ENSITE PRECISION™ CARDIAC MAPPING SYSTEM

Accuracy of the EnSite™ NavX™ Navigation and Visualization Technology, Sensor Enabled™

ST. JUDE MEDICAL

PRINCIPLE OF OPERATION

The EnSite Precision™ System is a 3-D cardiac mapping system that uniquely combines impedance and magnetic field technology to enable precise navigation and accurate tracking of conventional and St. Jude Medical™ Sensor Enabled™ electrophysiology catheters during the creation of three-dimensional maps based on the anatomy of the cardiac chamber. An EnSite Precision™ Cardiac Mapping System procedure using EnSite™ NavX™ Navigation and Visualization Technology, Sensor Enabled™ is performed using hardware components and disposable products.

Hardware

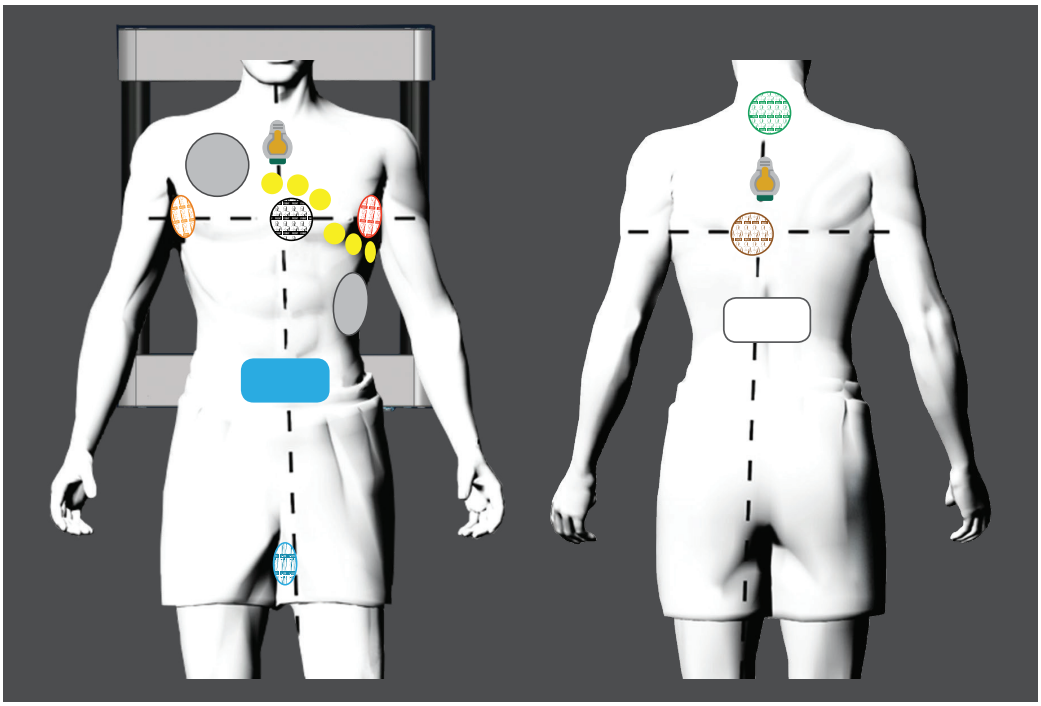
The EnSite Precision™ field frame universally mounts underneath the patient bed and generates a low-powered magnetic field within which the position of a Sensor Enabled™ device can be detected. The EnSite Precision™ link, Sensor Enabled™ connects Sensor Enabled tools, including catheters, patient reference sensors (PRSs) and the field frame and relays the information to the EnSite amplifier via fiber-optic connection.

Disposables

The EnSite Precision™ surface electrode kit consists of a system reference surface electrode and six surface electrodes that are placed on the patient in pairs: anterior to posterior, left to right lateral, and superior (neck) to inferior (leg) (Figure 1). The three electrode pairs form three orthogonal axes (X-Y-Z), with the heart at the center. Two PRSs are also used with the EnSite Precision System: a PRS anterior, and a PRS posterior. The PRSs are connected to the patient using disposable, self-adhesive patches, and primarily function as sensors for metal distortion and patient movement.

