Urgent Field Safety Notice

December 2017

Subject: **Technical programming information – Left Ventricular (LV) Offset interaction on Cardiac Resynchronization Therapy pacemakers (CRT-Ps) and defibrillators (CRT-Ds)**
Reference: 92179817-FA

Product name	Models
VALITUDE™ CRT-P	U125, U128
RESONATE™ CRT-D	G424, G425, G426, G428, G437, G447, G448, G524, G525, G526, G528, G537, G547, G548
MOMENTUM™ CRT-D	G124, G125, G126, G128, G138
AUTOGEN™ CRT-D	G160, G161, G166, G168, G172, G173, G175, G177, G179
INOGEN™ CRT-D	G140, G141, G146, G148
VISIONIST™ CRT-P	U225, U226, U228
VIGILANT™ CRT-D	G224, G225 , G228, G237, G247, G248
CHARISMA™ CRT-D	G324, G325, G328, G337, G347, G348
DYNAGEN™ CRT-D	G150, G151, G156, G158
ORIGEN™ CRT-D	G050, G051, G056, G058

Dear Doctor,

This letter includes important programming information to prevent an unintended asynchronous biventricular (BiV) pacing behaviour when tracking elevated atrial intrinsic rhythms in certain Boston Scientific Cardiac Resynchronization Therapy (CRT) pacemakers (CRT-Ps) and defibrillators (CRT-Ds). Repeated detection of this unintended asynchronous BiV pacing behaviour may result in the implanted device reverting to a permanent Safety Mode (Safety Core™) status thus requiring early replacement.
The unintended asynchronous BiV pacing behaviour can only occur when an infrequent combination of parameters are programmed, specifically:

- Left Ventricular (LV) Offset programmed to a positive[1] value which exceeds the Atrial Blank after Ventricular Pace (A-Blank after V-Pace) interval; and
- Tracking Preference = ON (nominal).

Until software is available to prevent programming of a susceptible combination of parameters, the enclosed programming recommendations eliminate the risks associated with early device replacement due to this device behaviour. CRT devices more commonly programmed to simultaneous BiV pacing (LV Offset = zero) or sequential BiV where LV precedes RV (negative LV Offset value) are not subject to the risks described in this letter.

Boston Scientific CRT-Ps and CRT-Ds are supported by different programmer software applications. The software update for CRT-Ps is in development. We anticipate submitting the CRT-P software update to Regulatory Agencies in March 2018 and pending approval, releasing in October 2018. Subsequently, development of CRT-D software will begin which we anticipate submitting in August 2018 and pending approval, releasing in March 2019.

Description and Clinical Implications
Appendix A describes the parameters and interactions necessary to result in early replacement of a CRT device due to this device behaviour.

[1]Positive LV Offset facilitates sequential BiV pacing where the right ventricular pacing pulse precedes the left ventricular pacing pulse by a programmed value in milliseconds.

Observed Rate
Of the 60,500 CRT devices distributed worldwide, Boston Scientific estimates approximately 300 CRT devices are programmed with the combination of parameters which may lead to this device behaviour. There have been two confirmed instances of early device replacement due to this device behaviour (0.7%). Of the two cases, a single patient death occurred due to complications related to the replacement procedure.

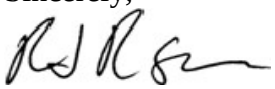
Recommendations
To eliminate the risk associated with early replacement due to this unintended asynchronous BiV pacing behaviour, perform the following steps:

1. Review programming records of patients implanted with the CRT devices included in Appendix B.
2. If the LV Offset parameter is programmed to Zero or a Negative value, the device is not at risk of this behaviour.
3. If the LV Offset parameter is programmed to a Positive value, determine if the following conditions are met:
   A. The positive LV Offset value exceeds the A-Blank after V-Pace interval, where "Smart" blanking is equivalent to a value of 37.5 ms; and
   B. Tracking Preference programmed to ON
4. For patients whose device has a positive LV Offset value exceeding A-Blank after V-Pace value and Tracking Preference is programmed to ON, schedule a clinic appointment to reprogram the CRT device as follows according to the patient's individual medical needs:
   A. Either program the CRT device such that the A-Blank after V-Pace value is greater than the positive LV Offset value; or
   B. Disable Tracking Preference by programming it to a value of "OFF".
5. Devices with an A-Blank after V-Pace value exceeding the positive LV Offset value are not affected and are not at risk of this behaviour.
6. Patients whose device has Tracking Preference programmed OFF are not affected and are not at risk of this behaviour.

If a positive LV Offset is desired for a newly implanted Boston Scientific CRT device, 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".
Appendix B includes a recommendations flow chart, potentially affected device list, and a sample device settings report. Note that U.S. configurations of these device models are not affected by the risks of early device replacement due to this behaviour, as positive LV offset values are not available. Appendix C includes programmer screenshots to support programming recommendations.

