Dexcom G6

Using Your G6

- Welcome
- Home Screen Overview
- Alarm and Alerts
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Chapter 1: Welcome!

Congratulations on making the Dexcom G6 Continuous Glucose Monitoring (CGM) System (G6) part of your life!

1.1 Get Started

To set up your G6, use the instructions in your Start Here guide or follow the steps in the tutorial (available at **dexcom.com/downloadsandguides**).

Both the tutorial and this guide, Using Your G6, introduce you to the home screen, guide you through making treatment decisions, and show you how to end your sensor session. In addition, this guide shows you how to customize your alert sounds, use Dexcom Share (Share) and Dexcom Follow (Follow), and make an alert schedule on your app.

Images in this guide are representational. Your materials may look different.

1.2 What is New for G6

Dexcom's G6 features include:

- No fingerstick calibrations!
- Wear sensor for 10 days
- Urgent Low Soon Alert
- Acetaminophen blocking
- New App features
- New sensor applicator
- Streamlined transmitter and transmitter holder
- See your G6 information on your smart watch and the new optional receiver

No Fingerstick Calibrations

With the G6, there is no need to calibrate! After entering the sensor code, you will not receive any calibration prompts.

10 Day Sensor Session

Your sensor session lasts 10 days! Settings show when your session will be over so you can plan ahead.

Urgent Low Soon Alert

The Urgent Low Soon Alert lets you know when your glucose is falling so fast it will drop to 3.1 mmol/L in less than 30 minutes. This gives you time to prevent yourself from going too low.

Acetaminophen Blocking

Previously, acetaminophen could affect your readings, making them look higher than they really were. With the G6, you can take acetaminophen and still use the G6 readings. Taking higher than the maximum dose of acetaminophen (> 1 gram every 6 hours in adults) may affect sensor readings and make them look higher than they really are.

New App Features

Use your app to create a night-time schedule, so you only hear your G6 alarm/alerts, not every email or text notification your phone gets.

Sensor Applicator

Inserting a sensor has never been easier! The redesigned sensor applicator lets you insert a sensor quickly and easily.

Streamlined Transmitter Holder and Transmitter

The redesigned transmitter and its holder have a lower profile. In addition, after your sensor session is over, you can easily break open the transmitter holder to remove the transmitter.

Support for Smart Watches and New Optional Receiver

You have options for how you view your information. You can use the app, the new receiver with a touchscreen, Apple Watch, and Android Wear.

Chapter 2: Safety Statements

Dexcom G6 Safety Statements

Indications for Use

The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 System or G6) is a glucose monitoring system indicated for the management of diabetes in persons age 2 years and older. The Dexcom G6 System is designed to replace fingerstick blood glucose (BG) testing for diabetes treatment decisions.

Interpretation of the Dexcom G6 System results should be based on the glucose trends and several sequential readings over time. The Dexcom G6 System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

The Dexcom G6 System is intended for use by patients at home and in healthcare facilities.

Important User Information

Please review the product instructions before using the G6. Indications, contraindications, warnings, precautions, and other important user information can be found in the product instructions that are included with the G6. Discuss with your healthcare professional how you should use the information displayed on the G6 to help manage your diabetes. The product instructions contain important information on troubleshooting the G6 and on the performance characteristics of the system.

Contraindication

- **No MRI/CT/Diathermy – MR Unsafe** 

Do not wear your CGM (sensor, transmitter, receiver, or smart device) for magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.

The G6 has not been tested in those situations. The magnetic fields and heat could damage the components of the G6, which may cause it to display inaccurate G6 sensor glucose readings (G6 readings) or may prevent alerts. Without G6 readings or alarm/alert notifications, you might miss a severe low or high glucose event.

Warnings

- **Read User Materials**

  Before you use your G6, carefully read the materials included with it. If you do not, you might:

  - Not use the G6 correctly
  - Not understand G6 information
  - Affect how well it works

- **Do Not Ignore Low/High Symptoms**

  Do not ignore how you feel. If your glucose alerts and G6 readings do not match what you are feeling, use your blood glucose meter (meter) to make diabetes treatment decisions or, if needed, seek immediate medical attention.

  When in doubt, get your meter out.

- **No Number, No Arrow, No CGM Treatment Decision**

  If your G6 does not show a number or arrow, or your G6 readings do not match your symptoms, use your meter to make diabetes treatment decisions.

  No number, no arrow, no treatment decision. When in doubt, get your meter out.

- **Do Not Use If…**

  Do not use the G6 if you are pregnant, on dialysis, or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the system. G6 readings may be inaccurate in these populations.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Precaution

- **Avoid Sunscreen and Insect Repellent**

  Some skin care products, such as sunscreens and insect repellents, can make the plastic used in your G6 crack. Before using your G6, make sure there are no cracks in your receiver, transmitter, and transmitter holder. If you find a crack, please contact Technical Support. Do not allow these skin care products to contact your G6. After using skin care products, wash your hands before touching your G6. If any skin care products get on your G6, immediately wipe with a clean cloth.

- **Hydroxyurea Precaution**

  If you are taking hydroxyurea, your G6 readings may be falsely elevated and result in missed hypoglycemia alerts or errors in diabetes management decisions. The level of inaccuracy depends on the amount of hydroxyurea in your body. Use your meter.

Start Up Safety Statements

Warnings

- **Use Meter During Startup**

  When you start a new sensor, you will not get any G6 readings or alarm/alerts until you enter your sensor code or two calibrations. Use your meter to make treatment decisions during the 2-hour sensor warmup period.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Precautions

- **Use Correct Sensor Code**

  When you start a new sensor, you must enter a code into your display device to use the G6 without fingerstick calibrations. Each sensor has its own code printed on the back of the adhesive patch. Do not use a code from a different sensor or make up a code. If you do not enter the correct code, your sensor will not work as well and could be inaccurate. If you lost the sensor code, you may calibrate the G6 using fingersticks.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Calibration Safety Statements

Calibration is not required if users enter a sensor code. If users do not enter a sensor code, the following warnings and precautions apply.

Warnings

- **Do Not Wait – Calibrate!**

  If you have not used the calibration code, you must manually calibrate your G6 daily, using values obtained from a blood glucose meter and fingersticks. You must calibrate immediately when the G6 notifies you. If you have not calibrated when notified, your G6 may not be accurate, so use your glucose meter to make treatment decisions until you calibrate your G6.

- **Use Fingertips**

  Use fingertips to calibrate from your BG meter. Blood from other places may be less accurate and not as timely.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Precautions

- **Be Accurate, Be Quick.**

  Enter the exact BG value displayed on your meter within five minutes of using your meter. Do not enter the G6 reading as a calibration.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

System/Hardware/Software Safety Statements

Warnings

- **Sensor Wire Breaks Off**

  Do not ignore broken or detached sensor wires. A sensor wire could remain under your skin. If this happens, please contact Technical Support.

  If a sensor wire breaks off under your skin and you cannot see it, do not try to remove it. Contact your Healthcare Professional. Also seek professional medical help if you have symptoms of infection or inflammation – redness, swelling, or pain – at the insertion site.

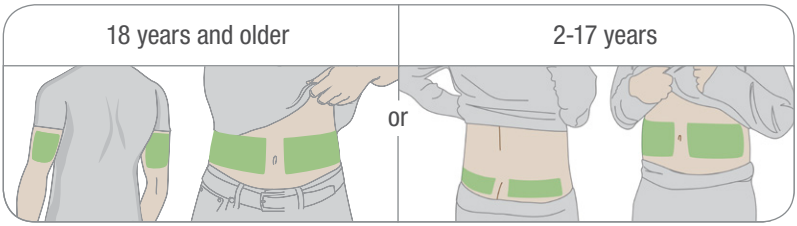
- **Where to Insert: Belly, Back of Arms, or Buttocks?**

  Adults can use their bellies or back of upper arms. Patients 2 to 17 years old can choose their bellies or upper buttocks. Look for a place on your belly, back of upper arms, or upper buttocks where you have some padding.

  The sensor is not tested or approved for other sites. Talk to your Healthcare Professional about the best site for you.

  Ages 2-17 years: Insert in your belly or upper buttocks

  Ages 18 and older: Insert in your belly or back of upper arms



- **Where to Store**

  You can store your sensors at room temperature or in your refrigerator – as long as it is between 2°C and 30°C. Do not store sensors in the freezer.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Precautions

- **Do Not Start Sensor Past Use By Date**

  Do not start a sensor past its Use By date because it may give incorrect results. The Use By date is in YYYY-MM-DD (Year-Month-Date) format on the sensor package label beside the hourglass symbol.

- **Check Package**

  Do not use sensor if its sterile package has been damaged or opened, because it might cause an infection.

- **Clean and Dry Skin**

  Clean and dry your hands and your insertion site before inserting your sensor.

  Wash your hands with soap and water, not gel cleaners, and then dry them before opening the sensor package. If your hands are dirty when you insert the sensor, you may get germs on the insertion site and get an infection.

  Clean your insertion site with alcohol wipes to prevent infections. Do not insert the sensor until your skin is dry. If your insertion site is not clean and completely dry, you run the risk of infection or the transmitter holder not sticking well.

  Make sure you do not have insect repellent, sunscreen, perfume, or lotion on your skin.

- **Where to Insert: Things to Check**

  Keep the safety guard on until you put the G6 applicator against your skin. If you remove the safety guard first, you may hurt yourself by accidentally pushing the button that inserts the sensor before you mean to.

  Change your insertion site with each sensor. Using the same site too often might not allow the skin to heal, causing scarring or skin irritation.

  Sensor placement is important. Choose a site:

  - At least 8 cm from insulin pump infusion set or injection site
  - Away from waistband, scarring, tattoos, irritation, and bones
  - Unlikely to be bumped, pushed, or laid on while sleeping

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Transmitter Safety Statements

Warnings

- **Inspect**

  Do not use a damaged or cracked transmitter. A damaged transmitter could cause injuries from electrical shocks and may make the G6 not work correctly.

- **Use as Directed**

  The transmitter is small and may pose a choking hazard. Do not put it in your mouth or let children hold it without adult supervision.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Precautions

- **Reuse – Do Not Throw Away**

  When ending a session, do not throw away the transmitter. The transmitter is reusable until the G6 notifies you that the transmitter battery is about to expire.

  For Healthcare Professionals: Please see cleaning and disinfection instructions in Professional Use Instructions.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

System Safety Statements

Precautions

- **Treatment Decisions**

  Use your G6 reading and trend arrow to make treatment decisions.

- **Use Correct Transmitter, Receiver, and Sensor**

  G6 components are not compatible with any previous Dexcom products. Do not mix transmitters, receivers, and sensors from different generations.

- **Going Through Security Check Point**

  When wearing your G6, ask for hand-wanding or full-body pat-down and visual inspection instead of going through the Advanced Imaging Technology (AIT) body scanner (also called a millimeter wave scanner) or putting any part of the G6 in the baggage x-ray machine.

You can wear the G6 for the walk-through metal detector. If you do, use your meter for treatment decisions until you leave the security area.

Because we have not tested every x-ray and scanner, we do not know if they damage the G6.

Not sure what kind of machine it is? Be safe – request either hand-wanding or full-body pat-down.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Display Device Safety Statements

Precautions

- **Keep Transmitter Close to Display Device**

  Keep your transmitter and display device within 6 meters with no obstacles (like walls or metal) between them. Otherwise, they might not be able to communicate. If water is between your transmitter and the display device – for example, if you are showering or swimming – keep them closer to each other. The range is reduced because *Bluetooth*® does not work as well through water.

- **Get Alarm/Alerts on Display Device You Use**

  To get your alarm/alerts, set them on the display device you use. Your receiver will not get the alarm/alerts you set on your app. Likewise, your app will not get the alarm/alerts you set on your receiver.

- **Is It On?**

  If the receiver or smart device is turned off (shut down), it will not show G6 readings or alarm/alerts. Make sure your display device is turned on.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Smart Device Safety Statements

Warnings

- **Check Settings**

  When using your smart device, you should confirm that your volume is turned up, your phone is not muted, and you do not have headphones plugged in. If your volume is not turned up, the device is muted, or headphones are plugged in, you will not hear the sound of any notifications, including important alarms. When you have headphones connected to your Android, alarm/alerts will sound through the headphones and the speaker. On your Apple, they will sound only in the headphones.

  When using *Bluetooth* headphones, speakers, etc., your alarm/alerts may sound on your primary smart device or on the accessory. Each accessory is different. Test yours so you know where you will hear your alarm/alerts.

  Some notifications are silent during the first visual and vibrate notification and then make a sound on the second notification. If you do not clear the alert, it repeats at half volume after 5 minutes and at full volume after 10 minutes.

  If your smart device is on mute and you have the Always Sound setting turned on (the default setting) only these notifications make a sound (when Sound setting isn't Vibrate Only):

  - Glucose Alarm/Alerts:
    - Urgent Low
    - Urgent Low Soon
    - Low Glucose
    - High Glucose
    - Rise Rate
    - Fall Rate
    - No Readings Alert
  - System Alerts:
    - Calibration Required (after 2-hour sensor warmup, only appears when a sensor code is not used)
    - Calibration Error (only appears when a user enters a calibration; calibration is not required)

    - Sensor Expired
    - Sensor Failed
    - Transmitter Failed
    - No Storage Error
    - App Stopped
- *Bluetooth*: Your transmitter talks to your app with *Bluetooth*. Make sure your smart device *Bluetooth* is on. If not, you will not get alarm/alerts or CGM information.
- Notifications:
    - Make sure your smart device settings allow Dexcom app notifications to show on your lock screen. This will allow you to see notifications without unlocking your phone.
    - During G6 setup, enable Dexcom app notifications or you will not get alarm/alerts.
- Battery: The app must always be running in the background and may drain your smart device battery. Keep the battery charged.
- Compatibility: Before upgrading your smart device or its operating system, check **dexcom.com/compatibility**. Automatic updates of the app or your device operating system can change settings or shut down the app. Always update manually and verify correct device settings afterward.
- Time: Let the date and time on your smart device automatically update when you travel across time zones or switch between standard and daylight-saving times. Do not manually change your smart device time, because it can make the time on the trend screen wrong and the app may stop displaying data.

- **Android users must allow Do Not Disturb Permission to use the app.**

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Precautions

- **Check Accessory Devices**

  Do you use headphones with your smart device? What about *Bluetooth* speakers or a smart watch? When using accessories, keep in mind you may get your alarm/alerts on only one device or accessory, not all. After connecting any accessory devices, make sure that your smart device settings allow you to continue receiving alarms or alerts.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Receiver Safety Statements

Warnings

- **Do Not Use if Damaged**

  Do not use a receiver that is damaged or cracked. A damaged receiver could cause injuries from electrical shocks and may make the G6 not work correctly.

- **Use Cable as Directed**

  Use USB cable only as directed, and store safely. Misuse of the USB cable can be a strangulation risk.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Precautions

- **Test Speaker and Vibrations**

  You have to hear or feel alarm/alerts to react to them, so test your receiver speaker and vibrations regularly.

  To make sure the speaker and vibrations work, plug in the receiver to charge. The Speaker Test screen appears for a few seconds. Follow the directions on the screen to test the speaker and vibrations. If you hear and feel them, great! But if it does not beep and vibrate – perhaps it got wet or was dropped – contact Technical Support.

- **Keep Clean and Dry**

  Do not submerge your receiver in water and do not get dirt or water in the USB port. That could damage it.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Dexcom Share Safety Statements

Important User Information

Dexcom Share (Share) lets you send your sensor information from your app to your Followers' smart devices! Read the indications, warnings, and precautions below to find out how you can safely use this app feature.

Share and Managing Your Diabetes Safety Statements

Indications for Use

- **Keep Followers Informed**

  Use Share to send your sensor information from your smart device to your Followers' smart devices.

- **Use as Secondary Notice**

  The information on your smart device is sent directly from your G6 transmitter. After it is on your device, Share sends it to your Followers. So your Followers' information is always older than yours. Use your current information to manage your diabetes, not your Followers' possibly outdated information.

  Your Followers can use the information they get to reach out to you and support you in managing your diabetes. The information they get is not meant to be used for treatment decisions, analysis, or teaching. Followers cannot change your information.

Warnings

- **Use Your G6 to Make Treatment Decisions**

  Do not use Share information for treatment decisions, like treating for a low or dosing for a high. Use the sensor information on your G6 instead.

- **Take Healthcare Professional Advice**

  Has your Healthcare Professional given you self-monitoring tasks? Keep doing them. Having Followers does not replace them.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Share Setup and Settings Safety Statements

Warning

- **Followers Must Follow and You Must Share**

  You have to turn Share on to make it send your sensor information to your Followers. Followers have to download the Dexcom Follow app to see what you send.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Precautions

- **Followers Do Not Manage Your Diabetes, You Do**

  Do not rely on your Followers to let you know you need to make a treatment decision. Stay on top of your diabetes management. Look at your G6 often. Respond to alarm/alerts. Do not wait for a Follower to reach out – they may not be getting your sensor information because of a technical issue.

- **Check Your Smart Device and Your Followers' Smart Devices**

  - Internet access required: Both smart devices need to be connected to the Internet to use Share. Try sending your Follower an email from your device. If your Follower gets it on their device, both smart devices are connected.
  - Batteries charged: Make sure the smart device batteries are charged. If either your or your Followers' smart device batteries are not charged, Share will not work.

- **Check Your Smart Device**

  App on: Whenever you power on your smart device, tap the G6 app to open it. If the app is not open, Share will not work.

- **Check Followers' Smart Devices**

  - Sounds on: Followers must keep their smart device volume on, or at least keep the vibration on, so they can hear and/or feel alarm/alerts. Smart device settings trump Follow app settings.
  - Sharing gaps: Followers will not get your sensor information when their smart device is off, not connected to the Internet, or in Do Not Disturb or Airplane mode. When the Followers fix those issues, missing information will backfill and they will resume getting information.

    - Cell carrier supports simultaneous voice and data: Most cell service carriers support using voice and data at the same time. Check yours and have Followers check theirs. If it is not supported, Share will not work during phone calls. Share will restart when the call is over and send any waiting notifications.

- **Customize Share So Followers Can Support You**
    - Customize Share to make sure your Followers have the information they need to help you manage your diabetes.
    - Delay feature: Your Follower will not get notified until after the delay time you set.
    - Not Share feature: You can stop sharing with a Follower any time by choosing Not Share. That Follower will stop getting any of your sensor information until you choose to share again.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Chapter 3: Home Screen Overview

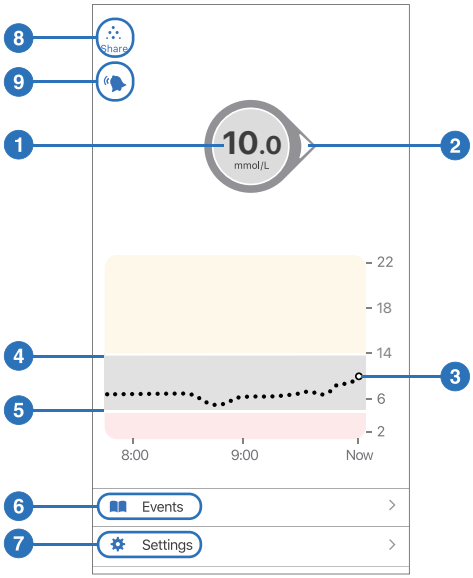
You will spend most of your time on the home screen. It gives you your G6 sensor glucose readings (G6 readings) and trend information and gets you to other G6 functions.

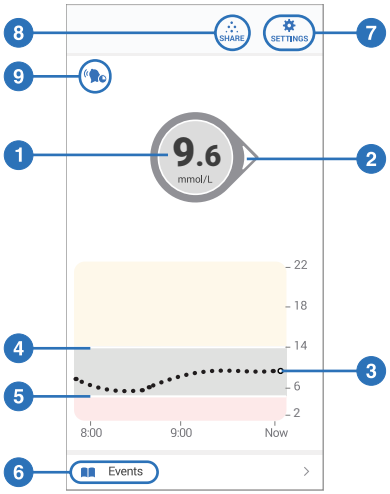
The next section describes the home screen features. Later we review how to interpret your G6 readings, trend arrows, and graph, followed by how to navigate to other functions.

