SUMMARY

This article summarizes appropriate device programming steps when a left ventricular (LV) lead is implanted but not being used, or if an LV lead is not physically attached to the device and the unused LV header port is plugged.

Products Referenced

All referenced Boston Scientific CRT-Ds and CRT-Ps and the LATITUDE Patient Management System.

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the full instructions for use found at: www.bsci.com/ifu.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker#
ICD: Implantable Cardioverter Defibrillator
S-ICD: Subcutaneous Implantable Defibrillator#

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Programming a CRT Device When a Left Ventricular Lead is Not Used

Cardiac resynchronization therapy (CRT) devices are intended to utilize a left ventricular (LV) lead to establish synchrony between the right and left ventricles. However, there may be clinical situations in which the LV lead is not used. For example:

- If the LV lead cannot be positioned, the physician may elect to use the CRT device without an LV lead temporarily, plugging the unused LV header port.
- If the implanted LV lead dislodges to a sub-optimal position, the lead may remain implanted and connected to the LV header port, but electronically deactivated.

If LV lead information will not be used, the programming adjustments described below may help to:

- Prevent reporting of invalid LV diagnostic information such as out-of-range LV lead impedance measurements, noise, or LATITUDE® yellow alerts/status indicators caused by invalid diagnostic information.
- Minimize[1] invalid accrual of LV counters, electrograms, markers, and intervals.
- Improve device longevity.[2]
- Minimize diaphragm stimulation if the LV lead is positioned near the phrenic nerve.

Device Programming

If the LV lead port is plugged, or if an implanted LV lead is not being used, consider reprogramming the following device parameters related to LV lead use:

- **Step 1:** Program BiV Trigger to Off (if feature is available).
- **Step 2:** Program LV Amplitude and LV Pulse Width to the minimum value for both normal brady therapy and post-shock therapy.
- **Step 3:** Program the pacing chamber to RV only.[1]
- **Step 4:** Turn off LV sensing.
- **Step 5:** Turn off LV Daily Measurements.

Reference the following tables for programming steps specific to device type and family. If these steps are performed in a different sequence certain steps may not be available.

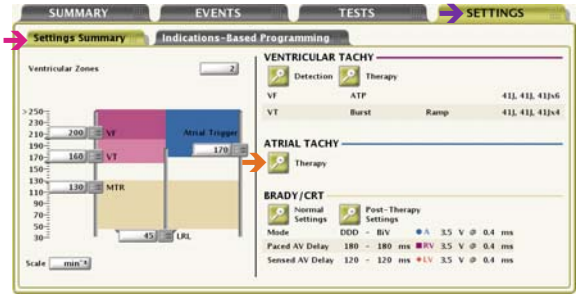
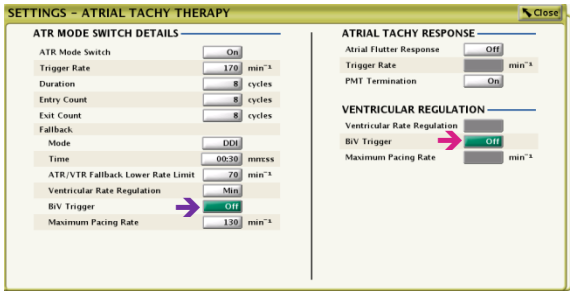
[1] Some device features will temporarily utilize BiV pacing, which may add LV data to the counters, electrograms, markers, and intervals regardless of LV lead configuration. Depending on device model and programming, these features may include ATR Mode Switch, ATP, and Electrocautery Protection mode.

[2] If the LV lead is not used, and no LV lead parameters are programmed to a minimum value or Off, device longevity will be equal to that of a device using an LV lead.

