Boston Scientific

Advancing science for life™

LABSYSTEM™ PRO

EP RECORDING SYSTEM

ExpertCare Service Program

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.

LABSYSTEM™ PRO
EP Recording System

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ExpertCare Service Program

EssentialCare

Detail	Benefit
Access to technicians via phone	First line of help for improved uptime
100% coverage on loaner equipment	Increased uptime with loaner units available when you need them
One preventative maintenance visit per year	Trained engineers provide in-depth analysis to keep system at peak performance
100% coverage on parts and labor charges	Predictable spending
Software updates	Latest updates for optimal performance

TotalCare

All the benefits of the *EssentialCare* Service Program PLUS:

Detail	Benefit
25% discount on upgrades off list price	Ensures access to the hardware and software that will be able to support future system features
One week clinical training	Expert training on the use of the equipment
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

Technical Assistance Center 1-800-949-6708

For more information please contact your **Boston Scientific Electrophysiology Sales Representative.**

EverCare

All the benefits of the *TotalCare* Service Program PLUS:

Detail	Benefit
Technology Assurance – one CPU hardware and one software upgrade to the LABSYSTEM PRO EP Recording System* if upgrades become available during the term of the service plan	Helps assure the life of your LABSYSTEM PRO investment will be prolonged and protected and ensures access to the upgrades that will be able to support future advancements in recording system features.

BiomedCare

Detail	Benefit
BioMed technical overview	Increase knowledge of BioMed team for minor troubleshooting, cleaning and maintenance
- Includes all the entitlements of LABSYSTEM PRO *TotalCare* or *EssentialCare** - 20% discount off of *TotalCare* or *Essential Care** for BioMed team shared responsibility	Partnership between Boston Scientific and Biomed team to provide training and service on LABSYSTEM PRO system

PMCare

Detail	Benefit
Access to technicians via phone	First line of help for improved uptime
100% coverage on loaner equipment during repair	Increased uptime with loaner equipment
One preventative maintenance visit per year	Trained engineers provide in-depth analysis to keep system at peak performance

*Exclusions apply. For a complete list of exclusions see LABSYSTEM PRO BioMed FirstCall Contract. For full terms and conditions of these plans, please see the plan service agreement.

