

**Boston  
Scientific**

PHYSICIAN'S TECHNICAL MANUAL

**COGNIS™ 100-D**

CARDIAC RESYNCHRONIZATION THERAPY HIGH  
ENERGY DEFIBRILLATOR

Model N118, N119

**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.

## Table of Contents

Additional Technical Information.....	1
New or Enhanced Features.....	1
Device Description.....	3
Additional Technical Information.....	5
Related Information.....	5
Indications and Usage.....	6
Contraindications.....	6
Warnings.....	7
Precautions.....	9
Potential Adverse Events.....	28
Mechanical Specifications.....	32
Lead Connections.....	33
Items Included in Package.....	35
Symbols on Packaging.....	36
Characteristics as Shipped.....	40
X-Ray Identifier.....	41
Federal Communications Commission (FCC).....	43
Industry Canada (IC).....	43
Pulse Generator Longevity.....	44
Warranty Information.....	47
Product Reliability.....	47
Patient Counseling Information.....	49

Patient Handbook..... 50

### **ADDITIONAL TECHNICAL INFORMATION**

For additional technical reference guides, go to [www.bostonscientific.com/ifu](http://www.bostonscientific.com/ifu).

### **NEW OR ENHANCED FEATURES**

These pulse generator systems include additional features as compared to previous products.

#### **Ease of Use**

- ZOOMVIEW Programmer Software: the new user interface offers the following benefits:
  - Clinical focus—features such as patient diagnostic trends and indications-based programming emphasize the patient's clinical condition over device status and parameters.
  - Consistency—ZOOMVIEW software will be available on future pulse generators, providing the same screens whether you are following a brady, tachy, or heart failure device.
  - Simplicity—screen complexity is reduced through the use of progressive disclosure (displaying the information you use frequently and minimizing the information you only rarely access) and exception-based reporting.

- Indications-Based Programming (IBP): the new ZOOMVIEW feature allows you to quickly set up programming parameters based on the patient's clinical needs and indications.

#### **Tachy Therapy**

- Rhythm ID and Onset/Stability detection: the selection between detection enhancements provides you the opportunity and flexibility to adjust for individual patient conditions.
- QUICK CONVERT ATP: in an attempt to avoid an otherwise scheduled charge and painful shock for a pace-terminable fast ventricular tachycardia (VT), the pulse generator delivers one rapid burst of antitachycardia pacing (ATP) for an episode detected in the ventricular fibrillation (VF) zone.
- Programmable Shock Vectors: this capability allows you to electronically change the shocking vectors for added flexibility in treating high defibrillation thresholds (DFTs).

#### **Sensing**

- Sensing is designed to combine the strengths of both implantable cardioverter defibrillator (ICD) and pacemaker sensing capabilities to improve detection and therapy by reducing inappropriate mode switching, pacing inhibition, and shocks.

### **DEVICE DESCRIPTION**

This manual contains information about the COGNIS 100 family of cardiac resynchronization therapy defibrillators (CRT-Ds) (specific models are listed in "Mechanical Specifications" on page 32).

#### **Therapies**

This family of pulse generators has a small, thin, physiologic shape that minimizes pocket size and may minimize device migration. Pulse generators within this family provide a variety of therapies, including:

- Ventricular tachyarrhythmia therapy, which is used to treat rhythms associated with sudden cardiac death (SCD) such as VT and VF
- 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 and to provide cardiac rate support after defibrillation therapy

Cardioversion/defibrillation therapies include:

- A range of low- and high-energy shocks using a biphasic waveform

- The choice of multiple shock vectors:
  - Distal shock electrode to proximal shock electrode and pulse generator case (TRIAD electrode system)
  - Distal shock electrode to proximal shock electrode (RV Coil to RA Coil)
  - Distal shock electrode to pulse generator case (RV Coil to Can)

#### **Leads**

The pulse generator has independently programmable outputs and accepts the following leads:

- One IS-1<sup>1</sup> atrial lead
- One IS-1 coronary venous pace/sense lead
- One LV-1 coronary venous pace/sense lead
- One DF-1/IS-1<sup>2</sup> cardioversion/defibrillation lead

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

---

1. IS-1 refers to the international standard ISO 5841-3:2000.  
2. DF-1 refers to the international standard ISO 11318:2002.

### **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 2868 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

### **ADDITIONAL TECHNICAL INFORMATION**

For additional technical reference guides, go to [www.bostonscientific.com/ifu](http://www.bostonscientific.com/ifu).

### **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.

The Physician's Technical Manual is packaged with the pulse generator. It provides the technical information needed at implant.

Refer to the PRM system Operator's Manual for specific information about the PRM such as setup, maintenance, and handling.

#### INDICATIONS AND USAGE

*These* Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacological therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with EF  $\leq$  35% and QRS duration  $\geq$  120 ms
- Left bundle branch block (LBBB) with QRS duration  $\geq$  130 ms, EF  $\leq$  30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

Boston Scientific cardiac resynchronization therapy defibrillators (CRT-Ds) are also intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

## WARNINGS

### General

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the system. 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.
- **Avoid shock during handling.** Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks.
- **Backup defibrillation protection.** Always have sterile external and internal defibrillation protection available during implant. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.

- **Resuscitation availability.** Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue.
- **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 MR device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Diathermy.** Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

**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 VT or VF.
- **Atrial-only modes.** Do not use atrial-only modes in patients with heart failure because such modes do not provide CRT.

- **Ventricular sensing.** Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition.
- **Slow VT.** Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones.

#### **Implant Related**

- **Do not kink leads.** Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.
- **Patch leads.** Do not use defibrillation patch leads with the pulse generator system, or injury to the patient may occur.
- **Separate pulse generator.** Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery.

#### **PRECAUTIONS**

##### **Clinical Considerations**

- **Pacemaker-mediated tachycardia (PMT).** Retrograde conduction combined with a short PVARP might induce PMT.

#### **Sterilization, Storage, and Handling**

- **If package is damaged.** The pulse generator blister trays and contents are sterilized with ethylene oxide gas before final packaging. When the pulse generator is received, it is sterile provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the device to Boston Scientific.
- **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 device system 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 and Device Programming

- **Lead system.** Do not use any lead with this device without first verifying connector compatibility. Using incompatible leads 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 the telemetry wand is connected to the programmer and that it is available throughout the session. Verify that the wand cord is within reach of the 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 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 within the range of 200  $\Omega$  and 2000  $\Omega$ .
- **Line-powered equipment.** Exercise extreme caution if testing leads using line-powered equipment because leakage current exceeding 10  $\mu$ A can induce ventricular fibrillation. Ensure that any line-powered equipment is within specifications.
- **Proper programming of the lead configuration.** If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.
- **Proper programming of the shock vector.** If the shock vector is programmed to RVcoil>RAcoil and the lead does not have an RA coil, shocking will not occur.

- **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.
- **Defibrillation power surge.** Defibrillation that causes a power surge exceeding 360 watt-seconds can damage the pulse generator system.
- **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.** Adaptive-rate 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 entering a fixed AV delay, consider the sensing outcomes.
- **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 the 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.
- **Do not bend the lead near the lead-header interface.** Improper insertion can cause insulation damage near the terminal end that could result in lead failure.
- **Shock waveform polarity.** For IS-1/DF-1 leads, never change the shock waveform polarity by physically switching the lead anodes and cathodes in the pulse generator header—use the programmable Polarity feature. Device damage or nonconversion of the arrhythmia post-operatively may result if the polarity is switched physically.

- **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.
- **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.
- **Tachy Mode to Off.** To prevent inappropriate shocks, ensure that the pulse generator's Tachy Mode is programmed to Off when not in use and before handling the device. For tachyarrhythmia therapy, verify that the Tachy Mode is activated.
- **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.

- **Defibrillation lead impedance.** Never implant the device with a lead system that has less than 15  $\Omega$  total shock lead impedance. Device damage may result. If a shocking lead impedance is less than 20  $\Omega$ , reposition the lead to allow a greater distance between the shocking electrodes.
- **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.
- **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.
- **Left Ventricular Protection Period (LVPP).** Use of a long LVPP reduces the maximum LV pacing rate and may inhibit CRT at higher pacing rates.

- **Shunting energy.** Do not allow any object that is electrically conductive to come into contact with the lead or device during induction because it may shunt energy, resulting in less energy getting to the patient, and may damage the implanted system.
- **Expected benefits.** Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose tachyarrhythmias require frequent shocks.
- **Device communication.** Use only the designated PRM and software application to communicate with this pulse generator.

#### **Environmental and Medical Therapy Hazards**

- **Avoid electromagnetic interference (EMI).** Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of EMI sources are:
  - Electrical power sources, arc welding equipment, and robotic jacks
  - 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
- **Elevated Pressures.** Elevated pressures due to hyperbaric chamber exposure or SCUBA diving may damage the pulse generator. The pulse generator has been tested to function normally at 1.5 Atmospheres Absolute (ATA) pressure or 15 ft (4.6 m) depth in sea water. For specific guidelines prior to hyperbaric chamber exposure, or if the patient is planning scuba diving activity, contact Technical Services at the number shown on the back cover of this manual.

### Hospital and Medical Environments

- **Mechanical ventilators.** During mechanical ventilation, respiration rate trending may be misleading; therefore, the Respiratory Sensor should be programmed to Off.
- **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.** Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator: Position the external defibrillation pads (or paddles) as far from the pulse generator as possible, position the defibrillation pads (or paddles) perpendicular to the implanted pulse generator-lead system, and set energy output of defibrillation equipment as low as clinically acceptable.

Following any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. Interrogate the pulse generator, perform a manual capacitor reformation, verify battery status and shock counters, verify pacing, and ensure that programmable parameters did not change.

- **Transcutaneous electrical nerve stimulation (TENS).** TENS may interfere with pulse generator function. If necessary, the following measures may reduce interference:

1. Place the TENS electrodes as close to each other as possible and as far from the pulse generator and lead system as possible.
2. Monitor cardiac activity during TENS use.

For additional information, contact Technical Services at the number shown on the back cover of this manual.

- **Electrocautery.** The use of electrocautery could induce ventricular arrhythmias and/or fibrillation, cause asynchronous or inhibited pulse generator operation, or cause the pulse generator to deliver an inappropriate shock. If electrocautery cannot be avoided, observe the following precautions to minimize complications:
  - Select Electrocautery Protection Mode. Avoid direct contact with the pulse generator or leads.
  - Monitor the patient and have temporary pacing equipment, external defibrillation equipment, and knowledgeable medical personnel available.
  - Position the ground plate so that the current pathway does not pass through or near the pulse generator system.
  - Use short, intermittent, and irregular bursts at the lowest feasible energy levels.
  - Use a bipolar electrocautery system where possible.

Remember to reactivate the Tachy Mode after turning off the electrocautery equipment.

- **Ionizing radiation therapy.** 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 and defibrillation therapy.

Many sources of ionizing radiation are commonly used for the diagnosis and treatment of diseases; these sources 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. Most diagnostic tools, such as radiography (X-ray) and fluoroscopy, have not been identified as sources of pulse generator interference or damage.

Refer to the System Guide for further details regarding advance planning and follow-up assessment of pulse generators exposed to ionizing radiation.

- **Lithotripsy.** Lithotripsy may permanently damage the pulse generator if the device is at the focal point of the lithotripsy beam. If lithotripsy must be used, avoid focusing near the pulse generator site.

The lithotripter is designed to trigger off the R-wave on the ECG, resulting in shock waves being delivered during the VRP.

- If the patient does not require pacing, program the pulse generator Brady Mode to Off.
- If the patient requires pacing, program the pulse generator to the VVI mode because atrial pacing pulses can trigger the lithotripter.
- **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.
- **Radio frequency ablation.** Exercise caution when performing radio frequency ablation procedures in device patients. If the pulse generator Tachy Mode is programmed to Monitor + Therapy during the procedure, the device may inappropriately declare a tachycardia episode and deliver therapy. Pacing therapy may also be inhibited unless the device is programmed to Electrocautery mode. RF ablation may cause changes in pacing thresholds; evaluate the patient's thresholds appropriately.

Minimize risks by following these steps:

- Program the Tachy Mode(s) to Electrocautery Protection to avoid inadvertent tachycardia detection (sensing) or therapy.
- Monitor the patient and have external defibrillation equipment and knowledgeable medical personnel available.
- Avoid direct contact between the ablation catheter and the implanted lead and pulse generator.
- Keep the current path (electrode tip to ground) as far away from the pulse generator and leads as possible.
- Consider the use of external pacing support for pacemaker-dependent patients (i.e., using internal or external pacing methods).
- Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function.

Remember to reactivate the pulse generator after turning off the radio frequency ablation equipment.

- **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 include:
  - Cordless phone handsets or base stations
  - Certain patient monitoring systems
  - Remote control toys

### 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 devices
  - 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).** Advise patients to avoid lingering near antitheft devices such as those found in the entrances and exits of department stores and public libraries. Patients should walk through them at a normal pace because such devices may cause inappropriate pulse generator operation.

- **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**

- **Conversion testing.** Successful VF or VT conversion during arrhythmia conversion testing is no assurance that conversion will occur post-operatively. Be aware that changes in the patient's condition, drug regimen, and other factors may change the DFT, which may result in nonconversion of the arrhythmia post-operatively.
- **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.

#### **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 unwanted shocks, overwriting of important therapy history data, and audible tones:
  - Program the pulse generator Tachy and Brady Modes to Off.
  - Program the Magnet Response feature to Off.
  - Program the Beep When Explant is Indicated feature to Off.

Clean and disinfect the device using standard biohazard handling techniques.

- **Explanted devices.** Return all explanted pulse generators and leads to Boston Scientific. Examination of explanted pulse generators can provide information for continued improvement in device reliability and will permit calculation of any warranty replacement credit due.
  - Do not implant an explanted pulse generator in another patient as sterility, functionality, and reliability cannot be ensured.

#### **POTENTIAL ADVERSE EVENTS**

Based on the literature and on pulse generator implant experience, the following alphabetical list includes the possible adverse events associated with implantation of a pulse generator system:

- Air embolism

- Allergic reaction
- Bleeding
- 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)
- Failure to convert an induced arrhythmia
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Inability to defibrillate or pace
- Inappropriate therapy (e.g., shocks where applicable, ATP, pacing)
- Incisional pain
- Incomplete lead connection with pulse generator

- Infection
- Insulating myocardium during defibrillation with internal or external paddles
- Lead dislodgment
- Lead fracture
- Lead insulation breakage or abrasion
- Lead tip deformation and/or breakage
- Myocardial infarction (MI)
- Myocardial necrosis
- Myocardial trauma (e.g., cardiac perforation, irritability, injury)
- Myopotential sensing
- Oversensing/undersensing
- Pacemaker-mediated tachycardia (PMT)
- Pericardial rub, effusion
- Pneumothorax
- Pulse generator migration
- Shunting current during defibrillation with internal or external paddles
- Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation
- Thrombosis/thromboemboli

30

- Valve damage
- 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 shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking

In addition to the implantation of a pulse generator system, 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

## Physician's Technical Manual

**CONTAK RENEWAL® 3**

REF H170/H175

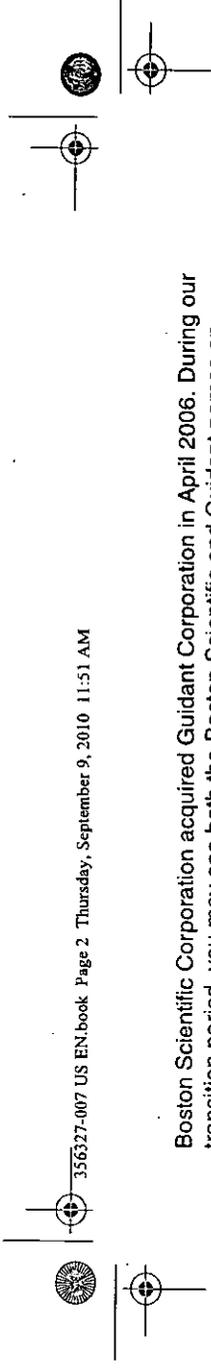
**CONTAK RENEWAL® 3 HE**

REF H177/H179

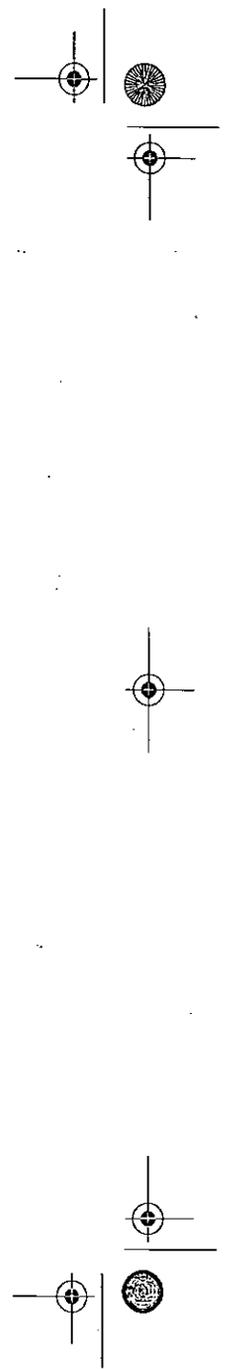
Cardiac Resynchronization  
Therapy Defibrillator

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

# GUIDANT



Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient materials. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.

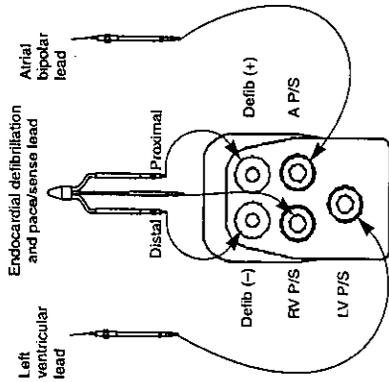
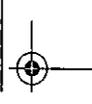


**Mechanical Specifications**

Characteristic	CONTAK RENEWAL 3 Models H170/H175	CONTAK RENEWAL 3 HE Models H177/H179
Dimensions H x W x D (cm)	7.78 x 5.94 x 1.15	8.26 x 6.30 x 1.15
Volume (cc)	37	40
Mass (g)	89	89
Connector Size	IS-1/LV-1, IS-1, DF-1	IS-1/LV-1, IS-1, DF-1
Case Electrode Surface Area (mm <sup>2</sup> )	6950	7655
Case Material	Hermetically sealed titanium	
Header Material	Implantation-grade polymer	
Power Supply (WGT)	Lithium-silver vanadium oxide cell	

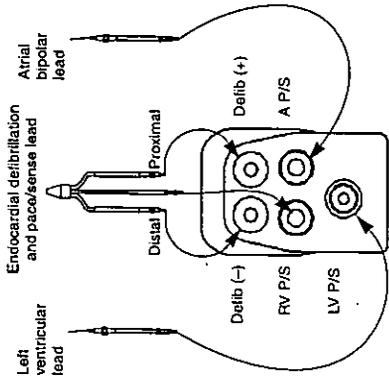
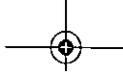
**Lead Connections**

- All models use the pulse generator case as a defibrillating electrode.
- For lead compatibility information, refer to the lead system precaution on page 4.
- LV-1 refers to the Guidant LV proprietary connector. IS-1 refers to the international standard ISO 5841-3:2000. DF-1 refers to the international standard ISO 11318:2002.



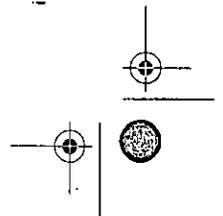
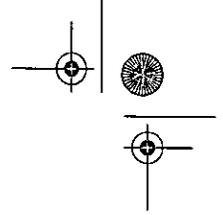
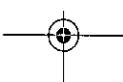
**Models H170/H177**

- DF-1 Defib ports
- IS-1 Right Ventricular P/S port
- IS-1 Atrial P/S port
- IS-1 Left Ventricular P/S port

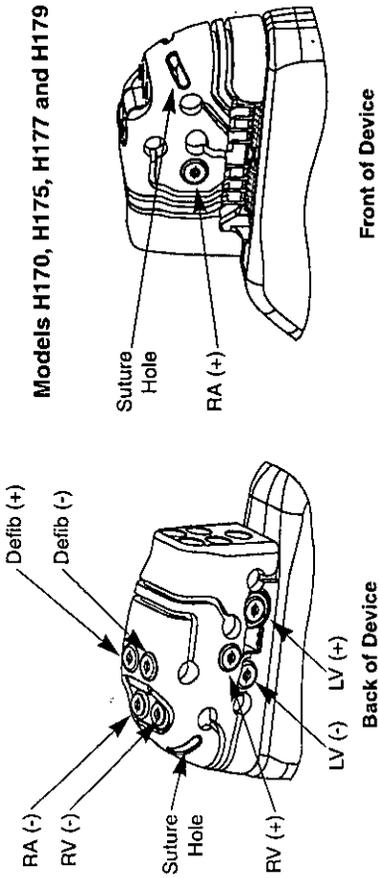


**Models H175/H179**

- DF-1 Defib ports
- IS-1 Right Ventricular P/S port
- IS-1 Atrial P/S port
- LV-1 Left Ventricular P/S port



### Setscrew Locations



### X-Ray Identifier

The pulse generators have an identifier that is visible on x-ray film or under fluoroscopy. This provides noninvasive confirmation of the device manufacturer. The identifier consists of the letters "GDT" to identify the manufacturer (Guidant), followed by 202, identifying the Model 2845 programmer software application needed to communicate with the pulse generator.

Refer to the Quick Start section in the Physician's System Guide for information on identifying the device via the programmer.

The model number of the pulse generator is stored in the device's memory and is available on the About screen selectable through the Utilities menu when the pulse generator is interrogated.

### Latitude Patient Management System

The LATITUDE Patient Management system is a remote monitoring system that provides pulse generator data to both clinicians and cardiac device patients. The LATITUDE system enables physicians to monitor patients and specific device information remotely. The LATITUDE system is

iii



able to generate alert notifications for a number of conditions, which vary depending on the implanted device model. (For conditions monitored, refer to the clinician's manual for the LATITUDE Patient Management System.) Use of the LATITUDE system can decrease the need for routine in-office follow-up visits.

A key component of the system is the LATITUDE Communicator, an easy-to-use in-home monitoring device for patients. The Communicator gathers data from a compatible Guidant pulse generator and sends it to the LATITUDE secure server through a standard telephone line. The LATITUDE server provides patient data to the LATITUDE website, which is readily available over the Internet to authorized physicians and clinicians. Contact your Guidant sales representative to enroll in the LATITUDE Patient Management system.

**Federal Communications Commission (FCC)**

This device complies with Title 47, Part 15 of the FCC rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation of the device.

**CAUTION:** Changes or modifications not expressly approved by Guidant could void the user's authority to operate the equipment.

**Items Included in Device Packaging**

The following items are packaged with the CONTAK RENEWAL 3 pulse generator:

- Torque wrench
- Product literature

**NOTE:** *Wrenches are intended for one-time use only and should not be resterilized or reused.*



### Factory Nominal Parameter Settings

Parameter	Factory Nominal Value <sup>a</sup>
Number of Zones	1
Tachy Mode	Storage
VF Rate	165 bpm
Shock Energy Stored <sup>b</sup>	31 J (41 J HE models)
Waveform <sup>c</sup>	Biphasic
Heart Failure/Brady Mode	DDD
Lower Rate Limit <sup>d</sup>	40 bpm
Amplitude <sup>e</sup>	3.5 V
Pulse Width <sup>e f</sup>	0.4 ms
Atrial Refractory—PVARP	Dynamic
Right Ventricular Refractory Period—RVRP	Dynamic
Left Ventricular Refractory Period—LVRP	250 ms
AV Delay	120 ms
Pacing Chamber	Biventricular

- Preset at factory at 37° C and 500 ohm load.
- Tolerance is ±40% for 2 J or less, ±20% for 3-29 J, and ±10% for 31 J. Tolerance is ±40% for 2 J or less, ±20% for 3-31 J, and ±10% for 41 J.
- Biphasic energy is specified. Monophasic energy is 6.7% less than biphasic energy.
- The basic pulse period is equal to the brady pacing rate and the pulse interval (no hysteresis). Runaway protection circuitry allows the pacing rate to increase to a maximum of 190 bpm before the protection circuit would inhibit pacing. Runaway protection is not an absolute assurance that runaways will not occur. Magnet application does not affect pacing rate (test pulse interval). Tolerance is ±5 ms.
- The pulse generator uses an automatic gain control circuit for varying the sensitivity of its rate sensing amplifiers. Following paced pulses delivered by the pulse generator, sensitivity is set to 4.0 mV (±1.2 mV) at the end of the refractory period. Tolerance is ±0.3 V at ≤3 V and ±10% at > 3 V.
- Tolerance is ±0.03 ms at < 1.8 ms and ±0.08 ms at ≥ 1.8 ms.

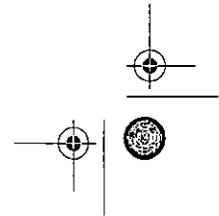
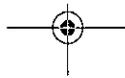
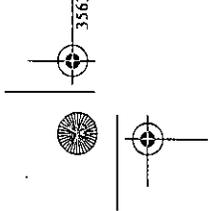
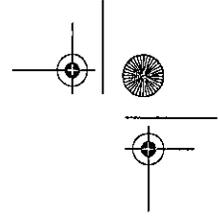
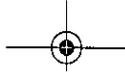
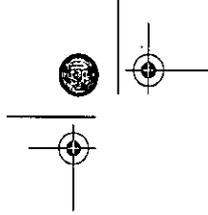
**NOTE:** Magnet use will not be enabled if the pulse generator is brought out of Storage mode using the STAT PACE or STAT SHOCK commands.

### Graphical Symbols for Medical Device Labeling

Symbol	Definition
	Opening instructions
	Wand placement indicator
	Reference Number
	Manufacturer

## CONTENTS

1. Device Description .....	1
1.1. Related Manuals and Information Tools .....	2
2. Indications and Usage .....	2
3. Clinical Outcomes .....	2
4. Contraindications .....	2
5. Warnings .....	2
5.1. General .....	2
5.2. Programming and Device Operation .....	3
5.3. Implant Related .....	4
6. Precautions .....	4
6.1. Clinical Considerations .....	4
6.2. Sterilization, Storage, and Handling .....	4
6.3. Implantation and Device Programming .....	4
6.4. Follow-up Testing .....	7
6.5. Explant and Disposal .....	7
6.6. Environmental and Medical Therapy Hazards .....	8
6.7. Home and Occupational Environments .....	11
7. Potential Adverse Events .....	11
8. Device Features .....	13
9. Maintaining Device Effectiveness .....	14
10. Pulse Generator Longevity .....	14
10.1. Warranty Information .....	15
11. Patient Counseling Information .....	15
11.1. Patient Manual .....	16
12. Product Reliability .....	16
13. Pre-Implant and Implant Information .....	17
14. Items Included in Device Packaging .....	17
15. Factory Nominal Parameter Settings .....	17
16. Implanting the Pulse Generator .....	19



### 1. DEVICE DESCRIPTION

The Guidant **CONTAK RENEWAL 3** cardiac resynchronization therapy defibrillator (**CRT-D**), Models **H170** and **H175**, and **CONTAK RENEWAL 3 HE CRT-D**, Models **H177** and **H179**, provide ventricular tachyarrhythmia and cardiac resynchronization therapies. Ventricular tachyarrhythmia therapy is for the treatment of ventricular tachycardia (VT) and ventricular fibrillation (VF), rhythms that are associated with sudden cardiac death (SCD). Cardiac resynchronization therapy is for the treatment of heart failure (HF) and uses biventricular electrical stimulation to synchronize ventricular contractions. The device also uses accelerometer-based adaptive-rate bradycardia therapy similar to Guidant's commercially available **VENTAK** family of implantable cardioverter defibrillators (ICDs). The pulse generator has independently programmable outputs and accepts one **IS-1** atrial lead, one **LV-1** or one **IS-1** coronary venous pace/sense lead, and one **DF-1/IS-1** cardioversion/defibrillation lead. The pulse generator and the leads constitute the implantable portion of the **CONTAK RENEWAL 3** system. The device's small, physiologic shape minimizes pocket size and may minimize device migration.

Cardioversion/defibrillation therapies include a range of low- and high-energy shocks using either a biphasic or monophasic waveform. The **CONTAK RENEWAL 3** device uses the **Guidant TRIAD** electrode system for defibrillation energy delivery. By using the metallic housing of the pulse generator as an active electrode, combined with the **Guidant ENDOTAK** two-electrode defibrillation lead, energy is sent via a dual-current pathway from the distal shocking electrode to the proximal electrode and to the pulse generator case. The **CONTAK RENEWAL 3** device also offers a wide variety of antitachycardia pacing schemes to terminate slower, more stable ventricular tachyarrhythmias. Bradycardia pacing with cardiac resynchronization therapy, including adaptive-rate features, is available to detect and treat bradyarrhythmias and to support the cardiac rhythm after defibrillation therapy.

The external portion of the **CONTAK RENEWAL 3** system allows interrogation and programming of the pulse generator, as well as access to the device's diagnostic features. The external components consist of an accessory telemetry wand, the Model **2845 CONSULT** Software Application, and the **ZOOM LATITUDE** Programming System, which includes the Model **3120 Programmer/Recorder/Monitor (PRM)**. The **CONTAK RENEWAL 3** system can be programmed

1. **IS-1** refers to the international standard ISO 5841-3:2000. **LV-1** refers to the Guidant LV proprietary connector. **DF-1** refers to the international standard ISO 11318:2002.

to provide a variety of therapy options. It also can provide noninvasive diagnostic testing and therapy history data.

**1.1. Related Manuals and Information Tools**

The System Guide for the **CONTAK RENEWAL 3** is a separate document and is used in conjunction with the Guidant PRIM and the Model 2845 software. The System Guide includes product specifications, operating characteristics, implant procedure recommendations, programming instructions, and follow-up recommendations. Copies can be obtained by contacting your Guidant representative.

