

LABSYSTEM™ PRO

EP RECORDING SYSTEM

LS 9900 COMPONENTS LIST



LS 9900 Workstation

BRAND: Model: LS 9900

PROCESSOR: Intel® Xeon® Processor E3-1225 v2 rated at 3.20 GHz with 8 MB Smart Cache

- RAM: 4 GB DDR3 1600MHz SDRAM Memory
- 2 x HDD: 1 TB (7,200 rpm)
- DVD Drive: TEAC CD/DVD±R ±RW (±R DL)/DVD-RAM
- Max Speed: DVD+R 24x, DVD+RW 4x/CD-48x
- Video Board: nVIDIA GeForce GT 730 PCIe 1GB
- Dimensions: 16.5" (41.9 cm) H, 7.8" (19.8 cm) W, 17.0" (43.2 cm) D
- Power: Auto Switching 100 VAC to 240 VAC, 50/60 Hz
- Power: 500W Active Power Factor Correction
- Weight: 20.1 lbs (9.1 kg)



CLEARSIGN™ II Amplifier

The CLEARSIGN™ II Amplifier is housed in a chassis that contains a backplane, an isolated power supply, and a stimulator relay with 4 stimulator inputs, ECG inputs, 4 blood pressure inputs, and intracardiac channels in 40-, 80-, 120-, and 160-channel configurations. Features 16-bit A to D conversion and allows for sampling rates of 1, 2, or 4 KHz.

- Physical Dimensions: 16" (40.5 cm) W, 11" (28 cm) H, 17.5" (44.5 cm) D
- Full Weight: 35 lbs (15.9 kg)
- Power: 100-120/200-240 VAC+/- 10%, 50/60 Hz

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Printers

BRAND: Hewlett-Packard, **MODEL:** P2035,
TYPE: B&W Laser Jet

- Physical Dimensions: 10.1" (25.7 cm) H, 14.5" (36.8 cm) D, 14.1" (35.8 cm) W
- Weight: 21.8 lbs (9.9 kg)
- Power: 115V 60 Hz
- Print Speed: Up to 30 ppm
- Processor Speed: 266 MHz
- Print Quality: 600 x 600 dpi
- Input Capacity, max: 250 sheets
- Memory: 16 MB
- Connectivity: IEEE 1284-compliant parallel port



Monitors

BRAND: EIZO®, **MODEL:** Flexscan® S210,
TYPE: LCD, **SIZE:** 21.3"

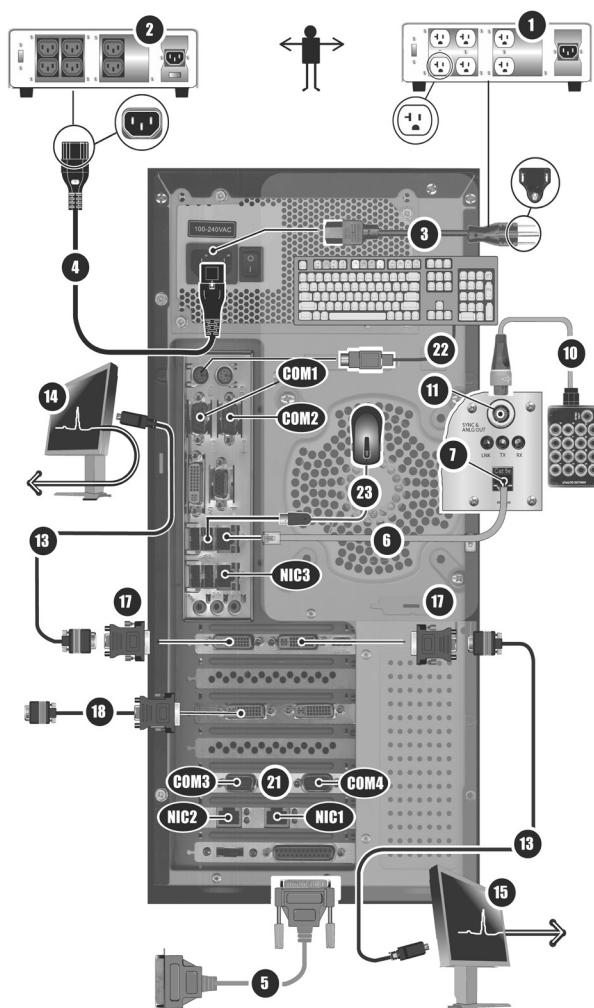
- Dual Inputs-compliant (DVI-I and D-Sub mini 15 connectors)
- Dot Pitch: 0.270 mm
- Native Resolution: 1,600 dots x 1,200 lines
- Power Supply: 100-120/200-240 V, 50/60 Hz
- Power Consumption: Max.: 70W, Typical: 33W
Power-Saving Mode: Less than 2W
- Dimensions: 18.3" (46.5 cm) W, 17.8" (45.3 cm) – 21.1" (53.5 cm) H, 8.2" (20.85 cm) D
- Dimensions Without Stand: 18.3" (46.5 cm) W, 14.2" (36.1 cm) H, 2.5" (6.4 cm) D
- Weight: 21.4 lbs (9.7 kg)
Without Stand: 14.8 lbs (6.7 kg)