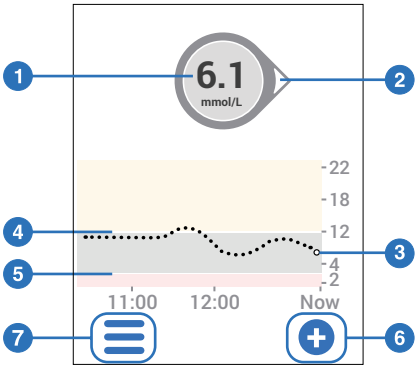
3.1 Home Screen Features

Below are home screens from the Apple app, Android app, and receiver. While the sensor glucose information is the same, navigation is slightly different.

For a list of current compatible smart devices and operating systems, go to: **dexcom.com/compatibility**.

Key	Apple
Number and Arrow 1. G6 Reading 2. Trend Arrow **Graph** 3. Current G6 Reading 4. High Alert Level 5. Low Alert Level **Navigation and Status** 6. Events 7. Settings 8. Share 9. Always Sound status	

Key	Android
Number and Arrow 1. G6 Reading 2. Trend Arrow **Graph** 3. Current G6 Reading 4. High Alert Level 5. Low Alert Level **Navigation and Status** 6. Events 7. Settings 8. Share 9. Always Sound status	

Key	Receiver
Number and Arrow 1. G6 Reading 2. Trend Arrow **Graph** 3. Current G6 Reading 4. High Alert Level 5. Low Alert Level **Navigation** 6. Add Event 7. Menu	

Be sure your fingers are dry when you touch the receiver screen.

3.2 G6 Reading, Trend Arrow, and Graph

Where You Are Now

On the home screen, numbers and colour tell you where you are now. The number is your G6 reading. It updates every 5 minutes. The number background colour shows whether your G6 reading is low, high, or in your target range.

Red = Low

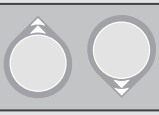
Yellow = High

Gray = In Target

The number background color is also red when your glucose is falling so fast you will be at or below 3.1 mmol/L within 30 minutes (see Urgent Low Soon Alert).

Where You Are Going

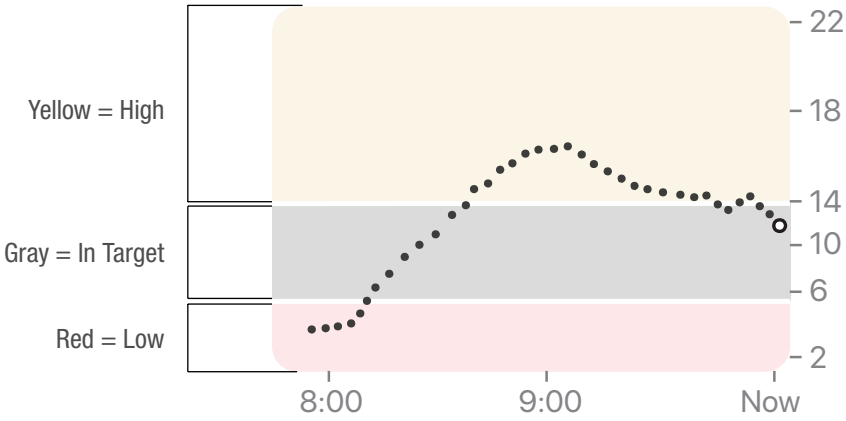
To know where you are going, look at your trend arrows.

Trend Arrows	Where Your Glucose Is Going	
	**Steady**	Changing up to: • 0.06 mmol/L each minute • 1.8 mmol/L in 30 minutes
	**Slowly rising or falling**	Changing: • Between 0.06–0.1 mmol/L each minute • Up to 3.4 mmol/L in 30 minutes
	**Rising or falling**	Changing: • Between 0.1–0.17 mmol/L each minute • Up to 5 mmol/L in 30 minutes
	**Rapidly rising or falling**	Changing more than: • 0.17 mmol/L each minute • 5 mmol/L in 30 minutes
	**No arrow**	Cannot determine trend

Where You Have Been

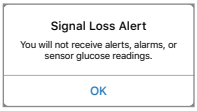
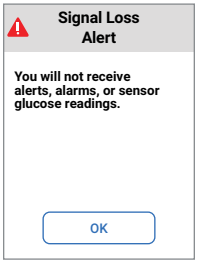
The dot on the right is the current G6 reading. The dots to the left are G6 readings taken earlier.

The graph background colours show where your G6 readings are:



Home Screen Issues

Sometimes you do not get G6 readings or you do not see a number, just a message.

<table>
<tr><th colspan="2">What You See</th><th>What It Means</th></tr>
<tr><td colspan="2"> 
</td><td>Your G6 reading is below 2.2 mmol/L</td></tr>
<tr><td colspan="2"> 
</td><td>Your G6 reading is above 22.2 mmol/L</td></tr>
<tr><td>App
 
</td><td>Receiver
 
</td><td>An error message means your G6 is not working and you will not get alarm/alerts or G6 readings. (See Appendix A Troubleshooting.)</td></tr>
</table>

3.3 Home Screen Navigation and Status Icons

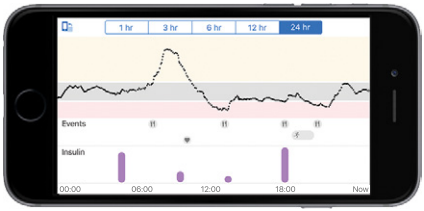
You can access other G6 features using the navigation icons.

The app and receiver home screen navigation icons are almost the same. The app has extra features.

Icon		Description
		**Share icon (app only):** Lets you send your glucose information to your Followers. See Chapter 7 Advanced App Features for more information.
		**Always Sound icon (app only):** Lets you control whether your alarm/alerts will sound even when your phone is on mute/Do Not Disturb. To change it, go to Settings. See Chapter 7 Advanced App Features for more information.
App 	**Receiver** 	**Events/Add Event:** Lets you record insulin, carbs, exercise, and health-related events.
App  SETTINGS	**Receiver** 	**Settings/Menu:** Lets you edit alerts, find help, change settings, customize sounds, and more.

3.4 See Past G6 Readings

On the app, to see your graph over 1, 3, 6, 12, and 24 hours (with events), turn your smart device on its side (for landscape view) and tap the tabs at the top of the screen.



On the receiver, tap the graph to switch between 1-, 3-, 6-, 12-, and 24-hour views.

Chapter 4: Alarm and Alerts

Your alarm and alerts help you stay in your target range. They sound and/or vibrate when you:

- Are out of your target range
- Are at or below 3.1 mmol/L
- Will be at 3.1 mmol/L in less than 30 minutes

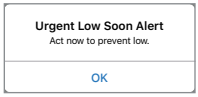
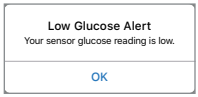
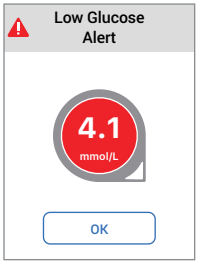
The alarm/alert vibrations feel the same as notifications you get from other apps on your smart device. The only way to know if it is from your G6 is to look at your smart device.

Keep your alerts on: They are an important part of making G6 treatment decisions. Talk to your healthcare professional about the best Low and High Alert settings for you.

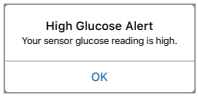
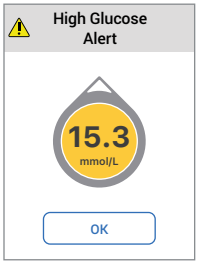
When using both the app and the receiver at the same time, change alert settings and confirm alarm/alerts on each device.

4.1 Low Alarm and Low Alerts

What You See		What It Means
App	**Receiver**	**Urgent Low Alarm**
		Lets you know when your sensor glucose is at or below 3.1 mmol/L. You cannot change or turn off your Urgent Low Alarm.

What You See		What It Means
App	**Receiver**	**Urgent Low Soon Alert**
		Lets you know you are falling **fast**. You will be at or below 3.1 mmol/L within 30 minutes regardless of where you are now. You can change your Urgent Low Soon alert: • On by default; can be turned off • Choose sound
App	**Receiver**	**Low Glucose Alert (Low Alert)**
		Lets you know your G6 reading is below your target range, but you are not falling fast enough to get an Urgent Low Soon Alert. You can change your Low Alert: • On by default; can be turned off • Choose the alert level and sound

4.2 High Alert

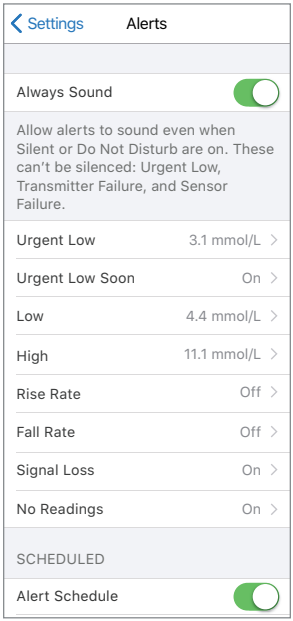
What You See		What It Means
App	**Receiver**	**High Glucose Alert (High Alert)**
		Lets you know when your G6 sensor reading is above your target range. You can change your High Alert: • On by default; can be turned off • Choose the alert level and sound

4.3 Changing Alerts

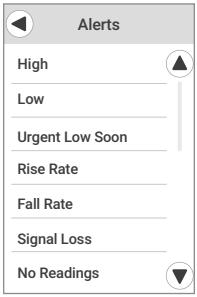
Talk to your healthcare professional about customizing your alert settings so they are appropriate for you. They can help you find the best settings to manage your diabetes without getting too many alerts.

Go to **Settings > Alerts** (Receiver: **Menu > Alerts**) and tap an alert to change it. Rise Rate and Fall Rate alerts are defaulted to OFF.

App

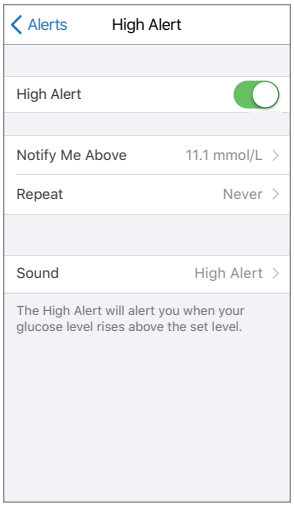


Receiver



Customizing Alert Sounds

You can pick alert sounds that work best for you. In the app, tap Sound from the alert to pick a different sound for that alert.



Unlike the app, you choose one sound for all of your alarm/alerts in the receiver's Sound menu. This list shows the different alarm/alert sounds available on the receiver, starting with the quietest.

Icon	Receiver Sound
	Vibrate only Exceptions: Urgent Low Glucose Alarm, Urgent Low Soon Alert, Sensor Failure, and Transmitter Failure always beep and vibrate.
	Quiet
	Medium

Icon	Receiver Sound
	Attentive • Rising tune for High and Rising Alerts • Falling tune for Low and Falling Alerts
	Hypo Repeat • Medium sound • Repeats Urgent Low Alarm and Urgent Low Soon Alert every 5 seconds

Tap Test Sound to sample the sound you picked. This does not select a sound; it just lets you hear it.

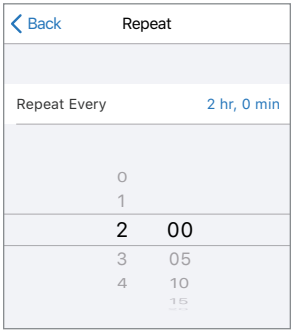
Use Alerts to Achieve Goals

Work with your healthcare professional to customize your alerts to help you achieve your goals. For example, are you worried about insulin stacking – taking doses too close together?

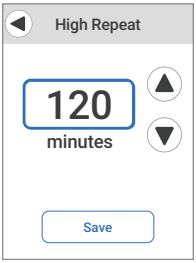
To use your G6 as a tool for watching and waiting – and avoiding insulin stacking – your healthcare professional may advise you to turn on the Repeat feature in your High Alert setting. That way, when you get a High Alert and confirm it, you will be re-alerted after the time you set in Repeat until your G6 readings go back in your target range. That reminds you to check your G6 readings later to make sure you come down.

The screens below show a High Alert Repeat at 2 hours. After you get your High Alert, 2 hours later, if you never get back into your target zone, your High Alert repeats to let you know you are still high and might want to take more insulin. On the other hand, if the 2 hours pass and you are back in your target range, your High Alert will not repeat.

App



Receiver



Changes you make to alerts in your app are not reflected in your receiver and vice versa. If you want the alerts to be the same, you need to make changes to both devices.

Chapter 5: Treatment Decisions

With Dexcom, you can make treatment decisions without using your blood glucose (BG) meter (meter).

Whether you are new to Dexcom or experienced, you should keep using your meter to make treatment decisions until you know how Dexcom works for you. Do not rush! It may take days, weeks, or months for you to gain confidence in using your CGM to make treatment decisions.

Confirm your G6 readings using your BG meter so you understand that:

- The accuracy you experience with each newly inserted sensor may vary
- A sensor might work differently in different situations (meals, exercise, first day of use, etc.)

There may be variations between sensors, so pay attention to how each newly inserted sensor is working for you when deciding whether to make treatment decisions based on your G6 readings. Sometimes you must use your meter instead of the G6. And other times it is best not to treat, just watch and wait.

Work with your healthcare professional to review what works best for you when making treatment decisions.

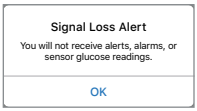
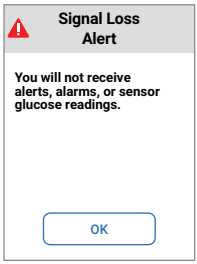
5.1 When to Use Meter Instead of G6

Rely on your BG meter for treatment decisions in these situations:

- G6 does not show both a number and arrow.

  For example, if your home screen displays any of these:

When you see	Notice
	No number
	No arrow

When you see		Notice
App	**Receiver**	No number or arrow
		

In other words, no number, no arrow, no CGM treatment decision.

- Your G6 readings do not match your symptoms.

  For example, you do not feel right but your G6 readings show you in target. Wash your hands thoroughly and use your meter. If the meter value matches your symptoms, use the meter value to treat. Then, if you want to align your G6 with your meter, calibrate. You do not have to calibrate, but you can. (See Appendix A Troubleshooting).

  In other words, when in doubt, get your meter out.

5.2 When to Watch and Wait

There are times when you should not treat at all, just watch and wait.

Stacking insulin: Do not stack insulin by taking doses too close together. Wait at least 2 hours between doses so you do not accidentally force your glucose down too low. Sometimes, it is best to watch and wait.

5.3 How to Use the Trend Arrows

The trend arrows help you decide how much to dose.

Up arrow: Take a little more insulin

Down arrow: Take a little less insulin

5.4 Practice Making Treatment Decisions

Use the examples below to practice making treatment decisions.

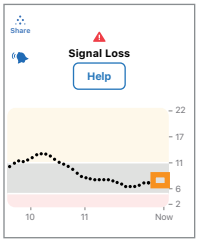
Discuss them with your healthcare professional and review:

- When you need to use your meter
- How you can use your G6
- When to watch and wait instead of treat

Situation	Solution

Early morning:
Your Low Alert wakes you up.
You see:
 
	Think about:
	• Number and Arrow: You have both.
	  • Number: Your glucose is low – 4.4 mmol/L.
	  • Slowly Falling Arrow: Glucose is falling up to 3.4 mmol/L in 30 minutes.
	What you should do:
	• Use your G6 to treat as you normally would.

Breakfast time: Ninety minutes later you are sitting down for breakfast. **You see:** 	**Think about:** • Number and Arrow: You have both. • Up Arrow: Glucose is rising up to 5 mmol/L in 30 minutes. **What you should do:** • Use your G6 to treat. Take your normal dose and, because of the up arrow, a little more.

Situation	Solution
After Breakfast: Thirty minutes after dosing to cover breakfast, you get a High Alert. **You see:** 	**Think about:** • Insulin: You took insulin less than an hour ago. It takes time to work. **What you should do:** • Nothing. Watch and wait to avoid stacking insulin. Do not treat for at least another hour and a half.
An hour later: You watched and waited. **You see:** 	**Think about:** • Insulin: The insulin you took with breakfast has you back in your target range. **What you should do:** • Nothing. No treatment needed.
Mid-morning: You are about to have a mid-morning snack. **You see:** 	**Think about:** • No Number and No Arrow: You have neither. Notice the gap in G6 readings. • Error Message: You are not getting G6 readings. **What you should do:** • Use your meter for treatment decisions.

Situation	Solution
Lunch time: Three hours later, you are about to dose for lunch. **You see:** 	**Think about:** • Number and Arrow: You have both. • Down arrow: Your glucose is falling up to 5 mmol/L in 30 minutes. **What you should do:** • Use your G6 to treat. Because of the down arrow, take a little less.
Mid-afternoon: It is 3 hours after lunch. **You see:** 	**Think about:** • Number and No Arrow: You do not have an arrow. **What you should do:** • Use your meter for treatment decisions.
Early Evening: Just before dinner, you feel a little shaky and sweaty. **You see:** 	**Think about:** • Symptoms and G6 Reading: Your symptoms do not match your sensor G6 readings. **What you should do:** • Thoroughly wash your hands and take a fingerstick. If your meter value matches your symptoms, use it for treatment decisions. Then consider calibrating your G6 to align it to your meter. You do not have to calibrate, but you can.

Chapter 6: Starting a New Sensor or Transmitter

A sensor session lasts up to 10 days. A transmitter is reusable for about 3 months. This section explains how to start a new sensor or transmitter when the current one expires.

If you are inserting your first sensor, follow the instructions in the **Start Here** guide included with your system.

6.1 Starting a New Sensor

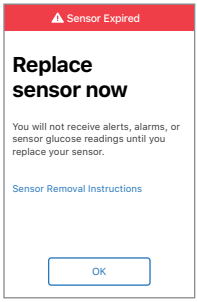
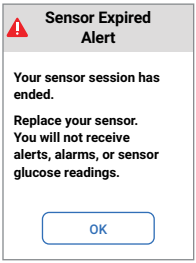
Your system alerts you when you have 24 hours left in your session, then 6 hours, 2 hours, and finally, 30 minutes. You can start a new sensor session:

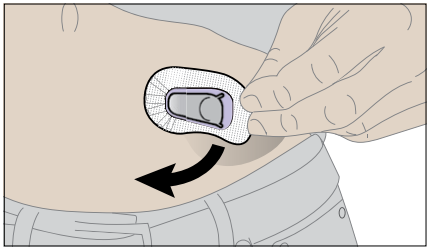
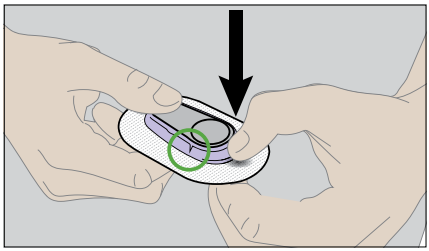
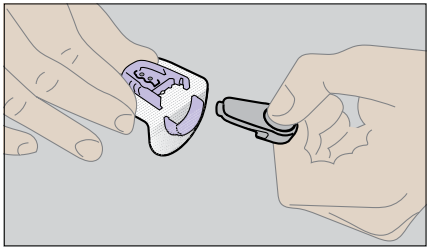
- *Automatically:* Wait until your sensor expires
- *Manually:* End your session early, at your convenience

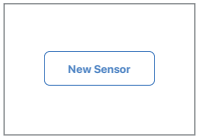
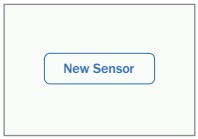
Automatically Start a New Sensor

Once your sensor expires, you will not get sensor readings until you start a new sensor session. Follow these steps to:

- Remove the sensor from your body
- Remove your transmitter from the holder
- Start a new sensor session

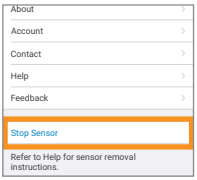
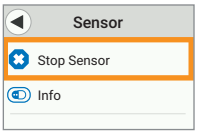
	App	Receiver	
1			G6 lets you know when to replace sensor. Tap **OK**.

