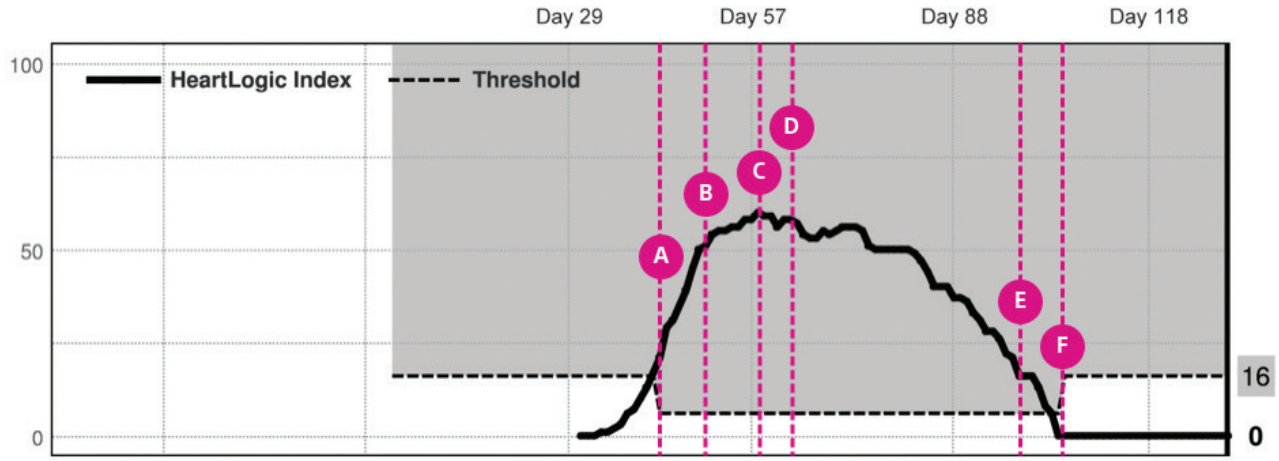
HeartLogic Utilized to Allow Intense Remote Monitoring of Patient After Implantation of VIGILANT CRT-D

Summary



Age and Gender: 68 yo female

Device Used: VIGILANT CRT-D Implant

Patient History: Dilated cardiomyopathy, severe mitral regurgitation, second degree HB and LBBB. 6 days prior to implant, patient presented in ER with symptoms of malaise/fatigue, dyspnea on exertion, shortness of breath

- LHC/RHC due to severe HF
- Vitals:
  - HR 48
  - BP 123/74
  - RR 18 O2 Sat 89% (6L nasal cannula)
  - Weight 63kg (139lb)
- Admitted for 25 days

Timeline prior to alert

Day 1: VIGILANT CRT-D Implanted

Day 12: Patient continues to have volume overload secondary to Acute/Chronic HF
IV treatment:
- Furosemide (LASIX) infuse 5mg/hr
- Milrinone (PRIMACOR) infuse 23.1375 mcg/min

Day 21: Discharged
- ACC/AHA stage D heart failure

Cardiac Medications:
- Lisinopril 10mg BID – reduced from 30mg qd
- Metoprolol (TOPROL-XL) 100mg daily - increase from baseline
- ALDACTONE 25mg daily – new

Day 34: Follow-up with CHF Clinic and Device Clinic
- Start PRN diuretic Demadex 10mg daily
  - Standard Protocol for this clinic

(A) Day 42: HeartLogic Alert Level 17
Home Health RN:
- Reports fever and non-productive cough

Medication change:
- None

(B) Day 49: Alert Level 50
Home Health RN:
- Weight Assessment +2 lb gain
- Patient has SOB and edema

