

February 2023

**Subject:** HeartLogic™ enabled in Model 6460 LATITUDE™ NXT Patient Management System for subset of U.S.<sup>1</sup> patients

Dear LATITUDE Healthcare Professional,

Our records indicate that you may have U.S. patients who did not have HeartLogic™ enabled as you may have intended in the Model 6460 U.S. LATITUDE™ NXT Patient Management System (LATITUDE). The patients included within this enclosed list had HeartLogic enabled in LATITUDE on February 14, 2023. If you intended HeartLogic to be enabled in LATITUDE, there are no actions for you to take aside from distributing this information to appropriate healthcare professionals (HCPs) within your center who manage HeartLogic alerts. If there are patients on the enclosed list for whom you do NOT want HeartLogic enabled in LATITUDE, please contact Boston Scientific.

### Description

The HeartLogic Heart Failure Diagnostic aggregates measurements from multiple device-based sensors including Heart Sounds, Thoracic Impedance, Respiration, Activity and Night Heart Rate and compares changes over time to the patient's baseline values. If a patient's HeartLogic Index meets or exceeds a pre-configured alert threshold, a Yellow Alert (when configured ON in LATITUDE) will notify your clinic of a potential heart failure (HF) event.

To enable HeartLogic within LATITUDE, HCPs can contact LATITUDE Customer Support or the local Boston Scientific sales representative. Upon request, U.S. Boston Scientific sales representatives can facilitate this request within our proprietary U.S. product registration system. Under specific circumstances, this U.S. product registration system did not send up to 1,531 HeartLogic enablement requests to U.S. LATITUDE Customer Support during an eight-month interval in 2022. Thus, for these patients, the HeartLogic Index and any associated Yellow Alerts were not visible in LATITUDE. Boston Scientific resolved this registration system behavior in November 2022.

### Clinical Impact

There have been no reported harms associated with this behavior. However, it is theoretically possible that if HeartLogic is not enabled in LATITUDE as expected, HCPs may not detect worsening HF in a timely manner which if left untreated may lead to HF decompensation requiring hospitalization.

### Recommendations.

- Distribute this information to appropriate HCPs within your center who manage HeartLogic alerts for the patients in the enclosed list.

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<sup>1</sup>Only the United States and U.S. territories are affected.

## HeartLogic Enablement Request for LATITUDE NXT Not Transmitted

- If you do NOT want HeartLogic enabled in LATITUDE for patients in the enclosed list, contact Boston Scientific LATITUDE Customer Support via [latitude@bsci.com](mailto:latitude@bsci.com), and identify which patients should NOT be enabled.

### **Additional Information**

Patient safety remains our highest priority. Although we recognize the impact of this letter on both you and your patients, we are committed to transparent communication with physicians and other HCPs to ensure you have relevant information for managing your patients. If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or LATITUDE Customer Support. Adverse events may also be reported to the FDA's MedWatch Adverse Event Reporting program. Up-to-date product performance information is available within our Product Performance Resource Center at [www.bostonscientific.com/ppr](http://www.bostonscientific.com/ppr).

Sincerely,



Alexandra Naughton

Vice President, Quality Assurance