2		Peel off patch from the edge.
3		Break purple transmitter holder at notches.
4		• Slide transmitter out of holder. • Keep transmitter to use with next sensor. • Throw out adhesive patch according to your local guidelines for disposal of blood-contacting components.

	App	Receiver	
5			Tap **New Sensor**. Follow onscreen instructions to: • Enter the new sensor code • Insert new sensor and re-attach your current transmitter (Instructions are available in the Start Here guide and at **dexcom.com**) • Start the 2-hour sensor warmup

Manually Start New Sensor

To stop a sensor session early, at your convenience:

	App	Receiver	
1			App: Go to **Settings > Stop Sensor** Receiver: Go to **Menu > Sensor > Stop Sensor**

Then, to:

- Remove the sensor from your body
- Start a new sensor

Follow the instructions in **Automatically Start a New Sensor**, beginning at step 2.

6.2 Starting a New Transmitter

Remember, your transmitter is reusable for about 3 months. When it is time to pair a new transmitter, you must also start a new sensor session.

Your system will alert you when you have 3 weeks left and again when you have 2 weeks left. Once you've used the transmitter for its last sensor session, the system tells you to replace your sensor and transmitter.

You can start a new transmitter:

- *Automatically:* Wait until the current transmitter expires
- *Manually:* End it early, at your convenience

Automatically Start New Transmitter and Sensor

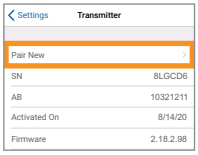
When your transmitter expires, you'll be prompted to pair a new transmitter. Follow these steps:

	App	Receiver	
1			Tap **Pair**. Follow onscreen instructions to: • **App:** Enter the new transmitter SN and new sensor code • **Receiver:** Enter the new sensor code and new transmitter SN • Insert new sensor and attach new transmitter (instructions are available in the **Start Here** guide and at **dexcom.com**) • Start the 2-hour sensor warmup

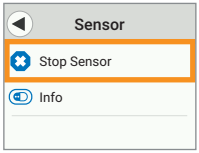
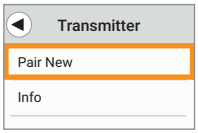
Manually Start New Transmitter and Sensor

To stop a transmitter early, at your convenience, follow these steps:

App

1		Go to **Settings > Transmitter > Pair New** Follow onscreen instructions to: • Stop your sensor • Enter the new transmitter SN and new sensor code • Insert new sensor and attach new transmitter (instructions are available in the **Start Here** guide and at **dexcom.com**) • Start the 2-hour sensor warmup

Receiver

1		Stop your sensor. Go to **Menu > Sensor > Stop Sensor**
2		Got to **Menu > Transmitter > Pair New** Follow onscreen instructions to: • Enter the new sensor code and new transmitter SN • Insert new sensor and attach new transmitter (instructions are available in the **Start Here** guide and at **dexcom.com**) • Start the sensor and the 2-hour sensor warmup

Chapter 7: Advanced App Features

7.1 Dexcom Share and Follow

You can use Share to invite people (your Followers) to view your current G6 readings and trends on their smart device. (For a list of compatible devices, go to: **dexcom.com/compatibility**.) Share helps your Followers support you.

Share and Follow Settings

When using Share or Follow, remember:

- You must keep your G6 app open to share glucose information and alerts with your Followers
- Battery: Keep display devices charged
- Internet:
  - Connect smart devices to the internet
  - Airplane Mode is off
- Voice and data at the same time:

  Do the cellular service carriers support voice and data at the same time (simultaneous voice and data)? If not, Share will not send data during phone calls. When your phone call is over, Share will fill in any missing glucose information.

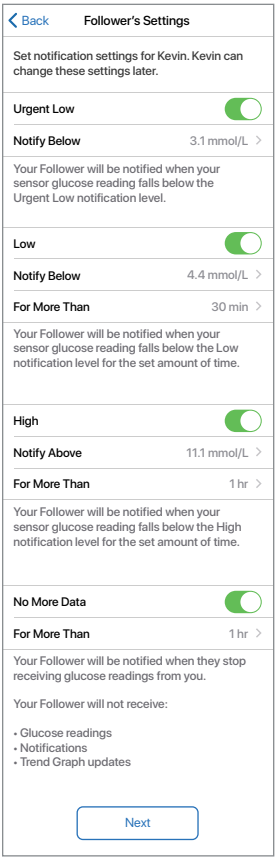
Share and Follow will not work if there is something wrong with the smart device(s). Refer to your smart device instructions for troubleshooting.

Set Up Share and Invite Followers

To set up Share, tap the Share icon on your app home screen. Then follow the instructions on the screens.

Once you are set up, invite someone to become your Follower by tapping Invite Followers.

You pick what your Follower can see in the Follower Settings screen, however, they can customize their settings in the Follow app.



When your Follower settings meet your needs, tap Next and then tap Send Invitation. Share sends your Follower an invitation email.

Follower Status

The Followers List shows the status of your Followers and lets you invite new ones.

Below are the statuses and what they mean:

Status	Description
Add Follower	Invite new Follower.
Invited >	You invited a Follower. They have not accepted yet.
Invitation Expired >	Follower did not accept invitation within 7 days. To re-invite, tap Add Follower.
	Follower gets notification(s).
	Follower sees trend graph.
Removed >	Follower stopped following you.

7.2 Dexcom Follow

Your Followers may feel more secure if they get your G6 information almost as soon as you do.

Additional Follow Recommended Settings

To set up and run Follow, set the Follower's smart device volume:

- Mute/Do Not Disturb is off
- Sound is on

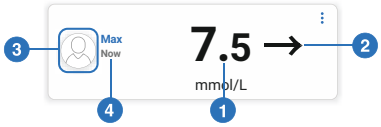
Follow Setup

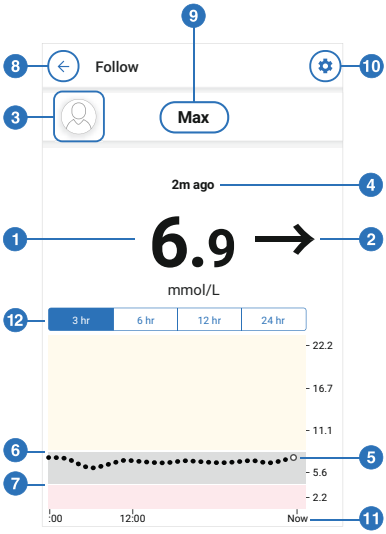
1. Follower gets and opens your email invitation on the smart device they will use to follow you.
2. They install and set up the Dexcom Follow app on their smart device.

   The email includes a link to download the app or they can get it from the app store.

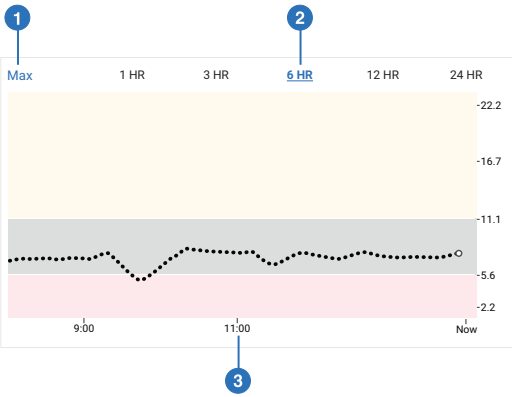
Now your Follower sees your G6 information!

What Followers See

Key	Share Number and Arrow Only
1. Sensor Reading 2. Trend Arrow 3. Sharer's Picture 4. Last Updated	

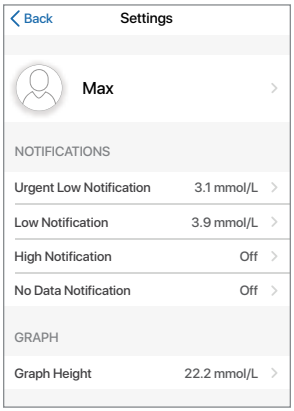
Key	Trend Graph
1. Sensor Reading 2. Trend Arrow 3. Sharer's Picture 4. Last Updated 5. Trend Graph 6. High Notification Level 7. Low Notification Level 8. Back to Dashboard 9. Sharer's Name 10. Notification Settings 11. Hours Shown 12. Views	

To see up to the last 24 hours of Sharer readings turn the smart device on its side (landscape). Touch and hold on the graph to see details.

Key	Trend Graph Landscape View
1. Back to Portrait 2. Views 3. Hours Shown	

Notification Settings

Your Follower can customize notifications. For example, they can change their settings so they know when you go below 3.9 mmol/L for more than 30 minutes. They can also change it to get notified every 2 hours if you stay under 3.9 mmol/L.



The Follower sees when you turn off Share, if they have been deleted, or if sharing stops for any other reason. The Follower can tap the blue help icon next to a Sharer for more information about their status.

If the Sharer is not getting sensor glucose readings, Follow shows their status as Active - No Data. The Follower should ask the Sharer to check their CGM.

There are times when Share information may be out of sync with your G6 information. Always depend on your G6 app to manage your diabetes, not your Followers'.

7.3 Control When Alarm/Alerts Sound

When you set up your smart device, the Always Sound icon displays. You can change how Always Sound works in **Settings > Alerts**.

Using Always Sound

When you are at school or work, you may want your phone sounds to be more discreet. Always Sound, combined with your phone's mute/Do Not Disturb setting, lets you control when you hear your alarm/alerts and your phone's other noises. Icons on your Home screen show what you will hear.

The mute/Do Not Disturb phone setting controls whether you hear phone noises, like text messages and phone calls. When Always Sound is on, you always hear your default and scheduled alerts, no matter what your phone's mute/Do Not Disturb setting is. So at night, you can turn on both Always Sound and mute/Do Not Disturb to avoid hearing anything except your G6 alarm/alerts.

When Always Sounds is on, these icons show on your home screen:

Default Alerts (those you established when you set up the app on your phone or in the Alerts menu)

Scheduled Alerts (described in the next section)

When Always Sound is off, it matters whether your phone is set to mute/Do Not Disturb.

- If mute/Do Not Disturb is also off, you will hear default and scheduled alerts and see these icons on your home screen. You also hear other non-G6 noises from your phone, like calls and texts.

  Default Alerts

  Scheduled Alerts

- However, if mute/Do Not Disturb is on, you hear only these alerts: Urgent Low Glucose Alarm, Transmitter Failed, Sensor Failed, and App Stopped. You do not hear any other noises from your phone. This may be the right setting combination for you during the school or workday. These icons on your home screen show this state:

  Default Alerts

  Scheduled Alerts

7.4 Alert Schedule

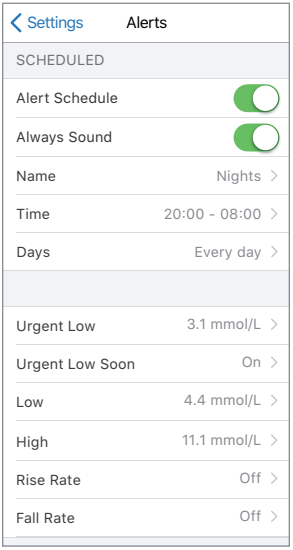
The app Alert Schedule lets you pick how your alarm/alerts notify you at different times and on different days. For example, you may choose to schedule the alarm/alerts to be the only sounds your smart device makes while you sleep.

Alert Schedule lets you set up one additional schedule.

Using Alert Schedule

When you turn on the Alert Schedule for the first time, your default glucose alert settings are copied into your schedule. The Alert Schedule guides you through creating an additional schedule.

To schedule the alarm/alerts to be the only sounds your smart device makes while you sleep, create a night alert schedule with Always Sound on, like the example below. Then, each night, switch your smart device to mute/Do Not Disturb.



When Alert Schedule is on, there are two groups of settings in the Alerts menu: Default and Scheduled.

- Default shows your regular, not scheduled settings
- Scheduled shows any alerts you changed from your default setting

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Appendix

- Troubleshooting
- Extend Your App
- Dexcom Clarity
- Taking Care of Your G6
- Packaging Symbols
- Warranty
- Technical Information
- Professional Use Instructions
- Glossary

Appendix A: Troubleshooting

This appendix has brief instructions for the most common questions. They are listed in alphabetical order, as shown below:

A.1 Accuracy – G6 Readings Do Not Match Blood Glucose Meter Value

A.2 Accuracy – G6 Readings Do Not Match Symptoms

A.3 Adhesive Patch

A.4 App Shuts Off

A.5 Calibrate Your G6

A.6 Cannot Hear Alarm/Alerts

A.7 Common Alerts

- Calibration and Recalibration Prompts
- No Readings Alert
- Signal Loss Alert
- Transmitter Alert
- Transmitter Battery Low and Last Session Alerts
- Transmitter Not Found Alert

A.8 End Sensor Session Early

A.9 Gap in Graph

A.10 Recharge Receiver

A.11 Start Sensor Session Without Sensor Code

A.12 Water and the G6

For full troubleshooting information, see the frequently asked questions section on the Dexcom website (**dexcom.com**), or contact Technical Support.

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the health authority of the country in which you are established.

A.1 Accuracy – G6 Readings Do Not Match Blood Glucose Meter Value

Different body fluids give different numbers:

- BG meter measures glucose from blood
- G6 sensor measures glucose from interstitial fluid

Calibrating may help align your G6 readings to your meter values. (See A.5 Calibrate Your G6.)

If your meter value and G6 reading are 20%-29% different, the G6 may be working but is off from your meter. Take a fingerstick if your expectations or symptoms do not match your G6 readings. Otherwise, use the G6 reading for treatment decisions. If you like, you can calibrate to align your G6 with your meter.

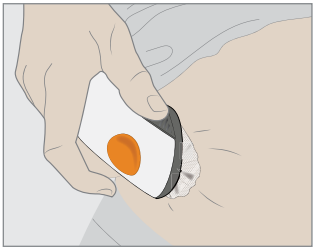
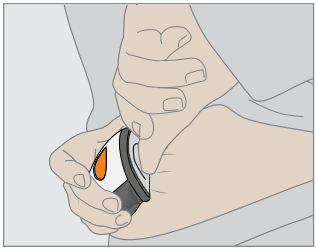
If your meter value and G6 reading are 30% or more different, G6 may be inaccurate. Take a fingerstick if your expectations or symptoms do not match your G6 readings. If you like, you can calibrate to align your G6 with your meter. If you feel more comfortable you can replace your sensor.

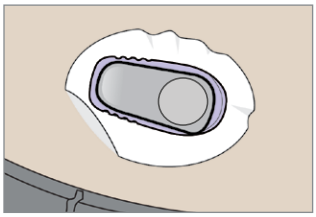
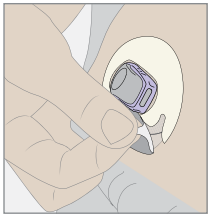
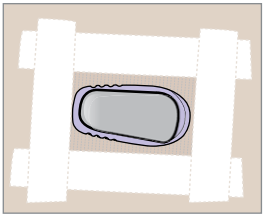
A.2 Accuracy – G6 Readings Do Not Match Symptoms

If your readings do not match your symptoms:

- Wash your hands with soap and water. Dry them. Then take a fingerstick with your meter. If your meter value matches your symptoms, use it to make treatment decisions.
- Calibrating may help align your G6 readings to your meter values. (See A.5 Calibrate Your G6.)

A.3 Adhesive Patch

Issue	Solution
Applicator will not come off 	 1. Gently peel off adhesive patch with applicator attached. 2. Check insertion site to make sure the sensor is not left in the skin. 3. Do not reuse applicator. 4. Contact Technical Support.

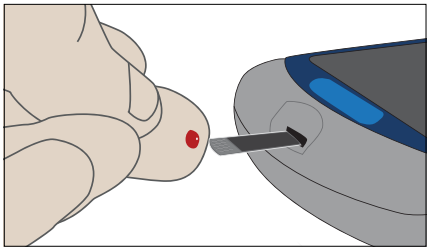
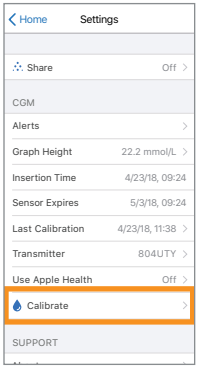
Issue	Solution
Adhesive patch peeling off body 	After your sensor is inserted, you can reduce peeling by: • Put Overpatch or medical tape (such as Blenderm) over adhesive patch. Do not cover transmitter. Avoid open wounds. • To order Overpatch, contact Technical Support.  Overpatch  Medical Tape For your next sensor session, you can prevent peeling before inserting your sensor by: • Making sure your skin is clean and dry before inserting sensor. • Using adhesive products (such as Mastisol®, SkinTac™) under patch. Avoid spot where needle inserts. • Thoroughly rubbing patch onto skin.
Skin irritation around sensor site	• Some people are sensitive to the sensor adhesive. If you have significant skin irritation, such as itching, burning, and/or rashes at the site of the adhesive patch, contact your healthcare professional.

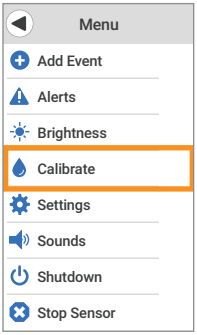
A.4 App Shuts Off

If your app shuts itself off, it may be because the smart device's memory or storage is full. To fix this, routinely close open apps that are not in use and delete files you do not use.

A.5 Calibrate Your G6

Follow these steps to calibrate your G6:

<table>
<tr>
<td>1</td>
<td>  </td>
<td>After thoroughly washing your hands with soap and water, dry them. Then use your meter to get a meter value.</td>
</tr>
<tr>
<td>2</td>
<td>App
 

Receiver
 
</td>
<td>Tap Calibrate on your G6 menu.

Follow onscreen instructions to enter, save, and confirm your meter value.</td>
</tr>
</table>

Only calibrate in one display device, even if you use both the app and receiver. The transmitter sends calibration information between each.

Only use your meter value for calibrations: never enter readings from your G6.

Do not calibrate when your glucose is changing rapidly – more than .2 mmol/L per minute.

Only calibrate with meter values between 2.2 mmol/L and 22.2 mmol/L.

A.6 Cannot Hear Alarm/Alerts

Receiver

Your receiver beeps, vibrates, and displays a message for Urgent Low Alarm, Urgent Low Soon Alert, Sensor Failed Alert, and the Transmitter Alert. For all other alerts, your receiver is more discreet. For the first alarm/alert, it vibrates and displays a message. If the alarm/alert repeats, the receiver adds a beep.

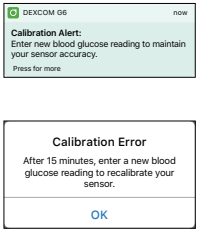
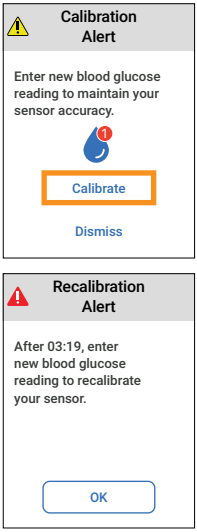
If you cannot hear your alarm/alerts on your app, verify that the app, *Bluetooth*, volume, and notifications are on. If you restart your smart device, reopen the Dexcom app. See Chapter 2 for smart device suggested settings.

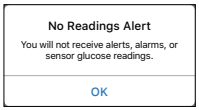
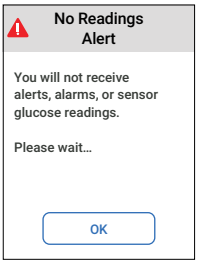
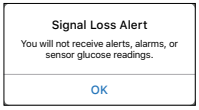
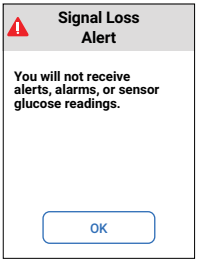
If you cannot hear your alarm/alerts on your receiver, change your alarm/alerts ringtone in **Menu > Sounds**. Use **Menu > Sounds > Test Sound** to try out the selected sound to make sure you can hear it easily.

