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Boston
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PHYSICIAN'S TECHNICAL MANUAL

**VALITUDE™ , VALITUDE™ X4,
INTUA™ , INVIVE™**

CARDIAC RESYNCHRONIZATION THERAPY
PACEMAKER

Model U125, U128, V272, V273, V172, V173

CAUTION: Federal law (USA)
restricts this device to sale by
or on the order of a physician
trained or experienced in
device implant and follow-up
procedures.

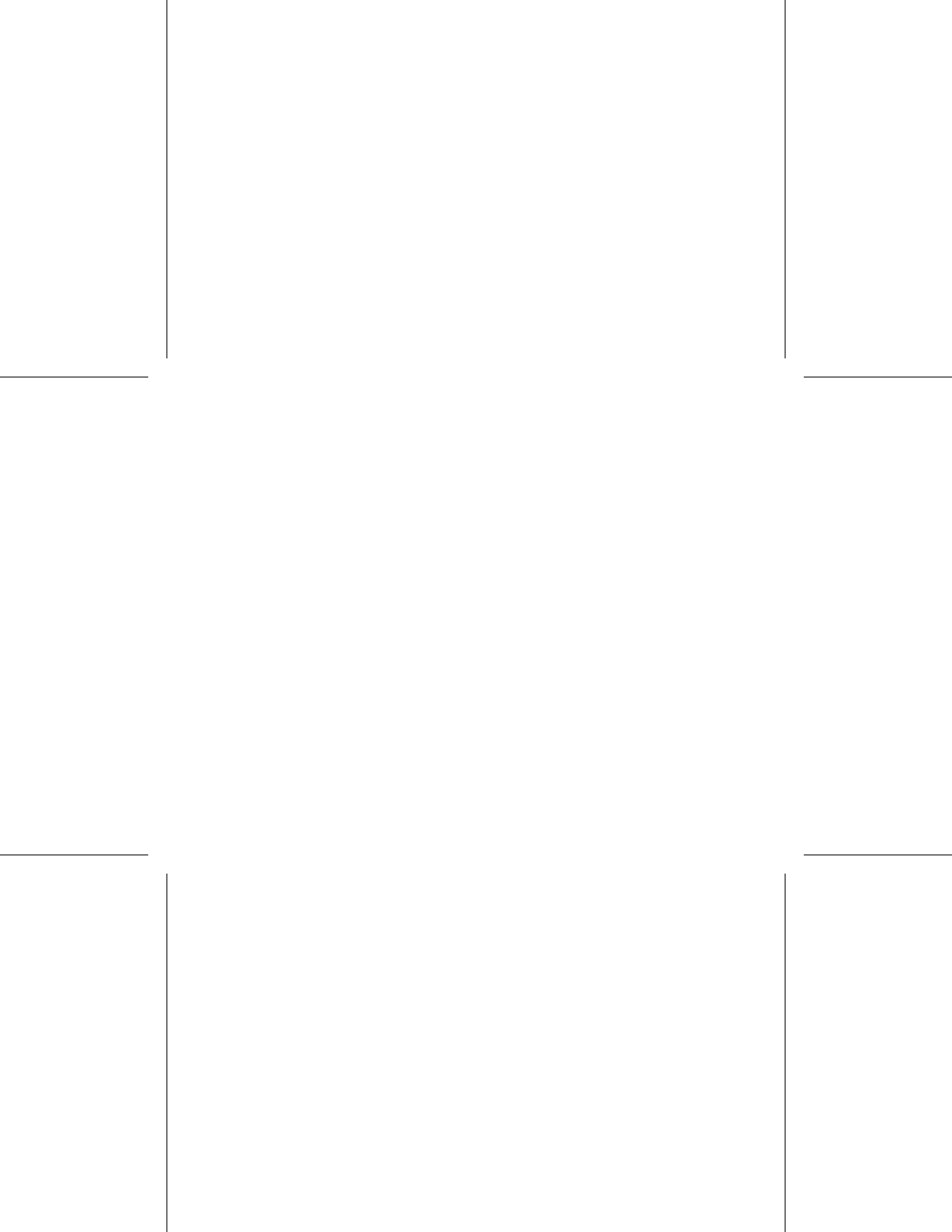


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ADDITIONAL INFORMATION

For additional reference information, go to www.bostonscientific.com/ifu.

DEVICE DESCRIPTION

This manual contains information about the VALITUDE, INTUA, and INVIVE families of cardiac resynchronization therapy pacemakers (CRT-Ps) (specific models are listed in "Mechanical Specifications" on page 31).

NOTE: *Specific features discussed in this manual may not apply to all models. References to names of non-quadripolar devices also apply to the corresponding quadripolar devices. References to "ICD" include all types of ICDs (e.g., ICD, CRT-D, S-ICD).*

Therapies

These pulse generators provide a variety of therapies, including:

- Cardiac Resynchronization Therapy (CRT), which treats heart failure by resynchronizing ventricular contractions through biventricular electrical stimulation
- Bradycardia pacing, including adaptive rate pacing, to detect and treat bradyarrhythmias

Leads

The pulse generator has independently programmable outputs and accepts one or more of the following leads, depending on the model:

- One IS-1¹ unipolar or bipolar atrial lead
- One IS-1 unipolar or bipolar right ventricular lead
- One LV-1 unipolar or bipolar left ventricular lead

1. IS-1 refers to the international standard ISO 5841-3:2013.

- One IS-1 unipolar or bipolar left ventricular lead
- One compatible IS4² quadripolar left ventricular lead³

The pulse generator and the leads constitute the implantable portion of the pulse generator system.

