

Medtronic

Medtronic International, Ltd. (Singapore Branch)

(Co.Reg.No. S98FC5604C)

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www.medtronic.com

MEDICAL DEVICE CORRECTION

Medtronic CareLink™ 2090 Programmer Autonomous Cursor

Includes 2090 Programmers with serial number prefixes PKK0 and PKK1

11 July 2024 | 14:17 SGT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear 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, please complete the enclosed Confirmation Form and hand or scan then email back to your local Medtronic representative to confirm receipt of this notification.

- 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,

DocuSigned by:



 Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 11 July 2024 | 14:14 SGT
90D0724C9B1C402A99B286449A1644B8

Quality and Regulatory Affairs Director

Mainland and Island Southeast Asia



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Customer Confirmation Form

UPDATE TO MEDICAL DEVICE CORRECTION

Medtronic CareLink™ 2090 Programmer Autonomous Cursor

Includes 2090 Programmers with serial number prefixes PKK0 and PKK1

For completion by Medtronic Customers Only - Please complete all fields below and return all pages immediately.

Customer Contact Details		Medtronic Contact Details	
Distributor/Hospital/Clinic/Patient name:		Name:	
		Contact:	
Address:		Email:	
Phone no:	Email:		

By signing this form, I confirm that I have read the Update to Medical Device Correction Notification Letter, dated 11 July 2024 | 14:17 SGT, from Medtronic regarding a Medtronic CareLink 2090 Programmer Autonomous Cursor for the referenced programmers and have taken appropriate action.

Please complete and sign the form as indicated below and hand or scan then email back to your local Medtronic representative.

Name (print): _____ Signature: _____ Stamp: _____ Date:

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Note: Reminders of this notice may continue to be sent until a response is received.

For questions, please contact your local Medtronic Field Representative.