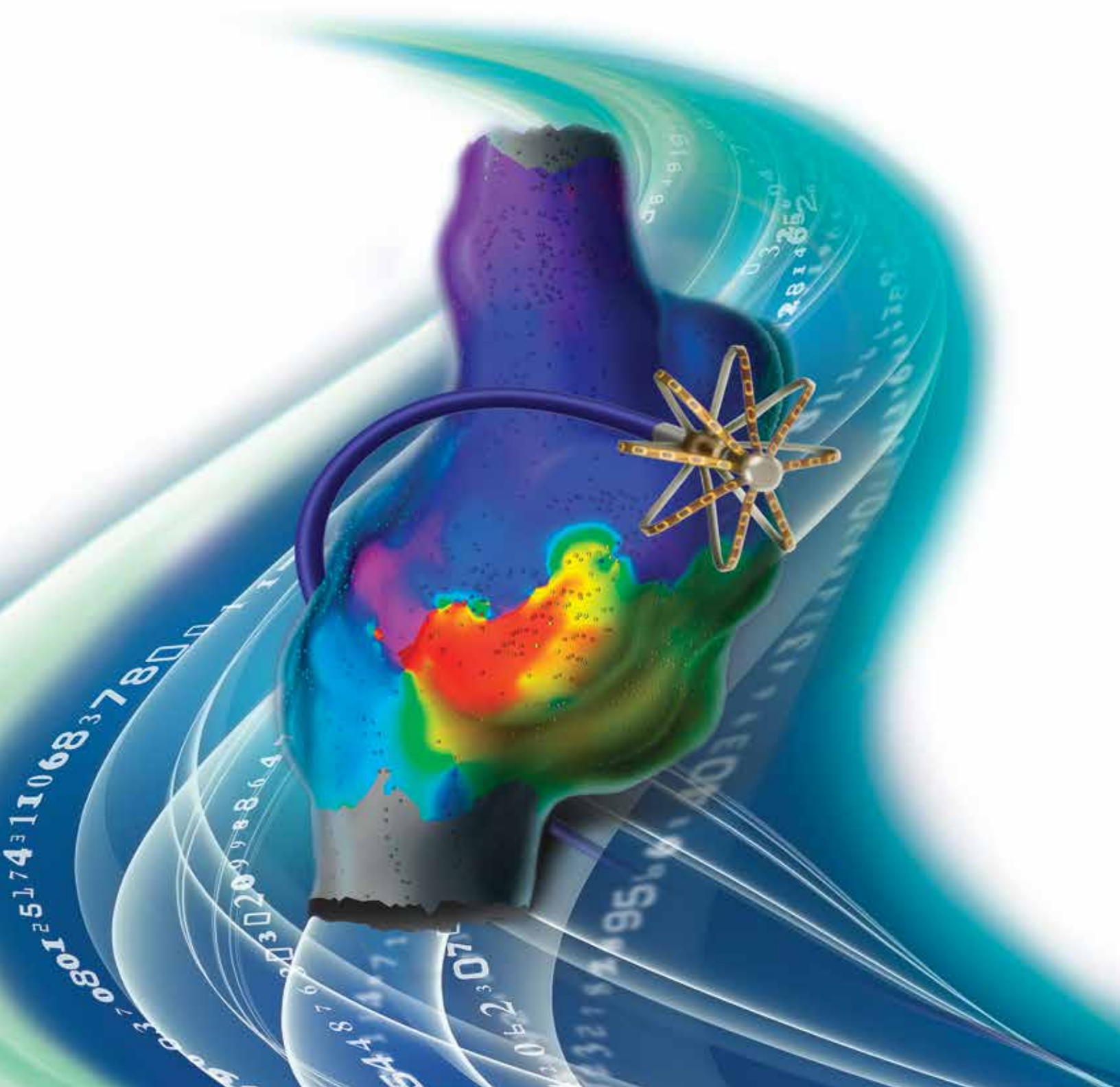


Rhythmia™ Mapping System

Mapping, Redefined.



