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URGENT FIELD SAFETY NOTIFICATION
BASAL RATES IN CARELINK™ REPORTS

CareLink™ Personal (MMT-7333) using CareLink™ uploader (ACC-7350)
CareLink™ system (MMT-7350) using CareLink™ uploader (ACC-7350)

April 21, 2021

Dear Valued Customer,

You are receiving this letter because our records indicate you, or your healthcare provider on your behalf, may have generated a report in CareLink™ software after October 17, 2020 and may have used an affected uploader software version. Because your 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.

Issue Description:

Medtronic released an update to the CareLink™ uploader on Saturday, October 17, 2020. The installation of the new uploader, version 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 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.

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 actions were taken based on a report generated using CareLink™ uploader version 3.1.5.000 that has missing or incomplete basal rates, and
c) you are using 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 is used to upload devices to the CareLink™ software system. Until the new CareLink™ uploader version 3.1.6.000 (or newer) is installed, the basal rates may be missing or incomplete on CareLink™ reports.

Please install the new CareLink™ uploader on each personal computer that you use to upload your insulin pump at your earliest convenience and do not use CareLink™ reports until this new installation has been performed.

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<u>Required Actions:</u>

1. Install the new CareLink™ uploader version 3.1.6.000 (or newer) available within the CareLink™ software to each computer 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. If you have had insulin settings adjusted that may have been made based on an impacted CareLink™ report, review your settings with your healthcare provider and determine if corrections are needed.

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.
    a. If you have received a new or replacement pump and cannot access prior device settings from your old insulin pump, verify or establish insulin settings with your healthcare provider.

4. If you or your healthcare provider installed the 3.1.5.000 uploader on any computer and viewed or generated CareLink™ reports after October 17, 2020, discard the report(s) and re-generate the report after installation of CareLink™ uploader 3.1.6.000 (or newer), as needed, in CareLink™ software.

At Medtronic, we are committed to delivering safe and effective therapies 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 call Medtronic 24-Hour Technical Support at 1-866-222-7304.

Sincerely,

Chirag Tilara
VP, Quality
Medtronic Diabetes

FREQUENTLY ASKED QUESTIONS:

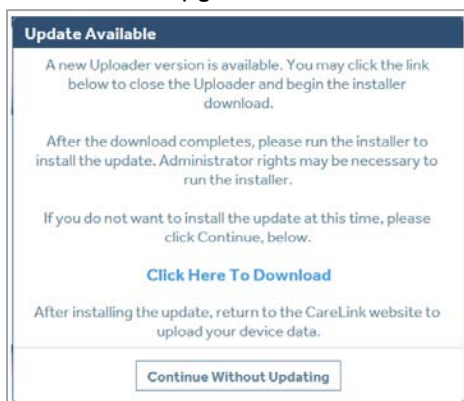### Q1. HOW DO I RESET MY CARELINK™ PERSONAL PASSWORD?

A "Forgot your password?" link is available on the CareLink™ Personal 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 Now" button. 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 (or newer).

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 attempt to upload your device. Simply click the blue text, "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 Now" button and follow the steps.

Q4. WHICH PUMPS WILL THE NEW UPLOADER SUPPORT?

All commercially available Medtronic insulin pump devices are supported by CareLink™ uploader version 3.1.6.000 (or newer).