

Over the last 24 months, physicians worldwide have updated approximately 406,000 implanted Abbott pacemakers and ICDs to improve cybersecurity. Based on the physician and patient experience with these updates, Abbott and FDA **continue to recommend the firmware update for all eligible patients to ensure protection against current and future cybersecurity risks.**

As a reminder, all new devices issued by Abbott offer our latest cybersecurity software, and for existing devices we are encouraging physicians to bring them to current standards.

To support our customers who may be seeking more information about the firmware download process, we are providing an update on the patient experience thus far and additional technical information related to ICD upgrades.

Reducing Risk to Your Patients

As of September 2019, approximately 25 percent of all active Abbott low- and high-voltage devices are estimated to have received the firmware update with a very low rate of complications. For the vast majority of patients, the process takes approximately 3 minutes to complete. As with any firmware update, there is potential risk.

To date, only 0.032 percent of more than 406,000 updates have resulted in complications of any type. Complications have included: pacing related discomfort due to backup VVI pacing settings (*0.020 percent*), minor harms such as dizziness or dyspnea (*0.007 percent*), major harms such as syncope (*0.0002 percent*) both associated with transient loss of pacing and devices requiring additional surgery (*0.004 percent*). These instances of additional surgery for ICDs were due to an existing hardware condition, and for pacemakers were due to physician discretion or situation specific issues.

The overall complication rate for pacemakers is very low (*0.050 percent*), and even lower for ICDs (*0.011 percent*).

Considerations for Updates

While Abbott recommends firmware updates for all ICDs and pacemakers, a small number of devices from **Unify, Fortify, Unify Assura, and Fortify Assura** ICD families, may not be able to complete the firmware update due to a previously existing telemetry hardware condition. In these cases, the ICD device may remain in back-up mode and not be able to return to normal function. Although the rate of occurrence is very low (*0.0037 percent*) we have seen some cases of device explant. Upon regulatory approval, which is expected in the next few months, Abbott will be able to avoid this scenario through new programmer software. You will be informed when this new programmer software is deployed, eliminating this particular complication and resulting in an estimated overall additional surgery rate of 0.002 percent.

The telemetry hardware condition discussed above does not impact any Ellipse ICDs or pacemaker families. For all of these devices, Abbott continues to recommend the firmware update for all eligible patients to ensure patients are protected against cybersecurity risks.

Working with Abbott Representatives to Perform Update

We have charged our field team to continue supporting you in prioritizing upgrades for devices that have not yet received firmware updates. If you have any questions, refer to Appendix A for detailed instructions on performing the update.

We anticipate regulatory approval for Merlin Programmer software v24.6.1 in the near future. Once available Abbott Field Sales Representatives will deploy this update which contains the mitigation for the telemetry hardware condition. You will then be notified by the representative that the mitigation to detect the telemetry hardware condition has been successfully installed on the programmers.

We appreciate your collaboration as we continue to update active devices. As technology evolves, we are committed to developing new advancements and necessary protections for patients. Abbott strongly believes that by staying at the forefront of technology related to our medical devices, we can offer the strongest protection possible to our customers and their patients.

Appendix A – Instructions for Performing Firmware Update

For physicians interested in performing the firmware update:

The firmware upgrade process takes approximately three minutes to complete, and during this time the device will operate in back-up mode (VVI pacing at 67 ppm) with high voltage therapy disabled. At the completion of the updates, the device will return to its pre-update settings. The process for the upgrade is as follows:

- The programmer will display an alert that an update is available on the FastPath summary screen. If you have previously declined the update, navigate to the Patient Data screen by selecting the Patient Data icon. Within the Patient Data screen, press the Device Upgrade Available button to open the Device Upgrade dialog.

Note: If the programmer detects that the patient is experiencing a high ventricular rate, the firmware update will not be available. This programmer behavior is intended to reduce risk by identifying patients who may be on the verge of needing therapy. During the firmware update, the device is placed in a mode where therapy is not available. Therefore, performing a firmware update at that time could prevent the patient from receiving therapy that is needed. Once the patient's ventricular rate returns to normal, the update may be performed.

- Confirm that the device upgrade is ready to be performed and press the Upgrade Device button.
- The programmer will download new firmware to the patient's device. The download should complete in approximately three minutes.

Note: The telemetry wand must remain over the device until completion of the firmware update. If telemetry is lost, reposition the wand over the device and re-attempt the firmware download.

- Upon upgrade completion, an "Upgrade Successful" alert will appear on the screen.
- To properly close the upgrade session, the End Session button must be pressed before removing the telemetry wand.
- Re-interrogate to verify proper device functionality.