THE FIRST EVER SUITE OF TOOLS TO STREAMLINE INTERPRETATION OF HD MAPPING DATA

RHYTHMIA HDx™ set a new standard with it's high definition, 3D maps. Now you can take that volume and quality of data to the next level.

HD CATHETER

HD HARDWARE

HD SOFTWARE

To learn more visit https://www.bostonscientific.com/LUMIPOINT

RHYTHMIA HDx™ Mapping System INTENDED FOR 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's 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. 92106607 (Rev. B)

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.

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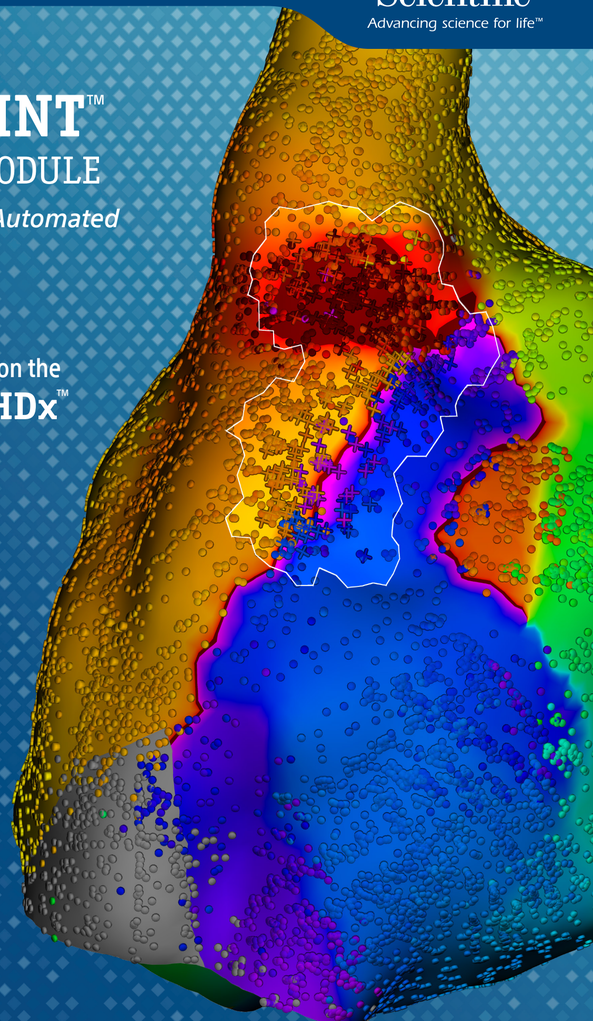
LUMIPOINT™
SOFTWARE MODULE

The Next Level of Automated HD Mapping

Available Exclusively on the
RHYTHMIA HDx™
Mapping System

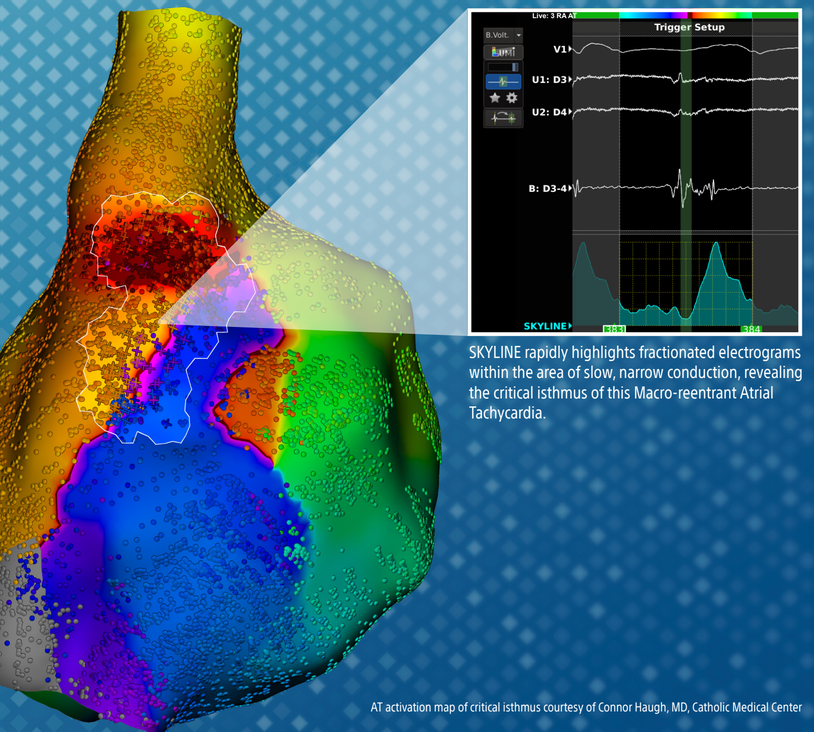


LOCALIZE SLOW AND NARROW CONDUCTION WITH SKYLINE™

SKYLINE™ presents a novel view of full chamber activation, displaying the amount of surface area activating at any time during the tachycardia cycle.

