Boston Scientific
Advancing science for life™

Hybrid Ablation of Atrial Fibrillation Using the Rhythmia™ Mapping System

J. Paul Mounsey, MD, PhD, MRCP, FACC
UNC Center for Heart and Vascular Care, University of North Carolina at Chapel Hill

Patient Introduction and History

The patient is a 65-year-old male with a 10-year history of persistent atrial fibrillation (AFib). An echocardiogram showed a left atrial diameter >5 cm along the short axis. After multiple antiarrhythmic drugs failed to manage the atrial fibrillation, a surgical solution was needed.

Rationale for Rhythmia Mapping System

For this case, we elected to perform a hybrid ablation rather than attempting a catheter ablation alone. Hybrid ablation of AFib is not a widespread procedure, although we perform them frequently at the University of North Carolina.

This case clearly highlights how the Rhythmia™ Mapping System's ability to quickly create multiple high-density propagation maps can be used to accurately assess linear block and locate existing gaps.

Rhythmia Mapping Procedure

Just prior to mapping with the Rhythmia system, a surgeon placed a catheter around the patient's pulmonary vein pedicles via thorascopy to isolate the the pulmonary veins. With an epicardial ablation catheter, the surgeon attempted to create a contiguous lesion across the left atrial roof, down the Coumadin ridge, around the posterior wall of the left atrium, and then up anterior to the two right-sided veins. These lesions were made with a combination of bipolar and unipolar radiofrequency (RF) ablation.

After the procedure, the surgeon checked the voltage he could record epicardially from the posterior left atrial wall and confirmed it had been reduced. The epicardial map he created was not particularly detailed, as it was limited to what he could get from a conventional quadripolar catheter on the end of his finger. The Orion catheter could not easily be maneuvered epicardially in this case.

Immediately following that procedure, we performed two transeptal catheterizations, and created both Sinus voltage and activation maps of the left atrium using the Orion catheter and Rhythmia Mapping System. Looking at the map (Figure 1), you can clearly see voltage on the posterior left atrial wall as well as voltage in the pulmonary veins. Therefore, we concluded that the epicardial lesions were incomplete.

