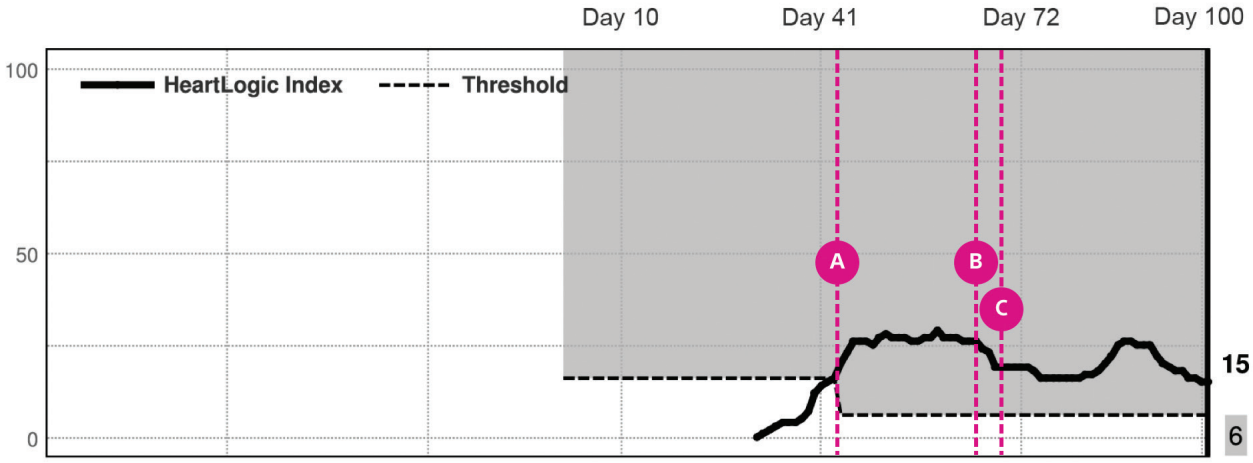
HeartLogic Alert Preceded Clinic Visit by 3 Weeks, Now Allows Remote Follow-Up of Patient

Summary



(A) Day 43: Following implantation of a Resonate™ family CRT-D, the patient failed to connect their LATITUDE Communicator. This prevented a HeartLogic alert from transmitting. At this time, the night heart rate, respiratory rate and S3 were all elevated.

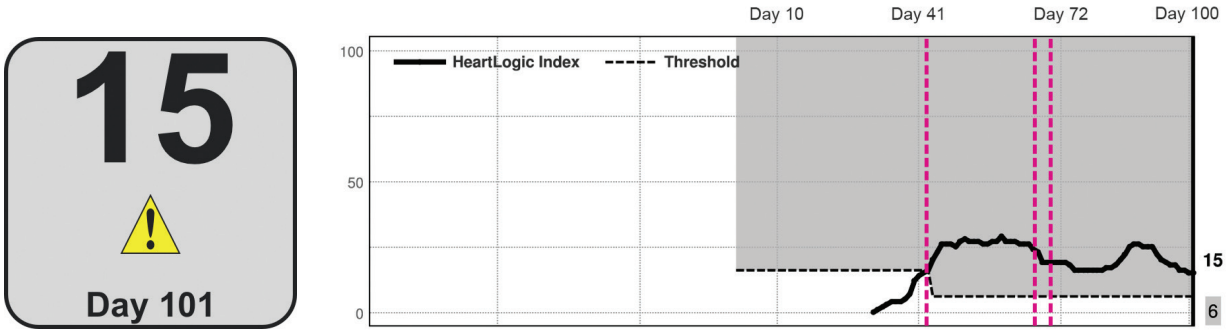
(B) Day 64: The patient was seen in-clinic for worsening heart failure (HF) symptoms, the CRT-D was interrogated using LATITUDE Consult™ and the patient was started on Entresto®.

