

PHYSICIAN'S TECHNICAL GUIDE

HeartLogic™ Heart Failure Diagnostic Service

This feature requires the following external device:

Model 6290, 6299

This feature is immediately available for the following pulse generators:

Model D500, D501, D512, D513, D520, D521, D532, D533, G524, G525, G526, G528, G537, G547, G548

This feature is available by subscription for the following pulse generators:

Model D120, D121, D220, D221, D232, D233, D400, D401, D412, D413, D420, D421, D432, D433, G124, G125, G126, G128, G138, G224, G225, G228, G237, G247, G248, G424, G425, G426, G428, G437, G447, G448

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

Table of Contents

FEATURE DESCRIPTION	1
SENSOR DATA COLLECTION FOR HeartLogic	2
Heart Sounds	4
Respiratory Sensor	4
Thoracic Impedance	5
Night Heart Rate	5
Sleep Incline	6
Longevity Information.....	8
HeartLogic INDEX AND ALERTS	9
Criteria for Alert State.....	9
Criteria for No Alert State	10
USING HeartLogic.....	11
Reading the HeartLogic Index	12
Configuring the HeartLogic Threshold	16
Configuring HeartLogic Alerts	20
Frequently Asked Questions (FAQs).....	22

FEATURE DESCRIPTION

The HeartLogic™ Heart Failure Diagnostic Service (HeartLogic) is comprised of a composite trend called the HeartLogic Index, a configurable yellow Alert, and the device measured Heart Sounds trends. These are all delivered via LATITUDE™ NXT. The HeartLogic Index and Heart Sounds trends are also available through the LATITUDE Consult™ system. The HeartLogic Index and Alert are a validated diagnostic tool to detect gradual worsening of heart failure (HF) over days or weeks using multiple physiologic measurements.

The HeartLogic Index aggregates measurements from multiple device-based sensors (Heart Sounds, Thoracic Impedance, Respiration, and Night Heart Rate) and reflects changes over time in the patient's sensor trend data from their respective baseline values. Baseline values for each sensor trend are assessed based on data spanning up to three recent months and are updated daily (i.e., moving baseline). HeartLogic provides additive information for clinicians to use in context with standard-of-care patient treatment and should not replace standard-of-care treatment.

HeartLogic can be turned On or Off via the LATITUDE system. It is nominally On in the NG4 premium tier devices (RESONATE HF and PERCIVA HF CRT-Ds and ICDs). In non-premium tier NG4 devices (RESONATE, PERCIVA, MOMENTUM, and VIGILANT), HeartLogic is nominally Off and can be turned On via subscription. The subscription is managed through LATITUDE customer service.

NOTE: *The HeartLogic Index and Alert were validated using data from the MultiSENSE study. The Multisensor Chronic Evaluations in Ambulatory Heart Failure Patients (MultiSENSE) study was a multi-center, non-randomized, feasibility study designed to collect chronic ambulatory data from multiple sensors available to implanted cardiac devices in order to develop an algorithm for the early detection of worsening Heart Failure (HF). The MultiSENSE data was divided into a Development Set and a Test Set. The Development Set*

was used to develop the HeartLogic Index and Alert algorithm, while the Test Set was used to independently validate the algorithm performance. For further details, refer to the MultiSENSE Study Summary.)

HeartLogic's impact on clinical outcome has not been established. HeartLogic has not been shown to reduce HF events. A post-approval study is planned to study clinical outcomes.

HeartLogic does not provide a real-time alert. Rather, it is designed to detect chronic worsening of HF and may not be sensitive to fast or abrupt changes of HF status. It does not actively alert the clinician in real-time, and use of individual HeartLogic Index values for day-to-day patient management has not been established.