The Operator's Manual for the Guidant Programmer/Recorder/Monitor provides information specific to the programmer, such as setting up the system, maintenance, and handling. Physician's manuals for the leads provide specific information and instructions regarding the implanted leads.

**2. INDICATIONS AND USAGE**

Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with EF  $\leq$  35% and QRS duration  $\geq$  120 ms
- Left bundle branch block (LBBB) with QRS duration  $\geq$  130 ms, EF  $\leq$  30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

**3. CLINICAL OUTCOMES**

See the appendices at the end of the System Guide to review detailed clinical study information.

**4. CONTRAINDICATIONS**

There are no contraindications for this device.

**5. WARNINGS**

**5.1. General**

- Labeling knowledge. Read this manual thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in injury to or death of the patient.

- **Do not kink leads.** Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.
- **Avoid shock during handling.** Program the pulse generator Tachy Mode to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks.
- **Backup defibrillation protection.** Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death.
- **Resuscitation availability.** Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.
- **Magnetic resonance imaging (MRI) exposure.** Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Diathermy.** Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator.
- **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.

## 5.2. Programming and Device Operation

- **Atrial tracking modes.** Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. (Applies to dual-chamber devices only)
- **Atrial only modes.** Do not use atrial only modes in patients with heart failure because such modes do not provide cardiac resynchronization therapy.
- **Ventricular sensing.** Left ventricular lead dislodgment to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. See the System Guide for more information.
- **Slow VT.** Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones. See the System Guide for more information.

### 5.3. Implant Related

- **Patch leads.** Do not use defibrillation patch leads with the pulse generator system, or injury to the patient may occur.
- **Separate pulse generator.** Do not use this pulse generator with another CRM pulse generator. This combination could cause pulse generator interaction resulting in patient injury or a lack of therapy delivery.
- **Subpectoral implantation.** When using subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to component failure and device malfunction.

## 6. PRECAUTIONS

### 6.1. Clinical Considerations

- **Pacemaker-mediated tachycardia (PMT).** Retrograde conduction combined with a short PVARP might induce PMT.

### 6.2. Sterilization, Storage, and Handling

- **If package is damaged.** The pulse generator blister trays and contents are sterilized with ethylene oxide gas before final packaging. When the pulse generator is received, it is sterile, provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the device to Guidant.
- **Storage temperature and equilibration.** Recommended storage temperatures are 0°–50°C (32°–122°F). Allow the device to reach a proper temperature before 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 electromagnetic interference (EMI) to avoid device damage.
- **Use before date.** Implant the device system before the USE BEFORE 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 1.

### 6.3. Implantation and Device Programming

- **Expected benefits.** Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose tachyarrhythmias require frequent shocks.
- **Lead system.** Do not use any lead with this device without first verifying connector compatibility. Using incompatible leads can damage the connector or result in potential adverse consequences, such as undersensing of cardiac activity or failure to deliver necessary therapy.

- **Telemetry wand.** Make sure the telemetry wand is connected to the PRM system and that it is available throughout the session. Verify that the wand cord is within reach of the pulse generator.
- **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.
- **Device communication.** Use only the designated PRM and software application to communicate with the 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 decrease device longevity.
- **Biventricular pacing.** 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 within the range of 200  $\Omega$  and 2000  $\Omega$ .
- **Line-powered equipment.** Exercise extreme caution if testing leads using line-powered equipment because leakage current exceeding 10  $\mu$ A can induce ventricular fibrillation. Ensure that any line-powered equipment is within specifications.
- **Proper programming of the lead configuration.** If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.
- **AV Delay.** For delivery of cardiac resynchronization therapy, the programmed setting for the AV Delay must be less than the patient's intrinsic intracardiac AV interval.
- **Adaptive-rate pacing.** Adaptive-rate 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 entering a fixed AV delay, consider the sensing outcomes.

- **Atrial Tachy Response (ATR).** ATR should be programmed Off unless the patient has a history of atrial tachyarrhythmias. The delivery of CRT is compromised because AV synchrony is disrupted.
- **Threshold test.** During the left ventricular threshold test, right ventricular backup pacing is unavailable.
- **Left ventricular pacing only.** The clinical effect of left ventricular pacing alone in heart failure patients has not been established.
- **Do not bend the lead near the lead–header interface.** Improper insertion can cause insulation damage near the terminal end that could result in lead failure.
- **Shock waveform polarity.** Never change the shock waveform polarity by physically switching the lead anodes and cathodes in the pulse generator header—use the programmable Polarity feature. Device damage or nonconversion of the arrhythmia post-operatively may result if polarity is switched physically.
- **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.
- **Electrode connections.** Do not insert a lead into the pulse generator connector without first visually verifying that the setscrew is sufficiently retracted to allow insertion. Fully insert each lead into its lead port and then tighten the setscrews onto the electrodes.
- **Tachy Mode to Off.** To prevent inappropriate shocks, ensure that the pulse generator's Tachy Mode(s) is programmed to Off when not in use and before handling it. When using Temporary HF/Brady, the Tachy Mode is Off. Do not use Temporary HF/Brady as a means to deactivate device tachyarrhythmia therapy. For tachyarrhythmia therapy, verify that the Tachy Mode(s) is programmed to On.
- **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. (Applies to dual-chamber devices only.)
- **Defibrillation lead impedance.** Never implant the device with a lead system that has less than 15- $\Omega$  total shock lead impedance. Device damage may result. If a shocking lead impedance is less than 20  $\Omega$ , reposition the shocking electrodes to allow a greater distance between the shocking electrodes.
- **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.
- **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.
- **Left Ventricular Protection Period (LVPP).** Use of a long LVPP reduces the maximum left ventricular pacing rate and may inhibit cardiac resynchronization therapy at higher pacing rates.
- **Shunting energy.** Do not allow any object that is electrically conductive to come into contact with the lead or device during tachyarrhythmia induction because it may shunt energy. This could result in less energy getting to the patient and damage to the implanted system.
- **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.

#### 6.4. Follow-up Testing

- **Conversion testing.** Successful VF or VT conversion during arrhythmia conversion testing is no assurance that conversion will occur post-operatively. Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in nonconversion of the arrhythmia post-operatively.
- **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.

#### 6.5. 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 unwanted shocks, overwriting of important therapy history data, and audible tones:
  - Program the pulse generator Tachy and Brady Modes to Off
  - Program the Magnet Response feature to Off
  - Program the Beep When ERI Is Reached feature to Off

- **Implanted devices.** Return all explanted pulse generators and leads to Guidant. Examination of explanted pulse generators can provide information for continued improvement in device reliability and will permit calculation of any warranty replacement credit due.  
Do not implant an explanted pulse generator in another patient as sterility, functionality, and reliability cannot be ensured.

#### 6.6. Environmental and Medical Therapy Hazards

- **Avoid electromagnetic interference (EMI).** Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of EMI sources are:
  - electrical power sources, arc welding equipment and robotic jacks
  - electrical smelting furnaces
  - large RF transmitters such as RADAR
  - radio transmitters including those used to control toys
  - electronic surveillance (anti-theft) devices
  - an alternator on a car that is running

#### 6.6.1. Hospital and Medical Environments

- **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.** Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator, consider the following:
  - Avoid placing a pad (or paddle) directly over the pulse generator. Position the external defibrillation pads (or paddles) as far from the pulse generator as possible.
  - Position the defibrillation 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 any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. Interrogate the pulse generator, perform a manual capacitor reformation, verify battery status and shock counters, verify pacing, and ensure that programmable parameters did not change.
- **Transcutaneous electrical nerve stimulation (TENS).** TENS may interfere with pulse generator function. If necessary, the following measures may reduce interference:

- Place the TENS electrodes as close to each other as possible and as far from the pulse generator and lead system as possible.
  - Monitor cardiac activity during TENS use.
- For additional information, contact Technical Services at the number shown on the back cover of this manual.
- **Electrical interference.** Electrical interference or "noise" from devices such as electrosurgical 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.
  - **Electrocautery.** The use of electrocautery could induce ventricular arrhythmias and/or fibrillation, cause asynchronous or inhibited pulse generator operation, or cause the pulse generator to deliver an inappropriate shock. If electrocautery cannot be avoided, observe the following precautions to minimize complications:
    - Select Off-Electrocautery Mode, which programs the pacing mode to VOO, AOO, or DDO and turns the Tachy Mode to Off. Note that Tachy Mode Off-Electrocautery cannot be initialized while the device is in a tachyarrhythmia episode or in the Post-Shock Pacing Period.
    - Avoid direct contact with the pulse generator or leads.
    - Monitor the patient and have temporary pacing equipment, external defibrillation equipment, and knowledgeable medical personnel available.
    - Position the ground plate so that the current pathway does not pass through or near the pulse generator system.
    - Use short, intermittent, and irregular bursts at the lowest feasible energy levels.
    - Use a bipolar electrocautery system where possible.
- Remember to program the Tachy Mode to On after turning off the electrocautery equipment. If Off-Electrocautery is canceled by an emergency therapy, the telemetry link must be maintained after the STAT Shock, STAT Pace, or Divert has completed to allow the device to exit Off-Electrocautery.
- **Ionizing radiation therapy.** Many sources of ionizing radiation are commonly used for the diagnosis and treatment of diseases; these sources 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 brachytherapy. Most diagnostic tools, such as radiography (X-ray), and fluoroscopy, have not been identified as sources of device interference or damage. 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 and defibrillation therapy. 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. Please refer to the System Guide for further details regarding advance planning and follow-up assessment of pulse generators exposed to ionizing radiation.

- **Lithotripsy.** Lithotripsy may permanently damage the pulse generator if the device is at the focal point of the lithotripsy beam. If lithotripsy must be used, avoid focusing near the pulse generator site.

The lithotriptor is designed to trigger off the R-wave on the ECG, resulting in shock waves being delivered during the VRP.

- If the patient does not require pacing, program the pulse generator Brady Mode to Off.
- If the patient requires pacing, program the pulse generator to the VVI mode because atrial pacing pulses can trigger the lithotriptor.
- **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.
- **Radio frequency ablation.** Exercise caution when performing radio frequency ablation procedures in device patients. If the pulse generator Tachy Mode is programmed On during the procedure, the device may inappropriately declare a tachycardia episode and deliver therapy. Brady pacing may be inhibited during electrocautery if Off-electrocautery mode is not selected. Minimize risks by following these steps:
  - Program the Tachy Mode to Off or Off-Electrocautery to avoid inadvertent tachycardia detection (sensing) or therapy.
  - Avoid direct contact between the ablation catheter and the implanted leads and pulse generator.
  - Keep the current path (electrode tip to ground) as far away from the pulse generator and leads as possible.
  - Have external defibrillation equipment available.
  - Consider the use of external pacing support for pacemaker-dependent patients.
  - Remember to reactivate the pulse generator after turning off the radio frequency ablation equipment.

### 6.7. 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 to avoid equipment or situations where they would have extended exposure to strong magnetic fields (>10 gauss or 1 mTesla) since this could inhibit pulse generator tachy therapy. Examples of magnetic sources are: industrial transformers and motors, magnetic resonance imaging (MRI) devices, large stereo speakers, telephone receivers if held within 0.5 inches (1.27 cm) of the pulse generator, and magnet
- **Electronic article surveillance (EAS).** Advise patients to avoid lingering near anti-theft devices, such as those found in entrances and exits of department stores and public libraries, and to walk through them at a normal pace, because such devices may cause inappropriate pulse generator operation.
- **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 6 inches (15 cm) of the implanted device since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

### 7. POTENTIAL ADVERSE EVENTS

Based on the literature and pulse generator implant/explant experience, the following alphabetical list includes possible adverse events associated with implantation and explantation of a pulse generator system:

- Air embolism
- Allergic reaction
- Bleeding
- 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)
- Failure to convert an induced arrhythmia
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Inability to defibrillate or pace
- Inappropriate therapy (e.g., shocks where applicable, ATP, pacing)
- Incisional pain
- Incomplete lead connection with pulse generator
- Infection
- Insulating myocardium during defibrillation with internal or external paddles
- Lead dislodgment
- Lead fracture
- Lead insulation breakage or abrasion
- Lead tip deformation and/or breakage
- Myocardial infarction
- Myocardial necrosis
- Myocardial trauma (e.g., cardiac perforation, irritability, injury)
- Myopotential sensing
- Oversensing/undersensing
- Pacemaker-mediated tachycardia (Applies to dual-chamber devices only.)
- Pericardial rub, effusion
- Pneumothorax
- Pulse generator migration
- Shunting current during defibrillation with internal or external paddles
- Tachyarrhythmias
- Thrombosis/thromboemboli
- Valve damage
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)
- Worsening heart failure

Patients may develop psychological intolerance to a pulse generator system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking

In addition to the implantation of a pulse generator system, potential adverse events associated with implantation of a coronary venous lead system are listed below in alphabetical order:

- 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

## 8. DEVICE FEATURES

By programming device parameters, the pulse generator provides ventricular tachyarrhythmia and cardiac resynchronization therapies. The device can detect and treat ventricular tachycardia and ventricular fibrillation with a combination of antitachycardia pacing and monophasic or biphasic cardioversion/defibrillation shocks. For the treatment of heart failure, the device uses biventricular electrical stimulation to synchronize ventricular contractions for the intent of providing mechanical synchronization. Left ventricular stimulation is delivered using a Guidant lead that is implanted in the coronary venous system. Detection of the atrial rate is available using an atrial lead. The pulse generator also detects and treats bradycardia conditions with pacing pulses in both the atrium and ventricles. Pulse generator memory provides a record of patient data, therapy delivery counts, and a therapy history consisting of arrhythmia episode data, conversion attempt data, stored electrograms (EGM), and annotated P-P and R-R intervals present during and following a tachyarrhythmic episode. The pulse generator automatically re-forms its capacitors and provides diagnostic data for evaluating battery status, lead integrity, and pacing thresholds.

The total system allows the physician to noninvasively interact with the pulse generator as listed below:

**Boston  
Scientific**

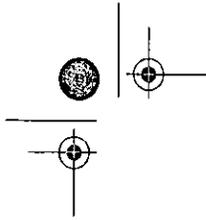
PHYSICIAN'S TECHNICAL MANUAL

**LIVIAN™**

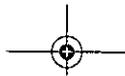
Cardiac Resynchronization Therapy Defibrillator

REF H220, H225, H227, H229

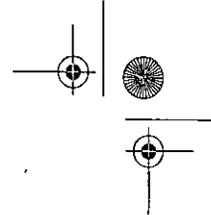
**CAUTION:** Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.



Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient materials. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.



The following trademarks are property of Boston Scientific or its affiliates: CONTAK, RENEWAL, EASYTRAK, ENDOTAK, LATITUDE, LIVIAN, QUICK NOTES, QUICK START, SmartDelay, VENTAK, ZIP, ZOOM.



**Mechanical Specifications**

Characteristic	LIVIAN Models H220 and H225	LIVIAN Models H227 and H229
Dimensions H x W x D (mm)	77.5 x 63.5 x 14.5	82.5 x 67.0 x 14.5
Volume (cc)	40	44
Mass (g)	79.5	87.5
Connector Size	IS-1/LV-1, IS-1, DF-1	IS-1/LV-1, IS-1, DF-1
Case Electrode Surface Area (cm <sup>2</sup> )	70.39	77.55
Case Material	Hermetically sealed titanium	
Header Material	Implantation-grade polymer	
Power Supply (WGT Model 2500)	Lithium-carbon monofluoride-silver vanadium oxide cell	

**Lead Connections**

- All models use the pulse generator case as a defibrillating electrode.
- For lead compatibility information, Refer to the lead system precaution on page 6.
- There are a total of eight (8) setscrews to tighten while connecting the leads to the pulse generator.

- LV-1 refers to the Guidant LV proprietary connector. IS-1 refers to the international standard ISO 5841-3:2000. DF-1 refers to the international standard ISO 11318:2002.

#### X-Ray Identifier

The pulse generators have an identifier that is visible on x-ray film or under fluoroscopy. This provides noninvasive confirmation of the device manufacturer. The identifier consists of the letters and numbers "BOS 203" to identify that the manufacturer is Boston Scientific, and that the Model 2945 programmer software application is needed to communicate with the pulse generator.

Refer to the Quick Start section in the operator's manual for the ZOOM LATITUDE Programming System for information on identifying the device via the PRM.

The model number of the pulse generator is stored in the device's memory and is available on the About screen selectable through the Utilities menu when the pulse generator is interrogated.

#### Latitude Patient Management System

The LATITUDE Patient Management system is a remote monitoring system that provides pulse generator data to both clinicians and cardiac device patients. The LATITUDE system enables physicians to monitor patients and specific device information remotely. The LATITUDE system is able to generate alert notifications for a number of conditions, which vary depending on the implanted device model. (For conditions monitored, refer to the clinician's manual for the LATITUDE Patient

Management System.) Use of the LATITUDE system can decrease the need for routine in-office follow-up visits.

A key component of the system is the LATITUDE Communicator, an easy-to-use in-home monitoring device for patients. The Communicator gathers data from a compatible pulse generator and sends it to the LATITUDE secure server through a standard telephone line. The LATITUDE server provides patient data to the LATITUDE website, which is readily available over the Internet to authorized physicians and clinicians. Contact your sales representative to enroll in the LATITUDE Patient Management system.

**Federal Communications Commission (FCC)**

This device complies with Title 47, Part 15 of the FCC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

**CAUTION:** Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate the equipment.

**Items Included in Device Packaging**

The following items are packaged with the LIVIAN pulse generator:

- One torque wrench

- Product literature
  - One Model 6627 Patient Data Disk
- NOTE:** *Wrenches are intended for one-time use only and should not be resternalized or reused.*

**Characteristics as Shipped**

<b>Tachy Mode</b>
Storage
<b>Tachy Therapy Available</b>
ATP, Shock
<b>Pacing Mode</b>
Storage
<b>Pacing Therapy</b>
DDDR
<b>Sensor</b>
Accelerometer
<b>Pace/Sense Configuration</b>
RA: B/BI
RV: B/BI
LV: UNI, BI/UNI, BI
<b>Monitoring Voltage</b>
3.10 V

iv

The pulse generator is shipped in a power-saving Storage mode to extend its shelf life. All features are inactive except telemetry support (allowing interrogation, programming), real-time clock, and commanded capacitor re-formation. STAT SHOCK and STAT PACE commands also are available from the Storage mode. The device will leave the Storage mode when STAT SHOCK or STAT PACE is commanded or when the Tachy Mode is programmed to Off, Monitor Only or Monitor + Therapy. Programming other parameters will not affect the Storage mode. Once programmed out of the power-saving Storage mode, the programmer cannot return the pulse generator to that mode.

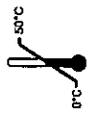
**NOTES:**

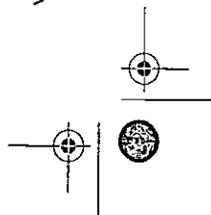
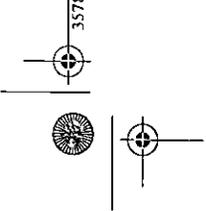
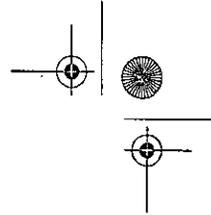
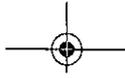
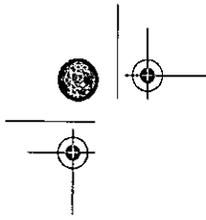
- Magnet use will not be enabled if the pulse generator is brought out of Storage mode using the STAT PACE or STAT SHOCK commands.
- The rate-sensing circuits may take up to eight seconds to begin tracking the cardiac signal after leaving the power-saving Storage mode. HF/Brady pacing is inhibited during this period. For pacemaker-dependent patients, the device should always be programmed out of the power-saving Storage mode to the Off mode before connection to the patient leads.

**Symbols on Packaging**  
 The symbols in Table 1 may be used on pulse generator packaging and labeling.  
**Table 1 Symbols on packaging**

	Reference number		Do not reuse
	Consult instructions for use		Sterilized using ethylene oxide
	Opening instructions		Use by
	Wand placement indicator		Date of manufacture
	Dangerous voltage		Lot number

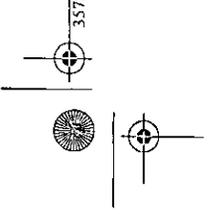
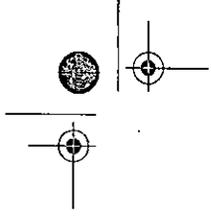
Table 1 Symbols on packaging

	Temperature limitation		Serial number
	Package contents		Pulse generator
	Torque wrench		Disk for data storage
	Literature enclosed		Non-ionizing electromagnetic radiation
	Manufacturer		

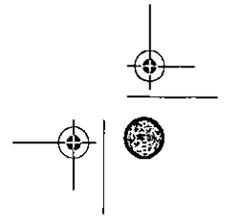
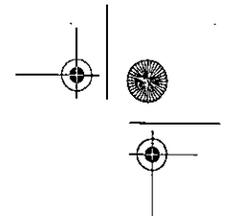
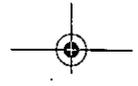


## CONTENTS

1. Device Description .....	1
1.1. Related Manuals and Information Tools .....	2
2. Indications and Usage .....	3
3. Clinical Outcomes .....	3
4. Contraindications .....	3
5. Warnings .....	3
5.1. General .....	3
5.2. Programming and Device Operation .....	4
5.3. Implant Related .....	5
6. Precautions .....	5
6.1. Clinical Considerations .....	5
6.2. Sterilization, Storage, and Handling .....	5
6.3. Implantation and Device Programming .....	6
6.4. Follow-up Testing .....	10
6.5. Explant and Disposal .....	11
6.6. Environmental and Medical Therapy Hazards .....	11
6.7. Hospital and Medical Environments .....	12
6.8. Home and Occupational Environments .....	16
7. Potential Adverse Events .....	17
8. Device Features .....	20
9. Pulse Generator Longevity .....	21
9.1. Warranty Information .....	24
10. Product Reliability .....	25
11. Patient Counseling Information .....	26



11.1. Patient Handbook ..... 26  
12. Implant Procedures ..... 27  
    12.1. Implanting the Pulse Generator ..... 27



### 1. DEVICE DESCRIPTION

The LIVIAN family of cardiac resynchronization therapy defibrillators (CRT-Ds), provide ventricular tachyarrhythmia and cardiac resynchronization therapies. Ventricular tachyarrhythmia therapy is for the treatment of ventricular tachycardia (VT) and ventricular fibrillation (VF), rhythms that are associated with sudden cardiac death (SCD). Cardiac resynchronization therapy is for the treatment of heart failure (HF) and uses biventricular electrical stimulation to synchronize ventricular contractions. The device also uses accelerometer-based adaptive-rate bradycardia therapy similar to the VENTAK family of implantable cardioverter defibrillators (ICDs). The pulse generator has independently programmable outputs and accepts one IS-1 atrial lead, one LV-1 or one IS-1 coronary venous pace/sense lead, and one DF-1/IS-1 cardioversion/defibrillation lead.

The LIVIAN device features enhanced telemetry communication with wireless ZIP telemetry.

The pulse generator and the leads constitute the implantable portion of the LIVIAN system. The device's small, physiologic shape minimizes pocket size and may minimize device migration.

Cardioversion/defibrillation therapies include a range of low- and high-energy shocks using either a biphasic or monophasic waveform. The LIVIAN device uses the TRIAD electrode system for defibrillation energy delivery. By using the metallic housing of the pulse generator as an active electrode, combined with the ENDOTAK two-electrode defibrillation lead, energy is sent via a dual-current pathway from the distal shocking electrode to the proximal electrode and to the pulse generator case. The LIVIAN device

also offers a wide variety of anti-tachycardia pacing schemes to terminate slower, more stable ventricular tachyarrhythmias. Bradyarrhythmia pacing with cardiac resynchronization therapy, including adaptive-rate features, is available to detect and treat bradyarrhythmias and to support the cardiac rhythm after defibrillation therapy.

The ZOOM LATITUDE Programming System, which includes the Model 3120 Programmer/Recorder/Monitor (PRM), the Model 2945 CONSULT Software Application, and accessory PRM antenna and telemetry wand, make up the external portion of the LIVIAN system. The external components allow interrogation and programming of the pulse generator as well as access to the device's diagnostic features. The LIVIAN system can be programmed to provide a variety of therapy options. It also can provide noninvasive diagnostic testing and therapy history data.

#### 1.1. Related Manuals and Information Tools

The System Guide for the LIVIAN is a separate document and is used in conjunction with the PRM and the Model 2945 software. The System Guide includes product specifications, operating characteristics, implant procedure recommendations, programming instructions, and follow-up recommendations. Copies can be obtained by contacting your Boston Scientific representative.

The Operator's Manual for the PRM provides information specific to the programmer, such as setting up the system, maintenance, and handling. Physician's manuals for the leads provide specific information and instructions regarding the implanted leads.

## 2. INDICATIONS AND USAGE

*HVS*  
*N*  
Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with EF  $\leq$  35% and QRS duration  $\geq$  120 ms
- Left bundle branch block (LBBB) with QRS duration  $\geq$  130 ms, EF  $\leq$  30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

## 3. CLINICAL OUTCOMES

See the appendices at the end of the System Guide to review detailed clinical study information.

## 4. CONTRAINDICATIONS

There are no contraindications for this device.

## 5. WARNINGS

### 5.1. General

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in injury to or death of the patient.
- **Avoid shock during handling.** Program the pulse generator Tachy Mode to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks.

- **Backup defibrillator protection.** Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death.
- **Resuscitation availability.** Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.
- **Magnetic resonance imaging (MRI) exposure.** Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Diathermy.** Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator.
- **For single patient use only.** Do not reuse, reprocess, or sterilize. Reuse, reprocessing, or sterilization 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 sterilization 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.

#### 5.2. Programming and Device Operation

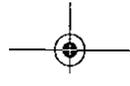
- **Atrial tracking modes.** Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF.
- **Atrial only modes.** Do not use atrial only modes in patients with heart failure because such modes do not provide cardiac resynchronization therapy.



- **Ventricular sensing.** Left ventricular lead dislodgment to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition.
- **Slow VT.** Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones.

**5.3. Implant Related**

- **Patch leads.** Do not use defibrillation patch leads with the pulse generator system, or injury to the patient may occur.
- **Separate pulse generator.** Do not use this pulse generator with another CRM pulse generator. This combination could cause pulse generator interaction resulting in patient injury or a lack of therapy delivery.
- **Do not kink leads.** Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.



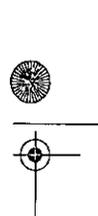
**6. PRECAUTIONS**

**6.1. Clinical Considerations**

- **Pacemaker-mediated tachycardia (PMT).** Retrograde conduction combined with a short PVARP might induce PMT.

**6.2. Sterilization, Storage, and Handling**

- **If package is damaged.** The pulse generator blister trays and contents are sterilized with ethylene oxide gas before final packaging. When the pulse generator is received, it is sterile, provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the device to Boston Scientific.
- **Storage temperature and equilibration.** Recommended storage temperatures are 0°–50°C (32°–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 electromagnetic interference (EMI) to avoid device damage.
  - **Use by date.** Implant the device system 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.
- 6.3. Implantation and Device Programming**
- **Lead system.** Do not use any lead with this device without first verifying connector compatibility. Using incompatible leads can damage the connector or result in potential adverse consequences, such as undersensing of cardiac activity or failure to deliver necessary therapy.
  - **Telemetry wand.** Make sure the telemetry wand is connected to the PRM system and that it is available throughout the session. Verify that the wand cord is within reach of the pulse generator.
  - **Expected benefits.** Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose tachyarrhythmias require frequent shocks.
  - **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 decrease device longevity.
  - **Biventricular pacing.** 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.

- **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.
- **Device communication.** Use only the designated PRIM and software application to communicate with the pulse generator.
- **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 with the range of 200  $\Omega$  and 2000  $\Omega$ .
- **Line-powered equipment.** Exercise extreme caution if testing leads using line-powered equipment because leakage current exceeding 10  $\mu$ A can induce ventricular fibrillation. Ensure that any line-powered equipment is within specifications.
- **Proper programming of the lead configuration.** If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.
- **AV Delay.** For delivery of cardiac resynchronization therapy, the programmed setting for the AV Delay must be less than the patient's intrinsic intracardiac AV interval.
- **Adaptive-rate pacing.** Adaptive-rate 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 entering a fixed AV delay, consider the sensing outcomes.

- **Atrial Tachy Response (ATR).** ATR should be programmed Off unless the patient has a history of atrial tachyarrhythmia. The delivery of CRT is compromised because AV synchrony is disrupted.
- **Threshold test.** During the left ventricular threshold test, right ventricular backup pacing is unavailable.
- **Left ventricular pacing only.** The clinical effect of left ventricular pacing alone in heart failure patients has not been established.
- **Do not bend the lead near the lead-header interface.** Improper insertion can cause insulation damage near the terminal end that could result in lead failure.
- **Shock waveform polarity.** Never change the shock waveform polarity by physically switching the lead anodes and cathodes in the pulse generator header—use the programmable Polarity feature. Device damage or nonconversion of the arrhythmia post-operatively may result if polarity is switched physically.
- **Absence of a lead.** 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.
- **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 tip seal plug before inserting the lead into the port, to release any trapped fluid or air.
  - Visually verify that the setscrew(s) is sufficiently retracted to allow insertion. Use the torque wrench to loosen the setscrew(s) if necessary.

