

Medtronic

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Urgent Medical Device Safety Notification

Guardian™ Connect CGM System

23 May 2019

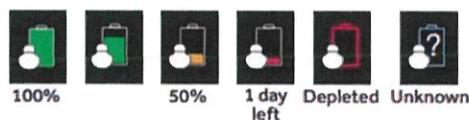
**Attention: Risk management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments**

Dear Valued Customer:

We are making you aware of a potential issue with the transmitter battery life of the Guardian™ Connect Continuous Glucose Monitoring (CGM) system. Customers using an Apple device with iOS version 12 or higher are being advised to update to the latest version (3.2.4) of the Guardian™ Connect app on their iPhone as soon as possible. We are providing this information to all patients who have received the Guardian™ Connect CGM system and are using it with iOS.

Explanation of the Issue

We recently became aware that customers using the Guardian™ Connect app on an iPhone, iPad or iPod Touch with iOS software version 12, 12.1, or 12.2 are likely to experience a shortened transmitter battery life (approximately 4-5 days instead of the normal 7 days or more) after a full charge. The iOS12 update created more frequent Bluetooth® connections that drain the transmitter battery faster than under the previous iOS versions. Rest assured, this does not impact sensor performance and the CGM system will work as expected, aside from having a shorter transmitter battery life. The system will continue to provide correct information about battery life and alerts related to low battery (as displayed below). While we have received reports from customers about the shorter battery duration of the transmitter we have not received any reports of injury.



Action Required

- Patients using iOS version 12 or higher should **update their Guardian™ Connect app now to the latest version (v3.2.4) located on the App Store®**. This update will return the Guardian™ Connect transmitter to the same battery performance experienced before the iOS 12, 12.1, and 12.2 updates.

- We recommend patients not using iOS 12 or higher to still update to the latest version of the Guardian™ Connect app.

We are committed to patient safety and appreciate your prompt attention to this matter should a patient make you aware. Any patients who continue to experience issue or have questions , please contact your local Medtronic Representative / our 24-Hour Technical Support Team at 1-800-646-4633.

Sincerely,



Diana Teo

QRA Lead Cluster 1