Programming for CRT-Ds

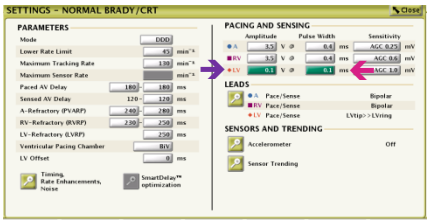
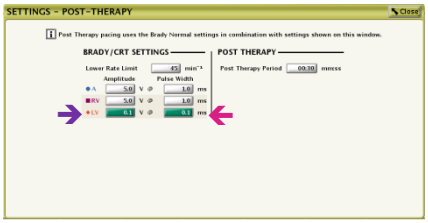
Table 1. Programming When an LV Lead is Not Used in COGNIS®, PUNCTUA™, INCEPTA™ and ENERGEN™ CRT-D Devices

Step 1: Turn ATR BiV Trigger and VENTRICULAR REGULATION BiV Trigger Off

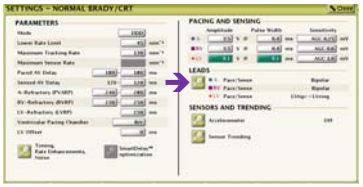
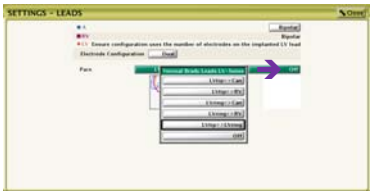
Go to SETTINGS tab (➔), then Go to SETTINGS SUMMARY tab (➔), then Go to Therapy (➔) under Atrial Tachy	Change ATR BiV Trigger (➔) to OFF Change VENTRICULAR REGULATION BiV Trigger (➔) to OFF Select the Close Button
	

Step 2: Change LV Amplitude/Pulse Width

Step 3: Program Pacing Chamber to RV Only

Go To Normal Settings (➔), under BRADY/CRT	Change LV Amplitude (➔) to 0.1 V Change LV Pulse Width (➔) to 0.1 ms	Change Ventricular Pacing Chamber (➔) to RV Only
		
Go To Post-Therapy Settings (➔) under BRADY/CRT	Change LV Amplitude (➔) to 0.1 V Change LV Pulse Width (➔) to 0.1 ms Select the Close Button	Return to Normal Settings on the BRADY/CRT Screen
		

Step 4: Change LV Sense and Electrode Configuration

Go to LEADS icon (➔)	Change LV Sense (➔) to Off (LV Electrode Configuration must be Single or Dual)	Change LV Electrode Configuration (➔) to None Select the Close Button twice
		

