

**Potential for Backup Operation of Implantable ICDs and IPGs as a Result of Interaction with a Merlin@home™ RF Remote Monitoring Transmitter Model EX1150**

**Merlin@Home Software 8.1.1 Upgrade Status**

December 23, 2015

Dear Dr.....

In August 2015, we informed you about the potential for Merlin@home transmitters to initiate a software reset in a subset of St. Jude Medical radio-frequency (RF) enabled implantable cardioverter defibrillators (ICDs) and pacemakers resulting in them operating in a back-up safety mode.

Since that time, the subject Merlin@home transmitters that are connected to power and either landline, cellular or broadband service have been scheduled for the new software upgrade that will prevent the occurrence of resetting the implanted devices. This upgrade is performed automatically without requiring any action from the patients.

This memo is to inform you that despite repeated attempts, the Merlin@Home transmitters listed in annex have not yet been upgraded to V8.1.1. The likely reasons for a transmitter not receiving the upgrade are: 1). It is not connected to power, 2). It is not connected to the landline or cellular telephone or broadband internet connection.

We therefore recommend you to contact the respective patient(s) and ensure that their Merlin@home transmitter is plugged in to power and connected to the appropriate communication source.

If you have any questions, please do not hesitate to contact your local St. Jude Medical Representative or our Technical Services department at +46-8474-4147.

Sincerely,



Jeff Fecho  
Vice President, Global Quality

**ANNEX**

**List of Merlin@Home transmitters not yet been upgraded to V8.1.1**

<i>ICD/IPG Serial number</i>	<i>ICD/IPG Model Number</i>	<i>Transmitter Serial Number</i>	<i>Current Transmitter Software version</i>	<i>Last communication with Transmitter</i>