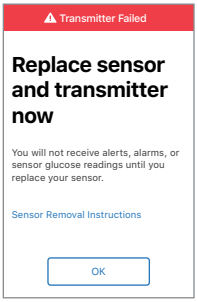
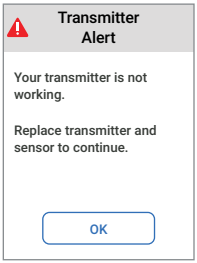
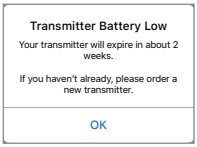
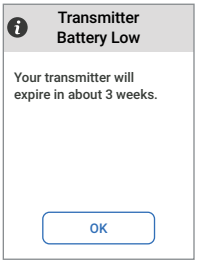
App

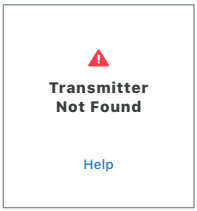
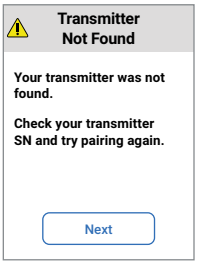
If you cannot hear your alarm/alerts on our app, verify that the app, *Bluetooth*, volume, and notifications are on. If your smart device is on mute/Do Not Disturb but you still want to get your critical alarm/alerts, make sure Always Sound is on. See Chapter 2 for smart device suggested settings. See your smart device product instructions to test the speaker.

A.7 Common Alerts

Issue	Solution
Calibration and Recalibration Prompts G6 needs you to calibrate. **App**  **Receiver** 	G6 prompts you to calibrate again when you entered a calibration outside the expected range.

Issue	Solution
No Readings Alert Sensor is temporarily unable to measure glucose. **App**  **Receiver** 	Do not calibrate. 1. Check transmitter; is it snapped into transmitter holder? 2. Wait up to 3 hours while the G6 fixes itself. 3. If not corrected after 3 hours, contact Technical Support. No alarm/alerts or G6 readings until fixed. Use your meter for treatment decisions. **App Only:** Tap **OK** to clear the alert, then tap **Help** on the home screen for more information.
Signal Loss Display device and transmitter are not communicating. **App**  **Receiver** 	Do not calibrate. 1. Verify display device and transmitter are within 6 meters of each other without obstructions. If you are in water, move device closer than 6 meters. 2. Wait up to 30 minutes. 3. If not corrected, contact Technical Support. No alarm/alerts or G6 readings until fixed. Use your meter for treatment decisions. **App Only:** Turn *Bluetooth* off, then on.

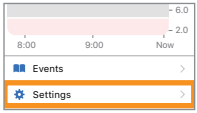
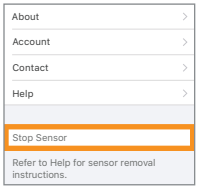
Issue	Solution
Transmitter Alert Transmitter not working. Sensor session automatically stops. **App**  **Receiver** 	Contact Technical Support. No alarm/alerts or G6 readings until replaced. Use your meter for treatment decisions.
Transmitter Battery Low and Last Session Alerts Transmitter battery expiring. **App**  **Receiver** 	Order new transmitter. When your transmitter battery is about to expire, the G6 tells you when it: • Has 3 weeks left • Has 2 weeks left • Has 1 more session • Is too low for another session • Is critically low and must be replaced immediately

Issue	Solution
Transmitter Not Found Alert G6 did not pair. **App**  **Receiver** 	1. Make sure transmitter is snapped into transmitter holder. 2. Verify transmitter serial number (SN) entered is correct. 3. If not fixed, sensor may not be inserted correctly. Insert a new sensor. For a replacement, contact Technical Support. No alarm/alerts or G6 readings until fixed. Use your meter for treatment decisions.

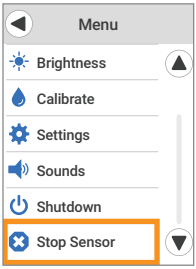
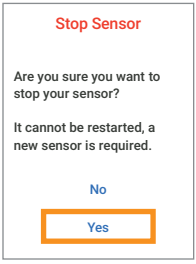
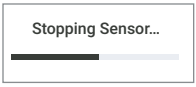
A.8 End Sensor Session Early

You might want to end your sensor session early. If you do, end it in either your app or your receiver. Both methods are shown below. Once you stop your sensor session, you will not be able to restart it.

App: End Sensor Session Early

	Apple	Android	
1			Tap **Settings**.
2			Tap **Stop Sensor**. Remove the transmitter and sensor. (See Chapter 6.)

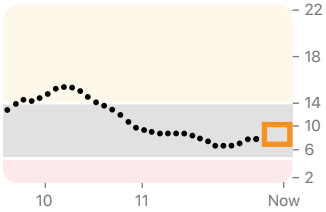
Receiver: End Session Early

1		Tap **Menu**.
2		Tap **Stop Sensor**.
3		Tap **Yes**. Remove the transmitter and sensor. (See Chapter 6.)
4		Wait.

A.9 Gap in Graph

When you are not getting G6 readings, your graph may show a gap on the right side in the trend dots. In the example, you can see the gap where your current dot should be:

When your G6 readings resume, up to 3 hours of missed G6 readings can fill in on the graph.



A.10 Recharge Receiver

Issue	Solution
Receiver charge light is on or Receiver will not turn on Receiver needs to be charged 	 • Charge receiver using electrical outlet, not computer/laptop • Full charge may take up to 3 hours

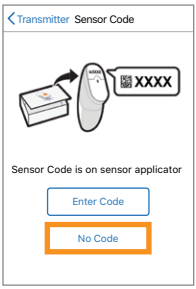
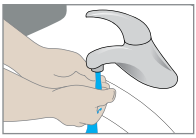
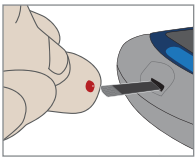
A.11 Start Sensor Session Without Sensor Code

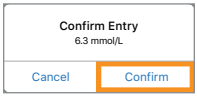
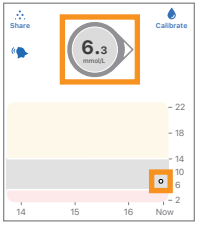
Do you want to start a sensor session now, but do not have the sensor code? The sensor code is on the applicator adhesive backing. Use only the sensor code from the applicator you insert; do not use other codes. The right sensor code makes the G6 work without prompting you to calibrate every day.

But even if you do not have a sensor code, you can still use the sensor. Throughout your sensor session, you will be prompted to calibrate daily. (See Calibration Prompt in section A.7 Common Alerts.)

Follow the prompts for Set Up Without Sensor Code.

App: Set Up Without Sensor Code

1		When setting up the app or inserting a new sensor without using a sensor code, on the Sensor Code screen, tap **No Code**. If you do not enter sensor code, you will have to calibrate your G6 daily during this sensor session. Only enter the sensor code from the applicator you insert. On the next few screens (not included in these steps), follow onscreen instructions to: • Enter transmitter SN (if you are using a new transmitter). • Insert sensor. • Attach transmitter.
2		Tap **Start Sensor**. Wait 2 hours for your sensor warmup to finish.
3		After your sensor warmup, your G6 prompts you to calibrate twice using two separate fingersticks. Tap Calibrate (icon) to start.
4		Wash your hands with soap and water, not a gel cleanser. Dry your hands. Washing and drying your hands before taking a meter value helps ensure accuracy.
5		Take a fingerstick BG measurement using your meter. Only use your fingertip, never another site.

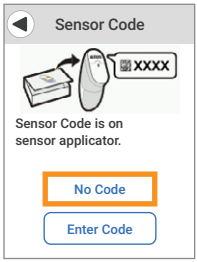
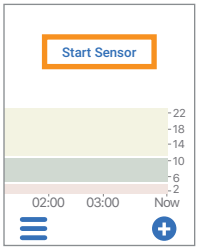
6		Enter exact BG number from your meter within 5 minutes of taking a fingerstick or faster if your glucose is changing rapidly.
7		Tap **Confirm** to save.
8		Time for your next calibration. Tap **Calibrate**. Repeat steps 4–8 and enter second fingerstick.
9		Five minutes after entering your second calibration, look for your first G6 reading! Each dot is a G6 reading taken every 5 minutes.

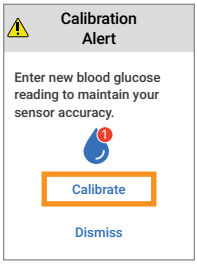
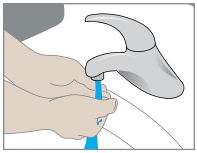
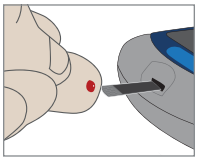
Twelve hours later, it reminds you to calibrate again. Then in another 12 hours, you get another reminder. For the rest of your sensor session, the G6 prompts you to calibrate once every 24 hours.

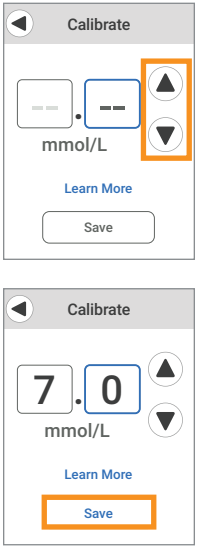
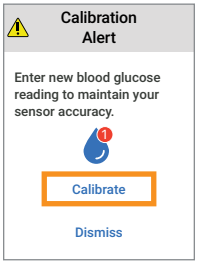
Make sure you calibrate when prompted. And make sure you thoroughly clean your hands before taking a fingerstick. If you do not, your G6 readings may not be aligned with your meter. (See Accuracy section.) In other words: Do not wait – calibrate!

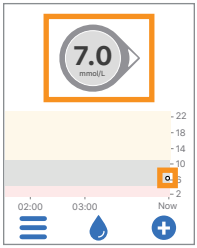
If using the app and receiver, just enter your calibration in one. In less than 10 minutes, the transmitter will send the information to the other device.

Receiver: Set Up Without Sensor Code

1		When setting up the receiver or inserting a new sensor without using a sensor code, on the Sensor Code screen, tap **No Code**. If you do not enter sensor code, you will have to calibrate your G6 daily during this sensor session. Only enter the sensor code from the applicator you insert. On the next few screens (not included in these steps), follow onscreen instructions to: • Enter transmitter SN (if you are using a new transmitter). • Insert sensor. • Attach transmitter.
2		Tap **Start Sensor**. Wait for 2-hour sensor warmup to finish.

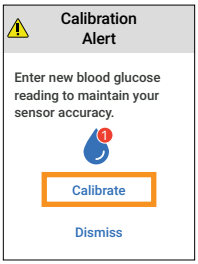
3		After your sensor warmup, the G6 prompts you to calibrate twice using two separate fingersticks. Tap **OK** to calibrate.
4		Wash your hands with soap and water, not a gel cleanser. Dry your hands. Washing and drying your hands before taking a meter value helps ensure accuracy.
5		Take a fingerstick BG measurement using your meter. Only use your fingertip, never another site.

6		Enter exact BG number from your meter within 5 minutes of taking a fingerstick. Tap Up and Down arrows to enter meter value. Then tap **Save**.
7		Tap **Yes** to confirm you entered the correct value.
8		Time for your next calibration. Tap **OK**. Repeat steps 4–8 and enter second fingerstick.

9		Five minutes after entering your second calibration, look for your first G6 reading! Each dot is a G6 reading taken every 5 minutes.

Twelve hours later, it reminds you to calibrate again. Then in another 12 hours, you get another reminder. For the rest of your sensor session, the G6 prompts you to calibrate once every 24 hours.

Make sure you calibrate when prompted. And make sure you thoroughly clean your hands before taking a fingerstick. If you do not, your G6 readings may not be aligned with your meter. (See Accuracy section.) In other words: Do not wait – calibrate!



If using the app and receiver, just enter your calibration in one. In less than 10 minutes, the transmitter will send the information to the other device.

A.12 Water and the G6

Once snapped into place, the transmitter is waterproof, but the receiver is not. Swim, shower, take a bath: no need to worry about water and your G6 – just leave your receiver in a dry area.

If you are in water, your display device needs to be closer than 6 meters to get G6 readings.

Appendix B: Extend Your App

With your Dexcom G6 Continuous Glucose Monitoring System (G6) app, you see notifications from your lock screen or smart watch.

Not seeing any data? Open your app.

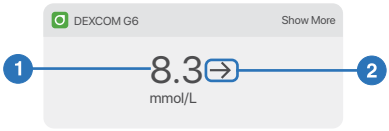
On your Apple smart device, you can set up Siri to tell you your G6 reading when you ask.

Do you use health apps? Share your glucose information with them for a more complete picture.

B.1 Today View (Apple)

Check your CGM information in the Today view, even when your smart device is locked. From the left edge of your Home or Lock screen, swipe right.

To add G6, scroll to the bottom and tap Edit. See your smart device instructions for details.

Key	Today View
Number and Arrow 1. G6 Reading 2. Trend Arrow	

Tap **Show More** to show your graph.

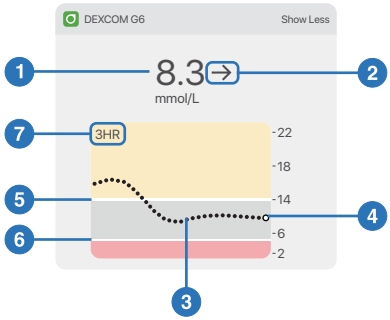
Key

Number and Arrow

1. G6 Reading
2. Trend Arrow

Graph

3. Trend Graph
4. Current G6 Reading
5. High Alert Level
6. Low Alert Level
7. Shows past 3 hours



B.2 Quick Glance (Android)

Check your G6 on your Lock screen or swipe down from the top.

Quick Glance

Drag down on the lower edge of Quick Glance to show your graph.

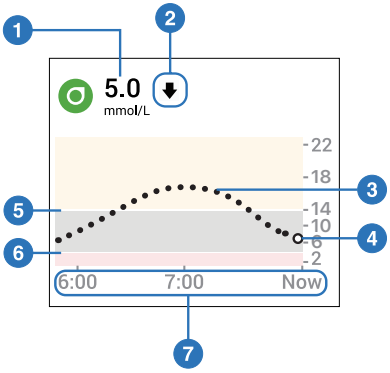
Key

Number and Arrow

1. G6 Reading
2. Trend Arrow

Graph

3. Trend Graph
4. Current G6 Reading
5. High Alert Level
6. Low Alert Level
7. Shows past 3 hours



Quick Glance is on by default. Turn it off in the app: **Settings > Quick Glance**

B.3 Smart Watches

Check your G6 on your Apple or Android smart watch.

Suggested Use

Using a smart watch with your G6 may change how you get alarm/alerts.

- Your smart watch only communicates with your smart device, not the transmitter.
- You will not get alarm/alerts or G6 readings on your watch unless it is connected to your smart device.

Make sure you understand how you get notifications when a watch is connected.

- You must wear the watch to see alerts and feel their vibrations.
- In your smart device settings, make sure notifications are sent to both your smart device and watch.
- Do not disable or block notifications from the app.

Waking up your watch updates your CGM data from your smart device. There may be a brief delay before your watch app shows current information.

Go to **dexcom.com/compatibility** to make sure your watch works with your G6.

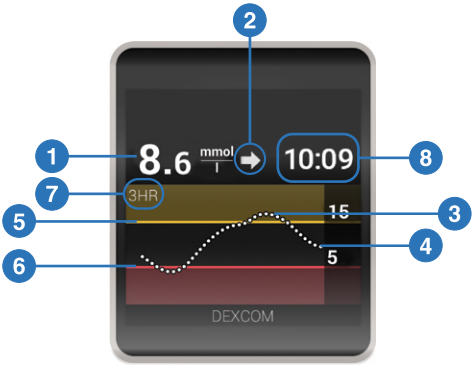
Apple Watch Setup (iPhone)

To install the app, use the Watch app on your iPhone.

See your watch instructions for details about installing apps.

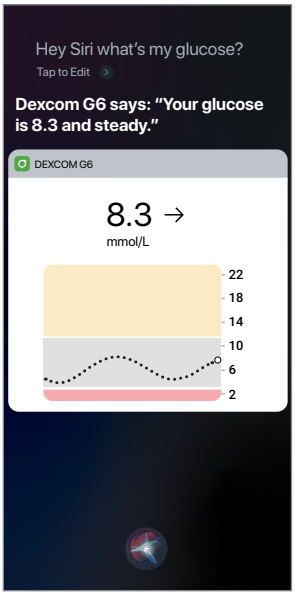
Android Wear Setup

Using the Dexcom G6 watch face, check your G6 information. See your watch instructions for details.

Key	Apple Watch
Number and Arrow 1. G6 Reading 2. Trend Arrow **Graph** 3. Trend Graph 4. Current G6 Reading 5. High Alert Level 6. Low Alert Level 7. Shows past 3 hours 8. Time	
	Android Wear
	

B.4 Siri (Apple)

Use your app settings to set up a Siri shortcut. Then you can ask Siri to say your G6 readings and trend anytime your app is running! When Siri answers, your graph shows on your lock screen.



Siri may not be available in all countries. Check Apple's website to see if Siri is available in your country.

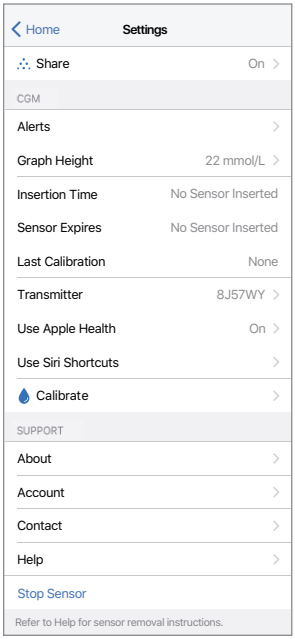
B.5 Health Apps

Send your glucose information to health apps.

Use **Settings > Health Apps** to start.

After you set up the health app, the last 30 days of glucose information is sent to the health app, except the last 3 hours.

Then, all new glucose information is sent after a 3-hour delay.



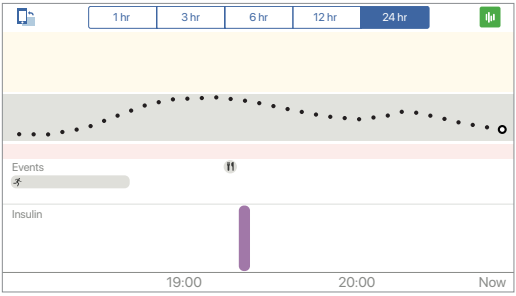
Appendix C: Dexcom Clarity

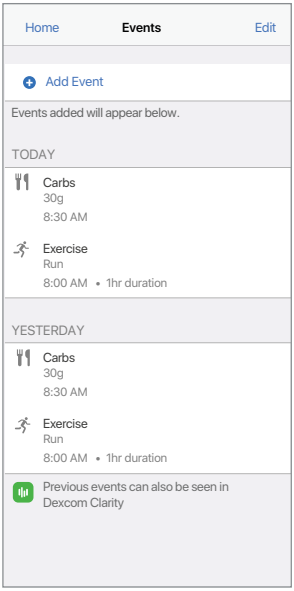
Dexcom Clarity software is an important part of your Dexcom CGM system.

Clarity highlights your glucose patterns, trends and statistics. Share Clarity with your clinic and monitor improvements between visits.

You can access Clarity from the Dexcom G6 app or on the internet. To go to Dexcom Clarity:

- **From your Dexcom G6 app:** Tap the Clarity icon on your Events screen or when you turn your smart device to landscape to view your events.
- **On the internet:** Log in at **clarity.dexcom.eu**. Use your current Dexcom login or create an account.





Appendix D: Taking Care of Your G6

D.1 G6 Maintenance

Transmitter

- Keep in box until ready for use. Check transmitter and do not use if damaged.
- Store between 0°C and 45°C.

Receiver

- Keep physical control of your Dexcom receiver to prevent unauthorized access to your personal information.
- Check receiver casing. If cracked or damaged, do not use or you may get an electric shock. Do not open casing.
- Use the supplied case to protect receiver from bumps and falls. When putting case on, make sure the speaker holes align with receiver speaker.
- Keep battery charged. Only use Dexcom USB charging/download cable.
- To wipe off receiver, use a clean, dry cloth.
    - Do not use abrasive cloths, towels, paper towels, or similar items.
    - Do not get moisture into any openings.
    - Do not use aerosol sprays, solvents, or abrasives.

