Abbott

CLOSE THE GAP

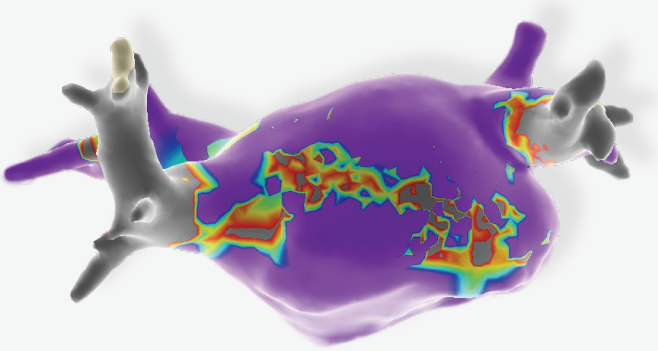
Advisor™ HD Grid
Mapping Catheter, Sensor Enabled™

FAST.[1] ACCURATE.[2] EASY TO USE.[3]

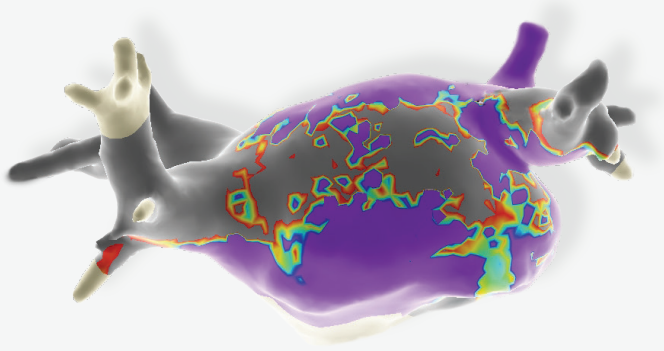
SEE THINGS DIFFERENTLY

WITH HD WAVE SOLUTION™ TECHNOLOGY

The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ (SE), offers a first-of-its-kind electrode configuration for high-density mapping.



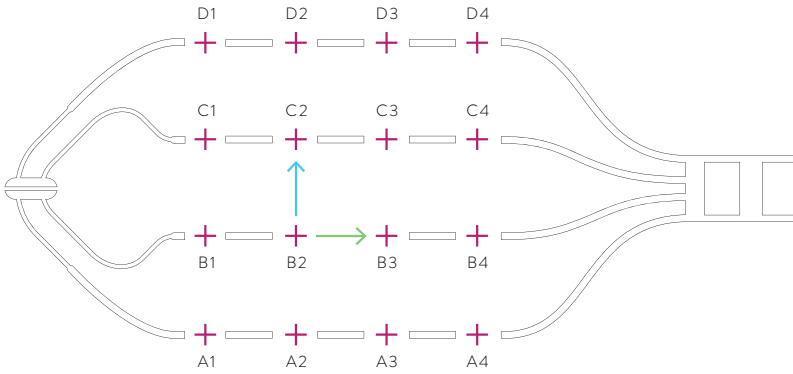
HD WAVE SOLUTION™ TECHNOLOGY



STANDARD CONFIGURATION

The HD Wave Solution Technology is intended to address directional sensitivity or bipolar blindness of recordings.[4] An HD Wave Solution Technology map features data where every electrode utilized has two orthogonal bipoles. When the Advisor HD Grid Mapping Catheter, SE, is used in conjunction with the EnSite Precision™ Software Best Duplicate Algorithm, the highest amplitude data are displayed on the map. The figures above show the difference between data gathered using the Advisor HD Grid Mapping Catheter, SE, with the HD Wave Solution Technology, and standard linear collection.

FAST.[1]
ACCURATE.[2]
EASY TO USE.[3]



FAST[1]

