SUMMARY

This article provides radiation oncologists, cardiologists, and electrophysiologists with information regarding administration of care to patients with implanted cardiac devices undergoing radiation treatment.

The article includes the following:

- Possible effects of radiation therapy on implanted devices
- Clinical recommendations and device programming mitigations
- Answers to frequently asked questions

Products Referenced

All BSC ICDs, CRT-Ds, CRT-Ps, and Pacing Systems, and the LATITUDE® Patient Management System

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

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

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

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

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Therapeutic Radiation and Implantable Device Systems

Many sources of ionizing radiation are commonly used for the diagnosis and treatment of diseases. These sources vary significantly in their potential impact on an implanted cardiac device, such as a pacemaker or defibrillator. Several therapeutic radiation sources are capable of interfering with or damaging an implanted device, including those used for the treatment of cancer (i.e., radioactive cobalt, linear accelerators, radioactive seeds, and betatrons). Most diagnostic tools, such as radiography (X-ray) and fluoroscopy, have not been identified as sources of device interference or damage. The impact of ionizing radiation varies from one implanted device to another and may range from no change in function to a loss of pacing or defibrillation therapy.

If a physician chooses to administer radiation therapy to pacemaker, ICD, CRT-D or CRT-P patients, advance planning and extra precautions are required, as outlined in pacemaker and defibrillator product labeling. Prior to a course of therapeutic radiation treatment, radiation oncologists should consult with the patient's cardiologist or electrophysiologist to develop strategies specific to each patient for monitoring patient health and verifying appropriate device operation during and following radiation treatment sessions.

Factors Determining the Impact of Radiation Therapy on Implanted Device Systems

The impact of therapeutic radiation on implanted devices is difficult to predict. Multiple factors collectively determine the impact of radiation therapy on an implanted device. These factors include:

- Type of implanted device
- Proximity of the implanted device to the radiation beam
- Type and energy level of radiation beam
- Orientation of the beam to the implanted device
- Dose rate
- Total dose delivered over the life of the device
- Shielding of the implanted device
- Patient anatomy and physiology
- Frequency of radiation treatments
- Concurrent therapies and diagnostics

Due to this variability, it is not possible to specify a "safe" radiation dosage or guarantee proper device function following exposure to ionizing radiation.

Potential Impact of Therapeutic Radiation on Implanted Device Systems

Therapeutic radiation, including scatter particles can have a temporary negative effect on the implanted device's electrical components, such as the microprocessor or memory, resulting in temporary alteration of device function. Additionally, the cumulative effects of radiation in sufficient doses (total dose or dose rate) can result in permanent degradation of performance below device specifications.[1]

Exposure to radiation may cause the device to experience one or more of the behaviors described in Table 1. The impact may be temporary or permanent.

Table 1. Potential Device Behaviors (temporary or permanent) Due to Radiation Exposure

ICDs/ CRT-Ds	Pacemakers/ CRT-Ps	Potential Device Behaviors (temporary or permanent)
•	•	Altered device status (e.g., premature elective replacement indicator)
•	•	Altered pacing outputs (e.g., decreased pacing amplitude)
•	•	Inhibition of pacing—pacing therapy not provided when needed
•		Altered tachyarrhythmia outputs (e.g., shock energy)
•		Inhibition of tachyarrhythmia therapy—shock therapy not provided when needed
•		Inappropriate shocks—shock therapy provided when not needed
•	•	Complete loss of device function
•		Reversion to a safety mode*
•	•	Loss of remote monitoring with the LATITUDE® Patient Management System

*These modes (Safety Mode, Safety Core, or Reset Mode), collectively referred to as "Safety Mode" throughout this article, were designed to provide backup pacing and/or shock therapy in some situations when normal device function is not possible. Specific device behavior in these modes varies by device family. If activated, Reset and Safety Mode reload the microprocessor from protected backup memory. Safety Core utilizes independent backup circuitry in case the microprocessor itself is no longer functional. Use of Read Only Memory (ROM) makes this back-up mode less susceptible to radiation damage.

