated to end expiration of the respiratory cycle.

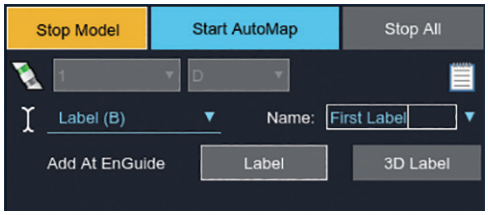
Setting the Active EnGuide and Active Electrodes

The display of an EP catheter in the model screen display is called an EnGuide. The Active EnGuide and Active Electrode are the catheter and electrode that are used for creating surfaces, placing labels, placing lesions, and collecting points for maps. Only Sensor Enabled™ catheters may be used as the Active EnGuide or Roving Source in EnSite™ VoXel mode. Any catheter may be the Active EnGuide in EnSite NavX™ mode.

The controls for selecting the Active EnGuide and Active Electrode are in the Points and Tools Panel. Use the drop-down menus to change these values. The Active Electrode is green; all other electrodes are silver.

NOTE: When in the Edit Model state, the Active EnGuide cannot be changed in the Points and Tools Panel. Change the Active EnGuide by changing the Roving source in the Mapping sub-tab or Mobile panel.

Figure 89. The Active EnGuide and Active Electrode selection in the Points and Tools Panel



Active EnGuide and Active Electrode selection in the Points and Tools Panel.

This is an example of an active electrode. The active electrode is green.

EnGuide Navigation Indicators

During 3D point collection, the EnGuide electrodes change color to indicate various conditions. For conditions that can impact individual electrodes, only the problematic electrode(s) will change color.

- Green – Active Electrode, Conditions are normal.
- Silver – Non-active electrode, Conditions are normal.
- Yellow – Irregular Respiration detected, Velocity Filter threshold has been exceeded, Electrode Issue (broken, disconnected, or out of the body), Metal Distortion threshold exceeded (EnSite™ VoXel Mode), PRS-P data invalid (EnSite™ VoXel Mode), Low Confidence Electrode (EnSite™ VoXel mode).
- Blinking red – There is a significant error. The location may be unreliable and 3D graphics (labels, lesions) cannot be placed at the Active EnGuide.

If the EnGuide electrodes turn red and point upward, there is a problem with one of the following: A surface electrode, the Active Electrode, a Non-Active EnGuide at the distal electrode. A warning appears indicating which electrode is causing the problem.

Modeling

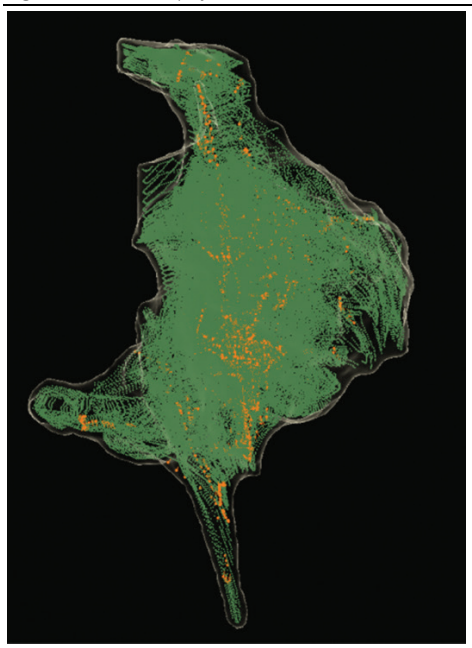
The EnSite™ X EP System displays contoured, three-dimensional surface models of the patient's cardiac anatomy. The purpose of creating a model is to collect and label the anatomic locations within the chamber. The software does not assume a specific chamber shape; therefore, it is important to collect enough points to provide sufficient chamber definition. A single model may consist of multiple surfaces.

A surface is created by navigating a selected catheter to locations within a cardiac structure. As the catheter moves, green model points are collected at and between all electrodes on the catheter. A surface is wrapped around the outermost points. This process can be repeated to create multiple surfaces. If surfaces in the same group overlap, the surfaces combine, and the overlapping section is clipped away.

WARNING: The EnSite™ X EP System model display should be used in conjunction with conventional EP techniques to confirm catheter location.

NOTE: A model is not required for EnSite™ X EP System studies but a model is required to use the Field Scaling algorithm.

Figure 90. Points Display



Green model points, available in both modes, track the locations of the selected catheter(s) which are then used to form the anatomic model surface. The method of wrapping a surface around the green points is dependent on the model type (OneModel, High detail, Low detail).

Sensor Enabled™ Catheter

Begin model creation using an Abbott Sensor Enabled™ tool. After model creation begins, initiate and compute EnSite NavX™ SE Field Scaling. As more model data is collected, the Field Scaling algorithm will automatically update. The user may display the orange EnSite NavX™ SE points to verify areas of the model that require further attention.

Standard Catheter

Begin model creation using any standard catheter. After model creation begins, initiate and compute EnSite NavX™ Field Scaling. As more model data is collected, the user can manually re-compute field scaling or choose to automatically update field scaling.

Collecting Surface Points

As the catheter moves, green model points are collected at and between all electrodes on the catheter. A surface is wrapped around the outermost points. Green model points are collected in both EnSite™ VoXel mode and EnSite NavX™ mode.

To Collect Points.

1. Set the Active EnGuide that is to be used to collect points from the Points and Tools Panel.
2. Select the [+] button in the work panel to create a new surface.
3. Use the Name drop-down to select an existing surface name or type the name of the new surface.
4. Use the Group drop-down to associate the surface with a group: Left, Right, or Other.
5. In EnSite NavX™ Mode, select an appropriate Field Scaling if desired.
6. Select [Collect Points] to begin collecting points on and between electrodes of the Active EnGuide. Navigate the catheter along the chamber walls and throughout the interior to create a surface.
7. Select [Stop Collecting Points] to stop collecting points.
8. Repeat steps 1-7 for all additional surfaces.
9. Select [Finish Model] when model creation is complete.

To Select and Edit Points.

As the model is created, the user may inspect and adjust the model to increase anatomical representation. Use the editing tools provided in the work panel.

NOTE: User may edit EnSite NavX™ SE points the same as geometry points.

Use the Edit Points tool to move or copy points from the current surface to another surface, or to delete a large group of points. Click the Edit Points icon, and then click on the map display to form a closed shape around the group of points to be reassigned. The points on the interior of the closed shape turn red. The map can then be rotated to confirm appropriate selection. Use the Assign to drop-down menu to move the points, or the Copy to drop-down menu to copy the points, to one of the available options:

- New assigns the points to a new surface.
- Delete removes the points.
- Existing surface. Selecting the name of an existing surface assigns the points to that surface.

NOTE: Reassigned and copied points cannot be undone by the [Discard Changes] function.

Point Collection, EnSite™ VoXel Mode

Only Abbott Sensor Enabled™ catheters can be used to collect green model points. Standard catheters may be visualized in this mode but cannot be used to collect 3D data. Standard catheters will be visualized when enough VoXel data has been collected with a Sensor Enabled™ catheter. VoXel mode allows user to collect modeling data using magnetic coordinates to provide accurate and linear visualization.

Point Collection, EnSite NavX™ Mode

In EnSite NavX™ mode, the user can collect green model points with Standard catheters (without a sensor) as well as Abbott Sensor Enabled™ catheters.

Field Scaling (EnSite™ NavX Mode Only)

Field Scaling uses known fixed characteristics of the catheter to adjust the dimensions of the navigation field. As the catheter is moved during model creation, the system records the location and spacing of characteristics on the active catheter. Field Scaling is only applied in the EnSite NavX™ mode of operation and is not applicable to the EnSite™ VoXel mode of operation where magnetics is the primary method of catheter location. There are two field scaling options: EnSite™ NavX™ SE Field Scaling (Sensor Enabled™ Catheters) and EnSite™ NavX™ Field Scaling (Standard Catheters). Field scaling is calculated based on the surfaces that are "included" at the time Field Scaling is computed.

NavX™ SE Field Scaling (Sensor Enabled™ Catheters)

EnSite NavX™ SE uses known offsets between the position and orientation of magnetic sensor(s) and electrodes on Abbott Sensor Enabled™ catheters to adjust the dimensions of the navigation field. Once initiated and Auto checkbox is selected, EnSite NavX™ SE Field Scaling continuously computes when sufficient points have been collected during model creation.

Showing EnSite NavX™ SE points will help ensure good coverage of the chamber, resulting in better EnSite NavX™ SE Field Scaling results. EnSite NavX™ SE points appear in the orange color.

NavX Field Scaling (Standard Catheters)

EnSite™ NavX™ Field Scaling uses known interelectrode spacing to adjust the dimensions of the navigation field when using standard catheters. Once initiated, the user may re-compute field scaling or select automatic field scaling updates.

Applying Field Scaling

Select the type of Field Scaling to be computed by checking either the EnSite™ NavX or the NavX™ SE checkbox radio buttons.

1. Select [Compute] to compute field scaling.
2. The Apply checkbox is automatically checked.

When using EnSite NavX™ SE Field Scaling, the [Auto] checkbox is automatically selected. When sufficient new EnSite NavX™ SE points are collected, Field Scaling is automatically updated.

When using EnSite NavX™ Field Scaling the user must manually select the [Auto] checkbox to enable automatic Field Scaling updates. When sufficient new EnSite NavX™ points are collected, Field Scaling is automatically updated.

To un-apply Field Scaling, uncheck the Apply box.

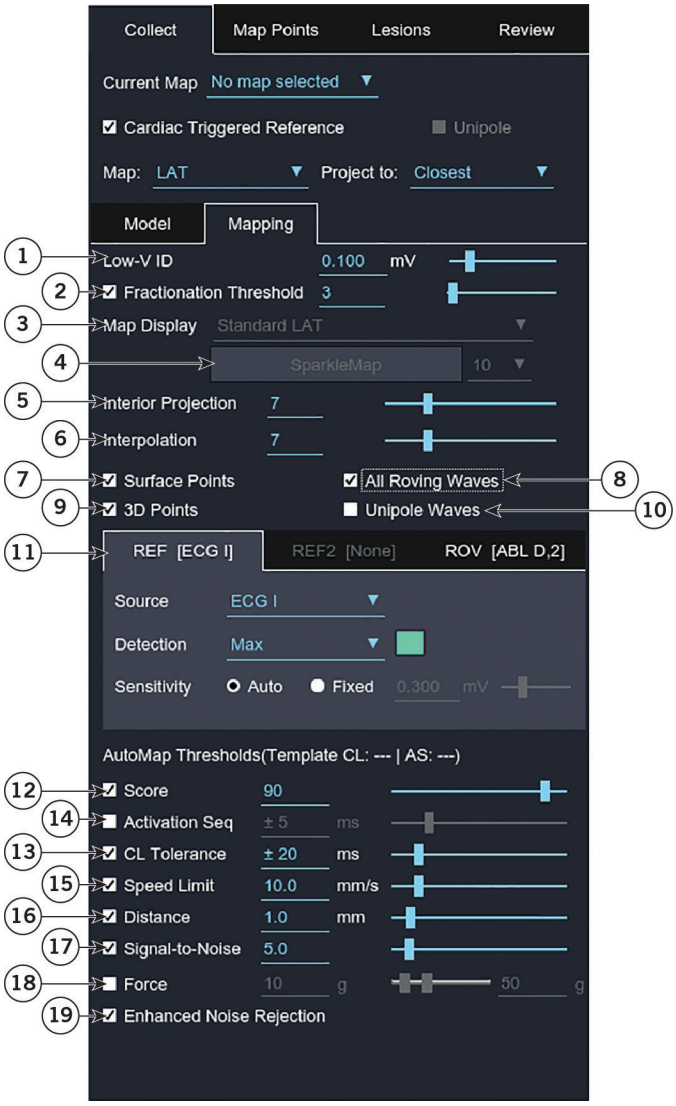
Field Scaling Notes

NOTE:

- EnSite NavX™ SE points are not collected under the following conditions:
  - When EnSite NavX™ SE locations are invalid.
  - When the Active EnGuide is not a Sensor Enabled™ catheter.
  - When the EnGuide has Stabilize ABL enabled.
  - When the Sheath Filter feature has detected that the catheter has been retracted into the catheter sheath.
  - When the Metal Distortion is out of range.
- When using EnSite NavX™ Field Scaling, Model points are not used for Field Scaling under the following conditions:
  - Electrodes having greater than 11.25 mm (center to center) spacing.
  - Collecting with a single electrode.
  - Catheters without defined interelectrode spacing or electrode length.
  - The distal electrode and at least one of electrodes 2, 3, or 4 must be enabled to collect EnSite NavX™ SE points for an ablation catheter.
  - For studies where Field Scaling is used, be sure that appropriate interelectrode spacing and size are specified for any catheter that is used for collecting points. Model points collected with catheters that are inappropriately described may yield unexpected Field Scaling results. This cannot be corrected by re-entering correct information after the fact. However, Field Scaling is an option which can be unapplied if unexpected results occur.
  - For optimal use of the Field Scaling feature, the points collected should represent all 3 axes (x-y-z) in all areas of the model.
  - Checking a Field Scaling type different from the one currently applied will automatically un-apply Field Scaling. Select the Compute button to recompute Field Scaling.
  - Model adjustments using Field Scaling are reversible, to un-apply Field Scaling, uncheck the [Apply] checkbox.

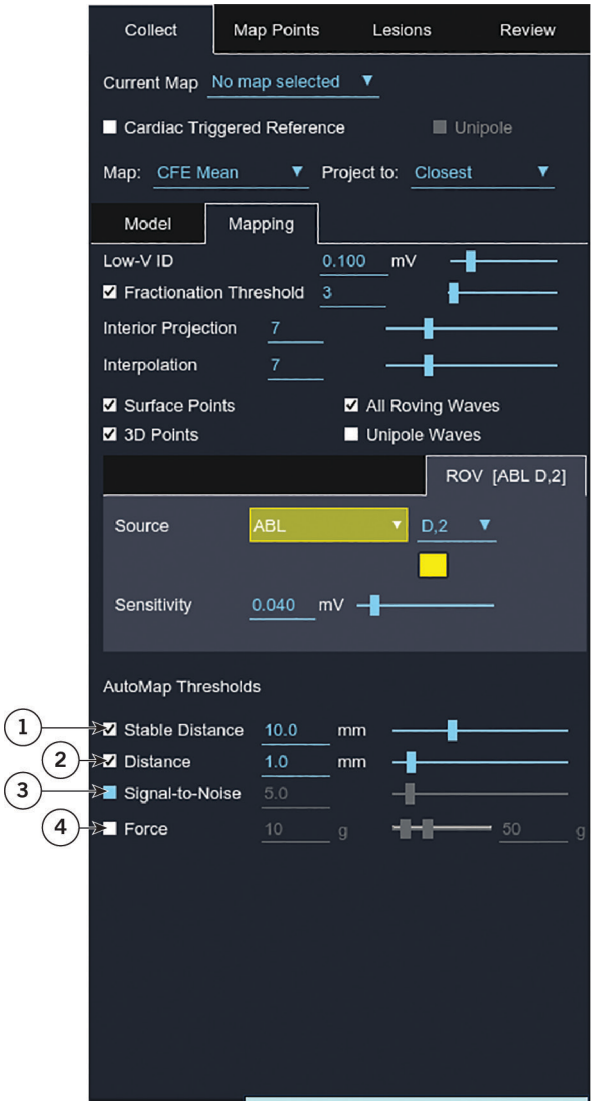
Collect Workpanel - Mapping Sub-tab

Figure 91. Collect Workpanel – Mapping Sub-tab



1. Low-V ID slider – (Applies to the map that has focus when in Split Screen mode.) Identifies low-voltage zones in LAT or CFE maps. If a collected point's P-P value is lower than the specified Low-V ID value, then that point will display a gray area instead of the color- coded scale for the current map type. Grey points do not interpolate with color points.
2. Fractionation Threshold checkbox/slider – Renders points that are fractionated as larger spheres. Default value=3 (renders points with a fractionation value of >= 3.
3. Map Display – (LAT maps only) The type of LAT map: Standard LAT, Reentrant Map, Full-Color Propagation or Propagation Map.
4. Sparkle Map button – Displayed the activation sequence overlaid on top of another map. The SparkleMap shows the propagation sequence using a series of circular flashes. The button changes to "Stop" while Sparkle Map is playing and will stop Sparkle Map when selected. The speed that the Sparkle Map is played is controlled by the drop-down next to the button. Sparkle Map button is unavailable when the Map Display control is set to either type of propagation map.
5. Interior Projection slider – (Applies to both maps when Split Screen mode is active.) This slider controls the maximum distance that an interior 3D Point (represented as a triangle) can project to a location on the surface (represented by a square). For multiple-surface models, points will project to the nearest surface.
6. Interpolation slider – (Applies to the map that has focus when in Split Screen mode.) This slider controls the minimum distance between surface points necessary for the system to interpolate color. For multiple surface models, points will interpolate between surfaces in the same group.
7. Surface Points checkbox – (Applies to the map that has focus when in Split Screen mode.) Enables/disables the display of small square points on the surface. These squares represent the point on the surface closest to a collected 3D point.
8. All roving Waves checkbox – Select to display all roving waves. When deselected, only one roving wave is displayed in the Acquisition Waveform Display.
9. 3D Points checkbox – (Applies to the map that has focus when in Split Screen mode.) Enables/disables the display of collected points as triangular markers. The triangular markers are placed on the negative electrode of the roving signal channel.
10. Unipole waves checkbox – Select to display unipolar waves of the roving signals in the Acquisition Waveform Display.
11. REF and ROV tabs – this area will be described in later sections.
12. Score checkbox/slider – Score Threshold: Full or any combination of the 12 Surface Leads. Only collect mapping points if the 12-Lead Surface Morphology is XX% similar or higher compared to the original template beat 12-Lead Surface Morphology. The user can set the Score Threshold from 0 to 100%. By default, the Score Threshold is enabled and is set to 90%.
13. CL Tolerance checkbox/slider - Cycle Length Tolerance: Only collect mapping points if the intracardiac measured (CS, HIS, other) Cycle Length is within +/- XX ms of original template beat Cycle Length. User can set the Cycle Length Tolerance from +/- 0 to 150 ms. Default the Cycle Length Tolerance is enabled and is set to +/- 20 ms.
14. Activation Seq checkbox/slider – Activation Sequence is defined as the timing between the primary reference (REF) detection and the secondary reference (REF 2) detection when both the REF and the REF 2 are set to intracardiac signals. Mapping points when the Activation Sequence of the current beat is within +/- XX ms of the template beat Activation Sequence. The user can set the Activation Sequence tolerance slider from +/-0 to 25 ms with a default of +/- 5 ms.
15. Speed Limit checkbox/slider – Speed Limit: Only collect mapping points if the mapping catheter is moving less than XX.X mm/s. User can set the Speed Limit from 0.1 to 75 mm/s. Default the Speed Limit is enabled and is set to 10.0 mm/s.
16. Distance checkbox/slider – Distance Threshold: Only collect mapping points if the 3D position of the roving catheter electrode is X.X mm or more from the previously collected mapping point from that electrode. User can set the Distance Threshold from 0.1 to 10 mm. Default Distance Threshold is enabled but the default value is set to 1.0 mm.
17. Signal to Noise checkbox/slider – SNR Threshold: Only collect mapping points if the Signal-To- Noise Ratio on the roving catheter signal is X.X or higher. User can set the SNR Threshold from 1 to 50. Default the SNR Threshold is enabled and is set at 5.0.
18. Force checkbox/slider – Force (Contact Force Range): This criteria can only be used if the EnSite™ X Contact Force Module is installed and the physician is mapping with a TactiCath™ catheter. Only collect mapping points if the Average Contact Force (as measured by a TactiCath™ Contact Force Catheter) is at least X grams and less than Y grams. User can set the Lower Threshold from 0 to 30 grams. User can set the Upper Threshold from 30 grams to 150 grams. Default the Contact Force Threshold is not enabled but the default lower threshold is 10 grams and the default upper threshold is 50 grams.
19. Enhanced Noise Rejection checkbox – Enhanced Noise Rejection: Only collect mapping points if the roving catheter signal does not have certain types of noise (Signals with saturations, electrode-to-electrode contact, open electrode noise, signals with degraded conditions such as no location or dropped data). Only uncheck for pace mapping. User can set the Enhanced Noise Reduction on or off. Default the Enhanced Noise Reduction is enabled.

Figure 92. Collect Workpanel – Mapping Sub-tab - Automap



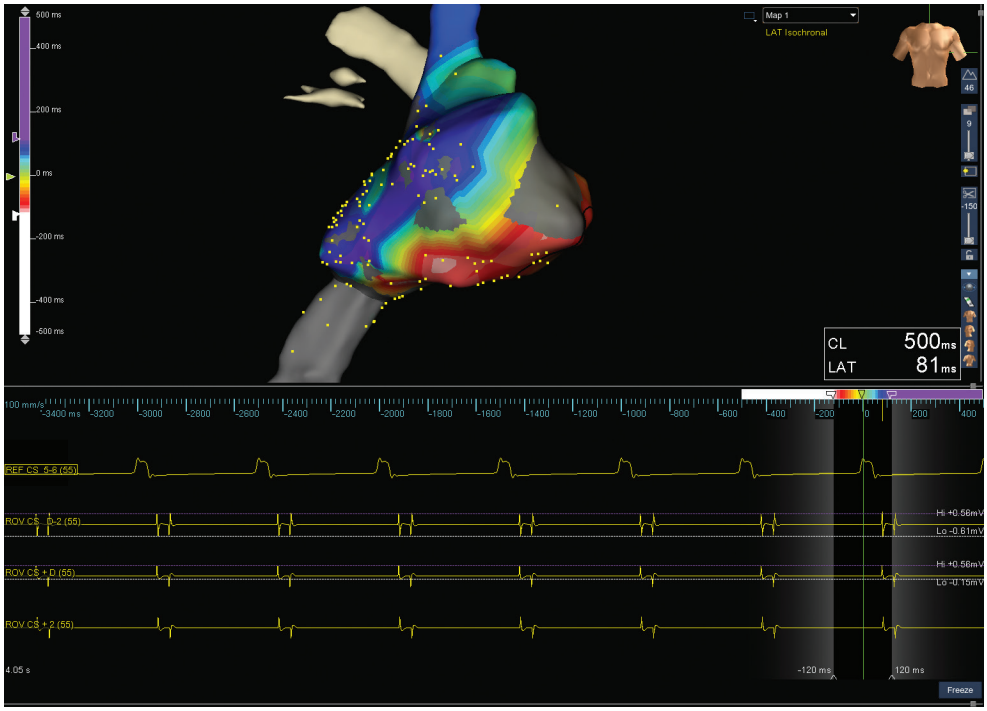
1. Stable Distance checkbox/slider – Area in which the user must keep the catheter for the algorithm to consider it the same collection.
2. Distance checkbox/slider – Distance Threshold: Only collect mapping points if the 3D position of the roving catheter electrode is X.X mm or more from the previously collected mapping point from that electrode. User can set the Distance Threshold from 0.1 to 10 mm. Default Distance Threshold is enabled but the default value is set to 1.0 mm.
3. Signal to Noise checkbox/slider – SNR Threshold: Only collect mapping points if the Signal-To- Noise Ratio on the roving catheter signal is X.X or higher. User can set the SNR Threshold from 1 to 50. Default the SNR Threshold is enabled and is set at 5.0.
4. Force checkbox/slider – Force (Contact Force Range): These criteria can only be used if the EnSite™ X Contact Force Module is installed and the physician is mapping with a TactiCath™ catheter. Only collect mapping points if the Average Contact Force (as measured by a TactiCath™ Contact Force Catheter) is at least X grams and less than Y grams. User can set the Lower Threshold from 0 to 30 grams. User can set the Upper Threshold from 30 grams to 150 grams. The Lower Threshold cannot be set higher than the Upper Threshold. Default the Contact Force Threshold is not enabled. The default lower threshold is 10 grams and the default upper threshold is 50 grams.

Collect Workpanel - Mapping REF, REF2 and ROV Sub-tabs

Figure 93. Collect Workpanel – Mapping Sub-tab

1. REF Source – Cardiac Triggered Maps Only. Sets the primary reference signal for mapping which can be either a surface electrocardiogram or an intra-cardiac electrogram. Multiple ECGs can be selected. Default is set to ECG I.
2. REF Tick Mark Color - The user can assign a color to the primary reference tick mark on the waveform display using the color control.
3. REF Detection – Cardiac Triggered Maps Only. Sets the detection algorithm for the Primary Reference Source.
4. REF Sensitivity – Cardiac Triggered Maps Only. Sets the P-P Sensitivity for the Primary Reference Source. The default sensitivity setting is Automatic, but Fixed sensitivity is an option unless Multiple ECGs is selected as the reference source.
5. REF 2 Source – Cardiac Triggered Maps Only when the Primary Source is set to an intracardiac electrogram. Sets the secondary reference signal used for calculating the Acquisition Sequence. The secondary reference can be set to an intracardiac electrogram.
6. REF2 Tick Mark Color - The user can assign a color to the secondary reference tick mark on the waveform display using the color control.
7. REF 2 Detection –Cardiac Triggered Maps Only. Sets the detection algorithm for the secondary reference source. First deflection and last deflection are not available for the secondary reference detection.
8. ROV Source – Defines the signal used for sampling local activation times and voltages from various locations in the heart. The roving signal can be set to one specific intracardiac signal, all intracardiac signals on a catheter, or all intracardiac signals on all catheters.
9. ROV Tick Mark Color - The user can assign a color to the roving tick mark on the waveform display using the color control.
10. ROV Detection – Cardiac Triggered Maps Only. Sets the detection algorithm for the Roving Source.
11. ROV Sensitivity – Sets the P-P Sensitivity for the Roving Source. In cardiac triggered mapping, this is only available when using First Deflection or Last Deflection.

Figure 94. The contact mapping screen



Surface Type

The system can use several methods to create a model with the collected points: OneModel, High, and Low.

The OneModel tool is a cardiac model creation tool that wraps the model surface tightly around collected points without tying it back to a center point. It provides enhanced anatomic detail of the cardiac model when creating a single surface model, and reduces the time required to create a finished model without requiring the user to change the point collection techniques.

High (detail): Cardiac model creation tool that less extensively fills the space between model points.

Low (detail): Cardiac model creation tool that more extensively fills the space between model points.

NOTE:

- When creating the model, the user can switch back and forth between definition Types: High, Low, and OneModel. Items projected onto the surface may adjust their positions based on the surface generated by each type.
- Moving surfaces to separate surface groups can help in situations where visible separation between surfaces is desired.

Types of Contact Maps

The mapping tool organizes data collected during conventional electrophysiology procedures and displays the data in three- dimensional maps. During mapping, the clinician samples various heart locations (points) in a stable rhythm. The 3D location of each sampled location (point) is saved along with voltage and activation data, which can be displayed on the nearest surface as color. A single set of collected data can be used to display several types of maps.

Cardiac Triggered Maps

Cardiac triggered maps use a surface electrocardiogram or an intra-cardiac electrogram as the reference to which collected points are measured. There are several types of cardiac triggered maps:

- Local Activation Time (LAT) isochronal maps display color-coded activation times for each collected location (or nearest surface). The local activation time is the difference in milliseconds between detected activation on the roving waveform and the primary reference waveform. Colors range from white (early) to purple (late).
- Peak-to-Peak (P-P) voltage maps display color-coded voltage values for each collected location (or nearest surface). The P-P voltage is the difference in millivolts between the peak positive and Peak-Negative components of the detected activation complex on the roving waveform. Colors range from gray (low voltage) to purple (high voltage).
- Peak Negative (P-Neg) voltage maps display color-coded voltage values for each collected location (or nearest surface). The P- Neg voltage is the difference in millivolts between baseline and the Peak-Negative component of the detected activation complex on the roving waveform. Colors range from gray (low voltage) to purple (high voltage).
- CFE Mean maps provide a fractionation index based on the cycle length between multiple, discrete, local activations in an electrogram. Collected points with a lower value are mapped toward the white end of the color spectrum.
- CFE Standard Deviation maps provide a fractionation index based on the cycle length between multiple, discrete, local activations in an electrogram. The CFE standard deviation calculates the standard deviation between activations. Collected points with a lower value are mapped toward the white end of the color spectrum.
- Fractionation maps indicate the number of CFE detections.
- Score maps compare the surface lead morphology of each mapping point collected to the originally collected template beat surface lead morphology. Points collected with a higher score are mapped toward the purple end of the color spectrum.

- Point Count maps indicate the number of points co-located with that point on the map.

  NOTE:

  - For Peak-to-Peak and Peak Negative, the user can select the Unipole box to display unipole maps. Unipole waveforms display on the right. Deselect the Unipole box to display bipole maps.
  - At least one LAT point must be mapped and saved in order for other map types to become available. Prior to this action, these options are grayed out.
  - When the remove white checkbox is selected the color ranges defined above will change from red to purple.

Non-Cardiac Triggered Maps

Non-cardiac triggered maps collect points at user defined period of time, the default is at a one second interval.

- CFE Mean maps provide a fractionation index based on the cycle length between multiple, discrete, local activations in an electrogram. Collected points with a lower value are mapped toward the white end of the color spectrum.
- CFE Standard Deviation maps provide a fractionation index based on the cycle length between multiple, discrete, local activations in an electrogram. The CFE standard deviation calculates the standard deviation between activations. Collected points with a lower value are mapped toward the white end of the color spectrum.
- Fractionation maps indicate the number of CFE detections.
- Point Count maps indicate the number of points co-located with that point on the map.

Signals Collection - Setting the Reference

Primary Reference Signal Source

Cardiac triggered maps require a primary reference signal. The primary reference signal is provided by a surface electrocardiogram or an intra-cardiac electrogram. Multiple ECGs can be selected. The electrodes that provide the primary reference signal must remain in a stable position throughout the mapping procedure. The primary reference signal is set once before beginning a mapping procedure and is used for timing of the roving signals.

Non-cardiac triggered maps do not use any part of the cardiac signal as a reference. Instead, the waveform window refreshes once each second.

The color of the primary reference signal tick mark can be changed by selecting a different color from the color picker. The primary reference signal is highlighted with a box around the waveform's label in the Acquisition Waveform Display.

Figure 95. Boxed label of reference signal

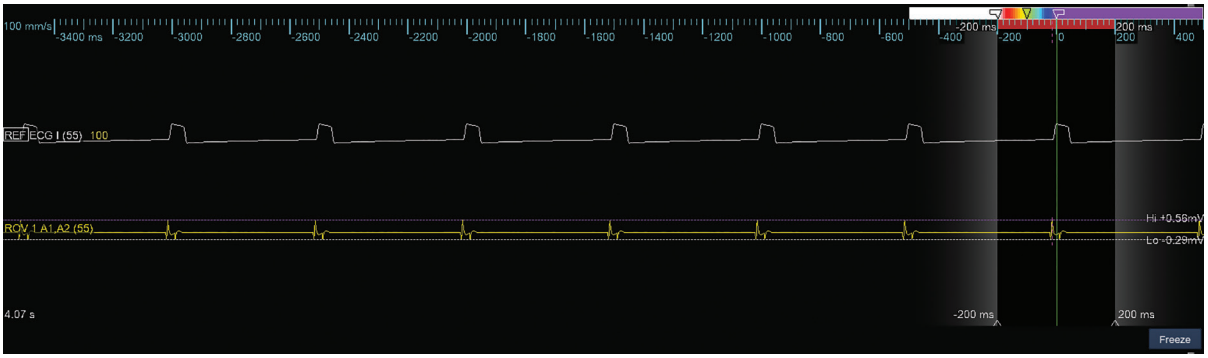
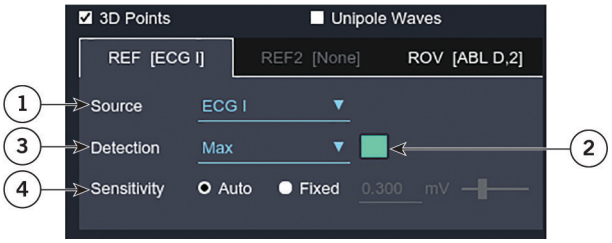


Figure 96. Collect Workpanel – Mapping Sub-tab - Primary Reference tab



1. REF Source – Cardiac Triggered Maps Only. Sets the primary reference signal for mapping which can be either a surface electrocardiogram or an intra-cardiac electrogram. Multiple ECGs can be selected. Default is set to ECG I.
2. REF Tick Mark Color – The user can assign a color to the primary reference tick mark on the waveform display using the color control.
3. REF Detection – Cardiac Triggered Maps Only. Sets the detection algorithm for the Primary Reference Source.
4. REF Sensitivity – Cardiac Triggered Maps Only. Sets the P-P Sensitivity for the Primary Reference Source. The default sensitivity setting is Automatic, but Fixed sensitivity is an option unless Multiple ECGs is selected as the reference source.

Secondary Reference Signal Source

The secondary reference signal is a method to monitor intracardiac activation sequence patterns to ensure the current map point has the same rhythm as the rest of the map. The secondary reference signal is used to calculate the Activation Sequence. The Activation Sequence is the time difference in milliseconds between the detected activation on the secondary reference signal and the primary reference signal. The Activation Sequence of the current map point can be compared against the Activation Sequence of the template beat to ensure the rhythms are consistent. The secondary reference source detection tick mark can be adjusted by clicking and dragging on the tick mark.

Figure 97. Collect Workpanel – Mapping Sub-tab - Secondary Reference tab

The secondary reference source can be set to an intra-cardiac electrogram. The ability to set the secondary reference signal source is only available in cardiac-triggered maps when the primary reference signal is set to an intra-cardiac electrogram.

The color of the secondary reference signal tick mark can be changed by selecting a different color from the color picker. The secondary reference signal is highlighted with a box around the waveform's label in the Acquisition Waveform Display.

Roving Signal Source

Both cardiac triggered and non-cardiac triggered maps require a roving signal. The roving signal is used for sampling local activation times and voltages from various locations in the heart. The roving signal source can be any intracardiac electrode; it can be changed during a procedure, and data can be sampled from one or from multiple electrodes. The color of the roving signal tick mark can be changed by selecting a different color from the color picker.

Figure 98. Collect Workpanel – Mapping Sub-tab - Cardiac Triggered Roving tab

Detection Algorithm

The reference signals and roving signals require a detection algorithm. Detection algorithms locate the best point on the waveform signal to use to identify activation. The detection algorithm first uses a P-P sensitivity to identify activation complexes in the signal. A detection marker is then placed on the activation complex according to the selected Detection Algorithm.

Figure 99. Collect Workpanel – Mapping Sub-tab - Non-Cardiac Triggered Roving tab

Sensitivity – (Applies to the map that has focus when in Split Screen mode.) The minimum peak-to-peak voltage required for the detection algorithm to operate. Incoming signal complexes must be larger in amplitude than the Sensitivity in order to be considered activations by the system. While changing the Sensitivity, red amplitude lines will appear on the related signal in the acquisition panel to indicate the current setting. Set this sensitivity to just above the noise floor. If 1.5 seconds has elapsed since the last reference signal detection, the algorithm will identify an optimal activation complex, even if it does not meet the Sensitivity setting.

> NOTE: For the primary reference signal, the default sensitivity setting is Automatic, but Fixed sensitivity is an option unless Multiple ECGs is selected as the reference source. For Roving for Cardiac Triggered maps, the Fixed Sensitivity is available when using First Deflection or Last Deflection.

Detection Algorithm – The available selections are:

- -dVdt – Sharpest negative slope
- +dV/dt – Sharpest positive slope
- abs dVdt – Sharpest slope, regardless of positive or negative
- Max – Peak positive amplitude
- Min – Peak negative amplitude
- abs Peak – Largest peak amplitude (difference from baseline) regardless of positive or negative
- First Deflection – First deflection from baseline
- Last Deflection – Last deflection from baseline

Setting up the Detection Algorithm

1. Select a primary reference signal.
2. If applicable, set the sensitivity slightly above the noise floor.

3. Select the appropriate detection algorithm.
4. Repeat for the roving signal.
5. If using a secondary reference signal, repeat steps 1 and 3.

   NOTE:

   - The user can drag the green Reference Offset line to the desired position, and the system calculates the timing automatically from that position. The aqua-colored line is the reference line placed by the detection algorithm and cannot be moved.
   - Do not change the reference offset after saving the first beat when using Score Map. Changing of the reference offset after the first beat may lead to an incorrect mapping display.
   - Cardiac triggered CFE maps use the same detection algorithm as LAT, P-P, and P-Neg. Non-cardiac CFE maps use the one second screen refresh signal as a trigger. The detection algorithm is not selectable.
   - Detection on the roving waveform takes place within the Roving Activation Interval.

Additional Signals (see Mapping Settings Panel for more information)

Additional ECG or intracardiac signals can be selected to facilitate confirmation of rhythm stability. These signals are only for visualization and are not involved in detection.

Mapping Considerations

CFE Maps

- Multiple detections are possible in a single sample.
- Tick marks in CFE maps are not individually adjustable.
- In CFE maps, some detection settings can be adjusted retrospectively and affect all points in the current map, including Sensitivity, Width, Refractory, the RAI, and Segment Length.
- The Width slider controls the minimum complex width to consider for activation.
- The Refractory slider controls the minimum amount of time between detections.
- The Segment Length slider controls the number of seconds per sample. This control is only available for non-cardiac triggered maps.

Reentrant Maps

- Reentrant maps present the mapping of reentrant arrhythmias and are displayed in a manner similar to LAT maps. The color displayed within the map is linked to the cardiac cycle length (CL) and allows the adjacent display of "early" (white) and "late" (purple) activation times.
- The CL of a Reentrant LAT map is determined by the spacing between the curtains. Adjustment of the CL can be made by clicking and dragging the edge of the curtains to the desired location. The CL will not take effect until the Reentrant checkbox is turned on.

  NOTE: Adjusting the CL and then collecting points may invalidate the map.

Propagation Maps

- Propagation maps display areas of activations times that fall within a specific time interval. The interval can be moved forward through one heart cycle either automatically or by user control.
- Propagation maps can be played in Realtime or RealReview but recordings can only be exported in Offline Review.
- A button beneath the Propagation dropdown controls automatic motion of the activation interval with [Play] and [Freeze] options. [Play] loops over the user-selected cycle length.
- There are two type of Propagation maps available. A mono-color propagation map and a full-color propagation map.
- The speed that the Propagation Maps are played is controlled by the drop-down next to the Play/Sparkle Map button. The speed is related to the amount of time it takes to play through one RAI cycle.

Propagation

- When Propagation is selected, the colors of the map change to purple and white only. The leading edge of the white stripe is brighter than the trailing edge of the stripe to indicate the direction of travel activation.
- Using the side color bar, the stripe can be widened (increasing the interval in milliseconds [ms]), by clicking and dragging above the white stripe. This action can also be accomplished by clicking to the right of the stripe in the color bar at the top of the screen.

Full-Color Propagation

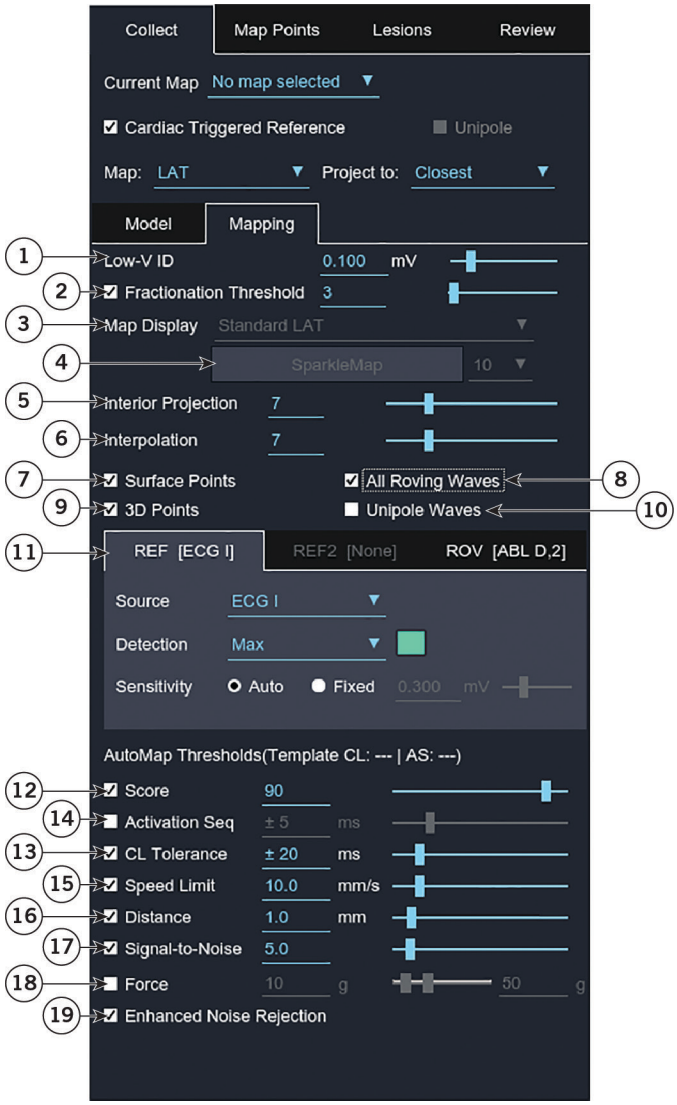
- When Full-Color Propagation is selected, all the colors of the map are used to show the cardiac activation wavefront. The color of the spectrum move through the heart cycle and the map is updated accordingly.

SparkleMap

- The SparkleMap feature allows you to view the activation sequence on top of another map (ex. Voltage map) which allows the physician to simultaneously view multiple datasets on the same anatomic model. The SparkleMap shows the propagation sequence via a series of circular flashes.
- Select the SparkleMap button in the Mapping Tab of the Collect Work Panel to activate.

Collect Workpanel – Mapping Sub-tab

Figure 100. Collect Workpanel – Mapping Sub-tab

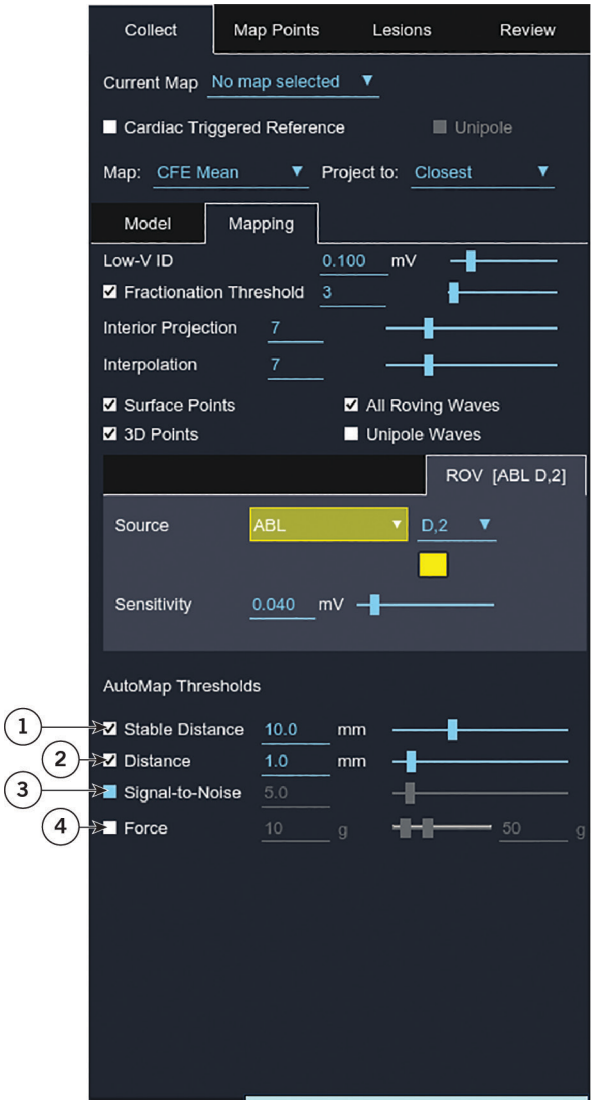


1. Low-V ID slider – (Applies to the map that has focus when in Split Screen mode.) Identifies low-voltage zones in LAT or CFE maps. If a collected point's P-P value is lower than the specified Low-V ID value, then that point will display a gray area instead of the color- coded scale for the current map type. Grey points do not interpolate with color points.
2. Fractionation Threshold checkbox/slider – Renders points that are fractionated as larger spheres. Default value=3 (renders points with a fractionation value of >= 3.
3. Map Display – (LAT maps only) The type of LAT map: Standard LAT, Reentrant Map, Full-Color Propagation or Propagation Map.
4. Sparkle Map button – Displayed the activation sequence overlaid on top of another map. The SparkleMap shows the propagation sequence using a series of circular flashes. The button changes to "Stop" while Sparkle Map is playing and will stop Sparkle Map when selected. The speed that the Sparkle Map is played is controlled by the drop-down next to the button. Sparkle Map button is unavailable when the Map Display control is set to either type of propagation map.
5. Interior Projection slider – (Applies to both maps when Split Screen mode is active.) This slider controls the maximum distance that an interior 3D Point (represented as a triangle) can project to a location on the surface (represented by a square). For multiple-surface models, points will project to the nearest surface.
6. Interpolation slider – (Applies to the map that has focus when in Split Screen mode.) This slider controls the minimum distance between surface points necessary for the system to interpolate color. For multiple surface models, points will interpolate between surfaces in the same group.
7. Surface Points checkbox – (Applies to the map that has focus when in Split Screen mode.) Enables/disables the display of small square points on the surface. These squares represent the point on the surface closest to a collected 3D point.
8. All roving Waves checkbox – Select to display all roving waves. When deselected, only one roving wave is displayed in the Acquisition Waveform Display.
9. 3D Points checkbox – (Applies to the map that has focus when in Split Screen mode.) Enables/disables the display of collected points as triangular markers. The triangular markers are placed on the negative electrode of the roving signal channel.
10. Unipole waves checkbox – Select to display unipolar waves of the roving signals in the Acquisition Waveform Display.
11. REF and ROV tabs – this area will be described in later sections.
12. Score checkbox/slider – Score Threshold: Full or any combination of the 12 Surface Leads. Only collect mapping points if the 12-Lead Surface Morphology is XX% similar or higher compared to the original template beat 12-Lead Surface Morphology. The user can set the Score Threshold from 0 to 100%. By default, the Score Threshold is enabled and is set to 90%.
13. CL Tolerance checkbox/slider - Cycle Length Tolerance: Only collect mapping points if the

intracardiac measured (CS, HIS, other) Cycle Length is within +/- XX ms of original template beat Cycle Length. User can set the Cycle Length Tolerance from +/- 0 to 150 ms. Default the Cycle Length Tolerance is enabled and is set to +/- 20 ms.

14. Activation Seq checkbox/slider – Activation Sequence is defined as the timing between the primary reference (REF) detection and the secondary reference (REF 2) detection when both the REF and the REF 2 are set to intracardiac signals. When activated, this controls only collects mapping points when the Activation Sequence of the current beat is within +/- XX ms of the template beat Activation Sequence. The user can set the Activation Sequence tolerance slider from +/-0 to 25 ms with a default of +/- 5 ms.
15. Speed Limit checkbox/slider – Speed Limit: Only collect mapping points if the mapping catheter is moving less than XX.X mms/s. User can set the Speed Limit from 0.1 to 75 mm/s. Default the Speed Limit is enabled and is set to 10.0 mm/s.
16. Distance checkbox/slider – Distance Threshold: Only collect mapping points if the 3D position of the roving catheter electrode is X.X mm or more from the previously collected mapping point from that electrode. User can set the Distance Threshold from 0.1 to 10 mm. Default Distance Threshold is enabled but the default value is set to 1.0 mm.
17. Signal to Noise checkbox/slider – SNR Threshold: Only collect mapping points if the Signal-To- Noise Ratio on the roving catheter signal is X.X or higher. User can set the SNR Threshold from 1 to 50. Default the SNR Threshold is enabled and is set at 5.0.
18. Force checkbox/slider – Force (Contact Force Range): These criteria can only be used if the EnSite™ X Contact Force Module is installed and the physician is mapping with a TactiCath™ catheter. Only collect mapping points if the Average Contact Force (as measured by a TactiCath™ Contact Force Catheter) is at least X grams and less than Y grams. User can set the Lower Threshold from 0 to 30 grams. User can set the Upper Threshold from 30 grams to 150 grams. Default the Contact Force Threshold is not enabled but the default lower threshold is 10 grams and the default upper threshold is 50 grams.
19. Enhanced Noise Rejection checkbox – Enhanced Noise Rejection: Only collect mapping points if the roving catheter signal does not have certain types of noise (Signals with saturations, electrode-to-electrode contact, open electrode noise, signals with degraded conditions such as no location or dropped data). Only uncheck for pace mapping. User can set the Enhanced Noise Reduction on or off. Default the Enhanced Noise Reduction is enabled.

Figure 101. Collect Workpanel – Mapping Sub-tab - Automap

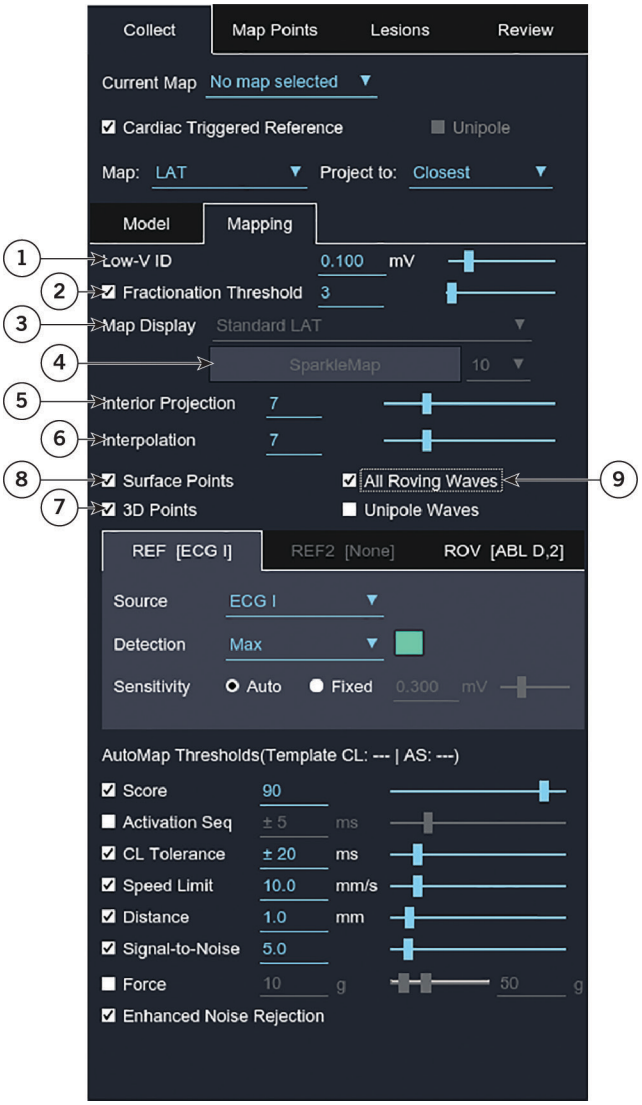


1. Stable Distance checkbox/slider – Area in which the user must keep the catheter for the algorithm for it to consider it the same collection.
2. Distance checkbox/slider – Distance Threshold: Only collect mapping points if the 3D position of the roving catheter electrode is X.X mm or more from the previously collected mapping point from that electrode. User can set the Distance Threshold from 0.1 to 10 mm. Default Distance Threshold is enabled but the default value is set to 1.0 mm.
3. Signal to Noise checkbox/slider – SNR Threshold: Only collect mapping points if the Signal-To- Noise Ratio on the roving catheter signal is X.X or higher. User can set the SNR Threshold from 1 to 50. Default the SNR Threshold is enabled and is set at 5.0.
4. Force checkbox/slider – Force (Contact Force Range): These criteria can only be used if the EnSite™ X Contact Force Module is installed and the physician is mapping with a TactiCath™ catheter. Only collect mapping points if the Average Contact Force (as measured by a TactiCath™ Contact Force Catheter) is at least X grams and less than Y grams. User can set the Lower Threshold from 0 to 30 grams. User can set the Upper Threshold from 30 grams to 150 grams. The Lower Threshold cannot be set higher than the Upper Threshold. Default the Contact Force Threshold is not enabled but the default lower threshold is 10 grams and the default upper threshold is 50 grams.

Cardiac Triggered Mapping Settings

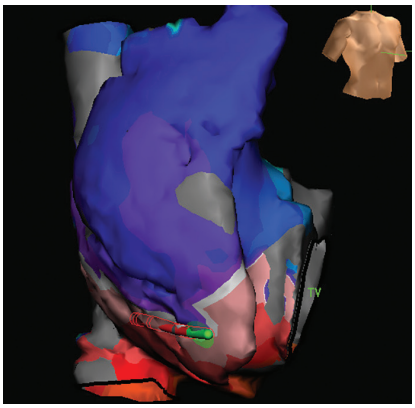
Settings apply to the map that has focus when in Split Screen mode unless noted.

Figure 102. Cardiac Triggered Mapping Work Panel

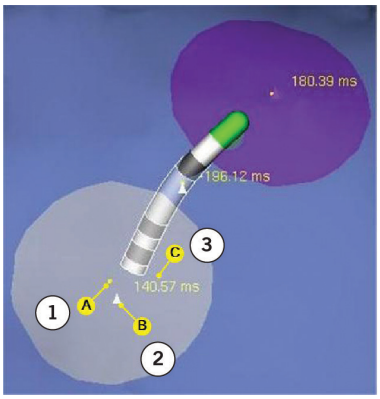


1. Low-V ID - Identifies low-voltage zones for all maps except voltage and score maps If a collected point's P-P value is lower than the specified Low-V ID value, then that point will display a gray area instead of the color-coded scale for the current map type. Grey points do not interpolate with color points.
2. Fractionation Threshold - Renders points that are fractionated as larger spheres. Default value=3 (renders points with a fractionation value of >= 3.
3. Map Display (LAT maps only) - The type of LAT map: Standard LAT, Reentrant Map, Propagation Map or Full-Color Propagation Map.
4. SparkleMap - Displays the activation sequence overlaid on top of another map. The SparkleMap shows the propagation sequence using a series of circular flashes. The button changes to "Stop" while Sparkle Map is playing and will stop Sparkle Map when selected. SparkleMap button is unavailable when the Map Display control is set to either type of propagation map.
5. Interior Projection - (Applies to both maps when Split Screen mode is active.) This slider controls the maximum distance that an interior 3D Point (represented as a triangle) can project to a location on the surface (represented by a square). For multiple-surface models, points will project to the nearest surface.
6. Interpolation - (This slider controls the minimum distance between surface points necessary for the system to interpolate color. For multiple surface models, points will interpolate between surfaces in the same group.
7. 3D Points - Enables/disables the display of collected points as triangular markers. The triangular markers are placed on the positive electrode of the roving signal channel.
8. Surface Points- Enables/disables the display of small square points on the surface. These squares represent the point on the surface closest to a collected 3D point.
9. All roving Waves checkbox - Select to display all roving waves. When deselected, only one roving wave is displayed in the Acquisition Waveform Display.

Figure 103. LAT Isochrone with Low-V ID and Collected Points Example



LAT isochrone with Low-V ID



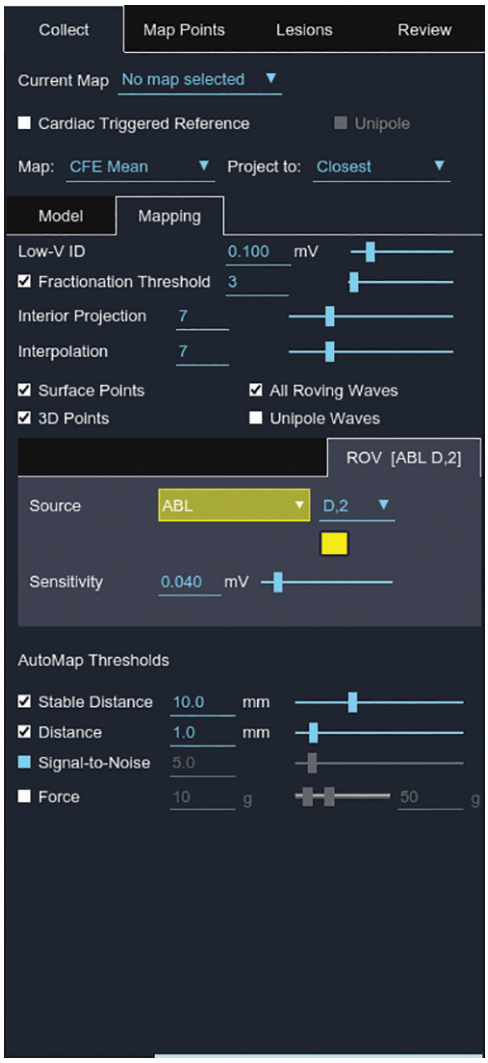
Collected points

1. A: surface point
2. B: 3D point
3. C: 3D label

Non-Cardiac Triggered Mapping Tab

Notice that in the Mapping Tab of the Collect Work panel the available settings have changed slightly. The Map Display controls have been removed and there is no option to select a primary or secondary reference.