(C) Day 69: Following the clinic visit, the patient connected the LATITUDE Communicator and began using their Bluetooth®-enabled weight scale and blood pressure cuff. This recorded a 30-pound decrease in the patient's weight over the following month. Note that thoracic impedance did not detect the worsening heart failure symptoms.

HeartLogic was able to detect worsening heart failure 3 weeks before the patient was seen in-clinic with visible symptoms, which would have been reported had the communicator being connected. Importantly, following medication adjustment and connection to the LATITUDE system, the patient was able to be followed daily via remote monitoring without in-office visits.

Clinical Data

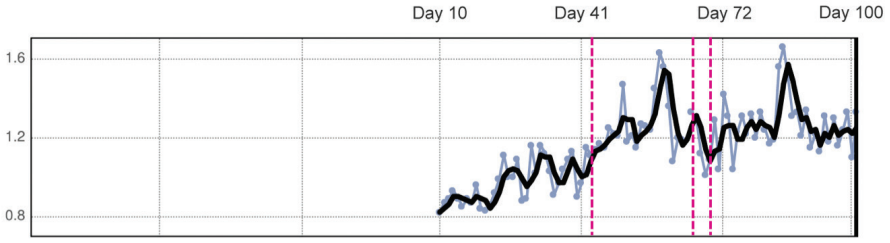
HeartLogic Heart Failure Index



Trend Graphs

Day 101

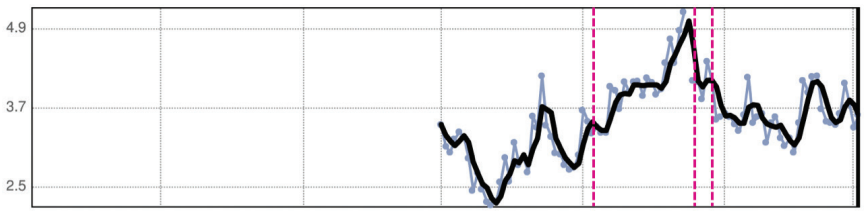
1.33
mG



S3

Day 101

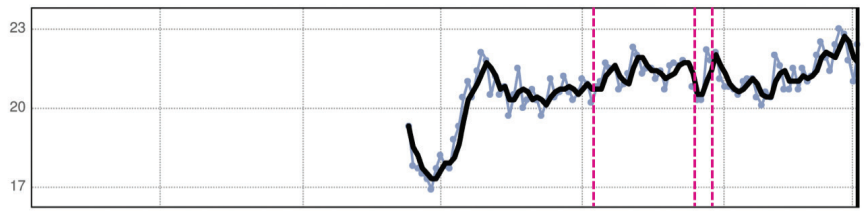
3.59
mG



S1

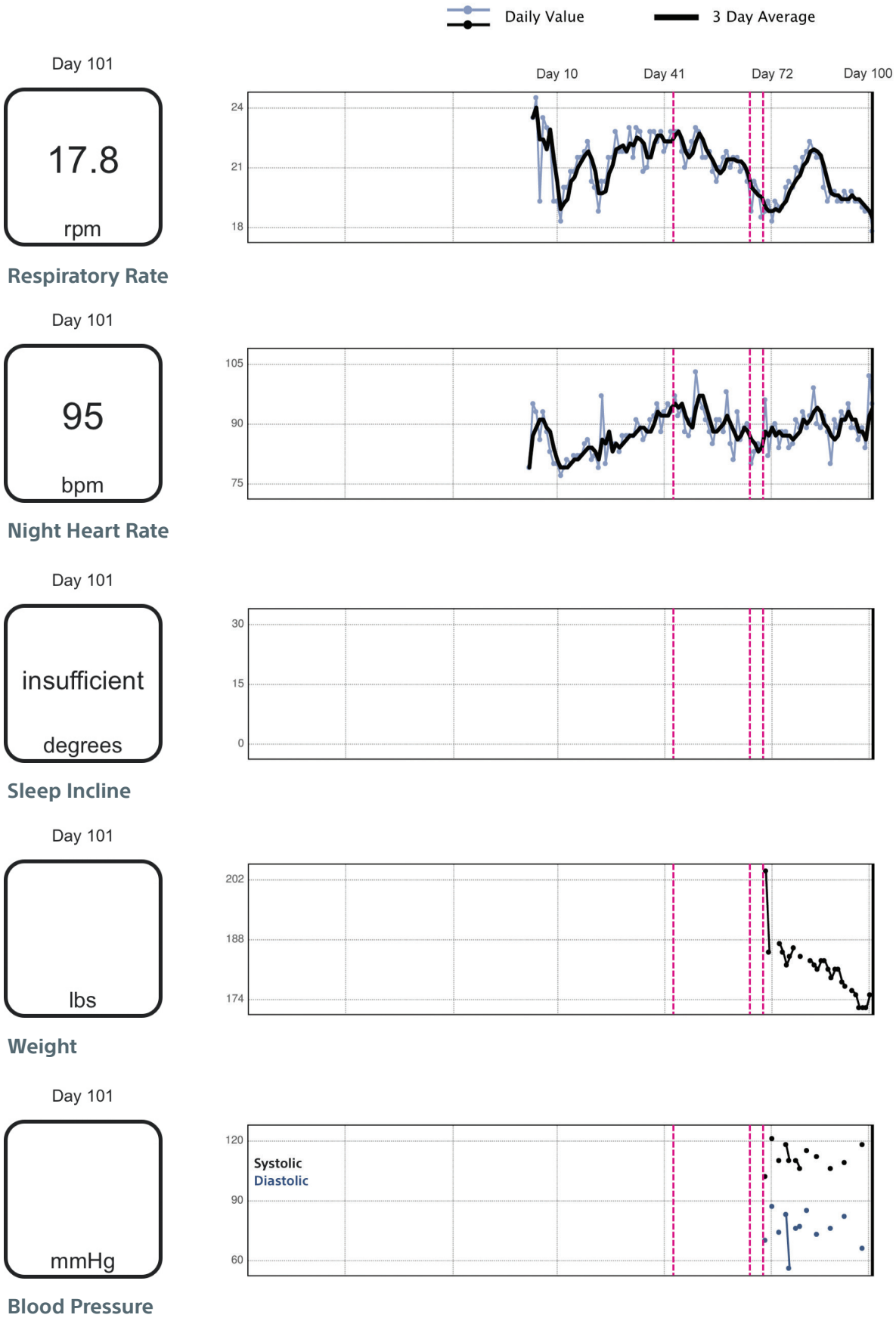
Day 101

22.4
Ω

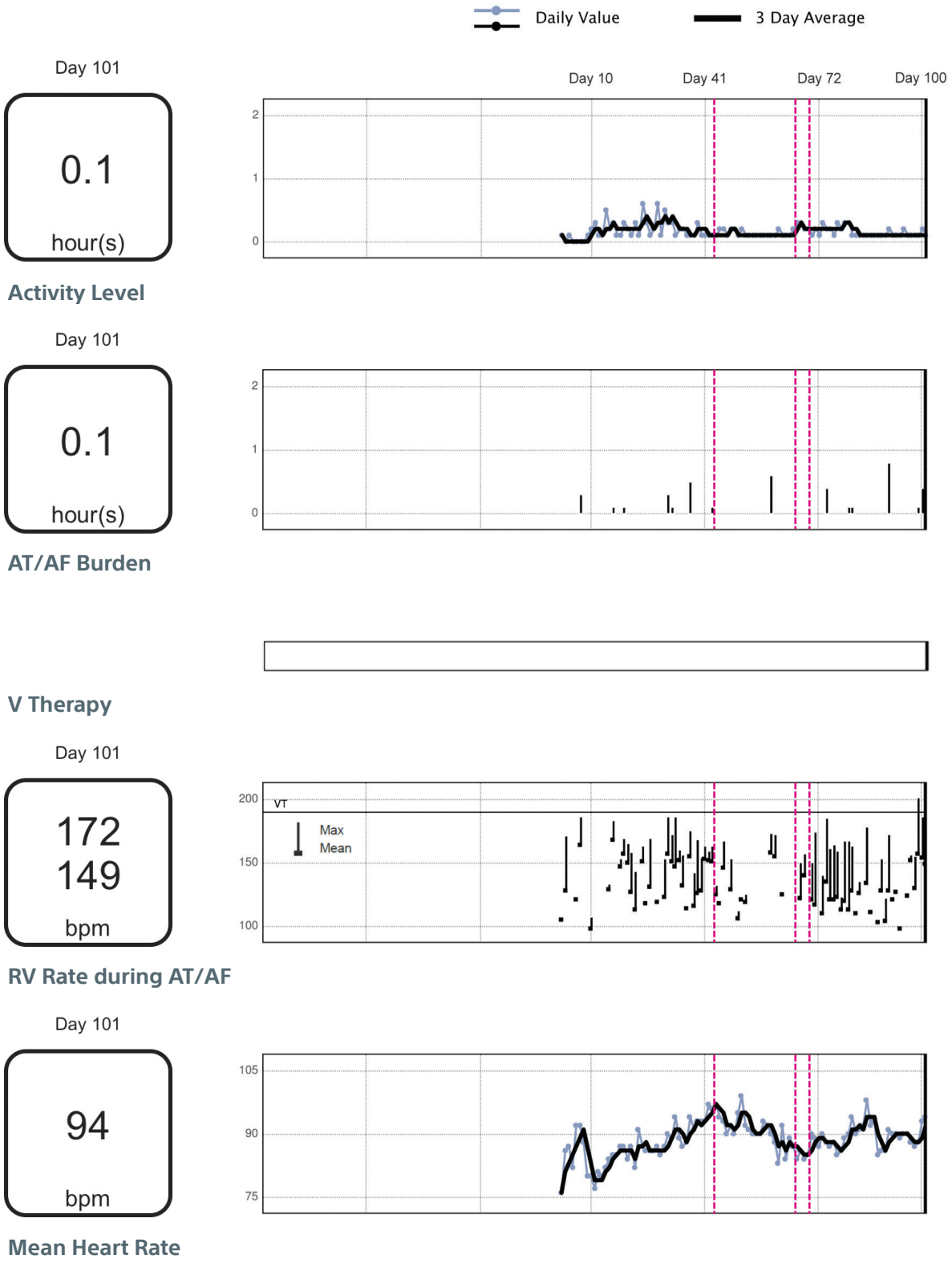


Thoracic Impedence

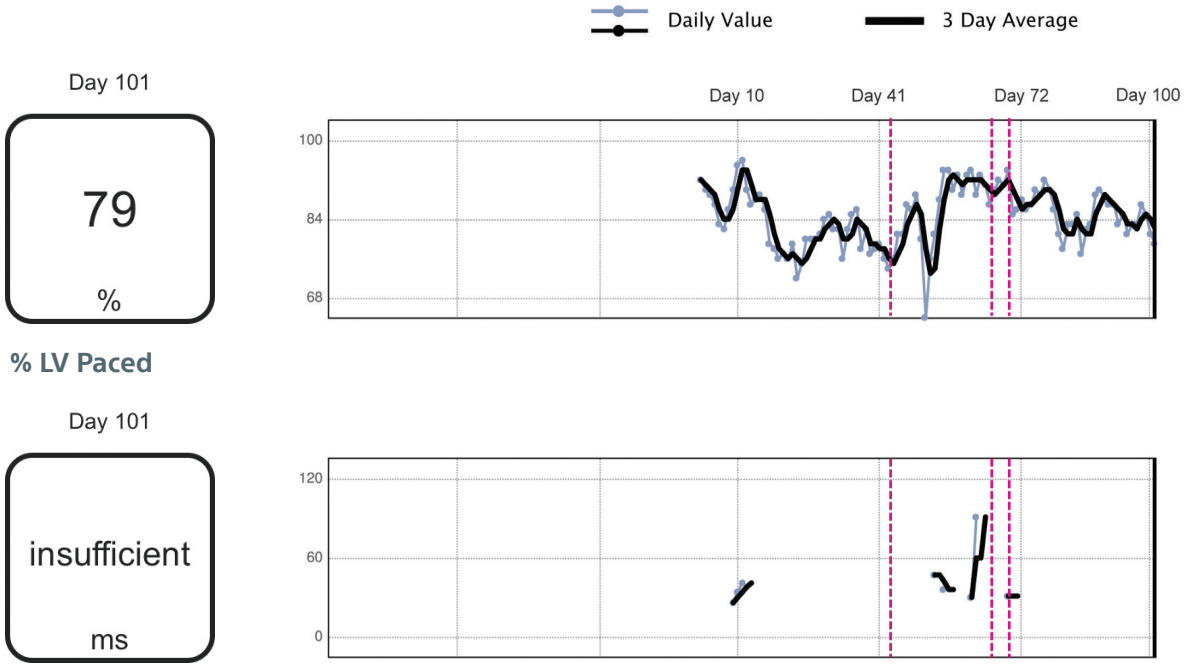
Trend Graphs



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 101	15	1.33	3.59	22.4	17.8	95	N/R		
Day 100	15	1.10	3.40	21.0	18.8	102	N/R	175	
Day 99	16	1.33	3.75	21.8	18.8	84	N/R	172	
Day 98	16	1.24	4.07	22.8	19.0	89	N/R	172	118/66
Day 97	18	1.16	3.61	23.0	19.3	86	N/R	172	
Day 96	18	1.30	3.44	22.4	19.3	89	N/R	175	
