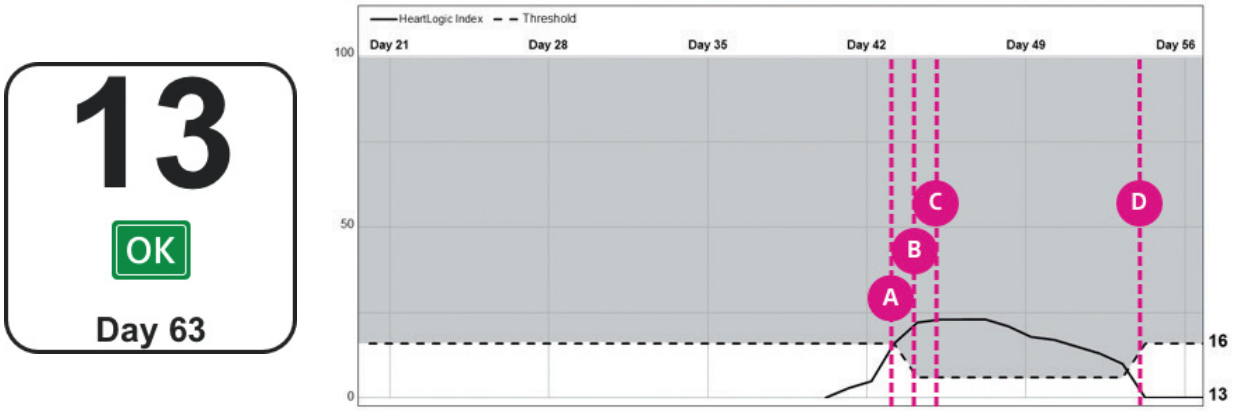
HeartLogic Enables Proactive Care in the Outpatient Setting

Summary

HeartLogic Heart Failure Index

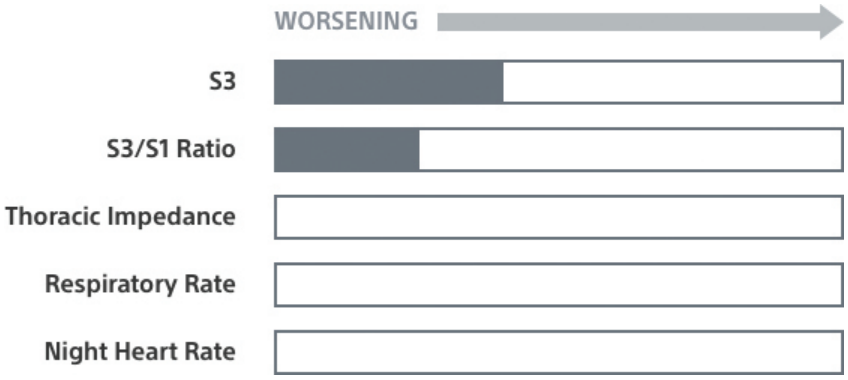


Contributing Trends

Day 1: Vigilant CRT-D implanted

(A) Day 43: Patient seen by NP for follow-up –patient "feels fine" with no HF symptoms

(B) Day 44: HeartLogic alert issued
- HeartLogic Index is 16.
- Contributing Trends: S3 and S3/S1



(C) Day 45: HeartLogic Index is 22.
Patient seen by Interventional Cardiologist:
- Swelling in right foot
- Excessive sweating
- Shortness of Breath
- Furosemide increased (40 mg 3x/day to 4x/day)

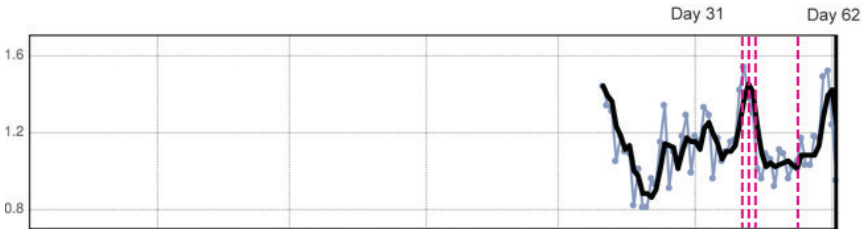
(D) Day 54: HeartLogic Index returns to Baseline
- S3 measurements trending down to below 1mG.
- Thoracic Impedance was not a contributing trend and did not detect worsening HF.