During model collection, both impedance-based points and magnetic-based points are collected from a Sensor Enabled™ tool.

Figure 1: Surface electrodes placed in three transthoracic pairs and two patient reference sensors, along with other surface electrodes, for an EnSite™ NavX™ Navigation and Visualization Technology, Sensor Enabled™ study.



System Reference Electrode

Defibrillator Patch

RF Dispersive Patch

EnSite Precision™ Surface Electrode

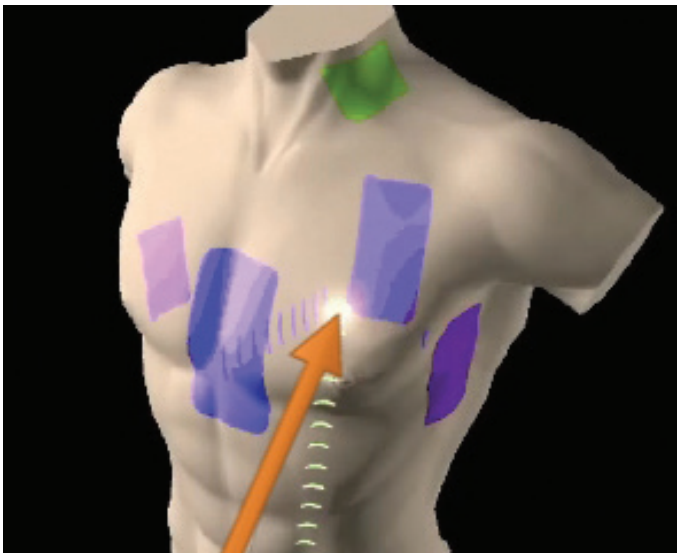
Patient Reference Sensor

Impedance Data

Catheter location and navigation of all compatible tools, both conventional and Sensor Enabled™, is based on the impedance field generated by the EnSite™ surface electrodes. When the surface electrodes are connected to the EnSite Precision™ System, an 8 kHz signal is sent alternately through each pair of surface electrodes to create a voltage gradient along each axis, forming a transthoracic electrical field.

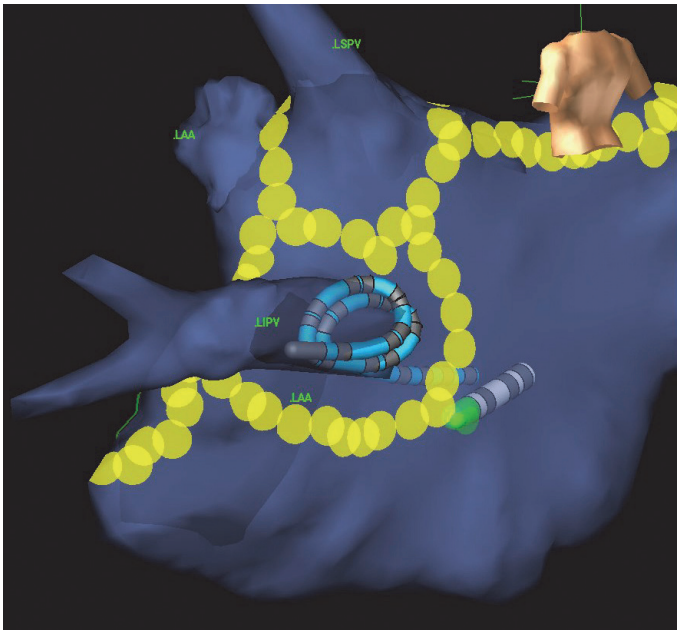
Conventional or Sensor Enabled electrophysiology catheters are connected to the EnSite Precision System and advanced to the heart. As a catheter enters the transthoracic field, each catheter electrode senses voltage, timed to the creation of the gradient along each axis (Figure 2). Using the sensed voltages compared to the voltage gradient on all three axes, the EnSite Precision System calculates the three-dimensional position of each catheter electrode for all electrodes simultaneously.