Day 95	19	1.18	3.47	21.4	19.8	89	N/R	176	
Day 94	20	1.31	3.49	21.9	19.3	95	N/R		
Day 93	22	1.13	3.68	22.5	19.8	91	N/R	177	109/82
Day 92	25	1.22	4.18	22.0	19.3	93	N/R	178	
Day 91	25	1.15	4.17	21.2	19.3	89	N/R	181	
Day 90	25	1.34	3.93	21.0	19.8	91	N/R	181	
Day 89	26	1.21	4.11	21.5	19.8	80	N/R	179	106/76
Day 88	26	1.33	3.47	20.7	19.3	88	N/R	181	
Day 87	25	1.31	3.02	21.5	20.0	92	N/R	183	
Day 86	22	1.50	3.24	20.7	21.5	89	N/R	183	
Day 85	20	1.66	3.12	20.7	21.5	90	N/R	181	112/73
Day 84	18	1.56	3.24	21.6	21.8	99	N/R	182	
Day 83	17	1.19	3.56	22.0	22.3	92	N/R	183	
Day 82	17	1.17	3.47	20.4	21.8	89	N/R		115/85
Day 81	16	1.24	3.17	20.6	21.5	93	N/R		
Day 80	16	1.33	3.61	20.1	20.8	89	N/R	184	106/77
