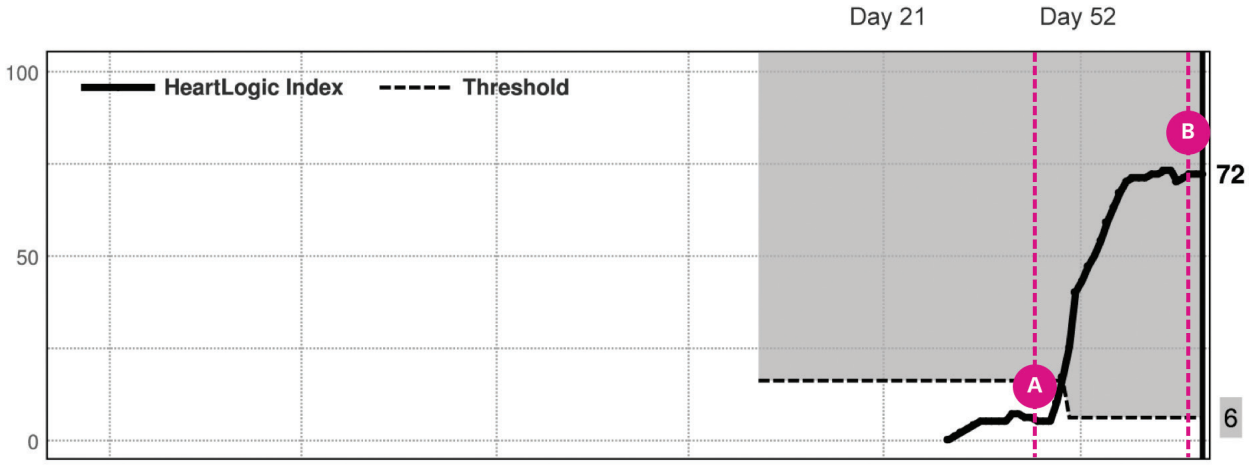
HeartLogic Sensors Provide Objective Measure of Heart Failure Physiology

Summary



(A) Day 42: Patient implanted with a Resonate™ family CRT-D was admitted to the hospital for heart failure symptoms, including abdominal pain. Patient discharge occurred on Day 42 after implant without eliminating the abdominal pain.

Day 48: HeartLogic alert was triggered on Day 48, but the LATITUDE Communicator was not set up and therefore the alert was not communicated.

(B) Day 57: The patient presented to the emergency department (ED) on Day 57 with complaints of shortness of breath, difficulty sleeping and continuing vague abdominal pain. Physical exam did not find swelling in the ankles or obvious edema. Patient was considered for discharge but then the device was interrogated using LATITUDE Consult™, which detected a highly elevated HeartLogic index.

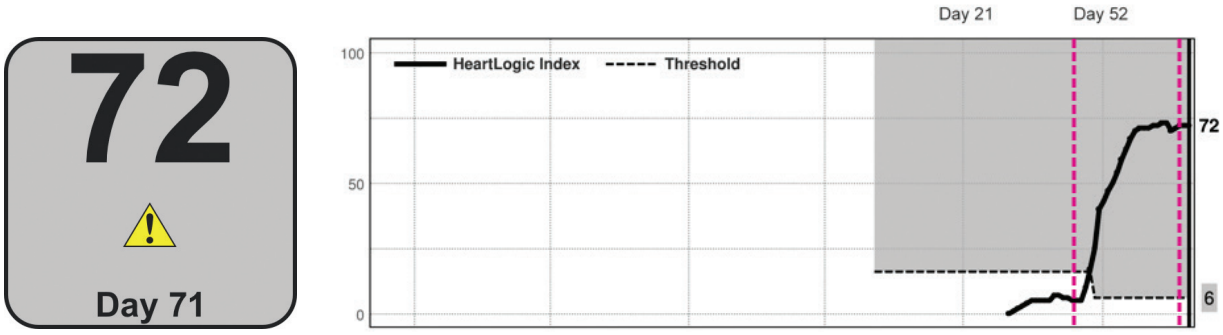
The S3 heart sound, respiratory rate and night heart rate were all significantly elevated, beginning at the prior hospital discharge.

