Dexcom G6 Pro Continuous Glucose Monitoring System

User Guide

Dexcom G6 Pro CGM System and pictured smart devices are sold separately. Graphic of Dexcom CLARITY report is for illustration only.

Dexcom G6 PRO

WARNING:

Failure to use the Dexcom G6 Pro Continuous Glucose Monitoring System (G6 Pro) and its components according to the instructions for use and all indications, contraindications, warnings, precautions, and cautions may result in your patient missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence and/or making a treatment decision that may result in injury. If glucose alerts and readings from G6 Pro do not match symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter to make diabetes treatment decisions. Seek medical attention when appropriate.

Please review the product instructions with your patient before using the G6 Pro. Indications, contraindications, warnings, precautions, cautions, and other important user information are in the product instructions included with, or accompany, the G6 Pro. Patients should discuss with their healthcare professional (HCP) how they should use the information displayed on the G6 Pro to help manage their diabetes. The product instructions contain important information on troubleshooting the G6 Pro and on the performance characteristics of the system.

Page intentionally left blank

Table of Contents

Chapter 1: Welcome

1.1 Introduction: Welcome to G6 Pro

Dexcom G6 Pro Continuous Glucose Monitoring System (G6 Pro) is an important part of helping your patients manage their diabetes. How? By looking at your patient's results, you can give them insights to better control their diabetes. G6 Pro can be used either in real time (unblinded) where your patient sees their sensor readings, gets the Urgent Low alarm and G6 Pro alerts, trend arrows or blinded, where they don't see their data. You determine which mode works best for your patient.

The Dexcom CLARITY app highlights your patient's glucose patterns, trends and statistics. They can even get weekly notifications with the Dexcom CLARITY Reports app.

Your patient goes to the Dexcom CLARITY app from their Dexcom app. They tap the Dexcom CLARITY icon on the events screen or when they turn their smart device to landscape to view events.

G6 Pro was redesigned with your patient's care in mind and an improved workflow efficiency for you.

1.2 Resources

G6 Pro has a number of resources to get you, and your patient, up and running.

Dedicated Website

Dexcom has a website just for you and your needs. Go to provider.dexcom.com to see how Dexcom can help you and your patients.

Product Instruction

User Guide

Available online, the user guide gives you the most detailed information about the G6 Pro. Want a printed copy for yourself or your patient? Call toll-free **1.888.738.3646**, or go online to dexcom.com/guides to request one.

This user guide has one section and an appendix.

The first section introduces you to the G6 Pro. It helps you determine which mode is best for your patient. For both blinded and unblinded patients, it guides you through inserting the sensor in your patient and what they'll see when their sensor session is ending. Also included are the basics your unblinded CGM patient needs to know to use G6 Pro app, including treatment decisions and entering events.

In-Box Materials

The G6 Pro box has instructions you'll use for each patient visit.

- Healthcare Professional:
  - Start Here Card
- Patient Materials:
  - Unblinded CGM (2-part)
  - Blinded CGM

The in-box materials are meant as guides to help you during the patient visit. Review them with your patient, then give applicable materials to your patient for them to take home.

In-App Help

If your unblinded patient wants additional help within their smart device, from the home page, they go to **Settings**>**Help**

Here they can review information on G6 Pro, such as:

- FAQs
- Safety Statements
- Sensor removal
- Setup Wizard
- User Guide
- In-app videos

1.3 Your Dexcom Account

Need help or have a question about the system? Contact Technical Support:

- **General:** 1.844.607.8398, 24/7 Toll Free USA
- **Healthcare Professionals:** 1.844.436.2271, 6 am–6 pm (PST), Monday–Friday

Next?

The next chapters review how to keep your patient safe while on G6 Pro, and risks and benefits when using the system (Chapter 2: Safety Statement and Chapter 3: Risks and Benefits).

Page intentionally left blank

Chapter 2: Safety Statements

2.1 Indications for Use

The Dexcom G6 Pro Continuous Glucose Monitoring System (Dexcom G6 Pro System) is a real time continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. The Dexcom G6 Pro System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the real-time Dexcom G6 Pro System results should be based on the glucose trends and several sequential readings over time.

The Dexcom G6 Pro System may also be used as a retrospective glucose recording device indicated for assessing glycemic variability in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. Retrospective interpretation of data recorded by the Dexcom G6 Pro System should be conducted solely by a healthcare professional.

