

General

What is Guardian™ Connect?

The Guardian Connect app is part of the Guardian Connect Continuous Glucose Monitoring (CGM) system. CGM is a sensor glucose monitoring tool that uses a glucose sensor placed below your skin to continuously measure the amount of glucose in your interstitial fluid. The Guardian Connect CGM System includes the mobile app, transmitter, glucose sensor, and sensor inserter.

How does Guardian™ Connect work?

The Guardian Connect system measures subcutaneous sensor glucose and sends it to the Guardian Connect app approximately every five minutes (about 288 readings a day).

All components within the Guardian Connect system communicate on Bluetooth Low Energy (BLE) and/or wireless or cellular data connection. The transmitter communicates with the mobile app via BLE connection. The mobile app utilizes wireless connection to send data to CareLink Personal.

Your care partners can also access your information from the CareLink website on most smartphones, tablets, or computers. These must be connected to the internet to receive information. Care partners can also elect to receive SMS messages for any applicable alerts.

When can I buy Guardian™ Connect?

We will obtain CE Mark approval for the Guardian Connect system in Q1FY17 and publicly launch the product shortly thereafter. Guardian Connect should be available for purchase in summer of 2016. We will announce Guardian Connect via press release, on applicable Medtronic websites, and via our salesforce.

Where can I buy Guardian™ Connect?

Guardian Connect should be available for purchase in summer of 2016. Please reach out to your health care providers or contact Medtronic customer service to know whether Guardian Connect is available in your country.

How much does Guardian™ Connect cost?

The price of Guardian Connect will vary depending on where it is sold and will be aligned with the price of current transmitters and sensors on the market. Please reach out to your local Marketing Lead.

[In which countries will Guardian™ Connect be available?](#)

Guardian Connect will initially be available in most European countries, Australia, and Chile. More countries will have Guardian Connect in the future. Please visit the Medtronic Guardian Connect website for the most recent information on system availability.

[Do I need a prescription to obtain Guardian™ Connect?](#)

A prescription is not necessarily needed to purchase Guardian Connect system in your country. Please reach out to your health care providers or contact Medtronic customer service to know more.

[What components are required to use this system?](#)

To use Guardian Connect, you will need the following components:

1. Compatible iOS device (e.g. iPhone, iPod Touch or iPad) with Guardian Connect app with Bluetooth enabled and either Wi-Fi or cellular connection
2. Guardian Connect transmitter with relevant charger and test plug
3. Applicable glucose sensor
4. Applicable server.

To be noted that your care partners can access your information from the CareLink website on most smartphones, tablets, or computers. These must be connected to the internet to receive information. Care partners can also elect to receive SMS messages for any applicable alerts.

[When I order will I receive a mobile device?](#)

In most cases, you will not receive a mobile device when you order your Guardian Connect transmitter. You will be able to download the Guardian Connect app to your own mobile device and to pair the transmitter to your own mobile device.

[Can I buy an iPhone or iPod Touch from Medtronic?](#)

In most cases, you cannot buy an iOS device from Medtronic.

[How long will it take me to get initially set up?](#)

Depending on the person, it is estimated that it will take two to three hours to set up the Guardian Connect system. It is estimated to take approximately one hour to insert your sensor the first time, pair your transmitter, and set up the app. Once inserted, it will take approximately up to two hours for the sensor to warm up.

[How many calibrations are required with the Guardian™ Connect?](#)

You will be required to calibrate at least at least every 12 hours. The system may prompt for additional calibrations for accuracy purposes. You may

calibrate three to four times at regular intervals throughout the day to improve accuracy.

Is Guardian™ Connect available for children?

Yes, there is no age restriction to use Guardian Connect.

How is Guardian™ Connect different from blood glucose meter?

The Guardian Connect app is intended for continuous or periodic monitoring of glucose levels in the interstitial fluid under the skin, in persons with diabetes mellitus. It allows users to track patterns in glucose concentrations and to possibly identify episodes of low and high glucose. The Guardian Connect app displays alerts if a glucose level reaches, falls below, or rises above set values.

It requires that you have a functioning mobile electronic device with the correct settings (such as a supported operating system and Bluetooth enabled) for accurate operation. A non-functioning mobile device, or incorrect settings on your mobile device, may prevent the Guardian Connect app from properly displaying alerts.

You must test your blood glucose levels at least two times per day, or as indicated by the system. If the Guardian Connect app indicates that your sensor glucose is not within your glucose target range, check your blood glucose using your blood glucose meter.

