

## SUMMARY

The Boston Scientific Model 3120 Programmer/Recorder/Monitor (PRM) allows the user to save patient data to a USB pen drive for use in later sessions. Use of a USB Switch Box, detailed in this article, minimizes the need to plug and unplug the USB pen drive.

### Products Referenced

ZOOM® LATITUDE® Programming System, PUNCTUA™, ENERGEN™, INCEPTA™, ADVANTIO®, INGENIO®, VITALIO®, FORMIO™, INVIVE™, INTUA™, ALTRUA®, DISCOVERY®, DISCOVERY® II, INSIGNIA® Entra, INSIGNIA® I Plus, INSIGNIA® AVT, INSIGNIA® Ultra, PULSAR MAX II, PULSAR MAX, PULSAR, MERIDIAN, VENTAK PRIZM®, VITALITY®, CONTAK RENEWAL®, CONTAK RENEWAL TR®, CONFIENT®, LIVIAN®, COGNIS®, and TELIGEN®

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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](http://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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## Use of a USB Switch Box While Saving and Managing Patient Data on a USB Pen Drive

Patient and device data from the referenced Boston Scientific implantable devices can be downloaded from device memory and stored on a USB pen drive for future use or for transfer to an Electronic Records Management System. This process is detailed in the **A Closer Look** article “Saving and Managing Patient Data on a USB Pen Drive”.

Use of a USB Switch Box minimizes the need to plug and unplug the USB pen drive. A USB Switch Box (Figure 1) allows two or more computers, such as a Model 3120 ZOOM® LATITUDE® Programmer/Recorder/Monitor (PRM) and a clinic computer, to connect to a single pen drive at the same time. Pressing a button on the Switch Box allows the pen drive to simultaneously serve both associated computers, thereby reducing the need to connect and disconnect cables to facilitate transfer of data from one computer to another.

### Compatible USB Switch Boxes

Several models of USB Switch Box are commercially available. They may also be referred to as a “share switch” or a “hub.” Testing of two randomly selected models resulted in successful data transfer. The models tested were:

- 4-PC-to-1 USB 2.0 Device ABCD Switch Box
- USB-3100 4 to 1 USB 2.0 Automatic Switch Box

Based on the compatibility analysis, USB Switch Boxes equivalent to those tested should be acceptable for use.

### Setting Up the Connection

USB Switch Boxes normally have one Type- A connector for the USB pen drive and two or more Type-B connectors for the USB cables connecting the PRM and the clinic computer (Figure 1).

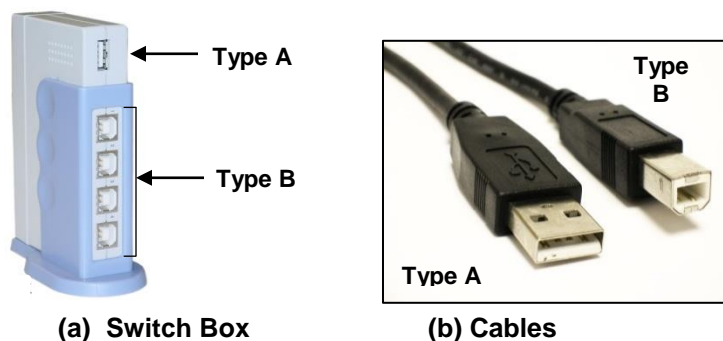
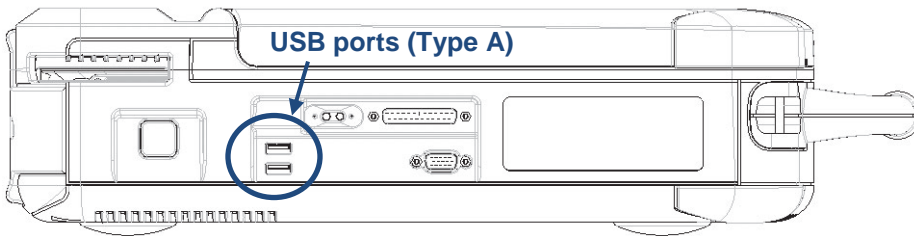


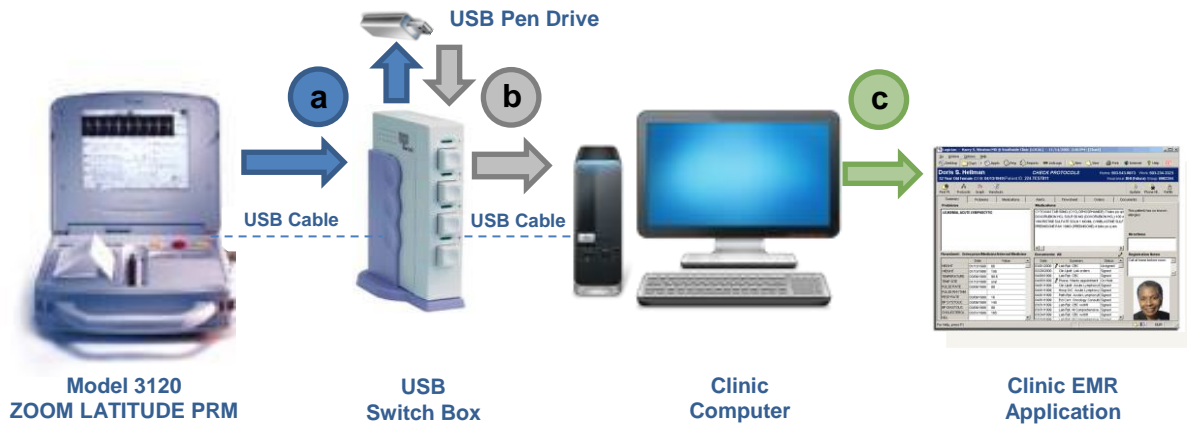
Figure 1. Type- A and Type-B USB connectors shown on a 4-port USB Switch Box and cables.