BRAND: EIZO®, **MODEL:** Flexscan® S2433,
TYPE: LCD, **SIZE:** 24.1"

- Inputs: D-Sub mini 15 pin, DVI-D 24 pin (with HDCP), Display Port (with HDCP)
- Dot Pitch: 0.270 mm
- Native Resolution: 1,920 dots x 1,200 lines
- Power Supply: 100-120/200-240 V, 50/60 Hz
- Power Consumption: Max.: 95W, Typical: 40W
- Power-Saving Mode: Less than 1.5W
- Dimensions: 22.3" (56.6cm) W, 17.9" (45.6 cm) – 21.1" (53.8 cm) H, 8.2" (20.8 cm) D
- Dimensions Without Stand: 22.3" (56.6 cm) W, 14.4" (36.7 cm) H, 3.35" (8.5 cm) D
- Weight: 22.5 lbs (10.2 kg)
Without Stand: 15.9 lbs (7.2 kg)

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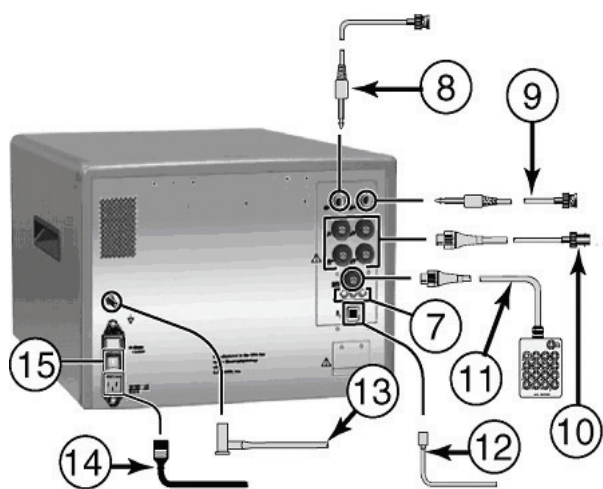
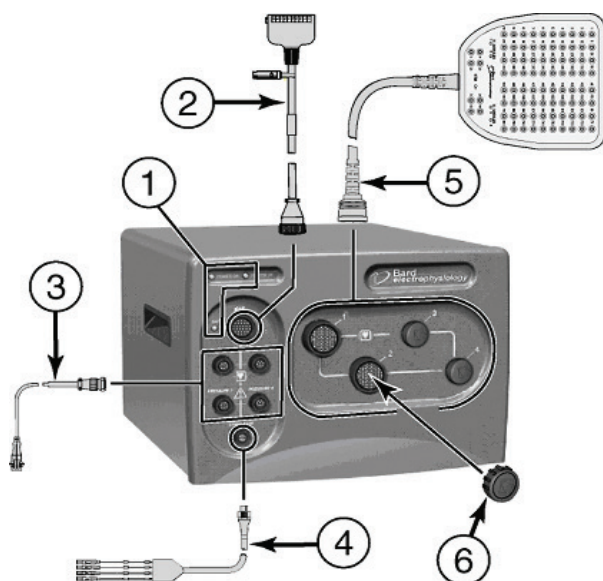


LS 9900 Diagram and Cables

1. 115V Isolation Transformer
2. 220V Isolation Transformer
3. Power Cord (115 VAC)
4. Power Cord (220 VAC)
5. Printer Interface Cable
6. Cable, Ethernet
7. Connector on rear panel of the CLEARSIGN™ II Amplifier to LABSYSTEM™ PRO EP Recording System
10. Analog Output and RTO Cable
11. "SYNC ^ ANALOG OUT" Connector at the rear of the CLEARSIGN™ II Amplifier
13. VGA Cables
14. Main Application LCD Video Display
15. Real-Time LCD Video Display
17. DVI to VGA Adapter (Supplied with Video Card)
18. Image Capture (Fluoro) Cables
21. Dual Serial COM Ports
23. Mouse, USB

