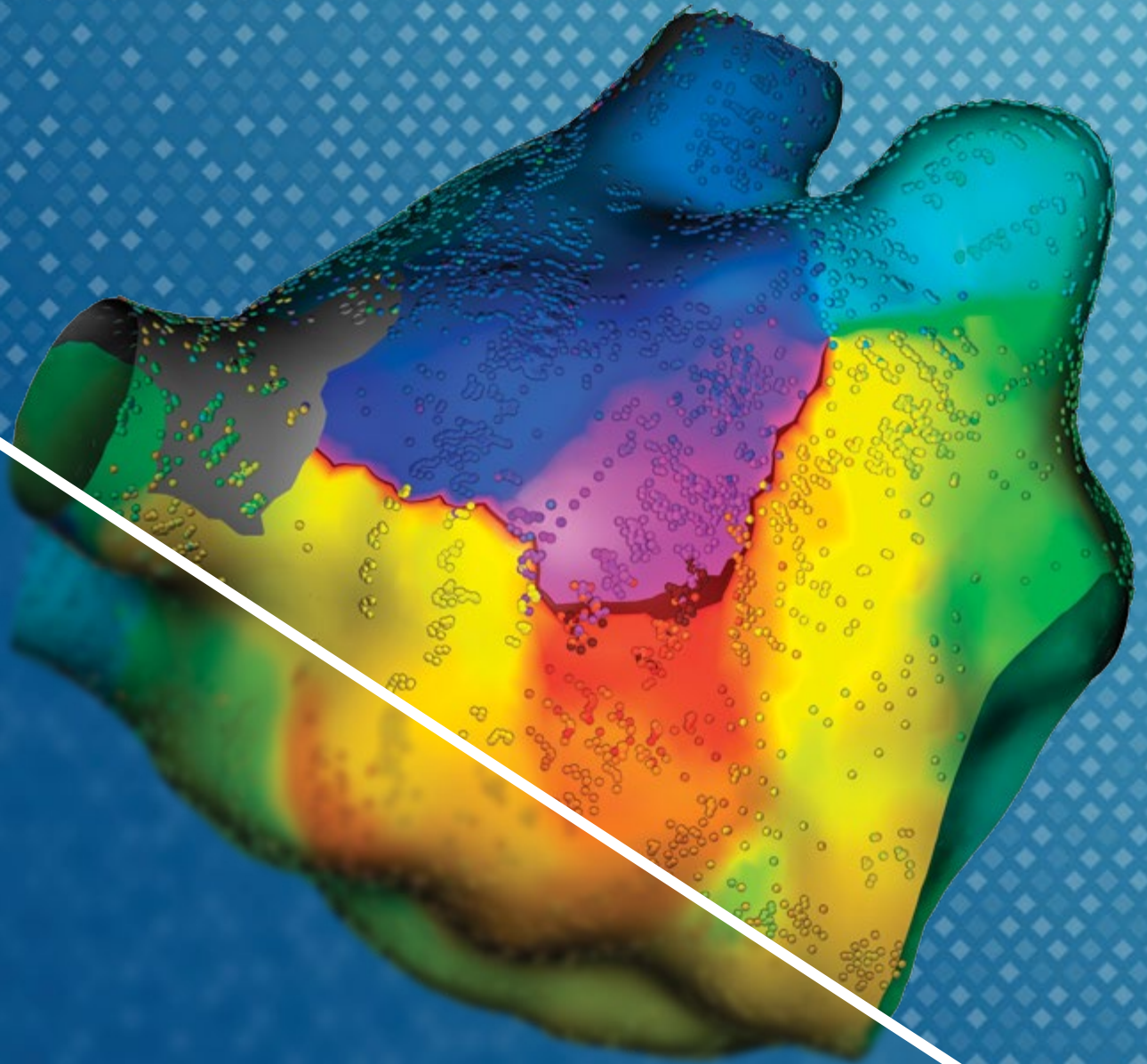


RHYTHMIA HDx™

MAPPING SYSTEM

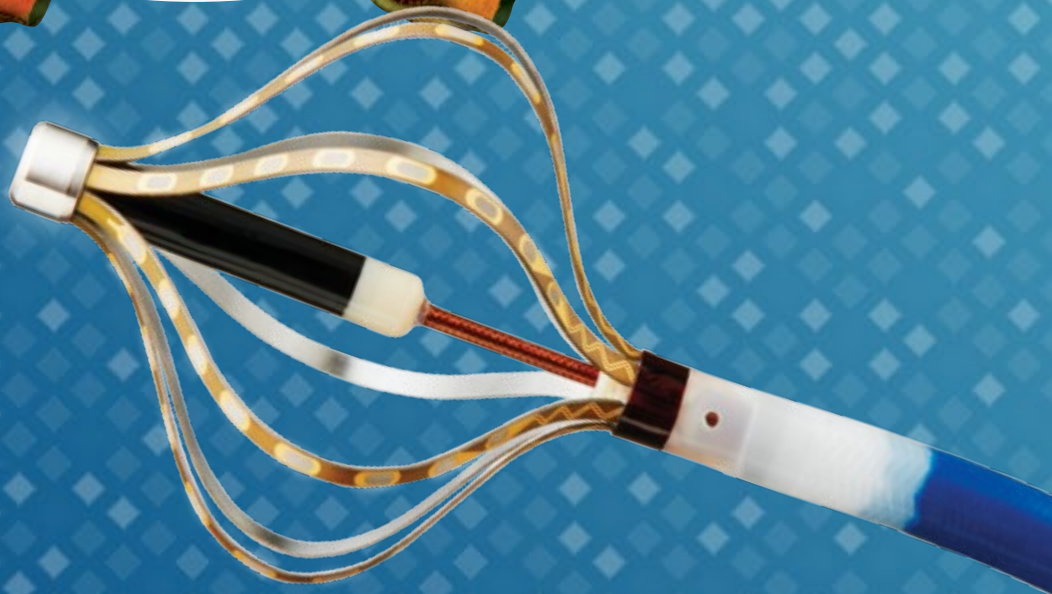


CLARITY
for any level of complexity

THE RHYTHMIA HDx™ MAPPING SYSTEM SETS THE STANDARD OF PERFORMANCE IN HIGH-DEFINITION MAPPING.



RHYTHMIA HDx
MAPPING SYSTEM



HD CATHETER



HD HARDWARE



HD SOFTWARE



THE RHYTHMIA HD \times TM MAPPING SYSTEM WAS BUILT FROM THE GROUND UP FOR HIGH-DEFINITION MAPPING.



HD CATHETER

"THE HIGH NUMBERS OF ELECTRODES PROVIDE

comprehensive and accurate electrical information to enable insight into underlying AT mechanisms and activation patterns that have rarely been available in this detail before."

– Schaeffer et al.,¹ 2016



HD HARDWARE

"THIS SYSTEM IS FOR THE FIRST TIME ABLE TO DISPLAY LOW-VOLTAGE CRITICAL ISTHMUSES, *which are far below the current scar cutoff of classically available systems."*

– Lațcu et al.,^{2,3} 2017



HD SOFTWARE

"THE COMBINATION OF INCREASED SAMPLING DENSITY, MAPPING RESOLUTION AND A NOVEL ALGORITHM *to improve the accuracy of activation timing resulted in the ability to construct activation maps with better characterization of the circuit as compared to standard mapping technologies."*

