HEARTLOGIC™
Heart Failure Diagnostic

Boston Scientific
Advancing science for life™

Managing HeartLogic™ in LATITUDE™ NXT

ABOUT THIS GUIDE

This guide is designed to help healthcare providers and associated personnel to identify and execute steps and best practices needed to configure LATITUDE™ NXT Remote Patient Management System successfully for remote patient monitoring of HeartLogic™ Heart Failure Diagnostic. The document will help you explore configuration options in order to optimize your workflow.

Within this guide you will find the following resources:

1. HeartLogic Summary
2. Preparing to Remotely Monitor with HeartLogic
3. HeartLogic Data Review using LATITUDE NXT
4. Customize LATITUDE NXT to Support HeartLogic Workflow
5. Patient Education
6. Additional Resources

The recommendations throughout this guide have been developed based on conversations with allied health professionals (AHPs), clinic managers, physicians, patients, and other health professionals who interact with HeartLogic, LATITUDE NXT and existing data management systems.

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HeartLogic™ Heart Failure Diagnostic is the first FDA approved Heart Failure Diagnostic implantable cardiac therapy device that uses multiple sensors to track physiologic trends and combines them into one composite index. When the index crosses over a configurable threshold, HeartLogic provides a proactive alert via the LATITUDE™ NXT Remote Patient Management System. HeartLogic is available in the RESONATE™ family devices and will alert clinicians when patients are at significantly increased risk of worsening heart failure to facilitate early clinical intervention.

The MultiSENSE Study validated that HeartLogic:

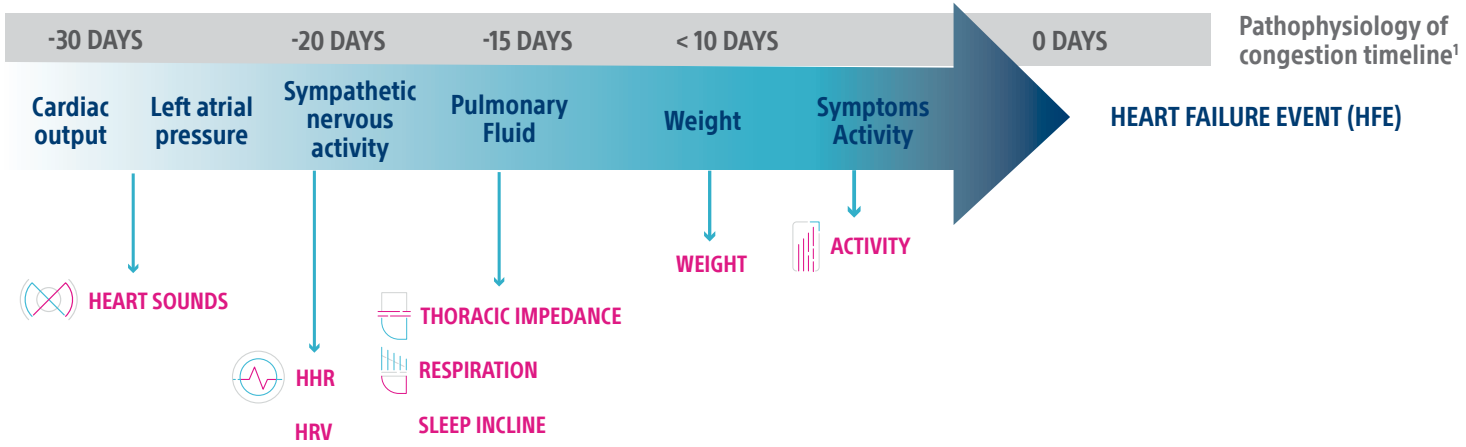
Had **high sensitivity** of 70% in detecting heart failure events[1]

Had a **very low alert burden** of less than 2 alerts per patient per year[1]

Would have provided **weeks of advance notice** of a potential heart failure event[1]

1. Boehmer JP, Hariharan R, Devecchi FG, Smith AL, Molon G, Capucci A, An Q, Averina V, Stolen CM, Thakur PH, Thompson JA, Wariar R, Zhang Y, Singh JP. A Multisensor Algorithm Predicts Heart Failure Events in Patients With Implanted Devices: Results From the MultiSENSE Study. JACC Heart Fail. 2017; 5 (3): 216-25. http://heartfailure.onlinejacc.org/content/jhf/5/3/216.full.pdf

HeartLogic™ was designed to detect the early warning signs of worsening heart failure from a diverse set of sensors chosen to target the different aspects of heart failure.



Sensors available with HeartLogic, BSC's RESONATE™ Family of ICD's and CRT's, or other BSC RPM offerings.
****There is a large individual variability in presentation and time course, even for the same patient. Thus, several patterns may precede a decompensation.**

HEART SOUNDS
Reveals signs of elevated filling pressure and weakened ventricular contraction via S3 and S1 heart sounds, respectively.

THORACIC IMPEDANCE
Measures impedance between electrodes on the RV lead and the pulse generator, which is indicative of fluid accumulation and pulmonary edema.

RESPIRATION
Monitors respiratory patterns associated with shortness of breath. In particular, it monitors respiratory rate and rapid shallow breathing via RSBI (rapid shallow breathing index), which is a ratio of respiratory rate (RR) to tidal volume.

HEART RATE
Monitors night heart rate, captured between midnight to 6 am, which for most patients is indicative of the resting heart rate.

ACTIVITY
Shows the number of hours per day a patient is active and reflects the patients overall status and fatigue.

HeartLogic™ and Heart Failure Sensor Suite

HeartLogic was validated in the MultiSENSE Study to detect worsening heart failure by combining data from 5 physiologic sensors into a single composite index.

In addition, HeartLogic compatible devices provide a comprehensive picture of the patient's heart failure and arrhythmia status.

Below highlights the HeartLogic and Heart Failure Sensors. For additional information click the pink buttons below:

HeartLogic Resources | **HeartLogic Continuing Education Training** | **HeartLogic Multi-Sensor Technology** | **Heartlogic Alert Management Guide**

HeartLogic and Heart Failure Sensors	
Heart Sounds (S3 & S1) 	Measured from the accelerometer and reveals signs of elevated filling pressure and weakened ventricular contraction via S3 and S1 heart sounds, respectively. Heart sounds are measured every 20 minutes at rest and aggregated throughout the day.
Thoracic Impedance 	Measures impedance between electrodes on the RV lead and the pulse generator, which is indicative of fluid accumulation and pulmonary edema. Thoracic impedance is measured very 2 minutes and aggregated throughout the day.
Respiration 	Monitors respiratory patterns associated with shortness of breath. In particular, it monitors respiratory rate and rapid shallow breathing via RSBI (rapid shallow breathing index), which is a ratio of respiratory rate (RR) to tidal volume.
Night Heart Rate 	Night HR is measured beat by beat then aggregated between midnight and 6 am, which for most patients is indicative of the RESTING heart rate.
Activity 	Monitors a patient's activity in hours per day reflecting overall status and fatigue.

Sensors found in both HeartLogic™ Heart Failure Diagnostic and the Overall Heart Failure Sensor Suite	
Sleep Incline	Measures angle between the patient's torso and the horizontal plane, measured during a sleep period specified by the patient. *Requires Calibration at least 7-10 days after implant.
AT/AF Burden	Displays the total amount of time spent in an atrial tachy response (ATR) mode switch, in hours per day.
Ventricular Therapy	Provides an abbreviated summary of antitachycardia pacing (ATP) and shock therapy type delivered each day.
Mean Heart Rate	Displays mean heart rate.
Heart Rate Variability (SDANN)	Measures Standard Deviation of Averages of Normal Sinus to Normal Sinus intervals.
RV Rate During AT/AF	Shows maximum and mean RV during AT/AF. *Only in Health Tab or HF Management Report in RESONATE™ and MOMENTUM™ devices (see Summary Tab in LATITUDE™ for VIGILANT™ devices).
% LV Paced	Trend is percent of cardiac beats paced with a left ventricular (LV) lead per day. *Only available on Health Tab or HF Management Report in RESONATE and MOMENTUM devices (see Summary Tab in LATITUDE for VIGILANT devices)

For a deeper discussion into the individual HeartLogic sensors or overall HF Sensor Suite, click the buttons below to the HeartLogic™ Heart Failure Diagnostic page on the Boston Scientific website or review information on the HeartLogic EDUCARE website.

HeartLogic Resources

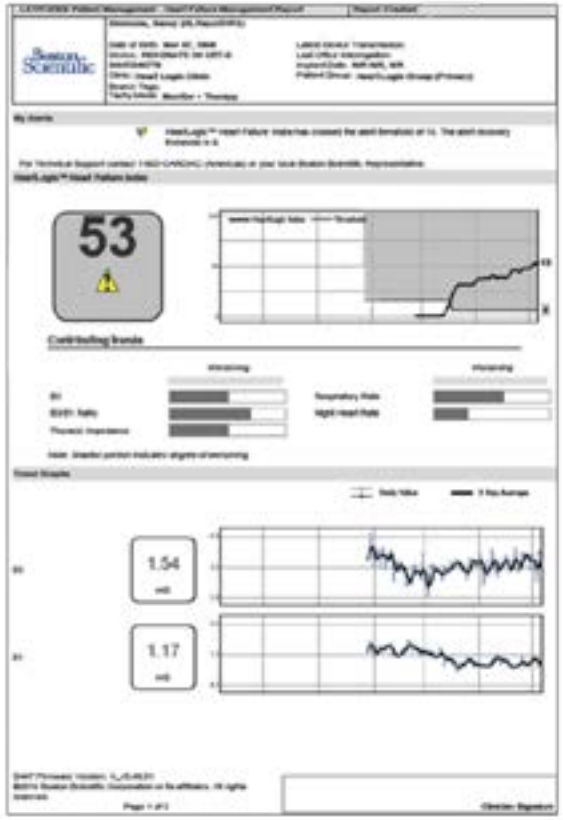
HeartLogic Heart Failure Diagnostic Page

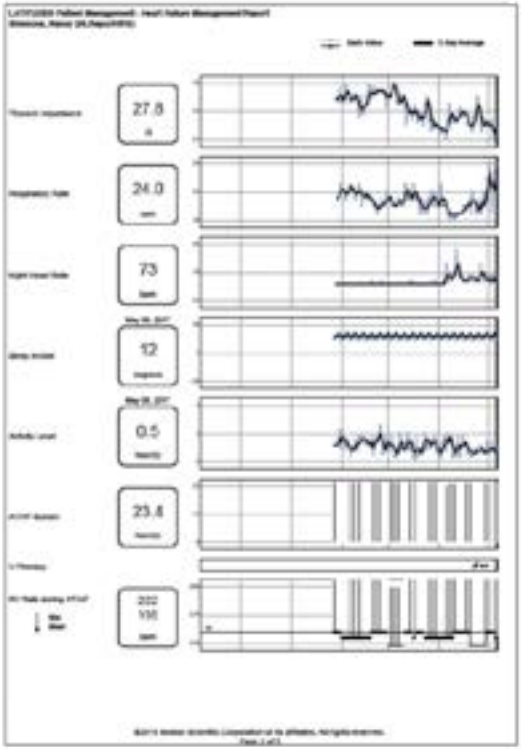
HeartLogic™ Heart Failure Diagnostic is available on the Heart Failure Management Report which can be accessed remotely via LATITUDE NXT or in-person via the LATITUDE™ Programming System, Model 3300, or the LATITUDE Consult™ System.

LATITUDE NXT Communicator

LATITUDE Programming System, Model 3300

LATITUDE Consult System (US only)





Preparing to Remotely Monitor with HeartLogic™ Heart Failure Diagnostic

The following checklist may be helpful in implementing an efficient and successful workflow. It is suggested to have completed or considered the following prior to managing HeartLogic patients.

Basic Understanding of LATITUDE™ NXT

- ☐ Enroll Clinic in LATITUDE NXT
    - o Contact your Boston Scientific Rep for assistance, if needed
- ☐ Obtain Username and Password
- ☐ Navigation of LATITUDE NXT
- ☐ Patient Groups and Schedule/Alert Configuration
- ☐ Patient Enrollment
- ☐ Creation of a Heart Failure Management Report
- ☐ Remote Monitoring Statuses
- ☐ Utilizing self-guided LATITUDE CEU training, access by clicking the button below:

LATITUDE Continuing Education Training

Understand the HeartLogic™ Heart Failure Diagnostic

- ☐ Utilize self-guided HeartLogic CEU training and resources, access by clicking the button below:

HeartLogic Continuing Education Training **HeartLogic Resources**

- ☐ See HeartLogic Data Review using LATITUDE NXT

Consider Roles and Responsibilities

- ☐ Patient Enrollment in LATITUDE NXT
  - o Device Clinic, Heart Failure Clinic, Rep
- ☐ Maintain active Communicator status
- ☐ Identify Team(s) Responsible for HeartLogic alerts
- ☐ HeartLogic™ Alert Management
  - ☐ Receive alert
  - ☐ Generate report
  - ☐ Contact patient
  - ☐ Send to appropriate management team
  - ☐ Implement care plan
  - ☐ Document in EMR
  - ☐ Dismiss alert

✪TIP

To realize the full potential of HeartLogic™ Heart Failure Diagnostic, patients need to be actively monitored in LATITUDE NXT.

