SUMMARY

Boston Scientific's LATITUDE™ NXT Patient Management System enables a clinician to periodically monitor patient and device information remotely via a Communicator placed in the patient's home. The clinician can review this information on the LATITUDE NXT website[1] to supplement in-clinic visits.

The LATITUDE NXT system generates alerts for a number of conditions. Alerts are designed to notify the clinician of potential health problems or device clinical events but are not intended to be used as the sole basis for making decisions about patient care.

Products Referenced

LATITUDE NXT Patient Management System
Pacing and Defibrillation Products Supported by LATITUDE NXT

For comprehensive information on device operation, reference the full instructions for use or found at: **www.bostonscientific-elabeling.com**.

CAUTION: US Federal 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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LATITUDE™ NXT Alerts

The LATITUDE Communicator, positioned in the patient's home, periodically collects data from the implanted device and from the optional weight scale and blood pressure monitor, and transmits it to a secure LATITUDE NXT website[1] for clinician review. Data are collected by the LATITUDE NXT system as scheduled by the clinic. Sources of data are as follows:

- Some types of data are ***automatically*** measured by the implanted device and are then made available for collection by the LATITUDE Communicator. For example, battery status is automatically measured by the device throughout its life.
- Other data can also be collected daily by the implanted device when programmed to do so by the clinician. For example, when 'Daily Measurements' are programmed On, lead impedance, intrinsic amplitude, and threshold measurements are performed and available for upload into the LATITUDE NXT system. ***NOTE****: Most Daily Measurements are nominally On.*
- Data from the optional home health monitoring equipment (weight and blood pressure measurements) is transmitted to the patient's Communicator via a wireless connection.

Alerts

Clinicians can review the remotely collected data on the LATITUDE NXT website at their convenience. However, the LATITUDE NXT system will also generate "alert notifications" for a number of potential patient health problems or implanted device clinical events. Alert conditions may be detected during daily alert interrogations, weekly alert interrogations[2], remote scheduled follow-up interrogations, and patient-initiated interrogations. The LATITUDE NXT system notifies the patient's clinicians via the LATITUDE NXT website of any detected alert conditions. Additional alert notifications are also available via text and email messages (see ***Alert Notes***).

There are two levels of alert conditions: red alerts and yellow alerts.

Red Alerts

Red alerts are declared when conditions are detected within the implanted device that could potentially leave the patient without device therapy. They are provided to clinicians in the Primary Patient Group[3] via the LATITUDE NXT website if the Communicator reports that an alert condition has been detected. To receive red alerts, the clinician must log onto the LATITUDE NXT website and review the View Patient List page. If the Communicator is unable to connect and transfer the red alert data within 24 hours, an indicator is illuminated on the Communicator directing the patient to call for further instructions.

1 The LATITUDE NXT website was developed to support Internet Explorer, Mozilla Firefox, and Apple Safari on the Mac, iPad, and iPhone web browsers. The website may not function properly when using browser versions that were subsequently released. Call LATITUDE Customer Support for a list of supported web browsers.

2 Availability dependent on type of implanted device and model of Communicator.

3 Each LATITUDE NXT patient can be associated with up to two different clinics or two different patient groups in one clinic (primary or secondary). The primary clinic /patient group is typically responsible for monitoring a patient's device, including regularly scheduled device follow-ups. This clinic is also responsible for managing red alerts detected when the patient's implanted device is interrogated. The primary clinic is also responsible for managing yellow alerts if notification has been configured. All LATITUDE NXT patients must have an assigned primary clinic in order to be monitored.
NOTE*: Patient Groups provide default alert and schedule configuration settings for associated patients. A patient can have customized settings that differ from the Patient Group default settings.*

Yellow Alerts

Yellow alert notifications are declared when a certain device condition or patient heart-health issue is detected that may warrant clinician review or investigation. Yellow alert notification preferences can be configured by the clinician to ON or OFF. Clinicians may receive all, some, or no yellow alerts. Yellow alerts are provided and accessed through the LATITUDE™ NXT website. For complete instructions on configuring yellow alerts, reference the LATITUDE NXT Patient Management Clinician Manual.

For a complete listing of Alerts, reference Tables 1 and 2.