Figure 104. Non Cardiac Triggered Mapping control panel



Cardiac Triggered Reference checkbox is unchecked.

AutoMap Description

The AutoMap feature automates the point collection process, based on the user-defined settings. As the catheter is moved, points are collected when the user-defined settings are met.

Figure 105. Mapping Screen

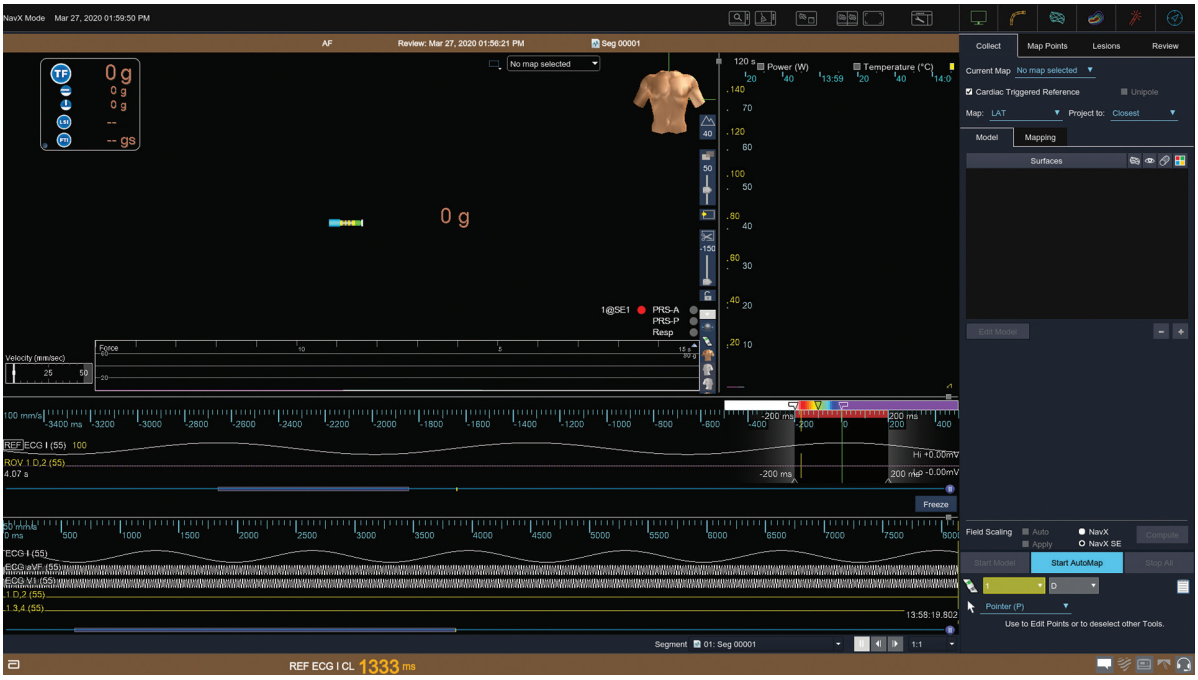
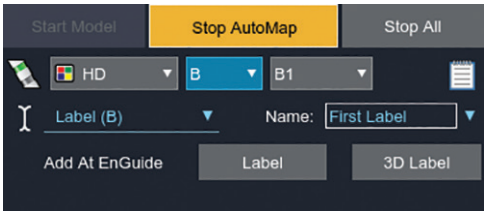


Figure 106. Start/Stop Automap



Start AutoMap/Stop AutoMap button: Select to begin automatic mapping point collection — select again to stop automatic mapping point collection.

Stop All button: Stops automatic mapping point collection AND stops anatomic model point collection.

The user can also start/stop the AutoMap feature by using shift+F11 key.

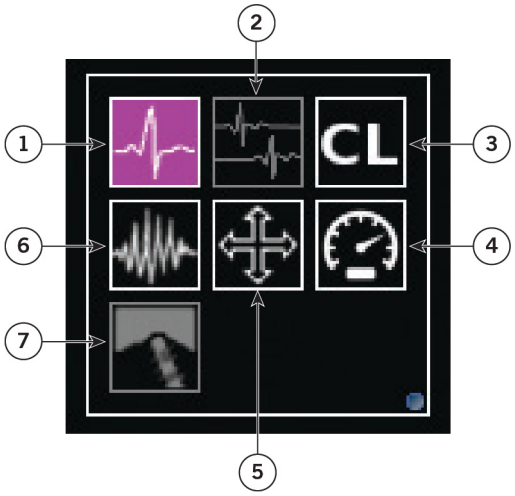
AutoMap Settings

AutoMap Settings define the minimum criteria that must be met for a mapping point to be automatically collected. Select the box next to each criterion to be used for automatic point collection. The settings for AutoMap differ between cardiac and non-cardiac triggered references.

Point Collection Status Meter

The point collection status meter provides feedback on whether the AutoMap threshold criteria are being met during point collection. To view this meter in the model/map display, select the Point Collection Status checkbox in the Meter & Display Options settings panel.

Figure 107. Points collection status icons



Icons correspond to AutoMap thresholds:

Cardiac triggered map-only

1. Score icon (Score threshold)
2. Activation Sequence icon (Activation Sequence threshold)
3. Cycle Length icon (CL Tolerance threshold)
4. Speed Limit icon (Speed Limit threshold)

Non-cardiac triggered and cardiac triggered maps

1. Distance icon (Distance threshold)
2. Noise icon (Signal to Noise and Enhanced Noise Rejection thresholds)
3. Force icon (Force threshold)

Non-cardiac triggered maps-only

1. Stable Distance icon (Stable Distance threshold)

   NOTE: The entire circle must turn green before a point will be collected. The circle will increasingly fill with green as the catheter electrodes remain stable (i.e. within the distance specified in the Stable Distance threshold). The entire circle will become green if the catheter electrodes remain stable for the duration of time defined by the Segment Length setting.

The color of an icon corresponds to the following states:

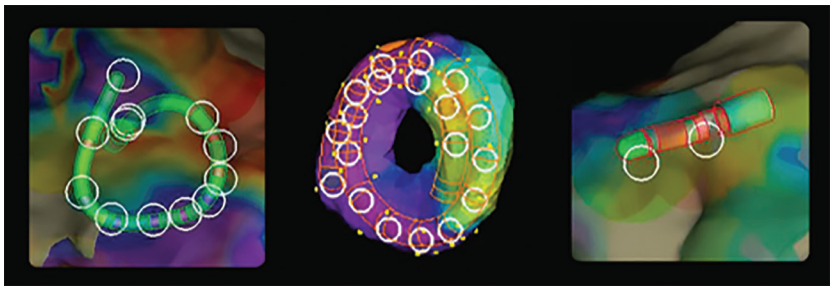
- Black with white graphic - AutoMap threshold is enabled.
- Black with grayed-out graphic - AutoMap threshold is not enabled.
- Flashing red - Points are not being collected because they do not meet AutoMap threshold criteria associated with icon.

  NOTE: The Speed Limit icon will turn red if the AutoMap threshold criteria is unmet for all roving electrodes collecting points, e.g. the signal to noise ratio would have to be beneath the threshold for every roving electrode collecting points, for the icon to turn red.
- Magenta - The following icons will be magenta when the setup requirements described below have not been met:
  - Score icon - At least one ECG signal must be selected in the acquisition waveform display.
  - Activation Sequence icon - Primary and secondary reference signal source must be set to intra-cardiac electrograms.
  - Force icon - Roving signal source must be set to an EnSite™ Contact Force-compatible catheter and TactiSys™ Quartz Equipment must be connected.

  NOTE: The entire point collection status meter flashes white when any point is collected.

Points Display

Figure 108. Points Display Examples



Mapping points are collected, and a brief flash occurs at the active mapping electrodes that meet all the user defined point collection criteria. The flash at electrodes indicators may be disabled by unchecking the Flash New Points box on the Meters and Display Options Setting Panel.

Figure 109. Mapping metrics display – example for LAT map

1. Score - Score value

   NOTE: Score is display when there is at least one ECG signal selected in the acquisition waveform display.
2. CL - Reference cycle length
3. Seq - Activation sequence timing value

   NOTE: Seq is displayed when the primary and secondary reference sources are set as intra-cardiac signals.
4. Map type-dependent metric - A metric relevant to the type of map selected will be displayed, e.g. LAT will be displayed when the current map type is LAT.

The color in which data values are displayed indicates the following:

- White when viewing data in real time.
- Gold when viewing data in review mode.
- Brown when mapping point is frozen or selected.
- Red when AutoMap threshold criteria associated with metric are not being met.
- Purple when a frozen or selected mapping point contains unreliable data.
- Purple dash when:
  - the reference detection is degraded for the current beat or previous beat or
  - the previous detection beat does not exist due to clearing the beat buffer.

Score Map

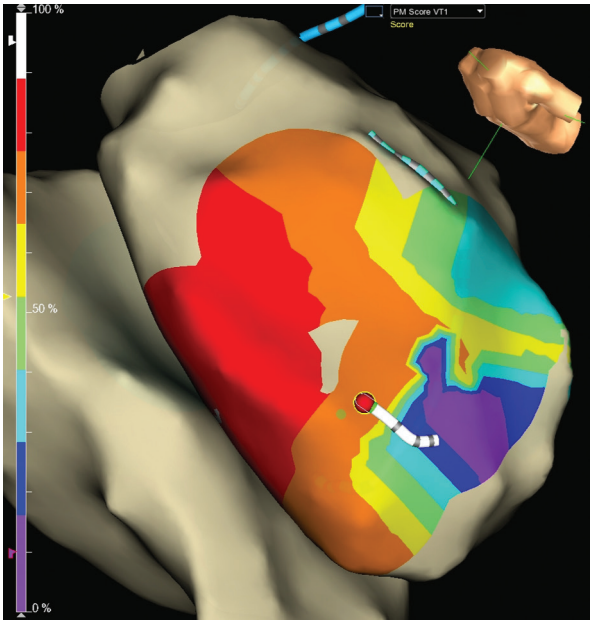
A Score Map is a map type that plots the surface lead morphology match score associated with each mapping point collected compared to the originally collected template beat surface lead morphology. The physician may want to use this feature during pace mapping where it may be useful to plot the 90%-100% morphology match scores in the area of interest.

The user may also sort the points list by score from highest score surface lead morphology match compared to the template beat to lowest score surface lead morphology match compared to the template beat. When the user clicks on the mapping point, they will be able to view the current mapping point surface lead morphology on top of the template beat surface lead morphology trace. This may be useful to determine which surface lead(s) are different from the template beat.

It is possible to adjust the map scale to only display the 90-100% matches on the map.

The Score Map can also be used during automated mapping to allow users to automatically collect only those points with morphology match scores that are XX% similar or higher compared to the template beat and automatically reject those points that are not XX% similar or higher compared to the original template beat.

Figure 110. Score Map Example

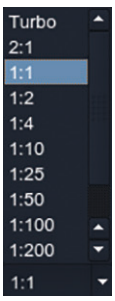


When Start AutoMap is activated, the software automatically records the data from 10 seconds before the EnSite™ X AutoMap feature was activated and continues recording as long as the EnSite™ X AutoMap feature is active.

TurboMap

Once original mapping has occurred, the user may change mapping criteria and play back through the original dataset at Max speed to generate a new map at 10x's real-time speed. This is called the TurboMap feature. As an example, if the original mapping time was 10 minutes, the user can generate a second map in only 1 additional minute. This same concept can be employed for multiple maps. This may be useful if the physician is mapping Sinus Rhythm and intermittent, multiple PVC or VT morphology beats are occurring. This may also be useful if the physician is trying to map multiple, distinct Cycle Length atrial tachycardias.

Figure 111. Playback Speed Selection Menu



There is no limit to the number of mapping points that may be collected per map. The number of mapping points in the map is listed on the screen.

There is no limit to the number of maps that may be collected per study.

Catheters for Use with Automated Mapping with the EnSite X™ AutoMap Feature

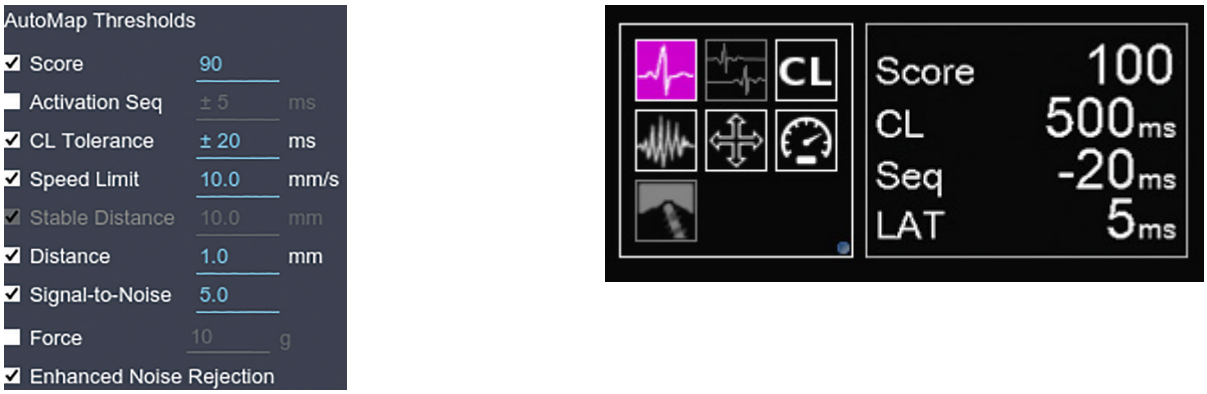
The Navigation mode determines the catheters available for mapping. In EnSite NavX™ mode physicians may take advantage of automated mapping with the EnSite™ X AutoMap Feature with standard EP catheters with any number of electrodes. In EnSite™ VoXel mode mapping data can only be collected from Sensor Enabled™ catheters. Physicians may take advantage of automatically including/excluding mapping points based on average contact force when the EnSite™ X Contact Force Module is installed and when the physician is using a TactiCath™ Contact Force Catheter to map.

Example 1 (atrial mapping with multiple distinct cycle length atrial tachycardias)

In the atrial chambers, physicians may want to automatically collect mapping points as long as the intracardiac (CS, HIS, etc) measured Cycle Length is within +/- XX ms of the original template beat (first point saved into the map). In the example below the physician simultaneously and automatically built the right atrial anatomy and atrial tachycardia LAT timing and voltage maps in the right atrium by:

1. Saving the first atrial tachycardia (Cycle Length 1) beat into the map, ensuring that the Roving Activation Interval does not include a ventricular complex.
2. Checking the "Cycle Length Tolerance" box and setting it to +/- 20 ms.
3. Checking the "Score Threshold" box and setting it to 50 (this may eliminate roving catheter points polluted with far field ventricular activity).
4. Select "Start AutoMap".

Figure 112. Atrial mapping with multiple distinct cycle length atrial tachycardias example



5. If a secondary atrial tachycardia (Cycle Length 2) was intermittently occurring during original mapping, the user can save one of those points into a new map, pulling up the primary AutoMap mapping segment, setting the AutoMap Settings for the secondary map, and clicking Max speed to generate this new map with the TurboMap feature.

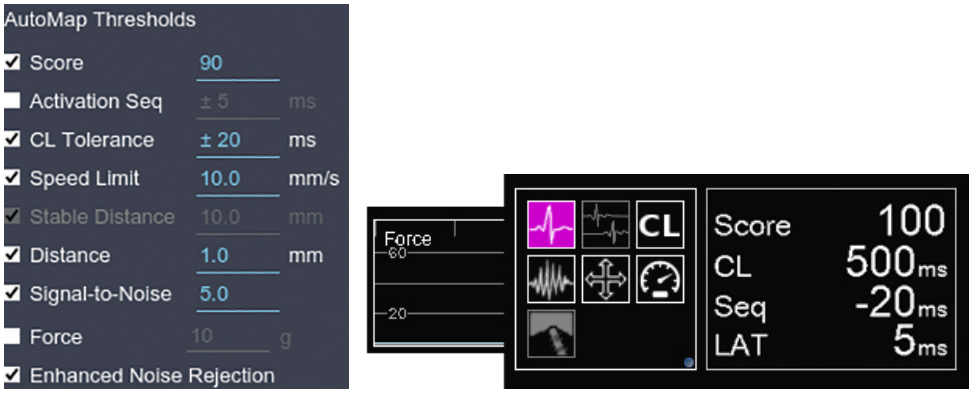
Example 2 (ventricular mapping with multiple distinct surface lead morphologies)

In the ventricular chambers physicians may want to automatically collect mapping points as long as the surface lead morphology is XX% similar to the template beat (first point saved into the map). For example the physician can simultaneously and automatically build the left ventricle anatomy and Sinus Rhythm voltage/timing maps in the left ventricle by:

1. Saving the first Sinus Rhythm beat into the map.
2. Checking the "Score Threshold" box and setting it to 90.
3. Select "Start AutoMap".

   NOTE: When the surface lead morphology is not 90% similar to the template Sinus Rhythm 12-lead Surface Morphology, the red box turns red indicating that mapping points were not collected because the Surface Lead Morphology Match Score was outside the morphology of interest. This feature can be used to automatically reject ectopy as the ectopy would not be 90% similar to the template beat.

Figure 113. Ventricular mapping with multiple distinct surface lead morphologies example



In some instances secondary arrhythmias may intermittently occur during primary map collection. If this occurs, the physician could use the TurboMap feature to create a map with points only associated with that secondary intermittent arrhythmia by:

1. Placing a bookmark when the secondary arrhythmia occurred during primary map collection.
2. Saving a mapping point of the secondary arrhythmia into a new map.
3. Pulling up the AutoMap Mapping Segment of the original map.
4. Select Start AutoMap.
5. Selecting Max speed to play back through the original dataset at 10x's real-time speed.
6. Selecting Play on the segment.

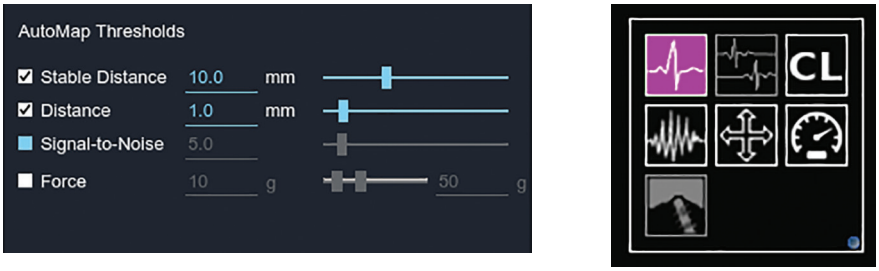
   NOTE: When the surface lead morphology is not 90% similar to the secondary arrhythmia template beat morphology, the red box turns red indicating that mapping points were not collected because the Surface Lead Morphology Match Score was outside the morphology of interest.

This same concept could be applied to other secondary arrhythmias that occurred during the original map creation.

Automatic Non-Cardiac Triggered Maps

1. Setup a non-cardiac triggered map as usual.
2. Setup the AutoMap Settings as shown in the image below.
3. Select Start AutoMap.

Figure 114. Automatic Non-cardiac Triggered Map Controls



Collecting Points

The waveform display is used to evaluate waveforms and collect points.

Figure 115. The waveform display for contact maps

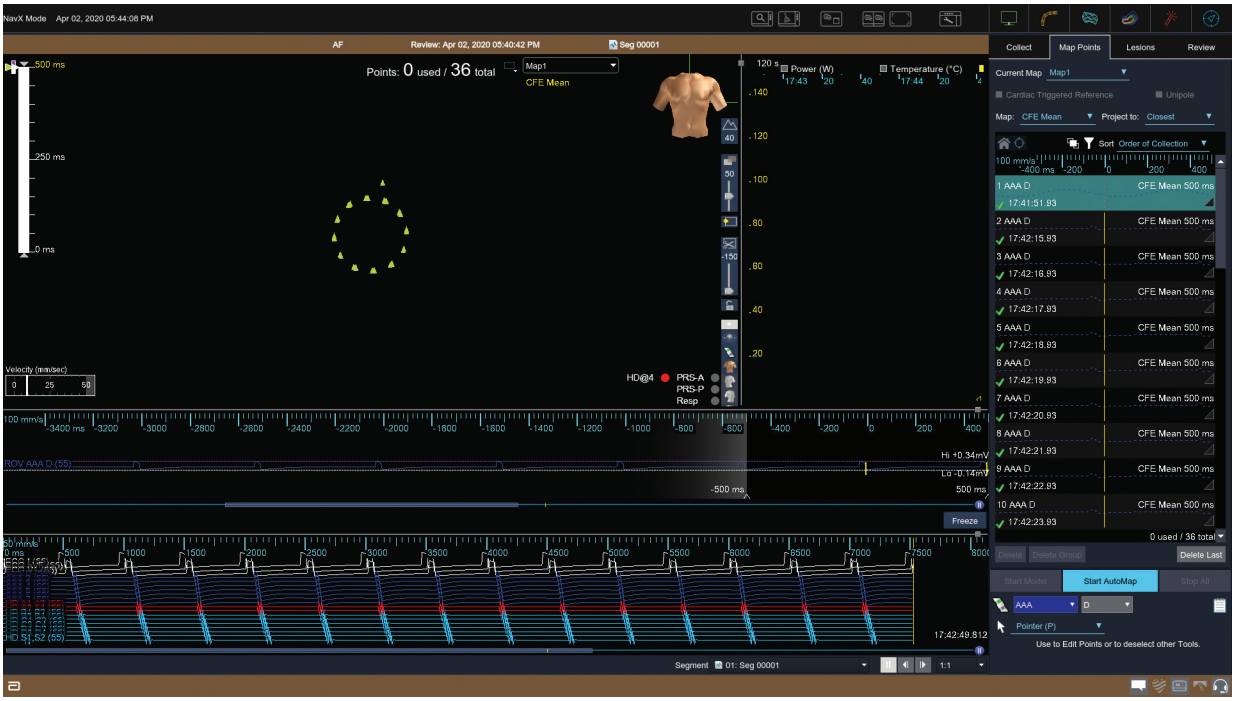


Table 3. Horizontal Split Screen mode Elements

Callout	Item	Description
1	Time scale	The time scale (in milliseconds) at the top edge of the waveform display. The detected timing reference appears at 0 ms. Right-click on the Time Scale to display a menu to set the sweep speed, font size, and

		waveform thickness.
2	Color bar	(LAT maps only) When collecting or displaying LAT isochronal data, the color bar displays above the waveform display. The function of the color bar duplicates the color bar in the map display. Dragging the pointers on the color bar will adjust the range.
3	Roving Activation Interval (RAI)	The Roving Activation Interval is a timing parameter that is used in the detection of roving catheter activation. The RAI is defined by the black area between the curtains. The curtains appear as shaded areas on either side of the RAI. Roving catheter activation will not be reliably detected unless the beat falls within the black-background portion of the waveform display. To adjust the RAI, click and drag the edge of the shaded background.
4	RAI Curtain	Select and drag the curtain to adjust the RAI.
5	Reference Activation Tick Mark	Reference catheter activation as defined by the selected reference detection algorithm. The reference tick mark will always appear at (0) ms on the time scale. NOTE: If the current rhythm does not meet the reference detection settings, this tick mark will be magenta. Points can still be collected and adjusted.
6	Reference Offset Caliper (Green)	Drag to place the Reference Offset Caliper to the desired point in the waveform. Waveform timing calculations will be based upon the offset location.
7	Roving Activation Tick Mark	Roving catheter activation as defined by the selected roving detection algorithm, within the Roving Activation Interval. When adjusting this tick mark, the associated location in the map display will move to reflect the roving position at the time of the tick mark measurement. NOTE: ▪ If the current rhythm does not meet the roving detection settings, this tick mark will be magenta. Points can still be collected and adjusted. If a time is adjusted and there are error conditions in the signal and the reference caliper is not purple, the caliper will turn yellow. ▪ For CFE maps, multiple tick marks may appear on the roving waveform. Activation tick marks for CFE maps are not adjustable.
8	Voltage Low Caliper	Roving catheter low voltage. This voltage caliper is set to the lowest voltage within 100 ms of detected roving activation, within the RAI. This caliper is used in determining peak-to-peak (P-P) voltage and peak-negative voltage.
9	Voltage High Caliper	Roving catheter high voltage. This voltage caliper is set to the highest voltage within 100 ms of detected roving activation, within the RAI. This caliper is used in determining peak-to-peak (P-P) voltage.
10	RAI Values	The current RAI values appear at the lower corner on each side of the curtains. These combined values equal the amount of time occupied by the curtains. For non-cardiac CFE maps, the RAI is equivalent to the segment length, and appears at the lower left and right. Only the left value changes for non-cardiac triggered CFE maps. For cardiac triggered CFE maps, the RAI is set independently for CFE maps and other contact map types.
11	[Freeze]/[Save]	When data is being collected (gated to detection of the timing reference), click the [Freeze] button to stop the display and review data. After pressing [Freeze], the label on the button changes to [Save]. Clicking [Save] allows you to save the current point and point display to the current map, a different map, or a new map using the pulldown menu. The following data is saved with each collected beat: electrode position, current waveforms (reference, roving, signal1, signal2, signal3), buffered waveforms and related roving electrode locations, timing, and voltage. Performance may begin to slow after 1000 points. When mapping is used in Review mode, [Freeze] will also freeze the waveform display and [Save] will cause the waveform display to play. Hot key: <F11> duplicates the function of the [Freeze] and [Save] buttons.
12	[Cancel]/[Resume]	When the waveform display is frozen, [Cancel] will remove the currently displayed beat and resume gated data collection without adding information to the map. [Resume] will resume gated data collection. Hot key: <F12> duplicates the function of the [Cancel] button.
13	Collected point buffer	As data is collected, each detected beat is temporarily saved in a buffer. When the waveform display is frozen, buffered data can be accessed using the buffer controls below the waveform display. The beat that was present at the time that [Freeze] was selected is represented by [0]. Previous beats can be accessed by selecting the buttons for [-1], [-2], etc. When reviewing beats in the buffer, the associated location in the map display will change to reflect the roving location at each selected beat. Hot key: The left and right arrow buttons in the beat buffer are duplicated by the left and right arrow keys on the keyboard.

Mapping Settings Panel – Settings Tab

NOTE: Controls are disabled in the Mapping Settings Panel when that control is not applicable to the current map.

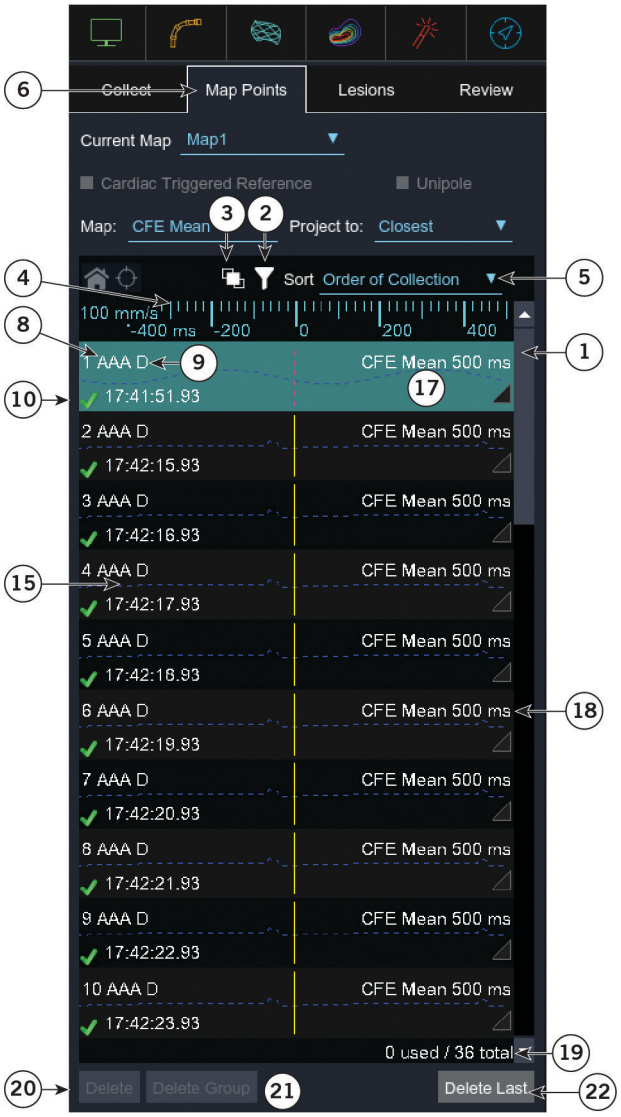
Map Points Workpanel

Select the Map Points workpanel to display the collected points. The display is a combined waveform segment, synchronized in time, of every roving catheter waveform incorporated into the map. Each waveform includes a tick mark indicating the activation point and a numeric metric that is determined by the current map type.

Selecting a waveform in the Map Points display shows the original data for that heartbeat in the waveform display including all saved waveforms, up to ten timing calipers per point (timing calipers can be adjusted), voltage calipers, and all buffered data. The beat of interest and voltage caliper settings can be adjusted. All changes are saved automatically. The point in the map display that is related to the highlighted waveform will flash red.

NOTE: The first point(s) in the map are highlighted green to indicate that they are the template beat for the map. These points, while first chronologically, may appear at different places in the list with other sort orders. These template beats are colored green so they are not inadvertently deleted, as doing so would change the map.

Figure 116. Map Points Workpanel (Points list and point display options)



1. Scroll to Selected icon – Scrolls the list to the selected point.
2. Locate Point icon – Locates the selected point in 3D space.
3. Show Duplicate of Selected icon – Show duplicates of the selected point.
4. Show/Hide Unused Points icon – Show all points or only the used points.
5. Sort drop-down list – Sort waveforms by order of collection, current map type, and cycle length. (After making timing adjustments, the user must select sort by LAT again.)
6. Map Points list – Displays the list of points saved to the current map.
7. Timescale: The time scale, in milliseconds (ms), displays at the top edge of the waveform display. The timing reference of all waveforms is synchronized to 0 msec. Adjust the Sweep Speed by right-clicking in the black background and selecting Sweep Speed. The available options are 40, 50, 100, 200, and 400 mm/sec.
8. Waveform Number - Indicates the order of waveform collection. When multiple points are acquired simultaneously, all the related points have the same waveform number.
9. Electrode Polarity - Polarity of the electrodes on the catheter. Unipolar is indicated with the single electrode preceded by a "+" sign.
10. Hide Point Checkbox - When checked, this checkbox indicates that this point on the map may show. Clear the check mark to hide this point. When unchecked, the point is hidden, and a red circle displays.
11. Duplicate Points - A star above the check box indicates a duplicate point. There are 3 types of duplicate points:
    - Blue outline star - duplicate point, but not used
    - Solid blue star - point has duplicates, but this point is used by the system
    - Solid gold start - point has duplicates, but the user chose to use this point
1. Dashed Waveform Line - A dashed waveform line indicates that a point is not used to color the map (not shown). The following types of points are drawn as dashed: hidden points, duplicate points, points outside the projection distances, and points with no locations.
2. Solid Waveform Line - Indicates a point that is used in the map.
3. Blue background - Indicates the selected waveform. The data for the waveform is shown in the waveform display. If the corresponding point is used in the map, the 3D point, its projection on the map surface, and its text, flash red.
4. Map point measurement - The Timing (in ms) or Voltage (in mV) of the map point.
5. Number of points - The number of points that have been selected/used/collected. The list may have to be scrolled to see all the waveforms.
6. Delete button – To delete a waveform from the Points display and its corresponding point from the map, select the waveform and select [Delete].
7. Delete Group button – Removes the selected group of points.
8. Delete Last button – Removes the selected group of point(s) last saved.

Amplitude – Waveform amplitude can be adjusted by middle-clicking the waveform and dragging up or down. For the Points display, amplitudes are ganged for all waveforms.

Panning – The Points display will default to centering on the timing reference. The display can be panned by <Shift> + middle- clicking in the background and dragging left or right.

Waveform indicators – The type of line used in the waveform indicates the effect of the waveform on the map.

- Solid, bold with blue background – The waveform is selected. The original data for this waveform is currently displayed in the waveform display. If displayed in the map display, the 3D point, 3D text, and surface point for this waveform flashes red.

- Solid – The waveform is used by the map.
- Dashed – The point is a duplicate or is degraded.

Delete Hidden Points – To delete points that were hidden using the Show checkbox, right-click in the waveform display or Points display and select Delete Hidden Points.

Delete Unused Points – To delete all points that are not displayed due to the current projection settings, right-click in the waveform display or Points display and select Delete Unused Points.

> NOTE: Due to the potential collection of duplicate points, the action to "Delete Unused Points" may cause more unused points to appear. To delete duplicates, sort by point status, then select and delete all of the unused duplicates.

Scroll bar – Use this control to scroll through all activation points.

Hot key: When the Points display is open, the up and down arrow keys select the previous or next point, respectively. When the Points display is open, [Delete] will remove the current beat in the waveform display. The left and right arrow keys select a point backward and forward in time respectively in the beat buffer.

Creating a Map

Setting Up a New Map

1. From the Collect Workpanel, select New Map from the Current Map drop-down menu, or choose No Map Selected from the drop-down menu in the Model/Map Display Window.
2. The user may choose to name the map.
3. From the Mapping sub tab, select the primary reference timing signal.
   a. Select a primary reference source from the drop-down menu.
   b. Select a detection algorithm from the Detection drop-down menu.
   c. Sensitivity defaults to auto, if using fixed Sensitivity, adjust the Sensitivity to a level just outside of baseline noise.
4. Select a secondary reference source and algorithm if using a secondary intracardiac reference.
   a. Select a secondary reference source from the drop-down menu.
   b. Select a detection algorithm from the Detection drop-down menu.

   NOTE: A secondary reference can only be used if the primary reference is an intracardiac signal.
5. Select an initial roving catheter signal. The roving catheter can be any intracardiac electrogram that is actively being located (hidden electrodes cannot be used as Roving).
   a. Select a roving source from the drop-down menu. The roving signal can be changed during mapping, allowing any intracardiac electrode to be used as part of the mapping process.
   b. Select a detection algorithm from the Detection drop-down menu.
   c. Adjust the Sensitivity to a level just outside of baseline noise. Sensitivity is adjustable only for First Deflection and Last Deflection detection algorithms in cardiac triggered reference maps. Sensitivity is always adjustable for non-cardiac triggered reference maps.

After the references and detection algorithms have been selected, waveforms will begin to refresh in the waveform display, gated to detected activation on the primary reference.

6. Adjust the Roving Activation Interval by clicking and dragging the edge of the shaded boundary. Generally, the Roving Activation Interval should be set to encompass one activation sequence on the roving catheter.

Collecting Points (Select template beat)

If in Edit Model on the Model subtab, the Active EnGuide is automatically changed to be the same as the Roving catheter and the Active EnGuide control is not selectable.

1. With the patient in the clinical rhythm, place the roving catheter to collect data. When a beat of interest appears in the RAI, select [Freeze].

   NOTE: Selecting [Freeze] will automatically enable [Collect Points] when model type is set to OneModel.
2. In the frozen mapping screen, review the morphology of the beat and placement of the caliper lines. If necessary, select an optimal beat from the collected point buffer and/or adjust calipers.
3. Select [Save] or select a New Map or an existing map from the pulldown menu to save the point; otherwise, select [Cancel]. The waveform display will return to acquisition mode.

Figure 117. Map from Segment Example

To Map from a Segment

1. Click the Split Screen mode button in the upper right corner of the Mapping screen.

   NOTE: You will need to switch the secondary screen from Live to Review mode.

2. Select the appropriate segment from the drop-down list at the bottom of the right display.

3. If necessary, use the Waveform control panel in the right display to set the roving catheter and electrode.

4. Reference 11 through 13 under the Horizontal Split Screen Mode Elements table in the section titled Collecting Points.

   NOTE: Points can be added to either the left or right display and will be applied to both displays. Offline Review only.

Managing Maps

New Map – New Map can be selected from the drop-down menu in the upper right corner of the Collect Work Panel. Select New Map; the Map Name screen comes up with a prompt to name the map. Type a name in the Name field and click [OK].

Copy Open Map - Copy Open Map can be selected from the drop-down menu in the upper right corner of the Collect Work Panel. Select Copy Open Map; the Map Name screen comes up with a prompt to name the map. Type a name in the Name field and click [OK].

NOTE: You can rename a map by double-clicking in the Map Name field at the top of the Collect Work Panel and typing in the new name.

Lesions Work Panel

The Lesions Work Panel provides controls to allow the user to place lesion marker manually or to automatically place lesion markers using AutoMark. Lesion markers are primarily used to identify ablation therapy locations. When placed, Lesion Markers are projected from the 3D center of the Active EnGuide electrode to the nearest model surface. If the model surface is edited, lesions projections are recalculated using the original 3D location of the electrode used to create the lesion marker.

Lesions Work Panel - Manual Sub-tab

Allows the user to manually place lesion markers on the 3D model. The Manual sub-tab contains a list of lesion markers and controls for modifying their appearance. When using the Lesion Marker tool, you can place lesion markers with the mouse or use the tool bar to place surface and 3D lesions at the Active Electrode.

Lesion markers are used to identify ablation lesion marker sites. Up to 1024 manual lesions can be placed in the map display.

An adjustable distance control allows you to edit the distance allowed for projection. Lesion markers that are present and do not meet the 3D distance requirement are displayed as 3D objects (without being tied to a surface). You have the option to project, or not to project the lesion.

Each lesion marker has a numeric name that is displayed in a list. This number increments each time a lesion marker is placed on the map. If a lesion marker is deleted, the numeric list is updated to keep numbers consecutive.

Figure 118. Map with Lesion Markers on the Surface

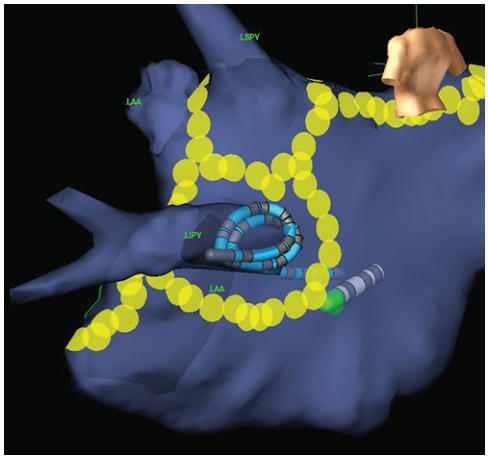
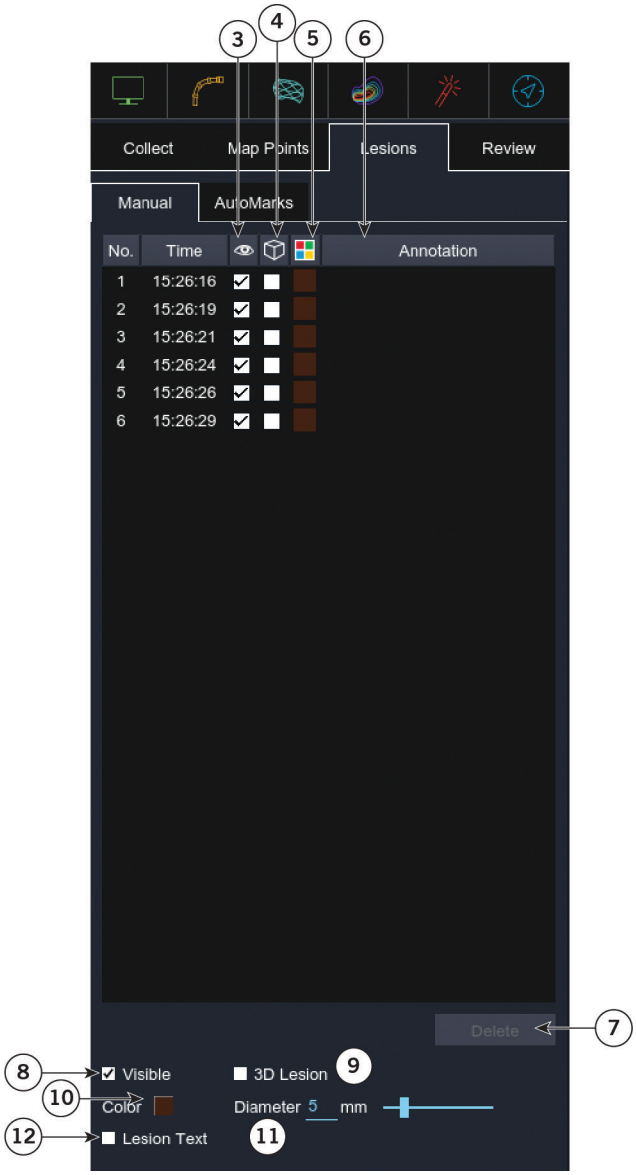


Figure 119. Lesions Tab – Manual Sub-tab



1. No. (list column) – Lesion ID number based on order of Lesion placement.
2. Time (list column) – Time when the lesion was created.
3. Lesion Visibility (list column) – Use the Lesion Visibility checkbox to show or hide a lesion.
   - Checked: Lesion is visible
   - Unchecked: Lesion is hidden
4. 3D Lesion (list column)– Use the 3D Lesion checkbox to control how a lesion is displayed.
   - Checked: Lesion is displayed as a 3D Lesion
   - Unchecked: Lesion is projected on to the model surface
5. Color (list column) – Use the color chart to select the color of a lesion. Select the colored square to open the color selector, and then select the desired color.
6. Annotation (list column) – Select field to manually enter annotation text for individual Lesions.
7. Delete button – Use the delete button to delete a selected lesion.
8. Visible checkbox – Use the checkbox to show/hide selected lesions.
   - Checked: Lesion is displayed as a 3D Lesion
   - Unchecked: Lesion is projected on to the model surface
9. 3D Lesion checkbox – Use the 3D Lesion checkbox to control how a selected lesion is displayed.
   - Checked: Lesion is displayed as a 3D Lesion
   - Unchecked: Lesion is projected on to the model surface
10. Color – Use the color chart to select the color of selected lesions. Select the colored square to open the color selector, and then select the desired color.
11. Diameter slider – Adjust the diameter of selected lesions.
12. Lesion Text checkbox – controls the visibility of Annotation text within the map screen.
    - Checked: Annotation text is visible in the map screen.
    - Unchecked: Annotation text is not visible in the map screen.

Lesions Work Panel - AutoMark Sub-tab

AutoMark will color and size lesion markers on the 3D model based on physician defined RF metrics and ablation catheter stability requirements. AutoMark provides the following functions:

- Automatic coloring and sizing of AutoMarks based on user-defined ablation criteria.
- Automatic placement of AutoMarks based on user-defined catheter stability criteria.
- Automatic segment recording during RF ablation.
- Display of live RF generator information.
- Export of AutoMark data.
- Cataloging of data for retrospective review.

AutoMark Parameters

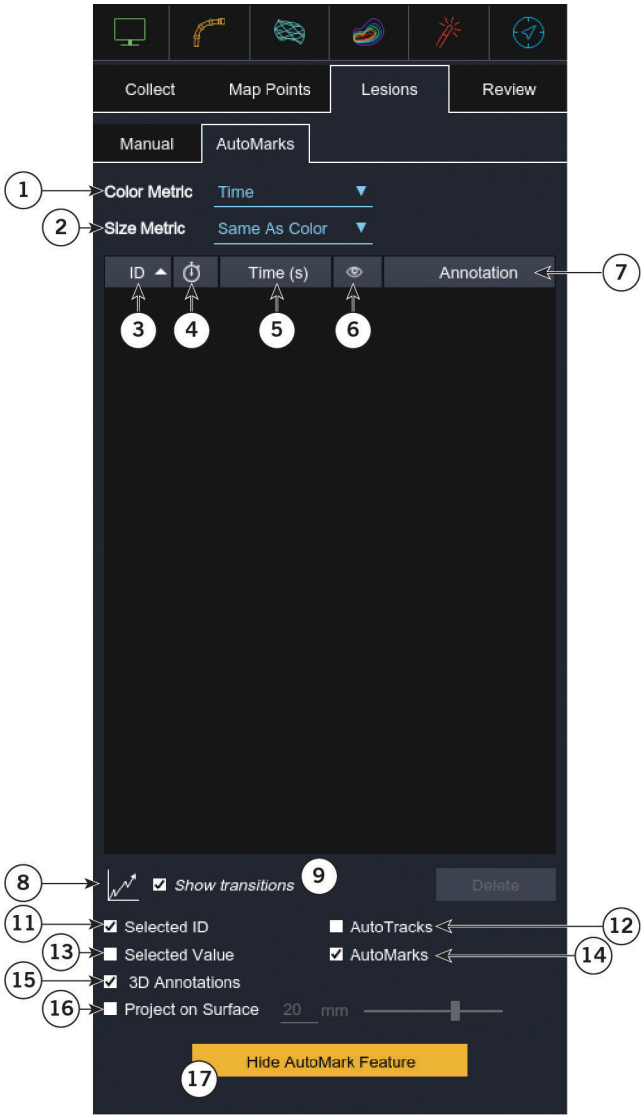
The color and size of the AutoMarks can be configured based on the following criteria:

- Energy (Joules).
- Time (Seconds).
- Impedance Drop (Ohms).
- Impedance Drop (%).
- Average Power (Watts).
- Maximum Power (Watts).
- Average Temperature (Degrees Celsius).
- Max Temperature (Degrees Celsius).
- FTI (OUS only).
- LSI (OUS only).

Average Force (grams).

Max force (grams).

Figure 120. Lesions Tab – AutoMark Sub-tab

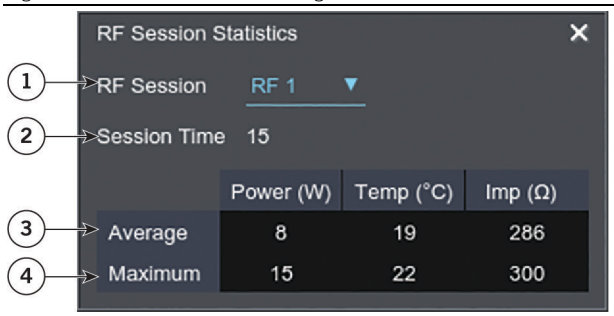


1. Color Metric – Metric used to define the color of AutoMarks.
2. Size Metric – Metric used to define the size of AutoMarks. This may be set to "Same as Color".
3. ID (list column) – RF Session ID and AutoMark ID automatically assigned by the system and increases sequentially. An RF Session is defined by one complete cycle of RF on/off. If AutoMark placement criteria are met, an RF Session will contain one or more AutoMarks.
4. Duration (list column) – Denotes duration of the RF Session, individual AutoMark or transition in seconds.
5. Metric Column (list column) [example displayed: Time] – Displays metric data for each AutoMark. Column displays metric selected for Color Metric (#1).
6. Visibility (list column) – Use the visibility checkbox to show or hide the item. When the checkbox is selected, the item is visible. To hide the item, select the checkbox.
7. Annotation (list column) – Double-click on an AutoMark to add a text annotation.
8. RF Statistics icon – Choose this to open the RF Session Statistics dialog box.
9. Show Transitions checkbox – Displays the transient RF data that is not associated with an individual AutoMark (that is, when the catheter is moving to a new location while RF is still on). Transition items in the AutoMark list are grayed out and do not have an ID or a 3D sphere in the Map Display.
10. Delete button – Deletes selected AutoMarks. RF Sessions cannot be deleted.
11. Selected ID checkbox – Displays the AutoMark ID in the map screen for selected AutoMarks.
12. AutoTracks checkbox – Displays catheter location data in the form of a line in 3D space tracking the path taken by the tip of the ablation catheter during RF.
13. Selected Value checkbox – Displays the metric value for selected AutoMarks in the map screen. Metric value displayed is the metric selected for Color Metric (#1).
14. AutoMarks checkbox – controls the display of all AutoMarks.
15. 3D Annotations checkbox – Displays the AutoMark annotations on the 3D map. The user can add or edit an annotation by double-clicking in the annotation column for the desired AutoMark from the AutoMark list.
16. Project on Surface checkbox/slider – Projects AutoMarks to the closest model surface if they are within the user defined distance threshold.
17. Show/Hide AutoMark Feature button – Controls the display of all AutoMark data including AutoTracks.

RF Session Statistics dialog box

The RF Session Statistics dialog box displays RF Session data from the Ampere™ generator.

Figure 121. RF Session Statistics dialog box



1. RF Session drop-down list.
2. Session Time (in Seconds).
3. Average [Power (W), Temperature (°C), Impedance (Ω)].
4. Maximum [Power (W), Temperature (°C), Impedance (Ω)].

Configure AutoMark Thresholds

The user must first define the AutoMark color and size thresholds. These can be saved in a preset for use in subsequent procedures if desired.

NOTE: If using less than 4 thresholds, start from the top row.

The default Color Metric and Size Metric is Time, the user may set as below:

- Color: Gray.
- Diameter: 4.
- Value (seconds): 0.

To configure the AutoMark thresholds:

1. From the Lesions Workpanel, select the AutoMark sub-tab.
2. Select the desired Color Metric and Size Metric from the respective drop-down lists.

   NOTE:

   - AutoMark collection is disabled until the user accesses the AutoMark tab for the first time in each study. When the user has accessed the tab for the first time, AutoMark collection can be enabled/disabled as desired using the button in the Metrics Setup dialogue box.
   - If AutoMark Collection is disabled, AutoMarks, RF Session AutoSegments, and RF On/Off events (in the Notebook) will not be recorded.
3. From the Metrics Setup dialog box drop menu, select the desired Metric to configure.

Figure 122. AutoMap Threshold Configuration

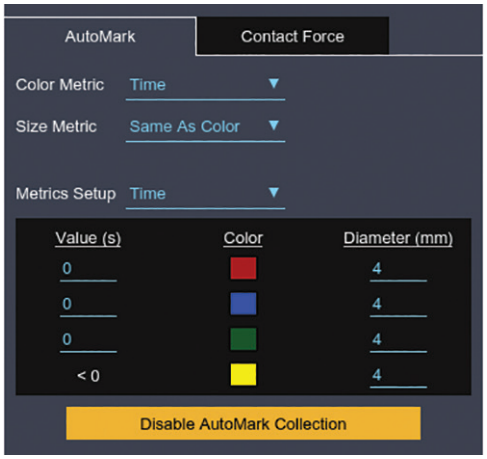
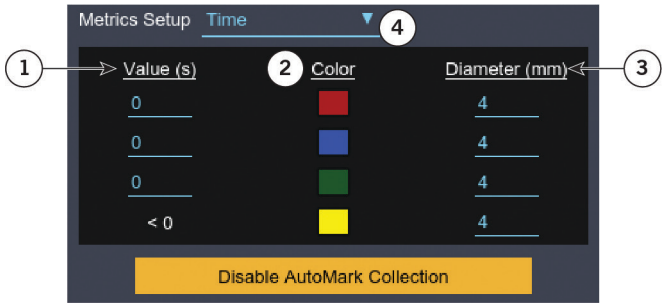


Table 4. Available Metrics

Energy	Avgerage Power	Average Force
Time	Maximum Power	Maximum Force
Impedance Drop (Ohms)	Average Temperature	FTI (OUS only)
Impedance Drop (%)	Maximum Temperature	LSI (OUS only)

For Contact Force related parameters refer to the EnSite™ X Contact Force IFU.

Figure 123. AutoMap Threshold Values

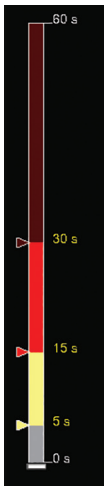


1. Define the Value for each threshold. This is the value at which the Color and Diameter of the AutoMark will be set.
2. Select the color box and choose a Color to associate with each value.
3. Define the Diameter to associate with each value.

   NOTE: The Diameter, or Size, of the AutoMark is relative to one another: e.g., "1" is smaller than "2."
4. Repeat steps 1 through 3 for all desired metrics from the pulldown menu.

   NOTE: Threshold values for the currently selected color metric can be changed by dragging on the transition values in the color bar shown on the map display.

Figure 124. Threshold values on the map display



AutoMark Placement

AutoMark placement is based on three user-defined settings.

AutoMark Region:

- The spatial catheter stability requirement for each AutoMark, which defines the AutoMark region.
- This is also the minimum distance between AutoMarks.
- Default = 1.5 mm (millimeters).

Min AutoMark Time:

- The minimum amount of time the catheter tip must remain within the AutoMark region before a new AutoMark is placed.
- Default = 3.0 seconds.

Away Time:

- The maximum amount of time the catheter can move away from the AutoMark region before that AutoMark is completed.
  - For example, if an AutoMark has been created and the catheter moves away from the AutoMark region for a duration longer than the Away Time, the AutoMark will be completed. If the catheter returns to that location at a later point in the procedure, a new AutoMark will be created, and the data will not be combined. If the catheter returns to the AutoMark region within the Away Time, the data will continue to be collected in to the current AutoMark.
- Default = 8.0 seconds.

  NOTE:

  - It is recommended to set the Away Time to a duration that is greater than the respiration cycle of the patient.
  - The accuracy of the AutoMark placement is dependent on the catheter Navigation Accuracy.

AutoMark Placement Overview

Ablation catheters will move in three-dimensional space due to heart beat and respiration. The AutoMark placement algorithm must take these motions into account when determining placement of AutoMarks.

AutoMarks are placed at the average three-dimensional location of the data included for each AutoMark. AutoMarks can be visualized either as three-dimensional spheres whose center point is this location or projected to the closest surface. If projected to the surface, a representation of the AutoMark is shown on the geometry using the same projection algorithm as for manual lesion markers.

AutoMarks serve as a record of therapy delivered and are not intended to be definitive as to whether or not a lesion has or has not been formed.

As shown in the figure below, the AutoTrack represents the string of data points collected. The x,y,z points are based on a cluster of data points that are determined by the marker time interval, which is calculated using the placement parameters. The placement algorithm breaks up the data points along

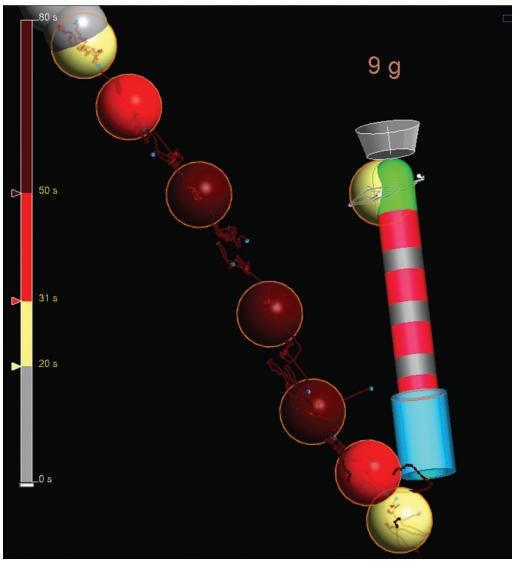
squiggly path according to the thresholds that the user sets. The average location calculation is the sum of all the x,y,z values divided by the number of x,y,z values based on the set of data locations along each path:

x = (1/n) * sum(x(1), ..., x(n)).

y = (1/n) * sum(y(1), ..., y(n)).

z = (1/n) * sum(z(1), ..., z(n)).

Figure 125. Average Location Calculation



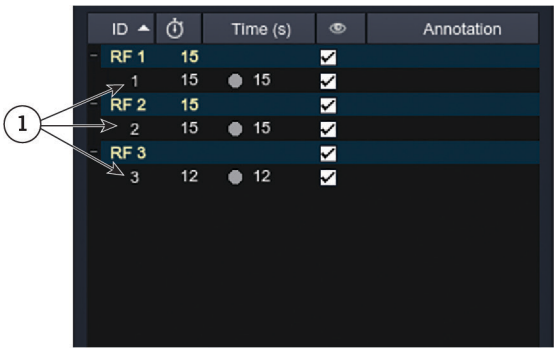
The system automatically places an AutoMark at the center of the tip electrode when the catheter remains within the AutoMark region (1.5 mm) for at least the Min AutoMark Time (3 seconds).