PRM System

These pulse generators can be used only with the ZOOM LATITUDE Programming System, which is the external portion of the pulse generator system and includes:

- Model 3120 Programmer/Recorder/Monitor (PRM)
- Model 3140 ZOOM Wireless Transmitter
- Model 2869 ZOOMVIEW Software Application
- Model 6577 Accessory Telemetry Wand

You can use the PRM system to do the following:

- Interrogate the pulse generator
- Program the pulse generator to provide a variety of therapy options
- Access the pulse generator's diagnostic features
- Perform noninvasive diagnostic testing
- Access therapy history data
- Store a 12 second trace of the ECG/EGM display from any screen
- Access an interactive Demonstration Mode or Patient Data Mode without the presence of a pulse generator
- Print patient data including pulse generator therapy options and therapy history data

2. IS4 refers to the international standard ISO 27186:2010.

3. Compatibility with St. Jude Quartet IS4 lead has been demonstrated through chronic in-vivo animal GLP testing.

- Save patient data

You can program the pulse generator using two methods: automatically using Indications-Based Programming (IBP) or manually.

RELATED INFORMATION

Refer to the lead's instruction manual for implant information, general warnings and precautions, indications, contraindications, and technical specifications. Read this material carefully for implant procedure instructions specific to the chosen lead configurations.

Refer to the PRM system Operator's Manual or ZOOM Wireless Transmitter Reference Guide for specific information about the PRM or ZOOM Wireless Transmitter such as setup, maintenance, and handling.

LATITUDE NXT is a remote monitoring system that provides pulse generator data for clinicians. These pulse generators are designed to be LATITUDE NXT enabled; availability varies by region.

LATITUDE NXT is available for the following devices: VALITUDE, INTUA, INVIVE.

- Physicians/Clinicians—LATITUDE NXT enables you to periodically monitor both patient and device status remotely and automatically. The LATITUDE NXT system provides patient data that can be used as part of the clinical evaluation of the patient.
- Patients—A key component of the system is the LATITUDE Communicator, an easy-to-use, in-home monitoring device. The Communicator automatically reads implanted device data from a compatible Boston Scientific pulse generator at times scheduled by the physician. The Communicator sends this data to the LATITUDE NXT secure server through a standard analog telephone line or over a cellular data network. The LATITUDE NXT server displays the patient data on the LATITUDE NXT Web site, which is readily accessible over the Internet to authorized physicians and clinicians.

Refer to the LATITUDE NXT Clinician Manual for more information.

INTENDED AUDIENCE

This literature is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

INDICATIONS AND USAGE

Boston Scientific cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients with moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF \leq 35%) and QRS duration \geq 120 ms and remain symptomatic despite stable optimal pharmacological therapy (OPT) for heart failure.

Atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony.

Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in physical activity.

CONTRAINDICATIONS

These Boston Scientific pulse generators have the following contraindications:

- This device is contraindicated in patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads.
- Unipolar pacing or use of the Respiratory Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) is contraindicated because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy.
- Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction.
- Atrial tracking modes are contraindicated in patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing.
- Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

WARNINGS

General

- **Labeling knowledge.** Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death.
- **For single patient use only.** Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
- **Backup defibrillation protection.** Always have external defibrillation equipment available during implant and electrophysiologic testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.
- **Separate pulse generator.** Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions ("Minimizing Pacemaker/S-ICD Interaction" on page 21).
- **Safety Core operation.** In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Safety Core pacing is unipolar, which may interact with an ICD ("Minimizing Pacemaker/S-ICD Interaction" on page 21).

Handling

- **Do not kink leads.** Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage.

- **Handling the lead without Connector Tool.** For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. This could damage the lead terminal, possibly compromising the sealing integrity and result in loss of therapy or inappropriate therapy, such as a short within the header.
- **Handling the terminal while tunneling.** Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place.

Programming and Device Operations

- **Atrial tracking modes.** Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias.
- **Atrial-only modes.** Do not use atrial-only modes in patients with heart failure because such modes do not provide CRT.
- **Lead Safety Switch.** Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD.
- **RAAT testing.** Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. The RAAT feature performs automatic threshold testing in a unipolar pacing configuration.
- **Ventricular sensing.** Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition.
- **Sensitivity settings and EMI.** If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. This increased susceptibility should be taken into consideration when determining the follow-up schedule for patients requiring such a setting.

Post-Implant

- **Protected environments.** Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator.
- **Magnetic Resonance Imaging (MRI) exposure.** Do not expose a patient to MRI scanning. Strong magnetic fields may damage the pulse generator and/or lead system, possibly resulting in injury to or death of the patient.
- **Diathermy.** Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

PRECAUTIONS

Clinical Considerations

- **STAT PACE.** STAT PACE will initiate unipolar pacing. Unipolar pacing due to STAT PACE may cause inappropriate therapy or inhibition of appropriate S-ICD therapy.
- **Pacemaker-mediated tachycardia (PMT).** Programming minimum PVARP less than retrograde V–A conduction may increase the likelihood of a PMT.
- **Rate Adaptive Pacing in Heart Failure Patients.** The clinical benefit of Rate Adaptive Pacing in heart failure patients has not been studied. Rate Adaptive Pacing should be used with medical discretion if the patient develops an indication such as chronotropic incompetence. Patients with heart failure may have hemodynamic compromise at rapid sensor-driven rates, and the physician may wish to program less aggressive rate adaptive parameters in accordance with patient condition. Rate Adaptive Pacing may be helpful for heart failure patients with coexisting bradyarrhythmic conditions. It is not recommended for patients who exhibit only heart failure-induced chronotropic incompetency.

