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

Product Defect Correction July 2024

Medtronic CareLink™ 2090 Programmer Autonomous Cursor

PRGM 2090 PROGRAMMER-PORTABLE CRM; Model 2090
PROGRAMMER 2090W TELEMETRY C; Model 2090W

Serial numbers: Devices with serial number prefixes PKK0 and PKK1

TGA Reference:
RC-2024-RN-00552-1

Australian Register of Therapeutic Goods (ARTG):
116038

Wand Notification Reference:
33367

Advisory grade TGA:
Class II
(Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not class I.)

Committee Members:
Paul Gould (Chair), Rajesh Subbiah, Paul Weatherley, Nigel Lever, Jason Davies, Susan Sinclair, Justin Phan

Description:
Medtronic CareLink™ 2090 programmers with serial number prefixes PKK0 and PKK1 have the potential for autonomous cursor motion when Finger Touchscreen capability is enabled by software version 3.2 or higher.

Through 11 June 2024, Medtronic has received 23 reports of autonomous cursor behaviour, with 2 reports of unintended therapy delivered when the programmer was not under the control of trained personnel during a patient session.

There have been no reports of permanent harm or death associated with this behaviour.

Number of affected devices in Australia and New Zealand:
~ 300

Presentation:
If a programmer is unattended while in an active patient device session, a risk to patients may exist if an autonomous cursor motion engages in unintended programming.

Rate of occurrence:
Medtronic estimates that 1.0% of Model 2090 programmers with serial # prefixes PKK0 or PKK1 could display this behaviour when updated to software version 3.2 or higher.

Recommendation:

1. No action is required by physicians or clinical staff.
    a. Medtronic have advised that programmers available for use will either have the older software version, which is unaffected, or will have passed testing to ensure there is "no risk" of this behaviour occurring under normal use.
    b. Medtronic Representatives will progressively update these programmers to the latest software (3.2 or higher).
        i. "Software version 3.2 is an important update as it allows for other updates to occur related to prior communications, new device software ahead of product launches, etc"

c. Immediately following the update to version 3.2, there is a test that can be run to immediately identify whether or not that particular programmer has been impacted by this rare occurrence of autonomous cursor behaviour

d. If any programmers fail this test, they will be immediately replaced on site and returned for repair

e. Each programmer that is being updated will remain under Medtronic control until it has passed the autonomous cursor test

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**