

iLAB™ Ultrasound Imaging 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.

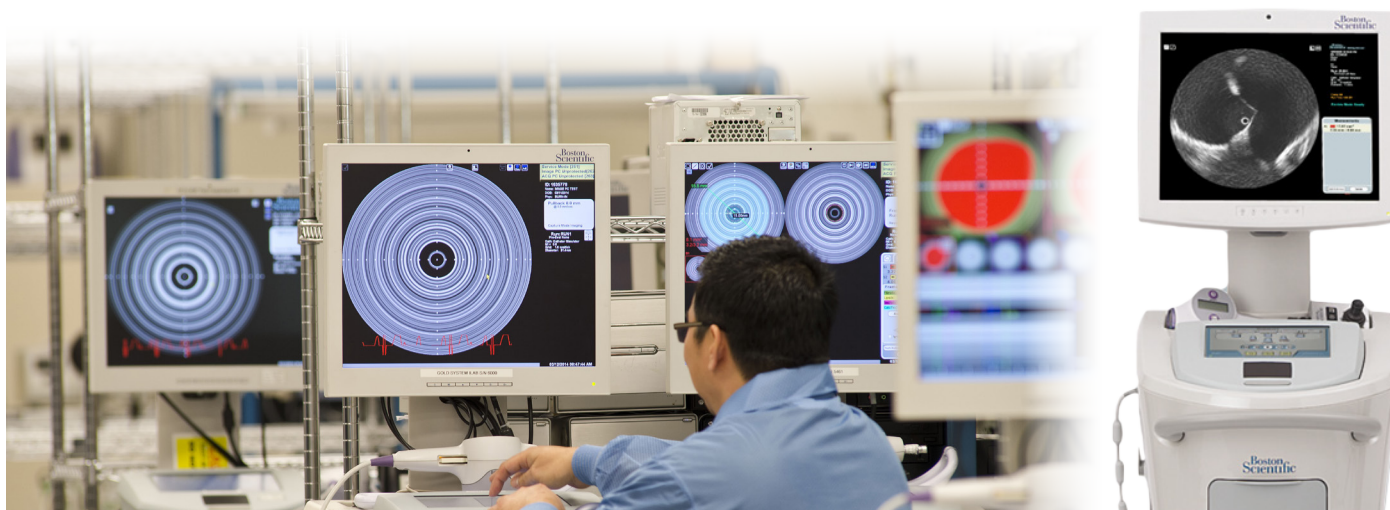
EssentialCare

| Detail | Benefit |
|---|--|
| Unlimited service repair visits | Peace of Mind, increased productivity |
| Manufacturer-approved replacement parts | Reliability, compatibility and improved life-span |
| Software updates | Latest updates for optimal performance |
| One preventative maintenance visit per year | Trained engineers provide in-depth analysis to keep system at peak performance |
| Access to technicians via phone | First line of help for improved uptime |

TotalCare

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

| Detail | Benefit |
|--|---|
| Technology Assurance - hardware upgrades | Ensures access to the hardware that will be able to support future advancements |
| Priority designation | Units prioritized ahead of those without a service agreement |



iLAB™ Ultrasound Imaging System

ExpertCare Service Program

BiomedCare

Requires three-year agreement

| Detail | Benefit |
|---|---|
| Manufacturer-approved replacement parts | Reliability, compatibility and improved life-span |
| Access to technicians via phone | First line of help for improved uptime |
| Software updates | Latest updates for optimal performance |
| Certified Biomed training | Biomed training provided by expert technicians on system use and repair |

PMCare

| Detail | Benefit |
|---|--|
| One preventative maintenance visit per year | Trained engineers provide in-depth analysis to keep system at peak performance |
| Access to technicians via phone | First line of help for improved uptime |

Technical Assistance Center 1-800-949-6708

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

For full terms and conditions of these plans, please see the plan service agreement.

iLAB™ Ultrasound Imaging System

INTENDED USE/INDICATIONS FOR USE The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy. Refer to the Catheter Directions for Use provided with all Boston Scientific Ultrasound Imaging Catheters to determine compatibility with the iLab System. All Ultrasound Imaging Catheters will be referred to as Imaging Catheters throughout the remainder of this user's guide. The Imaging Catheters generate ultrasound images and are intended for ultrasound examination of vascular and cardiac pathology. Boston Scientific manufactures a wide variety of catheters for different applications. The recommended use of each of these catheters may vary depending on the size and type of the catheter. Please refer to Imaging Catheter Directions for Use, packaged with each catheter.

