Medtronic

49 Changi South Avenue 2
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www.medtronic.com

tel +65 6436 5000
fax +65 6776 6355

URGENT MEDICAL DEVICE SAFETY NOTIFICATION
Guardian™ Connect Mobile App (Part Number: CSS7200)

2 July 2018

Dear Health Care Provider,
CC: The Chairman Medical Board and Relevant Head of Departments

Because the safety of our patients is our top priority, we are making you aware of a potential connectivity issue and advise that you update to version 3.2.2 of the Guardian™ Connect app on your iPhone as soon as possible.

Explanation of the Issue

Medtronic has identified an issue in Apple iOS 11.3 & 11.4 that can sometimes prevent you from receiving a 'Lost Communication' alert after your 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 the user that the app is no longer running or communicating with the Guardian™ Connect transmitter. If the app is closed, you will not receive alerts that could be associated with hypoglycemic or hyperglycemic events. While we have received reports from customers about 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 your App User Guide, Medtronic cannot guarantee that your iPhone will always allow for the Guardian™ Connect app to run in the background. If the iPhone automatically closes your Guardian™ Connect app, you may receive a 'Lost Communication' alert. To ensure you continue receiving sensor glucose data and alerts, we recommended that you periodically check that the Guardian™ Connect app is still running, being especially mindful when running several applications at once or after using gaming and video apps that use a lot of your iPhone's power or memory resources.

We apologize for any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. Please refer to the attached Frequently Asked Questions for additional information.

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.

Yours Sincerely,

Diana Teo
Quality System Manager
Medtronic

FREQUENTLY ASKED QUESTIONS
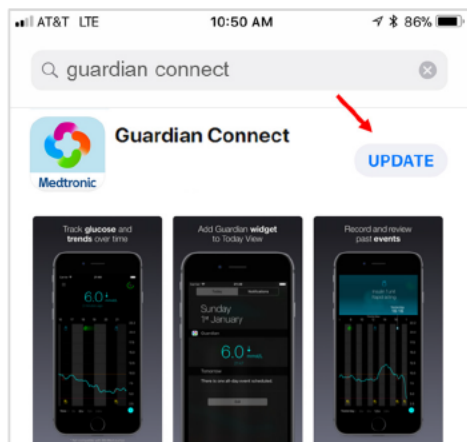
Q1. WHO SHOULD PERFORM THIS UPDATE?

This issue has been identified on Apple operating systems iOS 11.3 & 11.4. However, we recommend all customers who are using the Guardian™ Connect app to update to the latest software regardless of the operating system they are currently running.

Q2. HOW DO I KNOW WHICH OPERATING SYSTEM IS RUNNING ON MY DEVICE?

- Locate and open the Settings ⚙ app from the home screen of your mobile device
- Tap General
- Tap About
- Locate the version in the list

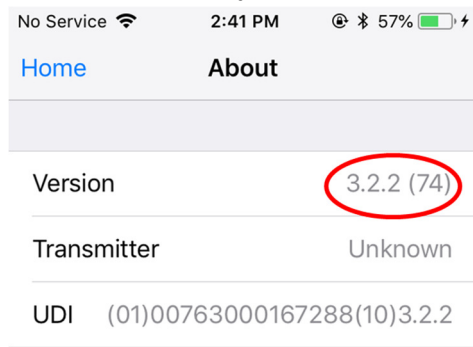## Q3. HOW DO I UPDATE MY GUARDIAN™ CONNECT APP?

- Open the App Store 🅰 from the home screen of your mobile device
- Search for the Guardian Connect App and select Update

- Follow the instructions on the screen to walk through Startup.
- All previously saved settings will be preserved.

Q4. HOW DO I CHECK TO SEE IF I HAVE THE MOST UPDATED GUARDIAN™ CONNECT APP?

- Open the Guardian™ Connect app and tap the menu screen icon ☰ on the top left corner.
- Select "About" from the list of menu options and note the version number on the top line.
- Check to see that you have version 3.2.2

Q5. HOW DO I KNOW IF MY APP HAS STOPPED RUNNING?

Follow these steps to check if the app is running:

- From the "Home" screen, quickly press the Home button (at the bottom) twice.
- Swipe the screen left or right to view the list of apps currently running.
- If the Guardian™ Connect app is not running, you will need to relaunch the app by tapping on the Guardian™ Connect app icon from the home screen of your device.