– Anter et al.,^{3,4} 2016

QUANTITY
DENSITY

OF DATA

HD CATHETER

QUALITY

RESOLUTION

OF DATA

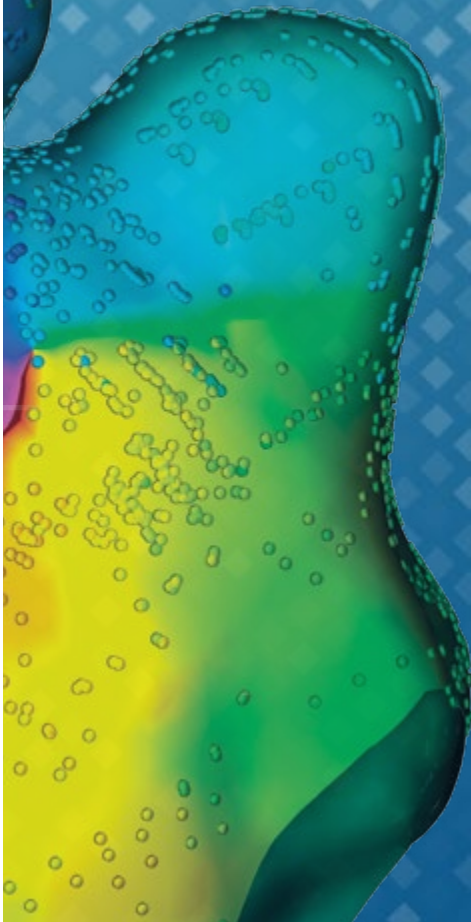
HD HARDWARE

SPEED AND
ACCURACY

AUTOMATION

OF DATA
PROCESSING

HD SOFTWARE



*Only the combination of a high-resolution mapping **CATHETER**, advanced noise-filtering **HARDWARE** and intelligent **SOFTWARE** working together can achieve the **DENSITY, RESOLUTION** and **AUTOMATION** required for true high-definition mapping.*

DENSITY

*The INTELLAMAP ORION™ has **64 ELECTRODES** that were shown to generate maps with 5x higher point densities^{5,6} than competitive automated mapping systems.*

*RHYTHMIA HDx™ has **NO POINT LIMITATION**.*

RESOLUTION

*ORION's **0.4 mm², 2.5 mm** spaced, **IRIDIUM-OXIDE** coated, **FLAT** electrode design produces sharp, high-quality, high-resolution signals.*

*RHYTHMIA HDx™ **0.01mV NOISE FLOOR** reveals signals that cannot be visualized with standard-definition mapping systems.*

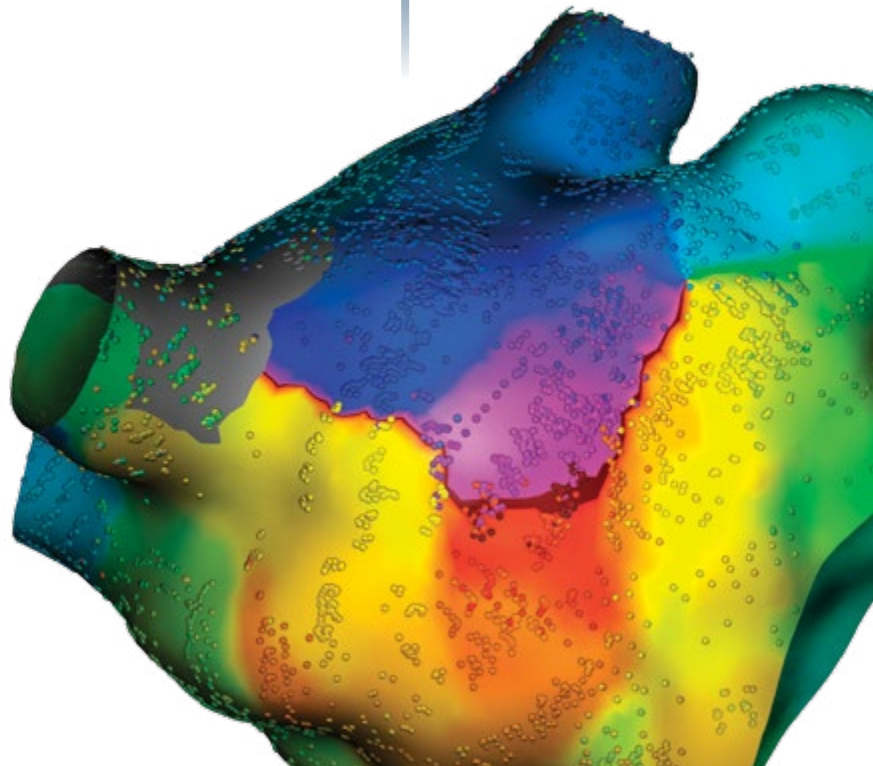
AUTOMATION

*Continuous mapping leverages **4 ROBUST TRIGGERS** and **7 BEAT ACCEPTANCE CRITERIA** to ensure that only beats from the rhythm of interest are accepted into the map, at **SPEEDS GREATER THAN 1,000 POINTS/MINUTE**.⁷*