It is suggested that EP and Heart Failure work together to maintain monthly Communicator connection

Heart Failure Billing Process

- ☐ HeartLogic and other Heart Failure diagnostics may be eligible for reimbursement
- ☐ Determine billing plan
- ☐ Team Responsible for Billing
- ☐ Frequency
  - ☐ Monthly – All HeartLogic patients
  - ☐ Monthly – Only patients in alert
  - ☐ Quarterly – All HeartLogic patients
  - ☐ No billing - Alert monitoring only

See Customize LATITUDE NXT to support HeartLogic workflow on page 29.

Resources regarding billing - Billing and Reimbursement on page 57.

HeartLogic™ Heart Failure Diagnostic Data Review using LATITUDE™ NXT Remote Patient Management System

The HeartLogic within the Boston Scientific family of devices is viewed remotely via the LATITUDE NXT. This section contains the following information:

HeartLogic Patient information on LATITUDE NXT
- o Where HeartLogic can be found within LATITUDE NXT
- o How to confirm if HeartLogic is enabled
- o HeartLogic may be disabled
- o HeartLogic Alert is OFF
- o Viewing HeartLogic on LATITUDE NXT
- o HeartLogic Initialization Period
- o HeartLogic Heart Failure Index and Contributing Trends
- o Navigating HeartLogic Trends in LATITUDE NXT

HeartLogic Alerts on LATITUDE NXT
- o HeartLogic Nominal Threshold
- o HeartLogic Recovery Threshold
- o In Alert vs. Out of Alert
- o Perform daily interrogations until alert condition is resolved
- o Dismissing Alerts

LATITUDE NXT Reports that include HeartLogic

HeartLogic on LATITUDE™ Programming System (Model 3300) & LATITUDE Consult™ System

The information in this section is intended to be used by device clinic staff, clinicians, and sales personnel who are familiar with the use of LATITUDE NXT and the technology behind HeartLogic.

For additional resources regarding LATITUDE NXT fand HeartLogic, click the buttons below.

LATITUDE Continuing Education Training | HeartLogic Continuing Education Training | HeartLogic Resources

HeartLogic Information on LATITUDE NXT

HeartLogic patient data is available within LATITUDE NXT for patients who have a HeartLogic compatible device including CRT-Ds and ICDs AND have HeartLogic enabled.

The RESONATE™ family of devices encompasses the following categories and corresponding Model Numbers as noted in table below:

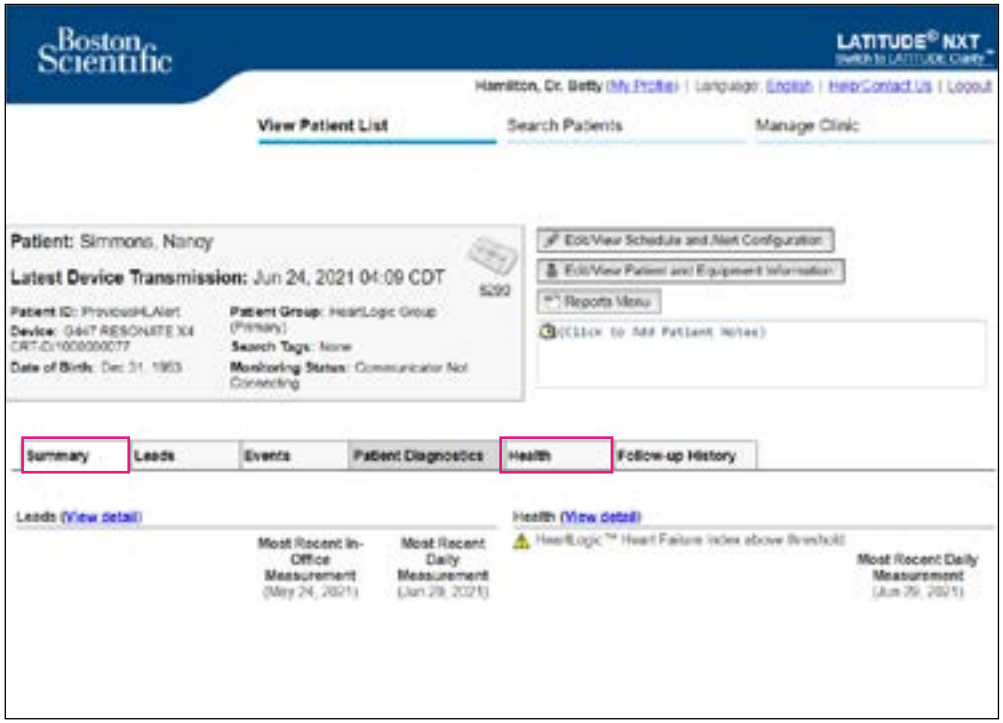
	ICD Model Numbers	CRT-D Model Numbers
RESONATE™	D432, D433, D420, D421 D532, D533	G447, G547 G448, G424, G425, G426, G428, G437
VIGILANT™	D232, D233, D220, D221	G247, G248, G224, G225, G228, G237
MOMENTUM™	D120, D121	G124, G125, G126, G138, G128
PERCIVA™	D400, D401, D412, D413	N/A
RESONATE™ HF	D532, D533	G547
For more information on the RESONATE Family of devices please click the pink button below to refer to the Boston Scientific Electrophysiology Products page.		

Boston Scientific Electrophysiology Products Page

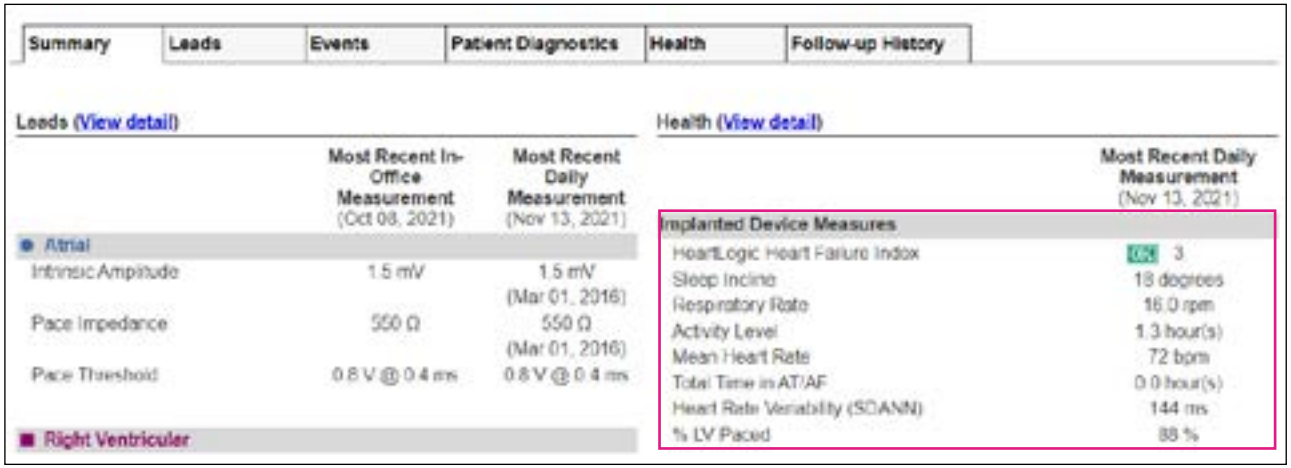
Where HeartLogic can be found within LATITUDE NXT

HeartLogic patient information is accessed in LATITUDE NXT by selecting the patient you wish to view and clicking on your patient's name (link).

You will be brought to your patient's profile page where HeartLogic information can be found within two locations:
Summary Tab and Health Tab.



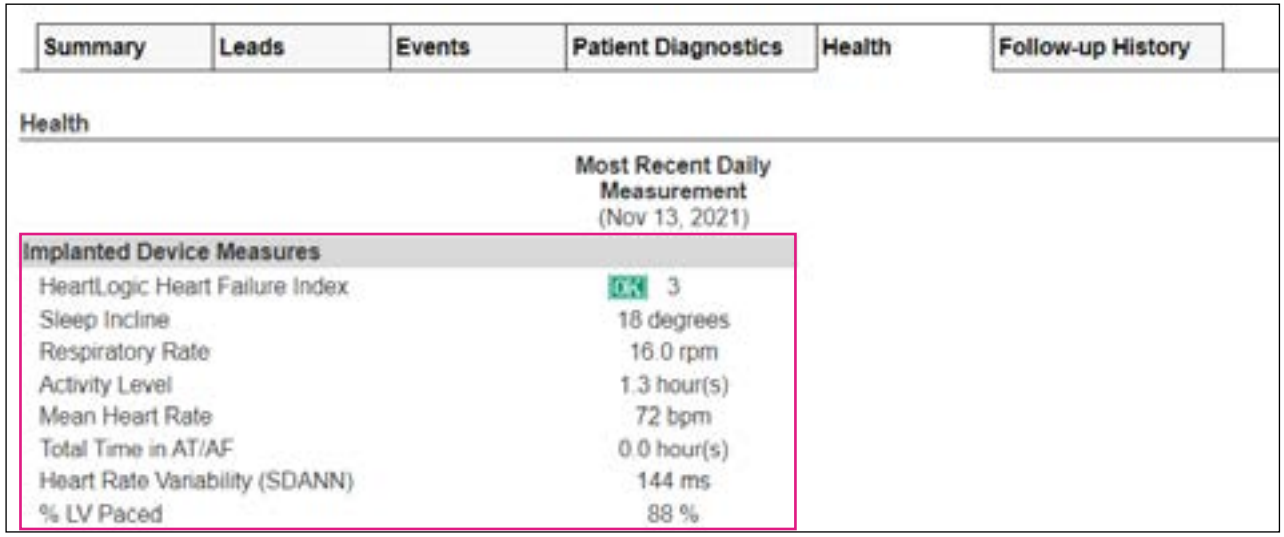
- **Summary Tab:** Provides a summary of device settings and measurements used primarily by those who are following a patient's overall device diagnostics. (often those working in a device clinic or primary EP practice)
    - o Within this tab, the HeartLogic index can be viewed under "Implanted Device Measures"



TIP

Your LATITUDE NXT access may default directly to the Summary Tab upon selecting your patient's device information to review. You can customize this to link directly to the Health Tab and your patient's HeartLogic information. See Additional Resources.

- **Health Tab:** Provides a comprehensive summary of a patient's HeartLogic data. This is used by clinicians who primarily follow or manage a patient's heart failure or are interested in patient heart failure data.



TIP

If your patient's device has not had HeartLogic enabled, the HeartLogic Index will not be visible under the Implanted Device Measures data in the Summary Tab nor will the HeartLogic Index, Trend Graph, Contributing Sensors, or Heart Sounds be visible under the Health Tab.

How to Confirm if HeartLogic is Enabled

1. Navigate to the Summary or Health Tab for your specific patient
2. On the Summary Tab, you will see the HeartLogic Index under the Implanted Device Measures heading within the Health section if enabled
3. On the Health Tab you will see the HeartLogic index and trend graph if enabled

If you don't see the information described above, HeartLogic may be disabled.

HeartLogic may be disabled for the following reasons:

- Enablement was not completed at time of implant (often at the discretion or direction of the implanting or referring providers).
- Patient is enrolled in an on-going clinical trial where study protocol precludes enablement.

Figure 1: View of Summary vs. Health tabs in LATITUDE NXT

HeartLogic Disabled

HeartLogic Enabled

✪TIP

To enable HeartLogic for your patient, please contact LATITUDE Customer Support at 1-800-CARDIAC (1-800-227-3422) for assistance.

The HeartLogic™ Alert is currently OFF

You may also find a situation where your patient has HeartLogic enabled however upon viewing your patient's information you see that the HeartLogic alert has been disabled. This occurs when either at the clinic or patient level the HeartLogic Yellow Alert has been disabled within LATITUDE NXT. An example of this appears below.

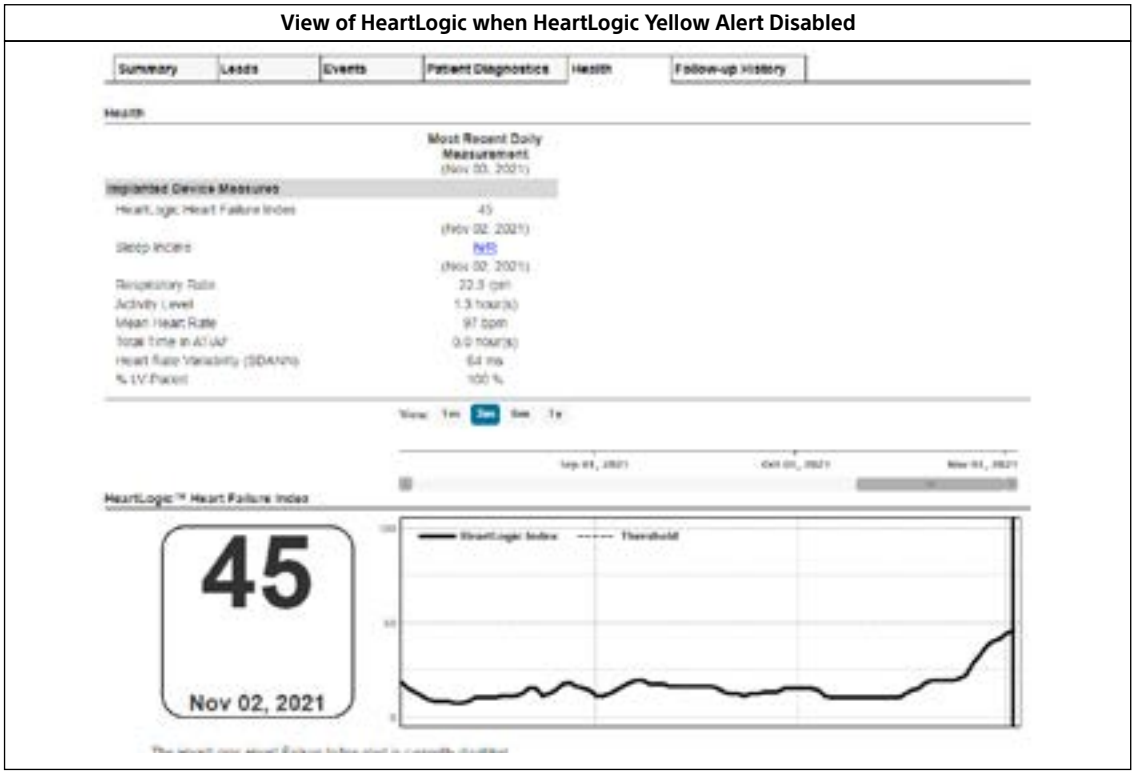
- To understand how to configure Yellow Alerts in LATITUDE NXT please see Additional Resources on page 55.