The Dexcom G6 Pro System aids in detecting glucose excursions facilitating care plan adjustments. The Dexcom G6 Pro System is also intended to interface with digitally connected devices. The Dexcom G6 Pro System can be used alone or in conjunction with these digitally connected medical devices for managing diabetes or assessing glycemic variability.

Warning

Failure to use the G6 Pro and its components according to the instructions for use and all indications, contraindications, warnings, precautions, and cautions may result in missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence and/or making a treatment decision that may result in injury.

If glucose alerts and readings from G6 Pro do not match symptoms or expectations, use a fingerstick blood glucose value from blood glucose meter to make diabetes treatment decisions.

Your patient should seek medical attention when appropriate. Please review the product instructions with your patient before using the G6 Pro. Indications, contraindications, warnings, precautions, cautions, and other important user information can be found in the product instructions that are included with, or accompany, the G6 Pro. Discuss with your patient how they should use the information displayed on the G6 Pro to help them manage their diabetes.

The product instructions contain important information on troubleshooting the G6 Pro and on the performance characteristics of the system.

2.2 Contraindication

No MRI/CT/Diathermy – MR Unsafe

Your patient shouldn't wear CGM (sensor, transmitter, or smart device) for magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.

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

2.3 Warnings

Read User Materials

Before using G6 Pro, carefully read the included materials with your patient. If the patient doesn't, they might:

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

Don't Ignore Low/High Symptoms

Patient shouldn't ignore how they feel. If glucose alerts and G6 Pro readings don't match what they're feeling, they should use blood glucose meter (meter) to make diabetes treatment decisions or, if needed, seek immediate medical attention.

When in doubt, get meter out.

No Number, No Arrow, No CGM Treatment Decision

If G6 Pro doesn't show a number or arrow, or readings don't match symptoms, use meter to make diabetes treatment decisions.

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

Don't Use G6 Pro if Pregnant, on Dialysis, or Critically Ill

It is not known how different conditions or medications common to theses populations may affect performance of the system. G6 Pro readings may be inaccurate in these populations.

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

Check Settings

When using a smart device, confirm that volume is turned up, phone is not muted, and headphones aren't plugged in. If volume is not turned up, the device is muted, or headphones are plugged in, patient won't hear the sound of any notifications, including important alarms. Have your patient check their smart phone's instructions on how to change its settings.

When headphones are connected to most Android® devices, alarm/alerts will sound through the headphones and the speaker. On Apple devices, they will sound only in the headphones.

Some notifications are silent during the first visual and vibrate notification and then make a sound on the second notification. If an alert isn't cleared, it repeats at half volume after 5 minutes and at full volume after 10 minutes.

The smart device vibrations for alerts aren't different than vibrations originating from sources other than the Dexcom CGM app. (Vibratory annunciation only available in smart devices with vibratory functionality.)

Alarm and important alerts sound and display information even when volume is low or muted. Specifically, if smart device is on mute, only these notifications make a sound:

Glucose Alarm/Alerts:

- Urgent Low
- Low Glucose
- High Glucose
- No Readings Alert

System Alerts:

- Sensor Expired
- Transmitter (not working)
- No Storage Error
- App Stopped

There's one exception: On Apple devices, Signal Loss doesn't sound when volume is low or muted.

Bluetooth®

The transmitter talks to the app with *Bluetooth*. Make sure smart device *Bluetooth* is on. If not, patient won't get alarm/alerts or CGM information.

Notifications

Make sure smart device settings allow Dexcom app notifications to show on Lock screen. This will allow notifications to be seen without unlocking the phone.

Apple Devices: During G6 Pro setup, enable Dexcom app notifications or patient won't get alarm/alerts.

Battery: The app must always be running in the background and may drain smart device battery. Keep the battery charged.

App Use: Smart device may close the Dexcom app automatically other apps are being used, like a game, or if too many apps are open. If the Dexcom app is closed, patient won't get sensor glucose information. Occasionally verify Dexcom app is open.

Compatibility: Dexcom tests the app's compatibility with smart device's Operating System to ensure it works. Before upgrading smart device or its operating system, always check dexcom.com/compatibility.

Automatic updates of the app or device operating system can change settings or shut down the app.

Time

Let the date and time on smart device automatically update when traveling across time zones or switch between standard and daylight-saving times.

Don't manually change smart device time. It can make the time on the trend screen wrong and the app may stop displaying data.