Additional Information
Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (If appropriate).
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: Description of parameters involved in the December 2017 LV Offset product advisory

Description of Parameters
The combination of programmable and non-programmable parameters involved in the unintended asynchronous BiV device behaviour is described below. Additional detail on these parameters is included within the product manuals, available online at www.BostonScientific-eLabeling.com.

Tracking Preference is designed to reestablish atrial tracking at sub-MTR rates by shortening PVARP temporarily when an atrial event is sensed in PVARP for two successive cardiac cycles. Tracking Preference is nominally enabled "ON" in CRT devices and is rarely changed. CRT devices programmed with Tracking Preference programmed "OFF" are not subject to the risks described in this product advisory.

LV Offset allows adjustment to the pacing interval between delivery of the LV and RV pacing pulse. LV Offset is nominally programmed to zero or simultaneous BiV pacing. Studies suggest sequential BiV pacing may reduce mechanical dyssynchrony due to longitudinal contraction delays between ventricles and may improve ejection fraction[2]. A positive LV Offset value produces RV pacing before LV pacing (programmable up to 100 ms). Because of the nominal setting and prevalence of left bundle branch blocks in the cardiac conduction system of CRT indicated heart failure patients, LV Offset values are more frequently programmed to zero or negative values. CRT devices programmed with a zero or negative LV Offset value are not subject to the risks described in this product advisory.

A-Blank after V-Pace is designed to promote the appropriate sensing of intrinsic atrial cardiac events and prevent oversensing of cross-chamber events following either an RV or LV pace. Typically, blanking parameters are a programmable interval. Smart blanking is a programmable value when automatic gain control sensing is configured in the device. Smart blanking employs a combination of a 37.5 ms blanking period and elevation of the automatic gain control sensing threshold. The nominal value for CRT-Ds is Smart blanking and the nominal value for CRT-Ps is 125 ms. CRT devices programmed with A-Blank after V-Pace value greater than a positive LV Offset value are not subject to the risks described in this product advisory.

Safety Core™ (Safety Mode) is intended to provide life-sustaining therapy if certain non-recoverable or repeat fault conditions occur and cause a system reset. If the CRT device experiences three resets in 48 hours, the device reverts to Safety Mode operation permanently and should be replaced.

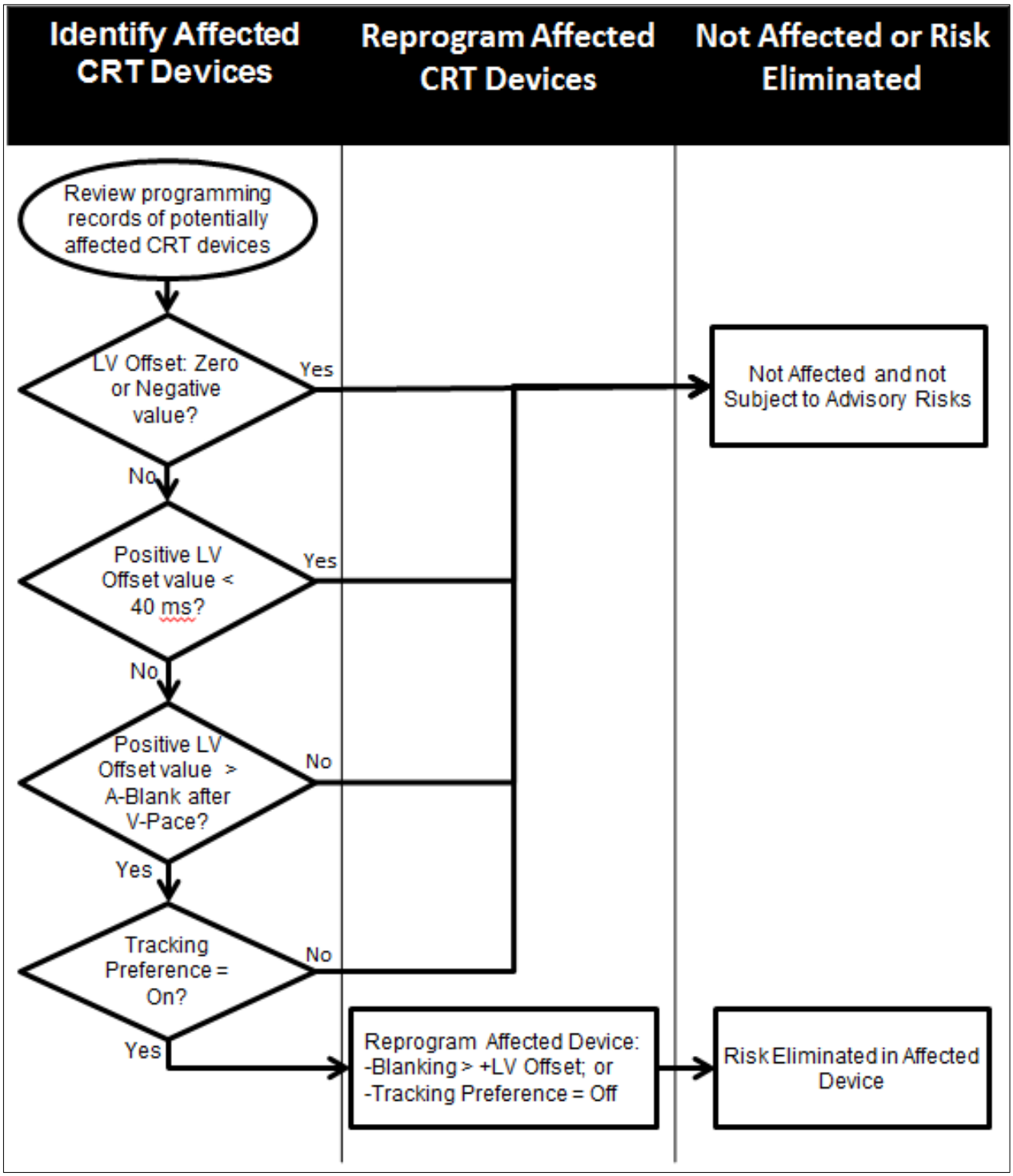
Description of Clinical Implications
To provoke this CRT device behaviour, the intrinsic atrial rate must be elevated sufficiently to engage Tracking Preference whereby PVARP is shortened. While Tracked Preference is active, if the positive LV Offset value is greater than A-Blank after V-Pace and an atrial event is sensed after an RV pace but before the positive offset LV pace, a second LV pace will be scheduled and thus the timing of RV and LV pacing will not be properly synchronized as intended. The asynchronous LV pacing is detected as intended by Safety Architecture's pacing monitor causing a fault and subsequent device reset. If this sequence of events repeats two more times (a total of 3 device resets) within 48 hours, the device reverts permanently to Safety Core and the device should be replaced.

