

SUMMARY

This article describes programmable Boston Scientific pacemaker and defibrillator features that are designed to assist with management of retrograde conduction and to help terminate or avoid pacemaker-mediated tachycardia (PMT). Suggestions are also included to help evaluate a recorded PMT episode and determine if the episode was the result of retrograde conduction or normal tracking of intrinsic atrial events.

Products Referenced

All Boston Scientific dual chamber pacemakers and defibrillators

The following are trademarks of Cardiac Pacemakers Inc., a Boston Scientific company: ZOOM[®] LATITUDE[®]

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

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Pacemaker-Mediated Tachycardia (PMT) and Dual-Chamber Pacemakers and Defibrillators

Retrograde Conduction and PMT

Pacemaker and defibrillator patients may lose A-V synchrony for many reasons, including atrial fibrillation, AV block, premature ventricular contractions (PVCs), atrial oversensing, or loss of atrial capture. If the patient has an intact retrograde conduction pathway at the time A-V synchrony is lost, the unsynchronized ventricular beat may conduct retrograde to the atria, resulting in premature atrial depolarization. If the patient's pacemaker or defibrillator is programmed to a DDD/R or VDD/R pacing mode and senses the retrograde-induced atrial event outside of the refractory period, it will respond by pacing the ventricle at the end of the A-V Delay. The repeated cycle of sensing and tracking retrograde conduction (atrial-sense, ventricular-pace), is known as pacemaker-mediated tachycardia (PMT), and can continue until retrograde conduction is lost or the atrium becomes refractory. PMT can result in ventricular pacing rates as high as the Maximum Tracking Rate (MTR).

Programmable Parameters and Features to Manage the Device's Response to Retrograde Conduction and to Help Terminate PMT

Identifying the patient's retrograde conduction time can be useful in programming device refractory periods and other parameters that help control the pacemaker's response to retrograde conduction, should it occur. For example, where available, consider utilizing:

- *Certain refractory periods* to reduce the likelihood of tracking retrograde events:
 - Extended **PVARP** (Post Ventricular Atrial Refractory Period)
 - **Dynamic PVARP**
 - **PVARP after PVC/PAC**
- *Rate Smoothing* to help control the pacemaker's response to fluctuations in the paced rate caused by retrograde conduction.
- *A non-tracking mode* (e.g., VVI/R, DDI/R) to eliminate atrial tracking when PMT cannot be controlled by other programming options.

Retrograde conduction times may vary over a patient's lifetime due to their changing medical condition. Occasionally, the patient may need to be re-evaluated and the device reprogrammed to accommodate changing retrograde conduction times.

Boston Scientific pacemakers and defibrillators incorporate **PMT Termination** to address situations in which the device's response to retrograde conduction has not been controlled by other programming options. **PMT Termination** is an algorithm designed to detect and terminate PMT within 16 cycles of onset when both of the following conditions have been satisfied:

1. Sixteen consecutive AS (atrial sensed) events followed by VP (ventricular paced) events at the MTR.
2. All 16 V-A intervals are within 32 ms from the measured baseline interval.

NOTE: The measured baseline interval used for stability analysis will vary, depending on the device model.

When these conditions have been met, PVARP extends to 500 ms for one cardiac cycle in an effort to prevent the retrograde event from being tracked (Figure 1). The lack of a subsequent paced ventricular event may allow repolarization of the retrograde pathway and thereby terminates the PMT episode.