All G6 Components

- To keep your G6 working safely, do not change any G6 component.

D.2 Storage

Storing your G6 correctly helps prevents system failures.

Sensor

- Keep in its sterile packaging until you are ready to use it.
- Store at temperatures between 2°C and 30°C.

Transmitter

- Keep protected when not in use
- Store at temperatures between 0°C and 45°C
- Store between 10% and 95% relative humidity

Receiver

- Keep protected when not in use
- Fully charge the battery before storing for over 3 months
- Store at temperatures between 0°C and 40°C
- Store between 10% and 95% relative humidity

D.3 System Disposal

Different places have different requirements for disposing of electronics (receiver and transmitter) and parts that have come in contact with blood or other bodily fluids (sensor). Follow your area's local waste management requirements.

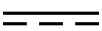
Appendix E: Packaging Symbols

Symbols are on the sensor, transmitter, and receiver packaging. They show proper and safe use of the G6. For symbol descriptions, see below or **dexcom.com/symbols**.

Some of these symbols may not apply to your region and are listed for informational purposes only.

~	Alternating Current
EC REP	Authorized Representative in the European Community
CH REP	Authorized Representative of Switzerland
LOT	Batch/Lot Number
	Bluetooth is on; device pairing is enabled
REF	Catalog Number
	Caution, Consult Instructions for Use
CE 2797	CE Marking of Conformity
	Class II Equipment
	Consult Instructions for Use

Date of Manufacture



Direct Current

Do Not Reuse

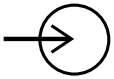
Do Not Use if Package is Damaged

For Indoor Use Only

Waste Electrical and Electronic Equipment (WEEE) – Follow local requirements for proper disposal

Humidity Limitation

Importer



Input

Degrees of Ingress Protection Provided by Enclosure
Objects > 12.5 mm diameter; water drops (15° tilted)

Degrees of Ingress Protection Provided by Enclosure
Objects > 12.5 mm diameter; immersion in water

Keep Away from Heat

	Keep Dry
	Manufacturer
MD	Indicates the item is a Medical Device
	MR (Magnetic Resonance) Unsafe
PN	Part Number
RX Only (United States)	Prescription Required (United States)
SN	Serial Number
	Single sterile barrier system with protective packaging outside
STERILE R	Sterilized Using Irradiation
	Temperature Limit
	Type BF Applied Part
UDI	Unique device identifier
	Use By Date

Appendix F: Warranty

Sometimes stuff happens. Dexcom has you covered!

This appendix covers our warranty information outlining what we cover and for how long.

F.1 Dexcom Receiver Limited Warranty

What Is Covered and for How Long?

Dexcom, Inc. ("Dexcom") provides a limited warranty to the original Purchaser ("you" or "Purchaser") that the Dexcom receiver (the "receiver") is free from defects in material and workmanship under normal use ("Limited Warranty") for the period commencing on the date of shipment by the original purchaser and expiring one (1) year thereafter.

Note: If you received this receiver as a replacement for an in-warranty receiver, the Limited Warranty for the replacement receiver shall continue for the remaining Warranty Period on the original receiver, but the replacement is not subject to any other warranty.

What Is Not Covered?

This Limited Warranty is based on Purchaser properly using the continuous glucose monitoring system in accordance with the documentation provided by Dexcom. You are not permitted to use the continuous glucose monitoring system otherwise. Misusing the continuous glucose monitoring system, improperly accessing it or the information it processes and transmits, "jailbreaking" or "rooting" your continuous glucose monitoring system or cell phone, and taking other unauthorized actions may put you at risk, cause the continuous glucose monitoring system to malfunction, are not permitted, and void your Limited Warranty.

This Limited Warranty does not cover:

- Defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage.
- Equipment with the SN number removed or made illegible.
- All surfaces and other externally exposed parts that are scratched or damaged due to normal use.

- Malfunctions resulting from the use of the receiver in conjunction with accessories, ancillary products, and peripheral equipment, whether hardware or software, not furnished or approved by Dexcom.
- Defects or damage from improper testing, operation, maintenance, installation, or adjustment.
- Installation, maintenance, and service of products or services other than the CGM system (which may be subject to a separate limited warranty), whether provided by Dexcom or any other party; this includes your cell phone or smart device and your connection to the Internet.
- A receiver that has been taken apart physically or has had any of its software accessed in any unauthorized manner.
- Water damage to the receiver.
    - The receiver is not water resistant.
    - Do not get the receiver wet at any time.

Dexcom's Obligations Under the Limited Warranty

During the Warranty Period, Dexcom will replace, without charge to Purchaser, any defective receiver.

To obtain assistance regarding a defective receiver, contact Technical Support.

Limits on Dexcom's Warranty and Liability Obligations

The Limited Warranty described above is the exclusive warranty for the receiver, and in lieu of all other warranties, expressed or implied, either in fact or by operation of law, statutory or otherwise.

Dexcom expressly excludes and disclaims all other warranties, express or implied, including without limitation any warranty of merchantability, fitness for a particular purpose, or non-infringement, except to the extent prohibited by applicable law.

Dexcom shall not be liable for any special, incidental, consequential, or indirect damages, however caused, and on any theory of liability, arising in any way out of the sale, use, misuse, or inability to use, any Dexcom G6 or any feature or service provided by Dexcom for use with the Dexcom G6.

These limits on Dexcom's warranty and liability obligations apply even if Dexcom, or its agent, has been advised of such damages and notwithstanding any failure of essential purpose of this Limited Warranty and the limited remedy provided by Dexcom.

This Limited Warranty is only provided to the original Purchaser and cannot be transferred to anyone else, and it states Purchaser's exclusive remedy.

If any portion of this Limited Warranty is illegal or unenforceable by reason of any law, such partial illegality or enforceability shall not affect the enforceability of the remainder of this Limited Warranty. This Limited Warranty will be enforced to the maximum extent permitted by law.

F.2 Dexcom Transmitter Limited Warranty

What Is Covered and for How Long?

Dexcom, Inc. ("Dexcom") provides a limited warranty to the original purchaser ("you" or "Purchaser") that the Dexcom G6 transmitter (the "transmitter") is free from defects in material and workmanship under normal use ("Limited Warranty") for the period commencing on the date of first use by the original purchaser (the "Date of First Use") and expiring three (3) months thereafter; provided, that, the Date of First use occurs within five (5) months of the date of shipment (or disbursement) of the transmitter to you ("Warranty Period").

Note: If you received this transmitter as a replacement for an in-warranty transmitter, the Limited Warranty for the replacement transmitter shall continue for the remaining Warranty Period on the original transmitter, but the replacement is not subject to any other warranty.

What Is Not Covered?

This Limited Warranty is based on Purchaser properly using the continuous glucose monitoring system in a timely manner and in accordance with the documentation provided by Dexcom. You are not permitted to use the continuous glucose monitoring system otherwise. Misusing the continuous glucose monitoring system, improperly accessing it or the information it processes and transmits, "jailbreaking" or "rooting" your continuous glucose monitoring system or cell phone, and taking other unauthorized actions may put you at risk, cause the continuous glucose monitoring system to malfunction, are not permitted, and void your Limited Warranty.

This Limited Warranty does not cover:

- Defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage.
- Equipment with the SN number removed or made illegible.
- All surfaces and other externally exposed parts that are scratched or damaged due to normal use.
- Malfunctions resulting from the use of the transmitter in conjunction with accessories, ancillary products, and peripheral equipment, whether hardware or software, not furnished or approved by Dexcom.
- Defects or damage from improper testing, operation, maintenance, installation, or adjustment.
- Installation, maintenance, and service of products or services other than the continuous glucose monitoring system (which may be subject to a separate limited warranty), whether provided by Dexcom or any other party; this includes your cell phone or smart device and your connection to the Internet.
- A transmitter that has been taken apart physically or has had any of its software accessed in any unauthorized manner.
- Water damage to transmitter.
- Beyond specifications listed in the Dexcom G6 Using Your G6 guide.

Dexcom's Obligations Under the Limited Warranty

During the Warranty Period, Dexcom will replace, without charge to Purchaser, any defective transmitter.

To obtain assistance regarding a defective transmitter, contact Technical Support.

Limits on Dexcom's Warranty and Liability Obligations

The Limited Warranty described above is the exclusive warranty for the transmitter, and in lieu of all other warranties, expressed or implied, either in fact or by operations of law, statutory or otherwise.

Dexcom expressly excludes and disclaims all other warranties, express or implied, including without limitation any warranty of merchantability, fitness for a particular purpose, or non-infringement, except to the extent prohibited by applicable law.

Dexcom shall not be liable for any special, incidental, consequential, or indirect damages, however caused, and on any theory of liability, arising in any way out of the sale, use, misuse, or inability to use, any Dexcom G6 or any feature or service provided by Dexcom for use with the Dexcom G6.

These limits on Dexcom's warranty and liability obligations apply even if Dexcom, or its agent, has been advised of such damages and notwithstanding any failure of essential purpose of this Limited Warranty and the limited remedy provided by Dexcom.

This Limited Warranty is only provided to the original Purchaser and cannot be transferred to anyone else, and it states Purchaser's exclusive remedy.

If any portion of this Limited Warranty is illegal or unenforceable by reason of any law, such partial illegality or enforceability shall not affect the enforceability of the remainder of this Limited Warranty. This Limited Warranty will be enforced to the maximum extent permitted by law.

Appendix G: Technical Information

G.1 Device Performance Characteristics

When LOWER is better

Adults	Performance Metrics*	Pediatrics
9.8%	**Overall Accuracy** **Mean ARD% (MARD), 2.22–22.22 mmol/L** (% average absolute error versus reference across all glucose levels)	7.7%
Day 1: 8.6% Day 2: 8.7% Days 4–5: 10.7% Day 7: 10.6% Day 10: 10.6%	**Accuracy Over Time** **Mean ARD% (MARD), 2.22–22.22 mmol/L**	Day 1: 10.5% Day 2: 7.8% Days 4–5: 7.2% Day 7: 6.2% Day 10: 7.1%

When HIGHER is better

Adults	Performance Metrics*	Pediatrics
92% [100%]	**Clinical Accuracy** **% of readings that were in the Clarke Error Grid (CEG) A Zone** [% CEG A+B Zone]	96% [99.8%]

*Reference is YSI (Yellow Springs Laboratory Instrument)

NOTE: We recommend that you review the information in this chapter with your healthcare professional to understand how well the Dexcom G6 performs.

The Dexcom G6 (G6) uses a glucose sensor to continuously measure and monitor your glucose levels. Once the sensor code is entered, the G6 reports glucose readings up to every 5 minutes. The G6's performance was evaluated in clinical studies in which G6 readings were assessed against blood glucose values tested by a laboratory reference method for subjects 6 years of age and older and by fingerstick blood glucose meter for pediatric subjects 2 to 5 years of age. The performance characteristics of the G6 presented in the following sections conform to the guidance for devices in the same classification.

Clinical Study Overview

To demonstrate the performance of the G6, two prospective clinical studies were conducted at 11 centers across the United States. The studies included both adult (18 years and older) and pediatric (2 to 17 years) participants. The studies evaluated the G6 performance, in terms of its safety, effectiveness, and precision. The studies enrolled a total of 380 participants with 99% having Type 1 diabetes mellitus and 1% having insulin using Type 2 diabetes mellitus.

Participants wore either one or two sensors for up to 10 days. A subset of participants wore two sensors for the precision study to compare variability of readings between sensors. Adult participants wore their G6(s) in the abdomen only; pediatric subjects had the choice of either abdomen or upper buttocks. Clinic session(s) took place at the beginning (Day 1, 2), middle (Day 4, 5), and end (Day 7, 10) of the G6 lifecycle. Depending on the participant's age, they participated in either 1, 2 or 3 clinic sessions of varying duration.

- Adult subjects: two (2) or three (3) 12-hour clinic sessions
- Pediatric subjects 13-17 years of age: one (1) 12-hour clinic session
- Pediatric subjects 6-12 years of age: one (1) 6-hour clinic session
- Pediatric subjects 2-5 years of age: one (1) 4-hour clinic session (compared to fingerstick blood glucose meter measurements only).

While using the G6 in the clinic, subjects had their blood glucose measured every 15 minutes with a laboratory reference method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." Readings from the G6 were reported every 5 minutes and paired with YSI values in order to

characterize the accuracy of the G6's glucose reading. No venous sampling was obtained for 14 pediatric subjects aged 2 to 5 years.

In Study 1, under close observation by the study investigator staff, the participant's glucose levels were deliberately manipulated per a protocol to raise or lower glucose to achieve YSI glucose samples within target glucose bins. Glucose manipulations were done to assess performance over the range that CGM measures glucose (2.2–22.2 mmol/L). In Study 2, participants managed their glucose as they normally do; glucose was not deliberately manipulated.

The data from these prospective clinical studies were further processed and analyzed at Dexcom to assess performance of factory calibration.

Accuracy

Accuracy of the G6 is characterized by assessing its readings against blood glucose values from YSI. Accuracy of the G6 was assessed with paired G6 readings to YSI blood glucose values. For blood glucose values less than or equal to 3.9 mmol/L, the absolute difference in mmol/L between the two glucose results was calculated. For values greater than 3.9 mmol/L, the absolute difference (%) relative to the YSI values was calculated. In addition, the mean absolute relative difference (MARD) shows the average amount the sensor readings differ from the YSI glucose. The percentages of total readings within 1.1 mmol/L or 20% (20/20%) are provided in Tables 1-A. The tables are further categorized within CGM glucose ranges, within age groups, and sensor wear locations (Tables 1-B to 1-E) and categorized within YSI glucose ranges (Tables 1-F to 1-I). When you see a CGM reading on your receiver or mobile application, these tables show you how likely that reading matches your blood glucose level (measured by YSI in the study). These tables include overall pooled data from both G6 studies.

For example, the total number of data pairs considered in the analysis was 25,101. Of these, 91.7% of the G6 readings fall within ± 1.1 mmol/L of the YSI blood glucose values < 3.9 mmol/L and within ± 20% of YSI blood glucose values ≥ 3.9 mmol/L.

Table 1-A. G6 Accuracy to YSI (n=324)

Patient Population	Number of subjects	Total number of paired CGM-YSI	Percent within 20/20% YSI % (95% LB)	Day 1 Percent within 20/20% YSI	MARD (%)
Overall	324	25,101	91.7 (90.6)	87.8	9.8
Adults (18+ YO)	159	19,329	91.6 (90.3)	87.1	9.9
Pediatrics (6-17 YO)	165	5,772	92.0 (89.8)	90.2	9.6
Pediatrics (2-5 YO)*	8	82	92.7 (86.6)	NA	9.9

** No YSI measurements were taken for this age group; results presented are from in-clinic CGM-SMBG matched paired measurements.*

[1]CGM readings are within 2.2–22.2 mmol/L, inclusive.

Table 1-B. G6 Accuracy to YSI within CGM Glucose Ranges (Adults; n=159)

CGM Glucose Range[1] (mmol/L)	Number of paired CGM-YSI	Percent within 0.8 mmol/L YSI	Percent within 1.1 mmol/L YSI	Percent within 2.2 mmol/L YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mmol/L)	MARD (%)
<3.00	383	84.3	90.6	98.4				-0.38	13.8
3.00–3.88	1,537	89.6	95.1	99.5				-0.03	11.5
3.89–10.00	9,453				73.9	86.6	99.3	-0.15	10.9
10.01–13.90	4,093				80.2	92.1	99.9	-0.55	9.3
>13.90	3,863				91.1	97.7	100.0	-0.21	7.1

[1]CGM readings are within 2.2–22.2 mmol/L, inclusive.

Table 1-C. G6 Accuracy to YSI within CGM Glucose Ranges (Pediatrics*; n=165)

CGM Glucose Range[1] (mmol/L)	Number of paired CGM-YSI	Percent within 0.8 mmol/L YSI	Percent within 1.1 mmol/L YSI	Percent within 2.2 mmol/L YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mmol/L)	MARD (%)
<3.00	90	48.9	62.2	85.6				-1.11	26.0
3.00–3.88	262	85.5	88.5	96.6				-0.33	13.3
3.89–10.00	3,144				79.8	90.8	99.5	-0.02	9.7
10.01–13.90	1,360				83.4	93.5	99.9	-0.07	8.9
>13.90	916				89.3	95.9	99.9	0.51	7.4

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

[1] CGM readings are within 2.2–22.2 mmol/L, inclusive.

Table 1-D. G6 Accuracy to YSI within CGM Glucose Ranges (Pediatrics*, Abdomen; n=99)

CGM Glucose Range[1] (mmol/L)	Number of paired CGM-YSI	Percent within 0.8 mmol/L YSI	Percent within 1.1 mmol/L YSI	Percent within 2.2 mmol/L YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mmol/L)	MARD (%)
<3.00	60	40.0	51.7	80.0				-1.34	28.9
3.00–3.88	177	87.0	88.1	96.0				-0.35	13.4
3.89–10.00	1,910				80.5	91.0	99.5	-0.06	9.7
10.01–13.90	775				81.9	95.0	100.0	-0.13	9.1
>13.90	574				89.2	96.5	99.8	0.44	7.5

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

[1] CGM readings are within 2.2–22.2 mmol/L, inclusive.

Table 1-E. G6 Accuracy to YSI within CGM Glucose Ranges (Pediatrics*, Buttocks; n=66)

CGM Glucose Range[1] (mmol/L)	Number of paired CGM-YSI	Percent within 0.8 mmol/L YSI	Percent within 1.1 mmol/L YSI	Percent within 2.2 mmol/L YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mmol/L)	MARD (%)
<3.00	30	66.7	83.3	96.7				-0.65	20.1
3.00–3.88	85	82.4	89.4	97.6				-0.29	13.2
3.89–10.00	1,234				78.8	90.4	99.4	0.05	9.7
10.01–13.90	585				85.3	91.6	99.8	0.01	8.5
>13.90	342				89.5	94.7	100.0	0.62	7.3

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

[1] CGM readings are within 2.2–22.2 mmol/L, inclusive.

