**A Closer Look**

**SUMMARY**

Boston Scientific pulse generators have an electrocautery mode that can be used to disable device therapy during a surgical procedure where noise generated from electrosurgical equipment (for example, TENS, electrocautery, electrolysis, etc.) could potentially cause inappropriate therapy or device damage.

This article provides instructions on how to use the electrocautery mode feature in BSC defibrillators and pacemakers.

**Electrocautery Mode in BSC Defibrillators and Pacemakers**

Boston Scientific pulse generators have a programmable electrocautery mode that can be used to prevent noise-induced inappropriate therapy and help prevent pulse generator circuitry damage during a medical procedure where electrosurgical equipment is used. Prior to such procedures, consider programming the pulse generator to an electrocautery mode. **NOTE:** Other options to manage device therapy (programming or magnet application) are described in pulse generator Instructions for Use (Reference Guide and Physician’s Technical Manual).

**Electrocautery Mode in Boston Scientific Defibrillators**

**Electrocautery Protection Mode** for current generations of Boston Scientific defibrillators, or **Off-Electrocautery Mode** for older generations of BSC defibrillators, deactivates the tachyarrhythmia detection and therapy features of the pulse generator during use of electrosurgery or other electronic surgical equipment. When the electrocautery mode is enabled by the physician, bradycardia pacing is still functional; however, the pacing mode switches to an asynchronous pacing mode. For example, any Dual mode changes to DOO, any Ventricular mode changes to VOO and any Atrial mode changes to AOO. Pacing is at the Lower Rate Limit (LRL) and outputs remain at the programmed settings. Once enabled, Electrocautery Protection/Off-Electrocautery does not require constant telemetry to remain enabled.

**NOTE:** If a higher asynchronous rate is desired, the LRL should be adjusted prior to enabling the electrocautery mode.

**CAUTION:** The pulse generator will not detect or deliver therapy for tachyarrhythmias when electrocautery mode is enabled. When use of electrosurgical equipment is complete, it is important to cancel Electrocautery Protection Mode/Off-Electrocautery and to verify the programmed parameter settings.

**Electrocautery Mode in Boston Scientific Pacemakers**

**Electrocautery Protection Mode** in current generation BSC pacemakers provides asynchrony pacing at the programmed outputs and LRL. For example, any Dual mode changes to DOO, any Ventricular mode changes to VOO, and any Atrial mode changes to AOO. If Brady Mode is Off prior to enabling Electrocautery Protection, it will remain Off during Electrocautery Protection. Once enabled, Electrocautery Protection does not require constant telemetry to remain enabled.

**NOTES:**

- **If a higher asynchronous rate is desired, the LRL should be adjusted prior to enabling the electrocautery mode.**
- **When use of electrosurgical equipment is complete, it is important to cancel Electrocautery Protection Mode and to verify the programmed parameter settings.**

This article provides step by step instructions on how to use (enable and cancel) Electrocautery modes in BSC defibrillators and pacemakers.

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STEP 1: Power On the ZOOM® LATITUDE® Programmer and start a telemetry session.

STEP 2: Review messages and/or System Summary screen. If there are any red or yellow warning screens, information or stop sign icons, call Technical Services before proceeding.

STEP 3: Enable the Electrocautery Mode.

For current generations of BSC defibrillators¹

- Select the Tachy Mode button at the top of the Main Application screen, which will open the Change Device Mode screen (Figure 4).
- Select the Electrocautery Protection Mode checkbox.
- Select Apply Changes button.
- **Electrocautery Protection Mode is enabled** (Figure 5).

For older generations of BSC defibrillators²

- Select Tachy Mode at top of the Main Application screen (Figure 6).
- Select Off- Electrocautery.
- **Off-Electrocautery Mode is enabled** (Figure 7).

NOTES:

- To print a record of Electrocautery Mode being enabled, press one of the print speed keys on the programmer prior to activating Electrocautery Protection Mode, then enable Electrocautery Protection. An entry is made at the bottom of the printer paper that reads “Electrocautery Protection Enabled.”

- Once enabled, Electrocautery Protection Mode/Off-Electrocautery will be canceled if the DIVERT, STAT SHOCK, or STAT PACE buttons are pressed, and will result in the Tachy Mode reverting to the previous mode. If the electrosurgical procedure is not complete, the electrocautery mode will need to be enabled as desired.

- When using Electrocautery Protection Mode or Off-Electrocautery for extended periods of time, consider exiting the session by powering the programmer Off once Electrocautery Protection Mode has been enabled. This will avoid prolonged ZIP telemetry use which can impact pulse generator longevity.