Step 5: Turn LV Daily Measurements Off

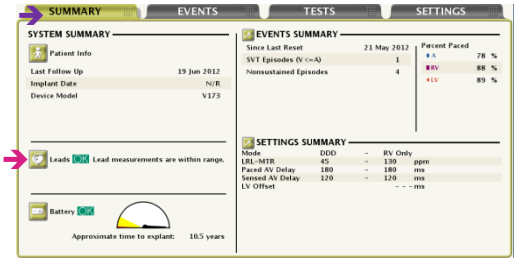
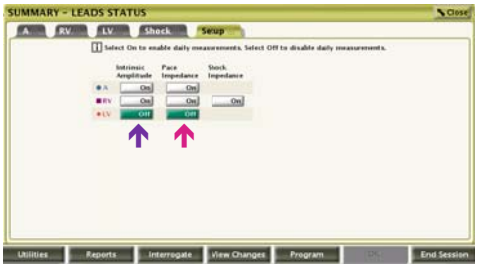
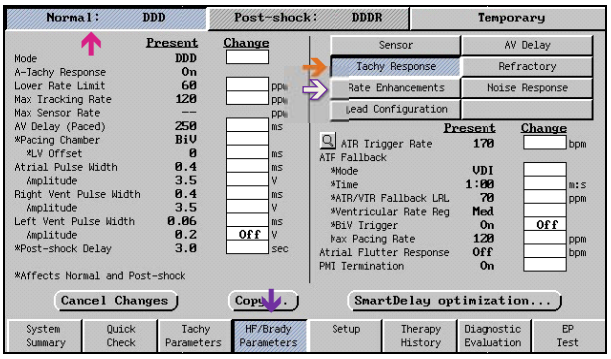
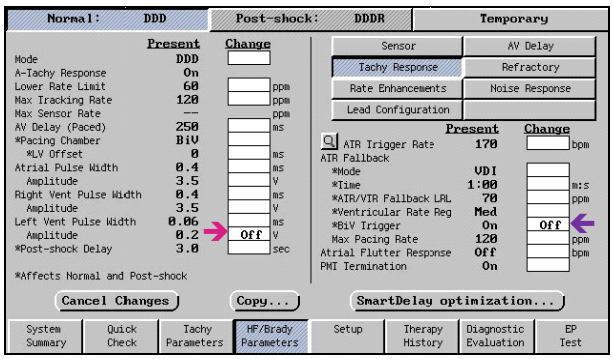
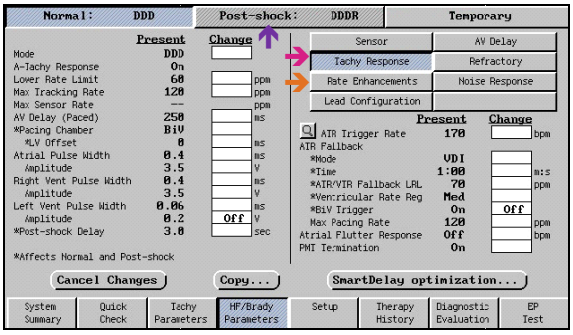
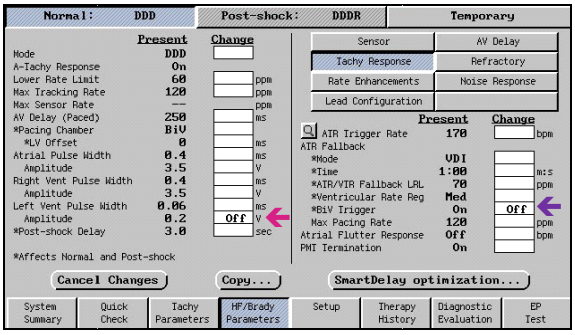
Go to Main SUMMARY tab (➔), then Go to Leads (➔)	From the Setup Tab, Change LV Intrinsic Amplitude (➔) to Off Change LV Pace Impedance (➔) to Off Select the Close Button and Program
	

Table 2. Programming When an LV Lead is Not Used in LIVIAN® and CONTAK RENEWAL® CRT-D Devices (all models)[3]

Steps 1a/2a: Turn BiV Trigger[4] and LV Amplitude Off under Normal Parameters
(If BiV is not available, change LV Amplitude only)

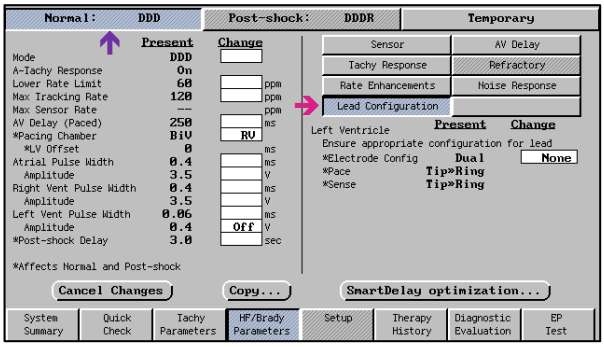
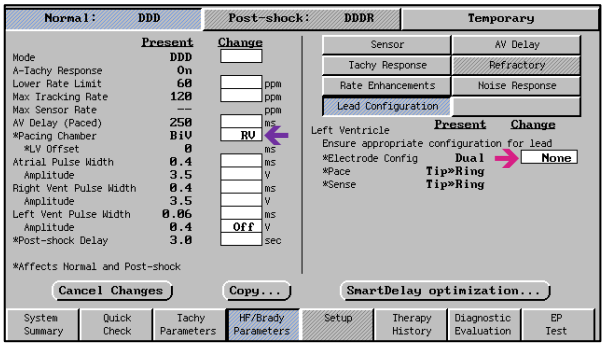
Go to HF/Brady Parameters tab (➔), then Go to Normal[5] tab (➔), then Go to Tachy[5] Response (➔) (if DDD(R)/VDD(R)), or Rate Enhancements (⇨) (if DDI(R)/VVI(R))	Change BiV Trigger (➔) to Off (if applicable) Change LV Amplitude (➔) to Off (if applicable)
	