Diuretic treatment resulted in significant fluid loss, which had been stored in the abdomen. Additional work-up detected coronary artery disease, which was treated with coronary stenting.

Because at admission to the ED, the patient had not yet connected the LATITUDE Communicator, the HeartLogic index was not known. The ED was ready to discharge the patient, but interrogation of the device revealed the HeartLogic data and elevated index. Therefore, that decision was reversed and the patient was treated for worsening heart failure and discharged after symptoms resolved to be monitored remotely.

Clinical Data

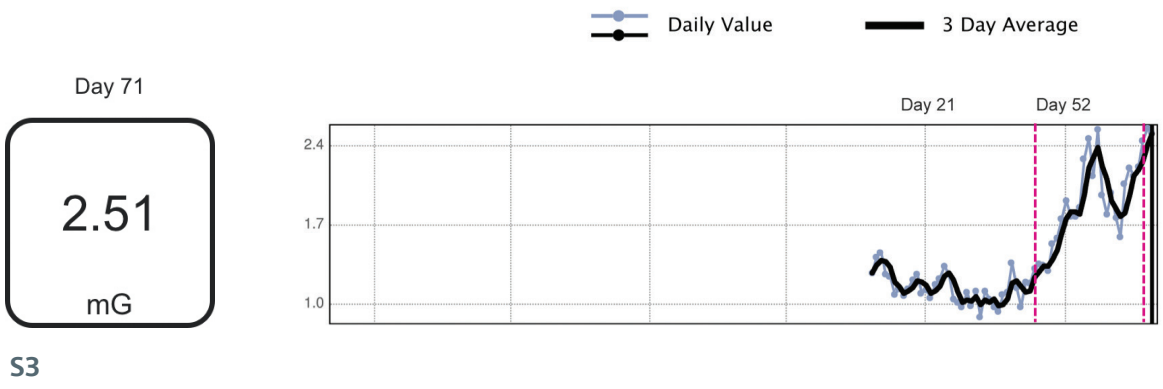
HeartLogic Heart Failure Index



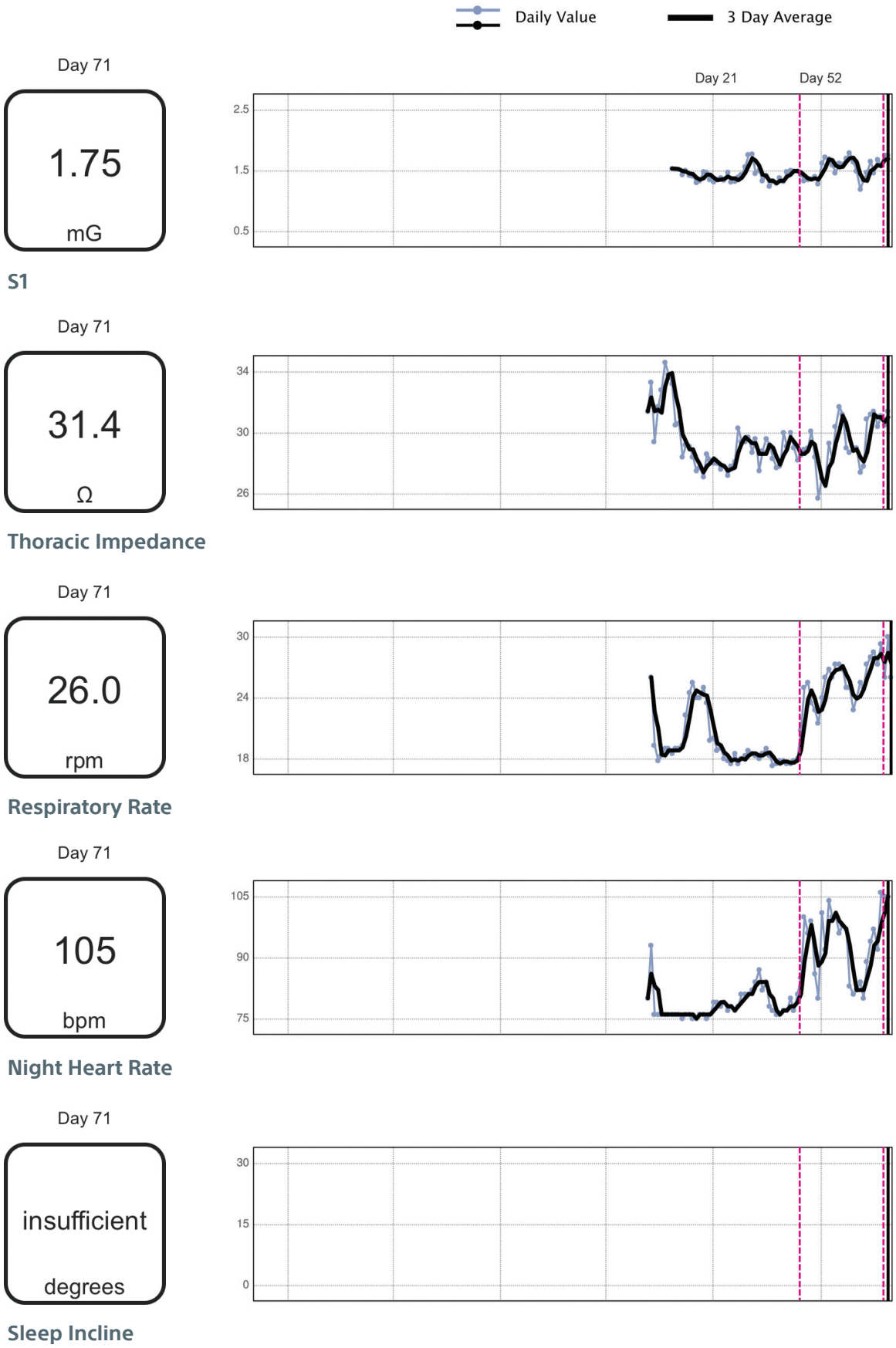
Contributing Trends

Note: Shaded portion indicates degree of worsening on Day 71.