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

Inspect

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

Use as Directed

The transmitter is small part and poses a choking hazard, particularly for children.

Use Meter During Sensor Warmup

When a new sensor is started, there won't be any G6 Pro readings or alarm/alerts. Use meter to make treatment decisions during the 2-hour sensor warmup period.

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

Wire Breaks Off

Don't ignore broken or detached sensor wires. A sensor wire could remain under the skin. If this happens, please contact our 24/7 Technical Support.

If a sensor wire breaks off under the skin and your patient can't see it, tell them not to remove it, but to contact you or seek professional medical help. Advise your patient to seek professional medical help if they have symptoms of infection or inflammation – redness, swelling, or pain – at the insertion site.

Where to Insert: Belly or Buttocks?

All patients can use their bellies (abdomen). Patients 2 to 17 years old can also choose their upper buttocks. Look for a place on the belly or upper buttocks where there is some padding.

The sensor is not tested or approved for other sites.

Where to Store

Store sensors at room temperature or in a refrigerator – as long as it's between 36°F and 86°F. Don't store sensors in the freezer.

2.4 Precautions

Avoid Sunscreen and Insect Repellent

Some skin care products, such as lotions, sunscreens and insect repellents, can make the plastic used in G6 Pro crack. Before using G6 Pro, make sure there are no cracks in transmitter, and transmitter holder. If you find a crack, please contact Technical Support.

Do not allow these skin care products to contact the G6 Pro. After using skin care products, wash hands before touching G6 Pro. If any skin care products get on G6 Pro, immediately wipe with a clean cloth.

Don't Start Past "Use By Date"

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

Check Package

Don't use sensor if its sterile package has been damaged or opened, because it might cause an infection.

Clean and Dry Skin

Clean and dry hands and put on gloves before inserting sensor on patient.

Clean insertion site with alcohol wipes to prevent infections. Don't insert the sensor until skin is dry. If insertion site is not clean and completely dry, the patient runs the risk of infection or the transmitter holder not sticking well.

Make sure patient doesn't have insect repellent, sunscreen, perfume, or lotion on their skin.

Where to Insert: Things to Check

Don't remove sensor or transmitter from packaging until you are ready to use. Keep the safety guard on until you put the G6 Pro applicator against the patient's skin. If you remove the safety guard first, you may hurt the patient by accidentally pushing the button that inserts the sensor before you mean to.

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

Sensor placement is important. Choose a site:

- At least 3 inches 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 Pro instructions. If not, your patient could have a severe low or high glucose event.

Use Correct Transmitter, and Sensor

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

Going Through Security Check Point

When wearing G6 Pro, your patient should 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 Pro in the baggage x-ray machine.

Your patient can wear the G6 Pro for the walk-through metal detector. If patient does, have them use their meter for treatment decisions until they leave the security area.

Not sure what kind of machine it is? Be safe – have patient ask the TSA officer, request hand-wanding, or request full-body pat-down.

Interfering Substance Risks

Acetaminophen

In previous generations of Dexcom CGM systems (G4/G5), acetaminophen could affect sensor readings, making them look higher than they really were. However, with the G6 Pro, patient can take a standard or maximum acetaminophen dose of 1 gram (1,000 mg) every 6 hours and still use the G6 Pro 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 Pro readings and make them look higher than they really are.

Hydroxyurea

Hydroxyurea is a medication used in the treatment of diseases including cancer and sickle cell anemia. It is known to interfere with glucose readings from the sensor. The use of hydroxyurea will result in sensor glucose readings that are higher than actual glucose levels. The level of inaccuracy in sensor glucose readings is based on the amount of hydroxyurea in the body. Relying on sensor glucose results while taking hydroxyurea could result in missed hypoglycemia alerts or errors in diabetes management, such as giving a higher dose of insulin than necessary to correct falsely high sensor glucose values. It can also result in errors when reviewing, analyzing and interpreting historical patterns for assessing glucose control. Do not use the

Dexcom CGM System for making diabetes treatment decisions or assessing glucose control when taking hydroxyurea.

Follow G6 Pro instructions. If not, your patient could have a severe low or high glucose event.

Know Your System

Don't rely on the G6 Pro app until your patient understands how to use it and their device's *Bluetooth*.

If water is between the transmitter and the display device – for example, if the patient is showering or swimming – keep them closer than 20 feet to each other. The range is reduced because *Bluetooth* doesn't work as well through water.

Does the Smart Device Work?