When the Guardian™ Connect app has been closed by the iPhone's operating system you may receive a 'Lost Communication' notification.
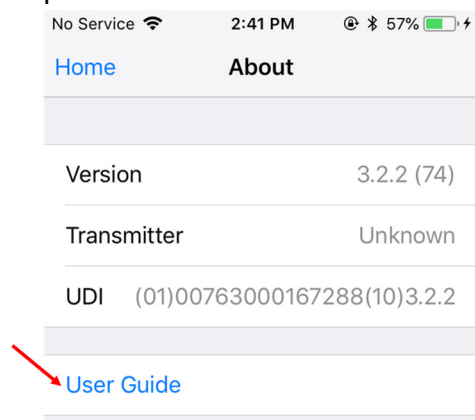
Q6. WHAT DO I DO IF I AM STILL HAVING PROBLEMS WITH MY APP AFTER THE UPDATE?

Please contact your local help line for assistance. Refer to the Medtronic Diabetes International Contacts list at the beginning of the app user guide for the help line representative in your area.

To access the app user guide from within the Guardian™ Connect app:

- Open the Guardian™ Connect app and tap the menu screen icon ☰ on the top left corner.
- Select "About" from the list of menu options
- Tap User Guide

No Service 📶	2:41 PM	⊕ ✳ 57% 🔋 ⚡
Home	**About**	
Version		3.2.2 (74)
Transmitter		Unknown
UDI	(01)00763000167288(10)3.2.2	
User Guide		

- A browser window will open displaying the app user guide.

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Customer Confirmation Form
URGENT MEDICAL DEVICE SAFETY NOTIFICATION
Guardian™ Connect Mobile App (Part Number: CSS7200)

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	**Name:**
	E-mail:
Address:	**Phone:**
Telephone no:	
Fax no:	
E-mail:	

Please tick below to acknowledge:

☐ **Yes, my Guardian™ Connect app have been upgraded to the latest release (v3.2.2) located on App Store.**

☐ **No, my Guardian™ Connect app have not upgraded to the latest release (v3.2.2) located on App Store.**
*Reason (please specifiy)*_____

I have read and understand the instructions provided and acknowledge the receipt of the Guardian™ Connect Mobile App (Part Number: CSS7200) notification dated 2 July 2018 by signing below:

Name: _____ (print) Signature: _____Stamp: _____ Date:_____

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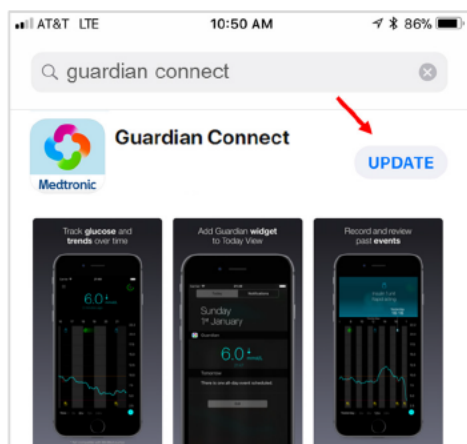## Q1. WHO SHOULD PERFORM THIS UPDATE?

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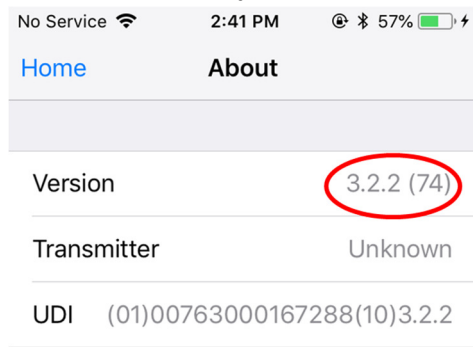## Q3. HOW DO I UPDATE MY GUARDIAN™ CONNECT APP?

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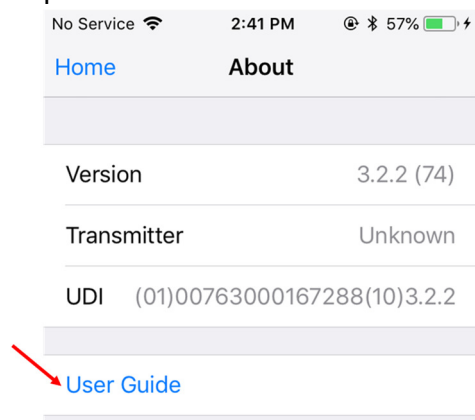
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