- Fully insert each lead into its lead port and then tighten the setscrew(s) onto the terminal pin.
- **Tachy Mode to Off.** To prevent inappropriate shocks, ensure that the pulse generator's Tachy Mode is programmed to Off when not in use and before handling it. When using Temporary HF/Brady, the Tachy Mode is Off. Do not use Temporary HF/Brady as a means to deactivate device tachyarrhythmia therapy. For tachyarrhythmia therapy, verify that Tachy Mode is reactivated.
- **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.
- **Defibrillation lead impedance.** Never implant the device with a lead system that has less than 15  $\Omega$  total shock lead impedance. Device damage may result. If a shocking lead impedance is less than 20  $\Omega$ , reposition the shocking electrodes to allow a greater distance between the shocking electrodes.
- **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.
- **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.
- **Left Ventricular Protection Period (LVPP).** Use of a long LVPP reduces the maximum left ventricular pacing rate and may inhibit cardiac resynchronization therapy at higher pacing rates.
  - **Shunting energy.** Do not allow any object that is electrically conductive to come into contact with the lead or device during tachyarrhythmia induction because it may shunt energy. This could result in less energy getting to the patient and may damage the implanted system.
  - **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.
- 6.4. Follow-up Testing**
- **Conversion testing.** Successful VF or VT conversion during arrhythmia conversion testing is no assurance that conversion will occur post-operatively. Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in nonconversion of the arrhythmia post-operatively.
  - **Pacing Threshold testing.** If the patient's condition or drug regimen have changed or device parameters have been reprogrammed, consider performing a pacing threshold test to confirm adequate margins for pace capture.

### 6.5. 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 unwanted shocks, overwriting of important therapy history data, and audible tones:
  - Program the pulse generator Tachy and Brady Modes to Off.
  - Program the Magnet Response feature to Off.
  - Program the Beep When ERI is Reached feature to Off.
- **Explant devices.** Return all explanted pulse generators and leads to Boston Scientific. Examination of explanted pulse generators can provide information for warranty improvement in device reliability and will permit calculation of any warranty replacement credit due.
- Do not implant an explanted pulse generator in another patient as sterility, functionality, and reliability cannot be ensured.

### 6.6. Environmental and Medical Therapy Hazards

- **Electromagnetic interference (EMI).** Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of EMI sources are:
  - electrical power sources, arc welding equipment and robotic jacks
  - electrical smelting furnaces
  - large RF transmitters such as radar
  - radio transmitters including those used to control toys
  - electronic surveillance (anti-theft) devices

- an alternator on a car that is running
- **Elevated Pressures.** Elevated pressures due to hyperbaric chamber exposure or SCUBA diving may damage the pulse generator. The pulse generator has been tested to function normally at 1.5 Atmospheres Absolute (ATA) pressure or 15 ft (4.6 m) depth in sea water. Please contact Technical Services for specific guidelines prior to hyperbaric chamber exposure, or if the patient is planning scuba diving activity.

#### 6.7. Hospital and Medical Environments

- **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.** Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator, consider the following:
  - Avoid placing a pad (or paddle) directly over the pulse generator. Position the external defibrillation pads (or paddles) as far from the pulse generator as possible.
  - Position the defibrillation 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 any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. Interrogate the pulse generator, perform a manual capacitor reformation, verify battery status and

shock counters, verify pacing, and ensure that programmable parameters did not change.

- **Transcutaneous electrical nerve stimulation (TENS).** TENS may interfere with pulse generator function. If necessary, the following may reduce interference:

1. Place the TENS electrodes as close to each other as possible and as far from the pulse generator and lead system as possible.
2. Monitor cardiac activity during TENS use.

For additional information, contact Technical Services at the number shown on the back cover of this manual.

- **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 PRM 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 such as cordless phone handsets, cordless phone base stations, patient monitoring systems, remote control toys, or any other devices operating at frequencies near the ISM band (902 MHz to 928 MHz) may interfere with establishing or maintaining ZIP telemetry for interrogating or programming the device. This RF interference can be reduced by increasing the distance between the interfering device, and the PRM and pulse generator.
- **Electrocautery.** The use of electrocautery could induce ventricular arrhythmias and/or fibrillation, cause asynchronous or inhibited pulse generator operation, or cause the pulse generator to deliver an inappropriate shock. If electrocautery cannot be avoided, observe the following precautions to minimize complications:

- Select Off-Electrocautery Mode, which programs the pacing mode to VOO, AOO, or DOO and turns the Tachy Mode to Off.
- CAUTION:** When using Off-Electrocautery Mode for extended periods of time, to manage the amount of time ZIP telemetry is used, exit the session by powering off the PRM once Off-Electrocautery Mode has been selected. This will avoid prolonged ZIP telemetry use which can impact pulse generator longevity.
- Note that Tachy Mode Off-Electrocautery cannot be initialized while the device is in a tachyarrhythmia episode or in the Post-Shock Pacing Period.
  - Avoid direct contact with the pulse generator or leads.
  - Monitor the patient and have temporary pacing equipment, external defibrillation equipment, and knowledgeable medical personnel available.
  - Position the ground plate so that the current pathway does not pass through or near the pulse generator system.
  - Use short, intermittent, and irregular bursts at the lowest feasible energy levels.
  - Use a bipolar electrocautery system where possible.

Remember to reactivate the Tachy Mode after turning off the electrocautery equipment. If Off-Electrocautery is canceled by an emergency therapy, the telemetry link must be maintained after the STAT Shock, STAT Pace, or Divert has completed to allow the device to exit Off-Electrocautery.

- **Ionizing radiation therapy.** 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 and defibrillation therapy.

Many sources of ionizing radiation are commonly used for the diagnosis and treatment of diseases; these sources 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. Most diagnostic tools, such as radiography (X-ray), and fluoroscopy, have not been identified as sources of pulse generator interference or damage. Refer to the System Guide for further details regarding advance planning and follow-up assessment of pulse generators exposed to ionizing radiation.

- **Lithotripsy.** Lithotripsy may permanently damage the pulse generator if the device is at the focal point of the lithotripsy beam. If lithotripsy must be used, avoid focusing near the pulse generator site. The lithotripter is designed to trigger off the R-wave on the ECG, resulting in shock waves being delivered during the VRP.
- If the patient does not require pacing, program the pulse generator Brady Mode to Off.
- If the patient requires pacing, program the pulse generator to the VVI mode because atrial pacing pulses can trigger the lithotripter.
- **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.
- **Radio frequency ablation.** Exercise caution when performing radio frequency ablation procedures in device patients. If the pulse generator F tachy Mode is programmed on during the procedure, the device may inappropriately declare a tachycardia episode and deliver therapy. Brady pacing may be inhibited during electrocautery if Off-Electrocautery mode is not selected. Minimize risks by following these steps:

- Program the Tachy Mode to Off or Off-Electrocautery to avoid inadvertent tachycardia detection (sensing) or therapy.
  - Avoid direct contact between the ablation catheter and the implanted lead and pulse generator.
  - Keep the current path (electrode tip to ground) as far away from the pulse generator and leads as possible.
  - Have external defibrillation equipment available.
- Remember to reactivate the pulse generator after turning off the radio frequency ablation equipment.

#### 6.8. 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 to avoid equipment or situations where they would have extended exposure to strong magnetic fields (>10 gauss or 1 mT) since this could inhibit pulse generator therapy. Examples of magnetic sources are: industrial transformers and motors, magnetic resonance imaging (MRI) devices, large stereo speakers, telephone receivers if held within 0.5 inches (1.27 cm) of the pulse generator, and magnetic wands such as those used for airport security and in the game "Bingo."
- **Electronic Article Surveillance (EAS).** Advise patients to avoid lingering near anti-theft devices, such as those found in entrances and exits of department stores and public libraries. Patients should walk through them at a normal pace, because such devices may cause inappropriate pulse generator operation.

- **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 over or within 6 inches (15 cm) of the implanted device since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

#### 7. POTENTIAL ADVERSE EVENTS

Based on the literature and pulse generator implant/explant experience, the following alphabetical list includes potential adverse events associated with implantation and explanation of a pulse generator system:

- Air embolism
- Allergic reaction
- Bleeding
- 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)
- Failure to convert an induced arrhythmia
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Inability to defibrillate or pace
- Inappropriate therapy (e.g., shocks where applicable, ATP, pacing)
- Incisional pain
- Incomplete lead connection with pulse generator
- Infection
- Insulating myocardium during defibrillation with internal or external paddles
- Lead dislodgment
- Lead fracture
- Lead insulation breakage or abrasion
- Lead tip deformation and/or breakage
- Myocardial infarction
- Myocardial necrosis
- Myocardial trauma (e.g., cardiac perforation, irritability, injury)
- Myopotential sensing
- Oversensing/undersensing

- Pacemaker-mediated tachycardia
- Pericardial rub, effusion
- Pneumothorax
- Pulse generator migration
- Shunting current during defibrillation with internal or external paddles
- Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation
- Thrombosis/thromboemboli
- Valve damage
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)
- Worsening heart failure

Patients may develop psychologic intolerance to a pulse generator system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost

- Imagined shocking

In addition to the implantation of a pulse generator system, potential adverse events associated with implantation of a coronary venous lead system include:

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

## 8. DEVICE FEATURES

By programming device parameters, the pulse generator provides ventricular tachyarrhythmia and cardiac resynchronization therapies. The device can detect and treat ventricular tachycardia and ventricular fibrillation with a combination of antitachycardia pacing and monophasic or biphasic cardioversion/defibrillation shocks. For the treatment of heart failure, the device uses biventricular electrical stimulation to synchronize ventricular contractions for the intent of providing mechanical synchronization. Left ventricular stimulation is delivered using a lead that is implanted in the coronary venous system. Detection of the atrial rate is available using an atrial lead. The pulse generator also detects and treats bradycardia conditions with pacing pulses in the atrium and ventricles. Pulse generator memory provides a record of patient data, therapy delivery counts, and a therapy history consisting of arrhythmia episode data, conversion attempt data, stored electrograms (EGMs), and annotated P-

**Boston  
Scientific**

SYSTEM GUIDE

**COGNIS™ 100-D**

CARDIAC RESYNCHRONIZATION THERAPY  
HIGH ENERGY DEFIBRILLATOR

Model N118, N119

**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.

1-4 INFORMATION FOR USE  
INDICATIONS AND USAGE

The Physician's Technical Manual is packaged with the pulse generator. It provides the technical information needed at implant.

Refer to the PRM system Operator's Manual for specific information about the PRM such as setup, maintenance, and handling.

## INDICATIONS AND USAGE

*These*  
^ Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with EF  $\leq$  35% and QRS duration  $\geq$  120 ms
- Left bundle branch block (LBBB) with QRS duration  $\geq$  130 ms, EF  $\leq$  30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

## CONTRAINDICATIONS

There are no contraindications for this device.

## WARNINGS

### General

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the system. 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.
- **Avoid shock during handling.** Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks.
- **Backup defibrillation protection.** Always have sterile external and internal defibrillation protection available during implant. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.
- **Resuscitation availability.** Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue.
- **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 MR device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

## System Guide

**CONTAK RENEWAL<sup>®</sup> 3 RF**  
MODELS H210/H215

**CONTAK RENEWAL<sup>®</sup> 3 RF HE**  
MODELS H217/H219

**Cardiac Resynchronization Therapy  
Defibrillator (CRT-D)**

**RESTRICTED DEVICE:**  
Federal law (USA) restricts this device to sale, distribution, and use by, or on the lawful order of, a physician trained or experienced in device implant and follow-up procedures.

**GUIDANT**

## Related Manuals and Information Tools

Refer to the PRM Operator's Manual for specific information about the PRM, such as setup, maintenance, and handling. Physician's manuals for the leads provide specific information and instructions regarding the implanted leads. The *Physician's Technical Manual* provides information needed to implant the device at nominal parameter settings. All information in the *Physician's Technical Manual* is also included in this manual.

## INDICATIONS AND USAGE

<sup>These</sup> Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with  $EF \leq 35\%$  and QRS duration  $\geq 120$  ms
- Left bundle branch block (LBBB) with QRS duration  $\geq 130$  ms,  $EF \leq 30\%$ , and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

## CLINICAL OUTCOMES

See the appendices at the end of this System Guide to review detailed clinical study information.

## CONTRAINDICATIONS

There are no contraindications for this device.

## WARNINGS

### General

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in injury to or death of the patient.
- **Avoid shock during handling.** Program the pulse generator Tachy Mode to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks.

**Boston  
Scientific**

SYSTEM GUIDE

**LIVIAN™**

**Cardiac Resynchronization Therapy Defibrillator (CRT-D)**

**REF** REFERENCE: H220, H225, H227, H229

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

## Related Manuals and Information Tools

Refer to the PRM Operator's Manual for specific information about the PRM, such as setup, maintenance, and handling. Physician's manuals for the leads provide specific information and instructions regarding the implanted leads. The *Physician's Technical Manual* provides information needed to implant the device at nominal parameter settings. All information in the *Physician's Technical Manual* is also included in this manual.

## INDICATIONS AND USAGE

These

Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with  $EF \leq 35\%$  and QRS duration  $\geq 120$  ms
- Left bundle branch block (LBBB) with QRS duration  $\geq 130$  ms,  $EF \leq 30\%$ , and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

## CLINICAL OUTCOMES

See the appendices at the end of this System Guide to review detailed clinical study information.

## CONTRAINDICATIONS

There are no contraindications for this device.

## WARNINGS

### General

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in injury to or death of the patient.
- **Avoid shock during handling.** Program the pulse generator Tachy Mode to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks.

## CLINICAL STUDY - MADIT-CRT

---

### APPENDIX H

#### CLINICAL STUDY POPULATIONS

The results from the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) were demonstrated in patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who have left bundle branch block (LBBB) with QRS duration  $\geq 130$  ms, EF  $\leq 30\%$ , and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

The results for the full MADIT-CRT patient population showed a significant reduction in the relative risk of the combined endpoint of all-cause mortality or first heart failure event by 39% ( $p < 0.001$ ) as compared to ICD (primary effectiveness endpoint). These devices also significantly reduced the relative risk of recurrent heart failure events by 32% ( $p < 0.001$ ) when compared to ICD (secondary endpoint).

The results of a subgroup analysis demonstrated a significant treatment interaction with the patient's baseline bundle branch block morphology such that CRT-D conferred the greatest benefit to patients with left bundle branch block (LBBB).

The LBBB sub-population were patients with heart failure who received stable optimal pharmacologic therapy for heart failure and who met any one of the following classifications:

- Mild heart failure (NYHA Class II) with EF  $\leq 30\%$ , QRS duration  $\geq 130$  ms, and LBBB
- Asymptomatic heart failure (NYHA Class I) of ischemic origin with EF  $\leq 30\%$ , QRS duration  $\geq 130$  ms, and LBBB

Boston Scientific has provided valid scientific data and reasonable assurance of safety and effectiveness in the LBBB sub-population that CRT-D devices demonstrate a statistically significant reduction in the relative risk of the combined endpoint of all-cause mortality or first heart failure event by 57% ( $p < 0.001$ ) as compared to ICD (primary effectiveness endpoint). These devices also significantly reduced the relative risk of recurrent heart failure events by 43% ( $p = 0.001$ ) when compared to ICD (secondary endpoint). Commercially available Boston Scientific

CRT-Ds were used in the MADIT-CRT clinical trial; therefore, the Indications and Usage apply to all Boston Scientific CRT-Ds.

## SUMMARY

Boston Scientific sponsored MADIT-CRT to demonstrate the safety and effectiveness of Boston Scientific CRT-Ds in the MADIT-CRT patient population. MADIT-CRT was a prospective, randomized, controlled, multicenter study conducted in the U.S., Europe, Israel, and Canada at 110 investigational centers. A total of 1820 patients were enrolled and randomized in a 3:2 ratio to receive a CRT-D (1089 full patient population/761 LBBB patient sub-population) or an ICD (731 full patient population/520 LBBB patient sub-population). Randomization was stratified by clinical center and ischemic status. Each randomized patient remained counted as a member of the original randomized assignment (intention-to-treat) regardless of subsequent crossover or protocol adherence.

MADIT-CRT used an Executive Committee, Data Safety Monitoring Board (DSMB), Heart Failure Events Review Committee, and Mortality Events Review Committee for study strategy, safety, heart failure event adjudication, and mortality adjudication, respectively.

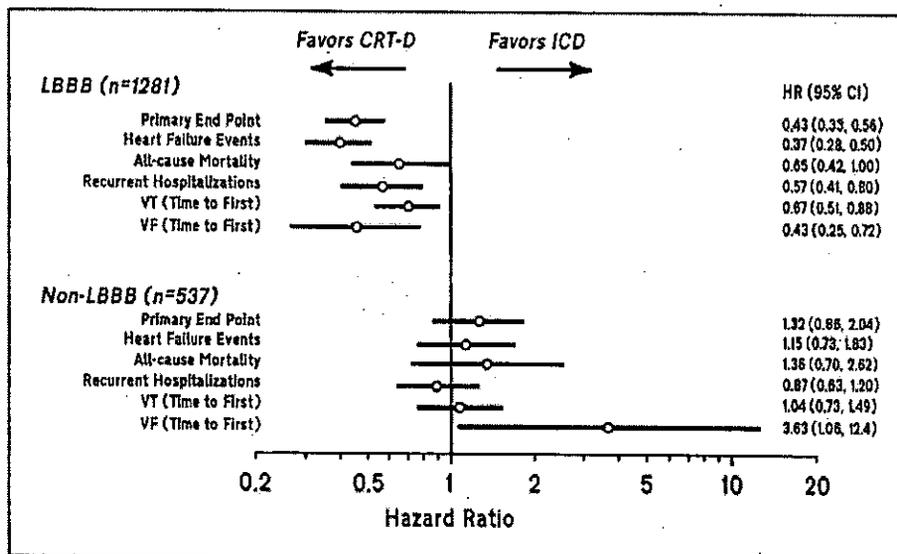
Patients were enrolled from December 22, 2004, through April 23, 2008. On June 22, 2009, Boston Scientific announced that the MADIT-CRT study met its primary effectiveness endpoint that showed the superiority of CRT-D as compared to ICD ( $p=0.003$ ). Data continued to be collected and events were adjudicated until December 31, 2009. These results from June 22, 2009 were sustained through follow-up extending through December 31, 2009.

Of the 1820 patients randomized in MADIT-CRT, 1281 (70%) had LBBB morphology at the time of study entry.

A subgroup analysis based on pre-specified clinical baseline characteristics revealed statistically significant interactions with sex and QRS width such that female patients and those patients with  $QRS \geq 150$  ms derived the greatest benefit from CRT-D. In a subgroup analysis of benefit in female patients, a disparity in the prevalence of left bundle branch block (LBBB) morphology between women and men was discovered in which women were more likely than men to have LBBB. Furthermore, when compared to the non-LBBB cohort, LBBB was associated with

substantially greater improvement across the primary endpoint and its components, the secondary endpoint, and tertiary endpoints as shown below.

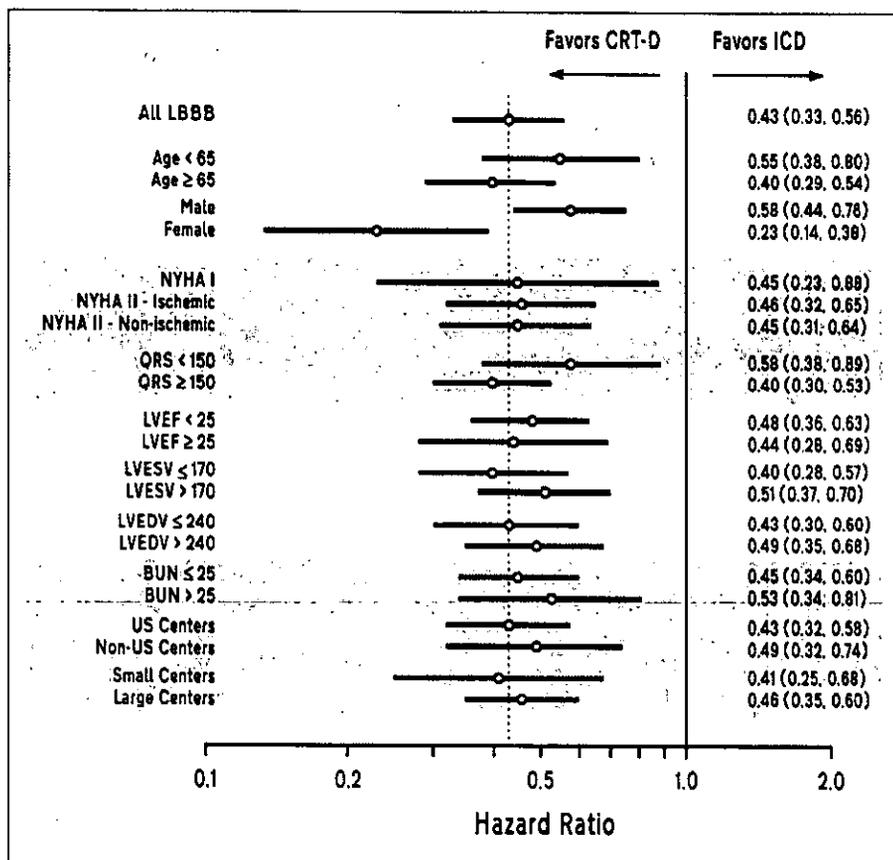
Figure H-1. Selected Outcomes Stratified by Bundle Branch Morphology



VT=ventricular tachycardia, VF=ventricular fibrillation

An exploratory analysis restricted to the LBBB patient sub-population revisited the primary endpoint of the pre-specified subgroups. As seen below, each patient population demonstrated consistent improvement with CRT-D.

Figure H-2. Primary Endpoint for Pre-specified Subgroups - LBBB Patient Sub-Population



## Primary Trial Objectives

### Safety

Determine if the CRT-D system-related complication-free rate observed was greater than 70% after three months of follow-up post-implant.

### Primary effectiveness

Determine whether CRT-D resulted in a statistically significant reduction in the combined endpoint of all-cause mortality or heart failure event, whichever came first, when compared to ICD.

All deaths were reviewed and adjudicated by the Mortality Event Committee. All heart failure events were reviewed and adjudicated by the Heart Failure Event Committee and the members were blinded to the randomized therapy.

## Secondary Trial Objective

Evaluate the effects of CRT-D, relative to ICD, on the patient-specific rates of recurrent heart failure events over the full study period.

## Tertiary Trial Objective

Evaluate the effects of CRT-D on:

- All-cause mortality
- Appropriate defibrillator therapy for ventricular tachycardia (VT) and ventricular fibrillation (VF)
- Changes in echocardiographic volumes and ejection fraction at 12 months (echo-determined left ventricular internal volume at end-systole (LVESV) and end-diastole (LVEDV) and changes in left ventricular ejection fraction (LVEF) at 12 months)
- Changes in New York Heart Association (NYHA) functional class at 12 months
- Changes in quality of life at 12 months and over the full study period
- Mitral regurgitation at 12 months
- Functional capacity (six-minute hall walk) at 12 months
- The association between Brain Natriuretic Peptide (BNP) and outcome with CRT-D
- BNP levels at 12 months

- Holter-recorded electrocardiographic parameters and hemodynamic response

## OBSERVED ADVERSE EVENTS

### Adverse Event Definitions

Investigators were responsible for providing a description of each reported adverse event including the suspected cause, corrective actions, and clinical outcome. All adverse events reported by centers were reviewed and classified as described below.

Adverse events were defined as any untoward clinical event, including events that were not related to the implanted system. Adverse events were ranked by severity. Events that were life-threatening, required an invasive intervention, resulted in hospitalization, permanent loss of device therapy, permanent disability, or death were defined as *complications*. Those events that were transient and reversible and resolved non-invasively without hospitalization were defined as *observations*. In Europe (per International Organization for Standardization (ISO) 14155)<sup>1</sup> reportable adverse events were classified as *serious* (equivalent to complications) or *non-serious* (equivalent to observations).

The adverse events were also classified by type, accounting for the suspected cause of the event and whether or not the event was related as defined below:

- Type I - Related to the investigational device, therapy or procedure related to the implant of the device.
- Type II - Related to the protocol or procedures specifically related to protocol testing that is not patient standard of care.
- Type III - Related to commercially available implanted components or commercially available features of an investigational device, or the procedure of a commercially available device.
- Type IV - Related to a change in the patient's condition or to therapies other than delivered by the implanted system.

1. International Standards 14155 First edition ISO 14155-2:2003 (E).

### Summary of Adverse Events - Full Patient Population

System- and procedure-related adverse events for the full MADIT-CRT patient population occurring within 91 days post-randomization (N=369) are shown in the tables below. Infrequent events (defined as observations occurring in fewer than four patients) are summarized at the end of each section within the table.

Table H-1. System-Related Adverse Events Within 91 Days - Full Patient Population

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
<b>Total Adverse Events</b>	<b>540 (369)</b>	<b>15.2 (164)</b>	<b>0.67 (213)</b>	<b>23.0 (248)</b>	<b>1.04 (327)</b>
<b>PG Related Events</b>					
Extracardiac stimulation - LV	79 (72)	0.2 (2)	0.01 (2)	6.5 (70)	0.24 (77)
Pacemaker-mediated tachycardia (PMT)	69 (58)	0.1 (1)	0.00 (1)	5.3 (57)	0.22 (68)
Threshold elevated/unable to capture - LV	11 (11)	0.0 (0)	0.00 (0)	1.0 (11)	0.03 (11)
Inappropriate tachy therapy	8 (7)	0.2 (2)	0.01 (2)	0.5 (5)	0.02 (6)
Infection (> 30 days post-implant)	5 (5)	0.3 (3)	0.01 (3)	0.2 (2)	0.01 (2)
Oversensing - RA	5 (5)	0.0 (0)	0.00 (0)	0.5 (5)	0.02 (5)
Elevated DFT - Defibrillation	4 (4)	0.3 (3)	0.01 (3)	0.1 (1)	0.00 (1)
Early elective replacement indicator	2 (2)	0.2 (2)	0.01 (2)	0.0 (0)	0.00 (0)
Migration	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Threshold elevated/unable to capture - RV	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Unable to convert - Defibrillation	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)

**H-8** | CLINICAL STUDY - MADIT-CRT  
OBSERVED ADVERSE EVENTS

**Table H-1. System-Related Adverse Events Within 91 Days - Full Patient Population**

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
Programmer / Software error code	1 (1)	0.1 (1)	0.00 (1)	0.0 (0)	0.00 (0)
Infrequent events include: Inappropriate AV delay (3), Oversensing - RV (1), PG system diagnosis - other (3), RA threshold elevated/unable to capture (3), Seroma - Pocket (> 30 days post-implant) (1)					
<b>Subtotal PG Related Events</b>	<b>201 (170)</b>	<b>1.6 (17)</b>	<b>0.05 (17)</b>	<b>14.2 (153)</b>	<b>0.58 (184)</b>
<b>RA Lead Related Events</b>					
Lead dislodgment - RA	34 (34)	3.1 (33)	0.10 (33)	0.1 (1)	0.00 (1)
Threshold elevated/unable to capture - RA	3 (3)	0.2 (2)	0.01 (2)	0.1 (1)	0.00 (1)
<b>Subtotal RA Lead Related Events</b>	<b>37 (37)</b>	<b>3.2 (35)</b>	<b>0.11 (35)</b>	<b>0.2 (2)</b>	<b>0.01 (2)</b>
<b>RV Lead Related Events</b>					
Lead dislodgment - RV	8 (8)	0.7 (8)	0.03 (8)	0.0 (0)	0.00 (0)
Threshold elevated/unable to capture - RV	7 (7)	0.5 (5)	0.02 (5)	0.2 (2)	0.01 (2)
Oversensing - RV	2 (2)	0.0 (0)	0.00 (0)	0.2 (2)	0.01 (2)
<b>Subtotal RV Lead Related Events</b>	<b>17 (17)</b>	<b>1.2 (13)</b>	<b>0.04 (13)</b>	<b>0.4 (4)</b>	<b>0.01 (4)</b>
<b>LV Lead Related Events</b>					
Lead dislodgment - LV	56 (51)	4.3 (46)	0.16 (51)	0.5 (5)	0.02 (5)
Extracardiac stimulation - LV	25 (24)	0.8 (9)	0.03 (9)	1.5 (16)	0.05 (16)
Threshold elevated/unable to capture - LV	7 (7)	0.1 (1)	0.00 (1)	0.6 (6)	0.02 (6)
Insulation breach - LV	1 (1)	0.1 (1)	0.00 (1)	0.0 (0)	0.00 (0)
Oversensing - LV	1 (1)	0.0 (0)	0.00 (0)	0.1 (1)	0.00 (1)

Table H-1. System-Related Adverse Events Within 91 Days - Full Patient Population

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
<b>Subtotal LV Lead Related Events</b>	<b>90 (81)</b>	<b>5.3 (57)</b>	<b>0.20 (62)</b>	<b>2.5 (27)</b>	<b>0.09 (28)</b>
<b>Defibrillator Lead Related Events</b>					
Inappropriate tachy therapy	3 (3)	0.0 (0)	0.00 (0)	0.3 (3)	0.01 (3)
Elevated DFT/ unable to convert	2 (2)	0.2 (2)	0.01 (2)	0.0 (0)	0.00 (0)
<b>Subtotal Defibrillator Lead Related Events</b>	<b>5 (5)</b>	<b>0.2 (2)</b>	<b>0.01 (2)</b>	<b>0.3 (3)</b>	<b>0.01 (3)</b>
<b>Procedure Related Events</b>					
Hematoma - Pocket ( $\leq$ 30 days post-implant)	38 (38)	1.3 (14)	0.04 (14)	2.2 (24)	0.08 (24)
Pneumothorax - Procedure	19 (19)	1.4 (15)	0.05 (15)	0.4 (4)	0.01 (4)
Adverse reaction	18 (17)	0.6 (6)	0.02 (6)	1.0 (11)	0.04 (12)
Post-surgical wound discomfort	16 (15)	0.0 (0)	0.00 (0)	1.4 (15)	0.05 (16)
Thromboembolic events	13 (13)	0.7 (8)	0.03 (8)	0.5 (5)	0.02 (5)
Post-surgical infection ( $\leq$ 30 days post-implant)	12 (12)	0.5 (5)	0.02 (5)	0.6 (7)	0.02 (7)
Other - PG system - Procedure	11 (11)	0.1 (1)	0.00 (1)	0.9 (10)	0.03 (10)
AV block	10 (10)	0.6 (6)	0.02 (6)	0.4 (4)	0.01 (4)
Pericardial effusion	7 (5)	0.3 (3)	0.01 (4)	0.2 (2)	0.01 (3)
Coronary venous perforation without tamponade	6 (6)	0.2 (2)	0.01 (2)	0.4 (4)	0.01 (4)
Other - Lead - Procedure	5 (5)	0.5 (5)	0.02 (5)	0.0 (0)	0.00 (0)
Coronary venous dissection	4 (4)	0.0 (0)	0.00 (0)	0.4 (4)	0.01 (4)