If the smart device is turned off (shut down), it will not show G6 Pro readings or alarm/alerts. Make sure the display device is turned on, the battery is charged, the screen is not broken and the speaker works.

Follow G6 Pro instructions. If your patient doesn't, they could have a severe low or high glucose event.

Check Peripheral Devices

Use headphones with a smart device? What about *Bluetooth* speakers or a smart watch? When using peripherals, patient may get alarm/alerts on only one device or peripheral, or not all. After connecting any peripheral devices, make sure that smart device settings still allow for receiving alarms or alerts.

2.5 Caution

US Federal law restricts the sale of G6 Pro to the sale by or on the order of a physician.

Chapter 3: Risks and Benefits

When using any medical device, there are risks and benefits. In this chapter, you'll learn what they are.

3.1 Risks

The risks with using G6 Pro are:

- Sensor insertion issues
- Local skin irritation from adhesive patch
- Additional risks of using the G6 Pro app are:
  - Not getting alarm/alerts
  - Your patient using G6 Pro to make treatment decisions when they shouldn't

This section covers each of those risks in detail.

Follow system instructions. If not, your patient could have a severe low or high glucose event.

Sensor Insertion Risks

There is a remote chance a sensor wire could break or detach and remain under the skin. Sterile broken or detached sensor wires usually don't pose a significant medical risk. It's uncommon, but inserting the sensor can cause infection, bleeding, or pain. Only a few patients in the clinical studies got slight redness and swelling. If a sensor wire breaks off or detaches and remains under the skin, the user should contact an HCP and Technical Support:

- TechSupport@dexcom.com
- **General:** 1.844.607.8398, 24/7
- **Professionals Toll Free:** 1.844.436.2271, 6 am–6 pm (PST), Monday–Friday
- **Professionals Toll Call:** 1.858.200.0200, 6 am–6 pm (PST), Monday–Friday

Not Getting Alarm/Alerts

If the user is using the G6 Pro system in real-time and isn't getting alarm/alerts, they could have severe low or high glucose without knowing it. Check smart device:

- Battery charged: If the smart device battery is dead, the user won't get readings or alarm/ alerts.
- App on: Keep the app on to get readings or alarm/alerts.
- Alerts on: Leave the alert function on to get alarm/alerts.
- Volume up: Keep the volume loud enough to hear alarm/alerts.
- Speaker and vibrations work: If the speaker or vibrations aren't working, the user won't hear or feel alarm/alerts.
- In range: Keep smart device no more than 20 feet from transmitter, with no obstacles between them. They have to be that close to communicate. If they aren't in range, the user won't get readings or alarm/ alerts.
- No System errors: If the user gets a system error – such as No Readings, Sensor Error, or Signal Loss – they won't get readings or alarm/alerts.
- During warmup and after session ends: The user won't get alarm/ alerts or readings during the 2-hour warmup or after a G6 Pro session ends.

Using G6 Pro for Treatment Decisions

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

Situation	Treatment Decision Tool
How you feel is consistent with your G6 Pro reading	Use your CGM to make a treatment decision
How you feel is inconsistent with your CGM G6 Pro 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 Pro reading (number) or arrow(s), or both	Take a fingerstick with your meter to make a treatment decision

3.2 Benefits

Some benefits of using G6 Pro are:

- Knowing trends
- Managing your patient's diabetes without the need for routine fingersticks
- Getting alerted for low and high readings
- Determining how often your patient's glucose is high, low, or in range

This section covers each of those benefits in detail.

Knowing Your Patient's Trends

The G6 Pro sends a reading every 5 minutes. It also provides reports and displays of your patient's information so you can detect and reflect on trends, patterns, and how your patient's body responds to different things, like exercise, stress, or food your patient has eaten. This provides your patient with a more complete picture of their glucose and lets you see how your patient's daily habits impact their glucose control.

Making Treatment Decisions Using G6 Pro

You can use your G6 Pro reading and trend arrow to make treatment decisions – like treating for a low or dosing for a high. See 'Can I make treatment decisions with G6 Pro,' 'No Number, No Arrow, No CGM Treatment Decision' and 'Using G6 Pro for Treatment Decisions' for more information. With G6 Pro there is no need to take fingersticks to calibrate the system or for treatment decisions (as long as your symptoms match your readings). This can reduce the pain and burden of excessive fingersticks (Aleppo 2017) and reduce potential errors due to inaccurate calibration.