Mapping, Redefined.

Introducing the Rhythmia Mapping System, marking the beginning of a new era in cardiac ablation technology. This breakthrough technology is the only system designed to provide all the information you need to better diagnose and treat all types of arrhythmias — from the simplest to the most complex — with greater clarity, efficiency and confidence.



Clarity. Efficiency. Confidence.

System Overview

IntellaMap Orion™ High Resolution Mapping Catheter

Versatile, elegant design

- 64-electrode basket design facilitates rapid collection of clear signals
- Bi-directional steerability and variable deployment through all chambers



Signal Station

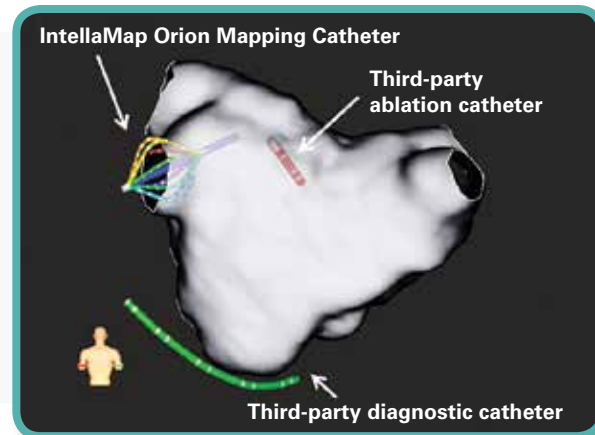
Sophisticated, clear communication

- Advanced front-end technology filters and collects high quality signals with low noise
- Easy connectivity to IntellaMap Orion and other compatible EP catheters

Localization System

Advanced, flexible open architecture

- Open architecture allows you to visualize and use the diagnostic and ablation catheters of your choice
- Optimal blend of magnetic and impedance location technologies expedites clear, accurate tracking



Rhythmia™ Algorithm Suite

Smart, efficient mapping

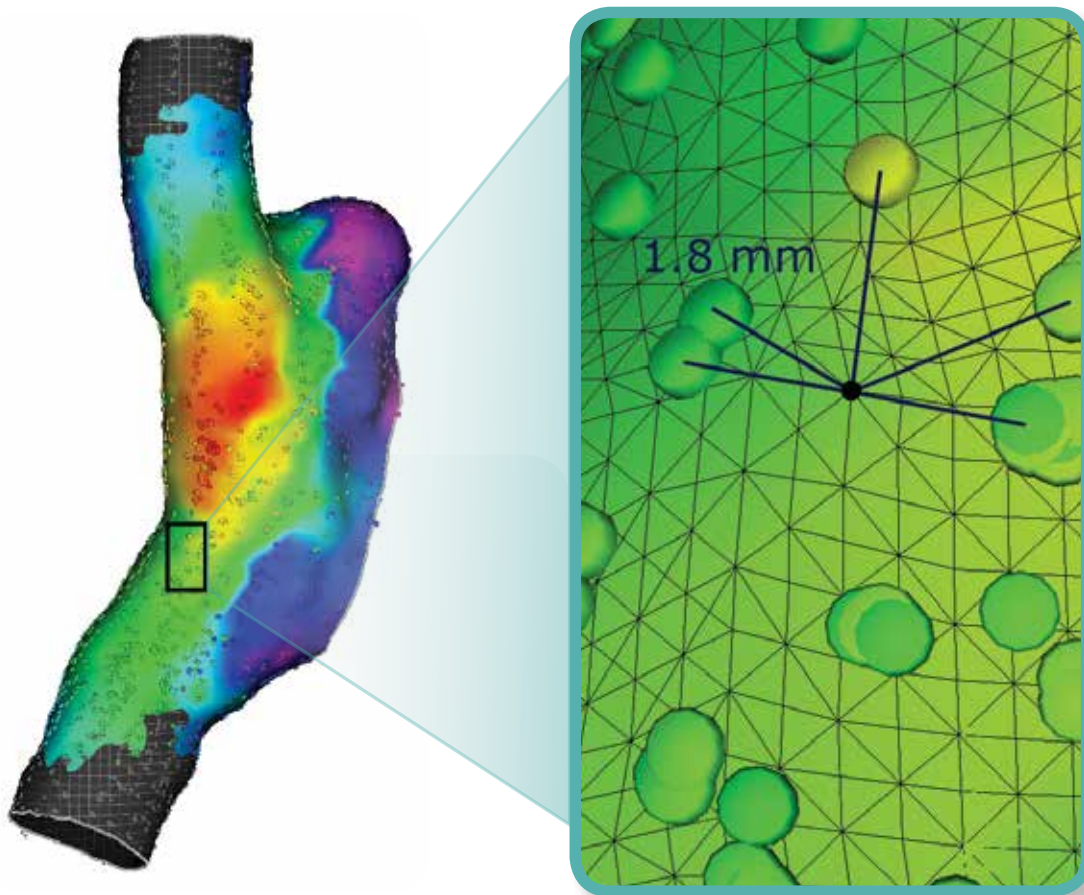
- Continuous Mapping simultaneously generates accurate, high-resolution 3D electroanatomical maps
- Dynamic Review allows you to quickly review and edit data points
- Automated, intelligent annotation eliminates time-consuming manual annotation