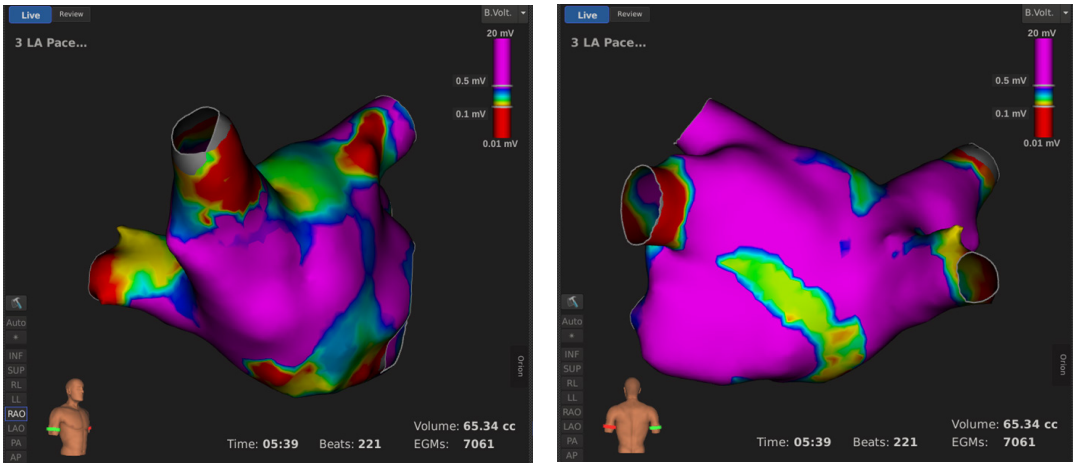

Figure 1. Voltage map following the initial epicardial catheter ablation

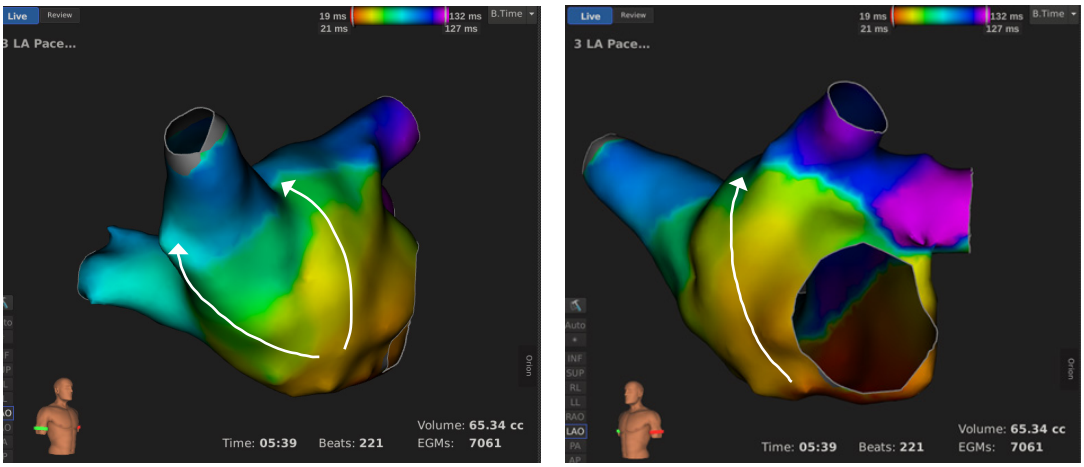

Figure 2. Activation time map during coronary sinus pacing

Figure 2 shows an activation time map obtained during coronary sinus pacing. We see activation passing freely through the septum, and it seems to cross the roof, albeit slowly, to the posterior wall. It also seems to be passing in the cleft between the two right-sided pulmonary veins.

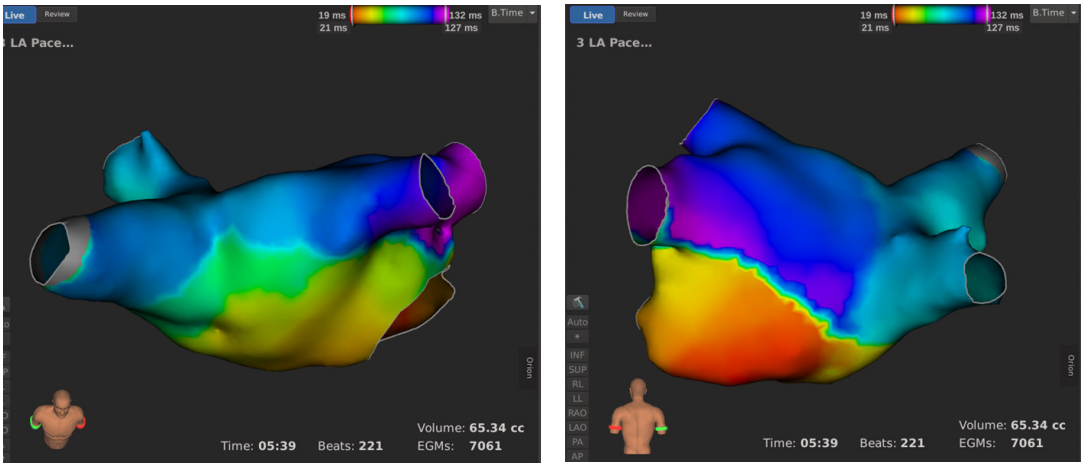

Figure 3. Activation map during coronary sinus pacing

Figure 3 shows an activation map taken during coronary sinus pacing. It shows that the line posteriorly between the left inferior pulmonary vein and the right inferior pulmonary vein appears complete, but there is a sign of leakage across the roof.

