

Urgent Field Safety Notice

Guardian™ Connect App connectivity to CareLink™ personal software

Guardian™ Connect iOS app: CSS7200

July 2020

Medtronic reference: FA922

Dear Healthcare Professional,

We recently released an update to the CareLink™ Personal software on Saturday, June 27, 2020. We want to make sure you are aware of a potential issue related to the Guardian™ Connect app's ability to sync your patients' data with the CareLink™ software and care partner notifications. This may be affecting your patients who are using the Guardian™ Connect app on an Apple iOS device. 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 patients 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 and your patients may see data gaps in CareLink™ reports

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

Actions Required: How Your Patients Can Check If They Are Experiencing the Issue **(refer to the Frequently Asked Questions included for detailed instructions)**

1. Patients should attempt to manually upload 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. Patients should check their account to see if they are experiencing this issue
 - a. From their mobile device visit <https://carelink.minimed.eu> and log in to their CareLink™ account
 - b. Confirm that data is visible in the CareLink™ Connect web app
 - c. If data is visible, no further action is needed – they are not experiencing the issue
 - d. If data is not visible, the patient may be experiencing the issue and they should complete the steps in the next section to resolve the issue.

Data Visible





Instructions for Patients to Resolve the Issue

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

1. If data was not visible after step #2, patients can uninstall the Guardian™ Connect app from their mobile device. ***For help, please refer to FAQ below #1***
2. Unpair the transmitter from the mobile device. ***For help, please refer to FAQ below #1***
3. Re-install the Guardian™ Connect app on a mobile device – this will restore the CareLink™ connection. ***For help, please refer to FAQ below #2***

**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 at 8002472288.


Sincerely,

Erfan Al-Lababidi
Senior Business Manager, Diabetes, APS

FREQUENTLY ASKED QUESTIONS

Q1. HOW CAN PATIENTS UNINSTALL THEIR GUARDIAN™ CONNECT APP?

First, follow the below steps to uninstall the app. Note – doing this will re-set alerts, sensor glucose, Logbook data, and unpair the Guardian™ Connect transmitter.

1. Before uninstalling the app, patients should review and take note of their 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 the transmitter from the Bluetooth® history by navigating to the 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"*

Q2. HOW CAN PATIENTS REINSTALL THEIR GUARDIAN™ CONNECT APP?

Follow the steps below to reinstall the Guardian™ Connect app on the mobile device. Note, they will need to re-pair their transmitter and set up notifications.

1. Search for "Guardian Connect" in the mobile device's App Store and download the app
2. Open the Guardian™ Connect app and follow the setup instructions
3. When patients get to the pairing step, they should remove and discard their sensor before charging and re-pairing the transmitter. They will need to insert and start a new sensor.

Q3. WHEN UNINSTALLING THE APP, WILL PATIENTS NEED TO RE-REGISTER THEIR CARE PARTNER?

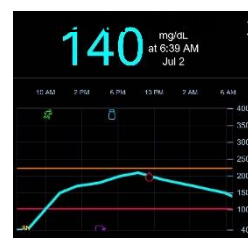
No, they do not need to re-register their care partner. After reinstalling the Guardian™ Connect app, normal use of the CareLink™ software with the Guardian™ Connect app should be restored, along with the care partner's ability to view data and receive notifications. In addition, the care partner will not need to re-establish his / her notifications **as long as the same username is being used**. No action is required by the care partner. Patients can return to the CareLink™ Connect web app to confirm data is available.

Q4. WHEN UNINSTALLING THE APP, WILL PATIENTS NEED TO SET UP THEIR ALERTS AGAIN?

Yes, after uninstalling the Guardian™ Connect app, the data and settings previously in the app will be removed. Therefore, patients will need to set up their alerts again. Before uninstalling the app, patients should review and note their current settings. We recommend they contact their health care provider for questions on their alert settings. For assistance with setting up the alerts, patients can refer to the Guardian™ Connect user guide or call 8002472288.

Q5. HOW CAN PATIENTS CONFIRM THAT REINSTALLING THEIR APP RESOLVED THE ISSUE?

1. From their mobile device visit <https://carelink.minimed.eu> and log in to their CareLink™ account
2. Confirm that data is visible in the CareLink™ Connect web app
3. If data is visible, the issue has been resolved
4. If data is not visible, patients can call the Medtronic Helpline at 8002472288 for further assistance





Q6. WILL DATA BE LOST AFTER DATA AFTER DELETING THE APP?

Some data may be lost since either the last upload to CareLink™ software or since June 27, 2020. We recommend patients try manually uploading data to the CareLink™ software prior to deleting the Guardian™ Connect app, which may delete 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.

