

## FIELD SAFETY NOTICE – FOLLOW UP ACTION

### St. Jude Medical Accent SR Model PM1110 and Accent DR Model 2112 Pacemakers Resolution of the Potential for the Inability to Provide Rate Responsive Sensor Driven Pacing Rates

19<sup>th</sup> April 2013

Dear Customer,

In our 7 December 2012 letter, St. Jude Medical informed customers about the potential for a subset of Accent SR single chamber model 1110 and Accent DR dual chamber model 2112 pacemakers that would not provide a change in sensor driven (rate responsive) pacing rates in response to patient physical activity due to an incorrect software setting. A copy of the original letter is attached for your reference. At that time we indicated that a non-invasive, programmer based software solution would become available to correct the issue in all affected devices. This software (17.2.1.1 Merlin Patient Care System Programmer software) has now been installed on your programmer(s). The software includes an automatic feature that will correctly set the rate response sensor during the patient's next follow-up, enabling proper sensor driven rate response pacing.

You will find attached some information on the software upgrade as well as our original Safety Notice issued last December.

**This document contains important information for the continued safe and proper use of your equipment**

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

If you need any further information or support concerning this issue, please contact your local St. Jude Medical Representative or Technical Support at +46 8 474 4147.

We apologize for any inconvenience this issue may have caused and trust that this information is adequately addressing any concerns you may have.

Sincerely,



Philip Tsung  
Vice President, Quality Assurance

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<b>Object of this update</b>	Resolution of the Potential for the Inability to Provide Rate Responsive Sensor Driven Pacing Rates (Field Safety Notice issued on 7 December 2012)
<b>Device affected</b>	Limited amount of St. Jude Medical Accent SR Model PM1110 and Accent DR Model 2112 Pacemakers
<b>Action to be taken</b>	<ul style="list-style-type: none"> <li>• Software upgrade of the Merlin PCS programmer with the 17.2.1.1 software.</li> <li>• Your St. Jude Medical Representative has assisted you in upgrading your Merlin PCS programmer.</li> <li>• With this software installed, upon interrogation, the programmer will automatically program the correct sensor software setting to enable rate responsive sensor driven pacing when programmed ON.</li> </ul>
<b>Recommendations</b>	<ul style="list-style-type: none"> <li>• Verify that the rate response parameters are appropriate for the patient prior to turning the sensor ON.</li> <li>• Document in the patient records that the device has been interrogated with the new software indicating that the sensor has been properly reprogrammed to ensure compliance with the Field Safety Notice Follow Up Action.</li> </ul>
<b>Further information and support</b>	If you need any further information or support concerning this issue, please contact your local St. Jude Medical Representative or Technical Support at +46 8 474 4147.