

# URGENT MEDICAL DEVICE INFORMATION



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**Subject: Product Advisory** – Missed Alerts from a subset of LATITUDE® in-home communicators (Models 6468 and 6476)

Dear Doctor,

This letter provides important information regarding Boston Scientific's LATITUDE Patient Management system. Our records indicate that your clinic has enrolled or is already using LATITUDE to remotely monitor patients with Boston Scientific defibrillator systems. This advisory applies only to a subset (~20%) of active LATITUDE communicators, which are used to transfer memory information from the implanted device to a physician-accessible website. It does not involve the implanted defibrillator, lead system, or programmer.

## Background

Boston Scientific defibrillators include a *Daily Measurements* feature that conducts several diagnostic tests on a daily basis to monitor the implanted defibrillator and leads. At the next in-clinic visit, test results are displayed on the programmer, with out-of-range results appropriately highlighted.

To supplement in-clinic visits, the LATITUDE Patient Management system enables clinicians to monitor the status of the implanted system remotely between clinic visits. Status information from the implanted defibrillator is transferred by an in-home communicator to the LATITUDE Website according to a schedule set by the clinician. If *Daily Measurements* are programmed On in the implanted defibrillator (nominally On) **and** the desired Alerts are configured On in LATITUDE, out-of-range *Daily Measurements* will generate a corresponding Red or Yellow Alert on the LATITUDE Website.

## Description

Boston Scientific has determined that alert conditions for a limited subset of out-of-range *Daily Measurements* related to leads may not be recognized by Model 6476 (United States) or Model 6468 (Europe) LATITUDE in-home communicators. If a communicator fails to recognize a valid alert situation, notification for this or subsequent alerts for the same test will not be displayed for physician review on the LATITUDE Website. However, *Daily Measurement* values uploaded from the implanted defibrillator will be available from the ALL PATIENTS page after completion of the next full device interrogation, which occurs during *Weekly Device Alert Interrogations* and scheduled remote follow-ups.

Although a limited subset of alerts may not display on the LATITUDE Website, it is important to note that all *Daily Measurement* tests within the implanted defibrillator function normally, and results will be displayed as designed when the defibrillator is interrogated with a programmer.

## Rate of Occurrence

We have identified 8 missed Red Alerts and 223 missed Yellow Alerts from approximately 19,000 patients in the United States with implanted Boston Scientific defibrillators followed with a LATITUDE Model 6476 Communicator. One missed Yellow Alert has been identified from approximately 50 patients in Europe followed with a LATITUDE Model 6468 Communicator. However, root cause analysis indicates that both communicators are subject to missed alerts at the same rate of occurrence.

The observed rate for a missed Red Alert (highest priority) has been approximately 0.01% per month of monitoring. No patient deaths or injuries have been associated with this communicator behavior.

## **Patient Management**

Until this behavior is corrected, Boston Scientific will review weekly interrogation data collected by affected Model 6468 and 6476 Communicators and will contact you by phone or fax if any out-of-range *Daily Measurements* fail to display a corresponding Red or Yellow Alert on the LATITUDE Website.

Boston Scientific will reconfigure patient schedules as needed to ensure that communicator data is available for weekly review. Specifically, for each patient with *Daily Device Check* configured On, we will reconfigure the patient's *Weekly Device Alert Interrogations* to On (if needed). Boston Scientific will notify you on an ongoing basis if *Weekly Device Alert Interrogations* will be or has been reconfigured for any patients at your clinic. Individual alert settings will not be altered.

We recommend that LATITUDE *Weekly Device Alert Interrogations* **remain** configured On to facilitate Boston Scientific review of interrogation information. However, you may wish to alter individual Yellow Alert selections if the *Weekly Device Alert Interrogations* feature was configured On by Boston Scientific.

The root cause of these missed alerts is understood. Following regulatory approval, software will be implemented through the LATITUDE Website to correct this issue. You will be notified when *Weekly Device Alert Interrogations* and *Daily Device Check* may once again be configured as desired.

## **Devices Affected**

This Product Advisory pertains to the LATITUDE Patient Management system when used with a Model 6468 or Model 6476 in-home communicator. Other communicator models are not subject to missed alerts. The implanted defibrillator, lead system, and programmer are not affected.

## **Further Information**

Boston Scientific recognizes the impact of this communication on your clinic and the patients you follow, and wants to reassure you that patient safety remains our primary concern. If you have any questions regarding this communication, please contact your local Boston Scientific CRM representative.

Sincerely,



William E. Young  
Vice President, Reliability and Quality Assurance  
Boston Scientific Cardiac Rhythm Management