Adding patients to new patient groups or transferring patients to your clinic

When patients are added to new patient groups or are transferred to your clinic, the HeartLogic data may not be available until the patient's Communicator calls into the server to receive these changes.

- The HeartLogic data will typically be available within 7 to 10 days, as long as the Communicator is plugged in and collecting/sending data

View of HeartLogic when HeartLogic Yellow Alert Disabled



✪NOTE

For more information regarding adding patients to new patient groups and transferring patients, see Additional Resources.

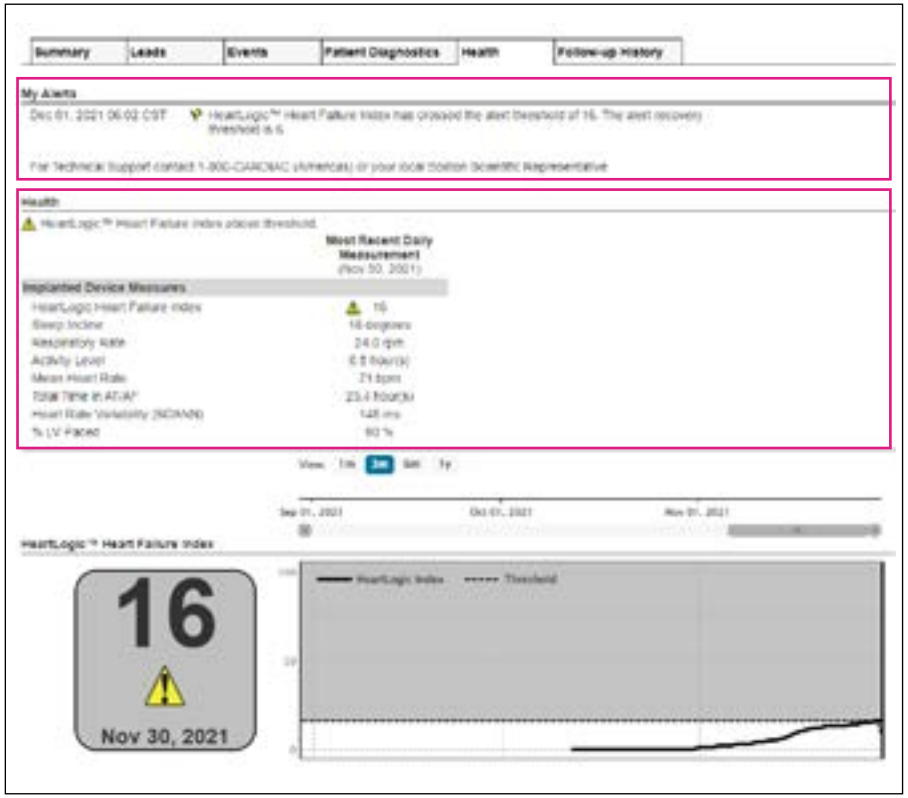
Viewing HeartLogic on LATITUDE NXT

Upon selecting your patient, you will find the following information:

Under the "Health" section, you will see a brief table of "Implanted Device Measures" which provides a quick snapshot of your patient's key HeartLogic data which includes:

- HeartLogic Index
- Sleep Incline
- Respiratory Rate
- Activity Level
- Mean Heart Rate
- Total Time in AT/AF
- Heart Rate Variability (SDANN)
- % LV Paced (where applicable)

Under the "My Alerts" section you will see your patient's active HeartLogic alerts (or other alerts you may have enabled within LATITUDE NXT.



TIP

Implanted Device Measures table is available while viewing in LATITUDE NXT but not within a printed/ saved HeartLogic Management Report.

Below the Health section, you will see information related to your patient's HeartLogic Index, Contributing Trends, and Trend Graphs.

HeartLogic Heart Failure Index

Contributing Trends

Trend Graphs

HeartLogic™ Heart Failure Initialization Period

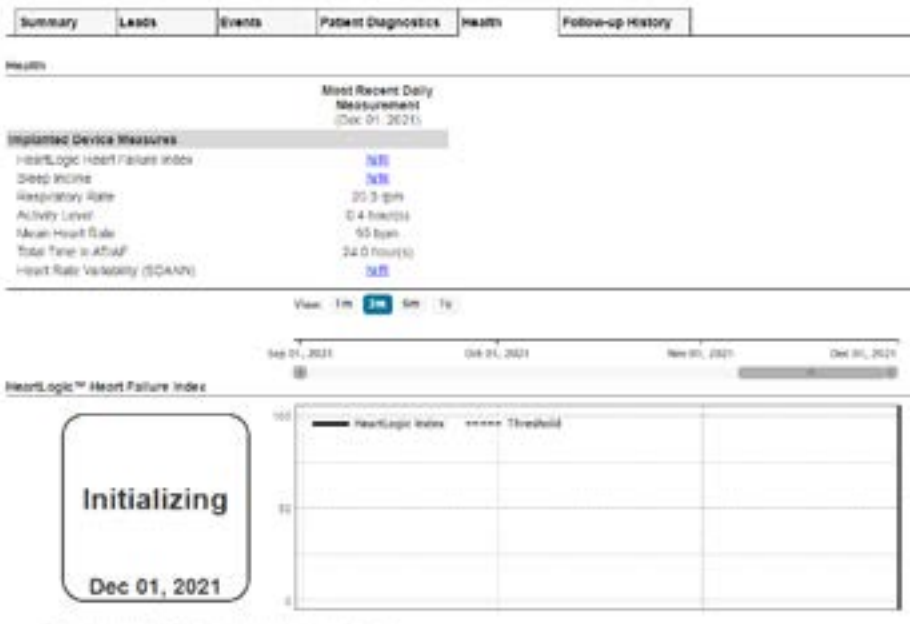
Upon implant, your patient's device is immediately collecting physiologic sensor information to aggregate data for the HeartLogic algorithm to create a unique and personalized baseline i.e. the device starts "learning" your patient upon implantation. To provide an accurate baseline, the HeartLogic algorithm requires 30-37 days of data before the HeartLogic index will be visible for your patient.

If HeartLogic is within this "initialization period" the status indicator will simply say "initializing."

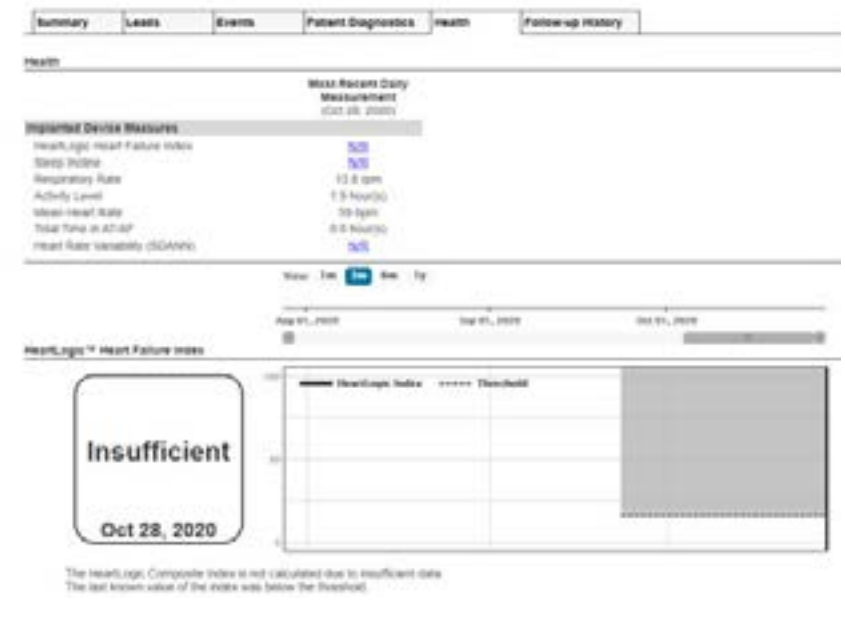
If HeartLogic has initialized but the algorithm has not collected enough data to generate a HeartLogic index, it will show "insufficient."

View of HeartLogic when Initializing and Insufficient

Initializing



Insufficient



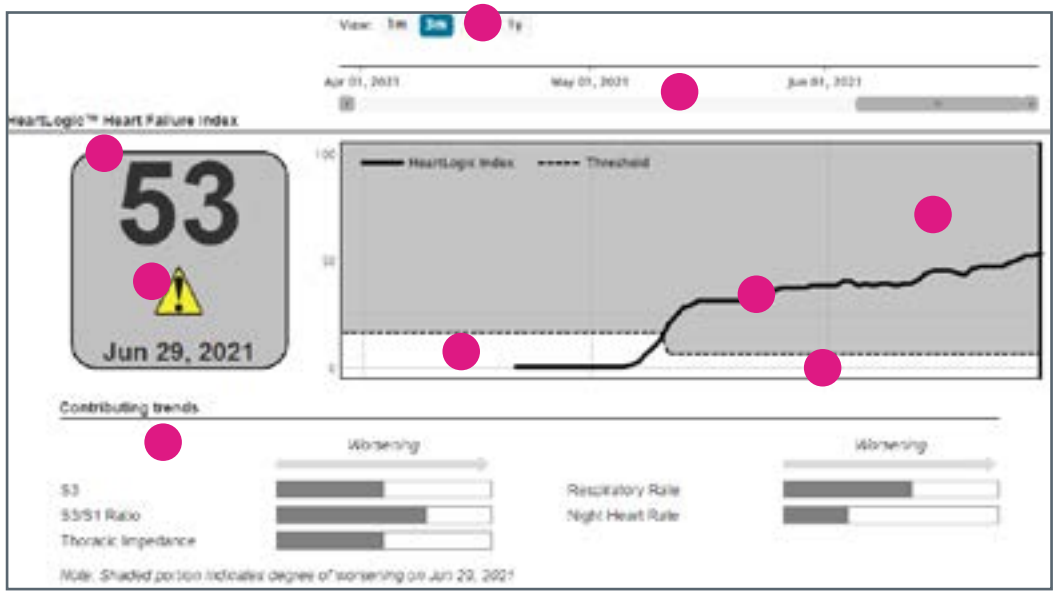
TIP

If you have a patient that you know has completed initialization, but the HeartLogic™ Index shows "insufficient", please call LATITUDE Customer Support at 1-800-CARDIAC.

HeartLogic Heart Failure Index and Contributing Trends

See below for highlights of information on the HeartLogic Heart Failure Index graph.

Note:
Click on circles below for details on each section of the graph.



HeartLogic Alerts on LATITUDE NXT

As with other LATITUDE NXT alerts, HeartLogic provides a proactive Yellow Alert to identify a patient at risk for a worsening HF event.

- The alert is issued on the first day the alert state transitions from NO Alert to ALERT.
- The alert is delivered via the LATITUDE NXT System the next day.
- The alert is available for review and can be dismissed by the user through LATITUDE NXT; however, if the alert is dismissed and the patient continues to be in alert state, another alert will be issued 7 days later.

HeartLogic Nominal Threshold

The default or nominal HeartLogic threshold of 16 is set at time of implant and based upon data published from MultiSENSE. At the nominal threshold of 16, HeartLogic demonstrates a sensitivity of 70%, specificity of 85.7%, and allows a median for 34 days advanced warning of a heart failure event.

Notably, this threshold is configurable from 10 to 40 in increments of 2 to allow customization for your patient. As with any diagnostic testing, adjustment of this threshold can alter the performance data of HeartLogic between balance of sensitivity and specificity.

Patients are considered "in alert" once they cross the set threshold (nominal alert threshold 16). Patients remain "in-alert" until they cross below the recovery threshold (nominal recovery threshold is 6) at which time they would be considered "out of alert."

HeartLogic Heart Failure Recovery Threshold

The recovery threshold represents a patient's return to their previous baseline correlating with clinical improvement in response to a HeartLogic alert state. For the nominal threshold of 16, a patient's HeartLogic threshold must fall below 6 to be considered "out of alert."

This recovery threshold will vary should you change the configurable HeartLogic alert threshold as above. Notably, the recovery thresholds were empirically developed from the MultiSENSE Development Set and are not configurable. The figure below shows possible HeartLogic alert thresholds and corresponding recovery thresholds:

When a patient' HeartLogic Index crosses from an out of alert state to an in-alert state, it is called an Initial Alert. To provide comprehensive monitoring and allow vigilance of those patients at risk for a HF event, the system will generate a re-alert every 7 days while the HL Index remains in an alert-state. This re-alert will be triggered until the HL Index falls below the threshold, recovery.