**H-10** | CLINICAL STUDY - MADIT-CRT  
OBSERVED ADVERSE EVENTS

**Table H-1. System-Related Adverse Events Within 91 Days - Full Patient Population**

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
Inadvertent VT/VF	4 (4)	0.4 (4)	0.01 (4)	0.0 (0)	0.00 (0)
Renal failure due to contrast media - Procedure	4 (4)	0.4 (4)	0.01 (4)	0.0 (0)	0.00 (0)
Myocardial perforation with tamponade	3 (3)	0.3 (3)	0.01 (3)	0.0 (0)	0.00 (0)
Pleural effusion - Procedure	3 (3)	0.1 (1)	0.00 (1)	0.2 (2)	0.01 (2)
Post-surgical pocket hemorrhage	3 (3)	0.2 (2)	0.01 (2)	0.1 (1)	0.00 (1)
Seroma - Pocket ( $\leq$ 30 days post-implant)	3 (3)	0.1 (1)	0.00 (1)	0.2 (2)	0.01 (2)
Arterial perforation - Procedure	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Inadvertent SVT	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Venous occlusion	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Infrequent events include: Chest pain (1), Hemorrhage (2), Vasovagal (1)					
<b>Subtotal Procedure Related Events</b>	<b>189 (155)</b>	<b>7.0 (75)</b>	<b>0.27 (84)</b>	<b>8.4 (91)</b>	<b>0.33 (105)</b>
<b>Protocol Testing Related Events</b>					
Chest pain	1 (1)	0.0 (0)	0.00 (0)	0.1 (1)	0.00 (1)
<b>Subtotal Protocol Testing Related Events</b>	<b>1 (1)</b>	<b>0.0 (0)</b>	<b>0.00 (0)</b>	<b>0.1 (1)</b>	<b>0.00 (1)</b>

Patient-related adverse events within 91 days post-randomization are shown in the table below. Note that some patients may have events in both categories

Table H-2. Patient-Related Adverse Events Within 91 days - Full Patient Population

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
<b>Total Adverse Events</b>	<b>385 (261)</b>	<b>11.9 (128)</b>	<b>0.56 (177)</b>	<b>15.2 (164)</b>	<b>0.66 (208)</b>
<b>Subtotal Cardiovascular - HF Related Events</b>	<b>138 (57)</b>	<b>3.3 (36)</b>	<b>0.27 (86)</b>	<b>2.2 (24)</b>	<b>0.16 (52)</b>
<b>Cardiovascular - Non-HF Related Events</b>					
Supraventricular tachyarrhythmias	39 (35)	1.2 (13)	0.04 (13)	2.2 (24)	0.08 (26)
Chest pain	28 (26)	1.5 (16)	0.06 (18)	0.9 (10)	0.03 (10)
Ventricular tachyarrhythmias	17 (17)	0.7 (8)	0.03 (8)	0.8 (9)	0.03 (9)
Dizziness	16 (15)	0.2 (2)	0.01 (2)	1.2 (13)	0.04 (14)
Hypo/hypertension	16 (15)	0.3 (3)	0.01 (3)	1.1 (12)	0.04 (13)
Other - Patient condition - Cardiovascular	12 (12)	0.5 (5)	0.02 (5)	0.6 (7)	0.02 (7)
Vascular	10 (10)	0.6 (7)	0.02 (7)	0.3 (3)	0.01 (3)
Palpitations	7 (7)	0.1 (1)	0.00 (1)	0.6 (6)	0.02 (6)
Bleeding	4 (4)	0.3 (3)	0.01 (3)	0.1 (1)	0.00 (1)
Bradyarrhythmias	4 (4)	0.0 (0)	0.00 (0)	0.4 (4)	0.01 (4)
Myocardial infarction	4 (4)	0.4 (4)	0.01 (4)	0.0 (0)	0.00 (0)
Fatigue	3 (3)	0.0 (0)	0.00 (0)	0.3 (3)	0.01 (3)
Dyspnea	2 (2)	0.0 (0)	0.00 (0)	0.2 (2)	0.01 (2)
Syncope	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
<b>Subtotal Cardiovascular - Non-HF Related Events</b>	<b>164 (138)</b>	<b>5.5 (60)</b>	<b>0.21 (65)</b>	<b>8.2 (89)</b>	<b>0.31 (99)</b>

**H-12** | CLINICAL STUDY - MADIT-CRT  
OBSERVED ADVERSE EVENTS

**Table H-2. Patient-Related Adverse Events Within 91 days - Full Patient Population**

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
<b>Subtotal Non-cardiovascular Related Events</b>	<b>152 (120)</b>	<b>5.3 (58)</b>	<b>0.22 (69)</b>	<b>6.5 (71)</b>	<b>0.26 (83)</b>

**Summary of Adverse Events - LBBB Patient Sub-Population**

**Table H-3. System-Related Adverse Events Within 91 Days - LBBB Patient Sub-Population**

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
<b>Total Adverse Events</b>	<b>400 (262)</b>	<b>16.6 (126)</b>	<b>0.63 (169)</b>	<b>22.6 (171)</b>	<b>0.87 (231)</b>
<b>PG Related Events</b>					
Extracardiac stimulation - LV	60 (55)	0.3 (2)	0.01 (2)	7.0 (53)	0.22 (58)
Pacemaker-mediated tachycardia (PMT)	39 (33)	0.1 (1)	0.00 (1)	4.2 (32)	0.14 (38)
Threshold elevated/ unable to capture - LV	10 (10)	0.0 (0)	0.00 (0)	1.3 (10)	0.04 (10)
Inappropriate tachy therapy	6 (6)	0.3 (2)	0.01 (2)	0.5 (4)	0.02 (4)
Infection (> 30 days post-implant)	5 (5)	0.4 (3)	0.01 (3)	0.3 (2)	0.01 (2)
Oversensing - RA	3 (3)	0.0 (0)	0.00 (0)	0.4 (3)	0.01 (3)
Early elective replacement indicator	2 (2)	0.3 (2)	0.01 (2)	0.0 (0)	0.00 (0)
Elevated DFT - Defibrillation	2 (2)	0.3 (2)	0.01 (2)	0.0 (0)	0.00 (0)

Table H-3. System-Related Adverse Events Within 91 Days - LBBB Patient Sub-Population

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
Migration	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Threshold elevated/ unable to capture - RA	2 (2)	0.0 (0)	0.00 (0)	0.3 (2)	0.01 (2)
Unable to convert - Defibrillation	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Programmer / Software error code	1 (1)	0.1 (1)	0.00 (1)	0.0 (0)	0.00 (0)
Threshold elevated/ unable to capture - RV	1 (1)	0.1 (1)	0.00 (1)	0.0 (0)	0.00 (0)
Infrequent events include: Inappropriate AV delay (2), PG system diagnosis - other (2), Seroma - Pocket (> 30 days post-implant) (1)					
<b>Subtotal PG Related Events</b>	<b>140 (121)</b>	<b>2.1 (16)</b>	<b>0.06 (16)</b>	<b>13.9 (105)</b>	<b>0.47 (124)</b>
<b>RA Lead Related Events</b>					
Lead dislodgment - RA	27 (27)	3.4 (26)	0.10 (26)	0.1 (1)	0.00 (1)
Threshold elevated/ unable to capture - RA	1 (1)	0.1 (1)	0.00 (1)	0.0 (0)	0.00 (0)
<b>Subtotal RA Lead Related Events</b>	<b>28 (28)</b>	<b>3.6 (27)</b>	<b>0.10 (27)</b>	<b>0.1 (1)</b>	<b>0.00 (1)</b>
<b>RV Lead Related Events</b>					
Lead dislodgment - RV	4 (4)	0.5 (4)	0.02 (4)	0.0 (0)	0.00 (0)
Threshold elevated/ unable to capture - RV	3 (3)	0.3 (2)	0.01 (2)	0.1 (1)	0.00 (1)
Oversensing - RV	2 (2)	0.0 (0)	0.00 (0)	0.3 (2)	0.01 (2)
<b>Subtotal RV Lead Related Events</b>	<b>9 (9)</b>	<b>0.8 (6)</b>	<b>0.02 (6)</b>	<b>0.4 (3)</b>	<b>0.01 (3)</b>
<b>LV Lead Related Events</b>					
Lead dislodgment - LV	38 (35)	4.2 (32)	0.13 (35)	0.4 (3)	0.01 (3)

**H-14** | CLINICAL STUDY - MADIT-CRT  
OBSERVED ADVERSE EVENTS

**Table H-3. System-Related Adverse Events Within 91 Days - LBBB Patient Sub-Population**

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
Extracardiac stimulation - LV	23 (22)	1.2 (9)	0.03 (9)	1.8 (14)	0.05 (14)
Threshold elevated/ unable to capture - LV	5 (5)	0.1 (1)	0.00 (1)	0.5 (4)	0.02 (4)
Insulation breach - LV	1 (1)	0.1 (1)	0.00 (1)	0.0 (0)	0.00 (0)
Oversensing - LV	1 (1)	0.0 (0)	0.00 (0)	0.1 (1)	0.00 (1)
<b>Subtotal LV Lead Related Events</b>	<b>68 (61)</b>	<b>5.7 (43)</b>	<b>0.17 (46)</b>	<b>2.8 (21)</b>	<b>0.08 (22)</b>
<b>Defib Lead Related Events</b>					
Elevated DFT/ unable to convert	2 (2)	0.3 (2)	0.01 (2)	0.0 (0)	0.00 (0)
Inappropriate tachy therapy	1 (1)	0.0 (0)	0.00 (0)	0.1 (1)	0.00 (1)
<b>Subtotal Defib Lead Related Events</b>	<b>3 (3)</b>	<b>0.3 (2)</b>	<b>0.01 (2)</b>	<b>0.1 (1)</b>	<b>0.00 (1)</b>
<b>Procedure Related Events</b>					
Hematoma - Pocket (≤ 30 days post-implant)	28 (28)	1.7 (13)	0.05 (13)	2.0 (15)	0.06 (15)
Pneumothorax - Procedure	18 (18)	2.0 (15)	0.06 (15)	0.4 (3)	0.01 (3)
Adverse reaction	16 (15)	0.8 (6)	0.02 (6)	1.2 (9)	0.04 (10)
Thromboembolic events	11 (11)	0.9 (7)	0.03 (7)	0.5 (4)	0.02 (4)
AV block	10 (10)	0.8 (6)	0.02 (6)	0.5 (4)	0.02 (4)
Other - PG system - Procedure	10 (10)	0.1 (1)	0.00 (1)	1.2 (9)	0.03 (9)
Post-surgical infection (≤ 30 days post-implant)	10 (10)	0.5 (4)	0.02 (4)	0.8 (6)	0.02 (6)

Table H-3. System-Related Adverse Events Within 91 Days - LBBB Patient Sub-Population

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/ 100 Device Months (N Events)	% of Patients (N Patients)	N Events/ 100 Device Months (N Events)
Post-surgical wound discomfort	10 (9)	0.0 (0)	0.00 (0)	1.2 (9)	0.04 (10)
Pericardial effusion	6 (4)	0.3 (2)	0.01 (3)	0.3 (2)	0.01 (3)
Coronary venous perforation without tamponade	5 (5)	0.3 (2)	0.01 (2)	0.4 (3)	0.01 (3)
Coronary venous dissection	4 (4)	0.0 (0)	0.00 (0)	0.5 (4)	0.02 (4)
Inadvertent VT/VF	3 (3)	0.4 (3)	0.01 (3)	0.0 (0)	0.00 (0)
Myocardial perforation with tamponade	3 (3)	0.4 (3)	0.01 (3)	0.0 (0)	0.00 (0)
Renal failure due to contrast media - Procedure	3 (3)	0.4 (3)	0.01 (3)	0.0 (0)	0.00 (0)
Inadvertent SVT	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Other - Lead - Procedure	2 (2)	0.3 (2)	0.01 (2)	0.0 (0)	0.00 (0)
Pleural effusion - Procedure	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Post-surgical pocket hemorrhage	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Arterial perforation - Procedure	1 (1)	0.0 (0)	0.00 (0)	0.1 (1)	0.00 (1)
Venous occlusion	1 (1)	0.1 (1)	0.00 (1)	0.0 (0)	0.00 (0)
Infrequent events include: Chest pain (1), Hemorrhage (2), Vasovagal (1)					
<b>Subtotal Procedure Related Events</b>	<b>151 (119)</b>	<b>8.3 (63)</b>	<b>0.27 (72)</b>	<b>8.7 (66)</b>	<b>0.30 (79)</b>
<b>Protocol Testing Related Events</b>					
Chest pain	1 (1)	0.0 (0)	0.00 (0)	0.1 (1)	0.00 (1)
<b>Subtotal Protocol Testing Related Events</b>	<b>1 (1)</b>	<b>0.0 (0)</b>	<b>0.00 (0)</b>	<b>0.1 (1)</b>	<b>0.00 (1)</b>

**H-16** | CLINICAL STUDY - MADIT-CRT  
OBSERVED ADVERSE EVENTS

**Table H-4. Patient-Related Adverse Events within 91 days - LBBB Patient Sub-Population**

Adverse Event	Total Number Of Events (Number of Patients)	Complications		Observations	
		% of Patients (N Patients)	N Events/100 Device Months (N Events)	% of Patients (N Patients)	N Events/100 Device Months (N Events)
<b>Total Adverse Events</b>	<b>247 (173)</b>	<b>9.8 (74)</b>	<b>0.38 (100)</b>	<b>15.2 (115)</b>	<b>0.55 (147)</b>
<b>Subtotal Cardiovascular - HF Related Events</b>	<b>72 (33)</b>	<b>2.5 (19)</b>	<b>0.15 (40)</b>	<b>2.0 (15)</b>	<b>0.12 (32)</b>
<b>Cardiovascular - Non-HF Related Events</b>					
Supraventricular tachyarrhythmias	28 (24)	1.2 (9)	0.03 (9)	2.2 (17)	0.07 (19)
Chest pain	21 (19)	1.4 (11)	0.05 (13)	1.1 (8)	0.03 (8)
Hypo/hypertension	13 (12)	0.3 (2)	0.01 (2)	1.3 (10)	0.04 (11)
Dizziness	11 (10)	0.3 (2)	0.01 (2)	1.1 (8)	0.03 (9)
Ventricular tachyarrhythmias	10 (10)	0.7 (5)	0.02 (5)	0.7 (5)	0.02 (5)
Other - Patient condition - Cardiovascular	8 (8)	0.3 (2)	0.01 (2)	0.8 (6)	0.02 (6)
Palpitations	7 (7)	0.1 (1)	0.00 (1)	0.8 (6)	0.02 (6)
Vascular	7 (7)	0.8 (6)	0.02 (6)	0.1 (1)	0.00 (1)
Bleeding	3 (3)	0.3 (2)	0.01 (2)	0.1 (1)	0.00 (1)
Bradyarrhythmias	2 (2)	0.0 (0)	0.00 (0)	0.3 (2)	0.01 (2)
Dyspnea	2 (2)	0.0 (0)	0.00 (0)	0.3 (2)	0.01 (2)
Syncope	2 (2)	0.1 (1)	0.00 (1)	0.1 (1)	0.00 (1)
Fatigue	1 (1)	0.0 (0)	0.00 (0)	0.1 (1)	0.00 (1)
Myocardial infarction	1 (1)	0.1 (1)	0.00 (1)	0.0 (0)	0.00 (0)
<b>Subtotal Cardiovascular - Non-HF Related Events</b>	<b>116 (97)</b>	<b>5.4 (41)</b>	<b>0.17 (44)</b>	<b>8.3 (63)</b>	<b>0.27 (72)</b>
<b>Subtotal Non-cardiovascular Related Events</b>	<b>95 (77)</b>	<b>4.1 (31)</b>	<b>0.14 (36)</b>	<b>6.7 (51)</b>	<b>0.22 (59)</b>

## Deaths

### Deaths - Full Patient Population

Deaths for the full patient population are shown below. The overall results are similar to that of the LBBB sub-population with pump failure (62, 38.8%) and non-cardiac deaths (49, 30.6%) comprising the most common causes trailed by arrhythmic (15, 9.4%) and unknown (16, 10.0%).

Table H-5. Cause of Death - Full Patient Population

Cause of Death	ICD (N=731)	CRT-D (N=1089)	Total (N=1820)
Cardiac: Pump failure	30 (44.1%)	32 (34.8%)	62 (38.8%)
Non-Cardiac	16 (23.5%)	33 (35.9%)	49 (30.6%)
Cardiac: Arrhythmic	8 (11.8%)	7 (7.6%)	15 (9.4%)
Unknown	7 (10.3%)	9 (9.8%)	16 (10%)
Cardiac: Ischemic	2 (2.9%)	6 (6.5%)	8 (5%)
Cardiac: Other procedure	2 (2.9%)	0 (0%)	2 (1.3%)
Cardiac: Other	1 (1.5%)	1 (1.1%)	2 (1.3%)
Net yet classified	2 (2.9%)	4 (4.3%)	6 (3.8%)
<b>Total</b>	<b>68 (100%)</b>	<b>92 (100%)</b>	<b>160 (100%)</b>

**Deaths - LBBB Patient Sub-Population**

The most common causes of death in the MADIT-CRT LBBB sub-population were pump failure (41, 39.0%), non-cardiac (33, 31.4%), and arrhythmic (10, 11.0%). Additionally, deaths from 12 patients (11.0%) were adjudicated and classified as unknown due to a lack of information from the investigational center. There were no statistically significant differences in the cause of death between treatment groups. The cause of death data are summarized below.

**Table H-6. Cause of Death - LBBB Patient Sub-Population**

<b>Cause of Death</b>	<b>ICD (N=520)</b>	<b>CRT-D (N=761)</b>	<b>Total (N=1281)</b>
Cardiac: Pump failure	22 (43.1%)	19 (35.2%)	41 (39%)
Non-Cardiac	16 (31.4%)	17 (31.5%)	33 (31.4%)
Cardiac: Arrhythmic	6 (11.8%)	4 (7.4%)	11 (9.5%)
Unknown	5 (9.8%)	7 (13%)	12 (11.4%)
Cardiac: Ischemic	1 (2%)	4 (7.4%)	2 (1.9%)
Cardiac: Other	1 (2%)	1 (1.9%)	2 (1.9%)
Net yet classified		2 (3.7%)	2 (1.9%)
<b>Total</b>	<b>51 (100%)</b>	<b>54 (100%)</b>	<b>105 (100%)</b>

**STUDY DESIGN**

Boston Scientific sponsored MADIT-CRT to demonstrate the safety and effectiveness of Boston Scientific CRT-Ds in the MADIT-CRT patient population. MADIT-CRT was a prospective, randomized, controlled, multicenter study conducted in the U.S., Europe, Israel, and Canada at 110 investigational centers. A total of 1820 patients were enrolled and randomized in a 3:2 ratio to receive a CRT-D (1089 full patient population/761 LBBB patient sub-population) or an ICD (731 full patient population/520 LBBB patient sub-population). Randomization was stratified by clinical center and ischemic status. Each randomized patient remained counted as a member of the original randomized assignment (intention-to-treat) regardless of subsequent crossover or protocol adherence. The MADIT-CRT study design have been previously described in the medical literature.<sup>2</sup>

2. Moss A, Brown M, Cannom D, et al. Multicenter automatic defibrillator implantation trial (MADIT-CRT): design and clinical protocol. ANE 2005;10(4)Supplement: 34-43.

## Safety Endpoint

The MADIT-CRT study assessed the CRT-D safety by the system-related complication-free rate observed within the date of implant and three months of follow-up. For the purposes of the safety analysis, three month follow-up was defined as 91 days post-implant.

## Primary Effectiveness Endpoint

The MADIT-CRT study assessed the effectiveness of CRT-D by the relative reduction of the risk of the combined endpoint of all-cause mortality or HF event, whichever occurred first, when compared to ICD.

## Secondary Endpoint

The MADIT-CRT study also evaluated the effects of CRT-D, relative to ICD, on the patient-specific rates of recurrent HF events over the full study period.

## Tertiary Endpoints

There were ten pre-specified tertiary endpoints for this study (All-Cause Mortality, Appropriate Defibrillator Therapy, Echocardiographic Volumes and Ejection Fraction, New York Heart Association Class, Quality of Life, Mitral Regurgitation, Functional Capacity, Association of Brain Natriuretic Peptide and Outcome, Brain Natriuretic Peptide, Holter Recorded Non-Invasive Electrocardiographic Parameters and Hemodynamic Benefit). For each endpoint, the objective, data analysis and conclusion are provided on page H-48.

## Inclusion/Exclusion Criteria

### Inclusion Criteria

Patients who met the following criteria were given consideration for inclusion in the MADIT-CRT clinical investigation:

NYHA Class I or II patients for the three calendar months prior to and at the time of enrollment with ischemic heart disease defined as:

- one or more clinically documented (Q wave or enzyme positive) prior myocardial infarction, but not within three calendar months of enrollment *and/or*.

- one or more prior coronary artery bypass graft surgeries or percutaneous coronary intervention (balloon and/or stent angioplasty), but not within three calendar months of enrollment;

OR

NYHA Class II patients for the three calendar months prior to and at the time of enrollment with non-ischemic heart disease defined as including dilated cardiomyopathy characterized by a low EF and increased ventricular volume, with ventricular compliance that is normal or increased;

AND all of the following:

- OPT including ACEs (Angiotensin Converting Enzymes) / ARBs (Angiotensin Receptor blockers), Beta Blockers, and Diuretics. Ischemic patients were required to have a statin prescribed.
- An EF  $\leq$  30% by angiographic, radionuclide, or echocardiographic methods within one year prior to enrollment and measured during the enrollment echocardiogram
- Resting QRS duration  $\geq$  130 ms on print-out of a current ECG using a market-approved electrocardiographic recorder
- Sinus rhythm by ECG (including Right Bundle Branch Block (RBBB) and first degree heart block with PR < 250 ms.)
- Men and women 21 years of age or older (no upper-age cut off)

### Exclusion Criteria

Patients were excluded from the MADIT-CRT clinical investigation if any of the following conditions applied:

- Existing indication for CRT therapy
- Implanted pacemaker
- Existing ICD or CRT device
- NYHA Class I with non-ischemic cardiomyopathy
- NYHA Class III or IV in the past 3 calendar months prior to or at the time of enrollment
- Coronary artery bypass graft surgery or percutaneous coronary intervention (balloon and/or stent angioplasty) within the past three calendar months prior to enrollment
- Enzyme-positive myocardial infarction within the past three calendar months prior to enrollment

- Angiographic evidence of coronary disease who are candidates for coronary revascularization and are likely to undergo coronary artery bypass graft surgery or percutaneous coronary intervention in the foreseeable future
- Second or third degree heart block
- Irreversible brain damage from preexisting cerebral disease
- Pregnant or plan to become pregnant during the course of the study. Note: Women of childbearing potential must have a negative pregnancy test within seven days prior to enrollment
- Reversible non-ischemic cardiomyopathy such as acute viral myocarditis or discontinuation of alcohol in alcohol-induced heart disease
- Chronic atrial fibrillation within one month prior to enrollment
- Presence of any disease, other than the patient's cardiac disease, associated with a reduced likelihood of survival for the duration of the trial, e.g., cancer, uremia (Blood Urea Nitrogen (BUN) > 70mg/dl or creatinine > 3.0mg/dl), liver failure, etc.
- Participating in any other clinical studies
- Unwilling or unable to cooperate with the protocol
- Live at such a distance from the clinic that travel for follow-up visits would be unusually difficult
- Did not anticipate being a resident of the area for the scheduled duration of the trial
- Unwilling to sign the consent for participation

## Follow-up Schedule

Table H-7. Follow-Up Schedule

Screening	Initial assessment of patient eligibility; taking of patient history.
Pre-randomization confirmation testing	ECG and echocardiogram
Randomization	Randomization status (CRT-D or ICD) was assigned
Baseline Testing	Six-minute walk, Holter, QoL, BNP (US only)
Routine clinic follow-ups	1, 3, and every 3 months.
Special testing	Echocardiogram, 6-minute walk, Holter, BNP (US only), QoL (every 6 months)

## DATA ANALYSIS

### Safety Endpoint

All patients who underwent an implant procedure were included in the safety analysis and were analyzed according to randomization assignment. A system-related complication (Type I, II, or III) that occurred within 91 days post-implant was included as an event in this analysis.

The safety endpoint defined the system as including all components required for implantation of the CRT-D device, leads, and the associated implant procedure. A complication was defined as a clinical event that resulted in invasive intervention after implant, injury, or death, including at least one of the following outcomes:

- Life-threatening condition
- Significant, persistent, or permanent disability
- Invasive intervention as a corrective action to preclude permanent impairment/damage (e.g., device explant, lead revision, ventilation)
- Congenital anomaly
- Hospitalization or prolongation of an existing hospitalization
- Permanent loss of device function

The hypothesis for the system-related complication-free rate was evaluated using the lower one-sided 95% confidence bound from the Kaplan-Meier estimated system-related complication-free rate. The rate reported was based on Kaplan-

Meier estimates and the lower confidence bound was based on a log cumulative hazard transformation.

Patients who did not have a system-related complication within 91 days post-implant were censored at their date of death, withdrawal (if the patient did not agree to phone contact to collect event data), or at 92 days post-implant.

### Primary Effectiveness Endpoint

Statistical tests of the difference in the primary effectiveness endpoint (rate of combined all-cause mortality or HF event, whichever occurred first) between the randomized CRT-D and ICD groups were performed. The primary effectiveness analysis was based on comparing the Kaplan-Meier life-table event-free survival time graphs for the CRT-D and ICD groups. The stratified log-rank test (stratified by clinical center and ischemic status) was used to evaluate statistical significance, adjusting for the group-sequential stopping rule of the study. The hazard ratio for CRT-D relative to ICD, based on proportional hazards modeling, was also estimated, along with the corresponding 95% confidence limits.

A *heart failure event* was defined as a patient having symptoms and/or signs consistent with congestive heart failure in an in-patient or out-patient setting and receiving either:

- intravenous decongestive therapy (IV diuretics, IV nesiritide, IV inotropes), that did not involve formal in-patient hospital admission, regardless of the setting (i.e. in an emergency room setting, in the physician's office, etc.) (out-patient), or
- an augmented heart failure regimen with oral or intravenous medications during an in-hospital stay (formal hospital admission is defined as admission to hospital that includes a calendar date change) (in-patient).

All analyses were carried out according to the intention-to-treat principle and include data occurring on or before December 31, 2009. Patients who did not have a primary effectiveness endpoint by December 31, 2009, were censored at either their date of withdrawal (if the patient did not agree to phone contact to collect event data) or last visit.

### Secondary Endpoint

The analysis was based on the intention-to-treat principle. The counts of HF events occurring within the period of active follow-up of each patient were analyzed to determine whether the average rate within the CRT-D group differed from that in the ICD group. The protocol specified a negative binomial regression analysis to

evaluate the relative difference in the average rate of heart failure events between treatment groups, using treatment and ischemic status as covariates with active follow-up time as an offset. However, an assumption of negative binomial regression was not fulfilled. Therefore, a more appropriate Andersen-Gill regression analysis was performed to assess the benefit of CRT-D on recurrent HF events. In the Andersen-Gill regression analysis, patients were censored at their date of death, withdrawal (if the patient did not agree to phone contact to collect event data) or last visit.

### **Tertiary Endpoints**

See "Tertiary Endpoints - LBBB Patient Sub-Population" on page H-48 for data analysis specific to each endpoint.

## STUDY RESULTS

### Demographic Data - Full Patient Population

All baseline patient characteristics are presented in the table below.

**Table H-8. Baseline Demographics (all patients randomized, N=1820) - Full Patient Population**

Characteristic	Measurement	ICD (N=731)	CRT-D (N=1089)	P-value
Age at Implant (years)	Mean ± SD	64 ± 11	64 ± 11	0.74
	Range	32 - 88	25 - 90	
Gender [N (%)]	Female	178 (24.4)	275 (25.3)	0.66
	Male	553 (75.6)	814 (74.7)	
Race [N (%)]	White	658 (90.8)	980 (90.4)	
	Black/African American	56 (7.7)	87 (8.0)	0.97
	Other*	11 (1.5)	17 (1.6)	

\* Other races include Asian, American Indian/Alaska Native, Native Hawaiian or other Pacific Islander, and more than one race.

**Table H-9. Cardiac History (all patients randomized, N=1820) - Full Patient Population**

Characteristic	Measurement	ICD (N=731)	CRT-D (N=1089)	P-value
NYHA Class [N (%)]	Class I Ischemic	113 (15.5)	152 (14.0)	0.63
	Class II Ischemic	288 (39.4)	446 (41.0)	
	Class II Non-Ischemic	330 (45.1)	491 (45.1)	
Worst NYHA class more than 3 months prior to enrollment [N(%)]*	Class III/IV	73 (10.4)	109 (10.4)	0.99

**Table H-9. Cardiac History (all patients randomized, N=1820) - Full Patient Population**

Characteristic	Measurement	ICD (N=731)	CRT-D (N=1089)	P-value
Number of CHF Hospitalizations prior to enrollment [N(%)]	None	451 (63.3)	656 (61.3)	0.69
	1-2	231 (32.4)	365 (34.1)	
	3 or more	31 (4.3)	50 (4.7)	

\*Patients who were Class I or II at enrollment but had prior history of Class III or IV more than 3 months prior to enrollment.