Figure 2: Each intracardiac electrode measures voltage along the gradient of each axis



The EnSite Precision™ System displays the located electrodes as catheter bodies with real-time navigation. It permits the simultaneous display of multiple catheter electrodes (Figure 3) and also reflects real-time motion of ablation and diagnostic catheters in the heart.[1] By tracking the position of the catheters, the system enables the creation of 3-D electroanatomical models of the cardiac chambers.

Figure 3: The EnSite Precision™ System displays the catheter bodies in real time



Magnetic Data

When a Sensor Enabled catheter is introduced and EnSite™ NavX™ Navigation and Visualization Technology, Sensor Enabled™ Field Scaling is applied, the EnSite Precision System dynamically optimizes the model by adjusting the dimensions of the navigation field using known offsets between the position and orientation of magnetic sensor(s) and electrodes.

The EnSite Precision System also uses magnetic information as an input for the EnGuide stability monitor to monitor field stability for unexpected changes. This feature can be enabled and used to monitor the location of a Sensor Enabled tool real time within an EnSite™ NavX™ Navigation and Visualization Technology, Sensor Enabled™ field scaled mode.

ACCURACY TESTING AND VERIFICATION[2]

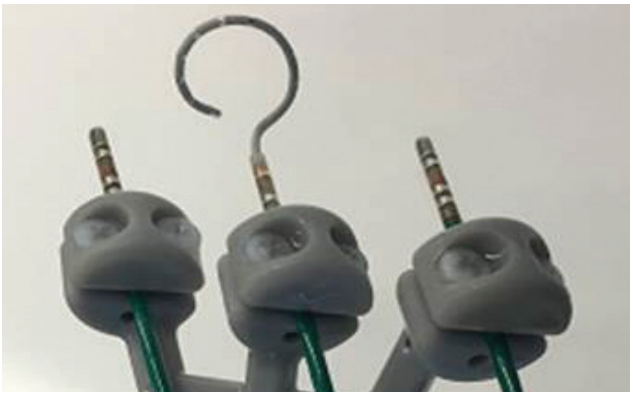
Performance bench testing was conducted to verify the tracking and navigation accuracy of the magnetic navigation and visualization technology utilized in the EnSite Precision™ System.

Accuracy Dynamic Wet Lab Study

This study tested the tracking accuracy and the navigation accuracy of the EnSite™ NavX™ Sensor Enabled™ technology in the EnSite Precision module with the Advisor™ FL circular mapping catheter, Sensor Enabled™ in two different sizes (15 mm and 20 mm).

Testing was performed using a calibrated robotic dynamic wet lab (DWL) to create a 10 cm 3-D geometric cube phantom model using sensor enabled catheter(s) held in an orthogonal fixture (Figure 4). Each catheter movement between 14 horizontal and 10 vertical displacement locations provided multiple electrode measurements during model creation (Figure 5a). Cube models were created using EnSite™ NavX™ Navigation and Visualization Technology, Sensor Enabled™ field scaling in static mode, and in dynamic mode with simulated cardiac (30–120 BPM) and respiration (10–12 RPM) motion enabled.

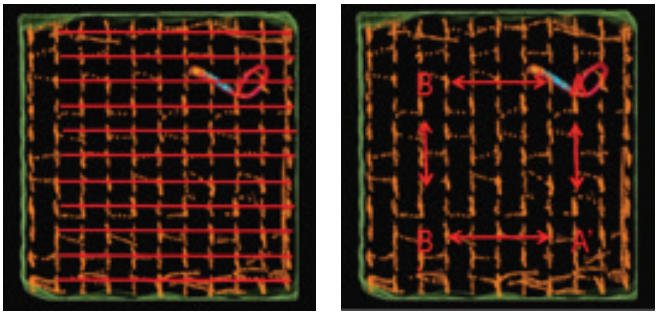
Figure 4: DWL fixture showing the Advisor™ FL circular mapping catheter, Sensor Enabled™ (in center)