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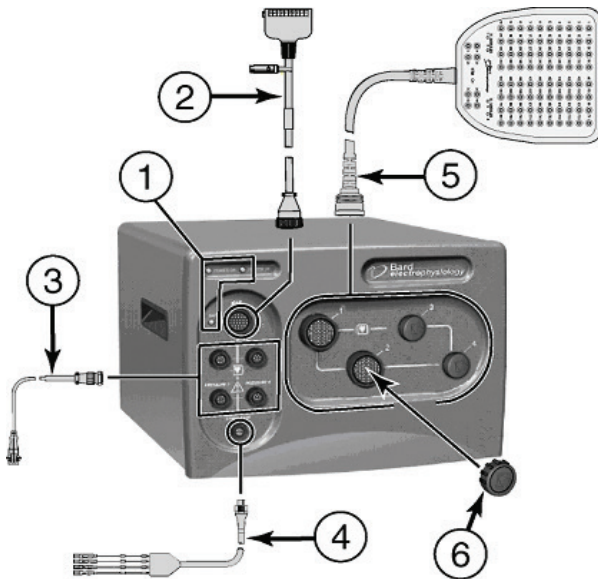


CLEARSIGN™ II Amplifier Diagram and Cables

1. LED Indicators
2. 12-Lead ECG Cables
3. Blood Pressure Cable
4. Stimulator Cable
5. 40-Channel Junction Box Cable
6. Protective Cap for IC Connector
7. LED Indicators: Link, TX, RX
8. Analog Output Cable
9. Sync Output Cable
10. Analog Input Cable
11. Analog Output 16 Cable
12. Ethernet Cable
13. Equipotential Cable
14. Power Input Cable
15. Main On/Off Switch

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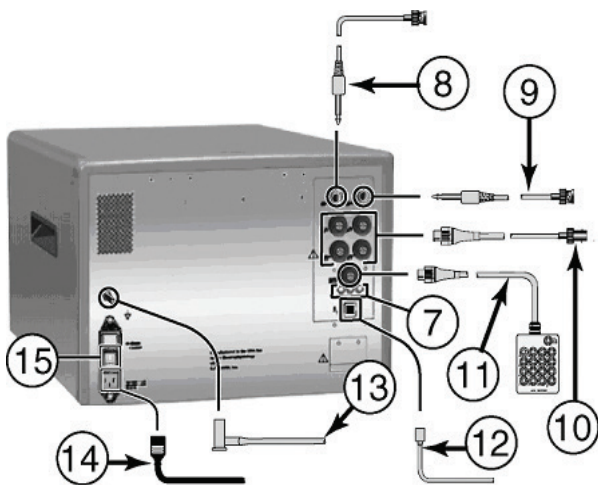
Power Cord, CLEARSIGN™ II Amplifier Platform (Used with 115V configuration)

The power cord connects to the IEC 320 standard power input receptacle on the back of the CLEARSIGN™ II Amplifier. It has a North American hospital-grade power plug on the opposite end.

Lead Wire, Ten 36-in. ECG

Each lead wire set consists of ten 36-in. lead wires, terminated as indicated, which plug into the receptacle on a 12-lead ECG cable. A push button on the side of the receptacle head releases the lead wires.

NOTE: If any of the ten lead wires are not used, it is recommended that any vacant position(s) on the 12-lead ECG Cable be plugged with an HPCS Shorting Plug.



12-Lead ECG Cable

These trunk cables accept ten ECG lead wires. There is a single connector to the CLEARSIGN™ II Amplifier. The CLEARSIGN™ II Amplifier has a single ECG cable connector.

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HPCS Shorting Plug

This is an input termination plug connected in place of any unused ECG lead wires.

Cable, 40-Channel Junction Box

The cable is a 40-channel (80-electrode) intracardiac junction box cable and provides emergency backup of the pacing capability. In normal operation, the stimulus pulse may be directed to any of the intracardiac junction box sockets on the system. However, the cable also includes a hard-wired circuit, which bypasses the amplifier and terminates in a reserved pair of sockets on the junction box. In case of a CLEARSIGN™ II Amplifier failure, stimulation/pacing can be maintained by moving the pacing electrode pins to these two sockets.

Cable, Analog Input (Four Rear-Panel Connections)

This cable provides a single BNC input connection for analog instrumentation inputs with a voltage range of up to +/- 5 volts, DC coupled. The CLEARSIGN™ II Amplifier accepts up to four of these cables.