Clarity for Accurate Mapping

Highly detailed electroanatomical maps facilitate clear, confident clinical decisions.

True High-Resolution, Real High-Density

- Captures thousands vs. hundreds of data points to provide a more accurate view of the arrhythmia
- Eliminates the guesswork in locating the ablation target
- Uncovers small channels and gaps in lesion sets



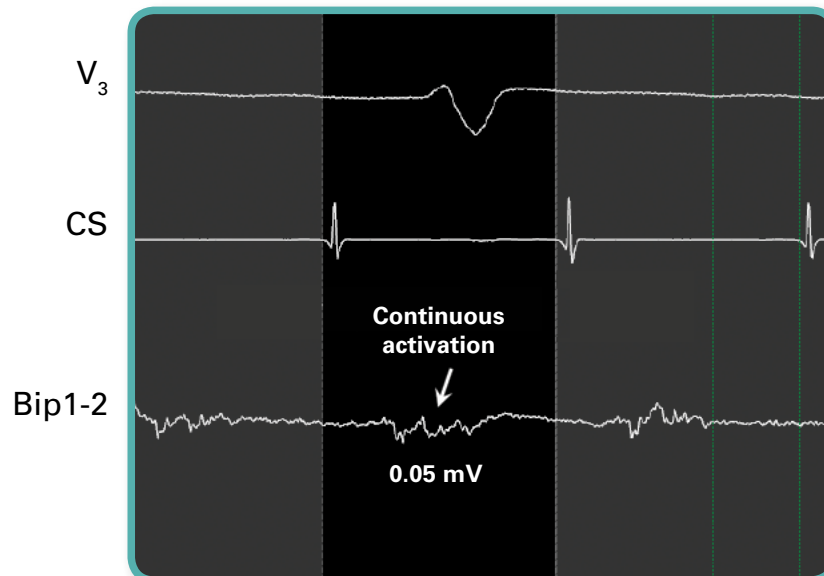
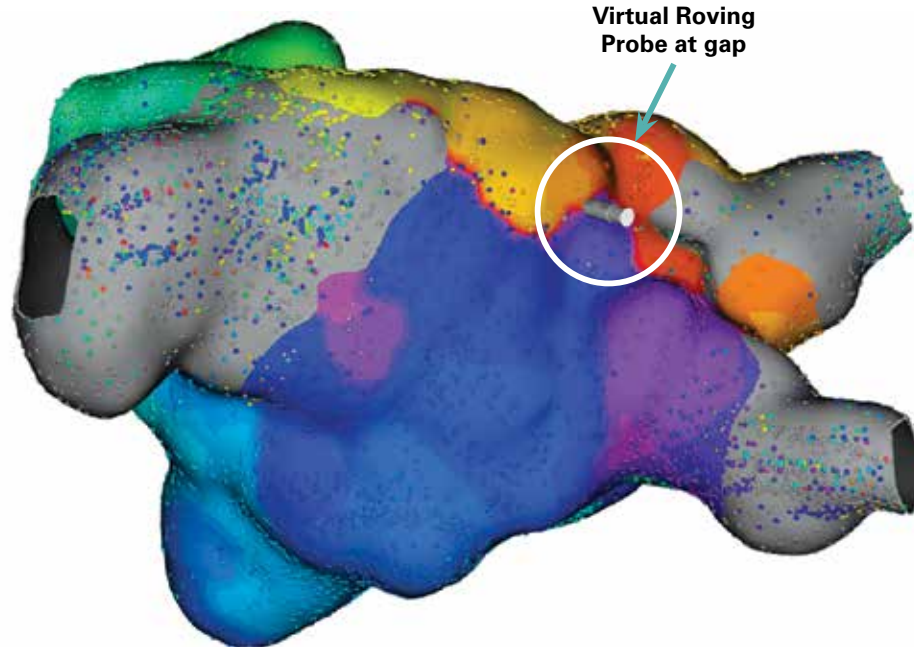
High-density chamber coverage provides contact electrograms less than 2mm from any point on the map.¹

