Urgent Field Safety Notice

Battery Performance Alert and Cybersecurity Firmware Updates for Certain ICD & CRT-D Devices

23 April 2018

Dear Doctor,

As part of a planned series of system updates that began in 2017 with the release of Merlin@home™ v8.2.2 software, we are writing to make you aware of new firmware intended to further strengthen the security and improve the performance of our high voltage implantable cardiac devices (ICDs and CRT-Ds). The firmware upgrade is recommended for all eligible patients and includes the following updates:

1. a **battery performance alert update** to provide further detection capability for premature battery depletion in certain high voltage devices (i.e., Battery Advisory Devices), and
2. a **cybersecurity update** to provide an additional layer of protection against unauthorized device access.

This firmware upgrade will be made available following local regulatory approval. The information provided below is intended to assist clinicians and patients in understanding this firmware upgrade and the associated benefits and risks.

Firmware Update for Device-Based Detection of Abnormal Battery Performance in Battery Advisory Devices

This firmware upgrade incorporates the Battery Performance Alert (BPA) for device-based detection of abnormal battery performance due to lithium cluster induced shorts in our Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™, and Unify Quadra™ devices manufactured between January 2010 and May 2015 which are subject to the October 11, 2016 Medical Device Advisory ("**Battery Advisory Devices**").

As communicated in August 2017, the BPA algorithm is a management tool and is intended to provide earlier notification of abnormal battery performance for Battery Advisory Devices prior to premature battery depletion. Until now, detection of this alert has only been available through the Merlin.net™ remote monitoring system and the Merlin™ programmer during routine follow-up evaluations. This firmware update now allows for device-based detection of abnormal battery performance and if BPA is triggered, a vibratory notification is delivered to the patient, thereby ensuring continuous monitoring in situations where adherence to transmission schedules is challenging (e.g., travel). Additionally, an alert will continue to be provided to physicians through the Merlin.net™ remote monitoring system and the Merlin™ programmer during follow-up evaluations.

Additional information, including the above referenced physician communications and detailed information on the BPA algorithm, testing methods and performance can be found on our website www.sjm.com/notices.

Finally, please review the updated information regarding a small number of your Battery Advisory patients who are eligible for this firmware update provided in Attachment A to this letter.

Firmware Update for Cybersecurity

The cybersecurity firmware update provides additional security to reduce the risk of unauthorized access to the following high voltage device families that utilize wireless radio frequency (RF) communication: Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™, Unify Quadra™, Promote Quadra™ and Ellipse™.

Older generation devices (i.e., Current™ and Promote™) are not capable of accepting the firmware update due to technology limitations. If you have any concerns relating to device cybersecurity for patients implanted with Current™/Promote™ devices, you do have the option to permanently disable the RF communication capability in the device. However, if you choose that option, the patient can no longer be monitored remotely using an RF Merlin@home transmitter. For most patients, permanently disabling RF is not advisable.

As with our 2017 cybersecurity updates for pacemakers, we have received no reports of device compromise related to cybersecurity vulnerabilities in the implanted devices associated with this communication. According to the U.S. Department of Homeland Security, compromising the security of these devices would require a highly complex attack. If there were a successful attack, an unauthorized individual (i.e., a nearby attacker) could gain access and issue commands to the implanted medical device through radio frequency (RF) transmission capability, and those unauthorized commands could modify device settings (e.g., stop pacing) or impact device functionality.[1]

Battery Performance and Cybersecurity Firmware Upgrade Process and Associated Risks

The firmware upgrade process takes approximately 3 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 upgrade, the device will return to its pre-upgrade settings. Refer to Appendix for detailed back-up mode settings including pacing outputs, and for further description of the firmware upgrade process.

As with any software update, there is the potential for a very low rate of malfunction resulting from the update. These risks do not change or increase depending on which update(s) the device is receiving (i.e., cybersecurity and/or BPA). During our recent low voltage firmware upgrade experience, there were no serious adverse events reported. Approximately 0.62% of devices experienced an incomplete upgrade and remained in the back-up pacing mode. However, in each case, the devices were restored to the prior firmware version or received the upgrade successfully after Technical Services was contacted and intervened. Additionally, a small percentage (0.14%) of patients complained of diaphragmatic or pocket stimulation or general discomfort for the time that the device

[1] Refer to the ICS-CERT Communication ICSMA-18-135-0X

was in the back-up pacing mode. **There have been no (zero) cases reported to Abbott where the device remained in back-up mode following an attempted firmware upgrade.**

Potential risks with the firmware upgrade include, but are not limited to:

- discomfort due to back-up VVI pacing settings,
- reloading of previous firmware version due to incomplete upgrade,
- inability to treat VT/VF while in back-up mode given high voltage therapy is disabled,
- device remaining in back-up mode due to unsuccessful upgrade, and
- loss of currently programmed device settings or diagnostic data

Patient Management Recommendations (Battery Advisory and Cybersecurity)

Prophylactic replacement of affected devices is not recommended.