When the catheter moves greater than the AutoMark region, the AutoMark metrics display will blink to indicate that a new AutoMark is preparing to be created. While blinking, data values will continue to accumulate. Once the Min AutoMark Time at the new location is met, an AutoMark is created and the blinking stops. Values for the previous AutoMark will be finalized and the metrics display will switch to displaying the metrics values for the new AutoMark. If, due to cardiac motion, respiration, or other catheter movement, the ablation catheter is away from the AutoMark region for less than the Away Time, once the catheter returns the data will be added to the current AutoMark. If the catheter does not return within the Away Time, the AutoMark will end. If the catheter returns at a later time, a new AutoMark will be placed, and the data will not be cumulative.

Transition Data

Transient RF data that is not associated with an individual AutoMark (i.e. when the catheter is moving to a new location while RF is still on). Transitions in the AutoMark list are grayed out and do not have an ID or a 3-D sphere in the Map Display. Transitions can be shown by checking the "Show Transitions" checkbox.

Figure 126. Transition Data Rows

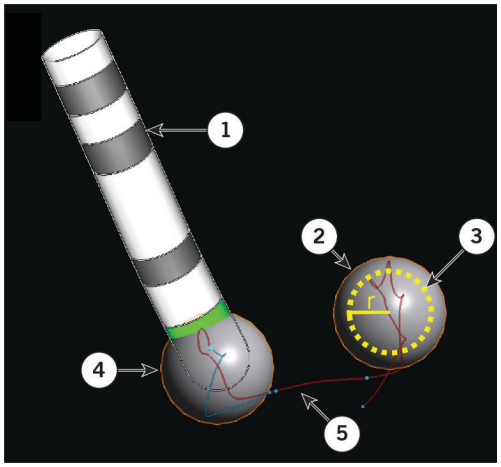


1. Arrows indicate transition data rows.

Placement Example

In the example below, a new AutoMark was created because the ablation catheter moved more than 1.5 mm (AutoMark region) from the active AutoMark and stayed within a new 1.5 mm location for a duration longer than 3 seconds (Min AutoMark time).

Figure 127. AutoMark Placement Example



1. Ablation Catheter
2. Active AutoMark
3. AutoMark Region (1.5 mm)
4. New AutoMark
5. AutoTrack

AutoMark Placement Examples

The following images provide examples of the same study displayed with different AutoMark placement options, including AutoMark region, Min AutoMark Time, and Away Time.

For all examples below, the AutoMark Color is defined as: Time (0-5s, White; 5-10s, Gray; 10-20s, Light Red; 20+s, Dark Red).

Table 5. AutoMark Placement Examples

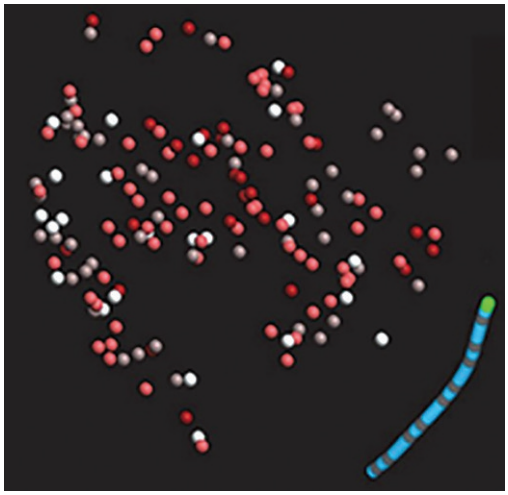
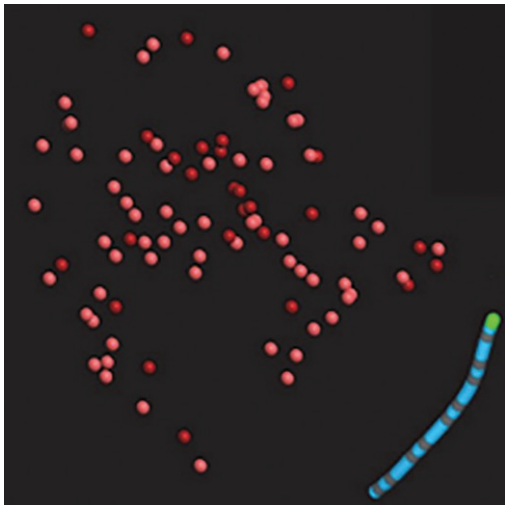
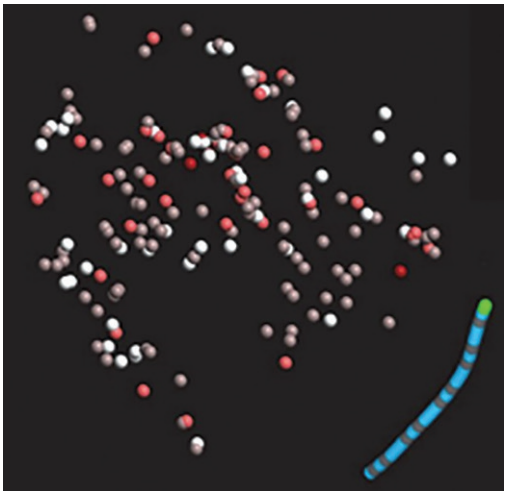
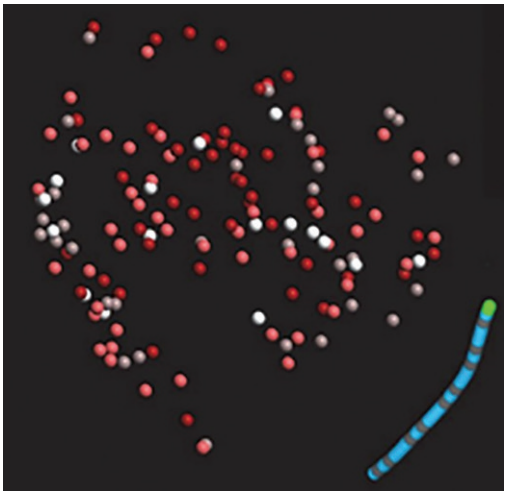
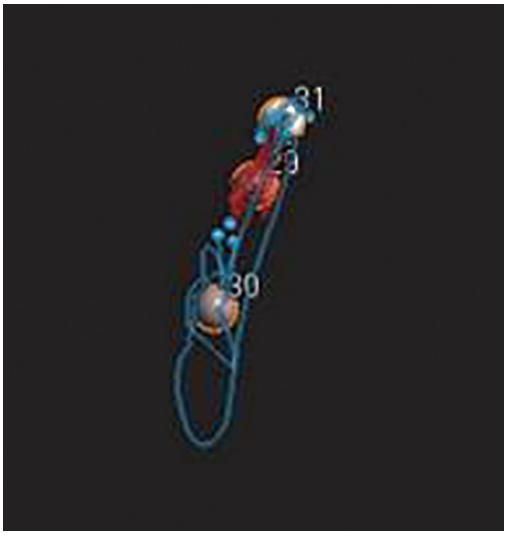
Example 1 (default) Away Time: 8 s Min AutoMark Time: 3 s AutoMark Region: 1.5 mm	Example 2 Away Time: 8 s Min AutoMark Time: 10 s AutoMark Region: 1.5 mm
	
	Fewer AutoMarks are created because the ablation catheter must remain within the AutoMark region for 10 seconds (instead of 3 seconds). Additionally, no White or Gray AutoMarks are shown because all placed AutoMarks have a value of greater than 10 seconds.

Table 5. AutoMark Placement Examples

Example 3 Away Time: 8 s Min AutoMark Time: 3 s AutoMark Region: 5.0 mm	Example 4 Away Time: 8 s Min AutoMark Time: 3 s AutoMark Region: 2.5 mm
	
More AutoMarks are created because the spacing between AutoMarks is only 0.5 mm (instead of 1.5 mm). Additionally, the AutoMarks tend to have a lower corresponding time as only data within the 0.5 mm region is collected.	Fewer AutoMarks are created because the spacing between AutoMarks is 2.5 mm (instead of 1.5 mm). Additionally, the AutoMarks tend to have a higher corresponding time as data within the 2.5 mm region is collected.
Example 5 Away Time: 8 s Min AutoMark Time: 3 s AutoMark Region: 1.5 mm	Example 6 Away Time: 2 s Min AutoMark Time: 3 s AutoMark Region: 1.5 mm
	
AutoTrack shows larger catheter movement for each AutoMark because all catheter movement resulting from respiration motion is included in the AutoMark data.	AutoTrack shows smaller catheter movement for each AutoMark because less catheter movement resulting from respiration motion is included in the AutoMark data due to the shorter Away time.

Configure AutoMark Placement Settings

Configure the Placement Settings as described above. The user can click and drag the slider or type a value directly into the field.

NOTE: Placement Settings can be updated at any time. When Placement Settings are updated, all existing AutoMarks will be updated to reflect the new settings. It is recommended to set the Away Time to a duration that is greater than the respiration cycle of the patient.

Figure 128. AutoMark Display Settings

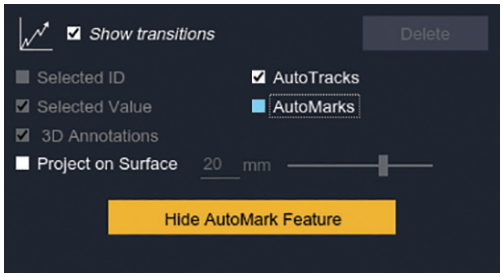
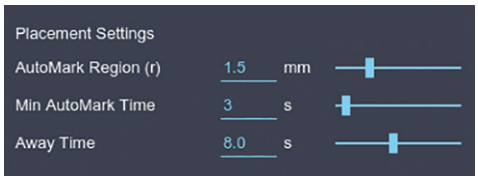


Figure 129. AutoMark Placement Settings



AutoMark Display Settings

These controls configure how the AutoMarks are displayed on the 3D map.

- Show Transitions - Displays the transient RF data that is not associated with an individual AutoMark (i.e. when the catheter is moving to a new location while RF is still on). Transition items in the AutoMark list are grayed out and do not have an ID or a 3D sphere in the Map Display.
- Selected ID - Displays the AutoMark ID on the 3D model when selected.
- AutoTracks - Displays the raw catheter location for each AutoMark.
- Selected Value - Displays the metric value for selected AutoMarks in the map window. Metric value displayed is the metric selected for Color Metric.
- 3D Annotations - Displays the AutoMark annotations on the 3-D map. The user can add or edit an annotation by clicking in the annotation column for the desired AutoMark from the AutoMark list.
- Project on surface - Projects the AutoMarks to the closest surface on the 3D model if they are within the user defined distance, as defined by the slider bar.
- AutoMarks - controls the display of all AutoMarks.
- Show/Hide AutoMark Feature - Controls the display of all AutoMark data including AutoTracks.

Configure AutoMark Visible Thresholds

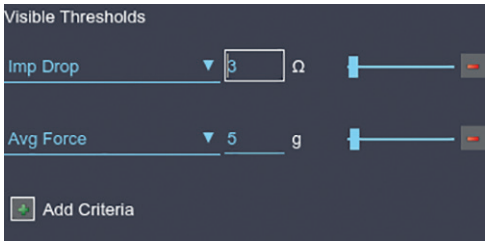
When used, an AutoMark will not display until the value exceeds the defined visible threshold. Visible Thresholds can be defined based on one or more of the AutoMark Parameters.

Default: No Visible Thresholds are configured.

Table 6. AutoMark Parameter.

Energy	Average Power	Avgerage Force
Time	Maximum Power	Maximum Force
Impedance Drop (Ohms)	Avgerage Temperature	FTI (OUS only)
Impedance Drop (%)	Maximum Temperature	LSI (OUS only)

Figure 130. AutoMark Visibility Thresholds



AutoTrack

AutoTracks provide the ability to see and review the raw ablation catheter location during RF and may be useful when assessing lesion continuity or ablation catheter stability for each particular lesion. There are two types of AutoTracks:

- Live AutoTrack is the white line that displays for a current RF session or the most recent RF session. Live AutoTrack always displays when the AutoTracks checkbox is enabled.
- Selected AutoTrack is the blue line that may be displayed for RF sessions prior to the most recent one. To display a Selected AutoTrack, highlight the desired AutoMarks and transitions.
- When reviewing AutoMarks via the Generator Waveforms window, the exact location of the ablation catheter can be pinpointed on the AutoTrack via a color change to the line, as the user moves the time cursor throughout the RF event. The portion of the AutoTrack behind the catheter location is red, while the portion in front of the catheter location may be either white or blue, depending on if the AutoTrack being reviewed is Live or Selected.

Generator Metrics Display

The Generator Metrics Display provides a configurable numeric display of generator information. The Generator Metrics Display window can be positioned anywhere in the Model/Map workspace and can be positioned anywhere on the map display.

1. Select the Generator Metrics checkbox from the Meter and Display Options Settings Panel. The meter will display in the Model/Map Display.
2. To Add/Remove Metrics to the Generator Metrics Display.
   - Right-click on the metric display and clicking the "+" or "-" button.
   - Configure the display of each box by right-clicking on the box and selecting the metric for display.

Figure 131. The Meter Displays Menu

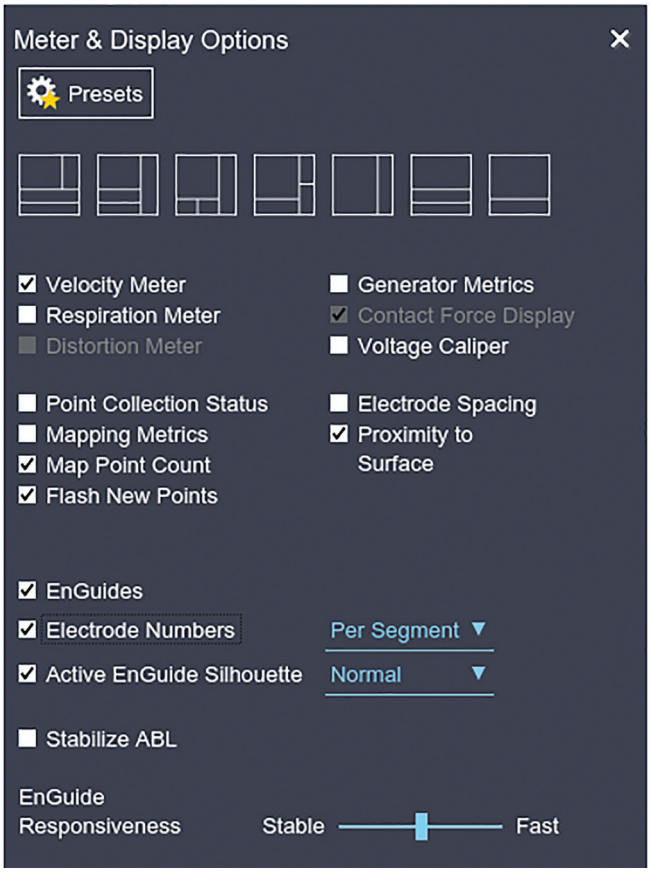


Figure 132. Metric Display

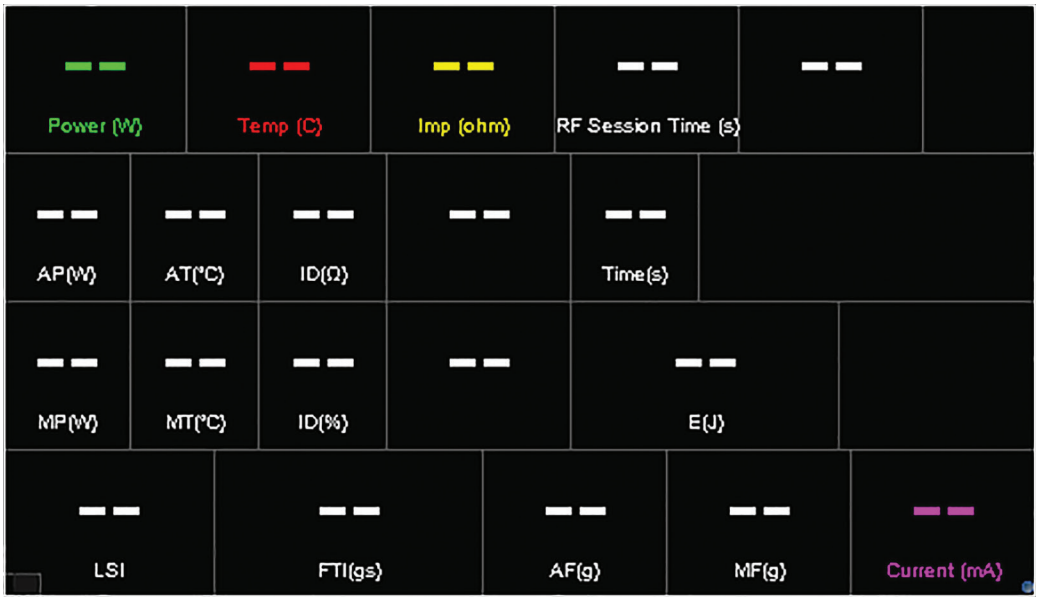


Table 7. Available Generator Metrics.

Avg. Force	Max Force
Energy	Time
Impedance Drop	Impedance Drop (%)
Avg. Power	Max Power
Avg. Temperature	Max Temperature
RF Session Time	Power
Temperature	Impedance

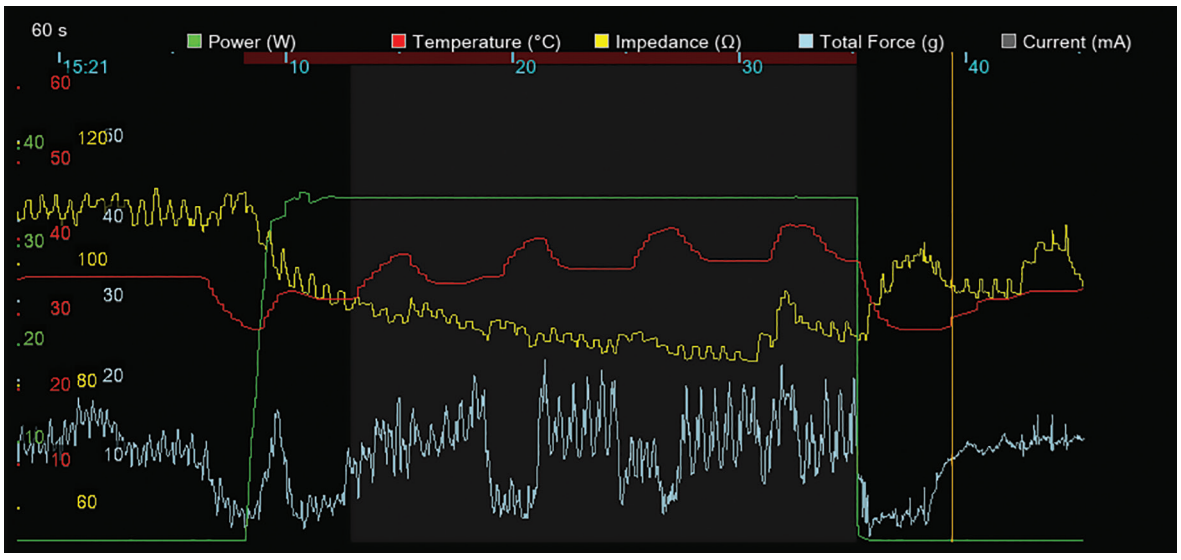
NOTE:

- The user can change the shape of the Generator Metrics Display by selecting and dragging the small, gray circle at the lower right corner when two or more metrics are displayed.
- The user can change the shape of the Metric Display by selecting and dragging the small, gray circle in the lower right corner when two or more metrics are displayed.

Generator Waveform Displays

This display allows for live and review visualization of the RF generator and Contact Force information.

Figure 133. Generator Waveform Display



1. Enable the display of generator and contact force information by clicking the box next to each parameter.

Table 8. Available Parameters.

Power	Temperature
Impedance	Total Force
Current	

2. Define the screen range by clicking on the range and editing the maximum and minimum values. The range for each trace in the Generator Waveform Display can be modified in a number of ways:
   - Select a trace by clicking the wave, scale, or name in the title bar. Select the maximum/minimum value that appears at the top or bottom of the vertical scale and type the new desired value.
   - Move the trace up or down with a left-click and drag on the wave, scale, or name.
   - Scale the trace up or down with a middle-click and drag on the wave, scale, or name.
   - When zoomed in on review data, the user can move the time range using a shift + middle click combination and dragging in an empty area on the Generator Display.
3. Adjust the time scale by right-clicking on the time display or by zooming on the display using middle mouse.

Export AutoMark Data

Summary and raw AutoMark data can be exported to a USB device, CD/DVD, or network drive. Refer to the Data Export section in the EnSite™ X EP System Instructions for Use.

Review AutoMark Data

Double click on an AutoMark from the AutoMark list to open a review panel that will allow the user to review all the information associated with the selected AutoMark, including catheter location and stability, ablation electrograms, and RF generator information. The user can use the cursor to scroll through the information and assess the various parameters at any given timepoint.

Manually Editing AutoMarks

If the user would like to edit the placement of specific AutoMarks, it is possible to manually combine or split them. Only AutoMarks within the same RF session can be manually edited, and only in review after the RF session has completed.

NOTE: Changing the AutoMark Placement settings, Field Scaling, and Fusion will re-apply the Auto Placement algorithm and all manual AutoMark edits will be lost.

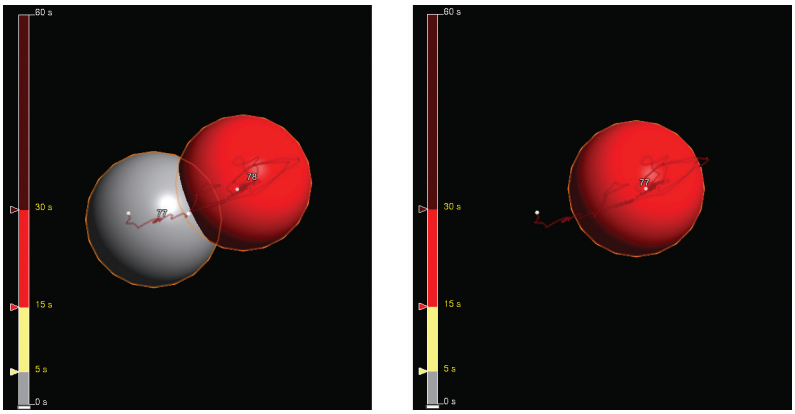
Combining AutoMarks

Manually combining two or more consecutive AutoMarks within the same RF session will combine their respective data into a single AutoMark. When AutoMarks are combined, the new AutoMark will be placed at the average three-dimensional location of the combined AutoMark.

NOTE: There is no distance limitation for combining AutoMarks; however, only consecutive AutoMarks (i.e. sequential in time) within a single RF session may be combined.

To combine AutoMarks:

Figure 134. Combining AutoMarks: Before, Left; After, Right



1. Select two or more consecutive AutoMarks from the AutoMark list.

   NOTE: Ensure that Transitions are shown when combining.
2. Right click on the AutoMark list and select Combine AutoMarks.

Splitting AutoMarks

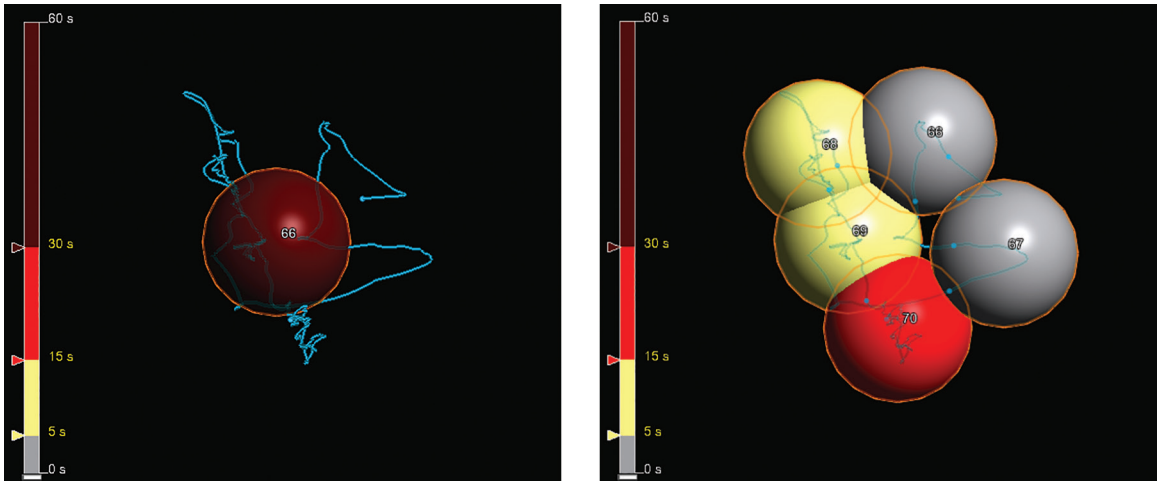
Splitting an AutoMark at a specific point in time will create two AutoMarks with the data being split at the exact point in time defined by the user. A split AutoMark will remain in the same RF Session in the AutoMark List.

When the AutoMark is split, two AutoMarks will be placed at the average three-dimensional location of their respective data.

To manually split AutoMarks:

1. Select an AutoMark from the AutoMark list.

Figure 135. Splitting AutoMarks: Before, Left; After, Right



2. Drag the time cursor in the Generator display to the time that the new AutoMark should start.
3. Right click the Generator Display and select Split AutoMark.

Re-splitting

Re-splitting re-applies the Auto Placement algorithm to the selected AutoMark and will undo any manual editing of the selected AutoMarks.

To re-split AutoMarks:

1. Select an AutoMark from the AutoMark list.
2. Right-click in the Generator display and select Re-split AutoMarks.

Review Work Panel

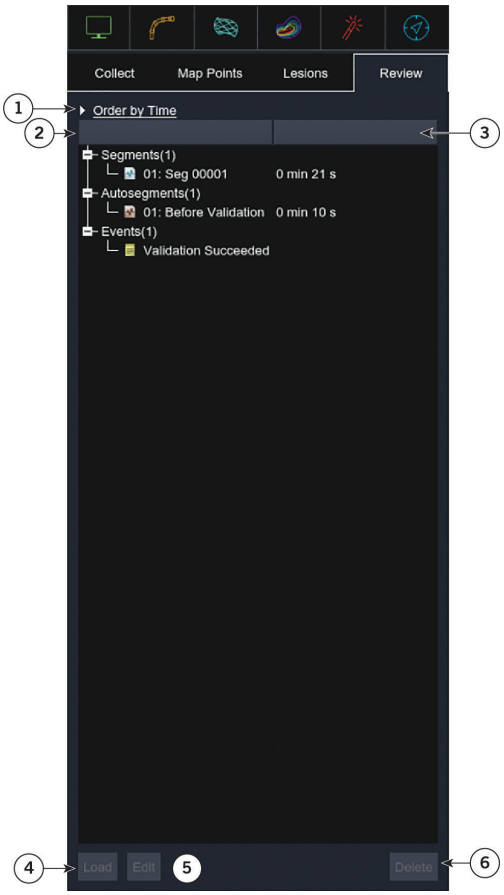
The Review Work Panel allows the user to review the study notebook recorded in the current study.

Notebook

The Notebook allows recorded data and study information to be filed and annotated for future review. Events (realtime) and Bookmarks (offline review) can be added to the Notebook to mark specific times in a study which allow the system to return to a specific time in review environment.

The Notebook is accessible in the Review Work panel.

Figure 136. Review Work Panel - Notebook



1. Order by Time/Order by Type – Text changes based on view. Select this text to change the format of the Notebook organization.
2. Order by Type – Shows a list of the items in the notebook that fit the criteria of each item type. Item types include:
   - Animation
   - Bookmark
   - Mapping
   - Image Sequence
   - Segment
   - Stop Time
   - Auto Segment (System automatically adds)
   - Comment
   - Image
   - Model
   - Start Time
   - Events
3. Order by Time - Shows a list of all items in the notebook in order of time the item was created. Items that were created in review are ordered based on the original time stamp in the study and are highlighted in brown to distinguish from items created during the live study.
4. Load button – Loads the selected item from the Notebook list. Items can also be loaded by double-clicking the item in the Notebook list.
5. Edit button – Allows the text of the selected item from the Notebook list to be edited.
6. Delete button – Deletes the selected item from the Notebook list.

Table 9. Feature descriptions for Review functions.

Feature Name	Realtime	Realtime Split Screen Review	Offline review
Saving an Event	X	X	
Saving a Bookmark			X
Recording Manual Segments	X		
Recording Automatic Segments	X		
Playing Recorded Segments		X	X

Review Functions Feature Descriptions

Saving an Event

An event can be added to the Notebook to mark important activities (e.g. drug administration). An event is always stamped with the current Realtime clock (not the time cursor, in RealReview mode).

NOTE: The key sequence for saving an event is <Ctrl> + <E>. The time is stamped when the key sequence is executed.

From the menu bar, select File > Save Event. The Save Event window will appear.

Type the text of the annotation in the text area, and then select Save.

Saving a Bookmark

Bookmarks create Notebook entries that allow the system to return to a specific time.

NOTE: The key sequence for saving a bookmark is <Ctrl> + <B>. The time is stamped when the key sequence is executed.

If the segment is playing, click the pause button.

From the menu bar, select File > Save Bookmark. The Save Bookmark window will appear.

Type the annotation for the bookmark in the text area, and then select Save.

Recording Manual Segments

Segment recording is used to save a segment of information to the Notebook for future review.

From the bottom bar, select the green Record button to begin recording. The Record button will change to an orange Stop button. The recorded segment begins approximately 10 seconds before the Record button was clicked. The length of the segment being recorded and the number of segments recorded during the study appear in the Notebook.

Hotkey: <F4> key can be used in place of Record and Stop.

Select Stop to stop recording.

An annotation can be added to the segment by typing in the text area on the bottom bar. Annotations can be added or modified at a later time from the Notebook.

Recording Automatic Segments

The system automatically records segments. These automatically recorded segments are added to the Notebook where they are identified as Auto Segments. Automatic recording occurs under the following circumstances:

- After validating
- When the positional reference is changed
- When positional reference dislodgement is detected
- When positional reference dislodgement is adjusted and accepted
- When the user collects Respiration Compensation data
- Right-click menu in Model/Map Display and select Sheath Filter Baseline
- When the model is finished
- Before and after EnGuide Alignment
- Every 15 minutes
- At the end of a study
- When AutoMap is collecting data (unless option is turned off)
- When an RF session is in progress (unless option is turned off)

NOTE: Auto segments do not appear in the segment drop down menu.

Accessing Recorded Segments

The purpose of the RealReview task and Offline Review mode is to review data recorded during Realtime mode.

To access a recorded segment (RealReview or Offline Review modes) from the same study, use the notebook:

1. From the list, select a recorded segment or bookmark.
2. Select [Load] or double click on the segment or bookmark name, if doing it from the Notebook in Realtime.

A recorded segment can also be accessed from the Segment drop-down menu in the control bar.

Playing Recorded Segments

Recorded segments can be played in the RealReview or Offline review by loading a segment from the Notebook or from the Segment drop-down selection in the bottom bar.

Realtime - By default, when RealReview mode is first entered, the system waits for the user to select a segment in that study.

Offline Review - Opening a study from the Past Studies screen opens the study in the Model task. The last recorded segment will automatically be played. The brown status bars indicate Offline Review environment

Overview – The segment overview shows the length of the entire recorded segment in black. The portion of the entire recorded segment that is shown in the waveform display appears in gray in the Overview.

Click and drag the gray area of the Overview to display that area in the waveform display.

The time cursor and any placed calipers also appear in the Overview.

Time Cursor – The time cursor is a vertical yellow line in the waveform display that indicates the time represented by the map display. The specific time represented by the time cursor appears in the lower right corner of the waveform display.

Clicking in the waveform display background (not on a trace) makes the time cursor appear at the mouse pointer.

Dragging the time cursor moves the cursor across the waveform display.

Moving the time cursor in the waveform display also affects the time represented by the map display.

Segment drop-down menu – Select a manual segment, event, or bookmark from the drop-down list to load the item.

Play button – starts the time cursor moving to the right. When the cursor reaches the right edge of the waveform display, segment playback starts over again. After clicking the play button, the button turns into a pause button (pauses playback).

Arrow buttons – While the waveform display is frozen, the left and right arrow buttons move the time cursor one sample to the left or right, respectively. Holding down an arrow button causes the time cursor to scroll. To set a sample (in 1, 10, or 100ms), right click on the right or left arrow keys and make a selection from the windows. Hot key: The arrow keys on the keyboard can be used to scroll the time cursor left or right.

Review Speed – In Review environments, the Review Speed drop-down menu controls the speed of the time cursor as it moves to the right, which controls how fast the waveforms scroll across the screen. To choose a speed, select the drop-down menu button and select a speed from the available list: 1:1 (real time speed), 1:2 (half speed), 1:4 (quarter speed), 1:10, 1:25, 1:50, 1:100, 1:200, 1:500, 1:1000, 2:1 (double speed), TurboMap (maximum speed).

Reviewing Segments

Selecting a segment from the notebook will display it in the right pane. Playback controls become enabled beneath the view.

Reviewing Bookmarks

Selecting a bookmark from the control panel list opens the recorded segment with the time cursor frozen at the bookmarked location. This point is marked by a yellow line in the waveform display and segment overview.

Reviewing Images

Double clicking on an image listed in the control panel causes the image to be displayed in the center of the display window. The image size can be adjusted by dragging the lower right corner of the window.

Reviewing Annotations

The annotation list area can be used to view and modify the annotations (labels, anatomic markers, tape measures, lesion markers, and EnGuide shadows). Select a type icon from the Tool Palette. Annotations created in Offline Review will have a brown background in the control panel. To modify an annotation, select the annotation in the list (it will be selected in the model) then use the controls to show/hide, delete, and change the appearance of the annotation.

Figure 137. Play Bar.

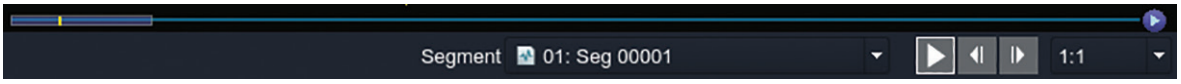
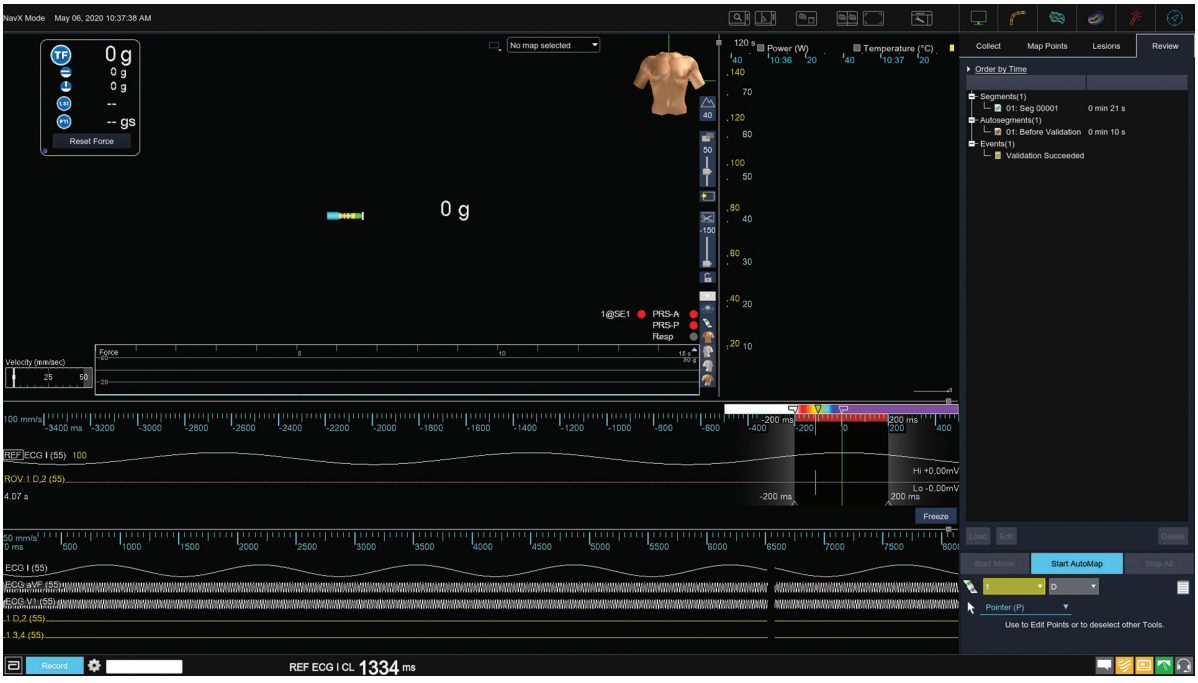


Figure 138. RealReview screen. A: Notebook listings; B: Annotation lists.

Figure 139. Offline Review screen. Note the brown status bars.



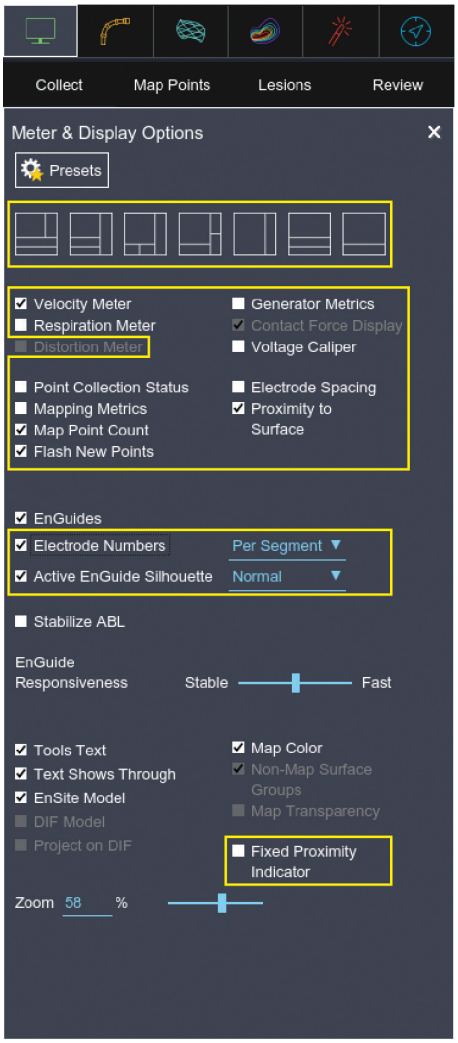
Settings Panels

The Settings Panels contain controls and settings less often modified during a case. Presets can be managed from the settings panels and are context sensitive. When the user is within any specific Settings Panel, the user may manage the presets for that Settings Panel only. The contents of a Settings Panel temporarily displays in the Work Panel space when an individual control is accessed. Panels are minimized using the 'Close' icon, or when another panel icon is selected. Once Settings Panels are closed, the Work Panel returns to view.

> NOTE: Areas marked within a box are settings and values saved with a preset. The example below shows the Meter and Display Options settings panel. All items within a box will be saved as a preset. These values change in all corresponding areas of the user interface (Work Panels, Settings Panels and the Mobile Work Panel.).

Not all settings captured in a preset are configured or displayed in panels including display size and location of screens and/or meters/metrics, font sizes, Waveform amplitude, RAI screen, etc.

Figure 140. Settings Panel Preset Options



Study Presets

The use of study presets enables a user to quickly and easily setup a new study with a set of settings that is consistently used for studies. Users can enable or manage presets from the Settings Panels in the Workspace (Catheter presets can also be enabled in Setup.).

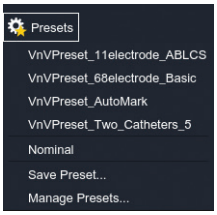
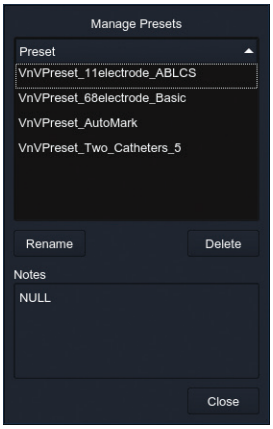
Changes made on the Work Panel are reflected on the corresponding Settings Panel. To Save the changes the user must go to the corresponding Settings Panel and save.

Although there are some differences in the use of presets in these three areas, the basic ideas in their use are the same.

Typically, a user will enable one or more presets at the beginning of a study to save time and avoid manually changing options and settings; rarely are presets changes during a study. One exception is the preset for "Meters & Display Options". This preset may be used to setup the workspace for the different stages of a study (Mapping vs. Therapy) or to configure the display of screens for split-screen viewing or saving images.

When a preset is enabled, options and settings update for all corresponding values in the Work Panels, Settings panels and the Mobile Work Panel.

Preset Dropdown Menu	Save Preset	Manage Preset
Preset Button: The Presets drop-down menu is used to load a preset, save a preset, and manage presets. **To Use Default or Factory Settings Presets:** Select Nominal from the Preset drop-down	**To Save a Preset:** To save the current setup as a preset, open the Preset menu in the upper- left corner of the control panel and select Save Preset. In the Save Preset screen, type a name for the preset, and	**To Rename a Preset:** To rename the preset, double-select the name then enter the new name or select the preset to be renamed then select Rename. **To Delete a Preset:**

Preset Dropdown Menu	Save Preset	Manage Preset
menu. **To Load a Preset:** To load a preset for the current physician, open the Preset menu in the upper-right corner of the control panel and select a preset from the list. The menu lists the presets for the current physician followed by presets from other physicians. Select the desired preset and then select OK.	then select OK.	To delete a preset for the current physician, open the Preset menu in the upper-right corner of the control panel and select Manage Presets. In the Manage Presets screen, select a preset from the list. To delete the preset, select Delete. **To Add a Note to a Preset:** To add a note for the preset, type in the Note text area. When renaming is complete, select Close.
		

Meter & Display Options Settings Panel

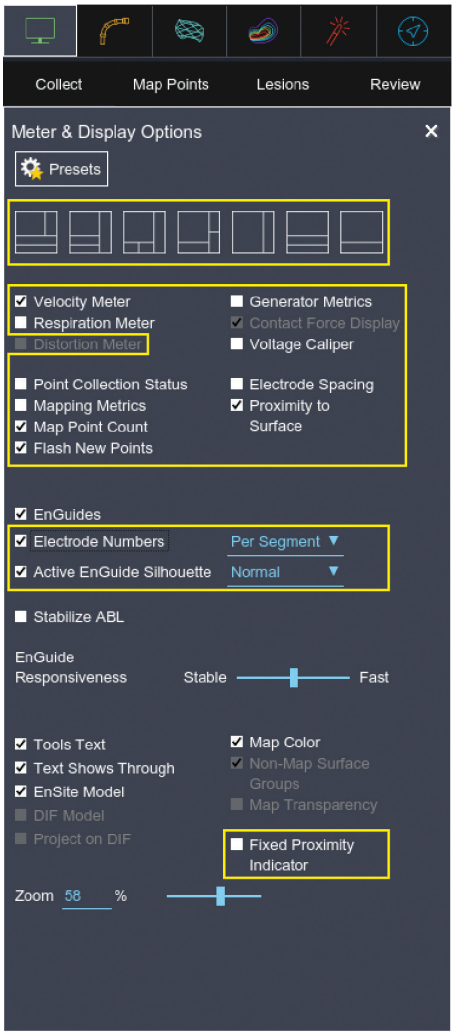
The Meter and Display Options Settings Panel enables a user to make changes to the layout and display options:

- Layout options – size, location and content of waveforms and map display.
- Display options – meters, filters, model and map display settings, Contact Force display, EnGuide display options, and zoom.

  NOTE:

  - Although Contact Force, Point Collection Status and Mapping Metrics content is setup elsewhere, the display of the related Waves/Meters/Metrics is controlled in the Meters & Display Options panel.
  - Areas marked with a yellow border are values saved with a preset. These values change in all corresponding areas of the user interface.

Figure 141. Meter & Display Options Settings Panel



1. Layout Options icons – Allows the user to select several overall Workspace screen layout options.
2. Velocity Meter checkbox – The Velocity Filter prevents model point collection during rapid catheter movements.
3. Generator Metrics checkbox – Shows the numeric values of the Ampere Generator on the screen.
4. Respiration Meter checkbox – The Respiration Meter shows the current level of respiration, as computed by the relative impedance on the EnSite™ X surface electrodes. The data in this display is identical to the respiration waveform available in the Waveform Display.
5. Contact Force Display checkbox – Displays Contact Force for Force enabled ablation catheter. Numeric value is displayed near the tip. Does not display if the Content Force module is not installed. Displays disabled when no TactiSys™ Quartz equipment connection is detected or if the Metrics, Wave, Tip Indicator, and Tip Force Number features are all disabled in the Contact Force settings panel. When enabled, mouse-over tool tip provides instructional text. Default is checked.
6. Distortion Meter checkbox – A Distortion Meter is available that displays the current level of relative magnetic field distortion.
7. Voltage Caliper checkbox – Turn on/off display of the Voltage Caliper which displays the measured potential at the selected signal of the Active Electrode. To select the signal displayed, right select the Voltage Caliper and Select Signal. Select Auto Adjust and the caliper automatically adjusts to the peak to peak value of the waveform.
8. Point Collection Status checkbox – Select to show the AutoMap point collection criteria status panel.
9. Electrode Spacing checkbox – Turn on/off display of electrode spacing for the selected catheter. Electrode spacing is calculated form the edges of the electrodes. Not center to center.
10. Mapping Metrics checkbox – (Applies to the map that has focus when in Split Screen view.) Enables/disables the display of the reference cycle length in mm (CL), and the measurement of the current roving point (LAT). The reference rate and cycle length are computed from detections on the reference catheter. CL and LAT display in yellow when points are frozen. The live heart rate (HR) displays in the lower-left bottom bar and is calculated on the reference the user is using.
11. Proximity to Surface checkbox – The surface proximity distance is the distance from the Active Electrode to the model or DIF surface (Fusion must be applied). To display this measurement on an EnSite™ X NavX model, field scaling must be applied.

    In EnSite™ VoXel mode Proximity to Surface may be displayed at any time when enabled. The proximity distance is displayed (in millimeters) at the bottom of the map display in the following fasion: the current value, followed by the average calculated value over 12 seconds, shown in parentheses. A negative value indicates that the electrode is inside the model surface, while a positive value indicates the electrode is outside the model surface.

12. Map Point Count checkbox – Displays the Map Point Count totals (those currently displayed at the bottom of the Map Points list) in the Model Space. Only displays when a map is displayed and reflects current Map point counts. Option checkbox defaults to "Off".
13. Flash New Points checkbox – New map points flash as collected.
14. EnGuides checkbox – Select to show/hide EnGuides.
15. Electrode Numbers checkbox/drop-down filter list – Select this checkbox to show catheter electrode numbers on the map display to facilitate navigating the ablation catheter to specific electrodes. The user can show electrode numbers on all or none. In Dual View, Split Screen, and RealReview, this checkbox affects each view independently.
16. Active EnGuide Silhouette checkbox/drop-down list – Select this checkbox to produce an outline of the Active EnGuide, which displays over the model, showing where it resides inside the chamber. The silhouette is displayed in the color selected for the Active EnGuide. Select "Off", "Normal", or "Enhanced".
17. Stabilize ABL – (EnSite™ NavX™ Model) Select this checkbox to enable Stabilize ABL; default setting is off, or unselected. Stabilize ABL is applied to Ablation catheters connected to the Ampere™ RF Generator. Stabilize ABL corrects the location of the distal electrode based on the properties of the catheter. ABL electrodes 2, 3, and 4 need to be displayed for Stabilize ABL to be enabled.

    NOTE: If Stabilize ABL is enabled for the catheter, EnSite NavX™ points cannot be collected.

    WARNING: Do not use Stabilize ABL in situations where electrodes 2, 3, or 4, on the ablation catheter, are covered by a sheath.

    - **If Stabilize ABL is enabled and the display of electrodes 2, 3, or 4 is turned off, Stabilize ABL is disabled and a message displays to alert the user.**
    - **If multiple ablation catheters are setup, Stabilize ABL is applied to each catheter independently and only when appropriate.**
18. EnGuide Responsiveness slider – This slider controls the response speed between catheter motion and EnGuide navigation.
19. Tools Text checkbox – Shows/hides the label text for all map labels, anatomic markers, tape measures, lesions, and EnGuide Shadows.
20. Map Color checkbox – Causes surface to be colored using the current map color.
21. Text Shows Through checkbox – Allows or prevents label text for all map labels, anatomic markers, tape measures, lesion markers, and EnGuide Shadows from showing through other objects.
22. Non-map Surface Groups checkbox – Hide surfaces that have no maps projected on them.
23. EnSite Model checkbox – Enables/disables the display of the contoured, three-dimensional surface model(s) of a patient's cardiac anatomy.
24. Map Transparency checkbox – Display map colors with values greater than Color High as transparent instead of purple. Areas of the contact map that are not colored will be hidden.

    NOTE: Do not select the Map Transparency On box unless a map is displayed.
25. DIF Model checkbox – Allows the DIF model (that is, CT scan or MRI) to either be hidden or displayed.
26. Project on DIF checkbox – (After registration has been performed using the EnSite™ X Fusion™ Registration Module) Enabling this checkbox allows the user to project or un-project 3D Labels and/or Lesions (referred to as 3DP), and map data onto the DIF surface rather than onto the EnSite model surface.
27. Fixed Proximity checkbox – The EnGuide proximity indicator represents the position of the Active Electrode. The position of the indicator is size scaled based upon the distance from the Active Electrode to the closest model surface. The proximity indicator is drawn on the surface as a colored translucent spot, matching the color of the Active Electrode. The maximum diameter of the proximity indicator can be displayed based on either the current lesion size or by checking the Fixed Proximity Indicator box, located under the drop-down menu in the map display under the eyeball.

    NOTE: The Proximity Indicator only displays on finished surfaces.
28. Zoom slider – Increases/decreases the size of the model in the display screen. The middle mouse / scroll wheel can also be used to zoom.
29. VoXel Cloud checkbox – Select to display the VoXel point cloud in EnSite™VoXel Mode.

Catheters & Waveforms Settings Panel

Catheters and Waveforms are located together in the Settings Panel and separated by sub-tabs.

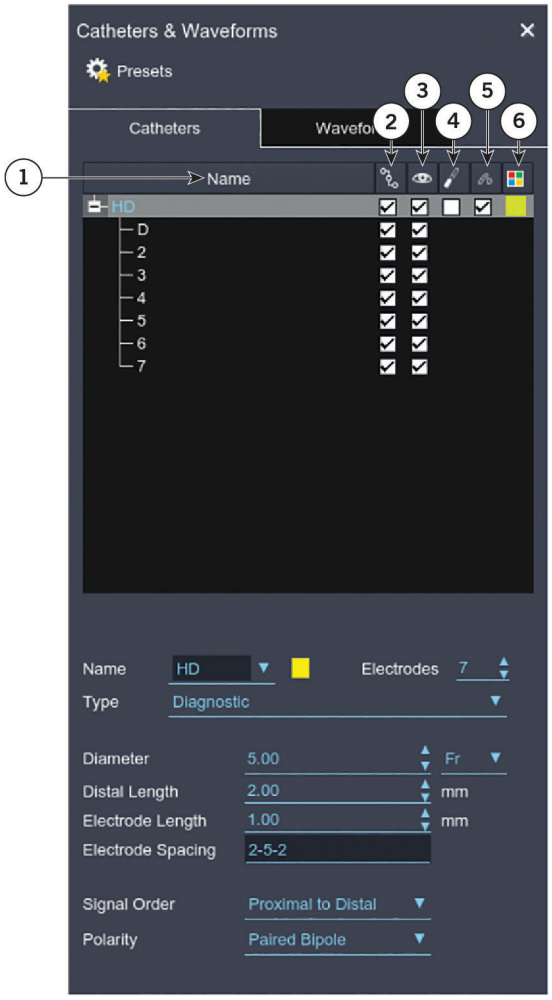
Catheters & Waveforms Settings Panel - Catheters Sub-tab

The Catheter lists and details are available from within the workspace allowing the user to access and modify elements without the need to return to setup. Functionality to expand the electrodes is like the behavior available for waveforms. A user may include or exclude (disconnect) an electrode in addition to controlling its visibility. If an electrode is excluded, its visibility is also removed, and the appearance of the electrode and the corresponding waveform is removed from view. If the electrode remains included but its visibility is removed, the display of the waveform is unaffected.

Refer to Catheter Setup for a full description of the controls.

NOTE: Areas marked with a yellow border are values saved with a preset. These values change in all corresponding areas of the user interface.

Figure 142. Catheters & Waveforms Settings Panel – Catheters Sub-tab



1. Name – Catheter name
2. Connected icon – Allows the user to connect or disconnect individual electrodes on the catheter.
3. Visibility icon – Show or hide a catheter in the Model/Map display area.
4. Sheath Filter icon – Turn Sheath Filter on/off for applicable catheter.
5. Show Electrode Numbers icon – Shows the electrode numbers on the catheter being displayed. Requires Show Electrode Numbers to also be selected from the Display Settings panel.
6. Color icon – Select the color the catheter is displayed.

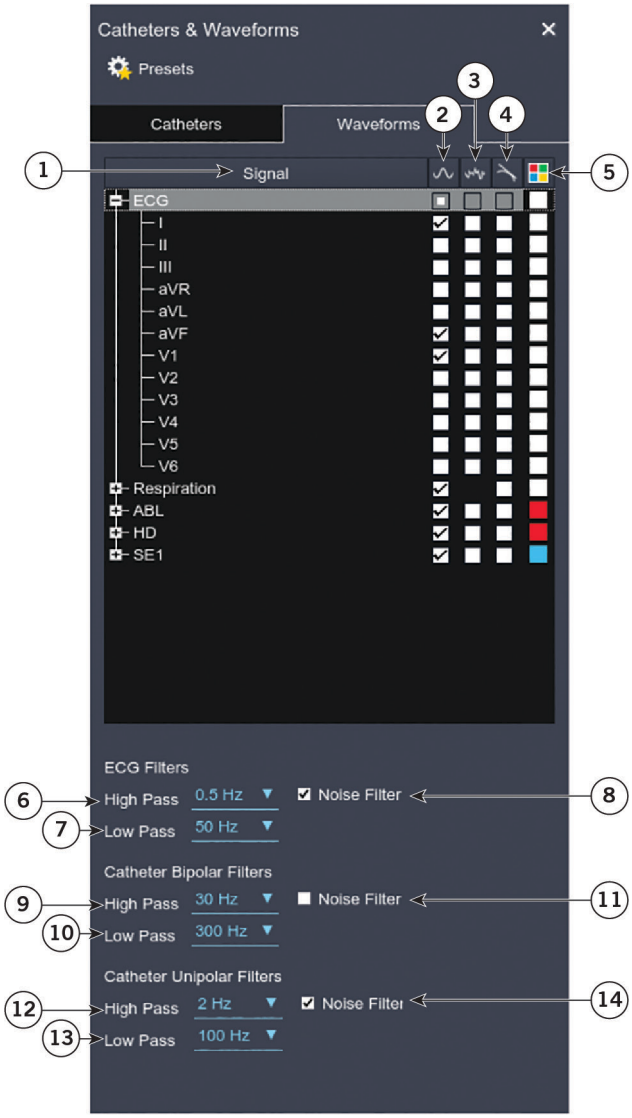
For more infomation on currently selected catheter panel, refer to: "EnSite™ X EP System Setup, Catheter Tab - Catheter List" (page 27).

Catheters & Waveforms Settings Panel - Waveforms Sub-tab

Use the Waveforms tab to select the signals to display and the ECG Filters panel to select the filtering options for the displayed traces. Signals are listed in a tree-like structure and can be checked to be visible or hidden in the Waveform display. The settings for each signal, including the color, d/dt, and filtering can be adjusted. Filters can be turned on or off for individual signals. If the filter settings are changed, the filter settings for all signals in that group are changed. By default, ECG signals and EP catheters are included in the signals list.

NOTE: Areas marked with a yellow border are values saved with a preset. These values change in all corresponding areas of the user interface.