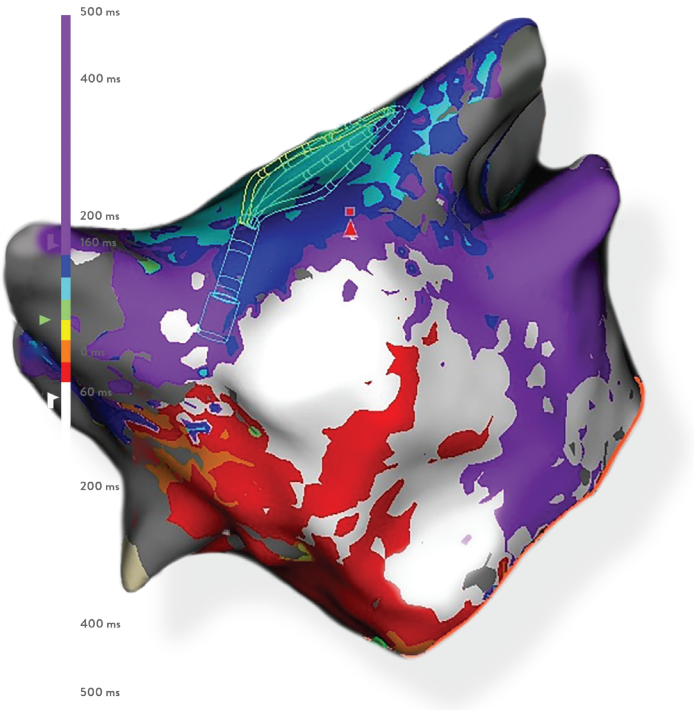
- Fast mapping time and point collection when used in conjunction with the EnSite Precision™ Cardiac Mapping System AutoMap Module and TurboMap feature
- The Advisor™ HD Grid Mapping Catheter, SE, allows you to place 16 electrodes where you need them, allowing for FASTER DATA COLLECTION in a given location[1]

ACCURATE[2]

- Enables voltage recordings in direction independent mapping[4]
- Investigate areas of interest ACCURATELY[2] and repeatably[5,6]

EASY TO USE[3]

- Bi-directional high-density mapping catheter designed to MANEUVER WITHIN ALL CHAMBERS
- Image shows visual confirmation of grid pliability and catheter contact, which can be achieved in any chamber of the heart[7]



ADDRESS BIPOLAR BLINDNESS WITH EVERY BEAT

EnSite™ LiveView Dynamic Display is a software designed to allow mapping data to be visualized in real time from the current location of Advisor HD Grid Mapping Catheter, SE.

- Allows for **RAPID AND EFFECTIVE DETECTION** of pulmonary vein isolation (PVI) and ablation line gaps[9, 10]
- **INSTANTANEOUS VISUALIZATION** with **REAL-TIME ASSESSMENT** of EGM data **IMPROVING OUTCOMES** by ensuring successful lesion delivery and signal termination[10]
- May **DECREASE MAPPING TIME** and prevent loss of relevant data by accurately displaying immediate changes in activation[11]
- **COMPLEMENTS** comprehensive chamber or surface maps in atrial and ventricular arrhythmias[9-12]

"EnSite LiveView Dynamic Display in combination with the Advisor HD Grid Mapping Catheter, SE provides a new technology which quickly visualizes isolation of the pulmonary veins and identifies ablation gaps in real time. It is a valuable addition to standard mapping techniques and EKGs and could streamline procedural workflows."

- PROF. ISABEL DEISENHOFER

CLOSE THE GAP

CONFIRM ACUTE PVI[8]

