

July 2022

Subject: Field Safety Notice – Uninstallation of Model 2868 software from Model 3120 ZOOM™ programmers. (Boston Scientific Field Action Reference: 92822246-FA)

The Model 2868 software on the Model 3120 ZOOM programmer is outdated and will be uninstalled. Your local Boston Scientific sales professionals have begun this uninstallation process.

Model 2868 software facilitates interrogation of transvenous defibrillators¹ by the 3120 ZOOM programmer. For Model 3300 LATITUDE the programmers, an enhanced version of TV defibrillator software was developed that upgrades firmware of each TV defibrillator as needed during the first interrogation. When 2868 software is uninstalled from the 3120 ZOOM programmer, it can no longer interrogate TV defibrillators. If a user attempts to interrogate a device without applicable software, a message is displayed (Figure 1) 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 Please note that 2868 software is the only outdated application on the 3120 ZOOM programmer.

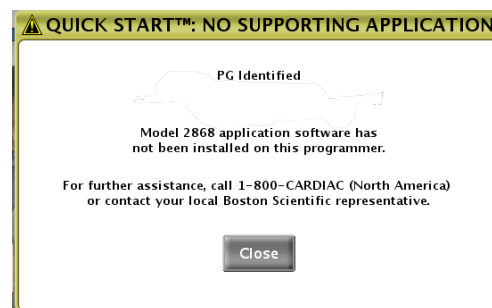


Figure 1. Message that displays when a Boston Scientific TV defibrillator is interrogated by a 3120 ZOOM programmer if 2868 software is uninstalled.

Clinical Impact

Continued use of 3120 ZOOM programmer with outdated Model 2868 software has the potential to result in an inability to interrogate a TV defibrillator. 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 work with your local Boston Scientific sales professional to identify/uninstall Model 2868 software from affected 3120 ZOOM programmers at your facility.

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. Please complete and return the enclosed Acknowledgement Form. It is mandatory for each customer receiving this letter from Boston Scientific to

¹Transvenous defibrillators (TV defibrillators) include both cardiac resynchronization therapy defibrillators (CRT-Ds) and implantable cardioverter defibrillators (ICDs)

Uninstall Model 2868 Software from Model 3120 ZOOM Programmers

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

Sincerely,



Alexandra Naughton
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