LABSYSTEM™ PRO (w/CLEARSIGN™) INTENDED USE/INDICATIONS FOR USE The LABSYSTEM PRO EP Recording System is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of intracardiac electrophysiological data. When integrated with the Biosense Webster® CARTO® 3 system, the LABSYSTEM PRO EP Recording System is designed to: a) send patient demographics to Biosense Webster CARTO 3, and b) acquire (from Biosense Webster CARTO 3), store and display: i) synchronized 3D mapping events, ii) stimulation pacing data, and iii) images of completed 3D electro-anatomical maps of the human heart. The 3D mapping events and images are created by the Biosense Webster CARTO 3 device and stored on the LABSYSTEM PRO EP Recording System for review and insertion into the final clinical report. Integration also supports bidirectional communication of stimulation pacing channel selection and information sharing between the two systems. The CLEARSIGN/ CLEARSIGN II Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (the LABSYSTEM PRO EP Recording System) that can record and display the information.**CONTRAINDICATIONS** None known.**WARNINGS** The CLEARSIGN/CLEARSIGN II Amplifier is not a vitals monitor, does not transmit alarms and does not have arrhythmia detection capability. If arrhythmia monitoring is needed use a separate ECG monitor with arrhythmia detection capability. A protective cover should be used to shield any unused or unterminated patient connections. This measure provides increased protection to the operator during patient defibrillation. To avoid potential patient shock hazard, a protective cover should be used to cover any unused 2 mm pins that are not plugged into the catheter junction box or unipolar reference cable. Furthermore, all catheter pins connected to the junction box must be fully inserted. If any lead wire is removed from the 12 Lead ECG cable, the HPCS shorting plug should be inserted into the open socket to avoid potential patient shock hazard. To avoid stimulation at an undesired pacing site, always be sure the Stim Setup is appropriate before stimulating. Stim Setup, including the stimulator connection settings, is stored with Amplifier Configuration information. Selecting a new Channel Setup could result in a change to the current stimulator pacing site(s). DO NOT stimulate the patient until confirming that the changes to Stim Setup are appropriate. If there is a discrepancy between the data displayed by the LABSYSTEM™ PRO computer and the data displayed by the RF Generator, always use the RF Generator as your primary source of information. When interconnecting any RF generator to the LABSYSTEM PRO Computer, confirm that the fully cabled combination meets all current requirements of IEC 60601-1 for Type CF devices. The method for calculating the dP/dt values displayed in the Status Window utilizes a continuously variable waveform. These values are intended to provide a relative reference only. To avoid inaccurate values, the user should independently verify the data. A waveform recording can become invalid if the application continuously records waveform data to a point where the recording file size exceeds two (2) gigabytes. A CLEARSIGN™/CLEARSIGN™ II Amplifier recording one hundred sixty channels at a 1 K Sampling Rate for over five and one half hours can create a file that large. Waveform data can become invalid if the sampling rate is changed from 4 K to 2 K when the scroll rate is set to the maximum setting of 800 mm/second. The waveform data displayed on the RT screen and saved to the files will contain periodic gaps. Intervals created during the Stimulation Detection process may not be displayed if the user changes amplifier configuration options during the detection process. Boston Scientific assumes no responsibility for the accuracy of any user defined formulas. It is the users responsibility to ensure the accuracy of any formulas that they create. Do not apply unfiltered RF ablation voltage directly to any patient connected input of the amplifier. Doing so may result in a concentration of RF energy at one or more surface ECG electrode locations, which, under some circumstances, could result in patients being burned. Always make sure a full set of ECG electrodes are properly placed on the patient's body and properly connected to the Amplifier. Do not touch any pacing catheter electrodes with an active RF ablation electrode while ablating as damage to the stimulator and/or excessive RF leakage current may result. Do not connect additional multiple portable socket-outlets or extension cords to the system. Do not connect items, which are not specified as part of the system. The multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment, which is intended to form part of the system. Connect all intended medical and non-medical equipment to the multiple portable socket-outlet as specified in the instructions for use and not to any wall outlet. To assure safety and proper function, do not contact patient connections during activation/data acquisition. Defibrillation protection of hardware components can only be assured using cables and accessories supplied by Boston Scientific. An unexpected termination of LABSYSTEM™ PRO due to loss of power or software malfunction may result in the loss of the most recent segment of recorded waveform data. After restarting the application, check the latest recording to make sure that all required information has been captured. Boston Scientific recommends that users**.WARNINGS** create new recording segments periodically (e.g., every 15 minutes) at convenient times in order to minimize the size of the potential lost segment. Diagnostic filter settings (Low Cutoff = 0.05 Hz and High Cutoff 100 Hz (or greater)) should be used, per professional training, during the diagnostic phase of the procedure. The 1 Hz Low Filter and notch filter settings are typically used to maintain a stable ECG for timing reference to intracardiac signals and should not be used for diagnostic ECG. **WARNINGS (CLEARSIGN™ / CLEARSIGN™ II AMPLIFIER ONLY)** To avoid electrical safety hazard, do NOT connect patient electrodes to any analog input connector. To avoid electrical safety hazard, do NOT connect external equipment to the patient connections. Connect external equipment to the analog input connectors. Protection caps are provided for all IC connectors that are accessible for use. Whenever the 40 Channel Junction Box cable is removed from an accessible IC connector, a protective cap must be installed on the exposed connector. A lanyard, attached to both the connector and the cap, prevents the loss of the cap. The CLEARSIGN/CLEARSIGN II Amplifier ethernet connector is intended to be connected to a Boston Scientific supplied computer only. To avoid a potential safety hazard, do not touch the CLEARSIGN/CLEARSIGN II Amplifier and the patient simultaneously. No