Device memory is the component most likely to be affected by therapeutic radiation (either direct beam or scatter particles). Boston Scientific CRM devices include periodic self-diagnostic memory checks to locate and correct many memory errors. If the degree of memory alteration is beyond the capability of self-correcting algorithms, devices may enter Safety Mode; this mode is designed to provide continuous patient protection by providing basic pacing and/or shock therapy. In other situations, the effects of radiation may cause sufficient damage that Safety Mode may not be available, resulting in loss of therapy. Multiple exposures to any source of ionizing radiation source over the life of the device further increases the likelihood of impacting device function.

Clinical Considerations

Advance planning

Prior to a course of therapeutic radiation treatment, radiation oncologists should consult with the patient's cardiologist or electrophysiologist to develop strategies specific to each patient. When developing a radiation treatment program for patients with implanted devices, the physician team should consider the best method for treating the patient's disease, as well as for protecting the patient's implanted device. Strategies for monitoring patient health and verifying appropriate device operation during and following radiation treatment sessions should be discussed. Additionally, discussion of current patient conditions, including disease state, type of implanted device, and tolerance to potential device function disruptions as previously described will help to optimize success of the radiation treatment program while reducing the potential impact to the implanted device and the patient.[2] The possibility and timing of device replacement should be considered during advance planning as device operation cannot be guaranteed following exposure to therapeutic radiation.

Emphasis should be placed on shielding within the radiation equipment and optimization of the treatment field, as well as focus, direction and energy level of the primary beam. An estimation of the absorbed dose to be received by the device may be calculated. No single total dose limit can be specified for a given device family due to the variations listed above; however, clinical studies provide some insight into the effects of ionizing radiation from the clinical perspective.[2,3,4,5] Furthermore, some clinical studies do provide a recommended maximum total dose of 2 Gy to the implanted device. [2,5]

Shielding

To reduce the probability of interaction with a primary beam or secondary radiation scatter, consider using all available shielding options, including both internal shielding on the radiation equipment as well as external shielding for the patient. Shielding within the head of the machine should be maximized, and the primary beam should not be aimed directly at the implanted device. If the beam cannot be moved, the physician team may consider other options as described in published studies, such as moving the device to a different location.[2,5,6] The treatment field design should include maximum shielding regardless of the distance from the primary beam, thereby minimizing the potential effects of scatter particles on the device.[5]

Patient care during therapy session

The physician team should determine the most appropriate level of monitoring during treatment. Because each patient's medical condition and type of device is different, the cardiologist or electrophysiologist should provide patient-specific recommendations to promote safety. For example, a pacemaker-dependent patient may require continuous cardiac monitoring during every therapy session.[2]

Device programming considerations

Programming considerations are described in Table 2.

Table 2. Device Programming Considerations

Products	Potential Interactions	Programming Considerations
ICDs & CRT-Ds	• Inhibition of pacing therapy • Inappropriate shock therapy • Inhibition of shock therapy	If inhibition of pacing is observed, a programmer can be used to initiate temporary asynchronous pacing (VOO/AOO/DOO). ➢ Wanded telemetry: the wand must remain in place over the implanted device and the session should be monitored during asynchronous pacing. ➢ Wandless (RF ZIP™) telemetry: the telemetry session should be monitored. Switch to wanded telemetry if necessary. Deactivate tachy therapy. ➢ Program the device Tachy Mode to Electrocautery Protection Mode or to Off-Electrocautery, if available. In these modes, tachyarrhythmia detection and therapy features are deactivated, and the pacing mode switches to an asynchronous mode (VOO, AOO, or DOO). **or** ➢ Program the device Tachy Mode to Off, or place a magnet over the device to temporarily inhibit or deactivate tachy therapy.* The brady pacing mode remains as programmed. **NOTE:** Re-activate the Tachy Mode (Monitor + Therapy) following the session
Pacemakers & CRT-Ps	• Inhibition of pacing therapy	A magnet can be placed over the device to pace asynchronously at the magnet rate. **or** The device can be programmed to an asynchronous pacing mode (VOO, AOO, or DOO).

