Rapid, high-resolution electroanatomical mapping: evaluation of a new system in a canine atrial linear lesion model

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Introduction
Using a canine right atrial (RA) linear lesion model, researchers produced a complex pattern of RA activation to evaluate a novel mapping system for rapid, high-resolution (HR) electroanatomical mapping – the RHYTHMIA™ Mapping System from Boston Scientific.

Methods
The RHYTHMIA Mapping System uses an 8F deflectable catheter with a mini-basket (1.8 cm diameter) of 8 splines of 8 electrodes (total 64 electrodes, 2.5 mm spacing). The system automatically generates chamber geometry and a HR activation map using electrograms (EGMs) recorded within 5 mm of the chamber surface. It automatically acquires EGM and location information based on EGM stability and respiration phase.

In 10 anesthetized dogs, high-resolution RA maps were obtained by maneuvering the mini-basket catheter during sinus rhythm and coronary sinus pacing. Then, a right thoracotomy was performed, and either one or two epicardial linear lesions were created to form a gap on the RA free wall. RA maps during RA pacing close to the linear lesions were obtained.

Results
A total of 73 RA maps were obtained, with the following results:

- Accepted beats: 44–729 (median 237)
- Accepted EGMs: 833–12,412 (median 3589)
- Resolution: 1.8–5.3 mm (median 2.7)
- Mapping time: 2.6–26.3 minutes (median 7.3)

Without manual annotation, the system accurately created RA geometry and demonstrated RA activation, identifying the lines of block and the presence or absence of a gap in all 10 dogs (Fig). Endocardial radiofrequency catheter ablation (guided by the activation map) produced complete block across the gap in all 3 dogs tested with this method.

Conclusion
The RHYTHMIA Mapping System accurately and quickly identified geometry and complex patterns of activation in the canine RA with little or no manual annotation of activation time.

This study was conducted in a canine preclinical model. These canine’s had small right atriums. Further study is required in a clinical setting and with a variety of atrium sizes.

TO READ THE FULL ARTICLE, CLICK HERE http://circep.ahajournals.org/content/5/2/417.full.pdf
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 is intended to verify that a localized source may cause an electric arc, which may lead to inaccurate tracking. Do not connect or disconnect 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. 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 (ICEDs). 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. Only use a functioning, properly tested ground (earth) to power the Rhythmia Mapping System. The use of a faulty, ungrounded supply may increase 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 cause the Signal Station and accessories to malfunction. 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 injury or damage, never use only the back cover to hold the Workstation and Workstation-related accessories. Do not place the Workstation near flammable anesthetics. System operation near flammable anesthetics may cause an explosion that could cause injury or death to the patient or user. 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 cause the Signal Station and accessories to malfunction. To reduce 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). Do not use excessive gel as this may lead to shorts between different electrodes. 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 disrupt localization. Magnetic Localization System managements should only be used as a reference, for example to identify anatomic risk the area of 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)

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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.