ANZCDACC Implant Hazard Alert June 2021

Device: Boston Scientific dual chamber INGENIO family pacemakers and Cardiac resynchronisation (CRTPs).
Models: ADVANTIO DR EL (K084, K087), INGENIO DR EL (K184, K187), VITALIO DR EL (K287), INVIVE CRT-P (V182, V183)

TGA Reference: RC-2021-RN-01305-1
Australian Register of Therapeutic Goods (ARTG): 194925, 194926, 194927, 202980, 202981, 202982, 213922, 213923, 213924, 213925, 213926, 213927, 194920, 194921, 194924, 202999, 203000, 203004, 213930, 213931, 194928 and 194929

Advisory grade TGA: Class I
(Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk of health).

ANZDACC Advisory Grade: Semi-urgent

Description:
Boston Scientific has determined that the above listed pacemakers or CRT-Ps may initiate Safety Mode later in device life (i.e., prior to reaching the Explant battery indicator) when the device's battery exhibits high internal impedance. This latent battery condition puts a device at risk for system resets to occur due to temporary high-power consumption related to telemetry attempts, by either a programmer or a remote monitor (LATITUDE™ communicator). If the battery voltage drops below a minimum threshold during communication attempts, the device will temporarily halt telemetry, and a system reset will be performed. The battery voltage recovers and pacing function resumes within one (1) second; however, subsequent telemetry attempts, which will automatically occur with a LATITUDE™ communicator, may result in additional system resets due to the high battery impedance. If three (3) system resets occur within a 48-hour period, the device is designed to immediately enter Safety Mode to maintain back-up pacing with pre-defined, non-programmable settings (Table 1). There is no delay in resumption of pacing when the device enters Safety Mode. Although therapy is still provided when a device is in Safety Mode, replacement is required.

Based on the available information and subsequent modelling, **all** dual chamber INGENIO EL pacemakers and CRT-Ps are potentially susceptible to this latent battery condition and subsequent initiation of Safety Mode. Approximately 48,000 active dual chamber INGENIO family pacemakers and CRT-Ps built with the Extended Life (EL) battery are included within this advisory population.

No affected devices remain available for implant. No patient deaths have been reported. The potential for life-threatening harm due to prolonged inhibition or loss of pacing over a device's lifetime is estimated to be less than 1 in 15,000; this has not been observed. The most common clinical impact has been early device replacement.

Table 1. Safety Mode Non-Programmable Parameters.

Mode	VVI (for CRT-Ps: biventricular pacing)
Rate	72.5 ppm
Sensitivity	Automatic Gain Control (AGC) 0.25mV
Output	5.0V at 1.0 ms RV (and LV for CRT-Ps)
Lead Configuration	RV Unipolar sensing/pacing LV Unipolar (tip to can)
RV refractory period	250ms
Noise response	VOO
LV Offset (CRT-Ps only)	0ms
Magnet Response	Disabled

Number of devices affected in Australia and New Zealand:
Approximately 8000 devices

Presentation:

- Myopotential oversensing-associated pacing inhibition, as well as phrenic nerve stimulation have been reported in some patients prior to device replacement due to non-programmable Safety Mode pacing parameters.
- If a device goes into Safety Mode and the patient is on remote monitoring it will attempt to send a red alert to the Latitude website.
    - Note: LATITUDE™ communicators which fail to connect to the network will display the red 'call doctor' icon and after 14 days will appear on the Latitude website as 'Not Monitored'.
- If the device resets in clinic, the failed telemetry attempts will be displayed as follows in Figure 1. The programmer will automatically try to communicate with the device again when the 'close' button is pressed. After the third system reset within a 48-hour period, the device will immediately enter Safety Mode and display the programmer warning screen illustrated in Figure 2.

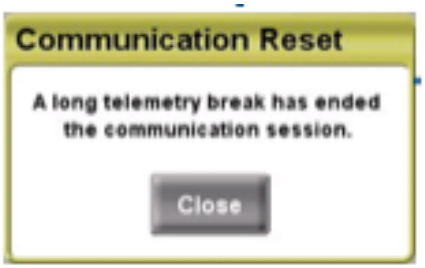

Figure 1. Programmer notification that reset has occurred.

