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Urgent Field Safety Notice
Guardian™ Connect App connectivity to CareLink™ personal software
Guardian™ Connect iOS app: CSS7200

July 2020

Medtronic reference: FA922

Dear Valued Customer,

Our records indicate you may be using the Guardian™ Connect app on an Apple iOS device. We want to make sure you are aware of a potential issue related to the Guardian™ Connect app's ability to sync your data with the CareLink™ software and care partner notifications. Read below for a full description of the issue and how to resolve it.

Issue Description:

We released an update to the CareLink™ Personal software on Saturday, June 27, 2020. Following this release, some customers using the Guardian™ Connect app on iOS devices experienced data connectivity disruptions to the CareLink™ software. As a result, the following disruptions may occur:

1. Care partners may not receive SMS alerts from the Guardian™ Connect app
2. Care partner remote access monitoring in the CareLink™ Connect web app may show data gaps
3. You may see data gaps in CareLink™ reports

Please note, normal use of your Guardian™ Connect app is *not impacted* – you will still be able to view your CGM data and receive alerts in your Guardian™ Connect app.

Actions Required: Check If You Are Experiencing the Issue
(refer to the Frequently Asked Questions included for detailed instructions)

1. Attempt to manually upload your data to the CareLink™ software via the Guardian™ Connect app:
    a. Tap ☰ on the top left corner of the Home Screen
    b. Confirm "Sync to CareLink" is enabled
    c. Tap "Upload Now"
    d. Wait 10 minutes before moving to step #2

2. Check your account to see if you are experiencing this issue
    a. From your mobile device visit https://carelink.minimed.eu and log in to your CareLink™ account
    b. Confirm that your data is visible in the CareLink™ Connect web app
    c. If your data is visible, no further action is needed - you are not experiencing the issue
    d. <u>If your data is not visible, you may be experiencing the issue and you should complete the steps in the next section to resolve the issue.</u>

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Instructions for Resolving the Issue
(refer to the Frequently Asked Questions included for detailed instructions)

1. If your data was not visible after step #2, uninstall the Guardian™ Connect app from your mobile device.
    For help, please refer to FAQ below #3
    > Note – doing this will re-set your alerts, sensor glucose, Logbook data, and unpair the Guardian™
    > Connect transmitter. **Before uninstalling the app, review and take note of your current settings.**

2. Unpair your transmitter from your mobile device. ***For help, please refer to FAQ below #3***

3. Re-install the Guardian™ Connect app on your mobile device – this will restore the CareLink™
    connection. ***For help, please refer to FAQ below #4***

*Uninstalling the Guardian™ Connect app may delete visible data from the app. All data that has been uploaded to the CareLink™ software will continue to be visible in CareLink™ reports. However, any data generated since June 27, 2020 may not have been uploaded.

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies of the highest quality and reliability possible. We appreciate your time and attention in reading this important notification.

As always, we are here to support you. If you have any further questions or need assistance, please contact the Medtronic Helpline.

Sincerely,

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FREQUENTLY ASKED QUESTIONS

Q1. DO I NEED MY CARELINK™ PERSONAL USERNAME / HOW DO I GET IT?
In order to check whether your data is being uploaded to CareLink™ software, you will need to log in to your CareLink™ Personal account with your username. In the Guardian™ Connect app, tap on the Menu on the upper left corner, tap on "CareLink", scroll to the bottom of the page to see your Username.

Q2. HOW DO I RESET MY CARELINK™ PERSONAL PASSWORD?
A "Forgot your password?" link is available on the CareLink™ Personal home page. You must enter your username, email address, and confirm the ReCaptcha to submit a password reset request. After successfully submitting your request, an email will be sent to the email address on file with a link to reset your password.

Q3. HOW DO I UNINSTALL MY GUARDIAN™ CONNECT APP?
First, follow the below steps to uninstall your app. Note – doing this will re-set your alerts, sensor glucose, Logbook data, and unpair the Guardian™ Connect transmitter.
1. Before uninstalling the app, review and take note of your current settings
2. Touch and hold app on the Home screen, then tap Edit Home Screen. The apps will begin to jiggle.
3. Tap ⊗ on the Guardian™ Connect app, then tap Delete
4. Tap Done (on an iPhone with Face ID) or press the Home button (on other iPhone models)

Next, remove your transmitter from your Bluetooth® history by navigating to your device's Bluetooth® settings and disabling the transmitter:

Settings > Bluetooth >
tap blue "i" next to device that begins with "GT" >
Forget This Device > confirm by tapping "Forget Device"

Q4. HOW DO I REINSTALL MY GUARDIAN™ CONNECT APP?
Follow the steps below to reinstall the Guardian™ Connect app on your mobile device. Note, you will need to re-pair your transmitter and set up your notifications.
1. Search for "Guardian Connect" in your mobile device's App Store and download the app
2. Open the Guardian™ Connect app and follow the setup instructions
3. When you get to the pairing step, remove and discard your sensor before charging and re-pairing the transmitter. You will need to insert and start a new sensor.

Q5. WHEN UNINSTALLING THE APP, WILL I NEED TO RE-REGISTER MY CARE PARTNER?
No, you do not need to re-register your care partner. After reinstalling the Guardian™ Connect app, normal use of the CareLink™ software with the Guardian™ Connect app should be restored, along with your care partner's ability to view your data and receive notifications. In addition, your care partner will not need to re-establish his / her notifications **as long as the same username is being used**. No action is required by your care partner. You can return to the CareLink™ Connect web app to confirm data is available.

Q6. WHEN UNINSTALLING THE APP, WILL I NEED TO SET UP MY ALERTS AGAIN?
Yes, after uninstalling your Guardian™ Connect app, the data and settings you previously had will be removed. Therefore, you will need to set up your alerts again. Before uninstalling the app, review and note your current settings. If you have questions about your alert settings, contact your health care provider. For assistance with setting up your alerts, please refer to the Guardian™ Connect user guide or call the Medtronic Helpline.

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Q7. HOW CAN I CONFIRM THAT REINSTALLING MY APP RESOLVED THE ISSUE?

1. From your mobile device visit https://carelink.minimed.eu and log in to your CareLink™ account
2. Confirm that your data is visible in the CareLink™ Connect web app
3. If your data is visible, the issue has been resolved
4. If your data is not visible, call the Medtronic Helpline for further assistance

Q8. WILL I LOSE ANY DATA AFTER DELETING MY APP?

You may lose some data since either your last upload to the CareLink™ software or since June 27, 2020. We recommend you try manually uploading your data to the CareLink™ system prior to deleting the Guardian™ Connect app, which may delete your visible data and history from the app.

All data that has been uploaded to the CareLink™ software will continue to be visible in CareLink™ reports. However, any data generated since June 27, 2020 may not have been uploaded.