



Urgent Field Safety Notice
CareLink™ iPro™ Therapy Management Software
New CareLink iPro Uploader Feature and Time Zone Issue

October 2017

Medtronic reference: FA789

Dear Healthcare Professional,

We are contacting you to provide important information related to the installation and use of the new CareLink iPro Uploader feature for use with the CareLink iPro software (MMT-7340). There have been no reports of adverse events associated with this issue. However, the safety of our patients is our highest concern so we are advising affected clinics of this potential issue.

Due to a time conversion error, data uploaded from the iPro™2 recorder to the CareLink iPro software using the new CareLink iPro Uploader feature may result in incorrect reports. This pertains only to reports generated between September 23, 2017 and September 27, 2017 that used the new CareLink iPro Uploader feature. Specifically, when data from the iPro2 recorder was uploaded using the new CareLink iPro Uploader feature, the glucose reading timestamps inadvertently defaulted to Greenwich Mean Time (GMT) /Coordinated Universal Time (UTC). We have determined that the difference in time zones could result in calculation and display errors on the reports. This could lead to potential differences or inaccuracies in the sensor tracings, which also affect the display of meals and activities and the resulting report.

Medtronic has disabled the CareLink iPro Uploader feature for all users. Your CareLink iPro software has automatically reverted to using the previous Java™ Applet function.

Medtronic will be providing replacement sensors at no charge to you for each evaluation with affected reports. There is no need to initiate a request for replacement sensors, and further details will be provided soon.

Actions Recommended for You

Reports generated using the uploader feature may contain inaccurate data, and should not be used to make therapy adjustments. Medtronic advises repeating iPro2 evaluations for those studies uploaded between September 23, 2017 and September 27, 2017.

Clinics do not need to uninstall the uploader feature. As stated above, the Uploader has been disabled, and the Java™ Applet will upload your recorder and meter data.

If you have any additional questions, call the Medtronic Helpline.

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

Medtronic considers patient safety and customer satisfaction our primary priorities. We appreciate your time and attention in reading this important notification.

Sincerely,



Additional Questions and Answers

What is the CareLink iPro Uploader?

A: The CareLink iPro Uploader is an application to upload iPro2 recorder or meter data to the CareLink iPro software. It was launched as a new feature to replace the Java Applet on September 23rd. Medtronic temporarily disabled this feature on September 27th.

What is the time conversion error?

A: iPro2 recorders uploaded using the new Uploader feature caused the reports' time to default to Greenwich Mean Time (GMT) /Coordinated Universal Time (UTC).

Have any patients been harmed as a result of this issue?

A: There have not been any reported events to Medtronic.

Were iPro2 evaluations impacted that used the Java Applet to upload data?

A: This issue is only related to reports where the iPro2 recorder data was transmitted by the new Uploader feature.

I think I have a patient who was put at risk due to this issue. Who can I contact to file a complaint?

A: You can share details with the Medtronic Helpline Support team.

What is Medtronic going to do to make this right for me and my patients?

A: Please know that patient safety is our top priority. We are working diligently to solve and validate the right solution. We will notify you once we have more information.

Will Medtronic provide me with replacement sensors?

A: Yes, Medtronic will be providing replacement sensors at no charge to you for each evaluation with affected reports. There is no need to initiate a request for replacement sensors.

I have not installed the CareLink iPro Uploader. Do I need to do anything?

A. No, continue to use CareLink iPro as normal.

Do I need to call Medtronic if I installed the CareLink iPro Uploader?

A: No, customers do not need to call Medtronic. Continue to use CareLink iPro as normal. Medtronic will notify CareLink iPro customers when the updated version of the Uploader is available.

Should I uninstall the CareLink iPro Uploader feature from my computer?

A: No, we are not recommending that you uninstall the uploader. The CareLink iPro software has automatically reverted to using the Java Applet to transmit recorder and meter data.