SENSOR DATA COLLECTION FOR HeartLogic

The heart failure sensor data collection is nominally set to On. Sensor data collection is required for the HeartLogic index calculation. Heart failure sensor data collection can be activated or deactivated through the Programmer by accessing the Setup Tab under Heart Failure Management and turning the Heart Failure Sensor Suite On or Off (see Figure 1 on page 3). The Heart Failure Sensor Suite activation includes Heart Sounds, Thoracic Impedance, Night Heart Rate, and Sleep Incline. See below for a description of these trends.

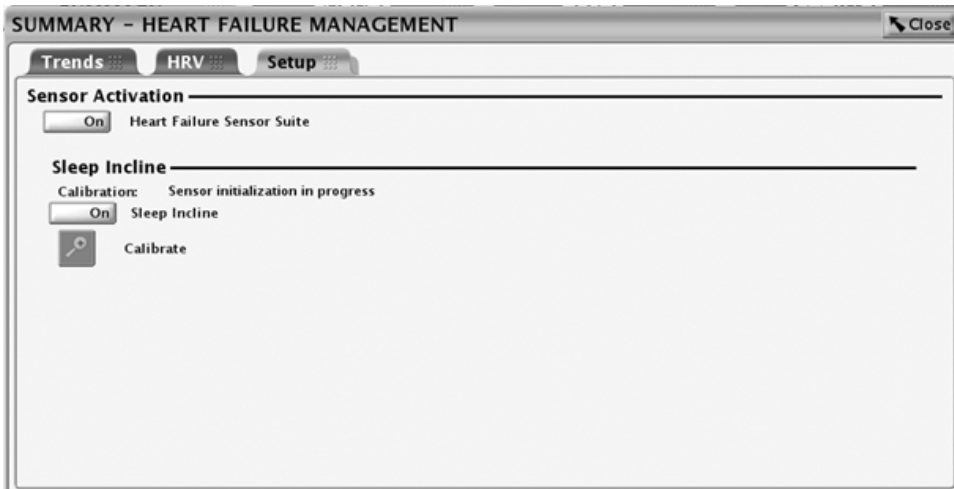


Figure 1. Heart Failure Management Setup Tab

If left at the nominal at the time of device implant, sensor data collection begins the next day. However, due to initialization, the HeartLogic Index is not available until 30 days after the data collection begins. In certain patients, this initialization period may extend up to 37 days. The HeartLogic Index also may not be available if there is insufficient data or if some of the input sensor data are not available.

If the sensors are reprogrammed from On to Off and then back to On, some sensors may become temporarily unavailable (until automatically re-initialized), which may subsequently impact the availability of the HeartLogic Index.

Heart Sounds

Heart Sounds uses the pulse generator's accelerometer to detect cardiac vibrations, which are used to measure the intensity of the following 2 heart sounds:

- Device-measured S1
- Device-measured S3

The daily value of each trend is aggregated from multiple samples each day. If a minimum number of valid samples are not collected, then a daily value will not be available for that day.

Heart Sounds data collection has an interaction with rate responsive pacing. Heart Sounds is only collected during periods of patient inactivity. Once data collection for a Heart Sounds sample has started, activity sensor for rate responsive pacing is not available for 30 seconds. A Heart Sounds sample is typically taken every 20 minutes.

A Heart Sounds sample cannot be measured if the patient's heart rate is too high or too variable. For example, if frequent PVCs result in too high a heart rate, or if AF causes heart rate to be too variable, these conditions may affect the device's ability to record Heart Sounds. In addition, other criteria are used to qualify a given sample.

Respiratory Sensor

The Respiratory Sensor uses transthoracic impedance measurements to collect respiration-related data, specifically respiration rate and tidal volume. Respiration rate and tidal volume are combined to produce additional respiration metrics.

NOTE: *The Respiratory Sensor is controlled independently and is nominally On. If the Respiratory Sensor is turned Off, the HeartLogic Index does not take respiration data into account. The performance is the best when all sensors are available. HeartLogic is still validated in the Respiratory Sensor Off configuration. See the MultiSENSE Study Summary for supporting data.*

Thoracic Impedance

The Thoracic Impedance sensor measures impedance between electrodes on the RV lead and the pulse generator (PG) can. Thoracic Impedance may be associated with the fluid level in the patient's chest and may track fluid level changes. When a patient's fluid level increases, thoracic impedance decreases. Any lead integrity issue may affect the device's ability to record transthoracic impedance.

