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.

**iLAB™ Ultrasound Imaging System**

**ExpertCare Service Program**

**Working together to maximize productivity and patient care**

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### EssentialCare

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

### TotalCare

All the benefits of the EssentialCare Service Program PLUS:

<table>
<thead>
<tr>
<th>Detail</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology Assurance - hardware upgrades</td>
<td>Ensures access to the hardware that will be able to support future advancements</td>
</tr>
<tr>
<td>Priority designation</td>
<td>Units prioritized ahead of those without a service agreement</td>
</tr>
</tbody>
</table>
**INDICATIONS FOR AUTO PULLBACK USE**

The use of the Imaging Catheter 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. Ultrasound imaging 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, intraventricular or intra-ventricle thrombosis, life-threatening rhythm 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 determining 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 Lab 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 Lab System contains 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 Lab System. For instructions on proper disposal methods for the following consumable items, please refer to the Directions for Use packaged with the item. Disposoble Sled, Motordrive Sterile Bag, Imaging Catheter (and packaged accessories), Tableside Controller Drape. Care should also be exercised in adjusting all displayed 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.

**PRECAUTIONS 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 Lab 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 Lab System” in the chapter, Using the Lab System in the User’s Guide.

**CONTRAINDICATIONS FOR SYSTEM USE**

Use of the Imaging Catheter 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.

**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.