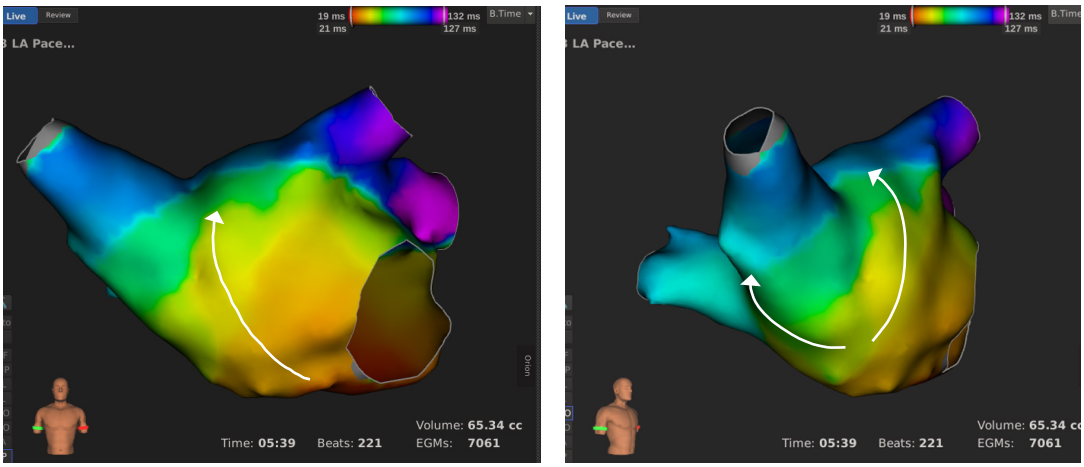

Figure 4. Detailed activation map

Figure 4 shows a more detailed propogation map. Now we see activation passing up the anterior wall on the left side and passing slowly across the roof and more particularly, we see activation on the right-hand map appearing in the cleft between the two right-sided pulmonary veins. The effect of both leaks is that the posterior wall fills with electrical activity from the top and the right side.

Figure 3 clearly shows that electrical activity does not pass across the low posterior line. Between the maps in Figures 1-4 we know that we are looking for gaps in the roof and in the cleft between the right upper pulmonary vein and the right lower pulmonary vein. We're confident that there aren't gaps anywhere else.

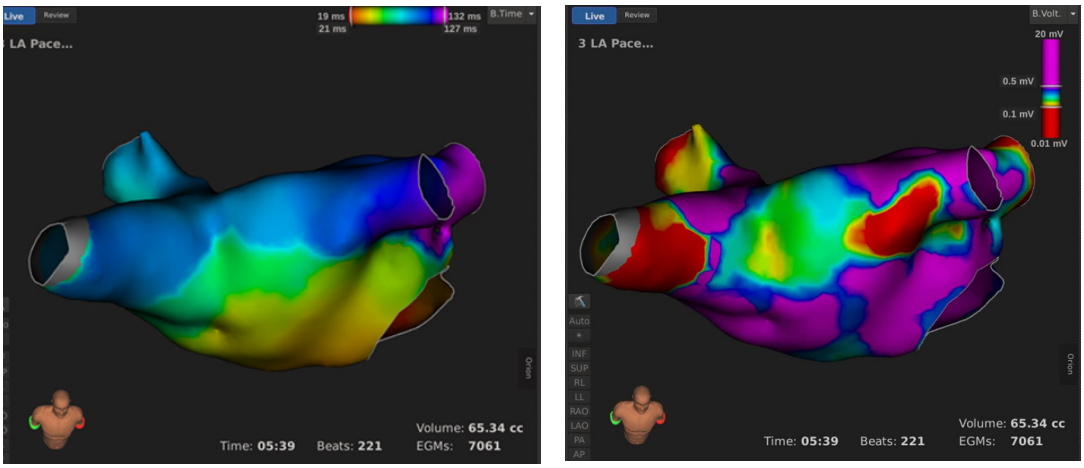

Figure 5. Voltage and activation maps of the roof

Figure 5 shows a voltage and timing map showing the area of the likely gap across the roof.