CONTRAINDICATIONS FOR SYSTEM USE Use of the Imaging Catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety. This instrument is contraindicated for fetal imaging. The contraindications include the following patient characteristics: General: bacteremia or sepsis, major coagulation system abnormalities, unsuitability for coronary artery bypass surgery, unsuitability for balloon angioplasty (PTCA), total occlusion, severe hemodynamic instability or shock, coronary artery spasm, myocardial infarction, intra-arterial or intra-ventricle thrombosis, life-threatening rhythmic disorders, mechanical heart valves that would be crossed by the imaging catheter.

INDICATIONS FOR AUTO PULLBACK USE Automatic Pullback is indicated when the following occurs: the physician/operator wants to standardize the method in which intravascular ultrasound images are obtained and documented: procedure-to-procedure, operator-to-operator. The physician/operator wants to make linear distance determinations post-procedurally, which requires the imaging core of a catheter to be pulled back at a known uniform speed. Two-dimensional, longitudinal reconstruction of the anatomy is desired.

CONTRAINDICATIONS FOR AUTO PULLBACK USE Use of the Automatic Pullback is contraindicated where introduction of any catheter would constitute a threat to patient safety. For further information, please consult the Imaging Catheter Directions for Use packaged with each Imaging Catheter.

WARNINGS, CAUTIONS, AND PRECAUTIONS LISTS Inappropriate use of the iLab System may lead to patient illness, injury, or death. Please read this User's Guide and the package inserts for the Imaging Catheters carefully and completely before attempting to use the System. To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth. Other than the fuses on the AC Power Isolation Transformer, the iLab System enclosures contain no operator-serviceable components. Refer servicing to Boston Scientific-authorized personnel only. Possible explosion hazard if used in the presence of flammable anesthetics. Use only Imaging Catheters that are specifically approved for the iLab System. For instructions on proper disposal methods for the following consumable items, please refer to the Directions for Use packaged with the item: Disposable Sled, Motordrive Sterile Bag, Imaging Catheter (and packaged accessories), Tableside Controller Drape. Care should also be exercised in adjusting all settings to avoid obscuring low-level signals that may have diagnostic value. Improper settings can seriously degrade image quality. Do not attempt to autoclave, immerse, or sterilize the Motordrive Unit. The user has the ultimate responsibility for any use of these measurements in the direction of interventions.

CAUTIONS LIST

Ensure that the Imaging Catheter is carefully inserted through the opening in the Motordrive Sterile Bag, without catching any part of the Bag between the Imaging Catheter and the Motordrive. Do not attempt to manually move the Motordrive in the Sled once it is installed in a Sled without first depressing the Release Lever. The AC Power Isolation Transformer is intended to be used only with iLab System equipment. Always begin powering off the system by first using the Control Panel and then turning off the main AC power switch. For more information, refer to "Powering Down the iLab System" in the chapter, Using the iLab System in the User's Guide.

PRECAUTIONS LIST

Verify that both latches on the Sled are fully engaged with the Motordrive. Observe the precautions provided from the manufacturer of the media regarding handling, labeling, and storage. If the iLab System does not produce a usable image when connected to a Catheter Simulator, please contact your Boston Scientific representative for technical assistance. **NOTE:** Medical electrical equipment requires special precautions regarding EMC. This equipment needs to be installed and put into service according to the EMC information contained within the accompanying documents. Due to the unique nature of archived (DICOM) files on CD, DVD or Removable Hard Drive media should be labeled, handled, and stored according to individual manufacturer's recommendations to avoid data loss or corruption over time.

POTENTIAL SYSTEM USAGE COMPLICATIONS

The following complications may occur as a consequence of intravascular or intracardiac imaging: abrupt closure, angina, cardiac arrhythmias including but not limited to: ventricular tachycardia, ventricular fibrillation, and complete heart block, catheter/guidewire/pressure wire entrapment, embolism, Emergent Coronary Artery Bypass Graft (CABG) surgery, infection, myocardial infarction, myocardial ischemia, myocardial perforation, stent strut damage, stroke (including Cerebral Vascular Accident and Transient Ischemic Attack), thrombus formation, total occlusion, valvular injury, vessel dissection, injury, or perforation, vessel spasm.

For further information, please consult the Catheter Directions for Use packaged with each Imaging Catheter. (Rev B)

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
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