Figures 2 and 3 show how to connect the PRM, Switch Box and clinic computer:

- 1) Connect the Type-A end of a USB cable to the USB port on the left side of the 3120 ZOOM LATITUDE PRM
- 2) Connect the other end of the cable to one of the Type-B ports on the Switch Box
- 3) Connect the Type-A end of a USB cable to the USB port in the clinic computer
- 4) Connect the other end of the cable to one of the Type-B ports on the Switch Box
- 5) Insert a USB pen drive into the Type-A connector on the Switch Box



**Figure 2.** Two USB ports are located on the of the Model 3120 ZOOM® LATITUDE® Programmer/Recorder/Monitor.



**Figure 3.** The 3120 Programmer/Recorder/Monitor, USB Switch Box, and clinic computer are connected via USB cables (dotted lines). Data flow (colored arrows) is as follows: PRM through the Switch Box, to the USB pen drive (a); then, after the switch is toggled, from the USB pen drive, through the Switch Box, to the clinic computer (b). From this computer it is shared via the clinic’s Electronic Medical Records application (c).

**PRECAUTION:** Although any optional external equipment connected to the programmer may meet leakage-current requirements for commercial products, it may not meet the more stringent leakage requirements for medical products. Consequently, the external equipment must be kept outside the patient environment (at least 1.5 m [4.9 feet] away from the patient).

Additionally, equipment connected to the external connections must comply with applicable standards (e.g., IEC/EN 60950-1 for data processing equipment and IEC/EN 60601-1 for medical equipment).

**WARNING:** The use of any cables or accessories with the programmer other than those specified by Boston Scientific in the Instructions for Use (IFU) may result in increased emissions or decreased immunity of the programmer. Anyone connecting such cables or accessories to the programmer may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.

## Transferring Patient Data Using a USB Switch Box

To transfer data from the PRM to the clinic computer using the USB Switch Box (Figure 3):

- 1) Select the USB Switch Box channel for the PRM
- 2) Transfer data from the PRM to the USB pen drive. Follow instructions in PRM labeling and the **A Closer Look** article “Saving and Managing Patient Data on a USB Pen Drive”.
- 3) After data has been transferred to the USB pen drive, switch the USB Switch Box channel to the clinic computer
- 4) Use the client Electronic Medical Records application on the clinic computer to access and/or import patient data from the USB pen drive (Figure 3b).
- 5) Remove the USB pen drive from the Switch Box and safely store.
- 6) Review patient data within the clinic’s Electronic Medical Records application (Figure 3c).

If you require further assistance, please contact Boston Scientific Technical Services at the numbers listed on page 1.

## CRT-P Systems from Boston Scientific - INVIVE™ and INTUA™

### Indications

The INVIVE™ and INTUA™ 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. C)*

## 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. N)*

## Pacing Systems from Boston Scientific – INGENIO™, ADVANTIO™, and VITALIO™

### Indications

INGENIO™, ADVANTIO™, and VITALIO™ 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 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 ≤ 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.

### 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 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. C)*

## Pacing Systems from Boston Scientific ALTRUA® and INSIGNIA®

### 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 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.

### Contraindications

Pacemakers are contraindicated for the following patients under the circumstances listed: patients with unipolar pacing leads or in MV mode with an implanted ICD because it may cause unwanted delivery or inhibition of ICD therapy; use of the MV sensor in patients with only unipolar leads, because a bipolar lead is required in either the atrium or the ventricle for MV detection (INSIGNIA® Plus, ALTRUA® 20/40); MV mode in patients with both unipolar atrial and ventricular leads (INSIGNIA® Ultra, ALTRUA® 60); single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias, 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 resterilize devices. 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: MV sensor calibration at implant; clinical considerations; sterilization, storage and handling; lead evaluation and connection; implantation; programming and pacemaker operation; MV initialization; environmental and medical therapy hazards; elevated pressure; explanted pacemakers. Advise patients to avoid sources of electric or magnetic interference (EMI). If the pacemaker inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of the EMI, moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation.

### 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. R)

## 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 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.

### 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. S)

## 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.

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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. C)

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

#### ICD Indications and Usage

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 of these 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 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 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 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; 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), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic 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. C)

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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 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. 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 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 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), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic 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. R)

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### 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 SystemGuide 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)