Trend Graphs

Day 63

0.95

mG

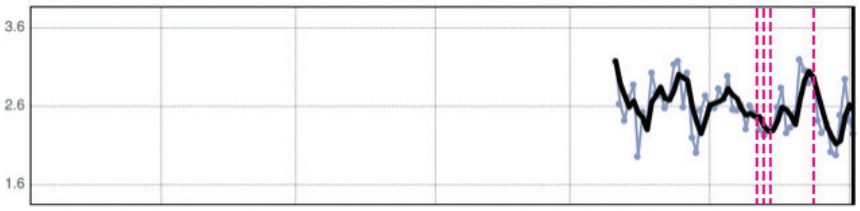


S3

Day 63

2.24

mG



S1

Day 63

46.1

Ω

Thoracic Impedence

Day 63

12.5

rpm

Respiratory Rate

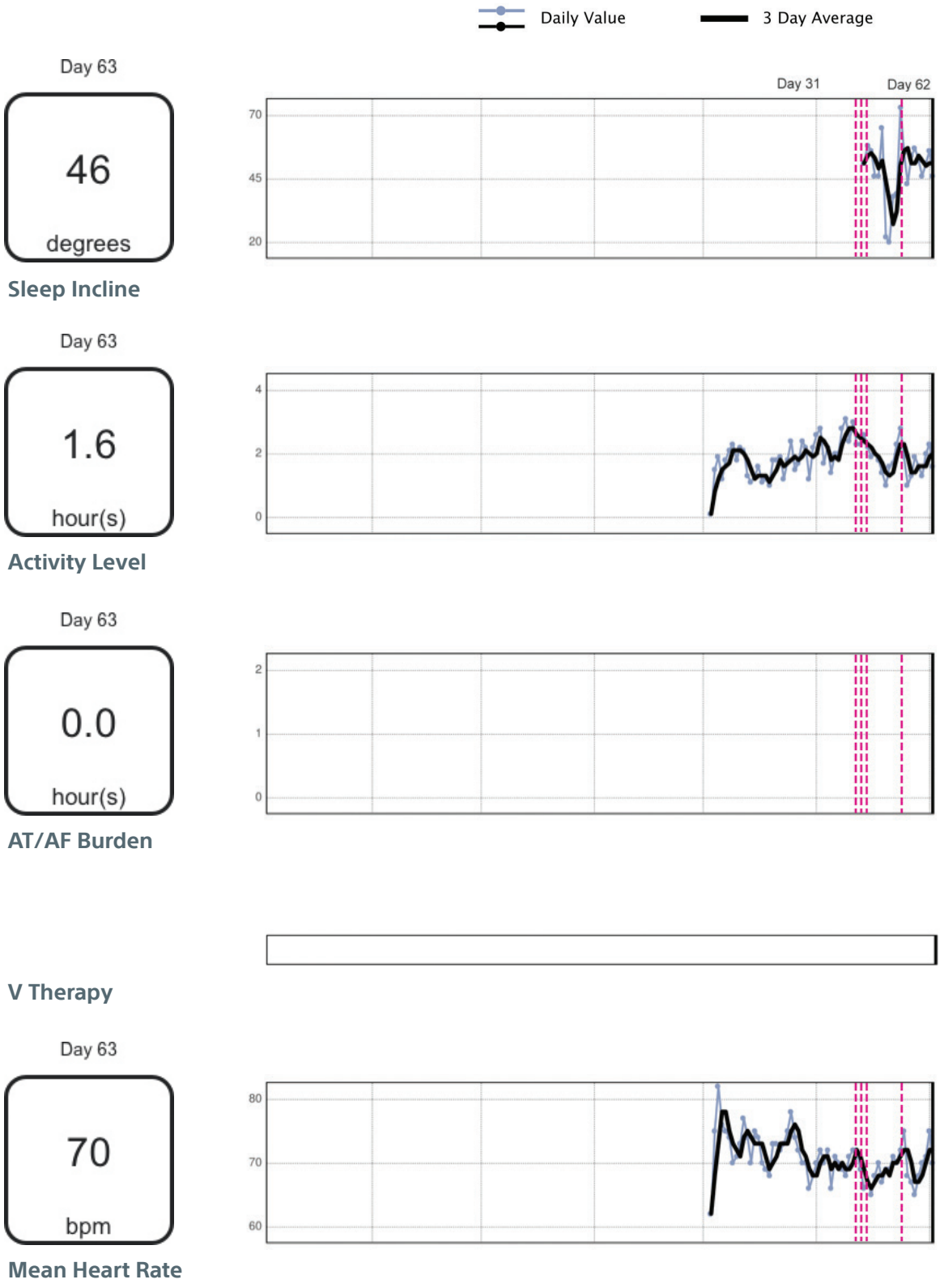
Day 63

62

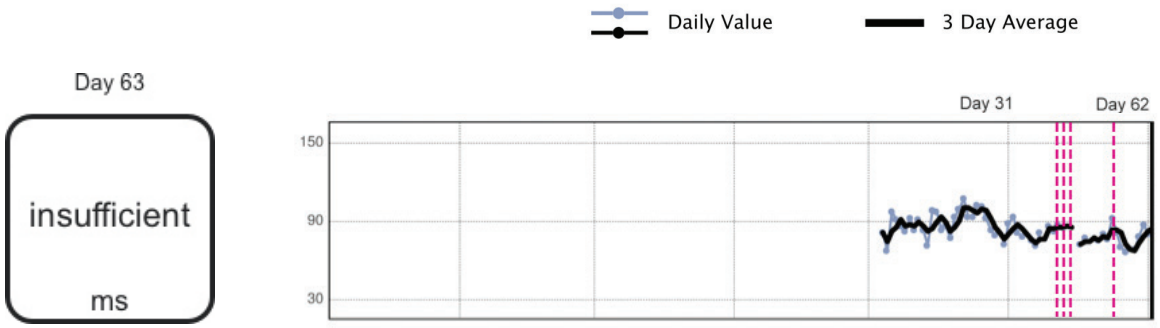
bpm

Night Heart Rate

Trend Graphs



Trend Graphs



Heart Rate Variability (SDANN)