Night Heart Rate

The Night Heart Rate sensor measures a patient's heart rate between the hours of midnight and 6 AM. This period is non-programmable. The data from this trend can be affected if a patient travels to another time zone or if the pulse generator (PG) clock is incorrect. The PG clock can be programmed by synchronizing it to the programmer clock at the time of device interrogation. For accurate PG clock programming, it is important to ensure that the programmer clock is correct.

Sleep Incline

The Sleep Incline sensor measures the patient's average nighttime elevation angles (sleep incline).

NOTE: *Sleep Incline is part of the Heart Failure Sensor Suite but does not contribute to the HeartLogic Index.*

Initialization and calibration must be completed before Sleep Incline trending occurs. Initialization is automatic; calibration requires clinician and patient action.

- **Initialization.** The initialization of the Sleep Incline sensor occurs automatically after implant and typically takes 5 to 7 days. Initialization may take longer if a patient lacks diversity in their body orientations during this period.

Once the initialization is complete, calibration can take place.

- **Calibration.** Calibration is performed via the programmer during a patient follow-up visit, after implant and initialization are complete. Calibration determines PG orientation within the patient's body. To perform calibration, the patient must adopt an upright posture, either sitting or standing, before the physician presses the Calibrate button on the programmer. The Calibrate button is shown in Figure 2 Heart Failure Management Setup screen on page 7.

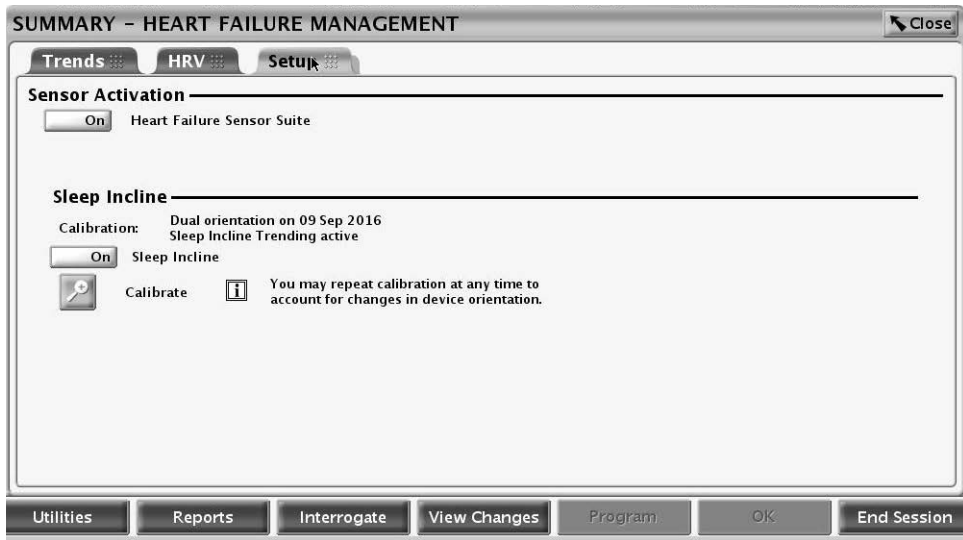


Figure 2. Heart Failure Management Setup screen

The programmer notifies the clinician of the completion of calibration for the particular posture. If not enough stable data was collected, the programmer will indicate this and ask for the posture to be repeated.

While an upright posture is the only required posture for calibrating the Sleep Incline sensor, accuracy is increased by performing a second calibration using a supine posture. Repeat the above process to collect readings for the second posture. The accuracy of the sleep incline trend depends on a proper body calibration. If the patient is not fully vertical or horizontal when the programmer captures the upright and supine postures respectively, then the trend values will be distorted. Calibration can be repeated as often as the clinician desires.