SKYLINE aids in HD map interpretation

- Automatically highlight critical areas of the map
- Rapidly identify potential critical isthmuses
- Easily distinguish earliest sites of activation



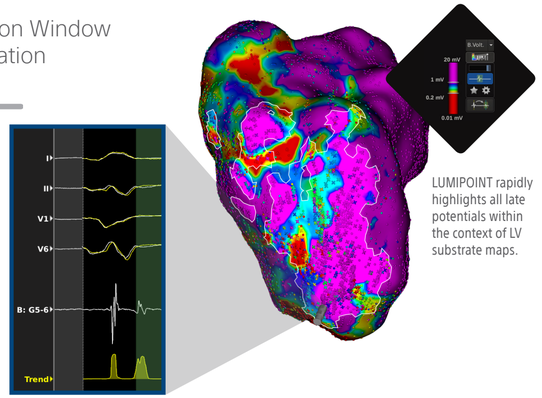
SKYLINE rapidly highlights fractionated electrograms within the area of slow, narrow conduction, revealing the critical isthmus of this Macro-reentrant Atrial Tachycardia.

AT activation map of critical isthmus courtesy of Connor Haugh, MD, Catholic Medical Center

LUMIPOINT AUTOMATES IDENTIFICATION OF CLINICALLY RELEVANT AREAS OF INTEREST

Automatically highlight electrograms of interest within the context of activation and voltage maps

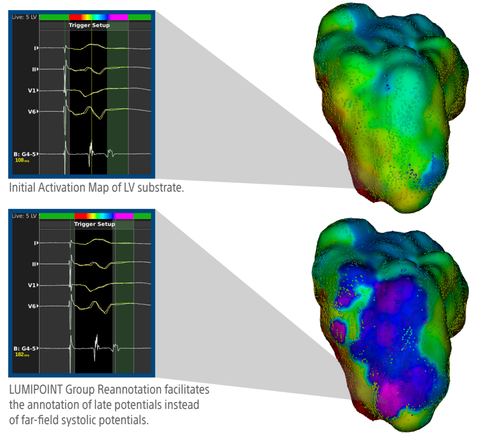
LUMIPOINT Activation Window
LUMIPOINT Propagation



LUMIPOINT rapidly highlights all late potentials within the context of LV substrate maps.

Customize activation maps with rapid electrogram reannotation

LUMIPOINT
Group Reannotation

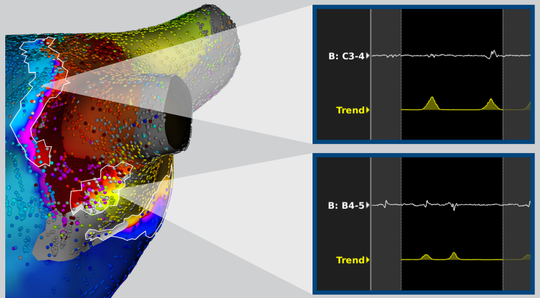


Initial Activation Map of LV substrate.

LUMIPOINT Group Reannotation facilitates the annotation of late potentials instead of far-field systolic potentials.

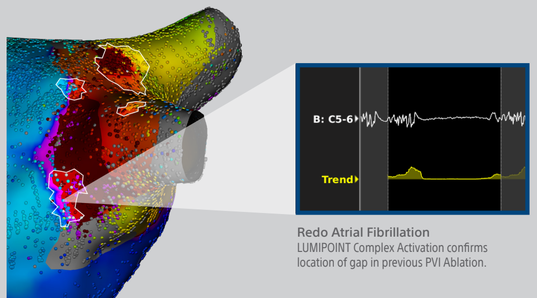
Rapidly highlight lines of block and fractionated signals

LUMIPOINT
Split Activation



Redo Atrial Fibrillation
LUMIPOINT Split Activation identifies line of block in previous PVI Ablation.

LUMIPOINT
Complex Activation



Redo Atrial Fibrillation
LUMIPOINT Complex Activation confirms location of gap in previous PVI Ablation.

Images provided courtesy of Prof. Jaïs, LIRYC Institute, Bordeaux

LUMIPOINT FACILITATES OPTIMIZATION OF ANY WORKFLOW, FOR ANY PROCEDURE