- The programmer may be turned Off by pressing the power button on the left side—as Electrocautery Protection does not require constant telemetry from the programmer to remain enabled. **CAUTION:** The user will be required to interrogate the device again in order to cancel Electrocautery Protection Mode and re-enable therapy.
STEP 3: Enable the Electrocautery Mode continued…

For current generations\(^1\) of BSC pacemakers

- Select the Device Mode button at the top of the Main Application screen. This will open the Change Device Mode screen (Figure 8).
- Select the Electrocautery Protection Mode checkbox.
- Select Apply Changes button.
- Electrocautery Protection Mode is enabled (Figure 9).

**NOTES:**

- To print a record of Electrocautery Mode being enabled, press one of the print speed keys on the programmer prior to activating Electrocautery Protection Mode, then enable Electrocautery Protection. An entry is made at the bottom of the printer paper that reads “Electrocautery Protection Enabled”.
- Except for STAT PACE, no commanded therapies, inductions, or diagnostic tests will be allowed while Electrocautery Protection is enabled.
- Electrocautery Protection will be cancelled if the STAT PACE or the Divert Therapy programmer key is pressed. If the electrosurgical procedure is not complete, the electrocautery mode will need to be enabled as desired. **CAUTION:** The user will be required to interrogate the device again in order to cancel Electrocautery Protection Mode and resume demand pacing.

STEP 4: Cancel the Electrocautery Protection Mode.

If Electrocautery Protection Mode is enabled, the device will be returned to its previous settings by cancelling Electrocautery Protection Mode when the electrosurgical procedure is complete.

- If the ZOOM LATITUDE programmer has been powered Off, power it back On and start a telemetry session.
- Select the Cancel Electrocautery Protection button (Figures 10-12).

**NOTES:**

- To print a record of Electrocautery Mode being cancelled, press one of the print speed keys on the programmer prior to deactivating Electrocautery Protection Mode, then cancel Electrocautery Protection. An entry is made at the bottom of the printer paper that reads “Electrocautery Protection Disabled”.
- For BSC defibrillators, after cancelling Electrocautery Protection Mode/Off-Electrocautery Mode, the Ventricular Tachy Mode and Brady Mode will revert to the previously programmed settings.
- For BSC pacemakers, after cancelling Electrocautery Protection Mode, the Brady Mode will revert to the previously programmed settings.
**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-V)** with EF $\leq 35\%$ and QRS duration $\geq 120$ ms
- **Left bundle branch block (LBBB) with QRS $\geq 130$ ms, EF $\geq 30\%$, 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 re-use, reprocess, or re-sterilize. 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 expose a patient with an implanted pulse generator to diathermy. Do not use anti-tracking modes in patients with chronic refractory atrial tachycard/arythmias. 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, 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:

- **Moderate to severe heart failure (NYHA Class III-V)** with EF $\leq 35\%$ and QRS duration $\geq 120$ ms
- **Left bundle branch block (LBBB) with QRS $\geq 130$ ms, EF $\geq 30\%$, 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 re-use, reprocess, or re-sterilize. 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 expose a patient with an implanted pulse generator to diathermy. Do not use atrial-tracking modes in patients with chronic refractory atrial tachycardias. 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; 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, warnings/precautions and adverse events. Rx only. (Rev. B)

**ICD Systems from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™**

**ICD Indications and Usage**

The PUNCTUA™, ENERGEN™, and INCEPTA™ ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

**Contraindications**

Use these ICDs are contraindicated in Patients whose ventricular tachycard/arythmias may have reversible cause, such as 1) digitals intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachycardias 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 re-use, reprocess, or re-sterilize. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem 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. 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 scanning. Do not expose a patient with an implanted pulse generator to diathermy. Do not use atrial tracking modes in patients with chronic refractory atrial tachycardias. 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 DF-4-LHH or DF-4-LLO 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 DF-4-LHH or DF-4-LLO 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, warnings/precautions and adverse events. Rx only. (Rev. B)

**ADDENDUM TO: 100000007471, Rev. A, US**

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ICD Systems from Boston Scientific – TELIGEN®

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 external defibrillator protection available during implant and electrophysiologic testing. 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 scanning. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias. Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads. 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 pulse 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 and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments follow-up testing; explant and disposal; supplemental precautionary information. 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), hematomas/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 atrianthythmic 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. Q)

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 may 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 ≤ 2000 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), hematomas/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)

Pacing Systems from Boston Scientific – INGENIO™ and ADVANTIO™

Indications

Ingenio and Advantio 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 hypotensive 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 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. 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 ≤ 2000 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.

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, lead or accessory breakage (fracture/insulation/lead tip), hematomas/seromas, inappropriate or inability to provide therapy (shocks/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. A)
ZOOM® LATITUDE® Programming System from Boston Scientific

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 indications, contraindications, warnings/precautions and adverse effects. Rx only. (Rev. E)