***NOTE**: If any programming changes were made, the device should be reprogrammed back to the desired settings following the procedure.*

***NOTE**: If using wanded telemetry during the session, the programmer should be located as far from the primary beam as possible.*

*Use of a magnet depends on feature availability and device programming. For additional information, refer to the **A Closer Look** article on this topic.

Assessment of device function after therapy sessions

Boston Scientific recommends evaluation of device function following radiation treatment. The extent, timing and frequency of this evaluation relative to the radiation therapy regimen depend upon current patient health, and therefore should be determined by the attending cardiologist or electrophysiologist. A thorough post-therapy follow-up may include:

- Interrogation of the device with a programmer
- Review of clinical events and fault codes
- Review of the Arrhythmia Logbook, including stored electrograms (EGMs)
- Review of real-time EGMs
- Testing, in all chambers, the pacing threshold, intrinsic amplitude and lead impedance
- Manual capacitor re-formation (only for ICDs and CRT-Ds) ‡
- Programming any Brady setting in permanent Brady Parameters and then reprogramming it back to the desired value
- Programming the Tachy Mode to a new value and then reprogramming back to the desired value (only for ICDs and CRT-Ds)
- Performing a Save All to Disk (exercises additional memory locations)

If any abnormalities are observed during this evaluation, please contact Technical Services; the consultant may request that a Save All to Disk be submitted for analysis.

If any programming changes were made, the device should be reprogrammed back to the desired settings prior to allowing the patient to leave the clinic. **Re-activate the Tachy Mode (Monitor+Therapy) on ICDs and CRT-Ds.**

Patient health may dictate the timing of post-therapy device evaluation activities (for example, timely verification of appropriate pacing is important for a pacer-dependent patient). Many device diagnostics are performed automatically once per hour, so device evaluation should not be concluded until device diagnostics have been updated and reviewed — at least one hour after radiation exposure.

The effects of radiation exposure on the implanted device may remain undetected until sometime following exposure. For example, a malfunction due to radiation exposure may not be discovered until a previously unused device feature is activated several months after completion of a radiation treatment regimen. For this reason physicians should continue to monitor device function closely and use caution when programming a feature following radiation therapy.

‡Longevity impact of manual capacitor reformations varies by device as described in product labeling, and ranges from 5 to 19 days per capacitor reform.

Frequently Asked Questions

Q1. Why doesn't Boston Scientific quote a radiation dosage level that would be considered "safe"?

A1. It is not possible to specify a safe radiation dosage or guarantee proper pulse generator function following exposure to ionizing radiation. Multiple factors collectively determine the impact of radiation therapy on an implanted pulse generator, including proximity of the pulse generator to the radiation beam, type and energy level of the radiation beam, dose rate, total dose delivered over the life of the pulse generator, and shielding of the pulse generator. The impact of ionizing radiation will also vary from one pulse generator to another and may range from no changes in function to a loss of pacing and defibrillation therapy.

It is theoretically possible to quote a dosage level that would result in permanent hardware circuitry damage. However, random alteration of device memory or electrical components by scatter particles (rather than permanent physical damage) is a more concerning issue in modern devices and is difficult to predict by dosage level.[3] Precautions to reduce scatter (shielding, beam focus, energy level selection, treatment field design, etc.) may significantly reduce the probability of impact to device memory. Some devices are susceptible to other sources of radiation that do not originate as scatter. Specifically, thermal neutrons can be generated by linear accelerators and they can adversely affect device behavior.[4,10] Since it is impossible to fully shield against ionizing radiation, devices will always be susceptible to some extent to the effects of ionizing radiation, regardless of the selected energy level or distance from the primary beam.

Q2. If you cannot quote a "safe" radiation dosage level, can you at least quote a "safe" distance from the primary beam?