Step 1b/2b: Turn BiV Trigger[3] and LV Amplitude Off under Post-Shock Parameters
(If BiV is not available, change LV Amplitude only)

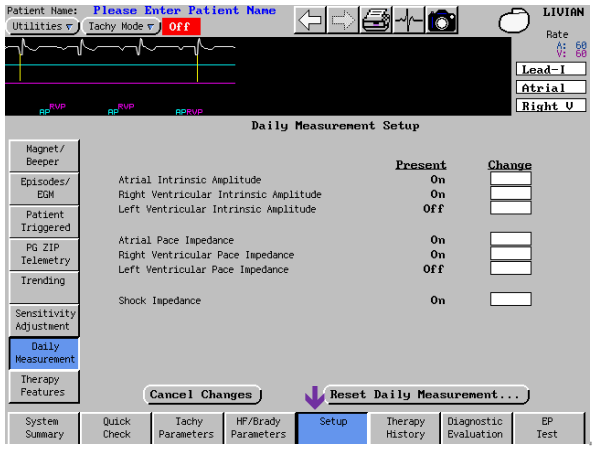
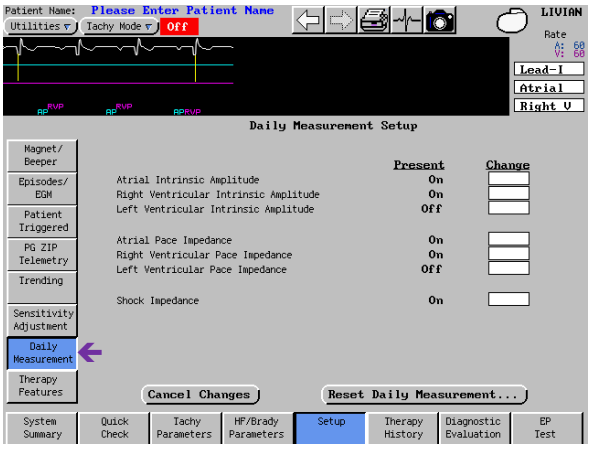
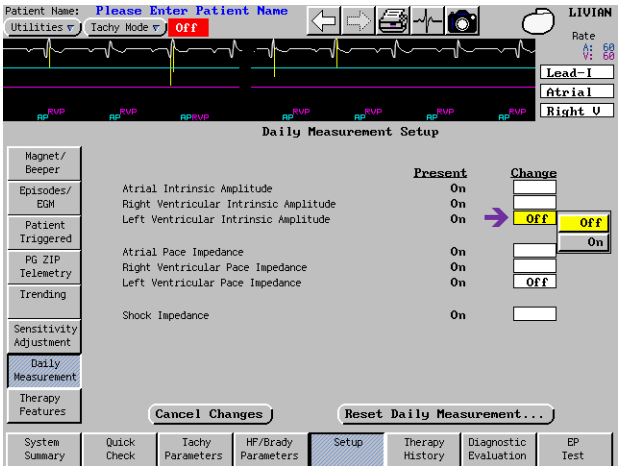
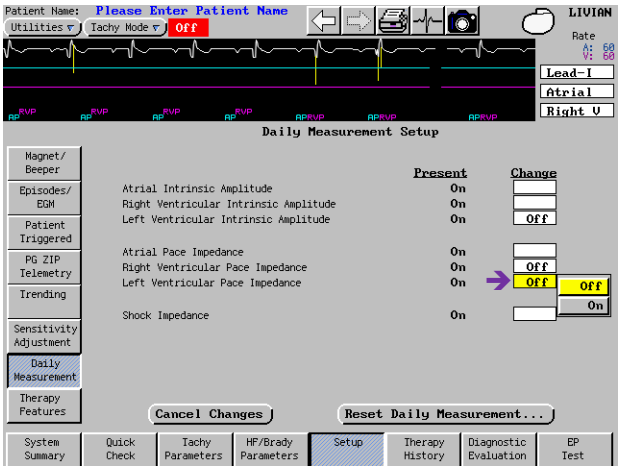
From HF/Brady Parameters tab Go to Post-shock tab (➔), then Go to Tachy Response (➔) (if DDD(R)/VDD(R)), or Rate Enhancements (➔) (if DDI(R)/VVI(R))	Change BiV Trigger (➔) to Off (if applicable) Change LV Amplitude (➔) to Off Press the Program button
	

