FSN Reference: FSN 22-007
FSCA Reference: FSCA 22-007

20th October, 2022

Dear [Dr. name],

URGENT: FIELD SAFETY NOTICE
WiSE CRT Transmitter Model 4100

The attached Field Safety Notice is being released to alert you to the potential for premature Battery depletion due to an issue with the WiSE CRT Transmitter Model 4100. If this occurs, the System will continue to function normally and deliver biventricular pacing until the Battery is depleted.

EBR Systems is actively working to identify, develop and evaluate process and design solutions for this matter. As such, we are pausing further shipments of this Transmitter for new patients until product with improvements is available.

All healthcare professionals involved in the follow-up of the WiSE CRT System should refer to the attached Field Safety Notice, which includes:

i. Patient management recommendations (Appendix A)
ii. A list of potentially affected devices implanted by your hospital (Appendix B)
iii. Clinical Impact (Appendix C)
iv. An Acknowledgement Form (Appendix D) that will need to be completed and returned via email to: compliance@ebrsystemsinc.com, via Adobe Sign, or to your local EBR representative

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Field Safety Notice
WiSE CRT Transmitter Model 4100

20th October, 2022

Applicable Serial Numbers: SN T01701 to SN T02057
Applicable Implant Date Period: May 2021 to October 2022

EBR Systems (EBR) is notifying you of the potential risk of premature Battery depletion due to an issue with the WiSE CRT Transmitter Model 4100. An insulation breach within the Transmitter could result in the development of an electrical current leakage pathway, causing the power to drain at a higher rate and lead to premature Battery depletion. If the electrical leakage occurs, the device will continue to function normally and deliver biventricular pacing until the Battery is depleted. Current leakage can be suspected if a fluctuating Battery voltage curve is observed.

The Competent Authority in your country has been notified.

A total of one Transmitter (in the US) has been explanted, returned for analysis, and replaced with a new device. There were no other clinical sequelae reported with the Transmitter breach or the replacement. Analysis of this device confirmed that the failure mode was an insultation breach in the Transmitter feedthrough, resulting in a failure rate of 0.8% (1 out of 127 devices implanted globally). The time from implant to suspected onset was 4.1 months; with time from suspected onset to loss of therapy for this patient was 4.9 months. An additional seven implanted Transmitters are suspected of having a similar issue that could raise the failure rate to 6.3%. The mean time from implant to suspected onset for these seven units was 7.4 months (range: 4.1 – 13); the mean implant duration is 13.4 months (range: 11.9 – 15.7). Clinical impact (patient risk) is provided as **Appendix C**.

EBR Systems will pause further shipment of the Transmitter Model 4100 for new patient implants effective immediately. There are no Transmitter Model 4100 on consignment.

The root cause analysis is ongoing, but preliminary analysis has identified manufacturing process and design elements as contributors. The insulating material used in the Transmitter feedthrough appears susceptible to dendritic growth between the positive feedthrough pin and the chassis, resulting in the observed current leakage. EBR Systems is evaluating process and design solutions to fix the issue.

In the interim, patient management recommendations are provided in **Appendix A**. The Battery Model 3100 will continue to be made available for existing patients. EBR Systems is continuing to characterize the nature and timing of this current leakage. An update will be provided if anything is identified to help assist ongoing patient management.

Should you have questions about patient management, including observed changes in Battery longevity, please contact your local EBR Field Representative or EBR Technical Support at support@ebrsystemsinc.com.

We regret the difficulties this may cause you and your patients.

Sincerely,

[redacted]

Appendix A

Patient Management Recommendations

For patients already implanted with a unit impacted by this FSN, EBR recommends the following patient management steps:

1. **Continue to conduct patient follow-up per the WiSE System Instructions for Use (IFU)**.
   - ✓ Patients should be reviewed every 3-months

2. At the next scheduled study follow-up visit:
   - ✓ **Advise patients that an audible notification alert will sound if their battery gets low.** The notification is generated from the Transmitter and will beep for 20 seconds every 8 hours.
   - ✓ Your EBR Field Representative will perform a patient notification test to educate the patient (and their family member/caregiver, as appropriate) about the audible alert.
   - ✓ Advise the patient to contact your clinic promptly should they hear the audible alert.
   - ✓ Patients who are unable to hear the audible alert may experience loss of Battery and/or loss of device function without their awareness.
   - ✓ Advise the patient of the potential for the return/worsening of their heart failure symptoms and to promptly contact your clinic with any changes in their heart failure symptoms.

3. **Repeated audible notification test** will be performed by your EBR Field Representative at each device check to remind the patient (and their family member/caregiver, as appropriate) about the audible alert.

4. **Monitor for any unexpected fluctuations in the Battery voltage curve.** The EOS and RRT (Recommended Replacement Time) dates should not be used if fluctuations in the Battery voltage curve are observed. If so, the Battery curve should be used to estimate longevity. ERI is reached when Battery voltage drops below 2.36V.

5. **Patients that have suspected Transmitter failure**:
   - **a)** Any treatment plan should be based on your clinical assessment and needs to be evaluated on a patient-by-patient basis.
   - **b)** If Battery depletion due to Transmitter failure is suspected, treatment options include:
     - ✓ Replacement of the Model 3100 Battery only. Premature Battery depletions will likely occur more rapidly than the first depletion when replaced on a previously affected Transmitter.
     - ✓ Provide RV only pacing until a replacement Transmitter is available. RV only pacing in this patient group may worsen heart failure symptoms.
     - ✓ Provide an alternative therapy for the patient.
   - **c)** If the patient has been informed of the risk of device failure, and the decision is made to replace the affected devices, EBR will provide replacement devices under warranty. Please contact your EBR representative to coordinate the replacement.
   - **d)** Please return any explanted devices to EBR for further evaluation.

Appendix B

List of Potentially Affected Active Devices Implanted in Your Hospital

Appendix C

Clinical Impact (Patient Risk)

In the event the WiSE CRT System Battery becomes depleted, the immediate outcome for the patient is that they will no longer receive Left Ventricular (LV) pacing and will revert to Right Ventricular pacing alone. Short-term, the risk to the patient is that their heart failure status may worsen which may require medical treatment until the Battery is replaced, or the patient receives an alternative therapy that is more suitable.

There are other potential risks that may occur from revision surgery. These risks include, but are not limited to, those associated with the use of general anesthesia, infection, and pocket hematomas. No clinical sequelae were reported in the one replacement.

Appendix D

Acknowledgement Form

Please complete this Acknowledgement Form electronically via Adobe Sign or return via email to compliance@ebrsystemsinc.com.

i. We confirm that we have received, read and understood the information in this Field Safety Notice.
ii. We confirm that we will take into advisement the actions defined in this Field Safety Notice.

Form completed by:

NAME	TITLE / ROLE		
SIGNATURE	**DATE**		
	DD	MM	YYYY
HOSPITAL NAME			
COUNTRY			