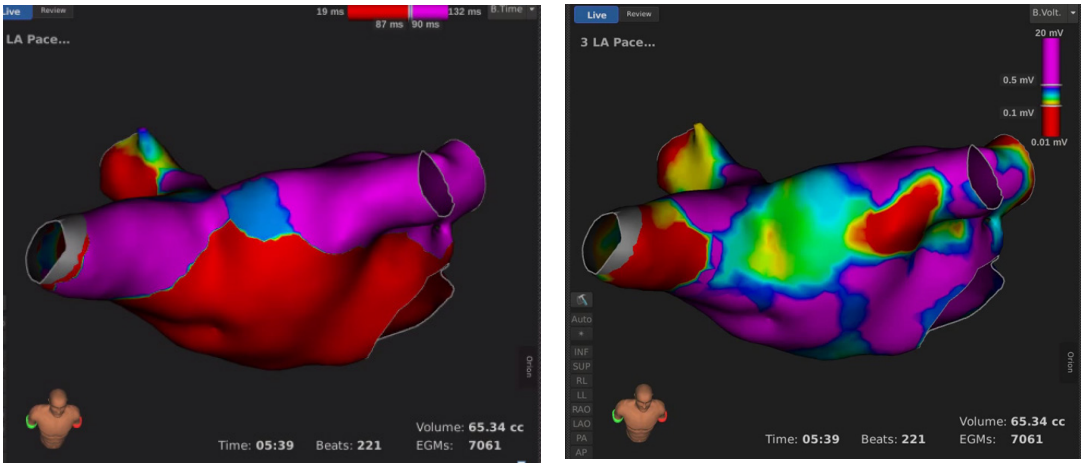

Figure 6. Gap in epicardial roof line

The propagation map in Figure 6 shows the same location of delayed conduction across a gap in the roof - line lesion. There is a narrow isthmus of viable tissue in the epicardial roof line. The Dynamic Review Probe was used here to confirm, via electrograms, that there was a gap in the roof line (Figure 6A).

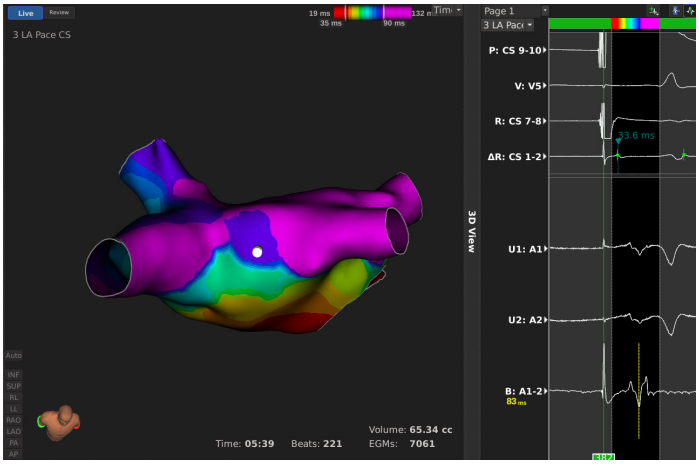

Figure 6A. Dynamic Review confirming location of gap

Figure 7 shows a much wider isthmus of tissue between the right superior pulmonary vein and the right inferior pulmonary vein. You'll see there is free spread of electrical activity in that isthmus, and it's clear that we need to make a few more lesions there.

