

## **URGENT: FIELD SAFETY NOTICE**

### **WiSE CRT Transmitter Model 4100 - potential premature Battery depletion**

03 March, 2021

Dear \_\_\_\_\_

**EBR Systems, Inc** is issuing a **Field Safety Notice** on **WiSE CRT Transmitter Model 4100**. **Competent Authorities are aware of this action.**

Our records indicate that you have implanted the WiSE CRT Transmitter Model 4100 and may have received the product serial numbers subject to this Field Safety Notice identified in **Appendix B and C**.

This Field Safety Notice is **EFFECTIVE IMMEDIATELY – DO NOT USE** identified affected products.

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL PERSONNEL RESPONSIBLE FOR or WHO MAY USE the WiSE CRT Transmitter Model 4100 in your facility.**

EBR Systems, Inc has initiated a voluntary Field Safety Corrective Action (FSCA) for WiSE CRT Transmitter Model 4100 because of increasing rate of premature Battery depletion associated 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. Other WiSE CRT system components are unaffected by this action.

**Product intended use:** The WiSE CRT System is an implantable wireless cardiac pacing system intended for the leadless, endocardial stimulation of the left ventricle in patients indicated for cardiac resynchronization therapy. The WiSE CRT Transmitter Model 4100 is a subcutaneously implanted ultrasound transmitter that initiates an ultrasonic energy pulse that travels through the tissue to intersect an ultrasound receiver implanted in the heart.

A total of 8 Transmitters were explanted, returned for analysis and replaced with new devices. One Battery pocket infection was associated with these revision surgeries. There were no other clinical sequelae reported. Analysis of these 8 devices confirmed the failure mode was an insulation breach in the Transmitter feedthrough, resulting in a failure rate of 2.8% (8 out of 288 devices implanted globally). The time to loss of therapy for these 8 patients ranged from 7.1 to 22.6 months. An additional 8 Transmitters are suspected of having a similar issue that could raise the rate to as high as 5.6%. Clinical impact (patient risk) is provided as **Appendix D**.

For these reasons, EBR Systems will pause further shipments of the Transmitter Model 4100 for patients until product which do not have propensity for premature Battery depletion are available.

Although investigation to date does not indicate all units are prone to premature Battery depletions, users of WiSE CRT Transmitter Model 4100 who have un-implanted units are advised to not implant these units as a precaution. EBR Systems, Inc will continue to monitor any adverse events related to the issue.





FSN Reference: FSN 20-001  
FSCA Reference: FSCA 20-001

Hence, all healthcare professionals, affected staff, service and/or facilities working with/using 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. A list of devices currently at your site to be returned (Appendix C)
- iv. Clinical impact (Appendix D) and
- v. An Acknowledgement Form (Appendix E) that will need to be completed and returned via email to [compliance@ebrsystemsinc.com](mailto:compliance@ebrsystemsinc.com) or to your local EBR representative.

**ACTION REQUIRED: NEXT STEPS and IDENTIFICATION OF THE PRODUCT SERIAL NUMBERS SUBJECT TO THIS FIELD SAFETY NOTICE:**

1. Refer to **Appendix C** for assistance in identifying the product serial numbers subject to this Field Safety Notice. Examine your inventory immediately to determine if you have any products subject to this Field Safety Notice in stores or at points of use and quarantine such product(s).
2. Remove the products subject to this Field Safety Notice from your inventory and communicate the issue to all relevant cath lab or materials management personnel, or anyone else in your facility who needs to be informed.
3. Complete relevant **Acknowledgement Form (Appendix E)** confirming receipt of this notice and return it to EBR Systems, Inc immediately upon receipt. Please return Acknowledgement Form (Appendix E) even if you do not have the product serial numbers subject to this Field Safety Notice. Please feel free to contact EBR Systems, Inc, local EBR representative, EU Authorised Representative (for affected products in the EU) or UK Responsible Person (for affected products in the UK) if you require any assistance completing the **Acknowledgement Form (Appendix E)**.
4. Customers are required to immediately return all unused WiSE CRT Transmitter Model 4100 subject to this Field Safety Notice that are in their inventory. EBR Systems, Inc will provide detailed instructions for product return once **Acknowledgement Form (Appendix E)** received by customer service. Additionally, EBR Systems, Inc will supply product for any patients requiring device replacement based on your clinical assessment.