Medication change:
- Demadex 10mg x 1 per protocol

(C) Day 58: Alert Level 56
- Patient has edema and SOB
- Demadex 10mg M W F

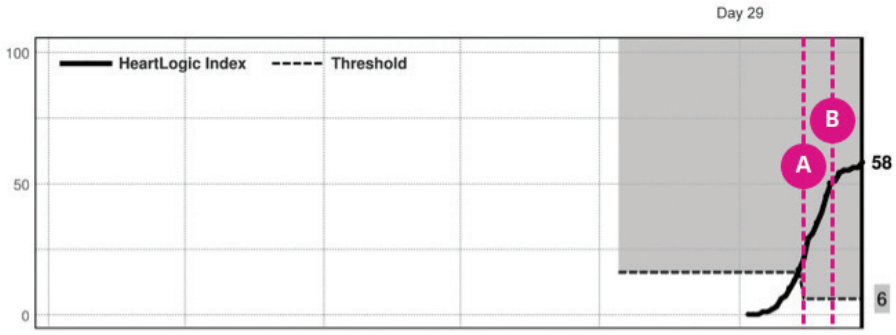
(D) Day 63: Alert Level 58
NP Visit:
- +3 lb weight gain
- Demadex 10mg daily

(E) Day 98: Alert Level 16
- Lisinopril – Discontinued
- Entresto 49/51mg started

(F) Day 104: Alert Level 0
- No SOB or edema noted
- Patient states "I'm feeling much better and have started walking around the block again"
- Continue Remote Monitoring of HeartLogic

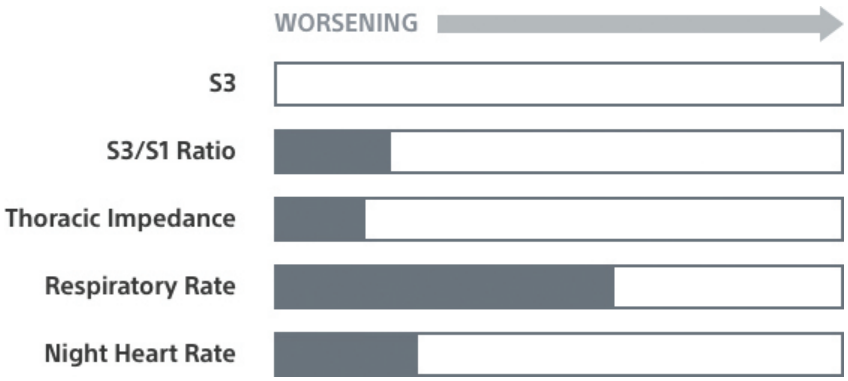
Clinical Data

HeartLogic Heart Failure Index



Contributing Trends

Note: Shaded portion indicates degree of worsening on Day 42.



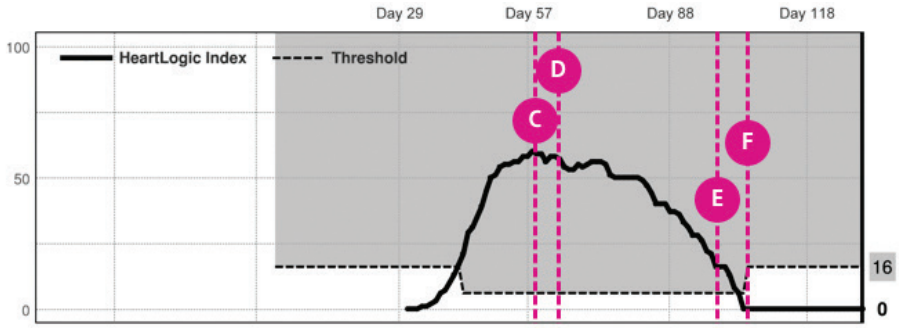
(A) Day 42: Alert Level 17
Home Health RN:
- Reports fever and non-productive cough
- Patient ER visit; discharged with nonproductive cough

Medication change:
- None
- BNP = 1,236
- Previous BNP = 2,272 (5 months earlier)

(B) Day 49: Alert Level 50
Home Health RN:
- Weight Assessment
- Weight = 124.35 lbs
- Patient has SOB and edema