Table 1-F. G6 Arm Accuracy to YSI within CGM Glucose Ranges (Adults; n=44)

CGM Glucose Range (mmol/L)	Number of paired CGM-YSI	Percent within 0.8 mmol/L YSI	Percent within 1.1 mmol/L YSI	Percent within 2.2 mmol/L YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean Bias (mmol/L)	MARD (%)
<3.00	61	68.9	82.0	98.4				-0.49	19.1
3.00–3.88	232	87.5	94.8	99.6				-0.03	12.1
3.89–10.00	2,449				75.3	87.0	98.9	0.02	10.7
10.01–13.90	616				76.8	88.5	100.0	-0.65	10.2
>13.90	698				88.3	97.7	100.0	-0.47	7.6

Table 1-G. G6 Accuracy to YSI within YSI Glucose Ranges (Adults; n=159)

YSI Glucose Range (mmol/L)	Number of paired CGM-YSI	Percent within 0.8 mmol/L YSI	Percent within 1.1 mmol/L YSI	Percent within 2.2 mmol/L YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mmol/L)	MARD (%)
<3.00	483	88.2	95.9	99.8				0.33	15.8
3.00–3.88	1,783	88.8	96.1	99.9				0.22	12.4
3.89–10.00	8,713				76.8	89.0	99.6	-0.05	10.3
10.01–13.90	3,940				83.0	92.7	99.8	-0.40	8.8
>13.90	4,410				83.4	93.3	99.8	-0.75	8.6

Table 1-H. G6 Accuracy to YSI within YSI Glucose Ranges (Pediatrics*; n=165)

YSI Glucose Range (mmol/L)	Number of paired CGM-YSI	Percent within 0.8 mmol/L YSI	Percent within 1.1 mmol/L YSI	Percent within 2.2 mmol/L YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mmol/L)	MARD (%)
<3.00	47	95.7	100.0	100.0				0.28	11.8
3.00–3.88	309	86.1	95.1	100.0				0.16	13.7
3.89–10.00	3,099				79.9	90.4	98.8	0.10	9.8
10.01–13.90	1,401				84.9	93.3	99.8	-0.04	9.0
>13.90	916				85.2	94.0	100.0	-0.18	8.0

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

Table 1-I. G6 Accuracy to YSI within YSI Glucose Ranges (Pediatrics*, Abdomen; n=99)

YSI Glucose Range (mmol/L)	Number of paired CGM-YSI	Percent within 0.8 mmol/L YSI	Percent within 1.1 mmol/L YSI	Percent within 2.2 mmol/L YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mmol/L)	MARD (%)
<3.00	28	100.0	100.0	100.0				0.23	11.3
3.00–3.88	201	90.0	96.0	100.0				0.17	12.8
3.89–10.00	1,904				79.3	89.5	98.5	0.02	10.2
10.01–13.90	761				84.9	94.9	99.6	-0.08	9.1
>13.90	602				85.4	95.8	100.0	-0.22	8.1

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

Table 1-J. G6 Accuracy to YSI within YSI Glucose Ranges (Pediatrics*, Buttocks; n=66)

YSI Glucose Range (mmol/L)	Number of paired CGM-YSI	Percent within 0.8 mmol/L YSI	Percent within 1.1 mmol/L YSI	Percent within 2.2 mmol/L YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mmol/L)	MARD (%)
<3.00	19	89.5	100.0	100.0				0.34	12.6
3.00–3.88	108	78.7	93.5	100.0				0.13	15.2
3.89–10.00	1,195				80.8	92.0	99.2	0.21	9.3
10.01–13.90	640				84.8	91.4	100.0	0.00	8.8
>13.90	314				84.7	90.4	100.0	-0.12	7.8

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

Table 1-K. G6 Arm Accuracy to YSI within YSI Glucose Ranges (Adults; n=44)

YSI Glucose Range (mmol/L)	Number of paired CGM-YSI	Percent within 0.8 mmol/L YSI	Percent within 1.1 mmol/L YSI	Percent within 2.2 mmol/L YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mmol/L)	MARD (%)
<3.00	73	76.7	87.7	100.0				0.44	21.8
3.00–3.88	306	85.9	93.1	99.0				0.30	13.7
3.89–10.00	2,277				77.6	88.3	99.3	0.09	10.1
10.01–13.90	584				79.3	92.0	99.8	-0.45	9.6
>13.90	816				81.3	92.2	100.0	-0.96	9.1

Agreement When CGM Reads "LOW" or "HIGH"

The G6 reports glucose readings between 2.2 and 22.2 mmol/L. When the G6 determines the glucose reading is below 2.2 mmol/L, it displays "LOW" in the Receiver or Mobile Application Status Box. When the G6 determines that the glucose level is above 22.2 mmol/L, it displays "HIGH" in the Receiver or Mobile Application Status Box. Because the System does not display glucose values below 2.2 mmol/L or above 22.2 mmol/L, the comparisons to the actual blood glucose levels (as determined by the YSI analyzer) when CGM is classified as "LOW" or "HIGH" are included separately in Table 2 (data is combined from Study 1 and Study 2). The tables include the numbers and the cumulative percentages when YSI values were less than certain glucose levels (for "LOW"), and when YSI values were greater than certain glucose levels (for "HIGH").

For example, when the G6 displayed "LOW" (139 occasions), 84% (117 out of 139) of the YSI values were less than 4.4 mmol/L. When the G6 displayed "HIGH" (54 occasions), 100% (54 out of 54) of the YSI values were greater than 15.6 mmol/L.

Table 2. Distribution of YSI Values When CGM Readings are "LOW" or "HIGH"

CGM Readings	CGM-YSI Pairs	YSI (mmol/L)					Total
		< 3.1	< 3.3	< 3.9	< 4.4	≥ 4.4	
"LOW"	n	65	80	95	117	22	139
	Cumulative Percent	47%	58%	68%	84%	16%	
CGM Readings	**CGM-YSI Pairs**	**YSI (mmol/L)**					**Total**
		> 18.9	> 17.8	> 15.6	> 13.9	≤ 13.9	
"HIGH"	n	53	53	54	54	0	54
	Cumulative Percent	98%	98%	100%	100%	0%	

Concurrence of G6 and Laboratory Reference

Tables 3-A to 3-D categorize concurrence by CGM reading and YSI values. Tables 3-A and 3-B describe, (row percent), for each range of CGM glucose readings, what percentage of paired YSI values was in the same glucose range (shaded) or in glucose ranges above and below the paired CGM readings. For example, Table 3-A shows that for adults, when CGM readings are within 4.5 to 6.7 mmol/L, you can expect your blood glucose levels are within 4.5 to 6.7 mmol/L 70 % of time. Tables 3-C and 3-D describe (column percent), for each range of YSI values, what percentage of paired CGM readings was in the same glucose range (shaded) or in glucose ranges above and below the paired YSI values. For example, Table 3-D shows that for pediatrics, when YSI values are within 4.5 to 6.7 mmol/L, you can expect your CGM readings to be within 4.5 to 6.7 mmol/L 78% of time.

Table 3-A. Concurrence of G6 CGM Readings and YSI Values by CGM Glucose Range (Adults; n=159)

CGM Glucose Range (mmol/L)	YSI (mmol/L)											
	<2.22	2.22–3.35	3.36–4.46	4.47–6.68	6.69–8.91	8.92–11.13	11.14–13.91	13.92–16.68	16.69–19.46	19.47–22.22	>22.22	Total
<2.22	13.5%	56.7%	24.0%	3.8%	1.9%	.	.	.	.	.	.	104
2.22–3.35	1.2%	67.8%	27.9%	2.7%	0.2%	0.1%	.	.	.	.	.	917
3.36–4.46	0.1%	21.3%	61.4%	16.9%	0.3%	0.1%	.	.	.	.	.	2,275
4.47–6.68	.	0.4%	13.6%	70.3%	15.1%	0.6%	0.0%	.	.	.	.	3,782
6.69–8.91	.	.	0.0%	14.2%	64.3%	20.1%	1.3%	0.0%	0.0%	.	.	3,026
8.92–11.13	.	.	.	0.1%	14.5%	56.7%	26.9%	1.5%	0.2%	0.0%	.	2,597
11.14–13.91	.	.	.	.	0.2%	12.1%	59.4%	25.4%	2.9%	0.0%	.	2,869
13.92–16.68	.	.	.	.	.	0.1%	13.7%	59.1%	25.3%	1.9%	.	2,268
16.69–19.46	.	.	.	.	.	.	0.2%	22.3%	63.4%	13.7%	0.5%	1,212
19.47–22.22	.	.	.	.	.	.	.	0.8%	43.9%	52.5%	2.9%	383
>22.22	.	.	.	.	.	.	.	.	5.9%	76.5%	17.6%	34

Table 3-B. Concurrence of G6 CGM Readings and YSI Values by CGM Glucose Range (Pediatrics*; n=165)

CGM Glucose Range (mmol/L)	YSI (mmol/L)											
	<2.22	2.22–3.35	3.36–4.46	4.47–6.68	6.69–8.91	8.92–11.13	11.14–13.91	13.92–16.68	16.69–19.46	19.47–22.22	>22.22	Total
<2.22	2.9%	22.9%	28.6%	42.9%	2.9%	.	.	.	.	.	.	35
2.22–3.35	0.6%	37.9%	43.5%	13.7%	3.7%	0.6%	.	.	.	.	.	161
3.36–4.46	.	11.5%	65.8%	20.4%	1.9%	0.4%	.	.	.	.	.	485
4.47–6.68	.	0.2%	12.5%	76.3%	10.5%	0.6%	.	.	.	.	.	1,282
6.69–8.91	.	.	.	13.6%	71.9%	13.6%	0.9%	.	.	.	.	1,013
8.92–11.13	.	.	.	0.2%	18.6%	59.4%	20.2%	1.6%	.	.	.	1,087
11.14–13.91	.	.	.	.	0.1%	19.2%	63.8%	15.7%	1.2%	.	.	828
13.92–16.68	.	.	.	.	.	0.2%	28.1%	59.6%	11.8%	0.4%	.	544
16.69–19.46	.	.	.	.	.	.	1.0%	32.8%	56.4%	9.8%	.	287
19.47–22.22	.	.	.	.	.	.	.	5.9%	52.9%	38.8%	2.4%	85
>22.22	.	.	.	.	.	.	.	.	5.0%	55.0%	40.0%	20

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

Table 3-C. Concurrence of G6 CGM Readings and YSI Values by YSI Glucose Range (Adults, n=159)

CGM Glucose Range (mmol/L)	YSI glucose range (mmol/L)										
	<2.22	2.22–3.35	3.36–4.46	4.47–6.68	6.69–8.91	8.92–11.13	11.14–13.91	13.92–16.68	16.69–19.46	19.47–22.22	>22.22
<2.22	51.9%	5.0%	1.1%	0.1%	0.1%	.	.	.	.	.	.
2.22–3.35	40.7%	52.7%	11.7%	0.7%	0.1%	0.0%	.	.	.	.	.
3.36–4.46	7.4%	41.0%	63.7%	11.0%	0.2%	0.1%	.	.	.	.	.
4.47–6.68	.	1.3%	23.4%	75.8%	19.7%	1.0%	0.0%	.	.	.	.
6.69–8.91	.	.	0.0%	12.2%	66.9%	24.8%	1.4%	0.0%	0.1%	.	.
8.92–11.13	.	.	.	0.1%	13.0%	59.9%	25.3%	1.7%	0.4%	0.2%	.
11.14–13.91	.	.	.	.	0.2%	14.1%	61.9%	30.6%	5.1%	0.2%	.
13.92–16.68	.	.	.	.	.	0.1%	11.3%	56.2%	35.9%	9.6%	.
16.69–19.46	.	.	.	.	.	.	0.1%	11.3%	48.0%	38.0%	26.1%
19.47–22.22	.	.	.	.	.	.	.	0.1%	10.5%	46.0%	47.8%
>22.22	.	.	.	.	.	.	.	.	0.1%	5.9%	26.1%
Total	27	1,180	2,191	3,503	2,910	2,457	2,755	2,383	1,601	437	23

Table 3-D. Concurrence of G6 CGM Readings and YSI Values by YSI Glucose Range (Pediatrics*; n=165)

CGM Glucose Range (mmol/L)	YSI glucose range (mmol/L)										
	<2.22	2.22–3.35	3.36–4.46	4.47–6.68	6.69–8.91	8.92–11.13	11.14–13.91	13.92–16.68	16.69–19.46	19.47–22.22	>22.22
<2.22	50.0%	6.3%	1.8%	1.2%	0.1%	.	.	.	.	.	.
2.22–3.35	50.0%	48.0%	12.5%	1.8%	0.6%	0.1%	.	.	.	.	.
3.36–4.46	.	44.1%	57.1%	7.9%	0.8%	0.2%	.	.	.	.	.
4.47–6.68	.	1.6%	28.6%	78.0%	12.4%	0.8%	.	.	.	.	.
6.69–8.91	.	.	.	11.0%	67.3%	14.5%	1.0%	.	.	.	.
8.92–11.13	.	.	.	0.2%	18.7%	67.6%	24.1%	3.0%	.	.	.
11.14–13.91	.	.	.	.	0.1%	16.6%	57.8%	22.8%	3.5%	.	.
13.92–16.68	.	.	.	.	.	0.1%	16.8%	56.8%	22.7%	2.7%	.
16.69–19.46	.	.	.	.	.	.	0.3%	16.5%	57.4%	37.8%	.
19.47–22.22	.	.	.	.	.	.	.	0.9%	16.0%	44.6%	20.0%
>22.22	.	.	.	.	.	.	.	.	0.4%	14.9%	80.0%
Total	2	127	559	1,254	1,081	955	913	570	282	74	10

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

Trend Accuracy

Trend accuracy explains how well the G6 captures the time-dependent characteristics of glucose fluctuation.

The following examples quantify G6's Trend Accuracy:

1. When the G6 CGM rate of change is rapidly rising (> 0.11 mmol/L/min), how often is reference glucose also rising (> 0.06 mmol/L/min)? The answer is 93.3% of the time for adults and 90.8% for pediatrics.
2. When the G6 CGM rate of change is rapidly falling (< 0.11 mmol/L/min), how often is reference glucose also falling (< -0.06 mmol/L/min)? The answer is 88.3% of the time for adults and 84.8% for pediatrics.
3. When the G6 CGM rate of change is stable (≥ -0.06 mmol/L/min and ≤ 0.06 mmol/L/min), how often is glucose changing rapidly (> 0.11 mmol/L/min or < 0.11 mmol/L/min)? The answer is only 1.0% of the time for adults and 0.7% for pediatrics.

Table 4-A. Trend Accuracy Rate of Change (Adults; n=159)

CGM Rate Range (mmol/L/min)	YSI Rate Range (mmol/L/min)							CGM-YSI Pairs (n)
	<-0.17	[-0.17, -0.11)	[-0.11, -0.06)	[-0.06, 0.06]	(0.06, 0.11]	(0.11, 0.17]	>0.17	
<-0.17	46.0%	27.4%	16.8%	9.7%	0.0%	0.0%	0.0%	113
[-0.17,-0.11)	8.6%	38.3%	40.9%	12.0%	0.0%	0.3%	0.0%	350
[-0.11,-0.06)	0.9%	6.5%	56.9%	35.4%	0.3%	0.0%	0.0%	2,077
[-0.06,0.06]	0.1%	0.2%	6.2%	88.4%	4.5%	0.6%	0.1%	13,185
(0.06,0.11]	0.0%	0.0%	0.4%	29.9%	52.9%	13.8%	3.0%	1,734
(0.11,0.17]	0.1%	0.0%	0.2%	8.8%	30.3%	44.4%	16.1%	818
>0.17	0.0%	0.0%	0.0%	2.9%	9.8%	29.9%	57.4%	549

Table 4-B. Trend Accuracy Rate of Change (Pediatrics*; n=165)

CGM Rate Range (mmol/L/min)	YSI Rate Range (mmol/L/min)							CGM-YSI Pairs (n)
	<-0.17	[-0.17, -0.11)	[-0.11, -0.06)	[-0.06, 0.06]	(0.06, 0.11]	(0.11, 0.17]	>0.17	
<-0.17	40.7%	33.3%	16.7%	9.3%	0.0%	0.0%	0.0%	54
[-0.17,-0.11)	4.5%	34.4%	43.9%	16.6%	0.0%	0.6%	0.0%	157
[-0.11,-0.06)	0.4%	6.1%	55.5%	37.2%	0.6%	0.0%	0.1%	686
[-0.06,0.06]	0.1%	0.2%	5.3%	89.0%	5.0%	0.3%	0.1%	3,714
(0.06,0.11]	0.0%	0.0%	0.4%	40.3%	48.0%	10.1%	1.3%	546
(0.11,0.17]	0.0%	0.0%	0.9%	13.7%	32.5%	39.3%	13.7%	234
>0.17	0.0%	0.0%	0.0%	2.6%	12.7%	30.7%	54.0%	189

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

Hypoglycemia and Hyperglycemia Alerts

Low and High Glucose Alerts

The ability of the G6 to detect high and low glucose levels is assessed by comparing G6 results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The G6 and YSI values were compared by pairing the G6 reading and the YSI value within before or after 15 minutes of each other. We suggest that you ask your doctor what alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Tables 5-A and 5-B. Tables 5-A and 5-B represent the hypoglycemic alert evaluation within 15 minutes of the YSI value in the study and the hypoglycemic event evaluation within 15 minutes of each hypoglycemic alert for adults and pediatrics, respectively.

Hypoglycemic Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was above the alert setting within 15 minutes before or after the device alarmed.

For example, if you set the Low Glucose Alert to 3.9 mmol/L and your alarm sounds, how often can you expect your blood sugar to actually be low? Based on results for adults in the G6 Study (Table 5-A), when your alarm sounds, you can expect your blood sugar to be below 3.9 mmol/L approximately 85.5% of the time and above 3.9 mmol/L approximately 14.5% of the time within the 15 minute period before or after your alarm sounds.

When the hypoglycemic alert rate was set at 3.1 mmol/L, and an alert was provided, glucose was <3.9 mmol/L 85% of the time within 15 minutes of the alert. (Data not presented in table.)

When the hypoglycemic alert rate was set at 3.3 mmol/L, and an alert was provided, glucose was <3.9 mmol/L 87% of the time within 15 minutes of the alert. (Data not presented in table.)

Hypoglycemic Detection Rate

The Detection Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 minutes before or after the hypoglycemic event. The Missed Detection Rate is the % of time the device did not alarm when the blood glucose level was at or below the alert setting within 15 minutes before and after the hypoglycemic event.

For example, if you set the Low Glucose alert to 3.9 mmol/L, how often will your alarm alert you if your blood glucose goes below 3.9 mmol/L? Based on results for pediatrics in the G6 Study (Table 5-B), when your blood sugar goes below 3.9 mmol/L, you can expect your alarm to sound 81.6% of the time and not to sound approximately 18.4% of time within the 15 minute period before or after your blood sugar goes below 3.9 mmol/L.

Table 5-A. Hypoglycemic Alert and Detection Rate Evaluations (Adults, n=159[1])

Hypoglycemic Alert Level (mmol/L)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
3.1	1,408	66.6	33.4	642	63.9	36.1
3.3	2,370	74.6	25.4	1,158	74.1	25.9
3.9	5,079	85.5	14.5	2,365	86.0	14.0
4.4	8,187	89.1	10.9	3,372	92.7	7.3
5.0	11,147	89.4	10.6	4,287	94.6	5.4

[1] All subjects were considered in the analysis; however, not all subjects experienced hypo event.

Table 5-B. Hypoglycemic Alert and Detection Rate Evaluations (Pediatrics*, n=165[1])

Hypoglycemic Alert Level (mmol/L)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
3.1	358	31.6	68.4	66	68.2	31.8
3.3	521	44.1	55.9	119	73.1	26.9
3.9	1,054	68.0	32.0	369	81.6	18.4
4.4	1,794	80.5	19.5	671	88.1	11.9
5.0	2,746	86.3	13.7	1,030	92.8	7.2

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

[1] All subjects were considered in the analysis; however, not all subjects experienced hypo event

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Tables 5-C and 5-D. Tables 5-C and 5-D represent the hyperglycemic alert evaluation within 15 minutes of the YSI value in the study and the hypoglycemic event evaluation within 15 minutes of each hyperglycemic alert for adults and pediatrics, respectively.

Hyperglycemic Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was below the alert setting within 15 minutes before or after the device alarmed.

For example, if you set the High Glucose alert to 11.1 mmol/L and your alarm sounds, how often can you expect your blood sugar to actually be high? Based on results for adults in the G6 Study (Table 5-C), when your alarm sounds, you can expect your blood sugar to be at or above 11.1 mmol/L approximately 96% of the time and not be above 11.1 mmol/L approximately 4% of the time within the 15 minute period before or after your alarm sounds.

Hyperglycemia Detection Rate

The Detection Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 minutes before or after the hyperglycemic event. The Missed Detection Rate is the % of time the device did not alarm when the blood glucose level was at or above the alert setting within 15 minutes before and after the hyperglycemic event.

For example, if you set the High Glucose alert to 13.3 mmol/L and your blood sugar rises above 13.3 mmol/L, how often can you expect your device to correctly alarm you? Based on results for pediatrics in the study (Table 5-D), if your blood sugar was at or above 13.3 mmol/L, you can expect your alarm to sound approximately 90.2% of the time within 15 minutes and an alarm not to sound approximately 9.8% of the time.