Sensor glucose values displayed on the screen are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a meter blood glucose measurement may be required.

Why is this not available for pumps?

Guardian Connect is intended for people who are on insulin injections and are either not indicated for or interested in pump-therapy. With Guardian Connect, people on injections can better track their injections and other events related to their diabetes and have easier access to their glucose levels. If you use Guardian Connect, you are certainly welcome to use pump-therapy; however the pump and transmitter are not compatible.

When will it be available for pumps?

Guardian Connect will not be compatible with pumps.

What is the difference between MiniMed Connect and Guardian™ Connect?

MiniMed Connect is not available within the EMEA region. Still while MiniMed Connect and Guardian Connect both take readings from Bluetooth-enabled transmitters and display them on mobile apps, there are a few key differences. In particular:

1. MiniMed Connect is intended for people who are on Medtronic pump-therapy; while Guardian Connect is intended for people on insulin injections
2. MiniMed Connect displays some key pump information, such as active insulin
3. Guardian Connect allows people to track activities related to their diabetes, such as meal intake, exercise, and insulin intake.

Can I use this product with Dexcom CGM?

The Dexcom sensor and transmitter are not compatible with the Guardian Connect app.

How is this different from Dexcom Share?

The key differences between the Guardian Connect system and Dexcom Share are as follows:

1. The Guardian Connect transmitter has a one-year warranty (special exceptions apply); while Dexcom transmitters need to be replaced every six months (G4) and every three months (G5)
2. With the Guardian Connect system, you can allow your HCPs to easily access your CareLink data if CareLink Professional and Personal are synced; while with Dexcom, this information must be emailed
3. With the Guardian Connect system, you can choose to have SMS messages sent to care partners; while with Dexcom, care partners can only receive alerts within the app.

How is this different from Abbott Libre?

The key difference between the Guardian Connect system and Abbott Libre is that with the Guardian Connect system, you will receive continuous sensor glucose readings from your transmitter without having to scan the transmitter.

Can a hospital use a Guardian™ Connect system with multiple patients successively?

While the app and transmitter are not optimized for multi-patient use, they can be used as such in the clinical setting.

In an ideal case, the hospital would provide the transmitter to the patient and the patient would use his/her own mobile device. Whenever the transmitter is paired with a new mobile device, the data will be wiped from the transmitter. Hence if the patient's device is used with the same transmitter, previous patient data will not be made available after the subsequent patient's device has been paired with the transmitter.

If the hospital also provides the mobile device, the hospital **MUST** delete and reinstall the app in between patients. If the app is deleted and reinstalled, the old data will not show in the newly downloaded app. It is imperative to take this intermediate step to ensure that private data is not shared between patients. Therefore if the hospital uses only one device, the

Guardian Connect app must be reinstalled to erase previous patient data history.

Guardian™ Connect Transmitter

How big is the Guardian™ Connect transmitter?

The transmitter is approximately 1.4 x 1.6 inches or 3.5 x 4.0cm.

What is the Guardian™ Connect transmitter warranty?

The Guardian Connect transmitter comes with a one-year warranty. The warranty period shall be automatically extended to two (2) years if the product is sold to consumers within the territory of the European Union, in accordance with applicable local legislation. The sensors and app do not come with specific warranties. For additional information, please refer to the user's guide that was included in the shipment box.

How to apply the 2 year warranty per EU directive 99/44/EG (only applies in EU):

The statutory warranty requires the seller to warrant that the products are free from any defect for a period of 2 years after the products have been handed over to the consumer (date of purchase). If a product is defective, the seller has to basically either replace or repair it.

First 6 months: The seller has to prove that the defect was caused e.g. by improper handling of the consumer, and that the defect was not inherent to the product during transfer to the buyer.

After 6 months: The buyer bears the burden of proof that the product has been defective at the time it was handed over, and did not get defective later e.g. because of improper handling.

In summary, if a product fails after our warranty period but during the first 2 years (e.g. a Guardian Connect transmitter failing after 14 months) we are not obliged to replace it, unless the customer can prove that the defect existed at the date of purchase.

Does the existing 640G transmitter work with Guardian™ Connect?

No, the existing 640G transmitter will not be compatible with the Guardian Connect system. The Guardian Connect transmitter is the only transmitter that is compatible with the Guardian Connect app.

How often do I need to charge the Guardian™ Connect transmitter?

You should charge your transmitter before inserting your sensor. A fully charged Guardian Connect transmitter will last at least six days without

recharging. You should also charge your transmitter until the green light displays (could take up to two hours).