[3] Steps 1a/2a, 3, 4 and 5 in this section also pertain to CONTAK RENEWAL TR CRT-P devices.
[4] BiV Trigger is only available in LIVIAN and CONTAK RENEWAL 4/ 4 AVT/ 3 AVT
[5] Specific to CONTAK RENEWAL TR devices: No Normal tab, proceed to next line; Tachy Response is called A-Tachy Response.

Steps 3 and 4: Change Pacing Chamber to RV and LV Lead Configuration to None

From HF/Brady Parameters tab Go to Normal[5] tab (➔) Go to Lead Configuration (➔)	Change Pacing Chamber (➔) to RV Change Left Ventricle Electrode Config (➔) to None Press the Program button
	

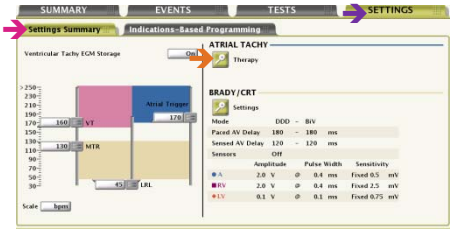
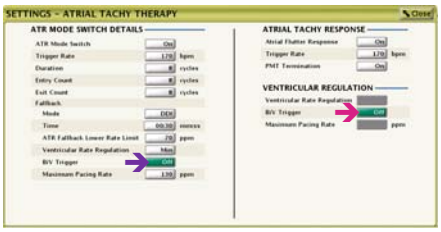
Step 5: Turn LV Daily Measurements Off

From the Setup tab (➔)	Select Daily Measurement (➔)
	
Turn Left Ventricular Intrinsic Amplitude Off (➔)	**Turn Left Ventricular Pace Impedance Off (➔) Press the Program button**
	

Programming for CRT-Ps[6]

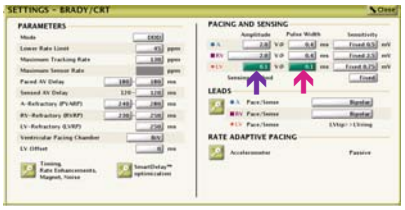
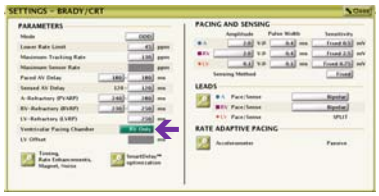
Table 3. Programming When an LV Lead is Not Used in INVIVE™, INTUA™ and INLIVEN™ CRT-P Devices

Step 1: Turn ATR BiV Trigger and VENTRICULAR REGULATION BiV Trigger Off

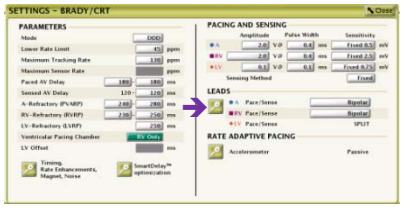
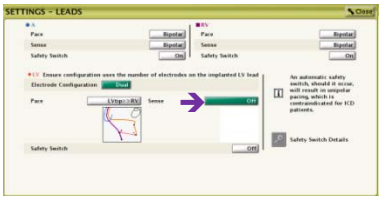
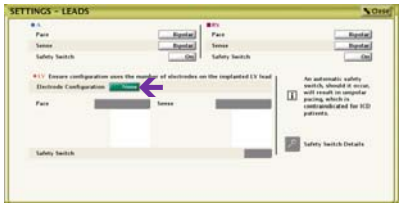
Go to SETTINGS tab (➔), then Go to SETTINGS SUMMARY tab (➔), then Go to Therapy (➔) under Atrial Tachy	Change ATR BiV Trigger (➔) to OFF Change VENTRICULAR REGULATION BiV Trigger (➔) to OFF Select the Close Button
	