Sterilization and Storage

- **If package is damaged.** The blister trays and contents are sterilized with ethylene oxide gas before final packaging. When the pulse generator and/or lead is received, it is sterile provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the pulse generator and/or lead to Boston Scientific.
- **If device is dropped.** Do not implant a device which has been dropped while outside of its intact shelf package. Do not implant a device which has been dropped from a height of more than 24 inches (61 cm) while within its intact shelf package. Sterility, integrity and/or function cannot be guaranteed under these conditions and the device should be returned to Boston Scientific for inspection.
- **Storage temperature and equilibration.** Recommended storage temperatures are 0°C–50°C (32°F–122°F). Allow the device to reach a proper temperature before using telemetry communication capabilities, programming or implanting the device because temperature extremes may affect initial device function.
- **Device storage.** Store the pulse generator in a clean area away from magnets, kits containing magnets, and sources of EMI to avoid device damage.
- **Use by date.** Implant the pulse generator and/or lead before or on the USE BY date on the package label because this date reflects a validated shelf life. For example, if the date is January 1, do not implant on or after January 2.

Implantation

- **Expected benefits.** Determine whether the expected device benefits provided by programmable options outweigh the possibility of more rapid battery depletion.
- **Evaluate patient for surgery.** There may be additional factors regarding the patient's overall health and medical condition that, while not related to device function or purpose, could render the patient a poor candidate for implantation of this system. Cardiac health advocacy groups may have published guidelines that may be helpful in conducting this evaluation.

- **Lead compatibility.** Prior to implantation, confirm the lead-to-pulse generator compatibility. Using incompatible leads and pulse generators can damage the connector and/or result in potential adverse consequences, such as undersensing of cardiac activity or failure to deliver necessary therapy.
- **Telemetry wand.** Make sure a sterile telemetry wand is available should loss of ZIP telemetry occur. Verify that the wand can easily be connected to the programmer and is within reach of the pulse generator.
- **Line-powered equipment.** Exercise extreme caution if testing leads using line-powered equipment because leakage current exceeding 10 μ A can induce ventricular fibrillation. Ensure that any line-powered equipment is within specifications.
- **Replacement device.** Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
- **Do not bend the lead near the lead-header interface.** Insert the lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation or connector damage.
- **Absence of a lead.** The absence of a lead or plug in a lead port may affect device performance. If a lead is not used, be sure to properly insert a plug in the unused port, and then tighten the setscrew onto the plug.
- **Dual chamber device without a functional RV lead.** If a dual-chamber device is programmed to AAI(R), ensure that a functional RV lead is present. In the absence of a functional RV lead, programming to AAI(R) may result in undersensing or oversensing.

- **Electrode connections.** Do not insert a lead into the pulse generator connector without taking the following precautions to ensure proper lead insertion:
 - Insert the torque wrench into the preslit depression of the seal plug before inserting the lead into the port, to release any trapped fluid or air.
 - Visually verify that the setscrew is sufficiently retracted to allow insertion. Use the torque wrench to loosen the setscrew if necessary.
 - Fully insert each lead into its lead port and then tighten the setscrew onto the terminal pin.
- **Do not suture directly over lead.** Do not suture directly over the lead body, as this may cause structural damage. Use the suture sleeve to secure the lead proximal to the venous entry site to prevent lead movement.
- **Diaphragmatic stimulation.** Patients should be tested for diaphragmatic stimulation by pacing the LV lead through the pulse generator at 7.5 V and adjusting the lead configurations and lead position as necessary. PSA testing at higher outputs (e.g., 10.0 V) may also be considered to better characterize stimulation margins. The probability of diaphragmatic stimulation increases when a pacing system includes an LV lead because of this lead's proximity to the phrenic nerve.

Device Programming

- **Device communication.** Use only the designated PRM and software application to communicate with this pulse generator.
- **STAT PACE settings.** When a pulse generator is programmed to STAT PACE settings, it will continue to pace at the high-energy STAT PACE values if it is not reprogrammed. The use of STAT PACE parameters will likely decrease device longevity.

- **Biventricular pacing therapy.** This device is intended to provide biventricular pacing therapy. Programming the device to provide RV-only pacing, or programming the RV pace amplitude below the pacing threshold (resulting in LV-only pacing), is not intended for the treatment of heart failure. The clinical effects of LV-only or RV-only pacing for the treatment of heart failure have not been established.
- **Pacing and sensing margins.** Consider lead maturation in your choice of Pacing Amplitude, pacing Pulse Width, and Sensitivity settings.
 - An acute Pacing Threshold greater than 1.5 V or a chronic Pacing Threshold greater than 3 V can result in loss of capture because thresholds may increase over time.
 - An R-Wave Amplitude less than 5 mV or a P-Wave Amplitude less than 2 mV can result in undersensing because the sensed amplitude may decrease after implantation.
 - Pacing Lead Impedance should be greater than the programmed Low Impedance Limit and less than 2000 Ω (or the programmed High Impedance Limit).
- **Lead impedance values and Lead Safety Switch.** If properly functioning leads with stable measured impedance values near the programmed impedance limits are used, consider programming Lead Safety Switch Off or changing the impedance limits to avoid undesirable switching to a Unipolar Lead Configuration.
- **Proper programming of the lead configuration.** If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.
- **Programming for supraventricular tachyarrhythmias (SVTs).** Determine if the device and programmable options are appropriate for patients with SVTs because SVTs can initiate unwanted device therapy.
- **AV Delay.** To ensure a high percentage of biventricular pacing, the programmed AV Delay setting must be less than the patient's intrinsic PR interval.
- **Adaptive-rate pacing.** Rate Adaptive Pacing should be used with care in patients who are unable to tolerate increased pacing rates.