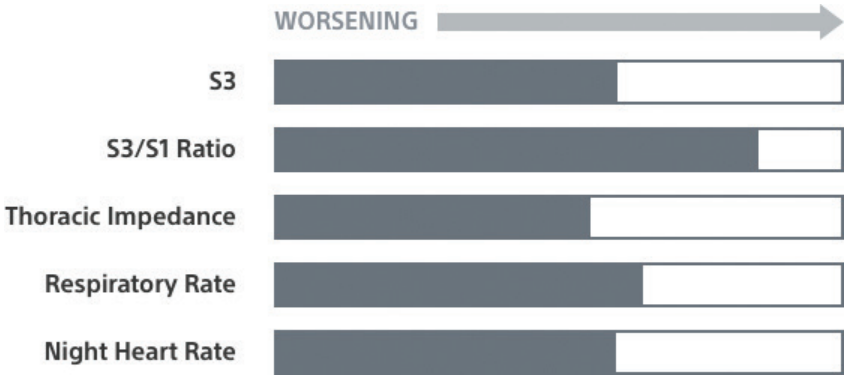
Medication change:
- Demadex 10mg x 1 per protocol

HeartLogic Heart Failure Index



Contributing Trends

Note: Shaded portion indicates degree of worsening on Day 56.



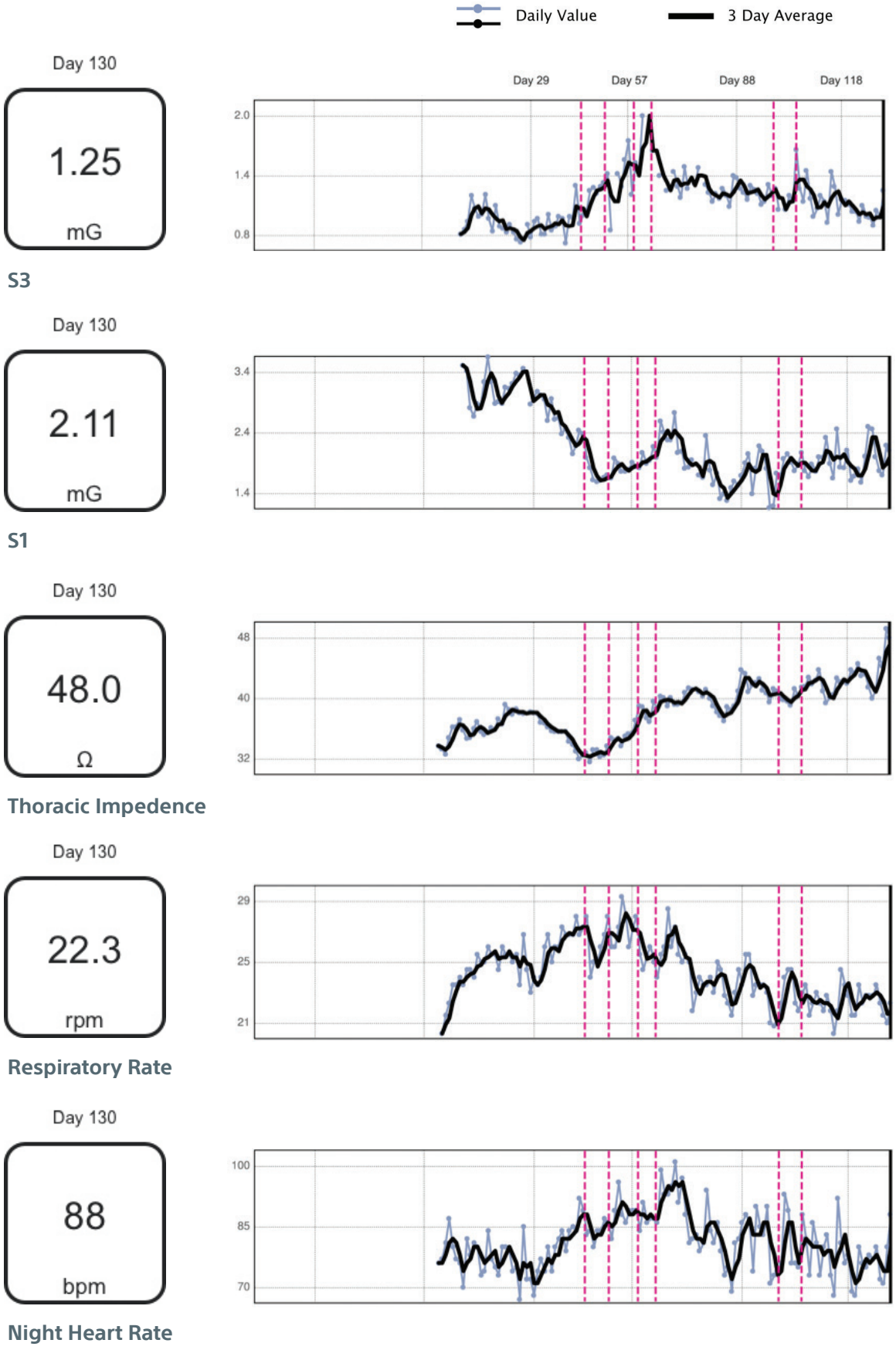
(C) Day 58: Alert Level 56
- Patient has edema and SOB
- Demadex 10mg M W F

(D) Day 63: Alert Level 58
NP Visit:
- Weight = 127lbs
- Demadex 10mg daily

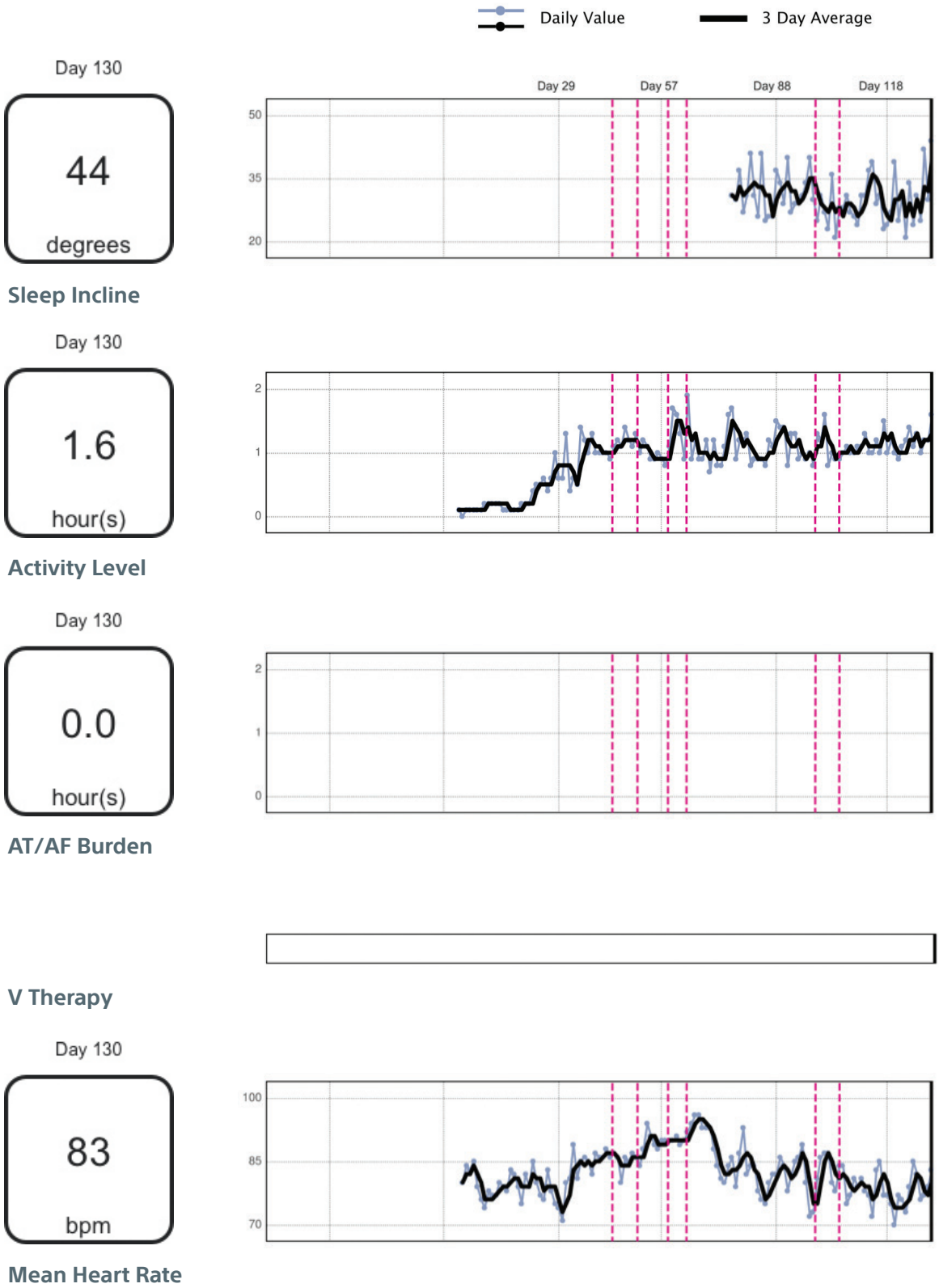
(E) Day 98: Alert Level 16
- Weight = 127lbs
- Lisinopril – Discontinued
- Entresto 49/51mg started