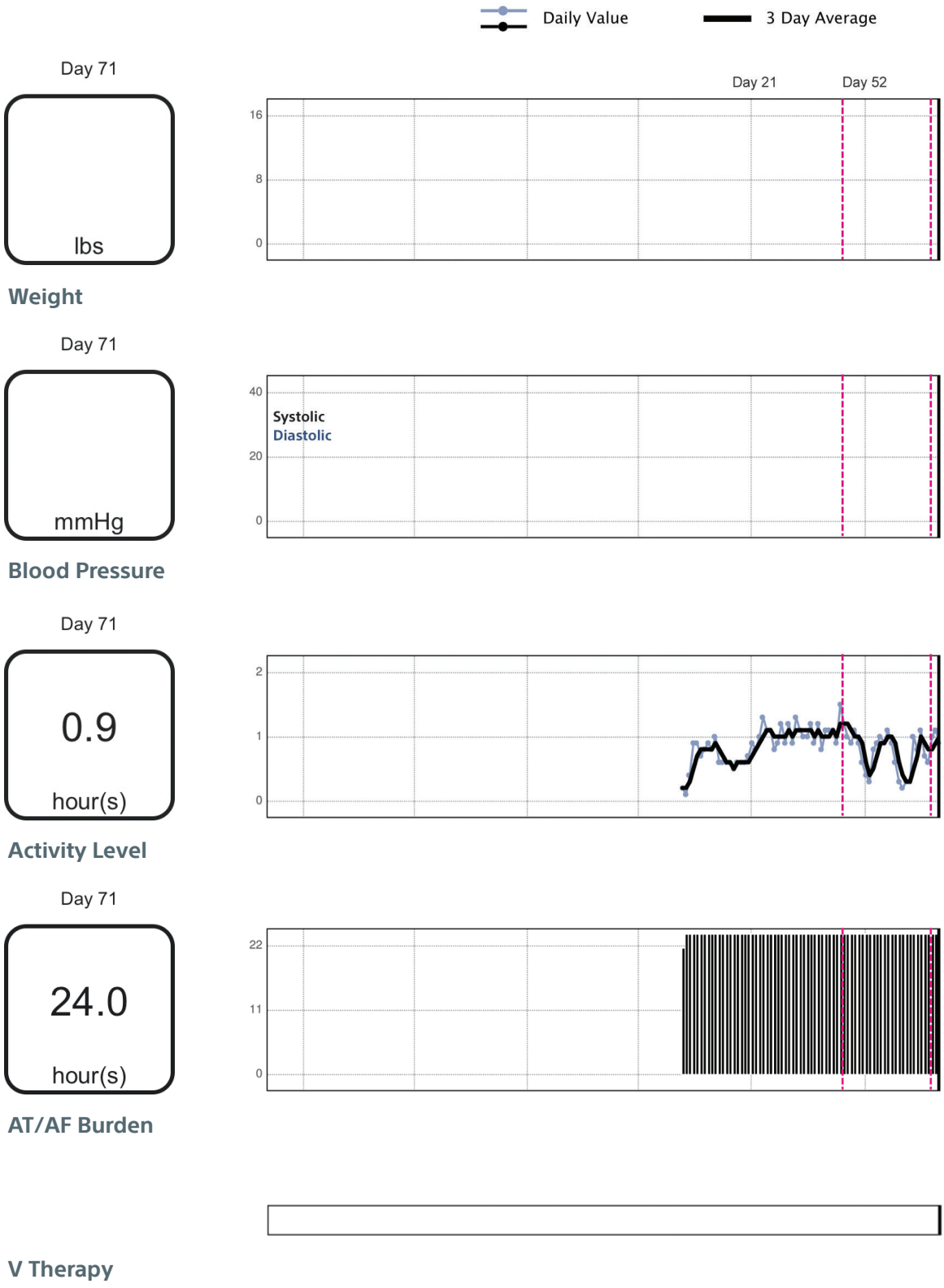
Trend Graphs



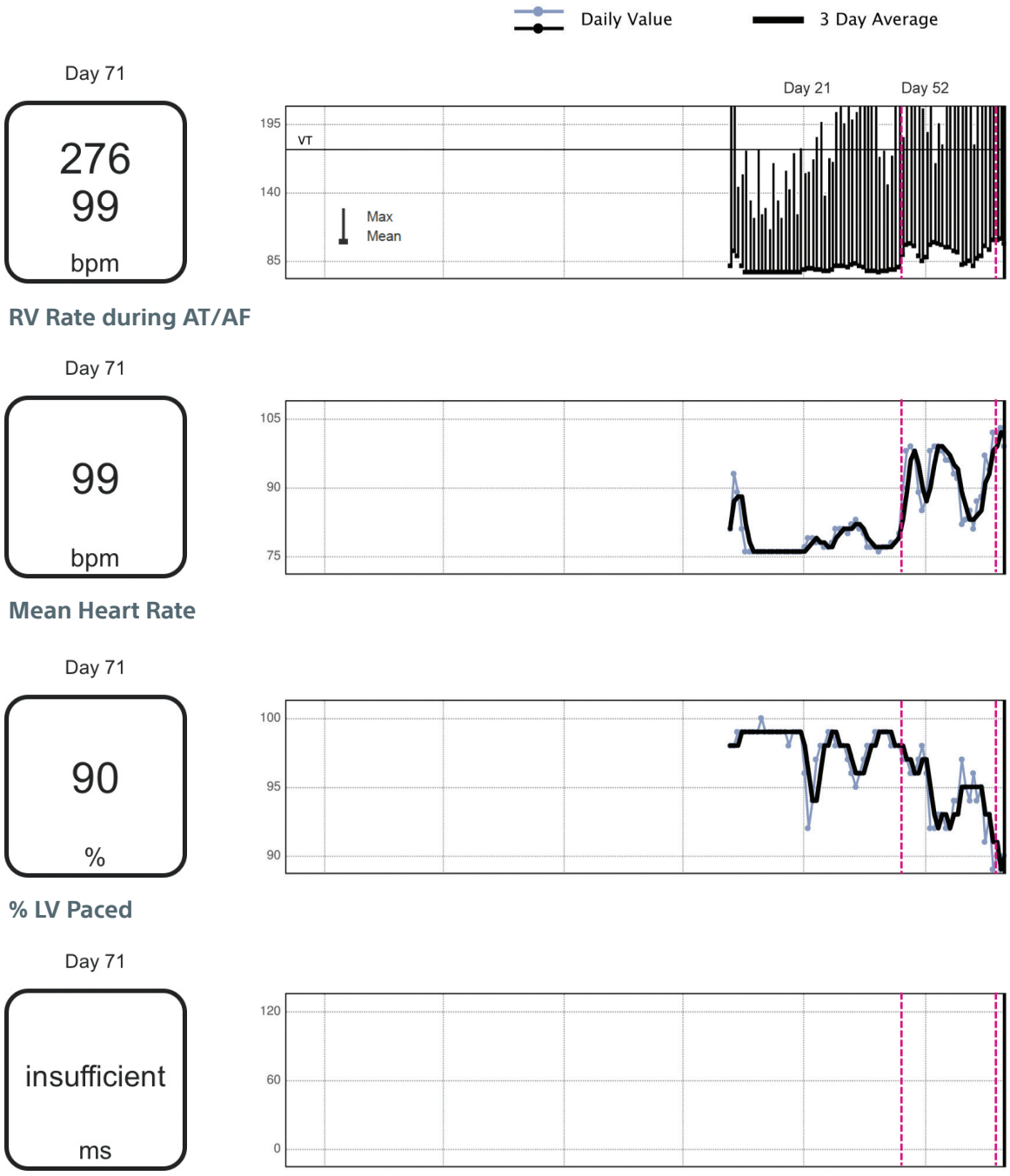
Trend Graphs



Trend Graphs



Trend Graphs



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)	Weight (lbs)	Blood Pressure (mmHg)
Day 71					26.0				
Day 70	72	2.51	1.75	31.4	30.0	105	N/R		
Day 69	72	2.55	1.75	30.5	26.0	105	N/R		
Day 68	72	2.44	1.59	31.1	29.3	106	N/R		
Day 67	71	2.21	1.68	30.4	27.3	92	N/R		
Day 66	70	2.13	1.46	31.4	28.5	97	N/R		
Day 65	73	2.20	1.65	31.2	28.0	94	N/R		
Day 64	73	2.06	1.47	30.9	27.3	89	N/R		
Day 63	72	1.59	1.34	27.8	25.0	80	N/R		
Day 62	72	1.76	1.19	27.4	25.5	84	N/R		