- **Trending.** The Sleep Incline Trend aggregates periodic measurements over the patient's sleep schedule. To program the patient's sleep schedule, access the General tab of the Patient Information screen. The first sample is taken 1 hour after the programmed Sleep Start and the last sample is taken 1 hour prior to the end of the programmed Sleep Duration. For a measurement to be successful, the patient must be at low activity.

Longevity Information

When the Heart Failure Sensor Suite is programmed to Off for the life of the device, longevity is increased by approximately 1 month.

A HeartLogic subscription with 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.

Refer to the Physician's Technical Manual for more information about device longevity.

HeartLogic INDEX AND ALERTS

The HeartLogic Index values have a range between 0 and 100. In general, a large sensor change relative to its moving baseline in the direction of worsening HF leads to a higher HeartLogic Index value. Based on the HeartLogic Index value, an alert state is assigned each day, consisting of two distinct values:

- “Alert” (which is indicative of an increased likelihood of experiencing a worsening HF event), and
- “No Alert”

These values are based on the comparison of the HeartLogic Index value to the HeartLogic Alert threshold and recovery threshold.

- The alert threshold is configurable between 10 and 40, with a nominal value of 16.
- The recovery threshold is set automatically based on the selected alert threshold, and it is always less than the corresponding alert threshold.

Criteria for Alert State

On a given day, the state is considered to be Alert if:

- The value of the HeartLogic Index on that day is at or above the alert threshold, or
- The value of the HeartLogic Index on that day is at or above the recovery threshold, and the alert state on the preceding day was Alert, or
- The value of the HeartLogic Index on that day is not available, and the alert state on the preceding day was Alert.

Criteria for No Alert State

On a given day, the state is considered to be No Alert if:

- The value of the HeartLogic Index on that day is below the recovery threshold, or
- The value of the HeartLogic Index on that day is below the alert threshold, and the alert state on the preceding day was No Alert, or
- The value of the HeartLogic Index on that day is not available, and the alert state on the preceding day was No Alert.

The alert is issued on the first day that the alert state transitions from No Alert to Alert. The alert is designed to detect gradual worsening HF events (HFEs). The feature was validated using data from the MultiSENSE study, in which HFEs were defined as worsening HF with signs/symptoms of congestive heart failure **that occur at least 45 days following the start of sensor data collection** and:

- Patient was hospitalized overnight (i.e., calendar date change).
- Patient was not hospitalized and received one or more IV medications including diuretics, inotropes, vasodilators, other parenteral therapy, or aquapheresis.

Because the sensor data is aggregated only at the end of each day, the alert is delivered via LATITUDE NXT System the next day. The alert is available for review and can be dismissed by the user through the LATITUDE NXT System; however, if the alert is dismissed and the patient continues to be in alert state, another alert will be issued 7 days later. The LATITUDE NXT System also displays a status indicator whenever the HeartLogic Index is in the alert state; this indicator cannot be dismissed. Reports from the LATITUDE Consult system show the status indicator when the HeartLogic Index is in the alert state.

The alert is considered recovered when the alert state transitions from Alert to No Alert. Such a transition is indicative of current sensor values no longer being different than the moving baseline. Changing from a state of Alert to No Alert does not necessarily indicate that a patient is no longer in worsening heart failure; instead, the patient may be improving, staying the same, or worsening at a slower rate. Additionally, abrupt unavailability of individual sensor data may result in a sudden decrease in the HeartLogic Index.

USING HeartLogic

HeartLogic is intended to be used by qualified health care practitioners via remote monitoring or at the point of care for HF surveillance, such as hospitals or clinic facilities, in conjunction with clinical evaluation that is part of standard clinical practice.