- **Ventricular refractory periods (VRPs) in adaptive-rate pacing.** Adaptive-rate pacing is not limited by refractory periods. A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods since the combination can cause a very small sensing window or none at all. Use Dynamic AV Delay or Dynamic PVARP to optimize sensing windows. If you are programming a fixed AV Delay, consider the sensing outcomes.
- **MTR/MSR programming.** The pulse generator's MTR and MSR should be programmed to a rate lower than a concomitant S-ICD's lowest tachycardia detection zone.
- **Atrial Tachy Response (ATR).** ATR should be programmed to On if the patient has a history of atrial tachyarrhythmias. The delivery of CRT is compromised because AV synchrony is disrupted if the ATR mode switch occurs.
- **Threshold test.** During a manual LV Threshold test, RV Backup Pacing is unavailable.
- **Left ventricular pacing only.** The clinical effect of LV pacing alone for heart failure patients has not been studied.
- **Atrial oversensing.** Take care to ensure that artifacts from the ventricles are not present on the atrial channel, or atrial oversensing may result. If ventricular artifacts are present in the atrial channel, the atrial lead may need to be repositioned to minimize its interaction.
- **ATR entry count.** Exercise care when programming the Entry Count to low values in conjunction with a short ATR Duration. This combination allows mode switching with very few fast atrial beats. For example, if the Entry Count was programmed to 2 and the ATR Duration to 0, ATR mode switching could occur on 2 fast atrial intervals. In these instances, a short series of premature atrial events could cause the device to mode switch.
- **ATR exit count.** Exercise care when programming the Exit Count to low values. For example, if the Exit Count was programmed to 2, a few cycles of atrial undersensing could cause termination of mode switching.

- **Proper programming without an atrial lead.** If an atrial lead is not implanted (port is plugged instead), or an atrial lead is abandoned but remains connected to the header, device programming should be consistent with the number and type of leads actually in use.
- **Atrial sensing programmed to Off.** When atrial sensing is programmed to Off in a DDI(R) or DDD(R) mode, any atrial pacing that occurs will be asynchronous. Additionally, features that require atrial sensing may not function as expected.
- **High atrial rates.** Sensing high atrial rates may impact device longevity. Therefore, the Atrial Sense lead configuration will be seeded to Off when programming from an atrial sensing mode to a non-atrial sensing mode.
- **Cross-chamber artifacts.** Sensitivity adjustments associated with Smart Blanking may not be sufficient to inhibit detection of cross-chamber artifacts if the cross-chamber artifacts are too large. Consider other factors that impact the size/amplitude of cross-chamber artifacts including lead-placement, pacing output, and programmed Sensitivity settings.
- **Sensor signal artifacts.** If Respiratory Sensor signal artifacts are observed on EGMs, and the leads are otherwise shown to be performing appropriately, consider programming the sensor to Off to prevent oversensing.
- **Single pass VDD leads.** When a single pass VDD lead is used with a dual-chamber device, the atrial electrodes may not be in contact with the atrial wall. In this case, the measured depolarization signal has a relatively low Amplitude and could require a more sensitive setting.
- **Left ventricular lead configuration.** Proper programming of the LV coronary venous Lead Configuration is essential for proper LV lead function. Program the Lead Configuration in accordance with the number of electrodes on the LV lead; otherwise, erratic LV sensing, loss of LV pacing, or ineffective LV pacing might occur.
- **Quadripolar pacing configuration.** When an LVRing4>>RV pacing configuration is programmed with an IS4-LLLL lead, the LV tip may be used as the anode rather than the RV ring. When programming to this configuration, evaluate the pacing threshold and ensure no extracardiac stimulation is present.

- **Left Ventricular Protection Period (LVPP).** Use of a long LVPP reduces the maximum LV pacing rate and may inhibit CRT at higher pacing rates.
- **Sensing adjustment.** Following any Sensitivity parameter adjustment or any modification of the sensing lead, always verify appropriate sensing. Programming Sensitivity to the highest value (lowest sensitivity) may result in undersensing of cardiac activity. Likewise, programming to the lowest value (highest sensitivity) may result in oversensing of non-cardiac signals.
- **Sensitivity in unipolar lead configuration.** The amplitude and prevalence of myopotential noise is increased in unipolar lead configurations, as compared to bipolar lead configurations. For patients with a unipolar lead configuration and myopotential oversensing during activity involving the pectoral muscles, the programming of Fixed Sensitivity is recommended.
- **Use of Patient Triggered Monitor.** Use care when using Patient Triggered Monitor, because the following conditions will exist while it is enabled:
 - All other magnet features, including asynchronous pacing, are disabled. The Magnet feature will not indicate magnet position.
 - Device longevity is impacted. To help reduce the longevity impact, PTM only allows storage of one episode, and PTM is automatically disabled after 60 days if data storage was never triggered.
 - Once the EGM is stored (or 60 days elapses), PTM is disabled and the device Magnet Response automatically will be set to Pace Async. However, if a magnet is used, the pulse generator will not revert to asynchronous operation until the magnet is removed for 3 seconds and placed on the device again.

Environmental and Medical Therapy Hazards

- **Avoid electromagnetic interference (EMI).** Advise patients to avoid sources of EMI. The pulse generator may inhibit pacing due to oversensing, or may switch to asynchronous pacing at the programmed pacing rate or at the magnet rate in the presence of EMI.

Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.