Day 61	71	1.98	1.49	29.0	24.0	82	N/R		
Day 60	71	1.79	1.64	28.9	22.8	81	N/R		
Day 59	71	1.96	1.79	28.7	25.0	83	N/R		
Day 58	70	2.54	1.70	29.0	25.0	97	N/R		
Day 57	67	2.13	1.60	31.2	26.8	98	N/R		
Day 56	63	2.46	1.62	31.7	27.3	96	N/R		
Day 55	59	2.28	1.46	30.4	27.3	100	N/R		
Day 54	54	1.85	1.59	28.2	26.0	100	N/R		
Day 53	50	1.77	1.69	29.3	26.8	104	N/R		
Day 52	47	1.77	1.72	26.8	26.0	92	N/R		
Day 51	43	1.91	1.62	27.0	24.0	101	N/R		
Day 50	40	1.75	1.28	25.7	21.5	80	N/R		
Day 49	25	1.58	1.40	28.4	22.8	86	N/R		
Day 48	17	1.53	1.36	30.1	23.5	99	N/R		
Day 47	10	1.29	1.35	29.0	25.5	96	N/R		
Day 46	5	1.34	1.33	28.9	25.0	100	N/R		
Day 45	5	1.35	1.43	28.5	20.8	85	N/R		
Day 44	5	1.31	1.49	28.2	18.0	81	N/R		
Day 43	6	1.18	1.49	29.0	17.8	77	N/R		
Day 42	6	1.19	1.50	30.0	17.5	80	N/R		
Day 41	7	1.14	1.32	30.0	17.8	77	N/R		
Day 40	5	1.36	1.38	27.8	17.8	76	N/R		
Day 39	5	1.10	1.29	27.7	17.5	76	N/R		
Day 38	5	1.08	1.33	28.3	17.3	77	N/R		
Day 37	5	0.93	1.24	29.2	18.3	78	N/R		
Day 36	5	0.97	1.42	29.6	19.0	84	N/R		
Day 35	4	1.04	1.33	28.8	18.5	82	N/R		
Day 34	3	1.11	1.50	27.5	18.0	87	N/R		
Day 33	2	0.88	1.45	29.6	18.3	84	N/R		
Day 32	1	1.11	1.77	28.7	18.5	82	N/R		
Day 31	0	0.98	1.76	29.7	18.8	81	N/R		
Day 30	N/R	1.10	1.56	29.4	18.3	81	N/R		