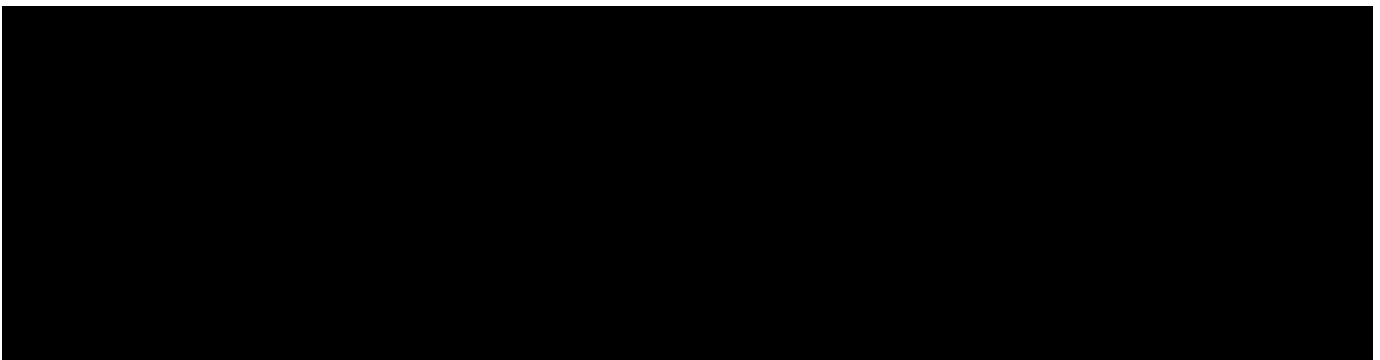
If you have additional questions regarding this Field Safety Notice, please contact EBR Systems, Inc via the contact details below:

Manufacturer:

EBR Systems, Inc

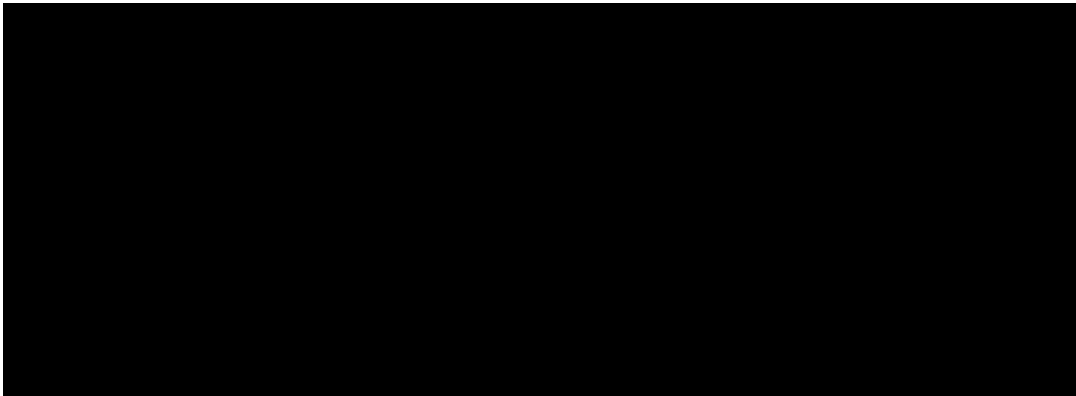
E-mail: [support@ebrsystemsinc.com](mailto:support@ebrsystemsinc.com)

Telephone: +1 408.720.1906



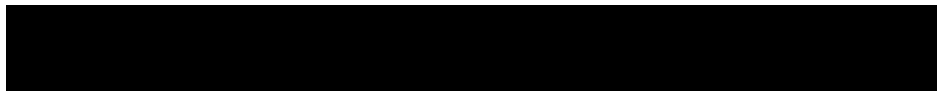
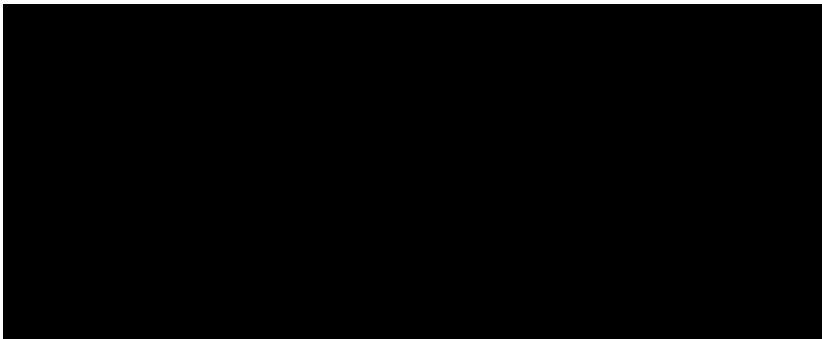


FSN Reference: FSN 20-001  
FSCA Reference: FSCA 20-001



We regret any inconvenience that this action may cause, but we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Sincerely,



## **Field Safety Notice**

03 March 2021

### **WiSE CRT Transmitter Model 4100**

EBR Systems (EBR) is updating you on the increased rate 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 a leakage pathway, causing the current to drain at a higher rate and lead to premature Battery depletion. If the leakage occurs, the device will continue to function normally and deliver biventricular pacing until the Battery is depleted.