Step 2: Change LV Amplitude/ Pulse Width

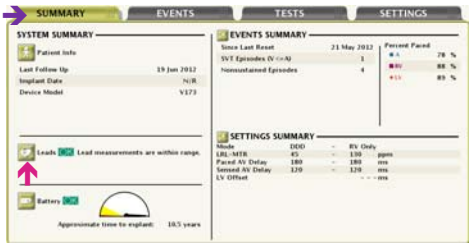
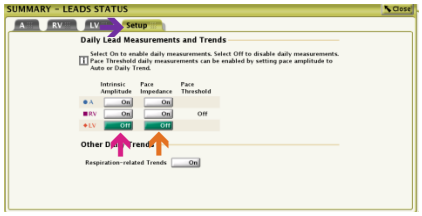
Step 3: Change Ventricular Pacing Chamber to RV only

Go to Settings icon (➔) under BRADY/CRT	Change LV Amplitude (➔) to 0.1 V Change LV Pulse Width (➔) to 0.1 ms	Change Ventricular Pacing Chamber (➔) to RV Only
		

Step 4: Change LV Sense and Electrode Configuration

From current location (SETTINGS – BRADY/CRT), Go to LEADS (➔)	Change LV Sense (➔) to Off (LV Electrode Configuration must be Single or Dual)#	Change LV Electrode Configuration (➔) to None Select the Close button twice
		

Step 5: Turn LV Daily Measurements Off

Go to main SUMMARY (➔) tab, then Go to Leads (➔)	Go to the Setup (➔) tab, then Change LV Intrinsic Amplitude (➔) to Off Change LV Pace Impedance (➔) to Off	Select Close and Program
		

[6] For CONTAK RENEWAL TR, see Table 2, steps 1 and 2a, 3, 4, and 5

NOTES:

1) Daily Measurements can be accessed through the Setup button > Daily Measurements button. CONTAK RENEWAL and CONTAK RENEWAL 2 do not have a Daily Measurement feature.

2) If an LV lead is implanted, but not being used:

- *During commanded Impedance and Threshold Tests performed through Quick Check or Diagnostic Evaluation, the patient may feel temporary diaphragm stimulation while the test is run.*
- *During a commanded Threshold Test performed through Quick Check, when prompted to start the LV Threshold Test, select Cancel or consider de-selecting the LV Threshold Test prior to starting commanded test. If the LV threshold test commences, consider closing the LV Threshold window; this will cancel the test.*

CRT-P Systems from Boston Scientific - INVIVE™

Indications
The INVIVE cardiac resynchronization therapy pacemaker (CRT-Ps) is indicated for patients who have moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF ≤ 35%) and QRS duration ≥ 120 ms and remain symptomatic despite stable, optimal pharmacologic therapy for heart failure. Atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in physical activity.

Contraindications
These devices are contraindicated in patients who have a separate implanted cardioverter-defibrillator (ICD). Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction. Atrial tracking modes are contraindicated for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single use only. Do not reuse, reprocess or resterilize. Always have external defibrillation protection available during implant and electrophysiologic testing. Do not use this pulse generator with another pulse generator. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversible to Safety Core operation. Do not kink, twist, or braid leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial only modes in patients with heart failure. In devices with the lead safety switch programmed to On, the lead polarity will switch to unipolar in the presence of a lead impedance of ≤ 200 or ≥ 2000 Ω. If programmed to a fixed atrial sensitivity value of 0.15 mV, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. Left ventricular (LV) lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments ; home and occupational environments; follow up testing; explant and disposal; and supplemental precautionary information. Advise patients to avoid sources of electric or magnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events
Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, lead tip deformation and/or breakage, procedure related, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/ precautions and adverse events. Rx only.(Rev. A)

