Medtronic

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 Professional,

you are receiving this letter because our records indicate that one or more of your patients may be using the GuardianTM 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.

The purpose of this letter is to make you aware that Medtronic will be notifying all impacted users who have the Guardian App version 1.3.0 installed by enclosed letter. There is no action to be taken by you.

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 our Helpline at 0800 633 333.

Sincerely,

Medtronic

Enclosure:

- User Letter