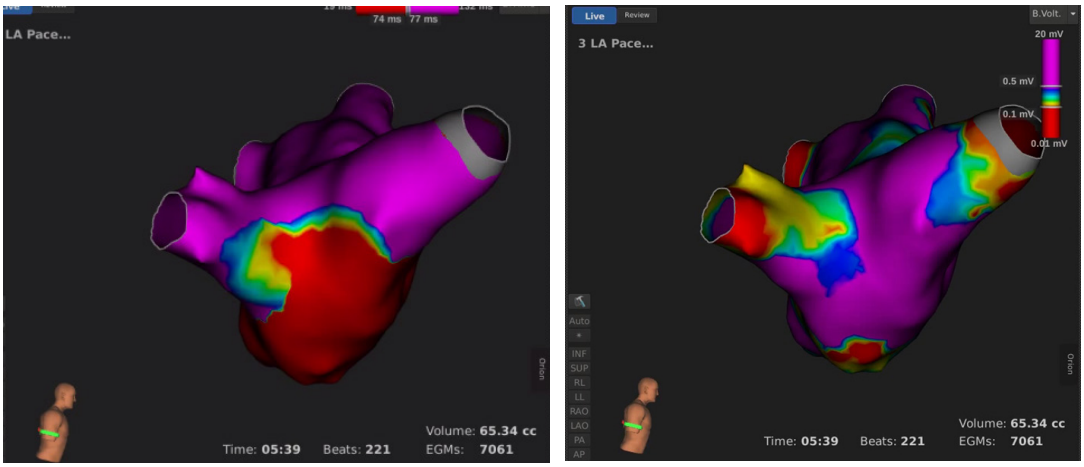

Figure 7. Voltage and activation maps showing gap along the carina

Case Outcome

Figure 8 shows the result of the additional lesions across the roof and in the isthmus. Now we have complete isolation of the posterior wall (no voltage, shown as grey), which was the result we wanted for this patient. Having completed isolation of the posterior wall, we could no longer induce AFib during the case, and the patient has subsequently (> 1 year) done very well.

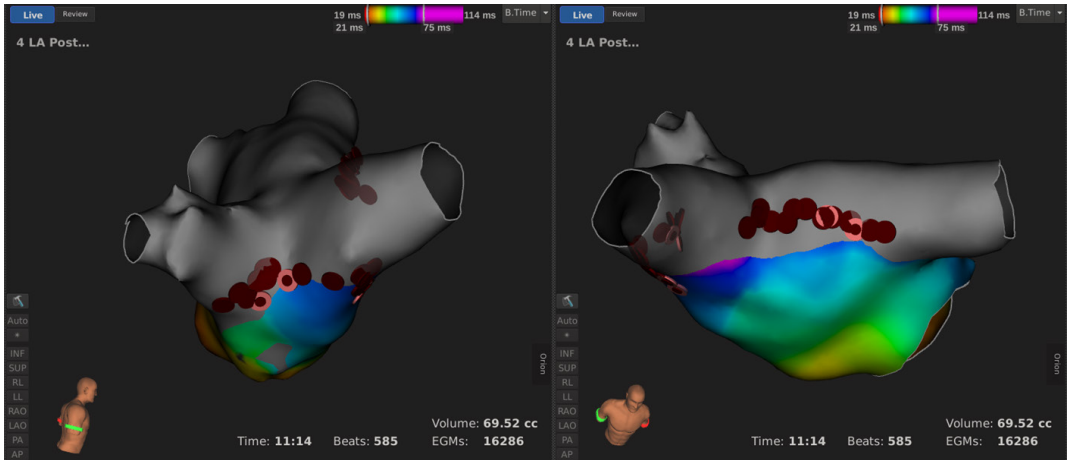

Figure 8. Complete isolation of the posterior wall

Case Commentary

When we first got the Rhythmia System we happened to have a run of hybrid cases. Because I thought Rhythmia would work well in assessing linear block, I thought, "Let's try and use it in the hybrid cases," and it turned out to be true. What we're trying to do in hybrid cases is two things. One is to assess linear block and the other is to map unusual flutters that sometimes occur. This just happens to be a good example of where Rhythmia helped us assess linear block.

The features that helped us were first the ability to quickly demonstrate that there was obviously block in the left atrial low posterior wall line. Knowing this immediately was a great boon. Another factor that helped us in this case was identifying the gap in the roof line with the dynamic probe. We probably made a few more burns than needed because, at least by electrogram characteristics, the gap was quite small.

RHYTHMIA™ MAPPING SYSTEM

INTENDED USE/INDICATIONS FOR USE The Rhythmia™ Mapping System and accessories are indicated for catheter-based atrial and ventricular mapping. The mapping system allows real-time visualization of intracardiac catheters as well as display of cardiac maps in a number of different formats. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be recorded and displayed on the system's display screen.