Table 5-C. Hyperglycemic Alert and Detection Rate Evaluations (Adults, n=159)

Hyperglycemic Alert Level (mmol/L)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
6.7	37,061	97.5	2.5	12,664	97.6	2.4
7.8	32,148	97.2	2.8	11,175	96.8	3.2
10.0	23,424	96.6	3.4	8,455	95.2	4.8
11.1	19,586	96.0	4.0	7,265	93.6	6.4
12.2	15,689	95.6	4.4	6,143	91.2	8.8
13.3	12,279	94.6	5.4	5,007	88.7	11.3
16.7	4,211	85.9	14.1	2,095	74.8	25.2

Table 5-D. Hyperglycemic Alert and Detection Rate Evaluations (Pediatrics*, n=165)

Hyperglycemic Alert Level (mmol/L)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
6.7	11,683	97.3	2.7	3,930	97.8	2.2
7.8	10,113	96.2	3.8	3,388	97.7	2.3
10.0	6,821	93.4	6.6	2,366	94.7	5.3
11.1	5,190	93.3	6.7	1,874	91.2	8.8
12.2	4,096	90.4	9.6	1,453	91.7	8.3
13.3	3,068	86.9	13.1	1,093	90.2	9.8
16.7	1,010	77.2	22.8	374	84.8	15.2

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

Urgent Low Soon Alert

The Urgent Low Soon Alert lets you know when your glucose is falling so fast it will drop to 3.1 mmol/L in less than 30 minutes. This gives you time to take action to prevent your glucose from dropping to this low glucose level. Table 5-E shows Urgent Low Soon alert and detection rates that the user experiences a hypoglycemic event within 30 minutes after the System alerts. For example, if the current CGM value is above 3.9 mmol/L and the System gives an alert, there is 84.0% chance that the user's true glucose level will experience a hypoglycemic event (glucose less than 3.9 mmol/L) within 30 minutes; and there is 92.6% chance that at least one System hypoglycemia alert would be given 30 minutes prior to a hypoglycemic event.

Table 5-E. Urgent Low Soon Alert and Detection Rate Evaluations (Overall*; n=324[1])

Hypoglycemic Alert Setting (mmol/L)	Alerts			Detections		
	# of Alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of Events (N)	Correct Detection Rate (%)	Missed Detection Rate (%)
3.1	50	48.0%	52.0%	706	85.0%	15.0%
3.9	50	84.0%	16.0%	2,729	92.6%	7.4%

** Includes pediatric subjects 6+ years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

[1] All subjects were considered in the analysis; however, not all subjects experienced hypo event.

Example 1 - Hypoglycemic Alert Setting 3.1 mmol/L:

If the current CGM value is above 3.9 mmol/L and the System gives an alert (either Urgent Low Soon or 3.1 mmol/L threshold Low Glucose alert), there is a 48% chance that the user's true glucose level will experience a hypoglycemic event ≤3.1 mmol/L within the next 30 minutes. There is an 85% chance that a System alert would be given within 30 minutes before a user's true glucose level reaches ≤3.1 mmol/L.

Example 2 - Hypoglycemic Alert Setting 3.9 mmol/L:

If the current CGM value is above 3.9 mmol/L and the System gives an alert (either Urgent Low Soon or 3.9 mmol/L threshold Low Glucose alert), there is an 84% chance that the user's true glucose level will experience a hypoglycemic event ≤3.9 mmol/L within the next 30 minutes. There is an 92.6% chance that a System alert would be given within 30 minutes before a user's true glucose level reaches ≤3.9 mmol/L.

Sensor Stability

Sensors can be worn for up to 10 days. Performance was estimated by calculating the percentage of G6 readings within 0.83 mmol/L or 15% (15/15%), 1.1 mmol/L or 20% (20/20%), and 2.2 mmol/L or 40% (40/40%), of the YSI values at the beginning (Day 1, 2), middle (Day 4, 5) and end (Day 7, 10) of the G6 lifecycle. For blood glucose values less than or equal to 3.9 mmol/L, the absolute difference in mmol/L between the two glucose results was calculated. For values greater than 3.9 mmol/L, the absolute difference (%) relative to the YSI values was calculated. In addition, the mean absolute relative difference (MARD) shows the average amount the sensor readings differ from the YSI glucose. The MARD values included in Table 6-A and 6-B show consistent accuracy and sensor stability over the 10-day life of the sensor.

Table 6-A. Sensor Stability Relative to YSI (Accuracy over Time[1]) (Adults; n=159)

Wear Period	Number of paired CGM-YSI	MARD (%)	Percent within 15/15% YSI (%)	Percent within 20/20% YSI (%)	Percent within 40/40% YSI (%)
Beginning	6,696	10.9	76.5	88.0	99.6
Middle	6,464	9.2	84.3	94.6	99.8
End	6,169	9.6	82.3	92.4	99.8

[1] CGM readings are within 2.2–22.2 mmol/L, inclusive.

Table 6-B. Sensor Stability Relative to YSI (Accuracy over Time[1]) (Pediatrics*; n=165)

Wear Period	Number of paired CGM-YSI	MARD (%)	Percent within 15/15% YSI (%)	Percent within 20/20% YSI (%)	Percent within 40/40% YSI (%)
Beginning	2,167	9.9	81.2	92.1	99.8
Middle	1,268	9.1	83.1	93.7	99.8
End	2,337	9.4	83.1	91.1	98.5

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*

[1] CGM readings are within 2.2–22.2 mmol/L, inclusive.

Sensor Life

Sensors can be worn for up to 10 days (238 hours; 240 hours less 2 hours warm-up period). To estimate how long a sensor will work over 10 days, all sensors worn were evaluated to determine how many days/hours of readings each sensor provided.

For adults, a total of 164 sensors were evaluated. Ninety-four percent (94%) of the sensors lasted through the end of the entire wear period (e.g., Day 10) (see Figure 1-A). Among the 164 sensors evaluated, 8 sensors (4.9%) had "early sensor shut-off" where the sensor algorithm would have detected sensors that did not function as intended and shut them off.

For pediatrics, a total of 210 sensors were evaluated. Seventy-seven percent (77%) of the sensors lasted through the end of the entire wear period (e.g., Day 10) (see Figure 1-B). Among the 210 sensors evaluated, 28 sensors (13.3%) had "early sensor shut-off" where the sensor algorithm would have detected sensors that did not function as intended and shut them off.

Table 7-A. Sensor Survival Rate by Wear Day (Adults; n=164)

Wear Day	Number of Sensors	Survival Rate (%)
1	162	99.4%
2	160	98.8%
3	158	98.8%
4	155	98.8%
5	154	98.1%
6	154	98.1%
7	150	96.8%
8	146	96.2%
9	144	94.9%
10	139*	93.5%

** Includes sensors that survived more than 9.5 days (228 hours) of wear.*

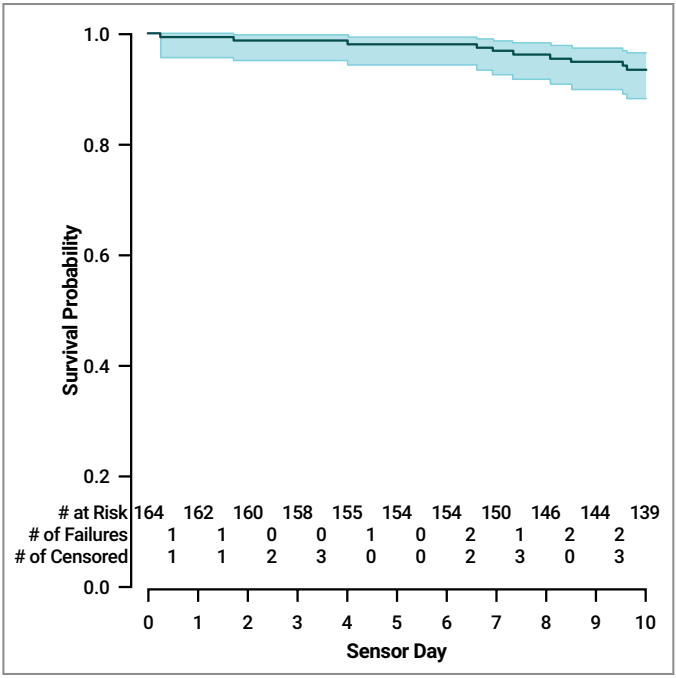


Figure 1-A. Kaplan Meier Curve of Sensor Life (Adults; N = 164)

Note: "# of Censored" refers to sensors excluded from the survival analysis due to reasons not related to the device (e.g., subject dropped out of study)

Table 7-B. Sensor Survival Rate by Wear Day (Pediatrics; n=210)

Wear Day	Number of Sensors	Survival Rate (%)
1	206	99.0%
2	204	99.0%
3	196	97.1%
4	193	95.6%
5	184	91.1%
6	175	88.6%
7	164	85.5%
8	157	83.4%
9	146	79.2%
10	142*	76.8%

** Includes sensors that survived more than 9.5 days (228 hours) of wear.*

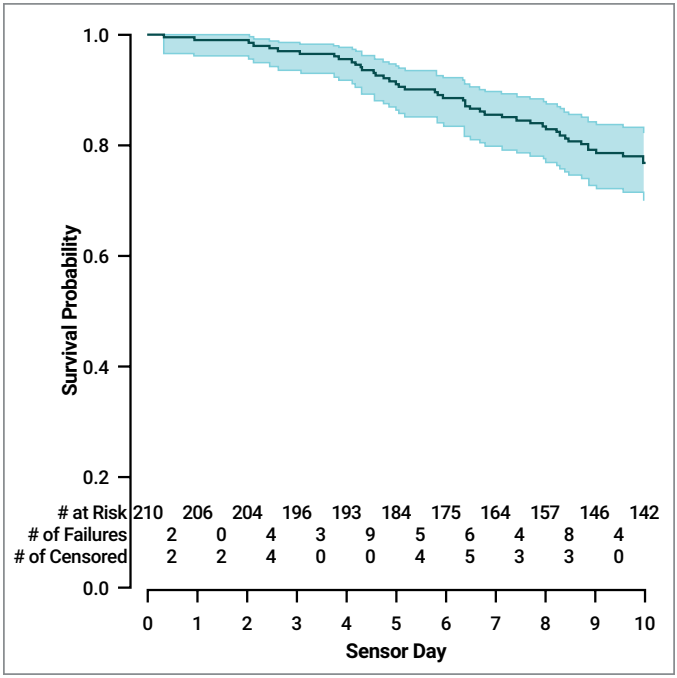


Figure 1-B. Kaplan Meier Curve of Sensor Life (Pediatrics; N = 210)

Note: "# of Censored" refers to sensors excluded from the survival analysis due to reasons not related to the device (e.g., subject dropped out of study)

Number of Readings Provided

The G6 is capable of providing a reading every 5 minutes, or up to 288 readings per day. For a variety of reasons, the G6 may not display a glucose reading and readings are "skipped." The percentage of readings you can expect to receive from the G6 over the sensor life is 98.6%. More than 97% of the sensors captured readings at least 90% of the time. For the G6 with auto-applicator, approximately 99% of the sensors displayed reading every 5 minutes at least 90% of the time. Table 8 below describes the reading captured rate by each wear day over the sensor life.

Table 8. Reading Capture Rate by Wear Day (n=374)

Wear Day	Number of Sensors	Capture Rate (%)
1	374	97.6
2	368	98.6
3	364	98.7
4	354	98.6
5	348	98.5
6	338	98.5
7	329	98.2
8	314	97.8
9	303	97.0
10	290	96.4

Precision of System Readings

A subset of randomly selected subjects wore two Systems at the same time (n=67). This was to look at how similarly two Systems function on the same subject (sensor precision) under the same condition. Precision was evaluated by comparing the glucose readings from the two Systems worn on the same subject at the same time on the same location.

Table 9 shows that the readings from the two sensors generally agreed with each other. For adults (18+ years old) on abdomen, absolute relative difference (ARD) between the two Systems was 8.9% with coefficient of variation (CV) of 7.9%. For pediatrics (2-5 years old) on upper buttocks, paired ARD was 5.2% with CV of 4.8%.

Table 9. Precision by Wear Location

	Adults (18+ YO) Abdomen	Pediatrics (6-17 YO) Abdomen	Pediatrics (6-17 YO) Upper Buttocks	Pediatrics (2-5 YO) Upper Buttocks
CGM-CGM Matched Pairs (n)	23,019	1,255	12,230	2,638
Paired Absolute Difference (mmol/L)	0.78	0.81	0.91	0.52
Paired Absolute Relative Difference (%)	8.9	9.4	10.7	5.2
Coefficient of Variation (%)	7.9	7.6	8.5	4.8

Study 2 Overview

The purpose of the Study 2 was to assess the performance of the System with an automatic sensor applicator, which is the final G6 CGM System configuration. The automatic applicator was designed to provide more consistent sensor insertions.

The study was a prospective, multi-center, single-arm study that enrolled 76 subjects at four (4) US clinical sites. No glucose manipulations were performed in this sub-study. Subjects participated in assigned clinic sessions (Day 1, 2, 4-5, 7 and/or 10):

- Adult subjects: two (2) 12-hour clinic sessions
- Pediatric subjects 13–17 years of age: one (1) 12-hour clinic session
- Pediatric subjects 6–12 years of age: one (1) 6-hour clinic session.

The data from Study 2 was also further processed at Dexcom to assess performance of factory calibration.

Accuracy (Study 2 - Automatic Applicator)

Accuracy of the G6 is characterized by assessing its readings against blood glucose values from YSI. Accuracy of the G6 was assessed with paired G6 readings to YSI blood glucose values. For glucose value less than or equal to 3.9 mmol/L, the absolute difference in mmol/L between the two glucose results was calculated. For glucose value greater than 3.9 mmol/L, the absolute difference (%) relative to the YSI values was calculated. The percentages of total readings within 1.1 mmol/L or 20% over the System lifecycle and on Day 1 are provided in Table 10. The results are also presented for pediatrics and adults separately.

For example, the total number of data pairs considered in the analysis was 3,532. Of these, 92% of the System readings fall within ± 1.1 mmol/L of the YSI blood glucose values < 3.9 mmol/L and within ± 20% of YSI blood glucose values ≥ 3.9 mmol/L for adults and 96% readings fall within 20/20% for pediatrics.

Table 10. G6 Accuracy to YSI (n=62)

Patient Population	Number of subjects	Total number of paired CGM-YSI	Percent within 20/20% YSI	Day 1 Percent within 20/20%YSI	MARD (%)
Overall	62	3,532	93.5 (89.9)	91.1	9.0
Auto-app (≥18 years)	25	2,145	91.9 (86.6)	91.0	9.8
Auto-app (6-17 years old)	37	1,387	95.8 (92.3)	91.3	7.7

Patient Comfort (Study 2 - Automatic Applicator)

Enrolled patients were asked to complete questionnaires on comfort and ease of use of the G6 with automatic applicator. The questionnaires were completed by the subjects or their parents/guardians. Subjects were asked to focus on ease or difficulty with their initial experience of sensor insertion and transmitter attachment.

Eighty-four percent (84%) of subjects felt the automatic sensor applicator was painless. All reported subjects (100%) found that the automatic applicator was easy to use and the IFU was easy to understand.

Table 11. Survey on Automated Applicator (n=76)

Question	Number of subjects (n)	Percent
Comfort: Painless (mild, no pain)	76	84%
Ease of use: easy (somewhat or very)	76	100%
IFU ease of use: easy (somewhat or very)	61	100%

Adverse Events

No serious adverse events (AEs) or device-related serious adverse events occurred during the studies. There was a total of 24 mild to moderate AEs which occurred during the studies (among 374 sensors). 13 of these AEs occurred due to either skin irritation, such as erythema (redness) or edema (swelling), at the sensor needle insertion area or around the adhesive area, or mild to moderate excoriation and infection.

G.2 Product Specifications

WARNING: Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the G6 CGM system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The device behaves normally while charging, however, do not hold the receiver while charging for over a minute as the device can get warm to the touch.

No cleaning methods are recommended or tested for the receiver. Only wipe with a clean, dry cloth.

CAUTION: If you have difficulty reading your receiver in bright sunlight, you may need to seek a shady location.

Sensor Product Specifications

Glucose Range	2.2–22.2 mmol/L
Sensor Useful Life	Up to 10 days
Storage and Transport Conditions	Temperature: 2°C–30°C Store sensors in a cool, dry place
Sterilization	Sterile by radiation

Transmitter and Receiver Product Specifications

Model	G6 Transmitter	Dexcom Receiver
Memory Storage		30 days of glucose data 10 days of tech support data
Electrical Safety Class	Internally Powered	Internally Powered
Battery Longevity (Typical)	3 months	2 days
Battery Charging Time	Non-rechargeable	3 hours
Operational Conditions	Temperature: 10°C–42°C Humidity: 10%–95% RH Enclosure temperature rises less than 0.5°C above ambient temperature	Temperature: 0°C–45°C Humidity: 15%–95% RH
Operating Temperature while Charging	N/A	0°C–40°C
Storage and Transport Conditions	Temperature: 0°C–45°C Humidity: 10%–95% RH	Temperature: 0°C–40°C Humidity: 10%–95%RH
Operating Altitude	-396 meters to 4,206 meters	-365 meters to 4,114 meters
Maximum Enclosure Temperature	42.8°C	N/A
Ingress Protection	IP28: Protection against insertion of large objects and immersion in water for up to 2.4 meters for 24 hours	IP22: Protection against insertion of large objects and vertically falling water drops
Protection Against Electrical Shock	Type BF applied part	N/A

Transmitter and Receiver Product Specifications

Model	G6 Transmitter	Dexcom Receiver
Alarm Audible Output	N/A	50 dB_{SPL} at 1 meter
TX/RX Frequencies	2.402–2.480 GHz	
Bandwidth	1.07 MHz	1.39 MHz
Maximum Output Power	1.0 mW EIRP	2.4 mW EIRP
Modulation	Gaussian Frequency-Shift Keying	
Data Rate	1 Mbps	
Data Communication Range	6 meters	

The maximum surface temperature of Applied part = 43°C.

Essential performance

The Dexcom G6 system measures patients' glucose sensor readings with specified accuracy under the stated operating conditions. The Essential Performance of the Dexcom G6 CGM system also includes reporting the corresponding measured glucose sensor readings and alerts on the display device.

Quality of Service Summary

Quality of Service for the G6 System wireless communication using *Bluetooth* Low Energy is assured within the effective range of 6 meters, unobstructed, between the G6 transmitter and paired display device at regular 5-minute intervals. If connection is lost between the transmitter and display device, upon re-connection any missed packets (up to 3 hours) will be transmitted from the transmitter to the display device. The G6 CGM System is designed to only accept radio frequency (RF) communications from recognized and paired display devices.

Security Measures

The G6 System is designed to transmit data between the transmitter and designated display devices in accordance to the industry standard BLE protocols. It will not accept radio frequency (RF) communications using any other protocol, including *Bluetooth* classic communication protocols.

In addition to the security provided by the BLE connection, communication between the G6 transmitter and the G6 receiver and mobile applications is protected by additional levels of security and safety mitigations using an encrypted and proprietary data format. This format embeds various methods to verify data integrity and to detect potential instances of data tampering. While the format is proprietary, industry standard encryption protocols (e.g., RSA and AES) are used in different parts of this proprietary data format.

Unless disabled, the G6 mobile application regularly communicates with Dexcom Servers. Communication between the G6 applications and Dexcom Servers is protected by a number of mechanisms, designed to safeguard against data corruption. This includes industry standard JWIT token based authentication and authorization. All such communication takes place exclusively over an encrypted data path using industry standard SSL format.