**Table H-10. Cardiac Risk Factors (all patients randomized, N=1820) - Full Patient Population**

Risk Factor	ICD (N=731) [N(%)]	CRT-D (N=1089)[N(%)]	P-value
Treatment for Hypertension	461 (63.2)	691 (63.7)	0.82
Atrial fibrillation > 1 month before enrollment	90 (12.3)	118 (10.8)	0.33
Diabetes Mellitus	223 (30.6)	329 (30.2)	0.87
Cigarette Smoking	92 (12.8)	122 (11.4)	0.37
Body-mass index $\geq$ 30	256 (35.4)	378 (35.2)	0.95
Coronary-bypass surgery	208 (28.5)	317 (29.1)	0.77

**Table H-11. Cardiac Findings at Enrollment (all patients randomized, N=1820) - Full Patient Population**

Characteristic	Measurement	ICD (N=731) [N(%)]	CRT-D (N=1089) [N(%)]	P-value
Conduction	LBBB [N(%)]	520 (71.3)	761 (69.9)	0.51
	RBBB [N(%)]	92 (12.6)	136 (12.5)	0.93
	IVCD [N(%)]	111 (15.2)	182 (16.7)	0.40
Systolic Blood Pressure (mm Hg)	N	719	1074	0.001*
	Mean $\pm$ SD	121 $\pm$ 18	124 $\pm$ 17	
	Range	80 - 193	78-194	

Table H-11. Cardiac Findings at Enrollment (all patients randomized, N=1820) - Full Patient Population

Characteristic	Measurement	ICD (N=731) [N(%)]	CRT-D (N=1089) [N(%)]	P-value
Diastolic Blood Pressure (mm Hg)	N	719	1074	
	Mean ± SD	71 ± 10	72 ± 10	0.002*
	Range	37 - 107	40 - 110	
BUN ≥ 26 mg/dL	N (%)	173 (24.0)	254 (23.5)	0.79
Creatinine (mg/dl)	N	725	1083	
	Mean ± SD	1 ± 0	1 ± 0	0.51
	Range	1 - 7	0 - 6	
QRS duration ≥ 150 ms	N (%)	476 (65.1)	699 (64.2)	0.68
LVEF (%)	N	731	1089	
	Mean ± SD	24 ± 5	24 ± 5	0.33
	Range	6 - 32	7 - 35	
BNP (pg/ml)	N	473	724	
	Mean ± SD	114 ± 141	132 ± 173	0.06
	Range	1 - 1209	1 - 1433	
6 Minute Walk Distance (meters)	N	696	1069	
	Mean ± SD	363 ± 108	358 ± 106	0.44
	Range	31 - 896	0 - 744	
EuroQoL index	N	726	1086	
	Mean ± SD	0.84 ± 0.13	0.84 ± 0.14	0.58
	Range	0.27 - 1.00	-0.04 - 1.00	
KCCQ Overall Summary Score	N	727	1087	
	Mean ± SD	75 ± 19	76 ± 18	0.43
	Range	10 - 100	17 - 100	

**Table H-11. Cardiac Findings at Enrollment (all patients randomized, N=1820) - Full Patient Population**

Characteristic	Measurement	ICD (N=731) [N(%)]	CRT-D (N=1089) [N(%)]	P-value
KCCQ Clinical Summary Score	N	727	1087	
	Mean ± SD	80 ± 18	80 ± 17	0.66
	Range	4 - 100	16 - 100	
KCCQ Quality of Life Score	N	727	1087	
	Mean ± SD	66 ± 25	67 ± 23	0.84
	Range	0 - 100	0 - 100	

\*Statistically significant differences were found between systolic and diastolic blood pressure; these differences are not considered clinically meaningful.

**Table H-12. Baseline Echocardiographic Volumes (all patients randomized, N=1820) - Full Patient Population**

Characteristic	Measurement	ICD (N=731) [N(%)]	CRT-D (N=1089) [N(%)]	P-value
Left ventricular end-systolic volume (ml)	N	724	1085	
	Mean ± SD	180 ± 52	176 ± 48	0.10
	Range	94 - 465	83 - 434	
Left ventricular end-diastolic volume (ml)	N	724	1085	
	Mean ± SD	251 ± 65	246 ± 60	0.10
	Range	134 - 601	134 - 564	

**Table H-13. Cardiac Medications (all patients randomized, N=1820) - Full Patient Population**

Characteristic	ICD (N=731) [N(%)]	CRT-D (N=1089) [N(%)]	P-value
ACE (Angiotensin Converting Enzyme) / ARB (Angiotensin Receptor blockers)*	699 (95.6)	1039 (95.4)	0.83
Aldosterone Antagonist**	226 (30.9)	352 (32.3)	0.53
Amiodarone**	51 (7.0)	78 (7.2)	0.88
Beta Blockers*	681 (93.2)	1016 (93.3)	0.91
Class I antiarrhythmic agent**	3 (0.4)	12 (1.1)	0.11
Digitalis**	177 (24.2)	291 (26.7)	0.23
Diuretic*	533 (72.9)	824 (75.7)	0.19
Statin*	491 (67.2)	735 (67.5)	0.88

\*Required Optimal Pharmacologic Therapy (OPT), unless contraindicated. Ischemic patients were required to have a statin prescribed.

\*\* Adjunctive medications per medical discretion.

### Demographic Data - LBBB Patient Sub-Population

Table H-14. Baseline Demographics (all LBBB patients randomized, N=1281) - LBBB Patient Sub-Population

Characteristic	Measurement	ICD (N=520)	CRT-D (N=761)	P-value
Age at Implant (years)	Mean ± SD	64 ± 11	64 ± 11	0.59
	Range	34 - 88	28 - 90	
Gender [N (%)]	Female	155 (29.8)	239 (31.4)	0.54
	Male	365 (70.2)	522 (68.6)	
Race [N (%)]	White	474 (91.7)	693 (91.5)	0.97
	Black/African American	37 (7.2)	56 (7.4)	
	Other*	6 (1.2)	8 (1.1)	

\* Other races include Asian, American Indian/Alaska Native, Native Hawaiian or other Pacific Islander, and more than one race.

Table H-15. Cardiac History (LBBB patients randomized, N=1281) - LBBB Patient Sub-Population

Characteristic	Measurement	ICD (N=520)	CRT-D (N=761)	P-value
NYHA Class/ Ischemic [N (%)]	Class I Ischemic	60 (11.5)	83 (10.9)	0.93
	Class II Ischemic	171 (32.9)	249 (32.7)	
	Class II Non-Ischemic	289 (55.6)	429 (56.4)	
Worst NYHA class > 3 mos prior to enrollment [N (%)]	Class III/IV	53 (10.6)	82 (11.2)	0.77
Number of CHF Hospitalizations Prior to Enrollment [N (%)]	None	319 (62.8)	455 (60.4)	0.67
	1 - 2	167 (32.9)	266 (35.3)	
	3 or more	22 (4.3)	32 (4.2)	

**Table H-16. Cardiac Risk Factors (patients randomized, N=1281) - LBBB Patient Sub-Population**

Risk Factor	ICD (N=761) [N (%)]	CRT-D (N=520) [N (%)]	P-value
Treatment for Hypertension	335 (64.5)	471 (62.1)	0.38
Atrial fibrillation > 1 month before enrollment	69 (13.3)	71 (9.3)	0.03
Diabetes Mellitus	161 (31.1)	225 (29.6)	0.57
Cigarette Smoking	59 (11.6)	75 (10.1)	0.39
Body-mass index $\geq$ 30	172 (33.5)	257 (34.2)	0.78
Coronary-bypass surgery	113 (21.8)	169 (22.2)	0.84

**Table H-17. Cardiac Findings at Enrollment (patients randomized, N=1281) - LBBB Patient Sub-Population**

Characteristic	Measurement	ICD (N=520)	CRT-D (N=761)	P-value
Systolic Blood Pressure (mm Hg)	N	513	754	
	Mean $\pm$ SD	121 $\pm$ 17	124 $\pm$ 17	0.010*
	Range	82 - 193	80 - 182	
Diastolic Blood Pressure (mm Hg)	N	513	754	
	Mean $\pm$ SD	70 $\pm$ 10	72 $\pm$ 10	<0.001*
	Range	37 - 107	46 - 105	
BUN $\geq$ 26 mg/dL	N (%)	121 (23.5)	176 (23.2)	0.89
Creatinine (mg/dl)	N	516	758	
	Mean $\pm$ SD	1.1 $\pm$ 0.3	1.1 $\pm$ 0.3	0.50
	Range	0.5 - 2.5	0.4 - 2.7	
QRS duration $\geq$ 150 ms	N (%)	406 (78.1)	575 (75.6)	0.30

**Table H-17. Cardiac Findings at Enrollment (patients randomized, N=1281) - LBBB Patient Sub-Population**

Characteristic	Measurement	ICD (N=520)	CRT-D (N=761)	P-value
LVEF (%)	N	520	761	
	Mean ± SD	23 ± 5	24 ± 5	0.13
	Range	6 - 30	10 - 30	
BNP (pg/ml)	N	332	490	
	Mean ± SD	109 ± 138	119 ± 154	0.35
	Range	1 - 1209	1 - 1401	
6 Minute Walk Distance (meters)	N	495	749	
	Mean ± SD	363 ± 106	364 ± 105	0.77
	Range	31 - 731	0 - 744	
Euro Qol Index	N	516	758	
	Mean ± SD	0.84 ± 0.13	0.85 ± 0.13	0.66
	Range	0.27 - 1.00	-0.04 - 1.00	
KCCQ Overall Summary Score	N	517	759	
	Mean ± SD	75 ± 19	77 ± 17	0.19
	Range	10 - 100	20 - 100	
KCCQ Clinical Summary Score	N	517	759	
	Mean ± SD	80 ± 18	81 ± 16	0.29
	Range	4 - 100	16 - 100	
KCCQ Quality of Life Score	N	517	759	
	Mean ± SD	66 ± 24	67 ± 22	0.57
	Range	0 - 100	0 - 100	

\*Statistically significant differences were found between systolic and diastolic blood pressure; these differences are not considered clinically meaningful.

**Table H-18. Baseline Echocardiographic Volumes (patients randomized, N=1820) - LBBB Patient Sub-Population**

Characteristic	Measurement	ICD (N=520)	CRT-D (N=761)	P-value
Left ventricular end-systolic volume (ml)	N	514	760	
	Mean ± SD	183 ± 56	178 ± 51	0.13
	Range	94 - 447	83 - 434	
Left ventricular end-diastolic volume (ml)	N	514	760	
	Mean ± SD	254 ± 69	249 ± 63	0.14
	Range	134 - 571	134 - 564	

**Table H-19. Cardiac Medications (patients randomized, N=1820) - LBBB Patient Sub-Population**

Medication	ICD (N=520) [N (%)]	CRT-D (N=761) [N (%)]	P-value
ACE/ARB*	500 (96.2)	731 (96.1)	0.93
Aldosterone Antagonist**	164 (31.5)	265 (34.8)	0.22
Amiodarone**	36 (6.9)	43 (5.7)	0.35
Beta Blockers*	488 (93.8)	716 (94.1)	0.86
Class I antiarrhythmic agent**	1 (0.2)	4 (0.5)	0.35
Digitalis**	132 (25.4)	227 (29.8)	0.08
Diuretic*	362 (69.6)	511 (67.1)	0.35
Statin*	326 (62.7)	485 (63.7)	0.70

\*Required Optimal Pharmacologic Therapy (OPT), unless contraindicated. Ischemic patients were required to have a statin prescribed.

\*\* Adjunctive medications per medical discretion.

## Patient Accountability and Follow-up Duration

### Patient Accountability - Full Patient Population

In the MADIT-CRT study 1820 patients were randomized to CRT-D or ICD and enrolled between December 22, 2004 and April 23, 2008. As of December 31, 2009, the total patient follow-up months were 62,335 months: 24,683 in the ICD group and 37,653 in the CRT-D group. The mean follow up duration was  $34.3 \pm 12.2$  months;  $33.8 \pm 12.9$  months in the ICD arm and  $34.6 \pm 11.7$  months in the CRT-D arm. There was no statistically significant difference in the follow-up duration between treatment arms. The follow-up duration details are summarized below:

Table H-20. Follow-up Duration (all patients randomized, N=1820)

Measurement	Follow-up Duration (months)	ICD (N=731)	CRT-D (N=1089)
Mean $\pm$ SD	$34.3 \pm 12.2$	$33.8 \pm 12.9$	$34.6 \pm 11.7$
Range	0.03 - 58.97	0.03 - 58.94	0.03 - 58.97
Total Patient Months	62,335	24,683	37,653

## Safety Endpoint

### Safety Endpoint - Full Patient Population

A total of 1079 patients underwent an implant procedure. Of these, 164 unique patients experienced 214 system-related complications (SRCs) within 91 days post-implant. The CRT-D Kaplan-Meier system-related complication-free rate was 84.8% with a lower one-sided 95% confidence bound of 82.9%. This rate was statistically significantly greater than 70% and therefore passed the pre-specified safety

endpoint. The Kaplan-Meier system-related complication-free graph and supporting data are shown below.

Figure H-3. System-Related Complication-Free Rate Within 91 days -Full Patient Population

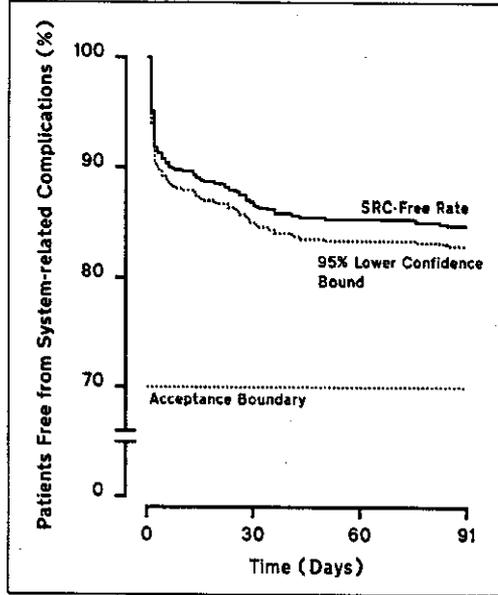


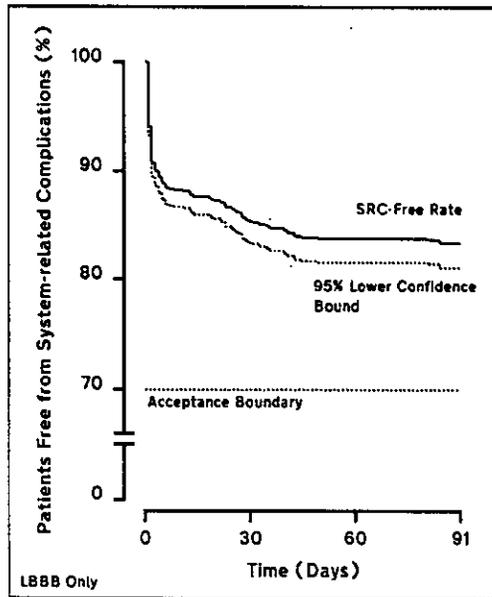
Table H-21. System-Related Complication-Free Summary Data - Full Patient Population

Statistic	Days from Implant		
	0-30 Days	31-60 Days	61-91 Days
Number at Risk at Start of Interval	1079	933	917
Number of Events in Interval	144	14	6
Cumulative Number of Events	144	158	164
Number Censored in Interval	2	2	0
Cumulative Number Censored	2	4	4
Percent Free from Event	86.6%	85.3%	84.8%
95% Lower Confidence Bound	84.8%	83.5%	82.9%

### Safety Endpoint - LBBB Patient Sub-Population

A total of 758 patients underwent an implant procedure. Of these, 126 unique patients experienced 169 system-related complications (SRC)s within 91 days post-implant. The CRT-D Kaplan-Meier system-related complication-free rate was 83.4% with a lower one-sided 95% confidence bound of 81.0%. This rate was statistically significantly greater than 70% and therefore passed the pre-specified safety endpoint. The supporting data are shown below.

Figure H-4. CRT-D Kaplan-Meier Curve of Time to System-Related Complication - LBBB Patient Sub-Population



**Table H-22. Summary of CRT-D Kaplan-Meier System-Related Complications (patients randomized, N=1820) - LBBB Patient Sub-Population**

Statistic	Days from Implant		
	0-30 Days	31-60 Days	61-91 Days
Number at Risk at Start of Interval	758	646	632
Number of Events in Interval	111	12	3
Cumulative Number of Events	111	123	126
Number Censored in Interval	1	2	0
Cumulative Number Censored	1	3	3
Percent Free from Event	85.4%	83.8%	83.4%
95% Lower Confidence Bound	83.1%	81.4%	81.0%

### Conclusion

The full patient population CRT-D system-related complication-free rate within 91 days post-implant was 84.8%, with a lower one-sided 95% confidence bound of 82.9%; this result was statistically significantly greater than the pre-specified boundary of 70%. The safety endpoint was met; thus, Boston Scientific CRT-D systems are safe in the MADIT-CRT full patient population.

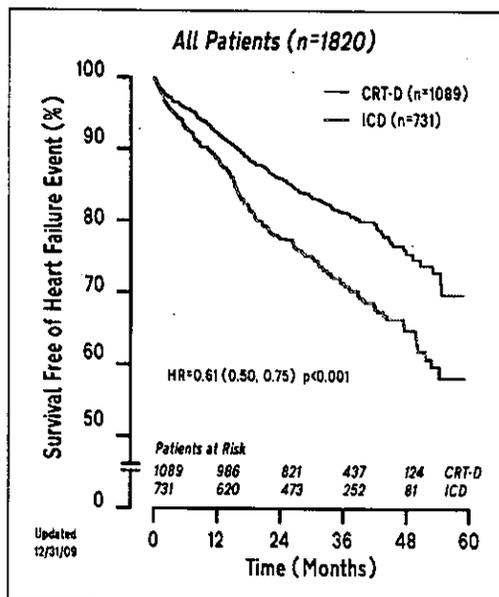
The LBBB patient sub-population CRT-D system-related complication-free rate observed within 91 days post-implant was 83.4%, with a lower one-sided 95% confidence bound of 81.0%; this result was statistically significantly greater than the pre-specified boundary of 70%. The safety endpoint was met; thus, Boston Scientific CRT-D systems are safe in the MADIT-CRT LBBB patient sub-population.

## Primary Effectiveness Endpoint

### Primary Effectiveness Endpoint - Full Patient Population

CRT-D was associated with a statistically significant reduction in the combined endpoint of all-cause mortality or HF event, whichever occurred first, when compared to ICD (adjusted log-rank  $p < 0.001$ ). The Kaplan-Meier curves demonstrate separation in the early months and continue to separate throughout the subsequent follow-up period as shown below. The adjusted hazard ratio was 0.61, with 95% confidence interval (0.50 to 0.75), and  $p < 0.001$ .

Figure H-5. Time to All-Cause Mortality or HF Event - Full Patient Population



The components of the primary effectiveness endpoint are shown below. A higher percentage of patients had a primary event in the ICD group as compared to the CRT-D group. The primary effectiveness endpoint was predominantly driven by a reduction in heart failure events with CRT-D.

Table H-23. Primary Effectiveness Endpoint Components - Full Patient Population

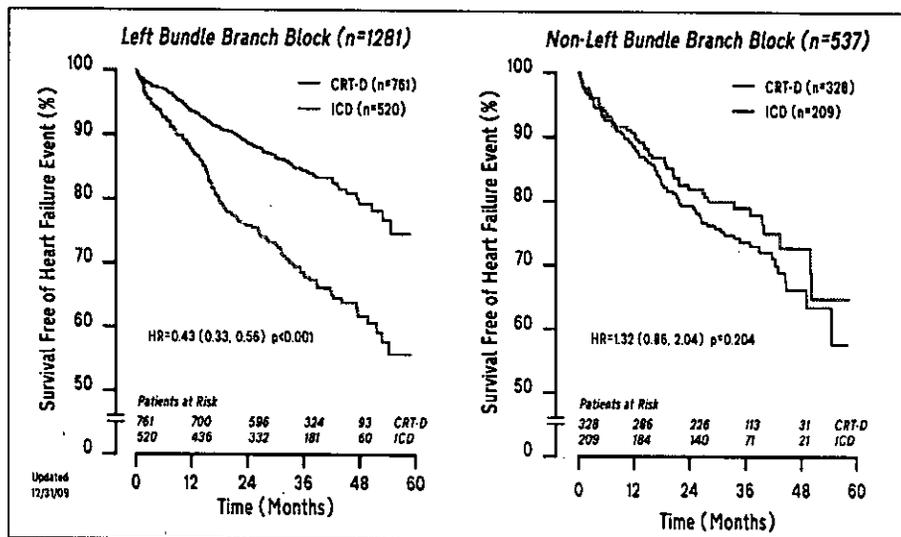
Item	Number of Patients (% of All Patients in Treatment Group)		Hazard Ratio (95% Confidence Interval)	P-value
	ICD (N=731)	CRT-D (N=1089)		
Patients with Primary Endpoint Event	208 (28%)	208 (19%)	0.61 (0.50, 0.75)	<.001
Patients with All-Cause Mortality at Any Time*	68 (9%)	92 (8%)	0.90 (0.64, 1.24)	0.509
Patients with HF Event	186 (25%)	161 (15%)	0.54 (0.43, 0.67)	<.001
Inpatient HF Event	155 (21%)	144 (13%)		
Outpatient HF Event	31 (4%)	17 (2%)		

\* This category includes all deaths, including those that occurred after the first heart-failure event.

### Primary Effectiveness Endpoint - LBBB Patient Sub-Population

CRT-D was associated with a statistically significant reduction in the combined endpoint of all-cause mortality or heart failure event, whichever occurred first, when compared to ICD (adjusted log-rank  $p < 0.001$ ). The Kaplan-Meier curves demonstrate separation in the early months and continue to separate throughout the subsequent follow-up period as shown below. The adjusted hazard ratio was 0.43, with 95% confidence interval (0.33 to 0.56), and  $p < 0.001$ .

Figure H-6. Time to All-Cause Mortality or HF Event - LBBB vs. non-LBBB Patient Sub-Population



A higher percentage of patients had a primary event in the ICD group as compared to the CRT-D group. The primary endpoint was predominantly driven by a reduction in heart failure events with CRT-D. The components of the primary effectiveness endpoint are shown below.

Table H-24. Primary Effectiveness Endpoint Components - LBBB Patient Sub-Population

Item	Number of Patients (% of All Patients in Treatment Group)		Hazard Ratio (95% Confidence Interval)	P-value
	ICD (N=520)	CRT-D (N=761)		
Patients with Primary End-point Event	162 (31%)	120 (16%)	0.43 (0.33, 0.56)	<.001
Patients with All-Cause Mortality at Any Time*	51 (10%)	54 (7%)	0.65 (0.42, 1.00)	0.044
Patients with HF Event	144 (28%)	89 (12%)	0.37 (0.28, 0.50)	<.001
Inpatient HF Event	116 (22%)	76 (10%)	---	---
Outpatient HF Event	28 (5%)	13 (2%)	---	---

\* This category includes all deaths, including those that occurred after the first heart-failure event.

Figure H-7. Time to First HF Event - LBBB vs. Non-LBBB Patient Sub-Populations

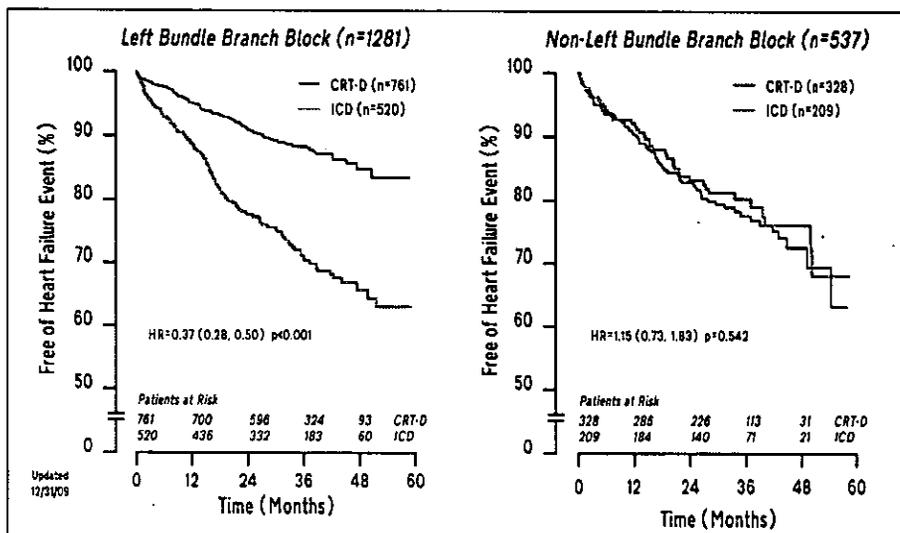
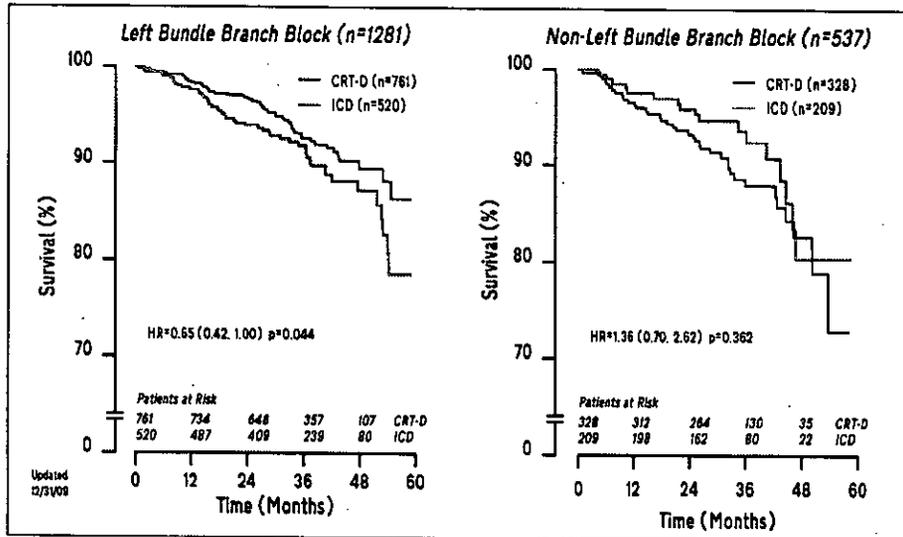


Figure H-8. Time to All-Cause Mortality - LBBB vs. Non-LBBB Patient Sub-Populations



### Conclusion

In the full patient population, CRT-D was associated with a statistically significant reduction in the relative risk of death or heart failure event as compared to ICD. However, there was no evidence of benefit in the non-LBBB patient sub-population as the results were predominately driven by the LBBB patient sub-population.

In the LBBB patient sub-population, CRT-D was associated with a statistically significant reduction in the relative risk of death or heart failure event by 57% as compared to ICD. The primary effectiveness endpoint was met by reducing the risk of all-cause mortality or heart failure event in the MADIT-CRT LBBB patient sub-population.

## Secondary Endpoint

### Secondary Endpoint - Full Patient Population

A summary of the number of all heart failure events experienced for all patients according to treatment group is presented below.

**Table H-25. Number of Heart Failure Events by Treatment Arm - Full Patient Population**

Number of HF Events	Number of Patients (% of All Patients in Treatment Group)	
	ICD (N=731)	CRT-D (N=1089)
0	545 (74.6%)	928 (85.2%)
1	107 (14.6%)	93 (8.5%)
2 +	79 (10.8%)	68 (6.2%)

Rates of heart failure events are presented two ways, separately for each treatment group: first as the count of heart failure events per 100 patients and second as the count of heart failure events per 100 patient-years of follow-up. Patients randomized to ICD experienced 50 HF events for every 100 patients and 17.1 HF events for every 100 patient-years of follow-up, whereas patients randomized to CRT-D experienced 27 HF events for every 100 patients and 9.5 HF events for every 100 patient-years of follow-up.

**Table H-26. Rate of All Heart Failure Events by Treatment Group - Full Patient Population**

Randomized Arm	Total HF Events	Total Follow-up (Years)	Total HF Events per 100 Patients	Total HF Events per 100 Patient-Years
ICD	365	2056.9	50	17.1
CRT-D	299	3137.7	27	9.5

The presence of dependent events was clearly seen in the Andersen-Gill regression analysis as shown below. The risk of experiencing a heart failure event was almost nine times greater if a previous event had occurred. A CRT-D benefit was still observed after accounting for the dependency of events. This corresponds with a

32% overall reduction in the risk of recurrent heart failure events, comparing CRT-D to ICD.

Table H-27. Andersen-Gill Recurrent HF Events Model - Full Patient Population

Covariate	Hazard Ratio		
	Estimate	95% Confidence Interval	P-Value
Treatment (CRT-D/ICD)	0.68	(0.54, 0.85)	<.001
Previous experienced HF event in study	8.91	(7.02, 11.30)	<.001

### Secondary Endpoint - LBBB Population

A summary of the number of all heart failure events experienced for all LBBB patients according to treatment group is presented below.

Table H-28. Number of Heart Failure Events by Treatment Arm - LBBB Patient Sub-Population

Number of HF Events	Number of Patients (% of All Patients in Treatment Group)	
	ICD (N=520)	CRT-D (N=761)
0	376 (72.3%)	672 (88.3%)
1	89 (17.1%)	51 (6.7%)
2 +	55 (10.6%)	38 (5.0%)

Rates of heart failure events are presented two ways, separately for each treatment group: first as the count of heart failure events per 100 patients and second as the count of heart failure events per 100 patient-years of follow-up. Patients randomized to ICD experienced 53 HF events for every 100 patients and 18.5 HF events for every 100 patient-years of follow-up, whereas patients randomized to CRT-D

experienced 22 HF events for every 100 patients and 7.5 HF events for every 100 patient-years of follow-up.

**Table H-29. Rate of all HF Events by Treatment Group - LBBB Patient Sub-Population**

Randomized Arm	Total HF Events	Total Follow-up (Years)	Total HF Events per 100 Patients	Total HF Events per 100 Patient-Years
ICD	274	1483.0	53	18.5
CRT-D	168	2237.1	22	7.5

The presence of dependent events was clearly seen in the Andersen-Gill regression analysis as shown below. The risk of experiencing a heart failure event was eight times greater if a previous event had occurred. A CRT-D benefit was still observed after accounting for the dependency of events.