CONTRAINDICATIONS There are no known contraindications.

WARNINGS AND PRECAUTIONS The use of the Rhythmia Mapping System in conjunction with radio frequency ablation and other medical devices, as a part of the diagnosis and treatment of cardiac arrhythmias, may pose a risk of adverse events, such as cardiac perforation and arrhythmias (new and/or exacerbation of existing arrhythmias) that may require additional intervention. Do not operate the Rhythmia Mapping System near flammable anesthetics. System operation near flammable anesthetics may cause an explosion that could cause injury or death to the patient or user. All devices that are connected to the Rhythmia Mapping System must meet IEC 60601-1 requirements and any other relevant safety standards. When connected to other devices, the combined systems' configuration must meet the IEC 60601-1-1 safety standards. The use of the Rhythmia Mapping System with accessories and devices that do not comply with relevant standards may reduce the safety of the system, cause equipment damage or system malfunction, or harm to the patient or user. Only stimulators that are certified for IEC 60601 should be used with the Rhythmia Mapping System. Do not connect life-sustaining pacing through the Rhythmia Mapping System. The system is not intended to provide life-sustaining therapy and should not be used as such. In case of need for emergency pacing, or any failure of stimulator routing, directly connect the desired paced channel to the stimulator. The Rhythmia Mapping System is only designed to route the stimulation signal to the desired channel. To start or stop stimulation, always use the controls on the external stimulator. Use the Rhythmia Mapping System only with one of the following RF ablation generators: Maestro 3000™, Stockert™, or IBI™. Do not use the system with other RF ablation generators. Compatibility with other RF ablation generators has not been demonstrated. Do not apply RF energy larger than 150W to ablation catheters that are connected to the Maestro 3000 RF generator and the Rhythmia Mapping System. Do not apply RF energy larger than 70W to ablation catheters that are connected to the Stockert RF generator and the Rhythmia Mapping System. Do not apply RF energy larger than 50W to ablation catheters that are connected to the IBI RF generator and the Rhythmia Mapping System. To reduce the risk of electric shock or equipment damage, do not clean the Rhythmia Mapping System when it is plugged in, turned on, or connected to a patient. Cleaning the system while it is in use and connected to a power source may cause an electrical shock that could cause injury or death to the patient or user. To reduce the risk of electric shock, assure that any ECG cables and electrodes are not in contact with any other conductive parts, including ground. To reduce the risk of electric shock during defibrillation, assure that the exposed connector tips on the ECG output box are covered at all times with the protective, non-conductive material provided with the ECG output boxes. Do not use the ECG output box if the protective cover is damaged (see ECG Output Box). The system generates electrical impedance fields as part of its normal operation. Do not use other systems that also generate electrical impedance fields in the same procedure, as this may interfere with the system's normal operation and reduce the quality of catheter localization, and signals. Magnetic Localization System Do not operate the Localization Generator within 200 mm of installed cardiac implantable electronic devices (CIEDs). Doing so may affect pacing, temporarily suspend tachycardia therapy delivery, or lead to patient discomfort. Signal Station To minimize the risk of electric shock, connect the Signal Station only to supply mains with a protective ground (earth) connection. Use only a functioning, properly tested supply main with protective ground (earth) to power the Rhythmia Mapping System. The use of a faulty, ungrounded supply main increases the risk of electrical shock and system malfunction. To minimize the risk of electric shock, prior to using the Rhythmia Mapping System, connect the equipotential socket (located on the Signal Station rear panel) to a common ground. This connection grounds the Rhythmia Mapping System and must remain connected at all times (see Signal Station Setup in the DFU). The Signal Station requires a dedicated, 24V DC power supply, which is provided by Boston Scientific with the Signal Station. To reduce the risk of Signal Station damage, use only the power supply provided by Boston Scientific for use with the Signal Station. To reduce the risk of Signal Station damage, do not connect or disconnect the Signal Station to its power supply while the Signal Station is turned on. To minimize potential exposure to water or liquid, prevent fluids from entering air vents. Do not place beverages or containers of water or liquid directly on or near the Signal Station