Day 79	16	1.20	3.56	20.4	21.0	91	N/R		110/76
Day 78	16	1.32	3.47	21.1	20.0	85	N/R	186	
Day 77	16	1.22	4.16	21.1	20.3	84	N/R	184	110/56
Day 76	16	1.31	3.59	21.0	20.0	88	N/R	182	118/83
Day 75	16	1.23	3.35	20.5	19.0	88	N/R	185	
Day 74	18	1.04	3.45	20.7	19.0	84	N/R	187	110/74
Day 73	19	1.31	3.56	20.8	19.3	90	N/R		
Day 72	19	1.42	3.61	20.8	18.3	89	N/R		121/87
Day 73	19	1.31	3.56	20.8	19.3	90	N/R		
Day 72	19	1.42	3.61	20.8	18.3	89	N/R		121/87
Day 71	19	1.04	3.56	21.1	19.3	82	N/R	185	
Day 70	19	1.29	3.52	22.1	18.8	96	N/R	204	102/70
Day 69	19	1.09	4.11	21.8	18.5	84	N/R		
Day 68	19	1.01	4.40	22.2	19.8	85	N/R		
Day 67	23	1.12	3.83	20.3	20.3	83	N/R		
Day 66	24	1.29	4.09	20.3	18.8	80	N/R		
