ANZCDACC Advisory Notice 24th of January 2019

Device:

Medtronic Adapta DR: Model numbers affected

Affected Model numbers	ARTG
ADDR01	125076
ADDR03	125077
ADDR06	125078
ADDRL1	125084
ADDRS1	125085
ADVDD01	125080

Not all Adapta devices are affected by this recall. Patients and clinicians may determine if a specific device is affected by looking up the serial number of Medtronic's Product Performance website.

http://wwwp.medtronic.com/productperformance/

TGA Reference: RC-2019-RN-00080-1

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Urgent

Number of CIEDs affected in Australia and New Zealand: 335

Description:

Devices in the affected subset, when programmed to a dual chamber mode with atrial-sensing, may experience a circuit error that affects device functionality. See the following table for modes that are susceptible to this circuit error. For this error to occur, a unique combination of events must take place while the device is processing an atrial-sensed event. If this error occurs, the device will be unable to provide pacing until a ventricular-sensed event (VS) is detected. Once a VS is detected, normal pacing functionality is restored immediately. **If a VS is not detected, the device will withhold both atrial and ventricular pacing. In addition, until a VS is detected, the device will be unable to initiate a session with a programmer, initiate a session with a CareLink™ remote monitor, or respond to a magnet.** Single chamber and dual chamber pacing modes that do not sense atrial activity are not susceptible to this circuit error (see the table below).

Modes Susceptible to circuit error	Modes **NOT** susceptible to circuit error
DDD, DDDR	VVI, VVIR
DDI, DDIR	DVI, DVIR
VDD	AAI, AAIR
ADI, ADIR	VOO, VOOR
VDI, VDIR	AOO, AOOR
ODO	DOO, DOOR
OAO	VVT, AAT
MVP – when operating in DDD, DDDR, DDI or DDIR mode	OVO

The root cause for this issue is related to a design change to an integrated circuit in a subset of devices that were distributed to above models between 10 March 2017 and 7 January 2019.

Medtronic is developing a software update that can be installed into affected devices to correct this issue. **Medtronic estimates submission of this software update to regulatory agencies by the second half of 2019. Upon subsequent regulatory approval, Medtronic will notify customers of its availability.**

Risk:

Through 4 January 2019, Medtronic is aware of four (4) reported occurrences in two (2) patients where a pause in pacing therapy was clinically apparent due to this circuit error. These reported events occurred in three (3) devices from a total of 156,957 devices sold worldwide. No deaths have been reported as a result of this issue.

Patient risk is determined by the patient's underlying cardiac rhythm and whether the device is in a susceptible pacing mode as described above. Medtronic estimates that on average, a device in a susceptible pacing mode has a 2.8% chance per month of experiencing a pacing pause of 1.5 seconds or longer. Risk is minimised in patients who have an escape rhythm adequate to prevent syncope during a loss of ventricular pacing, since a VS restores full device functionality. No risk of a pause due to this circuit error exists for patients programmed to a non-susceptible pacing mode.

The estimated per patient mortality risk due to this issue is 0.021% when programmed to a susceptible pacing mode over the estimated time until the software update becomes available. This risk is comparable to the Medtronic estimated per-patient mortality risk associated with a device replacement (0.027%).

Presentation:

- Patients may present with symptoms consistent with a pacing pause;

Advice:

Each patient needs to be considered individually. **The ANZDACC and Medtronic recommends programming to a non-susceptible pacing mode as the primary mitigation for patients implanted with an affected device until the software update has been installed.** Specific patient risk assessment and programming recommendations are outlined below and provided in Appendix A.

• For patients whose device is programmed to a non-susceptible mode (see Table), no action is needed at this time. Continue routine clinical monitoring.

• For patients whose device is programmed to a susceptible mode and are in permanent atrial fibrillation, reprogramming the device to the non-susceptible VVI or VVIR mode is recommended to eliminate risk due to this issue until the software update has been installed. Continue routine clinical monitoring.

• For patients whose device is programmed to a susceptible mode **and** either: *have no underlying ventricular escape rhythm;* ***or*** *are at risk for a symptomatic pause until a ventricular escape beat occurs,* programming to a non-susceptible mode is recommended to eliminate risk due to this issue until the software update has been installed. Continue routine clinical monitoring.