Figure 143. Catheters & Waveforms Panel – Waveforms Sub-tab



1. Signal – Name of displayed signal source
2. Filtered icon – Show filtered signals and waveforms
3. Unfiltered icon – Show unfiltered signals and waveforms
4. dv/dt icon – Show the dv/dt of signals waveforms
5. Color icon – Use the color chart to select a color for the item. Select the colored square to open the color chart, and then select the desired color. Changing the color of a waveform changes the color in the Waveform Display and in the Acquisition Waveform Display.
6. ECG Filters High Pass drop-down list – Use to set the High Pass filter for ECG waveforms.
7. ECG Filters Low Pass drop-down list – Use to set the Low Pass filter for ECG waveforms.
8. ECG Filters Noise Filter checkbox – Use to turn on/off the Noise Filter for ECG waveforms.
9. Catheter Bipolar Filters High Pass drop-down list – Use to set High Pass filter for Bipolar waveforms.
10. Catheter Bipolar Filters Low Pass drop-down list – Use to set Low Pass filter for Bipolar waveforms.
11. Catheter Bipolar Filters Noise Filter checkbox – Use to turn on/off the Noise Filter for Bipolar waveforms.
12. Catheter Unipolar Filters High Pass drop-down list – Use to set High Pass filter for Unipolar waveforms.
13. Catheter Unipolar Filters Low Pass drop-down list – Use to set Low Pass filter for Unipolar waveforms.
14. Catheter Unipolar Filters Noise Filter checkbox– Use to turn on/off the Noise Filter for Unipolar waveforms.

Model, DIF & Fusion Settings Panel

The Model, DIF and Fusion Panel provide access to Model Surface presets and DIF & Fusion functionality.

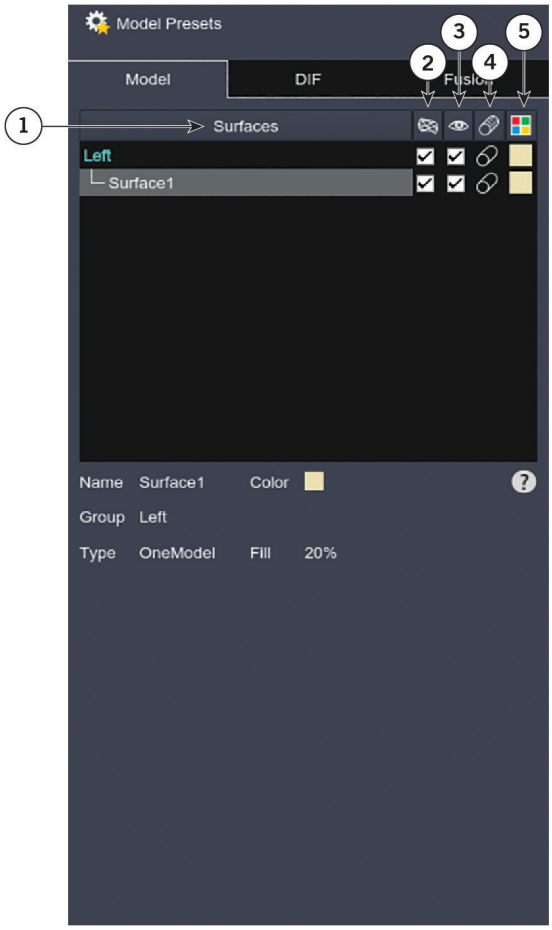
Model, DIF & Fusion Panel - Model Sub-tab

The Model tab allows provides the ability to define or change a Surface preset or surface details. The addition or deletion of surfaces is available on the Collect Panel - Model Sub-tab.

Model presets are used to initialize a model using a predefined list of surfaces. When a model preset is loaded, the surfaces do not exist, but they have properties such as names and colors. This list can serve as a starting point for which surfaces to collect points. Refer to the Model, Diff & Fusion Settings Panel to load and manage Model presets.

NOTE: Areas marked with a yellow border are values saved with a preset. These values change in all corresponding areas of the user interface.

Figure 144. Model, DIF& Fusion Panel – Model Sub-tab



1. Surfaces – List of model surfaces
2. Included icon – Select a checkbox to include a surface. Deselect a checkbox to not include a surface. A surface that is not included is not displayed, used for labeling, or intersecting overlapping surfaces.

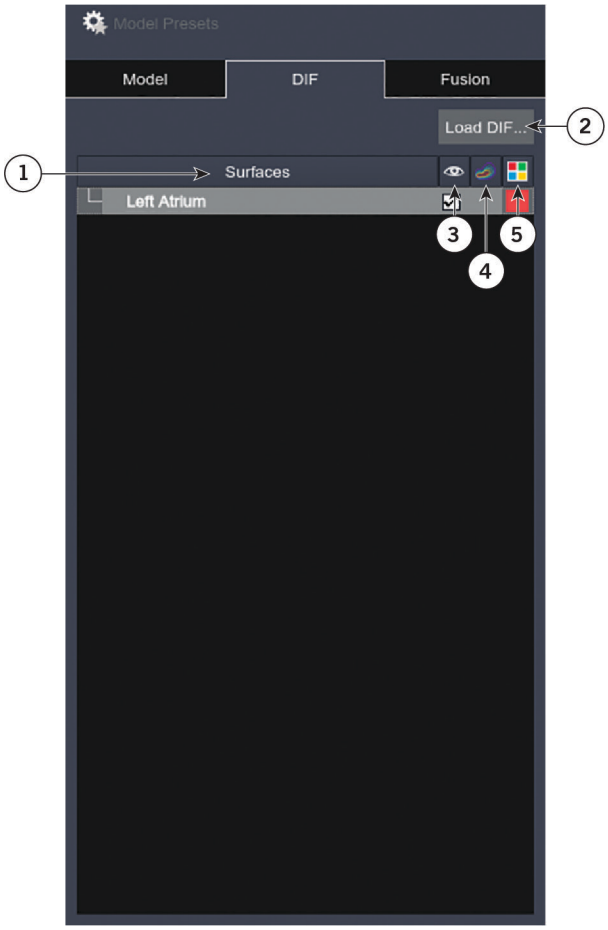
   NOTE: Excluding unnecessary surfaces optimizes performance. This checkbox controls whether a surface is displayed in the model. When the check mark is visible, the surface is displayed for labeling, intersecting, and overlapping surfaces. When the checkbox is unchecked, the entire surface is excluded from view.
3. Visibility icon – Use the visibility icon to show or hide the item. When the checkbox is selected, the item is visible. To hide the item, select the checkbox. Hiding an item does not delete the item.
4. Grid Control icon – The number of clicks (1, 2, or 3) on cylinder will determine where a surface grid is placed on the model. Clicking once, places the grid on the interior of the model, clicking twice, places the grid on the exterior of the surface. Clicking a third time turns the grid off.
5. Color icon – Use the color chart to select a color for the item. Select the colored square to open the color chart, and then select the desired color.

Model, DIF & Fusion Settings Panel - DIF Sub-tab

The DIF list shows both surfaces and associated maps as defined in the EnSite™ Verismo™ Segmentation Tool or the third-party application.

NOTE: There are no Presets for the DIF sub-tab.

Figure 145. Model, DIF& Fusion Panel – DIF Sub-tab



1. Surfaces – List of surfaces
2. Load DIF – Select to load a DIF file.
3. Visibility icon – Use the visibility icon to show or hide the item. When the checkbox is selected, the item is visible. To hide the item, select the checkbox. Hiding an item does not delete the item.
4. Map icon – Use the Map icon to show or hide the DEMRI map if one is imported.
5. Color icon – Use the color chart to select a color for the item. Select the colored square to open the color chart, and then select the desired color.

Digital Image Fusion (DIF)

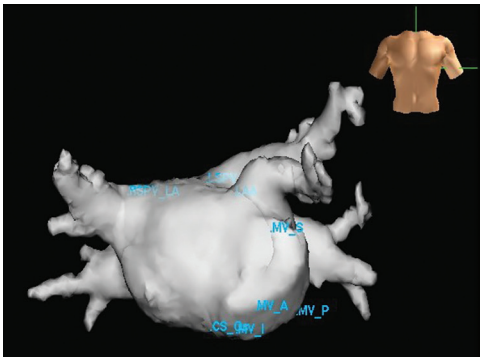
- Three-dimensional models created from digital images collected from Spiral CT, MRI, and DEMRI (Delayed Enhancement MRI) can be imported into the EnSite™ X EP System for display.

Creating a Model to Import

Models for import into the EnSite™ X EP System can be created using segmentation tools such as the EnSite™ Verismo™ Segmentation Tool. When using the EnSite™ Verismo™ Segmentation Tool, the creation of a model involves the following steps.

- The patient is scanned. See the EnSite™ X Verismo™ Segmentation Tool section (page 152) for the optimal EnSite™ X Verismo™ Segmentation Tool scan file characteristics.
- The scanned image is exported to a CD/DVD in DICOM3 format.
- The CD/DVD is imported into an EnSite™ X Display Workstation (DWS) with the EnSite™ Verismo™ Segmentation Tool, and the segmentation process is used to create a DIF file according to the EnSite™ Verismo™ Segmentation Tool Instructions for Use.

Figure 146. An imported DIF left atrium



If the DIF file is created on the same EnSite™ X EP System DWS that will be used during the clinical study, the DIF file can be accessed from the hard drive. If the DIF file will be used on a separate EnSite™ X EP System, the DIF file can be exported to a USB device, network, or CD/DVD for import into the clinical EnSite™ X EP System.

- In addition to the DIF file format, the EnSite™ X EP System also supports CardEP file format for digital images, as well as Siemens, Phillips, Toshiba (Vital Images), and Terra Recon formats; however, formats other than DIF may not be able to use all DIF-related functions, such as the ability to show or hide individual chamber surfaces.

Importing a Digital Image

1. Click the DIF icon at the top of the Model control panel.
2. From the DIF control panel, select Load DIF.

   The Import DIF window appears.
3. From the Load DIF window, select a DIF file for import: select a source, either hard drive or DVD/CD, for import from the drop-down menu at the top right corner of the window.
   - HardDrive – DIF files created by the EnSite™ Verismo™ Segmentation Tool on the same EnSite™ X EP System DWS are stored on the workstation's hard drive. As additional models are added, the oldest models are deleted first. Models can also be manually deleted by selecting a model from the list and selecting Delete.
   - DVD/CD – Digital image models can be imported using DVD and CD. Models can be formatted as Digital Image Fusion (.xml), or GE DICOM3 models processed using CardEP software. For GE CardEP models, the original CD/DVD from the GE workstation is required for import, not just the file of the model itself. Select an image type to display the appropriate models.

Select Load to load the model.

NOTE: The colors applied to the DIF model are the EnSite™ X EP System software model colors, not the colors that were used during segmentation.

Additional Options for DIF Files

Models created by the EnSite™ Verismo™ Segmentation Tool have additional features:

Patient information – In the Import Digital Image window, models are displayed with information from the patient, scan, and saved model name. Clicking on the category name at the top of a column sorts the data by that column.

DIF viewer – A viewer is available for previewing DIF models. Select View to display the selected DIF model. The following controls are available in the viewer:

- Rotate – Hold down the middle mouse button and drag.
- Zoom – Use the roller wheel on the mouse.
- Wireframe – Options > Wireframe.
- Bounding box display – Options > Bounding Box.
- Default views – Views > AP/PA/LL/RL/CRA/CAU.

Viewing a DIF Image for Reference

DIF models can be shown by selecting the DIF Model checkbox in the Meters and Display Options Settings Panel. Deselect to hide the DIF Model.

- The digital image appears in the map display.
- To compare the two models, select Dual View. The EnSite™ X EP System model appears on the left side of the screen, and the DIF model appears on the right side of the screen.

Digital images are saved with rotational information included. The orientation reference will automatically appear for the digital image.

In an EnSite™ X System study, the EnSite™ model and DIF model rotate together when the system is validated.

NOTE: Clipping, Map Scale, rotation, spin, Edge Enhancement, and panning can be used to change the appearance of the model.

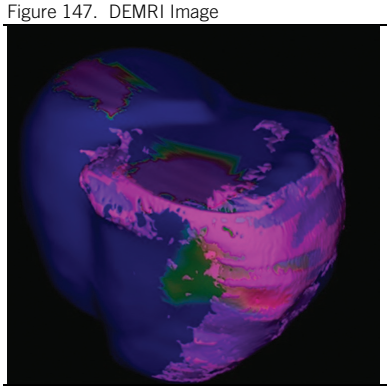
DEMRI (Delayed Enhancement MRI) Image Integration

The use of delayed enhancement MRI is sometimes used to analyze areas of electrically nonviable tissues such as areas of fibrosis, scar, or ischemia. The import of this model type into the EnSite™ X EP System may provide a faster, higher resolution of substrate over traditional voltage mapping. The system can now accept Visualization Tool Kit files, or VTK files, and Visualization Toolkit Polygons, or VTP files. These files are created from a third-party application rather than through the EnSite™ Verismo™ Segmentation Tool.

Once imported, interaction is like a DIF file, with options to view or use with the EnSite™ Fusion™ Registration Module. The DIF list shows both surfaces and associated maps as defined in the third-party application. The color spectrum bar on the left is displayed just as it is for timing and voltage maps within the system. One map tool data set can be displayed on the surface at a time.

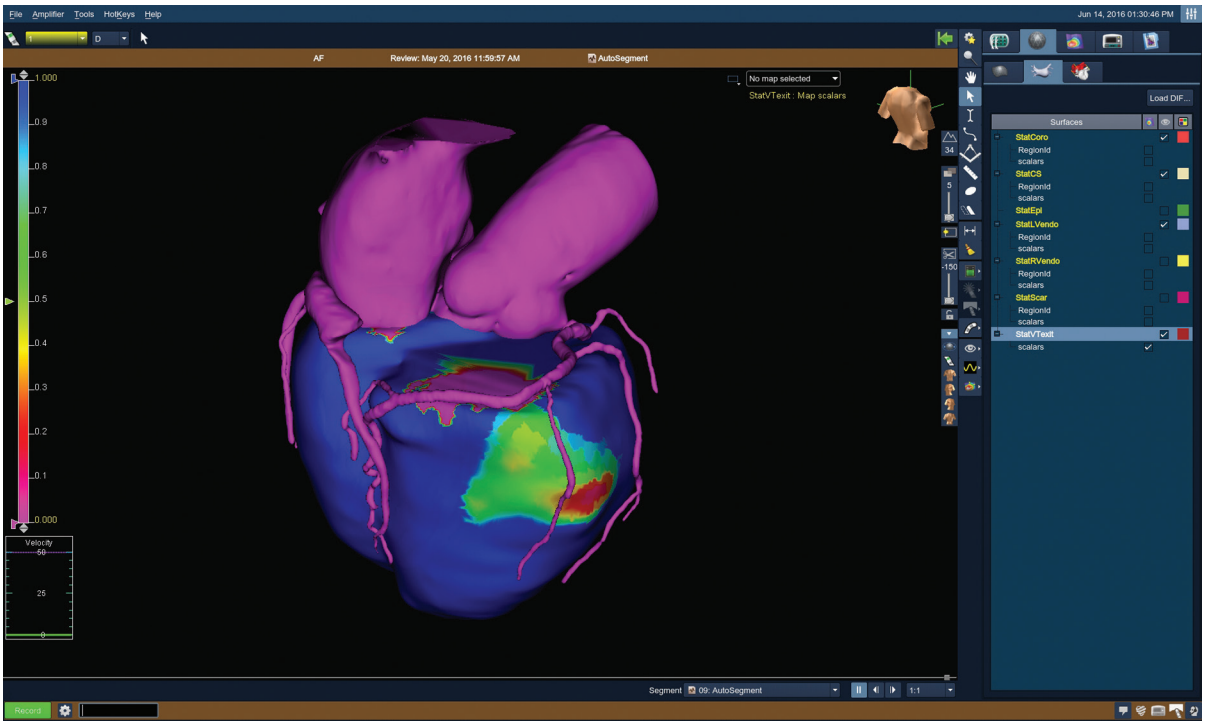
NOTE: If using this model in the EnSite™ Fusion™ Module's registration process in single map display, the user will be able to either visualize the associated imported map or project a contact map on the surface, but not both.

Figure 147. DEMRI Image



In Split Screen view, the user can display an EnSite model in one screen and the DEMRI in the other.

Figure 148. Imported DEMRI Image



File limitations for VTK or VTP files include:

- Total number of vertices cannot exceed 1,000,000.
- Total number of polygons cannot exceed 2,000,000.
- Polygons are limited to only containing three points (triangles).
- Only one occurrence of the <Piece> tag is supported.

Selecting and Adjusting the Waveforms

Waveforms can be selected and adjusted by clicking on the waveform in the waveform display.

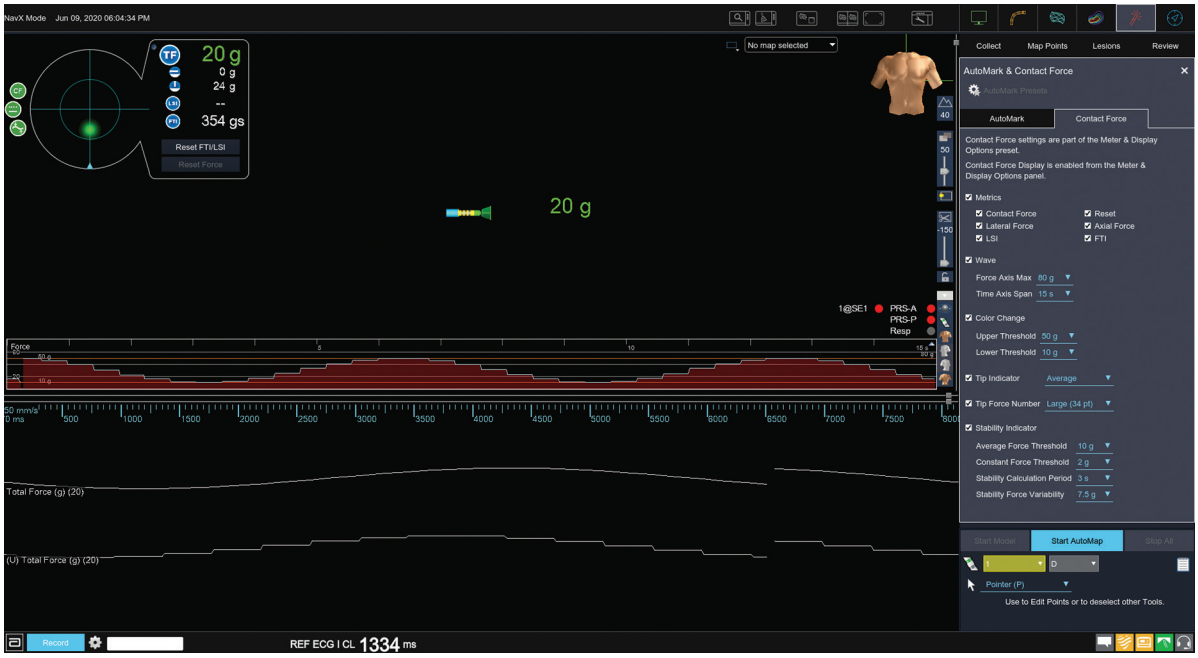
- Selecting waveforms: Shift-left-clicking on a waveform makes the selected trace bold and displays a dotted white line at 0 mV. The color calipers are rail lines indicating the current Color High and Color Low values. Shift-left-click on a waveform again to remove the rail lines and color calipers.
- Moving waveforms: To move a waveform, left-click on the waveform and drag up or down.
- Adding waveforms: To add a waveform to the waveform display, turn on the waveform's checkbox in the Catheters & Waveforms Settings Panel - Waveforms Sub-tab.
- Removing waveforms: To remove a waveform from the waveform display, turn off the waveform's checkbox in the Catheters & Waveforms Settings Panel - Waveforms Sub-tab, or left-click on the waveform and drag it off the left edge of the screen.
- Adjusting amplitude: To adjust the waveform amplitude, middle-click the waveform and drag up or down to increase or decrease the amplitude for all waveforms of that signal type. To adjust the amplitude for a single waveform, hold <Shift> + middle-click and drag up or down.
- Right click in the black background for waveform options menu:
  - Sweep Speed: Adjusts the number of mm/sec. in the waveform display (time scale).
  - Reset Offsets: Evenly spaces all visible waveforms vertically in the waveform display, without changing the order of the display.
  - Reorder Waveforms: Rearranges the waveforms according to the trace number and types as defined by the order in the Catheters & Waveforms Settings Panel - Waveforms Sub-tab.
  - Font Size: Used to select a font size for the label text in the waveform display.
  - Thickness: Used to adjust the thickness of all waveforms in the waveform display.
  - Hi/Lo Lines: Doing a shift-left-click on a selected waveform, causes the waveform to bold and for color calipers to display. The color calipers are horizontal rail lines that indicate the current Color High and the current Color Low values of the selected waveform. Doing a shift-left-click again will remove them.

Using the Waveform Displays

The two types of waveform display windows in the GUI are shown below:

1. Waveform Display.
2. Acquisition Waveform Display.

Figure 149. Waveform displays.



1. Waveforms – Signals can be simultaneously displayed as waveforms. Each waveform consists of a label and a trace. The label identifies the source of the signal, and includes whether the signal is unfiltered, whether contact catheters are unipolar, the signal label, and the signal amplitude. If the traces turn purple, then the data should not be used.
2. Time cursor – (Waveform Display only) The time cursor is a vertical yellow line in the waveform display that indicates the time represented by the map display. The specific time represented by the time cursor appears in the lower right corner of the waveform display. The following controls are available for the time cursor in review mode:
   - Left-clicking in the waveform display background (not on a trace) makes the time cursor appear at the mouse pointer.
   - Dragging the time cursor moves the cursor across the waveform display.

   NOTE: In Realtime, the cursor is not shown when one or more waves are visible.
3. Time scale – The time scale (in milliseconds) appears at the top edge of the waveform display. Right-click between waveforms in the window to display a menu for setting the sweep speed, font size, and waveform thickness.
4. Calipers – Calipers are used to measure timing between signal features in the waveform display during review mode. See “Using Calipers” for information about using calipers.

Model, DIF & Fusion Settings Panel - Fusion Sub-tab

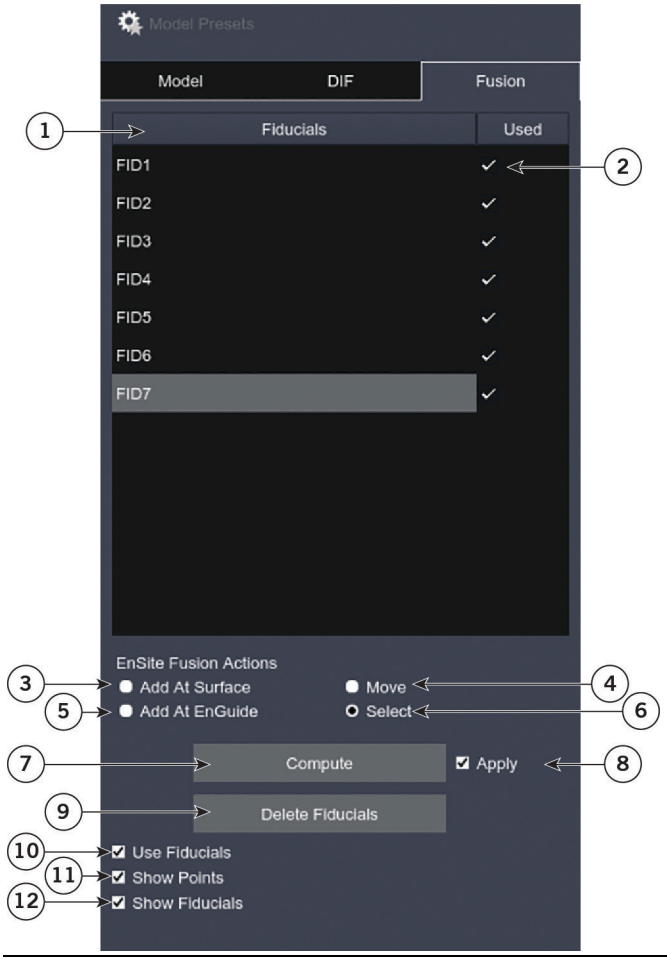
The EnSite™ Fusion™ sub-tab is used to place and edit fiducial point pairs.

NOTE: There are no Presets for the Fusion sub-tab.

The EnSite™ X Fusion™ Registration Module is a software expansion module for the EnSite™ X EP System that provides non-fluoroscopic navigation registered to a model of patient anatomy generated by CT or MR scanners. The EnSite™ Fusion™ Registration Module is intended for use with the EnSite™ X EP System Surface Electrode Kit and cardiac models from CT or MR scans segmented into a compatible file format.

Once the registration is applied, mapping and labeling functions can be applied to the Digital Image Fusion (DIF) surface, including Contact Mapping, Map Labels, Lesion Markers, and Anatomic Markers.

Figure 150. Model, DIF& Fusion Panel – Fusion Sub-tab



1. Fiducials – The name of the fiducial.
2. Used checkbox – A check mark in this column indicates that the fiducial is being used. No check mark indicates that the fiducial is not being used.
3. Add at Surface radio button – Select to place a fiducial point at the mouse location on the EnSite™ model and DIF model.
4. Move radio button – Select to move one end of a fiducial point pair.
5. Add at EnGuide radio button – Select to place a fiducial point at the Active EnGuide on the EnSite™ model and mouse location on the DIF model.
6. Select radio button – Select to select individual fiducial points.
7. Compute button – Compute the registration between the EnSite™ Model and the DIF Model.
8. Apply checkbox – Select to show the registration. Deselect to remove the registration.
9. Delete Fiducials button – Click to delete the selected fiducial point.
10. Use Fiducials checkbox – Select to use the selected fiducial point. Deselect to not use the selected fiducial point.
11. Show Points checkbox – Select to show the EnSite™ model point cloud; deselect to hide.
12. Show Fiducials checkbox – Select to show all fiducial points; deselect to hide all fiducial points.

Performing Registration

The EnSite™ X Fusion™ Registration Module provides non-fluoroscopic navigation, mapping, and labeling on a DIF model. The dynamic registration process involves the following steps:

- Importing a DIF model. Refer to Model, DIF & Fusion Settings Panel - DIF Sub-tab for instructions (page 111).
- Scaling the EnSite NavX™ navigation field (only applicable to EnSite NavX™ mode).
- Placing fiducial point pairs.

Importing a DIF Model

When used for registration, a DIF model is a surface rendering segmented from slice-based CT or MR data using the EnSite™ Verismo™ Segmentation Tool. A DIF model is imported in the Model task. For information on importing DIF models and compatible formats, see the Importing a Digital Image (page 112).

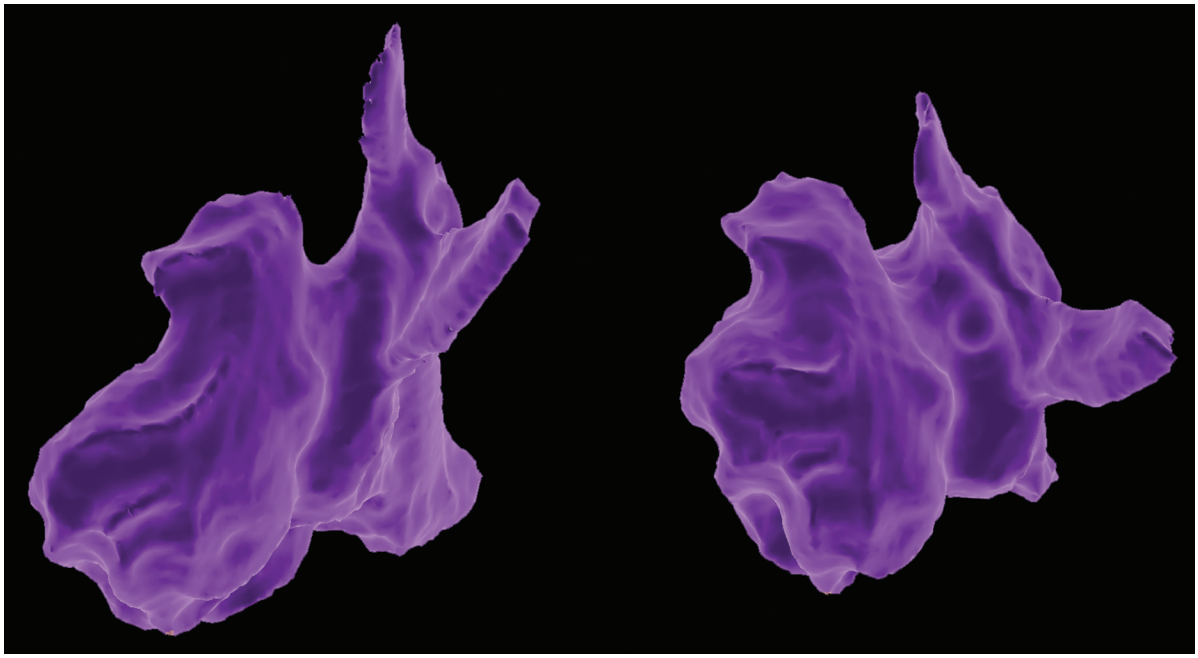
NOTE: Registration should be performed for one cardiac chamber at a time. A high-quality scan is necessary for the creation of an accurate registration. The quality of the scan is fundamental to the user's ability to create a highly detailed model during the segmentation process. In turn, a detailed segmentation is essential to the user's ability to identify precise fiducial points during the registration process.

Scaling the EnSite NavX™ Navigation Field (EnSite NavX™) Mode only)

Field Scaling, available in EnSite NavX™ Mode, compensates for local changes in impedance fields. For further information on Field Scaling, see the Field Scaling (EnSite NavX™ Mode Only) (page 65).

NOTE: Field Scaling the EnSite NavX™ field is optional but recommended.

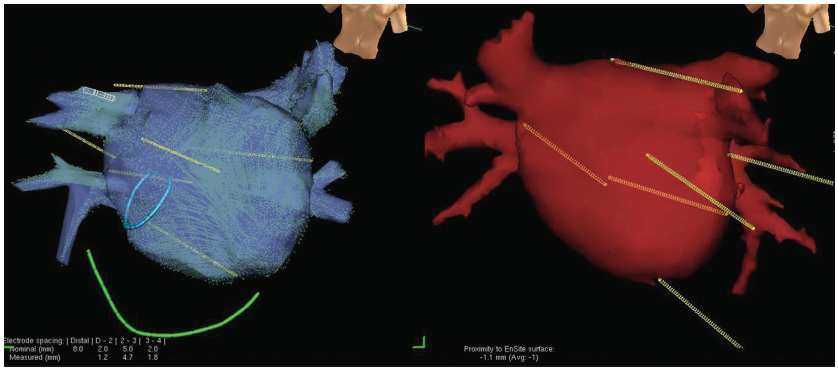
Figure 151. An EnSite NavX™ model before (left) and after field scaling



Placing Fiducial Point Pairs

Fiducial point pairs are markers that link matching locations between an EnSite™ X EP System model and a DIF model. The points are connected by a spring-shaped icon.

Figure 152. Fiducial point pairs linked by a spring-shaped icon



Placing Fiducial Points

NOTE: The buttons referred to in the following instructions are located on the EnSite™ X Fusion™ Registration Module control panel.

1. Display the models in Dual Views display.
2. Click the EnSite™ Fusion™ Registration Module icon in the Model control panel.
3. Place fiducial points to link common locations between the EnSite™ model and DIF model.
   - To place a fiducial point at the mouse:

     Select the Add at Surface button. While this button is selected, the left mouse button is used to place fiducial points on both the EnSite™ model, and DIF surfaces. When the cursor is over the EnSite™ map display, it will be cross-hair shaped.

     On the EnSite™ model surface, left-select a model location that is also recognizable on the DIF surface. After placing a fiducial point on the EnSite™ model side of the screen, the cursor will change to a cross-hair inside a square.

   NOTE: When a fiducial point is placed on the EnSite™ model surface, the fiducial point will link to the nearest model point, not the model surface. This ensures that the location is tied to a previous catheter position.

     Left-select the matching anatomic location on the DIF model. A spring-shaped icon will appear to connect the paired fiducial points.

   - To place a fiducial point at the Active EnGuide:

     Manipulate the Active EnGuide catheter so that the Active Electrode is at an anatomic location on the EnSite NavX™ model that can also be easily recognized on the DIF side of the screen.

     Select the Add at EnGuide button.

Left-select the matching anatomic location on the DIF model. A spring-shaped icon displays to connect the paired fiducial points.

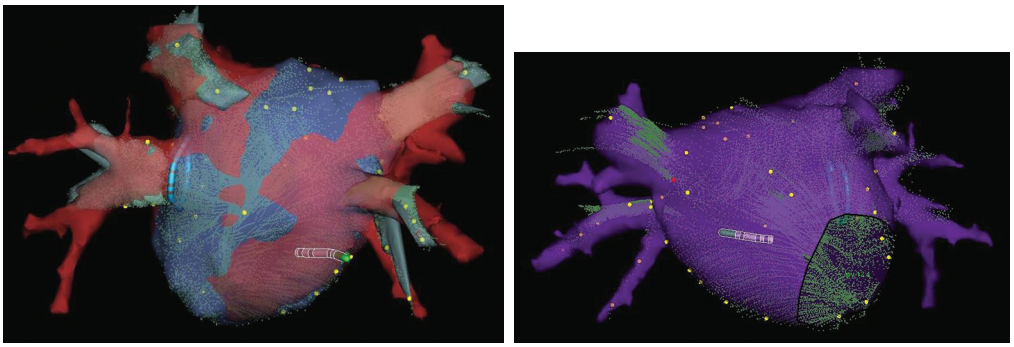
NOTE: A point is created at the active EnGuide position when the mouse is clicked on the DIF model.

4. Click Compute to compute an initial registration. The model surfaces, point cloud, and DIF model will be superimposed.

   In EnSite™ VoXel™ Mode: Regardless of the number of fiducial point pairs that are used, the registration will be a rigid overlapping registration. Spring-shaped icons connecting fiducial points will not necessarily collapse to a common location.

   In EnSite NavX™ Mode: If three or fewer fiducial point pairs are in use, the registration will be a rigid overlapping registration. Spring-shaped icons connecting fiducial points will not necessarily collapse to a common location. However, if four or more fiducial point pairs are in use the system will use a non-rigid dynamic registration to fuse the linked fiducial locations together. In this scenario, registered points will appear as dots instead of springs.

Figure 153. The overlapping point cloud, DIF model, and EnSite NavX™ model



5. Evaluate the registration and continue placing fiducial points if necessary. When defining fiducials in the overlapping view, the first point will be placed on the EnSite™ model, and the second point will be placed on the DIF model.

   NOTE

   - After any change to fiducial point pairs, select Compute to apply the change.
   - Select the Apply button to see the results of any changes.

Editing Fiducial Points

Several options are available for editing placed fiducial points. The controls for editing fiducial points are located on the EnSite™ X Fusion™ control panel.

To move one end of a fiducial point pair:

1. Select the Move button and select one end of the fiducial. If the points are registered and overlapping, the end of the point that is connected to the EnSite™ model will be selected.
2. Drag the point to a new location.

Disabling/enabling individual points

To disable or enable an individual fiducial point pair:

1. Select the Select button and select either the fiducial in the map display or select it in the fiducial list. The selected fiducial will turn red in the map display.
2. Select or deselect the Use Fiducial button to enable or disable the selected fiducial. In the fiducials list, all fiducials in use will have a check mark in the Used column.
3. Select Compute to recompute the registration.
4. Confirm the catheter position relative to the anatomy using conventional means (for example, fluoroscopy, intracardiac echocardiography).

Deleting a point - To delete a fiducial point, select the point in the fiducial list, and then select Delete Fiducials.

Removing a registration - De-select the Apply button to remove a registration. When registration is removed, navigation and labeling at EnGuide will apply to the EnSite™ model.

The Map Settings panel groups Map Settings, Detection Settings sources and Signals.

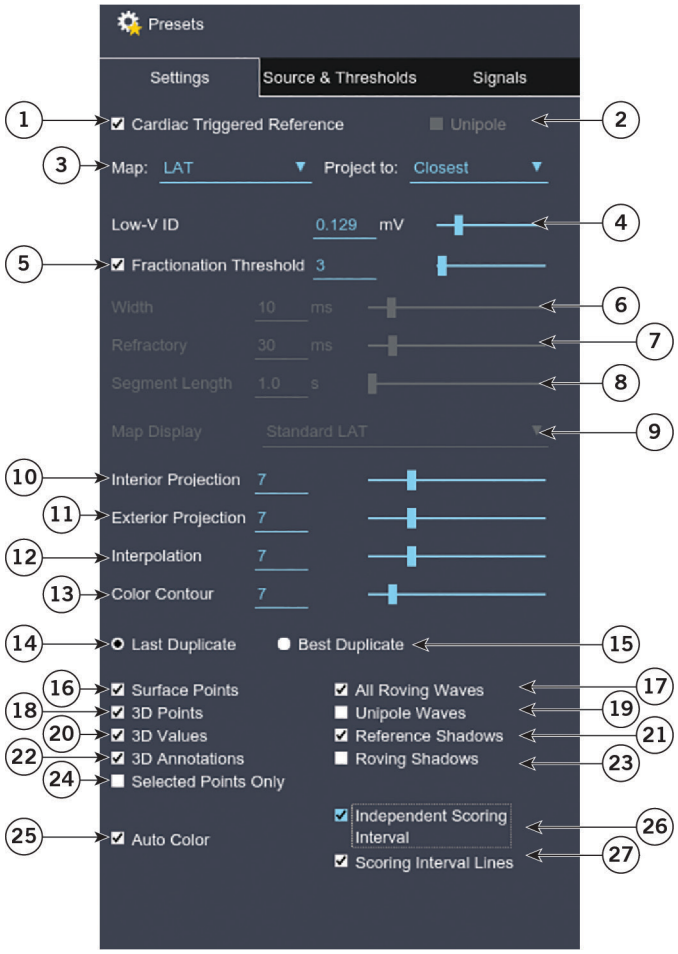
Mapping Settings Panel - Settings Sub-tab

Mapping Settings Options associated with maps types that do not apply for the selected map type display are disabled.

NOTE:

- Areas marked with a yellow border are values saved with a preset. These values change in all corresponding areas of the user interface.
- All settings options below apply to the map that has focus when in Split Screen view.

Figure 154. Mapping Settings Panel – Settings Sub-tab



1. Cardiac Triggered Reference checkbox – Determines which map types (Cardiac Triggered or Non-Cardiac Triggered) are available for use.
2. Unipole checkbox – Toggle on or off unipolar map. Available only for Peak to Peak and Peak-Negative maps.
3. Map drop-down list –
   - LAT: Local Activation Time isochrone
   - Peak-to-Peak: Peak-to-Peak voltage
   - Peak-Negative: Peak-Negative voltage
   - CFE Mean: Complex Fractionated Electrogram Mean activation time between complexes
   - CFE Std Dev: Complex Fractionated Electrogram Standard Deviation between complexes
   - Fractionation: Number of CFE detections
   - Score: Morphology match of the correct ECG signals to the template beat.
   - Point Count: Number of co-located points.
4. Low-V ID slider – Identifies low-voltage zones in LAT or CFE maps. If a collected point's P-P value is lower than the specified Low-V ID value, then that point will display a gray area instead of the color-coded scale for the current map type. Grey points do not interpolate with color points.

1. Fractionation Threshold checkbox/slider – Renders points that are fractionated as larger spheres. Default value=3 (renders points with a fractionation value of >= 3.
2. Width slider – The Width slider (CFE maps only) determines the minimum complex width to consider for activation. Applies to the map that has focus when in Split Screen view.
3. Refractory slider – The Refractory slider (CFE maps only) determines the minimum amount of time between detections. Applies to the map that has focus when in Split Screen view.
4. Segment Length slider – The Segment Length slider (CFE maps only) determines the duration of the selected segment length. Applies to the map that has focus when in Split Screen view.
5. Map Display drop-down list – (LAT maps only) The type of LAT map: Standard LAT, Reentrant Map, or Propagation Map. Sparkle Map: When any map type other than Propagation Map is selected, the Play button is marked SparkleMap and activates the SparkleMap feature.
6. Interior Projection slider – This slider controls the maximum distance that an interior 3D Point (represented as a triangle) can project to a location on the surface (represented by a square). For multiple-surface models, points will project to the nearest surface.
7. Exterior Projection slider – This slider controls the maximum distance that an exterior 3D Point (represented as a triangle) can project to a location on the surface (represented by a square). For multiple-surface models, points will project to the nearest surface.
8. Interpolation slider – This slider controls the minimum distance between surface points necessary for the system to interpolate color. For multiple surface models, points will interpolate between surfaces in the same group.
9. Color Contour slider – Adjusts the gradation between colors on the map. At low Color Contour values, colors appear as distinct bands. At high Color Contour values, there is a smooth transition

between colors.

10. Last Duplicate radio button – Uses the most recent duplicate.
11. Best Duplicate radio button – Uses duplicate with the best combined timing and voltage. Favors points with large voltages that are close to the average timing.
12. Surface Points checkbox – Enables/disables the display of small, yellow square points on the surface. These squares represent the point on the surface closest to a collected 3D point.
13. All Roving Waves checkbox – Select to display all roving waves in the Acquisition Waveform Display. When deselected, only one roving wave is displayed in the Acquisition Waveform Display.
14. 3D Points checkbox – Enables/disables the display of collected points as triangular markers. The triangular markers are placed on the negative electrode of the roving signal channel.
15. Unipole Waves checkbox – Select to display unipolar waves of the roving signals in the Acquisition Waveform Display.
16. 3D Values checkbox – Allows data to be numerically displayed adjacent to the triangular 3D points. 3D points must be enabled to show 3D labels.
17. Reference Shadows checkbox – Displays or hides the Reference Shadows. The first point saved in a map will store the displayed Reference and "extra" waveforms as gray shadows and will be displayed in the RAI behind subsequent detected beats. If the first saved point is deleted, the next point saved will generate the shadows.

    NOTE:

    - Changing the reference signal of the waveform will remove the shadow.
    - Shadows will be stored for all 12 surface ECG leads even if not displayed when the first point is collected.

1. 3D Annotations checkbox – Displays or hides the user-defined annotations associated with 3D points.
2. Roving Shadows checkbox – Displays or hides the Roving Shadow which is a dark red shadow that appears behind the current waveform for the roving catheter. This waveform indicates the morphology of the previous beat for this catheter. This shadow is used to confirm beat-to-beat stability.

   NOTE: If data does not exist for the previous beat (earliest beat in the buffer, etc.), then the dark red shadow will not appear.

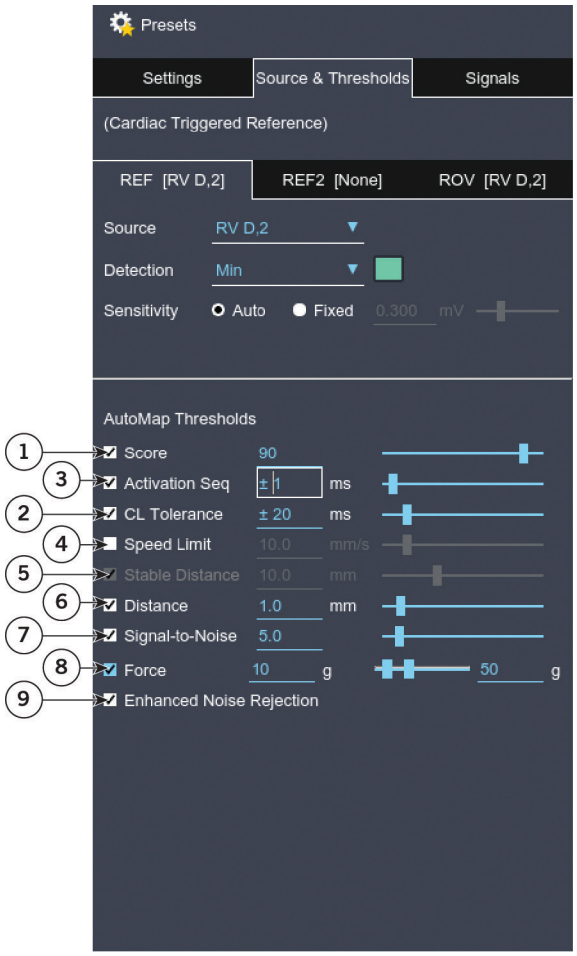
3. Selected Points Only checkbox- When selected, the system draws only the selected points in the 3D display.
4. Auto Color checkbox – Controls whether the system automatically controls the pointers on the color bar during mapping. If Auto Color is enabled, the pointers will adjust to the minimum and maximum data values for all points in the current map. Auto Color applies separately for each display type. Auto Color will be disabled if any color is manually adjusted.
5. Independent Scoring Interval checkbox – The Independent Scoring Interval defines the portion of the template mapping point's 12-lead surface morphology that is used to compare with the current beat's 12-lead surface morphology to determine the Score of correlation between the two. If the independent scoring interval is not enabled

(the checkbox is not selected), then the 12-lead surface morphology match score will be determined using the entire portion of the roving activation interval.

6. Scoring Interval Lines checkbox – Select the checkbox for Show Scoring Interval Lines so that the two, red Independent Scoring Interval lines are displayed and can be adjusted to contain the relevant portion of the signal.

Mapping Settings Panel – Source and Thresholds Sub-tab

Figure 155. Mapping Settings Panel – Source & Thresholds Sub-tab (AutoMap Thresholds)



1. Score checkbox/slider – Mapping points will be collected if the morphology match between the 12-lead surface morphology and the original template best's 12-lead surface morphology is equal to or greater than the specified threshold (measured as a percentage). Note at least one ECG signal must be selected in the Acquisition waveform display to enable the Score threshold. Change the Score percentage slider as needed.
2. CL Tolerance checkbox/slider – Cycle Length Tolerance: Only collect mapping points if the intracardiac measured (CS, HIS, other) Cycle Length is within +/- XX ms of original template beat Cycle Length. User can set the Cycle Length Tolerance from +/- 0 to 150 ms. Default the Cycle Length Tolerance is enabled and is set to +/- 20 mm/s.
3. Activation Seq checkbox/slider – Only collect mapping points if the timing between REF and REF 2 is less XX ms as compared to the template beat. Note Activation sequence requires intracardiac signals to be defined for REF and REF 2.
4. Speed Limit checkbox/slider – Only collect mapping points if the mapping catheter is moving less than XX.X mm/s. User can set the Speed Limit from 0.1 to 75 mm/s. Default the Speed Limit is enabled and is set to 10.0 mm/s.
5. Stable Distance checkbox/slider – Non-cardiac triggered, area in which the user must keep the catheter for the algorithm for it to consider it the same collection.
6. Distance checkbox/slider – Only collect mapping points if the 3D position of the roving catheter electrode is X.X mm or more from the previously collected mapping point from that electrode. User can set the Distance Threshold from 0.1 to 10 mm. Default Distance Threshold is enabled but the default value is set to 1.0 mm.
7. Signal to Noise checkbox/slider – Only collect mapping points if the Signal-To- Noise Ratio on the roving catheter signal is X.X or higher. User can set the SNR Threshold from 1 to 50. Default the SNR Threshold is enabled and is set at 5.0.
8. Force checkbox/slider – (Contact Force Range): This criterion can only be used if the EnSite™ X Contact Force Module is installed and the physician is mapping with a TactiCath™ catheter. Only collect mapping points if the Average Contact Force (as measured by a TactiCath™ Contact Force Catheter) is at least X grams and less than Y grams. User can set the Lower Threshold from 0 to 30 grams. User can set the Upper Threshold from 30 grams to 150 grams. Default the Contact Force Threshold is not enabled but the default lower threshold is 10 grams and the default upper threshold is 50 grams.
9. Enhanced Noise Reduction checkbox – Only collect mapping points if the roving catheter signal does not have certain types of noise (Signals with saturations, electrode-to-electrode contact, open electrode noise, signals with degraded conditions such as no location or dropped data). Only uncheck for pace mapping. User can set the Enhanced Noise Reduction on or off. Default the Enhanced Noise Reduction is enabled.

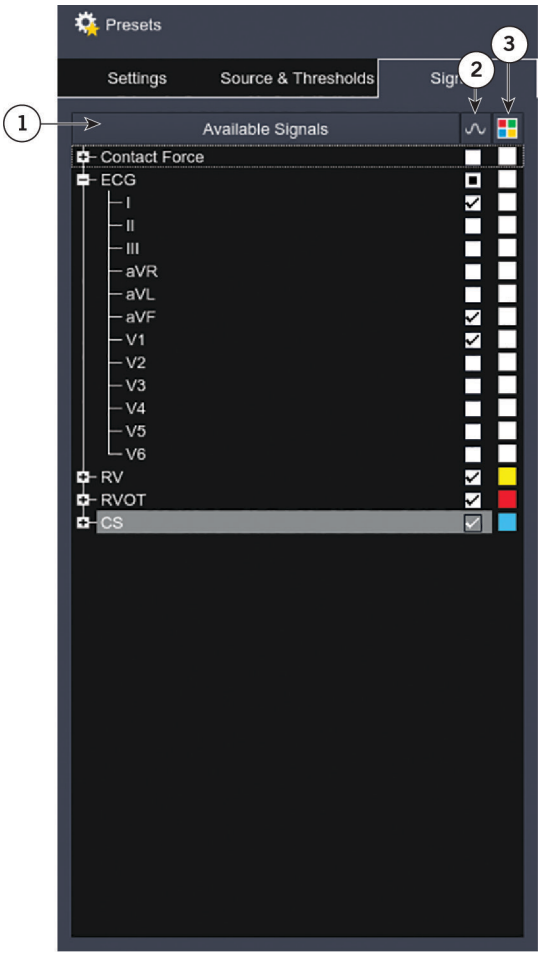
Mapping Settings Panel

Mapping Settings Panel - Signals Sub-tab

The Signals list works in the same manner as Waveforms and Catheters from the Setup Panel.

NOTE: Areas marked with a yellow border are values saved with a preset. These values change in all corresponding areas of the user interface.

Figure 156. Mapping Settings Panel – Signals Sub-tab



1. Available Signals list – Displays Signals with expandable/collapsible tree; colors changed with the color picker control updates color selections for Waveforms and Catheters.
2. Filtered icon – Display filtered signals.
3. Color icon – Choose the color of the displayed Signal trace. Color changes updates color selections for Waveforms and Catheters.

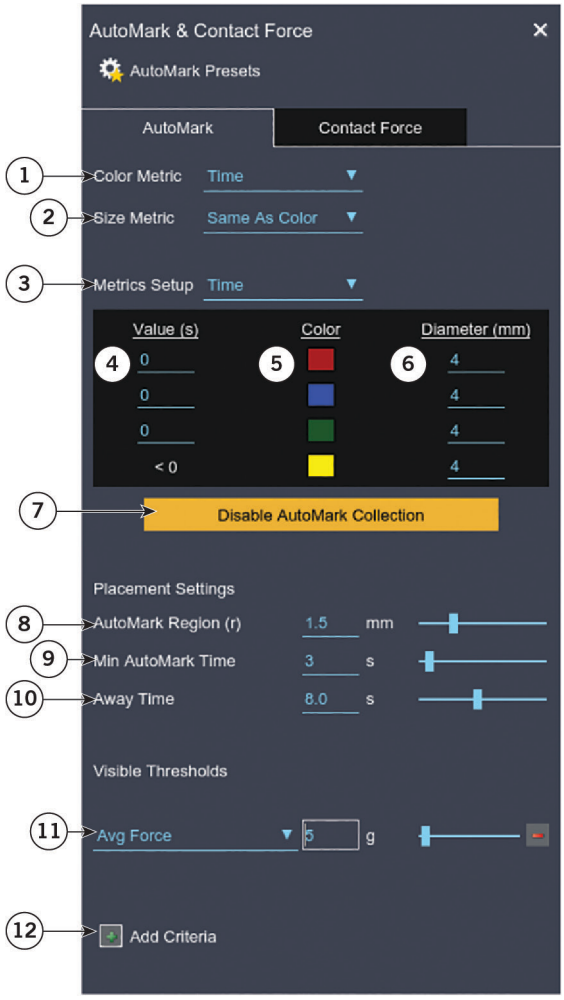
AutoMark and Contact Force Settings Panel

AutoMark & Contact Force Settings Panel - AutoMark Sub-tab

The AutoMark and Contact Force Settings Panel provides access to the Metrics, Placement and Criteria settings and controls.

NOTE: Areas marked with a yellow border are values saved with a preset. These values change in all corresponding areas of the user interface.

Figure 157. AutoMark and Contact Force Setting Panel - AutoMark Sub-tab



1. Color Metric drop-down list – Used to define the AutoMark metric for color.
2. Size Metric drop-down list – Used to define the AutoMark metric for size. The Size Metric can be set to same as Color Metric.
3. Metrics Setup drop-down list – Used to select the AutoMark metric to configure; threshold values, color and size.

   NOTE: The default AutoMark configuration does not have any threshold values, colors or diameters configured. Without configuration, all AutoMarks will appear as grey spheres with a diameter of 4 mm.

   Available Metrics:
   - Avgerage Force
   - Maximum Force
   - Energy
   - Time
   - Impedance Drop
   - Impedance Drop (%)
   - Avgerage Power
   - Maximum Power
   - Avgerage Temperature
   - Maximum Temperature
   - FTI (available only outside the US)
   - LSI (available only outside the US)
4. Value(s) – User defined thresholds for each AutoMark metric.
5. Color – User defined color for each threshold value.
6. Diameter – User defined AutoMark diameter for each threshold value.
7. Disable/Enable AutoMark Collection button – Turn on/off AutoMark data collection. When disabled no data from the Ampere generator will be stored.

Placement Settings

8. AutoMark placement is based on three user defined settings: AutoMark Region, Min AutoMark Time, and Away Time. Any changes to the placement settings will result in recalculation of all AutoMark data.
9. AutoMark Region (r) slider – The radius of a catheter stability considered sufficiently stable to allow formation of an AutoMark. This value is also the minimum center-to-center distance between AutoMarks. Default = 1.5 mm (millimeters).
10. Min AutoMark Time slider – The minimum amount of time the catheter tip must remain within the AutoMark region before a new AutoMark is placed. Default=3 seconds.
11. Away Time slider – The maximum amount of time the catheter can move away from the AutoMark region before that AutoMark is completed. – For example, if an AutoMark has been created and the catheter moves away from the AutoMark region for a duration longer than the Away Time, the AutoMark will be completed. If the catheter returns to that location at a later point in the procedure, a new AutoMark will be created, and the data will not be combined. If the catheter returns to the AutoMark region within the Away Time, the data will continue to be collected in to the current AutoMark. Default = 8.0 (seconds).

    NOTE: It is recommended to set the Away Time to a duration that is greater than the respiration cycle of the patient.
12. Visible Thresholds drop-down list/slider – User defined visibility thresholds. AutoMarks will not appear until all visibility thresholds have been met or exceeded. Visible Thresholds can be defined based on one or more of the AutoMark Parameters.

    NOTE: The default is no Visible Thresholds are configured. A Visibility Threshold must be selected to make AutoMarks visible on the map.

    Available Metrics:
    - Avgerage Force
    - Maximum Force

- Energy
- Time
- Impedance Drop
- Impedance Drop (%)
- Avgerage Power
- Maximum Power
- Avgerage Temperature
- Maximum Temperature
- FTI (available only outside the US)
- LSI (available only outside the US)

13. Add Criteria icon – Select to add additional Visible Thresholds.

AutoMark & Contact Force Settings Panel - Contact Force Sub-tab

The Contact Force tab provides access to the Metrics, Display and Stability settings.

This tab is grayed out if there is no Contact Force License installed on the system. If a Contact Force License is present, refer to the EnSite™ X Contact Force Instructions for Use for description of the controls.

NOTE:

- The display of the related Contact Force Waves, Meters, and Metrics are controlled in the Meters & Display Options panel.
- Presets for the Contact Force are set and managed from the Meters and Display Options Settings Panel.

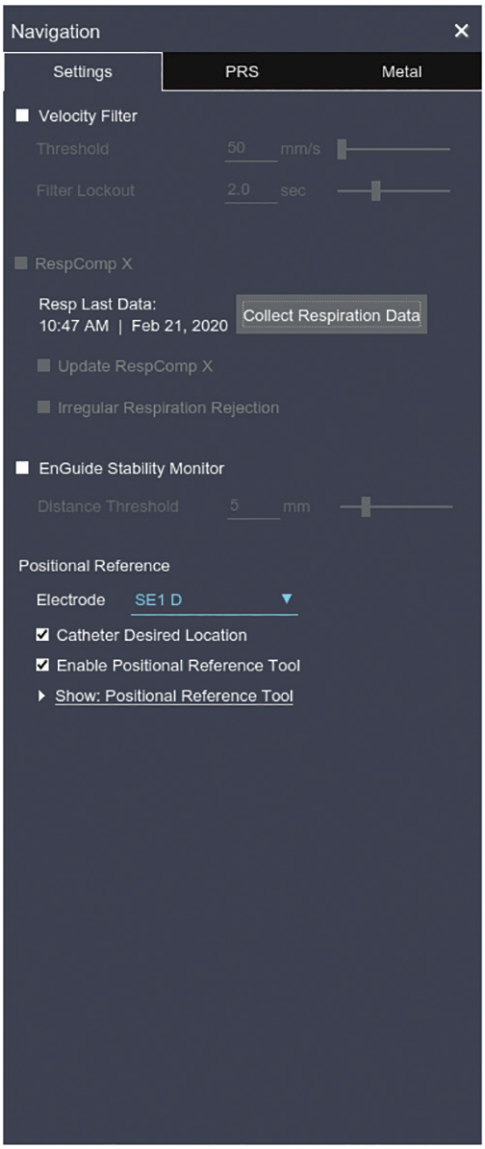
Figure 158. AutoMark & Contact Force Panel – Contact Force Sub-tab

Navigation Settings Panel

The Navigation Settings Panel provides quick access to setup functions and parameters. It contains functions related to the catheter navigation, respiration compensation, PRS setup, and Metal setup.

