Medtronic

URGENT FIELD SAFETY NOTICE

Medtronic CareLink™ 2090 Programmer Autonomous Cursor

Includes 2090 Programmers with serial number prefixes PKK0 and PKK1

July 2024

Medtronic Reference: FA1418

Dear Health Care Professional, Risk/Account Manager:

Medtronic CareLink™ 2090 programmers with serial number prefixes PKK0 and PKK1 have the potential to display 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 behavior, with two 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 behavior.

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

Instrument Management Recommendations

Software updates are necessary to maintain proper programmer function.

Medtronic representatives will assist in performing the software update on all Medtronic CareLink™ 2090 programmers and assess proper function. Medtronic representatives will assist with returning programmers needing repair or replacement.

- Following review of this letter, sign and return the enclosed Customer Acknowledgement Form.
- Please forward this notice to others who need to be aware within your organization.

Medtronic has notified the Competent Authority of this action.

We remain dedicated to ensuring the highest level of quality and will continue to monitor performance of our products to ensure we meet your needs and those of your patients.

Sincerely,

Local / OU Manager