Boston Scientific

PHYSICIAN'S TECHNICAL GUIDE

HeartLogic™ Heart Failure Diagnostic Service

This feature requires the following external device:

REF 6290

This feature is immediately available for the following pulse generators:

REF 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:

REF D120, D121, D220, D221, D232, D233, D320, D321, D332, D333, D400, D401, D412, D413, D420, D421, D432, D433, G124, G125, G126, G128, G138, G224, G225, G228,G237 G247, G248, G324, G325, G328, G337, G347, G348, G424, G425, G426, G428, G437, G447, G448.

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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™. 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. HeartLogic provides additive information for clinicians to use in context with standard-of-care patient treatment and should not replace standard-of-care treatment.

NOTE: *The HeartLogic Index and Alert were validated using data from the MultiSENSE study; however, HeartLogic's impact on clinical outcome has not been established. Establishment of the impact will require a post market trial designed specifically to study clinical outcomes directly related to the use of this feature.*

TURNING ON SENSOR DATA COLLECTION FOR HeartLogic

Heart failure sensor data collection can be activated through the Programmer by accessing the Setup Tab under Heart Failure Management and turning on Heart Failure Sensor Suite (see Figure 1 on page 2). The Heart Failure Sensor Suite activation includes Heart Sounds, Sleep Incline, Thoracic Impedance, and Night Heart Rate. See below for a description of Heart Sounds. The other trends are described in the Reference Guide. This action activates the sensor data collection needed for the HeartLogic index calculation. The heart failure sensor data collection is nominally set to On.

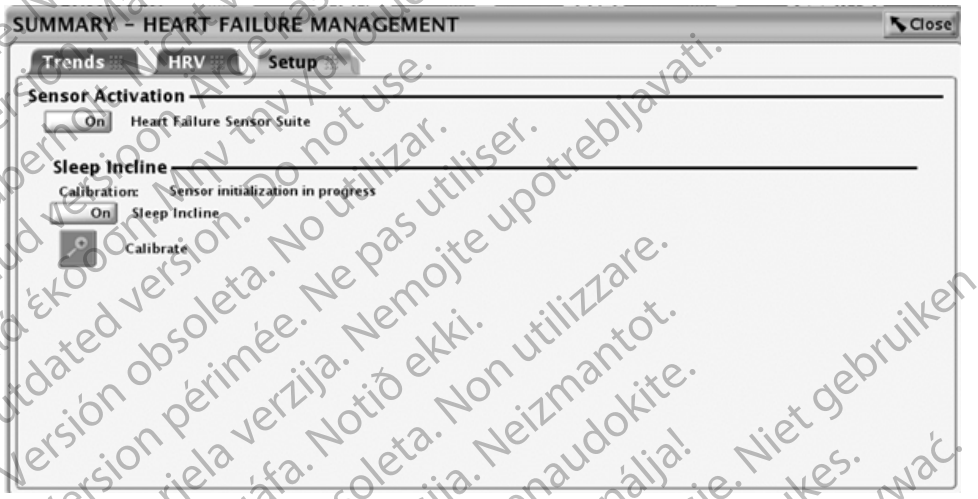

Figure 1. Heart Failure Management Setup Tab

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.

NOTE: *The Respiratory Sensor is controlled independently. If the Respiratory Sensor is turned off, HeartLogic Index does not take respiration data into account.*

HeartLogic INDEX AND ALERTS

The HeartLogic Index values have a range between 0 and 100. In general, a large sensor change 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 HeartLogic Index is in the alert state; this indicator cannot be dismissed.

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. 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**.

The HeartLogic Index 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.

Reading the HeartLogic Index

Figure 2 on page 7 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).

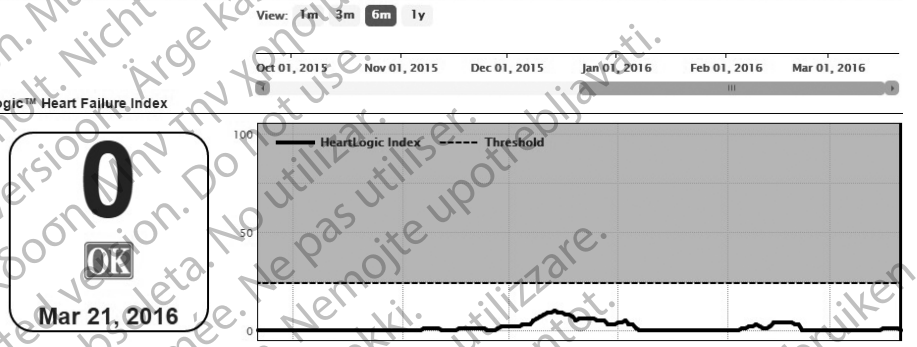

Figure 2. HeartLogic Index Example

Figure 3 on page 8 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.