1. Nakagawa H., Ikeda A., Sharma T., Lazzara R., Jackman W., Rapid high-resolution electroanatomical mapping: Evaluation of a new system in a canine atrial linear lesion model. *Circulation Arrhythmia Electrophysiology*. 2012 Apr;5(2):417-24.

Enhanced Substrate Identification

- Advanced design produces sharp signals with limited far field, ablation and pacing artifacts
- Superior signal quality enhances precise arrhythmia visibility despite low voltage signals
- EGM clarity facilitates definition of scar, and scar boundaries, with increased sensitivity

Case Example – Atrial Tachycardia (Prior AF Ablations)



High signal clarity reveals continuous low voltage activation (0.05 mV), indicating gap in lesion set.

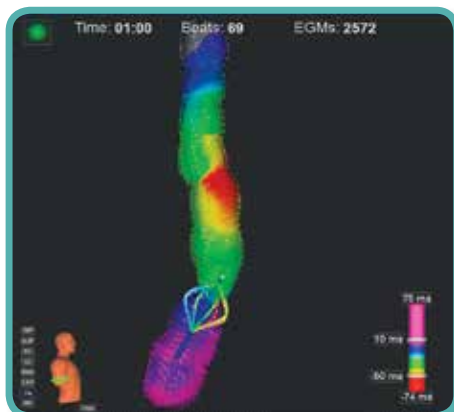
Efficiency in Diagnosis and Treatment

Ideal blend of speed, automaticity and ease-of-use allows you to collect thousands of relevant data points within minutes.

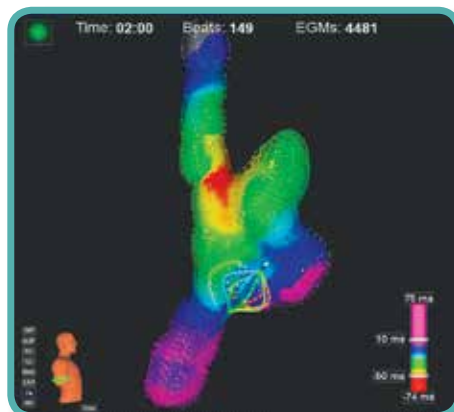
Continuous Mapping

- Continuous acquisition of points based on user-defined criteria creates maps in 1/3 of the time
- Repeatable maps generated in minutes offer more predictability and less variability
- Seamless map creation for all rhythm types, including ectopic beat maps
- 99.8% accuracy in automated annotation algorithm eliminates the need for manual beat acceptance²