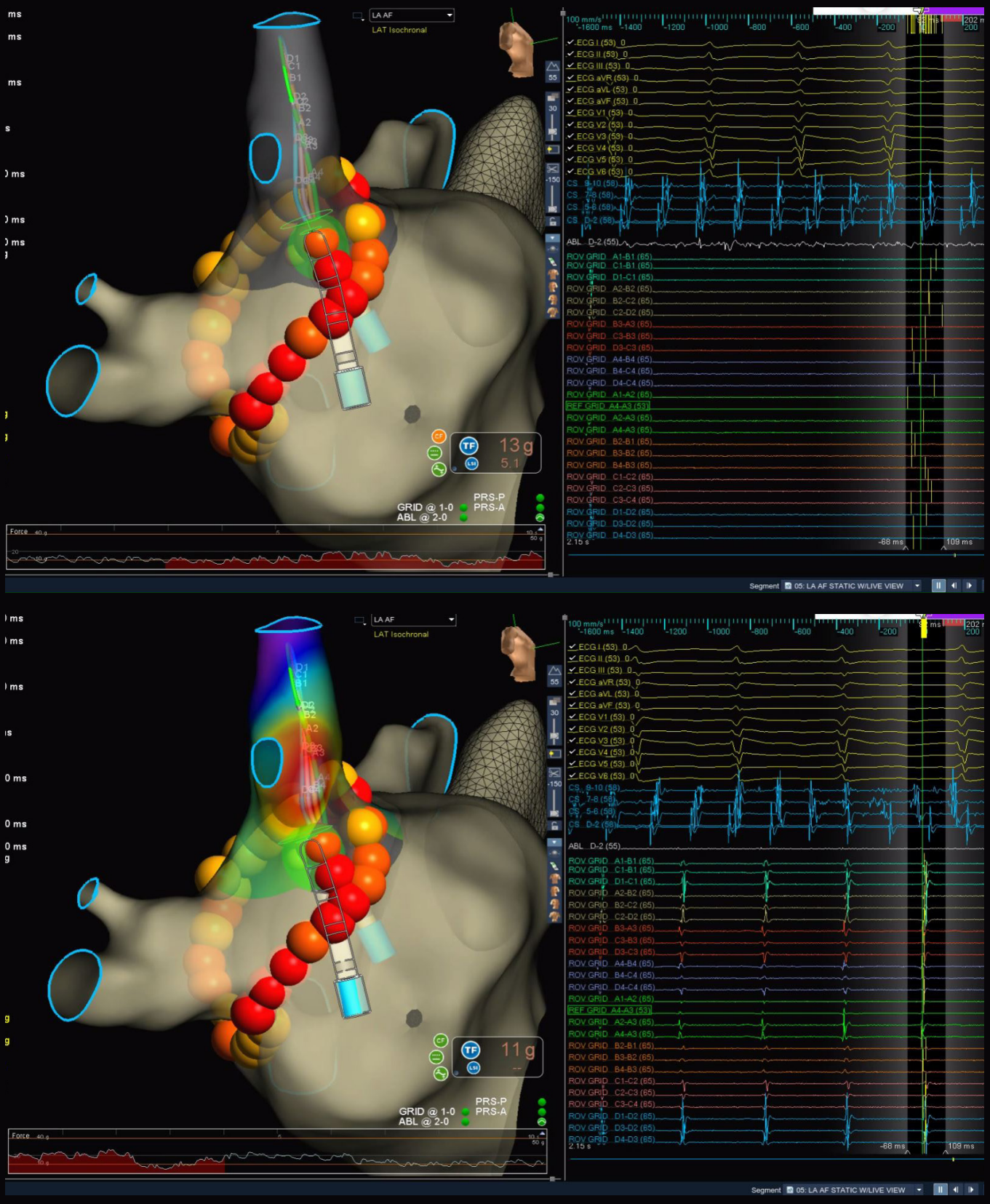


Image on the top shows EnSite LiveView Dynamic Display being used to assess a PV gap during Wide Area Circumferential Ablation (WACA) for Atrial Fibrillation (AF); image on the bottom shows EnSite LiveView Dynamic Display being used for real-time RF lesion assessment during RSPV ablation.

WHEN YOU CHECK FOR GAPS IN PULMONARY VEIN ISOLATION, ARE YOU SEEING THEM ALL?

Published data supports the utility of the Advisor HD Grid Mapping Catheter, SE in the confirmation of PVI compared to traditional workflows, including long-term outcomes, and direct and indirect comparisons.

LONG-TERM OUTCOMES DATA[13]

A recently published manuscript compared long-term outcomes of AF procedures completed with a circular mapping catheter (CMC) to those completed with the Advisor HD Grid Mapping Catheter, SE. The findings showed that the use of the Advisor HD Grid Mapping Catheter, SE resulted in a **STATISTICALLY SIGNIFICANT IMPROVEMENT**[13] in both:

12-MONTH FREEDOM FROM ATRIAL ARRHYTHMIAS

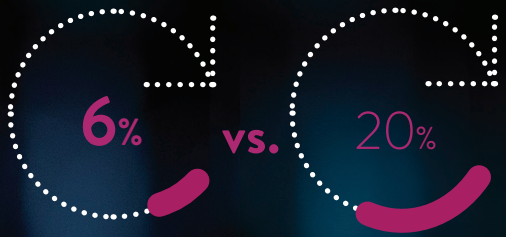
87%

Advisor™ HD Grid Mapping Catheter, SE

75%

CMC

REDUCTION IN REDO PROCEDURES



Redo rate when Advisor HD Grid Mapping Catheter, SE was used

Redo rate when CMC was used

ACUTE DATA COLLECTION - PVI CONFIRMATION WORKFLOW COMPARISONS

CIRCULAR MAPPING CATHETERS[14]

The incidence and location of gaps following PVI were tracked utilizing either a 10-pole circular mapping catheter (CMC10), a 20-pole circular mapping catheter (CMC20) or the Advisor™ HD Grid Mapping Catheter, SE.

