EDUCARE

Boston Scientific

UNLOCK THE POTENTIAL

Real World HeartLogic™ Workflows

Clinic: Huntsville Hospital Heart Center Device Clinic
Hospital Affiliation: Huntsville Hospital
Location: 8 locations in the Huntsville, AL & surrounding area
370 HeartLogic Patients[1]

- 15% of HL patients in Alert (active alert-based management)
- 85% of HL patients out of Alert (standard remote monitoring schedule)
- 91% of HL patients regularly remotely transmitting physiologic data

HEART CENTER
HUNTSVILLE HOSPITAL

Regina McGee Taylor, RN
Senior Device Nurse
The Heart Center

About Regina McGee Taylor & The Heart Center

Regina R. McGee Taylor, RN is a senior device nurse at The Heart Center Device Clinic in Huntsville, AL. She has over 15 years of experience with managing heart failure patients with Cardiac Rhythm Devices. She has developed protocols for and implemented a sub-specialty Congestive Heart Failure Device Clinic that now follows over 1300 patients. She developed a close working relationship with the Heart Failure Management Team at Huntsville Hospital and has built a successful remote monitoring program which includes a specific HeartLogic workflow and clinical protocol.
Huntsville Hospital's Heart Center and Heart Institute represents the largest and most experienced team of board-certified cardiologists, cardiothoracic surgeons and cardiac anesthesiologists in North Alabama and southern Tennessee as indicated by the American Hospital Directory[2]. The team consists of 5 EP's who perform over 3800 EP procedures per year, 8 full time RN's, and 5 dedicated support staff.

HeartLogic Program Overview

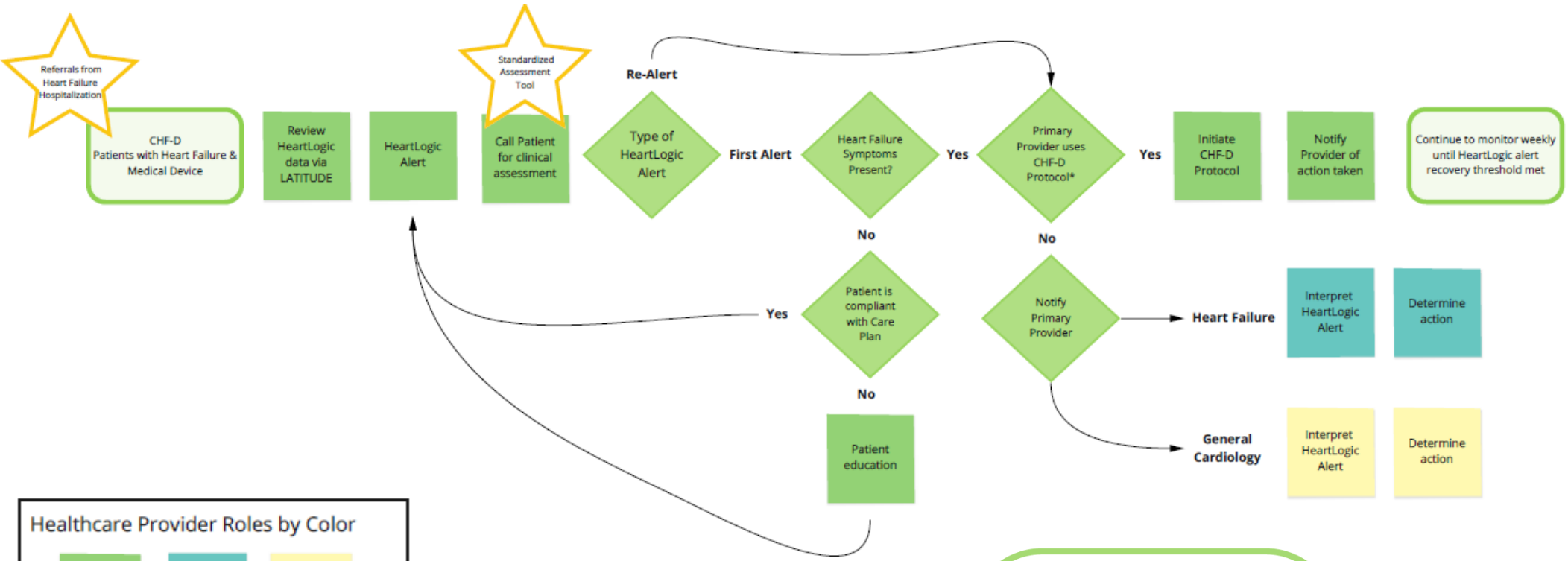
In 2013, a team of nurses was established within the EP practice focusing on patients who were at highest risk of congestive heart failure. The new team was aptly named the Congestive Heart Failure Device Clinic (CHF-D) team. They constructed criteria for which patients would receive care from this team in collaboration with their heart failure colleagues. The criteria prioritizes patients with a hospitalization for heart failure and a medical device. With the introduction of HeartLogic, the technology was a "game-changer" for the CHF-D clinic as it provided a streamlined solution for physiologic diagnostic monitoring with a predictive alert → allowing the team to intervene and prevent worsening heart failure for at risk patients with the advanced early warning. Together, the Huntsville care teams established a consistent approach to patient assessment, education, and guideline directed protocols for medication titration, laboratory testing, and provider visits.