Data Table & Timeline

LATITUDE™ NXT Patient Management – Heart Failure Management Report

Date	Activity Level (hour(s))	AT/AF Burden (hour(s), events)	RV Rate during AT/AF (max, mean) (bpm)	Mean Heart Rate (bpm)	% LV Paced (%)	Heart Rate Variability (SDANN) (ms)
Day 71	0.9	24.0, 0	276, 99	99	90	N/R
Day 70	1.1	24.0, 0	215, 103	103	89	N/R
Day 69	1.0	24.0, 0	297, 102	102	90	N/R
Day 68	0.6	24.0, 0	291, 102	102	89	N/R
Day 67	0.7	24.0, 0	278, 94	94	93	N/R
Day 66	1.1	24.0, 1	303, 97	97	91	N/R
Day 65	0.8	24.0, 0	233, 89	88	95	N/R
Day 64	1.0	24.0, 1	306, 87	87	94	N/R
Day 63	0.3	24.0, 0	179, 81	81	96	N/R
Day 62	0.3	24.0, 0	296, 85	85	94	N/R
Day 61	0.2	24.0, 1	286, 83	83	95	N/R
Day 60	0.3	24.0, 1	245, 82	82	97	N/R
Day 59	0.6	24.0, 3	278, 92	92	94	N/R
Day 58	0.9	24.0, 2	302, 93	93	94	N/R
Day 57	1.1	24.0, 2	294, 96	96	92	N/R
Day 56	0.9	24.0, 1	294, 96	96	92	N/R
Day 55	1.0	24.0, 0	179, 98	98	93	N/R
Day 54	0.9	24.0, 0	196, 99	99	93	N/R
Day 53	0.8	24.0, 0	164, 100	99	92	N/R
Day 52	0.3	24.0, 0	217, 98	98	92	N/R
Day 51	0.4	24.0, 0	189, 88	88	96	N/R
Day 50	0.6	24.0, 1	208, 85	85	98	N/R
Day 49	0.9	24.0, 0	218, 89	89	97	N/R
Day 48	1.1	24.0, 1	269, 97	97	96	N/R
Day 47	0.9	24.0, 2	313, 99	99	96	N/R
Day 46	1.0	24.0, 0	273, 98	98	97	N/R
Day 45	1.2	24.0, 0	185, 90	90	97	N/R
Day 44	1.5	24.0, 0	267, 80	80	98	N/R
Day 43	0.9	24.0, 0	225, 78	78	98	N/R
Day 42	1.1	24.0, 0	170, 78	78	98	N/R
Day 41	1.1	24.0, 0	174, 77	77	99	N/R
Day 40	0.8	24.0, 0	169, 76	76	99	N/R
Day 39	1.2	24.0, 0	216, 77	77	99	N/R
Day 38	0.9	24.0, 0	229, 77	77	98	N/R
Day 37	1.2	24.0, 0	229, 77	77	98	N/R
Day 36	1.0	24.0, 0	219, 80	80	97	N/R
Day 35	1.0	24.0, 0	231, 81	81	96	N/R
Day 34	1.1	24.0, 0	205, 83	83	95	N/R
Day 33	1.3	24.0, 0	199, 82	82	96	N/R
Day 32	0.9	24.0, 0	217, 80	80	97	N/R
Day 31	1.2	24.0, 0	196, 81	81	98	N/R
Day 30	0.9	24.0, 1	255, 81	81	98	N/R

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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