or other system components. Do not block the air vent on the Signal Station during Signal Station use. Blocking the air vent during Signal Station use can cause the Signal Station to overheat, which may affect system operation. Use only a flat stable surface to hold the Signal Station and Signal Station-related accessories. Workstation To minimize potential exposure to water or liquid, do not place beverages or containers of water or liquid directly on or near the Workstation or other system components. Use only a flat stable surface to hold or transport the Workstation and Workstation-related accessories. To prevent loss of data, frequently back up the data by archiving cases no longer needed for immediate access. Cables Use only the ECG cables supplied by Rhythmia™ Medical for use with the Rhythmia Mapping System. ECG cables provided by Rhythmia Medical are designed and tested to protect the Signal Station from defibrillation energy. Using other ECG cables may cause serious damage to the system hardware. Prior to using the Rhythmia Mapping System, inspect all external connections and cable connectors. Make sure all connections are secure. Tighten any loose connections prior to using the system. Do not use excessive force when connecting or disconnecting cable connectors. Excessive force can damage the connectors, which may cause system malfunction. Do not kink or sharply bend cables. Kinks and sharp bends can damage the cables, which may cause system malfunction. To minimize the risk of damage, store unused system cables in a clean, dry, and secure location, consistent with storage guidelines (see Equipment Storage & Transporting in the DFU). Electrical Never use ungrounded electrical outlets to power any system components. Do not use extension cords or adapters for ungrounded outlets. Using ungrounded outlets, extension cords, or adapters may cause equipment damage, system failure or malfunction. Body Surface Electrodes Use care when attaching the body surface electrodes to lead connectors. To minimize the risk of electric shock, make sure that electrodes and lead connectors do not contact one another or contact ground. To prevent low quality signals from body surface electrodes, properly prepare the skin prior to attaching the electrodes. Do not use excessive gel as this may lead to shorts between different electrodes. Environmental Do not immerse any cable connectors in water or liquid. Immersion in water or liquid may damage connectors, which may cause system malfunction. Magnetic Localization System Manually disabling the Localization Generator disables all catheter visualization and localization capabilities, including impedance tracking. Do not place the Localization Unit (SCU) or Sensor Interface Unit (SIU) within 1m of the Localization Generator. Doing so may lead to inaccurate tracking. Do not place cables used with the Rhythmia Mapping System within 30mm of the Localization Generator cable. If these cables are within 30mm or less, particularly if they are parallel to each other, inaccurate tracking or "noisy" signals may occur. Do not coil the Localization Generator cable. Doing so can disturb the magnetic field of the Localization Generator, which may lead to inaccurate tracking. Do not use the Magnetic Localization System in the presence of other magnetic fields or large metal objects. Doing so may lead to inaccurate tracking. Localization Generator Manually disabling the Localization Generator disables all catheter visualization and localization capabilities, including impedance tracking. During the Procedure To reduce catheter configuration mistakes, when connecting catheters to the system, always verify the signals by reviewing the signal display and recording system to ensure correct configuration of catheter electrodes to displayed channels. To ensure correct clinical decisions, use fluoroscopy, ultrasound, pace mapping or other visualization techniques to verify mapping results and catheter position. Always compare the anatomical map to the patient's expected anatomy. When a catheter localization error is encountered, use fluoroscopy or other visualization techniques to verify catheter location. Imported geometrical shells should only be used as a reference, for example to identify anatomical features in advance of mapping. Use other visualization tools, such as fluoroscopy or echocardiography to verify catheter location. During the mapping procedure, do not disconnect the Localization Unit from the Signal Station and/or the Localization Generator from the Localization Unit. Ensure caps are installed on Localization Unit SIU connection ports that are not in use. (Rev A)

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Boston Scientific does not have any catheters approved for the treatment of atrial fibrillation.

Boston Scientific

Advancing science for life™

Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Customer Service:
1.888.272.1001

EP-386822-AA APR2016