

## URGENT MEDICAL DEVICE CORRECTION

### CareLink™ Clinic

#### Dashboard Display Correction Notification

Product	Model/CFN Number
CareLink™ Clinic	MMT-7350 (Clinical Research Study Software versions 4.2A and 4.2.1A and Commercial Software version 4.2B)

21 October 2025 | 17:36 SGT

**Attention: Risk Management Director and O.R Materials Management**

**CC: The Chairman Medical Board and relevant Head of Departments**

Medtronic reference: FA1524

Dear Valued Healthcare Professional,

#### Issue Description:

We recently identified two issues causing the data that was displayed on the 24-hour Sensor Glucose Overview graph within CareLink™ Clinic to be incorrect. CareLink™ Clinic (also known as ProWeb) is a diabetes therapy management software for users who have access to the Internet. The purpose of this software is to take information transmitted from insulin pumps, glucose meters, and continuous glucose monitoring systems, and create CareLink™ reports that provide information that can be used to identify trends and track daily activities, for example carbohydrates consumed, mealtimes, insulin delivery, and glucose readings.

Both issues were limited to the 24-hour Sensor Glucose Overview graph on the Patient Dashboard and occurred when switching between the 14-day view and the 30-day view. The first issue occurred when the user changed the graph from the 14-day view to the 30-day view, and the graph would sometimes display hypoglycemic patterns from both the 14-day and 30-day date ranges when only the 30-day pattern should

have been visible. The second issue occurred when a user navigated back to the Patient Dashboard tab from another tab within CareLink Clinic and selected to view the 30-day date range on the Sensor Glucose Overview graph, the graph would indicate that it is in the 30-day view, but would incorrectly display data from the 14-day date range rather than the 30-day date range.

Please note: The information displayed on the Patient Dashboard other than the 24-hour Sensor Glucose Overview graph, the data in the "Reports" tab, and the individual patient CareLink™ Clinic reports remained accurate.

Our records indicate that you logged into your CareLink™ Clinic account between September 11th, 2025, and October 4th, 2025. During this time, an update applied to CareLink™ Clinic created the two issues with the data displayed on the 24-hour Sensor Glucose Overview Graph. To address this, we temporarily disabled user access to the Patient Dashboard between October 4th, 2025, and October 8th, 2025, when CareLink™ Clinic software version 4.2C was released to correct the issues with the data displayed on 24-hour Sensor Glucose Overview graph.

#### **Risk to Health:**

If a therapy decision was made using incorrect data on the 24-hour sensor glucose overview graph, this may lead to hypoglycemia or hyperglycemia for the patient with changed settings. Medtronic cannot attribute any user complaints to this issue.

#### **Your Recommended Actions:**

- If you made individual diabetes treatment recommendations to patients based on the hypoglycemic patterns or on the 30-day sensor glucose data displayed on the 24-hour Sensor Glucose Overview graph on the Patient Dashboard between September 11th, 2025 and October 4th, 2025 (e.g. if you increased a user's active insulin time and/or decreased a user's insulin-to-carbohydrate ratio based on the incorrectly displayed data), please revisit those recommendations utilizing patients' individual CareLink reports, as they were not impacted by this issue.

The Competent Authority of your country has been notified of this action.

**Please acknowledge that you've read and understand this notification and have followed the actions listed by completing the attached Confirmation Form.**

Patient safety is our top priority, and we appreciate your time and attention in carefully reviewing this important notification. We apologize for the disruption this may have caused and thank you for your patience

as we work to continuously improve the therapy experience for your patients.

**Adverse reactions or quality problems experienced with the use of this product may be reported to your local Medtronic representative.**

If you have any questions, please contact Medtronic 24-Hour Technical Support lines at the numbers below. For countries not yet supported by the Medtronic 24-Hour Technical Support lines, please contact your local Medtronic field representative.

**Malaysia**      **local number** (+60)-3-7883-8290  
**toll free**        **1-800-8-16672**

**Singapore**    **local number** (+65)-6-5064874  
**toll free**        **1-800-120-6276**

Sincerely,

Signed by:  
  
 Signer Name: Chloe Tan  
Signing Reason: I approve this document  
Signing Time: 21 October 2025 | 17:35 SGT  
90D0724C9B1C402A99B286449A1644B8

**Quality and Regulatory Affairs Director**  
Southeast Asia

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## Healthcare Provider Confirmation Form

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**Please complete all fields below and return all pages immediately.**

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

**By signing this form, I confirm that I have read and acknowledged the Urgent Medical Device Correction letter dated 21 October 2025 | 17:36 SGT from Medtronic regarding the CareLink™ Clinic Dashboard Display Correction and have taken all the appropriate actions listed in the letter.**

Please complete and sign the form as indicated below and return the completed form to your local Medtronic representative.

Name (print): \_\_\_\_\_ Signature: \_\_\_\_\_ Date: 

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			yyyy

For questions, contact our 24-Hour Technical Support line or your local Medtronic field representative.

**As always, thanks for your support.**