Abbott

URGENT FIELD SAFETY NOTICE

Battery Performance Management Tool for Implantable Cardioverter Defibrillator with Risk of Premature Battery Depletion from Lithium Cluster Induced Shorts

28 August 2017

Dear Doctor,

We are writing to make you aware of an impending update to 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 ("Impacted Devices", see Table 1 below for affected devices).

Previously, there has been no method to identify devices subject to premature battery depletion prior to devices reaching the ERI voltage. However, we have developed a new management tool for patients who have Impacted Devices, in order to provide an earlier notification of abnormal battery performance that may lead to premature battery depletion due to short circuits from lithium clusters. This tool is not currently available, but will be launched in your region following local regulatory approval.

New Battery Performance Alert for Identification of Abnormal Battery Performance

The Battery Performance Alert (BPA) is intended to provide notification of abnormal battery performance for Impacted Devices prior to premature battery depletion, and before the device reaches the ERI voltage. Battery information is uploaded automatically each night to Merlin.net™ where the most recent 32 days of data are analyzed each day to determine if an anomalous battery voltage trend is observed. Once the BPA is triggered, notification is provided to physicians through the Merlin.net™ remote monitoring system and the Merlin™ programmer during routine follow-up evaluations. For patients not followed remotely with Merlin.net, the status of their battery and whether the BPA has triggered an alert can only be determined with in-person interrogation using the Merlin™ programmer.

The algorithm was developed by evaluating diagnostic data from returned devices to identify battery voltage trends that commonly indicate premature battery depletion. Testing of the new BPA has shown that it can accurately differentiate between normal and abnormal battery behavior with 97.8% sensitivity and 99.8% specificity. Therefore, it can be used as a patient management tool to assist in predicting future premature battery depletion in Impacted Devices that suffer short circuits from lithium clusters. More detailed information on the BPA algorithm testing methods and performance can be found on our website www.sjm.com/notices.

The BPA alert will be implemented for remote monitoring patients via Merlin.net and will also be available on the Merlin™ programmer. For patients followed via Merlin.net™ remote monitoring, the system will be automatically configured for daily transmission. Upon configuration, any deviation from normal battery function identified using BPA will be reported to the clinician within 24 hours of being detected. Additionally, once a Merlin™ programmer is updated with the latest (Model 3330 Version23.1.2) software, interrogation of an Impacted Device will allow for display of the BPA when triggered.

Patient Management Recommendations

In the absence of a BPA being triggered in a patient's device, we will continue to recommend adhering to the patient management recommendations from the 2016 Premature Battery Depletion advisory. However, once the BPA is triggered, a short circuit is occurring so **immediate device explant and replacement is recommended** as functionality may be limited to **days rather than weeks.** The previous patient management recommendations with the inclusion of the BPA are listed below:

- Do not implant unused affected devices.
- 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. (Updated recommendation)**
- 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 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 an ERI indication triggers a vibratory alert. At the next scheduled office visit:
    - Interrogate the patient's device to determine if an ERI alert has been triggered. Premature battery depletion can be identified by physicians through home monitoring showing 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 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.

Should you have questions about patient management now or at the time this tool is launched, including observed changes in battery longevity, please contact your local Sales Representative or Abbott Technical Services at +46-8474-4147 (EU),which is available 24 hours a day, 7 days a week. Information on this BPA algorithm management tool can be found on www.sjm.com/notices along with information on the prior updates.

Sincerely,

Susan Jezior Slane
Divisional Vice President, Global Quality Systems and Compliance
Cardiovascular and Neuromodulation

Attachments

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APPENDIX

Table 1 – O.U.S. Models

Model	Trade Name	Model	Trade Name	Model	Trade Name	Model	Trade Name
CD1233-40	Fortify™ VR	**CD2233-40Q**	Fortify™ DR	**CD3251-40**	Unify Quadra™	**CD3361-40C**	Unify Assura™
CD1233-40Q		**CD2235-40**	Fortify™ ST DR	**CD3251-40Q**		**CD3361-40Q**	
CD1235-40	Fortify™ ST VR	**CD2235-40Q**		**CD3255-40**	Unify Quadra MP™	**CD3361-40QC**	
CD1235-40Q		**CD2259-40**	Fortify Assura™ DR	**CD3255-40Q**		**CD3367-40**	Quadra Assura™
CD1259-40	Fortify Assura™ VR	**CD2259-40Q**		**CD3261-40**	Unify Assura™	**CD3367-40C**	
CD1259-40Q		**CD2299-40**	HeartMinder™ ST DR	**CD3261-40Q**		**CD3367-40Q**	
CD1299-40	HeartMinder™ ST VR	**CD2299-40Q**		**CD3267-40**	Quadra Assura™	**CD3367-40QC**	
CD1299-40Q		**CD2359-40**	Fortify Assura™ DR	**CD3267-40Q**		**CD3371-40**	Quadra Assura MP™
CD1359-40	Fortify Assura™ VR	**CD2359-40C**		**CD3271-40**	Quadra Assura MP™	**CD3371-40C**	
CD1359-40C		**CD2359-40Q**		**CD3271-40Q**		**CD3371-40Q**	
CD1359-40Q		**CD2359-40QC**		**CD3281-40**	Excelis Quadra™	**CD3371-40QC**	
CD1359-40QC		**CD2391-40C**	HeartMinder™ + DR	**CD3281-40Q**		**CD3385-40C**	Quadra + Excelis™
CD1391-40C	HeartMinder™ + VR	**CD2391-40QC**		**CD3297-40**	Excelis™ CRT-D	**CD3385-40QC**	
CD1391-40QC		**CD3235-40**	Unify™	**CD3297-40Q**		**CD3389-40C**	Excelis™ +
CD2233-40	Fortify™ DR	**CD3235-40Q**		**CD3361-40**	Unify Assura™	**CD3389-40QC**	