Day 65	26	1.33	4.11	20.8	20.3	90	N/R		
Day 64	26	N/R	N/R	N/R	21.0	89	N/R		
Day 63	26	1.19	5.15	21.8	20.8	86	N/R		
Day 62	27	1.20	4.87	21.6	21.5	93	N/R		
Day 61	27	1.08	4.38	21.7	21.5	81	N/R		
Day 60	27	1.36	4.74	21.6	21.0	85	N/R		
Day 59	29	1.56	4.38	20.7	21.8	98	N/R		
Day 58	27	1.63	3.98	21.4	21.5	88	N/R		
Day 57	27	1.45	3.90	21.1	21.0	91	N/R		
Day 56	26	1.24	4.08	21.5	20.3	91	N/R		
Day 55	26	1.26	4.15	21.5	20.8	85	N/R		
Day 54	27	1.27	3.88	21.3	21.8	88	N/R		
Day 53	27	1.15	4.10	22.0	21.5	91	N/R		
Day 52	27	1.21	4.09	22.3	21.5	94	N/R		
Day 51	28	1.18	3.93	21.3	22.8	96	N/R		
Day 50	27	1.47	4.09	20.9	23.0	103	N/R		
Day 49	25	1.21	3.68	20.7	22.3	91	N/R		
Day 48	26	1.22	3.96	21.5	21.8	87	N/R		