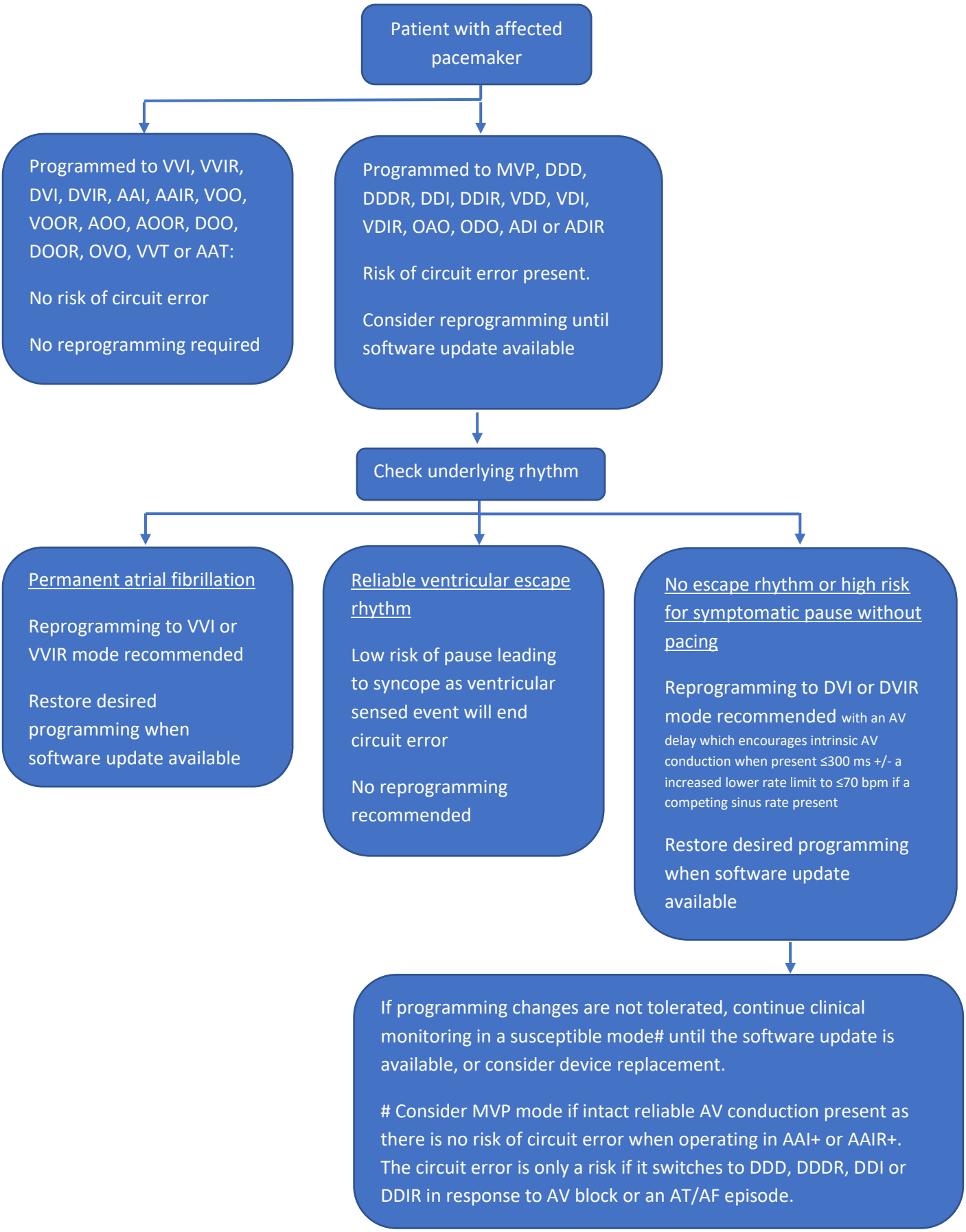
• For patients who do not tolerate programming to a non-susceptible pacing mode and either: *have no underlying ventricular escape rhythm; or are at risk for a symptomatic pause until a ventricular escape beat occurs,* continue clinical monitoring in a susceptible mode[#] until the software update is available, or consider device replacement. As previously mentioned, the estimated per patient mortality risk due to this issue (0.021%) is comparable to the Medtronic estimated per-patient mortality risk associated with a device replacement (0.027%).

For patients with intact reliable AV conduction, MVP mode poses less risk than the other susceptible modes as there is no risk of circuit error when operating in AAI+ or AAIR+ modes. The circuit error is only a risk if it switches to DDD, DDDR, DDI or DDIR in response to AV block or an AT/AF episode.

• Advise patients remaining in a susceptible mode to seek immediate medical attention if they experience new or unexpected symptoms consistent with a pacing pause.

• If a patient reports symptoms consistent with a pacing pause, and you would like assistance assessing whether a patient had a pause due to this issue, contact your Medtronic representative.

Appendix A: Programming decision flow chart



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