Urgent Field Safety Notice

Boston Scientific

January 2019

Subject: Software updates for Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Pacemakers (CRT-Ps) address the November 2018 Positive Left Ventricular (LV) Offset Interaction (see previous communications issued in December 2017 and more recently November 2018 with reference 92179817-FA).

Summary Field Safety Notice (FSN):

- New software supporting CRT-Ps in Table 1 for ZOOM™ Model 3120 Programmer addresses the previously communicated risk 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
- Software supporting CRT-Ds in Table 2 was previously launched

Table 1. Affected CRT-Ps[1], with software update Model 2869 v2.06.

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

Table 2. Affected CRT-Ds[1] with previously released software update Model 2868 v4.07.

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

[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 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 Defibrillators (CRT-Ds) and Pacemakers (CRT-Ps). At that time, Boston Scientific committed to providing software updates to address this behavior.

Boston Scientific has received approval of Model 2869 v2.06 software for CRT-Ps and previously released Model 2868 v4.07 for CRT-Ds and your local representative will arrange to upgrade your programmer(s) soon. This letter describes how the software resolves this behavior.

Description of Software
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 affected CRT-D or CRT-P devices to enter into a permanent Safety Core status, which would require premature device replacement. Affected devices 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.

Actions for Software Enhancement
- Confirm all your center's/clinic's Model 3120 ZOOM programmers are upgraded with Model 2869 v2.06 and previously released Model 2868 v4.07 software.
    - Appendix A includes instructions for confirming software installation.
    - Affected devices in Table 1 and 2 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 device 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 device.

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.
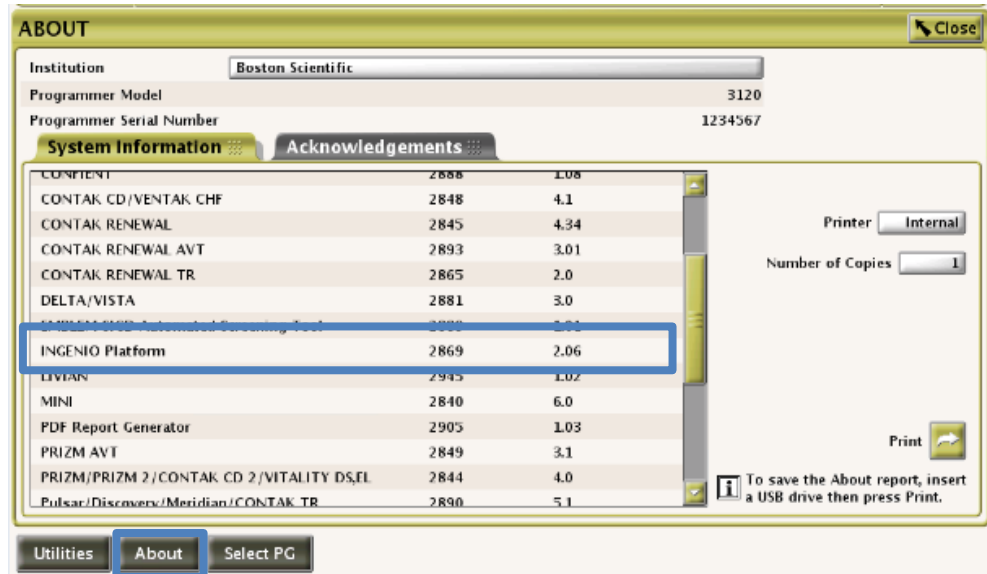
Sincerely,

Renold Russie
Vice President, Quality Assurance

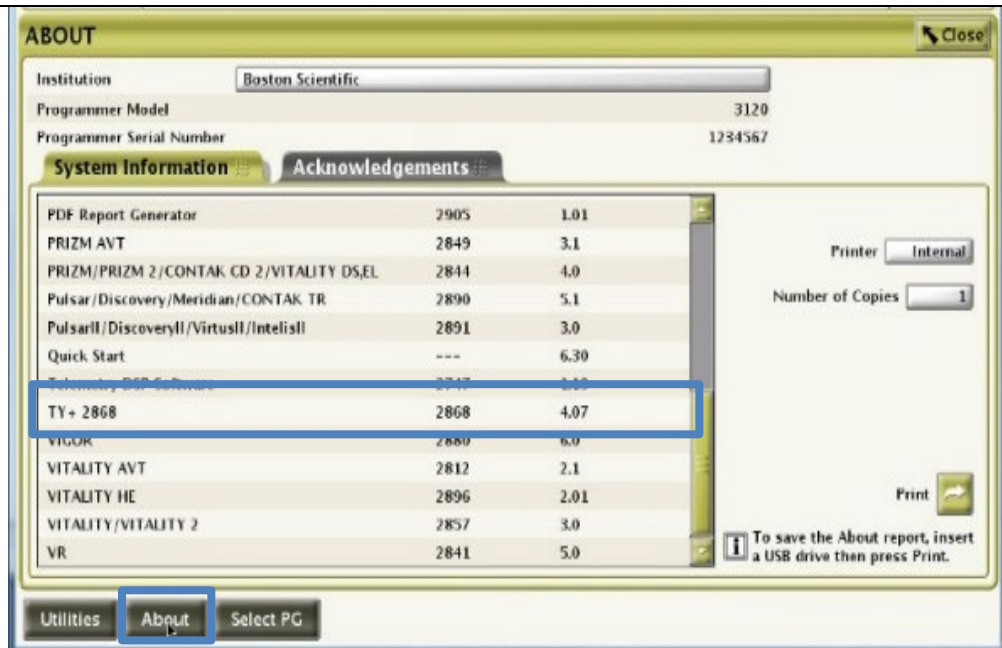# Appendix A – Identification of Programmer Software

Confirm software upgrades	**Model 3120 ZOOM™ Programmer**
	Model 2869 v2.06 supports CRT-Ps in Table 1
Select About button and Confirm Software Model and Version	Previously released model 2868 v4.07 supports CRT-Ds in Table 2
Software Enhancement	Supported devices 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.