How do I pair my transmitter with my iOS device?

You can easily pair your transmitter with your iOS device if your Bluetooth is turned on. In the Sensor Set up page of the Guardian Connect app, you can click 'Pair Transmitter.' The app will search for nearby transmitter and display the applicable device. You can select the device to pair, click on the device number, and pair within just a few moments.

What can I do if my transmitter is not pairing with my device?

If your transmitter is not pairing with your device, we recommend turning Bluetooth on your mobile device OFF and then ON again and try to search for your transmitter once again.

How does the transmitter send data to my mobile device?

The transmitter sends data to the mobile device via your phone's Bluetooth connection. The Guardian Connect system requires Bluetooth 4.0 and above. You can still use your headsets and other Bluetooth connected while using Guardian Connect.

What is the distance the transmitter can be from the app to transmit data?

The transmitter must be within 6 meters of the mobile device (similar to range between Bluetooth headset and phone) to properly transmit data.

If my transmitter is out of range of my iOS device, what happens to the data?

If the transmitter is out of range from the iOS device, your transmitter will continue to calculate and record sensor glucose until next required calibration. The sensor glucose values will display on your app when you reconnect.

What is the data backfill on the Guardian™ Connect transmitter?

Internal transmitter data storage is 10 days.

Is the transmitter waterproof?

It is waterproof up to 2.5 meters for up to 30 minutes.

Does the transmitter transmit through water?

No, the transmitter is not designed to transmit data while under water, so you may see an out of range notification if it is in water.

How long does the transmitter battery last?

If fully charged before insertion, the Guardian Connect transmitter will last the full life of the sensor.

How will I know if my transmitter battery is running low?

If your transmitter battery is running low, you will get an alert on your mobile app when you have one day of battery life. You can also refer to the System Status menu of the Guardian Connect app to see how much battery life is left. Always charge your transmitter before inserting your sensor to ensure your transmitter has enough battery life to last for six days.

[What happens if I lose my transmitter?](#)

If the Guardian Connect transmitter is lost, you can order a new one.

Guardian™ Connect App

[How can I download the Guardian™ Connect app?](#)

You can download the Guardian Connect app by visiting the Apple App Store and searching for 'Guardian Connect.' If the Guardian Connect system is available in your country, you will see the listing for the Guardian Connect app and you can download it for no cost.

[Can I download the app to my iPad?](#)

Yes, you can download the app to any compatible iPad.

[What mobile phones and OS is it compatible with?](#)

The Guardian Connect app is compatible with iOS11.4 and above as well as Android 7.0 & Android 8.0 & Android 9.0. The app is compatible with the following iOS devices:

- iPhone 5S
- iPhone 6
- iPhone 6 Plus
- iPhone 6S
- iPhone 6S Plus
- iPhone 7
- iPhone 7 Plus
- iPhone SE
- iPhone 8
- iPhone 8 Plus
- iPhone X
- iPhone XS
- iPhone XS Max
- iPhone XR
- iPod Touch (6th generation)
- iPad Air
- iPad Air 2
- iPad Pro
- iPad Pro
- iPad Mini 2
- iPad Mini 3

iPad Mini 4

The Guardian Connect app is compatible with Android 7.0 & Android 8.0 & Android 9.0. The app is compatible with the following Android devices:

Samsung Galaxy S7 (Android 7.0.x, Android 8.0)
Samsung Galaxy S7 Edge (Android 7.0.x, Android 8.0)
Samsung Galaxy S8 (Android 7.0.x, Android 8.0, Android 9.0.0)
Samsung Galaxy S8+ (Android 7.0.x, Android 8.0, Android 9.0.0)
Samsung Galaxy A5 (2016) (Android 7.0.x)
Samsung Galaxy A5 (2017) (Android 7.0.x, Android 8.0)
Samsung Galaxy S9 (Android 7.0.x, Android 8.0, Android 9.0.0)
Samsung Galaxy S9+ (Android 7.0.x, Android 8.0, Android 9.0.0)
[Samsung Galaxy S10 \(Android 9.0.0\)](#)
[Samsung Galaxy S10+ \(Android 9.0.0\)](#)
[Samsung Galaxy S10e \(Android 9.0.0\)](#)

[Along with the Android app launch, why do you require a printed instruction for use manual for the Guardian Connect?](#)

For the safe use of the app, Medtronic is required to provide all users a printed copy of the updated Guardian Connect CGM instructions for use manual. We want to ensure that all users are set up for success with their Guardian Connect CGM system and have the best possible experience. If you are planning to use the Guardian Connect CGM with your Android device, please email (*insert email*) to request a printed copy of the updated instructions for use manual to ensure that you receive the manual before using the Guardian Connect CGM system.