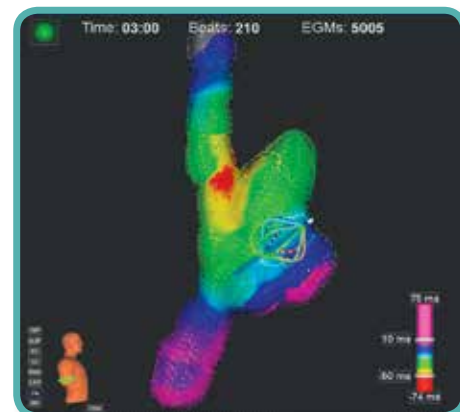
High-Resolution, 3D Electroanatomical Map Captured in 3 Minutes



1-minute
of EGMs = 2,572



2-minute
of EGMs = 4,481



3-minute
of EGMs = 5,005

The IntellaMap Orion™ Mapping Catheter traverses the chamber while contact electrograms are continuously annotated and added to the map based on user pre-defined criteria.

2. Data on file.

Case images courtesy of W. Jackman, MD & H. Nakagawa, MD. University of Oklahoma Health Sciences Center. Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

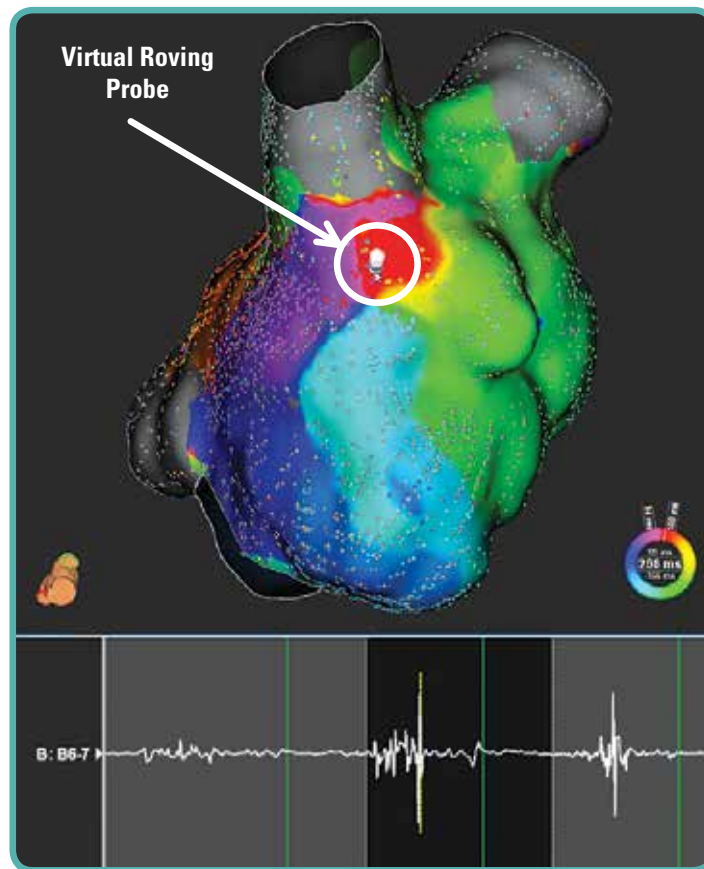
Dynamic Review

- Virtually review and edit high-density maps quickly
- Manually accept/reject beats or change annotations with full control

Tissue Targeting

- Rapidly and precisely identify target ablation sites away from the patient table
- Reduce intracardiac catheter manipulations and exposure to fluoroscopy with Virtual Roving Probe

Case Example – Macroreentrant Atrial Tachycardia



From the workstation PC, Virtual Roving Probe sweeps the left atrium to aid in the identification and tagging of the target ablation site.

