ANZCDACC Advisory Notice 24th December 2017

Device: Boston Scientific VALITUDE™ CRT-P Model U128, RESONATE™ CRT-D Model G447, MOMENTUM™ CRT-D Model G124, G125, G126, G128, AUTOGEN™ CRT-D Models G172, G173, G175, G177, G179 VISIONIST™ CRT-P Models U225, U226, U228, DYNAGEN™ CRT-D Models G151, G156, G158

TGA Reference: RC-2017-RN-01510-1

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Routine

Description: A programming interaction can occur with 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 positive1 value which exceeds the Atrial Blank after Ventricular Pace (A-Blank after V-Pace) interval; and

• Tracking Preference = ON (nominal).

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 at risk.

Number of devices affected in Australia and New Zealand: 1900 devices.

Presentation: Patients will present with device in irreversible Safety Mode (Bradycardia VVI (BiV) asynchronous at 5.0 V at 1msec unipolar pacing and sensing rate 72.5 bpm and Tachycardia therapies VF only at 165 bpm for 1 second 5 shocks at 41 joules). This may cause worsening of heart failure, arrhythmias, pacemaker syndrome and rarely syncope.

Rate of occurrence: 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.

Recommendation:

If Safety Mode (Safety Core™) has occurred in the advisory device, this is irreversible, and the device requires replacement. Otherwise to eliminate the risk associated with early replacement due to this unintended asynchronous BiV pacing behaviour (Safety Mode (Safety Core™)), the Committee recommends the following steps:

1. Review programming records of patients implanted with the affected advisory CRT devices

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:

3A. 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

3B. 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:

4A. Program the CRT device such that the A-Blank after V-Pace value is greater than the positive LV Offset value;

OR

4B. 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.

7. 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”.

A software fix will be available in the near future which will be required to be installed on devices at risk. Until then vigilance and reprogramming as described above will be required.

The ANZCDACC encourage you to report any adverse event or near (potential) adverse event associated with the use of a medical device including any abnormal CIED or lead function. We encourage reporting to ANZCDACC directly via the Committee chair Dr Paul Gould drpgould@gmail.com and to the following regulators.

In Australia, report to the TGA;

Online	https://www.tga.gov.au/reporting-problems

In New Zealand, report to Medsafe;

Post	Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6145.
Email	devices@moh.govt.nz
Fax	04 819 6806