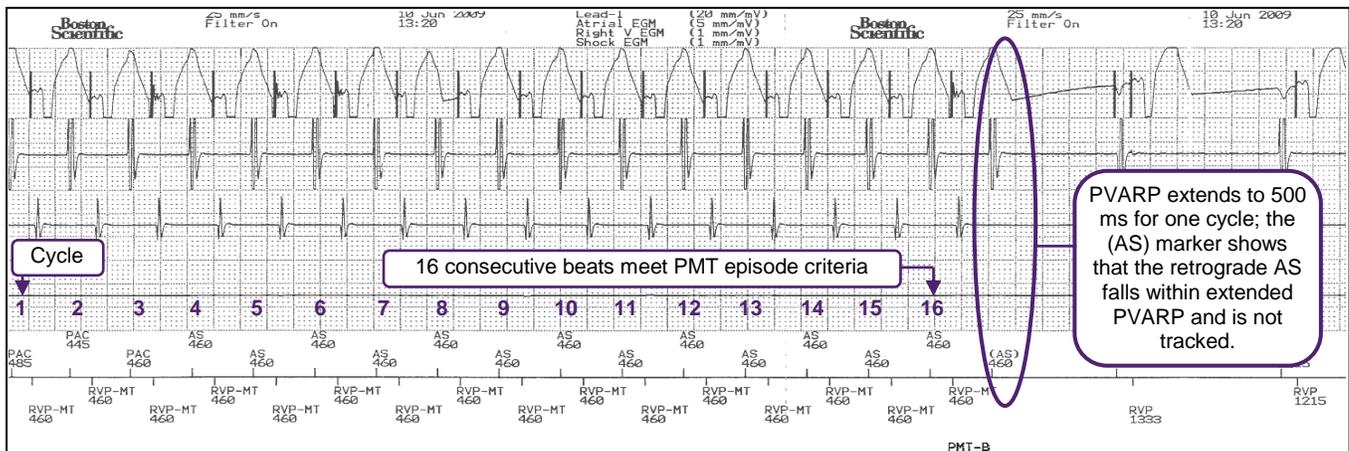


Figure 1. Example of the PMT Termination algorithm terminating PMT by extending PVARP in a CRT-D.

Although the PMT interval evaluation helps discriminate true PMT (stable V-A intervals) from upper rate behavior due to sinus tachycardia or normal exercise response (typically unstable V-A intervals), it is possible that, on occasion, a patient's intrinsic atrial rate can meet PMT detection criteria. In such cases, the algorithm will declare the rhythm a PMT and extend PVARP on the 16th cycle (Figure 2).

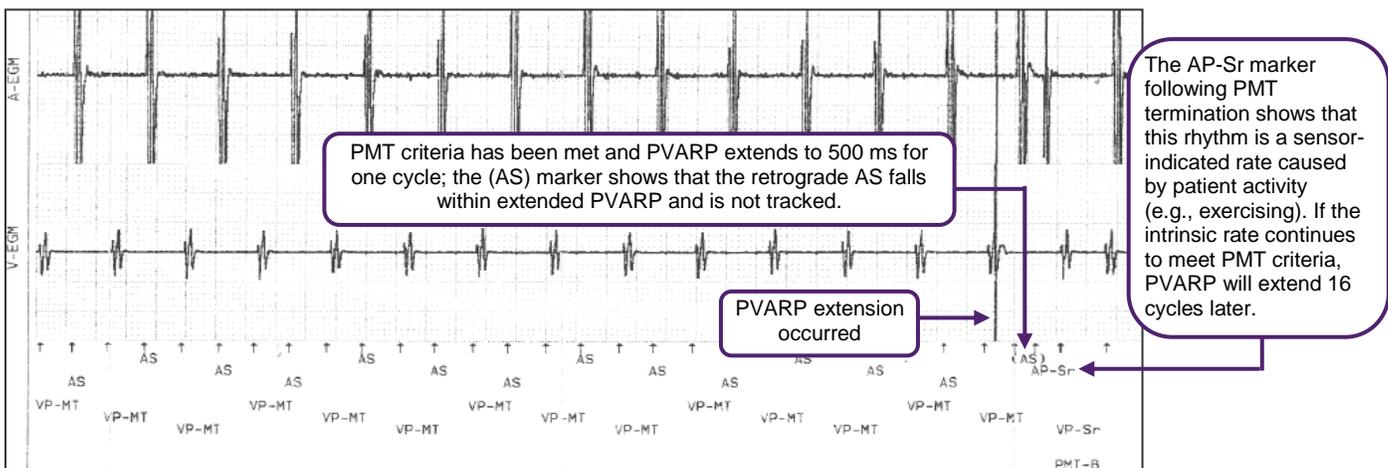


Figure 2. Example of a PMT episode caused by tracking of normal intrinsic atrial activity (EGM from DR pacemaker).