[Are there any major differences between the iOS version and Android version of the Guardian Connect app?](#)

The Guardian Connect app functions exactly the same way on both OSes, except for three key differences:

1. On Android, location services must be enabled the first time the transmitter is paired with your phone; this is not the case for iPhone
2. On Android, Do Not Disturb permission needs to be granted in DND settings; this is not the case for iPhone
3. The procedure whereby you restart the Guardian Connect app on the iPhone versus the Android phone is different.

Please refer to the instructions for use manual to get more details.

[Is there a Guardian™ Connect Widget in the Apple Today View?](#)

Yes.

How many devices can I have the app on? Can multiple apps get information from one transmitter?

You can pair your transmitter to one iOS device. Transmitters and iOS devices are compatible on a 1:1 basis.

What data is sent from the transmitter to the app?

Every five minutes while your transmitter and mobile device are in the operating range (up to 6 meters), the transmitter will send the most recent sensor glucose reading from your sensor. If you travel out of range, the data will backfill once you are back in range as long as the calibration is not timed out.

How often does the transmitter send data to the app?

The transmitter sends data to the app via Bluetooth. The transmitter sends data to the app approximately every five minutes. People using Guardian Connect will receive approximately 288 readings per day if their transmitter is within range of the phone.

What data does the app send to CareLink™?

Approximately every five minutes while your transmitter and mobile device are in range (6 meters) and while you are in Wi-Fi or cellular range, the mobile app will send the most recent sensor glucose reading from your sensor and any un-cleared alarm. Every twenty four hours, your mobile device will send full details from your phone, including sensor glucose readings and graphs, alerts, and event markers. You can choose to deactivate such option within your app by turning off the 'Sync to CareLink' setting.

How does the app send data to CareLink™?

The app sends data to CareLink via your mobile device's cellular data or Wifi connection.

How much data is stored or used?

Storage required to install the Guardian Connect app on your iOS device is around 17MB. Then the app sends data to CareLink via your mobile device's cellular data or Wi-Fi connection. It uses the equivalent amount of data as does downloading 10 MP3s per month (meaning about 30MB a month or about 1MB per day).

How will this impact my phone's battery life?

The use of Bluetooth in the Guardian Connect system will have minimal impact on your phone's battery life, as will the data being sent to CareLink. Users will see small battery impact depending on how frequently they interact with the app.

Can I view my Guardian™ Connect data on Apple Watch?

At this time, you cannot view your Guardian Connect data on your Apple Watch.

What do I do if I am not hearing any alerts on my device?

When the Guardian Connect app is not open, or your device is locked, the style and appearance of alerts depends on the notification settings on your mobile device.

Do not turn off notifications or enable the Do Not Disturb setting on your mobile device. Doing so may result in missing important alerts requiring your immediate attention.

Do not force the Guardian Connect app to quit. Doing so will stop transmission of sensor glucose data, and you will not receive any alerts. If the app is running in the background on your mobile device, you will still receive sensor glucose data and may still receive alerts depending on your mobile device's notification settings.

If I get a calibration error message, how long do I have to wait to recalibrate?

You will need to wait up to 15 minutes until you can recalibrate.

What if I am traveling and my data plan does not cover, will I still be able to transmit data?

As long as Bluetooth is on, your app will still be able to show data. You should refer to your carrier for more information on cellular data while traveling with your iOS device. If you are worried about data charges, you can disable CareLink uploads while you are traveling.

If I am out of cellular or Wi-Fi range, what happens with the alerts?

You will still receive your alerts on your phone. If you have cleared your alerts before coming back in range, your care partner will never be alerted via SMS message. If the alert is still displayed on your screen when you come back in range, your care partner will be notified via SMS message.

While your care partner will not be able to see the data or receive SMS messages while you are out of range, the app will store the data and upload to CareLink when you are back in range. It is important to note that if you have cleared your alerts before coming back in range, your care partner will never be alerted via SMS message.

If I lose my phone who can access my data?

Access to your phone is dependent on the security measures you've enabled on your phone.

What new alerts are available for GC 3.2? How are these alerts communicated to existing and new customers?

For existing customers that upgrade to new Guardian Connect app:

You will notice several new screen flows when you load the Guardian Connect app, version 3.2. These screen flows refer to some new alerts that have been designed to provide you more assistance in your diabetes management.

