Urgent Medical Device Correction

Rhythm Management
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August 2026

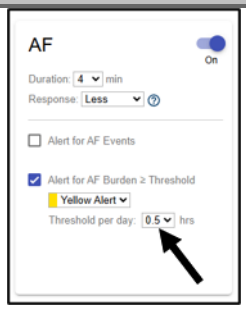
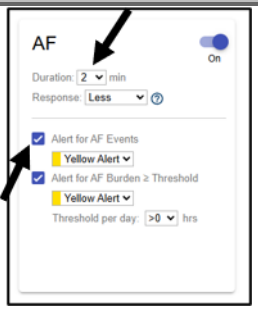
Subject: Product Advisory – Potential delayed AF Burden Alert notification from LATITUDE™ Clarity when AF Burden Alert Threshold is set to “>0 hours per day” for LUX-Dx™ family of Insertable Cardiac Monitors (ICMs). Field Action Reference 97627645A-FA

Dear LATITUDE Clarity Clinic Account Manager,

Boston Scientific is notifying you of the potential for a delay in AF Burden Alert notification affecting the LATITUDE™ Clarity server software which supports the LUX-Dx™ family of ICMs. This delayed AF Burden Alert notification behavior by LATITUDE Clarity may occur if the Alert for AF Burden ≥ Threshold is configured to ">0 hours per day" setting (a non-default configuration).

The ICM is performing as intended with continued AF detection, data storage, and transmission of device data. Boston Scientific has received one complaint related to this delayed notification behavior by the LATITUDE Clarity System. No patient injuries or deaths have been reported. A server software update is planned to correct this behavior.

Configuration Options for Atrial Alert Notifications: Atrial arrhythmia alert notification preferences may vary, and AF configurations may be set for individual patients and/or group settings. Until updated server software is available, consider the following options:

Change Threshold for AF Burden Alert Setting	Enable AF Events Alert with Minimum Duration	If Unchanged, Potential Delay in AF Burden Alert Notification
		
Changing the AF Burden Alert setting to any setting other than “>0 hours per day” will mitigate notification delays and minimize alerts for each arrhythmia event.	Changing Duration setting to 2 min and enable AF Events Alert will provide most timely AF alert.	If there is no configuration change in AF Burden Alert ≥ Threshold setting from “>0 hours per day”, a notification delay may occur.
Implication: The next shortest interval setting is “0.5 hours per day.” If an atrial arrhythmia remains above the threshold for multiple days, only one alert is initiated (e.g., one alert per AF event).	*Implication*: If an atrial arrhythmia remains above the threshold for multiple days, then AF alerts will be initiated each day the arrhythmia persists (e.g., potential for multiple alerts per AF event).	*Implication*: If delaying AF Burden notifications until next scheduled remote follow-up is not clinically meaningful for the patient, then no changes are required.

- Boston Scientific does not recommend replacement of the implanted ICM.
- Please share this notification with all HCPs within your organization who manage patients using the LUX-Dx ICM and LATITUDE Clarity System.

Description of the Behavior. Boston Scientific has identified that, when the Alert for AF Burden ≥ Threshold is configured to ">0 hours per day" setting, LATITUDE does not convert the daily device check to a full device interrogation as intended. In the absence of a full device interrogation, the LATITUDE Clarity system is unable to evaluate the alert.

As a result, notification of an AF Burden Alert may be delayed until the next full device interrogation. A full interrogation is initiated by detecting another alert, a scheduled remote follow-up, or a patient-/clinic-initiated interrogation. The following pre-conditions must be met for a delayed notification of atrial arrhythmias to occur:

1. The AF Burden ≥ Threshold Alert is set to ">0 hours per day"; and
2. An arrhythmia meeting the alert criteria is present in the AF Burden trend data; and
3. The absence of any other event triggers to initiate a full device interrogation before the next scheduled follow-up.

If a full device interrogation occurs—for example, through another alert, scheduled remote follow-up, or a patient-/clinic-initiated interrogation—the AF Burden Alert notification is displayed for clinical review.

Mitigation. The LATITUDE Clarity system is designed to detect atrial fibrillation through two independent mechanisms: AF Burden and AF Event Alerts. Until a software update to the LATITUDE Clarity server software is available, configuring AF Events or changing AF Burden Alerts settings can mitigate delays in full device interrogation and enable the LATITUDE Clarity system to display alert notification as intended.

Potential Clinical Impact. The most common outcome associated with a delayed clinician notification of the AF Burden Alert is no patient harm. While delayed notification of an AF Burden Alert may delay clinical evaluation or therapeutic intervention of an atrial arrhythmia, no patient injuries or deaths have been reported, and the most serious clinical consequences for untreated atrial arrhythmias remain hypothetical.

Products Affected. This advisory applies to the following LATITUDE Clarity server software models which support the LUX-Dx ICM System.

Geography	GTIN	Model	Description
United States	00802526613838	7260	LATITUDE Clarity server software
Europe	00802526613883	7246	LATITUDE Clarity server software
Australia / New Zealand	00802526613852	7248	LATITUDE Clarity server software

Additional Information. The Regulatory Authority of your country has been informed of this communication. Adverse events should be reported to Boston Scientific or the FDA's MedWatch Adverse Event Reporting program.

Boston Scientific is committed to providing high-quality products and appreciates your partnership in caring for patients. We apologize for any inconvenience this may cause. If you have questions regarding this advisory, please contact your local Boston Scientific representative or Boston Scientific RhythmCARE Services.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance