

January 25, 2010

Subject: Completion of Product Advisory activities related to the potential for missed alerts from a subset of LATITUDE[®] communicators (Models 6468 and 6476)

On September 9, 2009, Boston Scientific issued a product advisory to health care professionals regarding the potential for missed alerts from LATITUDE Model 6468 and Model 6476 in-home communicators. At that time, health care professionals with patients enrolled in the LATITUDE Patient Management system were notified of this advisory by their local Boston Scientific representative and/or via registered mail. This advisory applied only to remote monitoring equipment, used to transfer memory information from an implanted device to a physician-accessible website. It did not involve the implanted defibrillator, lead system, or programmer.

For several months, Boston Scientific has manually reviewed weekly interrogation data collected by affected Model 6468 and 6476 communicators and contacted you by phone or fax if an out-of-range *Daily Measurement* failed to display a corresponding Red or Yellow Alert on the LATITUDE Website. Boston Scientific also reconfigured patient schedules as needed to ensure that communicator data was available for weekly review.

Boston Scientific has implemented software enhancements that will display alerts as intended. When a patient's communicator next establishes contact with the LATITUDE website, new software will be automatically downloaded to the communicator, which ensures that both red and yellow alert notifications are sent to the LATITUDE Website as described in Instructions for Use and according to the schedule prescribed by the physician. ***Weekly Device Alert Interrogations and Daily Device Check may once again be configured as desired.*** No further actions are required by clinicians or patients.

Further Information

If you have any questions regarding closure of this advisory communication, please contact your local Boston Scientific CRM representative or LATITUDE Customer Support at 1.800.CARDIAC (227.3422).

LATITUDE Customer Support