For description of controls and on the Settings sub-tab, refer to the Setup section for detailed descriptions of the controls and settings.

Figure 159.

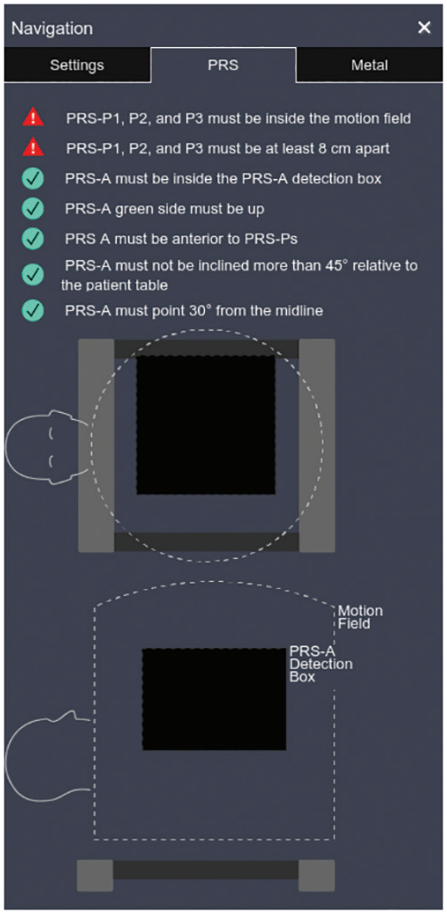


Refer to the Setup section for detailed descriptions of the controls and settings.

Navigation Panel - PRS Sub-tab

The PRS sub-tab provides quick access to PRS setup functions and parameters. Refer to the Setup section for detailed descriptions of the controls and settings.

Figure 160.

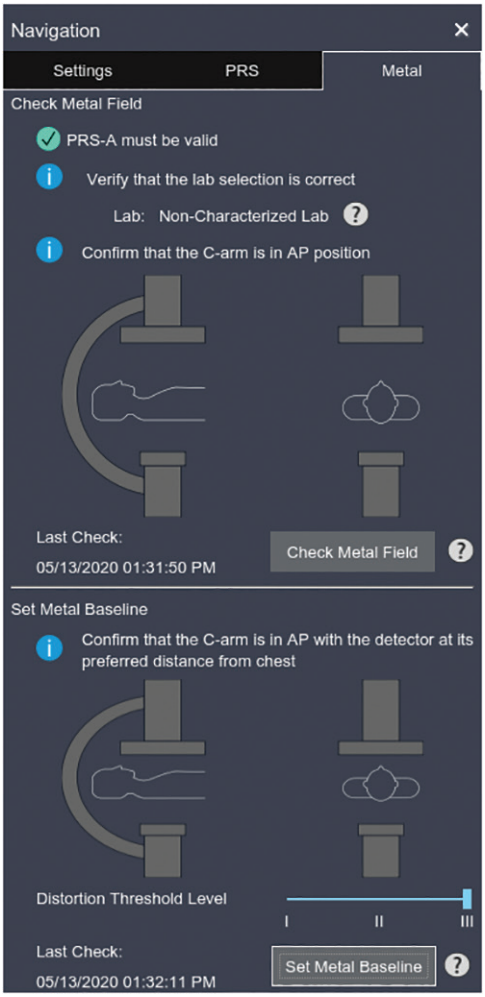


Refer to the Setup section for detailed descriptions of the controls and settings.

Navigation Settings Panel - Metal Sub-tab

The Metal sub-tab provides quick access to Metal environment setup functions and procedure. Refer to the Setup section for detailed descriptions of the controls and settings.

Figure 161. Navigation Settings Panel – Metal Sub-tab.



Refer to the Setup section for detailed descriptions of the controls and settings.

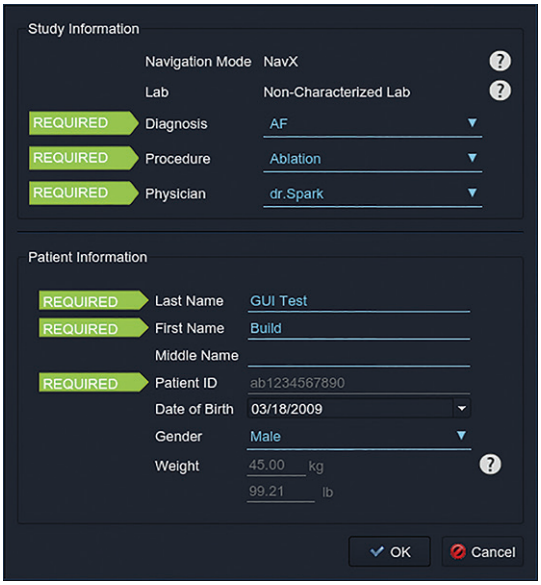
Ending a Study

WARNING: If the DWS is powered off by the user, rather than shutdown by the operating system, data on the hard drive may become corrupted and the EnSite™ X EP System may cease to be operational.

CAUTION: When removing the system reference surface electrode from the patient's abdomen, disconnect the electrode from the patient before disconnecting its connection from the SurfaceLink Module.

Use the following procedure to end a study:

Figure 162. Study and Patient Information screen.



1. From the top bar, select File > End Study. The system will prompt the user with "End the current study? Yes/No." Select Yes. If study and patient information has already been specified, go to step 3.
2. If study and patient information has not been specified, the system will prompt the user with "Cannot end study without entering study and patient information. Enter study and patient information? Yes/No." Select Yes. The system will display the Study and Patient Information screen. Fill in the required information and Select OK.
3. The system will prompt the user with "Remember to backup study information".
4. Select OK to continue.
5. The system will return to the Login screen.

NOTE: To backup, or archive, the study, see "Archiving Studies".

Capturing, Exporting, and Importing Information

Exporting Data to External Devices

Images and study data can be stored to a USB device, a network drive, or CD/DVD. Compatible CD/DVD formats are: CD-R, CD+R, CD-RW, CD+RW, DVD-R, DVD+R, DVD+RW, and DVD-R Dual Layer.

NOTE: CD/DVDs must be handled with care. Do not allow a CD/DVD to fall on a hard surface. To label a CD/DVD, never use a paper label, always write directly onto the CD/DVD using a permanent marker.
NOTE: Information can only be exported to a CD/DVD from outside of a study.
NOTE: A CD/DVD may contain multiple images, but only one study.
NOTE: If export to a USB device fails, try an alternate external storage device, a network location, or CD/DVD.
NOTE: Network File System (NFS) versions prior to NFSv3 may experience limitations to the addressable file system size to less than 4.2GB. (This is a protocol limitation.)
NOTE: File system access errors may be experienced when using Server Message Block (SMB) versions prior to 2.0. Some files may become inaccessible.
NOTE: USB devices having FAT32 file systems may be unable to store Velocity studies, due to the number of files, file name length, or file size limitations of FAT32. NTFS or ext3 file systems are recommended to be used.

When images are stored to external media, they are listed by their annotation and an index number to differentiate duplicate annotations. Images are stored as JPEG files.

Selecting an Area for Capture

When capturing images or creating animations, the entire screen or a selected area of the screen can be captured. In addition, the images and animations can be captured with a white background. The user specifies what is to be captured in the Capture Image, Record Movie, and Capture Images windows.

- To capture the entire screen, select Full Screen.
- To define the area of the screen to be captured, select Selected Area. To define the area to be captured, Click and hold down the left mouse button and drag a box around the desired area of the screen. Adjust the box if necessary.
- To capture the entire screen or selected area with a white background, select White Background. A white background is beneficial if the images are going to be printed on a printer.

When the desired area has been selected, click [Capture Image] to capture an individual image, or click [Start] to capture an animation. The captured image or animation is stored in the Notebook.

NOTE: Individual images can be captured at any time during a study.
NOTE: MPEG and JPEG animations can only be captured in Offline Review.

Saving and Accessing Individual Images

Images of entire screens can be saved. These images can also be viewed.

Saving an Image

To save an individual image:

1. Select File > Save Image to display the Capture Image window.
2. Type a description of the image in the text area.
3. Indicate the screen area to be captured:
   - Select Full Screen to capture the entire screen.
   - Select Selected Area to manually select the screen area to capture. Refer to “Selecting an Area for Capture” for more information about selecting the screen area.
4. Select White Background if a white background is desired.
5. Click [Capture Image]. The image is captured and saved as a part of the patient study and is added to the Notebook.

Accessing an Image

NOTE: Images are saved with their appropriate study. If a study containing images created in Offline Review mode is removed from the workstation hard drive, the images are removed as well. Be sure to backup studies so the images are saved.

1. Access the Notebook in the Review work panel.
2. Select an annotation from the list. Use the buttons described below to view or manage image files:
   - [Load] displays the image.

   NOTE: This is the only location where printing can be done.

   - [Delete] erases the selected image.
   - [Edit] allows the user to edit the annotation of the image.
3. Click [Close] to exit the window.

Creating Animations

NOTE: Offline Review Mode only.

A series of continuous images of the entire screen can be exported from the system as either an mpeg movie file or a sequence of jpeg images.

Creating an MPEG Movie

Creating and MPEG Movie

1. Select the Application menu icon at the bottom left of the screen, then choose Save Animation > Start Capturing MPEG Movie to display the Record Movie window.
2. Indicate the screen area to be captured:
   - Select Full Screen to capture the entire screen.
   - Select Selected Area to manually select the screen area to capture. Refer to “Selecting an Area for Capture” for more information about selecting the screen area.
3. Select White Background if a white background is desired.
4. Click Start to start recording a movie.

To stop recording an MPEG movie:

1. Click the Animation Recording icon located in the bottom right corner of the screen.

or

Select the Application menu icon and choose Stop Capturing Animation.

2. A dialog box will appear in the center of the screen. Enter a description for the movie in Description field.
3. Click [Create Movie] to create the movie or [Cancel] to cancel the operation.

Creating a JPEG Image Sequence

To start recording a JPEG image sequence:

1. Select the Application menu icon then choose Save Animation > Start Capturing JPEG Images to display the Capture Images window.
2. Indicate the screen area to be captured:
   - Select Full Screen to capture the entire screen.
   - Select Selected Area to manually select the screen area to capture. Refer to “Selecting an Area for Capture” for more information about selecting the screen area.
3. Select White Background if a white background is desired.
4. Click Start to start recording a movie.

To stop recording a JPEG movie:

1. Click the Animation Recording icon located in the bottom right corner of the screen.

or

Select the Application menu icon and choose Stop Capturing Animation.

2. Enter a description for the movie in Description field.
3. Click [OK] to save the images or [Discard Images] to discard the captured images.

Data Export

NOTE: Offline Review Mode only.
NOTE: This option exports data only to the DWS hard drive.

To begin Data Export, select Application menu icon and choose Export to bring up the Data Export window.

Waveform Data

Near the top of the window is a list of the types of data that can be exported. Any or all of them can be selected using the check boxes, and each will be written to its own file. When the user selects any type of data that changes over time (e.g. Waveforms, or Electrode Locations), the Export Interval options become available to choose the time interval for the export.

The Displayed Waveforms option is a special shortcut selection that exports only those waveforms (of any type) that are currently displayed, over the current span of the waveform window. The Export Data and Export Interval options do not apply to this selection.

In EnSite NavX™ mode, if Use System Reference at the top of the window is checked, the Positional Reference will be set to System Reference before the export begins, regardless of its setting during the study. This can standardize the positions of electrodes and labels, but also export them in positions different than how they appear on the screen. If this option is checked, the user must revert the Positional Reference manually after the export is complete.

Directory Name

A directory prefix is assigned in the Directory Name field of the Data Export window. Each time the Export button is clicked, a folder is created using this name and the current date and time of the button click, and the exported data files are saved into this folder.

Export Interval Options

NOTE: The caliper and the cursor are only available in the following workflows: Model, Therapy, or RealReview.

Caliper: Select this option to use the green calipers in the waveform display to capture the time interval desired.

Displayed Window: Selecting this option captures the visible time interval in the waveform display.

Cursor Location: Selecting this option exports the segment beginning at the cursor. This option requires that one of two sub-options also be selected:

- Export until segment end, which will continue exporting data until the segment ends.
- Duration (in seconds), in which the exact segment interval is determined by the user and is manually entered in the field supplied.

NOTE: Selecting [Clear Selections], at the top of the Data Export window, will clear all Export Option check marks. Deselecting items can be done anytime prior to Export.

Exporting

When [Export] is clicked, a progress bar is displayed for each option selected. If Export Data: All is selected, all available data for the selected type(s) will be exported from the study (e.g., all EP Catheter Unipole Waveform channels). In contrast, when Export Data: Displayed is selected, only those channels currently displayed in the waveform window will be exported.

Once an Export begins:

- All graphical user interface objects are disabled, except [Cancel].
- A progress bar is displayed for each option selected.
- Application configuration changes recorded as part of the segment are inhibited.
- The configuration at the start of the Export will be maintained for the duration of the Export.

NOTE: When the progress bar(s) is displayed, [Cancel] can be selected to stop the Export. The Export may not stop immediately; a slight delay can be expected.

Export is not available if Segment: None is selected.

When exporting data from the EnSite™ X EP System, the segment playback speed is automatically set to 1:4. This ratio allows for internal processing and the Export of data.

Presets

The user can choose to save a Preset for application configurations that will be used in more than one Export.

Once all the desired parameters are set, click on the Preset icon located in the upper right of the Data Export window. Click on Save Preset to bring up the Save Preset window. Type in a name for the preset and click [OK].

To reapply a Preset, click on the Preset icon and click on the appropriate Preset name.

NOTE: Export Presets can be applied to any segment in the study in which they are defined.

However, Export Presets cannot be applied to a different study.

Archiving Studies

This option allows the user to archive entire studies to a USB device, a network drive, CD/DVD, or to the DWS to remove later via SJM™ Connect.

1. Click Archive from the Clinical Menu.
2. Select the Archive Study tab.
3. Highlight the desired study.
4. Insert the desired media, and select the Archive Destination (USB, CD/DVD, network drive, DICOM Server, or SJM™ Connect).
5. Select the Identifier (name of the USB device or enter the name of the CD/DVD).
6. Select one or both options:
   - "Delete the selected studies from the local drive after successful archiving"
   - "Overwrite the previous archive on the selected destinations" (does not apply to CD/DVD media)
7. Click Archive.

Archiving Media

This option allows the user to archive individual images and animations from a study, rather than the entire study.

1. Click Archive from the Clinical Menu.
2. Select the Archive Media tab.
3. Highlight the study that contains the desired images and animations.
4. Select a File Name in the right section of the screen.
   - The selected image or animation displays below.
5. Insert the desired media, and select the Archive Destination (USB, CD/DVD, network drive, or DICOM Server).
6. Select the Identifier (name of the USB device or enter the name of the CD/DVD).
7. Click [Archive].
   - A progress bar displays "Store in Progress."
   - The images and animations are archived on the selected media when the progress bar finishes.

Importing Studies

The user can import studies to the DWS from a USB device, a network drive, or CD/DVD.

1. Click Import from the Clinical Menu.
2. Select a source from the Import From: pulldown menu.
   - If importing from USB or CD/DVD, make sure the media is present in the USB port or CD/DVD drive.
3. Click the [Query] or [Browse] button.
   - For CD/DVD, only [Browse] is available.
   - The list of studies on the media displays:
4. Select a study from the list and click the [Import Study] button.
   - A progress bar displays “Store in Progress.”
   - The study is imported to the DWS when the progress bar finishes.

Troubleshooting

Troubleshooting Tools

Technical Support may ask that the user access one or more of the following software resources.

EnSite Connect – Technical Support can electronically access your EnSite™ X EP System to perform troubleshooting.

About the EnSite™ X EP System – This information provides your Abbott Technical Support representative with general information about your DWS and EnSite™ X Amplifier.To access during a study, from the menu bar, select Help > About. From the title screen, Select About EnSite™ X EP System.

Amplifier Logs – This function displays messages from the EnSite™ X Amplifier during a study. From the menu bar, select Amplifier > Log. A window appears that displays all the collected logs.

Collect Log Files – This function collects all the log files from the DWS and exports them to external media. From the title screen, select Services, then Collect Logs from the Services menu. Follow the on-screen prompts to complete the process. This operation can take several minutes to complete.

Viewing recorded settings – Some settings used in Realtime environment can be viewed (but not changed) in Offline Review environment. Hardware settings can be viewed by selecting Amplifier > Settings from the menu bar.

Catheter settings can be viewed in the Setup task. EnSite NavX™ settings can be viewed in the Setup task.

Run external program – This function allows utilities to be accessed. Service utilities can be accessed from the Launcher's service page.

Study Files – Record a segment that shows relevant information (if possible) and save the study using the option to remove personal patient information. The option will explain what information was removed and remain.

Error Messages

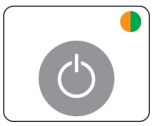
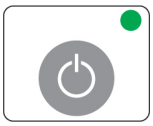
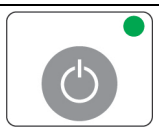
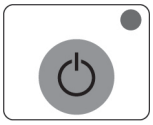
Error Message	Problem
DVD Drive Not Detected You will be able to conduct real-time studies but it will not be possible to review studies from or save data to CD or DVD Contact EnSite System technical support Press [Continue] when ready	Indicates a hardware fault with the CD/DVD drive.
Resource Checks Problems were found in checking system resources. Restart using normal procedures. Press [OK] when ready to shut down for a re-start.	If the error persists after re-start contact technical support.
Bad System Time Detected (A date and time will be displayed) Please correct the system time and date. If the trouble persists, Contact EnSite technical support. Press [Continue] when ready.	The system administrator can check the system time setting to adjust to the correct time.
Unexpected error occurred Application exited with (number)	Restart the computer. A user with Service access may run collect logs and contact technical support.
No Base License Detected The system does not have an EnSite X EP System base license. Contact EnSite technical support Press [Continue] when ready.	The user should discontinue system usage and contact technical support for a license.
Resource Checks Problems were found in checking system resources. SecurityLauncher program is already running. Re-start using normal procedures. Press [OK] when ready to shut down for a re-start.	If the error persists, contact technical support.
SecurityLauncher failed to execute	Restart the computer. If the error persists, contact technical support.
SecurityLauncher binary not present on the system.	Restart the computer. If the error persists, contact technical support.
Resource Checks Problems were found in checking system resources Courier program is already running. Re-start using normal procedures. Press [OK] when ready to shut down for a re-start.	Restart the computer. If the error persists, contact technical support.

Troubleshooting Common Problems

System Hardware Problems

Many hardware problems can be identified/resolved by checking	Check all status lights The EnSite™ X Amplifier will perform a self-test. Both LEDs that comprise the status light are illuminated. Check the

status lights and cable connections.	amplifier status lights. When the system is powered up, the amber light will stay lit for approximately two minutes while the system performs self-testing. After two minutes, the green light should come on and remain solid. See table below for amplifier status. The EnSite™ X Amplifier status and any fault information can be uploaded by the workstation after the EnSite™ X Amplifier connects to the workstation. Verify proper cable connections: - Turn the system power off. - Unplug the system components from power outlets. - Check all connections for damage (such as bent or broken pins). - Verify there are no loose connections. - Check the integrity of the wall power outlet. - EnSite™ X Display Workstation (DWS): The power LED on the front of the workstation should be on.

Color		State	Action
Orange / Green		Steady	Restart or call technical service.
Orange		Steady	Self-test running.
Orange		Flashing	Restart or call technical service.
Green		Flashing	Check fiber-optic cable between the EnSite™ X Amplifier and EnSite™ X DWS is connected; verify EnSite™ X DWS is powered on.
Green		Steady	System ready.
Off		Off	System Off.

Power Failures: A power blackout will cause a total system shutdown. In the case of a brownout or (low power), the system may totally shutdown or may show signs of abnormal system behavior.	If there is reason to believe that some type of power failure has occurred, turn the EnSite™ X Amplifier power switch to OFF immediately. Try to end the study and shutdown the workstation. If the normal shutdown procedure is unsuccessful: - Try Ctrl-Alt-Delete - Try Alt-F10 > [Exit EnSite X] > [Exit] - Try momentarily pressing the power button on the front of the DWS - As a last resort, press and hold the power button on the front of the DWS. When the power resumes and appears to be stable, power up the system. Monitor the automated system check during the power-up procedure. If any system problems occur, contact Abbott Technical Support immediately.
There is a problem with the EnSite™ X Amplifier, indicated by an amber LED on the amplifier front panel after the two- minute power on self-test.	- A solid amber LED indicates a self-test problem in the EnSite™ X Amplifier. - A flashing amber LED indicates an error in the EnSite™ X Amplifier. - Contact Abbott Technical Support.
The EnSite™ X Amplifier is not communicating with the workstation.	The EnSite™ X Amplifier is unresponsive or is not collecting data in Realtime mode or RealReview mode. Try to re- establish communication with the EnSite™ X Amplifier by selecting Amplifier > Reconnect. If communication is not reestablished, perform the following: - Check the fiber-optic cable connection at the EnSite™ X Amplifier and at the workstation. - Power off and on the EnSite™ X Amplifier and all peripherals. - Power off and on the workstation. - Verify that the lights are blinking on the fiber SFP modules at both the EnSite™ X Amplifier and the DWS.
There is a problem with the EnSite™ X Amplifier indicated by the workstation.	The workstation displays a yellow warning dialog: The user should contact Abbott Technical Support.

The workstation will not turn on, will not boot, or turns off unexpectedly.	- Verify that the isolation transformer switch is on. - Verify that the power cable is properly connected between the workstation and the isolation transformer. - If the system should cease to function due to a power outage or other failure, turn off all power switches. Then restart the system. System recovery may take several minutes. - Try momentarily pressing the power button on the front of the DWS. - As a last step, press and hold the power button on the front of the DWS.
Hard drive has run out of space.	If there is insufficient space on the hard drive to load a study from the external media, delete studies from the hard drive, then load the study.
There is a broken connector pin.	Contact Abbott Technical Support or Customer Service to order a replacement cable.
The printer does not print images.	- Ensure the printer is enabled. To do this, go to the Services menu and select [Select Printer]. Select the desired printer and click "Apply." - Ensure that printer ink cartridges are not depleted; replace depleted cartridges. Ensure that there is paper in the printer.

Patient Signal Problems

Problem	Possible Solutions
Interference between devices is evident.	This equipment has been tested and found to comply with the limits for medical devices to EN 60601-1-2: 2001. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in an installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, try to correct the interference by one or more of the following measures: - Reorient or relocate the devices. - Increase the separation between the devices. - Connect the equipment to an outlet on a different circuit. - Contact Abbott Technical Support for further assistance.
There is excessive waveform noise.	If noise levels are excessive in general, check the following: - Under catheter setup / waveform controls, evaluate signals with noise filters enabled and disabled. - Adjust noise filter settings. - Ideally, the power source for the EnSite™ X Amplifier should be a properly grounded, dedicated 15-amp circuit. - Ensure the EnSite™ X Amplifier is connected to an Abbott supplied isolation transformer.
An EnSite™ X electrode has become disconnected or loose, indicated by a warning message.	- Verify that all cable connections between the electrodes and the SurfaceLink™ Module are secure. - Verify that none of the electrodes have come loose. If an electrode has come loose from the patient, re-apply the electrode in the same location and verify that navigation is accurate, compared to fluoroscopy and signals. It may be necessary to re-validate.
ECG signals are not functioning properly.	- Verify that the system reference patch is connected to the patient. - Verify that the ECG cables are connected properly.

EnGuide Stability Problems

An EnGuide electrode position seems to be incorrect: The EnGuide electrode intermittently displays jumps in location or changes in color. Displayed location of the roving catheter on the system differs from the displayed catheter location on fluoroscopy or another mapping system. The movement of the EnGuide is inconsistent with the movement of the roving catheter. The EnGuide “jitters.”	- Verify to the Ampere Connect cable is connected between Ampere™ and the EnSite™ X Amplifier. - Verify that EnGuide is locating the intended electrode. - Verify that catheter cables and/or pin connectors are connected properly. - Verify that the electrodes are properly adhered to the patient and connected to the system. - Verify that the wires for the electrodes are positioned in a way that there is no tension on the wire. - Attempt to use a different catheter. Signal improvement may indicate a damaged EP catheter or connecting cable. - Select “Application Menu, then select Amplifier > Reset Amplifier.
An EnGuide appears kinked or displays fewer electrodes than expected.	- In an EnSite™ X EP System study, if the EnGuide appears kinked, there may be a problem with the catheter. A new catheter or extension cable may display better results. - If the EnGuide is displaying fewer electrodes than expected (based on EnGuide settings) the electrodes may be spaced too close to one another for EnGuide to display different electrodes, or there may be a problem with the roving catheter, such as a weak electrode or short.

Patient	Irregular Respiration Patterns Patient – sleep apnea, coughs, snoring	Follow these steps: 1. Wait for the respiration pattern to stabilize. The EnGuide may return to its original expected location. 2. Manually recollect respiration compensation data. 3. Switch to manual to prevent additional collection (disable adaptive respiration compensation). 4. If multiple shadows have been placed use EnGuide Alignment tool to adjust the visually realign the catheter to the model. 5. Build a new model if steps above do not resolve the problem.
Patient	Rate or Rhythm change	- Heart rate or rhythm changes have the potential to change the physical anatomical volume of the heart chamber. If the rate or rhythm changes occur after a model has been created, new model may need to be created for the new rate or rhythm.
Patient	Isoproterenol bolus	- Wait for the respiration pattern to stabilize. The EnGuide may return to its original expected location.
Patient	Heart Motion	- If the heart has physically moved from its original position, create a new model if necessary.
Device Interaction	Cardioversion	Follow these steps: 1. Wait for the EnGuide to return to its original expected location. 2. If multiple shadows have been placed use EnGuide Alignment tool to adjust the visually realign the catheter to the model. 3. Build a new model if steps above do not resolve the problem.
Device Interaction	Introduction of a guide wire	- Remove the guide wire if it is not in use.
Device Interaction	Pacing – connection of a stimulation channel to electrodes	- If there is no active pacing on the electrode pair, remove the connection of the stimulation channels.
Electrode Changes	Electrode Detachment	Follow these steps: 1. Replace the detached electrode with a new electrode. 2. Build a new model.
Electrode Changes	Electrode movement relative to the location of the heart	Follow these steps: 1. Switch to an intracardiac reference if available to prevent additional instability due to electrode movement. 2. If multiple shadows have been placed, use the EnGuide Alignment tool to visually realign the catheter to the model. 3. Build a new model if use of the alignment tool is not successful.
Electrode Changes	Pushing on a patch - Inflation of a blood pressure cuff	Try the following options: - Avoid pushing on the patch or remove the object pushing on the patch. - Switch to an intracardiac reference if available.
Electrode Changes	Adding or removing patient bedding materials	- Avoid moving bedding materials such as a pillow that have the potential to disturb the electrode.

System Related	Positional Reference Moves	Try the following options: - Move catheter to original location as observed on Fluoroscopy images. If Positional Reference Tool is enabled use the tool to realign the reference. - Switch from the intracardiac Positional Reference to the System Reference. Then choose a different electrode for positional reference. - Build a new model if use of the Positional Reference Tool is not successful.

Magnetic Tracking Problems

System not recognizing PRS	- Verify the EnSite™ X Field Frame cable is connected to the EnSite™ X Amplifier. - Ensure that the EnSite™ X Field Frame cable is not coiled. - Ensure a 12 coil Field Frame model ENSITE-FF-BRCKT-01 or ENSITE-FF-ABRKT-01 is connected to the system. - Ensure the Field Frame cable is model ENSITE-FF-3MC-01 or ENSITE-FF-4.5C-01. - Replace the PRS.
PRS icons are gray	- Ensure that the EnSite™ X Field Frame cable is not coiled. - Ensure the PRS sensors are connected to the EnSite™ X Amplifier. - Ensure that the PRS sensors are separated and are not being separated by a pillow or other piece of equipment.
Valid PRS status is intermittent	- Ensure that the EnSite™ X Field Frame cable is not coiled. - Ensure the PRS sensors are located within the motion field, adjust PRS placement or location of Field Frame on the patient table. - Replace the PRS.

PRS-A is gray or red	- Confirm position of PRS is within the PRS-A detection box as viewed on the PRS tab.
	  - Adjust the EnSite™ X Field Frame or patient position on the table.
	  - Confirm all PRS-A position criteria on the PRS tab are met.
	- Perform the Metal Baseline or return the Fluoroscopy detector to the Metal Baseline position.
	- Remove presence of metallic equipment in the presence of the magnetic field Example: patient warming equipment, monitor boom.

System not collecting EnSite NavX™ SE points	- Correct any Metal Distortion issues. - Confirm PRS and catheter status indicators are green. - Confirm a Sensor Enabled™ catheter selected as Active EnGuide for NavX Mode. - Verify the electrodes on the catheter are out of the sheath. - For ablation catheter, ensure Stabilize ABL is off. - Irregular respiration patterns may cause points to not be collected. Monitor the Respiration meter.

Software Interface Problems

Unable to enter Review Mode or end study.	An action is incomplete. Verify that the model has been completed. Verify that recorded segments have been completed and annotated, verify patient information has been entered.
Unable to access controls to export information to the external media.	- Verify the system is in Offline Review; the external media is not intended to be used to export data or animations during a study.

The study screen display freezes.	If the system appears to be running but does not respond to keyboard or mouse input, press and hold the <Alt> key on your keyboard, then press the <Tab> key. The system should then return to normal operation.
	The study screen freezes after a manual reset of the EnSite™ X Amplifier or an inadvertent reset following a defibrillation.
	- Power cycle the EnSite™ X Amplifier by turning the EnSite™ X Amplifier power switch off and (after five seconds) then on.
	  - Select Amplifier > Reconnect and wait up to 2 minutes for the EnSite™ X Amplifier to complete its self-test routines.
	  - Select <Alt> + <Tab> to see if the study screen starts responding.
	  - To force the system to shut down, select <Alt> + <F10>.
	  - To end the current session, or to force the system to shut down or restart, select <Ctrl> + <Alt> + <Del>, and choose the desired option.
	  - If the problem persists, contact Abbott Technical Support.

An on-screen warning message has appeared.	Follow any on screen instructions to resolve the issue. NOTE: Further details on problems related to the current version of the software can be viewed in the Software Anomalies Addendum. Other information may be displayed along with these messages indicating what caused the problem. Note this information for future reference should you wish to contact support personnel.

SJM™ Connect

SJM™ Connect is a feature that is available on the EnSite™ X EP System. It allows an Abbott Technical Support representative to connect to your DWS through a broadband Internet connection. SJM™ Connect provides users with access to a secure remote connection to tech support to aid in remote servicing. All communications are encrypted with TLS. When connected to your DWS, the Abbott System Technical Support representative can see the interface. The user will also be able to chat with the Technical Support Representative through a chat window.

NOTE:

- SJM™ Connect is intended for troubleshooting purposes. SJM™ Connect is not intended to be used in lieu of an on-site system operator.
- Personal patient information is automatically deleted from uploaded studies. The Technical Support representative uses these anonymous studies to research any technical issues. When possible, record and annotate segments of any unusual behavior for analysis.
- The local user must launch the SJM™ Connect remote client and then call Abbott Technical Services to initiate the remote connection. The local user must accept the request for access which is sent by the remote user based on the level of access they require. The local user can end the session at any time. Select the Disable button when SJM™ Connect is not in use.

Using SJM™ Connect

Figure 163. The SJM™ Connect Icon

Call Abbott Technical Support.

Abbott Technical Support will assess the issue over the phone and may need additional information from Collect Logs or remote access to the DWS.

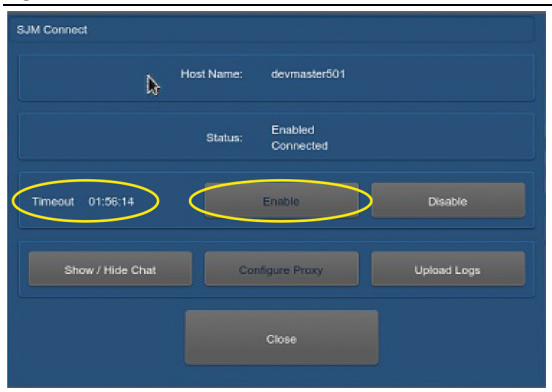
If Abbott Technical Support requires remote access to the DWS, select the SJM™ Connect icon on the EnSite™ X EP System's tool bar.

NOTE:

An Ethernet cable with Internet access must be plugged into the hospital network port on the back of the DWS. This is an encrypted, secure connection used by Technical Support.

Only enable SJM™ Connect if instructed to do so by Abbott Technical Support.

Figure 164. SJM™ Connect Window

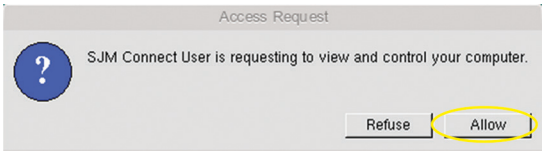


The SJM™ Connect window displays. Select the timeout from drop down list and select Enable. The SJM™ Connect icon will turn bronze.

NOTE: SJM™ Connect will be enabled for the selected amount of time, ranging from 0.1 hour (6 minutes), 1 hour, 2 hours, 24 hours, and 48 hours. The default timeout is 0.1 hour (6 minutes). The timeout determines how long the session can remain idle before being terminated. The session will not timeout at any time during a study.

If Technical Support initiates a remote connection to the DWS, a prompt displays requesting to view and control your computer.

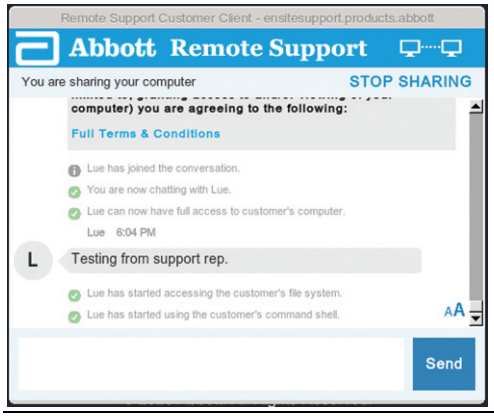
Figure 165. SJM™ Technical Support Access Request Example



Select Allow. If nothing is selected after 15 seconds, Technical Support will automatically connect. The SJM™ Connect icon will turn green.

Technical Support will now have access to the system to troubleshoot the problem. A chat window will display if Technical Support initiates a chat session.

Figure 166. Technical Support Chat Window



If necessary, drag this window to the side of the monitor or select the SJM™ Connect icon. and select "Show / Hide Chat" in the SJM™ Connect dialog. The minimized chat window will pop up if Technical Support initiates a chat. Select Show Chat to bring screen back on the display.

After the Technical Support session has ended, select the SJM™ Connect icon on the EnSite™ X EP System's tool bar and select Disable button in the SJM™ Connect window. The SJM™ Connect icon will turn gray.

NOTE: The default status of SJM™ Connect on system startup is disabled. SJM™ Connect should only be enabled when a Technical Support session is necessary.

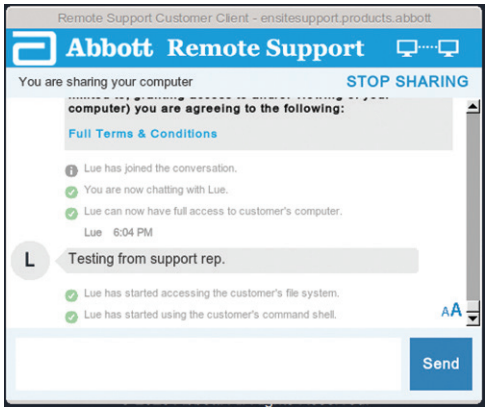
If not disabled manually, SJM™ Connect will stay enabled until the specified timeout irrespective of user logouts or system shutdown. It will disable automatically after the specified timeout if no Technical Support is connected at that time. If a Technical Support is connected and the timeout expires, the SJM™ Connect session will stay enabled until Technical Support terminates the connection.

Whenever SJM™ Connect window is not active window on the screen, it will close itself. It can always be launched by selecting the SJM™ Connect icon on the EnSite™ X EP System's tool bar.

Sending Files

The chat function allows the user to send files from the DWS to Technical Support.

Figure 167. SJM™ Connect Chat Window



If Technical Support requests any logs, select Upload Logs from the SJM™ Connect window.

After the Technical Support session has ended, select the SJM™ Connect icon on the EnSite™ X EP System's tool bar and select Disable button in the SJM™ Connect window. The SJM™ Connect icon will turn gray.

NOTE: The default status of SJM™ Connect on system startup is disabled. SJM™ Connect should only be enabled when a Technical Support session is necessary.

Figure 168. SJM™ Connect File Browser

Browse the folders and select the desired file to send and select OK.

Uploading Logs

If Abbott Technical Support requests the user to upload logs:

1. Select Upload Logs from the SJM™ Connect window.
2. Select the logs to upload.

   NOTE: The logs will not be uploaded automatically. They will remain on the DWS until Abbott Technical Support connects to the DWS to collect them.

Uploading Studies

If Abbott Technical Support requests the user to upload patient studies:

1. Select the Clinical button, then the Archive button from the EnSite™ X EP System main page.

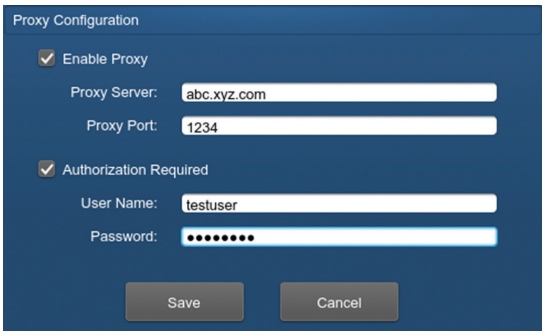
2. Select the study or studies to upload.
3. Select the SJM™ Connect checkbox and select Archive.
4. Select Close.

   NOTE: The studies will not be uploaded automatically. They will remain on the DWS until Technical Support connects to the DWS to collect them.

Proxy Configuration

The hospital's IT department may request the user to configure the proxy server to establish a connection to the DWS. The SJM™ Connect Proxy Configuration Window.

Figure 169. SJM™ Connect File Browser



1. Select Configure Proxy in the SJM™ Connect window.

   NOTE: The Configure Proxy button will be inactive if SJM™ Connect is enabled.
2. Select the Enable Proxy checkbox and enter the proxy server and proxy port information.
3. If the proxy server requires authentication, select the Authorization Required checkbox and enter the authorized user name and password.
4. Select Save to save the proxy configuration.

   NOTE: Do not configure a proxy if the hospital network does not require a proxy for Internet access. By default, no proxy is configured and all the fields from the Proxy Configuration windows will be inactive.

EnSite™ Courier™ PACS Module

The EnSite™ Courier™ PACS Module v.3.0 allows the EnSite™ X EP System user to communicate with the hospital PACS server for the purposes of storing and retrieving patient data in DICOM format. Specifically, the EnSite™ Courier™ PACS Module can be used to perform the following:

- Retrieve CT/MR/XA (rotational angiography) images to segment with EnSite™ Verismo™ Segmentation Tool and store the resulting segmented 3D model on a PACS (Picture Archiving and Communication System) server.
- Retrieve pre-segmented 3D models from a PACS server or receive pre-segmented 3D models from a third-party advanced visualization workstation. Pre-segmented 3D models can be loaded directly into a realtime or review studies.
- Store and retrieve studies on a PACS server and import the retrieved studies for review.
- Store study screenshots for viewing on a standard DICOM viewer.

  NOTE: Refer to the EnSite™ Courier™ PACS Module DICOM Conformance Statement for information about compatible file types and vendors.

Configuring the EnSite™ Courier™ PACS Module

This chapter specifies the steps to configure the EnSite™ X EP System Display Workstation (DWS) for use with the EnSite™ Courier™ PACS Module.

1. Configure DWS Network Settings.
   - Connect the DWS to the network.
   - Configure the IP Address.
2. Configure the EnSite™ Courier™ PACS Module.
   - Configure PACS server settings.
   - Configure EnSite™ Courier™ PACS Module settings.
3. Register the EnSite™ Courier™ PACS Module on the PACS server.

Configure DWS Network Settings

Connect the DWS to the Network

Configure the IP Address

The EnSite™ X EP System uses DHCP as the default setting for obtaining an IP address from the hospital network. If the user has received a new system and plans to use DHCP, the user does not need the DHCP configuration steps below. Simply connect the ethernet cable as described in "Connect the DWS to the Network".

If the hospital does not allow use of a dynamic IP address, configure the EnSite™ X EP System with a static IP address.

Configure a Dynamic IP Address

Follow these instructions to verify DHCP settings or switch a system from a static IP configuration to DHCP.

1. From the Launcher screen, select Services > Configure Network.
2. The Network Configuration window will be displayed.
   a. Select the Devices tab.
   b. Select eth0.
   c. Select the Edit button and the Ethernet Device Window will be displayed.

Figure 170. Network Configuration window

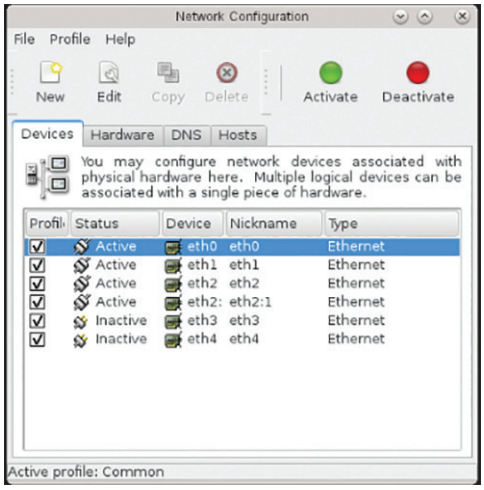
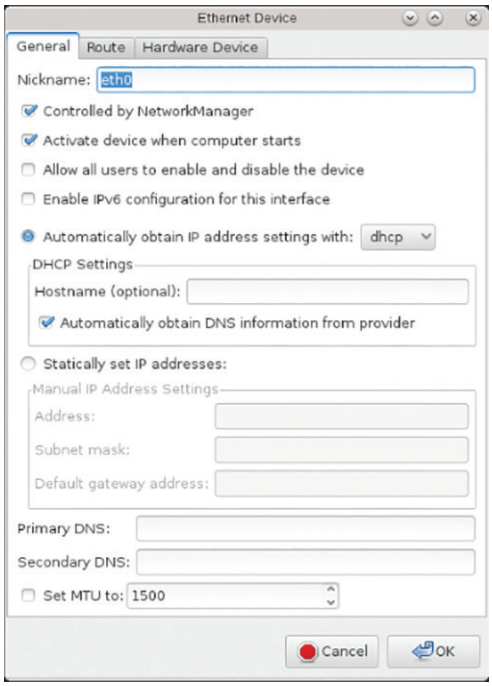
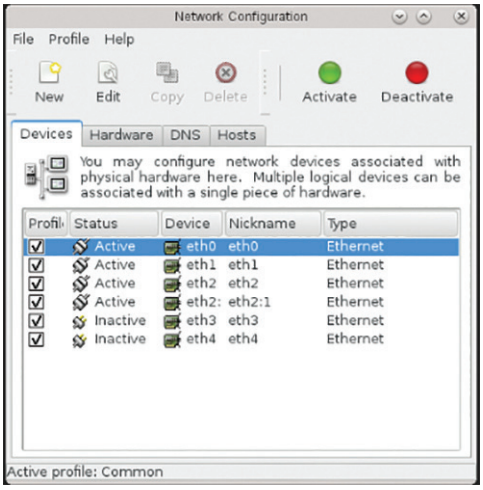


Figure 171. Ethernet Device window



3. In the Ethernet Device window:
   a. Verify that Activate device when computer starts is not checked.
   b. With the Automatically obtain IP address settings with radio button selected, choose dhcp in the dropdown menu.
   c. Select OK. The Ethernet Device window will close.
4. In the Network Configuration window's Devices tab:
   a. Verify that the Profile boxes are selected for all eth* interfaces within the Devices tab.
   b. Select File > Save. The following message will be displayed: "Changes are saved. The user may want to restart the network and network services or restart the computer." Select OK.
   c. Select File > Quit.

Figure 172. Network Configuration, Devices tab



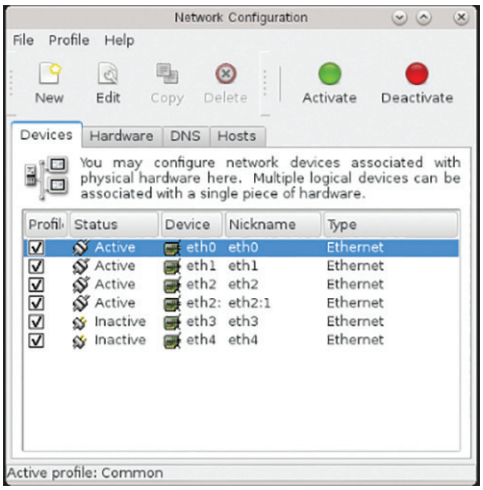
Configure a Static IP Address

NOTE: If the EnSite™ X EP System DWS is physically moved, make sure that the IP address, subnet mask, and default gateway address are valid for the new location.

To configure the EnSite™ X EP System DWS with a static IP address:

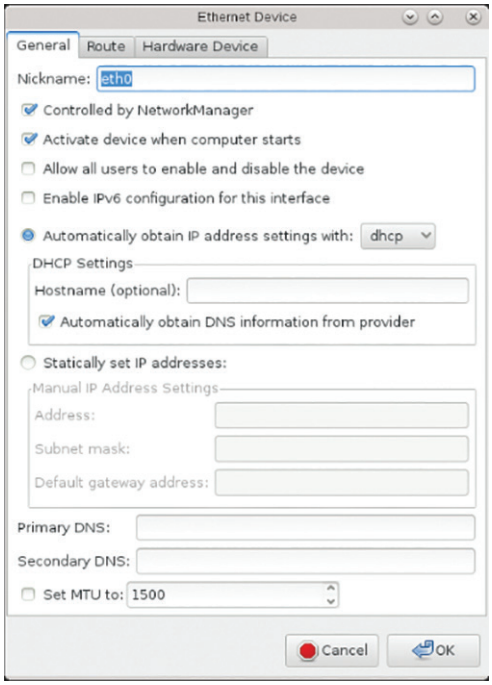
1. From the title screen, select Services > Configure Network.
2. The Network Configuration window will be displayed.

Figure 173. Network Configuration window



3. In the Network Configuration window:
   a. Select the Devices tab.
   b. Select eth0.
   c. Select Edit. The Ethernet Device window will be displayed.

Figure 174. Ethernet Device window



4. In the Ethernet Device window:
   a. Verify that the Activate device when computer starts option is selected.
   b. Select Statically set IP addresses.
   c. Specify the Address, Subnet mask, and Default gateway address. This information should be obtained from the hospital IT department.
   d. Select OK.
5. In the Network Configuration window's Devices tab:
   a. Verify that the Profile boxes are selected for all eth* interfaces within the Devices tab.
   b. Select File > Save. The following message will be displayed: "Changes are saved. The user may want to restart the network and network services or restart the computer." Select OK.
   c. Select File > Quit.

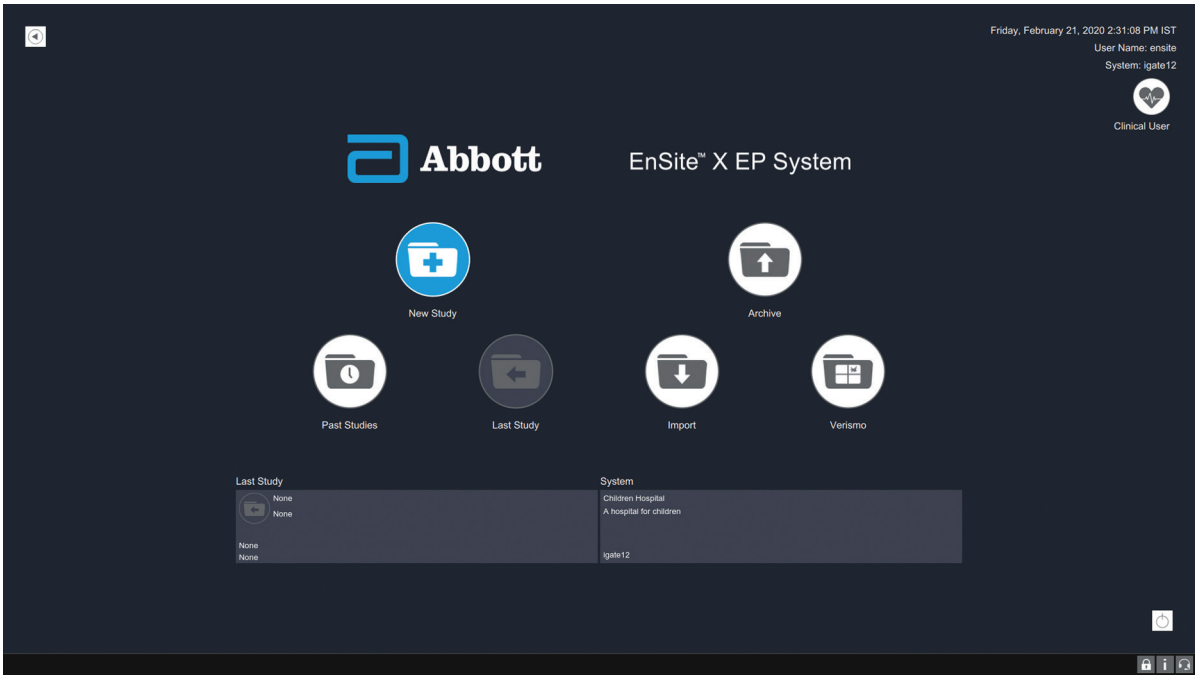
Configure PACS Server Settings

The PACS Server Settings window is used to set the connection parameters for the PACS servers. At least one PACS server must be configured before the EnSite™ Courier™ PACS Module can be used.

To configure the PACS server settings:

1. From the clinical screen, select Archive or Import.

Figure 175. EnSite™ X EP System Clinical Menu



2. From the EnSite™ Courier™ PACS Module main window, select the Settings icon in the upper right corner of the screen, open the PACS Servers tab.
3. Select the Edit button.

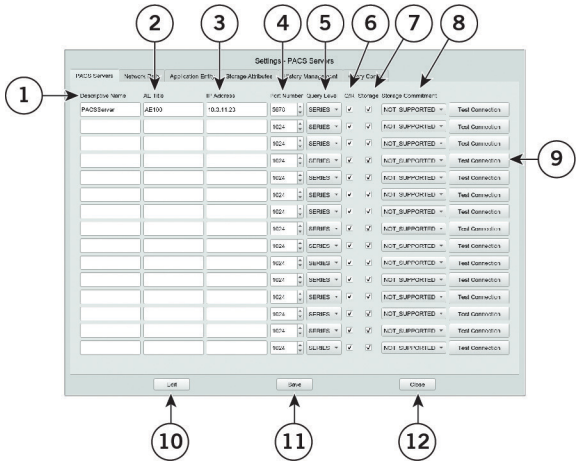
   Select within a data field to enter information. Each line represents one PACS server. Input all required information, items 1-8 in "Description of PACS Server Settings", to setup the PACS server.
4. Select the Test Connection button to test the connection to the PACS server.

   If the connection does not work, check that the information entered in each field is correct. If the IP Address, AE Title, or Port Number are incorrect, the system will not be able to communicate with the PACS server.

Once a connection has been established select Save to save the settings.

Description of PACS Server Settings

Figure 176. PACS Servers Tab



1. Descriptive Name – The Descriptive Name cannot be blank. Input a name for the PACS server. This will be the name used to identify the PACS server in the software when archiving or importing files. To remove a PACS server from the list, delete the Descriptive Name and select Save.
2. AE Title – Enter the Application Entity (AE) Title of the PACS server. The AE Title is case sensitive.
3. IP Address – Enter the IP address of the PACS server.
4. Port Number – Enter the port number of the PACS server.
5. Query Level – Select the tier of information to be returned when performing a query (STUDY, SERIES or IMAGES).
6. Q/R (Query/Retrieve) – Select the checkbox if this PACS server can be used for Query/Retrieve.
7. Storage – Select the checkbox if this server can be used for storage.
8. Storage Commitment – Select from ASYNCHRONOUS, SYNCHRONOUS, or NOT SUPPORTED.
   - When ASYNCHRONOUS is selected, the system will attempt a Storage Commitment request to the PACS server and will continue to wait for a response. The system will complete the storage operation only when the Storage Commitment status notification is received from the PACS server.
   - When SYNCHRONOUS is selected, the system will attempt a Storage Commitment request to the PACS server and will wait for a specified timeout period for the response. The system will complete the storage operation either when the Storage Commitment status notification is received from the PACS server or when the timeout period expires.
   - When NOT SUPPORTED is selected, the system will not attempt a Storage Commitment request to the PACS server and the storage operation will complete as soon as transmission is complete.
9. Test Connection – Select this button to test the connection to the PACS server.
10. Edit – Select to edit PACS server settings.
11. Save – Select to save the changes.
12. Close – Select the Close button to cancel any changes made and close the windows.

Configure the EnSite™ Courier™ PACS Module Application Entity Settings

NOTE: If multiple EnSite™ X EP Systems are in use on the same network, make sure that each DWS has a unique AE Title and is registered properly by the PACS Administrator.

To configure the EnSite™ Courier™ PACS Module Settings:

1. From the EnSite™ Courier™ PACS Module main window, select the Settings icon in the upper right corner of the screen.

   The Courier Settings window is displayed. Default settings are shown and should be changed only when necessary—for example, when there are hospital-specific rules regarding AE Title and/or Port Number.
2. Click the Edit button.
3. Click within a field to enter information.
4. After all information has been entered, select the Save then Close button to save the settings.

Description of EnSite™ Courier™ PACS Module Settings

Image Receiver Settings

These settings are used when receiving images.

AE Title – The AE title. The user can change the AE title, which can be up to 16 characters.

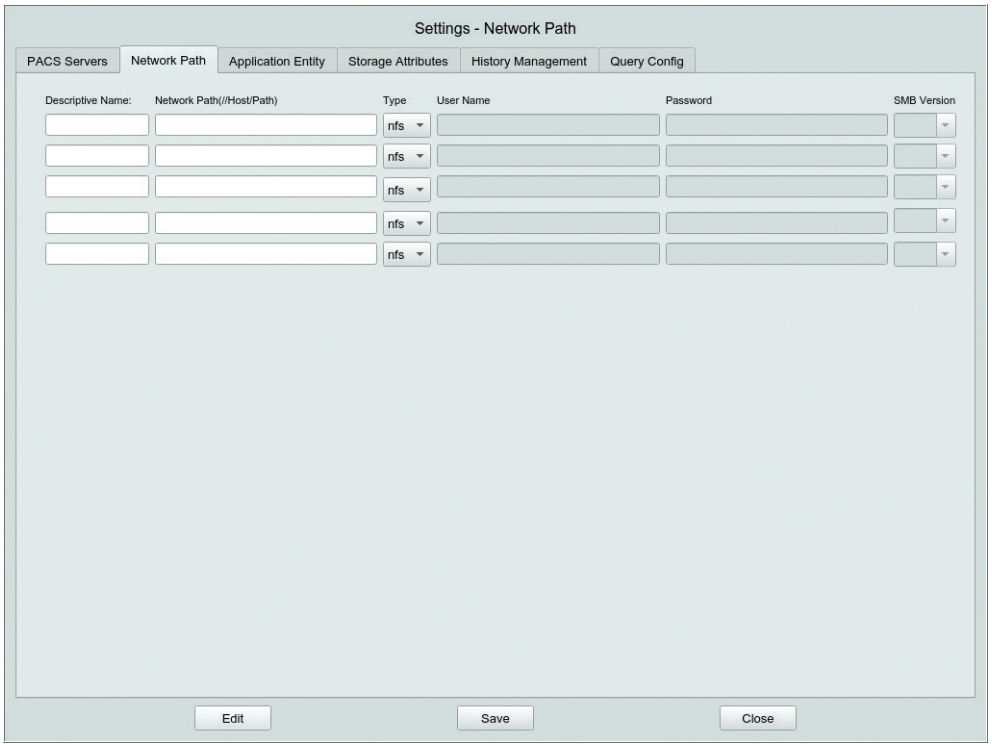
Port Number – The port number used by the to receive images. This field should not be changed by the user.