USB Charging/Download Cable* Specifications

Input/Output	5 V DC, 1A
Type	USB A to USB micro B
Length	0.91 meters

Power Supply/Charger Specifications

Class	II
Input	AC Input 100–240 Vac, 50/60Hz, 0.2A, 0.2A rms at 100 Vac
DC Output	5V DC, 1A (5.0 Watts)

Electromagnetic Immunity and Emissions Declaration and Guidance

The transmitter and receiver are intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Immunity Test	Transmitter Compliance Level	Receiver Compliance Level
Electrostatic Discharge (ESD) **IEC 61000-4-2**	± 8 kV Contact ± 15 kV Air	
Magnetic Field (50Hz) **IEC 61000-4-8**	30 A/m	
Electrical Fast Transient/Burst **IEC 61000-4-4**	N/A	± 2 kV for power supply lines
Surge **IEC 61000-4-5**	N/A	± 0.5 kV, ± 1 kV line(s) to line(s)
Voltage Dips and Interruptions **IEC 61000-4-11** **IEC 60601-1-11**	N/A	0% 230V for 1 cycle 0% 230V for 0.5 cycle at 8 phase angles 70% 230V (30% dip in 230V) for 25 cycles 0% 230V for 250 cycles
Conducted Fields Disturbance **IEC 61000-4-6**	N/A	6 Vrms 150 kHz to 80 MHz
Radiated Fields Disturbance **IEC 61000-4-3**	10 V/m at 80 MHz to 2700 MHz (AM Modulation)	
Radiated and Conducted Fields **Aircraft use**	FAA RTCA /DO-160 edition G Section 20 Category T. Can be used on aircraft according to the directions provided by the operator of the aircraft	

Electromagnetic interference can still occur in the home health care environment as control over the EMC environment cannot be guaranteed. An interference event can be recognized by gaps in G6 readings or gross inaccuracies. The user is encouraged to try to mitigate these effects by one of the following measures:

- If the G6 reading changes by 30% or more in 5 minutes and the change does not reflect symptoms or recent actions, take a meter reading. Compare the two readings and contact Technical Support if they do not follow the 30/30 rule. The 30/30 rule is the following: If the meter shows less than 3.9 mmol/L, CGM should read within ± 1.7 points. If the meter shows 3.9 mmol/L and above, the CGM should read ± 30%. Example: a 11.2 mmol/L sensor reading and a 10.4 mmol/L glucose meter value = a 8% difference (this is still considered accurate). If a reading is outside of the 30/30 rule, if you want, calibrate again to more closely align your CGM and meter.
- If display device misses 20 minutes of sensor glucose data (4 readings), the Signal Loss error displays. To resolve, see Appendix A Troubleshooting.
- If display device shows the loading screen unexpectedly and does not display the trend screen within 3 minutes, contact Technical Support. For more information, see Appendix A Troubleshooting.
- If your receiver touch panel does not work for 6 minutes, contact Technical Support.

Electromagnetic Emissions Specifications

Emissions Test	Compliance
Radio frequency Emissions CISPR 11	Group 1, Class B
Radio Frequency Emissions Aircraft Use	Meets FAA RTCA /DO-160 edition G Section 21, Category M for in-cabin use.

G.3 Radio Regulations Compliance

This CGM system complies with Industry Canada's license-exempt RSSs. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

G6 Transmitter

Transmitter Part Number	9445-02	9445-18, 9445-24
IC :	9290A-944502	9290A-944518

Appendix H: Professional Use Instructions

H.1 Introduction

The G6 supports multi-patient use. You just prepare the G6 for your patient, prepare your patient for the G6, set up the G6 with the patient, and then follow up with them to share insights on their glucose trends, patterns, and statistics. This helps both of you manage their diabetes better. The following sections go through each step and give you resources to share with your patients as you guide them through a sensor session.

H.2 Prepare G6 for Patient

First, decide whether the patient should be able to see their G6 readings (unblinded). Will this motivate them to manage their diabetes better?

Whether the G6 receiver is blinded or unblinded, all G6 patients:

- Must carry their receiver so it records their data for later analysis.
- Get system alerts (including: Pair Transmitter, Start Sensor, New Sensor, Signal Loss, No Readings, Calibration).

The differences between blinded and unblinded are:

- Unblinded: Receiver shows patient's G6 reading, arrow, graph, and all glucose-related alarm/alerts (that is: Urgent Low Glucose, Urgent Low Soon, Low Glucose, High Glucose, Rise Rate, or Fall Rate).
- Blinded: Receiver does not show any unblinded information. In addition, it does not show the Warmup Complete message.

Go to **clarity.dexcom.eu** for more information.

Follow the instructions to wipe and disinfect the receiver and transmitter between patients. When using for multiple patients, do not use the optional, soft plastic receiver case.

1	Prepare Receiver

	a. Charge and Reset
	• Charge receiver
	• Reset:
	  • Resetting the receiver removes the previous patient's data. To ensure patient privacy, reset the receiver after each use.
	  • Decide whether your patient needs to see their sensor information (unblinded) or not (blinded) while they use G6.

	b. Wipe
	• To wipe off receiver, use a clean, dry cloth
	  • If necessary, remove and discard old shield before wiping. Follow local precautions for discarding potentially infectious material.
	  • Do not use abrasive cloths, towels, paper towels, or similar items
	  • Do not get moisture into any openings
	  • Do not use aerosol sprays, solvents, or abrasives

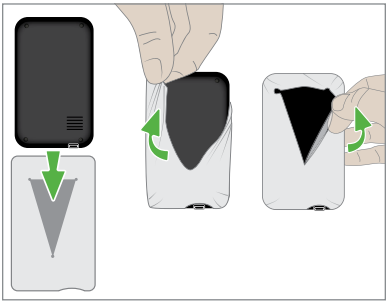
2 Put Shield on Receiver (Receiver is not disinfected; shield is used instead)

a. Prepare

- Wash hands and wear clean gloves
- Use a new shield for each patient to protect patients from contamination
- Get a shield, triangle seal, and USB cover

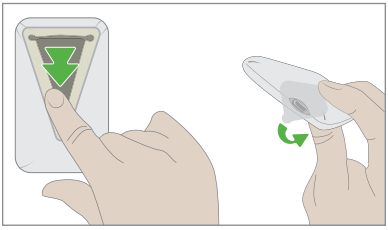
b. Put Receiver in Shield

- Align receiver with shield so receiver screen faces away from opening and USB port aligns with shield USB opening
- Slide receiver into V-shaped opening
- Stretch shield over receiver



c. Tape shut

- Peel triangle seal from adhesive backing
- Place seal over shield opening on back of receiver
- Peel square seal from adhesive backing
- Place over USB opening to create a door



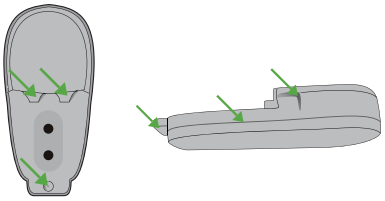
3	Clean Transmitter

a. Prepare

- Protect: Wear clean gloves and goggles
- Prepare Soak: Put Clorox Healthcare® Bleach Germicidal Cleaner solution (Clorox) in a container deep enough to submerge the transmitter

b. Clean

- Rinse and Scrub: Rinse transmitter in cold tap water while brushing with a soft bristle brush until all visible soil is gone
- Soak and Scrub:
  - Put transmitter in prepared soak for 3 minutes
  - While immersed, scrub uneven areas (see green arrows) with a soft bristled brush or a pre-saturated bleach wipe



c. Rinse and Dry

- Rinse: Remove from soak and rinse transmitter under flowing cold tap water for 10 seconds
- Dry: Wipe transmitter dry with cloth

d. Inspect

- Verify there is no visible soil. If there is, clean again.

4	Disinfect Transmitter

a. Prepare

- Protect: Wear clean gloves and goggles
- Prepare Soak and syringe:
  - Put CaviCide® solution (Cavicide) in a container deep enough to submerge the transmitter
  - Fill syringe with about 30 mL of CaviCide

b. Disinfect

- Flush:
  - Focus on the uneven areas
  - Swirl in Cavicide for 10 seconds
  - Refill syringe
- Scrub:
  - Saturate clean cloth or wipe with Cavicide
  - Wipe entire transmitter for at least 3 minutes or until all soil is removed
  - Focus on the uneven areas
- Flush:
  - Focus on the uneven areas
  - Swirl in Cavicide for 10 seconds
- Soak:
  - Put transmitter in prepared soak
  - Swirl it for 30 seconds
  - Then let it soak for another 3 minutes

c. Rinse and Dry

- Rinse: Remove from soak and rinse transmitter under flowing cold tap water for 10 seconds
- Dry: Wipe transmitter dry with cloth

H.3 Prepare Patient for G6

This table shows what to explain to your patients and where you can find patient-centered information to help them understand.

Explain	Show
What CGM is	See Start Here guide's What It Does section
G6 Components	See Start Here guide's G6 Overview section
Receiver Shield and USB cover	Tell your patients to keep the receiver in the shield and to keep the shield dry. Show them how to open and close the USB cover when they charge the receiver. The receiver needs to be charged every two days. Give them extra USB covers. Tell them to replace the USB cover when it no longer sticks to the shield. Tell your patients to let you know and return the receiver to you if: • The shield develops a hole • They run out of USB covers

H.4 Set Up G6 with Patient

Set Up with Blinded and Unblinded Patients

With your patient, follow the setup instructions in Start Here to set up the app or receiver.

Be sure to enter the Sensor Code found on the applicator adhesive backing.

The setup instructions include inserting the sensor and attaching the transmitter.

Additional Set Up with Blinded Patients

Explain why the patient is using the blinded mode.

Additional Set Up with Unblinded Patients

While setting up the G6 with your patient, you will create a personalized glucose target zone by setting low and high alerts appropriate for their A1C.

During the 2-hour sensor warmup, use the table below to explain how to interpret the information on the G6.

Explain	Show
Introduce Home Screen	Chapter 3 Home Screen Overview
What are Alarm/Alerts	Chapter 4 Alarm and Alerts
Managing Diabetes with G6	Chapter 5 Treatment Decisions
Resource	Suggest your patient do the tutorial on their own to review the information you introduce.
Dexcom Clarity App	Let your patients who use the app know about Clarity's trends, statistics, and patterns. See **clarity.dexcom.eu** for more information.

H.5 Follow Up with Patient

For patients using the app, at any time during the sensor session, you can go to **clarity.dexcom.eu** to see their glucose data. For patients using the receiver, that information is available after they return the receiver and you upload the data (see **clarity.dexcom.eu**). Clarity identifies trends, patterns, and presents statistics. You can review this information with the patient to give them insights about how to better manage their diabetes.

At the end of the session, remove the G6 from the patient. See Chapter 6 Ending Your Sensor Session for more information.

H.6 Next Steps

Your patient may want to have their own G6. It is available for personal use. Direct them to call Dexcom Canada Sales & Customer at 1-844-832-1810 or visit **dexcom.com** for more information.

You are ready to use the G6 on another patient and introduce them to the benefits of the G6.

Appendix I: Risks and Benefits

When using any medical device, there are risks and benefits. In this appendix, you will learn what they are.

I.1 Risks

The risks with using G6 are:

- Not getting your alarm/alerts
- Using G6 to make treatment decisions when you should not
- Sensor insertion issues

This section covers each of those risks in detail.

Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

Not Getting Alarm/Alerts

If you are not getting your alarm/alerts, you could have severe low or high glucose without knowing it. Check your display device:

- Battery charged: If the display device battery is dead, you will not get G6 readings or alarm/alerts.
- App on: Keep the app on so you get G6 readings or alarm/alerts.
- Alerts on: Leave the alert function on to get alarm/alerts.
- Volume up: Keep the volume loud enough to hear your alarm/alerts.
- Speaker and vibrations work: If the speaker or vibrations are not working, you will not hear or feel your alarm/alerts.
- In range: Keep your display device no more than 20 feet from your transmitter, with no obstacles between them. They have to be that close to communicate. If they are not in range, you will not get G6 readings or alarm/alerts.

- No System errors: If you get a system error – such as No Readings, Sensor Error, or Signal Loss – you will not get G6 readings or alarm/alerts.
- During warmup and after session ends: You will not get alarm/alerts or G6 readings during the 2-hour warmup or after a sensor session ends.

See Troubleshooting (Appendix A), recommended settings (Chapter 2), and notifications that sound while smart device is silenced/muted (Chapter 7) for more information.

Using G6 for Treatment Decisions

You can use your G6 to treat for a low or dose for a high in all but a few situations. See table below for details.

Situation	Treatment Decision Tool
How you feel is consistent with our G6 reading	Use your CGM to make a treatment decision
How you feel is inconsistent with your CGM G6 reading	Take a fingerstick with your blood glucose meter to make a treatment decision
Your CGM displays a sensor glucose number and arrow(s)	Use your CGM to make a treatment decision
Your CGM display is missing G6 reading (number) or arrow(s), or both	Take a fingerstick with your meter to make a treatment decision

Use your G6 for treatment decisions, not your Followers: Dexcom Share allows you to share your sensor glucose information from your smart device to your Followers'. The main risk with Share is misunderstanding its purpose. The information on your display device is the most current – it comes straight from your transmitter – so only use yours for treatment decisions. There can be technical issues and delays in sharing information. Followers can reach out and support you, but do not rely on them or their information to manage your diabetes for you.

Some users found accuracy between different sensors varied significantly. When you insert each sensor, pay attention to its accuracy before deciding to use it for treatment decisions.

For more information on how to make treatment decisions using your G6, see Chapter 5. For more information on Share, see Chapter 7.

Interfering Substance Risks

In previous generations of Dexcom CGM systems (G4/G5), acetaminophen could affect your sensor readings, making them look higher than they really were. However, with the G6, you can take a standard or maximum acetaminophen dose of 1 gram (1,000mg) every 6 hours and still use the G6 readings to make treatment decisions. Taking higher than the maximum dose of acetaminophen (e.g. > 1 gram every 6 hours in adults) may affect the G6 readings and make them look higher than they really are.

Sensor Insertion Risks

It is uncommon, but inserting the sensor can cause infection, bleeding, or pain, and wearing the adhesive patch can irritate your skin. Only a few patients in the G6 clinical studies got slight redness and swelling.

No sensor wires broke in clinical studies; however, there is a remote chance a sensor wire could break or detach and remain under your skin. Sterile broken sensor wires usually do not pose a significant medical risk. If a sensor wire breaks off or detaches and remains under your skin, contact your HCP and Technical Support (24/7):

- Technical Support: 1.844.832.1809

I.2 Benefits

Some benefits of using your G6 are:

- Knowing your trends
- Making treatment decisions using your G6
- Managing your diabetes
- Getting alerted for low and high G6 readings

This section covers each of those benefits in detail.

Knowing Your Trends

The G6 sends you a G6 reading every 5 minutes. It also provides reports and views of your information so you can detect and reflect on trends, patterns, and how your body responds to different things, like exercise or pizza. This provides you with a more complete picture of your glucose and lets you see how your daily habits impact your glucose levels.

Making Treatment Decisions Using G6

You can use your G6 reading and trend arrow to make treatment decisions – like treating for a low or dosing for a high. See Chapter 5 for more information on treatment decisions. With G6, there is no need to take fingersticks to calibrate the system or for treatment decisions (as long as your symptoms match your G6 readings). This can reduce the pain and burden of excessive fingersticks (Aleppo 2017) and reduce potential errors due to inaccurate calibration.

Helping Your Diabetes Management

The alarm/alerts features (Chapter 3) keep you aware of your glucose levels. Alarm/alerts notify you when your glucose goes outside your target range, goes too low, or too high, or is rapidly falling or rising. This lets you take action to prevent glucose from going too low or high (Pettus 2015).

Some people perceive an increase in their quality of life and peace of mind when using real-time CGM (Polonsky 2017). Share may improve the quality of life and peace of mind for patients, their caregivers, and their support team because it sends Followers G6 readings and alarm/alerts remotely. Followers can then reach out when G6 readings go too low or high.

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Appendix J: Going Through Security

Concerned about the security equipment?

Tell the Security Officer you are wearing a continuous glucose monitor and want to be hand-wanded or get a full-body pat-down with a visual inspection of your sensor and transmitter. Let the Security Officer know you cannot remove the sensor because it is inserted under your skin.

Security Equipment to Use

Hand-wanding, pat-down, visual inspection, and walk-through metal detector: If you are wearing or carrying your G6, use any of these screening methods.

Security Equipment to Avoid

Body scanners: Do not go through an advanced imaging technology body scanner, like a millimeter wave scanner, when wearing your G6.

X-Ray machines: Do not put your G6 components through x-ray machines.

In a Plane

To use your smart device, receiver, or both to get sensor glucose information while in the plane:

- Smart device: After switching to airplane mode, turn *Bluetooth* on.
- Receiver: Keep receiver on.

For more information

Contact your airline for their policies.

Appendix K: Glossary

A1C	Blood test used to diagnose type 1 or 2 diabetes and to gauge how well you are managing your diabetes. A1C reflects your average blood sugar level for the past 2 to 3 months.
Accessory Device	Hardware connected to your smart device. For example, a *Bluetooth* head-set, Apple watch, or other smart watch.
Airplane Mode	A setting on a smart device where certain features are disabled to comply with airline regulations.
Alternative Site Testing	Using a blood sample from non-fingertip (alternate) sites such as the palm, forearm, or upper arm for meter values. Do not use alternative site testing to calibrate the G6. Only use fingerstick measurements.
Android	Operating system used for smart devices.
Android Wear	A type of smart watch.
App or Application	Software installed on a smart or mobile device. The G6 app is a display for continuous glucose monitoring.
App Store or Play Store	Internet store for downloading applications to a smart device.
Apple Watch	A smart watch for iPhone.
Blood Glucose (BG) Meter	A medical device used to measure how much glucose is in the blood.
Blood Glucose (BG) Value	Blood glucose value is the amount of glucose in the blood measured by a meter.
Bluetooth	A technology that allows devices to wirelessly communicate with each other.
Calibration	When you calibrate, you take a fingerstick measurement from your meter then enter the value into your receiver or smart device. Calibrating your G6 is optional. Calibration may align your G6 readings with your meter values.

Continuous Glucose Monitoring	A sensor inserted under the skin checks glucose levels in interstitial fluid. A transmitter sends readings to a display device.
Contraindication	A situation where the G6 should not be used because it may be harmful to you. The risk of use outweighs the benefit.
Default	A manufacturer's preset option for a device setting.
Follow or Dexcom Follow App	A Dexcom app used for monitoring another user's glucose information and alerts.
Follower	A person who receives a Sharer's information in Follow.
G6 Reading	The glucose concentration measured in the interstitial fluid.
Hyperglycemia	High BG. Same as "high" or high blood sugar. Hyperglycemia is characterized by an excess of glucose in the bloodstream. It is important to treat hyperglycemia. If left untreated, hyperglycemia can lead to serious complications. Consult your healthcare professional to determine the appropriate hyperglycemia setting for you.
Hypoglycemia	Low BG. Same as "low" or low blood sugar. Hypoglycemia is characterized by a low level of glucose in the bloodstream. It is important to treat hypoglycemia. If left untreated, hypoglycemia can lead to serious complications. Consult your healthcare professional to determine the appropriate hypoglycemia setting for you.
Indications	How, for what purposes, and under what circumstances you should use the G6.
iOS	Operating system used for Apple smart devices.

IP	The International Electrotechnical Commission (IEC) is a nonprofit, non-governmental, international organization created to produce safety standards for electronics. One of the safety standards is the Ingress Protection (IP) Marking, which classifies and rates how protected an electronic device is against dust, water, accidental contact, etc. IP ratings are numerical, with the number based on the conditions the electronic device encounters. An IP22 rating lets you know your electronic device will not allow you to stick your fingers in it and will not get damaged or be unsafe during specific testing with water dripping down.
Jailbroken or Rooted	The removal of limitations and security measures set by the manufacturer on a smart device. The removal poses a security risk and data may become vulnerable. Do not install the G6 app on a jailbroken or rooted smart device. It may not work correctly.
mmol/L	Millimoles per litre. A unit of measure for BG values.
Notification	An app message that appears on the screen of a smart device. Notification may also include a sound or vibration, depending on the smart device settings.
Precaution	Special care to be exercised by you or your healthcare professional for the safe and effective use of the G6.
Safety Statement	A statement of the intended uses of G6 and relevant warnings, precautions, and contraindications.
Sensor Session	The period after inserting a new sensor. During this period, your G6 reading shows on your display device(s) every 5 minutes.
Share or Dexcom Share	A feature of the Dexcom G6 app that lets you securely send your G6 information to Followers.
Sharer	The G6 user who shares their G6 information with Followers.
Simultaneous Voice and Data	The ability to make a phone call and access the Internet on the same cellular connection at the same time.

Smart or Mobile Device	An electronic device that is cordless, mobile, and connected to the internet, such as a smartphone or tablet.
Smart Watch	A watch that communicates with and extends a smart device. For example, an Apple Watch.
Stacking Insulin	Taking a dose of insulin soon after your most recent dose. This can result in low blood sugar. Does not apply to taking insulin doses to cover what you just ate.
Warning	Describes serious and life-threatening circumstances, the consequences, and how to avoid the hazard while using the G6.

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