The HeartLogic Alert signifies an increased risk for an HFE for the patient; consider contacting the patient for additional surveillance. As observed in the Test Set Cohort of the MultiSENSE data, less than 1% of all alerts resulted in an HFE in less than 3 days; detected HFEs occurred with a median duration of 34 days from the start of the alerts associated with the detected HFEs.

HeartLogic is designed to detect chronic worsening of HF and may not be sensitive to fast or abrupt changes of HF status, and it does not actively alert the clinician in real-time. Use of individual HeartLogic Index values for day-to-day patient management has not been established. Instead, consult the overall HeartLogic Index trend and/or Alert.

Since baseline values for each sensor trend are assessed based on data spanning up to three recent months, any sustained atypical deviation over this period may impact the moving baseline and subsequently the HeartLogic Index. For example, if the patient worsens and the sensor trends remain in a worsened state that is not further deteriorating for a sustained duration, it may result in a decrease in the HeartLogic Index and alert recovery in a patient whose HF status has not improved. In the MultiSENSE study, 3 patients experienced HFEs within 30 days after an alert had recovered.

These HFEs happened 4, 7, and 22 days after the alert recovery. Conversely, if there are unusually large and sustained excursions in the sensor data in the direction opposite to that of worsening HF (e.g., hypovolemic state) in the last three months, it may result in an unusually higher HeartLogic Index value and alert issuing in an otherwise stable patient.

Review all patient data (including those that contributed to the Index) on the Heart Failure Patient Management Reports in their entirety, and physiologic and/or clinical data from other sources. **No changes to patient treatment should be made based on a HeartLogic Alert alone without standard-of-care patient evaluation. Likewise, no reduction in patient care should be made based solely on the absence of a HeartLogic Alert.**

Reading the HeartLogic Index

Figure 3 on page 13 shows the HeartLogic Index in No Alert State.

- The solid black line depicts the HeartLogic Index, which changes over time for this specific sample patient.
- The Y-axis shows the value of the HeartLogic Index, which can range from 0 to 100.
- The horizontal dashed line shows the alert threshold. For this patient, the HeartLogic Index has remained below the alert threshold.
- The HeartLogic Index value for the most recent day is shown in the large box on the left side of the display.
- The Zoom settings, located in the upper left of the screen, can show up to one year of data (if data is available).

View: 1m 3m 6m 1y

Oct 01, 2015 Nov 01, 2015 Dec 01, 2015 Jan 01, 2016 Feb 01, 2016 Mar 01, 2016

HeartLogic™ Heart Failure Index

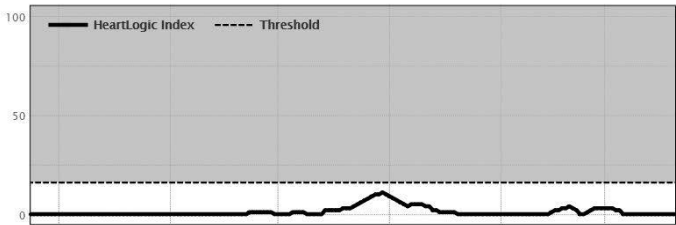


Figure 3. HeartLogic Index example

Figure 4 on page 15 shows the HeartLogic Index transitioning from an initial No Alert state to an Alert state.

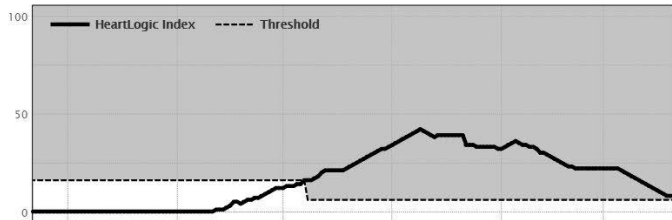
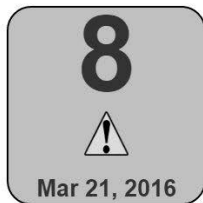
- In this case, the alert threshold appears as the dashed horizontal line in the initial portions of the graph, which corresponds to the patient being in the No Alert state (prior to November 2015).
- The HeartLogic Index crossed the alert threshold in November, transitioning into Alert state, at which point the alert threshold (dashed line) steps down to the recovery threshold. As described previously, the system automatically sets the recovery threshold based on the chosen alert threshold. Since the value of the HeartLogic Index for the most recent day is above the recovery threshold, and the alert state on the preceding day was Alert, the state continues to be Alert.

