

O PRIMEIRO CONJUNTO DE FERRAMENTAS FEITO PARA SIMPLIFICAR A INTERPRETAÇÃO DE DADOS EM MAPAS DE ALTA DEFINIÇÃO

O RHYTHMIA HDx™ estabelece um novo padrão de alta definição em mapeamentos 3D. Agora é possível analisar o volume e qualidade de dados em alta resolução.

HD CATHETER



HD HARDWARE



HD SOFTWARE



Para mais informações visite <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 recur. **Misinterpretation of data** Poor catheter localization may lead to clinical data misinterpretation and the potential of resultant patient injury. 92106607 (Rev. B)

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.fu-bsci.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France. 2022 Copyright © Boston Scientific Corporation or its affiliates. All rights reserved.

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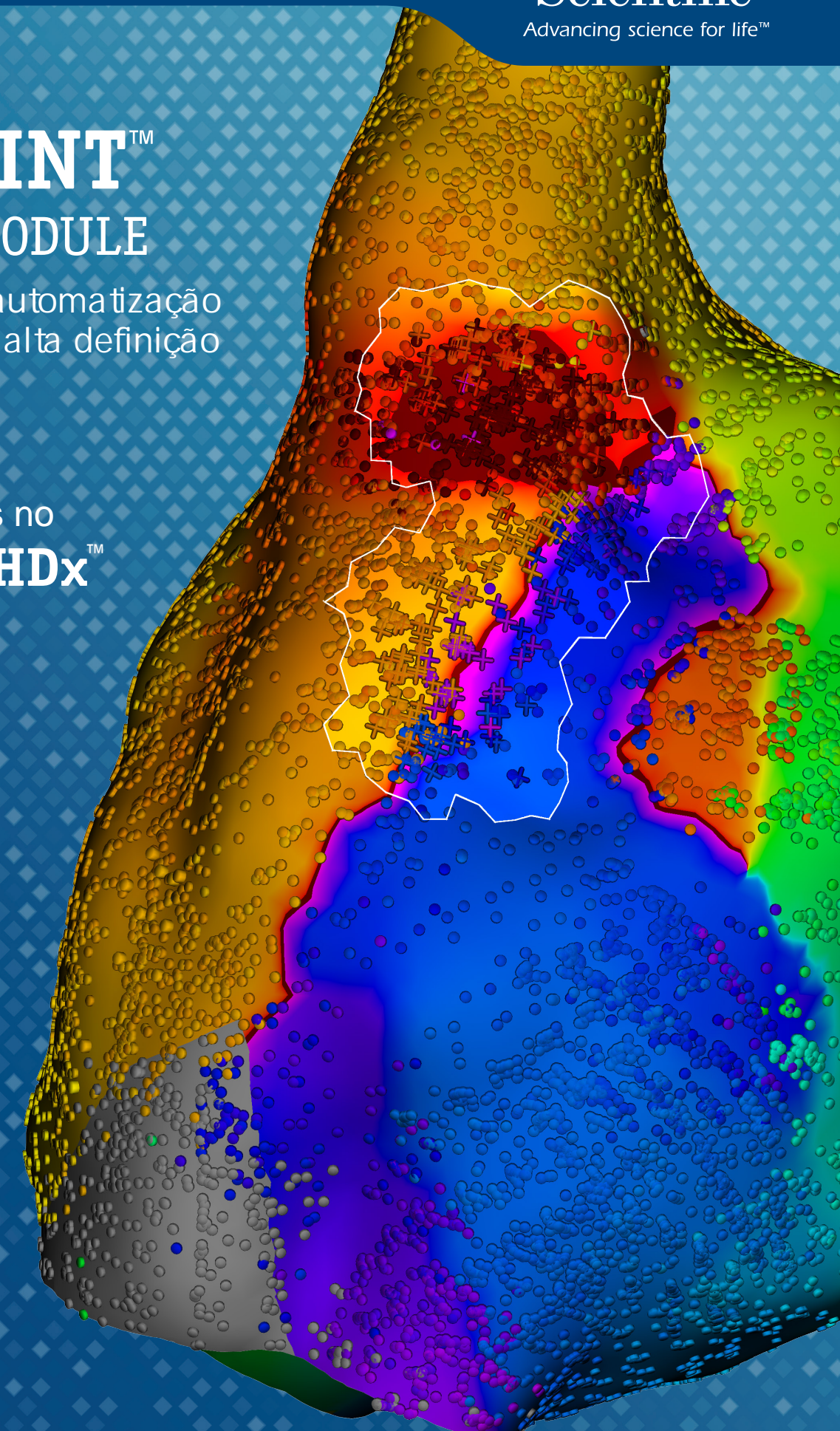
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LUMIPOINT™ SOFTWARE MODULE

