April 27, 2011

Urgent Medical Device Field Safety Notice
2.24 programmer software version and Reply / Esprit pacemakers

Dear Doctor,

The letter is written to provide you with important information regarding a programmer software anomaly in the European 2.24 programmer software version when interrogating Reply and Esprit pacemakers: this anomaly results in an incorrect magnet rate (30 min^{-1}). This will be addressed by a Sorin software update available mid-2011. The anomaly only affects the pacing rate when a magnet is applied (30 min^{-1}) but does not affect other functions of the device. Once the magnet is removed, the device reverts to programmed settings.

Description of the software anomaly

As of April 8, 2011, Sorin has received five (5) reports out of approximately 60000 units:

- In each of these 5 reports, a magnet rate of 30 min^{-1} was displayed upon device interrogation;

- In one of these 5 reports, an "End Of Life" message was also displayed.

These observations were inconsistent with the other battery information in these 5 devices: the battery impedance indicated that the devices were still at Beginning Of Life (BOL) and their residual longevity were adequate (i.e. several years). In one case, the inconsistency resulted in unnecessary device explant.

Sorin's investigation has shown that this inconsistency resulted from a programmer software anomaly **when using the latest European programmer software version (2.24)** with Reply or Esprit pacemakers:

- Only devices manufactured between November 2008 and mid-October 2010 are affected by the issue if they are interrogated with 2.24 version (refer to the note at the end of the document about potentially affected devices).

- 24 hours after a first interrogation with 2.24 version, a magnet rate of 30 min^{-1} is displayed upon new device interrogation on the programmer screen; if a magnet is applied, the pacemaker reverts to magnet mode (asynchronous mode) with a magnet rate of 30 min^{-1}. The battery depletion curve is also incorrect. **The battery impedance and the residual longevity are not affected by the software anomaly.**

- In addition, if the initial interrogation is performed prior to implant, then an "End Of Life" warning is also displayed upon device interrogation;

The anomaly only relates to the pacing rate (30 min⁻¹) during magnet test and does not affect other functions of the device; once the magnet is removed, the device reverts to programmed settings.

This programmer software anomaly does not affect any other Sorin implantable devices.

Immediate action

Sorin CRM has stopped installation of 2.24 software version. In case this version has already been installed on your Sorin programmer, your Sorin representative will promptly install a software version that will prevent new devices from being affected upon interrogation.

Recommendations

After consultation with Sorin CRM's independent Product Performance Monitoring Board, Sorin recommends that physicians continue to use the battery impedance and residual longevity to determine time for device replacement.

Sorin will release by mid-2011 a software update (2.28 or higher revision) that will address this anomaly and that will automatically correct the erroneous magnet rate upon interrogation with this new programmer software. Your Sorin representative will inform you when the software update is available, after regulatory approval.

Before this software update is available, devices that have already been interrogated with 2.24 can be reset to normal operation with the current programmer software; the attached Technical Note describes the steps to follow.

Depending on the circumstances (e.g. for pacemaker-dependent patients undergoing surgery during which the magnet could be applied to avoid pacing inhibition), you may consider scheduling a follow up for devices that have already been interrogated with 2.24 to correct the magnet rate (with the procedure described in the Technical Note or with the 2.28 or higher revision).

Sorin 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 or Esprit pacemakers in your organisation are aware of the information described in this letter.

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

Sincerely,

Note:
The potentially affected devices have the following eight-character serial number configuration:

Models	**Serial number configuration** (where x is any alphanumeric character)		
Reply DR	**8**xx**ZK**xxx	**9**xx**ZK**xxx	**0**xx**ZK**xxx
Reply D	**8**xx**ZL**xxx	**9**xx**ZL**xxx	**0**xx**ZL**xxx
Reply VDR	**8**xx**ZM**xxx	**9**xx**ZM**xxx	**0**xx**ZM**xxx

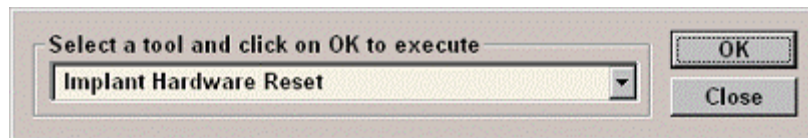|			
Reply SR	**8**xx**ZN**xxx	**9**xx**ZN**xxx	**0**xx**ZN**xxx
Esprit DR	**8**xx**ZP**xxx	**9**xx**ZP**xxx	**0**xx**ZP**xxx
Esprit D	**8**xx**ZR**xxx	**9**xx**ZR**xxx	**0**xx**ZR**xxx
Esprit SR	**8**xx**ZS**xxx	**9**xx**ZS**xxx	**0**xx**ZS**xxx
Esprit S	**8**xx**ZT**xxx	**9**xx**ZT**xxx	**0**xx**ZT**xxx

How to reset a Reply / Esprit pacemaker to normal operation if it has already been interrogated with Smartview 2.24?

Preliminary check once you have switched your programmer ON

1. Verify that both date and time displayed on the top of the screen are correct, and update them if needed.

2. Note the programmer software version. It is available on the "Information" tab

3. Check that the "Caps Lock" key is not activated (e.g. by entering some text in: "Information" tab | "Center Information" panel | field "Name")

Device reset procedure:

1. Proceed with the standard interrogation of the pacemaker to read AIDA memory data; otherwise these data will be lost after the reset procedure.

2. Select the "Information" tab

3. Press Ctrl+Alt+T in order to launch the tool. After that, the following pop-up is displayed :

4. Press "OK". After that, the following pop-up is displayed:

5. Press "Continue". Then, you shall enter the password in accordance with the programmer software version currently installed on your programmer:

Version installed on the programmer	Password (case sensitive)
2.22	▮▮▮
2.24	▮▮▮
2.26	▮▮▮

Note: the password is case sensitive, and letters are in uppercase.
        For a letter: Press "Shift" key + "Letter" key
        For a digit: Press "Digit" key only

If the password is entered correctly, the reset is performed and a message "Reset successfully performed" is displayed. At this time, the device is programmed in standby mode (VVI mode, 5V, 0.5ms, 70min-1).

In case of telemetry difficulties, a message "Telemetry error: try repositioning head. Do you want to continue ?" is displayed; select "OK" or "Cancel".

Device re-initialization procedure:

1. Interrogate the device. Then, the following pop-up is displayed: "Implant is in standby mode. Interrogation is stopped. Do you want to reinitialize the implant (which will require few minutes)?"
2. Press "OK". Then the following pop-up message is displayed: "Implant re-initialization is complete. New interrogation". At this time, the device is reprogrammed using the as-shipped values.
3. Press "Ok"
4. As soon as the interrogation is ended, you may reprogram the device, as needed.