While the HeartLogic Index is in the Alert state, the changes in some of the individual contributing trends (S3, S3/S1 Ratio, Thoracic Impedance, Respiratory Rate, and Night Heart Rate) are also displayed. The shaded portion of each bar corresponding to a contributing trend indicates the degree of worsening HF measured in that trend as of the date shown.

View: 1m 3m 6m 1y

Oct 01, 2015 Nov 01, 2015 Dec 01, 2015 Jan 01, 2016 Feb 01, 2016 Mar 01, 2016

HeartLogic™ Heart Failure Index



Contributing trends



Note: Shaded portion indicates degree of worsening on Mar 21, 2016

Figure 4. HeartLogic Index in transition to Alert state

Configuring the HeartLogic Threshold

The performance in the Test Set Cohort of the MultiSENSE study was used as the basis for the HeartLogic nominal alert threshold value. The sensitivity (proportion of HFEs detected) is 70% when each HFE is counted independently; the sensitivity is 65% when only the initial HFE is counted, and not repeated HFEs associated with a single alert. The alert threshold is configurable, enabling physicians to tailor the feature to their clinical practice preferences and inter-patient variability.

Using lower threshold settings increases HeartLogic Alert's sensitivity to detect worsening HF. If the user wants the HeartLogic Alert to be more sensitive to sensor changes reflected by the HeartLogic Index, the user should decrease the alert threshold. However, lower threshold settings may also lead to the generation of more alerts.

Conversely, if the user wants the HeartLogic Alert to be less sensitive to sensor changes reflected by the HeartLogic Index, the user should increase the alert threshold. Increasing the alert threshold reduces HeartLogic Alert's sensitivity to detect worsening HF, and it may result in the generation of fewer alerts.

Adjustments to the alert threshold should be based on user preference. See Figure 5 on page 18 and Table 1 on page 19 to see the relationship between sensitivity (proportion of HFEs detected) and the unexplained alert rate (UAR, the number of alerts per patient year that are not associated with worsening heart failure) in the Test Set Cohort of the MultiSENSE study as the threshold is changed.

Changing the alert threshold from the nominal is not recommended, unless:

- The patient has an HFE without an associated alert while the HeartLogic Index is available.
- Unexplainable alerts have occurred.

When configuring the HeartLogic Alert threshold, consider the following:

- Reviewing the HeartLogic Index values for previous HFEs, as well as when the patient was deemed to be clinically stable, aids in understanding the patient's history and condition.
 - To increase the likelihood of detecting an HFE, it is recommended to set the alert threshold below the calculated HeartLogic Index values of any previous HFEs.
 - To reduce the likelihood of alerting when the patient is not experiencing HFE, it is recommended to set the alert threshold above the calculated HeartLogic Index values when the patient was deemed to be clinically stable.
- Decreasing the alert threshold, may result in the following (see Figure 5 on page 18 and Table 1 on page 19):
 - The feature may be less likely to miss an HFE.
 - The feature may be more likely to issue an alert.
 - Minor changes in the physiologic measurements contributing to the HeartLogic Index are more likely to trigger an alert.
 - Clinicians may receive an increased number of alerts.
- Increasing the alert threshold may result in the following (see Figure 5 on page 18 and Table 1 on page 19):
 - The feature may be more likely to miss an HFE.
 - The feature may be less likely to issue an alert.
 - If the alert threshold is configured too high, clinicians may not receive alert for true HFEs.