A total of 8 Transmitters were explanted, returned for analysis, and replaced with new devices. One Battery pocket infection was associated with these revision surgeries. There were no other clinical sequelae reported. Analysis of these 8 devices confirmed the failure mode was an insulation breach in the Transmitter feedthrough, resulting in a failure rate of 2.8% (8 out of 288 devices implanted globally). The time to loss of therapy for these 8 patients ranged from 7.1 to 22.6 months. An additional 8 Transmitters are suspected of having a similar issue that could raise the rate to as high as 5.6%. Clinical impact (patient risk) is provided as **Appendix D**.

EBR Systems will pause further shipment of all product for new patient implants effective immediately. Any devices in inventory / stock should be returned to EBR Systems (See **Appendix C**).

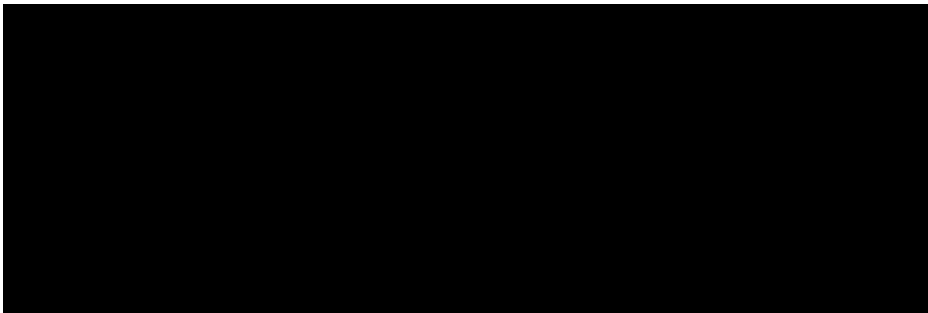
The root cause has been identified as manufacturing process variabilities at our contract manufacturer. EBR Systems has developed a solution for this matter and is actively working towards implementing the changes.

In the interim, patient management recommendations are provided in **Appendix A**. Model 3100 Batteries will continue to be made available for existing patients.

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](mailto:support@ebrsystemsinc.com).

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

Sincerely,



## Appendix A:

### Patient Management Recommendations

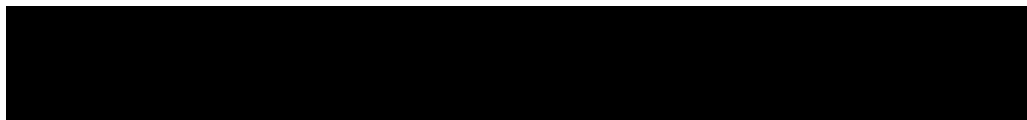
For patients already implanted with the WiSE CRT System, EBR recommends the following patient management steps:

1. **Continue to conduct patient follow-up per the WiSE System Instructions for Use (IFU).**
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 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 changes in Recommended Replacement Time indicator.** The RRT and battery voltage are reported on the screen and printout of the WiSE System Programmer Model 5100.
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. Continued use of a failed Transmitter will result in additional premature Battery depletions.
    - ✓ 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.



FSN Reference: FSN 20-001  
FSCA Reference: FSCA 20-001

**Appendix B**  
**List of Potentially Affected Active Devices Implanted in Your Hospital**

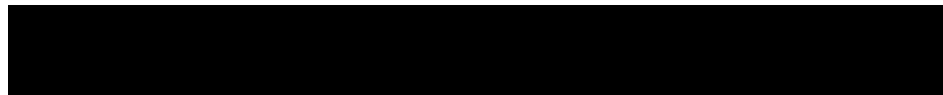




FSN Reference: FSN 20-001  
FSCA Reference: FSCA 20-001

**Appendix C**  
**List of WiSE CRT Devices in Your Hospital Inventory to be Returned**

Your EBR Field Representative will work with you to arrange collection of these.

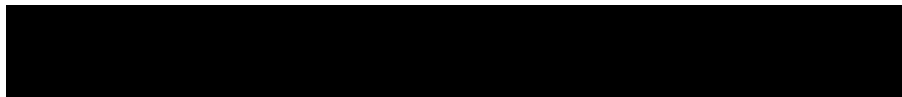


## **Appendix D**

### **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. Of the 8 revision surgeries conducted thus far, one infection was associated with the Battery pocket. No other clinical sequelae were reported. Additional long-term health consequences are not expected, and none has been reported to-date.





## **Appendix E**

### **Acknowledgement Form**

Please complete this Acknowledgement Form and return to via email to [compliance@ebrsystemsinc.com](mailto:compliance@ebrsystemsinc.com).

Form completed by:

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

- 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.
- iii. We have checked our inventory against Appendix C and will be returning devices listed in the table below.

Model	Serial Number