A2. No.. Despite distance and shielding opportunities, the impact of radiation on the implanted device remains a possibility,[2] and full precautions should be taken under all circumstances, regardless of the distance from implant site to beam location. The likelihood of radiation particles disrupting device function is reduced very quickly as the distance between the implant site and the primary beam increases. Radiation for the treatment of prostate cancer, for example, is more likely to impact an abdominally-placed device than a device implanted in the pectoral region.

Q3. What should be done if the implanted device is positioned in the immediate area to be irradiated?

A3. Consultation with the patient's cardiologist or electrophysiologist is recommended. The physician team may consider moving the device to a different location prior to radiation sessions.[5,6] However, a device may be subject to radiation damage at its new site as well. The physician team may prefer to alter the treatment design and maximize shielding, and then replace a damaged device only once, following completion of the radiation therapy regimen.

Q4. Are "self-check" diagnostics capable of detecting and correcting all modes of radiation-induced failure?

A4. No. As mentioned previously, many minor memory disruptions are found and corrected without any impact to device function. Major disruptions of memory are often identified by self-diagnostic checks, but may be beyond the scope of self-correcting algorithms. It is possible that temporary disruption of electrical components or permanent hardware failure could prevent detection and corrective action (such as memory repair or Safety Mode execution). In this case, diagnostics, therapy and/or telemetry may be non-functional. The location(s) and extent of the damaged components will determine the effect on device functionality.

Q5. Do all Boston Scientific/Guidant devices whose memory is affected revert to Safety Mode?

A5. No. There is also a possibility of permanent damage to the device, and the physician team must consider this possibility during treatment protocol design and post-therapy device assessment.

Q6. What should be done when a device is found in Safety Mode?

A6. While devices in Safety Mode may continue to provide basic pacing and/or shock therapy, these devices should be replaced if and when the physician deems it clinically appropriate for the patient. Limited programmability or complete loss of interrogation/programming and diagnostic features may lead a cardiologist or electrophysiologist to recommend device replacement if and when it is clinically appropriate for the patient. Until replacement, these devices should be monitored closely to verify therapy availability.

Q7. How can the LATITUDE Patient Management system be used to monitor patients undergoing therapeutic radiation?

A7. The LATITUDE Patient Management system can be a supplement to in-clinic evaluations, However, LATITUDE may not be able to alert for many of the possible device outcomes following radiation exposure. For example, LATITUDE may not be able to immediately alert for device conditions if RF ZIP telemetry and/or inductive telemetry are disabled as a result of radiation therapy. However, if the LATITUDE Communicator is unable to detect and interrogate an implanted device for 14 days, the LATITUDE System will generate a Data Collection Failure message which can result in a notification from LATITUDE Customer Support to the clinic. Additionally, LATITUDE cannot be used to command diagnostic functions, such as pacing threshold tests or lead impedance tests, nor can this patient monitoring system be used to program device modes, if needed. An in-clinic follow-up with a programmer is required

to perform these functions. It is important to note that the LATITUDE remote monitoring is currently not available in all geographies or for all products.

Q8. What if the device is damaged during the course of radiation treatment?

A8. If a device is damaged prior to completion of the therapy regime, the patient's cardiologist or electrophysiologist should consider all available options to determine the best course of action. For example, if the patient is pacemaker-dependent, immediate replacement of a device may be required, with special consideration given to location of the new implant (relative to the site of the primary beam). If the patient is not pacemaker-dependent, it may be acceptable to delay a device replacement until completion of all therapy sessions. Similarly, if an ICD or CRT-D is verified to be capable of delivering Safety Mode shock therapy following each treatment session, it may be possible to delay replacement of the device until completion of all therapy sessions.

Q9. Will warranty credit be provided for any device that must be replaced following radiation therapy?

A9. If the device must be replaced following radiation exposure and has not exceeded its defined warranty period, warranty credit will be applied in accordance with the regulations for the geography in which the device was sold. Warranty program requirements include replacement with another Boston Scientific product, as well as return of the device to Boston Scientific within the designated timeframe.

