

Field Safety Notice

Merlin@Home™ and Merlin.net Remote Monitoring Cybersecurity Enhancements

Merlin@Home™ Software Model EX2000 v8.2.2 for
Merlin@Home™ Transmitter Models EX1150, EX1150W,
EX1100, and EX1100W

3 April 2017

Dear Merlin Clinic Administrator,

St. Jude Medical, an Abbott Laboratories company, recently received CE Mark approval in the European Union to deploy the latest cybersecurity updates for its Merlin@home™ patient transmitter and Merlin.net™ remote monitoring system. In recognition of the changing cybersecurity landscape, and the increased public attention on medical device cyber risks, we are informing the clinical community about these ongoing updates so that physicians and patients with transmitters can continue to be confident about the benefits of remote monitoring. The Merlin@home™ patient transmitter software version 8.2.2 includes security updates that complement the company's existing security measures and further reduce the already extremely low cybersecurity risks.

ESTIMATION OF CYBERSECURITY IMPACTS:

Abbott has not received any reports that a specific Abbott device or system in clinical use has been targeted and is not aware of any patient harm associated with cybersecurity incidents related to an Abbott device.

Though the risk is extremely low, if a highly skilled attacker were to gain unauthorized access to communications infrastructure (e.g., by spoofing cellular towers or telephone networks) and gain or have knowledge of the Merlin@home™ communication protocols, that attacker could potentially exploit a vulnerability to alter the Merlin@home™ Transmitter. The altered Merlin@home™ transmitter could then be used to issue or modify programming commands to the patient's implanted device, which could result in premature or rapid battery depletion and/or administration of inappropriate pacing or shocks. As noted above, there has been no reported instance of such an attack occurring in any Merlin@home™ Transmitter in the field.

RECOMMENDATIONS FOR HEALTH CARE PROVIDERS AND PATIENTS:

- Patients should ensure that their Merlin@home™ transmitter is plugged in and connected via cellular adapter, wi-fi or landline so the transmitter can receive these and any future updates.
- Health Care Providers should continue to conduct patient management using the Merlin.net™ Patient Care Network (PCN) and in-office follow-ups per normal routine with patients who have an implantable cardiac device that is monitored using the Merlin@home™ transmitter.
- For further information, health care providers can contact the local sales representative. In addition, both health care providers and patients can visit www.sjm.com/Merlin for answers to questions and additional information regarding Abbott's implantable cardiac rhythm devices, or the Merlin@home™ transmitter.

IMPLEMENTATION PLAN

In conjunction with the distribution of this communication, Merlin@home™ transmitters in the EU will become eligible to receive the software version 8.2.2 upgrade automatically via the Merlin.net™ Patient Care Network (PCN). The process for deploying this automatic software upgrade and future upgrades for Merlin@home™ transmitters is as follows:

- The Merlin@home™ transmitter software upgrade will be enabled today in the Merlin.net™ Patient Care Network (PCN).
- An ‘Over-The-Wire’ (OTW) upgrade will be initiated by the Merlin@home™ transmitters at the next connection.
- Depending on the mode and quality of the connection, the upgrade process can take up to several hours. It is important for patients to leave the transmitters connected.
- Abbott monitors the PCN to verify each upgrade completed successfully, and that the transmitter continues to connect to the Merlin.net™ PCN.
- Following successful upgrade, the Merlin@home will resume normal functionality with no further intervention. Once the upgrade is complete, the software version displayed on Merlin.net™ for that transmitter is automatically updated.
- If a Merlin@home™ transmitter is enrolled and active in remote monitoring and does not connect during this upgrade period or exhibits unexpected behavior following the upgrade or if the upgrade process fails, Abbott will attempt to contact your clinic to coordinate with patients and assist them in troubleshooting the unit, or to replace transmitters with the most up-to-date software to support continued use of remote monitoring.
- Please note that the patient and therapy data that currently resides in Merlin.net™ PCN will not be affected by this upgrade process.
- Should you have any questions regarding the software upgrade, please do not hesitate to contact Abbott EU Tech Services at +46-8-474-4756 or remote.monitoring@sjm.com.

At Abbott, safety and security of patients is our primary focus. Abbott has taken, and will continue to take, appropriate steps to ensure the continued safety, security and effectiveness of its devices. We will continue to work with our Cyber Security Medical Advisory Board, regulators, researchers, physicians and others in the industry in a coordinated way to develop best practices and standards that further enhance the security of devices across the medical industry.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We would appreciate you clicking “Reply” to this email and completing the information below to send a reply to Abbott which confirms you have received this communication.

Sincerely,

Jeff Fecho
VP, Operations and New Product Quality

Merlin@home™ Transmitter Software Version 8.2.2 Upgrade Notice Confirmation

I am confirming receipt of the software upgrade notification.

Clinic Name: _____

Clinic Merlin Number: _____

Name of Person Replying: _____