RHYTHMIA HDx™ Mapping System

ExpertCare Capital Equipment Technical Services

Boston Scientific
Advancing science for life™

Working together to maximize productivity and patient care

Our **ExpertCare** Service Program is designed to provide you with continued confidence in Boston Scientific products, customer support and services. Our service team has the expertise that comes from years of collaboration with our customers to better support your goals and capital investments. The Boston Scientific Technical Service Center is available 24-hours a day, 7-days a week, 365-days a year to support your commitment to patient care.

Service Plan	EverCare Elite	EverCare Select	TotalCare	Benefit
Technology Assurance				
Years 4 and 5 of service plan **OR** If, during 2024, Boston Scientific receives FDA approval of any next-generation EP ablation system, Customer may elect to forgo the final two years of service coverage and instead receive such system at no additional charge.*	✓			Access to new software that supports future advancements in mapping system features and new functionality
All software upgrades to the RHYTHMIA™ Mapping System** **OR** If, during 2023, Boston Scientific receives FDA approval of any next-generation EP ablation system, Customer may elect to receive such system at no-charge in lieu of the software upgrade.***	✓	✓		Access to new software that supports future advancements in mapping system features and new functionality
New Technology Accessories**	✓	✓		Provides new technology accessories that support future advancements in mapping system features and new functionality
Service Program Features				
100% coverage on parts and labor charges	✓	✓	✓	Predictable spending
Software updates	✓	✓	✓	Latest updates for optimal performance
Priority designation in service repair queue	✓	✓	✓	Units prioritized ahead of those without a service agreement
48-hour on-site service guarantee	✓	✓	✓	Increased uptime and experts available on-site when needed
One system relocation per year	✓	✓	✓	Predictable spending for future moves
Access to technicians via phone	✓	✓	✓	First line of help for improved uptime
One preventative maintenance visit per year	✓	✓	✓	Trained engineers provide in-depth analysis to keep system at peak performance

For customers without a service contract, system relocation, on-site repair (parts plus labor charges) and an annual preventative maintenance visit can be quoted individually.

* Such election must be made at least one month prior to end of third year of coverage, and payment of the full contract price for this service agreement must be made prior to shipment of the next-generation ablation system.
** If any when they become commercially available during the term of your plan.
*** The EverCare Select and Elite service contracts do not cover service of any next-generation EP ablation system. Separate service agreements will be available following approval of any next-generation system.

ExpertCare
Capital Equipment Technical Services

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Technical Assistance Center
1-800-949-6708

For more information, please contact your **Boston Scientific AF Solutions Territory Manager.**

*Terms and conditions apply and are found in the service agreements for each program.

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 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: 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. Do not connect more than one ablation catheter simultaneously to the Ablation System when used with Rhythmia HDx Mapping System. 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. The patient may experience discomfort from the rapid pacing and/or the initiation of an 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. To ensure correct clinical decisions, the physician must use fluoroscopy, ultrasound, pace mapping or other visualization techniques to verify 3-D mapping results and catheter position. Electrical Hazards With any electrical system there is a potential risk of electrical shock to the user, patient, and service representative. 92106607 (Rev. E)

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

Medical Professionals:
1.800.CARDIAC (227.3422)
Customer Service:
1.888.272.1001

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