



Urgent Medical Device Correction

Confirm Rx™ Insertable Cardiac Monitors with Incorrect
Low Battery Indicators due to Cold Temperature

May 18, 2018

Dear Doctor,

Abbott is advising physicians that exposure to sub-freezing temperatures during our supply chain process caused a transient battery voltage drop for a small number of Confirm Rx™ Model DM3500 Insertable Cardiac Monitoring (ICM) devices. This drop is an expected and normal behavior for this battery chemistry, but causes an incorrect display of a low battery indicator even after the battery voltage returns to normal.

Overall, we have experienced a 0.41% rate of incorrect display due to cold temperatures experienced by the device, prior to implant, during recent winter months in the United States. Some of these affected devices are already implanted and there have been a small number of instances where the low battery indicator triggered an explant that was not medically necessary. While all affected devices continue to provide appropriate monitoring and arrhythmia detection, they exhibit slower communication speed due to the incorrect low battery indicator condition.

Updated Merlin™ programmer software version 24.2.x will be made available over the next several weeks and will allow physicians to detect the presence of a Confirm Rx™ device incorrect low battery indicator prior to implant. Additionally, the programmer software will provide a mechanism to resolve the incorrect display for already implanted devices.

Patient Management Recommendations

Prophylactic replacement of affected devices is not recommended.

In order to correct implanted devices or detect affected units before implant, it is required to update to Merlin™ programmer software version 24.2.x or later. If you do not yet have this software version, you may contact your Abbott representative to facilitate in upgrading your programmer(s).

Recommendations for Patients with Implanted Devices

Abbott reviewed data in Merlin.net™ Patient Care Network to identify implanted devices with an incorrect low battery indicator. Patients confirmed to be impacted can be found in the enclosed Patient List. Additionally, implanted patients who could not be assessed for this condition through data available in Merlin.net™ PCN are included in this list. We recommend performing the following actions at the patient's next regularly scheduled visit:

- For patients confirmed to be impacted, contact Abbott Technical Services to assist in correcting the battery indicator.
- For Confirm Rx™ device patients requiring further assessment to determine potential impact, review post-implant programmer printouts or session records to determine whether a low battery indicator is present.
 - If a low battery indicator is observed, contact Abbott Technical Services to assist in confirmation and correction of the battery indicator display.

Recommendations for Devices not yet Implanted


For new implants, Merlin™ programmer software version 24.2.x or later will detect this incorrect low battery indicator condition. Interrogate all new Confirm Rx devices prior to implant. If the notification pop-up is displayed, follow the on-screen instructions to proceed with contacting Abbott Technical Services and select an alternate device for the implant.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

If you have any questions about this communication or the patient management recommendations, please contact your Abbott representative or Abbott Technical Support at **1-800-722-3774 (U.S.)**. Additional materials, can be found on www.sjm.com/notices.

Sincerely,



Robert Blunt
Divisional Vice President, Quality
Cardiac Rhythm Management