PMT Episode Analysis

PMT episode information stored within the device can be evaluated to determine if the patient's episode was the result of PMT caused by retrograde conduction or if the episode was due to tracking of intrinsic atrial events (e.g., a sinus rate \geq MTR during exercise).

If retrograde conduction is evident in a stored electrogram, the clinician can evaluate the electrogram and/or perform a threshold test to confirm appropriate atrial pacing and sensing. If stored electrograms are not available for review, information in Table 1 provides information on how real-time diagnostics within ZOOM[®] LATITUDE[®] programmer can be used to assist in V-A interval evaluation. When evaluating pacemaker diagnostics, the PRM must be set up to enable event marker viewing.

Table 1. Using the ZOOM LATITUDE Programmer to Assist in V-A Interval Evaluation

Looking for retrograde conduction by temporarily programming the device to sense in the atrium and pace in the ventricle at different rates.
<p>A. Access the temporary parameter screen in the device.</p> <ul style="list-style-type: none">• Select Brady Parameters > Temporary Parameters. <p>B. Program the device to the appropriate atrial sensing mode that provides atrial markers for interval evaluation.</p> <ul style="list-style-type: none">• For pacemakers—select VDD• For defibrillators—select VDD or VVI <p>C. Program PVARP to a value shorter than the average retrograde conduction time. <i>NOTE: Scientific literature suggests that the average retrograde conduction time is 235 ± 50 ms (with a range of 110-450 ms).²</i></p> <p>D. Select a Lower Rate Limit (LRL) value to ensure pacing above the intrinsic atrial rate (e.g., 90, 100, 110,...).</p> <p>E. For pacemakers, turn on real-time intervals.</p> <p>F. Begin printing the real-time ECG.</p> <p>G. Select Start to enable the temporary parameters.</p> <p>H. When testing is complete for the specified LRL value:</p> <ul style="list-style-type: none">• <u>Select Cancel</u> on the programmer screen or remove the telemetry wand. <p>I. Stop printing real-time electrograms.</p> <p>J. Repeat steps D-H using different LRL values, as retrograde conduction may occur at different rates.</p>

Table 1. Continued.

- A. Evaluate the ECG strip for V-A conduction (VP followed by an AS event).
- B. Look for stable and consistent intervals suggestive of retrograde conduction (Figure 3).

Stable V-A intervals

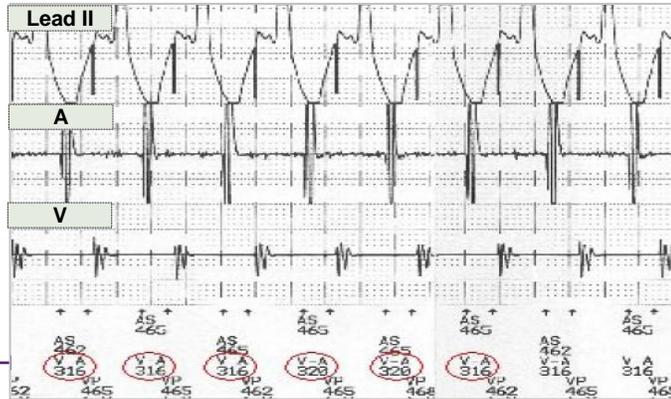


Figure 3. Example of retrograde conduction at stable intervals (pacemaker EGM).

After evaluation of V-A intervals, consider programming changes, if necessary.

If retrograde conduction was identified:

Compare the retrograde V-A interval time to the programmed refractory period (PVARP, Dynamic PVARP, and/or PVARP after PVC). Consider programming the minimum refractory period longer than retrograde V-A interval.

NOTE: When adjusting the minimum refractory period, the Total Atrial Refractory Period (TARP = AV Delay + PVARP) MTR may need to be adjusted in order to minimize unwanted upper rate behaviors such as 2:1 block.

If retrograde conduction was not identified:

The PMT episode may be due to normal tracking of intrinsic atrial rates. Review device Histograms to determine how often the rate is at the MTR and consider raising the MTR, if clinically appropriate.

