

[Physician / medical center contact information to be inserted]

November XX, 2013

Urgent Medical Device Field Safety Notice

Erroneous residual longevity displayed by the programmer

REPLY, ESPRIT and FACIL¹ Pacemakers

Dear Doctor,

The aim of this letter is providing you important information related to the overestimation of the residual longevity displayed by the programmer during a follow-up exam of patients implanted with a REPLY, ESPRIT or FACIL¹ pacemaker. Because of this incorrect information, the follow-up dates might not have been adjusted when nearing the ERI². The overall longevity of these devices is not impacted.

The erroneous residual longevity indicator affects the following pacemaker models:

- REPLY Models D, DR, VDR, SR
- ESPRIT Models D, DR, S, SR
- FACIL Model DR¹

When the device approaches the ERI, this overestimation of the residual longevity could result in ERI or EOL³ being reached between two follow-up visits. In typical conditions⁴, the longevity of these devices is well beyond the time elapsed since full commercialization in 2008. As a result, very few devices are at risk as of today. Please note that when the devices are programmed at high energy outputs (e.g. high pulse amplitude and width) associated to a high percentage of paced events, longevity can be reduced.

No permanent injury or death has occurred as a result of the reported events. In all reported events, pacing functions were maintained at follow-up time.

To avoid any risk for your patients in the future, Sorin CRM has taken corrective actions to address this issue through a new programmer software version.

Background information

Upon pacemaker interrogation by the Programmer, the battery status is displayed through four different indicators:

- Last battery impedance measurement (measurement performed every day).
- Color coded gauge representing the battery status according to the battery impedance.

¹ FACIL pacemakers are only commercialized in Japan.

² Elective Replacement Indicator.

³ End Of Life.

⁴ Refer to the user manual for battery longevity in different conditions.

- Magnet Rate: the magnet rate is equal to 96min⁻¹ at BOL⁵ and 80 min⁻¹ at ERI; its value depends on the battery impedance.
- Time to ERI: Estimated residual longevity of the device. This estimation is based on the programmed pacemaker settings, the percentage of pacing events, the lead impedance values and the measured battery impedance at the time of the interrogation.

Description

As of October 15, 2013, Sorin CRM received eight (8) reports out of more than 300 000 REPLY, ESPRIT or FACIL¹ pacemakers implanted worldwide (i.e. 0.0027%), in which the devices were found at ERI while the time to ERI indicated by the programmer during the previous follow-up was indicating an ERI at a later date.

These eight (8) devices were programmed with high pulse amplitude and width combined with a high percentage of paced events, which explains why they had already reached ERI. The longevity of these devices is conforming to specifications.

No permanent injury or death has occurred as a result of the reported events. At the time of the follow-up, pacing functions of the device were maintained in each reported event.

In -depth investigation of these reported events revealed that:

- The calculated residual longevity (i.e. the remaining time until the ERI) was overestimated.
- Because of this incorrect information, the follow-up dates might not have been adjusted when nearing the ERI; the ERI or EOL could therefore be reached between two follow-up exams, or during the follow-up exam itself.
- The overall longevity of the devices is not affected and corresponds to what is stated in the instructions for use.

Sorin CRM actions to address the issue

Sorin CRM has taken corrective actions to address this issue. A new programmer software version⁶ will be released to correct the Time to ERI and its presentation through the color-coded gauge. Your Sorin representative will inform you as soon as the software upgrade is available, following regulatory approval.

Patient Management Recommendations

After consulting with Sorin CRM's independent Product Performance Monitoring Board, Sorin CRM recommends:

- You should consider checking the battery impedance of the last follow-up exam. In case the battery impedance is greater than or equal to 3.5kΩ, a follow-up visit must be scheduled within a maximum of 6 months from the last follow-up visit.
- When pacemaker operation is checked by the simple application of a magnet, a magnet rate less than 95 min⁻¹ should trigger a follow-up exam in the pacemaker centre.
- As a general rule, a maximum of 6 month follow-up interval when the battery impedance becomes greater than or equal to **3.5 kΩ**. This recommendation should also be followed subsequent to the installation of the new programmer software version.

⁵ Beginning Of Life

⁶ SmartView 2.40 version or higher for European Community and Japan.

Sorin CRM is communicating this information to [*Name of the Local Competent Authority to be added*].

Please make sure that all personnel involved in the management of patients implanted with REPLY, ESPRIT and FACIL¹ pacemakers in your organisation are aware of the information described in this letter.

We apologize the inconvenience this could cause you and your patients. If you have any questions, please contact your local Sorin CRM representative or contact Sorin Group at [*local phone number to be inserted*].

Sincerely,