Timeout – The amount of time, in seconds, that the EnSite™ Courier™ PACS Module will allow for a single image to be transmitted from the PACS server or advanced visualization workstation. This field should not be changed by the user.

Network Path

The Network Path tab allows the user to define the destination for archiving. Archived data can be stored on a USB drive, a DVD, or a network drive.

Figure 177. Network Path Tab

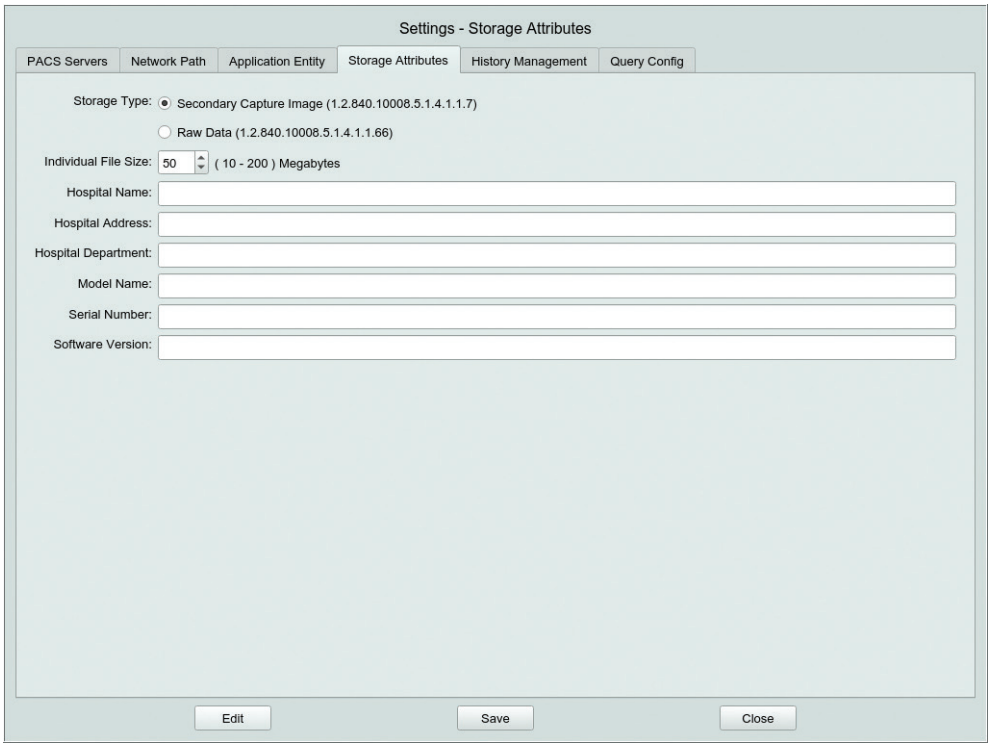


Application Entity

Storage Attributes

The Storage Attributes tab defines the size and amount of data that can be stored on a local network drive. This is a user-defined parameter, and the default setting is the secondary selection.

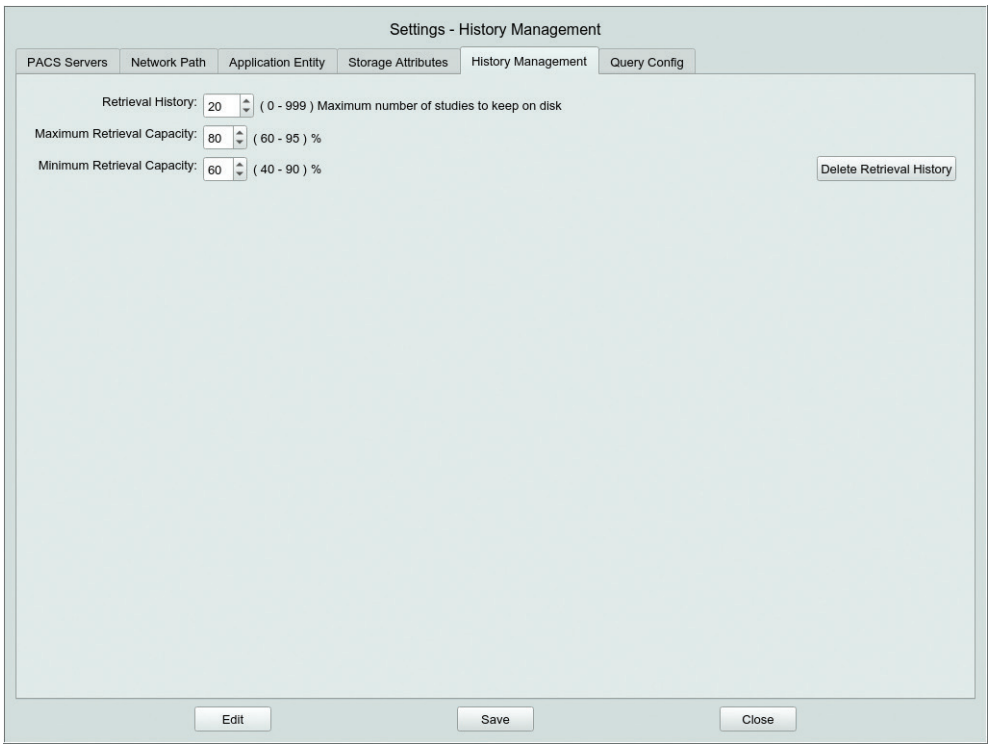
Figure 178. Storage Attributes Tab



History Management

The History Management tab allows the user to manage locally the number of studies to retain on the EnSite™ X EP System network. Once stored, the data can be retrieved from the Retrieval History function.

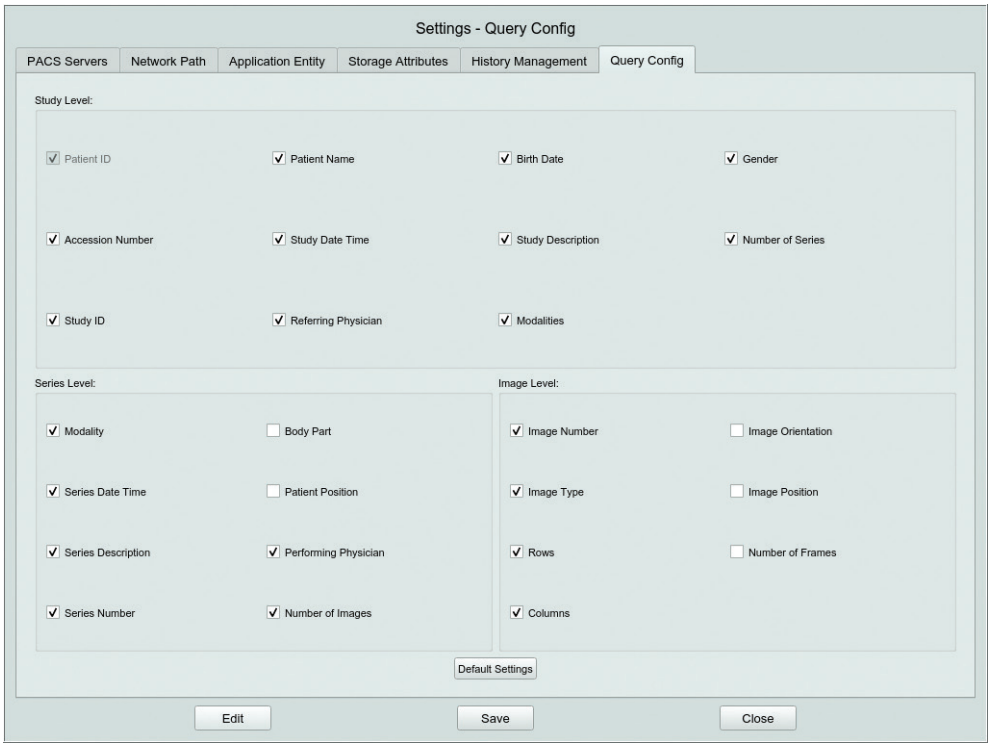
Figure 179. History Management Tab



Query Configuration

The Query Configuration tab allows the user to define the desired tier of data (study/series/image).

Figure 180. Query Configuration



Register the EnSite™ Courier™ PACS Module on the PACS Server

To exchange information between the EnSite™ Courier™ PACS Module and the PACS server, configure the PACS server with the information contained in the Courier Settings screen.

1. From the EnSite™ Courier™ PACS Module main screen, select the Courier Settings icon.
2. Talk with your PACS Administrator about entering these settings on the PACS server.
3. After these settings have been entered on the PACS server, test the connection from PACS server to the EnSite™ Courier™ PACS Module, if possible.

If the connection is successful, then the user is ready to begin using the EnSite™ Courier™ PACS Module.

Using the EnSite™ Courier™ PACS Module

After a patient has had a CT, MR, or XA scan, the user can import the images into the EnSite™ Verismo™ Segmentation Tool for segmentation and store the segmented 3D model to a PACS server, to the EnSite™ X EP System DWS hard drive, or to a CD/DVD.

Launch the EnSite™ Courier™ PACS Module

To launch the EnSite™ Courier™ PACS Module:

1. From the EnSite™ X EP System title screen, select the Verismo icon to launch the EnSite™ Courier™ PACS Module. The EnSite™ Courier™ PACS Module main screen will be displayed.
2. Use the next section, "Perform a Query", to locate the CT/MR/XA scan on the PACS server. Alternately, use the section "Receive Study or CT/MR Scans" to receive the images.

Perform a Query

To perform a query:

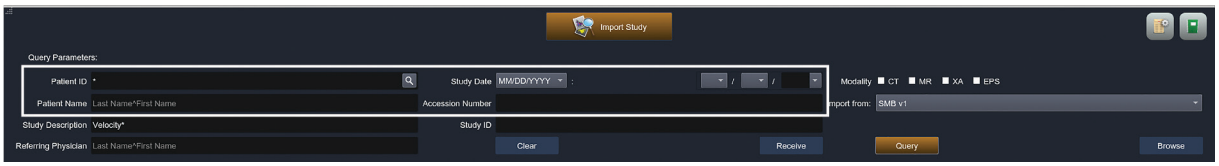
1. Confirm that the Versimo task is selected.
2. Specify the search criteria.

   NOTE: The asterisk (*) may be used as a wildcard, if supported by your PACS server. If a Chinese or Japanese keyboard is used, the asterisk must be entered in English input method.

   - At least one of the following must be entered: Patient ID, Patient Name, Accession Number, or Study Date (see yellow box highlighting these items in the figure below).
   - To specify Patient Name, type in the name with format "LastName^FirstName". If expected record is not returned, use wildcard search. Some example of wildcard search are LastName^FirstName*, LastName^*,Last Name*, *^FirstName. Similar wildcard searches can be used to specify the Referring Physician field.
   - To specify Study Date, select date, month and/or year in the format shown; the year also can be entered manually. Alternatively, select Today or Yesterday from the drop-down list to auto-populate the date, month, and year fields.
3. Select the Modality. The modality determines the types of images (CT/MR/XA) contained in the study. More than one Modality type may be selected. If none are selected, all studies matching the search criteria will be displayed.

   NOTE: Use CT, MR, and XA to query for images to segment in the EnSite™ Verismo™ Segmentation Tool.
4. Select the PACS server from the Import from drop-down menu.
5. Select Query to launch Verismo.

Figure 181. Retrieving a study



Import Study

Single or multiple series or one study may be selected.

- To select a single item, such as a CT/MR/XA scan, select the item.
- To select multiple items, hold down the <Ctrl> key and select each item.
- To select multiple consecutive items, hold down the <Shift> key, select an item and then select another item. Alternatively, select an item and drag to select additional consecutive items.

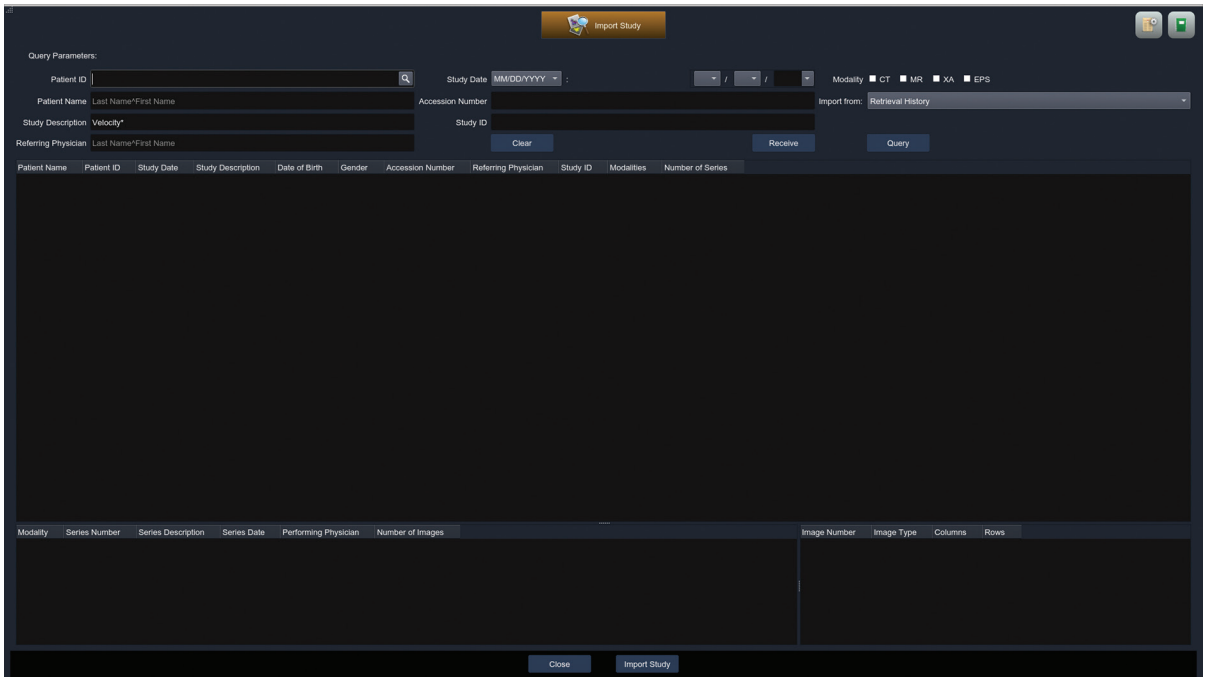
  NOTE:

  - Some PACS servers only support single item retrieval.
  - Only multiple studies for a single patient may be selected.

There are two ways to retrieve images:

- To retrieve a complete study, select the study and then select Launch Verismo button.
- To retrieve a single series, select the study, select the series, and then select Launch Verismo button.

Figure 182. Retrieving a study



When the Import Study button is clicked, the Retrieve in Progress bar will show the percentage of the images retrieved. After the Retrieve is done, the EnSite™ Verismo™ Segmentation Tool is launched.

NOTE:

- When the Retrieve in Progress bar is displayed, the EnSite™ Courier™ PACS Module main screen cannot be repositioned.
- If the user selects the Cancel button in the progress bar, image retrieval will be stopped; otherwise, image retrieval will continue until completed.
- If the Retrieve operation fails, a message will be displayed. Refer to the Retrieve Failed instructions under the Troubleshooting section to determine the cause.

Receive Study or CT/MR Scans

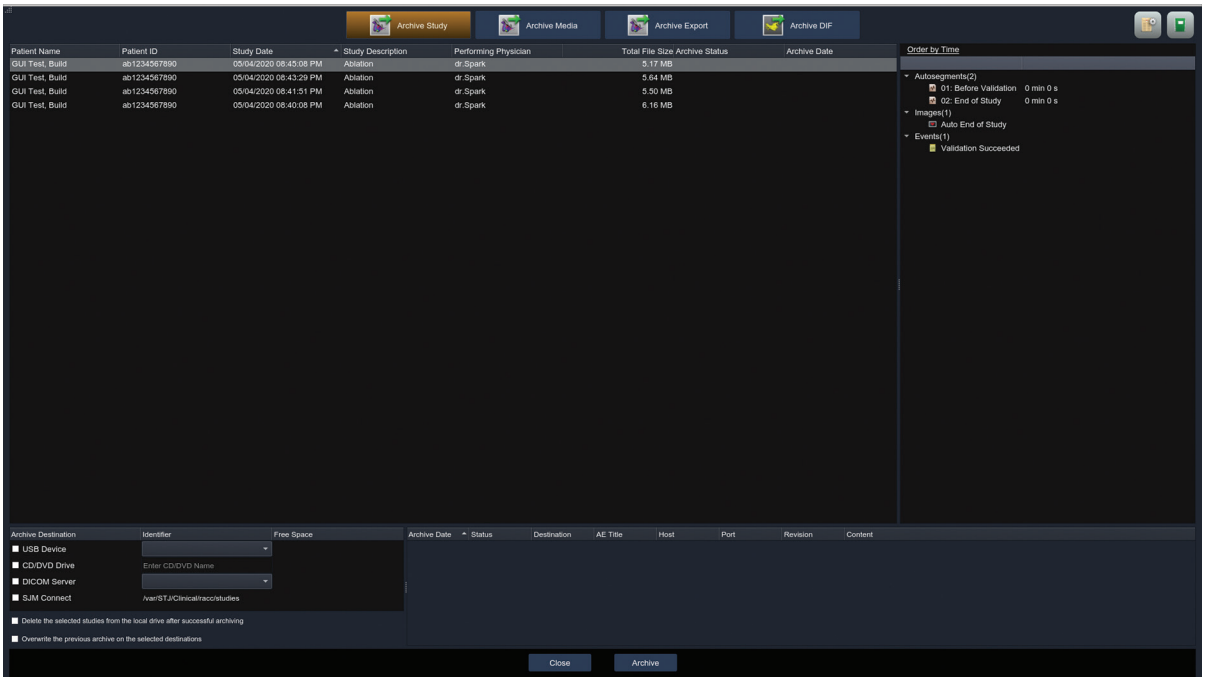
To receive a study or CT/MR scans:

1. From the EnSite™ X EP System title screen, select the Verismo icon to launch the EnSite™ Courier™ PACS Module. The EnSite™ Courier™ PACS Module main screen will be displayed.
2. To enable Receive mode, select the Receive button in the lower left corner of the Courier PACS screen. When the Receive button is selected, it will change to Stop Receive.
3. After all scans have been received, select Stop Receive. All received studies will be listed for selection.

Archive Segmented 3D Model/Map to PACS Server

This allows the user to store segmented 3D models generated by the EnSite™ Verismo™ Segmentation Tool.

Figure 183. Archiving a study



1. Return to the Clinical Menu and select Archive.
2. If not already in the EnSite™ Courier™ PACS Module: From the EnSite™ X EP System title screen, select the Archive icon to launch the EnSite™ Courier™ PACS Module.
3. Select the archive server PACS name associated with the server on which the user wants to archive the data.
4. Select the Archive DIF Workflow Task, at top of the EnSite™ Courier™ PACS Module main screen. A screen will display a list of the DIF files created by the EnSite™ Verismo™ Segmentation Tool.
5. Select the DIF file.
   - To select multiple items, hold down the <Ctrl> key and select each item.
   - To select multiple consecutive items, hold down the <Shift> key, select an item and then select another item. Alternatively, select an item and drag to select additional consecutive items.
6. Select the destination PACS server from the drop-down menu at the lower right of the EnSite™ Courier™ PACS Module main screen.
7. Select the Store button.

   The Store in Progress bar will show the percentage of the DIF models stored.

   NOTE: The user can overwrite a previously archived study by selecting the Overwrite previous archive option at the lower left of the Archive Study screen.

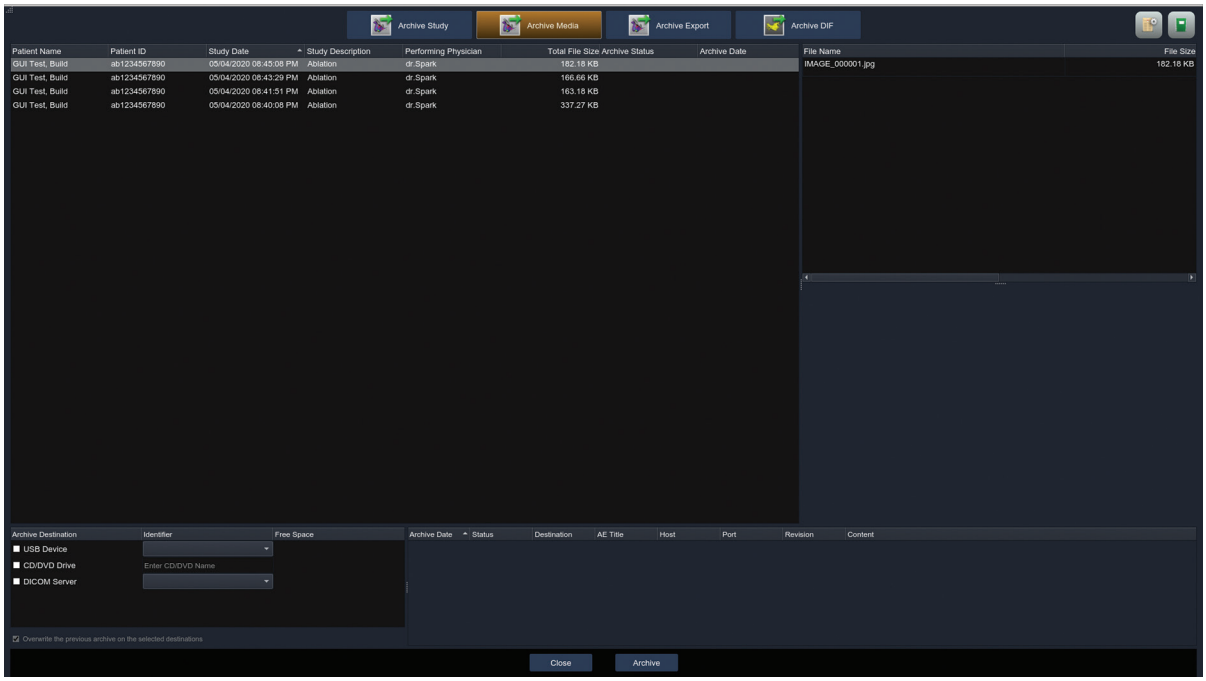
   If the user selects the Cancel button in the Store in Progress bar, any files that have already been transmitted or have started transmission will be stored; any files that have not started transmission will be canceled.
8. An entry will be made in the Archive History when the transmission is completed. A second entry will be made in the Archive History when Storage Commitment is completed, if this has been configured for the receiving PACS server.

   A final storage status will be displayed for each study in the Archive History.

Delete Study after Archiving

To delete a study after it is archived, select the Delete the selected studies from the local drive after successful archiving option at the lower left of the Archive Study screen.

Figure 184. Archiving Media



Receive Pre-Segmented 3D Models

The EnSite™ Courier™ PACS Module can accept pre-segmented 3D models from a third-party advanced visualization workstation. This capability, called Receive mode, must be enabled by the user. Any DICOM application entity that wants to send to the EnSite™ Courier™ PACS Module must use the correct the EnSite™ Courier™ PACS Module AE Title, IP Address, and Port Number.

To receive pre-segmented 3D models from within an EnSite™ X EP System study:

1. From an EnSite™ X EP System study, select the DIF icon at the top of the Model control panel. The DIF control panel will be displayed. From the DIF control panel, select Load DIF. The DIF window will be displayed.

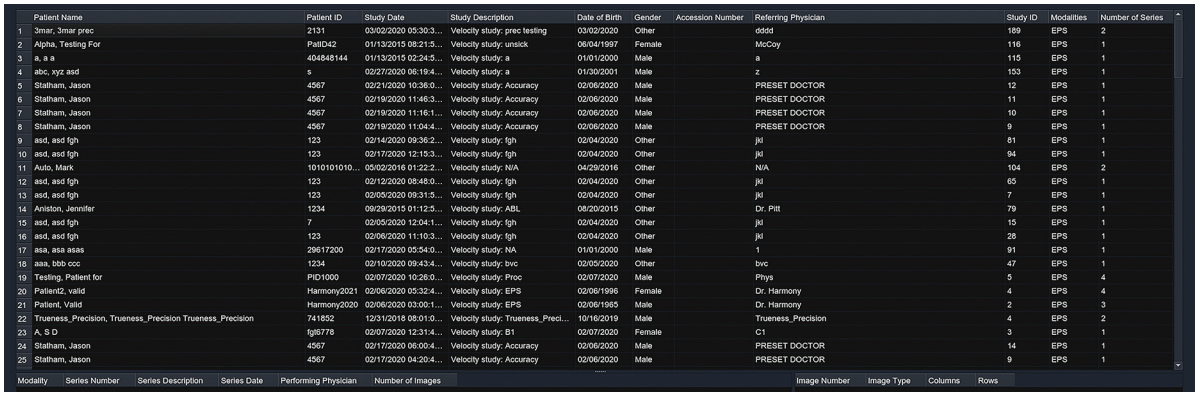
OR

To launch the EnSite™ Courier™ PACS Module from the EnSite™ X EP System top bar, select File > Load DIF... The DIF window will be displayed.

2. To enable Receive mode, select the Receive button.

When the Receive button is clicked, it will change to Stop Receive. Receive mode will stay active until Stop Receive is selected. After Received mode is stopped, all received studies will be displayed.

Figure 185. Received Studies



Select a Study

1. Select the Retrieve button and preview the 3D model.
2. Select the DIF file and select the Load DIF button to load the DIF file into the EnSite™ X EP System study. To receive pre-segmented 3D models from outside of an EnSite™ X EP System study:
   - From the EnSite™ X EP System Clinical Screen, select the Import icon to launch the EnSite™ Courier™ PACS Module. The EnSite™ Courier™ PACS Module main window will be displayed.
   - From the EnSite™ Courier™ PACS Module main window, select the Receive button in the lower left corner of the screen.

3. When complete, select the Stop Receive button. The received 3D models will be available in the retrieval history to be loaded into an EnSite™ X EP System study in the future.

   NOTE:

   - There is no limitation on the number of images received during a single connection.
   - If the EnSite™ Courier™ PACS Module is receiving images when the Stop Receive button is selected, the current transmission will continue; however, subsequent transmissions will be disabled. Receive mode must be re-enabled for subsequent transmissions. If the EnSite™ Courier™ PACS Module is not receiving images when the Stop Receive button is selected, Receive mode will immediately cease operation. Receive mode will remain active until stopped by the user.

Store EnSite™ X EP System Studies on PACS Server

1. If not already in the EnSite™ Courier™ PACS Module: From the EnSite™ X EP System Clinical Menu, select the Archive icon to launch the EnSite™ Courier™ PACS Module.
2. Select the Archive Study Workflow Task.

   A list of the EnSite™ X EP System studies on the DWS will be displayed.
3. Select one or more studies from the list to store.

   - If one study is selected, the notebook information and archive history of the study will be displayed on the righthand side of the screen.
   - To select multiple studies, hold down the <Ctrl> key and select each study.
   - To select multiple consecutive studies, hold down the <Shift> key, select a study and then select another item. Alternatively, select an item and drag to select additional consecutive items.
4. Select the PACS server to use for storing the studies.
5. Select the Archive button.

   The Store in Progress bar will show the percentage of the studies stored.
6. If the user selects the Cancel button in the Store in Progress bar, any files that have already been transmitted or have started transmission will be stored; any files that have not started transmission will be canceled.

A final storage status will be displayed for each study in the Archive History.

NOTE: The result of viewing the EnSite™ X EP System study on a standard DICOM viewer depends on the PACS server configuration and may be displayed as a blank screen. This behavior is expected and does not indicate an error in storage.

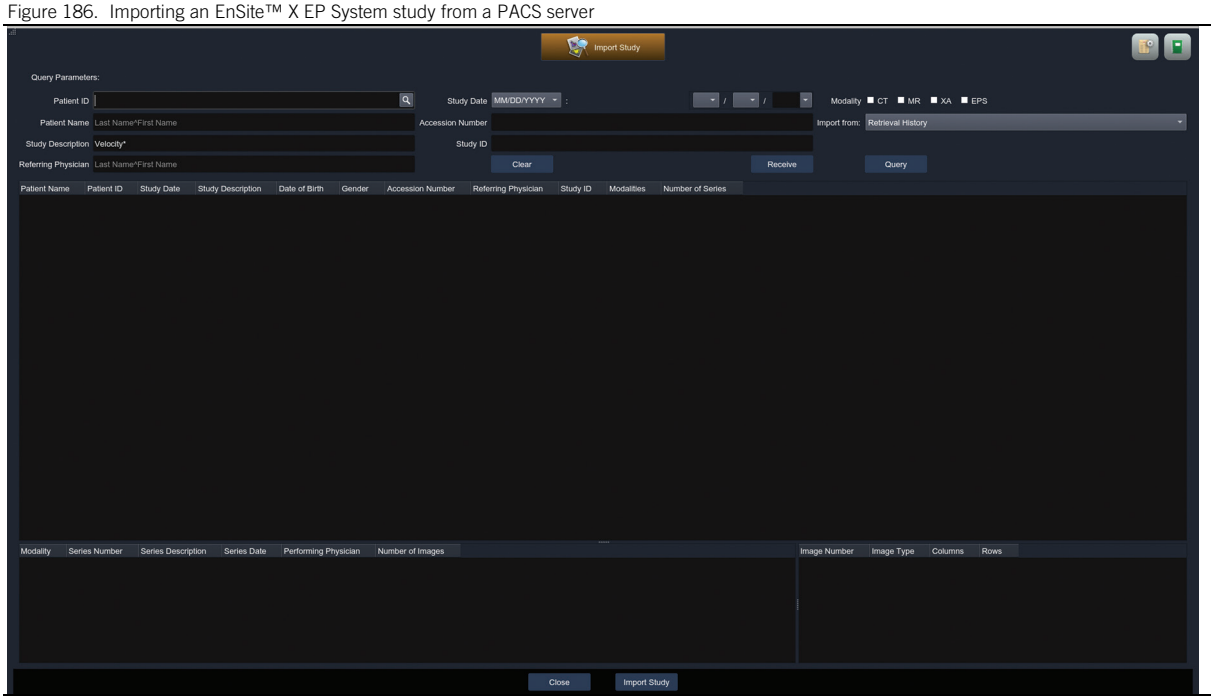
Import EnSite™ X EP System Studies from a PACS Server

1. From the EnSite™ X EP System Clinical Menu, select the Import icon to launch the EnSite™ Courier™ PACS Module.
2. From the EnSite Courier PACS Module Retrieve Workflow Task Window, make sure that EPS modality is selected (check mark displayed) and use the PACS Server drop-down menu to select the PACS server to query.

   NOTE: Some PACS servers may not support EPS modality type and may modify that field when an EnSite™ X EP System study is stored. If a query with EPS modality type checked does not return the expected EnSite™ X EP System study in the query result, clear all modality checkboxes and try the query again.
3. Enter the search criteria to locate the study.
4. Select the study and select Import Study.

   NOTE: If the PACS server supports Series level retrieval, select the series with Series Description "Study Data".

Figure 186. Importing an EnSite™ X EP System study from a PACS server



5. If only one study is retrieved, the study will be imported; If multiple studies or multiple version of the same study are retrieved, a study selection window will be displayed. Select the desired study, and then select the Continue... button to import the EnSite™ X EP System.

   NOTE: Only one study can be imported at a time.

6. If the selected study already exists on the DWS, a warning will be displayed: This study already exists on the system. Overwrite? Select Yes to replace the existing study with the newly-imported study.

7. When the import is complete, Courier exits.

8. To view the imported study from the EnSite™ X EP System title screen, select Past Studies.

Display EnSite™ X EP System Study Screenshots

EnSite™ X EP System study screenshots are saved as a separate series within the study and can be retrieved independently from the EnSite™ X EP System study. These screenshots can be viewed using any standard DICOM viewer.

View Screenshots from Standard DICOM Viewer

EnSite™ X EP System study screenshots also can be retrieved by any standard DICOM Query and Retrieve application connected to the PACS server and then displayed by any standard DICOM viewer. To retrieve the screenshots, simply retrieve the series within an EnSite™ X EP System study with the Series Description, "Study Images".

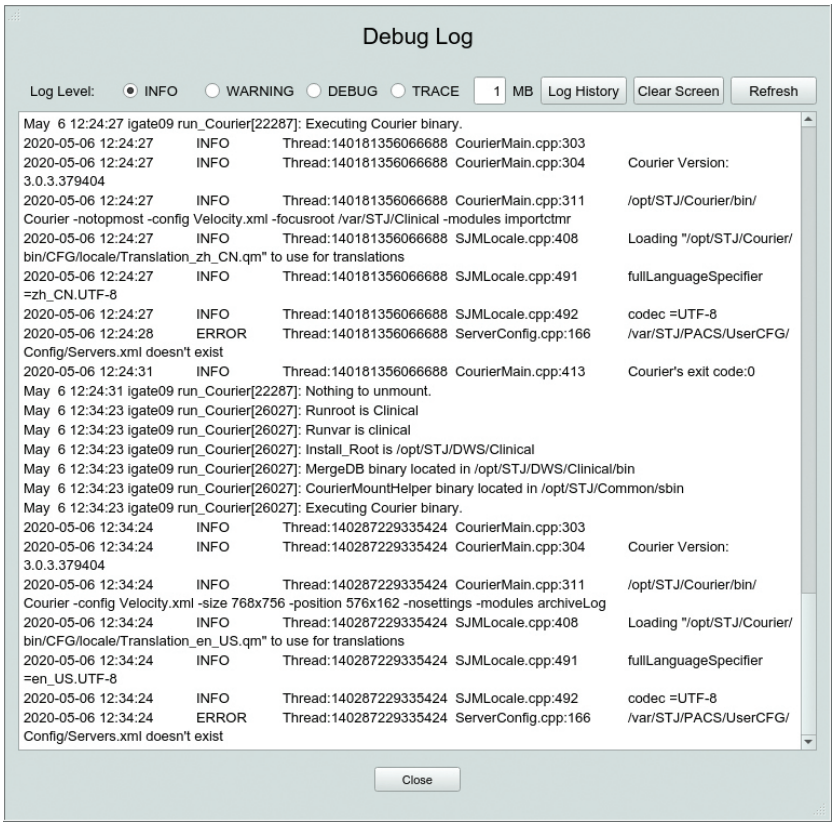
NOTE: If series level retrieval is not supported by the PACS server, retrieve the entire EnSite™ X EP System study, and select the proper screenshot series for display.

Troubleshooting

Courier Log

The Courier Log is used to troubleshoot communication related issues. Select the Courier Log icon on the EnSite™ Courier™ PACS Module main window to display the Courier Log window.

Figure 187. Debug Log



Log Level – The Log Level determines the type of information that is included in the Courier Log. The following levels are available:

- INFO – (default) User Operation (Query, Retrieve, Criteria, Operation Status).
- WARNING – General warning messages in addition to INFO.
- DEBUG – General debug messages in addition to INFO, WARNING.
- TRACE – Trace messages in addition to INFO, WARNING, DEBUG.

The default Log Level is INFO. The Log Level may be set higher. However, in most cases DEBUG is enough to debug any communication related issues. The log level will stay in effect until the EnSite™ Courier™ PACS Module is closed, or until it is changed.

NOTE: Log messages may be truncated. Select Log History to load the untruncated log entries.

- MB – This text box may be used to specify the megabytes of log messages from the end of the file to load.
- Log History – When the Courier Log window is displayed, only the tail of the log file is displayed. The user can load extra log history by selecting Log History.

- Clear Screen – Select this button to clear the entire log text window. Refresh- Select this button to load the newly added log entry to the log file. Close – Select the Close button to close the Courier Log window.

Query Failed

Follow these steps to troubleshoot a failed query:

1. Check that the Ethernet cable is properly connected. If it is not properly connected, connect the cable as shown in "Connecting to the Hospital Network" (page 8).
2. Open the PACS Server Settings window by selecting the Settings icon on the EnSite™ Courier™ PACS Module main window, and then select the PACS Servers tab.
3. Check that the Query/Retrieve checkbox has a checkmark selected.
4. Select Test Connection to verify the connection. If the connection is successful, skip steps 5 and 6.
5. Check that the AE Title, IP Address, and Port Number are correctly typed. If they are not correct, correctly type the parameters and select Test Connection to verify the connection.
6. If the PACS server was moved, check with the PACS Administrator to verify that the AE Title, IP Address, and Port Number are still valid. If they are not valid, correct the parameters and go to step 5.
7. Do a simple test query. If the test query is not successful, go to step 9.
8. Do the original query. If the original query is successful, stop here.
9. Increase the Log Level to DEBUG and perform the original query.
10. Call Technical Support to report the problem. Be sure to have logs available.

Receive Failed

1. Open the Courier Settings window by selecting the Courier Settings icon on the EnSite™ Courier™ PACS Module main window.
2. Have the PACS Administrator verify that the EnSite™ X EP System DWS is properly registered and that the AE Title, Port Number, and IP Address are correct. If more than one EnSite™ X EP System DWS is in use, each must be properly registered and have a unique AE Title.
3. Verify that the Timeout setting is enough and increase it if needed.
4. Have the PACS Administrator perform an echo test from the server to the DWS. Make sure that this operation is successful before proceeding.
5. Check the Courier Log for the presence of disk IO error messages. If the error is not present, skip step 6.
6. Select the Courier Settings icon and then select History Management tab then select Edit button and then select Delete Retrieval History button. At the prompt, Delete Retrieval History? select Yes.
7. Re-try the retrieve. If the retrieve is successful, stop here.
8. Re-start the EnSite™ Courier™ PACS Module and re-try the retrieve. If the retrieve is successful, stop here.
9. Re-boot the DWS and the PACS server and re-try the retrieve. If the retrieve is successful, stop here.
10. Increase the Log Level to DEBUG and perform the original retrieve.
11. Call Technical Support to report the problem. Be sure to have logs available.

Image Incompatibility

Follow these steps to troubleshoot an image incompatibility:

1. Follow steps 1 through 6 for "Retrieve Failed".
2. Try retrieving a simple image. If the retrieve is successful, stop here.
3. Increase the Log Level to DEBUG and perform the retrieve tried in step 2.
4. Call Technical Support to report the problem. Be sure to have logs available.

Receive Failed

Check that Receive mode is enabled. If it is enabled, then disable and re-enable Receive mode. If the receive still fails, follow the troubleshooting steps for "Retrieve Failed".

Storage Failed

1. Check that Storage mode is enabled on the PACS Server Settings.
2. If a pre-processing error occurs, the disk space may be full. Follow step 6 of the "Retrieve Failed" (page 151) section to clean the disk and try storage again.
3. If a transmission error occurs, follow steps 1 to 2 and steps 4 to 6 of the "Query Failed" (page 151) section.
4. Repeat the original storage. If it is successful, stop here.
5. Increase the Log Level to DEBUG and perform the original storage.
6. Call Technical Support to report the problem. Be sure to have logs available.

Storage Commitment Failed

1. Open the PACS Server Settings window by selecting the Courier Settings icon on the EnSite™ Courier™ PACS Module main window.
2. Confirm that the Storage Commitment setting (SYNCHRONOUS, ASYNCHRONOUS, NOT SUPPORTED) matches the setting on the PACS server.
3. If ASYNCHRONOUS has been selected for Storage Commitment, confirm that the Port Number setting is registered correctly on the PACS server.

4. If ASYNCHRONOUS has been selected for Storage Commitment, the EnSite™ Courier™ PACS Module does not time out waiting for the PACS server response. Select the Cancel button on the Store in Progress bar to stop the storage operation.
5. The message Storage Commitment not attempted occurs when the Storage Commitment option on the PACS Server Settings window is set to Not Supported.
6. The message Storage Commitment request failed occurs when the Storage Commitment request is rejected by the PACS server or there is no response from the PACS server before timeout occurs. Try increasing the timeout.
7. If a Committed Partial error is received, contact the PACS Administrator for assistance.
8. If Storage Commitment continues to fail, collect log and call Technical Support to report the problem.

EnSite™ X Verismo™ Segmentation Tool Description

Indications for Use

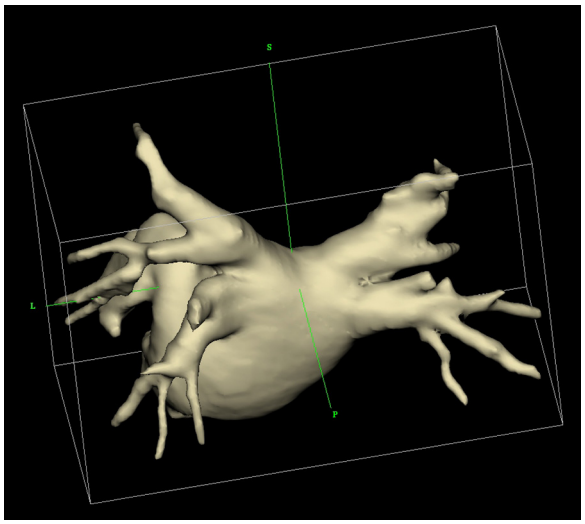
The EnSite™ Verismo™ Segmentation Tool is indicated for use in generating 3D models from CT, MR, or rotational angiography DICOM image data. Generated models are intended to be displayed on the EnSite™ X EP System.

Description

The EnSite™ Verismo™ Segmentation Tool is a software utility used to convert large volumes of sliced-based images into a manageable 3D model of cardiac structures.

The EnSite™ Verismo™ Segmentation Tool accepts DICOM images from most CT and MRI scanners, including enhanced CT/MR images. Once image data are imported into the EnSite™ Verismo™ Segmentation Tool, a 3D model can be extracted from the images in a process called segmentation. Segmentation is the process of isolating an object of interest from a digital image using the greyscale intensity of slice-based data. This model can be easily viewed and manipulated during an electrophysiology procedure using the EnSite™ EP System software.

Figure 188. Example of a Segmented Model



Overview of Segmentation

The following list provides an overview of the common segmentation tasks.

1. Power on the DWS and start the EnSite™ Verismo™ Segmentation Tool.
2. Select an image series to segment.
3. Subregion the series and begin segmentation.
4. Grow a structure using either the Region Grow or Chamber tool.
5. Edit the model:
   - Separate chambers or remove extraneous information using the Separator or Trace tool.
   - Grow tubular structures with the Vessel tool.
   - If necessary, use the Barrier tool to help the EnSite™ Verismo™ Segmentation Tool identify the edge of a structure.
6. Perform any final cleanup:
   - Hide extraneous structures in the structure list.
   - Use the Reassign tool to remove any small debris surrounding the model.
   - If the surface of the model has distracting complexity, consider smoothing the surface.
7. Save and review the model:
   - Save the model.
   - If the model will be used on a different workstation, export the DIF model to CD/DVD.
   - Review the model before exiting.

System Requirements and Considerations

The EnSite™ Verismo™ Segmentation Tool v.2.0.1 can only be installed on an EnSite™ X EP System workstation (DWS) with EnSite™ X v.1.0 Software or higher.

Verification – To ensure model accuracy, segmentation results should be compared to the original slice data by (or under the supervision of) a physician.

DICOM conformance – the EnSite™ Verismo™ Segmentation Tool allows importation of slice-based images in DICOM 3.0 (2009) data sets from CD/DVD or a PACS network.

The EnSite™ Verismo™ Segmentation Tool does not support direct connection to a PACS network. DICOM data sets located on a PACS network are retrieved by the EnSite™ Courier™ Module and written to the EnSite™ X EP System Display Workstation (DWS) hard drive.

The EnSite™ Verismo™ Segmentation Tool does not support image export.

The EnSite™ Verismo™ Segmentation Tool does not accept non-orthogonal enhanced CT/MR images.

The EnSite™ Verismo™ Segmentation Tool does not accept non-orthogonal cine images with missing or inconsistent timing information within each volume.

Refer to the EnSite™ Verismo™ Segmentation Tool v.2.0.1 DICOM Conformance Statement for details.

Optimal Characteristics for the EnSite™ Verismo™ Segmentation Tool Image Files

The following minimum requirements are provided to optimize the quality of the cardiac model generated through the EnSite™ Verismo™ Segmentation Tool segmentation process:

- Missing Slices	The EnSite™ Verismo™ Segmentation Tool cannot segment images with missing slices
- Slice Orientation	Do not use oblique slice orientations
- Slice Spacing	Must be uniform, .5 mm increments, such as .5 mm, 1.0 mm, and 1.5 mm.
- DICOM Header	Use only standard letters and numbers in the DICOM header. Do not use special characters, such as: ^ " & % $ # @ !

Loading Files for Segmentation

Starting the EnSite™ Verismo™ Segmentation Tool

The way DICOM files are loaded depends on whether the EnSite™ Courier™ Module is installed. If it is installed, DICOM files may be loaded from a PACS network or from CD/DVD. If it is not installed, DICOM files may be loaded only from CD/DVD.

Verismo Cleanup

Upon launching Verismo, the system allows you to perform a cleanup procedure before Verismo launches. Select the Clean Verismo button. This procedure removes all temporary files. Perform a Cleanup procedure if Verismo fails to launch.

NOTE: Performing a Cleanup will remove any data currently in the Verismo workspace, such as work in progress files. DIF files will not be deleted.

Loading DICOM Files

1. Power on the EnSite™ X EP System and login as described in the EnSite™ X EP System Instructions for Use manual.
2. From the EnSite™ X EP System launcher screen, Select Clinical, then Verismo.
3. Select an Import From: source.
4. Select Query to display a list of files.
5. Select the desired file and Select Launch Verismo.

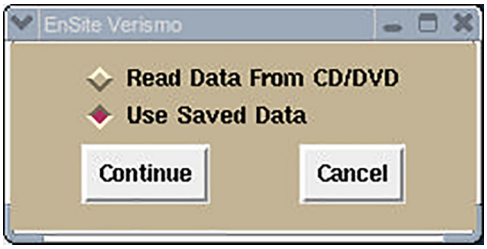
Using DICOM Files from Saved Data

To load DICOM files from data that you have previously saved:

1. Power on the EnSite™ X EP System, as described in the previous section. A pop-up message window will be displayed.
2. Select Use Saved Data Use Saved Data and press Continue.
3. The previously saved patient will be displayed.

Select on the patient to display and select a desired image series for new segmentation or select [File > Resume Previous Segmentation] File > Resume Previous Segmentation to resume the most recent segmentation series.

Figure 189. The Selection Window



1. Read Data From CD/DVD
2. Use Saved Data
3. Continue
4. Cancel

Using the Wizard

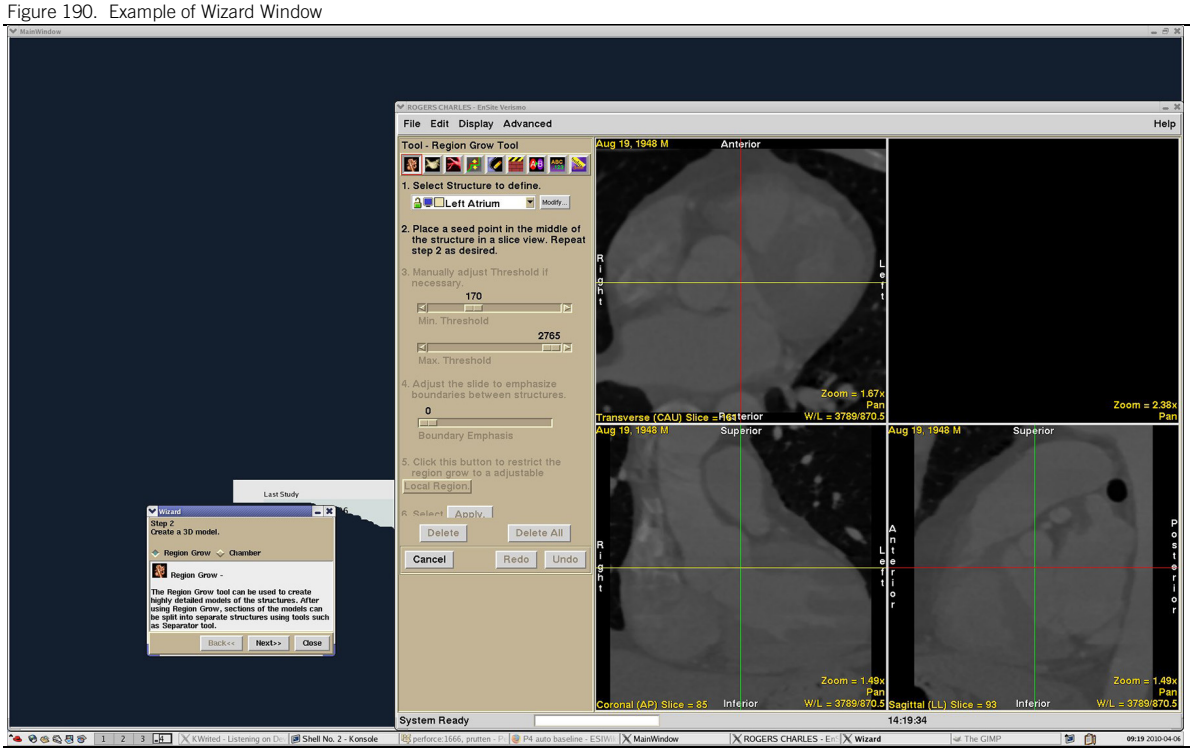
The Wizard is intended to guide the clinician through the segmentation process. The Wizard will describe how to load files and provides an overview of the segmentation tools.

- Follow the suggested task at the top of the Wizard.
- Below the task are several options. Selecting the option will provide additional details and describe how to access the controls.
- When a step is complete, select Next.

NOTE:

- Clicking Back will access the previous step.
- The Wizard may be closed by selecting Close or Finish. To access the Wizard again, select [File > Resume Wizard] File > Resume Wizard.

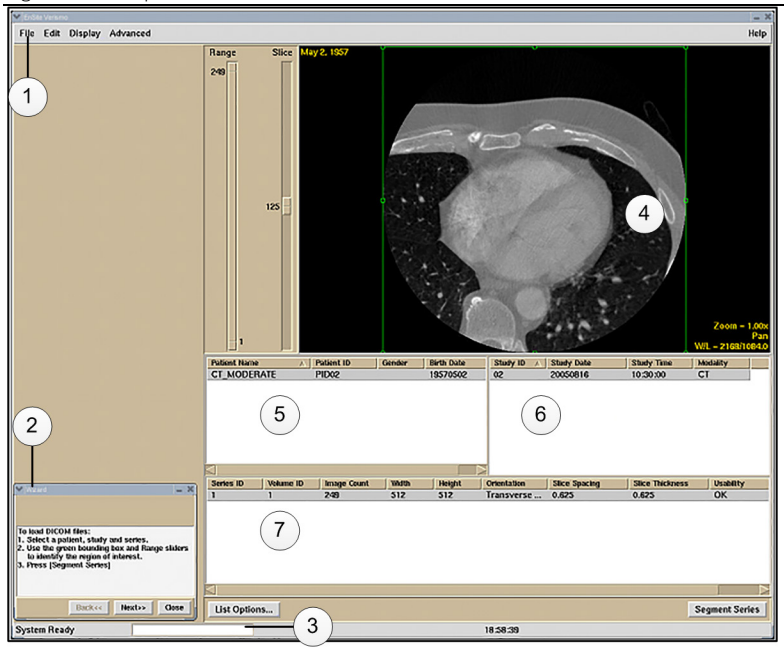
Figure 190. Example of Wizard Window



Introduction to the Patient Screen

The patient screen is the interface for loading DICOM data.

Figure 191. The patient screen.



1	Menu bar	The menu bar provides access to commonly used tools.
2	Wizard	The Wizard guides the clinician through the process of segmentation.
3	Progress bar	The progress bar indicates when the workstation is processing data. If the progress bar is labeled Cancel Cancel, clicking the progress bar will cancel the current task.
4	Series panels	These panels provide an interface for selecting a data series.
5	Patient panels	These panels provide an interface for selecting a data series.
6	Study panels	These panels provide an interface for selecting a data series.
7	Slice view	The slice view contains images from the selected data set. Data in the slice view can be manipulated.

Selecting a Series for Segmentation

A DICOM data disk may contain multiple patients, multiple radiology studies for each patient and multiple series per study. Use the panels on the lower half of the screen to select a series for segmentation.

1. From the patient panel, select a patient name.
2. From the study panel, select the study of interest.
3. From the series panel, select the series of interest.

   NOTE: Series that can be loaded for segmentation appear in black. If a series cannot be used for segmentation, the information for that series appears in gray in the series panel, and an explanation of why the series may not be usable appears in the Usability column.

Viewing Options

The following options are available for sorting patient data:

- To add or remove columns of information from the patient, study, or series panels, select List Options. A window will appear with display options. Select display options and select Close.
- Selecting on the heading at the top of a column will sort the data by that column.

Subregioning the Series

Subregioning is a process of identifying a region of interest within the scan for segmentation. Subregioning can improve the performance of the segmentation tool by processing only the regions of interest. The goal of subregioning is to minimize the volume to maximize processing speed.

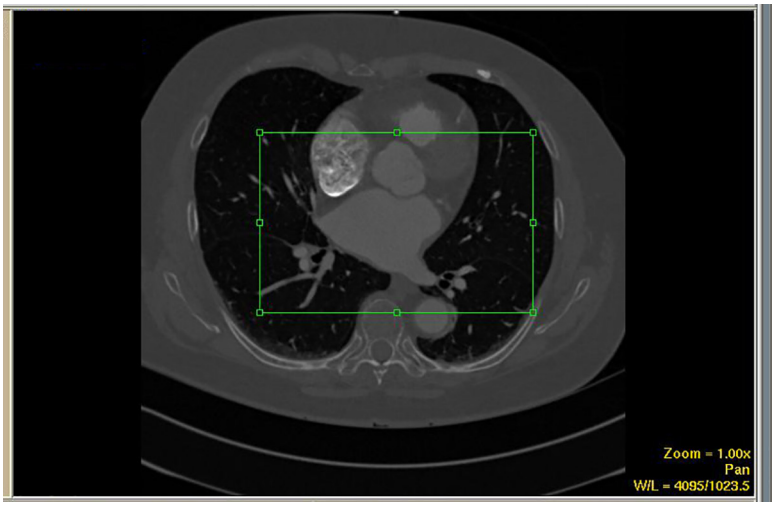
1. In the slice view, drag the handles of the green bounding box to outline the region of interest.

   NOTE: During subregioning, the Zoom, Pan, and W/L controls may help visualize the slice data.

2. Drag the Slice slider upward until the region of interest is no longer visible; then drag the upper Range slider to the same position.
3. Drag the Slice slider downward until the region of interest is no longer visible; then drag the lower Range slider to the same position.

   NOTE: The number of recommended slices is greater than 10.

Figure 192. Using the bounding box to subregion the slice data.



Loading the Series for Segmentation

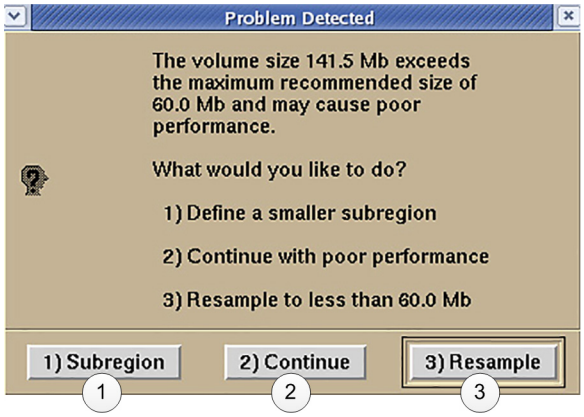
After subregioning the series, the data may need to be preprocessed, filtered and loaded into the segmentation interface.

Filtering removes grainy artifacts and non-uniformities that may affect thresholding operations. By default, filters are applied to CT, but not to MR images. To adjust filter defaults, go to [Advanced > Settings] Advanced > Settings and select the desired filter settings before loading the series for segmentation.

Loading a subregioned series – To load the subregioned data series, select Segment Series. A progress bar is shown while the subregioned volume is preprocessed, filtered, and then loaded.

NOTE: If the size of the subregioned series is larger than 60Mb, a message will appear providing the following options:

Figure 193. Message Indicating the Volume Size Exceeds 60.0 Mb



The volume size 141.5 Mb exceeds the maximum recommended size of 60.0 Mb and may cause poor performance.