(F) Day 104: Alert Level 0
Patient will continue to follow-up with CHF Clinic and Device Clinic
- May 22 – office visit with CHF clinic
- Weight = 124lbs
- No SOB or edema noted
- Patient states "I'm feeling much better and have started walking around the block again"
- Continue Remote Monitoring of HeartLogic

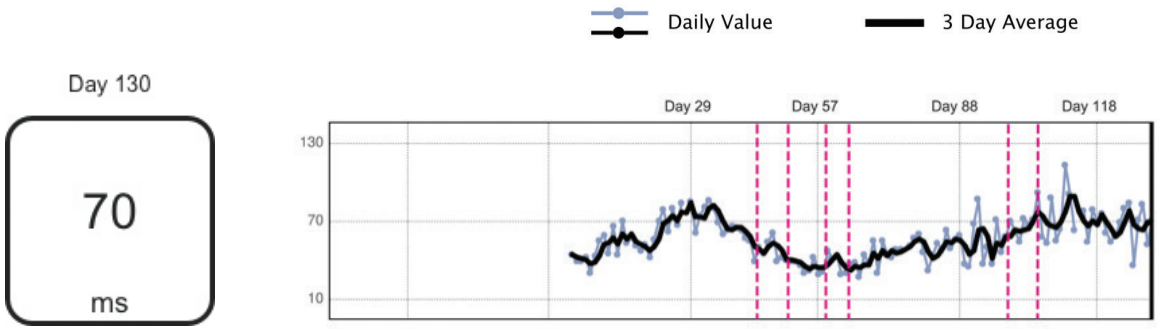
Trend Graphs



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 100	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Day 99	16	1.27	1.69	39.9	22.3	76	25	1.3	0.0, 0
Day 98	16	1.20	1.73	41.0	21.0	74	30	0.8	0.0, 0
Day 97	21	1.31	1.19	41.3	20.8	73	40	1.0	0.0, 0
Day 96	22	1.14	1.16	39.5	21.0	71	34	0.9	0.0, 0
Day 95	26	1.11	1.81	40.7	23.0	90	31	1.0	0.0, 0
Day 94	28	1.22	2.09	41.1	23.5	83	30	0.9	0.0, 1
Day 93	28	1.26	2.18	42.6	23.5	85	29	1.3	0.0, 1
Day 92	31	1.30	1.81	42.1	23.5	90	27	1.3	0.0, 0
Day 91	33	1.16	1.39	41.8	22.8	74	40	0.8	0.0, 0
Day 90	36	1.23	2.05	40.9	25.5	86	29	1.4	0.0, 0
Day 89	37	1.27	1.90	43.3	25.5	88	34	1.4	0.0, 0
Day 88	37	1.38	1.69	43.8	23.5	86	37	1.5	0.0, 0
Day 87	40	1.40	1.53	41.0	24.5	82	26	1.1	0.0, 0
Day 86	40	1.09	1.60	39.0	23.0	81	26	1.2	0.0, 0
Day 85	40	1.20	1.49	38.5	21.5	69	25	0.8	0.0, 0
Day 84	44	1.27	1.28	38.9	22.3	75	41	0.9	0.0, 0
Day 83	47	1.17	1.39	37.0	22.8	73	26	0.9	0.0, 0
Day 82	49	1.22	1.31	37.7	24.5	79	31	0.9	0.0, 0
Day 81	50	1.14	1.73	38.2	25.0	86	41	0.8	0.0, 0
Day 80	50	1.23	1.54	39.0	23.0	81	31	1.3	0.0, 0
Day 79	50	1.31	1.78	40.0	24.0	84	27	1.2	0.0, 0
Day 78	50	N/R	2.35	41.2	23.5	94	37	1.2	0.0, 0
Day 77	50	1.48	1.66	40.3	23.5	81	30	0.9	0.0, 0