Data Table & Timeline

LATITUDE™ NXT Patient Management – Heart Failure Management Report

Trend Data

Date	HeartLogic Heart Failure Index	S3 (mG)	S1 (mG)	Thoracic Impedance (Ω)	Respiratory Rate (rpm)	Night Heart Rate (bpm)	Sleep Incline (degrees)	Activity Level (hour(s))	AT/AF Burden (hour(s), events)
Day 63	13	0.95	2.24	46.1	12.5	62	46	1.6	0.0, 0
Day 62	13	1.24	2.41	45.7	13.3	70	56	2.3	0.0, 0
Day 61	10	1.52	2.94	44.3	13.0	65	51	2.0	0.0, 0
Day 60	6	1.49	2.48	42.7	12.3	67	46	1.3	0.0, 0
Day 59	2	1.17	1.97	41.2	11.8	67	52	1.6	0.0, 0
Day 58	1	1.18	2.01	42.3	12.0	64	57	1.9	0.0, 0
Day 57	0	1.03	2.37	44.9	13.5	67	54	1.3	0.0, 0
Day 56	0	1.03	2.25	43.9	14.0	63	43	1.0	0.0, 0
Day 55	0	1.17	2.41	44.4	14.3	77	55	1.9	0.0, 0
Day 54	0	1.05	2.95	44.4	13.5	65	73	2.8	0.0, 0
Day 53	10	1.02	2.89	44.1	13.8	62	39	2.3	0.0, 0
Day 52	13	0.96	3.05	44.4	14.5	66	38	1.7	0.0, 0
Day 51	15	1.09	3.19	46.4	15.5	65	20	1.6	0.0, 0
Day 50	17	1.11	2.51	45.9	14.0	61	22	1.0	0.0, 0
Day 49	18	0.92	2.32	47.0	13.3	64	65	1.4	0.0, 0
Day 48	21	1.06	2.25	41.6	13.3	65	46	1.8	0.0, 0
Day 47	23	1.09	2.83	42.9	13.3	64	46	2.0	0.0, 0
Day 46	23	0.96	2.58	42.8	12.8	63	56	1.9	0.0, 0
Day 45	23	1.01	2.32	41.4	13.0	64	58	2.2	0.0, 0
Day 44	22	1.30	2.30	39.2	12.8	64	51	2.6	0.0, 0
Day 43	16	1.38	2.22	38.0	13.0	66	N/R	2.3	0.0, 0
Day 42	8	1.54	2.29	38.9	12.8	66	N/R	2.3	0.0, 0
Day 41	3	1.42	2.49	37.2	13.3	66	N/R	3.0	0.0, 0
Day 40	0	1.16	2.60	39.5	12.0	68	N/R	2.4	0.0, 0
Day 39	N/R	1.15	2.30	38.3	11.8	64	N/R	3.1	0.0, 0
Day 38	N/R	1.10	2.61	37.6	12.0	64	N/R	2.8	0.0, 0
Day 37	N/R	1.05	2.54	38.8	13.8	66	N/R	2.0	0.0, 0
Day 36	N/R	1.17	2.55	37.7	13.3	68	N/R	2.0	0.0, 0
Day 35	N/R	0.96	2.98	38.2	12.0	62	N/R	1.4	0.0, 0
Day 34	N/R	1.29	2.68	36.4	13.5	67	N/R	2.2	0.0, 0

Data Table & Timeline

LATITUDE™ NXT Patient Management – Heart Failure Management Report

Date	Mean Heart Rate (bpm)	Heart Rate Variability (SDANN) (ms)
Day 63	70	N/R
Day 62	75	80
Day 61	71	87
Day 60	70	78
Day 59	68	68
Day 58	65	N/R
Day 57	67	66
Day 56	68	70
Day 55	75	81
Day 54	72	92
Day 53	70	76
Day 52	71	80
Day 51	69	75
Day 50	69	N/R
Day 49	67	N/R
Day 48	70	77
Day 47	68	72
Day 46	65	N/R
Day 45	67	N/R
Day 44	66	N/R
Day 43	69	85
Day 42	72	87
Day 41	72	82
Day 40	71	86
Day 39	68	N/R
Day 38	69	81
Day 37	70	71
Day 36	71	75
Day 35	66	N/R
Day 34	72	78

Brief Summary Statement
RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL ICD – Manual 360199-003

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.

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, 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 evets 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.

Indications, Safety and Warnings
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 VIGILANT devices with an IS-1/DF4/IS4 lead connection 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, 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 evets 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.

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

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Results from the case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

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Prior to use, review DFU for indications, contraindications, warnings, precautions, adverse events and operating instructions.

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