- For Initial or Re-Alerts, a proactive Yellow Alert will be generated within the LATITUDE NXT to identify the patient is at risk. This alert will appear on the For Review screen consistent with other Yellow Alerts.
- There is no alert or notification sent by LATITUDE NXT for recovery.

Alert Threshold	Recovery Threshold
40	12
38	12
36	12
34	11
32	11
30	11
28	10
26	10
24	10
22	9
20	8
18	7
16 (nominal)	6
14	5
12	5
10	5

Daily Interrogations Until Alert Condition is Resolved

By default, HeartLogic information uploads to LATITUDE NXT via a patient's communicator once per week. There is an option within LATITUDE NXT to be able to have this information uploaded daily while a patient is in an alert state. This can be configured at the individual patient or clinic level.

- Why would this feature be used? This may be utilized by clinicians who wish to more closely monitor and manage their HF patients while in a HeartLogic alert state.
- Does this affect battery life? Daily alert checks and weekly interrogations will decrease longevity by approximately 2 months when used for the life of the device. Daily interrogations to refresh HeartLogic following an alert for 30 days each year will decrease longevity by an additional 1 month.

Dismissing Alerts

In general practice, when an alert is generated within LATITUDE NXT it appears on the For Review page prompting inquiry into the corresponding patient's device information and status. Upon reviewing this information and taking appropriate actions, Boston Scientific recommends dismissing this alert to more efficiently manage your overall alert review process.

*Remember:

- HeartLogic will provide a re alert within 7 days should the patient remain in a HeartLogic alert state and will again show up on the For Review Page
- No data is lost upon dismissal of any alert

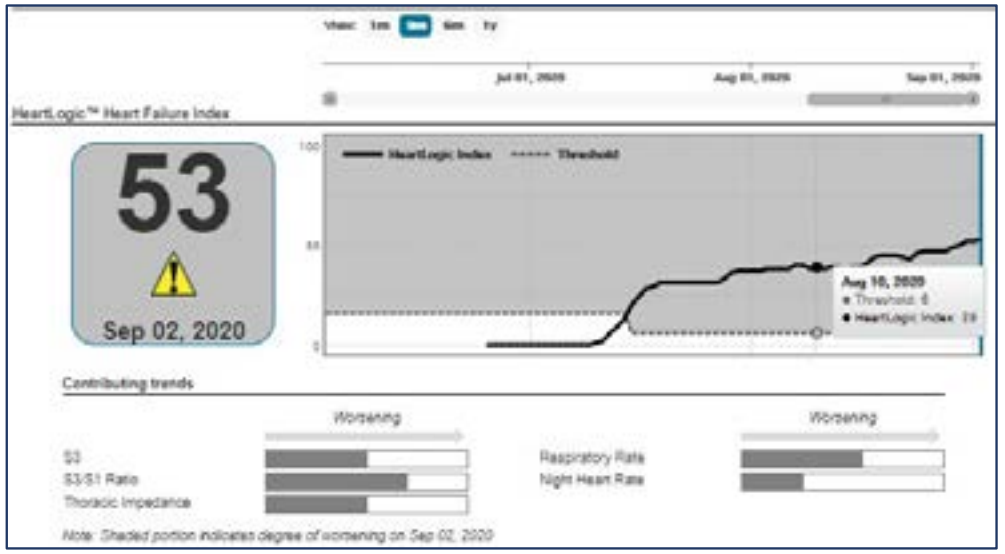
For additional information on overall management of LATITUDE NXT alerts, see Additional Resources.

In Alert vs. Out of Alert

Within this figure you see a patient who is in a HeartLogic alert state. The figure below compares the difference between a patient not in alert (green OK indicator) and a patient in an alert state (yellow status indicator).

TIP

Note contributing trends are only visible when patient is in an alert state as the purpose is to assist clinicians in identifying the degree of which each physiologic sensor is driving your patient's current alert state.



Navigating HeartLogic Trends in LATITUDE NXT

In reviewing HeartLogic trends within LATITUDE NXT, you will have access to multiple pieces of information and be able to scroll through this data to view multiple points in time.

*Note, In general HeartLogic information in LATITUDE NXT is available for up to a year from the most recent transmission.

Below you can see Graph Navigation which includes the ability to Time Scroll and Time Lock.

Time Scrolling allows you to change the view of the trends at different points in time to provide a narrower (1 month), near-term (3 month), or broader/wider (1 year) view depending on your needs.

Time Lock allows selection of a specific time on the graph. The HeartLogic™ Index, contributing trends (if in alert state), and subsequent sensors will lock the data at the selected point in time.

TIP
Toggling this view between the 1 month, 3 month, and 1 year views allows you to evaluate more near term clinical management (1 month) or compare to historical data (3 months, 1 year) providing a more comprehensive view of your patient's HeartLogic clinical course.

Cursor Data: With Time Lock selected, you can use your cursor to hover over another point in time to review "Cursor Data". This allows the comparison of different points in time to your selected Time Lock information.

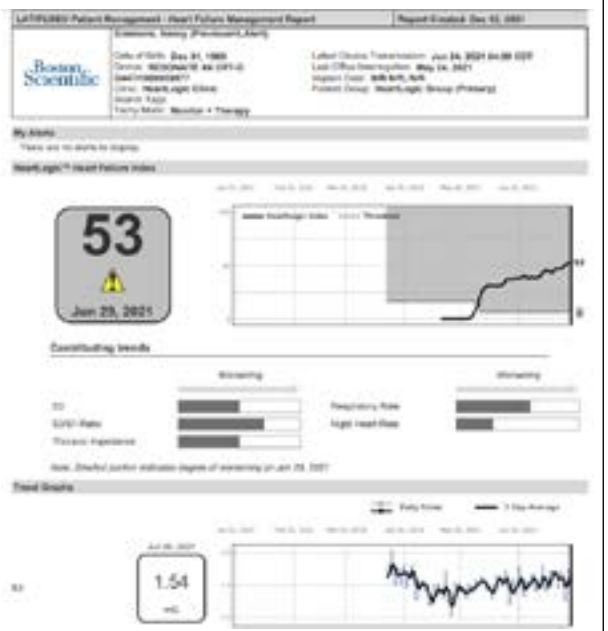
*This example is comparing "Time Lock" data for June 16th to the "Cursor Data" on May 20th.

LATITUDE NXT Reports that include HeartLogic

There are two reports that can be generated within LATITUDE NXT which contain HeartLogic information—the Combined Follow Up Report and the Heart Failure Management Report:

- The Combined Follow Up Report includes:
  - o A comprehensive summary of the patient's overall device diagnostic and performance data
  - o Primarily used by those in device clinics/EP monitoring a patient's overall device status
  - o Alerts, Events Since Last Reset, Battery Status, Leads Summary, Settings Summary, Histograms, Leads Trends, Health Trends, HRV Data, Presenting EGM
- The HF Management Report includes:
  - o A focused summary of HeartLogic and the overall HF Sensor Suite
  - o Primarily used by clinicians monitoring the patient's Heart Failure information
  - o Alerts, Health Trends, Battery Status

Comparison of a Combined Follow-Up Report and a HF Management Report



Printing a Heart Failure Management Report

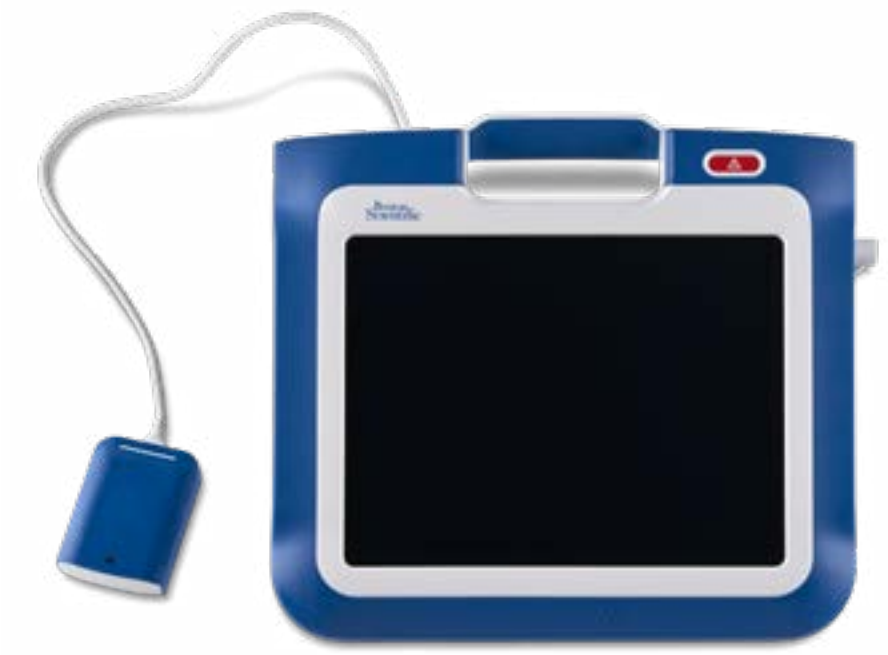
Printing HeartLogic Heart Failure Management Reports for your patients can be accomplished at the "patient list" or "individual" levels. For more information about generating reports, see Additional Resources.

HeartLogic™ Heart Failure Diagnostic on LATITUDE™ Programming System (Model 3300) & LATITUDE Consult™ System

Reports can be generated in-person with the use of the LATITUDE Programming System, Model 3300 or the LATITUDE Consult System (US only) in a Point of Care or Clinic setting. Reports with HeartLogic data can be generated in real-time at the: Clinic, Hospital, Emergency Department, or Operating Rooms.

The LATITUDE Programming System, Model 3300

- HeartLogic Composite Index along with the S3 & S1 Heart Sounds are available to view on the Model 3300 Programmer Heart Failure Management screen
- The Model 3300 Programmer can generate the Heart Failure Management Report and/or the Combined Follow-up Report including HeartLogic diagnostic information and trend graphs
- Users can transfer reports to a PC and/or EMR via the LATITUDE Link™ Data Management System, saving to USB or Hard Drive and Printing options are all available on the Model 3300 Programmer
  - o For more details about LATITUDE Link including how to download and install this free software, click the pink button below:



LATITUDE Link Data Management System

Customize LATITUDE™ NXT Remote Patient Management System to support HeartLogic™ Heart Failure Diagnostic Workflow

Examples of Clinic Workflow

1. **EP/Device Clinic –** Monthly ICPM Billing for All HeartLogic Patients
2. **EP/Device Clinic –** Monthly ICPM Billing While Patients in HeartLogic Alert
3. **EP/Device Clinic –** Quarterly Billing for All HeartLogic Patients
4. **EP/Device Clinic –** No ICPM Billing; Alert Monitoring Only
5. **Shared Care Model between EP and Heart Failure –** Monthly ICPM Billing for All HeartLogic Patients
6. **Shared Care Model between EP and Heart Failure–** Monthly ICPM Billing While Patients in HeartLogic Alert (Alert-Based)
7. **Shared Care Model between EP and Heart Failure–** No ICPM Billing; Alert Monitoring Only
8. **Stand Alone Heart Failure Clinic**

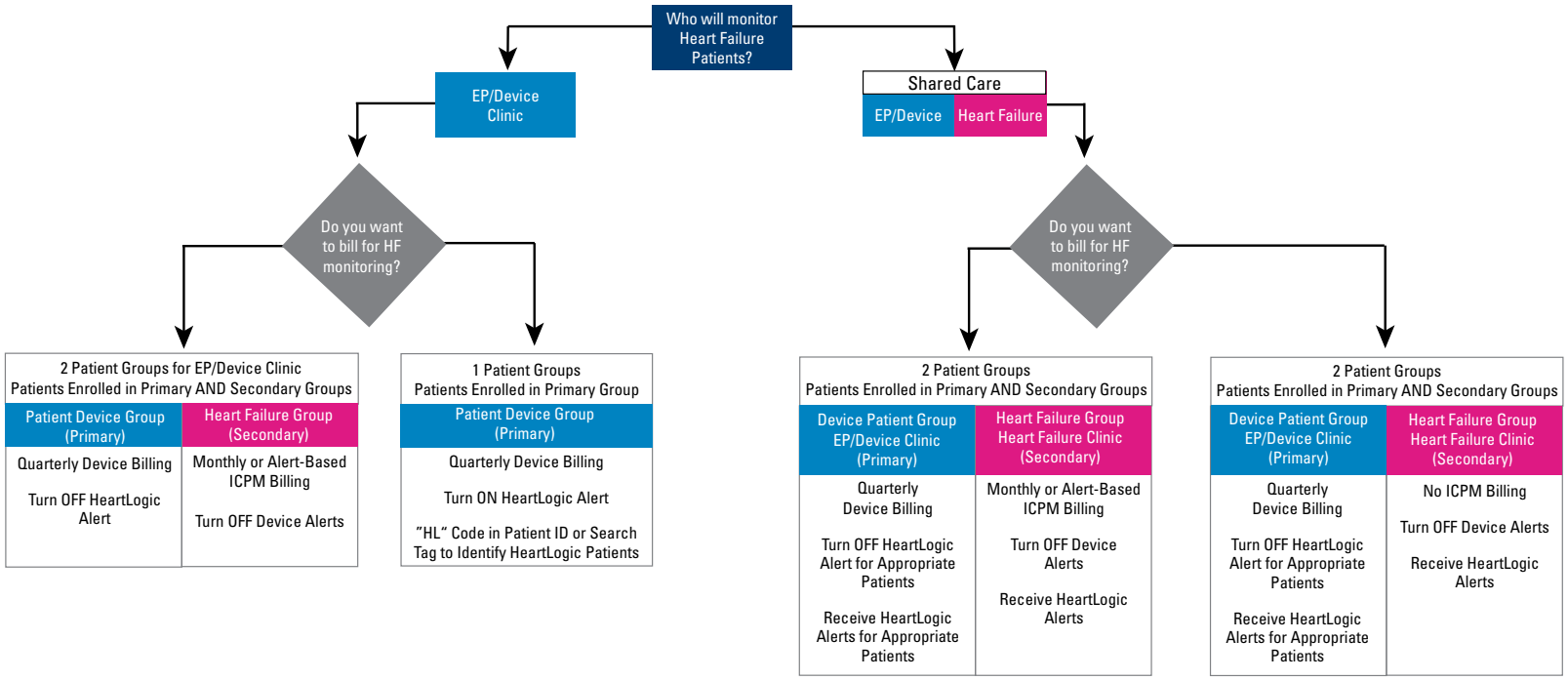
LATITUDE™ NXT Remote Patient Management System allows for a customized workflow. While we understand every hospital or clinic may function differently based on variances in infrastructure, we would like to highlight two best practice approaches that allow for streamlined care and integration between EP and Heart Failure Specialists. In addition to clinic workflows, considering who will be monitoring heart failure patients and seeking reimbursement will determine the best way to organize patients.