Recommendations for Devices Eligible for Firmware Upgrade

While not intended to serve as a substitute for your professional judgment, we, along with our Medical Advisory Boards, recommend the firmware upgrade for all eligible patients at the next regularly scheduled visit or when appropriate depending on the preferences of the patient and physician.

Please consider the following:

- Discuss the risks and benefits of the firmware update with your patients. As part of this discussion, it is important to consider whether the patient is implanted with a Battery Advisory device and take into account patient specific issues such as pacemaker dependence, frequency of high voltage therapy, age of device, and patient preference.
- If deemed appropriate, install this firmware update following the instructions on the programmer (and listed in the Appendix).
- The update should be performed with appropriate monitoring and external defibrillation equipment available.

The following additional recommendations **only** apply for patients implanted with Battery Advisory Devices:

- Patients receiving the firmware update should be advised that the device-based BPA will trigger a vibratory alert.
- In the absence of a BPA being triggered in a patient's device, through Merlin.net or the Merlin programmer, we continue to recommend adhering to the original patient management recommendations from the 2016 Premature Battery Depletion advisory (refer to Appendix). However, if the BPA is triggered, **immediate device explant and replacement is recommended**.

Recommendations for Current™ & Promote™ Devices not Eligible for Cybersecurity Firmware Update

For most patients, permanently disabling RF is not advisable given the proven benefits and improved survival associated with home monitoring.[2,3] If you have any concerns relating to device

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[2] Mittal, S., Piccini, J., Fischer, A., Snell, J., Dalal, N., & Varma, N. (2014, May). *Remote monitoring of ICD patients is associated with reduced mortality irrespective of device type*. Presented at the meeting of the Heart Rhythm Society, San Francisco, CA. This was a retrospective data review and had limitations.

cybersecurity for those patients implanted with Current™/Promote™ devices, you do have the option to permanently disable the RF communication capability in the device. However, if you choose that option, the patient can no longer be monitored remotely using an RF Merlin@home transmitter. Therefore we, along with our Medical Advisory Boards, recommend the following:

- Discuss the risks of cybersecurity vulnerabilities and proven benefits of remote monitoring with your patients at the next regularly scheduled visit.
- If deemed appropriate, RF communication may be permanently disabled during an in-clinic device interrogation with Merlin programmer software version 24.2.x or later by selecting the RF icon in the upper left corner of the FastPath summary screen.

If you have any questions about this device firmware update, you can contact your Abbott representative or our dedicated customer technical support hotline at +46-8474-4147 (EU). Additional materials, including a Patient Communication, can be found on www.sjm.com/notices.

Technology and security are always evolving, and Abbott is committed to ensuring our products include the latest advancements and protections for your patients. Your feedback is important to us, so please contact your Abbott representative with any questions or comments related to this update.

Sincerely,

Robert Blunt
Divisional Vice President, Quality
Cardiac Rhythm Management

[3] Mittal, S., Piccini, J., Fischer, A., Snell, J., Dalal, N., & Varma, N. (2014, May). *Increased adherence to remote monitoring is associated with reduced mortality in both pacemaker and defibrillator patients*. Presented at the meeting of the Heart Rhythm Society, San Francisco, CA. This was a retrospective data review and has limitations.

APPENDIX

Table 1 - Model Family Eligibility

Model Family	High Voltage Firmware Update Available with Merlin Programmer SW v24.2.x or later	Device-Based Detection of Abnormal Battery Performance Available through FW Download	Ability to Disable RF through Merlin Programmer with SW v24.2.x or later
Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™, Unify Quadra™	All	Battery Advisory Devices Only	N/A
Ellipse™, Promote Quadra™	All	N/A	N/A
Current™, Promote™	N/A	N/A	All

Table 2 - High Voltage Device Settings During Firmware Download

Device Type	Parameter	Setting	Parameter	Setting
ICD*	Pacing Mode	VVI	Rate	67 ppm
	Pacing Configuration	RV Bipolar	Pacing Output	5.0 V @ 0.6 ms
CRT-D*	Pacing Mode	VVI, BiV Simultaneous	Rate	67 ppm
	Pacing Configuration	RV Bipolar; LV Tip – RV Ring	Pacing Output	5.0 V @ 0.6 ms
* Tachy Therapy & Detection is OFF for duration of firmware download process.				