Alert Notes

- In addition to website review, secondary alert notification is available through text and email messages. These reminders can be configured for red alerts only, yellow alerts only or red and yellow alerts, but only at the Patient Group Level. The clinician can have alert messages sent 24 hours, 7 days a week or Monday through Friday from 8AM to 5PM. Although secondary notification through email and SMS text messages is available[4], these reminders are dependent on external systems and may be delayed or not occur. The secondary notification feature does not eliminate or reduce the need to check the LATITUDE NXT website.
- Alerts are an indicator that further investigation may be appropriate, but are not intended for use as the sole basis for making decisions about patient medical care.
- Alerts can be verified by viewing information on the LATITUDE NXT website and/or by reviewing diagnostic information from the implanted device during an in-clinic interrogation using a programmer.
- Most Daily Measurements are nominally On within the implanted device. However, if these features are programmed Off within the implanted device, the LATITUDE NXT system will ***not*** generate an alert for an event even if the LATITUDE alert is configured On. The implanted device must first measure, record, and detect data as out of range before the LATITUDE NXT system will detect and generate a red or yellow alert.
- If, during self-monitoring, an implanted Boston Scientific device detects certain device and/or lead conditions, a clinical event or status message will be triggered for that condition(s) and subsequent interrogation by a PRM will display either a clinical event and/or status message to alert the user. If the condition is still present when LATITUDE/NXT completes a remote interrogation, and the alert is configured On, then the condition will be displayed as a status message and/or will trigger a corresponding red or yellow alert.
- The LATITUDE NXT system does not provide continuous monitoring. As a remote monitoring system, the LATITUDE NXT system provides periodic patient monitoring as configured by the clinician. There are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of device and patient information as intended by the clinician. For a complete list of system limitations, reference the LATITUDE Patient Management Clinician Manual.

[4] SMS text alerts are not available in Japan.