*RHYTHMIA HDx Intelligent Annotation Algorithm was shown to deliver **99.98%** annotation **ACCURACY**.^{3,8}*

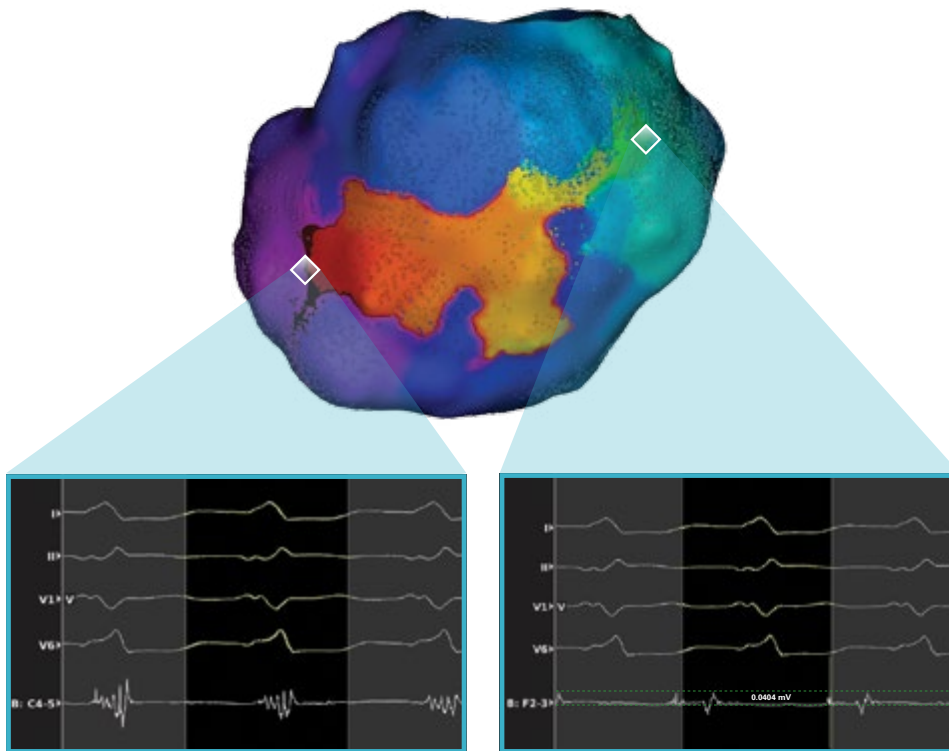
THE BETTER YOU CAN SEE IT, *the better you can treat it.*

The RHYTHMIA HDx™ Mapping System provides map clarity that cannot be achieved through standard-definition mapping technologies.



1

DIAGNOSE WITH COMPLETE DATA

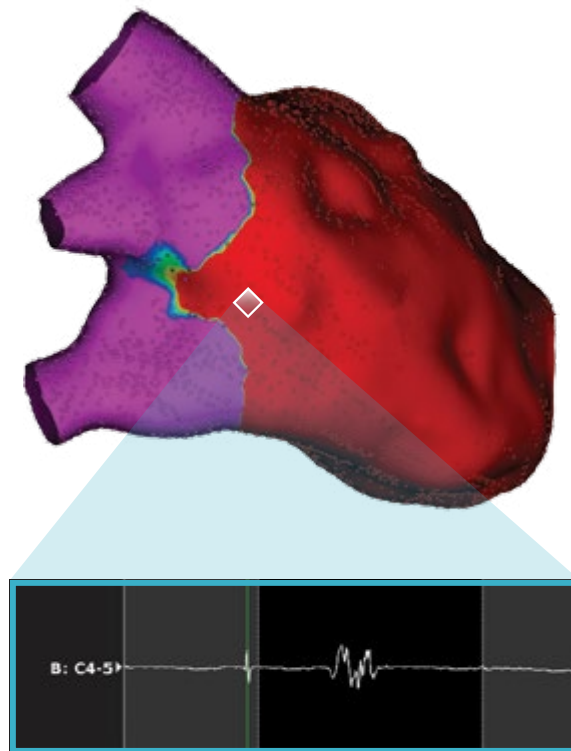


Ischemic VT activation map of a low-voltage critical isthmus. Courtesy of Frédéric Sacher, MD, CHU Bordeaux.