ISOLATION WAS TRACKED ACROSS 99 CASES

CMC10
n = 30

36.7% OF PATIENTS HAD GAPS

0.9 GAPS/ PATIENT

CMC20
n = 36

38.9% OF PATIENTS HAD GAPS

1.44 GAPS/ PATIENT

Advisor™ HD Grid
Mapping Catheter, SE
n = 33

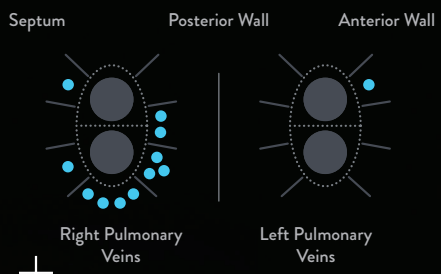
81.8%
OF PATIENTS HAD GAPS
2.15 GAPS/PATIENT

CRYOABLATION[15]

In a direct comparison, 18 patients received cryoablation with isolation confirmed by the Achieve‡ Mapping Catheter. Isolation was then checked again with the Advisor HD Grid Mapping Catheter, SE, revealing:

4 patients with ≥ 1 gap missed by the Achieve‡ Mapping Catheter

12 total gaps missed by the Achieve Mapping Catheter were identified by the Advisor HD Grid Mapping Catheter, SE

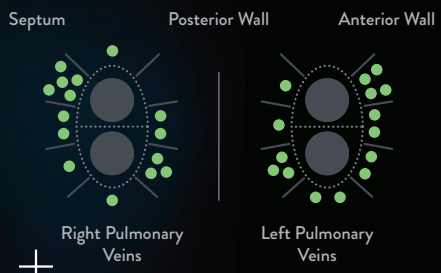


PACING ABLATION LINE[16]

In a direct comparison, 22 patients received ablation with isolation confirmed by pacing the ablation line. Isolation was then checked again with the Advisor HD Grid Mapping Catheter, SE, revealing:

15 patients with ≥ 1 gap missed by pacing

30 total gaps missed by pacing were identified by the Advisor HD Grid Mapping Catheter, SE



ORDER INFORMATION: ADVISOR™ HD GRID MAPPING CATHETER, SENSOR ENABLED™

DESCRIPTION	ORDER
Advisor™ HD Grid Mapping Catheter, Sensor Enabled™	D-AVHD-DF16
Sensor Enabled™ Diagnostic Catheter Cable	D-AVSE-CBL22

ORDER INFORMATION: ENSITE™ LIVEVIEW DYNAMIC DISPLAY

DESCRIPTION	ORDER
EnSite LiveView Dynamic Display License Kit	H702601
EnSite Precision™ Software Upgrade Kit v2.6	H702602

SEE THE ADVISOR HD GRID MAPPING CATHETER, SE IN ACTION WITH OUR EXTENSIVE CASE LIBRARY.

LEARN MORE AT
Cardiovascular.Abbott/HDGridLibrary

1. Abbott. Report on file. 90299533.
2. Abbott. Report on file. 90262900.
3. Abbott. Report on file. 90355919.
4. Abbott. Report on file. 90280703.
5. Abbott. Report on file. 90264963.
6. Abbott. Report on file. 90283998.
7. Abbott. Report on file. 90248530.
8. Karim N, Srinivasan N, Garcia J, et al. Early experience using the Advisor HD Grid catheter to map atrial fibrillation. *EP Europace, 2018; 20(4). Pages iv33–iv34, https://doi.org/10.1093/europace/euy205.015.*
9. Afzal M et al. Identification of pulmonary vein isolation gaps using novel dynamic mapping software. Poster Presentation P110. *Virtual APHRS 2020.*
10. Ling LH et al. Multicenter initial experience of novel dynamic mapping software using a high-density grid mapping catheter. Poster Presentation P111. *Virtual APHRS 2020.*
11. Al-Ahmad A et al. Dynamic mapping of ventricular tachycardia using novel software. Poster Presentation P108. *Virtual APHRS 2020.*
12. Latchamsetty R et al. Identification of the dominant circuit of a left atrial flutter using novel dynamic mapping software. Poster Presentation P109. *Virtual APHRS 2020.*
13. Day, J. D., Crandall, B., Cutler, M., Osborn, J., Miller, J., Mallender, C., & Lakkireddy, D. (2020). High Power Ultra Short Duration Ablation with HD Grid Improves Freedom from Atrial Fibrillation and Redo Procedures Compared to Circular Mapping Catheter. *Journal of Atrial Fibrillation, 13(2).*
14. Porterfield et al. Comparison of gap identification using three technologies for confirmation of pulmonary vein isolation. Europace. 2020; 22(S1):euaa162.075.
15. Eldadah et al. Incidence and location of PVI gaps identified post-cryoballoon ablation for atrial fibrillation. Europace. 2020; 22(S1):euaa162.073.
16. Giuggia et al. Incidence and location of residual gaps identified by a high-density grid-style mapping catheter after PVI is confirmed by pacing the ablation lines. Europace. 2020; 22(S1):euaa162.074.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at manuals.sjm.com or eifu.abbottvascular.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