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 47	26	1.25	4.02	21.5	21.0	88	N/R		
Day 46	26	1.15	3.32	21.7	21.8	94	N/R		
Day 45	23	1.17	3.32	21.0	22.8	92	N/R		
Day 44	20	1.14	3.41	20.8	22.8	97	N/R		
Day 43	16	1.11	3.31	20.2	22.8	93	N/R		
Day 42	15	1.15	3.49	20.9	22.3	95	N/R		
Day 41	14	0.97	3.66	21.1	21.8	93	N/R		
Day 40	12	0.90	2.98	20.6	22.8	88	N/R		
Day 39	7	1.13	2.79	20.3	22.3	95	N/R		
Day 38	5	1.09	2.76	20.6	22.8	92	N/R		

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 101	0.1	0.1, 14	172, 149	94	79	N/R
Day 100	0.2	0.4, 15	186, 154	93	81	N/R
Day 99	0.1	0.1, 10	201, 157	88	85	N/R
Day 98	0.1	0.0, 3	155, 130	87	87	N/R
Day 97	0.1	0.0, 1	156, 152	88	83	N/R
Day 96	0.1	0.0, 1	N/R, 124	90	83	N/R
Day 95	0.2	0.0, 0	N/R, N/R	90	81	N/R
Day 94	0.1	0.0, 1	N/R, 98	89	85	N/R
Day 93	0.1	0.0, 1	N/R, 127	90	83	N/R
Day 92	0.1	0.0, 1	N/R, 121	90	87	N/R
Day 91	0.2	0.8, 3	172, 128	91	87	N/R
Day 90	0.1	0.0, 2	122, 104	86	88	N/R
Day 89	0.1	0.0, 1	153, 128	86	90	N/R
Day 88	0.1	0.0, 1	N/R, 103	85	89	N/R
Day 87	0.1	0.0, 0	N/R, N/R	93	83	N/R
Day 86	0.1	0.0, 1	N/R, 111	92	82	N/R
Day 85	0.1	0.0, 2	178, 134	98	77	N/R
Day 84	0.1	0.0, 0	N/R, N/R	92	85	N/R
Day 83	0.1	0.0, 1	135, 126	91	83	N/R
Day 82	0.1	0.0, 4	109, 110	90	83	N/R
Day 81	0.1	0.1, 18	163, 128	94	78	N/R
Day 80	0.3	0.1, 45	167, 113	90	81	N/R
Day 79	0.3	0.0, 19	167, 120	89	86	N/R
Day 78	0.2	0.0, 1	123, 113	86	90	N/R
Day 77	0.3	0.0, 3	159, 123	85	92	N/R
Day 76	0.1	0.0, 5	164, 121	88	89	N/R
Day 75	0.2	0.0, 4	161, 121	87	90	N/R
Day 74	0.2	0.4, 3	185, 135	88	87	N/R
Day 73	0.3	0.0, 1	140, 110	90	86	N/R
Day 72	0.1	0.0, 0	N/R, N/R	87	88	N/R
Day 73	0.3	0.0, 1	140, 110	90	86	N/R
Day 72	0.1	0.0, 0	N/R, N/R	87	88	N/R
Day 71	0.2	0.0, 4	174, 117	89	86	N/R
Day 70	0.1	0.0, 3	150, 121	90	85	N/R
Day 69	0.2	0.0, 0	N/R, N/R	85	94	31
Day 68	0.2	0.0, 1	157, 140	84	91	N/R
Day 67	0.3	0.0, 1	150, 122	86	92	N/R
Day 66	0.3	0.0, 0	N/R, N/R	84	90	N/R
Day 65	0.2	0.0, 0	N/R, N/R	87	87	N/R
Day 64	0.1	0.0, 0	N/R, N/R	89	91	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 63	0.1	0.0, 0	N/R, N/R	84	93	N/R
Day 62	0.1	0.0, 1	N/R, 125	92	89	91
Day 61	0.2	0.0, 0	N/R, N/R	83	94	30
Day 60	0.1	0.0, 1	172, 155	88	93	N/R
Day 59	0.1	0.6, 1	173, 158	90	89	N/R
Day 58	0.1	0.0, 0	N/R, N/R	92	93	N/R
Day 57	0.1	0.0, 0	N/R, N/R	93	90	N/R
Day 56	0.1	0.0, 0	N/R, N/R	90	94	N/R
Day 55	0.1	0.0, 0	N/R, N/R	90	94	36
Day 54	0.1	0.0, 0	N/R, N/R	90	88	N/R
Day 53	0.1	0.0, 0	N/R, N/R	91	81	47
Day 52	0.1	0.0, 1	125, 119	92	76	N/R
Day 51	0.2	0.0, 1	N/R, 121	99	64	N/R
Day 50	0.1	0.0, 1	112, 106	95	80	N/R
Day 49	0.2	0.0, 0	N/R, N/R	90	89	N/R
Day 48	0.2	0.0, 1	153, 129	92	86	N/R
Day 47	0.1	0.0, 0	N/R, N/R	90	87	N/R
Day 46	0.2	0.0, 1	167, 146	93	81	N/R
Day 45	0.2	0.0, 3	N/R, 118	94	81	N/R
Day 44	0.1	0.0, 2	132, 125	97	76	N/R
Day 43	0.1	0.1, 11	163, 151	96	74	N/R
Day 42	0.1	0.0, 1	159, 152	97	76	N/R
Day 41	0.1	0.0, 2	163, 153	93	79	N/R
Day 40	0.1	0.0, 1	154, 128	93	78	N/R
Day 39	0.3	0.0, 2	168, 126	93	77	N/R
Day 38	0.1	0.0, 3	142, 116	91	82	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.

All trademarks are the property of their respective owners.

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

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