Examples of potential EMI sources are:

- Electrical power sources, arc welding or resistance welding equipment, and robotic jacks
- High voltage power distribution lines
- Electrical smelting furnaces
- Large RF transmitters such as radar
- Radio transmitters, including those used to control toys
- Electronic surveillance (antitheft) devices
- An alternator on a car that is running
- Medical treatments and diagnostic tests in which an electrical current is passed through the body, such as TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies
- Any externally applied device that uses an automatic lead detection alarm system (e.g., an EKG machine)

Hospital and Medical Environments

- **Mechanical ventilators.** During mechanical ventilation, respiration-based trending may be misleading; therefore, the Respiratory Sensor should be programmed to Off.

- **Conducted electrical current.** Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function.
 - External patient monitors (e.g., respiratory monitors, surface ECG monitors, hemodynamic monitors) may interfere with the pulse generator's impedance-based diagnostics (e.g., Respiratory Rate trend). To resolve suspected interactions with Respiratory Sensor-based diagnostics, deactivate the pulse generator's Respiratory Sensor by programming it to Off.
 - Medical therapies, treatments, and diagnostic tests that use conducted electrical current (e.g., TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies) may interfere with or damage the pulse generator. Program the device to Electrocautery Protection Mode prior to the treatment, and monitor device performance during the treatment. After the treatment, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" on page 20).
- **Internal defibrillation.** Do not use internal defibrillation paddles or catheters unless the pulse generator is disconnected from the leads because the leads may shunt energy. This could result in injury to the patient and damage to the implanted system.

- **External defibrillation.** It can take up to 15 seconds for sensing to recover after an external shock is delivered. In non-emergency situations, for pacemaker dependent patients, consider programming the pulse generator to an asynchronous pacing mode and programming the Respiratory Sensor to Off prior to performing external cardioversion or defibrillation.

External defibrillation or cardioversion can damage the pulse generator. To help prevent damage to the pulse generator, consider the following:

- Avoid placing a pad (or paddle) directly over the pulse generator. Position the pads (or paddles) as far from the pulse generator as possible.
- Position the pads (or paddles) in a posterior-anterior orientation when the device is implanted in the right pectoral region or an anterior-apex orientation when the device is implanted in the left pectoral region.
- Set energy output of external defibrillation equipment as low as clinically acceptable.

Following external cardioversion or defibrillation, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" on page 20).

- **Lithotripsy.** Extracorporeal shock wave lithotripsy (ESWL) may cause electromagnetic interference with or damage to the pulse generator. If ESWL is medically necessary, consider the following to minimize the potential for encountering interaction:
 - Focus the ESWL beam at least 15 cm (6 in) away from the pulse generator.
 - Depending on the pacing needs of the patient, program the Brady Mode to a non-rate-responsive VVI or VOO mode.
- **Ultrasound energy.** Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.

- **Electrical interference.** Electrical interference or "noise" from devices such as electrocautery and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. If telemetry is cancelled as a result of interference, the device should be re-interrogated prior to evaluating information from pulse generator memory.
- **Radio frequency (RF) interference.** RF signals from devices that operate at frequencies near that of the pulse generator may interrupt ZIP telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the PRM and pulse generator. Examples of devices that may cause interference in the 916.5 MHz frequency band include:
 - Cordless phone handsets or base stations
 - Certain patient monitoring systems
- **Central line guidewire insertion.** Use caution when inserting guidewires for placement of other types of central venous catheter systems such as PIC lines or Hickman catheters in locations where pulse generator leads may be encountered. Insertion of such guidewires into veins containing leads could result in the leads being damaged or dislodged.

Home and Occupational Environments

- **Home appliances.** Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There have been reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.

- **Magnetic fields.** Advise patients that extended exposure to strong (greater than 10 gauss or 1 mTesla) magnetic fields may trigger the magnet feature. Examples of magnetic sources include:
 - Industrial transformers and motors
 - MRI scanners
 - Large stereo speakers
 - Telephone receivers if held within 1.27 cm (0.5 inches) of the pulse generator
 - Magnetic wands such as those used for airport security and in the Bingo game
- **Electronic Article Surveillance (EAS) and Security Systems.** Advise patients to avoid lingering near or leaning against anti-theft and security gates or tag readers that include radio frequency identification (RFID) equipment. These systems may be found at the entrances and exits of stores, in public libraries, and in point-of-entry access control systems. These systems are unlikely to affect cardiac device function when patients walk through them at a normal pace. If the patient is near an electronic anti-theft, security, or entry control system and experiences symptoms, they should promptly move away from nearby equipment and inform their doctor.
- **Cellular phones.** Advise patients to hold cellular phones to the ear opposite the side of the implanted device. Patients should not carry a cellular phone that is turned on in a breast pocket or on a belt within 15 cm (6 inches) of the implanted device since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Follow-up Testing

- **Pacing threshold testing.** If the patient's condition or drug regimen has changed or device parameters have been reprogrammed, consider performing a pacing threshold test to confirm adequate margins for pace capture.

- **Follow-up considerations for patients leaving the country.** Pulse generator follow-up considerations should be made in advance for patients who plan to travel or relocate post-implant to a country other than the country in which their device was implanted. Regulatory approval status for devices and associated programmer software configurations varies by country; certain countries may not have approval or capability to follow specific products.

Contact Boston Scientific, using the information on the back cover, for help in determining feasibility of device follow-up in the patient's destination country.

Explant and Disposal

- **Incineration.** Be sure that the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.
- **Device handling.** Before explanting, cleaning, or shipping the device, complete the following actions to prevent overwriting of important therapy history data:
 - Program the pulse generator Brady Mode to Off
 - Program Ventricular Tachy EGM Storage to Off

Clean and disinfect the device using standard biohazard handling techniques.