Table 1. LATITUDE™ NXT Alerts for Pacemakers, ICDs, CRT-Ds, and CRT-Ps

Grouping	Alert	Pace-maker	CRT-P	ICD	CRT-D	Configurable via LATITUDE System (Nominal)	Programmable Limit via Model 3120 programmer (Nominal)
Battery	Remote monitoring disabled due to limited battery capacity	✓	✓	✓	✓	ON	
	Voltage was too low for projected remaining capacity [5]	✓	✓	✓	✓	ON	
	Explant indicator reached [5]	✓	✓	✓	✓	ON, OFF (ON)	
Right Ventricular LATITUDE Lead Check+™	Shock lead impedance out of range [5]			✓	✓	ON	Low (≤20 Ω) [15, 16] High 125-200 Ω (≥125 Ω) [15, 16]
	Low shock lead impedance detected when attempting to deliver a shock [5]			✓	✓	ON	
	High shock lead impedance detected when attempting to deliver a shock [5]			✓	✓	ON	
	Right ventricular or single chamber pacing lead impedance out of range [5, 6]	✓	✓	✓	✓	ON	Low 200-500 Ω (≤200 Ω) [15, 16, 17, 18] High (≥2000 Ω) [17] High 2000-2500 Ω (≥2000 Ω) [15] High 2000-3000 Ω (≥2000 Ω) [16, 18]
	Right ventricular pacing lead impedance abrupt change [7, 8]			✓	✓	ON, OFF (OFF)	
	Right ventricular non-physiologic signal detected [8]			✓	✓	ON, OFF (OFF)	
	Right ventricular or single chamber intrinsic amplitude out of range [5, 6]	✓	✓	✓	✓	ON, OFF (ON)	Low (≤3.0 mV) or (≤0.5 mV)
	Right ventricular automatic threshold detected as > programmed amplitude or suspended [5, 9]	✓	✓	✓	✓	ON, OFF (ON)	
Left Ventricular Pacing Leads	Left ventricular intrinsic amplitude out of range [5]		✓		✓	ON, OFF (ON)	Low (≤3.0 mV)
	Left ventricular pacing lead impedance out of range [5]		✓		✓	ON, OFF (ON)	Low 200-500 Ω (≤200 Ω) [15, 16, 17,18] High (≥2000 Ω) [17] High 2000-2500 Ω (≥2000 Ω) [15] High 2000-3000 Ω (≥2000 Ω) [16, 18]
	Left ventricular automatic threshold detected as > programmed amplitude or suspended [5, 10]				✓	ON, OFF (ON)	
Atrial Pacing Leads	Atrial intrinsic amplitude out of range [5]	✓	✓	✓	✓	ON, OFF (ON)	Low (≤0.5 mV)
	Atrial pacing lead impedance out of range [5, 11]	✓	✓	✓	✓	ON, OFF (ON)	Low 200-500 Ω (≤200 Ω) [15, 16, 17, 18] High (≥2000 Ω) [17] High 2000-2500 Ω (≥2000 Ω) [15] High 2000-3000 Ω (≥2000 Ω) [16, 18]
	Atrial automatic threshold detected as > programmed amplitude or suspended [5, 11, 12]	✓	✓	✓	✓	ON, OFF (ON)	
Tachy Mode/ Therapy	V-Tachy Mode set to value other than Monitor + Therapy [13]			✓	✓	ON	
Arrhythmias	Ventricular shock therapy delivered to convert arrhythmia			✓	✓	ON, OFF (ON)	
	Antitachycardia pacing (ATP) therapy delivered to convert arrhythmia			✓	✓	ON, OFF (ON)	
	Accelerated ventricular arrhythmia episode			✓	✓	ON, OFF (ON)	
	VT Episodes (V>A) [14]	✓	✓			ON, OFF (ON)	
	Atrial Arrhythmia burden of at least {>0, 0.5, 1, 3, 6, 12, 18, or 24} hours in a 24 hour period [7, 14]	✓	✓	✓	✓	ON, OFF (ON) (24 hours)	
	Patient triggered event stored	✓	✓	✓	✓	ON, OFF (ON)	
	Nonsustained ventricular arrhythmia episode(s)	✓	✓	✓	✓	ON, OFF (OFF)	
HeartLogic™ [20]	HeartLogic Index at or above {2,4,6,8,10,12,14,16,18,20,22,24,26,28,30,32,34,36,38,40} [19] Perform daily interrogations until condition is resolved {On/Off}			✓	✓	ON (16) OFF	
Pacing	Cardiac Resynchronization Therapy pacing of < {50, 60, 70, 80, 90, or 95} %		✓		✓	ON, OFF (OFF) (If ON, 80%)	
	Right ventricular pacing of > {10, 20, 30, 40, or 50} % [14]	✓		✓		ON, OFF (OFF) (If ON, 40%)	
Others	Possible device malfunction [5]	✓	✓	✓	✓	ON	
	High voltage detected on shock lead during charge [5]			✓	✓	ON	
	Device in Safety Mode [5, 16, 17]	✓	✓	✓	✓	ON	
	Device in Electrocautery Protection Mode [5]	✓	✓			ON	
	Device Brady Mode Off [13]	✓	✓			ON, OFF (ON)	
	Therapy history corruption detected [5]	✓	✓	✓	✓	ON, OFF (ON)	
	Weight gain of at least {0.45, 0.911, 1.36, 1.81, 2.27, 2,72, 3.18, 3.63, 4.08, or 4.54} kg(s) or {1, 2, 3, 4, 5, 6, 7, 8, 9, or 10) lb(s) in {1-7} day(s)	✓	✓	✓	✓	ON, OFF (OFF) (If ON,2.27 kgs / 5 lbs, 7 days)	
	Signal Artifact Monitor (SAM) device diagnostic	✓	✓			ON, OFF (ON[21], OFF[22])	

Table 2. LATITUDE™ NXT Alerts for the EMBLEM™ S-ICD

Grouping	Alert	Configurable via LATITUDE System (Nominal)
S-ICD	Device battery has reached End of Life (EOL)	ON
	High Electrode Impedance [5]	ON
	Therapy Off	ON
	Possible device malfunction [5]	ON
	Device battery has reached Elective Replacement Indicator (ERI)	ON, OFF (ON)
	Shock therapy delivered to convert arrhythmia	ON, OFF (ON)
	Untreated episode	ON, OFF (ON)
	Sensing not fully optimized	ON, OFF (ON)
	Measured AF of at least {> 0, 0.5, 1, 3, 6, or 12} hours in a 24 hour period (A219 only)	ON, OFF (ON) (If ON > 0 hours in a 24 hour period)
	Weight gain of at least {0.45, 0.911, 1.36, 1.81, 2.27, 2,72, 3.18, 3.63, 4.08, or 4.54} kg(s) or {1, 2, 3, 4, 5, 6, 7, 8, 9, or 10) lb(s) in {1-7} day(s)	ON, OFF (OFF) (If ON,2.27 kgs /5 lbs, 7 days)

Tables 1 and 2. LATITUDE™ NXT Alerts Footnotes

5 The LATITUDE NXT system sends one notification for an alert condition detected by the system. It does not repeat alert notifications for the same condition unless the condition is cleared/reset with a programmer and then reoccurs during a following data collection activity.