While dyssynchrony between RV and LV pacing may occur with any Boston Scientific CRT programmed in the manner described in this letter, the pacing monitor in previous generation CRT devices[3] was not designed to detect asynchronous RV and LV pacing and thus will not provoke a Safety Core response.

[2]Soggard P, Egeblad H., et al. Sequential vs. simultaneous biventricular resynchronization for severe heart failure. Circulation, 2002;106:2078-2084.
[3]COGNIS™, INCEPTA™, ENERGEN™, and PUNCTUA™ CRT-Ds and INVIVE™ and INTUA™ CRT-Ps.

Appendix B: Recommendation Flow Chart, Potentially Affected Device List, and Sample Device Settings Report for the November 2017 product advisory

Recommendation Flow Chart



Appendix B: Recommendation Flow Chart, Potentially Affected Device List, and Sample Device Settings Reports for the December 2017 LV Offset product advisory

Potentially Affected CRT Devices

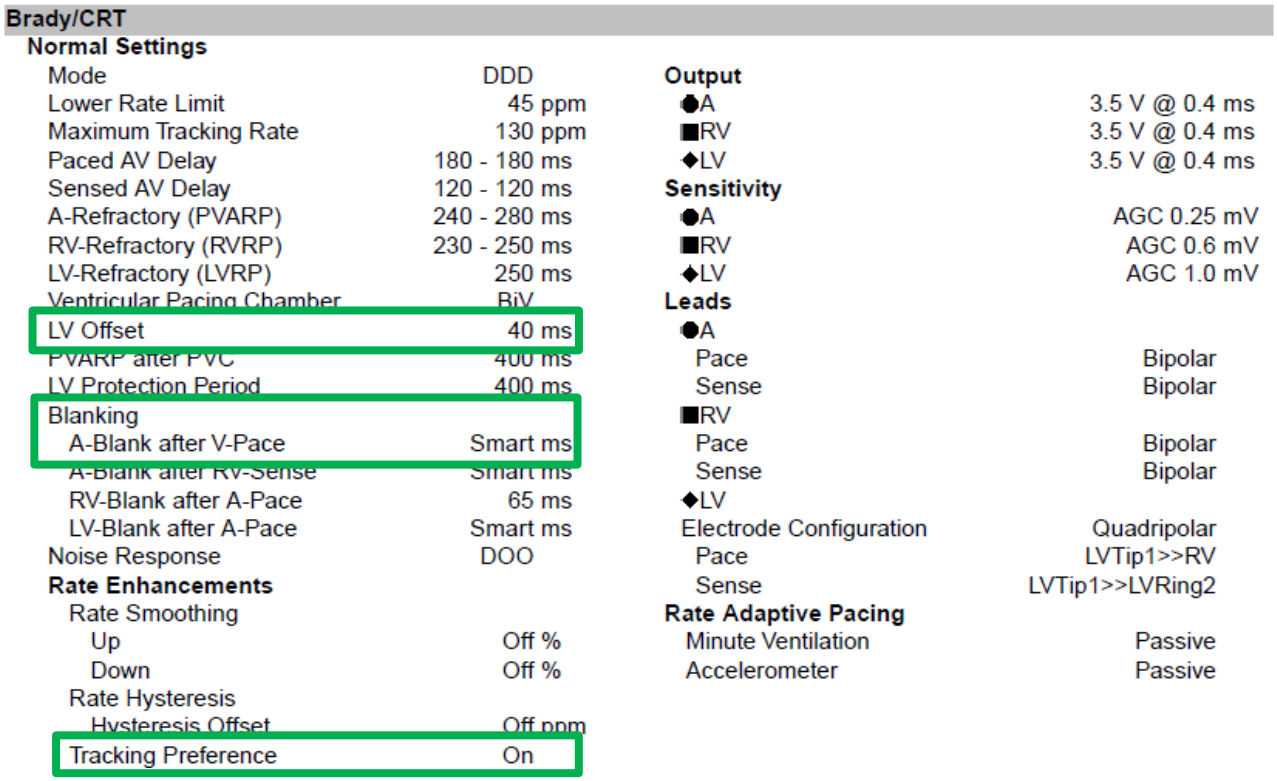
Cardiac CRT-Ps and CRT-Ds programmed with a zero or negative LV Offset value are not susceptible to the risks described in this letter. Only devices listed below with Tracking Preference and a positive LV Offset value exceeding the A-Blank after V-Pace interval are affected and thus subject to the risks described in this letter.

VALITUDE™ CRT-P Models U125 and U128	VISIONIST™ CRT-P Models U225, U226, and U228
RESONATE™ CRT-D Models G424, G425, G426, G428, G437, G447, G448, G524, G525, G526, G528, G537, G547, G548	VIGILANT™ CRT-D Models G224, G225 , G228, G237, G247, G248
MOMENTUM™ CRT-D Models G124, G125, G126, G128, G138	CHARISMA™ CRT-D Models G324, G325, G328, G337, G347, G348
AUTOGEN™ CRT-D Models G172, G173, G175, G177, G179	DYNAGEN™ CRT-D Models G150, G151, G156, G158
INOGEN™ CRT-D Models G140, G141, G146, G148	ORIGEN™ CRT-D Models G050, G051, G056, G058
U.S. configurations of these device models limit LV Offset values between -100 ms and 0 ms and are not affected by the risks of early device replacement due to this unintended asynchronous BiV pacing behaviour.	