Q10. To what extent are Boston Scientific sales and clinical representatives trained to verify proper device function following radiation therapy?

A10. Boston Scientific field representatives are extremely knowledgeable about the characteristics of appropriate function of Boston Scientific implantable devices. They are often present at implant procedures and subsequent in-clinic follow-up sessions to provide information about device function. However, support from Boston Scientific representatives should occur only under the direction of the attending cardiologist or electrophysiologist, who remains the focal point for prescriptions related to treatment of the patient's specific medical conditions.

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[3]Kobayashi H, Shiraishi K, Tsuchiya H, et al. Soft Errors in SRAM Devices Induced by High Energy Neutrons, Thermal Neutrons and Alpha Particles. *Electron Devices Meeting, 2002. IEDM Digest, International.* 2002:337-340.

[4] Wilkinson JD, Bounds C, Brown T, Gerbi BJ, Peltier J. Cancer-Radiotherapy Equipment as a Cause of Soft Errors in Electronic Equipment. *IEEE Transactions on Device and Materials Reliability.* 2005;5:449-451.

[5]Marbach JR, Sontag MR, VanDyk J, Wolbarst AB. Management of Radiation Oncology Patients with Implanted Cardiac Pacemakers. *American Association of Physicists in Medicine Report No. 45*. 1994:85-89.

[6]Solan A, Solan M, Bednarz G, Goodkin M. Treatment of patients with cardiac pacemakers and implantable cardioverter-defibrillators during radiotherapy. *Int J Radiat Oncol Biol Phys.* 2004;59:897-904.

CRT-D Systems from Boston Scientific CRM (PUNCTUA, ENERGEN and INCEPTA)

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. 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 DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

Precautions

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

Potential Adverse Events

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

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

(Rev. A) NOTE: Most Current Revision Found @ http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/CRT-D-systems.html

CRT-D Systems from Boston Scientific CRM (Other than PUNCTUA, ENERGEN and INCEPTA)

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. 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.

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

ICD Systems from Boston Scientific CRM (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. 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 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 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. A) NOTE: Most Current Revision Found @ http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/ICD-systems.html

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ICD Systems from Boston Scientific CRM (Other than PUNCTUA, ENERGEN, and INCEPTA)

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. 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.

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. P) NOTE: Most Current Revision Found @ http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/ICD-systems.html

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CRT-P Systems from Boston Scientific CRM (INVIVE)

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

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

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

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

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

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

(Rev. A) NOTE: Most Current Revision Found @ http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/CRT-P-systems.html

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CRT-P Systems from Boston Scientific CRM (CONTAK RENEWAL TR)

Indications and Usage
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 dual-chamber or singlechamber atrial pacing. Left ventricular (LV) lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition.

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

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

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

(Rev. M) NOTE: Most Current Revision Found @ http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/CRT-P-systems.html

Pacing Systems from Boston Scientific CRM (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 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 (e.g., 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. A) NOTE: Most Current Revision Found @ http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/pacing-systems.html

Pacing Systems from Boston Scientific CRM (other than INGENIO and ADVANTIO)

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. Q) NOTE: Most Current Revision Found @ http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/pacing-systems.html

ZOOM® LATITUDE® Patient Management System

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

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

Warnings
There are no warnings associated with this programming system.

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

- The Communicator is unplugged or is not able to connect to the LATITUDE system through an active phone line.
- The pulse generator and the Communicator cannot complete a telemetry session. This session must be initiated by the patient if he or she has a pulse generator that uses inductive telemetry.
- The Communicator is damaged or malfunctions.
- The patient is not compliant with prescribed use or is not using the LATITUDE system as described in the patient manual.

Up to two weeks may elapse before LATITUDE first detects the conditions mentioned above. Additional time may be required for clinic notification and resolution of the condition. During this time, no new patient data, device data, or alert notifications since the last successful data transmission are available.

Adverse Effects
None known.

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