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Urgent Field Safety Notice

July 2022

Subject: Field Safety Notice – Continued use of older Model 2868 software on Model 3120 ZOOM™ programmers to support transvenous CRT-Ds and ICDs until supply chain constraints on newer programmers[1] are resolved. See Appendix A for affected GTINs (Boston Scientific Field Action Reference: 92822246-FA)

Summary

- Global supply chain challenges have constrained availability of the newer programmers.

- Until the supply chain constraints are resolved locally, you may continue using older 3120 ZOOM programmers.

- The 2868 software on the 3120 ZOOM programmer has been uninstalled or is outdated. As such, users may observe unexpected behaviors when attempting communications with transvenous defibrillators[2] including the potential inability to interrogate or the display of incorrect/missing parameters[3]

- A software update has been developed to resolve some of the disruptive behaviors associated with continued use of 2868 software on the 3120 ZOOM programmer. Boston Scientific will release software after local approval.

Figure 1. Model 3120 ZOOM Programmer

- The risk of insufficient programmer supply outweighs the risks associated with these unexpected behaviors, therefore, Boston Scientific recommends continued use of 3120 ZOOM programmers for transvenous defibrillators until sufficient supply of the newer programmers can be achieved locally.

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[1] Model 3300 LATITUDE™ programmer are newer Boston Scientific programmers
[2] Transvenous defibrillators (TV defibrillators) include both cardiac resynchronization therapy defibrillators (CRT-Ds) and implantable cardioverter defibrillators (ICDs)
[3] Model 2868 is the only outdated software on the 3120 ZOOM programmer
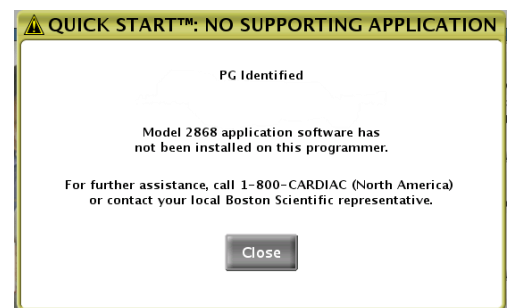
Dear Physician or Healthcare Professional,

We are writing to inform you that if limited supply of Model 3300 LATITUDE programmers exists locally, Boston Scientific recommends continued use of older Model 3120 ZOOM programmers. Consequently, users may observe some unanticipated behaviors not described in labeling if certain transvenous (TV) defibrillators are interrogated with outdated Model 2868 software on 3120 ZOOM programmers. The purpose of this letter is to describe potential interactions between TV defibrillators and the 2868 software installed on 3120 ZOOM programmers. These potential interactions do not alter TV defibrillation operation or programming.

Background

Model 2868 software facilitates interrogation of TV defibrillators by the 3120 ZOOM programmer. An enhanced version of TV defibrillator software was developed for newer Model 3300 LATITUDE programmers which upgrades firmware of each TV defibrillator as needed during the first interrogation.

As part of this software upgrade, product labeling was updated to direct users to avoid using outdated 2868 software and Boston Scientific began uninstalling this software from 3120 ZOOM programmers. Soon after, Boston Scientific became aware of the likelihood of pandemic-induced global supply chain constraints on 3300 LATITUDE programmer supply and discontinued the uninstallation process in most regions because there could be insufficient programmers to support implanted TV defibrillators. When 2868 software is uninstalled, the 3120 ZOOM programmer can no longer interrogate TV defibrillators. If a user attempts to interrogate a device without applicable software, a message is displayed (Figure 2) to notify the user that software has been uninstalled on the programmer. To determine if a programmer has 2868 software, select "About" on the programmer screen and review the list of software applications installed. Please note that, 2868 software is the only outdated application on the 3120 ZOOM programmer.
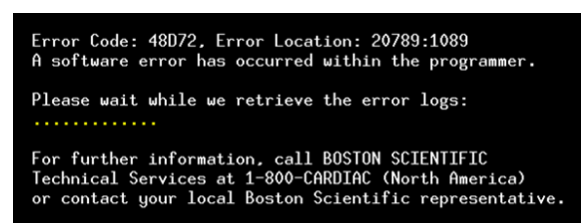

Figure 2. Message that displays when a Boston Scientific TV defibrillator is interrogated by a 3120 ZOOM programmer if 2868 software is uninstalled.