Sample Device Settings Reports

The programmable parameters appear differently for devices with and without LV Multisite Pacing (LV MSP). If the “Mode” is programmed to a non-tracking pacing mode (e.g. DDI, VVI, etc.), Tracking Preference will neither be available as a programmable parameter nor will it be displayed on the Settings Report. Devices with Tracking Preference disabled are not affected and not subject to the risks described in this letter.

Report for devices without LV MSP



Brady/CRT

Normal Settings

Mode	DDD
Lower Rate Limit	45 ppm
Maximum Tracking Rate	130 ppm
Paced AV Delay	180 - 180 ms
Sensed AV Delay	120 - 120 ms
A-Refractory (PVARP)	240 - 280 ms
RV-Refractory (RVRP)	230 - 250 ms
LV-Refractory (LVRP)	250 ms
Ventricular Pacing Chamber	BiV
LV Offset	40 ms
PVARP after PVC	400 ms
LV Protection Period	400 ms
Blanking	
A-Blank after V-Pace	Smart ms
A-Blank after RV-Sense	Smart ms
RV-Blank after A-Pace	65 ms
LV-Blank after A-Pace	Smart ms
Noise Response	DOO

Rate Enhancements

Rate Smoothing	
Up	Off %
Down	Off %
Rate Hysteresis	
Hysteresis Offset	Off ppm
Tracking Preference	On

Output

●A	3.5 V @ 0.4 ms
■RV	3.5 V @ 0.4 ms
◆LV	3.5 V @ 0.4 ms

Sensitivity

●A	AGC 0.25 mV
■RV	AGC 0.6 mV
◆LV	AGC 1.0 mV

Leads

●A	
Pace	Bipolar
Sense	Bipolar
■RV	
Pace	Bipolar
Sense	Bipolar
◆LV	
Electrode Configuration	Quadripolar
Pace	LVTip1>>RV
Sense	LVTip1>>LVRing2

Rate Adaptive Pacing

Minute Ventilation	Passive
Accelerometer	Passive

Appendix B: Recommendation Flow Chart, Potentially Affected Device List, and Sample Device Settings Reports for the December 2017 LV Offset product advisory

Report for devices with LV MSP

The pacing order "RV→LVa→LVb" indicates that RV pacing occurs before LV. Other pacing order values are not subject to the risks described in this letter. Devices with Tracking Preference disabled are not affected and not subject to the risks described in this letter.