6 For single-chamber devices, the amplitude values reported and out of range limits applied correspond to the selected lead position and programmed Brady Mode.

7 If more than 14 days elapse between alert checks, some data may not be assessed for this alert condition.

8 Alert is only available for ICDs and CRT-Ds (Table 2) with Wave™ Communicator Models 6498, 6280, 6290, and 6288.

9 Alert is only available for devices with the Right Ventricular Automatic Threshold feature, which include: ESSENTIO™, PROPONENT™, ACCOLADE™, VALITUDE™, VISIONIST™, ADVANTIO™, INGENIO™, VITALIO™, FORMIO™, INVIVE™, INTUA™, INLIVEN™ and AUTOGEN™, RESONATE™, CHARISMA™, VIGILANT™, MOMENTUM™, and PERCIVA™.

10 Alert is only available for devices with the Left Ventricular Automatic Threshold Feature, which include: VISIONIST™, AUTOGEN™, RESONATE™, CHARISMA™, VIGILANT™, and MOMENTUM™.

11 Alert is not available for Models J178 and K188.

12 Alert is only available for devices with the Right Atrial Automatic Threshold feature, which include: ESSENTIO™, PROPONENT™, ACCOLADE™, VALITUDE™, VISIONIST™, VITALIO™, FORMIO™, INTUA™, INLIVEN™, AUTOGEN™, RESONATE™, CHARISMA™, VIGILANT™, MOMENTUM™, and PERCIVA™.

13 The LATITUDE NXT system will provide one alert notification the first time it detects that the V-Tachy mode has been changed from Monitor + Therapy or the Brady mode has been changed to Off. LATITUDE notification for a new occurrence will not occur until the V-Tachy Mode value is programmed to Monitor + Therapy or the Brady mode value is programmed to a value other than Off in the implanted device at an in-clinic programmer follow-up.

14 Alert is not available for SSI devices.

15 Applies to PUNCTUA™, ENERGEN™, INCEPTA™, COGNIS™ and TELIGEN™ families of ICDs and CRT-Ds.

16 Applies to ORIGEN™, INOGEN™, DYNAGEN™ and AUTOGEN™, RESONATE™, CHARISMA™, VIGILANT™, MOMENTUM™, and PERCIVA™ families of ICDs and CRT-Ds.

17 Applies to ADVANTIO™, INGENIO™, VITALIO™, FORMIO™, INVIVE™, INTUA™ and INLIVEN™ families of pacemakers and CRT-Ps.

18 Applies to ESSENTIO™, PROPONENT™, ACCOLADE™, VALITUDE™, and VISIONIST™ families of pacemakers and CRT-Ps.

19 The LATITUDE NXT system will issue a re-alert if the patient is still in the alert state 7 days after the previous alert. The re-alerts will continue as long as the patient is in the alert state. The re-alert capability is automatic and is not user controlled. If a clinician wants to stop the re-alerting for a specific patient they need to either adjust the threshold, or turn the alert off.

20 HeartLogic™ is available with a subscription in RESONATE™, CHARISMA™, VIGILANT™, MOMENTUM™, and PERCIVA™ families of ICDs and CRT-Ds.

21 Applies to new clinics added to LATITUDE NXT as of July 21, 2019

22 Applies to existing clinics on LATITUDE NXT prior to July 21, 2019

Products Referenced

The following device families/models are supported by the LATITUDE NXT system. Not all devices are approved and/or market-released in all geographies. Please contact Boston Scientific Technical Services or LATITUDE Customer Support for information regarding a specific device model and/or geographic location.

Table 3. Pacing and Defibrillation Products Supported by LATITUDE NXT

Device Type	Device Family	Model Numbers
Pacemakers	ESSENTIO™	L100 L101 L110 L111 L121 L131
	PROPONENT™	L200 L201 L209 L210 L211 L221 L231
	ACCOLADE™	L300 L301 L310 L311 L321 L331
	ADVANTIO™	J062 J063 J064 J065 J066 J067 K062 K063 K064 K082 K083 K084 K085 K086 K087
	INGENIO™	J172 J173 J174 J175 J176 J177 J178 J179 K172 K173 K174 K175 K176 K177 K182 K183 K184 K185 K186 K187 K188 K189
	VITALIO™	J272 J273 J274 J275 J276 J277 K272 K273 K274 K275 K276 K277 K282 K283 K284 K285 K286 K287
	FORMIO™	J278 J279 K278 K279 K288 K289
CRT-Ps	VALITUDE™	U125 U128
	VISIONIST™	U225 U226 U228
	INVIVE™	V172 V173 V182 V183 W172 W173
	INTUA™	V272 V273 V282 V283 W272 W273
	INLIVEN™	V284 V285 W274 W275
ICDs	ORIGEN™	D000 D001 D002 D003 D050 D051 D052 D053
	INOGEN™	D010 D011 D012 D013 D140 D141 D142 D143
	DYNAGEN™	D020 D021 D022 D023 D150 D151D152 D153
	AUTOGEN™	D030 D031 D032 D033 D044 D045 D046 D047 D160 D161 D162 D163 D174 D175 D176 D177
	PUNCTUA™	E050 E051 E052 E053 F050 F052
	ENERGEN™	E140 E141 E142 E143 F140 F141 F142 F143
	INCEPTA™	E160 E161 E162 E163 F160 F161 F162 F163
	TELIGEN™	E102 E103 E110 E111 F102 F103 F110 F111
	RESONATE™	D420 D421 D432 D433 D520 D521 D532 D533
	PERCIVA™	D400 D401 D412 D413 D500 D501 D512 D513
	CHARISMA™	D320 D321 D332 D333
	VIGILANT™	D220 D221 D232 D233
	MOMENTUM™	D120 D121
CRT-Ds	ORIGEN™	G050 G051 G056 G058
	INOGEN™	G140 G141 G146 G148
	DYNAGEN™	G150 G151 G154 G156 G158
	AUTOGEN™	G160 G161 G164 G166 G168 G172 G173 G175 G177 G179
	ENERGEN™	N050 N051 N052 N053 P142 P143
	PUNCTUA™	N140 N141 N142 N143 P052
	INCEPTA™	N160 N161 N162 N163 N164 N165 P162 P163 P165
	COGNIS™	N106 N107 N108 N118 N119 P106 P107 P108
	RESONATE™	G424 G425 G426 G428 G437 G447 G448 G524 G525 G526 G528 G537 G547 G548
	CHARISMA™	G324 G325 G328 G337 G347 G348
	VIGILANT™	G224 G225 G228 G237 G247 G248
	MOMENTUM™	G124 G125 G126 G128 G138
S-ICD	EMBLEM™	A209 A219

LATITUDE™ NXT Patient Management System

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

Contraindications
The LATITUDE NXT Patient Management System is contraindicated for use with any implanted device other than a compatible Boston Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE NXT System. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being interrogated.

Precautions
Alerts may appear on the LATITUDE NXT website on a daily basis. Primary notification of alert conditions is through the View Patient List page on the LATITUDE NXT website. The clinician needs to log onto the LATITUDE NXT website in order to receive alerts. Although secondary notification through email and SMS text messages is available, these reminders are dependent on external systems and may be delayed or not occur. The secondary notification feature does not eliminate or reduce the need to check the website. Implanted device data and alerts are typically available for review on the LATITUDE NXT website within 15 minutes of a successful interrogation. However, data uploads may take significantly longer (up to 14 days). If the Communicator is unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE NXT server to upload data, up to 14 days may elapse before the LATITUDE NXT server detects these conditions and informs the clinic user that monitoring is not occurring. If both of these conditions occur at the same time, this notification could take up to 28 days. Implanted device data and alert notification may be delayed or not occur at all under various conditions, which include but are not limited to the following: System limitations; the Communicator is unplugged; the Communicator is not able to connect to the LATITUDE NXT server through the configured phone system; the implanted device and the Communicator cannot establish and complete a telemetry session; the Communicator is damaged or malfunctions; the patient is not compliant with prescribed use or is not using the LATITUDE NXT System as described in the patient manual; if subscribed to the LATITUDE Cellular Data Plan, missing two or more payments discontinues the subscription; the clinic user can identify any patients that are not being monitored as described above by using the Not Monitored filter on the View Patient List.