Regina McGee Taylor's Top 3 Pieces of Advice for a Successful HeartLogic Workflow

1. Repeated patient education leads to successful remote monitoring.
2. Established protocols allow your team to treat early HF events.
3. HeartLogic assures "you will know before they go", allowing you to prevent an admission.

HeartLogic™
Heart Failure Diagnostic

Huntsville Heart Center's HeartLogic Workflow



Healthcare Provider Roles by Color

- Congestive Heart Failure - Device (CHF-D) Nurse
- Heart Failure Provider
- General Cardiology Provider

*CHF-D Protocol

Contact Patient to assess for:
- Dietary noncompliance
- Medication noncompliance
- CHF clinic noncompliance (if enrolled)
- Increase fluid or sodium intake
- CHF hospitalization in last 30 days

If compliant, treat with burst diuretics
(provided normal serum creatinine within 6 months)

Follow up BMP, proBNP and CXR in one week

Arrange office visit with mid-level or CHF clinic

Follow weekly until trends improve or patient develops symptoms

If Patient admits to noncompliance
- Patient educated on importance of strict adherence to meds/diet/fluid

Patients are followed weekly and contacted via phone to re-assess until out of alert

Once out of alert they are followed monthly in the CHFD clinic but could resume quarterly follow up with an assurance device will alert for re-event

Workflows, Processes, Proposed Intervention, & Results from HeartLogic Workflows are not necessarily predictive of results in other situations and may vary.
Workflow depicted above documented October 2020

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Congestive Heart Failure (CHF) Device Team

If a patient has one or more of the following: a HF admission, HF symptoms reported to their general cardiologist, reports at the outpatient CHF Clinic, or has a HeartLogic alert, the patient is triaged to the CHF-D team. The CHF-D RN's interpret the HeartLogic data, contact patients for signs, symptoms, & compliance, and then determine the intervention through a standardized protocol.

Heart Failure and General Cardiologist Teams

For patients who are not enrolled in the CHF-D clinic, HeartLogic alerts and initial assessment from the CHF-D clinic are sent to the patient's primary cardiologist who determines 1) enrollment into the CHF-D clinic or 2) appropriate next steps/action. Upon CHF-D clinic enrollment, the Primary Cardiologist is notified of all HeartLogic alerts, the recommended intervention (from CHF-D clinic), and notification of further device diagnostic findings such as atrial fibrillation or drop in Bi-V pacing %.

The Device Clinic (EP Provider, Device RN's, Support Staff)

**Not shown in HeartLogic Alert Management Workflow*

The Huntsville Heart Center Device Clinic team manages all CRM devices and non-HeartLogic alerts. The device team is responsible for initial patient education, a 6-week post op clinic visit (which may include calibration of the Sleep Incline sensor), routine scheduled device interrogations, and regular remote monitoring and billing.

Empowering Patients Through Education

Huntsville Hospital + The Huntsville Heart Center have a keen focus on educating their HeartLogic patients; at implant, in the event of a HeartLogic alert, and recovery. The collaborative team of EP providers, a Hospital Nurse Educator, Boston Scientific Representatives, Device Clinic Staff, and CHF-D Nurses may account for as many as 9 unique patient education touchpoints from device implant to heart failure recovery. The education focuses on remote connectivity adherence and HeartLogic's ability to remotely track a patient's heart failure status. The focus on patient education has led to 91% of HeartLogic patients regularly remotely transmitting physiologic data.

The 3A Process for The Heart Center

ALERT

HeartLogic alerts are directly triaged by the device clinic team of RN's who specialize in HF remote patient management (CHF-D team) through the utilization of a secondary group in LATITUDE NXT.

ASSESSMENT

In coordination with the HeartLogic Index, the patient assessment includes: dietary & medication compliance, provider visit history, and HF hospitalizations within the last 30 days.

ACTION

The action is driven by a clinical protocol with escalation criteria for provider interpretation & intervention. The CHF-D RN communicates the recommended action to the patient and their provider.

HeartLogic™
Heart Failure Diagnostic

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.

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

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.

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.

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.

Workflows, Processes, Proposed Intervention, & Results from HeartLogic Workflows are not necessarily predictive of results in other situations and may vary.
All trademarks are the property of their respective owners

Sources

1. Boston Scientific Internal Data. Current as of September 16, 2020.
2. https://www.theheartcenter.md/about-us. Accessed 9/14/2020

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Heart Failure Diagnostic