Brady/CRT

Normal Settings

Mode	DDD
Lower Rate Limit	45 ppm
Maximum Tracking Rate	130 ppm
Paced AV Delay	180 - 180 ms
Sensed AV Delay	120 - 120 ms
A-Refractory (PVARP)	240 - 280 ms
RV-Refractory (RVRP)	230 - 250 ms
LV-Refractory (LVRP)	250 ms
Ventricular Pacing Chamber	BiV
PVARP after PVC	400 ms
LV Protection Period	400 ms
Blanking	
A-Blank after V-Pace	Smart ms
A-Blank after RV-Sense	Smart ms
RV-Blank after A-Pace	65 ms
LV-Blank after A-Pace	Smart ms
Noise Response	DOO
Rate Enhancements	
Rate Smoothing	
Up	Off %
Down	Off %
Rate Hysteresis	
Hysteresis Offset	Off ppm
Tracking Preference	On

Output

●A	3.5 V @ 0.4 ms
■RV	3.5 V @ 0.4 ms
◆LVa	3.5 V @ 0.4 ms
◆LVb	3.5 V @ 0.4 ms

Sensitivity

●A	AGC 0.25 mV
■RV	AGC 0.6 mV
◆LV	AGC 1.0 mV

Leads

●A	
Pace	Bipolar
Sense	Bipolar
■RV	
Pace	Bipolar
Sense	Bipolar
◆LV	
Electrode Configuration	Quadripolar
Pace (LVa)	LVRing2>>RV
Pace (LVb)	LVTip1>>RV
Sense	LVTip1>>LVRing2
LV MultiSite Pacing	
Pacing Order	RV→LVa→LVb
RV-LVa Offset	40 ms
LVa-LVb Offset	0 ms
Rate Adaptive Pacing	
Minute Ventilation	Passive
Accelerometer	Passive

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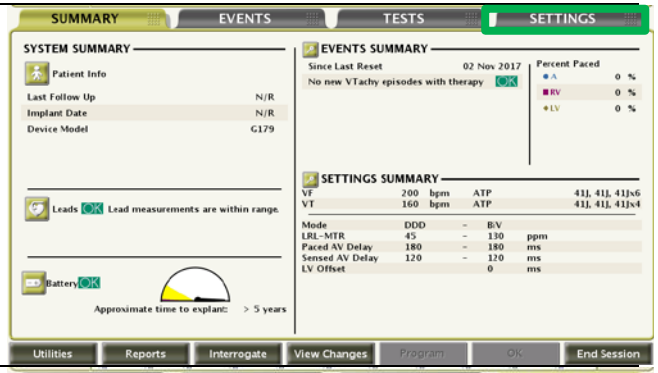
Appendix C: Navigation for programming recommendations for the December 2017 LV Offset product advisory

To eliminate the risk associated with early replacement of an affected CRT device for the behaviour described in this letter, reprogram the CRT device as follows according to the patient's individual medical needs.