Adverse Effects:
None known.

System Limitations:
The LATITUDE NXT System does not provide continuous real-time monitoring. As a remote monitoring system, the LATITUDE NXT System provides periodic patient monitoring based on clinician configured settings. There are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of implanted device, sensor, and patient information as intended by the clinician. These factors include: implanted device clock; patient environment; cellular data service; telephone system; communicator memory capacity; clinic environment; schedule/configuration changes; or data processing.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436260 Rev. A)*

Pacing Systems - ACCOLADE™, ACCOLADE™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™ MRI, INGENIO™, INGENIO™ MRI, ADVANTIO™ Pacemaker

INDICATIONS AND USAGE
Boston Scientific pacemakers are indicated for treatment of the following conditions:
- 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 (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block)
- 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.
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 treatment of the following:
- Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block
- VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm
- Low cardiac output or congestive heart failure secondary to bradycardia

CONTRAINDICATIONS
These Boston Scientific pacemakers are contraindicated in patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads.
Use of certain pacing modes and/or features available in these Boston Scientific pacemakers is contraindicated for the following patients under the circumstances listed:
- Unipolar pacing or use of the MV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy.
- 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 this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only**.** Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Automatic Lead Recognition should be programmed to Off before implant for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, 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. ACCOLADE MRI, PROPONENT MRI, ESSENTIO MRI, FORMIO MRI, VITALIO MRI and INGENIO MRI devices are considered MRI Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result. *All other devices covered by this statement are not MR conditional.* For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. 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.

POTENTIAL ADVERSE EVENTS
Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to pace; Inappropriate pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT) (applies to dual-chamber devices only); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation; dissection, erosion); Worsening heart failure.
For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.
Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of device malfunction.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436253 Rev. A)*

CRT-P Systems – VISIONIST™, VISIONIST™ X4, VALITUDE™, VALITUDE™ X4, INTUA™, INVIVE™ CRT-P

Indications and Usage
Boston Scientific cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients with 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 pharmacological therapy (OPT) 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 Boston Scientific pulse generators have the following contraindications:

- In patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads;
- Unipolar pacing or use of the MV/Respiratory Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) is contraindicated because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy;
- Minute ventilation is contraindicated in patients with both unipolar atrial and ventricular leads;
- Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction;
- Atrial tracking modes are contraindicated in patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing;
- And asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings
Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only**.** Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Safety Core pacing may be unipolar, which may interact with an ICD. Safety Core behavior is affected by MRI Protection Mode. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Automatic Lead Recognition should be programmed to Off before implant with patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, 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. VISIONIST X4 and VALITUDE X4 devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and /or damage to the implanted system may result. *All other devices covered by this statement are not MR conditional.* Do not expose patients with non-MR Conditional devices to MRI scanning. For potential adverse events when Conditions of Use are met or not met, refer to the MRI Technical Guide. 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. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

Potential Adverse Events
Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Inability to pace; Inappropriate pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion); Worsening heart failure.
For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.
Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of a device malfunction.
Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436229 Rev. A)*

ICD Systems – AUTOGEN™ EL, DYNAGEN™ EL, DYNAGEN™ MINI, INOGEN™ EL, INOGEN™ MINI, ORIGEN™ EL, ORIGEN™ MINI, INCEPTA™, ENERGEN™, PUNCTUA™, TELIGEN™100
INDICATIONS AND USAGE
Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS
Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

WARNINGS
Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only**.** Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. 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. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. 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. AUTOGEN, DYNAGEN, INOGEN, and ORIGEN devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. *All other devices covered by this statement are not MR conditional.* Do not expose a patient with non-MR conditional devices to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply 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.

POTENTIAL ADVERSE EVENTS
Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing);; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT)(Applies to dual-chamber devices only); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion); Worsening heart failure.
For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide.
Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of shocking while conscious; Fear that shocking capability may be lost; Imagined shocking; Fear of a device malfunction.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436232 Rev. A)*

ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL ICD
INDICATIONS AND USAGE
Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS
Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

WARNINGS
Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only**.** Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. 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. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. 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. RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, VIGILANT and MOMENTUM devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Do not expose patients with non-MR conditional devices to MRI scanning. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply 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, and supplemental precautionary information.