What would you like to do?

1) Define a smaller subregion

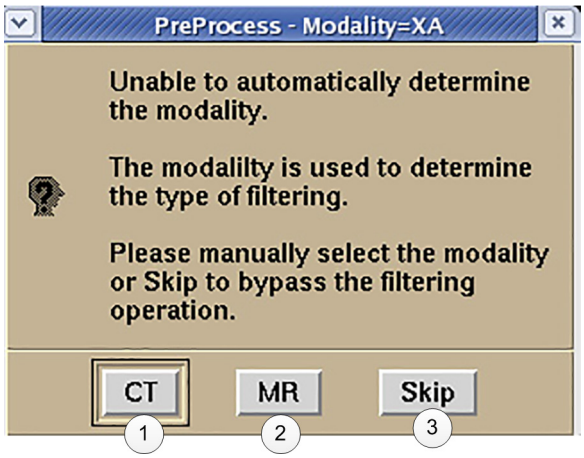
2) Continue with poor performance

3) Resample to less than 60.0 Mb

1. [Subregion] – Return to the subregioning tools and identify a smaller region of interest.
2. [Continue] – Use the identified data set without further subregioning or resampling. Processing speed may not be optimal.
3. [Resample] – Resampling will reduce the size of the data by adjusting the resolution of the images until the subregioned series is less than 60 MB. Resampling may decrease accuracy of measurement tools.

NOTE: If the image to be loaded for segmentation is not a CT or MR image, the dialog box shown below will appear:

Figure 194. PreProcess Window



Unable to automatically determine the modality.

The modality is used to determine the type of filtering.

Please manually select the modality or Skip to bypass the filtering operation.

1. [CT] – Select CT to preprocess the image as a CT image.
2. [MR] – Select MR to preprocess the image as an MR image.
3. [Skip] – Select Skip to not preprocess the image.

NOTE: For XA (rotational angiography) series, process the images as CT.

Using the Segmentation Interface

The segmentation screen is used to segment the scanned volume and render an output image for 3D visualization.

Figure 195. The segmentation screen.

1	Menu bar	The menu bar provides access to commonly used tools.

2	Control panel	The control panel contains segmentation tools. The icons on the control panel indicate which tool is currently active.
3	Structure list	The structure list, featured in several tools, selects which structures are affected by segmentation.
4	3D view	The 3D view shows the result of the current segmentation.
5	Slice views	The slice views contain images from the selected data series in transverse, coronal, and sagittal planes.
6	Slice views	The slice views contain images from the selected data series in transverse, coronal, and sagittal planes.
7	Slice views	The slice views contain images from the selected data series in transverse, coronal, and sagittal planes.

Table 10. Top bar Summary

Menu Option		Function
File	[New Segmentation] New Segmentation	Start a new segmentation session.
	[Resume Wizard] Resume Wizard	Continue the next step of the wizard.
	[Import DICOM Files] Import DICOM Files	Import currently saved DICOM files into the EnSite ™ Verismo ™ Segmentation Tool.
	[Resume Previous Segmentation] Resume Previous Segmentation	Resume the most recent segmentation session.
	[Save As] Save As	Save the displayed 3D model to the hard drive as a DIF file.
	[Save Work in Progress] Save Work in Progress	Save the segmentation results during a segmentation session, without creating a DIF file.
	[Load Work in Progress] Load Work in Progress	Reload a segmentation session from a previous Save Work in Progress.
	[Save Template] Save Template	Save the current settings as a template.
	[Load Template] Load Template	Load a previously saved template.
	[Export to CD/DVD] Export to CD/DVD	Save models to a CD/DVD.
	[Print] Print	Print the full segmentation screen, 3D heart model, or any of the slice views.
	[Exit] Exit	Exit the EnSite™ Verismo™ Segmentation Tool and return to the EnSite™ X EP System title screen.
Edit	[Modify Structure] Modify Structure	Modify the current structure.
	[Load Default Threshold] Load Default Threshold	Restore the default threshold after manual adjustments have been made.
	[Clear Segmentation Result] Clear Segmentation Result	Clear all segmented results.
Display	[Info] Info	Select preferences for displaying patient, study, and series information on the Slice views. Allows access to information from the DICOM header.
	[Options] Options	Set options for crosshairs display and the number of undo levels.
	[View Segmentation Model] View Segmentation Model	Show the 3D heart model.
	[View Segmentation Contours] View Segmentation Contours	Compare tiled model, rendered model, and slice contours.
Advanced	[Smooth All Structures] Smooth All Structures	Refine all visible structures.
	[Settings] Settings	Set preferences for filters and the Growth Limit for the Vessel Tool.
Help	[About EnSite™ Verismo™] About EnSite™ Verismo™	Display the software version.
	[Release Notes] Release Notes	Display information about the software not contained in the IFU.

Using Basic Interface Controls

The EnSite™ X Verismo™ Segmentation Tool interface provides controls for navigating in slice views, zooming, panning, and adjusting the intensity of the image. These controls are in the lower left and lower right corners of the slice and 3D views.

NOTE: After segmentation, if the Slice control is active, moving the mouse over the Zoom, Pan, or W/L controls will deactivate the Slice control. If the Zoom, Pan, or W/L control is active, moving the mouse over the Slice control will deactivate the Zoom, Pan, or W/L controls.

Navigating in Slice Views

Each slice view can be independently manipulated to find the slices and plane most suitable for segmentation. Use any of the following methods to select a slice in a single view:

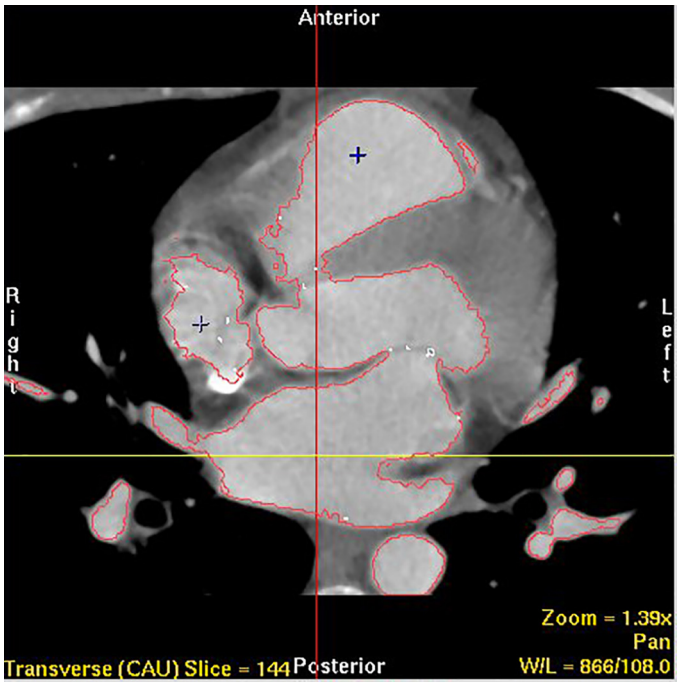
- Navigate slices from within a slice view.
  - Move the cursor up or down while pressing the wheel button within a slice view.
  - Press the Up or Down arrow keys with the cursor in a slice view.
  - Select the Slice control (in the lower left corner of a slice view) to activate the slice cursor. Move the slice cursor up or down while pressing the mouse button within a slice view. Select the Slice control again to disable the slice cursor.
  - Press and hold the right mouse button on the Slice control to open a menu and then select the First, Middle or Last slice.

- Use the crosshairs. The crosshairs facilitate navigation between slices and show the relationship between the slice view and the 3D model. In the slice view, the cursors indicate the position of the slice displayed in the other two views.
  - To move crosshairs in a slice view, drag a crosshair individually or drag from the intersection of two crosshairs to move both at once.
  - To move the crosshairs in the 3D view, drag from the intersection of the crosshairs.

  NOTE: When dragging the crosshairs in3D view, the crosshairs can only be positioned to a surface location on the model.

  - To disable the display of crosshairs in a one of the slice views, press and hold the right mouse button in the slice view and clear the Crosshairs checkbox. To disable the display of crosshairs in all the slice views, select [Display > Options] Display > Options, and clear the [Show Cross Hair] Show Cross Hair checkbox.

Figure 196. Transverse image with crosshairs indicating coronal (yellow) and sagittal (red) slice orientations



Using the Zoom Control

The Zoom control appears in the lower right corner of the slice and 3D views. By default, the Zoom control will be set to fit the image to the panel in each view. Use the following controls to adjust the zoom level:

- Select Zoom to activate the zoom cursor. Move the cursor up or down while pressing the mouse button to zoom in or out. Select Zoom again to disable the zoom cursor.
- Press and hold the right mouse button on Zoom to select preset zoom levels:
  - 0.25x – 4.00x – various magnifications.
  - Fit Window – fits to panel.
  - Fit Width – fits to panel width.
  - Fit Height – fits to panel height.

Using the Pan Control

The pan control appears in the lower right corner of the slice and 3D panels. By default, the image will be centered. Use the following controls to adjust the pan:

- Left-select on [Pan] Pan to activate the pan cursor. Then, left-select and drag the mouse in any direction to pan the image. Left-select on Pan again to disable the pan cursor.
- To center the image, hold down the right mouse button on Pan and select Reset.

Using the Intensity (W/L) Controls

The window Width/Level (W/L) control appears in the lower right corner of the slice panels. The W/L controls adjust the intensity of the displayed slice data. This adjustment allows visualization of structures in the data. By default, the W/L will be set to a range encompassing the minimum and maximum intensity values in the subregioned images. Adjusting W/L in any view will affect all three slice panels.

NOTE: W/L adjustments do not affect the result of automated segmentation tools. To adjust intensities for automated segmentation, use the thresholding and boundary emphasis controls under the related tools.

Use the following controls to adjust W/L:

- To manually control W/L, left-Select on W/L to display the W/L cursor. Then left-Select and drag the mouse to adjust window (left to right) and level (up and down). Left- Select on W/L again to disable the intensity cursor.
- To select a defined W/L, hold down the right mouse button on W/L and select a setting:
  - Intensity values that were saved as a part of the DICOM data set appear as numeric values.
  - Reset sets the W/L to a range encompassing the minimum and maximum intensity values in the subregioned images.

Rotating the 3D Model

The 3D model can be rotated to view the heart from various angles. The torso-shaped Orientation Reference in the upper right corner shows the current rotation. Use the following controls to adjust the rotation angle:

- To manually adjust the rotation, middle-Select on the 3D model, and drag to rotate.
- To select a pre-defined angle, left-Select one of the rotation angles listed at the top of the panel:
  - AP: Anterior to posterior, correlates to the coronal slice view.
  - PA: Posterior to anterior.
  - LL: Left lateral, correlates to the sagittal slice view.
  - RL: Right lateral.
  - CRA: Cranial.
  - CAU: Caudal, correlates to the transverse slice view.

Using Templates

Interface preferences may be saved in templates. The following attributes can be saved in templates:

- Structure names and colors.
- Default structure.
- Information displayed in the upper left corner of slice and 3D views.
- Show crosshairs on/off.
- Growth limit for the vessel tool.
- Font size for labels and tape measures.
- Number of undo levels.

To create a template – Modify the above attributes and select [File > Save Template] File > Save Template.

To load a template – Select [File > Load Template] File > Load Template.

NOTE: Templates can only be saved or loaded from the segmentation screen.

Performing Segmentation

Overview of Segmentation Tools

Segmentation is the process of isolating an object of interest using the gray-scale intensity of slice-based data. The EnSite™ Verismo™ Segmentation Tool uses two common segmentation techniques to create an accurate model for 3D visualization of cardiac structures.

- Thresholding is a method of selecting any values within a range of intensities.
- Boundary emphasis identifies sharp transitions in intensity.

Each segmentation tool is represented by an icon in the control panel. Clicking the icon will display the tool.

Figure 197. Segmentation Tools.

1	Region Grow tool	Segment a region that consists of many connected structures, such as the blood pool.
2	Chamber tool	Segment a heart chamber.
3	Vessel tool	Segment a cardiac vessel.
4	Separator tool	Separate connected structures from one another.
5	Trace tool	Manually trace a region.
6	Barrier tool	Enhance boundaries between structures to improve the use of the Region Grow, Chamber, Vessel, and Separator tools.
7	Reassign tool	Reassign a structure that was previously defined.
8	Label tool	Label the heart model.
9	Measure tool	Measure linear distances and volumes.

Additional Controls: Delete, Undo, Cancel

The following controls appear at the bottom of the control panel and apply to multiple tools:

- [Delete] Delete – Select Delete and the select the item to be deleted (seed point, barrier, trace, label or measurement) in the slice view or 3D view.
- [Delete All] Delete All – Select to delete all seed points, traces, labels, measurements and barriers.
- [Undo] Undo – Undoes the last segmentation process.
- [Redo] Redo – Restores the last process reversed with Undo.
- [Cancel] Cancel – Cancels all unapplied actions of the current segmentation tool and closes the tool.

Using the Structure List

The Structure list manages the display of up to 16 structures. It features a drop-down menu of 16 structures and an ***Undefined*** option. One structure may be selected from this list to be used by segmentation tools.

The ***Undefined*** option is used to remove information from the segmented model. All other structures add information to the segmented model. Undefined cannot be locked, displayed, colored, or renamed.

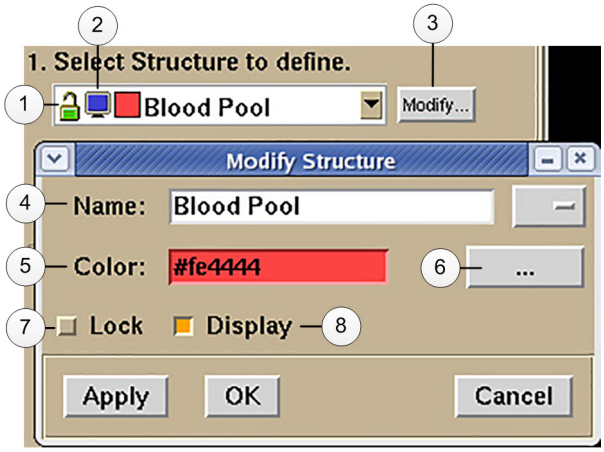
Figure 198. The Structure List

1	Lock	Locking a structure prevents modifications. To lock or unlock a structure, Select on the lock icon. The icon for an unlocked and modifiable structure appears in green (default), and the icon for a locked structure appears in red.
2	Display	Display controls whether the structure will be displayed in the 3D view. If the display is enabled (default), the display icon appears as a small monitor, and the structure is shown in 3D view. If the display is disabled, the icon appears as a monitor with a red slash, and the structure is hidden from 3D view. If a structure is not displayed, no part of that structure can be removed or assigned to a different structure; however, a structure that is not displayed can still have additional information added to it by other segmentation tools. NOTE: Structures that are not displayed when a model is saved will not be available when the model is displayed on the EnSite™ X EP System software.
3	Color	Color – The color controls the display color for the structure in the slice and 3D views.
4	[Modify...] Modify button	Select Structure attributes may be modified using the Modify Structure Window.

Modifying Structures

Structure attributes may be modified.

Figure 199. The Structure List and Modify Structure Window.



1. Select a structure from the drop-down list to modify.
2. Select the [Modify...] Modify button adjacent to the structure list or select [Edit > Modify Structure] Edit > Modify Structure. The Modify Structure window will appear.
3. [Name] Name – Type a name using up to 16 characters or select a name from the list.
4. [Color] Color – Type a color name (“red”) or select ... to display a color selection tool.
5. [Lock] Lock – Lock or unlock the structure.
6. [Display] Display – Display or hide the structure.
7. Select [Apply] Apply to apply modifications.
8. Select [OK] OK to apply modifications and close the Modify Structure window.
9. Select [Cancel] Cancel to discard modifications and close Modify Structure window.
10. [...] – Color chart

Using the Region Grow Tool

The Region Grow tool is used to quickly isolate a larger region of the scanned volume such as the blood pool. Other segmentation tools can then be used to separate individual structures from the blood pool. The Region Grow tool requires the placement of one or more seed points and manual adjustment of the threshold range.

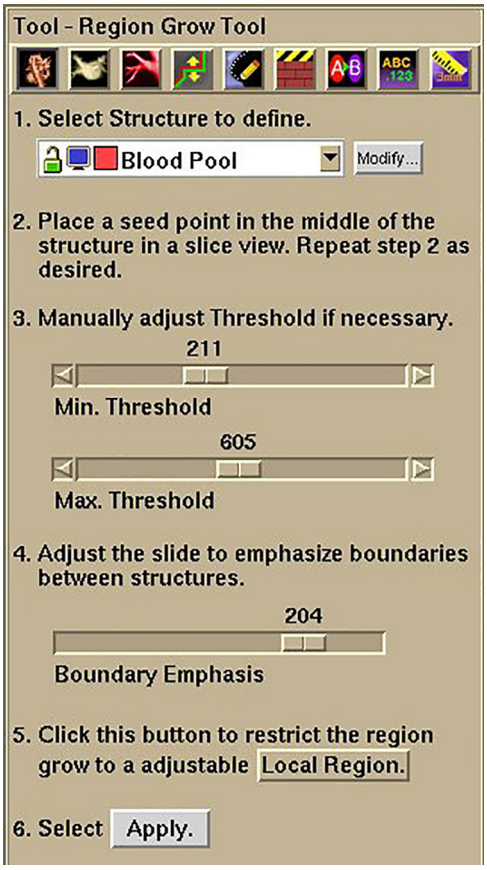
1. Select a structure of interest from the list.
2. In the desired Slice view, left-Select to place one or more seed points in the middle of the structure.

   NOTE: If seed points are placed incorrectly, use the Delete or Delete All buttons.
3. Adjust the Minimum Threshold, Maximum Threshold, and Boundary Emphasis sliders:
   - Lower the Minimum Threshold until the structures of interest fill in with translucent color. If boundaries between structures begin to fill with color, the Min. Threshold may be too low.
   - The Maximum Threshold generally does not need to be adjusted unless a hard structure (bone, implanted metal) is present.
   - Drag the Boundary Emphasis slider to emphasize the boundaries between structures. Raise the slider until a thin boundary appears around the structures in the slice views.

   NOTE: If thresholding and boundary emphasis do not identify separations that can be visually identified, consider using the Barrier tool before proceeding.
4. Adjust the slide to emphasize boundaries between structures.
5. Optional: To limit the area affected by Region Grow, select Local Region and adjust the bounding box in the slice views.
6. Select Apply to segment the defined structure. The segmented structure is shown in the 3D view.

   NOTE: If the effect of the segmentation is undesirable, use the Undo button to undo the last change to the 3D model

Figure 200. The Region Grow Tool.



1. [Select Structure to define.] Select Structure to define.
   Use the Modify button to make changes to the Structure.
2. [Place a seed point in the middle of the structure in a slice view. Repeat step 2 as desired.] Place a seed point in the middle of the structure in a slice view. Repeat step 2 as desired.
3. [Manually adjust Threshold if necessary.] Manually adjust Threshold if necessary.
   Use the [Min. Threshold] minimum threshold and [Max. Threshold] maximum threshold sliders to adjust threshold.
4. [Adjust the slide to emphasize boundaries between structures.] Adjust the slide to emphasize boundaries between structures.
   Use the Boundary Emphasis to adjust boundaries
5. [Click this button to restrict the region grow to a adjustable Local Region.] Click this button to restrict the region grow to a adjustable Local Region.
   Select the Local Region button to adjust a region
6. [Select Apply.] Select Apply.
   Select the Apply button to apply changes.

Figure 201. While the threshold sliders are adjusted, the affected portion of the model will be indicated with a translucent overlay of the structure color.

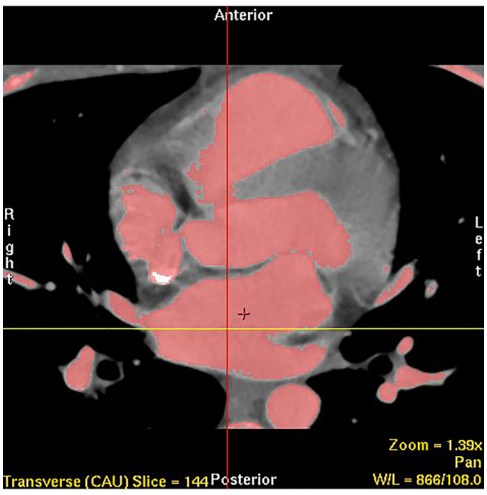


Figure 202. While the Boundary Emphasis slider is adjusted, areas with a sharp change in intensity are indicated in translucent white.

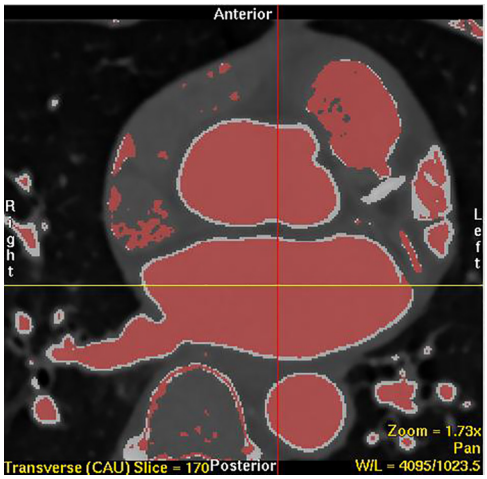
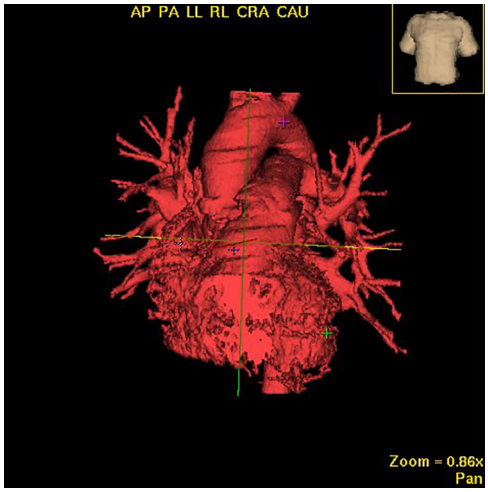


Figure 203. Initial 3D model from Region Grow tool



Using the Chamber Tool

The Chamber tool is used to quickly isolate a heart chamber from the scanned volume. This tool requires the placement of a seed point in the middle of the chamber of interest and manual adjustment of the threshold range. The Chamber tool emphasizes the segmentation of a single chamber using an erosion algorithm. The erosion algorithm uses thresholding and boundary emphasis values to automatically break thin connections to other structures. The Chamber tool is often faster than the Region Grow tool for segmenting a single chamber, but generally has slightly less resolution.

1. Select the chamber of interest from the list.
2. In the desired slice view, left-Select to place a seed point in the middle of the chamber.

   NOTE: If seed points are placed incorrectly, use the Delete or Delete All Delete All buttons.

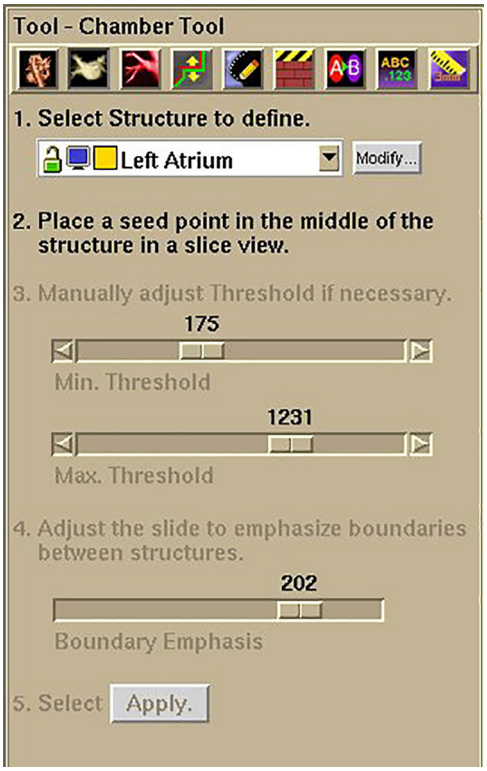
   - Adjust the Min. Threshold Min. Threshold, Max. Threshold Max. Threshold, and Boundary Emphasis Boundary Emphasis sliders:
   - Adjust the Min. Threshold Min. Threshold until a dotted line appears around the structure of interest. If the dotted line surrounds multiple structures, the Min. Threshold Min. Threshold may be too low.
   - The Max. Threshold Max. Threshold generally does not need to be adjusted unless a hard structure (bone, implanted metal) is present.
   - Drag the Boundary Emphasis Boundary Emphasis slider to emphasize the boundaries between structures. Raise the slider until a thin boundary appears around the structures in the slice views.

   NOTE: If thresholding and boundary emphasis do not identify separations that can be visually identified, consider using the barrier tool before proceeding.
3. Adjust the slide to emphasize boundaries between structures.
4. Select Apply to segment the defined chamber. The segmented structure is shown in the 3D view.

   NOTE:

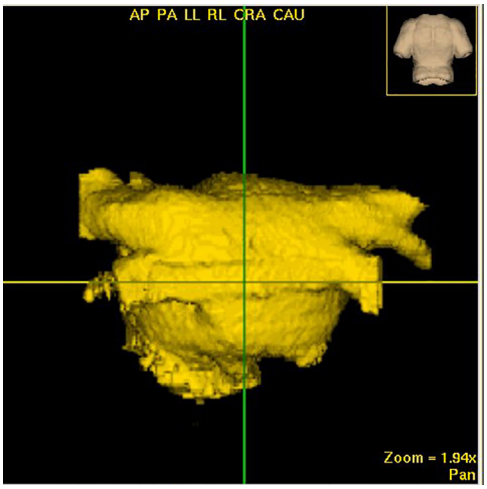
   - The segmented structure will not precisely match the initial dotted line because of the erosion algorithm described above.
   - If the effect of the segmentation is undesirable, use the Undo button to undo the last change to the 3D model.

Figure 204. The Chamber tool.



1. [Select Structure to Define.] Select Structure to Define.
2. [Place a seed point in the middle of the structure in a slice view.] Place a seed point in the middle of the structure in a slice view.
3. [Manually adjust Threshold if necessary.] Manually adjust Threshold if necessary.
   [Min. Threshold] Minimum Threshold
   [Max. Threshold] Maximum Threshold
4. [Adjust the slide to emphasize boundaries between structures.] Adjust the slide to emphasize boundaries between structures.
   [Boundary Emphasis] Bounday Emphasis
5. [Select Apply.] Select Apply.

Figure 205. A model produced by the Chamber tool.



Using the Vessel Tool

The Vessel tool is used to quickly isolate a vessel from the scanned volume. This tool grows a vessel on adjacent slices, using a seed point and a threshold range.

1. Select a structure from the list. In the desired slice view, left-Select to place a seed point in a vessel. The seed point should generally be placed in a plane perpendicular to the vessel, such as the sagittal view for pulmonary veins.

   NOTE: The growth of structures using the Vessel tool is controlled by the Growth Limit. The Growth Limit, available under Advanced > Settings Advanced > Settings, is user adjustable, but defaults to 1.5 times the size of the original slice.

2. In the desired slice view, left-Select to place a seed point in the middle of the chamber.

   NOTE: If seed points are placed incorrectly, use the Delete or Delete All buttons.

3. Adjust the minimum and maximum threshold sliders:

   - Adjust the minimum threshold until a dotted line appears around the structure of interest. If the dotted line surrounds multiple structures, the minimum threshold may be too low.
   - The maximum threshold generally does not need to be adjusted unless a hard structure (bone, implanted metal) is present.

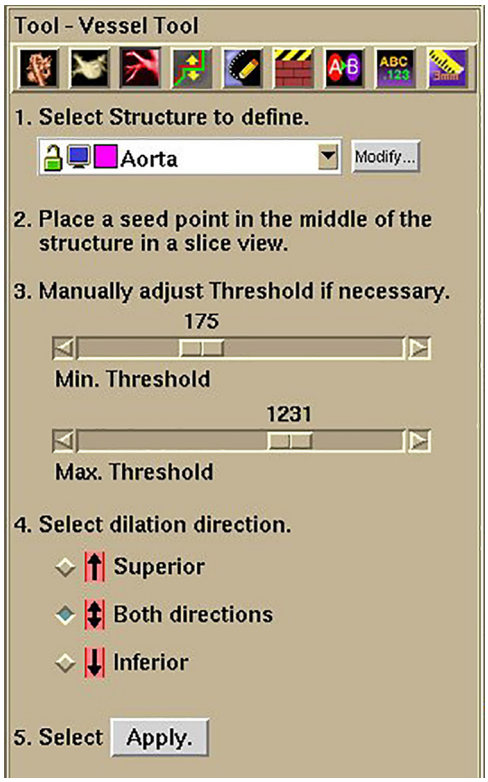
   NOTE: If thresholding does not identify separations that can be visually identified, consider using the Barrier tool before proceeding.

4. Select one of the following directions to grow the vessel:
   - (Superior/Anterior/Left) (Superior/Anterior/Left) to grow the vessel in the specified direction.
   - Both directions to grow the vessel in both directions.
   - (Inferior/Posterior/Right) (Inferior/Posterior/Right) to grow the vessel in the specified direction.
   - Select Apply to segment the vessel.
5. Select Apply to segment the defined chamber. The segmented structure is shown in the 3D view.

   NOTE:

   - The segmented structure will not precisely match the initial dotted line because of the erosion algorithm described above.
   - If the effect of the segmentation is undesirable, use the Undo button to undo the last change to the 3D model.

Figure 206. The Vessel tool.



1. [Select Structure to define.] Select Structure to define.
2. [Place a seed point in the middle of the structure in a slice view.] Place a seed point in the middle of the structure in a slice view.
3. [Manually adjust Threshold if necessary.] Manually adjust Threshold if necessary.

[Min. Threshold] Minimum Threshold

[Max. Threshold] Maximum Threshold

4. [Select dilation direction.] Select dilation direction.

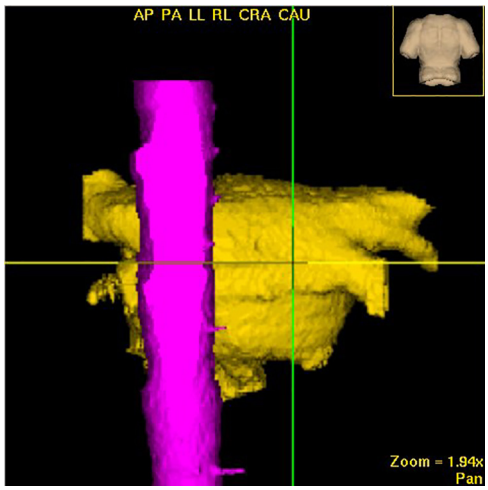
[Superior] Superior

[Both directions] Both directions

[Inferior] Inferior

5. [Select Apply.] Select Apply.

Figure 207. A completed vessel model of the descending aorta.



Using the Separator Tool

The Separator tool is used to separate structures for individual visualization, for example, separating the left ventricle from the left atrium. This tool can also be used to remove a portion of the 3D model if too much detail was segmented. Structures are separated between two or more seed points placed on the surrounding structures.

1. Select a structure to separate (e.g. Left Atrium).

   NOTE: Selecting “Undefined” from the structure list allows the separator tool to delete portions of the segmented model.

2. In the desired Slice or 3D view, left-Select to place one or more seed points on the appropriate structure (e.g. left atrium).

   NOTE: If seed points are placed incorrectly, use the Delete or Delete All buttons.

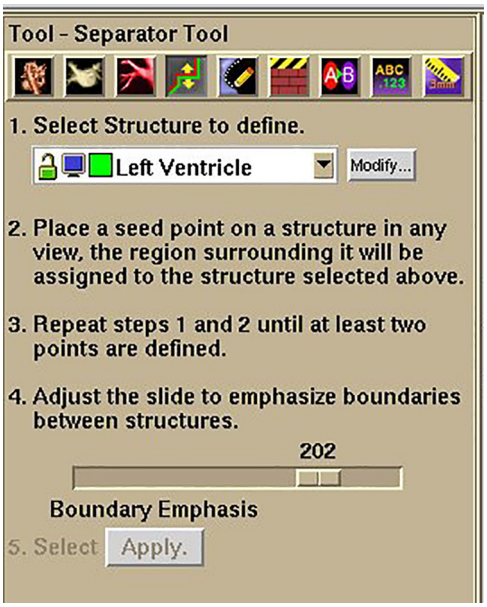
3. Repeat steps 1 and 2 as needed to continue identifying surrounding structures.

   NOTE: To preserve the original structure, be sure to place at least one point in the original structure. For example, if the “Left Atrium” structure also contains portions of the left ventricle and aorta, place points not only in the left ventricle and aorta, but also in the left atrium.

4. Drag the Boundary Emphasis slider to emphasize the boundaries between structures.

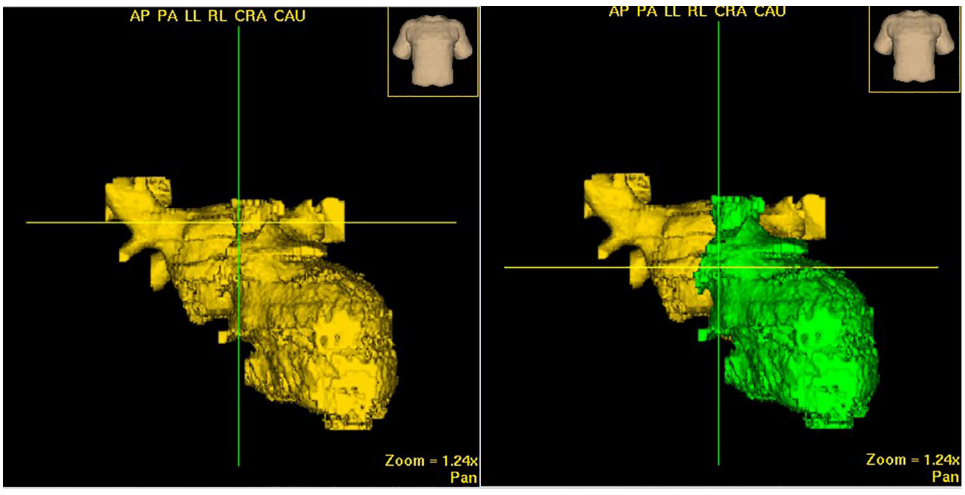
5. Select Apply to separate the defined structures.

Figure 208. The Separator Tool.



1. [Select Structure to define.] Select Structure to define.
2. [Place a seed point on a structure in any view, the region surrounding it will be assigned to the structure selected above.] Place a seed point on a structure in any view, the region surrounding it will be assigned to the structure selected above.
3. [Repeat steps 1 and 2 until at least two points are defined.] Repeat steps 1 and 2 until at least two points are defined.
4. [Adjust the slide to emphasize boundaries between structures.] Adjust the slide to emphasize boundaries between structures.
   [Boundary Emphasis] Boundary Emphasis
5. [Select Apply.] Select Apply.

Figure 209. Before (left) and after (right) using the Separator tool.



NOTE:

- If separations do not occur at locations that can be visually identified, consider using the Barrier tool before proceeding.
- If the effect of the segmentation is undesirable, use the Undo button to undo the last change to the 3D model.

Using the Trace Tool

The Trace tool is used to manually outline a structure. It can be used to create structures from slice views or reassign portions of the segmented model to a different structure.

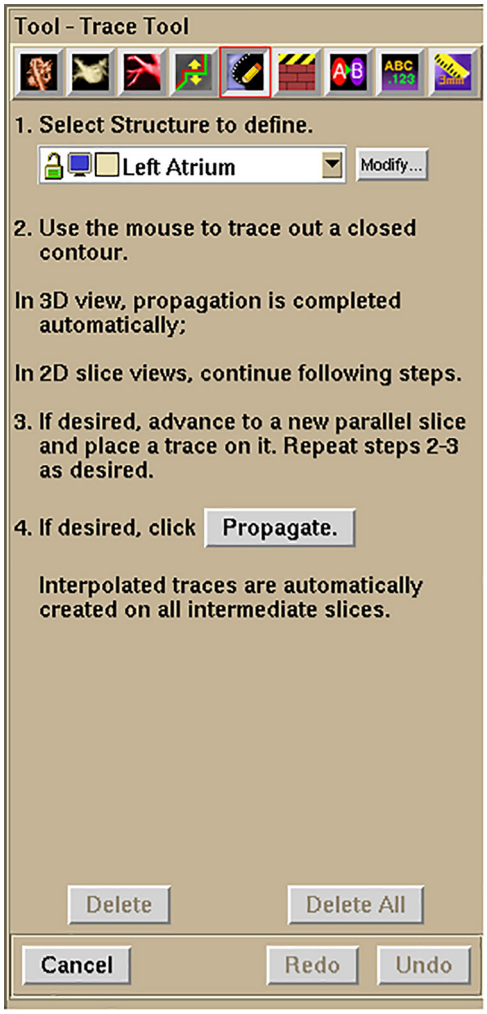
Using the Trace Tool in a Slice View

1. Select the structure to be traced, such as “Esophagus.”
2. In the desired slice view, left-Select along an edge of the structure to be traced. Left-Select and drag around the edge of the contour to trace the structure. Release the mouse button to complete the trace and connect the starting point of the line to the ending point. The structure will be created on a single slice.

   NOTE: To remove a trace from a single slice, use the Delete or Delete All buttons.
3. Advance to a parallel slice in the same view and trace the structure again.
4. To grow the structure through adjacent slices, Select Propagate.

   NOTE: If the effect of the segmentation is undesirable, use the Undo button to undo the last change to the 3D model.
5. Select Cancel to stop action.

Figure 210. The Trace Tool



1. [Select Structure to define.] Select Structure to define.
2. [Use the mouse to trace out a closed contour.] Use the mouse to trace out a closed contour.
   [In 3D view, propagation is completed automatically;] In 3D view, propagation is completed automatically;
   [In 2D slice views, continue following steps.] In 2D slice views, continue following steps.
3. [If desired, advance to a new parallel slice and place a trace on it. Repeat steps 2-3 as desired.] If desired, advance to a new parallel slice and place a trace on it. Repeat steps 2-3 as desired.
4. [If desired, click Propagate.] If desired, click Propagate.
   [Interpolated traces as automatically created on all intermediate slices.] Interpolated traces as automatically created on all intermediate slices.
   [Delete] [Delete All] Delete, Delete All
5. [Cancel] [Redo] [Undo] Cancel, Redo, Undo

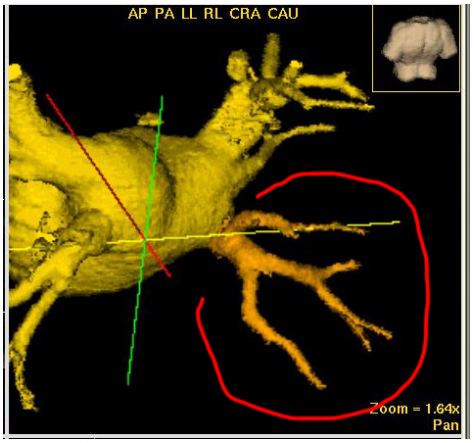
Using the Trace tool in the 3D View

1. Select the Trace icon.
2. Select a structure.

   NOTE: Selecting “Undefined” from the structure list allows the Trace tool to delete portions of the segmented model.
3. In the 3D view, left-Select and drag the cursor around the structure to be reassigned.
4. Release the mouse button to complete the trace.

   NOTE: If the effect of the segmentation is undesirable, use the Undo button to undo the last change to the 3D model.

Figure 211. Using the Trace tool.



Using the Barrier Tool

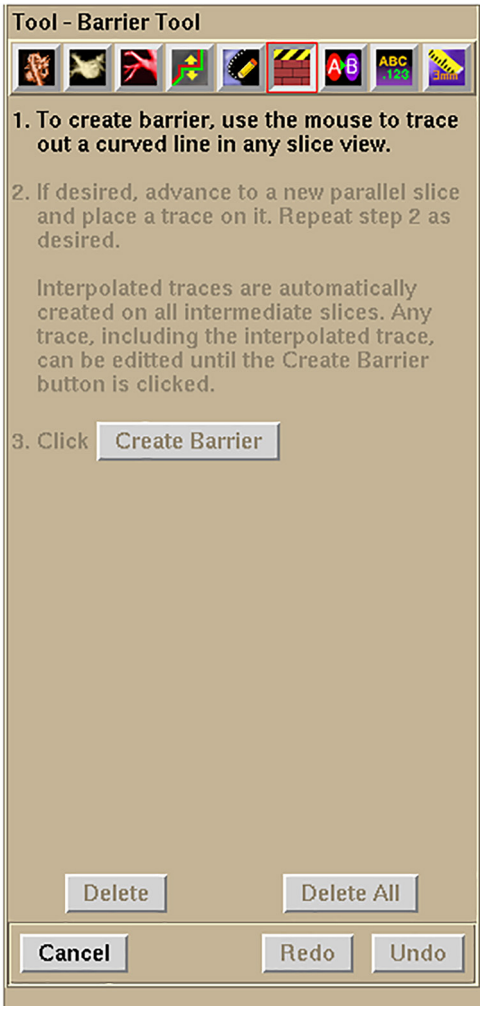
The Barrier tool is used to place divisions between structures that can be visually identified but may be difficult to automatically identify for a variety of reasons. The Barrier tool improves the use of the Region Grow, Chamber, Vessel, and Separator tools.

1. In the desired Slice view, left-select and drag to draw a line.
2. Advance to another slice in the same view and draw another line. Repeat this process until the barrier has progressed from one side of the structures to the other.
   - When drawing barriers, always draw in the same general direction (left- to-right, top-to-bottom, etc.)
   - Slices do not need to be consecutive.
   - The barrier tool will create an estimated line on all the slices between user-drawn lines. These estimated lines are displayed in purple; drawing a new line on this slice will remove the estimated line.
   - Drawing a new line on a slice that already contains a line will replace the previous line.
3. Select Create Barrier Create Barrier to grow the barrier through adjacent slices.

   NOTE:
   - After creating a barrier, additional barriers may be drawn.
   - To remove barriers, use the Delete or Delete All Delete All buttons.
4. Continue segmentation using the appropriate tools.

   NOTE: Barriers are not affected by Undo or Redo. Undo and Redo only affect changes to the segmented model; barriers only appear in the 2D view.

Figure 212. The Barrier tool.



1. [To create barrier, use the mouse to trace out a curved line in any slice view.] To create barrier, use the mouse to trace out a curved line in any slice view.
2. [If desired, advance to a new parallel slice and place a trace on it. Repeat step 2 as desired.] If desired, advance to a new parallel slice and place a trace on it. Repeat step 2 as desired.

   [Interpolated traces are automatically created on all intermediate slices. Any trace, including the interpolated trace, can be edited until the Create Barrier button is clicked.] Interpolated traces are automatically created on all intermediate slices. Any trace, including the interpolated trace, can be edited until the Create Barrier button is clicked.
3. [Click Create Barrier] Click Create Barrier.

   [Delete] [Delete All] Delete, Delete All
4. [Cancel] [Redo] [Undo] Cancel, Redo, Undo

Figure 213. A Drawn Barrier Line.

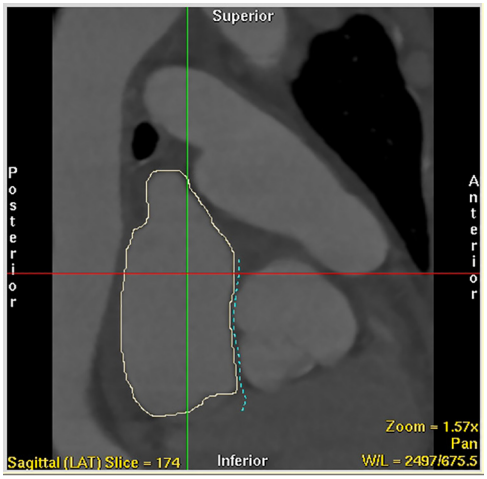
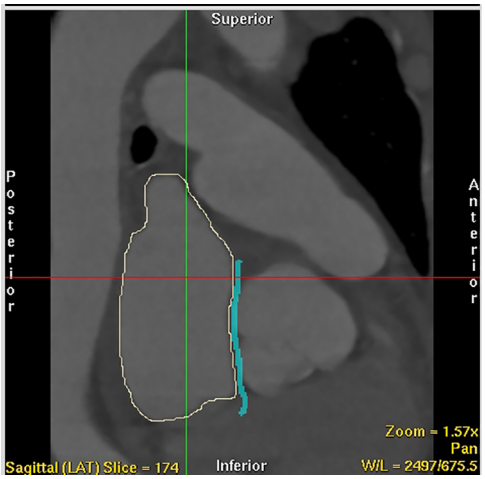


Figure 214. A created barrier.



Using the Reassign Tool

The Reassign tool is used to reassign a structure that has already been defined. It is an efficient way to segment the remaining structures from the slice or 3D views.

1. Select the structure to be reassigned.
2. Select from the following assignment methods:
   - Entire Structure reassigns all components of one structure to a different structure. For example, if a model of the left atrium was inadvertently assigned to the Left Ventricle structure, use Entire Structure to reassign the entire model to the Left Atrium structure.
   - Contiguous 3D reassigns all connected 3D regions to the defined structure. For example, if a model in the Blood Pool structure contained the anatomy of the descending aorta and the rest of the heart, and the aortic anatomy was not connected to the posterior wall of the heart, this option would allow the descending aorta to be reassigned to the Aorta structure.
   - Components less than 125 mm reassigns connected 3D regions less than 125 mm. A new number can be typed if desired. For example, if the Left Atrium structure includes many small disconnected and undesirable pieces, this option can be used to reassign the small pieces to the Unassigned structure.
3. In the desired slice or 3D view, left-Select to place a seed point on the structure to reassign.

   NOTE: If seed points are placed incorrectly, use the Delete or Delete All Delete All buttons.
4. Select Apply to reassign the defined structure.

Figure 215. The Reassign tool.

1. [Select Structure to define.] Select Structure to define.
2. [Select method.] Select method.
   [Entire Structure] Entire Structure
   [Contiguous 3D] Contiguous 3D
   [Components less than _____mm^3] Components less than _____mm^3
3. [Place a seed point on an object, the object will be assigned to the structure selected above.] Place a seed point on an object, the object will be assigned to the structure selected above.
4. [Click Apply.] Click Apply.

Using the Label Tool

The Label tool is used to label the 3D heart model. All labels are saved with the 3D model and will be included on models imported into an EnSite™ X EP System study.

1. Type a label (up to 16 characters), select a predefined label from the list, or select Location from the list. When Location is selected, a placed label will display Cartesian coordinates for the selected map location.

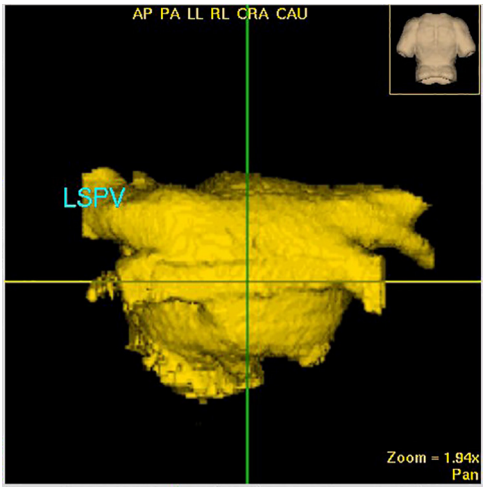
2. Select a font size for the label.
   - Small – 10 point
   - Medium – 12 point (default)
   - Large – 14 point
3. Left-Select in a slice view or on the 3D model to place a label.

   NOTE: If labels are placed incorrectly, use the Delete or Delete All buttons.

Figure 216. The Label tool.

1. [Type in or select label from the list.] Type in or select label from the list.
2. [Select font size:] Select font size:
   [Small] [Medium] [Large] Small, Medium, Large
   [Place label on the desired location.] Place label on the desired location.
3. [Delete] [Delete All] Delete, Delete All

Figure 217. Using the Label tool.



Using the Measurement Tools

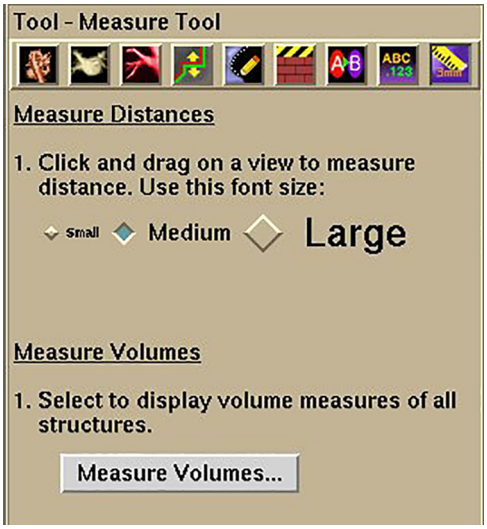
The Measure tool is used to measure linear and screen distances between two user-selected points. Measurement accuracy is based on the original scan data +/- one slice space.

1. Select a font size for displaying the measured distance.
   - Small – 10 point
   - Medium – 12 point (default)
   - Large – 14 point
2. In any slice view or the 3D view, left-Select and drag on the area to be measured.
   - Straight (slice or 3D views) is the shortest distance across the structure.
   - Screen (3D view only) is the projected screen distance, which changes as the 3D model is rotated. The screen measurement may be useful for analyzing a distance at various angles.

   NOTE:

   - Measurements are shown on a model only when the Measure tool is selected. Measurements are not saved with the final DIF file.
   - To delete tape measures, use the Delete or Delete All buttons. When using the delete tool with tape measures, Select on the red ends of a tape measure.
   - Resampling may decrease the accuracy of measurement tools.

Figure 218. The Measurement tool.



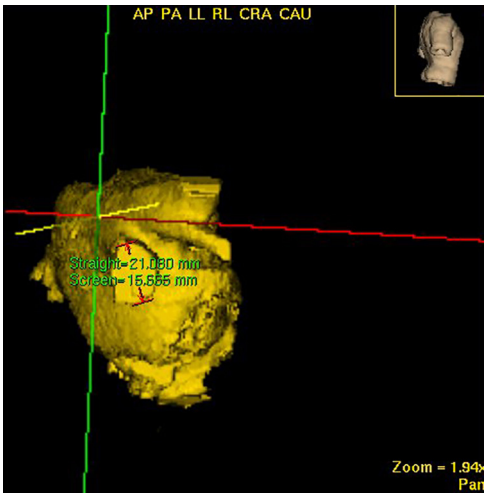
[Measure Distances] Measure Distances

1. [Click and drag on a view to measure distance. Use this font size:] Click and drag on a view to measure distance. Use this font size:
   [Small] [Medium] [Large] Small, Medium, Large

[Measure Volumes] Measure Volumes

2. [Select to display volume measures of all structures.] Select to display volume measures of all structures.
   [Measure Volumes…] Measure Volumes
   [Delete] [Delete All] Delete, Delete All

Figure 219. Using the Measurement Tool.



Measuring Volumes

Select Measure Volume to display the calculated volumes for all structures.

Saving and Exporting Models

Key Points About Saving Models

The following points are important considerations in saving a model:

- At the time that the model is saved, each visible structure is included in the final model. Disabling the view of a structure in the structure list will prevent that structure from being included.

  NOTE: When saving a model with more than one structure displayed in the structure list, the resolution of each individual structure will be slightly reduced. The greater the number of displayed structures, the lower the resolution on each individual structure.
- When segmentation is complete, the model must be saved to the hard drive, regardless of whether the model will be used on a different workstation. The model may be exported after saving.
- During the saving process, the final model is constructed by creating a thin shell around each visible structure in the 3D view. A viewer will appear to display the surface of this shell. A contour viewer is also available to compare the shape of this shell directly to the model in the 3D view and the original slice data.
- To save partially completed segmentations select [File > Save Work in Progress] File > Save Work in Progress. To return to a previously saved segmentation, select [File > Load Work in Progress] File > Load Work in Progress.

Saving the Model to the Hard Drive

1. Select [File > Save As] File > Save As.
2. Enter a File name.
3. In the Operator field, type the name of the clinician who performed the segmentation.

   NOTE: The operator name may also be accessed from a list. Use the drop-down menu to access an operator from the list. To add new operator names to the list, type the new operator name, and from the drop-down menu, select Add.

4. Optionally, notes about the segmentation session may be saved with the model in the Comments section. Comments will be available during the EnSite™ X EP System study.

5. Select Save to save the file on the EnSite™ X EP System. When a model is saved, the system creates a tiled surface of each displayed structure. The tiled model in DIF format is the version that will be accessed by the EnSite™ X EP System. After a model has been saved, it will be loaded and displayed in the DIF Viewer.

   NOTE: During saving, a message may appear stating that the complexity of the model may slow the EnSite™ X EP System application. If this occurs, consider performing the following action(s) to reduce the complexity of the model and then resaving:

   - Hide additional structures in the Structure List and save again.
   - Remove small debris from the model using either the Trace or Reassign tool and save again.
   - Reduce the surface complexity by selecting [Advanced > Smooth All Structures] Advanced > Smooth All Structures and save the model again.

Exporting Models to CD or DVD

To save the DIF file to a CD/DVD:

1. Select [File > Export] File > Export to CD/DVD. A list of saved models will appear.
2. Select saved files to back up on the CD/DVD.
3. Click OK to copy the files to the disk.

Saving Work in Progress

Saving work in progress will help preserve the model in various stages of segmentation and allow the user to return to a previous point in the segmentation process.

NOTE: Barriers, labels, and tape measures are not saved with work-in-progress files.

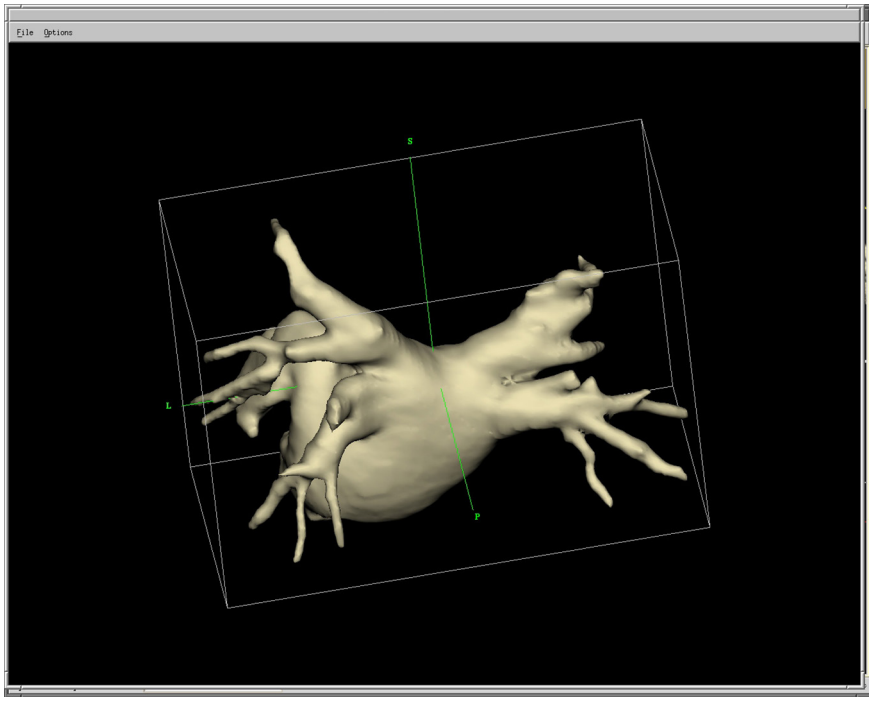
1. Select [File > Save Work in Progress] File > Save Work in Progress.
2. To recover this saved model at any time, select [File > Load Work in Progress] File > Load Work in Progress.

Reviewing the Final Model

Using the DIF Viewer

The DIF Viewer displays the final 3D model surface as it will appear on the EnSite™ X EP System.

Figure 220. The DIF viewer.



The viewer may be accessed by two methods:

- After saving a model by selecting [File > Save As] File > Save As. The viewer will appear with the model loaded.
- The viewer may also be accessed by selecting [Display > View Segmentation Model] Display > View Segmentation Model. A list of available models will appear. Select a model from the list.

The following controls are available in the viewer:

- Rotate – Hold down the middle mouse button and drag.
- Zoom – Use the roller wheel on the mouse.
- Wireframe – [Display > View Segmentation Model] Display > View Segmentation Model.
- Bounding box display – [Options > Bounding Box] Options > Bounding Box.
- Default views – [Views > AP/PA/LL/RL/CRA/CAU] Views > AP/PA/LL/RL/CRA/CAU.

- Close viewer – [File > Exit] File > Exit.