NOTE: If the Arrhythmia Logbook shows a large number of PMT episodes due to tracking of intrinsic atrial rates, PMT episode storage can be programmed Off in the device to help conserve space in the Arrhythmia Logbook.

CRT-D Systems from Boston Scientific CRM

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 \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

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. 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 device 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 specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs.

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, 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 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. P) NOTE: Most Current Revision Found @ <http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/CRT-D-systems.html>

ICD Systems from Boston Scientific CRM

ICD Indications and Usage

ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. ICDs (i.e. Vitality AVT) with atrial therapies are also intended to provide atrial antitachycardia pacing and atrial defibrillation treatment in patients who have or are at risk of developing atrial tachyarrhythmias.

Contraindications

Use of ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. For single patient use only Do not reuse, reprocess, or resterilize. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures. Always have sterile external and internal defibrillator protection available during implant. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing. Patients should 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 device scanning. Do not subject a patient with an implanted pulse generator to diathermy. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias.. (applies to dual-chamber devices only.) Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads.

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; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments follow-up testing; explant and disposal; post-therapy pulse generator follow-up. Advise patients to avoid sources of electromagnetic interference (EMI).

Potential Adverse Events

Potential adverse events from implantation of the ICD 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, psychological intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, 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. O) NOTE: Most Current Revision Found @ <http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/ICD-systems.html>

CRT-P Systems from Boston Scientific CRM

Indications and Usage

Cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients who have moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF \leq 35%) and QRS duration \geq 120 ms and remain symptomatic despite stable, optimal heart failure drug therapy. The 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 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 \leq 200 or \geq 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; TENS; electrocautery and RF ablation; ionizing radiation; elevated pressures. 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. L) NOTE: Most Current Revision Found @ <http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/CRT-P-systems.html>

Pacing Systems from Boston Scientific CRM

Indications

Pacemaker indications include: symptomatic paroxysmal or permanent second- or third-degree AV block; symptomatic bilateral bundle branch block; symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders; bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Pacemakers' dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual-chamber modes are specifically indicated for: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (eg, pacemaker syndrome) in the presence of persistent sinus rhythm or low cardiac output or congestive heart failure secondary to bradycardia.

Contraindications

Pacemakers are contraindicated for the following patients under the circumstances listed: patients who have a separate implanted cardioverter-defibrillator (ICD); use of Minute Ventilation in patients with both unipolar atrial and ventricular leads single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing; dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias; asynchronous pacing 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 sterilize. 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. 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 $\geq 2000 \Omega$. 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. Inappropriate sustained high-rate pacing occurred in the PULSAR™ MAX clinical study in 5 out of 130 patients with MV ON, 4 to 14 days after implant. If sustained high-rate pacing could be of concern, consider programming a reduced Max Sensor Rate or MV to Passive. These programming recommendations are intended to assure that MV calibration is evaluated and, if necessary, recalibrated (4 □ ON) when the patient and pacing system have stabilized post implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred.

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; TENS; electrocautery and RF ablation; ionizing radiation; elevated pressures. 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, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, 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. P) NOTE: Most Current Revision Found @ <http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/pacing-systems.html>

ZOOM® LATITUDE® Programming System from Boston Scientific CRM

Intended Use

The Model 3120 Programmer/Recorder/Monitor (PRM) is intended to be used as a complete system to communicate with Guidant or Boston Scientific implantable pulse generators. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the System Guide for the Guidant or Boston Scientific pulse generator being interrogated.

Contraindications

The Model 3120 PRM is contraindicated for use with any pulse generator other than a Guidant or Boston Scientific device. For contraindications for use related to the Guidant or Boston Scientific pulse generator, refer to the System Guide for the Guidant or Boston Scientific pulse generator being interrogated.

Warnings

There are no warnings associated with this programming system.

Precautions

For specific information on precautions, read the following sections of the product labeling: General, Preparation for Use, Maintenance, and Handling.

Adverse Effects

None known.

Refer to the product labeling for specific instructions for use. Rx only.

(Rev. E)