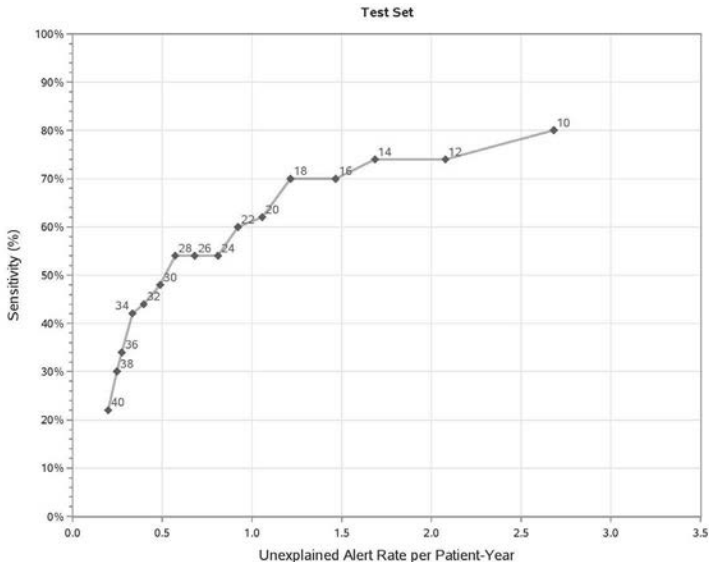


Figure 5. HeartLogic Alert Performance in terms of Sensitivity (proportion of HF events detected) and Unexplained Alert Rates (Alerts not associated with worsening HF) at various Configurable Alert Thresholds as observed during the independent validation in the Test Set Cohort of the MultiSENSE study (Nominal alert threshold = 16)


Table 1. Sensitivity and UAR of HeartLogic Alert algorithm at various configurable thresholds as observed during the independent validation in the Test Set Cohort of the MultiSENSE study

Alert Threshold	Sensitivity (%)	UAR (per patient year)
10	80	2.69
12	74	2.09
14	74	1.70
16 (nominal)	70	1.48
18	70	1.22
20	62	1.07
22	60	0.93
24	54	0.82
26	54	0.70
28	54	0.58
30	48	0.49
32	44	0.40
34	42	0.34
36	34	0.28
38	30	0.25
40	22	0.20


Configuring HeartLogic Alerts

To change when a HeartLogic Alert is issued, configure the HeartLogic Alert threshold through the LATITUDE NXT System. The alert configuration user interface for the LATITUDE NXT System is shown in Figure 6 on page 21. As described previously, the HeartLogic Alert threshold is nominally set to 16 and may be configured within the range of 10 to 40 with a step of 2. Changes made to the alert configuration will not be effective until the Communicator calls the LATITUDE server to obtain the new configuration (within 7 days). Also, the user may set the system to interrogate the device and upload data to the LATITUDE NXT System on a daily basis following an alert. This functionality may allow the user to more closely monitor the HeartLogic Index when it is in the alert state.

HeartLogic™

-  HeartLogic heart failure index at or above .
Perform daily interrogations until alert condition is resolved .

Pacing

-  Right ventricular pacing of > %.

Others





-  Possible device malfunction.
-  High voltage detected on shock lead during charge.
-  Device in Safety Mode.
-  Therapy history corruption detected.

Figure 6. LATITUDE NXT Alert Configuration

Frequently Asked Questions (FAQs)

1. Why did the HeartLogic Alert occur for my patient?

The HeartLogic Index aggregates measurements from multiple device-based sensors (Heart Sounds, Thoracic Impedance, Respiration, and Night Heart Rate) and reflects changes over time in the patient's sensor data from their respective moving baseline values. The alert occurred because the sensor changes resulted in a significant enough change in the HeartLogic Index to cross the alert threshold. The alert signifies an increased risk for a heart failure event for the patient; consider contacting the patient for additional surveillance per your standard of care for the patient.

