ST. JUDE MEDICAL

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Important Medical Device Correction Update
Potential for Backup Operation of an Implantable Device as a Result of Interaction with a Merlin@home™ RF Remote Monitoring Transmitter Model EX1150

Dear Doctor,

This letter will provide you with an update to a previous medical device correction from December 2014 pertaining to Merlin@home transmitters initiating a software reset that resulted in St. Jude Medical radio-frequency (RF) enabled implantable cardioverter defibrillators (ICDs) and pacemakers performing in a back-up safety mode. St. Jude Medical completed an automatic upgrade to correct the anomaly identified in the Merlin@home wireless transmitters. However, following additional reports of resets, we have identified that a second software anomaly coexisted in the Merlin@home system that also had the potential to cause software resets for St. Jude Medical devices. We are planning another software upgrade to Merlin@home transmitters and we expect it to be approved later this year. As a reminder, potentially affected RF devices include the St. Jude Medical Ellipse™, Fortify Assura™, Unify Assura™, and Quadra Assura™ ICDs and Assurity™ and Allure™ pacemakers.

Clinical Implications
In the event that an Ellipse, Fortify Assura, Unify Assura, or Quadra Assura ICD enters the back-up safety mode, the nominal operational settings will be VVI pacing mode, 67 ppm, 5.0v/0.6ms with bipolar pacing output and defibrillation settings of a VF detection rate of 146 bpm and 36J high voltage therapy. In the event an Assurity or Allure pacemaker enters backup mode, it will have output settings of VVI pacing mode, 67 ppm, 5.0v/0.6ms with unipolar pacing.

Please note, this anomaly can only occur when the patient is being actively monitored by a Merlin@home bedside transmitter. If a device enters backup mode, the ICD will deliver a patient vibratory alert and the pacemaker will deliver a patient audible alert. If backup operation is encountered, St. Jude Medical Technical Services (1-800-722-3774) can assist with non-invasively restoring the device to normal operation.

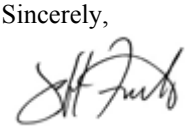
Root Cause
While both identified anomalies may result in a software reset of the device to a back-up safety mode, investigation of the issue has determined that the underlying root causes in the code are different. As indicated above, another software upgrade to Merlin@home transmitters is required.

Rate of Occurrence
To date, there have been no serious injuries reported to St. Jude Medical as a result of this anomaly. The likelihood of an RF-enabled ICD to be potentially impacted by this anomaly is .30 percent. The likelihood of an RF-enabled pacemaker to be potentially impacted by this anomaly is .07 percent.

Recommendations and Mitigations
The Merlin@home transmitter software has been modified to prevent this issue from occurring and is awaiting approval from FDA. Once available, a Merlin@home transmitter software update will be performed automatically over its telephone, broadband or cellular connection without requiring any action from you or your patients. No changes to your patient's remote or in-clinic follow up schedules are required. In the event a patient's device reverts to back-up mode, we recommend bringing the patient back in the clinic to clear the condition and return the device to full functionality.

We apologize for any inconvenience that this may cause you and your patients. At St. Jude Medical, our goal is to ensure all patients are treated with safe, effective and high-quality medical devices. If you have any questions or concerns, please do not hesitate to contact your local St. Jude Medical representative or St. Jude Medical's Technical Services Department.

Sincerely,



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