



Medtronic Ireland Limited

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Field Safety Notice

Guardian™ App Version 1.3.0

Notification of Software Update

November 2022

Medtronic Reference: FA1294

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

Dear User,

The purpose of this letter is to advise you that Medtronic has become aware of an issue with version 1.3.0 of the Guardian™ App for iOS and Android smartphone devices. We understand that you may have installed this version of the Guardian App, so we are reaching out today to inform you how you can resolve this issue.

ISSUE DESCRIPTION:

Users of Guardian App version 1.3.0 may be automatically logged out from CareLink™ more frequently than expected. If this issue occurs, users will receive a “Log into CareLink” message multiple times. When automatically logged out, the Guardian App is not able to upload data to CareLink. However, the Guardian App functionality is not impacted and it will still display sensor glucose (SG) values and send alerts and notifications to app users.

One of the features of the Guardian app is that care partners of patients may elect to get SMS text messages via CareLink. However, if the user is auto logged out of CareLink, linked care partners will not receive SMS notifications about the user’s high or low SG. If a care partner does not receive the SMS notification, which may be used to make treatment decisions for patients that are reliant on the care partner, this could potentially result in varying degrees of hypoglycemia or hyperglycemia, including Diabetic Ketoacidosis (DKA).

Another feature of the Guardian app is that it sends SG values from CareLink where they are used in the InPen App’s Dose Calculator feature. When the user is auto logged out, SG values will not be sent to the InPen App. InPen App users can still use the dose calculator feature by opening their Guardian App, locating their SG values and manually entering them into the InPen dose calculator. We apologize for any inconvenience this may cause. However, the inability of the Guardian app to send SG values to the dose calculator poses no risk to insulin delivery.

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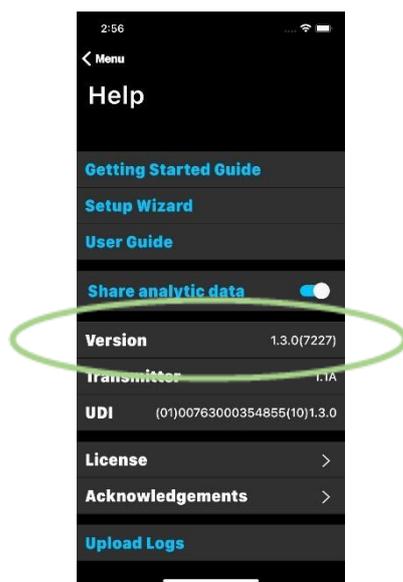
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We have received complaints related to being logged out of CareLink; However, no adverse events have been reported at this time.

ACTIONS TO IMMEDIATELY RESOLVE THE ISSUE:

For iOS users:

- 1) Verify what version of the app you are running by taking the following steps:
 - a) On the home screen, navigate to the settings menu on the upper left corner
 - b) Select "Help"
 - c) Confirm "Version"



- 2) If you are not running version 1.3.0, no action is necessary
- 3) If you have version 1.3.0, update to the latest app version currently available in the app store (1.3.1) by following these steps:
 - a) Open the **App Store** app.
 - b) Tap your profile icon at the top of the screen.
 - c) Scroll to see pending updates.
 - d) Tap **update** next to the mobile app icon to update the app.

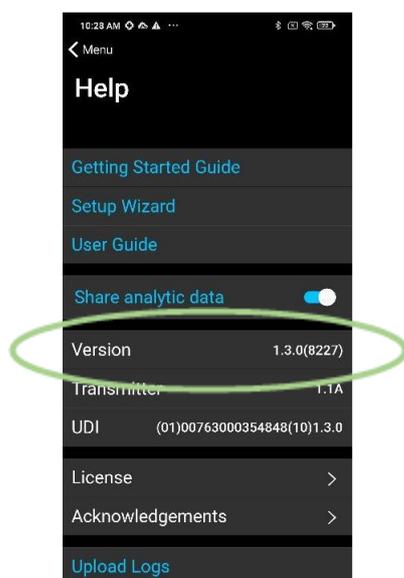
For Android users:

- 1) Verify what version of the app you are running by taking the following steps:
 - a) On the home screen, navigate to the settings menu on the upper left corner
 - b) Select "Help"

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c) Confirm "Version"



- 2) If you are not running version 1.3.0, no action is necessary
- 3) If you have Guardian App version 1.3.0, update to the latest app version currently available in the Google Play Store (1.3.1) by following these steps:
 - a) Open the **Google Play Store app**.
 - b) Tap **Menu** and then **Manage apps & devices**.
 - c) Apps with an update available are labelled "Update available". You can also search for a specific app.
 - d) Tap **Update**.

Once you update to version 1.3.1 and log in to the Guardian App all your past data from version 1.3.0 will remain available and visible.

It is not recommended or necessary to uninstall the current version of the app from your phone before installing the new version 1.3.1. If you choose to do so, your local app data will be gone and you will be prompted to once again pair your transmitter.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have further questions, please call our Helpline at Tel No: 01 511 1444 option 2, then option 0.

Sincerely, Natasha Mthethwa
Senior Regulatory Affairs Specialist