POTENTIAL ADVERSE EVENTS
Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Insulating myocardium during defibrillation with internal or external paddles; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion); Worsening heart failure.
For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide
Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of a device malfunction.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436178 Rev. B)*

CRT-D Systems –AUTOGEN™, AUTOGEN™X4, DYNAGEN™, DYNAGEN™X4, INOGEN™, INOGEN™ X4, ORIGEN™, ORIGEN™X4, INCEPTA™, ENERGEN™, PUNCTUA™, COGNIS™ 100-D CRT-D
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; or left bundle branch block (LBBB) with QRS duration ≥ 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 this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. 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. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implanting a system that uses both a DF4–LLHH or DF4–LLHO and IS4–LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. 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. AUTOGEN and DYNAGEN devices except for those with an RA: IS-1; RV: IS-1/DF-1; LV: LV-1 lead connection are considered MR Conditional. INOGEN, and ORIGEN devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result. *All other devices covered by this statement are not MR conditional.* Do not expose a patient with non-MR Conditional devices to MRI scanning. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered by the magnet and an EGM has been stored, 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 EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

POTENTIAL ADVERSE EVENTS
Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Insulating myocardium during defibrillation with internal or external paddles; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion); Worsening heart failure.
For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide
Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of a device malfunction.
Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436228 Rev. A)*

CRT-D Systems –RESONATE™HF, RESONATE™, RESONATE™X4, VIGILANT™, VIGILANT™X4, MOMENTUM™, MOMENTUM™ X4
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; or left bundle branch block (LBBB) with QRS duration ≥ 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 this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. 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. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implant a system that uses both a DF4–LLHH or DF4–LLHO and IS4–LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. 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. RESONATE HF, RESONATE, and MOMENTUM devices except for those with an RA: IS-1; RV: IS-1/DF-1; LV: LV-1 lead connection are considered MR Conditional. VIGILANT devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response 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 EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

POTENTIAL ADVERSE EVENTS
Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Insulating myocardium during defibrillation with internal or external paddles; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion); Worsening heart failure.
For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide
Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of a device malfunction.
Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436222 Rev. A)*

Emblem™ MRI S-ICD System

Indications for Use
The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications
Unipolar stimulation and impedance-based features are contraindicated for use with the S-ICD System.

Warnings
Concomitant use of the S-ICD System and implanted electromechanical devices (for example implantable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. The S-ICD is intended as lifesaving therapy and should be seen as priority in the decision and evaluation of concomitant system implants over non-lifesaving applications. Electromagnetic (EMI) or therapy delivery from the co-implanted device can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the coimplanted device and/or compromise its functionality. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. To help prevent undesirable interactions, test the S-ICD system when used in combination with the co-implanted device, and consider the potential effect of a shock on the co-implanted device. Induction testing is recommended to ensure appropriate detection and time to therapy for the S-ICD and appropriate post-shock operation of the co-implanted device. Failure to ensure appropriate detection and time to therapy delivery of the S-ICD system could result in patient injury or death. Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the coimplanted devices change or if patient conditions changes which may affect S-ICD sensing and therapy performance, re-evaluation of the co-implanted devices may be required. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature batter depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature batter depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.

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.

Potential Adverse Events
Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following: Acceleration/induction of atrial or ventricular arrhythmia, adverse reaction to induction testing, allergic/adverse reaction to system or medication, bleeding, conductor fracture, cyst formation, death, delayed therapy delivery, discomfort or prolonged healing of incision, electrode deformation and/or breakage, electrode insulation failure, erosion/extrusion, failure to deliver therapy, fever, hematoma/seroma, hemothorax, improper electrode connection to the device, inability to communicate with the device, inability to defibrillate or pace, inappropriate post shock pacing, inappropriate shock delivery, infection, injury to or pain in upper extremity, including clavicle, shoulder and arm, keloid formation, migration or dislodgement, muscle/nerve stimulation, nerve damage, pneumothorax, post-shock/post-pace discomfort, premature battery depletion, random component failures, stroke, subcutaneous emphysema, surgical revision or replacement of the system, syncope, tissue redness, irritation, numbness or necrosis.
Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436235 Rev. A)*