The information in this section is intended to be used by device clinic staff, heart failure staff, clinicians, and sales personnel who are familiar with the use of LATITUDE™ NXT Remote Patient Management System and the technology behind HeartLogic™ Heart Failure Diagnostic.

LATITUDE Continuing Education Training | HeartLogic Continuing Education Training | HeartLogic Resources

Best Practice LATITUDE™ Configuration Programming System

In general there are two main workflows; EP/Device Clinic manages both device and heart failure diagnostics or EP/Device Clinic manages device only and Heart Failure manages Implantable Cardiovascular Physiologic Monitoring (ICPM) only. Detailed configuration and workflow options are highlighted on subsequent pages.



Examples of Clinic Workflow

- **1. EP/Device Clinic –** Monthly ICPM Billing for All HeartLogic Patients
- **2. EP/Device Clinic –** Monthly ICPM Billing While Patients in HeartLogic Alert
- **3. EP/Device Clinic –** Quarterly Billing for All HeartLogic Patients
- **4. EP/Device Clinic –** No ICPM Billing; Alert Monitoring Only
- **5. Shared Care Model between EP and Heart Failure –** Monthly ICPM Billing for All HeartLogic Patients
- **6. Shared Care Model between EP and Heart Failure–** Monthly ICPM Billing While Patients in HeartLogic Alert (Alert-Based)
- **7. Shared Care Model between EP and Heart Failure–** No ICPM Billing; Alert Monitoring Only
- **8. Stand Alone Heart Failure Clinic**

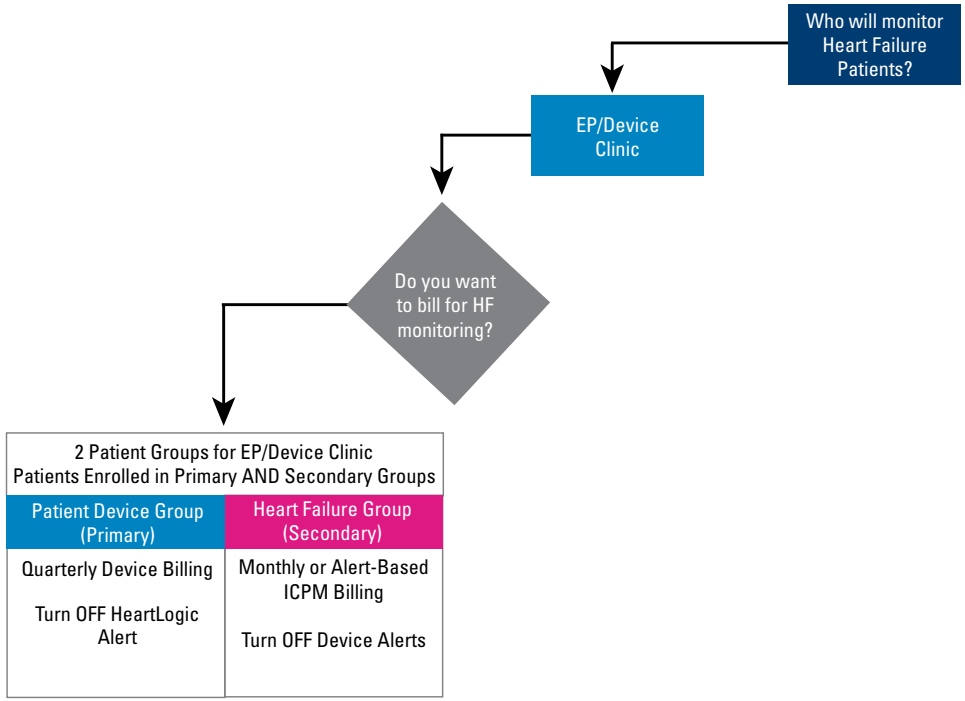
Best practice LATITUDE™ NXT Configuration Programming System		
	EP/Device Clinic	**Shared Care Model**
Patient Groups	Use both Primary and Secondary	Use both Primary and Secondary
Configuration	Primary: • Device Alerts ON • Heart Failure Alerts OFF Secondary: • Device Alerts OFF • Heart Failure Alerts ON User Access: • EP/Device Clinic has access to both Primary and Secondary patient groups	Primary: • Device Alerts ON • Heart Failure Alerts OFF Secondary: • Device Alerts OFF • Heart Failure Alerts ON User Access: • EP/Device clinic has access to Primary patient group • Heart Failure clinic has access to Secondary patient group
Scheduled Interrogations (For Professional and Technical Billing)	Primary: • Quarterly ICD/Pacemaker Secondary: • Monthly or Alert-Based ICPM	Primary: • Quarterly ICD/Pacemaker Secondary: • Monthly or Alert-Based ICPM
Alert Notification Email and/or Text	Optional Alert Notifications for device or heart failure alerts	Optional Alert Notifications for device or heart

1. EP/Device Clinic – Monthly ICPM Billing for All HeartLogic™ Patients

The EP/Device clinic will be responsible for following both device and heart failure patient diagnostics and for all quarterly device and monthly ICPM patient remote monitoring billing.

Patient Group Configuration:

- Device Patient Group(s) (Primary):
  - o Turn ON all Device alerts
  - o Turn OFF HeartLogic alert and other Heart Failure alerts
  - o Will receive red alerts
  - o Remote Scheduled Follow-ups every 3 months
- Create a Heart Failure Patient Group (Secondary):
  - o Turn OFF all device alerts
  - o Turn ON HeartLogic and any other desired Heart Failure alerts
  - o Will only receive selected yellow alerts (not red alerts)
  - o Remote Scheduled Follow-ups every 1 month or manual scheduling



***Note:** If the clinic wants to generate all Heart Failure reports on a specific day of the month, scheduling remote follow-ups in LATITUDE NXT is not required.

TIP

Duplicate patients: Complete Access users will notice duplicates since each Heart Failure patient is enrolled in a primary and a secondary group

1. EP/Device Clinic – Monthly ICPM Billing for All HeartLogic™ Patients

Patient Group Workflow:

• Heart Failure patients are enrolled in both the Primary Device AND Secondary Heart Failure patient groups

• Patient displays on the For Review page with an alert or scheduled follow-up

-(Primary):

• Device alerts and quarterly scheduled follow-ups

- (Secondary):

• Heart Failure alerts and monthly scheduled follow-ups

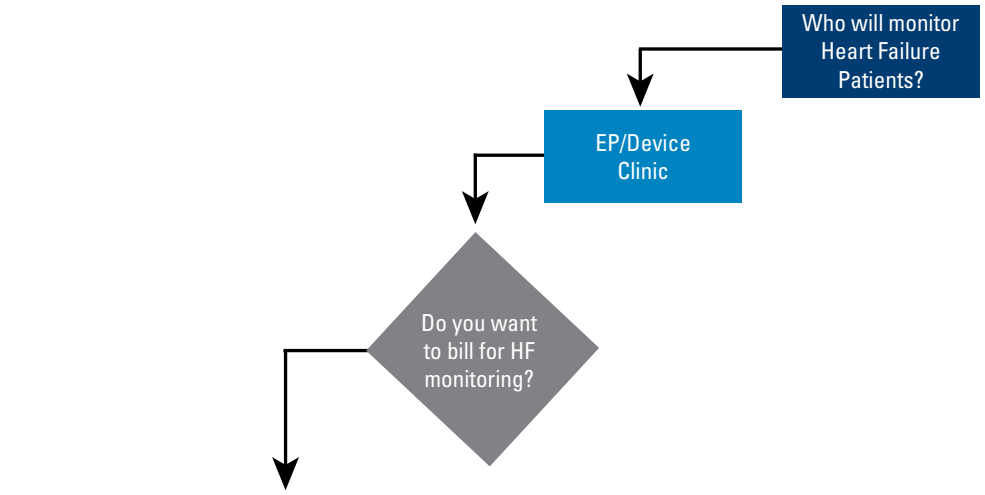
• Ensure patient Communicators remain connected and monitored in LATITUDE NXT

TIP

It is important to periodically check to ensure the patients are enrolled in the correct groups.

2. EP/Device Clinic – Monthly ICPM Billing While Patients in HeartLogic Alert (Alert-Based)

The EP/Device clinic will be responsible for following both device and heart failure patient diagnostics and for all quarterly device and monthly ICPM patient remote monitoring billing.



2 Patient Groups for EP/Device Clinic Patients enrolled in primary AND secondary groups	
Patient Device Group (Primary)	**Heart Failure Group (Secondary)**
Quarterly Device Billing Turn OFF HeartLogic alert	Monthly or Alert-Based ICPM Billing Turn OFF Device alerts

Option 1

Patient Group Configuration:

- Use existing device patient groups
- Turn ON HeartLogic alert for all patient groups
- Turn ON desired Device alerts for all patient groups
- Remote Scheduled Follow-ups every 3 months for Device

Workflow:

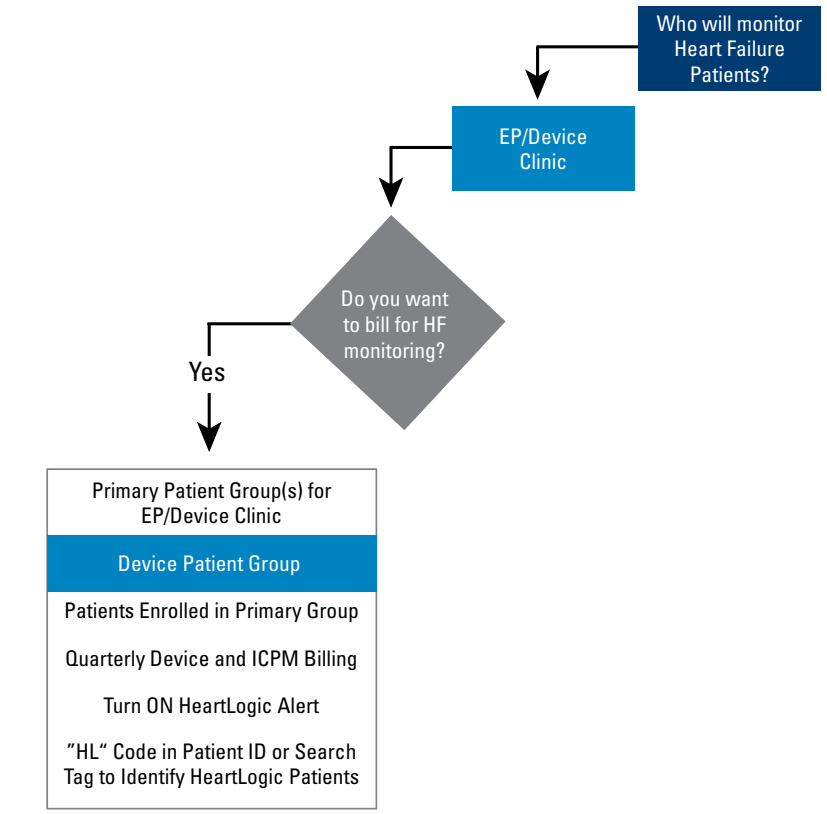
- All patients are enrolled in the appropriate Primary Device patient group(s)
- "HL" code in the Patient ID or Search Tag fields to identify HeartLogic patients
- Screenshot (need)
- HeartLogic alert received; timer starts for monthly billing
  - o Change scheduled follow-up date for patient out 1 month
  - o Continue until out of alert, then change date out 3 months
- Ensure patient Communicators remain connected and monitored in LATITUDE™ NXT

TIP

If it's important to know which patients/devices have the HL technology:

- Add a designation "HL" to the Patient ID or Search Tag fields

2. EP/Device Clinic – Monthly ICPM Billing While Patients in HeartLogic Alert (Alert-Based)



Option 2

Patient Group Configuration:

- Device Patient Group(s) (Primary):
  - o Turn ON all Device alerts
  - o Turn OFF HeartLogic alert and other Heart Failure alerts
  - o Will receive red alerts
  - o Remote Scheduled Follow-ups every 3 months
- Create a Heart Failure Patient Group (Secondary):
  - o Turn OFF all device alerts
  - o Turn ON HeartLogic and any other desired Heart Failure alerts
  - o Will only receive selected yellow alerts (not red alerts)
- Remote Scheduled Follow-ups every 1 month

Workflow:

- Heart Failure patients are enrolled in the Primary Device group(s)
- "HL" code in the Patient ID or Search Tag fields to identify HeartLogic patients. See Additional Resources.
- HeartLogic alert received; timer starts for monthly billing
  - o Add patient to Heart Failure patient group (secondary)
  - o Leave patient in this group indefinitely to bill every month going forward OR
  - o Remove patient from Heart Failure patient group once out of alert

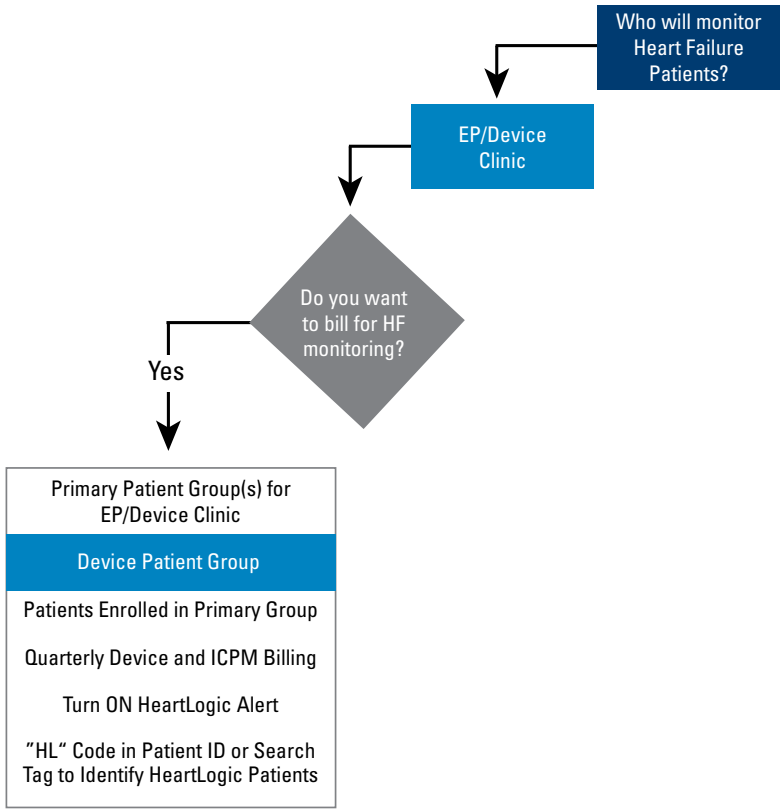
TIP

If it's important to know which patients/devices have the HL technology:

- Add a designation "HL" to the Patient ID or Search Tag fields

3. EP/Device Clinic – Quarterly Billing for All HeartLogic

The EP/Device clinic will be responsible for following both device and heart failure patient diagnostics and for all quarterly device and ICPM patient remote monitoring billing.



Patient Group Configuration:

- Use existing device patient groups
- Turn ON HeartLogic alert for all patient groups
- Turn ON desired Device alerts for all patient groups
- Remote Scheduled Follow-ups every 3 months for Device and ICPM

Workflow:

- All patients are enrolled in the Primary Device group(s)
- "HL" code in the Patient ID or Search Tag fields to identify HeartLogic patients

- Patient displays on For Review page, with an alert or a Scheduled follow-up
  - o Device alerts and quarterly scheduled follow-ups
  - o Heart Failure alerts and quarterly scheduled follow-ups
- Ensure patient Communicators remain connected and monitored in LATITUDE NXT

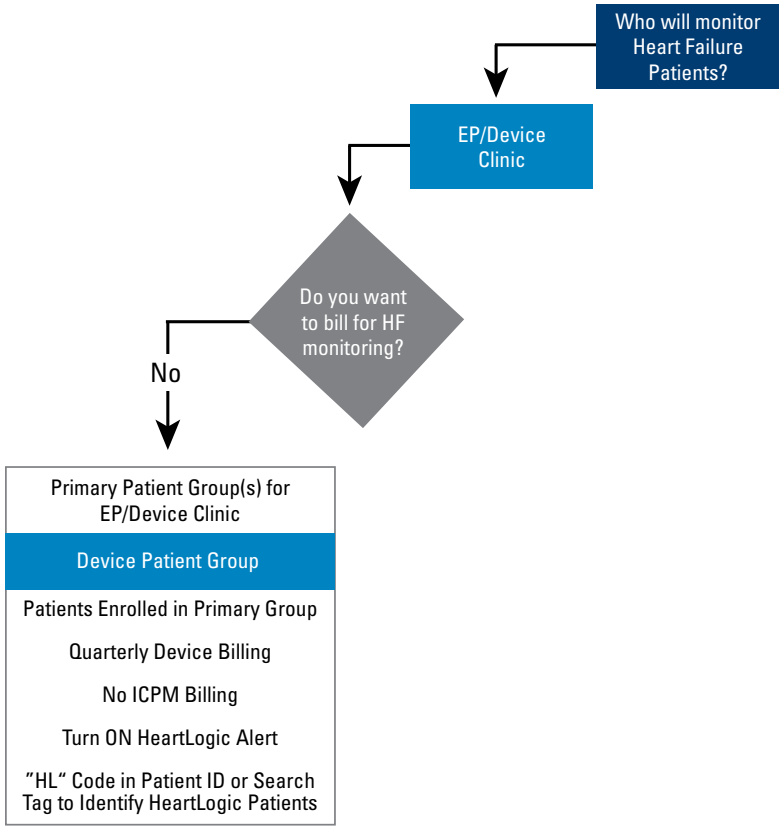
TIP

If it's important to know which patients/devices have the HL technology:

- Add a designation "HL" to the Patient ID or Search Tag fields

4. EP/Device Clinic – No ICPM Billing; Alert Monitoring Only

The EP/Device clinic will be responsible for following both device and heart failure patient diagnostics and for all device patient remote monitoring billing.



Patient Group Configuration:

- Use existing device patient groups
- Turn ON HeartLogic Alert for all patient groups
- Turn ON desired Device alerts for all patient groups
- Remote Scheduled Follow-ups every 3 months for device billing
- No Remote Scheduled Follow-ups for ICPM

Workflow:

- Heart Failure patients are enrolled in the Primary Device group(s)
- "HL" code in the Patient ID or Search Tag fields to identify HeartLogic patients

- Patient displays on For Review page, with an alert or a Scheduled follow-up
  - o Device alerts and quarterly scheduled follow-ups
  - o Heart Failure alerts only
- Ensure patient Communicators remain connected and monitored in LATITUDE NXT

✪TIP

If it's important to know which patients/devices have the HL technology:

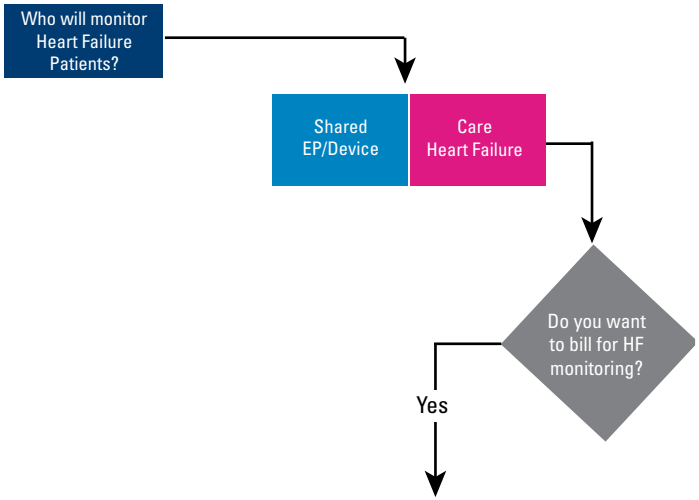
- Add a designation "HL" to the Patient ID or Search Tag fields

5. Shared Care Model between EP and Heart Failure– Monthly ICPM Billing for All HeartLogic Patients

- The EP/Device clinic is responsible for monitoring device patient diagnostics
- The Heart Failure clinic is responsible for monitoring heart failure diagnostics, including the HeartLogic alert
- The 2 care team collaborate regarding crossover of alert management
- ICPM billing is executed by the Heart Failure team
- Device billing is executed by the EP/Device team

Patient Group Configuration:

- Device Patient Group(s) (Primary):
  - o EP/Device Clinic has access to device group(s) only
  - o Turn ON all Device alerts
  - o Turn OFF HeartLogic alert and other Heart Failure alerts
  - o Will receive red alerts
  - o Remote Scheduled Follow-ups every 3 months
- Create a Heart Failure Patient Group (Secondary):
  - o Heart Failure Clinic has access to heart failure group(s) only
  - o Turn OFF all device alerts
  - o Turn ON HeartLogic and any other desired Heart Failure alerts
  - o Will only receive selected yellow alerts (not red alerts)
  - o Remote Scheduled Follow-ups every 1 month



2 Patient Groups Patients Enrolled in Primary AND Secondary Groups	
Device Patient Group EP/Device Clinic (Primary)	**Heart Failure Group Heart Failure Clinic (Secondary)**
Quarterly Device Billing Turn OFF HeartLogic Alert for Appropriate Patients Receive HeartLogic Alerts for Appropriate Patients	Monthly or Alert-Based ICPM Billing Turn OFF Device Alerts Receive HeartLogic Alerts

TIP
Duplicate patients; Complete Access users will notice duplicates since each Heart Failure patient is enrolled in a primary and a secondary group

5. Shared Care Model between EP and Heart Failure – Monthly ICPM Billing for All HeartLogic

Workflow:

• Heart Failure patients are enrolled in both the Primary Device AND Secondary Heart Failure patient groups

Patient displays on For Review page, with an alert or a Scheduled follow-up

o Heart Failure clinic is responsible for (Secondary):

• Heart Failure alerts and monthly scheduled follow-ups

o EP/Device clinic is responsible for (Primary):

• Device alerts and quarterly scheduled follow-ups

• Care teams will collaborate to ensure patient Communicators remain connected and monitored in LATITUDE NXT

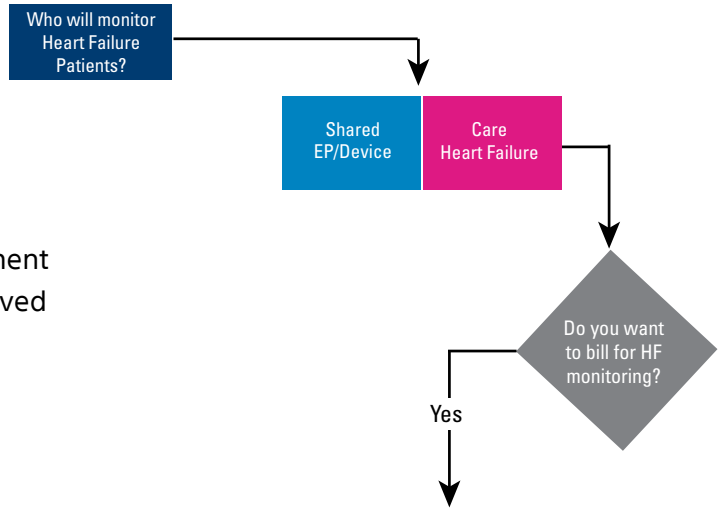
6. Shared Care Model between EP and Heart Failure– Monthly ICPM Billing While Patients in HeartLogic Alert (Alert-Based)

- The EP/Device clinic is responsible for monitoring device patient diagnostics
- The Heart Failure clinic is responsible for monitoring heart failure diagnostics, including the HeartLogic alert
- The 2 care team collaborate regarding crossover of alert management
- ICPM billing is executed by the Heart Failure team when alert received
- Device billing is executed by the EP/Device team

Option 1

Patient Group Configuration:

- Device Patient Group(s) (Primary):
  - o Turn ON all Device alerts
  - o Turn OFF HeartLogic alert and other Heart Failure alerts
  - o Will receive red alerts
  - o Remote Scheduled Follow-ups every 3 months
- **Create a Heart Failure Patient Group (Secondary):**
  - o Turn OFF all device alerts
  - o Turn ON HeartLogic and any other desired Heart Failure alerts
  - o Will only receive selected yellow alerts (not red alerts)
  - o Remote Scheduled Follow-ups OFF by turning on manual scheduling



2 Patient Groups Patients Enrolled in Primary AND Secondary Groups	
Device Patient Group EP/Device Clinic (Primary)	**Heart Failure Group Heart Failure Clinic (Secondary)**
Quarterly Device Billing Turn OFF HeartLogic Alert for Appropriate Patients Receive HeartLogic Alerts for Appropriate Patients	Monthly or Alert-Based ICPM Billing Turn OFF Device Alerts Receive HeartLogic Alerts

TIP

Duplicate patients; Complete Access users will notice duplicates since each Heart Failure patient is enrolled in a primary and a secondary group.

