

6.2 Pacemakers

6.2.3 Symphony and Rhapsody: 7 units

Original date of Field Safety Notice: November 2008

Field Safety Notice description

A Field Safety Notice was issued in relation to a limited series of 7 units of Symphony / Rhapsody cardiac pacemakers, for which the absence of a metallic spring was confirmed through retrospective inspection of the manufacturing records. This metallic spring is used to help ensure the contact between a proximal terminal of the pacemaker and a proximal ring of an IS-1 pacing lead, i.e. to ensure proper operation in BIPOLAR configuration; device operation in UNIPOLAR configuration was not affected by this Notice. No injury or death has occurred as a result of the absence of this component.

Patient recommendations

Because the absence of this component affected device operation in bipolar configuration only, it was recommended to re-program the pacing and sensing polarities to UNIPOLAR in the concerned chamber. Depending on the circumstances (patient's conditions, identified chamber with a missing spring, polarity of the implanted lead and programmed settings during the last follow-up visit), a prompt follow-up visit was recommended to re-program the polarities to Unipolar. It was also recommended to mark patient records – including the patient identification card – to indicate that these polarities must remain Unipolar.

6.2.4 Neway DR: 45 units

Original date of Field Safety Notice: July 2007

Field Safety Notice description

A Field Safety Notice was issued in relation to a limited series of 45 cardiac pacemakers, Neway DR model, distributed in Europe. The notification states that these devices contained a version of a microcontroller integrated circuit that did not allow automatic storing of the data coming from the intracardiac EGM (IEGM) into the device memory. To overcome this limitation, storing of data was performed by a dedicated software routine. This software routine caused additional current drain that reduced longevity in devices with IEGM activated, compared to the devices with the IEGM deactivated. Available programmer software did not take into account the additional current required for the IEGM function when estimating the remaining longevity.

Patient recommendations

Revised programmer software (SmartView 2.06 for Orchestra programmer – version 3.6.04 for PMP 2000 programmer or higher versions) was distributed to calculate the remaining longevity accurately with or without IEGM enabled. For all of the devices included in this field safety notice, a prompt follow-up visit and device interrogation was recommended utilizing this revised programmer software.

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6.2.5 Programmer software version associated with Reply SR

Original date of Field Safety Notice: September 2007

Field Safety Notice description

A Field Safety Notice was issued for an anomaly in programmer software, Smartview version 2.06 or earlier, when reprogramming Reply SR single chamber cardiac pacemakers (distributed in Europe). The notification stated that when the chamber was set to "V" (pacemaker connected to a lead implanted in the ventricle), reprogramming of the pulse amplitude and pulse width was not effective, and they remained equal to the as-shipped values (3.5 V amplitude, 0.35 ms pulse width). When the chamber was set to "A" (pacemaker connected to a lead implanted in the atrium), each programmable parameter – including pulse amplitude and pulse width – could be reprogrammed as expected. This software anomaly affected Reply SR single chamber pacemakers only; other pacemaker models were not affected.

Patient recommendations

Revised programmer software, SmartView version 2.08 for Orchestra programmer was distributed to correct this unexpected behavior. For some of the devices included in this field safety notice (Reply SR single chamber models set to "V" chamber), and based upon the evaluation of specific criteria (e.g. pacemaker reprogrammed after implant or not, pacemaker dependency, pacing threshold results at implant), a prompt follow-up visit and device interrogation were recommended utilizing this revised programmer software to check the programmed settings and correct the pulse amplitude and pulse width, if needed.