Q7. IS THERE A WAY THAT I CAN RETRIEVE ANY GAPS IN MY PATIENT'S DATA ASSOCIATED WITH THIS ISSUE?

Unfortunately, there is no definitive way that gaps in patient data can be retrieved. We recommend that patients try manually uploading their data to the CareLink™ software prior to deleting their Guardian™ Connect app. If that does not work, you may continue to see a gap in your patient's data in their CareLink™ reports since their last upload or since June 27, 2020.



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Dear Valued Care Partner,

Our records indicate you may be registered as a care partner to a person 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 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 the Guardian™ Connect app is **not impacted** – people using the Guardian™ Connect app will still be able to see their CGM data and receive alerts in their Guardian™ Connect app.

Actions Required: Check If the Person Using the Guardian™ Connect App Is Experiencing the Issue (refer to the Frequently Asked Questions included for detailed instructions)

1. Ask the person using the Guardian™ Connect app to attempt to manually upload 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. Either you or the person using the Guardian™ Connect app can check your / their CareLink™ account to see if this issue is affecting you:
 - a. From your mobile device visit <https://carelink.minimed.eu> and log in to your CareLink™ account
 - b. Confirm that data is visible in the CareLink™ Connect web app
 - c. If data is visible, no further action is needed – the person using the Guardian™ Connect app is not experiencing this issue
 - d. If data is not visible, the person using the Guardian™ Connect app may be experiencing the issue and should complete the steps in the next section to resolve the issue.

Data Visible





Instructions for the Guardian™ Connect User to Resolve the Issue
(refer to the Frequently Asked Questions included for detailed instructions)

1. If data was not visible after step #2, the Guardian™ Connect user should uninstall the Guardian™ Connect app from their 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 the transmitter from the mobile device. **For help, please refer to FAQ below #3**
3. Re-install the Guardian™ Connect app on the Guardian™ Connect user's 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 at 8002472288

Sincerely,

Erfan Al-Lababidi
Senior Business Manager, Diabetes, APS

FREQUENTLY ASKED QUESTIONS

Q1. DO I NEED MY CARELINK™ PERSONAL USERNAME / HOW DO I GET IT?


In order to check whether 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 CAN THE GUARDIAN™ CONNECT USER UNINSTALL THE GUARDIAN™ CONNECT APP?

First, follow the below steps to uninstall the Guardian™ Connect app. Note – doing this will re-set alerts, sensor glucose, Logbook data, and unpair the Guardian™ Connect transmitter.

1. Before uninstalling the app, the Guardian™ Connect user should review and take note of 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 the transmitter from the Bluetooth® history by navigating to the 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 THE GUARDIAN™ CONNECT APP?

Follow the steps below to reinstall the Guardian™ Connect app on a mobile device. Note, the transmitter will need to be re-paired and the notifications set up again.

1. Search for "Guardian Connect" in the 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 the 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 AS A CARE PARTNER?

No, you do not need to re-register as a 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 ability to view the data of the Guardian™ Connect user and receive notifications. In addition, you will not need to re-establish your notifications **as long as the same username is being used**. No additional action is required by you. You can return to the CareLink™ Connect web app to confirm data is available.

Q6. WHEN UNINSTALLING THE APP, WILL THE GUARDIAN™ CONNECT USER NEED TO SET UP ALERTS AGAIN?

Yes, after uninstalling the Guardian™ Connect app, the data and settings previously in the app will be removed. Therefore, the alerts will need to be set up again. Before uninstalling the app, review and note your current settings. The Guardian™ Connect user should contact their health care provider with questions about their alert settings. For assistance with setting up alerts, please refer to the Guardian™ Connect user guide or call 8002472288.

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

1. From your mobile device visit <https://carelink.minimed.eu> and log in to your CareLink™ account
2. Confirm that data is visible in the CareLink™ Connect web app
3. If your data is visible, the issue has been resolved
4. If data is not visible, call the Medtronic Helpline at 8002472288 for further assistance



Q8. WILL THE MISSING DATA BE RESTORED AFTER THE GUARDIAN™ CONNECT USER REINSTALLS THE APP?

The data may not be restored. The Guardian™ Connect user may lose some data since either the last upload to the CareLink™ software or since June 27, 2020. We recommend they try manually uploading their data to the CareLink™ system prior to deleting the Guardian™ Connect app, which may delete the 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.



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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. 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.

Data Visible





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***

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Sincerely,

Erfan Al-Lababidi
Senior Business Manager, Diabetes, APS

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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
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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 at 8002472288.

Medtronic

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 at 8002472288 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.

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