



## Urgent 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 Healthcare Institute / Health Organization / Service Provider,

You are receiving this letter because our records indicate that one or more of your patients may be using the Guardian™ App. For your patient's safety, we want to inform you of a potential issue associated with Guardian App version 1.3.0 for iOS and Android. This letter provides actions your patient should take so please carefully review the information below.

Medtronic asks that you inform impacted patients using the enclosed letter.

#### **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.

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

#### **ACTIONS REQUIRED BY YOU:**

# Medtronic

1. Inform impacted users of the Guardian App Version 1.3.0 about the Field Safety Notice using the enclosed user letter.
2. Please assist patients in updating the Guardian App to Version 1.3.1 per the instructions provided in the enclosed letter.
3. Pass this notice on to all those who need to be aware within your organization.

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

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 your Medtronic contact.

Sincerely,

Local/OU Manager

Enclosure:

- User Letter