SUPPLEMENTAL PRECAUTIONARY INFORMATION

Post-Therapy Pulse Generator Follow Up

Following any surgery or medical procedure with the potential to affect pulse generator function, you should perform a thorough follow-up, which may include the following:

- Interrogating the pulse generator with a programmer
- Reviewing clinical events and fault codes
- Reviewing the Arrhythmia Logbook, including stored electrograms (EGMs)

- Reviewing real-time EGMs
- Testing the leads (threshold, amplitude, and impedance)
- Reviewing respiratory sensor-based diagnostics
- Verifying battery status
- Programming any permanent brady parameter to a new value and then reprogramming it back to the desired value
- Saving all patient data
- Verifying the appropriate final programming prior to allowing the patient to leave the clinic

Minimizing Pacemaker/S-ICD Interaction

These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

A pacemaker can interact with an S-ICD in the following ways:

- If during a tachyarrhythmia the pacemaker is not inhibited and the pacing pulses are detected by the rate-sensing circuit of the S-ICD, the S-ICD could interpret the pacing pulses as a normal rhythm. The S-ICD would not detect the arrhythmia and therefore would not deliver therapy.
- Pacemaker failure to sense or to capture could result in two independent signals (intrinsic and pacing pulses) to the S-ICD. This could cause the S-ICD's rate measurement to be faster than the actual heart rate. As a result, the S-ICD could deliver unnecessary therapy.
- If the S-ICD counts both the pacing pulses and the resultant ventricular depolarizations, the S-ICD's rate measurement would be faster than the actual heart rate. This could result in unnecessary S-ICD therapy.

In Safety Mode, these pulse generators use a unipolar pacing and sensing configuration. Safety Mode is compatible for use with an S-ICD because the configured parameters mitigate the potential pacemaker and S-ICD interactions as follows:

- Sensing is AGC at 0.25 mV. The AGC sensing is able to effectively sense an intrinsic rhythm faster than the Safety Mode LRL of 72.5 bpm. As a result, pacing is inhibited and does not interfere with S-ICD tachyarrhythmia detection.
- When pacing is necessary, the elevated output of 5.0 V and 1.0 ms reduces the risk of not capturing.
- If double detection of the pace pulse and the resulting depolarization were to occur, it would not result in unnecessary S-ICD therapy provided the S-ICD tachy threshold is more than twice the Safety Mode LRL (145 ppm).

To help minimize device-device interaction of a bipolar pacemaker when an S-ICD is already implanted, follow these precautionary measures:

- Use bipolar pacing leads with close electrode spacing in both chambers. Significant spacing between electrodes may increase the likelihood that the S-ICD will detect the pacing pulses.
- Consider programming the pacemaker to (1) the lowest Amplitude allowable for safe capture in the chronic state, (2) the maximum Sensitivity (the lowest programmable level) while maintaining an adequate safety margin, and (3) the minimum cardiac rate acceptable for the patient.

In addition to the above steps, perform the following testing to assess device-device interaction:

- Use the S-ICD features, such as markers, real-time electrograms (EGMs), and/or beeping tones, to help evaluate potential for pacemaker interaction due to oversensing by the S-ICD.

NOTE: *If a single chamber pacemaker is implanted with an atrial lead, perform testing in both unipolar and bipolar configurations.*

- Ventricular fibrillation and all of the patient's ventricular tachycardias should be induced while the S-ICD is activated and the pacemaker is programmed to an asynchronous mode at maximum Amplitude and Pulse Width. This should provide the greatest opportunity for inhibition of arrhythmia detection due to detection of pacemaker pacing pulses. The pacemaker leads might have to be repositioned to eliminate detection of the pacing pulses by the S-ICD.

Temporarily deactivate the patient's S-ICD when (1) evaluating pacing and sensing thresholds, (2) when using an external temporary pacemaker during implant, and (3) when reprogramming an implanted pacemaker.

Following any S-ICD discharge, reinterrogate the pacemaker to ensure that the S-ICD shock did not damage the pacemaker.

If implanting an S-ICD in a patient who has a pacemaker already implanted, refer to the S-ICD manual for implantation considerations.

Refer to the Warnings section for additional information regarding pacemaker and S-ICD interactions.

Transcutaneous Electrical Nerve Stimulation (TENS)

CAUTION: TENS involves passing electrical current through the body, and may interfere with pulse generator function. If TENS is medically necessary, evaluate the TENS therapy settings for compatibility with the pulse generator. The following guidelines may reduce the likelihood of interaction:

- Place the TENS electrodes as close together and as far away from the pulse generator and leads as possible.
- Use the lowest clinically-appropriate TENS energy output.
- Consider cardiac monitoring during TENS use, especially for pacemaker-dependent patients.

Additional steps can be taken to help reduce interference during in-clinic use of TENS:

- If interference is suspected during in-clinic use, turn off the TENS unit.
- If pacing inhibition is observed, use a magnet to pace asynchronously.

- Do not change TENS settings until you have verified that the new settings do not interfere with pulse generator function.

If TENS is medically necessary outside the clinical setting (at-home use), provide patients with the following instructions:

- Do not change the TENS settings or electrode positions unless instructed to do so.
- End each TENS session by turning off the unit before removing the electrodes.
- If the patient experiences symptoms of lightheadedness, dizziness, or loss of consciousness during TENS use, they should turn off the TENS unit and contact their physician.