**Table H-30. Andersen-Gill Recurrent HF Events Model - LBBB Patient Sub-Population**

Covariate	Hazard Ratio		
	Estimate	95% Confidence Interval	P-value
Treatment (CRT-D/ICD)	0.57	(0.41, 0.80)	0.001
Previously experienced HF event in study	8.33	(5.97, 11.64)	<.001

### Conclusion

In the full patient population, CRT-D was associated with a statistically significant reduction in the risk of recurrent heart failure events when compared to ICD. However, there was no evidence of benefit in the non-LBBB patient sub-population as the results were predominately driven by the LBBB patient sub-population.

In the LBBB patient sub-population, CRT-D was associated with a statistically significant reduction in the risk of recurrent heart failure events by 43% when compared to ICD. The secondary endpoint was met by reducing the occurrence of recurrent heart failure events in the MADIT-CRT LBBB patient sub-population over the course of the study.

## **Additional Sex Subgroup Analysis**

In MADIT-CRT, both men and women demonstrated significant improvement with CRT-D as compared to ICD. A significant interaction by treatment and sex was detected such that females received greater benefit. MADIT-CRT was not designed to analyze outcomes by sex; consequently these results should be considered to be exploratory.

The data were analyzed by sex for all patients and for the left bundle branch block (LBBB) patients for the safety endpoint, primary effectiveness endpoint, and the secondary effectiveness endpoint.

### **Safety Endpoint**

The safety endpoint was met for both sexes in the full patient population as well as in the LBBB subpopulation.

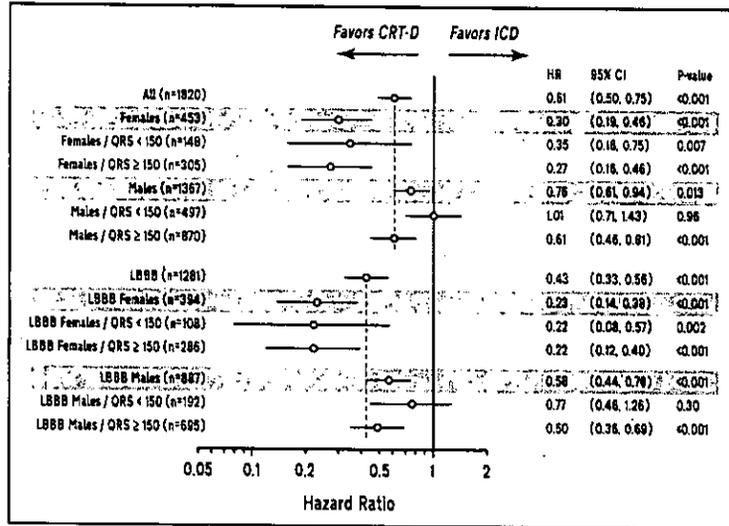
### **Primary Effectiveness Endpoint**

Both men and women experienced a CRT-D benefit; however, women received a greater benefit than men. Both men and women with LBBB experienced a greater benefit with CRT-D than patients without LBBB.

For both the full and the LBBB subpopulations, males with a wider QRS ( $\geq 150$  ms) had a greater risk reduction with CRT-D than males with a narrow QRS. Women

showed a more pronounced CRT-D benefit when compared to men, regardless of QRS width.

Figure H-9. Primary Effectiveness Stratified by Sex, LBBB Morphology and QRS Width



### Secondary Effectiveness Endpoint

In the both the full and LBBB subpopulations, CRT-D reduced the risk of recurrent heart failure events for both men and women; however the reduction was greater in women.

## Tertiary Endpoints - LBBB Patient Sub-Population

**NOTE:** *The following sections pertain to results obtained entirely within the LBBB sub-population alone.*

There were ten pre-specified tertiary endpoints for this trial and these results are presented below. These analyses are exploratory and the results should be considered suggestive and not definitive. Future studies would be needed to confirm these conclusions.

Core labs were utilized to reduce variability as well as evaluate and classify tertiary endpoint data specifically related to electrogram analysis and device interrogation, echocardiogram, QoL, BNP, and Holter.

### All-Cause Mortality - LBBB Patient Sub-Population

#### **Objective**

Evaluate the effects on CRT-D on all-cause mortality.

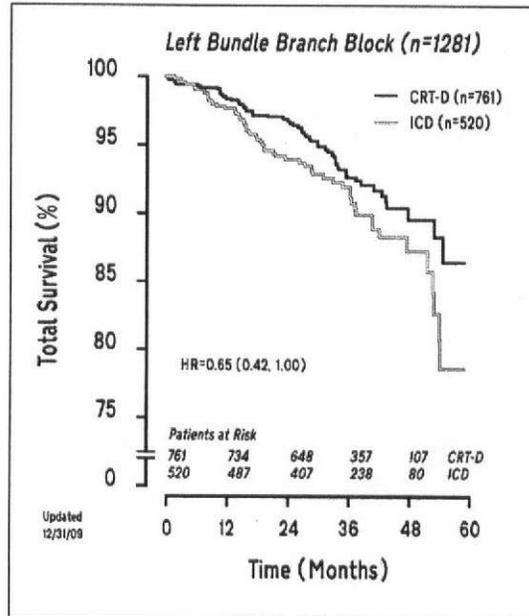
#### **Data Analysis**

Kaplan-Meier survival curves for the two treatment groups were generated and compared by the log-rank test. A proportional hazards regression analysis of time to death was fit, stratified by enrolling center and ischemic status, which provided an estimate of the hazard ratio for CRT-D relative to ICD and 95% confidence limits.

Death occurred in 7.1% (n=54) of the patients in the CRT-D group and 9.8% (n=51) of the patients in the ICD group. The hazard ratio for all-cause mortality was 0.65,

with a 95% confidence interval (0.42 to 1.00). These results indicated a similar all-cause mortality rate between the treatment groups.

Figure H-10. Kaplan-Meier Curves of Time to All-Cause Mortality - LBBB Patient Sub-Population



### Conclusion

Within the MADIT-CRT LBBB sub-population, CRT-D was associated with a reduction of 35% in the risk of all-cause mortality.

### Appropriate Defibrillator Therapy - LBBB Patient Sub-Population

#### Objective

Evaluate the effects of CRT-D on appropriate defibrillator therapy for ventricular tachycardia (VT) and ventricular fibrillation (VF).

#### Data Analysis

Cox proportional-hazards regression analysis was performed, comparing the CRT-D and ICD groups for time to first appropriate defibrillator therapy for VT, VF, and for

**H-50** | CLINICAL STUDY - MADIT-CRT  
STUDY RESULTS

either VT or VF. Similarly, an Andersen-Gill regression analysis with robust variance estimation was performed to account for recurrent events, comparing the mean rates of appropriate defibrillator therapy for VT, VF, and for either VT or VF between CRT-D and ICD groups. All patients were included in the analysis according to the intention-to-treat principle. Patients were censored at their date of death, withdrawal or last visit. Models were stratified by baseline ischemic status.

The frequencies of appropriate defibrillator therapy are shown below. Rates of tachyarrhythmias are calculated by the total number of events (VT, VF, and VT or VF) in the randomized group divided by the total follow-up years in the randomized group. Patients randomized to ICD experienced 49.6 VT events, 11.6 VF events, and 61.2 VT or VF events per 100 patient-years of follow-up; whereas patients randomized to CRT-D experienced 31.6 VT events, 2.0 VF events, and 33.7 VT or VF events per 100 patient-years of follow-up respectively.

**Table H-31. Appropriate Defibrillator Therapy - LBBB Patient Sub-Population ( N=1261 patients)**

Tachyarrhythmia	Randomized Arm	Total Events	Total Patients with Events	Total Patients	Total Follow-up (Years)	Total Events per 100 Patient-Years
VT	ICD	736	105	520	1483.0	49.6
	CRT-D	708	110	761	2237.1	31.6
VF	ICD	172	35	520	1483.0	11.6
	CRT-D	44	23	761	2237.1	2.0
VT or VF	ICD	908	120	520	1483.0	61.2
	CRT-D	753	124	761	2237.1	33.7

From the time-to-first event model shown below, CRT-D was associated with reductions in VT, VF, or combination of VT and VF of 33%, 57%, and 34% respectively.

**Table H-32. Appropriate Defibrillator Therapy (First Event Model) - LBBB Patient Sub-Population (N=1281)**

Outcome	Hazard Ratio	
	Estimate	95% Confidence Interval
VT	0.67	(0.51, 0.88)
VF	0.43	(0.25, 0.72)
VT or VF	0.66	(0.51, 0.85)

The results from the recurrent event model as shown below were consistent in magnitude with the first event model.

**Table H-33. Appropriate Defibrillator Therapy (Recurrent Event Model) - LBBB Patient Sub-Population (N=1281)**

Outcome	Hazard Ratio	
	Estimate	95% Confidence Interval
VT	0.77	(0.46, 1.29)
VF	0.38	(0.21, 0.69)
VT or VF	0.72	(0.45, 1.16)

**Conclusion**

When compared to ICD, CRT-D with the MADIT-CRT LBBB sub-population was associated with a reduction in the risk of ventricular tachyarrhythmias using a time to first event model. When using a recurrent events model, CRT-D was associated with reductions in VT, VF, or VT and VF combined.

## **Echocardiographic Volumes and Ejection Fraction - LBBB Patient Sub-Population**

### ***Objective***

Evaluate the effects of CRT-D, relative to ICD, on the changes from baseline to one year in echo-determined left ventricular internal volume at end-systole (LVESV) and at end-diastole (LVEDV). The changes from baseline to one year in left ventricular ejection fraction (LVEF) were also evaluated. CRT therapy was ON during echographic measurements and may have influenced the results.

### ***Data Analysis***

The changes from baseline to 12 months in LVESV, LVEDV, and LVEF were evaluated. This was done separately by linear regression models of change in the echo-determined outcome on treatment group, adjusting for the corresponding baseline value and baseline ischemic status. For the CRT-D group, only data from patients with CRT-D programmed on during the 12-month echo was included in the analysis.

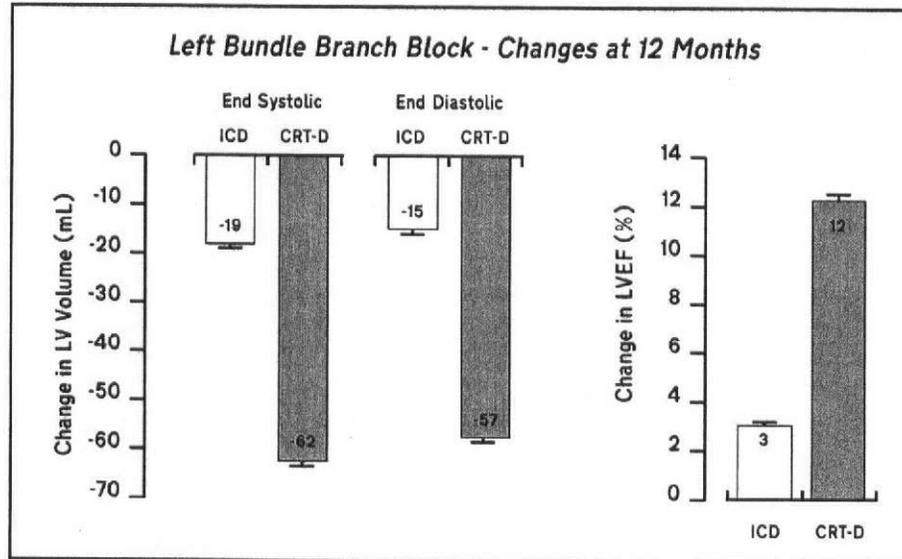
The echocardiographic volumes and EF at baseline and at 12 months are presented below. At 12 months, the mean change in LVESV in the CRT-D group was a reduction of 62 ml, as compared to 19 ml in the ICD group. Similarly, the mean change in LVEDV at 12 months in the CRT-D group was a reduction of 57 ml, as compared to 15 ml in the ICD group. Additionally, the mean change at 12 months in

LVEF in the CRT-D group was an increase of 12%, as compared to 3% in the ICD group.

Table H-34. Echocardiographic Parameters at 12 months - LBBB Patient Sub-Population

Variable	Measurement	ICD	CRT-D
Baseline LVESV (ml)	N	449	532
	Mean ± SD	183 ± 56	180 ± 47
	Range	94, 447	83, 411
Change in LVESV (ml) (12 months)	N	449	532
	Mean ± SD	-19 ± 17	-62 ± 31
	Range	-103, 41	-229, 164
Baseline LVEDV (ml)	N	449	532
	Mean ± SD	254 ± 70	252 ± 58
	Range	134, 571	149, 508
Change in LVEDV (ml) (12 months)	N	449	532
	Mean ± SD	-15 ± 15	-57 ± 34
	Range	-144, 31	-255, 144
Baseline LVEF (%)	N	449	532
	Mean ± SD	29 ± 3	29 ± 3
	Range	17, 40	19, 45
Change in LVEF (%) (12 months)	N	449	532
	Mean ± SD	3 ± 3	12 ± 5
	Range	-7, 14	-11, 30

Figure H-11. Echocardiographic Changes after 12 Months - LBBB Patient Sub-Population

**Conclusion**

CRT-D was associated with a reduction in left ventricular volumes and an increase in LVEF as compared to ICD. CRT therapy was ON during echographic measurements and may have influenced the results.

**New York Heart Association Class - LBBB Patient Sub-Population****Objective**

Evaluate the effects of CRT-D, relative to ICD, on the changes from baseline to one year in NYHA functional class. It was hypothesized that, at one year, the proportion of patients with symptomatic improvement would be greater with CRT-D when compared to ICD, after adjusting for any differences in baseline values.

**Data Analysis**

The change in NYHA class at 12 months (worsened, same, or improved from the baseline functional class) was compared between the CRT-D and ICD groups with chi-square tests. A lower NYHA class at 12 months is indicative of an improved status. Tests were performed for the following subgroups of patients: ischemic

NYHA class I, ischemic NYHA class II, and non-ischemic NYHA class II. These tests were performed at baseline with 1, 2 and 2 degrees of freedom respectively, and the three chi-square statistics were combined to perform an overall evaluation based on a five degree of freedom test. Additionally, all patients were compared for the change in NYHA class at 12 months combining the same and lower groups with a simple one degree of freedom test.

Overall, there were associations between treatment group and change in NYHA class based on the five degree of freedom test. For NYHA class I patients at baseline, there was not an association between NYHA functional class and treatment group. For NYHA class II patients at baseline, there was an association with a change in NYHA class for both the ischemic and non-ischemic subgroups. Combining the same and improved groups together also yielded an association between treatment group and change in NYHA class at 12 months, confirming analysis of all three change groups (same, worsened, improved).

Table H-35. NYHA Class Change (Worse/Same/Improved) at 12 Months - LBBB Patient Sub-Population

Group	ICD			CRT		
	Worse N (%)	Same N (%)	Improved N (%)	Worse N (%)	Same N (%)	Improved N (%)
Ischemic NYHA I	18 (32.1)	38 (67.9)	NA	25 (35.1)	48 (64.9)	NA
Ischemic NYHA II	12 (8.2)	105 (71.4)	30 (20.4)	9 (3.9)	114 (62.1)	79 (34.1)
Non-ischemic NYHA II	20 (7.6)	151 (57.2)	93 (35.2)	13 (3.2)	221 (54.7)	170 (42.1)

**Conclusion**

There was no evidence of an association between treatment group and improvement in NYHA at 12 months for the subgroup of patients who were NYHA I at baseline. However, there were associations between treatment group and improvement in NYHA class at 12 months in NYHA II patients, both overall and within the ischemic/non-ischemic patients. Thus, in the MADIT-CRT LBBB sub-population, CRT-D lowered NYHA class in the NYHA class II patients.

### **Quality of Life - LBBB Patient Sub-Population**

Quality of life was assessed with two tools, the EQ-5D questionnaire and the Kansas City cardiomyopathy questionnaire (KCCQ). EQ-5D, formerly known as EuroQol, is a generic assessment tool while KCCQ is specific to heart failure.

The EQ-5D assessment tool was used to describe and value patients' health related to mobility, self-care, usual activity, pain and discomfort, anxiety and depression, and overall health state. The range of the EQ-5D tool was from 0.0 (death) to 1.0 ("perfect health"), with 1.0 reflecting the best health state.

The KCCQ is an assessment tool for monitoring the physical function, symptoms (frequency, severity and recent change), social function, self-efficacy and knowledge, and quality of life for patients with congestive heart failure. The quality of life sub-scale was based on how much heart failure has limited the patient's enjoyment of life, how the patient would feel about spending the rest of his/her life at his/her current status of heart failure, and the extent the patient has felt discouraged because of his/her heart failure. The KCCQ clinical summary score incorporates physical functioning, symptom frequency, and symptom burden. The KCCQ overall summary score is based on physical and social functioning, including reported frequency and burden of heart failure symptoms like swelling, fatigue, and shortness of breath. The range of the KCCQ tool was from zero to 100, with 100 reflecting the best health state.

#### ***Objective***

Evaluate the effects of CRT-D, relative to ICD, on the changes in quality of life at 12 months and within the full study period. It was hypothesized that the assessed quality of life of the CRT-D group would, on average, exceed that in the ICD group.

#### ***Data Analysis***

Each quality of life assessment tool was evaluated separately using a linear regression model of the change in the quality of life measure on treatment arm, adjusting for the corresponding baseline value and baseline ischemic status. Analyses were performed for the outcome of change from baseline to 12 months, and again for the outcome of change from baseline to the last measured quality of life. For the latter, the time from baseline was added as an additional covariate. Analyses for the KCCQ and the EQ-5D tools were performed based on all observed data. Two additional EQ-5D analyses were performed; the first assigned patients

who died before 12 months scores of zero, and the second assigned patients who died before their last follow-up visit scores of zero.

Although the differences in EQ-5D summary utility score at 12 months and the last follow-up visit for each treatment group approaches or achieved statistical significance as shown below (Table H-36), the magnitude of changes is only modest.

Table H-36. EQ-5D Summary Utility Score - LBBB Patient Sub-Population

Variable	Measurement	ICD	CRT-D
Change in EQ-5D (12 Months)	N	464	715
	Mean ± SD	0.02 ± 0.13	0.04 ± 0.14
	Range	-0.57 , 0.53	-0.60 , 0.75
Change in EQ-5D (12 Months)\nDeaths as zero	N	476	726
	Mean ± SD	0.00 ± 0.18	0.02 ± 0.18
	Range	-1.00 , 0.53	-1.00 , 0.75
Change in EQ-5D (Last Visit)	N	493	738
	Mean ± SD	0.01 ± 0.15	0.03 ± 0.16
	Range	-0.62 , 0.53	-0.70 , 0.81
Change in EQ-5D (Last Visit)\nDeaths as zero	N	498	745
	Mean ± SD	-0.07 ± 0.28	-0.03 ± 0.28
	Range	-1.00 , 0.53	-1.00 , 0.81

The mean change in the KCCQ quality of life score at 12 months was 14.7 for the CRT-D group and 12.6 for the ICD group. The mean change in the KCCQ quality of

life score at the last observed measurement was 14.8 for the CRT-D group and 10.6 for the ICD group. All results are provided below (Table H-37).

**Table H-37. KCCQ Quality of Life Score - LBBB Patient Sub-Population**

Variable	Measurement	ICD	CRT-D
Change in KCCQ Quality of Life (12 Months)	N	463	715
	Mean ± SD	12.6 ± 22.7	14.7 ± 22.9
	Range	-58.3 , 100.0	-58.3 , 91.7
Change in KCCQ Quality of Life (Last Visit)	N	516	757
	Mean ± SD	10.6 ± 24.5	14.8 ± 24.3
	Range	-83.3 , 83.3	-100 , 91.7

The mean change in the KCCQ clinical summary score at 12 months was 5.0 for the CRT-D group and 3.3 for the ICD group. The mean change in the KCCQ clinical summary score at the last observed measurement was 3.4 for the CRT-D group and 1.3 for the ICD group. All results are provided below (Table H-38).

**Table H-38. KCCQ Clinical Summary Score - LBBB Patient Sub-Population**

Variable	Measurement	ICD	CRT-D
Change in KCCQ Clinical Summary Score (12 Months)	N	464	716
	Mean ± SD	3.3 ± 15.9	5.0 ± 15.6
	Range	-52.4 , 76.0	-65.6 , 59.9
Change in KCCQ Clinical Summary Score (Last Visit)	N	516	759
	Mean ± SD	1.3 ± 17.6	3.4 ± 17.1
	Range	-79.2 , 71.4	-87.0 , 65.1

The mean change in the KCCQ overall summary score at 12 months was 8.1 for the CRT-D group and 6.7 for the ICD group. The mean change in the KCCQ overall

summary score at the last observed measurement was 7.1 for the CRT-D group and 4.1 for the ICD group. All results are provided below (Table H-39).

**Table H-39. KCCQ Overall Summary Score - LBBB Patient Sub-Population**

Variable	Measurement	ICD	CRT-D
Change in KCCQ Overall Summary Score (12 Months)	N	464	716
	Mean ± SD	6.7 ± 16.8	8.1 ± 16.5
	Range	-50.0 , 72.7	-59.9 , 64.8
Change in KCCQ Overall Summary Score (Last Visit)	N	516	759
	Mean ± SD	4.1 ± 18.4	7.1 ± 18.6
	Range	-70.8 , 76.8	-83.1 , 64.8

**Conclusion**

Within the MADIT-CRT LBBB sub-population, improvements in quality of life as measured by the KCCQ and ED-5D assessment tools were observed with CRT-D when compared to ICD. However, the magnitude of these changes was modest, given that the patient population selected had relatively good quality of life scores at study entry.

**Mitral Regurgitation - LBBB Patient Sub-Population**

**Objective**

Evaluate the degree of mitral regurgitation by echocardiographic/Doppler technique between the treatment groups at 12 months.

**Data Analysis**

Color flow Doppler was obtained from the apical four-chamber view to assess mitral regurgitation. Mitral regurgitation was graded by severity on a scale from zero to three according to the standard by the American Society of Echocardiography<sup>3</sup> on a subset of patients with quality echocardiograms. The difference between groups in the change in MR severity was assessed with a general linear model.

3. Thomas L, Foster E, Hoffman J, et al. The mitral regurgitation index: an echocardiographic guide to severity. J Am Coll Cardiol, 1999; 33:2016-2022.

The distribution of the change in mitral regurgitation severity at 12 months was similar in both treatment groups, with the majority of all patients having no change. All results are provided below

**Table H-40. Mitral Regurgitation Severity at 12 months - LBBB Patient Sub-Population**

Variable	Measurement	ICD	CRT-D
Baseline MR Grade	N	79	183
	Mean ± SD	1.13 ± 0.46	1.15 ± 0.45
	Range	0.00 , 3.00	0.00 , 3.00
Change in MR Grade (12 Months)	N	79	183
	Mean ± SD	-0.03 ± 0.45	-0.15 ± 0.47
	Range	-2.00 , 1.00	-2.00 , 1.00

**Conclusion**

Although there was a difference between treatment groups in the change in mitral regurgitation score from baseline to 12 months in the MADIT-CRT LBBB sub-population, this change was not clinically meaningful.

**Functional Capacity - LBBB Patient Sub-Population**

**Objective**

Evaluate whether functional capacity (as measured by distance achieved during a six-minute hall walk (6 MHW)) at the 12-month follow-up was greater in the CRT-D group than in the ICD group.

**Data Analysis**

Functional capacity was assessed by analyzing the distance walked from the six-minute hall walk test. This was evaluated by a linear regression model of the change in the distance walked at 12 months on treatment group, adjusting for the baseline distance walked and baseline ischemic status.

The mean change in the distance walked at 12 months was 14 meters for the CRT-D group and 10 meters for the ICD group. All results are provided below.

**Table H-41. Functional Capacity Changes at 12 Months - LBBB Patient Sub-Population**

Variable	Measurement	ICD	CRT-D
Baseline 6 MHW	N	425	684
	Mean ± SD	369 ± 101	369 ± 103
	Range	36 , 731	76 , 744
Change in 6 MHW (12 Months)	N	425	684
	Mean ± SD	10 ± 85	14 ± 96
	Range	-341 , 300	-381 , 540

**Conclusion**

There was no evidence of an association between treatment group and change in functional capacity at 12 months in the MADIT-CRT LBBB sub-population.

**Association of Brain Natriuretic Peptide and Outcome - LBBB Patient Sub-Population**

**Objective**

Evaluate the association between the level of brain natriuretic peptide (BNP) at baseline and outcome (all-cause mortality or heart failure event) in patients randomized to CRT-D.

**Data Analysis**

A Cox proportional hazards model was fit for the primary effectiveness endpoint. A log10 transformed BNP was used as a continuous covariate and only CRT-D patients from US centers were included in this analysis.

The hazard ratio for the association of baseline log<sub>10</sub> BNP and outcome was 2.44 as shown below, indicating that patients with a one unit higher baseline log<sub>10</sub> BNP were at almost a 2.5-fold increased risk of having a heart failure event or death.

Table H-42. Association between BNP and Outcome in CRT-D Patients - LBBB Patient Sub-Population

Outcome	Hazard Ratio (per unit log BNP)	95% Confidence Interval
All-cause mortality or HF event	2.44	(1.55, 3.82)

**Conclusion**

In the CRT-D group there was an association between higher values of baseline log<sub>10</sub> BNP and the risk of having a heart failure event or death. Thus, in the MADIT-CRT LBBB sub-population, there was an association in baseline BNP and outcome with CRT-D.

**Brain Natriuretic Peptide - LBBB Patient Sub-Population**

**Objective**

Evaluate whether the level of brain natriuretic peptide (BNP) at the 12-month follow-up visit was lower in the CRT-D group than in the ICD group.

**Data Analysis**

The changes in BNP from baseline to 12 months were evaluated by a linear regression model of the change on treatment group, adjusting for the corresponding baseline value and baseline ischemic status. To account for the skewed BNP distribution, log base 10 transformations were used on the raw BNP values. The changes in log<sub>10</sub> BNP from baseline to 12 months was evaluated by a linear regression model of the change on treatment group, adjusting for the corresponding log<sub>10</sub> baseline value and baseline ischemic status. Only CRT-D patients from US centers were included in this analysis.

The mean change in BNP was -32 for the CRT-D group and +6 in the ICD group. Results were consistent when log transformed BNP was analyzed to account for the skewed distribution and are provided below.

**Table H-43. BNP Changes at 12 Months - LBBB Patient Sub-Population**

Variable	Measurement	ICD	CRT-D
Baseline BNP	N	254	405
	Mean ± SD	102.2 ± 125.9	121.4 ± 160.6
	Range	1.00, 709.0	1.00, 1401
Change in BNP	N	254	405
	Mean ± SD	5.67 ± 216.1	-31.9 ± 158.1
	Range	-708, 2404	-916, 893.0
Baseline Log (BNP)	N	254	405
	Mean ± SD	1.70 ± 0.59	1.76 ± 0.60
	Range	0.00, 2.85	0.00, 3.15
Change in Log (BNP) (12 Months)	N	254	405
	Mean ± SD	-0.13 ± 0.75	-0.34 ± 0.69
	Range	-2.85, 2.44	-2.96, 1.24

**Conclusion**

The CRT-D group had a larger reduction in BNP than the ICD group. Thus, in the MADIT-CRT LBBB sub-population, CRT-D was associated with lower BNP at 12 months.

### Holter Recorded Non-Invasive Electrocardiographic Parameters and Hemodynamic Benefit - LBBB Patient Sub-Population

#### Objective

Evaluate whether Holter-recorded non-invasive electrocardiographic parameters can identify patients with increased hemodynamic benefit in CRT responders and non-responders.

#### Data Analysis

A decrease of 20 or more milliliters (ml) in LVEDV at 12 months was the pre-specified definition of a CRT responder, indicating hemodynamic improvement. The association of baseline Holter-recorded non-invasive electrocardiographic parameters (QRS duration) among CRT-D patients was assessed via logistic regression modeling.

All results are provided below. In patients with a reduction of 20 ml or more in LVEDV at 12 months, their baseline QRS duration was associated with a hemodynamic benefit. Every ten millisecond increase in baseline QRS duration corresponded to a 34% greater odds of having a reduction of 20 ml or more in LVEDV.

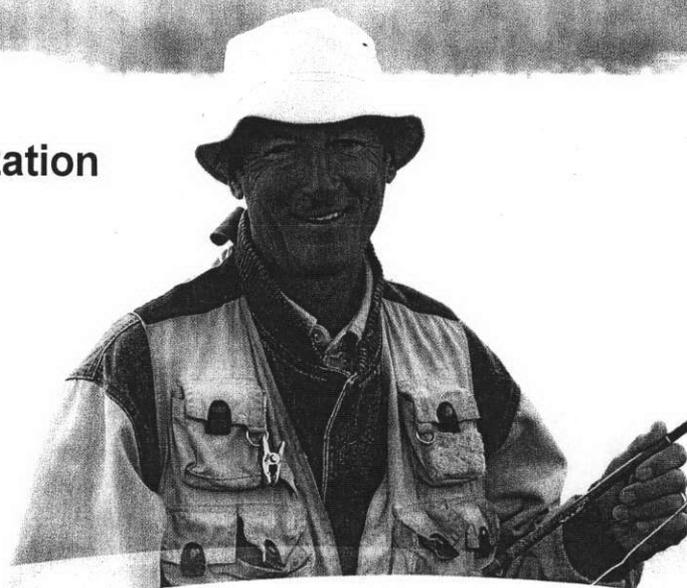
Table H-44. Association between Holter Recorded Baseline QRS duration and Hemodynamic Benefit - LBBB Patient Sub-Population

Predictor	Odds Ratio for LVEDV Responder (per 10 ms Higher QRS)	95% Confidence Interval
QRS duration	1.34	(1.14, 1.58)

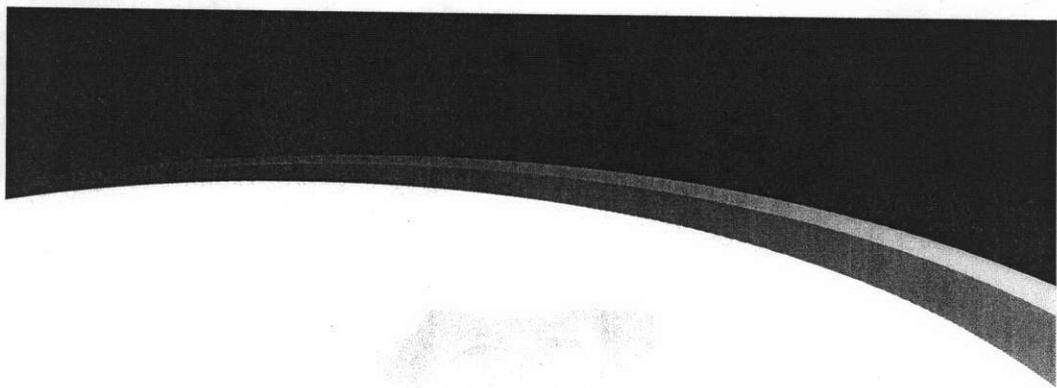
#### Conclusion

In the MADIT-CRT LBBB sub-population, baseline QRS duration was a predictor of CRT-D benefit as defined by a reduction in LVEDV of 20 ml or more.