Cable, Analog Output (Rear-Panel Connections)

Used to supply an isolated analog signal to an external analog device.

Cable, Analog Out 16 (Rear-Panel Connections)

Used to supply up to 16 isolated analog signals via phone jack connection to external analog devices. Sync connection is also provided.

Cable, Stimulator (Front-Panel Connections)

This cable provides a connection between an external stimulator, up to four channels, and the amplifier. An internal bypass connection in the CLEARSIGN™ II Amplifier provides direct connection for emergency pacing on the 40-channel junction box cable.

Cable, Sync Output (Rear-Panel Connections)

This cable provides a BNC-compatible output that can be used to trigger external equipment. The output is 0 to 5v. Any recorded channel (other than blood pressure) can be used as a trigger source.

Cable, Ethernet (Rear-Panel Connections)

The Cat 5E cable connects the CLEARSIGN™ II Amplifier Network Interface Card (NIC) board in the computer to the CLEARSIGN™ II Amplifier back panel. This cable and its receptacles are fragile and should be inspected for damage frequently and replaced if necessary.

Cable, Blood Pressure

This is an adapter cable from the CLEARSIGN™ II Amplifier to the Viggo-Spectramed® brand of disposable blood pressure transducers. For information on adapter cables for other brands of transducers, contact Boston Scientific technical support.

Cable, Equipotential Junction Box

The equipotential junction box provides an interconnection to a common ground for equipment used in series.

Cable, Equipotential Ground

The equipotential ground cable provides a chassis ground.

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DESCRIPTION

CLEARSIGN™ II AMPLIFIER

| | |
|---|--|
| Medical Class | Class IIB / Type CF |
| Amplifier Platform | Proprietary 4 Modules |
| Dimensions | 16" (40.5 cm) W, 11" (28 cm) H, 17.5" (44,5 cm) D |
| Weight | 35 lbs (15.8 kg) |
| Environmental/Electrical Specification | 100-120V~ 1.6A 220-240V~ 0.8A 50-60Hz |
| ECG Input | 12 |
| Voltage Range | (+/-) 1 mV to (+/-) 10 mV |
| Low Filter | 0.01 to 100 Hz |
| High Filter | 10 to 500 Hz |
| Notch Filter | 50/60 Hz |
| Input Impedance | >2.5 Mohm @10 Hz |
| Pressure Input | 4 |
| Range | 0 to 300 mmHg |
| Filter | DC to 100 Hz |
| Intracardiac Channels Input | 40- 80- 120- 160 |
| Catheters Input | 80, 160, 240, 320 |
| Voltage Range | (+/-)1 mV to (+/-) 100 mV |
| Low Filter | DC to 100 Hz |
| High Filter | 10 to 2,000 Hz |
| Rf Filter | 2,600 Hz fixed |
| Notch Filter | 50/60 Hz (user selectable in 0.1 Hz increments) |
| Adaptive Filter | Mortara |
| Amplification Factor | 2.5uV/bit resolution |
| Sample Rates | 1, 2, 4 KHz |
| Resolution | 16 bits |
| Stim Pacing Channels | 4 |
| Stim Monitor Channels | 4 (stim channel monitor), 4 (stim source monitor) |
| Analog Inputs | 4 |
| Analog Outputs | 16 |
| CMRR | > 98dB |
| Leakage Current | < 10uA (normal condition, patient auxiliary current) |
| Patient Sink | < 10uA (normal condition, applied part to ground) |
| Patient Sink Measured at Patient Leads Under Single-Fault Condition | < 50uA (single-fault condition) |
| Chassis Leakage Current | < 100uA (normal condition) |
| Communication Interface | Ethernet |
| Power Dissipation | < 220W |
| Operating Temperature | +10°C to +40°C |
| Storage Temperature | -40°C to +70°C |
| Humidity | 30-75% |
| Humidity Storage | 10-95% |

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ELECTRICAL CHARACTERISTICS

Required Electrical Main (U.S.): Dedicated 115 VAC/60 Hz/20 A

The power consumption of a LABSYSTEM™ PRO EP Recording System is approximately 1,300-1,400 VA at startup (115 VAC/8.5A peak current) with 800–900 VA consumed at steady state. This includes two monitors, a computer, a CLEARSIGN™ II Amplifier, and a laser printer.

LABSYSTEM™ PRO Recording System (w/CLEARSIGN™ Amplifier)

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 HPSC 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 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 Medical/Electrical 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 updates 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)

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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.

Boston Scientific
Advancing science for life™

Rhythm Management

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Customer Service:

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