

Product Correction

Model 3120 ZOOM Programmers

WAND #: 090701-WAND-671KBE

Medsafe Reference Number: 29645

Subject: Continued use of older Model 2868 TY+ software on Model 3120 ZOOM™ programmers to support transvenous CRT-Ds and ICDs until supply chain constraints on newer programmers¹ are resolved. (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 Model 3120 ZOOM programmers.
- The Model 2868 TY+ software on the Model 3120 ZOOM programmer has been uninstalled or is outdated. As such, users may observe unexpected behaviours when attempting communications with transvenous defibrillators² including the potential inability to interrogate or the display of incorrect/missing parameters³.
- A software update has been developed to resolve some of the disruptive behaviours associated with continued use of Model 2868 TY+ software on the Model 3120 ZOOM programmer. Boston Scientific will release software after regulatory approval.
- The risk of insufficient programmer supply outweighs the risks associated with these unexpected behaviours; therefore, Boston Scientific recommends continued use of Model 3120 ZOOM programmers for transvenous defibrillators until sufficient supply of the newer programmers can be achieved locally.



Figure 1. Model 3120 ZOOM Programmer

¹Model 3300 LATITUDE™ programmer are newer Boston Scientific programmers.

²Transvenous defibrillators (TV defibrillators) include both cardiac resynchronization therapy defibrillators (CRT-Ds) and implantable cardioverter defibrillators (ICDs).

³Model 2868 TY+ is the only outdated software on the 3120 ZOOM programmer.

July 2022

Dear Health Care 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unanticipated behaviours not described in labeling if certain transvenous (TV) defibrillators are interrogated with outdated Model 2868 TY+ software on 3120 ZOOM programmers.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 not been installed 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.

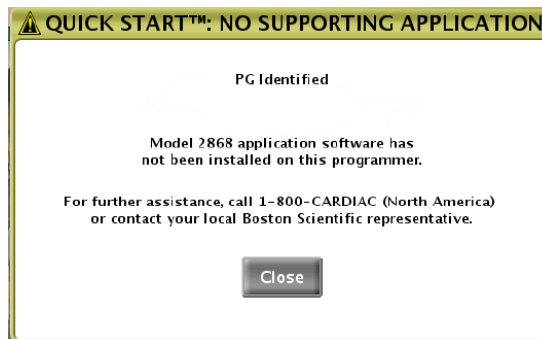
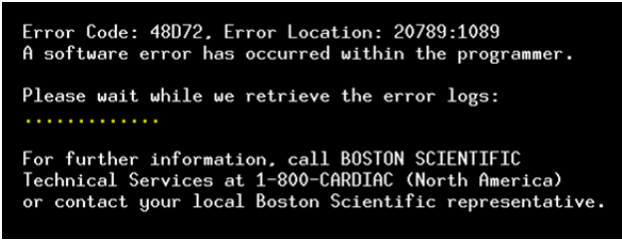


Figure 2. Message that displays when a Boston Scientific TV defibrillator is interrogated by a 3120 ZOOM programmer if 2868 TY+ software is uninstalled.

Description of Unanticipated Behaviours

In facilities whose 3120 ZOOM programmers still have 2868 software installed, there may be unanticipated behaviours observed when interrogating TV defibrillators. The most common behaviour 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 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.



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Error Code: 48D72. Error Location: 20789:1089
A software error has occurred within the programmer.

Please wait while we retrieve the error logs:
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For further information, call BOSTON SCIENTIFIC
Technical Services at 1-800-CARDIAC (North America)
or contact your local Boston Scientific representative.
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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 behaviours and recommends continued use of 3120 ZOOM programmers for TV defibrillators until sufficient supply of 3300 LATITUDE programmers can be achieved locally.

The behaviour 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 behaviour 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 enclosed 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 behaviour occurs, STAT PACE, STAT SHOCK, and DIVERT THERAPY programmer operations 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.

A 3120 ZOOM programmer update to 2868 software has been developed to resolve the Error Log and Halt behaviour 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 after approval.

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.

This action is being conducted following consultation with Medsafe, Ministry of Health.

Yours Sincerely



Seamus Gallagher
Quality Assurance Manager
Boston Scientific Pty Ltd Australia and New Zealand

Instructions

The Acknowledgment Form enclosed with this notification must be completed and returned **even if you no longer have any affected product.**

Please complete and email or fax your Acknowledgement Form immediately.

1. Please complete the enclosed acknowledgement form confirming you are aware of this Product Correction. Distribute this letter to Boston Scientific Model 3120 ZOOM Programmers users within your facility and ensure this information is known to all users of the device.

- Please complete the enclosed acknowledgement form confirming you are aware of this Product Correction.
- Return the form as described below:

Email: ANZ_Incident_Report@bsci.com

or

Fax to 0800 329 267

NOTE: If you respond to this notification to anyone other than Boston Scientific, Boston Scientific will not have received your response. Please respond using the email/fax information provided above.