**Cardiac  
Resynchronization  
Therapy  
Defibrillator**



**Boston  
Scientific**



## A Message to Patients

*Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient materials. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.*

## Your CRT-D system information

Have your doctor or nurse complete these forms before you go home from the hospital.

CRT-D Model Number: \_\_\_\_\_

CRT-D Serial Number: \_\_\_\_\_

CRT-D Features:  RF telemetry  LATITUDE

Implant Date: \_\_\_\_\_

Lead Model/Serial Numbers: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Your medical contact information

Electrophysiologist Name/Phone Number:

---

Cardiologist Name/Phone Number:

---

Hospital Name/Address/Phone Number:

---

---

Medications (list):

---

---

---

**By Mail:**

Boston Scientific  
4100 Hamline Avenue North  
St. Paul, Minnesota 55112-5798

**By Telephone:**

Patients and families: 1.866.484.3268  
Medical professionals: 1.800.CARDIAC (227.3422)  
Worldwide: 1.651.582.4000

**On the Internet:**

[www.bostonscientific.com](http://www.bostonscientific.com)

**By E-mail:**

[customercare@bsci.com](mailto:customercare@bsci.com)

**Medical Records:**

1.800.PATDATA (1.800.728.3282)  
7 a.m.–7 p.m. (Central Time), Monday–Friday  
e-mail: [medical.records@bsci.com](mailto:medical.records@bsci.com)

## Table of contents

<b>Introduction</b> .....	<b>1</b>
When is this device used?,	3
How reliable is this device?,	4
<b>Glossary</b> .....	<b>6</b>
<b>Your heart's natural pacemaker</b> .....	<b>24</b>
Heart failure,	26
Heart failure, arrhythmias, and your device,	30
Ventricular tachycardia,	32
Ventricular fibrillation,	34
Bradycardia,	36

<b>Sudden cardiac arrest</b> .....	<b>39</b>
Risk factors, 40	
Identifying your SCA risk, 41	
<b>Your CRT-D system</b> .....	<b>44</b>
The device, 44	
The leads, 46	
<b>Implanting your CRT-D system</b> .....	<b>47</b>
Implant risks, 50	
<b>After your implant</b> .....	<b>55</b>
Medications, 57	
Activities and exercise, 58	
Your CRT-D system information, 58	
Your identification card, 59	

<b>Living with your CRT-D.....</b>	<b>61</b>
Preparing for CRT-D shock therapy,	63
How therapy feels,	67
Special considerations,	70
Replacing your system,	80
<b>Important safety information.....</b>	<b>83</b>
Operating household appliances and tools,	83
Theft detection systems,	92
Airport security,	93
Cellular phones,	94
Dental and medical procedures,	96
<b>Summary.....</b>	<b>102</b>

<b>Visit us on the Internet .....</b>	<b>104</b>
<b>Notes and questions .....</b>	<b>105</b>
<b>Symbols on Packaging .....</b>	<b>107</b>
<b>Index .....</b>	<b>108</b>

## Introduction

Your doctor has determined that you have a form of heart failure—a medical condition in which your heart muscle is unable to pump enough blood to meet your body's needs. To treat your condition, your doctor has recommended an implantable cardioverter defibrillator (ICD) system with heart failure therapy.

Your doctor may also call this ICD system a cardiac resynchronization therapy defibrillator (CRT-D) system. A CRT-D system is designed to monitor and treat heart rhythm problems, greatly reducing the risks associated

with them. It is also designed to help your heart pump more effectively to meet your body's need for blood flow.

This handbook will tell you how a CRT-D system treats heart rhythms that are too fast and/or too slow. It will discuss activities you can begin and those you should avoid after your surgery. It will talk about some of the changes that may occur in your life. It will also answer many questions patients typically have. If you have questions about what you read in this handbook, ask your doctor or nurse. They are your best resource for information.

The glossary is located at the front of the handbook. It defines many of the words you will see in the upcoming

pages, as well as those you may hear from your doctors and nurses.

### **When is this device used?**

Your doctor has decided that you should receive a defibrillator with heart failure therapy because you have an increased risk of sudden cardiac death due to ventricular rhythm disturbances. Sudden cardiac death is a result of sudden cardiac arrest, which occurs when electrical problems in the heart cause a dangerously fast and irregular heart rhythm. Heart failure is a condition in which the heart cannot pump enough blood to meet your body's needs. Patients whose heart failure is not treated with drug therapy

should not receive this device. Also, you may or may not have heart failure symptoms despite drug therapy. If you have any questions about when this device is used, ask your doctor.

### **How reliable is this device?**

It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. Refer to Boston Scientific's *CRM Product Performance Report* on [www.bostonscientific.com](http://www.bostonscientific.com) for more information about device performance, including the types and rates of malfunctions that these devices have

experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products. Talk with your doctor about this product performance data, and the risks and benefits associated with the implantation of this system.

## Glossary

### **Adaptive rate**

The ability of a device to increase or decrease its pacing rate in response to bodily needs, activity, or exercise.

### **Antitachycardia pacing (ATP)**

A series of small, rapid, low-energy pacing pulses delivered to the heart to slow a rapid heartbeat to its normal rhythm.

### **Arrhythmia**

An abnormal heartbeat that is too fast, too slow, or irregular.

**Asynchrony**

A condition in which the heart fails to maintain a normal timing sequence between atrial and ventricular contractions.

**Atrioventricular (AV) node**

A cluster of cells located in the wall between the right and left atrium, just above the ventricles. This part of the heart's electrical pathway helps carry signals from the atria to the ventricles.

**Atrioventricular (AV) synchrony**

The normal timing sequence for an atrial contraction followed, after a fraction of a second, by a ventricular contraction.

**Atrium (plural: atria)**

One of the two upper chambers of the heart—specifically, the right atrium and left atrium. The atria collect blood as it comes into the heart and pump blood into the lower chambers (ventricles).

**Bradycardia**

An abnormally slow heartbeat, typically fewer than 60 beats per minute.

**Cardiac arrest**

See *sudden cardiac arrest (SCA)*.

**Cardiac resynchronization therapy**

Therapy administered by the device that coordinates the ventricles to help them contract at the same time, allowing the heart to pump more effectively.

**Cardiac resynchronization therapy  
defibrillator (CRT-D) system**

A device (also called a pulse generator) and leads. A CRT-D system is implanted to treat a condition called heart failure. It helps the heart pump more effectively to meet the body's need for blood flow by coordinating the left and right ventricular contractions. A CRT-D system can also function as a defibrillator by delivering an electrical shock to the heart to restore an extremely rapid and irregular heart rate to a normal rhythm. See also *defibrillator* and *heart failure*.

**Cardioversion**

Procedure in which a fast heart rate (i.e., ventricular tachycardia) is restored to a normal rhythm with a low- to moderate-energy electrical shock that is carefully timed with your heartbeat.

**Catheter**

A thin, flexible tube or wire inserted into the body for a variety of purposes. Catheters are inserted into the heart during an electrophysiology (EP) test to monitor your heart's electrical activity. Hollow catheters are also used to carry a lead through a blood vessel. See also *electrophysiology (EP) test or study*.

**Communicator**

See *LATITUDE® Communicator*.

**Defibrillation**

Procedure in which a fast heart rate (i.e., ventricular fibrillation) is restored to a normal rhythm by delivering an electrical shock.

**Defibrillator**

A device that delivers an electrical shock to the heart to restore an extremely rapid and irregular heart rate to a normal rhythm. A defibrillator may be an implanted medical device or external medical equipment.

**Defibrillator with heart failure therapy**

*See cardiac resynchronization therapy defibrillator (CRT-D) system.*

**Device**

*See pulse generator.*

**ECG/EKG (electrocardiogram)**

A graphic representation of your heart's electrical signals. The graph shows how electrical signals travel through your heart. Your doctor can tell what

kind of rhythm you have by looking at the pattern of your heartbeat.

**Ejection fraction**

The percentage of blood ejected from the left ventricle with each heartbeat. A healthy ejection fraction is usually higher than 55%, although this can vary depending on the individual. Patients with a low ejection fraction may have an increased risk of sudden cardiac arrest. Talk with your doctor about your ejection fraction and what impact it has on your health.

**Electromagnetic field**

Invisible lines of force that result from electrical fields (produced by voltage) and magnetic fields (produced by current flow). Electromagnetic fields decrease in strength the farther they are from their source.

**Electromagnetic interference (EMI)**

Interference that occurs when an implanted device interacts with an electromagnetic field. See also *electromagnetic field*.

**Electrophysiology (EP) test or study**

A test in which catheters (thin, flexible tubes or wires) are inserted into your heart to identify and measure the type of electrical signals in your heart. The test results can help your doctor identify the origins of your abnormal heart rhythms, determine how well medications work, and decide what treatment is best for your condition. The test can also be used to see how well your device operates during your abnormal heart rhythm.

**Fibrillation**

See *ventricular fibrillation*.

**Heart attack**

See *myocardial infarction (MI)*.

**Heart block**

A condition in which the electrical signals of your heart's natural pacemaker (SA node) are delayed or do not reach the ventricles.

**Heart failure**

A medical condition in which the heart muscle is unable to pump enough blood to meet the body's needs.

**Heart rhythm**

A series of heartbeats. You may hear your doctor refer to your rhythm as being normal or irregular. A normal heart rate typically ranges from 60 to 100 beats per minute at rest.

**Implantable Cardioverter Defibrillator (ICD) system**

See *defibrillator*.

**Interrogation**

The process whereby a computerized device (programmer or LATITUDE Communicator) uses telemetry communication signals to gather identification and status information from your device. Your doctor uses this information to evaluate how your device is performing and check for any arrhythmia episodes you may have had. See also *telemetry communication*.

**LATITUDE Communicator**

An in-home monitoring system that communicates with your device. The Communicator can gather and send device data to the LATITUDE Patient Management System, which your physician can then view via the Internet. Your device may or may not be configured to use the LATITUDE Patient Management System. See also *LATITUDE Patient Management System*.

**LATITUDE Patient Management System**

A remote monitoring system that collects important data from your device. This patient information can be viewed via the Internet, only by members of your health care support team. Your device may or may not be configured to use the LATITUDE Patient Management System. See also *LATITUDE Communicator*.

**Lead (pronounced "leed")**

An insulated wire that is implanted in the heart and connected to the device. The lead senses your heartbeat and delivers pacing pulses and/or shocks from the device to the heart. The leads are usually passed into your heart through a vein.

**Myocardial infarction (MI)**

Also called a heart attack. A myocardial infarction occurs when an artery that supplies blood to the heart becomes blocked. As a result, blood does not reach some parts of the heart, and some of the heart tissue dies. Symptoms of a myocardial infarction may include pain in the chest, arm, or neck; nausea; fatigue; and/or shortness of breath.

**Pectoral**

The area above the breast and below the collarbone. This is a common area for a device implant.

**Programmer**

Microcomputer-based equipment that is used to communicate with the device. The programmer is used during testing and follow-up exams to gather and display information from the device. The doctor or technician also uses the programmer to adjust the device so that it senses and treats your arrhythmias.

**Pulse generator**

Also called a device. The pulse generator is the part of the CRT-D system that contains the electronics and the battery; it is implanted under the skin in the pectoral (or, in some cases, abdominal) area. See also *pectoral*.

**Radio frequency (RF) telemetry communication**

Technology that allows the device to exchange information with a programmer or LATITUDE Communicator by communicating over radio signals. RF telemetry is sometimes referred to as ZIP™ Wandless Telemetry. Your device may or may not be configured for RF telemetry communication. See also *telemetry communication*.

**Sinoatrial (SA) node**

The heart's natural pacemaker. The SA node is a small group of specialized cells in the upper right chamber of the heart (right atrium) that normally generates an electrical signal. This signal runs through the heart and causes the heart to beat.

**Sudden cardiac arrest (SCA)**

The sudden, abrupt loss of heart function (i.e., cardiac arrest) usually due to electrical problems in the heart that cause a dangerously fast and irregular heart rhythm. If untreated, SCA can lead to death (also called sudden cardiac death).

**Sudden cardiac death (SCD)**

Death occurring from sudden cardiac arrest. See also *sudden cardiac arrest (SCA)*.

**Telemetry communication**

Technology that allows a device to exchange information with a programmer or LATITUDE Communicator by using ZIP Wandless Telemetry

or wanded telemetry communication. See also *radio frequency (RF) telemetry communication* and *wanded telemetry communication*.

**Ventricle**

One of two lower chambers of the heart. The right ventricle pumps blood to the lungs, and the left ventricle pumps oxygen-carrying blood from the lungs to the rest of the body.

**Ventricular dyssynchrony**

A condition in which the heart fails to maintain a normal timing sequence between the contractions of the left and right ventricles.

**Ventricular fibrillation (VF)**

A very fast, irregular heart rhythm caused by abnormal electrical signals starting from several areas of the ventricle. The ventricle beats so fast that it pumps very little blood to the body. A heart in VF may beat more than 300 beats per minute. Without immediate medical attention, VF can be fatal. Defibrillation is the only way to treat VF once it occurs.

**Ventricular tachycardia (VT)**

A fast rhythm caused by abnormal electrical signals coming from the ventricle. The rapid rate of 120 to 250 beats per minute may produce dizziness, weakness, blind spots, and eventual unconsciousness. VT may progress to ventricular fibrillation.

**Wanded telemetry communication**

Technology that allows a device to exchange information with a programmer or LATITUDE Communicator through a wand that is placed over the skin near the device. See also *telemetry communication*.

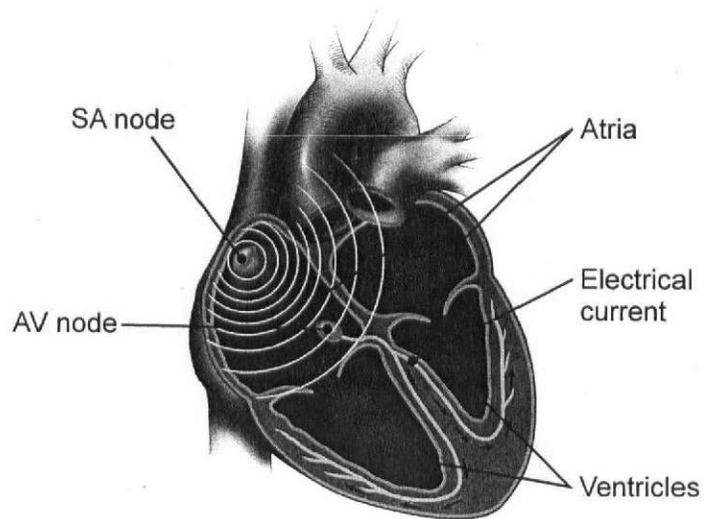
**ZIP™ Wandless Telemetry**

See *radio frequency (RF) telemetry communication*.

## Your heart's natural pacemaker

Your heart works as both a mechanical pump and an electrical organ. It is able to beat because it produces electrical signals. These signals travel through the electrical pathways of your heart (Figure 1), causing the muscle contraction that pumps blood throughout your body.

Normally these signals come from a small area in your heart called the sinoatrial (SA) node. This area is located in the upper right chamber, or right atrium. When the SA node signals the two upper chambers



**Figure 1. The heart and its electrical pathways.**

of the heart (the atria), they contract at the same time. The atrial contraction fills the two lower chambers (the ventricles) with blood (Figure 2). As the electrical signal travels through the ventricles, it causes them to contract, which pumps blood out to your body. The contraction of the heart muscle (ventricles) is what you feel as a heartbeat. After a brief rest, the cycle begins again.

### **Heart failure**

The heart may begin to fail for a variety of reasons. One reason may be a result of muscular damage from a heart attack. The heart can also be weakened

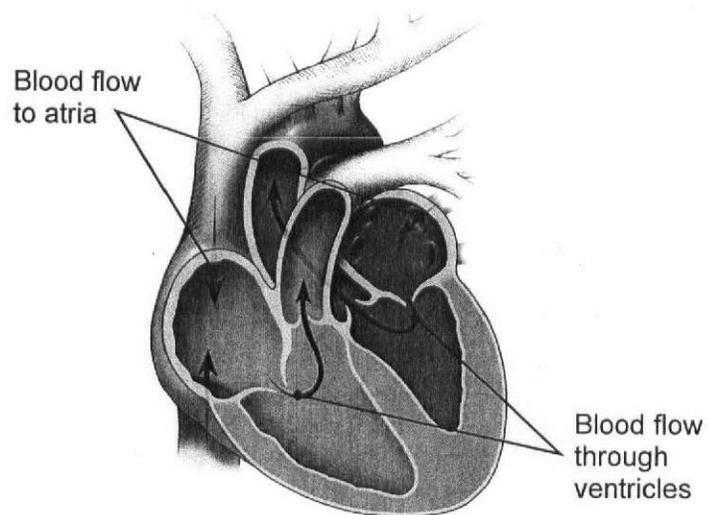


Figure 2. The heart and its blood flow.

from prolonged periods of pumping against high blood pressure in the arteries.

Over time, the heart muscle weakens and becomes enlarged (Figure 3). The ventricles are unable to contract with the same strength or coordination as before. As a result, the flow of blood and oxygen to the body is poor.

This failure of the heart to pump efficiently and meet the body's need for blood and oxygen is known as heart failure. When you have heart failure, you may feel short of breath, tired, or light-headed, or you may faint. Medications are often used to treat heart failure

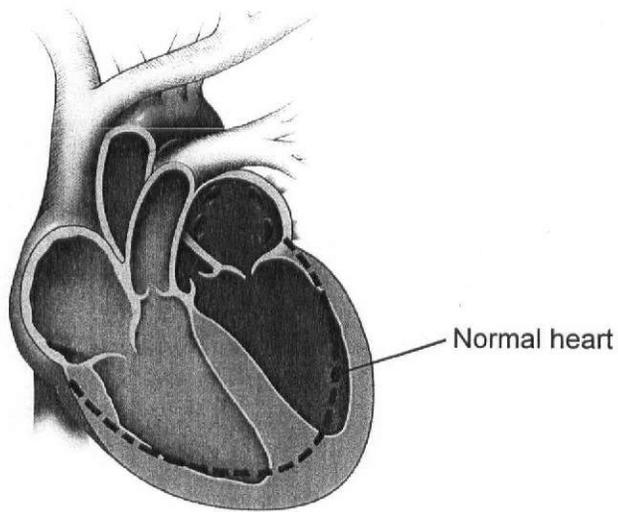


Figure 3. An example of an enlarged heart due to heart failure.

and its symptoms. However, some people may also need a CRT-D system to help the heart beat more efficiently again.

### **Heart failure, arrhythmias, and your device**

People with heart failure may also experience abnormal, irregular heartbeats called arrhythmias. An arrhythmia occurs when something goes wrong in the heart's electrical system. If the arrhythmia continues, it may prevent the heart from pumping enough blood throughout your body.

### **What your device does**

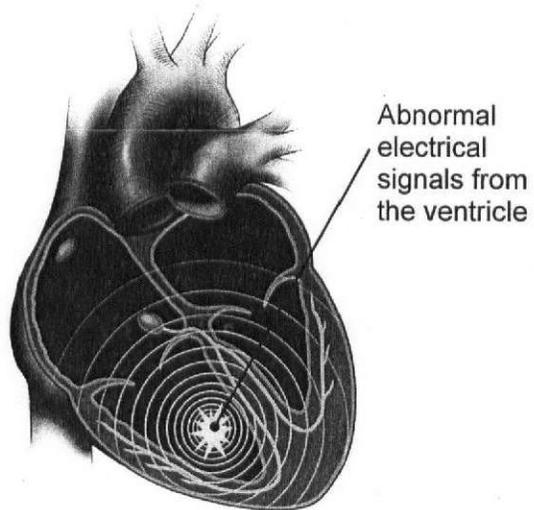
Your device is designed to monitor and treat certain rhythm problems and greatly reduce the risks associated with them.

Several types of arrhythmias are described in the following paragraphs. Ask your doctor which of these arrhythmias you may experience, and consider recording this information in the "Notes and questions" space on page 105.

### **Ventricular tachycardia**

One type of arrhythmia you may experience is ventricular tachycardia (VT). With this type of arrhythmia, your heart's electrical signals may come from one of the ventricles instead of the SA node (Figure 4). The electrical signal does not pass through the heart normally and causes a fast, sometimes irregular heartbeat. As your heart beats faster, it pumps less blood to your body. If this rapid heartbeat continues, you may feel skipped beats or dizziness. You could eventually become unconscious, and your heart might stop beating (cardiac arrest).

VT can sometimes be treated with medication. In other cases, an external defibrillator—such as those used by



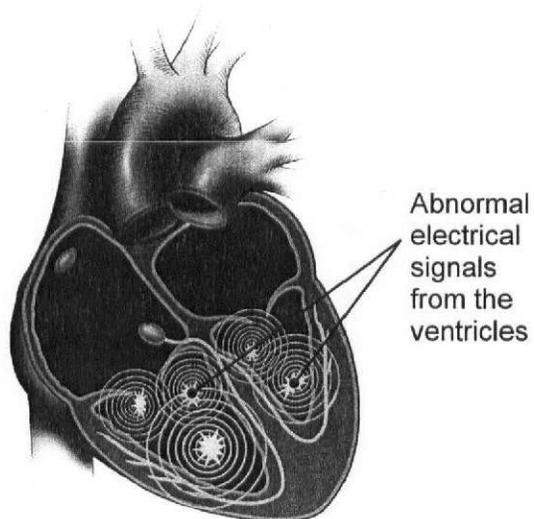
**Figure 4. An example of ventricular tachycardia.**

paramedics—or a CRT-D system may be used to stop the abnormal signals and return your heart to a more normal rhythm.

### **Ventricular fibrillation**

Another type of arrhythmia is ventricular fibrillation (VF). With this arrhythmia, irregular electrical signals come from several spots in the ventricles (Figure 5). This causes a rapid heart rate. In some cases, the heart will beat more than 300 beats per minute.

When you experience VF, very little blood is pumped from your heart to the rest of your body. When your heart is in VF, you will become unconscious very quickly. Like ventricular tachycardia, VF can be



**Figure 5. An example of ventricular fibrillation.**

treated with a defibrillator. The defibrillator produces an electrical shock that passes through the heart. The shock stops the abnormal signals and allows the SA node to return the heart to a more normal rhythm.

If an episode of VT or VF continues without medical treatment, your heart cannot supply enough oxygen-carrying blood to your brain and body tissues. Without oxygen, your brain and body tissues cannot function normally, which could be fatal.

### **Bradycardia**

Sometimes the heart beats too slowly. This can be caused by the SA node not working properly or by a condition called heart block (Figure 6). Heart block

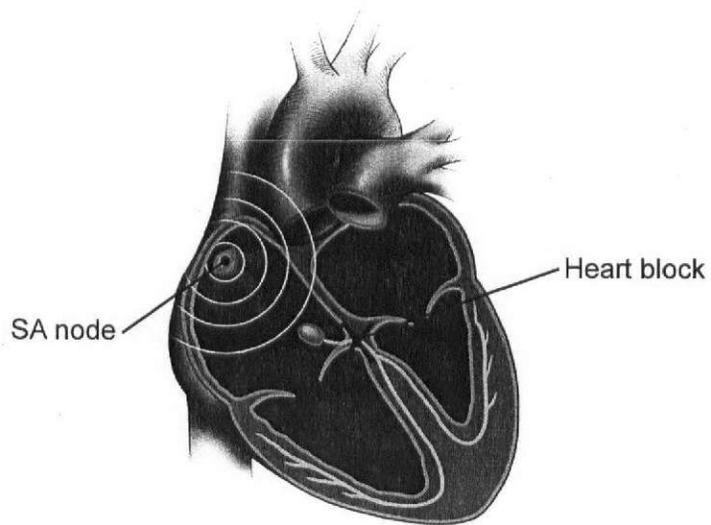


Figure 6. An example of heart block.

exists when there is a problem with the electrical pathway between the atria and the ventricles. The natural pacemaker signals sent out by the SA node could be delayed or may not reach the ventricles.

During bradycardia, the chambers of the heart do not contract often enough to supply the proper amount of blood to your body. If you have bradycardia, you may frequently feel tired or dizzy, or you may faint.

## Sudden cardiac arrest

If you have had a heart attack, you may also be at risk for sudden cardiac arrest (SCA). Sudden cardiac arrest occurs when the heart beats very fast and irregularly as a result of abnormal electrical signals (VF), causing it to pump very little blood to the body. Because the heart does not pump enough blood throughout the body, most people tend to lose consciousness suddenly. If SCA is not treated, it can lead to sudden cardiac death (SCD). The only way to stop this type of arrhythmia is to deliver an electrical shock with a defibrillator.

### **Risk factors**

Most people do not have obvious symptoms of SCA, so it is important to be aware of possible risk factors:

- Previous heart attack
- Impaired pumping function of the heart muscle
- Rapid, abnormal heart rhythms coming from the ventricles
- A family history of SCA or SCD

Early identification of your SCA risk is the key to prevention. If you are at risk, it is important to talk to your doctor.

### **Identifying your SCA risk**

Your doctor may perform one or more of the following tests to assess your risk for SCA.

**Echocardiogram:** An echocardiogram is a test that measures your heart's ejection fraction. The ejection fraction determines your heart's pumping function. During this test, ultrasound waves are used to provide a moving image of your heart. Based upon the results of this test, your doctor will determine if further testing is needed.

**Holter monitoring:** A Holter monitor is an external monitor that is worn for an extended period. The monitor records your heart's electrical activity,

including any arrhythmias you experience. Your doctor analyzes the recording to determine if you experience any abnormal rhythms.

**Electrophysiology (EP) testing:** An EP test identifies and measures the type of electrical signals in your heart. During this test, your doctor will insert catheters (thin, flexible tubes or wires) into your heart. The catheters record electrical signals within your heart. Your doctor can also use the catheters to stimulate your heart to see if you could develop an arrhythmia. This test can help your doctor recognize if you have an abnormal heart rhythm and identify its origins. It

will also determine how well certain medications or an implanted device would work to treat your heart rhythm. Your doctor can then decide what treatment is best for your condition.

## Your CRT-D system

Your CRT-D system is designed to monitor and treat your heart arrhythmias. The system consists of a pulse generator (also called a device), which is typically implanted in your chest, and three leads, which are implanted in your heart and connected to the device.

### **The device**

The device is a small computer. It runs on a battery that is safely sealed within its case. The device continuously monitors your heart rhythm and delivers electrical energy (as programmed by your physician)

to your heart when it senses an arrhythmia. The device can act as a pacemaker, cardioverter, or defibrillator. For more information about these types of therapies, see "How therapy feels" on page 67.

As the device monitors your heart rhythm, it can also store information about your heart. Your doctor can review this information using a special computer called a programmer. The programmer communicates with the device from outside your body (see "Patient follow-up options" on page 74). With the programmer, your doctor can better evaluate the programmed therapy for your heart rhythm and adjust the settings if necessary.

### **The leads**

A lead is an insulated wire implanted in your heart and connected to the device. The lead carries the heart signal to the device. It then carries energy from the device back to the heart to coordinate your heart rhythm.

## Implanting your CRT-D system

A CRT-D system is implanted during a surgical procedure. To keep you as comfortable as possible, you will be sedated for this surgery. During the procedure, your doctor will insert two leads into a vein, usually through a small incision near your collarbone. The doctor will then pass these leads through the vein into your heart (one in the right atrium and the other in the right ventricle), where the tips of the leads will rest directly against your heart's inner wall. A third lead will also be inserted into a vein near your collarbone, and

placed within a coronary vein, which lies on the outside surface of your heart's left ventricle (Figure 7).

In some cases, a patient may need to have the third lead placed on the heart's surface through an incision on the side of the chest instead of through a vein. Your doctor will discuss whether this type of chest surgery is an alternative for you.

After the leads are positioned, they will be tested to make sure they clearly sense your heart signal and can adequately pace your heart. After this testing, the device will be connected to the leads and placed in position (usually below the collarbone, just beneath the skin).

