215t March 2019

Dear Doctor,

This letter is to inform you that the WiSE CRT Model 4100 Transmitter may reset when powered with a beginning of life (BOL) Model 3000 Battery. These resets occur when acoustic pacing is first turned on with a new BOL battery, which is typically done during the Electrode implant procedure. The reset could cause communication loss between the programmer and Model 4100 Transmitter which can lead to a prolonged Electrode implant procedure. These resets are occurring in approximately 50% of procedures.

Devices affected are specific to Model 4100 Transmitter **when used with a new BOL Model 3000 Battery and it is important to note that this reset issue occurs only during the initial usage and has no impact on the longevity of the Model 3000 Battery.**

The reset issue does not occur in Model 4100 Transmitter paired with Model 3100 Battery or Model 4000 Transmitter paired with Model 3000/3100 Battery. Please be informed that Model 3100 Battery is currently under regulatory review for CE Marking and the device will be made available for use in the European Economie Area (EEA) once CE Mark is obtained.

Root Cause
At BOL the Model 3000 Battery has a high source resistance. This is a known characteristic of the cell chemistry used in the battery. It is due to an oxide layer that forms over time. Once current has begun to be drawn from the battery, the oxide layer burns off and the source resistance decreases. Depending on the rate of energy usage this occurs relatively quickly within the first seconds to minutes of operation.

The Model 4100 Transmitter was intentionally designed to use higher currents during acoustic pacing than the Model 4000 Transmitter because this significantly improves the energy efficiency of the device. The combination of these higher currents and high initia! source resistance of the Model 3000 Battery can cause a transient voltage dip that is low enough to result in a device reset. Once the source resistance of the Model 3000 Battery decreases, the system is no Jonger vulnerable to these resets. This typically occurs after less than a minute of acoustic pacing.

Patient Management Recommendations
A solution has been identified to address the immediate risk to the patient of a potentially prolonged Electrode procedure time. **This solution will be implemented by the EBR representative that is present at each of your WiSE System implant procedures.** It consists of programming an ultrasound pacing mode prior to the Electrode implant procedure. Though there is no Electrode to pace, entering into an ultrasound pacing mode causes the Battery/Transmitter to search for an implanted Electrode by transmitting multiple ultrasound targeting pulses, taken together equivalent to a 2.5ms pacing pulse.

This process shifts the time that the resets can occur from the most critica! point of the procedure (site evaluation prior to anchoring of the Electrode) to an earlier point in the procedure where there is no clinical impact. For single stage procedures (Battery/Transmitter and Electrode implants on the same day), this would be when the surgeon is closing the Battery/Transmitter pockets. Fora dual-stage procedure (Battery/Transmitter previously impl anted), this would be when they are prepping the patient before the insertion of catheters for Electrode implantation.

We apologize for any inconvenience this notice causes to you and your patients. If you have any additional questions, please do not hesitate to contact Technica! Support (+1.408.720.1906 / supp ort@ebrsystemsinc .com) or your local EBR Systems representative .

Regards,

Acknowledgement Form

Complete this Acknowledgement Form and return to Chi Chung-Thornton, Director of Regulatory Affairs / Regulatory Compliance via email:
cchung- thornton @ebrsystemsinc.c om

- We confirm that we have received, read and understood the information contained within the Field Safety Notice.
- We confirm that we understand that an EBR System representative present at the implant procedure will perform the indicated actions defined in the Field Safety Notice.

Form completed by:

NAME	TITLE/ROLE
SIGNATURE	**DATE**
HOSPITAL NAME	