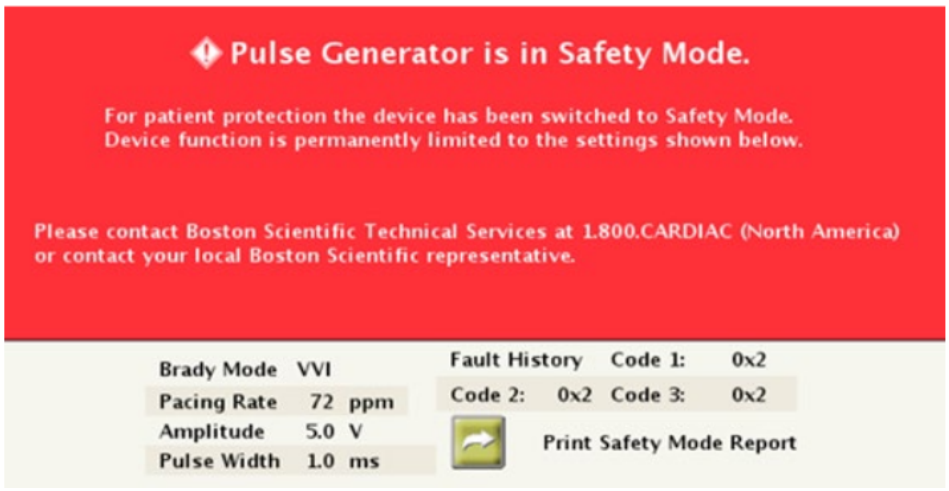

Figure 2. Programmer warning screen for safety mode.

Rate of occurrence:
Boston Scientific has received 65 reports of events associated with dual chamber INGENIO family EL pacemakers and CRT-Ps, in which devices transitioned to Safety Mode prior to reaching the Explant battery indicator during interrogation attempts by either a programmer or a LATITUDE™ communicator.

It is estimated that one third or more of affected devices will experience Safety Mode prior to reaching Explant battery indicator.

Recommendation:

1. **Individual patient evaluation.** As noted above, Safety Mode provides back-up pacing under critical circumstances; it is not intended to be a substitute for chronic pacing therapy. When assessing potential risk for a patient if their device initiates Safety Mode prior to the Explant indicator, consider patient-specific physiological factors (which may vary over time), including: adequacy of underlying escape rhythm and/or the need for AV/VV pacing for cardiac synchrony and the potential for pacing inhibition due to myopotential oversensing.
2. **Device reset in clinic rather than at home.** Remote monitoring increases the likelihood of telemetry attempts due to the chance of it sending alerts in-between scheduled checks, often for benign reasons. This would then theoretically both make device reset more likely to occur earlier than it otherwise would and creates the possibility of it occurring at home. Consider removing patients from remote monitoring in the case where;
    a. The patient is at a higher risk of symptoms (eg. Pacemaker dependent - see point 1)
    b. There is no need for intensified monitoring (eg. For lead issues or frequent/high-risk-for arrhythmia which would need early intervention).
    c. The patient can practically attend clinic
    d. The follow-up clinic can provide emergency care, such as external pacing.

    e. Early replacement is not planned (due to factors such as infection risk and advanced age of the patient). See point 5 below.
    f. Device estimated remaining longevity is 4 years or less for EL pacemakers, and 3 years or less for CRT-Ps.
3. **Response to reset.** If the programmer displays the notification shown in Figure 1 twice in a row in an affected device, turn the programmer off to allow the clinic to consider and plan for the chance of the device entering Safety Mode. This should include a risk assessment (see point 1) and depending on the result of this may include ensuring external pacing equipment is immediately available or even prompt generator change (see point 5).
4. **Follow-up interval.** Perform a system follow-up via remote or in-office interrogation at least every 12 months. For patients who may not require early device replacement, continue with existing follow-up protocols until the longevity reaches One-Year-Remaining and then follow-up every three (3) months thereafter until replacement is indicated (in accordance with the device's instructions for use).
5. **Replacement.** If a device enters Safety Mode, schedule replacement. Boston Scientific and ANZCDACC do not recommend general prophylactic replacement for affected devices. However, for individual patients, factors such as those listed above and shared decision-making may support consideration of early device replacement to mitigate unintended clinical impact(s) due to potential entry into Safety Mode prior to the Explant indicator. In these cases, the following guidance should be considered:
    a. For EL pacemakers, if early replacement is planned, schedule replacement when the longevity remaining is 4 years (or less, if the device currently indicates fewer than 4 years longevity remaining).
    b. For CRT-Ps, if early replacement is planned, schedule replacement when the longevity remaining is 3 years (or less, if the device currently indicates fewer than 3 years longevity remaining).

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