6. Shared Care Model between EP and Heart Failure– Monthly ICPM Billing While Patients in HeartLogic Alert (Alert-Based)

Workflow:

- Heart Failure patients are enrolled in both the Primary Device AND Secondary Heart Failure patient groups

- HeartLogic alert received; timer starts for monthly billing
  - o Change scheduled follow-up date for patient out 1 month
  - o Continue until out of alert
    - Once out of alert, do not continue to add monthly dates
- Ensure patient Communicators remain connected and monitored in LATITUDE™ NXT

6. Shared Care Model between EP and Heart Failure– Monthly ICPM Billing While Patients in HeartLogic Alert (Alert-Based)

Option 2

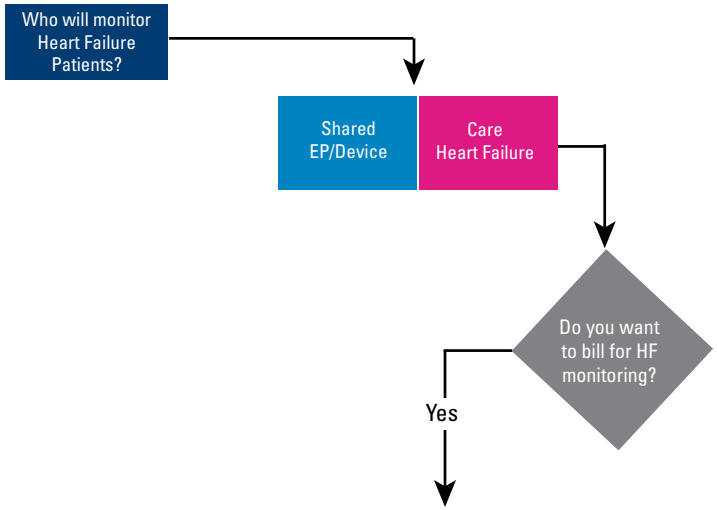
Patient Group Configuration:

- Device Patient Group(s) (Primary):
  - o Turn ON all Device alerts
  - o Turn OFF HeartLogic alert and other Heart Failure alerts
  - o Will receive red alerts
  - o Remote Scheduled Follow-ups every 3 months

- **Create 2 Heart Failure Patient Groups (Secondary):**

1. Heart Failure 'Alerts Only' Patient Group (Secondary):
   - o Turn OFF all device alerts
   - o Turn ON HeartLogic and any other desired Heart Failure alerts
   - o Will only receive selected yellow alerts (not red alerts)
   - o Remote Scheduled Follow-ups OFF by turning on manual scheduling

2. Heart Failure 'Monthly Billing' Patient Group (Secondary):
   - o Turn OFF all device alerts
   - o Turn ON HeartLogic and any other desired Heart Failure alerts
   - o Will only receive selected yellow alerts (not red alerts)
   - o Remote Scheduled Follow-ups every 1 month



2 Patient Groups Patients Enrolled in Primary AND Secondary Groups	
Device Patient Group EP/Device Clinic (Primary)	**Heart Failure Group Heart Failure Clinic (Secondary)**
Quarterly Device Billing Turn OFF HeartLogic Alert for Appropriate Patients Receive HeartLogic Alerts for Appropriate Patients	Monthly or Alert-Based ICPM Billing Turn OFF Device Alerts Receive HeartLogic Alerts

6. Shared Care Model between EP and Heart Failure– Monthly ICPM Billing While Patients in HeartLogic Alert (Alert-Based)

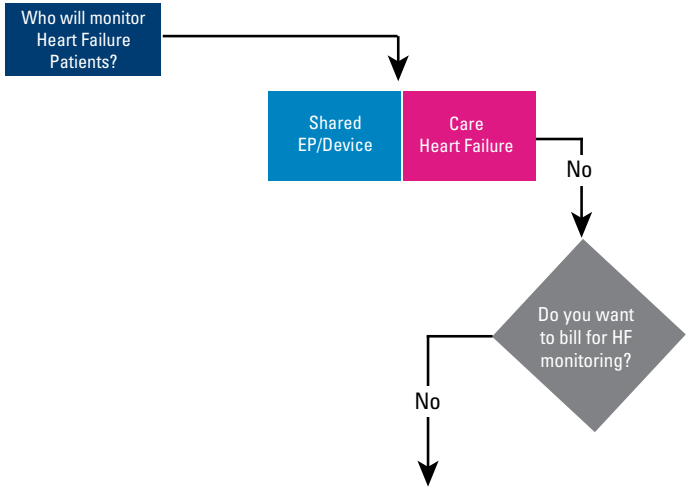
Workflow:

- Heart Failure patients are enrolled in both the Primary Device AND Secondary Heart Failure Patient Groups

- HeartLogic alert received; timer starts for monthly billing
  - o Move patient to Heart Failure 'Monthly Billing' patient group
    - o Leave patient in this group indefinitely to bill every month going forward **OR**
    - o Move patient back to Heart Failure 'Alerts Only' patient group once out of alert
- Ensure patient Communicators remain connected and monitored in LATITUDE™ NXT

7. Shared Care Model between EP and Heart Failure– No ICPM Billing; Alert Monitoring Only

- The EP/Device clinic is responsible for monitoring device patient diagnostics
- The Heart Failure clinic is responsible for monitoring heart failure diagnostics, including the HeartLogic alert
- The 2 care team collaborate regarding crossover of alert management
- ICD and pacemaker billing is executed by the EP/Device team
- No ICPM Billing (manual scheduling)



2 Patient Groups Patients Enrolled in Primary AND Secondary Groups	
Device Patient Group EP/Device Clinic (Primary)	**Heart Failure Group Heart Failure Clinic (Secondary)**
Quarterly Device Billing Turn OFF HeartLogic Alert for Appropriate Patients Receive HeartLogic Alerts for Appropriate Patients	No ICPM Billing (Manual Scheduling) Turn ON HeartLogic Alert Turn OFF Device Alerts Receive HeartLogic Alerts for Appropriate Patients

TIP

Duplicate patients: Complete Access users will notice duplicates since each Heart Failure patient is enrolled in a primary and a secondary group

7. Shared Care Model between EP and Heart Failure– No ICPM Billing; Alert Monitoring Only

Patient Group Configuration:

- Device Patient Group(s) (Primary):
  - o EP/Device Clinic has access to device group(s) only
  - o Turn ON all Device alerts
  - o Turn OFF HeartLogic alert and other Heart Failure alerts for appropriate patients
  - o Will receive red alerts
  - o Remote Scheduled Follow-ups every 3 months

- Create a new Heart Failure Patient Group (Secondary):
  - o Heart Failure Clinic has access to heart failure group(s) only
  - o Turn OFF all device alerts
  - o Turn ON HeartLogic and any other desired Heart Failure alerts for appropriate patients
  - o Will only receive selected yellow alerts (not red alerts)
  - o No Scheduled Remote Follow-ups; turn on manual scheduling

7. Shared Care Model between EP and Heart Failure– No ICPM Billing; Alert Monitoring Only

Workflow:

- Heart Failure patients are enrolled in both the Primary Device AND Secondary Heart Failure patient groups

Patient displays on For Review page, with an alert or a Scheduled follow-up

- EP/Device clinic is responsible for (Primary):
  - o Device alerts and quarterly scheduled follow-ups

- Heart Failure clinic is responsible for (Secondary):
  - o Heart Failure alerts and monthly scheduled follow-ups

- Care teams will collaborate to ensure patient Communicators remain connected and monitored in LATITUDE NXT

8. Standalone Heart Failure Clinic

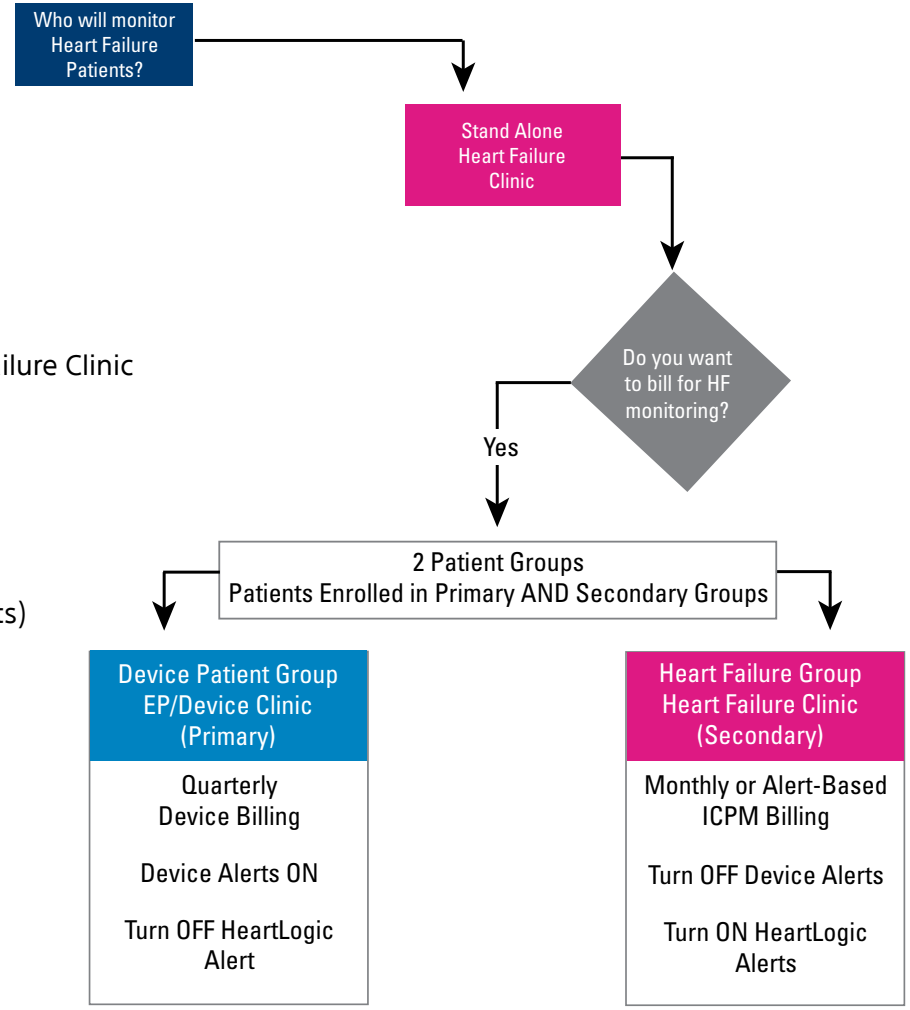
Heart Failure clinic that is a private practice or is not part of the EP/Device Clinic care system.

Patient Group Configuration:

- **Clinic 1** - Device Patient Group(s) (Primary):
  - o Turn ON all Device alerts
  - o Turn OFF HeartLogic alert and other Heart Failure alerts
  - o Will receive red alerts
  - o Remote Scheduled Follow-ups every 3 months

***This clinic and settings are not visible to the Heart Failure Clinic

- **Clinic 2** - Heart Failure Patient Group (Secondary):
  - o Turn OFF all device alerts
  - o Turn ON HeartLogic and any other desired Heart Failure alerts
  - o Will only receive selected yellow alerts (not red alerts)
  - o Remote Scheduled Follow-ups every 1 month or manual scheduling



*** Note: If the clinic wants to generate all Heart Failure reports on a specific day of the month, scheduling remote follow-ups in LATITUDE NXT is not required.

8. Standalone Heart Failure Clinic

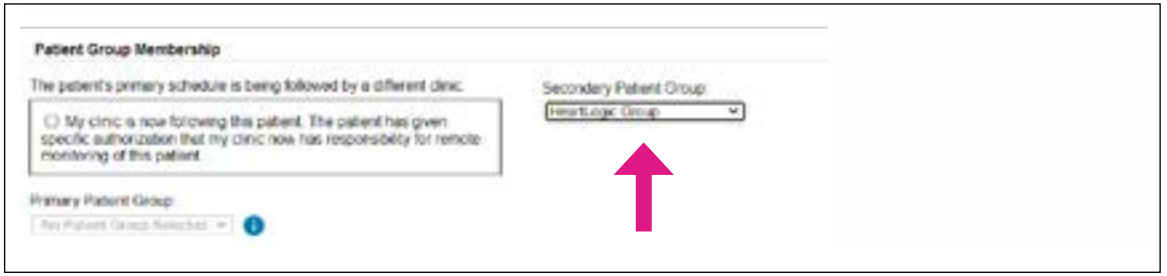
Patient Group Configuration:

Workflow:

- Heart Failure patients are enrolled in both the Primary Device Patient Group (clinic 1) AND Secondary Heart Failure Patient Group (clinic 2)

Clinic 1:

Clinic 2:



- Patient displays on For Review page, with an alert or a Scheduled follow-up
  - o (Primary):
    - Device alerts and quarterly scheduled follow-ups
  - o (Secondary):
    - -Heart Failure alerts and monthly scheduled follow-ups
- Ensure patient Communicators remain connected and monitored in LATITUDE NXT Remote

Patient Education

Educating patient's on how HeartLogic is remotely monitoring their heart health status and why you or your team may call them upon receiving a HeartLogic alert will help ensure any future interaction with them goes smoothly. It may also give your patient's more peace of mind knowing their care team can monitor their heart health remotely.

There are multiple patient education touchpoints that may occur; prior to implant, at the time of implant, before a patient is discharged, and/or upon their first post-operation device check. At one or all of these times, the following patient education materials can be shared to ensure both you and your patient get the most out of HeartLogic and remote monitoring. The materials described below are accessible for downloading and printing and are also available through your Boston Scientific field representative.

Education Materials

The HeartLogic Patient Brochure provides a high-level overview of a patient's RESONATE™ family ICD or CRT-D and how HeartLogic in combination with their LATITUDE™ NXT Communicator can securely transmit the device data to their care team. It also highlights simple steps for them to ensure HeartLogic is working for them.

To download an english or spanish version, click the pink buttons below:

YOUR BOSTON SCIENTIFIC RESONATE™ CRT OR ICD SYSTEM

Your doctor has recommended a Boston Scientific RESONATE Cardiac Resynchronization Therapy (CRT) or Implanted Cardioverter Defibrillator (ICD) device to help manage your heart condition. In addition to providing therapy for your heart condition on a daily basis, your RESONATE system has two important components that monitor your device and heart health:

1) HeartLogic™ Heart Failure Diagnostic

2) LATITUDE™ Communicator

HEARTLOGIC AND LATITUDE COMMUNICATOR

The HeartLogic diagnostic is a group of sensors within your device that continuously listens and checks on your heart. The information is sent from your LATITUDE Communicator to your healthcare team through a secure website on a daily basis.

