

March 2023

**Subject:** Product advisory for Model 6446 LATITUDE™ NXT Patient Management System not sending email or text message alert notifications for a subset of alerts in Norway (FA-96994570 RevA).

Dear Physician or Healthcare Professional,

This letter includes important information related to an inability of the Model 6446 LATITUDE NXT™ Patient Management System to deliver a subset of alerts (Table 1) via email or text message to clinics in Norway. This behavior does not affect the presentation of alerts on the View Patient List page on the LATITUDE NXT website<sup>1</sup>. The information within this letter only applies if your LATITUDE NXT clinic: 1) is in the country of Norway; and 2) has patient groups configured to deliver alert notifications via email or text message to physicians or healthcare professionals (HCPs).

### Description

The LATITUDE NXT system enables authorized HCPs to periodically monitor patient and Boston Scientific cardiac implantable electronic device (CIED) status remotely. The LATITUDE NXT system generates alert notifications for various device and patient conditions. HCPs can review their patient’s alerts by logging onto the website and viewing the View Patient List page which displays the patient’s name and alert type. The LATITUDE NXT website is considered the primary notification. Additionally, the LATITUDE NXT system can be optionally configured to send secondary notifications through email and/or text message which depend on external systems. These external systems cannot be guaranteed to always successfully transmit. Per LATITUDE NXT system instructions for use, the email and text message notification feature does not eliminate or reduce the need to check the LATITUDE NXT website.

Based on Norwegian privacy regulations, alert notifications which include measured data or patient parameters must be encrypted. Since the release of LATITUDE NXT v6.1 in January 2020, the de-encryption process for a subset of alerts has been inoperable and the alerts described in Table 1 are currently not being sent via email or text message. All alerts, including those described in Table 1, are available for review via the View Patient List on the LATITUDE NXT website.

**Table 1.** LATITUDE NXT Alerts Unavailable via Email or Text Message in Norway

Alert Description	Device Type <sup>2</sup>	Alert Type
Remote monitoring disabled due to limited battery capacity	Transvenous CIED	Red
Device in Safety Mode	Transvenous CIED	Red
Atrial Arrhythmia Burden condition over a 24-hour period exceeding user selected percentage	Transvenous CIED	Yellow
Cardiac Resynchronization Therapy pacing percentage less than user selected percentage	Transvenous CIED	Yellow
Right ventricular pacing exceeding user selected percentage	Transvenous CIED	Yellow

<sup>1</sup> [www.latITUDE.bostonscientific.com](http://www.latITUDE.bostonscientific.com)

<sup>2</sup> Transvenous CIED includes transvenous implantable pacemakers, defibrillators (ICD), and cardiac resynchronization pacemakers/defibrillators (CRT-P / CRT-D); S-ICD = subcutaneous implantable defibrillator

## Inability of LATITUDE NXT System To Send A Subset Of Alerts Via Email Or Text Message In Norway

Alert Description	Device Type <sup>2</sup>	Alert Type
HeartLogic heart failure index at or above threshold	Transvenous CIED	Yellow
Weight gain exceeding user selected limit	Transvenous CIED with weight scale	Yellow
Non-sustained ventricular arrhythmia episode(s)	Transvenous CIED	Yellow
Patient triggered event stored	Transvenous CIED	Yellow
Anti-tachycardia pacing (ATP) therapy delivered to convert arrhythmia	Transvenous CIED	Yellow
Accelerated arrhythmia episode (Ventricular)	Transvenous CIED	Yellow
Shock therapy delivered to convert arrhythmia	S-ICD	Yellow
Measured AF within a 24-hour period exceeding user selected percentage	S-ICD	Yellow

### Clinical Impact

There have been no reported complaints or harms associated with this behavior. The greatest foreseeable potential for harm would occur if a clinic relied solely on an email or text message to be notified of a red alert condition in Table 1. The risks associated with this behavior can be eliminated by reviewing alert conditions promptly via the View Patient List on the LATITUDE NXT website.

**Recommendations.** For HCPs in Norway receiving alerts via email or text message through the model 6446 LATITUDE NXT Patient Management System:

1. Review alert conditions via the View Patient List on the LATITUDE NXT website.
2. Do not rely on email or text message for alert notification.
3. Inform HCPs who review alerts in the LATITUDE NXT system of this behavior.

Please complete and return the enclosed acknowledgement form to verify receipt of this information.

### Additional Information

Adverse events should be reported to Boston Scientific or your local Regulatory Authority's Adverse Event Reporting Program. Boston Scientific will address this alert behavior in a future update to the LATITUDE NXT system and will notify clinics in Norway when the update is released.

Patient safety remains our highest priority. Although we recognize the impact of this letter on both you and your patients, we are committed to communicating with physicians and other HCPs to ensure you have relevant information for managing your patients. If you have additional questions regarding this information, please contact your Boston Scientific representative or LATITUDE Customer Support. 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