CRT-P System from Boston Scientific – CONTAK® RENEWAL™ TR

Indications
The CONTAK RENEWAL TR pulse generator is indicated for patients who have moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF ≤ 35%) and QRS duration ≥ 120 ms and remain symptomatic despite stable, optimal heart failure drug therapy (as defined in the clinical trials section in the System Guide). These devices provide atrial-ventricular tracking modes to help preserve AV synchrony and adaptive-rate pacing for patients who would benefit from adjusted pacing rates concurrent with physical activity.

Contraindications
These devices are contraindicated in patients who have a separate implanted cardioverter-defibrillator (ICD). Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction. Atrial tracking modes are contraindicated for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only Do not reuse, reprocess, or resterilize. Such damage can result in patient injury or death. Do not expose a patient to MRI device scanning. Do not expose a patient with an activated implanted pulse generator to diathermy. Do not use atrial-only modes in patients with heart failure. The clinical outcomes for patients with chronic refractory atrial tachyarrhythmias are not fully known. Safety and effectiveness studies have not been conducted. If a chronic refractory atrial tachyarrhythmia develops in a patient with these devices, do not use dualchamber or single-chamber atrial pacing. Left ventricular (LV) lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implantation and device programming; pulse generator explant and disposal; environmental and medical therapy hazards. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events
Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, lead tip deformation and/or breakage, procedure related, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/ precautions and adverse events. Rx only.(Rev. M)

CRT-D System from Boston Scientific – COGNIS®

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 ≤ 35% and QRS duration ≥ 120 ms
• Left bundle branch block (LBBB) with QRS ≥ 130 ms, EF ≤ 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
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures. Always have sterile external and internal defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. 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. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator to diathermy, Do not use atrialtracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist or braid the lead with other leads. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implant and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events
Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. R)

CRT-D Systems from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™

Indications and Usage
The PUNCTUA™, ENERGEN™, and INCEPTA™ 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 ≤ 35% and QRS duration ≥ 120 ms
• Left bundle branch block (LBBB) with QRS ≥ 130 ms, EF ≤ 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
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. 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. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator to diathermy, Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist or braid the lead with other leads. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet. For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; and supplemental precautionary information. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events
Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. B)

LATITUDE® Patient Management System from BostonScientific

Intended Use
The LATITUDE Patient Management system is intended for use to remotely communicate with a compatible pulse generator from Guidant or Boston Scientific CRM and transfer data to a central database. The LATITUDE system provides patient data than can be used as part of the clinical evaluation of the patient.

Contraindications
The LATITUDE system is contraindicated for use with any pulse generator other than a compatible pulse generator from Guidant or Boston Scientific CRM. Not all Guidant or Boston Scientific pulse generators are compatible with the LATITUDE system. For contraindications for use related to the pulse generator, refer to the System Guide for the pulse generator being interrogated.

Precautions
The LATITUDE system is designed to notify clinicians within 24 hours if new red alert conditions are detected by the Communicator. Alert notifications are based on clinician configured alert settings. Pulse generator data is typically available for review on the LATITUDE system within 15 minutes of a successful interrogation. However, data availability and alert notification can take up to 24 hours or the next business day. Note that pulse generator data will not be available and alert notification cannot occur if:

- The Communicator is unplugged or is not able to connect to the LATITUDE system through an active phone line.
- The pulse generator and the Communicator cannot complete a telemetry session. This session must be initiated by the patient if he or she has a pulse generator that uses inductive telemetry.
- The Communicator is damaged or malfunctions.
- The patient is not compliant with prescribed use or is not using the LATITUDE system as described in the patient manual.
- Up to two weeks may elapse before LATITUDE first detects the conditions mentioned above. Additional time may be required for clinic notification and resolution of the condition. During this time, no new patient data, device data, or alert notifications since the last successful data transmission are available.

Adverse Effects
None known.

Refer to the product labeling for specific instructions for use. Rx only. (Rev. L)