Helping Your Patient's Diabetes Management

The alarm/alerts features keep your patient aware of their glucose levels. Alarm/alerts notify your patient when their glucose goes outside their target range, goes too low, or too high. This lets your patient 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). The glucose information will provide an insight to the state of your patient's glucose control and the patterns you and your patient observe may help inform better treatment decisions.

References

Aleppo, Grazia, Katrina Ruedy, Tonya Riddlesworth, Davida Kruger, Anne Peters, Irl Hirsch, Richard Bergenstal, Elena Toschi, Andrew Ahmann, Viral Shah, Michael Rickels, Bruce Bode, Athena Philis-Tsimikas, Rodica Pop-Busui, Henry Rodriguez, Emily Eyth, Anuj Bhargava, Craig Kollman, and Roy Beck. 2017. "Replace-BG: a randomized trial comparing continuous glucose monitoring with and without routine blood glucose monitoring in well-controlled adults with type 1 diabetes." *Diabetes Care*. 40(4):538-545. doi: 10.2337/dc16-2482.

Beck, Roy, Tonya Riddlesworth, Katrina Ruedy, Andrew Ahmann, Richard Bergenstal, Stacie Haller, Craig Kollman, Davida Kruger, Janet McGill, William Polonsky, Elena Roschi, Howard Wolpert, and David Price for the DIAMOND Study Group. 2017. "Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: the DIAMOND randomized clinical trial." *JAMA*. 317(4):371-378. doi:10.1001/jama.2016.19975.

Lind, Marcus, William Polonsky, Irl Hirsch, Tim Heise, Jan Bolinder, Sofia Dahlqvist, Erik Schwarz, Arndis Finna Olafsdottir, Anders Frid, Hand Wedel, Elsa Ahlen, Thomas Nystom, and Jarl Hellman. 2017. "Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: the gold randomized clinical trial." *JAMA*. 317(4):379-387. doi:10.1001/jama.2016.19976.

Pettus, Jeremy, David Price, and Steven Edelman. 2015. "How patients with type 1 diabetes translate continuous glucose monitoring data into diabetes management decisions." *Endocr Pract*. 21(6):613-620. doi: 10.4158/ EP14520.OR.

Vigersky, Robert, Shrivastav, Maneesh. 2017. "Role of continuous glucose monitoring for type 2 diabetes management and research." *Journal of Diabetes and Its Complications*. 31(1):280-287. Doi: 10.1016/j.jdiacomp.2016.10.007.

Page intentionally left blank

Chapter 4: Overview

4.1 Introduction

This chapter gives you an overview of the system and your role in helping your patient.

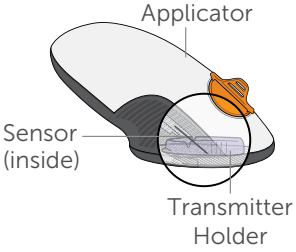
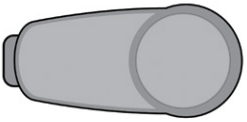
4.2 G6 Pro Components

In this section, you'll learn about the G6 Pro components, and how they work together.

G6 Pro has three main parts:

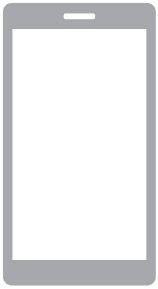
1. Single-use sensor (inside applicator)
2. Single-use transmitter
3. Dexcom G6 app on patients' smartphone (unblinded)

G6 Pro Box

	**Sensor and Applicator** • Sensor is inside the applicator. • Sensor gets glucose information. • Single-use. • Apply sensor to patient using applicator.
	**Transmitter** • Transmitter captures and stores data from sensor. • Single-use. • Attach to transmitter holder after inserting sensor.

Images are representational only. Your system may look different.

Unblinded CGM Patient Display Device

	**Unblinded Only** • To receive sensor information, patient downloads the G6 Pro app on their compatible smart phone (dexcom.com/compatibility). • Patient can do this in your office, but the Pro system was designed to have them do this at home. • Following on-screen instructions, patient sets up the app.

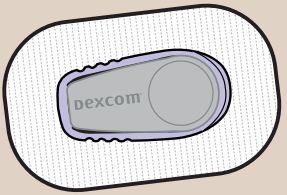
4.3 G6 Pro Reader

There's also a separate G6 Pro Reader (reader). Refer to the G6 Pro Reader instructions for information on how to use the reader with the G6 Pro CGM System. The reader can check system status and download patient data when they return the transmitter to you. The reader downloads the patient's sensor readings stored in the transmitter. After inserting the sensor and attaching the transmitter on your patient, it checks the G6 Pro system status. When your patient's sensor session is over, they return the transmitter to you. The reader downloads the patient's sensor readings stored in the transmitter.