United States — Required Safety Information

Indications: The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. **Contraindications:** The catheter is contraindicated for patients with prosthetic valves and patients with left atrial thrombus or myxoma, or interatrial baffle or patch via transseptal approach. This device should not be used with patients with active systemic infections. The catheter is contraindicated in patients who cannot be anticoagulated or infused with heparinized saline. **Warnings:** Cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Careful consideration must therefore be given for the use of this catheter in pregnant women. Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures. Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid device component damage, thromboembolism, cerebrovascular accident, cardiac damage, perforation, pericardial effusion, or tamponade. Risks associated with electrical stimulation may include, but are not limited to, the induction of arrhythmias, such as atrial fibrillation (AF), ventricular tachycardia (VT) requiring cardioversion, and ventricular fibrillation (VF). Catheter materials are not compatible with magnetic resonance imaging (MRI). **Precautions:** Maintain an activated clotting time (ACT) of greater than 300 seconds at all times during use of the catheter. This includes when the catheter is used in the right side of the heart. To prevent entanglement with concomitantly used catheters, use care when using the catheter in the proximity of the other catheters. Maintain constant irrigation to prevent coagulation on the distal paddle. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. If irrigation is interrupted, remove the catheter from the patient and inspect the catheter. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion. Always straighten the catheter before insertion or withdrawal. Do not use if the catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve and/or if any of the irrigation ports are blocked. Catheter advancement must be performed under fluoroscopic guidance to minimize the risk of cardiac damage, perforation, or tamponade.

Indications: The EnSite Precision™ Cardiac Mapping System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. The EnSite Precision™ System interfaces to either the MediGuide™ Technology System or the EnSite Precision™ Module to combine and display magnetic processed patient positioning and navigation mapping information. When used with the EnSite™ Array™ Catheter, the EnSite Precision™ Cardiac Mapping System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone. OR, when used with an EnSite Precision™ Surface Electrode Kit, the EnSite Precision™ Cardiac Mapping System is intended to display the position of conventional electrophysiology (EP) catheters in the heart. **Warnings:** Refer to the ablation catheter labeling for a listing of adverse events related to the use of this device in conjunction with radio frequency ablation, as a part of the diagnosis and treatment of cardiac arrhythmias. For patient safety, any connections that directly connect the patient to the EnSite Precision Cardiac Mapping System must be routed through the appropriate module: EnSite Precision Link, Sensor Enabled™ NavLink, EnSite Precision Field Frame, ArrayLink, CathLink, SJM ECG Cable, RecordConnect, or GenConnect. When using the EnSite Precision Module full protection against the effects of cardiac defibrillator discharge and other leakage currents is dependent upon the use of appropriate cables. Refer to the ablation catheter labeling for a listing of adverse events related to the use of this device in conjunction with radio frequency ablation, as a part of the diagnosis and treatment of cardiac arrhythmias. **Precautions:** Do not operate the EnSite Precision Field Frame within 10 meters (m) of another operating Field Frame. Do not place the EnSite Precision 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 Precision 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. Do not place the EnSite Precision Link, Sensor Enabled™ within 1 m of the EnSite Precision Field Frame - Do not place tool cables within 30 millimeters (mm) of the EnSite Precision 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. Metallic equipment used in close proximity to the magnetic field during the procedure, such as a sterile drape holder, may affect Sensor Enabled (SE) points and SE field scaling accuracy. Do not use the EnSite Precision Cardiac Mapping System in the presence of other magnetic fields. Do not drop the EnSite Precision Field Frame or subject it to impact. Physical damage to the Field Frame may alter the Field Frame's factory calibration.

Abbott
One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
Abbott.com

MAT-2004697 v3.0 | Item approved for use outside of the United States.

Abbott