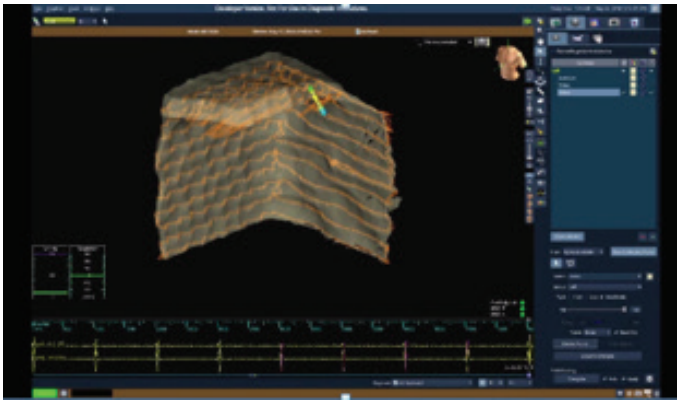
System error was calculated based on the differences in measurements between the cube models created by the EnSite Precision System and the known dimensions of the phantom cube geometry (Figures 5b and 6).

- **Tracking Accuracy** was measured as the error between an induced catheter displacement and the corresponding measured displacement, in this case as catheters were displaced by 50 mm from Position A to B. The specified maximum allowable Tracking Accuracy error in a field scaled model is 10%, or 5.0 mm in this test scenario.
- **Navigation Accuracy** was measured as the error in navigating a catheter back to a defined location (i.e., as catheters were then returned to Position A). The specified maximum catheter Navigation Accuracy error is 2.0 mm with a field scaled model.

Figures 5A (Left) And 5B (Right): DWL a. cube displacement levels and b. measurements of Tracking Accuracy (from position A to position B) and Navigation Accuracy (return to position A)



Figures 6: EnSite Precision™ System display during DWL cube model creation, with automatic EnSite™ NavX™ Navigation and Visualization Technology, Sensor Enabled™ magnetic field scaling enabled



Mean tracking accuracy error was under 0.5 mm and maximum tracking accuracy error was well under the specified maximum of 10% over the 50-mm tested displacement value in both static and dynamic test modes.

Maximum navigation accuracy error was within 0.8 mm for all catheter electrodes tested using the DWL system, also well below the specified maximum value of 2.0 mm (see Table 1 for details).

ACCURACY TEST RESULTS[2]

Table 1: Accuracy of EnSite Precision™ System (v2.0.1) with EnSite™ NavX™ Navigation and Visualization Technology, Sensor Enabled™ Magnetic Field Scaling

Sensor Enabled™ Catheters Tested	Tracking Accuracy Error (no. samples)	Navigation Accuracy Error (no. samples)
Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ (DWL phantom model)	**Dynamic:** **Mean: 0.48 ± 0.41 mm** (n=3,456)	**Dynamic:** **Max: 0.38 mm** **Std Dev: 0.07 mm** (n=2,304)
	Static: **Mean: 0.49 ± 0.47 mm** (n=3,456)	**Static:** **Max: 0.83 mm** **Std Dev: 0.15 mm** (n=2,304)

SUMMARY

Tracking and navigation accuracy are important in advanced cardiac mapping and ablation procedures, such as when it becomes necessary to guide a second ablation catheter to the same location as the first.[3] The accuracy of the EnSite™ NavX™ navigation and visualization technology, Sensor Enabled™ in the EnSite Precision™ System has been verified using dynamic bench testing to provide reliable catheter navigation and localization in electrophysiology procedures.

REFERENCES

1. Packer, D. L. (2005). Three-dimensional mapping in interventional electrophysiology: techniques and technology. *Journal of Cardiovascular Electrophysiology,* 16(10), 1110-1116.
2. Data on File. St. Jude Medical. Report 90237452.
3. Wittkampf, F. M., Wever, E. F., Derksen, R., Wilde, A. A., Ramanna, H., Hauer, R. N., & Robles de Medina EO. (1999). LocaLisa: new technique for real-time 3-dimensional localization of regular intracardiac electrodes. *Circulation,* 99, 1312-1317.

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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