Description of Unanticipated Behaviors

In facilities whose 3120 ZOOM programmers still have 2868 software installed, there may be unanticipated behaviors observed when interrogating TV defibrillators. The most common behavior observed is an inability to interrogate a TV defibrillator due to a Signal Artifact Monitor (SAM) episode. SAM is one of the new TV defibrillator features included in the enhanced software found on the 3300 LATITUDE programmer. SAM is designed to continually monitor the electrogram for Respiratory/Minute Ventilation (MV) sensor artifacts. If artifacts are detected or sensor vector lead impedance measurements are out of range, SAM either switches the vector or disables the sensor, and a SAM episode is recorded.

If a TV defibrillator has a stored SAM episode, the 3120 ZOOM programmer will present the Error Log and Halt message in Figure 3, and the user will need to use a 3300 LATITUDE programmer to interrogate the defibrillator. This error message (Figure 3) is an indication of an incompatibility of any 3120 ZOOM programmer with that specific TV defibrillator. However, the TV defibrillator will operate as intended with the permanently programmed settings. After power cycling the programmer, it may be used to interrogate TV defibrillators without stored SAM episodes. If the user attempts to interrogate the same TV defibrillator with the 3120 ZOOM programmer, the Error Log and Halt message will display again.

Figure 3. The specific Error Log and Halt Message on 3120 ZOOM Programmer when interrogation of TV defibrillator with a SAM episode is attempted.

When using a 3120 ZOOM programmer, some TV defibrillator parameters such as SAM, Post Operative System Test (POST), and rate adaptive pacing (MV and accelerometer) may be omitted or display incorrectly. This is due to the software being unable to recognize certain parameter data from the TV defibrillator. If these parameters are left unchanged during the programmer interrogation, they will not alter the TV defibrillator's operation or programming.

Clinical Impact
Boston Scientific has determined that the risk of having an insufficient available supply of programmers outweighs the risks associated with these behaviors and recommends continued use of 3120 ZOOM programmers for TV defibrillators until sufficient supply of 3300 LATITUDE programmers can be achieved locally.

The behavior most likely to be attributed to potential harm when using a 3120 ZOOM programmer is the inability to interrogate a TV defibrillator (e.g. Figure 2 or 3). There have been 9 reports of this behavior which have resulted in a delayed/prolonged procedure until the defibrillator can be interrogated with a 3300 LATITUDE programmer. Furthermore, there has been a single report of delays in reprogramming for phrenic nerve stimulation and a single report of an inability to interrogate for delivery of commanded therapy. None of the reports associated with 3120 ZOOM programmer have resulted in permanent injury.

Recommendations: Please distribute this letter to all users of the 3120 ZOOM programmer and complete/return the Acknowledgment Form. Continue using 3120 ZOOM programmers to interrogate Boston Scientific TV defibrillators, as needed, with the following in mind:
1) If unable to interrogate a TV defibrillator with a 3120 ZOOM programmer, use a 3300 LATITUDE programmer instead. If this behavior occurs, STAT PACE, STAT SHOCK, and DIVERT THERAPY programmer operations[4] are not available through a 3120 ZOOM programmer, so external pacing/defibrillation or magnet application (to divert shock) may be required if a 3300 LATITUDE programmer is not immediately available.
2) When disabling shock therapy, 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. Product labeling cautions that the introduction of conducted electrical current from medical equipment may interfere with pulse generator function. Interference may generate MV sensor artifacts that can be detected by SAM. 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.
3) Affected features:
    a) Use the 3300 LATITUDE programmer when attempting parameter changes or initiating SAM or POST. These features are not available using a 3120 ZOOM programmer.
    b) Use the 3300 LATITUDE programmer when evaluating or programming rate adaptive settings for MV or accelerometer in MOMENTUM CRT-Ds and ICDs distributed in the US. Rate adaptive MV sensor is new for these defibrillators and the 3120 ZOOM programmer does not display MV rate adaptive pacing settings.

