HeartLogic™ Best Practices

HeartLogic™
Heart Failure Diagnostic

Method to Determine Best Practice HeartLogic Workflows

Objective: *Create a resource for Health Care Provider's to learn and adapt workflows from colleagues across the United States*

Interviews
MDs, APP's, Nurses, Technicians, Administrators, Billers

Clinic Observations
Cardiology Care Teams including EP, HF and General Cardiology

Data Insights
of HeartLogic patients, Time in alert, Annual ICPM revenue

We analyzed:

- Small to large cardiology practices
- Community & academic
- % Patients in HeartLogic alert
- % Patients monitored
- Revenue
- Clinical Trials
- Real-World Evidence
- Case Studies

We asked:

- What is the current workflow?
- Who interprets the alert?
- Who decides the action?
- How do you keep patients "connected"?
- How do you bill?
- Do patients know about HeartLogic?

We heard:

- Shift to proactive HF care
- EP & HF collaboration
- HF experts interpret alert & decide action
- Teams work to the top of their license
- Patients are "connected"
- Billing protocols vary
- Engage patients with MyLATITUDE App

Clinical	Operational	Technology
EP & Heart Failure shared care model	Resources with expertise & capacity	Patient enrolled & connected in LATITUDE™ NXT
Device selection	Metrics for process & productivity	Alerts communicated to the right care team
Best practice for managing alerts	Revenue opportunities	Integrating multiple technologies

Select a tile to see best practices

Clinical

EP & Heart Failure Shared Care Model

REMOTE PATIENT MONITORING

- Shared goals across the cardiology practice
- Align resources to work at the top of their license
- Establish protocols & templates
- Embed tools into EMR, LATITUDE, device data management software
- Patient education is coordinated & consistent between EP and HF

HEART FAILURE CARE PATHWAY

- Design alert* protocol including who and when to act
- Review LATITUDE alert notifications annually (Device & HeartLogic)
- Conduct case reviews
- Measure outcomes

*Alert: HeartLogic index crosses the threshold *until* below the recovery value

PATIENT ENGAGEMENT

- Patient and caregiver understands who to call with questions or concerns
- Understands financial responsibility

ICPM BILLING

- Decide who will bill for what services
- Determine frequency of billing e.g., during alerts or monthly for all patients
- Coordinate billing cycles using technology (ICPM, ICD & Pacemaker)

Click to see more best practices

Clinical

Device Selection

REMOTE PATIENT MONITORING

Device selection protocol to match the patients' needs

Educate the patient & caregiver:
- Device features
- Remote Patient Monitoring Program
- Clinic billing protocol

Notify Heart Failure team of new patient

HEART FAILURE CARE PATHWAY

Heart Failure team receives new patient information

Heart Failure team meets patient during the hospital stay for device implant

Await first HeartLogic alert notification

PATIENT ENGAGEMENT

Review patient education materials

Create a list of questions for the care team

Activate MyLATITUDE™ Patient App

ICPM BILLING

Schedule ICPM billing per clinic protocol e.g., during alerts or monthly

Click to see more best practices

Clinical

Best Practice for Managing Alerts

REMOTE PATIENT MONITORING

- Design protocols including who and when to act
- Dedicate resources to monitor ongoing patient connection to LATITUDE
- Reduce hand-offs with data
- Design LATITUDE configuration for efficiencies
- Monitor metrics for efficiency and scaling resources to volume

HEART FAILURE CARE PATHWAY

- Heart Failure clinicians establish alert* protocols
- Heart Failure clinicians establish documentation templates
- Clinicians with Heart Failure expertise respond to HeartLogic alerts
- Conduct case reviews
- Measure outcomes

*Alert: HeartLogic index crosses the threshold until below the recovery value

PATIENT ENGAGEMENT

- Utilize MyLATITUDE™ Patient App
- Maintain Communicator connection
- Know who and when to call for help: clinic and/or Boston Scientific Patient Services (866.484.3268)

ICPM BILLING

- Determine frequency of billing e.g., during alerts or monthly for all patients
- Proactive patient communication on clinic remote monitoring billing practices
- Coordinate billing cycles using technology (ICPM, ICD & Pacemaker)

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Operational

Resources with Expertise & Capacity

REMOTE PATIENT MONITORING

- Align goals and budget across the cardiology practice
- Establish protocols
- Document workflows by function
- Cross-train staff
- Design documentation templates for measurement
- Monitor metrics monthly to adjust staffing

HEART FAILURE CARE PATHWAY

- Follow alert* protocols
- Designate personnel with expertise in Heart Failure and HeartLogic
- Align resources to work at the top of their license
- Dedicate a day of the week for HeartLogic
- Streamline documentation

*Alert: HeartLogic index crosses the threshold until below the recovery value

PATIENT ENGAGEMENT

- Actively engage with MyLATITUDE™ Patient App
- Understand who and when to call with questions or concerns
- Maintain Communicator connection