- Reduce the amount of interpolation between annotated points to more efficiently identify areas of interest
- Clearly visualize propagation of complex arrhythmia circuits
- Characterize complex substrates, including critical isthmuses, low-voltage regions of interest, scar and scar boundaries

2

DEVELOP A TARGETED ABLATION STRATEGY

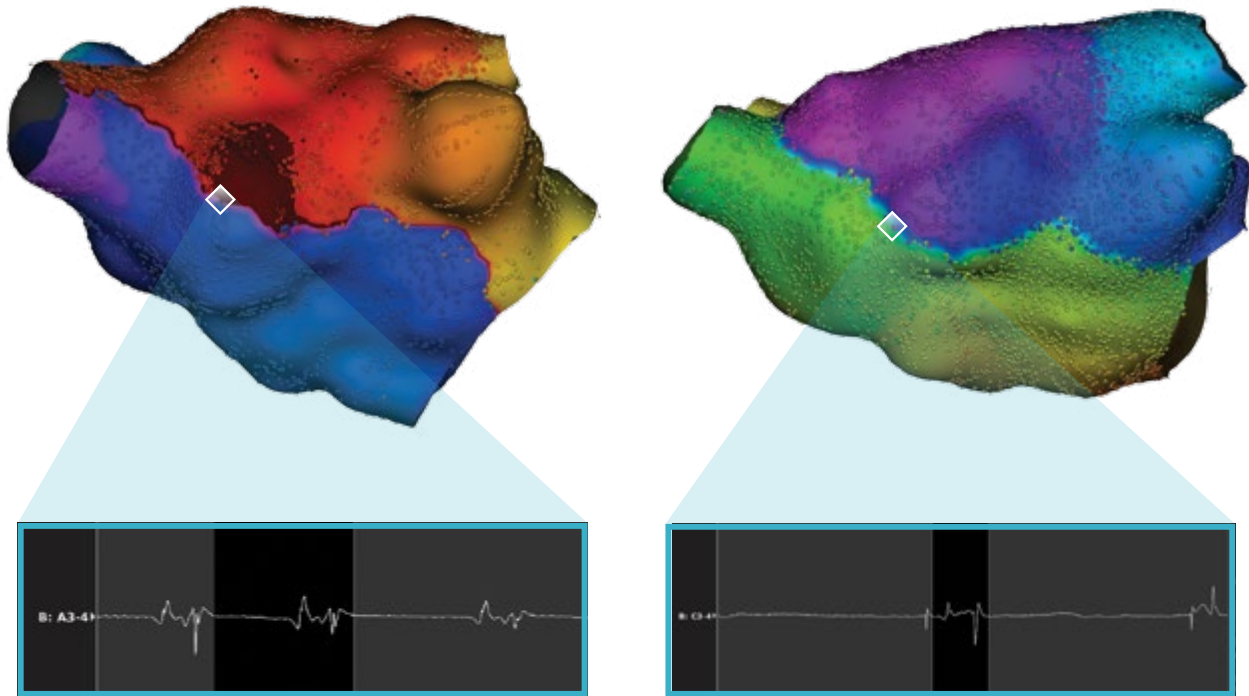


*Redo AF activation map revealing a low-voltage gap in a previous PVI line.
Courtesy of Jamie Kim, MD, Catholic Medical Center.*

- Uncover channels and small gaps in previously ablated lesion sets
- Clearly visualize low amplitude and complex fractionated electrograms that are not visible with standard-definition systems
- Precisely identify the ablation target so that you can limit ablation time

3

EFFICIENTLY CONFIRM PROCEDURAL ENDPOINTS



*LA activation map revealing a gap in previous anterior ablation line. vMap post-ablation confirms bidirectional block.
Courtesy of Vivek Reddy, MD, Mount Sinai Medical Center.*

- Remap areas of interest at speeds $>1,000$ points/minute⁷
- Rapidly assess lesion integrity through post-ablation vMaps™



RHYTHMIA HDx™ HYBRID LOCALIZATION PROVIDES YOU THE FLEXIBILITY TO WORK WITH YOUR CHOICE OF CATHETERS.

