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Online Patient Guide

Firmware Updates to Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)

Technology and its security are always evolving, and at Abbott, we are committed to ensuring our products include the latest advancements and protections for patients.

We want to inform you about a planned upgrade to the firmware installed on your implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D). This firmware upgrade incorporates two updates to improve performance and further strengthen the security of these devices. These updates are part of Abbott's ongoing commitment to continuously improve patient care.

The first update, called a battery performance alert, gives your device the ability to automatically detect abnormal battery function and notify you directly with a vibrating alert in the event it does. This battery performance alert update is for patients with Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™ devices manufactured between January 2010 and May 2015. The second update further strengthens security protections on your device to prevent anyone, other than your doctor, from changing the settings on your defibrillator. This security update is for patients with Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™, Unify Quadra™, Promote Quadra™ and Ellipse™ devices. Each of these is part of a planned series of updates that began with pacemakers, programmers and remote monitoring systems in 2017.

Firmware is a kind of software that is embedded in the ICD and CRT-D. Devices that use software, such as that in your ICD or CRT-D, may require updates from time to time, as technology and security for connected devices and systems continues to evolve.

As with any firmware or software update, there can be risks and we encourage you to discuss the risks and benefits of the update with your doctor to determine what is right for you. If you and your doctor feel that it is appropriate for you to receive the firmware upgrade, it can be done during your next regularly scheduled visit to your doctor, or when appropriate depending on your and your physician's preferences.

To help keep you informed, this patient guide provides responses to Frequently Asked Questions (FAQ) related to the ICD and CRT-D firmware upgrade. In addition, if you have any further questions, please contact Technical Services at 1-800-436-5056 (U.S.)

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or visit our website at www.sjm.com/notices. As always, you should discuss the risks and benefits of any medical procedure with your doctor.

FAQ

1. **What is the purpose of the new ICD and CRT-D firmware upgrade?**

   The ICD and CRT-D firmware upgrade incorporates two updates designed to strengthen the security and improve the performance of your ICD or CRT-D.

   The **battery performance alert (BPA) update** (BPA) provides an additional way to detect abnormal battery performance in your implanted device. The BPA update allows your device to monitor itself for abnormal battery behavior and provide an automatic vibrating alert directly to you if any abnormal battery performance and/or premature battery drain is detected. (This ability to detect potential premature battery depletion was previously only available on the Merlin.net remote monitoring system or during in-office doctor visits via the Merlin programmer).

   The **security update** provides an additional layer of protection against unauthorized access to your device. It is intended to prevent anyone other than your doctor from changing your device settings. Abbott has had **no** reports of hacking or unauthorized access to any patient's implanted device.

   Each of these are planned updates, and part of Abbott's ongoing commitment to improve patient care and make our products more secure.

2. **What do I need to know about the ICD and CRT-D upgrade process?**

   Abbott's recommendation, and that of our Medical Advisory Boards, is that you have a conversation with your physician to determine if the firmware upgrade is right for you. If you and your physician decide that it is, the firmware upgrade can be performed during your next regularly scheduled in-office visit, or whenever you and your physician deem appropriate. During the upgrade a wand will be placed over your ICD or CRT-D and will transfer the information to the device. At the end of the process, the final settings on your device will be reviewed to ensure that the updates have been completed successfully. The upgrade process takes approximately three minutes to complete.

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3. How do I know if I need these updates?

These updates are recommended for all eligible patients. We know every patient's circumstance is unique, however, so we encourage you to discuss these updates with your doctor. In some cases, doctors and patients will decide that the risks that could be associated with performing the ICD and CRT-D upgrade may outweigh the benefits for some patients. If you do not receive the upgrade, your defibrillator will continue to function as intended, and you can receive the upgrade at any future time.

The security update applies to the following ICD and CRT-D device families that use wireless radio frequency (RF) communication: Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™, Unify Quadra™, Promote Quadra™ and Ellipse™.

The battery performance alert update applies to the following devices: Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™, and Unify Quadra™ manufactured between January 2010 and May 2015.

The updates will be made available to current patients over the next several weeks.

Defibrillators distributed after April 19, 2018 will have these updates pre-loaded in the device.

For patients with Current™ or Promote™ devices, which are older generation devices that are not capable of accepting the firmware updates due to technology limitations, please refer to Question #8 below.

4. What are the risks associated with the new ICD and CRT-D updates?

We encourage you to discuss the risks and benefits of receiving the updates with your doctor. With any firmware update, there is the potential for a very low rate of device malfunction. However, we anticipate the updates will occur as planned. In our recent pacemaker firmware update experience, for example, there have been **zero** device failures and **zero** serious adverse events reported in the more than 50,000 updates to date.

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5. **How likely is it that my device will have premature battery drain?**

   The likelihood that this will impact your health is low, as the vast majority of devices have not experienced premature battery depletion. More information about this issue can be obtained from your physician or found at our website www.sjm.com/batteryupdate.

6. **How likely is it that someone could gain unauthorized access to my device?**

   We have received **no** reports of unauthorized access to any patient's implanted device. As with the previous pacemaker updates, the U.S. Department of Homeland Security reports compromising the security of these devices would be extremely difficult and require a high level of expertise.

7. **Does this mean I should have my ICD or CRT-D removed?**

   No, Abbott and the U.S. Food and Drug Administration do not recommend replacement of implanted defibrillator devices as a result of these updates. Your ICD or CRT-D remains fully effective for pacing and defibrillation, as designed.

8. **Should I continue to use my home monitor?**

   We recommend that you continue to use your Merlin@home™ device, as it allows your physician to more frequently receive, assess, and monitor your device's function.

   If you have a Current™ or Promote™ device and are concerned about cybersecurity, there are additional considerations related to remote monitoring that you and your physician may wish to discuss at your next visit. (Please refer to Question #9 below).

   If you are not connected to a Merlin@home™ device and would like to learn more, you can find additional information at www.sjm.com/cyberupdate.

9. **What should I do if I have a Current™ or Promote™ device?**

   For patients with older generation Current™ or Promote™ devices, which are not capable of accepting the firmware updates due to technology limitations, we have advised doctors of the option to disable your device's wireless RF communication capability using Merlin™ programmer software version 24.2.x or later.

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It's important to note that when RF communication is permanently disabled in the device, you can no longer be monitored remotely using an RF Merlin@home™ transmitter. Remote monitoring can be an important part of your care, as it allows your doctor to more frequently receive, assess, and monitor your device's function.

For patients followed through the Merlin.net™ remote monitoring system, we - along with our Medical Advisory Boards - recommend discussing the risks of cybersecurity vulnerabilities and benefits of remote monitoring with your physician at the next regularly scheduled visit.