Confidence with Validation Mapping (vMap™)

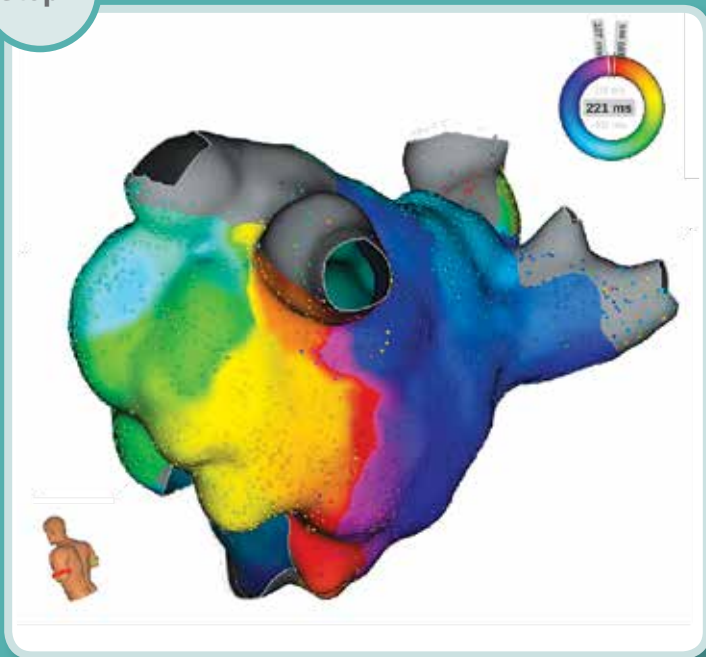
The Rhythmia Mapping System changes the paradigm for procedure outcomes with vMap. vMap produces fast, accurate validation maps that, for the first time, allow you to confirm ablation endpoints within just a few minutes.

vMap – Lesion Validation in Minutes

Case Example – Left Atrial Reentrant Tachycardia (Prior AF Ablation)

Step 1

Create Activation Map



Activation map enables identification of ablation target.

Step 2

Ablation Delivery



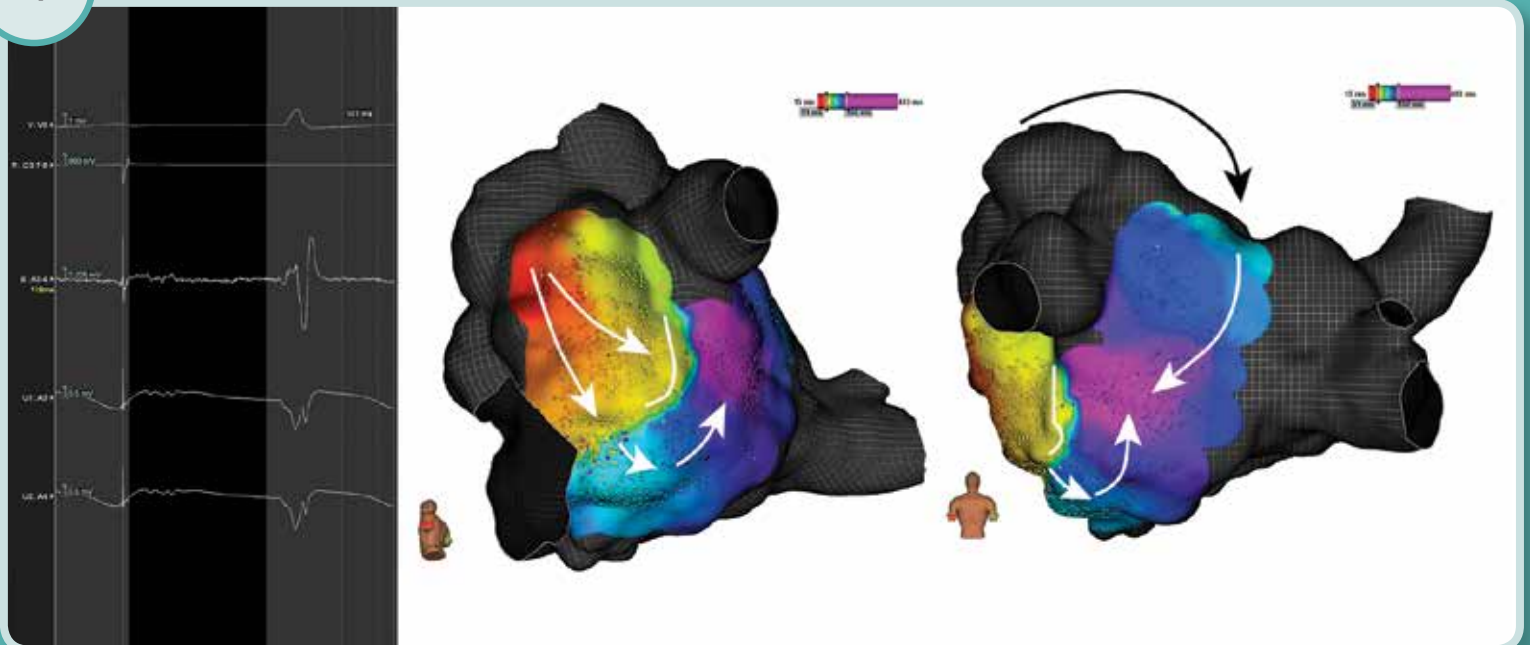
Ablation delivered to create line of block. Successful termination of acute tachycardia.

