



Urgent Field Safety Notice

BASAL RATES IN CARELINK™ REPORTS

CareLink™ Personal v14.1a (MMT-7333) using CareLink™ uploader (ACC-7350)
CareLink™ system v3.1a (MMT-7350) using CareLink™ uploader (ACC-7350)

December, 2020

Medtronic reference: FA947

Dear Healthcare Professional and Customer,

You are receiving this letter because our records indicate you may have generated a report in CareLink™ system software after 27 August, 2020 and may have used an affected uploader software version. Because your patients' safety is our top priority, we are making you aware of a potential issue related to missing or incomplete Basal Rate settings on CareLink™ reports. To date, we have not received any reports of patient harm or injuries due to this issue.

Read below for a full description of the issue and required actions.

Issue Description:

Medtronic released an update to the CareLink™ uploader on 27 August, 2020. The installation of the new uploader, version 3.1.2.000 or 3.1.5.000, to a computer that was subsequently used to generate a CareLink™ report may result in one of the following scenarios:

1. Some reports may be missing all programmed basal rates in the device. This may result in a blank value on the Device Settings report of the 24-hour basal total.
2. Some reports may only display certain programmed basal rates and some basal rates that are programmed in the device may be missing from the reports. This may result in a miscalculation on the Device Settings report of the 24-hour basal total.

Note: Actual delivered insulin calculations in all reports are NOT impacted. This includes total daily dose and total basal delivery.

The following reports from CareLink™ software may be affected by this issue: Device Settings, Daily Review/Daily Details, Weekly Review, and Sensor & Meter Overview.

Historically, CareLink™ reports have been utilized to adjust therapy settings or to transfer settings from an old pump to a new pump. If all of the following are true, it could lead to either over- or under-delivery of insulin which may result in low blood glucose (hypoglycemia, loss of consciousness), and/or high blood glucose (hyperglycemia):

- a) adjustments were made to therapy settings or if therapy settings were transferred from one device to another, and
- b) these adjustments or the transfer were based on a CareLink™ report generated using CareLink™ uploader version 3.1.2.000 or 3.1.5.000 that has missing or incomplete basal rates, and
- c) a patient is in Manual Mode

Resolution:

On November 12, 2020, a new version of the CareLink™ uploader was released. This uploader completely resolves this issue but must be installed on each computer that you use to upload devices to the CareLink™ system. Until the new CareLink™ uploader version 3.1.6.000 has been installed, the basal rates may be missing or incomplete on CareLink™ reports.

Please install the new CareLink™ uploader at your earliest convenience on each computer that you use to upload devices to the CareLink™ system and do not use CareLink™ reports to make insulin adjustments or transfer settings from one device to another until this new installation has been performed.

Required Actions:

Please complete the following steps:

1. Install the new CareLink™ uploader version 3.1.6.000 available within the CareLink™ system to all computers where you upload devices. To confirm your current uploader version or to learn how to install the latest uploader, see the FAQ section at the end of this letter.
2. For any patients who may have had insulin settings adjusted based on an impacted CareLink™ report, determine if corrections are needed.
 - a. Please note that, for patients whose CareLink™ report showed blank insulin settings, which may have resulted in no change in therapy, you should confirm with them the actual basal rate settings in their pump and determine if corrections are needed.
 - b. Instructions for viewing or editing the basal rate setting can be found in your patient's insulin pump user guide.
3. If transferring settings from one insulin pump to another before the new uploader has been installed, refer to the device settings in the old insulin pump only because the settings on an impacted CareLink™ report may be missing or incomplete until the new uploader has been installed, the device is uploaded again, and new reports are generated.
 - If the patient has received a new or replacement pump and cannot access prior device settings from their old insulin pump, verify or establish insulin settings.
4. If you or your patient installed the 3.1.2.000 or 3.1.5.000 uploader on any computer and viewed or generated CareLink™ reports after 27 August, 2020, discard the report(s) and re-generate the report after installation of CareLink™ uploader 3.1.6.000, as needed, in CareLink™ software.

At Medtronic, we are committed to delivering safe and effective therapies. 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 at <XXXX>.

Sincerely,

Country/BU manager

FREQUENTLY ASKED QUESTIONS

Q1. HOW DO I RESET MY CARELINK™ SYSTEM PASSWORD?

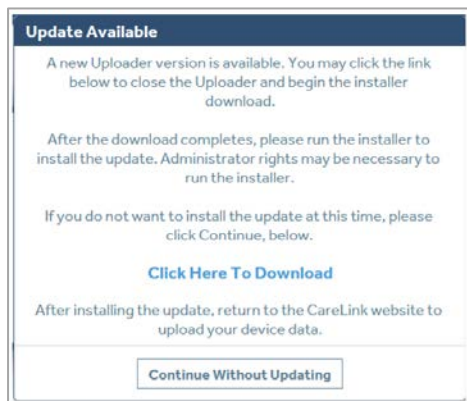
A "Forgot your password?" link is available on the CareLink™ system home page. You must enter your username, email address, and confirm the ReCaptcha to submit a password reset request. After successfully submitting your request, an email will be sent to the email address on file with a link to reset your password.

Q2. HOW DO I CHECK MY CURRENT UPLOADER VERSION?

To confirm your current version of CareLink™ uploader, click the "Upload Device" button from within any patient profile. Once the uploader window opens, look at the version number in the upper left corner of the pop-up window. The version should be 3.1.6.000.

Q3. HOW DO I INSTALL THE NEW UPLOADER?

If the CareLink™ uploader is already installed, an "Update Available" pop-up will show the next time you open the uploader. Simply click, "Click Here To Download" to upgrade to the newest version.



If the CareLink™ uploader is not installed, click "How to Install Uploader" located below the "Upload Device" button from within any patient profile and follow the steps. Note: This may require support from your local IT administrator.

Q4. WHICH PUMPS WILL THE NEW UPLOADER (VERSION 3.1.6.000) SUPPORT?

All commercially available insulin pump devices are supported by CareLink™ uploader version 3.1.6.000.