To Program A-Blank after V-Pace Value

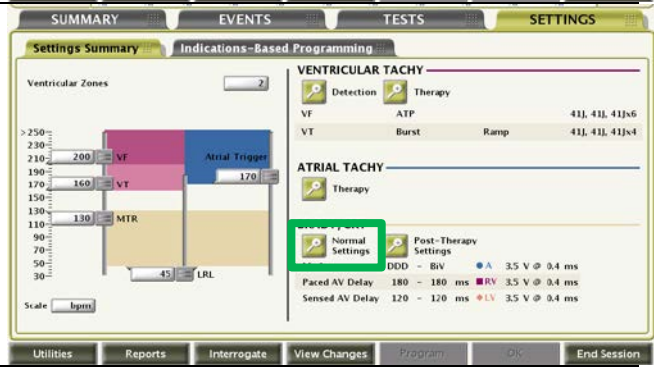
1. On the Summary page, select

   "*Settings*" Tab



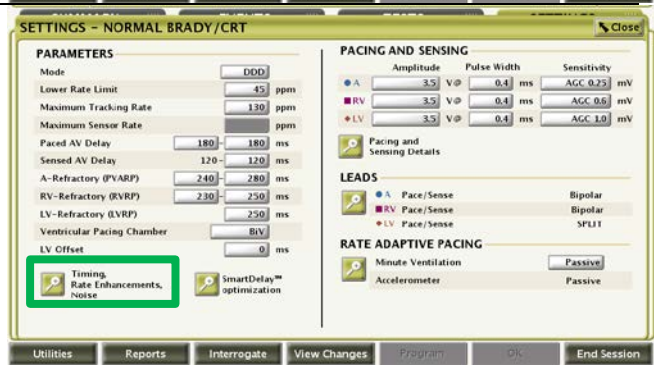
2. On Settings Summary Tab, select

   "*Normal Settings*" button



3. On Settings – Normal Brady/CRT page, select

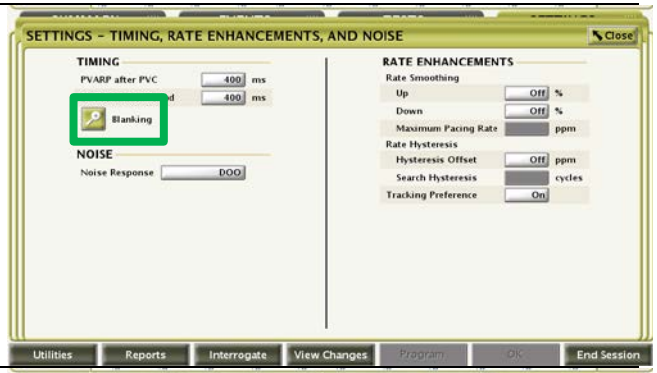
   "*Timing, Rate Enhancements, Noise*" button



To Program A-Blank after V-Pace Value

4. On the Settings – Timing, Rate Enhancements, and Noise page, select

   "*Blanking*" button



5. On Settings – Blanking, select

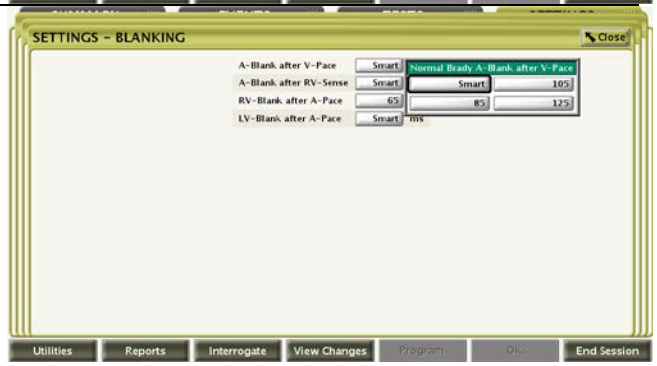
   A-Blank after V-Pace value greater than the positive LV Offset.

6. Programming options in ms for

   CRT-Ds: 85, 105, 125, and Smart (nominal);

   CRT-Ps: 85, 105, 125 (nominal), 150, 175, 200, and Smart*.

   *Available if AGC sensing (not fixed) is enabled.



Note: Smart blanking is the equivalent to a 37.5 ms value, any device programmed to a positive LV Offset of 35 ms or less is not affected and not subject to the risks described in this letter.

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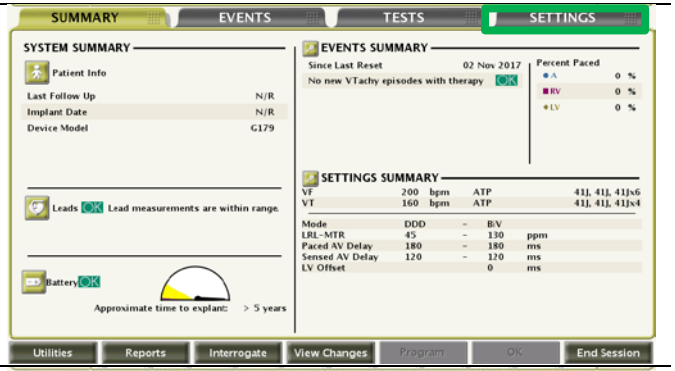
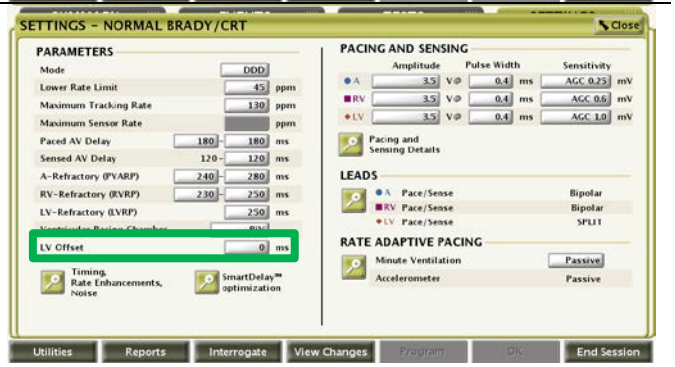
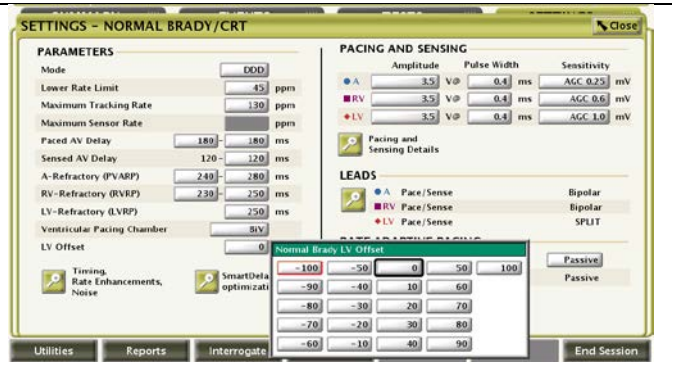
Appendix C: Navigation for programming recommendations for the December 2017 LV Offset product advisory