**NAVIGATIONAL
ACCURACY OF**



For optimal accuracy and efficiency, magnetic tracking supports mapping with the Boston Scientific INTELLAMAP™ and INTELLANAV™ catheters

**NAVIGATIONAL
ACCURACY OF**



Impedance tracking supports mapping and visualization of non-navigation-enabled catheters for flexibility of choice⁹



**INTELLANAV™
OPEN-IRRIGATED**
ABLATION CATHETER



**INTELLANAV
MIFI™ XP**
ABLATION CATHETER

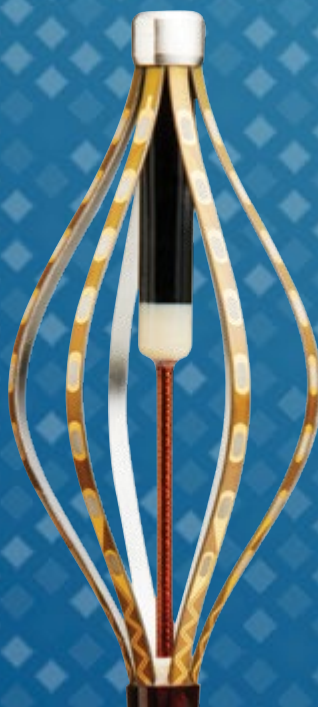


**INTELLANAV™
XP**
ABLATION CATHETER

Boston Scientific offers a full portfolio of INTELLANAV™ Ablation Catheters.

FOR THE HIGHEST LEVEL OF ACCURACY, *use the INTELLAMAP ORION™ Mapping Catheter plus an INTELLANAV Ablation Catheter for high-definition mapping and optimal tracking accuracy.*

INTELLAMAP ORION™
MAPPING CATHETER



RHYTHMIA HDx™ MAPPING SYSTEM

Intended Use

The RHYTHMIA HDx™ Mapping System (the system) is a 3D mapping and navigation system used in EP procedures. The SIS and related accessories provide data connection pathways for external input/output devices (e.g. catheters and recording systems) and serve as the data conduit to the system workstation and software.

Indications for Use

The RHYTHMIA HDx Mapping System and its accessories are indicated for catheter-based atrial and ventricular mapping. The system enables 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 display screen.

Contraindications

There are no known contraindications.

Warnings

Diagnosis and treatment of cardiac arrhythmias using the system in conjunction with radio frequency (RF) ablation and other medical devices may pose a risk of adverse events. Adverse events (e.g. cardiac perforation, new arrhythmias, exacerbation of existing arrhythmias) may require additional intervention. Do not use the system to route life-sustaining pacing signals. Only diagnostic stimulation signals (e.g. induction) may be routed through the system. All devices that are connected to system hardware must independently meet IEC 60601-1 requirements as well as any other relevant safety standards. The combined hardware configuration must also meet IEC 60601-1 safety standards. The use of system hardware 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. System hardware must be connected solely to a functional, properly-tested supply main with protective ground (earth). Do not use extension cords or adapters for ungrounded outlets. The use of a faulty or ungrounded supply main increases the risk of electrical shock and system malfunction. Use only Maestro™ or EP-Shuttle RF ablation generators with the system. Do not use the system with other RF ablation generators. Compatibility with other RF ablation generators has not been demonstrated. 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. Do not operate the localization generator within 200 mm of an implanted CIED (cardiac implantable electronic device.) Doing so may affect CIED pacing, temporarily suspend tachycardia therapy delivery, or lead to patient discomfort.

Cautions

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. Properly prepare the skin prior to attaching the electrodes to prevent receiving low quality signals from body surface electrodes. Do not use excessive gel as this may lead to signal crossover between electrodes. To minimize signal interference, route the surface ECG cables across the torso instead of alongside it. 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. Incorrect catheter localization may lead to incorrect clinical conclusion or patient injury. The localization generator may interfere with implanted cardiac implantable electronic devices (CIEDs). When mapping a patient with such a device, consider interrogating the device pre – and post-procedure. This will identify any changes in programmed parameters which could then be corrected before transferring the patient from the procedure room. Consult the CIED manufacturer instructions for additional information. If it becomes necessary to interrogate or program an implanted CIED while using the system, temporarily turn off the localization generator by using the on-screen button located on the annotating and editing maps toolbar.