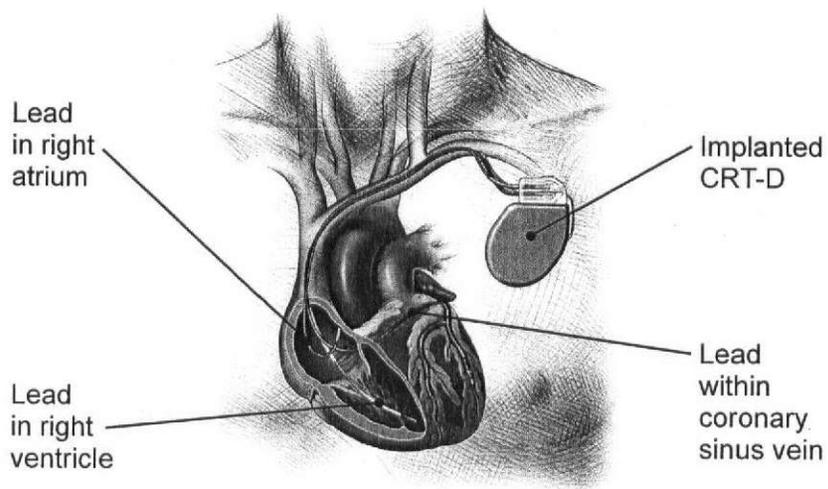


Figure 7. An implanted CRT-D system.

Your doctor will then test your CRT-D system. During this test, your doctor will start an arrhythmia in your heart. The device will recognize the rhythm and give the programmed treatment.

After your doctor has finished testing your system, the incision will be closed. You may experience some discomfort from the incision as you recover from the surgery. You should be able to return to normal activities soon after the procedure.

### **Implant risks**

As with any surgical procedure, it is important to understand that, while complications do not happen very often, there are risks associated with the

implantation of a device or lead. You should talk with your doctor about these risks, including those listed below.

Some of the risks encountered during the implant procedure include, but are not limited to, the following:

- Bleeding
- Formation of a blood clot
- Damage to adjacent structures (tendons, muscles, nerves)
- Puncturing of a lung or vein
- Damage to the heart (perforation or tissue damage)
- Dangerous arrhythmias

- Kidney failure
- Heart attack
- Stroke
- Death

Some of the risks encountered after the system is implanted may include, but are not limited to, the following:

- You may develop an infection.
- You may experience erosion of the skin near your device.
- The lead(s) may move out of place in the heart.

- The electrodes on the lead or the pacing pulses may cause an irritation or damaging effect on the surrounding tissues, including heart tissue and nerves.
- The device may move from the original implant site.
- You may have difficulty coping with having an implanted device.
- The device might be prevented from shocking or pacing due to electromagnetic interference (see "Important safety information" on page 83).
- You may receive a shock or pacing therapy when it is not needed (inappropriate therapy).

- The device might not be able to detect or appropriately treat your heart rhythms.
- The device may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. See "How reliable is this device?" on page 4.

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of this system.

## After your implant

As you recover from your implant surgery, you will find that your device may allow you to return to an active lifestyle. It is important that you become actively involved in your recovery by following your doctor's instructions, including:

- Report any redness, swelling, or drainage from your incisions.
- Avoid lifting heavy objects as instructed by your doctor.

- Walk, exercise, and bathe according to your doctor's instructions.
- Do not wear tight clothing that could irritate the skin over your device.
- Contact your doctor if you develop a fever that does not go away in two or three days.
- Ask your doctor any questions you may have about your device, heart rhythm, or medication.
- Avoid rubbing your device or the surrounding chest area.
- If directed by your doctor, limit arm movements that could affect your lead system.

- Avoid rough contact that could result in blows to your implant site.
- Tell your other doctors, dentists, and emergency personnel that you have an implanted device and show them your Medical Device Identification card.
- Contact your doctor if you notice anything unusual or unexpected, such as new symptoms or symptoms like the ones you experienced before you received your device.

### **Medications**

Your device is designed to help treat your heart condition. However, you may need to continue

taking certain medications as well. It is important that you follow your doctor's instructions regarding any medications.

### **Activities and exercise**

Your doctor will help you decide what level of activity is best for you. He or she can help answer your questions about lifestyle changes, travel, exercise, work, hobbies, and sexual intimacy.

### **Your CRT-D system information**

Have your doctor or nurse complete the "Your CRT-D system information" form at the front of this handbook before you go home from the hospital.

### **Your identification card**

Whether you are going away for the weekend or running a quick errand, carry your Medical Device Identification card with you. In an emergency, the card will alert medical and security personnel that you have an implanted device.

You will be given a temporary Medical Device Identification card when you receive your device. Boston Scientific will mail you a permanent Medical Device Identification card about six to eight weeks after your implant.

Your Medical Device Identification card contains your name, your doctor's name and phone number, and the model numbers of your device and leads.

### **Updating your identification card**

If you move or select a new doctor, please call Boston Scientific Medical Records at 1.800.728.3282 to update your records. When you notify us of a change, we will send you a new identification card reflecting the change.

## Living with your CRT-D

It is important to follow your doctor's instructions as well as these recommendations:

- Your doctor will arrange a follow-up plan with you to check your device and overall health on a regular basis. It is important that you attend your scheduled in-office follow-up visits, even if you are enrolled in the LATITUDE Patient Management System. LATITUDE does not eliminate the need for in-office visits, although it can minimize the number of them. For more information about the LATITUDE Patient

Management System, see "Patient follow-up options" on page 74.

- If you are enrolled in the LATITUDE Patient Management System, use your LATITUDE Communicator as directed by your doctor or clinician.
- Ask your doctor if you have any questions about or notice anything unusual with your device.
- Take the medications prescribed for you as instructed by your doctor.
- Carry your identification card and medication list with you at all times.

- Tell your family doctor, dentist, and emergency personnel that you have an implanted device.

### **Preparing for CRT-D shock therapy**

While the device's monitoring of your heart won't cause any noticeable sensations, shock therapy for an arrhythmia may be very noticeable. It is important that you know what to expect.

Before you experience symptoms or receive a shock, discuss with your doctor or nurse a plan for contacting your doctor and, if necessary, emergency personnel. Use the forms in this handbook to write down important telephone numbers and information about your current

medications. It might be helpful to keep this information near your phone.

If you have symptoms of a fast heart rate, it is likely that your device will deliver therapy within a few seconds. Try to remain calm, and find a place to sit or lie down. The sensation from receiving therapy should only last a moment.

It is possible, however, that you may require additional medical attention. Be sure to talk with your doctor about what you should do, and consider the following suggestions:

1. If possible, have someone who is prepared to perform cardiopulmonary resuscitation (CPR)—should you need it—stay with you through the event.

2. Make sure a friend or family member knows to phone your local emergency response system if you remain unconscious.
3. If you are conscious but do not feel well after a shock, have someone call your doctor.
4. If you feel fine after a shock and no more symptoms appear, it may not be necessary to seek medical help immediately. However, follow your doctor's instructions for when to call his or her office. For example, if a shock occurs at night, your doctor may tell you to call him or her the next morning. Someone at the doctor's office will ask you questions such as:
  - What were you doing right before the shock?

- What symptoms did you notice before the shock?
  - At what time did the shock occur?
  - How did you feel right after the shock?
5. It is possible that you could feel symptoms of an arrhythmia but not receive therapy. This depends on the programmed settings of your device. For example, an arrhythmia may cause symptoms, but it may not be fast enough for your device to deliver therapy. In any case, if your symptoms are severe or continue for more than a minute or so, you should seek immediate medical attention.

### **How therapy feels**

Your device is designed to always monitor your heart rhythm. If it senses an arrhythmia, it will deliver therapy to your heart. Remember that your doctor has programmed your device to meet your individual needs. The type of therapy you receive and when you receive it is based upon those programmed settings.

**Antitachycardia pacing (ATP):** If your arrhythmia is fast but regular, your device can deliver a series of small, rapid pacing pulses to interrupt the arrhythmia and return your heart to its normal rhythm. You may not feel the pacing therapy, or you may have a feeling of fluttering in your chest. Most patients who receive this pacing therapy say it is painless.

**Cardioversion:** If your arrhythmia is very fast but regular, your device can deliver a low- to moderate-energy shock to stop the arrhythmia and return your heart to its normal rhythm. Many patients say cardioversion is mildly uncomfortable, like a thump on the chest. This sensation will only last for a moment.

**Defibrillation:** If your arrhythmia is very irregular and fast, your device can deliver a high-energy shock to stop the arrhythmia and return your heart to its normal rhythm. Many patients faint or become unconscious shortly after a very fast VT or VF rhythm begins. As a result, many patients do not feel these high-energy shocks. Some describe the sudden but brief shock as a "kick in the chest." This sensation will only last for a

moment. While many find the shock reassuring, other patients may be upset for a short time after the shock is delivered.

**Cardiac resynchronization therapy (CRT):** To help treat heart failure, your device monitors your heart's signals and coordinates the right and left ventricles to help them contract at the same time. The electrical signals used for heart failure therapy are of very low energy. Patients do not typically feel this type of therapy.

**Bradycardia pacing:** If your heart signals are too slow, your device can pace your heart. It sends signals to your upper and/or lower chambers, telling them to contract more frequently to meet your body's needs.

This can help maintain your heart rate until your body's natural pacemaker is able to take control. Patients do not typically feel the electrical pulses used to pace the heart.

### **Special considerations**

Your doctor might ask you to avoid activities where the risk of unconsciousness could endanger you or others. These activities might include driving, swimming or boating alone, or climbing a ladder.

### **Driving**

Driving laws and symptoms caused by your arrhythmia are often the deciding factors in whether you will be

allowed to drive. Your doctor will advise you about what is best for your safety and the safety of others.

### **Sexual intimacy**

For most patients, sexual intimacy is not a medical risk. The natural heart rate increase that occurs during sex is the same as the heart rate increase when you exercise. Exercise testing at the hospital will help your doctor program your device settings so you should not get a shock during sex. If you receive a shock during sex, your partner may feel a tingling sensation. The shock is not harmful to your partner. Be sure to let your doctor know if you receive a shock during sex so he or she can consider reprogramming your device.

### **When to call your doctor**

Your doctor will provide guidelines for when you should contact him or her. In general, phone your doctor if you:

- Receive any arrhythmia therapy from your device and have been instructed to call.
- Have symptoms of an abnormal heart rhythm and have been instructed to call.
- Notice any swelling, redness, or drainage from your incisions.
- Develop a fever that does not go away in two or three days.
- Have questions about your device, heart rhythm, or medications.

- Plan to travel or move away.
- Hear any beeping sounds from your device. This indicates that your device needs to be checked immediately. See “What should you do if your device starts to beep?” on page 79.
- Notice anything unusual or unexpected, such as new symptoms or symptoms like the ones you had before you received your device.

Remember that your device is designed to monitor and treat your life-threatening arrhythmias. It can be a great source of reassurance for you and your friends and family.

## **Patient follow-up options**

Your doctor will schedule regular follow-up sessions to check your device and monitor your condition. There are two follow-up options: in-office visits and remote follow-up sessions.

### **In-office follow-up visits**

Your doctor will schedule regular in-office follow-up visits. It is important that you attend these visits, even if you are feeling well.

During your visit, the doctor or nurse will use a programmer to check your device. The programmer is a special external computer that can communicate with your device in two ways:

1. By using radio frequency (RF) telemetry communication, if you have an RF-enabled device.
2. By using wanded telemetry communication. In this case, the doctor or nurse will place a wand over your skin near your device.

A typical follow-up visit takes about 20 minutes. During your visit, your doctor or nurse will use the programmer to interrogate, or check, your device. They will review your device's memory to evaluate its performance since your last visit and check for any arrhythmia episodes you may have had. If necessary, they will adjust your device's programmed settings. They will also check the battery to see how much energy is left.

### **Remote follow-up sessions**

Your doctor may want you to use the LATITUDE Patient Management System. When using the LATITUDE Patient Management System, you will receive a home monitoring unit called a Communicator. The Communicator is used to interrogate your device on a regular schedule that is set by your physician. The Communicator then sends the data gathered from your device through a standard telephone connection to the LATITUDE Patient Management secure database. Your doctor can then access this database using an Internet-enabled personal computer.

While use of the Communicator does not eliminate the need for in-office visits that may be scheduled by your physician, it can minimize the number of them. The Communicator cannot reprogram or change any functions of your device. Your doctor or nurse can only do this using a programmer during an office visit.

### **What you should know about your device's battery**

A battery, safely sealed inside your device, provides the energy needed to monitor your heart rhythm, pace your heart, or deliver electrical therapy. Just like any other type of battery, the battery in your device will be used up over time. Since the battery is permanently

sealed within your device, it cannot be replaced when its energy is depleted. Instead, your entire device will need to be replaced (see "Replacing your system" on page 80). How long your device's battery lasts depends upon the settings your doctor programs and how much therapy you receive.

**How will you know if your device's battery is running down?**

Device batteries have very predictable behavior over time. Your device will regularly check its own battery. At every follow-up visit, the doctor or nurse will also check to see how much energy is remaining in the battery. When the battery's energy level decreases to a certain point, your device will need to be replaced.

Your doctor can turn on a feature that will cause your device to beep when replacement time is near. See "What should you do if your device starts to beep?" on page 79.

**What should you do if your device starts to beep?**

Under certain conditions, your device will beep 16 times every 6 hours. Call your doctor immediately any time you hear beeping tones from your device. Your doctor or nurse can demonstrate these beeping tones so you'll recognize them.

### **Replacing your system**

Eventually, the energy in your device's battery will decrease to a point where your device will need to be replaced (see "What you should know about your device's battery" on page 77). Your doctor will monitor your device's battery levels and determine when to replace your device.

To replace your device, your doctor will surgically open the pocket of skin where your device is located. He or she will disconnect your old device from your leads and then check to make sure your leads work properly with your new device.

In rare instances, your leads may not work properly with your new device, and your doctor may need to replace the leads. Your doctor will determine if your leads should be replaced.

Should a lead need to be replaced, your doctor will insert a new lead into a vein, similar to how the original lead was implanted. See "Implanting your CRT-D system" on page 47.

Your doctor will then connect the leads to your new device. Finally, he or she will test your new system to make sure it is working properly.

After the testing is complete, the pocket of skin will be stitched closed. You may experience some discomfort

from the incision as you recover from the surgery. You should be able to return to normal activities soon after the procedure.

### **Risks**

Risks encountered during a device and/or lead replacement procedure are similar to the risks of the initial implant, such as infection, tissue damage, and bleeding. See "Implant risks" on page 50.

Be sure to talk with your doctor about the potential risks when making decisions about replacing your system.

## Important safety information

Your device has built-in features that protect it from interference produced by most electrical equipment. Most of the things you handle or work around on a daily basis are not going to affect your device. However, your device is sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnetic fields.

### **Operating household appliances and tools**

Use the following guidelines for safe interaction with many common tools, appliances, and activities.

**Items that are safe under normal use:**

- Air purifiers
- Blenders
- CD/DVD players
- Clothes washing machines and dryers
- Electric blankets
- Electric can openers
- Electric invisible fences
- Electric toothbrushes
- Fax/copy machines
- Hair dryers

- Heating pads
- Hot tubs/whirlpool baths  
**NOTE:** *Consult with your doctor before using a hot tub. Your medical condition may not permit this activity; however, it will not harm your device.*
- Laser tag games
- Microwave ovens
- Ovens (electric, convection, and gas)
- Pagers
- Patient alert devices
- Personal computers

- Personal digital assistants (PDAs)

**NOTE:** *PDAs that also function as cell phones should be kept at least 6 inches (15 cm) away from your device. See "Cellular phones" on page 94.*

- Portable space heaters
- Radios (AM and FM)
- Remote controls (TV, garage door, stereo, camera/video equipment)
- Stoves (electric or gas)
- Televisions
- TV or radio towers (safe outside of restricted areas)
- Tanning beds
- Vacuum cleaners

- VCRs
- Video games

### **Warnings and precautions**

If you use any of the following items, it is important that you keep them the recommended distance away from your device to avoid interaction.

#### **Items that should not be placed directly over your device, but are otherwise safe to use:**

- Cordless (household) telephones
- Electric razors
- Hand-held massagers

- Portable MP3 and multimedia players (such as iPods®) that do not also function as a cellular phone (see "Cellular phones" on page 94)

**NOTE:** *While portable MP3 players themselves should not interfere with your device, the headphones or earbuds should be stored at least 6 inches (15 cm) away from your device.*

**Items that should remain at least 6 inches (15 cm) away from your device:**

- Cellular phones, including PDAs and portable MP3 players with integrated cellular phones

**NOTE:** *For more information about cellular phones, see "Cellular phones" on page 94.*

- Devices transmitting Bluetooth® or Wi-Fi signals (cellular phones, wireless Internet routers, etc.)

- Headphones and earbuds

**NOTE:** *It is safe to use headphones and earbuds, but you should refrain from storing them in a breast or other shirt pocket that places them within 6 inches (15 cm) of your device.*

- Magnetic wands used in the game of Bingo

**Items that should remain at least 12 inches (30 cm) away from your device:**

- Battery-powered cordless power tools
- Chain saws
- Corded drills and power tools

- Lawn mowers
- Leaf blowers
- Remote controls with antennas
- Shop tools (drills, table saws, etc.)
- Slot machines
- Snow blowers
- Stereo speakers

**Items that should remain at least 24 inches (60 cm)  
away from your device:**

- Arc welders
- CB and police radio antennas

- Running motors and alternators, especially those found in vehicles

**NOTE:** *Avoid leaning over running motors and alternators of a running vehicle. Alternators create large magnetic fields that can affect your device. However, the distance required to drive or ride in a vehicle is safe.*

**Items that should not be used:**

- Body-fat measuring scales (handheld)
- Jackhammers
- Magnetic mattresses and chairs
- Stun guns

If you have questions about the EMI safety of a particular appliance, tool, or activity, please call Boston Scientific Patient Services at 1.866.484.3268.

### **Theft detection systems**

Theft detection systems (often found in department store and library doorways) are sources of EMI, but should not cause you any worry if you follow these guidelines:

- Walk through theft detection systems at a normal pace.
- Do not lean against or linger near these systems.

- If you suspect interaction between your device and a theft detection system could occur, just move away from the system to decrease the interference.

### **Airport security**

Your device contains metal parts that may set off airport security metal detector alarms. The security archway will not harm your device. Tell security personnel that you have an implanted device and show them your Medical Device Identification card.

Airport security wands could temporarily affect your device or turn it off if the wand is held over it for a period of time (about 30 seconds). If possible, ask to be hand-searched instead of being searched with

a handheld wand. If a wand must be used, inform the security personnel that you have an implanted device. Tell the security personnel that the search must be done quickly and to not hold the wand over your device.

If you have questions about airport security, call your doctor or Boston Scientific Patient Services at 1.866.484.3268.

### **Cellular phones**

Keep your cellular phone at least 6 inches (15 cm) away from your device. Your cellular phone is a source of EMI and could affect your device's operation. This interaction is temporary, and moving the phone away

from your device will return it to proper function.  
To reduce the chance of interaction, follow these precautions:

- Maintain a distance of at least 6 inches (15 cm) between the cellular phone and your device. If the phone transmits more than 3 watts, increase the distance to 12 inches (30 cm).
- Hold the cellular phone to your ear on the opposite side of your body from your device.
- Do not carry a cellular phone in a breast pocket or on a belt if that places the phone within 6 inches (15 cm) of your device.

These precautions apply only to cellular phones, not to household cordless phones. However, you should avoid placing your household cordless phone receiver directly over your device.

### **Dental and medical procedures**

Some medical procedures could damage or otherwise affect your device. Be sure to always tell your dentist and physicians that you have an implanted device so that they can take the necessary precautions. Be especially careful with the following procedures:

- **Magnetic Resonance Imaging (MRI):** This is a diagnostic test that uses a strong electromagnetic field. MRI scans can severely damage your device

and should not be performed. Hospitals keep MRI equipment in rooms marked with signs that indicate magnets are inside. Do not go inside these rooms.

- **Diathermy:** This uses an electrical field to apply heat to tissues in the body and could damage your device or injure you. Diathermy should not be performed.
- **Electrocautery:** This is used during surgical procedures to stop vessels from bleeding. It should be used only when your device is turned off. Talk with your heart doctor and the doctor performing the medical procedure to determine who turns off your device.

- **External defibrillation:** This is a procedure, typically used in medical emergencies, that uses external equipment to deliver an electrical shock to your heart to restore a rapid and irregular heart rate to a normal rhythm. External defibrillation can affect your device, but can still be performed if necessary. If you receive external defibrillation, be sure to contact your physician as soon as possible following the emergency to verify that your device is functioning properly.
- **Lithotripsy:** This is a medical procedure that is used to break up stones in the urinary tract (e.g., kidney stones). Lithotripsy can damage your device if certain precautions are not taken. Talk with your

heart doctor as well as the doctor performing the procedure about what can be done to protect your device.

- **Therapeutic radiation treatment for cancer:**

This procedure can affect your device and will require special precautions. If you should need radiation treatment, talk with your heart doctor as well as the doctor performing the medical procedure.

- **Transcutaneous Electrical Nerve Stimulation (TENS) unit:** This is a device prescribed by physicians or chiropractors for control of chronic pain. A TENS unit can affect your device and will

require special precautions. If you must use a TENS unit, talk with your heart doctor.

Most medical and dental procedures will not affect your device. Some examples include:

- Dental drills and cleaning equipment
- Diagnostic X-rays
- Diagnostic ultrasound procedures
- Mammograms

**NOTE:** *Mammograms will not interfere with your device. However, your device could be damaged if it gets compressed in the mammogram machine. Make sure the doctor or technician knows that you have an implanted device.*

- EKG machines

- CT scans

If you need to undergo any surgical procedures, tell your dentist and/or doctor that you have an implanted device. They can contact the physician who monitors your device to find the best way to provide treatment.

If you have questions about a specific appliance, tool, medical procedure, or piece of equipment, please talk with your doctor or call Boston Scientific Patient Services at 1.866.484.3268.

## Summary

It is natural for you to feel anxious or nervous about receiving a device. You have been identified by your physician as having heart failure, as well as having a significant risk of sudden cardiac death. Remember that your device can be a great source of reassurance for you and your friends and family.

Talking with other CRT-D patients is often helpful while adjusting to your new device. Ask your doctor, nurse, or Boston Scientific representative if there is a local CRT-D patient support group in your area.

The information presented in this handbook is intended to help you understand more about your heart condition and your device. If you have questions about what you have read, be sure to ask your doctor or nurse. They are your best resource for information about your particular needs or situation.

## Visit us on the Internet

Boston Scientific's patient-focused website, LifeBeat Online, offers a variety of information of interest to people with cardiac devices, including cardiac news, health tips, patient stories, frequently asked questions about living with your implanted device, and links to additional resources. You can also subscribe to have the free newsletter delivered to your email address.

[www.lifebeatonline.com](http://www.lifebeatonline.com)

## Notes and questions

Use this space to write down questions or additional information about your device:

---

---

---

---

---

---

---

---

---

---



## Symbols on Packaging

Symbol	Definition
	Manufacturer

## Index

### A

Activities, 58, 70  
Airport security, 93  
Antitachycardia pacing, 67  
Arrhythmia, 30  
    *ventricular  
    fibrillation, 34*  
    *ventricular  
    tachycardia, 32*  
Atria, 26

### B

Battery, 77  
    *beeping tones, 73, 79*  
    *end of life, 78, 80*  
Beeping tones, *see* Battery  
Boating, 70  
Bradycardia, 36  
Bradycardia pacing, 69

## C

Calling your doctor, 72  
Cardiac resynchronization therapy, 69  
Cardioversion therapy, 68  
Cellular phones, 88, 94  
Communicator,  
see LATITUDE Patient Management System  
Cordless phones, 87, 96  
CRT-D system, 44  
    *device, 44*  
    *implanting, 47*  
    *leads, 46*  
    *reliability, 4*

*replacing, 80*  
    *risks, 50*

CT scans, 101

## D

Defibrillation therapy, 68  
Dental equipment, 100  
Dental procedures, 96  
Device, 44  
    *implanting, 47*  
    *reliability, 4*  
    *replacing, 80*  
Diathermy, 97  
Driving, 70

**E**

Echocardiogram, 41  
EKG machines, 101  
Electrocautery, 97  
Electromagnetic interference (EMI), 83  
Electronics  
    *precautions, 83*  
Electrophysiology (EP) test, 42  
Exercise, 58  
External defibrillation, 98

**F**

Follow-up visits, 74

**G**

Glossary, 6

**H**

Heart block, 36  
Heart failure, 26  
Heart function, 24  
Holter monitoring, 41  
Household appliances  
    *precautions, 83*

**I**

Identification card, 59  
Implanting the system, 47  
    *recovery, 55*  
    *risks, 50*

**L**

Ladders, 70  
LATITUDE Patient  
Management System, 61, 76  
    *Communicator, 62, 76*  
Leads, 46  
    *implanting, 47*  
    *replacing, 81*

Lithotripsy, 98

Living with your device, 61  
    *ID card, 59*  
    *preparing for therapy, 63*

**M**

Mammograms, 100  
Medical procedures, 96  
Medications, 57  
MRI, 96

**P**

Precautions, 87  
    *airport security, 93*

*cellular phones, 88, 94*  
*dental procedures, 96*  
*diathermy, 97*  
*electrocautery, 97*  
*external defibrillation, 98*  
*household*  
*appliances, 83*  
*lithotripsy, 98*  
*medical procedures, 96*  
*MRI, 96*  
*radiation treatment, 99*  
*TENS units, 99*  
*theft detection*  
*systems, 92*  
*tools, 83*

Programmer, 45, 74  
Pulse generator, see Device

**R**

Radiation treatment, 99  
Radio frequency  
(RF) telemetry, 75  
Recovery, 55  
Reliability, 4  
Replacing the system, 80  
*risks, 82*  
Risks, see Precautions  
*electromagnetic*  
*interference, 83*

*implant procedure, 51*  
*post-implant, 52*  
*replacement*  
*procedure, 82*  
*sudden cardiac*  
*arrest, 40*

## **S**

Safety, *see* Precautions  
Sexual intimacy, 71  
Sinoatrial (SA) node, 24  
Sudden cardiac arrest, 39  
    *diagnosis, 41*  
    *risk factors, 40*

Sudden cardiac death,  
*see* Sudden cardiac arrest  
Swimming, 70

## **T**

Telemetry communication  
    *radio frequency (RF), 75*  
    *wanded, 75*  
TENS units, 99  
Theft detection systems, 92  
Therapy  
    *antitachycardia*  
    *pacing, 67*  
    *bradycardia pacing, 69*

*cardiac resynchronization therapy, 69*  
*cardioversion, 68*  
*defibrillation, 68*  
*how it feels when delivered, 67*  
*preparing for, 63*

**Tools**

*precautions, 83*

Traveling, 58, 73

*airport security, 93*

**U**

Ultrasound, 100

**V**

Ventricles, 26

Ventricular fibrillation (VF), 34

Ventricular tachycardia (VT), 32

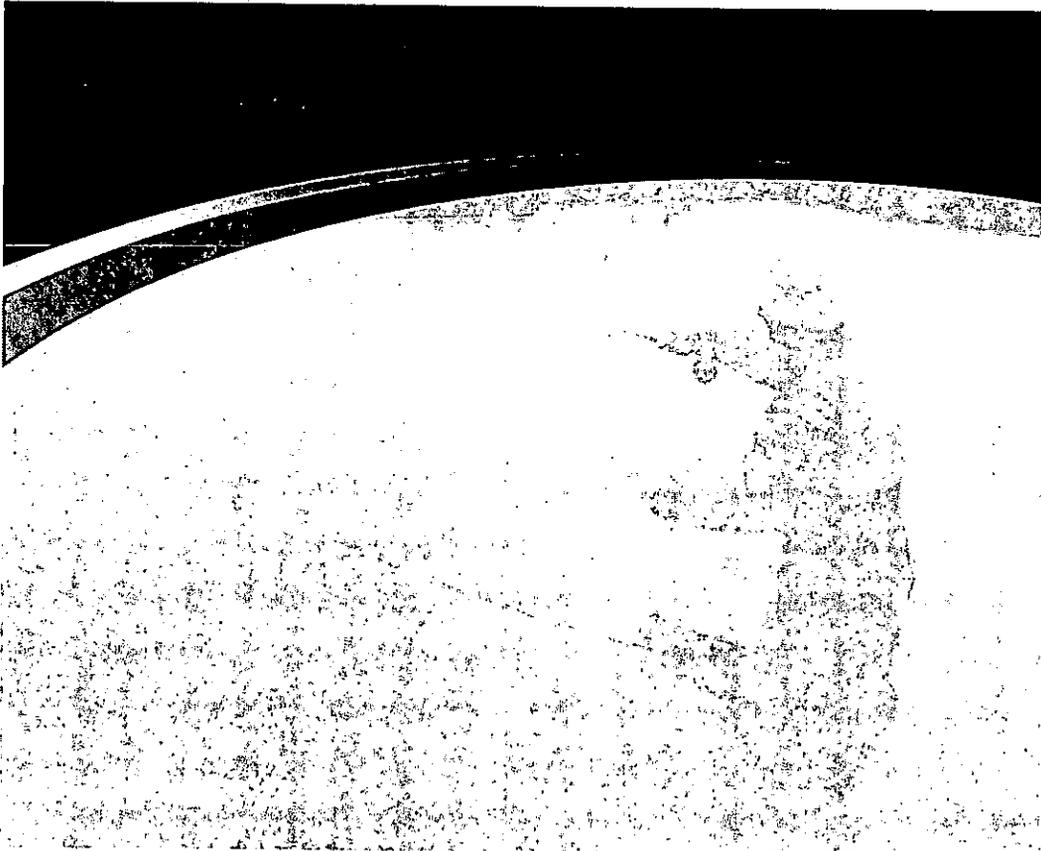
**W**

Wanded telemetry, 75

Warnings, *see* Precautions

**X**

X-rays, 100



# Boston Scientific

*Delivering what's next.™*

**Manufacturer:**



**Boston Scientific**  
4100 Hamline Avenue North  
St. Paul, MN 55112-5798 USA  
Tel: 651.582.4000

Medical Professionals:  
1.800.CARDIAC (227.3422)  
Patients and Families:  
1.866.484.3268

[www.bostonscientific.com](http://www.bostonscientific.com)

© 2009 Boston Scientific or its  
affiliates. All rights reserved.



**CRT-D**

356965-004 EN US 11/09