Day 76	50	1.32	1.70	40.9	24.0	79	31	1.7	0.0, 0
Day 75	51	N/R	N/R	N/R	23.0	83	N/R	1.6	0.0, 0
Day 74	55	1.27	1.95	41.2	21.8	82	N/R	1.1	0.0, 0
Day 73	56	1.49	1.83	41.4	25.0	81	N/R	0.8	0.0, 1
Day 72	56	1.18	1.81	40.8	25.5	88	N/R	0.8	0.0, 0
Day 71	56	1.29	2.09	39.4	25.0	97	N/R	1.2	0.0, 0
Day 70	55	1.44	2.07	39.2	25.5	91	N/R	0.7	0.0, 0
Day 69	54	N/R	2.73	39.2	27.3	101	N/R	1.2	0.0, 1
Day 68	55	1.25	2.28	40.1	26.0	95	N/R	0.9	0.0, 0
Day 67	53	N/R	2.28	39.0	28.5	93	N/R	0.9	0.0, 0
Day 66	53	1.40	2.41	40.1	26.0	93	N/R	1.2	0.0, 0
Day 65	54	N/R	2.59	40.3	25.5	99	N/R	0.9	0.0, 0
Day 64	57	1.65	1.99	38.6	24.0	86	N/R	1.9	0.0, 0
Day 63	58	N/R	2.17	39.6	25.0	87	N/R	0.9	0.0, 0
Day 62	58	N/R	1.94	36.9	26.0	87	N/R	1.3	0.0, 0
Day 61	56	2.00	1.89	37.4	25.5	86	N/R	1.6	0.0, 0
Day 60	59	1.47	2.07	38.9	24.5	91	N/R	1.7	0.0, 0
Day 59	59	1.53	1.82	39.0	25.5	84	N/R	1.1	0.0, 0
Day 58	60	1.21	1.84	37.1	28.0	89	N/R	0.8	0.0, 0
Day 57	58	1.75	1.91	35.4	27.3	89	N/R	0.9	0.0, 0
Day 56	58	1.56	1.79	35.3	26.0	89	N/R	1.0	0.0, 0
Day 55	56	1.29	1.76	35.0	28.0	86	N/R	0.9	0.0, 0
Day 54	56	1.42	1.76	33.7	29.3	88	N/R	0.9	0.0, 0
Day 53	55	N/R	1.89	34.7	27.3	96	N/R	1.1	0.0, 0
Day 52	55	0.85	1.98	34.5	26.0	89	N/R	1.2	0.0, 1
Day 51	54	1.42	1.65	34.8	26.0	82	N/R	1.0	0.0, 0
Day 50	51	1.33	1.70	33.7	28.0	86	N/R	1.3	0.0, 0
Day 49	50	1.29	1.66	32.5	26.8	87	N/R	1.1	0.0, 0
Day 48	45	1.22	1.61	32.3	26.0	84	N/R	1.2	0.0, 0
Day 47	39	1.28	1.59	33.2	25.0	84	N/R	1.4	0.0, 0
Day 46	35	1.25	1.62	33.2	25.0	80	N/R	1.1	0.0, 0
Day 45	31	1.05	1.82	31.6	24.0	84	N/R	1.2	0.0, 0