There is a “What’s new” screen that introduces these changes. You will notice that as soon as you load the Guardian app and have downloaded the new version.

After the EULA terms are agreed to by the user, the following new alerts will be described:

1. Low Battery - This screen describes that Guardian Connect will display an alert when your mobile device battery is low.
2. New Audio Alert - This screen describes the audio override alert. This override feature ensures that you will always be able to hear your alert, regardless of what your volume settings are or if your phone is silenced.
[Please refer to the training deck if you need more details about this Override Feature]
3. Low Glucose Alert - This screen describes that your Guardian Connect app will always alert you if your sensor glucose goes below 55 mg/dL.

For new customers downloading Guardian Connect app for the first time:

If you are a new user, you will follow the normal set up wizard. Simply follow the instructions as the app is laid out to walk you step-by-step through the set-up process. You will not see any “What’s New” screen pops - Low Battery, Low Glucose Alert, and New Audio Alert - you will just walk through the normal alert set up.

You can always encourage patients to reference the Guardian Connect IFU if they have any more questions about these alerts mentioned above.

What is the audio override feature on Guardian Connect?

The audio override feature enables the Guardian Connect user to hear alerts even when they want to silence other apps or notifications from other phone features. Many people put their phone on Do Not Disturb while sleeping; this ensures that alerts are received even when the phone is muted or silenced. By default, the feature is on. You can also assign the Audio Override feature to different alerts - low, high, and status alerts.

CareLink™ Personal

Do I need to have a CareLink™ account?

To use Guardian Connect, you do need a CareLink account. You do not necessarily have to send your information to CareLink and/or to enroll any care partners, but you do need to have a CareLink account in order to use Guardian Connect.

Will my existing CareLink™ account work with Guardian™ Connect?

Yes, absolutely your existing CareLink account will work with Guardian Connect.

Do I need to manually upload my data to CareLink™ Personal?

If you have turned on the 'Sync to CareLink' setting within your app, you no longer have to manually upload information to CareLink. Every five minutes, your information will be sent to the CareLink Connect tab. Every 24-hours, your full data will be uploaded to CareLink Personal.

How often will the app send data to CareLink™?

The app will send data to CareLink approximately every five minutes.

How many people may I share my data with?

You can share your data with up to five people.

Do my care partners need to have an Apple device?

No, care partners do not need to have Apple devices in order to access Guardian Connect data. Care partners can access the CareLink Connect tab data from any internet-connected device (any phone, computer, or tablet with internet connectivity).

Can I set up different alerts for myself and my care partner?

You have control over which alerts you set to receive within your mobile device. You also have control over whether your care partners can receive SMS messages at all - however, if enabled, your care partners choose for which alerts they'd like to receive SMS messages.

Will my care partners get an SMS message for every alert or alarm?

When care partners set up their CareLink accounts, they have the ability to specify for which alerts they wish to receive SMS messages. Care partners can also choose to set a delay period between when the alert is triggered in the app and when they receive the SMS message. This delay period was designed to allow the person with diabetes to take action to bring their sensor glucose levels within range before the care partner is notified.

How quickly are SMS messages sent to your care partner?

If the transmitter and iOS device are within range and you are in cellular or wireless network, the SMS should be sent within one minute from the time

that the alert has triggered from within the app (unless you care partner has set a delay).

Who pays for the SMS sent to care partners?

Medtronic pays for the service of the SMS message to be sent from CareLink to the care partner. Please refer to carrier for information on charges for received SMS messages.

Can a care partner follow more than one person with Guardian™ Connect?

Yes, care partners can follow more than one person using Guardian Connect. Care partners will need to have unique logins for each CareLink account in order to follow more than one person. Care partners can also receive SMS messages for more than one person using Guardian Connect. The name of each person will be prominently displayed in the relevant SMS messages.

How do I remove someone from seeing my data?

Within your CareLink Connect tab, you will be able to remove care partner from seeing your data. You can also choose to allow someone to see your data but to NOT receive SMS messages.

How will CareLink™ Personal help my healthcare professional?

If you have the 'Sync to CareLink' setting turned on, you will no longer have to manually upload your data to CareLink. This means that you'll save time during your office visits because you will not need to download your data while in the office. Furthermore, having more details about your diabetes will allow you to have productive conversations with your healthcare professional about your treatment options.

I am a parent to multiple children with diabetes; can I see all of their information in one place?

At this time, you cannot see all information in one place. You'll need to have separate credentials to login to each of your children's CareLink accounts.