Potential Adverse Events

Any potential clinical complications are in large part expected to be related to the accessory diagnostic and/or ablation catheters that are used with the system, rather than the system itself. In order to identify potential adverse events, the user is instructed to read pertinent directions for use documents associated with the catheters and ablation generators that will be employed during a mapping session. As with other mapping systems, the RHYTHMIA HDx™ Mapping System can be incidentally associated with minor or major clinical complications intrinsic to intracardiac procedures. Potential adverse events associated with the use of the system include, but are not limited to, the following: **Arrhythmias** Due to the programmed electrical stimulation performed during EP diagnostic procedures and catheter manipulations, patients undergoing EP procedures are at potential risk of arrhythmia. While the system has no active role in RF ablation, a risk does exist that the effectiveness of an RF ablation procedure could be suboptimal and cause the targeted arrhythmia to reoccur. **Misinterpretation of data** Poor catheter localization may lead to clinical data misinterpretation and the potential of resultant patient injury.

(Rev A)

INTELLAMAP ORION™ MAPPING CATHETER

Intended Use/Indications for Use

- The INTELLAMAP ORION™ High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

Contraindications

The INTELLAMAP ORION™ Catheter should not be used in:

- Patients who are not candidates for transvascular catheter procedures.
- Patients with a hypercoagulable state or who cannot tolerate heparin anticoagulation therapy.
- Patients with prosthetic or stenotic valves, in the chamber where the prosthetic or stenotic valve reside.
- Patients with active systemic infection.
- Pediatric patients.
- Pregnant and/or nursing patients.
- Patients with any other condition where catheter manipulation may not be safe.
- The INTELLAMAP ORION™ Catheter should not be used for radio frequency (RF) ablation.
- The INTELLAMAP ORION™ Catheter should not be used inside an MRI machine.

Warnings

- Keep the connector dry; wet connector pins may affect performance. Do not allow the handle or cabling to be immersed in fluid.
- Do not use the catheter to deliver ablation therapy.
- Do not expose the catheter to alcohol or other cleaning solvents.
- Do not operate the catheter against resistance. If resistance is felt during advancement, retraction, articulation, deployment or un-deployment, stop and evaluate device location under fluoroscopy.
- Do not advance or retract the catheter through a sheath when deployed or articulated.

In order to reduce the risk of clot formation:

- Maintain an activated clotting time (ACT) of greater than 300 seconds at all times during use of the catheter, and
- Continuously flush the electrode array with saline via the irrigation port at the proximal end.
- Do not use the catheter with equipment (such as stimulators or recording systems) that is not isolated.

Precautions

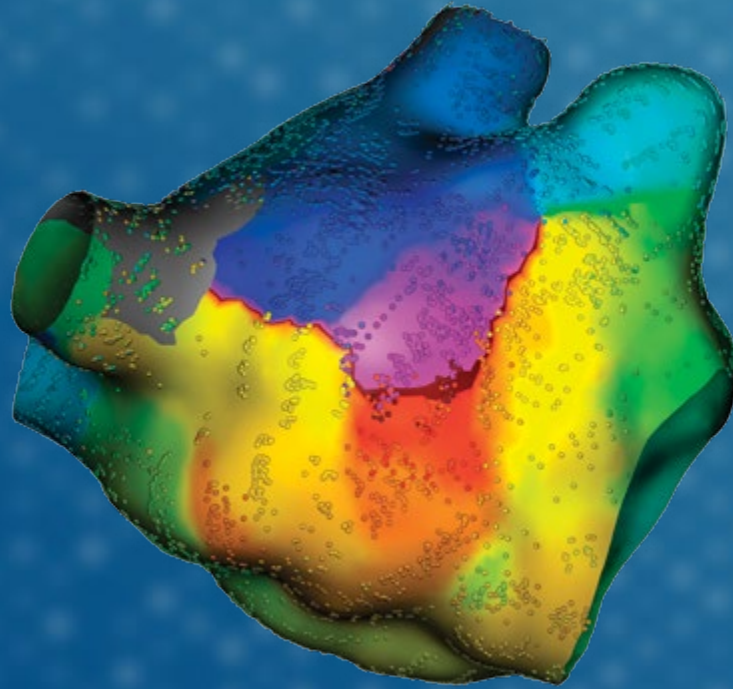
- To avoid cardiac damage, do not use excessive force when manipulating the catheter in vivo. Specifically, use caution when maneuvering while undeployed. Note that mapping and recording data do not require the use of force on the tissue.
- Always undeploy the catheter prior to removal from the patient. Use visualization (such as fluoroscopy) to verify undeployment.
- Always move the articulation control lever to its neutral position to straighten the catheter prior to removal from the patient.
- Only use guiding sheaths with curves that allow passage of the catheter without using excessive force.
- When used with a steerable guiding introducer sheath:
 - Ensure under fluoroscopy that the guiding introducer sheath distal end is straight or, if necessary, only minimally curved prior to advancing or retracting the catheter through the sheath.
 - Do not articulate the sheath while the catheter array is inside the articulating section.
- Do not deploy or articulate the catheter while the distal end is inside a sheath.
- Do not apply RF energy on an ablation catheter that is in direct contact with the electrodes on the IntellaMap Orion Catheter.
- To prevent entanglement, use care when using the catheter in the proximity of other catheters.
- When pacing, verify desired waveform is observed.
- Prior to insertion into vasculature, ensure removal of all air from the catheter lumen; use a pressured saline bag to flush saline through the catheter shaft and electrode array.