Follow these steps to use the PRM to evaluate pulse generator function during TENS use:

1. Observe real-time EGMs at prescribed TENS output settings, noting when appropriate sensing or interference occurs.

NOTE: *Patient triggered monitoring may be used as an additional method to confirm device function during TENS use.*

2. When finished, turn off the TENS unit.

You should also perform a thorough follow-up evaluation of the pulse generator following TENS, to ensure that device function has not been compromised ("Post-Therapy Pulse Generator Follow Up" on page 20).

For additional information, contact Boston Scientific using the information on the back cover.

Electrocautery and Radio Frequency (RF) Ablation

CAUTION: Electrocautery and RF ablation may induce ventricular arrhythmias and/or fibrillation, and may cause asynchronous pacing, inhibition of pacing, and/or a reduction in pulse generator pacing output possibly leading to loss of capture. RF ablation may also cause ventricular pacing up to the MTR and/or changes in pacing thresholds. Additionally, exercise caution when performing any other type of cardiac ablation procedure in patients with implanted devices.

If electrocautery or RF ablation is medically necessary, observe the following to minimize risk to the patient and device:

- Depending on the pacing needs of the patient, enable the Electrocautery Protection Mode, program to an asynchronous pacing mode, or use a magnet to switch to asynchronous pacing. An option for patients with intrinsic rhythm is to program the Brady Mode to VVI at a rate below the intrinsic rate to avoid competitive pacing.
- Have temporary pacing and external defibrillation equipment available.
- Avoid direct contact between the electrocautery equipment or ablation catheters and the pulse generator and leads. RF ablation close to the lead electrode may damage the lead-tissue interface.
- Keep the path of the electrical current as far away as possible from the pulse generator and leads.
- If RF ablation and/or electrocautery is performed on tissue near the device or leads, monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity and stability of the system.
- For electrocautery, use a bipolar electrocautery system where possible and use short, intermittent, and irregular bursts at the lowest feasible energy levels.
- RF ablation equipment may cause telemetry interference between the pulse generator and PRM. If device programming changes are necessary during an RF ablation procedure, turn off the RF ablation equipment before interrogation.

When the procedure is finished, cancel the Electrocautery Protection Mode in order to reactivate the previously programmed therapy modes.

Ionizing Radiation

CAUTION: It is not possible to specify a safe radiation dosage or guarantee proper pulse generator function following exposure to ionizing radiation. Multiple factors collectively determine the impact of radiation therapy on an implanted pulse generator, including proximity of the pulse generator to the radiation beam, type and energy level of the radiation beam, dose rate, total dose delivered over the life of the pulse generator, and shielding of the pulse generator. The impact of ionizing radiation will also vary from one pulse generator to another and may range from no changes in function to a loss of pacing.

Sources of ionizing radiation vary significantly in their potential impact on an implanted pulse generator. Several therapeutic radiation sources are capable of interfering with or damaging an implanted pulse generator, including those used for the treatment of cancer, such as radioactive cobalt, linear accelerators, radioactive seeds, and betatrons.

Prior to a course of therapeutic radiation treatment, the patient's radiation oncologist and cardiologist or electrophysiologist should consider all patient management options, including increased follow-up and device replacement. Other considerations include:

- Maximizing shielding of the pulse generator within the treatment field
- Determining the appropriate level of patient monitoring during treatment

Evaluate pulse generator operation during and following the course of radiation treatment to exercise as much device functionality as possible ("Post-Therapy Pulse Generator Follow Up" on page 20). The extent, timing, and frequency of this evaluation relative to the radiation therapy regimen are dependent upon current patient health, and therefore should be determined by the attending cardiologist or electrophysiologist.

Many pulse generator diagnostics are performed automatically once per hour, so pulse generator evaluation should not be concluded until pulse generator diagnostics have been updated and reviewed (at least one hour after radiation exposure). The effects of radiation exposure on the implanted pulse generator may remain undetected until some time following exposure. For this reason, continue to monitor pulse generator function closely and use caution when programming a feature in the weeks or months following radiation therapy.

Elevated Pressures

The International Standards Organization (ISO) has not approved a standardized pressure test for implantable pulse generators that experience hyperbaric oxygen therapy (HBOT) or SCUBA diving. However, Boston Scientific developed a test protocol to evaluate device performance upon exposure to elevated atmospheric pressures. The following summary of pressure testing should not be viewed as and is not an endorsement of HBOT or SCUBA diving.

CAUTION: Elevated pressures due to HBOT or SCUBA diving may damage the pulse generator. During laboratory testing, all pulse generators in the test sample functioned as designed when exposed to more than 1000 cycles at a pressure up to 5.0 ATA. Laboratory testing did not characterize the impact of elevated pressure on pulse generator performance or physiological response while implanted in a human body.

Pressure for each test cycle began at ambient/room pressure, increased to a high pressure level, and then returned to ambient pressure. Although dwell time (the amount of time under elevated pressure) may have an impact on human physiology, testing indicated it did not impact pulse generator performance. Pressure value equivalencies are provided below (Table 1 on page 27).

Table 1. Pressure Value Equivalencies

Pressure value equivalencies	
Atmospheres Absolute	5.0 ATA
Sea water depth ^a	40 m (130 ft)
Pressure, absolute	72.8 psia
Pressure, gauge ^b	58.1 psig

Table 1. Pressure Value Equivalencies (continued)

Pressure value equivalencies	
Bar	5.0
kPa Absolute	500

- a. All pressures were derived assuming sea water density of 1030 kg/m³.
b. Pressure as read on a gauge or dial (psia = psig + 14.7 psi).

