FSN Reference: FSN 22-004
FSCA Reference: FSCA 22-004

14 April, 2022

Dear Doctor

Re: Field Safety Notice for WiSE CRT Programmer Model 5100 Software Bug

The attached Field Safety Notice (FSN) is being released to alert you to a potential software error when using the Model 5100 Programmer to program the Model 4100 Transmitter. This error can result in unintentional programming of the sensor configuration used to locate and deliver ultrasound energy to EBR's implanted Model 1000 Electrode.

This FSN notifies the healthcare professionals of the potential for this error, how to prevent it, and recommendations for reprogramming the devices for specific patients that may have been impacted by it.

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

i. Programming Guidance (Appendix A)
ii. A list of *potentially* affected devices implanted by your hospital (Appendix B) along with patient specific reprogramming guidance
iii. Clinical Impact (Appendix C) and
iv. An Acknowledgement Form (Appendix D) that will need to be completed and returned via email to: compliance@ebrsystemsinc.com or to your local EBR representative.

Contact Details:

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Field Safety Notice

14 April, 2022

WiSE CRT Programmer Model 5100 Software Bug

EBR Systems, Inc. (EBR) is alerting you to a potential software error when using the Model 5100 Programmer (software version 6.2.3) to program the Model 4100 Transmitter (software version 1.1.3). This error can result in unintentional programming of the sensor configuration used to locate and deliver ultrasound energy to EBR's implanted Model 1000 Electrode.

EBR has reviewed available programmer data and identified a total of 9 patients globally (6 US, 2 UK, and 1 IT) that are impacted by this issue. EBR recommends near term follow up (within 2 weeks) to assess any impact on therapy and adjust programming as necessary. A list of potentially affected devices implanted in your hospital is included in **Appendix B**, along with patient specific reprogramming guidance.

The Model 4100 Transmitter allows for programming of single or multiple sensors for targeting ultrasound energy delivery. Typically, multiple (4) sensors are enabled after implant, and then, based on historical performance data, unused sensors are disabled at a subsequent follow up.

The Model 5100 Programmer includes a Simplified Follow-up feature. If multiple sensors are enabled on the Model 4100 Transmitter, using the "Optimize Targeting" button on the "Follow Up" display screen will disable all sensors other than the currently active one, resulting in a single programmed sensor. This feature is not intended to disable sensors; rather it is intended to optimize the distance limit, focal distance, and Global Search Center.

Depending on the patient and the single sensor that is enabled, therapy may be impacted. The possible implications are reduced BiV therapy, inability to provide therapy, excess energy consumption, potentially resulting in more frequent battery replacements. Clinical impact (patient risk) is provided as **Appendix C**.

EBR Systems will provide future software releases to correct the behavior of the "Optimize Targeting" feature. In the interim, **Appendix A** provides instructions to avoid this unwanted behavior and alternative user interface screens that should be used for patients with multiple enabled sensors. As such, no physical product containment is necessary.

Should you have questions about patient management, 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,

Andrew Shute
Andrew Shute (Apr 14, 2022 22:08 GMT+1)

Andrew Shute
Sr Vice President, Global Field Operations

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FSCA Reference: FSCA 22-004

Appendix A

Programming Guidance

This guidance applies to the WiSE-CRT™ Model 4100 Transmitters with software version 1.1.3 with use of Model 5100 Programmers running software version 6.2.3.

For devices programmed to utilize multiple targeting sensors, the Optimize Targeting mechanism in the FOLLOW-UP Screen (circled in Figure 1) **should not** be used as it will cause the currently active sensor to be the only enabled targeting sensor.

Do not use the FOLLOW-UP screen for patients that are programmed to utilize multiple targeting sensors.

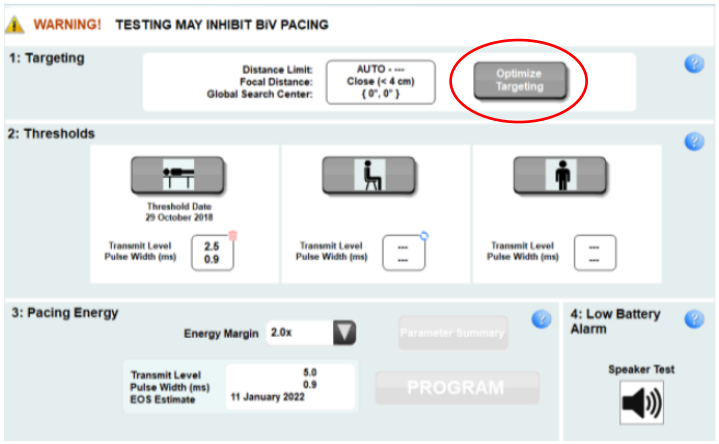

Figure 1: FOLLOW-UP screen with Optimize Targeting Button circled

Prior to utilizing the FOLLOW-UP Screen, check the TARGETING SENSORS section of the REPORT screen to confirm that the device is programmed to utilize only one targeting sensor.