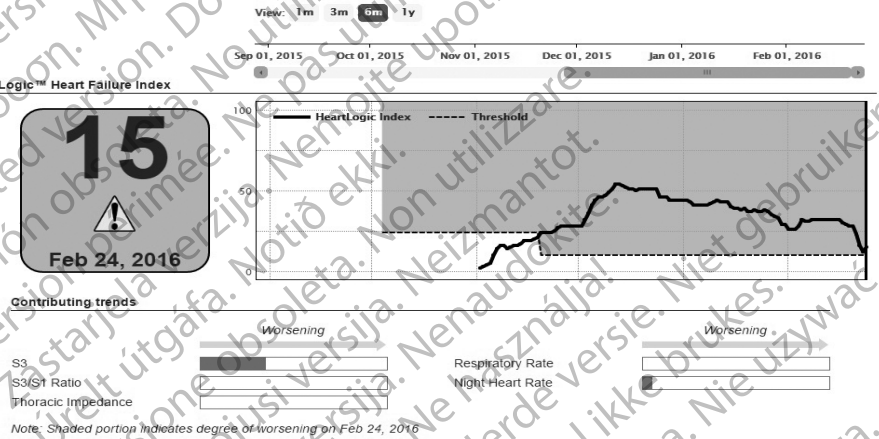

Figure 3. HeartLogic Index in transition to Alert state

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 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 4 on page 11 and Table 1 on page 12 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 4 on page 11 and Table 1 on page 12):
  - 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 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 4 on page 11 and Table 1 on page 12):
  - 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.

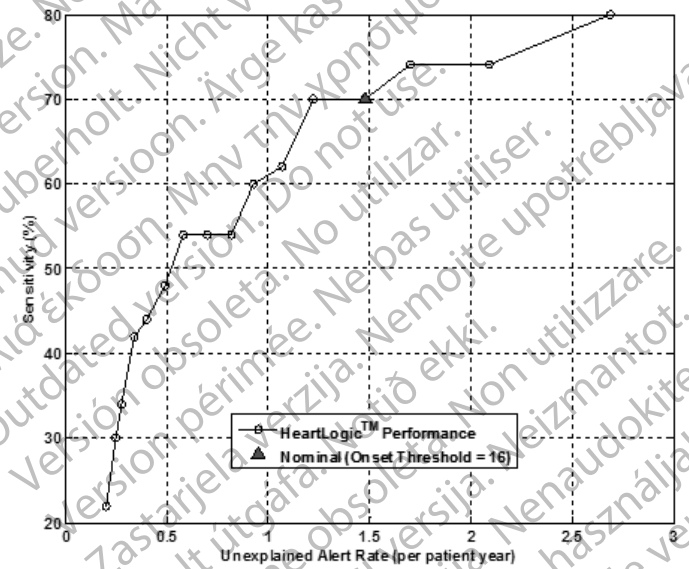

Figure 4. HeartLogic Alert Performance in terms of Sensitivity (proportion of HF events detected) and Unexplained Alert Rates (Alerts not associated with worsening HF) at various Configurable Alert Thresholds as observed during the independent validation in the Test Set Cohort of the MultiSENSE study

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	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 5 on page 14. 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.

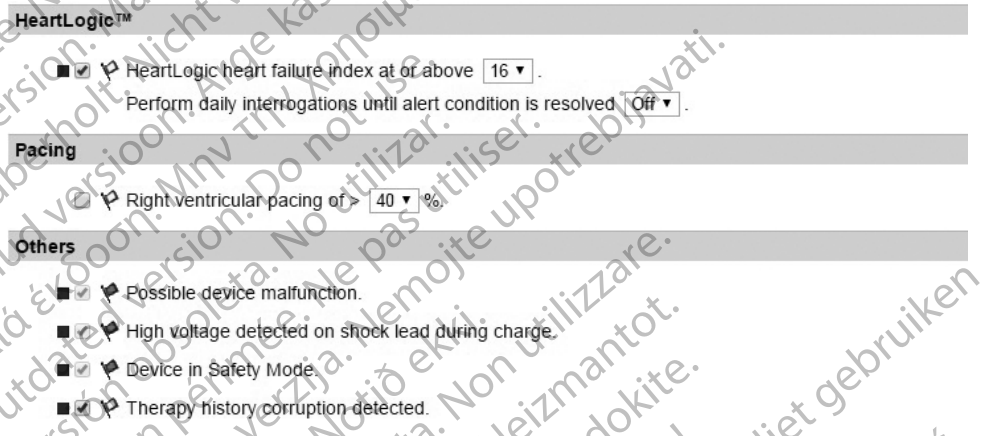

Figure 5. LATITUDE NXT Alert Configuration

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. In addition, other criteria are used to qualify a given sample.

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 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 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 3 on page 8) 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. To reduce the number of alerts, follow the instruction in the section “Configuring the HeartLogic Threshold” on page 9 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 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 12). 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.

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

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

EC REP Guidant Europe NV/SA
Boston Scientific
Green Square,
Lambroekstraat 5D
1831 Diegem, Belgium
1.800.CARDIAC (227.3422)
+1.651.582.4000
www.bostonscientific.com

AUS Australian Sponsor Address
Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY NSW 1455 Australia
Free Phone 1 800 676 133
Free Fax 1 800 836 666

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