Urgent Field Safety Notice

Boston Scientific

November 2018

Subject: Software update for Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) addresses the December 2017 Left Ventricular (LV) Offset Interaction. Reference: 92179817-FA

Summary Field Safety Notice (FSN)

- New software for ZOOM™ Model 3120 Programmer addresses the previously communicated risk for affected CRT-Ds of early replacement due to permanent Safety Mode status by a parameter interaction involving positive LV Offset values
- We are in the process of upgrading programmers with this new software
- The risk of early replacement due to this device behavior continues to exist for CRT-Ps as the software update is pending approval
- Continue managing affected CRT-Ps with previously distributed recommendations

Table 1. Affected CRT-Ds[1] with software update available.

Product name	Models	Product name	Models
RESONATE™ CRT-D	G424, G425, G426, G428, G437, G447, G448, G524, G525, G526, G528, G537, G547, G548	VIGILANT™ CRT-D	G224, G225, G228, G237, G247, G248
MOMENTUM™ CRT-D	G124, G125, G126, G128, G138	DYNAGEN™ CRT-D	G150, G151, G156, G158
AUTOGEN™ CRT-D	G172, G173, G175, G177, G179	CHARISMA™ CRT-D	G324, G325, G328, G337, G347, G348
INOGEN™ CRT-D	G140, G141, G146, G148	ORIGEN™ CRT-D	G050, G051, G056, G058

Table 2. Affected CRT-Ps[1], manage using December 2017 recommendations.

Product name	Models	Product name	Models
VISIONIST™ CRT-P	U225, U226, U228	VALITUDE™ CRT-P	U125, U128

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[1] CRT devices distributed in the United States do not include positive LV Offset values and are therefore are not affected.

Boston Scientific Software Update for CRT-Ds addresses Positive LV Offset Interaction

Dear Doctor,

In December 2017, Boston Scientific began notifying physicians about the rare potential for early replacement due to permanent Safety Mode status caused by a parameter interaction involving positive left ventricular (LV) offset values in Cardiac Resynchronization Therapy Pacemakers (CRT-Ps) and Defibrillators (CRT-Ds). At that time, Boston Scientific committed to providing software updates to address this behavior.

Boston Scientific recently received CE-Mark for Model 2868 v4.07 TY+ software for CRT-Ds and your local representative will arrange to upgrade your programmer(s) soon. This letter describes how the software resolves this behavior for affected CRT-Ds and affirms continuation of recommendations for affected CRT-Ps until software is available.

Description of Software for Affected CRT-Ds

This software imposes an interactive limit, which prevents programming a positive LV Offset value greater than the Atrial Blank (A-Blank) after Ventricular Pace (V-Pace) when Tracking Preference is enabled. As per our previous communication in December 2017, this programming had the potential to cause CRT-D devices to enter into a permanent Safety Core status, which would require premature device replacement. Affected CRT-Ds interrogated by an updated programmer are no longer susceptible to this issue.

Distribution. Distribute this letter to all physicians and healthcare professionals within your organization who need to be aware of this topic.

CRT-D Actions for Software Enhancement

- Confirm all your center's/clinic's Model 3120 ZOOM programmers are upgraded with Model 2868 v4.07 TY+ software.
    - Appendix A includes instructions for confirming software installation.
    - CRT-Ds in Table 1 interrogated by an upgraded programmer are no longer at risk of permanent Safety Mode status due to a parameter interaction between positive LV Offset, A-Blank after V-Pace values, and Tracking Preference.
- Upon interrogating a CRT-D programmed in a susceptible manner, the programmer displays an interactive limit error. Reprogram one or more of the parameters identified.
- Append the patient's medical record with this letter to maintain awareness of this topic for the remaining service life of their CRT-D.

CRT-P Recommendations for Positive LV Offset Interaction
- The software for CRT-Ps in Table 2 is not yet available, so continue with the December 2017 recommendations.
- If a positive LV Offset is desired for an affected CRT-P, consider the patient's individual medical needs and either program the A-Blank after V-Pace value greater than the positive LV Offset value, or disable Tracking Preference by programming it to a value of "OFF".
- Append the patient's medical record with this letter or the original FSN to maintain awareness of this topic for the remaining service life of their CRT-P.

Additional Information
U.S. configurations of affected device models are not affected by the risks of early device replacement due to this behavior, as positive LV offset values are not available. Boston Scientific recognizes the impact of communications on both you and your patients, and wants to reassure you that patient safety remains our highest priority. If you have additional questions regarding this information or would like to report clinical events, please contact your Boston Scientific representative or Technical Services.

Sincerely,

Renold Russie
Vice President, Quality Assurance

Appendix A – Identification of Programmer Software

Confirm your Model 3120 ZOOM™ Programmer has received this software upgrade	
Select About button and confirm Software Model and Version	 Model 2868 v4.07
Software Enhancement	Supported CRT-Ds interrogated with this software are no longer at risk of permanent Safety Mode status due to a parameter interaction between positive LV Offset, A-Blank after V-Pace values, and Tracking Preference.