

Urgent Field Safety Notice
CARBOHYDRATE RATIO IN CARELINK™ REPORTS

CareLink™ Personal v14.1a (MMT-7333) using CareLink™ reports v5.2b (ACC-7333)
CareLink™ system v3.1a (MMT-7350) using CareLink™ reports v5.2b (ACC-7333)

November 2020

Medtronic reference: FA934

Dear Valued Customer:

You may have already received a letter about the miscalculation of the carbohydrate ratio in the CareLink™ Device Settings report. We have learned that the carbohydrate ratio was also miscalculated on other CareLink™ reports, therefore we are sending you an update to ensure you take the appropriate action for reports other than the Device Settings report. Please read the letter below for more information.

You are receiving this letter because our records indicate you may have generated a Device Settings report in CareLink™ Personal software between August 29, 2020 and September 30, 2020. Because your safety is our top priority, we are making you aware of a potential issue related to a miscalculation of the carbohydrate ratio in CareLink™ reports.

This issue was fixed on September 30th, 2020. Read below for a full description of the issue and required action.

Issue Description:

Medtronic released an update to CareLink™ software on Saturday, August 29, 2020. Following this release, customers who generated a report from CareLink™ Personal or CareLink™ system software may have been presented with an inaccurate carbohydrate ratio setting on their CareLink™ report. This only occurred under the following circumstances:

1. The carbohydrate unit of measurement in CareLink™ software is set to grams, but the insulin pump is set to exchanges.
2. The carbohydrate unit of measurement in CareLink™ software is set to exchanges, but the insulin pump is set to grams.

If adjustments were made to the carbohydrate ratio based on the CareLink™ report, this could lead to either over or under delivery of insulin. This could cause low blood glucose (hypoglycemia, loss of consciousness, seizure, death), and/or high blood glucose (hyperglycemia).

On September 30, 2020, Medtronic released an automatic update to CareLink™ software which resolved the issue described above. However, some customers may have adjusted their carbohydrate ratio between August 29, 2020 and September 30, 2020 using incorrect data on the CareLink™ reports.

Required Action:

If you believe you may have been impacted, review any changes to the carbohydrate ratio setting made between August 29, 2020 and September 30, 2020 with your healthcare provider to determine if any corrections are currently needed. Instructions for how to view or edit your carbohydrate ratio setting can be found in your insulin pump user guide.

If you generated a Meal Bolus Wizard, Assessment & Progress or Device Settings CareLink™ report between August 29, 2020 and September 30, 2020, discard and re-generate the report, as needed, in CareLink™ software.

This issue was fixed on September 30, 2020. No further action is required on your part to receive the corrected version of CareLink™ software.

At Medtronic, we are committed to delivering safe and effective therapies that undergo rigorous clinical, quality, manufacturing, and regulatory controls for our customers. We appreciate your time and attention in reading this important notification.

As always, we are here to support you. If you have further questions or need assistance, please contact the Medtronic Helpline Tel No: 01 511 1444

Sincerely,

K.Taverner. Regulatory Affairs Manager UK & Ireland