modification of this equipment allowed. **PRECAUTIONS** Always exit the LABSYSTEM PRO software application before turning power off to the computer. This assures the integrity of the data. Accessory equipment connected to the analog and digital interfaces must be certified according to the applicable standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input port or signal output port is configuring a medical system, and is, therefore, responsible to ensure that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the Boston Scientific technical service department (800-872-3527) or your local representative. Do not spray or pour fluids into any component of the LABSYSTEM PRO EP Recording System. The ECG and pressure inputs of the amplifier are protected against the use of a defibrillator when used properly in conjunction with the appropriate pressure transducer and ECG cable. The conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts, including earth ground. Heart rate values may be temporarily adversely affected by cardiac arrhythmia or by the use of a cardiac defibrillator or cardiac pacemaker. Only high quality surface ECG electrodes should be used with the equipment. Electrodes should be applied according to laboratory procedure. Verify that the RS-232 RF generator cable is the proper type specified and that it is connected and properly seated at both ends prior to attempting to use the RF Ablation feature. Pay particular attention to messages indicating low space for archive media. Microsoft® Word, PowerPoint®, Excel®, Adobe® Reader®, McAfee VirusScan® Enterprise, Symantec™ AntiVirus Corporate Edition, pcAnywhere™ and LINKTOOLS® are the only applications that may be started separately and run simultaneously with LABSYSTEM™ PRO software. The LABSYSTEM PRO product is provided complete and ready for use. To ensure appropriate/proper compatibility and interface, the installation or connection of additional hardware, software, or updates of any kind to the LABSYSTEM PRO platform, other than that which is provided by and/or approved by Boston Scientific is prohibited. Computers that are part of the hospital's computer network may only be mapped to the LABSYSTEM PRO HIS Export Folder. If a patient's name or identifier (ID) is changed after a patient's data is archived and restored, the data will be placed in a new directory on an archive media. It is important that you regularly purge the patient record(s) that are stored in the backup folder if they are no longer needed. The LABSYSTEM PRO software is installed with user logins enabled. HIPAA regulations on patient safety recommend the use of user logins to prevent access by unauthorized parties. The LABSYSTEM PRO software is installed with user logins enabled after a screen saver starts up due to inactivity. Do not disable this feature. Do not set the time-out for the screensaver to less than 30 minutes. HIPAA regulations on patient safety recommend the use of user logins to prevent access by unauthorized parties. It is recommended that the user preference settings be backed up regularly to an external storage media. Portable and Mobile RF Communications Equipment can affect MedicalElectrical Equipment. The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system. The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used. If viewing signals from the ablation electrode is desired (while ablating), Boston Scientific recommends the use of an RF attenuating filter that may be available from your RF generator manufacturer. The CLEARSIGN™/ CLEARSIGN™ II Amplifier need not be plugged into an isolation transformer. Ensure that all the other LABSYSTEM PRO equipment is connected according to the LABSYSTEM PRO software operating instructions. Always DISCONNECT the pacing relays that are connected to the ablation catheter electrode prior to applying RF energy. If pacing and ablating from the same catheter (e.g. pace mapping) ensure that the pacing relays are turned OFF prior to RF delivery. To avoid loss of patient data during the archival process or afterward on the archival media: 1) Before using the archive process, create a backup of the folder(s) containing the patient data that is to be archived (D:\PatientData\<specific patient>). Version 1.1 requires that the user do the backup manually (e.g. using Windows Explorer). Version 2.0 or later will do the backup for the user. 2) Do not turn off the computer until sure that the archival process has completed successfully. In V1.1 watch for the archival progress bar to disappear. V2.0 or later will display a message stating that the process is complete. 3) Do not open the archival media drive door until sure that the archival process has completed successfully. In V1.1 watch for the archival progress bar to disappear. V2.0 or later will display a message stating that the process is complete. 4) Always place media in protective enclosures. Never place bare media on any surfaces (e.g., desktops, books). 5) Always use high quality archival media. 6) Always handle media by the edges, do not touch the top or bottom. 7) When writing on archival media, always use a soft tipped permanent marking pen; do not use ball point or pencil. 8) Do not write on the bottom of the media. Computer network security is the responsibility of the user. Any anti-spyware tool, firewall or other software of that nature that is required to protect the LABSYSTEM PRO computer must be installed on computer(s) other than the LABSYSTEM PRO computer. The LABSYSTEM PRO Computer will support anti-virus software, operating system updates and connection to a network under the following guidelines: 1) The user can only install software, software updates and virus definition updates that are approved by Boston Scientific using the instructions provided by Boston Scientific. 2) The user must conduct software and virus definition updates outside of LABSYSTEM™ PRO system operation. 3) The user must turn off automated updates for all supported software applications. 4) The user must conduct anti-virus manual system scans outside of LABSYSTEM PRO system operation. 5) The user must ensure the anti-virus software is running correctly after each LABSYSTEM PRO computer start up. Contact the hospital IT department if any issues are detected. 6) The user should contact the hospital IT department and Boston Scientific if anti-virus messaging is displayed during LABSYSTEM PRO system operation. Do not start or connect remote access software (e.g., Symantec™, pcAnywhere™) when the LABSYSTEM PRO software and CLEARSIGN™/ CLEARSIGN™ II Amplifier are connected to a patient. Refer to the Original Equipment Manufacturer (OEM) documentation for proper polarity connections with Stimulators and 3D Mapping Systems.
(Rev A)

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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