HeartLogic combines the information from multiple sensors into one HeartLogic Index Number for your healthcare team. If your HeartLogic Index Number reaches a certain threshold, your healthcare team may be notified of a potential change in your heart health and they may reach out to you.

LET'S LOOK AT HOW THE HEARTLOGIC SENSORS MONITOR YOUR HEART

YOUR HEART SOUNDS
Your device senses or "listens" to the vibration made by your heart beat to measure your heart sounds.

YOUR FLUID STATUS
Your device assesses your fluid status - how much water your body is retaining. Patients with heart failure and heart arrhythmias are often hospitalized for fluid overload, which may appear as swollen feet or a dry cough.

YOUR BREATHING
Your device records your breathing - how fast or shallow you might be breathing, a common indicator that your heart condition may be changing.

YOUR NIGHT HEART RATE
Your device measures your resting heart rate, which usually tends to be stable from day to day.

YOUR PHYSICAL ACTIVITY
Your device measures your activity or movement on a daily basis.

INTELLIGENT MONITORING ENGINEERED FROM A LARGE CLINICAL STUDY†

HeartLogic was built and validated with data from over 900 patients in the MultiSense Clinical Study.

The study proved that on average, the HeartLogic sensors **may detect worsening heart failure more than 30 days before you have a heart-related event.** Your heart failure team might contact you if they see your HeartLogic Index indicates potential worsening heart failure. At times, they may contact you before you feel symptoms of worsening heart failure.

MONITORING YOUR HEART REMOTELY

A RESONATE device with HeartLogic and your LATITUDE Communicator allows your healthcare team to monitor your device and overall heart health on a regular basis. In addition to any scheduled office visits, your healthcare team can review information sent to them remotely by your Communicator. However, if you are feeling symptoms at any time, notify your healthcare team about how you are feeling.

ENSURE HEARTLOGIC IS WORKING FOR YOU

- ☑ Confirm with your healthcare team that HeartLogic is turned on
- ☑ Ensure your LATITUDE Communicator is plugged in near your bedside and able to send secure data to your care team
- ☑ Download the MyLATITUDE™ Patient App for smartphones from the Apple Store or Google Play for more information about your device and monitoring status
- ☑ Go about your daily life knowing HeartLogic is monitoring your heart health

If you would like to learn more, contact your healthcare team or visit www.bostonscientific.com/heartlogic or www.bostonscientific.com/latitudepatient

Questions to ask your healthcare team:

- What information will HeartLogic provide about my heart health?
- Do I need to log or write down information about my symptoms?
- What happens next if HeartLogic shows a potential change with my heart's condition?

TIP

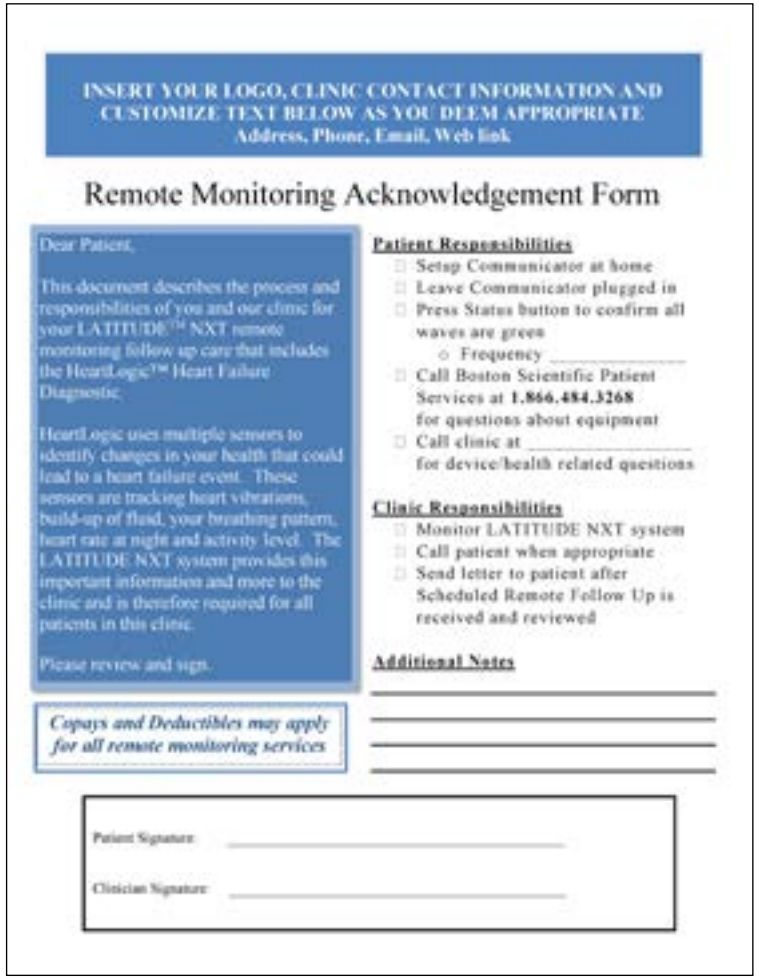
To order the HeartLogic Patient Brochure in English or Spanish, please contact LATITUDE Customer Support at 1-800-CARDIAC (1-800-227-3422) for assistance.

Remote Monitoring Acknowledgement Form:

The remote monitoring acknowledgement form is a customizable template hospitals and/or clinics can use with patients to describe HeartLogic, patient and clinic responsibilities in relation to remote monitoring, and potential copays and deductibles that may apply for the on-going remote monitoring services.

TIP

To obtain a copy of this form, please contact LATITUDE Customer Support at 1-800-CARDIAC (1-800-227-3422) for assistance.



INSERT YOUR LOGO, CLINIC CONTACT INFORMATION AND CUSTOMIZE TEXT BELOW AS YOU DEEM APPROPRIATE
Address, Phone, Email, Web link

Remote Monitoring Acknowledgement Form

Dear Patient,

This document describes the process and responsibilities of you and our clinic for your LATITUDE™ NXT remote monitoring follow up care that includes the HeartLogic™ Heart Failure Diagnostic.

HeartLogic uses multiple sensors to identify changes in your health that could lead to a heart failure event. These sensors are tracking heart vibrations, build-up of fluid, your breathing pattern, heart rate at night and activity level. The LATITUDE NXT system provides this important information and more to the clinic and is therefore required for all patients in this clinic.

Please review and sign.

Copays and Deductibles may apply for all remote monitoring services

Patient Responsibilities

- Setup Communicator at home
- Leave Communicator plugged in
- Press Status button to confirm all waves are green
  - Frequency _____
- Call Boston Scientific Patient Services at **1.866.484.3268** for questions about equipment
- Call clinic at _____ for device/health related questions

Clinic Responsibilities

- Monitor LATITUDE NXT system
- Call patient when appropriate
- Send letter to patient after Scheduled Remote Follow Up is received and reviewed

Additional Notes

_____
_____
_____
_____

Patient Signature _____

Clinician Signature _____

LATITUDE Communicator Connectivity Compliance

Compliance to Remote Monitoring is essential to ensure LATITUDE NXT always has the latest HeartLogic sensor data for you to base care decisions on.

Find your Not Monitored Patients on the Not Monitored filter in LATITUDE NXT.

If a patient's Communicator is not sending data, a status will be displayed. Please utilize the troubleshooting steps outlined below to ensure connectivity is restored. If additional assistance is required, ask the patient to call Boston Scientific Patient Services from 8am-5pm Central time at 1-866-484-3268.

- **No Communicator Assigned** – Once the patient receives their Communicator, encourage them to set it up.
- **Communicator Not Connecting** – Is the green light under the word LATITUDE on as shown in the image below?
  - If yes, remove the power cord from the Communicator for 60 seconds then reconnect it. Once rebooted, hold the white button on the back of the Communicator for 5 seconds to send data to your clinic.
  - If no, Communicator is not securely connected to electrical outlet. Reconnect the black power cable and once power is restored, press and release the Heart Button to complete an interrogation which will automatically be uploaded to your clinic.
- **Implanted Device Not Found** – Press and release the Heart Button. If yellow lights illuminate, move Communicator at least 3 feet away from nearby electronics and retry.

MyLATITUDE™ Patient App

How MyLATITUDE synergizes with HeartLogic™ Heart Failure Diagnostic

The MyLATITUDE Patient App is an easy-to-use app for patients and caregivers that delivers information and education designed to provide peace of mind and improve compliance to remote monitoring. When a patient's Remote Monitoring becomes disconnected for any reason, the MyLATITUDE Patient App will notify the patient and their caregivers and direct them to correct the problem.

By using the MyLATITUDE Patient App, patients and caregivers can understand if there is a problem with their Remote Monitoring, learn about how to fix the issue, and resolve it. By combining the MyLATITUDE Patient App with Heartlogic, patients will be empowered to stay connected to LATITUDE NXT to enable the daily flow of HeartLogic sensor data.

MyLATITUDE is supplemental to the patient's LATITUDE™ NXT Communicator and compatible with all Boston Scientific devices followed on LATITUDE NXT.

MyLATITUDE Patient App resources:

MyLATITUDE Patient App

Additional Resources

Additional Resources

If you didn't find what you need in this guide, you can find additional resources in the following places:

- HeartLogic™ Heart Failure Diagnostic has a dedicated section on Boston Scientific's Rhythm Management Learning Center hosted on EDUCARE This site can be found at the buttons below.

HeartLogic Resources

HeartLogic Continuing Education Training

- Talk to your Boston Scientific representative
- Contact LATITUDE™ Customer Support, available at 1-800-CARDIAC (1-800-227-3422)

HeartLogic™ Heart Failure Diagnostic has a dedicated section on Bostonscientific.com. This site can be found at the button below:

Boston Scientific HeartLogic Heart Failure Diagnostic Product Page

Click to navigate to a section

✪TIP

We're Here to Help

Our LATITUDE Customer Support team is happy to help answer all your questions about using your LATITUDE NXT System.

Phone: 866.484.3268

Hours: M-F 8:00 a.m - 5:00 p.m. Central

Billing and Reimbursement using LATITUDE™ NXT Remote Patient Management System

Reimbursement for HeartLogicTM Heart Failure Diagnostic monitoring is associated with CPT® codes 93297 and G2066 reserved for devices that collect "longitudinal physiologic cardiovascular data elements from one or more internal ... and/or external sensors for patient assessment and management."

- **CPT Code 93297, Remote Interrogation Professional fee.** Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional.

- **CPT Code G2066, Remote Interrogation Technical fee**. Implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results.

Rhythm Management - Reimbursement

Find CPT and ICD-10 procedure codes, physician RVUs, and Medicare national average reimbursement rates for cardiac rhythm management procedures.
Source: CMS 2023 FY PFS Final Rule Addenda
https://www.bostonscientific.com/en-US/reimbursement/rhythm-management.html
For additional questions, contact Boston Scientific Reimbursement CRM.Reimbursement@bsci.com

Billing and Reimbursement FAQ:

Q: Is HeartLogic remote monitoring billable in addition to quarterly device remote monitoring?
A: Yes, 30-day HeartLogic remote monitoring is billable in addition to the 90-day rhythm device remote monitoring. 10 days of HeartLogic data is needed in the 30-days to qualify for billing
Q: What if a patient has "opted out" of remote monitoring?
A: For in-person per encounter device interrogations use CPT code 93290

*Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, charges, and modifiers for services that are rendered. Boston Scientific recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters. It is always the provider's responsibility to understand and comply with national coverage determinations (NCD), local coverage determinations (LCD) and any other coverage requirements established by relevant payers which can be updated frequently.

Integrating LATITUDE™ NXT Remote Patient Management System with your EMR

LATITUDE NXT EMR Integration is available to all LATITUDE NXT clinics. The LATITUDE NXT EMR Integration allows your clinic to upload information from the LATITUDE NXT Communicator into your EMR on a scheduled basis. This seamless data management solution helps increase clinical efficiencies and improve patient outcomes.

LATITUDE NXT meets industry standards and was designed to integrate with EMR systems that accept Health Level 7 (HL7) or Implantable Device Cardiac Observation (IDCO) messages. Data from the Communicator flows to the EMR at the same time it uploads on the LATITUDE NXT webpage "For Review Patient List." The system offers AES encryption for secure transfer of the following patient and device data:

- LATITUDE Alert Information text
- Event Information
- Event and Pacing Counters
- Battery Status
- Settings, including Device Information, Tachy and Brady Zones, and ATR Settings
- Lead Information, including Intrinsic Amplitudes and Impedance
- PDF Reports, including Combined Follow-up, Heart Failure Report and Events

Resources

For more information about the LATITUDE EMR Integration go to https://www.bostonscientific.com/en-US/products/remote-patient-monitoring/latitude-nxt/data-management.html

LATITUDE EMR Integration Brochure: EMR Integration Brochure - LATITUDE NXT and LATITUDE Link

Installation

Work with your IT department to configure EMR integration, available at no charge, directly in LATITUDE NXT under Manage Clinic > Manage EMR Integration.

LATITUDE NXT EMR Integration works with most major EMR systems. For questions about compatibility or installation, contact your EMR vendor or Boston Scientific EMR Integration Support at 888-283-8713.

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.

Boston Scientific
Advancing science for life™

Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

CRM-1143002-AC