Figure 2 shows the TARGETING SENSORS of a REPORT screen for a device with one sensor enabled. The FOLLOW-UP screen can be utilized in this case with no impact on the single enabled targeting sensor.

TARGETING SENSORS (over last 42 days)	Mean	Std Dev	Usage	Noise
Pulse Generator / Battery* (uV)	140	78	100%	45 ± 10

Figure 2: One Enabled Targeting Sensor

Figure 3 shows the TARGETING SENSORS of a REPORT screen for a device with multiple sensors enabled. The FOLLOW-UP screen **should not** be used in this case. Note this example shows 4 sensors, however, the same applies if 2 or 3 sensors are enabled.

TARGETING SENSORS (over last 71 days)	Mean	Std Dev	Usage	Noise
Pulse Generator Vertical (uV)	83	44	0%	51 ± 21
Pulse Generator Horizontal (uV)	187	52	18%	54 ± 19
Pulse Generator Front-Back (uV)	78	8	0%	46 ± 11
Pulse Generator / Battery* (uV)	408	162	82%	85 ± 34

Figure 3: Multiple Enabled Targeting Sensors

If multiple sensors are enabled, targeting optimization should be performed using the ACOUSTIC WINDOW screen and threshold testing using the MODE/OUTPUT screen shown in Figure 4 rather than FOLLOW-UP screen.

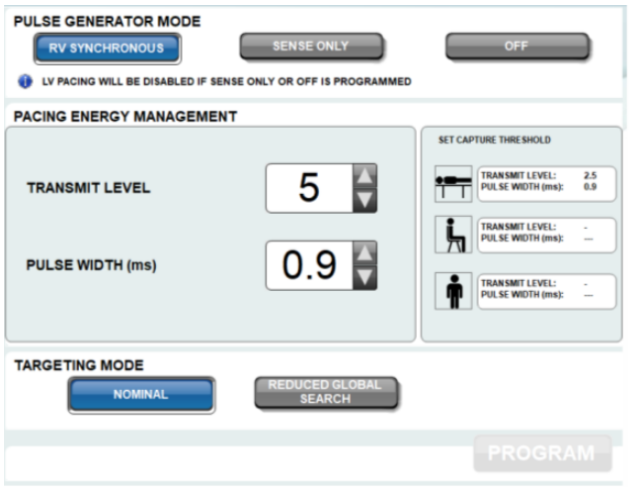

Figure 4: MODE/OUTPUT screen

FSN Reference: FSN 22-004
FSCA Reference: FSCA 22-004

Appendix B

List of Potentially Affected Devices Implanted in Your Hospital and Patient Specific Reprogramming Guidance

Appendix C

Clinical Impact (Patient Risk)

Pacing energy in the WiSE CRT system is delivered to the implanted electrode by the transmitter using focused ultrasonic transmissions. This requires the transmitter to determine the location of the implanted electrode prior to every pacing pulse delivery. The targeting sensors located on the transmitter and the battery provide information required to determine this location. Multiple sensors can be enabled to accommodate situations where changes in patient posture are significant enough to change sensitivity. The system only uses one sensor at a time, but if that sensor becomes insensitive the next available enabled sensor will be used.

To increase system performance, best practice is to enable all sensors post implant and then assess sensor usage over time at subsequent follow up, disabling any sensors used less than 5% of the time. This practice commonly results in patients with a single enabled sensor configuration. However, there are patients that end up with multiple sensors programmed on. This generally occurs because there are multiple sensors that are equally effective for locating the electrode. Many of these patients would have similar performance if their system was operating using a single sensor

Due to the potential software issue reported in this Field Safety Notice, in cases where multiple sensors are enabled, all sensors -- other than the one currently active – are disabled leaving the system with a single sensor enabled. There is a risk that the resulting single enabled sensor is not the optimal sensor to locate the electrode in every posture. In the worst case, this sensor does not provide sufficient information to locate the electrode (i.e., it is not sensitive enough) and no pacing is delivered, resulting in a loss of therapy for that beat. Since the locating process is performed prior to every attempted pace pulse delivery, the loss of therapy is temporary until the next attempted pace pulse. A side effect of this is the transmitter will expend more energy performing an extended attempt to locate the electrode than if it located it immediately, leading to increased battery consumption.

However, at the time a single sensor is enabled, that sensor is active and successful locating the electrode. This increases the likelihood that the sensor will be able to locate the electrode and provide therapy chronically reducing the potential clinical risk that could result from this issue.

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Appendix D

Acknowledgement Form

Please complete this Acknowledgement Form and 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			

UK FSN 22-004

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