

Urgent Field Safety Notice

Guardian™ Connect Mobile App (Model Number: CSS7200)

Apple iOS Version 11.3 and 11.4 App Closure Issue

July 2018

Dear Physician, Healthcare Professional,

Medtronic is contacting you to make you aware of a potential connectivity issue which requires for patients using the Guardian™ Connect system to update to version 3.2.2 of the Guardian™ Connect app as soon as possible. We are providing this information to all impacted patients.

Explanation of the Issue

An issue was identified in Apple iOS 11.3 & 11.4 that can sometimes prevent patients from receiving a 'Lost Communication' alert after their Guardian™ Connect app is closed by the iPhone's operating system (iOS) in certain situations. The operating system may close the Guardian™ Connect App without alerting patients that the app is no longer running or communicating with the Guardian™ Connect transmitter. If the app is closed, patients will not receive alerts that could be associated with hypoglycemic or hyperglycemic events. While we have received reports from patients of the app closing without warning, we have not received any reports of injury.

Action Required

- **Update your Guardian™ Connect app now to the latest release (v3.2.2) located on the App Store.**

Reminder

As described in the patient's App User Guide, Medtronic cannot guarantee that the iPhone will always allow for the Guardian™ Connect app to run in the background. If the iPhone automatically closes the Guardian™ Connect app, patients may receive a 'Lost Communication' alert. To ensure patients continue receiving sensor glucose data and alerts, we recommended that they periodically check that the Guardian™ Connect app is still running, being especially mindful when running several applications at once.

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

Note: Because the Guardian™ Connect app can also be used with compatible iPad and iPod Touch devices, this safety notification also applies to these devices.



Sincerely,

Keith Taverner: Regulatory Affairs Manager UK & Ireland