2. How do I know what triggered the alert?

The HeartLogic Index aggregates measurements from multiple device-based sensors and reflects changes over time in the patient's sensor data from their respective moving baseline values. When the HeartLogic Index transitions into an alert state, the degree of changes of individual contributing trends are shown as shaded area in the bar plots (see Figure 4 on page 15) below the HeartLogic Index.

3. What does the OK in the box next to the HeartLogic Index mean?

The display of OK means that the HeartLogic Index for the patient is not in alert state. No reduction in patient care should be made based solely on absence of a HeartLogic Alert.

4. I received another alert for a patient within 7 days. What do I do?

A subsequent alert within 7 days indicates that the patient continues to be in the alert state; consider contacting the patient for additional surveillance per your standard of care for patients.

5. What should I do when alert occurs? How soon should I act upon an alert?

Based upon MultiSENSE study data, less than 1% of the alerts resulted in an HFE in less than 3 days. Consider contacting the patient for additional surveillance per your standard of care for patients in an appropriate time frame.

6. What should I do if the patient is not symptomatic when I call to follow up on an alert?

The alert is an early indicator of potential HF event, and sensor changes driving the alert may precede symptom changes. Review all the data in the Heart Failure Management report, such as individual sensor trends, AT/AF burden, arrhythmic events, and percent pacing and/or clinical data coming from other sources, and follow your standard of care for patients.

7. What should I do if the patient is not symptomatic and the alert persists?

Continue to review all the data in the Heart Failure Management report such as individual sensor trends, AT/AF burden, arrhythmic events, and percent pacing, and follow your standard of care for patients.

8. Why am I getting alerts for a patient without any subsequent clinical worsening of HF?

Some patients have other comorbidities or conditions that may result in sensor changes common with worsening HF. Some patients may have more variations in their sensor data that are not always associated with subsequent worsening HF. Based on experience from MultiSENSE, atrial fibrillation is the most frequent cause of unexplained alerts despite the patient not having worsening HF. Ventricular arrhythmia and infection are the most common medical conditions that may cause alerts despite the patient not having worsening HF. To reduce the number of alerts, follow the instruction in the section “Configuring the HeartLogic Threshold” on page 16 to increase the threshold. However, increasing the alert threshold will also reduce the likelihood of detecting a future HFE.

9. Why did I not receive any alert for one of my patients that had an HFE?

Due to the heterogeneity of heart failure, some patients may have fewer changes in their sensor data prior to worsening HF. Absence of alert prior to an HFE indicates that the sensor changes leading up to HFE did not result in sufficient changes in the HeartLogic Index values to cross the alert threshold. Consider setting the alert threshold below the HeartLogic Index values just prior to the HFE event. However, lowering the alert threshold will also result in receiving an increased number of alerts in the future.

10. Can I tailor the alert threshold uniquely for my clinic?

The HeartLogic Alert threshold provides the opportunity to choose your own balance between unexplained alert rate and sensitivity to HFEs. The nominal alert threshold was chosen based upon sensitivity of 70% and an unexplained alert rate of 1.48 per patient year as observed during the algorithm validation in an independent Test Set Cohort of the MultiSENSE study (see Table 1 on page 19). If your clinic wishes to operate at a different sensitivity level, consider changing the alert threshold. However, note that increasing the alert threshold will also reduce the sensitivity of detecting future HFEs.

11. Can I use the HeartLogic Index value for day-to-day patient management?

Use of the HeartLogic Index for day-to-day patient management has not been established. Review all patient data, including those that contributed to the Index and physiologic and/or clinical data coming from other sources, and follow your standard of care for patients.

12. Following the HeartLogic Alert, I treated my patient, but the Index does not decrease and the alert is not turning off. What do I do?

Due to the long-term averaging involved, the Index may not be sensitive to faster changes in sensor data over a shorter time frame. As such, sensor changes due to acute interventions may not be immediately reflected in the Index. Use of the HeartLogic Index for day-to-day patient management has not been established.



For additional reference information, go to
www.bostonscientific-elabeling.com.

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360200-001 en USA 2017-05