vMap™

- Quickly create high-resolution validation maps multiple times during a procedure
- Clearly assess gaps and verify lesion integrity for greater confidence in outcomes
- Potentially reveal concealed arrhythmias more efficiently

Step 3

vMap to Confirm Efficacy



Time: 2.4 min / Mapping Points: 1,781

Validation map is created displaying the area of ablation. Propagation and breakthrough are visible on the line of ablation. In just a few minutes, vMap provides the ability to assess complete block before ending the procedure.

Rhythmia™ Mapping System

Redefining Ablation Technology

At Boston Scientific, we are committed to delivering new ablation technologies that are built upon a foundation of technical innovation and clinical success. The introduction of the Rhythmia Mapping System marks a significant milestone along Boston Scientific's journey to redefine ablation technology.



To learn more about Boston Scientific's breakthrough ablation technologies visit <http://www.bostonscientific.com/redefining-ep>.



Rhythmia™ Mapping System

Indications for Use, Contraindications, Warnings, Precautions

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 (abbreviated)** General: Use the Rhythmia Mapping System as intended, and according to the instructions that accompany the device. Failure to follow system warnings, precautions, and instructions may cause equipment damage, system malfunction, or harm 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®, Stockert™, or IBI™. Do not use the system with other RF ablation generators. Compatibility with other RF ablation generators has not been demonstrated. **PRECAUTIONS (abbreviated)** 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. During the procedure: 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.

IntellaMap Orion™ High Resolution Mapping Catheter

Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events

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. This catheter is intended for single patient use only. Do not reuse or re-sterilize. Resterilization may damage the device and reuse may increase the risk of cross contamination. 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 sec. 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** Store in a cool, dry place. Do not use if the sterile package is open or damaged. Do not use the device if the use-by-date has passed. 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. Remove the catheter in case of any observed malfunction. Federal Law (U.S.A.) restricts the sale of this device by or on the order of a physician only. **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, arrhythmia, AV fistula, hematomas, hemothorax, pneumothorax, pseudoaneurysm, thromboembolism, valvular damage, vascular bleeding and vasovagal reactions.



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CAUTION Federal Law (USA) restricts this device to sale by or on the order of a physician. Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess, and communicate to each patient all foreseeable risks of the procedure.