ICPM BILLING

- Automate remote monitoring billing (ICPM, ICD & Pacemaker)
- Create the business case for scaling resources with revenue

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Operational

Metrics for Process & Productivity

REMOTE PATIENT MONITORING

- Patient volume
- Volume by therapy type
- # of “clicks” per patient
- Time studies by function

HEART FAILURE CARE PATHWAY

- Percentage HeartLogic patients in alert*
- Time in HeartLogic alert*
- Number of HeartLogic alerts per patient
- Heart Failure Readmissions
- Cardiac Hospitalizations
- Cardiac Length of Stay
- Cardiac related ED visits

*Alert: HeartLogic index crosses the threshold until below the recovery value

PATIENT ENGAGEMENT

- Monitoring status
- In-person vs. remote patient interactions
- “No show” rates

ICPM BILLING

- Technical fees
- Professional Fees

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Operational

Revenue Opportunities

REMOTE PATIENT MONITORING

- Proactive patient communication of the clinic's billing practices
- Build upon existing billing workflows
- Systematic device interrogations with comprehensive reports
- Dedicate resources to monitor ongoing patient connection to LATITUDE

HEART FAILURE CARE PATHWAY

- Determine who will bill for what service e.g., technical and/or professional
- Systematic clinical documentation to meet payment requirements

PATIENT ENGAGEMENT

- Understands remote monitoring billing practices
- Complies with copay responsibilities
- Maintain Communicator connection

ICPM BILLING

- Determine frequency of ICPM billing e.g., during alerts or monthly for all patients
- Coordinate billing cycles (ICPM, ICD & Pacemaker)
- Offer an "opt-out" model for patients refusing remote monitoring billing e.g. office visits only
- Actively manage lost revenue opportunities e.g., not monitored, denials, gaps in documentation

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Technology

Patient Enrolled & Connected in LATITUDE™ NXT

REMOTE PATIENT MONITORING

- Enter new patients into LATITUDE
- Assign appropriate following group for managing alerts (care team)
- Configure device and HeartLogic alerts to notify the appropriate care team member
- Resolve changes in patient status e.g., transfers, deceased
- Review LATITUDE configuration annually for new efficiencies

HEART FAILURE CARE PATHWAY

- Decide mode of HeartLogic alert notifications e.g., email, text, or website
- Establish who will dismiss HeartLogic alerts in LATITUDE
- During an alert* episode, consider changing interrogations to daily in LATITUDE to monitor trends of the index.

*Alert: HeartLogic index crosses the threshold *until* below the recovery value

PATIENT ENGAGEMENT

- Utilize MyLATITUDE™ Patient App
- Maintain Communicator connection
- Know who and when to call for help: Clinic or Boston Scientific Patient Services (866.484.3268)

ICPM BILLING

- Schedule device interrogations to support clinic billing workflows (ICPM, ICD & Pacemaker)

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Technology

Alerts Communicated to the Right Care Team

REMOTE PATIENT MONITORING

Design LATITUDE configuration to alert the team member with expertise in Heart Failure and HeartLogic

Reduce the number of hand-offs

Reduce the number of alert* interpretations

*Alert: HeartLogic index crosses the threshold until below the recovery value

HEART FAILURE CARE PATHWAY

EP & Heart Failure teams collaboratively design LATITUDE alert configurations annually

Adjust patient level alert configuration in LATITUDE as needed

PATIENT ENGAGEMENT

Patient understands who is on their care team

Knows who and when to call for help

ICPM BILLING

Coordinate billing cycles (ICPM, ICD & Pacemaker)

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Technology

Integrating Multiple Technologies

REMOTE PATIENT MONITORING

Assess workflow for IT efficiencies

Eliminate unhelpful variation and duplication in the workflow and IT systems

Evaluate device data management technologies

HEART FAILURE CARE PATHWAY

Embed HeartLogic alert* management protocols into IT systems

Design IT tools to support measurement e.g., process and outcomes

Create visibility of HeartLogic data across hospitals, ED and clinics

*Alert: HeartLogic index crosses the threshold until below the recovery value

PATIENT ENGAGEMENT

Ensure patient access to MyLATITUDE™ Patient App

Ensure patient access to the health care provider's EMR Portal

ICPM BILLING

Maximize LATITUDE for cyclic device interrogations to support billing (ICPM, ICD & Pacemaker)

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Appendix

HeartLogic™
Heart Failure Diagnostic

Brief Summary | CRT-D Systems

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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, 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.

92436222 (Rev. A)

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.

Brief Summary | ICD Systems

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ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL ICD

NDICATIONS AND USAGE
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.

92436178 (Rev. B)

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.

Brief Summary | Latitude™ NXT

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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.

92436260 (Rev. A)

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.