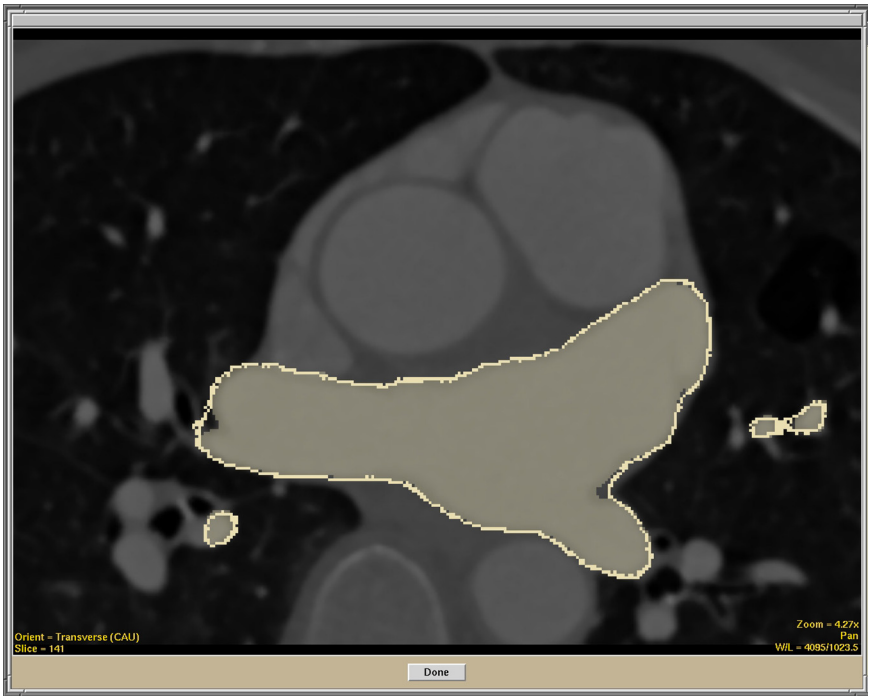
Viewing Segmentation Contours

The segmentation contour viewer allows the clinician to compare a DIF surface model to the current rendered model from the 3D view and the current slice data.

To access the segmentation contour viewer, select [Display>View Segmentation Contour] Display>View Segmentation Contour.

- The rendered model from the 3D view appears as shaded solid areas.
- The surface of the DIF model appears as thick opaque lines.
- The slice images appear in a single view, which may be navigated using the same controls as the other slice views.

Figure 221. The Segmentation Contour Viewer.



Printing Images

1. Select File > Print.
2. Select from the following options:
   - Full Screen prints the entire segmentation screen.
   - 3D Rendering prints the 3D heart model.
   - Transverse (CAU) prints the transverse slice view.
   - Coronal (AP) prints the coronal slice view.
   - Sagittal (LL) prints the sagittal slice view.

Troubleshooting Tools

Technical Support may ask you to access one or more of the following software resources:

About EnSite Verismo – This information will provide technical support with general information about your software version. From the EnSite™ Verismo™ Segmentation Tool menu bar, select [Help > About EnSite Verismo] Help > About EnSite Verismo.

Collect Log Files – This function collects all the log files from the system and exports them to a disk. Place a blank disk in the DVD/CD writable drive. From the EnSite™ X EP System title screen, Select on the [About EnSite ...] About EnSite button. Select on the Utilities tab then Select on the [Collect Log Files] Collect Log Files button. Follow the on-screen prompts to complete the process. This operation can take several minutes to complete.

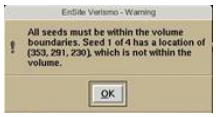
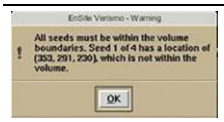
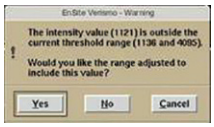
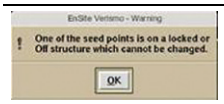
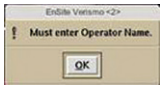
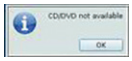
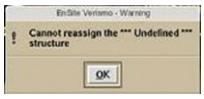
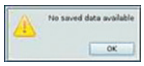
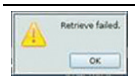
Troubleshooting Common Problems

When a problem occurs, perform the following steps:

Series will not load – Verify that the data was created in accordance with the optimal characteristics. If the series information displays but the series will not load, check the Usability indicator.

- [OK] OK – No problems were detected.
- [Bad Dircos] Bad Dircos – Coordinate information is missing, or vectors are not at right angles.
- [Rot###] Rot### – Volume is not orthogonal - direction cosines are reported.
- [NOT_3D] NOT_3D – Only one section or no slice locations, missing coordinate information or all slices are at the same location.
- [Unsupported orientation] Unsupported orientation – Volume is not a standard orthogonal.
- [Gantry Tilt] Gantry Tilt – Gantry tilt field is nonzero.
- [IRREGULAR_SPACING] IRREGULAR_SPACING – Spacing conflicts cannot be resolved.
- [EnSite™ X Verismo™ Segmentation Tool is not responding] EnSite™ X Verismo™ Segmentation Tool is not responding – If the EnSite™ X Verismo™ Segmentation Tool is not responding, press Alt + F10.

Error Messages

Error Window	Error Message	Additional Information
	Chamber tool Failed: Try another seed point or method. For best results pick a seed point near the 3D center of the structure to be extracted. OK	
	All seeds must be within the volume boundaries. Seed 1 or 4 has a location of (353, 291, 230), which is not within the volume. OK	The seed and location data are examples only.
	Seed placed outside any defined structure. OK	
	The intensity value (1121) is outside the current threshold range (1136 and 4095). Would you like the range adjusted to include this value? Yes No Cancel	The intensity value and threshold range are examples only.
	One of the seed points is on a locked or Off structure which cannot be changed. OK	
	Must enter Operator Name. OK	
	The selected structure is locked and cannot be changed. OK	
	2 out of 5 objects failed to generate geometry surface(s) from object map file:/var/STJ/Training/dicom/SJM_Surf/ DIF_20200302_205705.obj. OK	Error generated from file in training directory.
	Are you sure you want to exit EnSite Verismo? Yes No	
	CD/DVD not available OK	
	Cannot reassign the ***Undefined*** structure OK	***Undefined*** is the structure name.
	There is no usable DICOM data on this disk or the disk in empty. OK	
	No saved data available OK	
	Cannot establish connection with “server name” OK	
	Connection with “client name” has been established. OK	
	Retrieve failed. OK	
	The seed point is on a locked or Off structure which cannot be changed. OK	

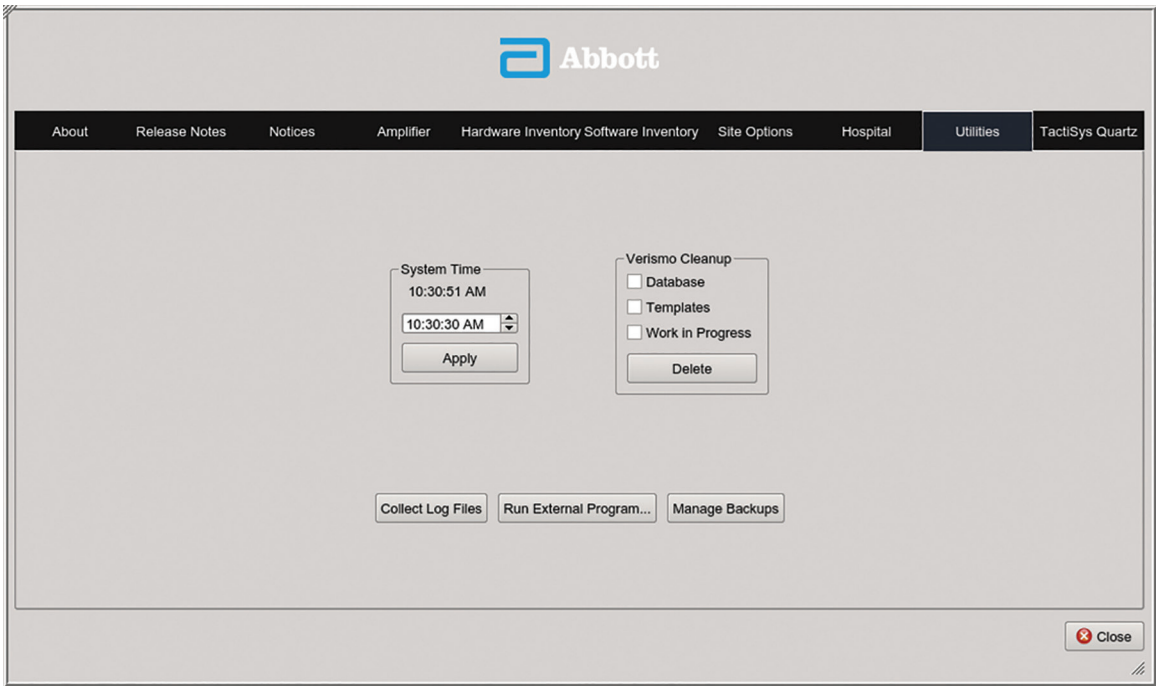
EnSite™ Verismo™ Segmentation Tool Cleanup

- EnSite™ Verismo™ Segmentation Tool Cleanup – If the EnSite™ Verismo™ Segmentation Tool fails to start, consider clearing out all temporary files.

- Open the Application menu at the bottom left corner of screen, select Help. Select About. The About window will open. Select the Utilities tab. Select the type of files to delete, and then select Delete.
  - Database – Delete the currently loaded DICOM files and all Work In Progress files.
  - Templates – Delete the user-defined templates.
  - Work in Progress Work in Progress – Delete all Work in Progress files.

  NOTE: The cleanup tool will not delete created DIF files. These models may be deleted from within the Load DIF window in the EnSite™ X EP System software.

Figure 222. Use the Utilities Tab to Delete Temporary Files.



Keyboard and Screen Languages

Set the language for the Graphical User Interface from this dialog box.

Languages can be selected for the keyboard and the screens. The default keyboard language and screen language is U.S. English. If a different keyboard language is to be used, follow the steps in “Selecting a Keyboard Language” to select the keyboard language. If a different screen language is to be used, follow the steps in “Selecting a Screen Language” to select the screen language.

Selecting a Keyboard Language

NOTE: The keyboard language applies to all users of the system.

To select a keyboard language, click the keyboard icon in the upper-right corner of the Login screen, and select the language from the displayed list that matches the keyboard to be used.

Selecting a Screen Language

NOTE:

- The screen language is associated with the login name.
- If the screen language selected is Chinese or Japanese, the user can toggle between English characters and Chinese characters, or between English characters and Japanese characters, by holding down the Ctrl key and pressing the spacebar.

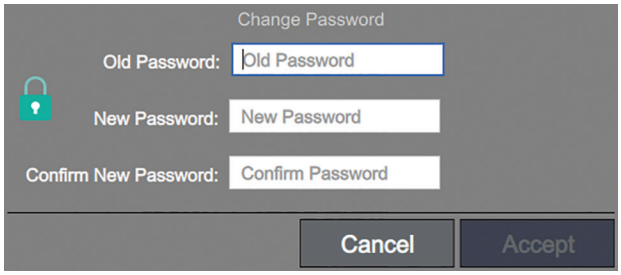
1. Log in to the system.
2. Click on the Language icon in the lower right corner of the screen.
3. Select a language from the displayed list, and then click the Change Language button. During login, the system will ask if the screen language selection is to be used for only the current session or for all sessions.

   NOTE: The user must log out and log back in to the system for the change to take effect.

Change Password

The current user may change their password from this dialog box.

Figure 223. Change Password dialog box.



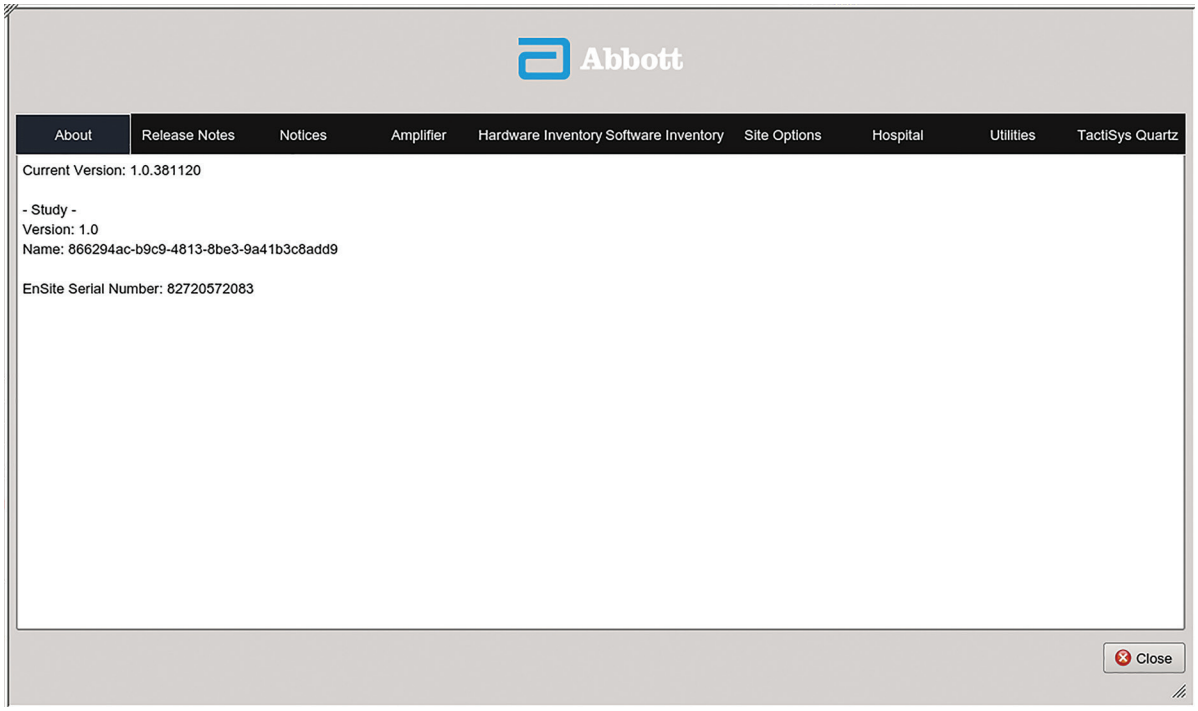
1. Old Password field – Enter old password
2. New Password field – Enter new password
3. Confirm New Password field – Confirm by typing new password again
4. Cancel button – Cancel changes to password
5. Accept button – Accept the new password

About the System

Displays a variety of system information, including the software release notes, controls for setting the system clock, controls for establishing the hospital name, utilities for advanced technical support, and notices.

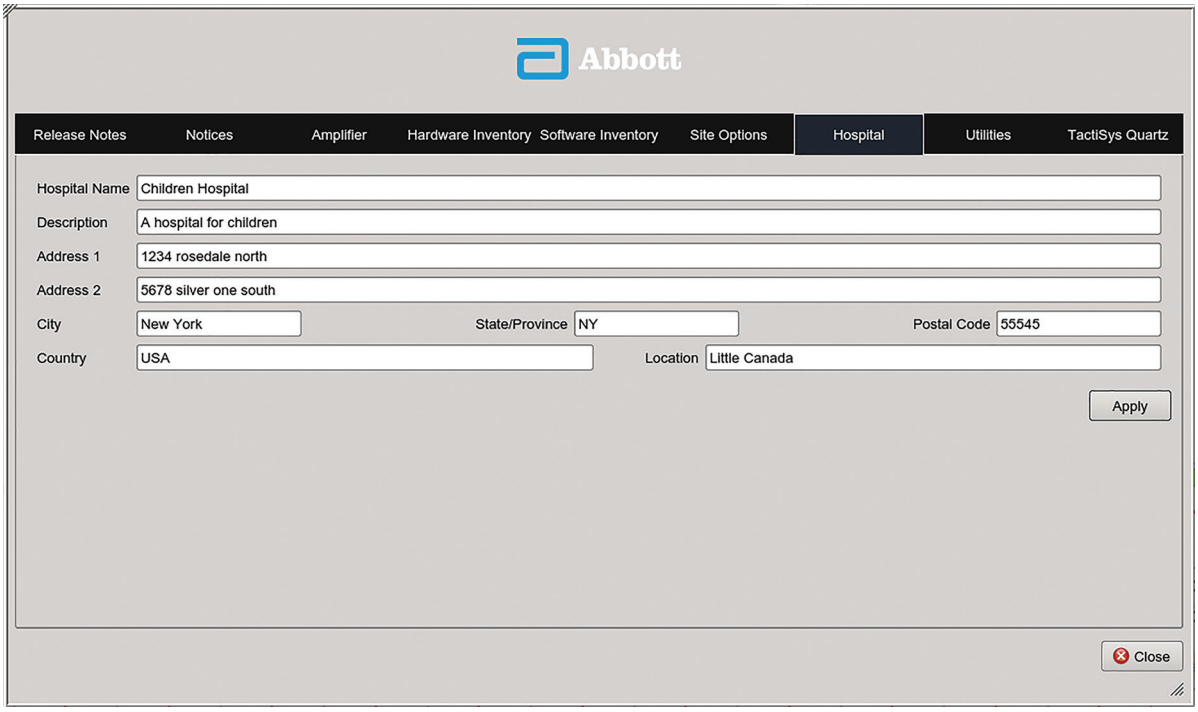
About the System - About tab

Figure 224. About the System – About tab



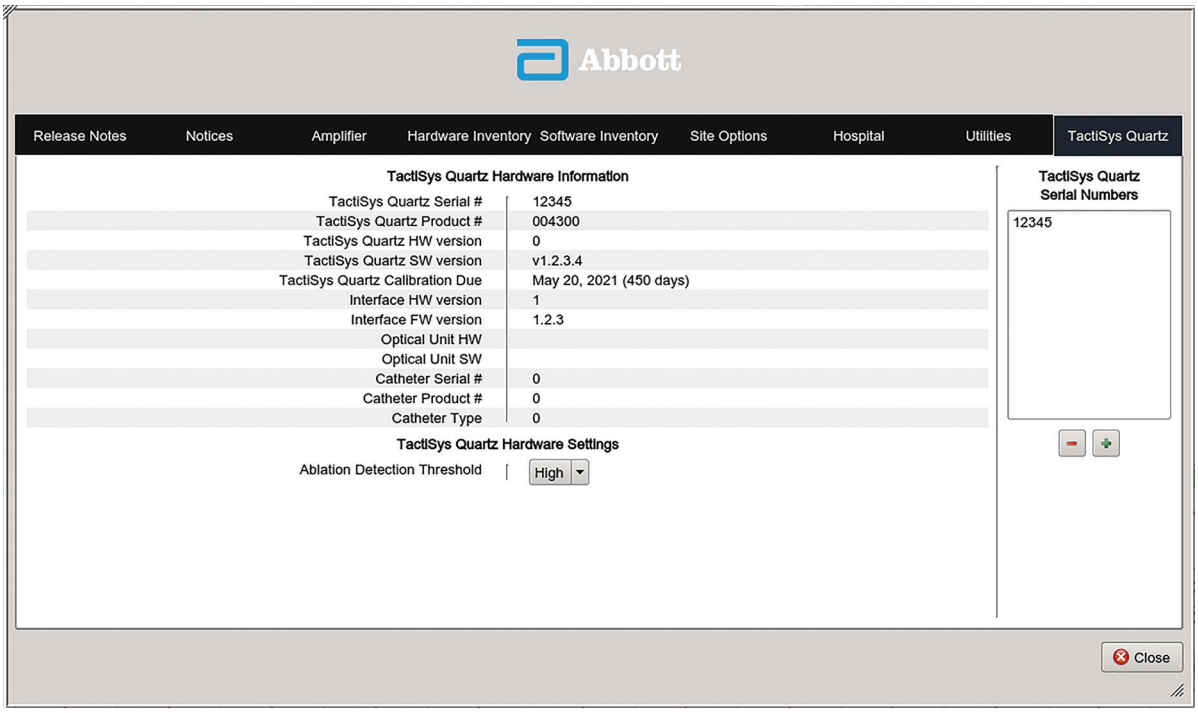
About the System - Hospital tab

Figure 225. About the System – Hospital tab



About the System - TactiSys Quartz tab

Figure 226. About the System – TactiSys Quartz tab



Services Menu

Services Menu Description

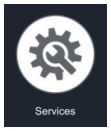
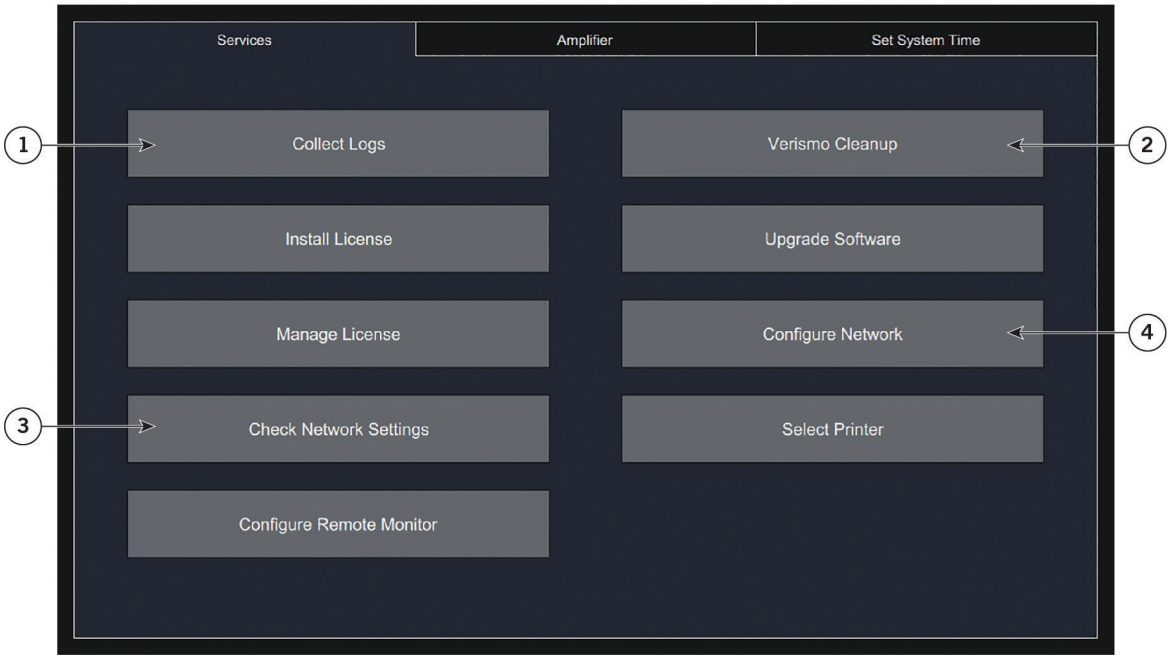


Figure 227. The Services Menu



1. Collect Logs: export logs to CD/DVD or USB device.
2. Verismo Cleanup: cleanup unneeded files.
3. Check Network Settings.
4. Configure Remote Monitor.

To Setup the Remote Monitor

1. Select the About EnSite™ X EP System button and then select the Utilities tab.
2. Select the Run External Program button.
3. Select the Remote_Monitor_Config tool and click Run.
4. Select the connected monitor from the drop-down box and click OK.
5. Select Reboot Now to complete the setup.

Setting the Site Information

Setting the System Clock

1. Login as the Service user.
2. From the title screen, click Services and select Set System Time.
3. Adjust the Set System Time section on the left side of the screen using the arrow buttons to set the current time.

   NOTE:

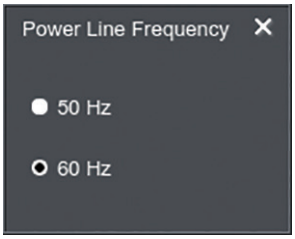
   - This is a 24-hour clock. The clock can only be set to a time that is at least 18 hours later than the time that the last study ended.
   - After the user sets the system clock, the system prompts the user to confirm system shutdown.

Setting the Powerline Frequency

The powerline frequency can be set to either 50 Hz or 60 Hz. For North American locations, 60 Hz is generally appropriate. For European locations, 50 Hz is generally appropriate.

1. During a study, select the Application Menu icon at the bottom left of the screen >Amplifier > Amplifier Settings > Power Line.
2. Use the Powerline Frequency checkboxes to select a powerline frequency.

Figure 228. Setting the Powerline Frequency



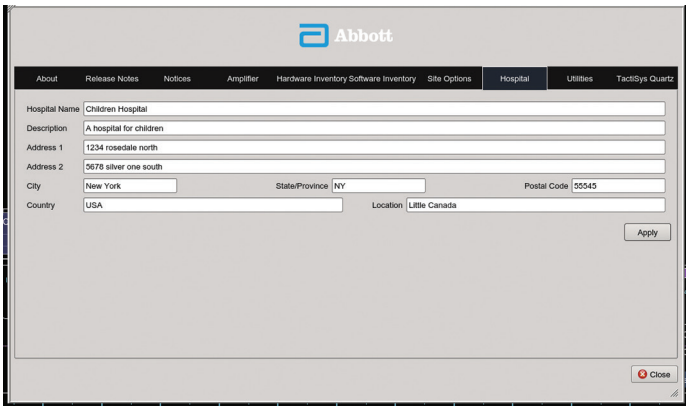
Setting the Owner Information

Information about the hospital can be entered into the software. The saved hospital name is displayed on the title screen and saved with studies on the external media. From the title screen, select Services and then click the Hospital tab. Complete the available fields and select Apply.

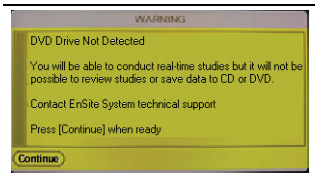
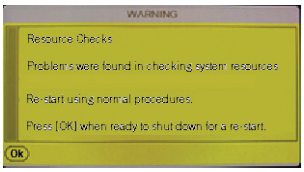
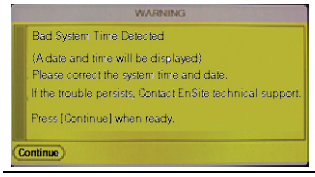
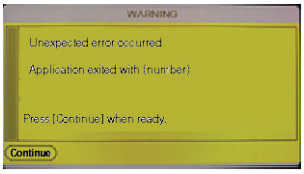
The owner information is used to administer support tools such as SJM™ Connect.

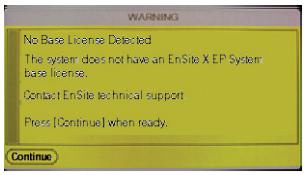
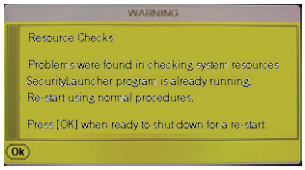
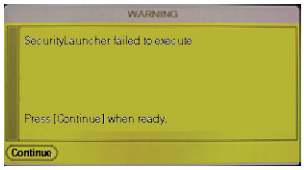
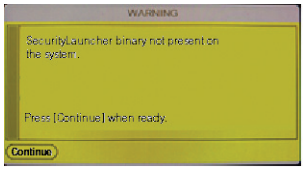
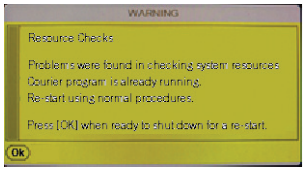
NOTE: If multiple EnSite™ X EP Systems are present at the same location, enter an identifier such as “LAB A.”

Figure 229. The owner information helps Abbott Technical Support organize information.



Error Messages

Error Window	Error Message	Additional Information
	DVD Drive Not Detected You will be able to conduct real-time studies but it will not be possible to review studies or save data to CD or DVD. Contact EnSite System technical support Press [Continue] when ready	Indicates a hardware fault with the CD/DVD drive
	Resource Checks Problems were found in checking system resources. Restart using normal procedures. Press [OK] when ready to shut down for a re-start.	If the error persists after re-start contact technical support.
	Bad System Time Detected (A date and time will be displayed) Please correct the system time and date. If the trouble persists, Contact EnSite technical support. Press [Continue] when ready.	The system administrator can check the system time setting to adjust to the correct time.
	Unexpected error occurred Application exited with (number) Press [Continue] when ready.	Restart the computer. A user with Service access may run collect logs and contact technical support.

Error Window	Error Message	Additional Information
	No Base License Detected The system does not have an EnSite X EP System base license. Contact EnSite technical support Press [Continue] when ready.	The user should discontinue system usage and contact technical support for a license.
	Resource Checks Problems were found in checking system resources. SecurityLauncher program is already running. Re-start using normal procedures. Press [OK] when ready to shut down for a re-start.	If the error persists, contact technical support.
	SecurityLauncher failed to execute Press [Continue] when ready.	Restart the computer. If the error persists, contact technical support.
	SecurityLauncher binary not present on the system. Press [Continue] when ready.	Restart the computer. If the error persists, contact technical support.
	Resource Checks Problems were found in checking system resources Courier program is already running. Re-start using normal procedures. Press [OK] when ready to shut down for a re-start.	Restart the computer. If the error persists, contact technical support.

System Icons

Table 11. System Icons

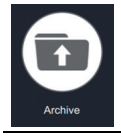
Icon	Description	Function
	Back Button	Returning to previous screen
	Power Button	Powering off the system
	Login Button	Logging into system
	New Study	User can begin a new study within the system
	Past Study	User can access a previously-recorded study in Off line Review environment
	Last Study	User can retrieve and access the most recent study completed in the system
	Import	User can import a study or information to the system
	Archive	User can archive files and studies
	Verismo	User can access the EnSite™ Verismo™ Segmentation tool

Table 11. System Icons

Icon	Description	Function
	Clinical	Grants permission to perform studies on cardiac mapping system
	Services	Grants permission to perform service on cardiac mapping system and provides access to functions required to maintain the DWS
	Training	Grants permission to access studies in training mode
	Administrator	Grants only the administrator permission to perform certain tasks
	Grant Credentials	Grant Credentials
	Research	Grants permission to access research information
	Access User	Internal access user
	CD	Icon found on past study studies review screens
	Tools List	Properties used to control the filter settings for the waveforms and the settings used for manipulating the displayed waveforms
	Auto-Record Settings	Allows a user to set-up a certain auto-record setting preference
	Presets	Provides access to the list of presets available for the current panel.
	Center Model	Centers the model back into view, if it is beyond the borders of the screen.
	Clean-Up Display	Cleans up items/elements from the screen
	Split View / Standard View	Switches between single and split screen views
	Full Screen	Hides the Work Panel and displays the Model/Map area in full screen view
	Mobile Panel	Allows the user access to Detection Sources and AutoMap Thresholds to support simultaneous workflow of mapping, therapy tasks, and full screen view.
	Access To Set-Up Link	Provides access to study setup screens (patient/study details, hardware map, etc.)
	Meters & Display Options Settings Panel	Display options for meters, filters, model & map display settings
	Catheters & Waveforms Settings Panel	Specifications, attributes, setup, signal settings, waveform attributes
	Model, Dif & Fusion Settings Panel	Model surface properties, DIF & fusion options
	Map Settings & Signals Settings Panel	AutoMap thresholds, CFE settings, detection settings, map appearance, map display, points/labels, settings
	Automark & Contact Force Settings Panel	Metrics, placements settings, visible thresholds, CF display, CF stability
	Navigation Settings Panel	Provides quick access to setup functions and parameters. It contains functions related to the catheter navigation, respiration compensation, PRS setup, and Metal setup.
	Active EnGuide Icon	Icon selector for Active EnGuide tools such as creating surfaces, placing labels, placing lesions, and collecting points for maps
	Waveform Display	Used to select the waveform type in the panels when changing the layout of the workspace- also used as links to the fly out options

Table 11. System Icons

Icon	Description	Function
	Detection Settings / Acquisition Waveforms	Used to select the waveform type in the panels when changing the layout of the workspace- also used as links to the fly out options
	Generator Waveforms	Used to select the waveform type in the panels when changing the layout of the workspace
	Color	Controls the color
	D/Dt	Sharpness of slope, regardless of positive or negative value
	Caution	Shown when there is a condition that might cause a problem in the future or if the user proceeds, but the user is still able to proceed
	Problem/Issue	Shown when a problem has already occurred, and the issue must be corrected to proceed
	Approved	Detectable components have been detected and approved by the system
	Notice	Informs and notify users of points and recommendations for efficient and accurate set up
	Help Tool Tip Icon	Displays additional help text when hovered over with the mouse cursor
	Question Mark Pop- Up	Configure signal detection settings
	No Button	Appears on "No" buttons on pop-up messages
	Yes Button	Appears on "Yes" buttons on pop-up messages
	Check Mark	Icon used for checking boxes
	"Stop Automap" Button Icon	Appears on "Stop AutoMap" button
	Rotate/Pan Tool	Used to rotate the model or map
	Pointer Tool	Used for selection
	Label Tool	Used to annotate a model or map
	Marker Tool	Used to create anatomic markers
	Tape Measure Tool	Used to create tape measures
	Lesion Tool	Used to create lesions
	Shadow Tool	Used to place a shadow on the selected EnGuide
	Caliper Tool	Add a timing caliper
	Double Arrow Tool	Used for dragging the appearance window in the workspace
	Chart With Gear	Displays the Courier Settings Window

Hot Keys

Shift+	Alt+	Ctrl+	CHR	Action
			A	Rotate around vertical axis
		X	A	Select All Points
			B	Enable Label Tool
		X	B	Save Bookmark
			C	Enable Caliper Tool
			D	Rotate around vertical axis
		X	E	Save Event
		X	G	Select all points in the group
X		X	G	Add all points in the group to existing selection
			H	Enable EnGuide Shadow Tool
			L	Enable Lesion Tool
		X	L	Locate selected point in the Map Display
			M	Enable Marker Tool
			O	Open (Show) Tool Tag List
			P	Enable Pointer (Arrow) Tool
		X	Q	End Study
			R	Enable Rand (Rotate/Pan) Tool
	X		R	Collect Respiration Data
			S	Rotate around horizontal axis
			T	Enable Tape Measure Tool
			W	Rotate around horizontal axis
			F1	Display Help Dialog
			F2	Not used
			F3	Synch display between split-screen views
			F4	Record a Segment
			F5	Enable/Disable EnGuide
			F6	Add Lesion at EnGuide
X			F6	Add 3D Lesion at EnGuide
			F7	Not used
			F8	Saturation Recovery
			F9	Stop All Collection (Model and AutoMap)
			F10	Not used
			F11	Freeze/Save a Mapping Point
X			F11	AutoMap Start/Stop
			F12	Cancel/Discard the Current Mapping Point
		X	PrtScr	Save Image
			Delete	Delete selected points
			Delete	Delete point group
			Right Arrow	Step Forward
			Left Arrow	Step Backward

F1	Quick Help		Right Arrow	Step Forward
F2			Left Arrow	Stop Backward
F3	Synchronize Split Screen			
F4	Record On/Off			
F5			Ctrl+F5	Impedance/NavX Current
F6	Add Lesion at EnGuide		Shift+F6	Add 3D Lesion at EnGuide
F7			Ctrl+B	Save Bookmark
F8	Saturation Recovery		Ctrl+Print	Save Image
F9	Stop All Collection		Ctrl+E	Save Event
F10	Force Exit		Ctrl+Q	End Study
F11	Freeze		Shift+F11	AutoMap Start/Stop
F12	Cancel			
			Alt+R	Collect Respiration Data

Glossary

Table 12. Glossary

Term	Defintion
3D	Three-dimensional.
ABL	Ablation.
Accession Number	Sequential numbers assigned by imaging vendors as unique identifiers of an examination.
Active EnGuide	The catheter that is used for creating surfaces, placing labels, placing lesions, and collecting points for maps.
Active EnGuide Silhouette	A silhouette outline of the Active EnGuide where it resides inside the chamber of interest. The outline takes on the color of the assigned Active EnGuide color.
Anatomic marker	A tool that is used to connect points on the surface of the model with lines.
Animations	Recorded video segments from a study.
AP	Anterior Posterior.
Application Context	The specification of the type of communication used between Application Entities. Example: DICOM network protocol.
Application Entity (AE)	An end point of a DICOM information exchange, including the DICOM network or media interface software; i.e., the software that sends or receives DICOM information objects or messages. A single device may have multiple Application Entities.
Asynchronous	Asynchronous Storage Commitment is returned to the requestor in a different DICOM association than the one by which the request was sent (see Synchronous).
Auto Segment	The system automatically records segments to periodically store study information. These automatically recorded segments are added to the Notebook where they are identified as type Auto Segment.
Bio Impedance Scaling	A feature that corrects for the slow drift of the EnSite NavX™ positions caused by a change in the saline concentration within body fluids over the course of a study.
Bookmark	A feature that allows the system to return to a specific time in review environment.
Boundary emphasis	Segmentation technique used to sharpen the edges of a structure so that the computer can identify what the user sees as boundaries.
Calipers	A tool that is used to measure and adjust timing between signal features in the waveform display.
Cardiac Triggered Maps	Maps that use a surface electrocardiogram or an intra-cardiac electrogram as the reference to which collected points are measured.
Catheter Catalog	A collection of predefined catheters that can be used in a study.
CFE	Complex Fractionated Electrogram.
CFE Mean maps	Maps that provide a fractionation index based on the cycle length between multiple, discrete, local activations in an electrogram.
CFE Standard Deviation map	A map that provides a fractionation index based on the cycle length between multiple, discrete, local activations in an electrogram.
CIFS	Common Internet File System.
CIM	Catheter input module.
CL	Cycle Length. Cardiac Cycle Length.
Clipping Plane	Clipping planes allow for a view of the interior and rear of the closed map by cutting a plane away from the viewing space.
Color High	A specific map value to be displayed as purple.
Color Low	A specific map value to be displayed as white.
Coronal plane	Image plane that divides the body vertically into a front and back. Also called the frontal plane.
CT	Computed Tomography.
CT scan	Imaging technique that provides a 3D computer model of a patient's anatomy. CT (computed tomography) scanners use detectors rather than film to collect and digitize x-ray images. CT images are used to examine cross-sections (slices) of the heart from all angles.
D3D	DIF three-dimensional.
DHCP	see Dynamic Host Configuration Protocol.
DICOM	Digital Imaging and Communications in Medicine; an industry standard that facilitates interoperability of medical imaging equipment.
DICOM Header	A text-based portion of a DICOM file that describes the image dimensions and other information about the scan.
DIF	Digital Image Fusion (DIF) Three-dimensional models created from digital images collected from Spiral CT or MRI scans.
Distal Length	The length of the distal electrode, which is located at the tip of the catheter.
DWS	Display Workstation.
Dynamic Host Configuration Protocol (DHCP)	Used to automatically assign IP addresses, deliver TCP/IP configuration parameters (such as the subnet mask and default router) and provide other configuration information such as the addresses of time servers. DICOM requires fixed IP addresses and the configuration of AE Titles at each individual device.
ECG	Electrocardiogram.
ECG electrodes	Patch electrodes on the patient's skin, used to collect extra-thoracic cardiac signals.
Electrode	A conductor which collects voltage signals from a patient.
Electrode Spacing	The distance from the edges of the electrodes on a catheter (not the distance from the centers of the electrodes).
Electrogram	A waveform which represents a voltage signal generated from a patient.

Table 12. Glossary

Term	Defintion
EnGuide Alignment	A tool used to manually adjust the alignment of EnGuides relative to the model.
EnGuide Shadows	A three-dimensional historic image of an EnGuide position a three-dimensional historic image of an EnGuide position.
EnGuide	The display of an EP catheter in the map display.
Enhanced CT and MR images	This refers to the multi-frame image objects defined by the DICOM standard for CT and MR. The new multi-frame image objects collect frames into a single file with a standard structured header. This reduces the data size and file transfer overhead.
Enhanced DICOM Object	The new enhanced objects for MR, CT, XA and RF (radiography/fluoroscopy) accommodate new developments and acquisition techniques. As an example, for MR, the image data will be exchanged not only as individual images, but as multiframe objects. Multiframe objects are a convenient way to package all the pixel data of a complete acquisition in one message (or envelope). The differences between the individual frames of the multiframe object, such as the frame-rate, are described in the multiframe header.
EnSite™ Courier™	A software application that enables the EnSite™ X EP System user to communicate with the hospital PACS server for the purposes of storing and retrieving patient data in DICOM format.
EnSite NavX™ Mode	A navigation mode where EP Catheter locations from sensed potential on each axis of an orthogonal electric field generated by body surface electrodes.
EnSite™ Verismo™ Segmentation Tool	a software utility used to convert large volumes of slice-based images into a manageable 3D model of cardiac structures.
EnSite™ VoXel™	A navigation mode where the catheter locations are mainly based on the magnetic signals generated by Sensor Enabled™ catheters in conjunction with the Field Frame.
EnSite™ X Amplifier	The EnSite™ Amplifier accepts signals from the accessory modules and converts these signals to digital format, and sends them to the DWS for processing. The EnSite™ Amplifier is connected to the DWS through a fiber optic cable.
EP catheter electrodes	The tip or ring electrodes on the shaft of an EP catheter which must be in contact with the endocardial wall to collect electrical signals.
EPS	a DICOM modality type for basic cardiac electrophysiology, the specification for digitalized electrical signals from the patient cardiac conduction system collected in the heart. EPS is the modality type used to store EnSite X™ Velocity™ Cardiac Mapping System studies.
Field Scaling	A feature that provides patient-specific scaling of EnSite™ NavX™ dimensions to allow for distance measurements in EnSite™ NavX™ mode studies.
Highpass Filter	A filter that reduces low-frequency signals (i.e., repolarization signals) and baseline drift.
IOD	Information Object Definition: the specified set of Attributes that comprise a type of data object; does not represent a specific instance of the data object, but rather a class of similar data objects that have the same properties. The Attributes may be specified as Mandatory (Type 1), Required but possibly unknown (Type 2), or Optional (Type 3), and there may be conditions associated with the use of an Attribute (Types 1C and 2C). Examples: MR Image IOD, CT Image IOD, Print Job IOD.
Intra-Cardiac Electrogram (IEGM)	An electrogram produced using catheters placed within the heart.
IP Address	a numerical label that is assigned to devices participating in a computer network that uses the Internet Protocol for communication between its nodes. An IP address serves two principal functions: host or network interface identification and location addressing. An IP Address can either be fixed or dynamic (see DHCP).
Isochronal Map	A map that shows the progression of activation through the first surface.
Isopotential Map	A map of voltages on the endocardial surface where similar voltages are represented by similar colors.
Labels	Markers that are used to identify points on the model.
LAO	Left Anterior Oblique.
LAT	Local Activation Time.
LED	Light Emitting Diode.
Lesion	Markers that are used to identify ablation points on the model.
Local Activation Time (LAT) Isochronal Map	A map that shows color-coded activation times for each collected location (or nearest surface).
Lowpass Filter	A filter that reduces high-frequency signals commonly caused by electronic interference.
Low-V ID	An adjustable low voltage identification option (Low -V ID) allows low-voltage potentials to appear in gray instead of affecting the color pattern. Low-V ID is available for Local Activation Time (LAT) isochronal maps and Complex Fractionated Electrogram (CFE) maps.
Model	The geometric surface model which describes the size, shape, and orientation of a heart chamber(s).
MRI	Magnetic Resonance Imaging.
MRI Scan	Imaging technique that uses magnetic signals rather than x-rays to provide a 3D model of the patient's anatomy. MRI (magnetic resonance imaging) is based on the absorption and emission of radio wave pulses of energy. MRI images are used to examine cross-sections (slices) of the heart from all angles.
Navigation Accuracy	The error in navigating a catheter back to a defined location.
NFS	Network File System.
Noise Filter	A notch filter that reduces powerline noise.
Non-Cardiac Triggered Maps	Maps that are created by collecting points at one second intervals.
Notebook	A feature that allows recorded data and study information to be filed and annotated for future access.
Offline Review	An operating mode in which data from a previous study is viewed and edited. The EnSite™ Amplifier does not need to be connected or powered on.
OneModel Tool	Default type for model creation. The OneModel tool wraps the model surface tightly around collected points without tying back to a center point and may provide enhanced anatomic detail of the cardiac model.

Table 12. Glossary

Term	Defintion
Orientation Reference	A torso-shaped icon in the upper right of a map that indicates the current orientation of the map by rotating as the map rotates.
Orthogonal	Intersecting or lying at right angles. The axes of scanned orthogonal images are perpendicular to each other and to the coronal (frontal), transverse (horizontal), and sagittal (medial) planes of the body.
PACS	Picture Archiving and Communication Systems: An electronic information system for acquiring, sorting, transporting, storing, and electronically displaying medical images.
Peak-Negative (P-Neg) Voltage Map	A map that displays color-coded voltage values for each collected location (or nearest surface).
Peak-to-Peak (P-P) Voltage Map	A map that displays color-coded voltage values for each collected location (or nearest surface).
Perspective View	A feature that allows the field of view, or perspective of the model, to be changed to increase the understanding of the model, the position of the catheters and/or the identification of points of interest.
Pixel	Smallest distinguishable element of a digital image.
Polarity	A voltage is the difference between positive and negative poles. The polarity defines these poles.
Port Number	a numerical identifier for the data structures of the endpoints for host-to-host communications.
Positional Reference	An electrode that will remain stable during an EnSite™ NavX™ study. The displayed position of all electrodes is relative to the location of the positional reference.
Proximal Electrode	Any catheter electrode other than the distal electrode.
RAO	Right Anterior Oblique.
RealReview	A task in which recorded segments can be viewed.
Realtime mode	An operating mode in which data is gathered, displayed, and recorded simultaneously while a patient is being studied. Patient connections to the EnSite™ Amplifier are required, and the EnSite™ Amplifier must be powered on.
Reference Signal	The reference signal monitors a specific voltage point, based on the detection algorithm, of a specific waveform to aid in the collection of activation data.
Render	To translate and regenerate an image. In the EnSite™ Verismo™ Segmentation Tool, heart structures are isolated from a volume of scanned images and rendered for 3D visualization.
Resolution	Minimum distance at which two adjacent objects can be distinguished as separate.
RespComp X	A feature that is used to compensate for catheter movement caused by a patient's breathing.
Respiration Meter	A meter that shows the current level of respiration, as computed by the relative impedance on the EnSite™ surface electrodes.
Irregular Respiration	A feature that is used to suspend model point collection and labeling functions when the patient's respiration falls outside of a percentage of the Respiration Compensation range.
RF	Radio Frequency.
Rotational Angiography (RA)	A type of X-ray angiography where a series of images is acquired while the RA modality C-arm performs a continuous rotation around the region of interest.
Roving Activation Interval	A timing parameter that is used in the detection of roving catheter activation.
Roving Signal	The roving signal is used for sampling local activation times (relative to the timing reference signal) and voltages from various locations in the heart.
Sagittal plane	Image plane that divides the body into a right and left half. Also called medial plane.
Saturated Waveform	When a signal amplitude has reached its maximum value.
Saturation Recovery	A feature that allows for the quick recovery of signals to facilitate identification of post-therapy complexes.
Seed point	Reference point used by the EnSite™ Verismo™ Segmentation Tool to identify the heart structure of interest.
Segment	A recorded part of a study.
Segmentation	In digital image analysis, segmentation is the process of isolating the object of interest (foreground) from the rest of the objects in the image (background).
Service Class Provider (SCP)	Role of an Application Entity that provides a DICOM network service; typically, a server that performs operations requested by another Application Entity (Service Class User). Examples: Picture Archiving and Communication System (image storage SCP, and image query/retrieve SCP), Radiology Information System (modality worklist SCP).
Service Class User (SCU)	Role of an Application Entity that uses a DICOM network service; typically, a client. Examples: imaging modality (image storage SCU, and modality worklist SCU), imaging workstation (image query/retrieve SCU).
Service/Object Pair (SOP) Class	The specification of the network or media transfer (service) of a particular type of data (object); the fundamental unit of DICOM interoperability specification. Examples: Ultrasound Image Storage Service, Basic Grayscale Print Management.
Service/Object Pair (SOP) Instance	An information object; a specific occurrence of information exchanged in a SOP Class. Examples: a specific x-ray image.
SJM™ Connect	A feature that enables an AbbottTechnical Support representative to connect to the DWS through a broadband Internet connection to perform remote technical support.
Stabilize ABL	Stabilize ABL corrects the location of the distal electrode based on the properties of the catheter. ABL electrodes 2, 3, and 4 need to be displayed for Stabilize ABL to be enabled. **WARNING: Do not use Stabilize ABL in situations where electrodes 2, 3, or 4, on the ablation catheter, are covered by a sheath.**
Std Dev	Standard Deviation.
Storage Commitment	The DICOM storage commitment service is used by the modality or workstation to confirm that an image has been permanently stored by a device, usually a server and/or archive station, and it is safe to delete the images locally.
Surface Proximity Distance	The distance from the Active Electrode to the model or DIF surface.
Sweep Speed	The number of mm/secs in the waveform display (time scale).

Table 12. Glossary

Term	Defintion
Synchronous	Synchronous Storage Commitment is returned using the same DICOM association (a DICOM communication session) as the one by which the Storage Commitment request was sent (see Asynchronous).
System Reference Surface Electrode	A surface electrode that is required for proper system operation for EnSite™ X EP System studies. The system reference surface electrode connects to the SurfaceLink™ Module.
Tape Measure	A tool that is used to measure the distance between points on the model of the endocardial surface.
Threshold	A voltage level at which an event is detected.
Thresholding	Segmentation technique that uses intensity values to distinguish between the foreground and background objects of a digital image. The intensity threshold is chosen from a histogram of intensity values for the image.
Time Cursor	A vertical yellow line in the waveform display that indicates the time represented by the map display.
Traces	Waveforms.
Tracking Accuracy	The error between an induced catheter displacement and the corresponding measured displacement.
Transfer Syntax	the encoding used for exchange of DICOM information objects and messages. Examples: JPEG compressed (images), Little Endian explicit value representation.
Transverse Plane	Image plane that divides the body into upper and lower portions. The transverse plane is perpendicular to the coronal and sagittal planes. Also called horizontal plane, axial plane, or transaxial plane.
Trigger Event	The detection event plus a user selectable time offset.
Triggering	To 'phase lock' both the waveform and the map displays, providing a view of the data which is synchronized with each triggering event. Thus, when the triggering event is a heartbeat the waveforms and maps shall be repeatedly displayed, frozen at the same point in time of each heart cycle.
Unipolar Reference	The signal return path for unipolar diagnostic catheter signals.
Unique Identifier (UID)	a globally unique “dotted decimal” string that identifies a specific object or a class of objects; an ISO-8824 Object Identifier. Examples: Study Instance UID, SOP Class UID, SOP Instance UID.
Velocity Filter	A feature that prevents model point collection during rapid catheter movements.
Velocity meter	A meter that shows the relative velocity of the fastest unsheathed enabled electrode of the Active EnGuide.
Voltage Caliper	A tool that displays the measured potential at the distal signal of the Active Electrode.
Volume	Set of cross-sectional images obtained when scanned slices are stacked in computer memory. A volume or volumetric data set is based on inter-pixel and inter-slice distances that represent a real-world volume.
Waveform	A representation on the screen of all the data from a signal within a defined timeframe where time moves from left to right and the height of the waveform represents the amplitude of the signal.
Waveform Display	The area on the screen in which waveforms are displayed.
XA	X-ray angiography images.

Service and Technical Support

The troubleshooting guide in this document is intended to help resolve problems with the system. If problems cannot be resolved by using the suggestions presented here, contact your EnSite™ X EP System field representative or distributor.

Local Number: 651-756-6985

Toll Free: 855-478-5833

Email: USDTechSupport@abbott.com

Technical Specifications

Environmental Specifications

Component	Operating Temperature	Operating Humidity	Operating Altitude	Storage and Transport Temp	Storage and Transport Humidity	Storage and Transport Altitude
DWS	Ambient Temperature: +18° C to +27° C, inclusive	Relative Humidity, non-condensing: 30% to 75%	Altitude: 0 m to 3000 m	Ambient Temperature: -10° C to +50° C, inclusive	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 5574 m

The EnSite™ X EP System has a Class I safety classification.

Standards of Compliance

ETL CLASSIFIED

C ETL LISTED US

Intertek 3166204

Conforms to EN 60601-1, EN 60601-1-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366-1; Certified to CAN/CSA 22.2 No.60601-1.

All configurations should comply with the system standard EN 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system and is, therefore, responsible that the system complies with the requirements of the system standard EN 60601-1-1. If in doubt, consult the technical services department or your local representative.

Isolation Transformer

EN 60601-1, Ed. 3.1 approved Isolation Transformer models ISB-1462 (US), ISB-1499 (JPN), or ISB-1520 (EU) to be used for connection of the EnSite™ X Amplifier and Medical Electrical (ME) System equipment installed on the Amplifier and DWS carts. A total of two (2) Isolation Transformers are used for a complete EnSite™ X EP System.

NOTE: Do not position the isolation transformer so that it is difficult to disconnect from power.

EN 60601-1, Ed. 3.1 approved Isolation Transformer models ABC600-11MED (US, JPN) or ABC750-22MED (EU) to be used for connection of the optional remote monitor stand.

NOTE: Do not position the isolation transformer so that it is difficult to disconnect from power.

Recording System Input Impedance

External recording equipment must meet the safety requirements of BS EN 60601-1 "Medical electrical equipment Part 1: General requirements for basic safety and essential performance".

Input impedance should be greater than 2.5 megohms when measured at 40Hz. Additionally, to optimize EnSite NavX™ performance, input impedance should be greater than 25k ohms channel-to-channel when measured at 8kHz.

Patient Environment Information

Non-Patient Environment

EnSite™ X EP System Display Workstation (DWS) Cart including: EnSite™ X EP System DWS, Keyboard, Mouse, Printer, Local Monitor, Isolation Transformer, Fiber Optic Video Extender and associated cabling.

NOTE: The EnSite™ X EP System DWS Cart is an optional component. Components are considered to be a part of the non-patient environment regardless of if they are on a cart.

Patient Environment

EnSite™ X EP System Amplifier Cart including: EnSite™ X EP System Amplifier, EnSite™ X EP System Field Frame, EnSite™ X EP System SurfaceLink Module, EnSite™ X EP System Patient Reference Sensors, and associated cabling.

NOTE: The EnSite™ X EP System Amplifier Cart is an optional component. Components are considered to be a part of the patient environment regardless of if they are on a cart.

EnSite™ X EP System Remote Monitor Stand including: Remote Monitor, Isolation Transformer, and Fiber Optic Video Extender, and associated cabling.

NOTE: The EnSite™ X EP System Remote Monitor Stand is an optional component. Components are considered to be a part of the patient environment regardless of if they are on a cart.
NOTE: The Remote Monitor is an optional component. If included, it can reside on the EnSite™ X EP System Remote Monitor Stand or the EnSite™ X EP System Amplifier Cart.

Disposal

- The IFU is recyclable.
- After use, device(s) and packaging should be appropriately classified for disposal, e.g. electrical equipment, non-hazardous waste, etc. and carefully disposed of in compliance with facility procedures and applicable laws and regulations. Discard any unused components after the procedure.

Reporting Device Incidents

If, in the course of use of this device, you have reason to believe that a serious incident occurred, please report it to the manufacturer. For customers in the European Union, report the serious incident to your national authority as well as to the manufacturer.

Cybersecurity

- The site controlling the device should have policies in place prescribing the physical safety and security of the devices in the electrophysiology laboratory. For example, physically securing devices and information should include policies that limit physical access, securing equipment in locked rooms, managing access to secured rooms, and restricting the ability to remove devices from a secure area.
- Inspect the device; discontinue use if there is visible evidence of tampering.
- In the event of a suspected cybersecurity issue, discontinue use of the EnSite™ X EP System and contact Abbott Technical Support.

Limited Warranty

Abbott Medical warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the "Expiration" date stated on any product labeling. The authorized uses and approved methods of use of each of our products is set forth in the related "Instructions for Use" that accompany each product. Abbott Medical disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. Abbott Medical's liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Abbott Medical disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. Abbott Medical neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete Abbott Medical warranty policy available from Abbott Medical or on the back of an Abbott Medical invoice.

Symbols

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Symbol	Definition
	Medical Device
	Unique device identification number
	Importer
	Consult instructions for use on this website
	Affixed to this device in accordance with European Council Directive 2012/19/EU. This directive calls for separate collection and disposal of electrical and electronic equipment. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem.

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

ETL CLASSIFIED C ETL LISTED US Intertek 3166204	Intertek Safety Agency Certification Mark
CE 2797	Conformité Européenne (European Conformity). Affixed in accordance with European Council Directive 93/42/EEC (NB 2797) and 2011/65/EU. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.
Rx ONLY	USA only: Federal law restricts this device to sale by or on the order of a Physician

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