

21st June 2018

Dear Doctor,

This letter is to inform you of an issue with a subset of the first generation WiSE CRT Model 4000 Transmitters that can result in premature depletion of the battery due to current leakage at the termination of the battery cable to the transmitter housing. As of the date of this letter, six returned devices have been confirmed to be affected by this.

Devices at risk have been isolated to six manufacturing lots that used a specific revision of metal chassis. Nineteen devices from these lots remain in active use. Refer to Appendix A for a list of affected active devices implanted in your hospital. Please note the Model 4000 Transmitter has not been distributed since September 2017.

The current leakage initially presents as an erratic battery curve with a sudden onset. Analysis of returned units to date has demonstrated this onset occurred at 4 to 9 months post implant. Refer to Appendix B for an example of typical and atypical battery curves. Because the current leakage draws energy from the battery, this particular mechanism of failure is also associated with a significant gap between predicted and actual longevity of the battery, by up to 60% reduction in capacity. Please note other factors can cause temporary changes in current drain including intermittent pacing and rapid fluctuations in the pacing rate.

Even in the presence of current leakage, the device will continue to function normally and deliver biventricular pacing. However, the battery longevity estimate will not be accurate. If the battery depletes prematurely, patients may experience a return of heart failure symptoms.

Root Cause

Engineering analysis on the six returned units demonstrate a loss of electrical isolation of the positive battery wire due to moisture intrusion at the junction between the cable and transmitter housing. This presence of moisture, in this area, initiated current leakage between the positive battery wire and battery ground, which prematurely depleted their connected batteries.

The failure that led to the moisture intrusion is linked to a specific revision of the outer housing or “chassis” of the transmitter.

Please note there were several changes to the design, materials and manufacturing process for the second generation Model 4100 Transmitter that would mitigate this type of failure.

Patient Management Recommendations

Nineteen devices from these affected lots remain in active use. Evaluation of post market surveillance and clinical trial data has identified nine devices with a battery curve suggestive of current leakage. The other ten devices displayed normal battery curves during their last follow-up.

For those devices with battery curve suggestive of current leakage (9 patients):

Patients should be followed up at one-month intervals. Remaining battery life should be based upon battery voltage rather than the longevity calculation. The elective replacement indicator (ERI) occurs at 2.65V; with end of service (EOS) at 2.1V. It is recommended that the transmitter should be replaced (with a Model 4100 Transmitter) at the next battery replacement.

For other devices from high risk lots (10 patients):

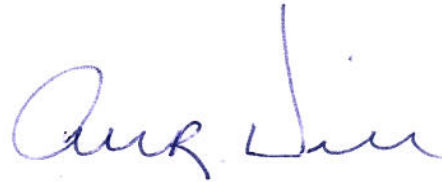
Patients should continue to be followed up at three-month intervals per Instructions For Use. Device replacement is not recommended for Transmitters displaying normal battery curves. These patients should be advised to seek attention if their heart failure symptoms return.

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

Regards,

A handwritten signature in black ink, appearing to read 'Mark Schwartz', written over a horizontal line.

Mark Schwartz
VP Clinical & Regulatory Affairs

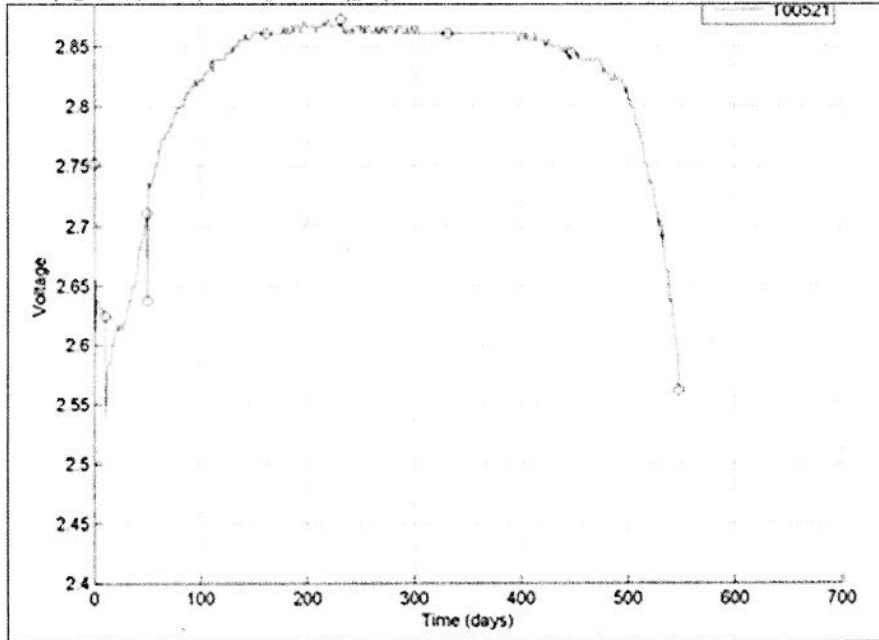
A handwritten signature in blue ink, appearing to read 'Allan Will', written over a horizontal line.

Allan Will
Chairman & CEO

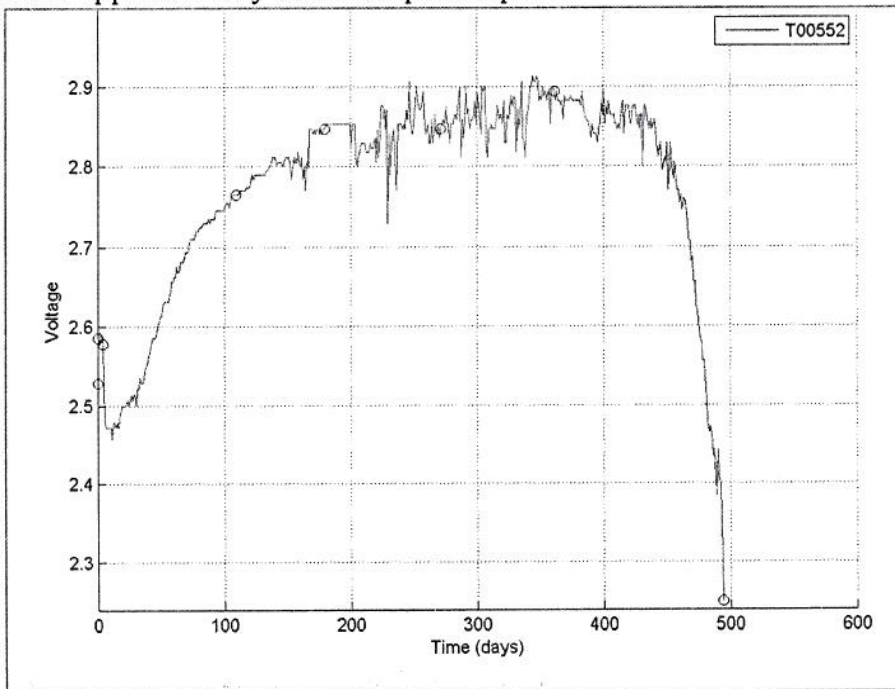
Appendix A: List of affected active devices implanted in your hospital

Appendix B: Example of battery curves

Example of a normal battery curve:



Example of a battery curve with current leakage. Note sudden onset of erratic battery curve approximately 6-months post implant.



Appendix C: Acknowledgement Form

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

- We confirm that we have received, read and understood information contained within the Field Safety Notice.
- We confirm that we will perform indicated actions defined in the Field Safety Notice.

Form completed by:

NAME	TITLE / ROLE
SIGNATURE	DATE
HOSPITAL NAME	