July 8, 2022

Canadian Heart Rhythm Society
Device Committee

Boston Scientific Model 2868 Software on Model 3120 ZOOM Programmers, When Used in Conjunction with Transvenous Defibrillators.

Nature of the Advisory: Boston Scientific has moved towards employing the use of newer Model 3300 LATITUDE programmers. However, global supply chain challenges have constrained availability of the newer programmers meaning that the older 3120 ZOOM programmers remain in clinical use. While these programmers function reasonably well in most circumstances, the continued use of the older 2868 software on the 3120 ZOOM programmer may lead to unexpected behaviors when attempting communications with transvenous defibrillators.

The 3120 ZOOM programmers where the 2868 software was uninstalled can no longer interrogate transvenous defibrillators. If a user attempts to interrogate a device without applicable software, a message is displayed notifying the user that software has been uninstalled on the programmer.

The 3120 ZOOM programmers where the 2868 software remains active may exhibit unanticipated behavior when interrogating a transvenous defibrillator. The newer Model 3300 LATITUDE programmers contain advanced software features, which are uploaded to the defibrillator firmware during the first interrogation with the newer Model 3300 LATITUDE programmers. When these updated devices are interrogated with the older generation 3120 ZOOM programmer, some parameters such as Signal Artifact Monitor (SAM), Post Operative System Test (POST), and rate adaptive pacing (MV and accelerometer) may be omitted or display incorrectly.

In the case where a Signal Artifact Monitor (SAM) episode is detected by the device, interrogation with the older generation 3120 ZOOM programmer will present the Error Log and Halt message. This error message is an indication of an incompatibility of any 3120 ZOOM programmer with that specific defibrillator. If this behavior occurs STAT PACE, STAT SHOCK, and DIVERT THERAPY programmer operations are not available. While the defibrillator will operate as intended with the permanently programmed settings it cannot be interrogated with any 3120 ZOOM programmer and the user will need to use a 3300 LATITUDE programmer to interrogate the defibrillator.

A 2868 software update for the 3120 ZOOM programmer has been developed to resolve the Error Log and Halt behavior associated with TV defibrillators having a stored SAM episode. This update does not address potential incompatibility because of Post Operative System Test (POST). Boston Scientific will release software after approval has been obtained.

Scope of the problem: In Canada there are an estimated 400 newer Model 3300 LATITUDE programmers and 200 older generation 3120 ZOOM programmers in use at 200 clinical centres.

Response of the CHRS Device Committee:

- Routine follow-up should remain as per local standard of care and clinical protocol.
- Use the 3300 LATITUDE programmer when attempting parameter changes or initiating SAM or POST.
- Use the 3300 LATITUDE programmer when evaluating or programming rate adaptive settings for MV or accelerometer in MOMENTUM CRT-Ds and ICDs.
- If unable to interrogate a transvenous defibrillator with a 3120 ZOOM programmer (due to software uninstall or Error Log and Halt message), use a 3300 LATITUDE programmer instead.
- Consider programming Electrocautery Protection Mode (inhibits shock therapy while providing asynchronous pacing) or taping a magnet over the defibrillator (inhibits shock therapy without changing permanent pacing settings) during a surgical procedure to prevent inappropriate SAM episode(s) from being stored.
    - When disabling shock therapy with either Electrocautery Protection Mode or magnet application, SAM is disabled and interference with defibrillator function is mitigated.
    - If unable to interrogate and enable shock therapy after surgery using a 3120 ZOOM programmer, monitor the patient for ventricular arrhythmias until a 3300 LATITUDE programmer is available to re-enable shock therapy.

CHRS Device Committee

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