

URGENT FIELD SAFETY NOTICE

CareLink™ Clinic

Dashboard Display Correction

Notification

Product	Model/CFN Number
CareLink™ Clinic	MMT-7350 (Commercial Software version 4.2B)

October 2025

Medtronic reference: FA1524

EU Manufacturer Single Registration Number (SRN): US-MF-000023100

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 Customer Acknowledgement 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.

If you have any questions, please contact Medtronic.

Sincerely,



Federico Gavioli

Sr. Vice President, International
Medtronic Diabetes



Ohad Cohen, MD

Sr. Medical Affairs Director
Medtronic Diabetes

Enclosure:

Customer Acknowledgement Form