Potential Adverse Events

Serious adverse events have been reported in the literature in relation to cardiac catheterization including: stroke, cardiac tamponade, perforation, myocardial infarction, pulmonary embolism, and death. Complications reported included also (in alphabetical order): air embolism, arrhythmias, AV fistula, hematomas, hemothorax, pneumothorax, pseudoaneurysm, thromboembolism, valvular damage, vascular bleeding, and vasovagal reactions.

1. Schaeffer B, Hoffmann BA, Meyer C, et al. Characterization, mapping and ablation of complex atrial tachycardia: Initial experience with a novel method of ultra high-density 3D mapping. *J Cardiovasc Electrophysiol.* 2016 Oct;27(10):1139-1150.
2. Lațcu DG, Bun SS, Viera F, et al. Selection of critical isthmus in scar-related atrial tachycardia using a new automated ultrahigh resolution mapping system. *Circ Arrhythm Electrophysiol.* 2017 Jan;10(1). pii: e004510.
3. Study performed using Rhythmia™ Mapping System. Product specifications that deliver density, resolution, and automation remain consistent with Rhythmia HDx.
4. Anter E, McElderry TH, Contreras-Valdes FM, et al. Evaluation of a novel high-resolution mapping technology for ablation of recurrent scar-related atrial tachycardias. *Heart Rhythm.* 2016 Oct;13(10):2048-55.
5. Based on approximate mapping speed of 95 pts / minute in the right atrium in 5 swine USING THE ST. JUDE MEDICAL PRECISION ENSITE MAPPING SYSTEM. Ptaszek LM, et al. Rapid High-Density Automated Electroanatomical Mapping Using Multiple Catheter Types. Poster Session PO097 APHRS 2015.
6. Based on approximate mapping speed of 491 pts / minute in the right atrium in 5 swine USING THE BOSTON SCIENTIFIC RHYTHMIA MAPPING & NAVIGATION SYSTEM. Ptaszek LM, et al. Rapid Acquisition of High-Resolution Electroanatomical Maps Using a Novel Multielectrode Mapping System. *JICE.* Nov 2012.
7. Based on a minimum of 5 clinical publications to date demonstrating mapping speeds > 1,000 points / minute.
8. Mantziari L, Butcher C, Kontogeorgis A, et al. Utility of a novel rapid high-resolution mapping system in the catheter ablation of arrhythmias: An initial human experience of mapping the atria and the left ventricle. *JACC: Clin Electrophysiol.* 2015 Oct;1(5):411-20.
9. Connection boxes in addition to the MAESTRO™ Ablation System are not yet cleared in the U.S. but currently available in regions outside of the U.S.

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.



RHYTHMIA HDx™

MAPPING SYSTEM

The difference is in the design.

**Boston
Scientific**

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

Medical Professionals:
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Customer Service:
1.888.272.1001

Left atrial activation map and cover image
courtesy of Elad Anter, MD, BIDMC.

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