Firmware Update Process

During the firmware update process the device will be temporarily placed in a back-up mode with high voltage therapy disabled. Clinicians are advised to record the programmed device settings before the update in case they are not properly restored after the update. The process for the update is as follows:

- **Abbott Representatives will update the Merlin™ programmer with new software**: The new programmer software will allow for device firmware to be updated.
- **The programmer provides an alert that an update is available when the device is interrogated**: After the programmer software has been updated and the device has been interrogated, the programmer will display an alert that an update is available on the FastPath summary screen. Before viewing the alert, device programmed parameters may be printed out as a record of the pre-update settings.
- **A follow up on-screen prompt is displayed on programmer**: Once the alert is selected, the physician will follow the on-screen instructions to continue.
- **The physician confirms and initiates the firmware update**: A 1-3 second pause in pacing is expected at the initiation of the update process. The programmer will download new firmware to the patient's device. The firmware update cannot be delivered remotely. During the update High Voltage therapy will be disabled automatically.

- **The download to device should complete within approximately three minutes**: 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.
- **After the update, re-interrogate to verify that the device is functioning appropriately and not in backup mode:** Check that the device parameters have been restored to the pre-update settings and confirm that high voltage therapy is enabled and diagnostic data are still present. If any of these do not occur, contact Abbott technical support.
- **If you have decided not to perform the update and wish to clear the firmware upgrade alert for future interrogations:** Select the alert from the FastPath summary screen on the Merlin™ programmer and follow the on-screen instructions to clear the device firmware upgrade alert. After clearing the alert, the firmware upgrade will only be accessible through the Patient Data screen.

Battery Advisory Device Patient Management Recommendations

- Conduct patient follow-up per standard practice.
- Prophylactic device replacement is **NOT** recommended because complications following replacement have been reported to occur at a greater rate than the rate of harm associated with premature battery depletion due to lithium cluster induced shorts.
- In the event of a BPA or ERI indicator in these devices, immediate device change is recommended.
- Physicians should reaffirm the availability of home monitoring to avoid or minimize time without device therapy for bradycardia and tachycardia events.
- Enroll patients in Merlin.net™ utilizing the "Direct Alerts" feature to provide you with an immediate alert notification in the event BPA is triggered or ERI is reached. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring.
- Review the most recent Programmed Parameters printout.
  - Ensure that under the "Trigger Alerts When" section, that the "Device at ERI" parameter is ON (it is normally ON) for both "Show on FastPath" and "Notify Patient" selections.
  - If the "Device at ERI" alert is OFF, we recommend that the patient be seen promptly to program this parameter ON.
- **Advise patients that the device-based BPA and ERI indications trigger a vibratory alert. (Updated recommendation)**
- At the next scheduled office visit:
  - Interrogate the patient's device to determine if a BPA or ERI alert has been triggered. Premature battery depletion can be identified by physicians through home monitoring showing BPA, ERI or more advanced battery depletion.
  - Perform a patient notifier test to confirm that the patient feels and recognizes the vibratory alert.
- Patients who cannot feel the vibratory alert may experience a BPA, loss of battery and/or loss of device function without their awareness.
- Advise the patient to contact your office promptly should they feel a vibratory alert.
  - In-office evaluation should be performed to determine the reason for the alert as other non-critical events can also trigger a vibratory alert.

ATTACHMENT A

Updated Information Regarding Battery Advisory Patients

The incorrect model number was communicated during the October 11, 2016 Medical Device Advisory for Lithium Clusters for a small number of devices impacted by the advisory. The serial number was correct, but the model number was not. For example, a device which was distributed as model CD2257-40Q and serial number 123456 was listed on the original notification letter as model CD2259-40Q and serial number 123456.

Subsequently, this same error prevented these devices from being incorporated correctly into Merlin.net™ and the Merlin™ Programmer software during implementation of the Battery Performance Alert (BPA) algorithm. As a result, these devices have not had BPA monitoring by the Merlin™ Programmer or Merlin.net™ since the introduction of the algorithm in August 2017. We have corrected the incorrect model information in Merlin.net™, such that any enrolled patient who is actively transmitting is now, and will continue to be, monitored for BPA going forward. Additionally, the Merlin™ Programmer software version 24.2.x has been updated to correct the model information and allow for BPA detection in-clinic.

Based on our records, you are currently managing one or more patients impacted by this issue and we are recommending that these patients receive the firmware upgrade as discussed in the enclosed physician letter. Details of these specific device model and serial number(s) are shown in Table 1, below.

Table 1 – Patient and Device Information

Patient Initials	Device Serial Number	Incorrect Model from October 2016 Advisory	Corrected Model Number