To eliminate the risk associated with early replacement of an affected CRT device for the behaviour described in this letter, reprogram the CRT device as follows according to the patient's individual medical needs.

To Program LV Offset Value in Devices without LV MSP or with LV MSP Disabled

1. On the Summary page, select "*Settings*" Tab	
2. On the Settings Summary Tab, select "*Normal Settings*" button	
3. On the Settings – Normal Brady/CRT page, select "*LV Offset*" value	

To Program LV Offset Value in Devices without LV MSP or with LV MSP Disabled

4. Program LV Offset to zero, any negative value, or a positive value that is less than the A-Blank after V-Pace value.	 Note: Smart blanking is the equivalent to a 37.5 ms value, any device programmed to a positive LV Offset of 35 ms or less is not affected and not subject to the risks described in this letter.

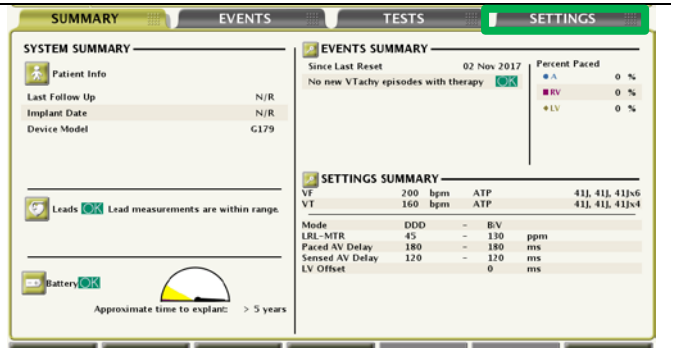
Appendix C: Navigation for programming recommendations for the December 2017 LV Offset product advisory

To eliminate the risk associated with early replacement of an affected CRT device for the behaviour described in this letter, reprogram the CRT device as follows according to the patient's individual medical needs.