Um novo padrão de automatização de mapeamentos de alta definição

Öis| onðve| a] enas no
RHYTHMIA HDx™
Mapping System



IDENTIFICA CONDUÇÕES LENTAS E ESTREITAS ATRAVÉS DO SKYLINE™

O SKYLINE™ oferece uma nova forma de visualizar toda a ativação da câmara cardíaca mapeada, mostrando a quantidade de áreas ativas em todos os momentos durante o ciclo da taquicardia.

O SKYLINE auxilia na interpretação dos mapas de alta definição.

- Destaca automaticamente áreas críticas no mapa
- Identifica rapidamente potenciais istmos críticos
- Destaca facilmente re-entrantes e precoces de ativação



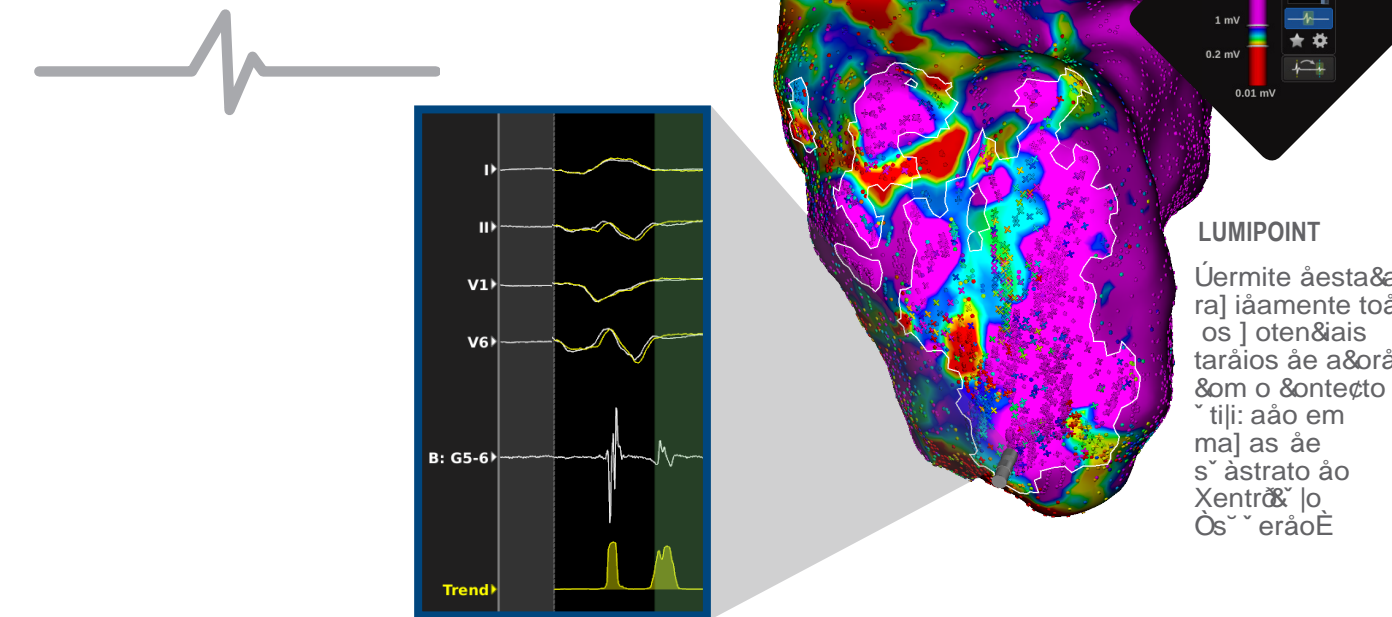
O SKYLINE consegue destacar rapidamente os eletrogramas fracionados dentro das áreas de condução lenta e estreita, revelando os potenciais istmos críticos de taquicardias reentrantes.

