Australia New Zealand Cardiac Device Advisory and Complication Committee (ANZCDACC)

Product Hazard Alert December 2023

Update to high battery impedance alert for Boston Scientific INGENIO ™ / VITALIO™/ ADVANTIO ™ extended life pacemakers and INLIVEN ™ / INVIVE ™ CRT pacemakers

TGA Reference:
RC-2023-RN-01027-1

Australian Register of Therapeutic Goods (ARTG):
194924, 203004, 194927, 202981, 213927, 194928, 194929, 213930, 213931

Advisory grade TGA:
Class I

Committee Members:
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Description:
This is an update to the June 2021 high battery impedance implant hazard alert (TGA reference RC-2021-RN-01305-1) affecting Boston Scientific INGENIO™, VITALIO™, and ADVANTIO™ dual chamber (DR) extended-life (EL) pacemakers, as well as INLIVEN™ and INVIVE™ cardiac resynchronisation therapy pacemakers (CRT-Ps). Boston Scientific Scientific Field Action Reference: 92705305D-FA.

Since the June 2021 alert, additional information is available about the potential for approximately 38000 remaining devices of the INGENIO™ family of DR EL pacemakers and CRT-Ps. These devices may exhibit a high battery impedance later in device life and initiate Safety Mode. These devices are no longer available for new implants.

Number of affected devices in Australia and New Zealand:
8000

Clinical Impact:
As a brief summary, in June 2021, a hazard alert was released regarding the INGENIO ™ family of DR EL and CRT-P devices transitioning to Safety Mode during interrogation either by a programmer or a LATITUDE™ programmer. Investigation showed that battery impedance increased over time in affected devices, influenced by implant duration and power usage. This increased battery impedance may cause a device to exhibit transient voltage decreases during periods of high-power consumption (e.g. interrogation by a programmer). If the battery voltage drops below a minimum threshold, a system reset is automatically performed. If three system resets occur within a 48 hour period, the device enters Safety Mode to maintain back-up pacing (Table 1).

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.

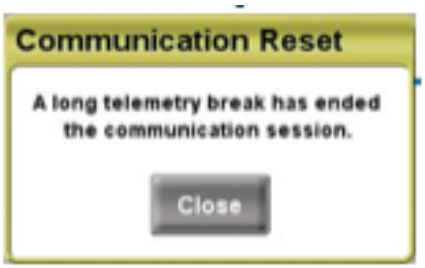

Figure 1. Programmer notification that reset has occurred.

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

Table 1. Safety Mode settings

The susceptibility of experiencing high battery impedance and entering Safety Mode is increased when an affected device reaches approximately 3-4 years of remaining battery.

The following data has been gathered since the June 2021 alert:

- The occurrence rate for this behaviour is up to 8% at 9 years, 12% at 10 years and 49% at 11 years.
- Most Safety Mode reports continue to be associated with telemetry options involving an external device. However, approximately 3.5% of reports are unrelated to telemetry operations with an external device, and may occur in an ambulatory setting by transient voltage drops during normal, higher power device operations, such as automatic radiofrequency telemetry circuit enablement and automated memory checks
- There have been 15 reports of a pause in pacing in order devices with less battery capacity experiencing extended transitions into Safety Mode (up to approximately 20 seconds) during telemetry operations with an external device. Thirteen were associated with an in-person programmed interrogation and two were associated with a LATITUDE™ patient-initiated interrogation.

- When Safety Mode is Initiated due to this behaviour, previously reported battery time remaining estimates are invalid because they were determined without accounting for Safety Mode's increased outputs or the battery's high impedance state

Safety Mode provides back-up pacing under critical circumstances and cannot substitute chronic pacing therapy. In certain patients, Safety Mode may result in pacing inhibition / pauses, muscle stimulation or heart failure. There have been three (3) deaths in pacemaker dependent patients whose affected devices were within the recommended replacement interval. The potential for life-threatening harm for the affected patient population is 1 in 769 (0.13%) at 11 years, which may be mitigated with early device replacement.

Recommendation:

1. Patient evaluation: Identify patients at high risk of harm due to Safety Mode's non-programmable parameters. High risk patients may include:
    a. Pacemaker-dependent patients
    b. Patients with CRT-P devices
    c. Patients who are known to tolerate VVI pacing poorly (e.g. symptomatic during VVI pacemaker testing)

2. Replacement:
    a. If a device enters Safety Mode, emergent replacement is recommended
    b. In patients at high risk of harm, schedule DR EL pacemaker patients for replacement when the remaining longevity is 4 years or less. For CRT-Ps, schedule replacement when the longevity is 3 years or less
    c. Outside of these parameters, the manufacturer does not recommend general prophylactic replacement, however, individual patient preferences and characteristics, and clinic circumstances should be considered.

3. Follow up:
    a. There is a potential for pacing pauses during in-person checks and LATITUDE patient-initiated interrogations who remain implanted beyond the recommended replacement interval. During in-person checks, if a patient is known to be high risk (e.g. pacemaker-dependent) consider patient recumbency and ensure that resuscitation equipment with

qualified personnel are available. Consider disabling patient-initiated interrogrations for patients on LATITUDE™.

b. If elective generator response is not performed, patients should have annual remote or in-office interrogation at least every 12 months.
c. If one-year longevity is reached, and elective generator replacement has not been performed, follow-up every 3 months is recommended until replacement is indicated.

4. Remote monitoring: 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 following:
    a. The patient is at a higher risk of symptoms (eg. Pacemaker dependent)
    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 (e.g. due to advanced patient age or high risk for generator replacement).
    f. If remote monitoring is absolutely required, consider early generator replacement at 4 years for DR EL pacemakers and 3 years for CRT-Ps.

5. Response to reset:
    a. 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.

6. Provide Patient Letter to patients with an affected device (available from Boston Scientific).

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@health.govt.nz**