To Program LV Offset Value in Devices with LV MSP

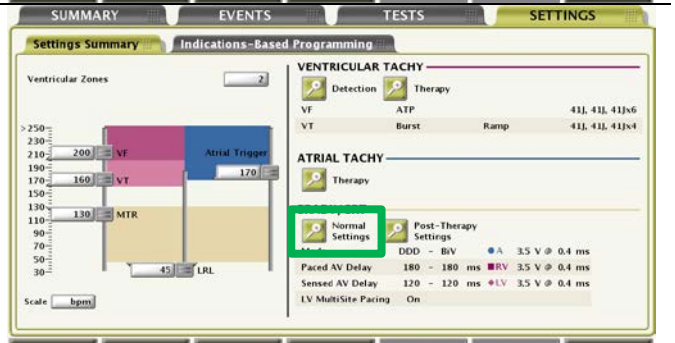
1. On the Summary page, select

   "*Settings*" Tab



2. On the Settings Summary Tab, select

   "*Normal Settings*" button



3. On the Settings – Normal Brady/CRT page, select

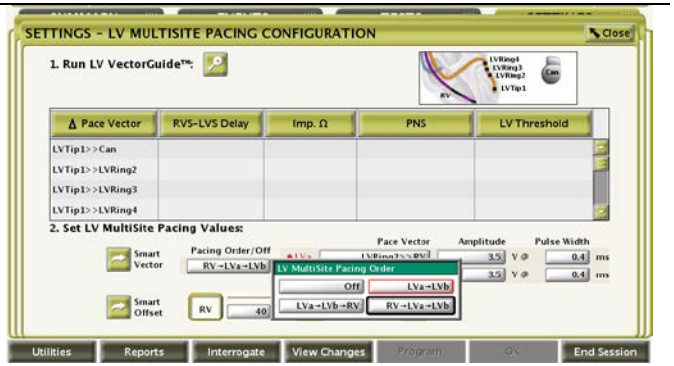
   "*LV Multisite Pacing*" button

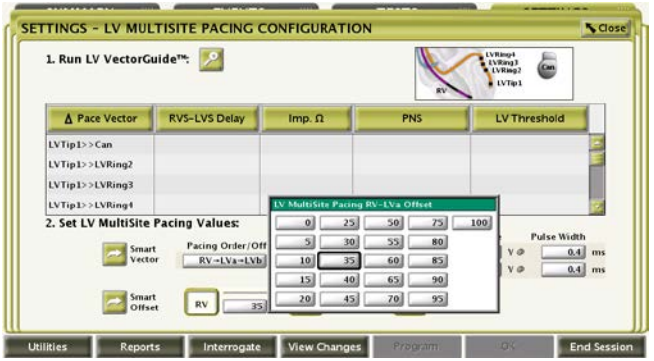
To Program LV Offset Value in Devices with LV MSP

4. Program Pacing Order to Off*, LVa→LVb→RV, or LVa→LVb

   *If OFF LV MSP is disabled. Use LV MSP Disabled Appendix to program LV Offset.

   Or, when Pacing Order is programmed RV→LVa→LVb, program the RV→LVa Offset to a value that is less than the A-Blank after V-Pace value.





Note: Smart blanking is the equivalent to a 37.5 ms value, any device programmed to a RV→LVa Offset of 35 ms or less is not affected and not subject to the risks described in this letter.

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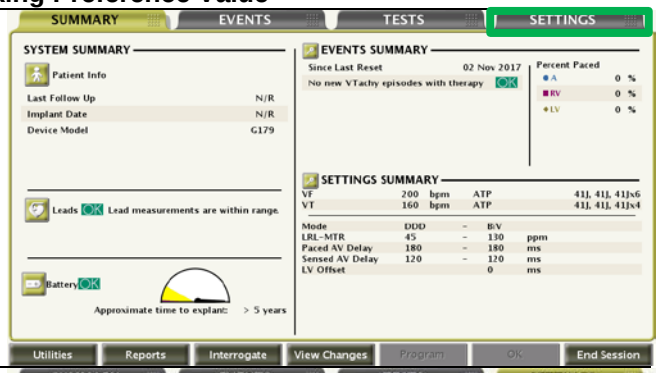
Appendix C: Navigation for programming recommendations for the December 2017 LV Offset product advisory

To eliminate the risk associated with early replacement of an affected CRT device for the behaviour described in this letter, reprogram the CRT device as follows according to the patient's individual medical needs.

To Program Tracking Preference Value

1. On the Summary page, select

   "*Settings*" Tab

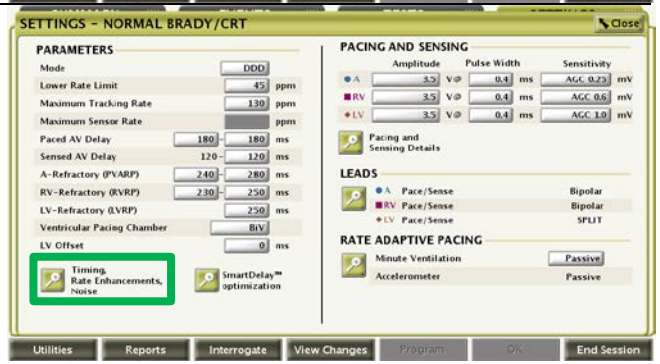


2. On the Settings Summary Tab, select

   "*Normal Settings*" button

3. On the Settings – Normal Brady/CRT page, select

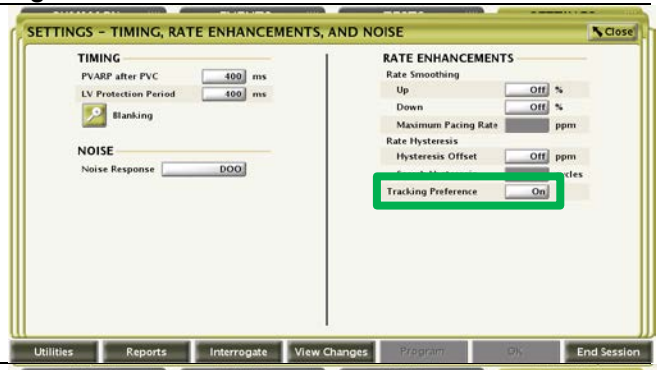
   "*Timing, Rate Enhancements, Noise*" button



To Program Tracking Preference Value

4. On the Settings – Timing, Rate Enhancements, and Noise page, select

   "Off" for Tracking Preference



5. Press the program button