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

O SWT QUANDO AVALIAR O PAINEL DE ATIVAÇÃO DE VENTRÍCULO DESTACA OS MAIORES E MENORES

Esta ferramenta automaticamente os eletrogramas de interesse dentro do contexto de ativação e mapas de voltagem

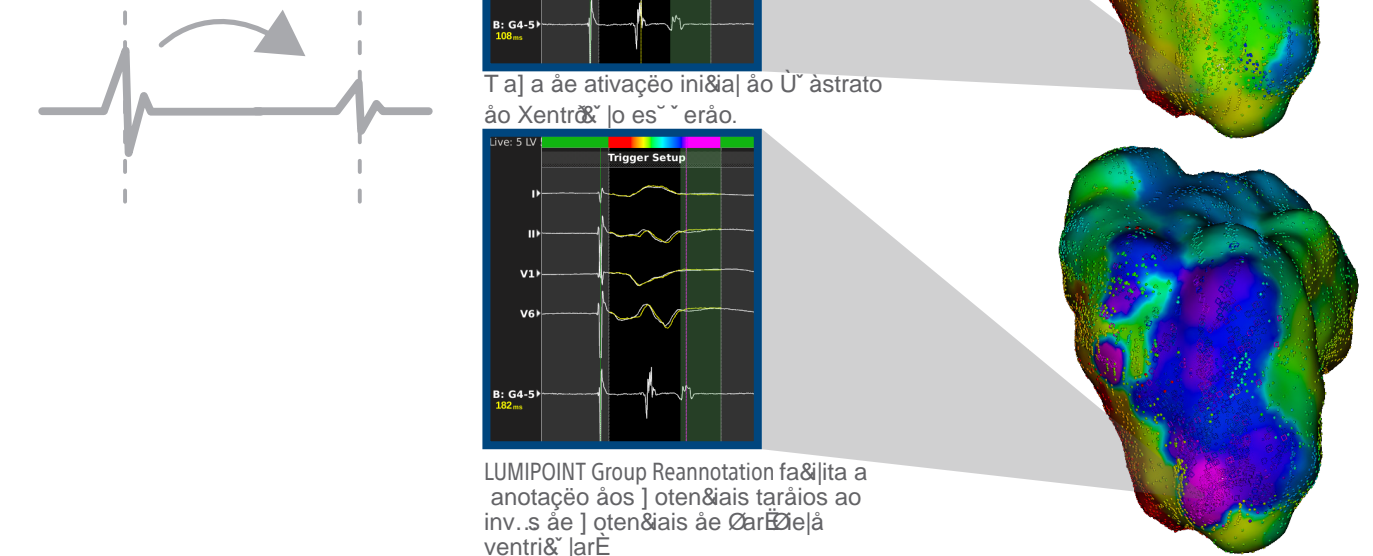
LUMIPOINT Activation Window
LUMIPOINT Propagation



LUMIPOINT
Permite automaticamente todos os potenciais tardios com o contexto de ativação em mapas de Xentron e outros