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 46	35	1.25	1.62	33.2	25.0	80	N/R	1.1	0.0, 0
Day 45	31	1.05	1.82	31.6	24.0	84	N/R	1.2	0.0, 0
Day 44	29	1.00	1.99	32.8	28.0	83	N/R	1.1	0.0, 0
Day 43	21	0.92	2.38	32.5	27.3	89	N/R	0.9	0.0, 0
Day 42	17	1.30	2.44	32.0	26.8	92	N/R	1.0	0.0, 0
Day 41	13	0.98	2.18	33.0	28.0	84	N/R	1.0	0.0, 0
Day 40	10	0.99	2.05	33.9	26.8	85	N/R	1.0	0.0, 0
Day 39	7	0.72	2.32	34.3	26.8	84	N/R	1.0	0.0, 0
Day 38	6	0.97	2.46	35.6	26.8	79	N/R	1.3	0.0, 0
Day 37	3	0.99	2.38	35.6	27.3	84	N/R	1.0	0.0, 0
Day 36	2	0.89	2.64	35.6	26.0	82	N/R	1.2	0.0, 0
Day 35	1	0.85	2.62	35.6	26.0	80	N/R	1.4	0.0, 0
Day 34	1	1.01	2.96	35.7	25.0	74	N/R	0.5	0.0, 0
Day 33	0	0.81	2.60	36.2	26.8	80	N/R	0.6	0.0, 0
Day 32	0	0.81	2.95	36.7	26.0	74	N/R	0.4	0.0, 0
Day 31	0	0.97	3.02	36.8	24.0	77	N/R	1.3	0.0, 0
Day 30	N/R	0.94	3.08	38.0	23.5	74	N/R	0.6	0.0, 0

Date	Mean Heart Rate (bpm)	Heart Rate Variability (SDANN) (ms)
Day 100	N/A	N/A
Day 99	81	70
Day 98	73	58
Day 97	72	46
Day 96	80	71
Day 95	89	37
Day 94	86	50
Day 93	85	37
Day 92	82	87
Day 91	78	68
Day 90	84	35
Day 89	86	37
Day 88	82	59
Day 87	82	56
Day 86	80	49
Day 85	75	63
Day 84	76	47
Day 83	78	53
Day 82	84	44
Day 81	84	32
Day 80	82	46
Day 79	93	60
Day 78	87	57
Day 77	79	51
Day 76	86	N/R
Day 75	84	48
Day 74	80	48
Day 73	81	42
Day 72	84	44
Day 71	88	55
Day 70	93	30

Data Table & Timeline

LATITUDE™ NXT Patient Management – Heart Failure Management Report

Date	Mean Heart Rate (bpm)	Heart Rate Variability (SDANN) (ms)
Day 71	88	55
Day 70	93	30
Day 69	93	55
Day 68	93	37
Day 67	96	44
Day 66	96	27
Day 65	94	38
Day 64	92	37
Day 63	90	30
Day 62	89	29
Day 61	91	43
Day 60	90	41
Day 59	90	47
Day 58	90	31
Day 57	90	29
Day 56	88	42
Day 55	89	32
Day 54	91	30
Day 53	94	36
Day 52	88	39
Day 51	84	39
Day 50	86	40
Day 49	87	42
Day 48	85	39
Day 47	86	61
Day 46	80	54
Day 45	86	45
Day 44	87	50
Day 43	86	39
Day 42	88	55
Day 41	86	57
Day 40	86	63
Day 39	87	65
Day 38	82	66
Day 37	85	63
Day 36	86	60
Day 35	85	69
Day 34	81	80
Day 33	89	86
Day 32	81	81
Day 31	80	74
Day 30	71	61

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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