Adverse reactions or quality problems experienced with the use of these, or any devices, should be reported to Boston Scientific and your local regulatory authority, as applicable. Appendix A includes a list of GTINs for the 3120 ZOOM programmer.

[4]Buttons on the programmer that allow the user to initiate emergency bradycardia pacing (STAT PACE button), emergency shock therapy (STAT SHOCK button), or divert tachyarrhythmia therapy (DIVERT THERAPY button) on the device being interrogated.

A 3120 ZOOM programmer update to 2868 software has been developed to resolve the Error Log and Halt behavior associated with TV defibrillators having a stored SAM episode. This software update does not represent a material reduction in patient safety risk, however, it does prevent clinical workflow interruptions and will be released subsequent to approval.

Please complete the attached acknowledgement form, even if you do not have a 3120 ZOOM programmer (Figure 1 and Appendix A). We appreciate your consideration while we work through these supply chain challenges. When an adequate supply of 3300 LATITUDE programmers is achieved within the country, Boston Scientific will resume uninstalling 2868 software from the 3120 ZOOM programmer.

If you have additional questions regarding this information, please contact your Boston Scientific representative or Technical Services.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance

<u>Appendix A</u>: Affected Programmers

A Model 3120 ZOOM programmer is only affected if Model 2868 software installed. If Model 2868 software is uninstalled, the programmer cannot interrogate transvenous defibrillators and is not affected by the unexpected behaviors described herein.

Table 1. Affected Model 3120 ZOOM Programmers if Model 28168 software is installed

Description	GTIN			
Model 3120 ZOOM Programmer. Only programmers with Model 2868 Application installed are affected when interrogating transvenous defibrillators.	00802526434723,	00802526478246,	00802526523212,	00802526602900
	00802526435430,	00802526478253,	00802526526602,	00802526602917
	00802526437458,	00802526479663,	00802526526800,	00802526602924
	00802526441974,	00802526479670,	00802526526817,	00802526602931
	00802526442827,	00802526479687,	00802526527609,	00802526604584
	00802526444807,	00802526479694,	00802526527616,	00802526605406
	00802526444814,	00802526480638,	00802526527623,	00802526605437
	00802526445262,	00802526480652,	00802526532832,	00802526605468
	00802526454301,	00802526484599,	00802526535406,	00802526606304
	00802526454950,	00802526484605,	00802526554209,	00802526606311
	00802526456961,	00802526484803,	00802526554810,	00802526606342
	00802526467288,	00802526486081,	00802526557002,	00802526606359
	00802526467295,	00802526486906,	00802526557019,	00802526606366
	00802526467301,	00802526486913,	00802526561900,	00802526606403
	00802526467653,	00802526486920,	00802526562600,	00802526611308
	00802526468582,	00802526486937,	00802526564703,	00802526611322
	00802526469343,	00802526486944,	00802526564802,	00802526612411
	00802526469350,	00802526494406,	00802526564819,	00802526612428
	00802526469374,	00802526496608,	00802526565304,	00802526612442
	00802526473449,	00802526496615,	00802526565427,	00802526615603
	00802526474170,	00802526496622,	00802526574801,	00802526615627
	00802526474859,	00802526496639,	00802526574818,	00802526615634
	00802526475450,	00802526497605,	00802526575303	
	00802526475467,	00802526497629,	00802526579707	
	00802526475474,	00802526497643,	00802526579905	
	00802526475757,	00802526506703,	00802526579929	
	00802526475764,	00802526515903,	00802526581021	
	00802526475771,	00802526515910,	00802526582004	
	00802526475788,	00802526515927,	00802526582011	
	00802526477669,	00802526516009,	00802526582028	
	00802526477676,	00802526517112,	00802526582301	
	00802526477683,	00802526517136,	00802526583803	
	00802526478239,	00802526517174,	00802526587405	