Estima: a os mapas de ativação através da reanotação de áreas

LUMIPOINT
Group Reannotation

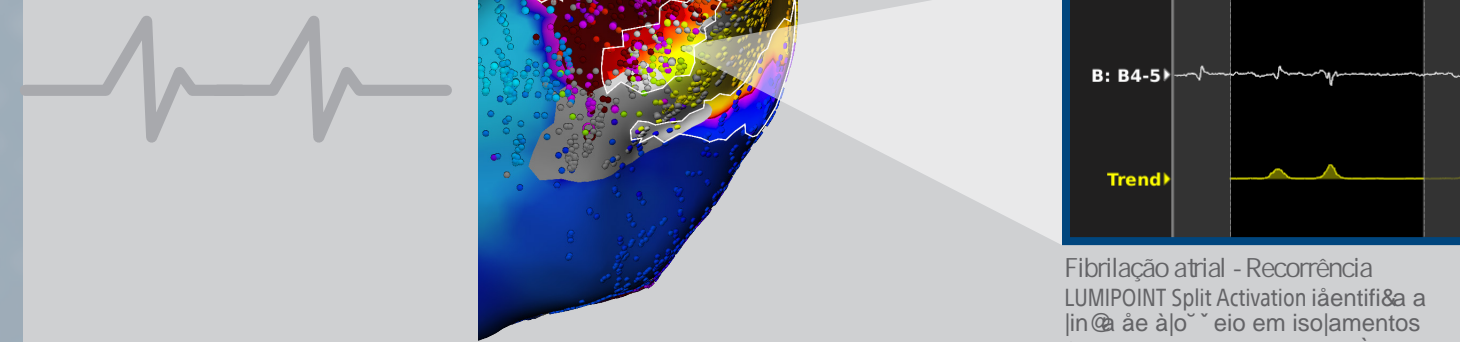


Tela de ativação inicial ao Ustrato ao Xentron e outros

LUMIPOINT Group Reannotation facilita a anotação dos potenciais tardios ao invés de potenciais de re-entrada ventricular

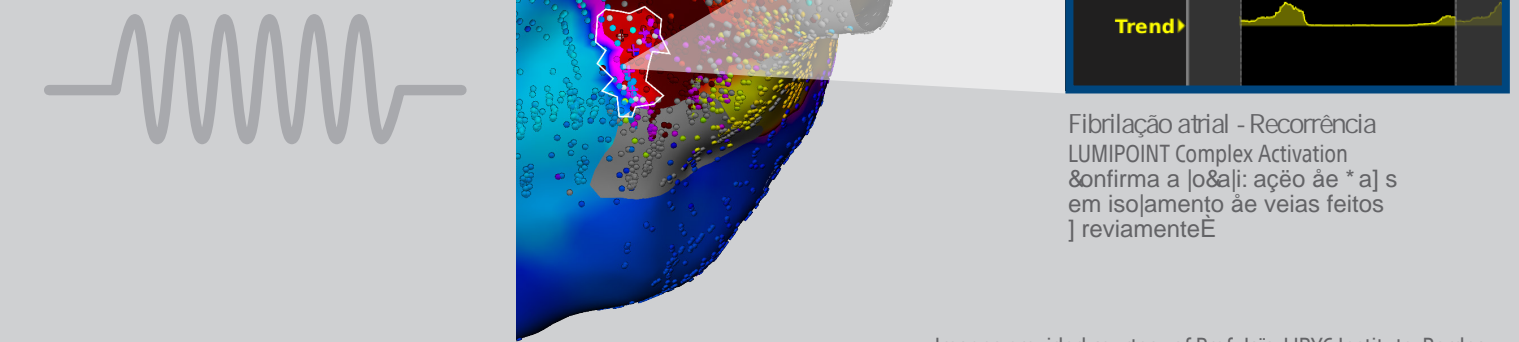
Esta ferramenta automaticamente as linhas de eixo e sinais fracionados

LUMIPOINT
Split Activation



Fibrilação atrial - Recorrência
LUMIPOINT Split Activation identifica as linhas de eixo em isolamento de veias feitas previamente

LUMIPOINT
Complex Activation



Fibrilação atrial - Recorrência
LUMIPOINT Complex Activation confirma a localização de áreas em isolamento de veias feitas previamente

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

SWT QUANDO AVALIAR O PAINEL DE ATIVAÇÃO DE VENTRÍCULO DESTACA OS MAIORES E MENORES