Prior to SCUBA diving or starting an HBOT program, the patient's attending cardiologist or electrophysiologist should be consulted to fully understand the potential consequences relative to the patient's specific health condition. A Dive Medicine Specialist may also be consulted prior to SCUBA diving.

More frequent device follow-up may be warranted in conjunction with HBOT or SCUBA diving. Evaluate pulse generator operation following high pressure exposure ("Post-Therapy Pulse Generator Follow Up" on page 20). The extent, timing, and frequency of this evaluation relative to the high pressure exposure are dependent upon current patient health, and should be determined by the attending cardiologist or electrophysiologist.

If you have additional questions, or would like more detail regarding the test protocol or test results specific to HBOT or SCUBA diving, contact Boston Scientific using the information on the back cover.

POTENTIAL ADVERSE EVENTS

Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature:

- Air embolism
- Allergic reaction
- Bleeding
- Bradycardia

- Cardiac tamponade
- Chronic nerve damage
- Component failure
- Conductor coil fracture
- Death
- Electrolyte imbalance/dehydration
- Elevated thresholds
- Erosion
- Excessive fibrotic tissue growth
- Extracardiac stimulation (muscle/nerve stimulation)
- Fluid accumulation
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Heart block
- Inability to pace
- Inappropriate pacing
- Incisional pain
- Incomplete lead connection with pulse generator
- Infection including endocarditis
- Lead dislodgment
- Lead fracture
- Lead insulation breakage or abrasion
- Lead perforation

- Lead tip deformation and/or breakage
- Local tissue reaction
- Loss of capture
- Myocardial infarction (MI)
- Myocardial necrosis
- Myocardial trauma (e.g., tissue damage, valve damage)
- Myopotential sensing
- Oversensing/undersensing
- Pacemaker-mediated tachycardia (PMT)
- Pericardial rub, effusion
- Pneumothorax
- Pulse generator migration
- Shunting current during defibrillation with internal or external paddles
- Syncope
- Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation
- Thrombosis/thromboemboli
- Valve damage
- Vasovagal response
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)
- Worsening heart failure

Patients may develop psychological intolerance to a pulse generator system and may experience the following:

- Dependency

- Depression
- Fear of premature battery depletion
- Fear of device malfunction

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include:

- Allergic reaction to contrast media
- Breakage/failure of implant instruments
- Prolonged exposure to fluoroscopic radiation
- Renal failure from contrast media used to visualize coronary veins

MECHANICAL SPECIFICATIONS

The following mechanical specifications and material specifications apply to VALITUDE devices.

All VALITUDE models have a case electrode surface area of 35.05 cm² and all VALITUDE X4 models have a case electrode surface area of 34.58 cm². Usable battery capacity is 1.6 Ah and residual usable battery capacity at Explant is 0.10 Ah.

Mechanical specifications specific to each model are listed below.

Table 2. Mechanical Specifications - VALITUDE CRT-Ps

Model	Dimensions W x H x D (cm)	Mass (g)	Volume (cm³)	Connector Type
U125	4.45 x 6.13 x 0.75	30.6	16.2	RA: IS-1; RV: IS-1; LV: IS-1
U128	4.45 x 6.17 x 0.75	33.0	17.6	RA: IS-1; RV: IS-1; LV: IS4

VALITUDE devices include ZIP telemetry operating with a transmit frequency of 402 to 405 MHz.

Material specifications are shown below:

- Case: hermetically sealed titanium
- Header: implantation-grade polymer
- Power Supply (VALITUDE): lithium-carbon monofluoride cell; Boston Scientific; 402294

The following mechanical specifications and material specifications apply to INTUA and INVIVE devices.

All INTUA and INVIVE models have a case electrode surface area of 35.98 cm². Usable battery capacity is 1.45 Ah and residual usable battery capacity at Explant is 0.09 Ah.

Mechanical specifications specific to each model are listed below.

Table 3. Mechanical Specifications - INTUA CRT-Ps

Model	Dimensions W x H x D (cm)	Mass (g)	Volume (cm³)	Connector Type
V272	4.45 x 6.10 x 0.75	34.0	15.0	RA: IS-1, RV: IS-1, LV: LV-1
V273	4.45 x 6.10 x 0.75	34.0	15.0	RA: IS-1, RV: IS-1, LV: IS-1

Table 4. Mechanical Specifications - INVIVE CRT-Ps

Model	Dimensions W x H x D (cm)	Mass (g)	Volume (cm³)	Connector Type
V172	4.45 x 6.10 x 0.75	34.0	15.0	RA: IS-1, RV: IS-1, LV: LV-1
V173	4.45 x 6.10 x 0.75	34.0	15.0	RA: IS-1, RV: IS-1, LV: IS-1

INTUA and INVIVE devices include ZIP telemetry operating with a transmit frequency of 916.5 MHz.

Material specifications are shown below:

- Case: hermetically sealed titanium
- Header: implantation-grade polymer
- Power Supply (INTUA and INVIVE): lithium-manganese dioxide cell; Boston Scientific; 402125

ITEMS INCLUDED IN PACKAGE

The following items are included with the pulse generator:

- One torque wrench
- Product literature

NOTE: *Accessories (e.g., wrenches) are intended for one-time use only. They should not be resterilized or reused.*

SYMBOLS ON PACKAGING

The following symbols may be used on packaging and labeling (Table 5 on page 34):

Table 5. Symbols on packaging











Symbol	Description
	Reference number
	Package contents
	Pulse generator

Table 5. Symbols on packaging (continued)

Symbol	Description
	Torque wrench
	Literature enclosed
	Serial number
	Use by
	Lot number
	Date of manufacture
	Sterilized using ethylene oxide