For more information about the reader, see your Dexcom G6 Pro Reader User Guide.

	**Reader**
	• For HCP use only.
	  • Don't give to patient.
	  • Doesn't display readings.
	• Checks system status before patient leaves.
	• Uploads transmitter data after sensor session is over and transmitter is returned to the office.

4.4 How They Work Together

	After inserting the sensor, sensor takes glucose readings every five minutes during the 10-day sensor session. Sensor sends readings to transmitter. Transmitter retains sensor session data. After sensor session, patient returns transmitter to you.
	Compatible Data Tool: See G6 Pro Reader User Guide for complete information. Before patient leaves, and after sensor insertion, you have the option to check the G6 Pro system status. Once patient returns the transmitter, download its data. When download is complete, HCP uploads reader data into Dexcom CLARITY. Review Dexcom CLARITY report with patient. Throw away transmitter and sensor following local guidelines.

4.5 Unblinded/Blinded

Your patient can use G6 Pro in blinded or unblinded mode. In each case, the first step is to insert the sensor and attach the transmitter. Using the app on a smart phone determines whether a sensor session is blinded or unblinded.

Regardless of which mode your patient uses, the transmitter records the sensor data. After the sensor session is over and your patient returns the transmitter, you download its data into the reader via *Bluetooth*.

Once the reader information is uploaded to Dexcom CLARITY, generate a report and review the patient's results with them.

Unblinded

If you want your patient to use G6 Pro unblinded, first check to make sure their smart device is compatible with the Dexcom app. Go to: dexcom.com/compatibility.

In unblinded CGM mode, your patients get the full benefit of the Dexcom app.

They:

- See their glucose readings
- Get glucose alarm and alerts
- See system notifications
- See historical glucose information
- Can enter Events
- View their data on their smart devices

Don't give the transmitter SN to your blinded patient. If you do, your blinded patient may get unblinded data without you knowing.

Why Choose Unblinded?

Some of your patients are very interested in learning more about their daily readings and trends. Or they may want to try Dexcom before getting one, to see how the alarm/alerts work, or get a feel for the system as a whole. As long as your patient has a compatible smartphone, they can give the Dexcom app a try.

In unblinded mode, use the 2-part Unblinded CGM materials to train your patient on the Dexcom system. After going over the handout with your patient, give it to them so they can refer to it at home.

Blinded

In blinded mode your patient doesn't use the app or any type of display device, so they won't see or know their glucose readings or get any alarm or alerts.

Don't give the transmitter SN to your blinded patient. If you do, your blinded patient may get unblinded data without you knowing.

Why Choose Blinded?

You may want your patient to be blinded, so they don't make changes to their day to day life that would impact their glucose levels. This gives you an opportunity to look at their patterns retrospectively. Some of your patients may not have a compatible smartphone, so they can't use the app. Other patients may not be as interested in following their glucose patterns on a daily basis. Blinded allows them to use G6 Pro and, after the sensor session is over, you can share their results using the Dexcom CLARITY reports.

In blinded mode, since they don't use the app, they don't need to know how the system works, they just need to know how to use it safely and what to do after the sensor session is over.

After going over the handout with your patient, give it to them so they can refer to it at home.

4.6 Dexcom CLARITY

Using the reader, upload your patient's sensor readings into Dexcom CLARITY. Dexcom CLARITY takes your patient's glucose information and processes it into different reports, helping you analyze your patient's glucose trends and patterns. Reviewing Dexcom CLARITY reports with your patient provides them with insights about, and ways to manage, their diabetes. Save the reports on your computer or print them out. The transmitter only captures your patient's glucose readings. If they entered Events into the G6 Pro app, they won't be reflected on your Dexcom CLARITY report unless your patient gives you permission to view all of their information. Go to Dexcom CLARITY and to ask your patient to share their information with you.

For more information about Dexcom CLARITY, go to clarity.dexcom.com/professional for the Dexcom CLARITY user guide.

4.7 Getting Your Patient Started

Getting your patient up and running:

1. Insert the sensor and attach the transmitter holder.
2. Train your patient on the system based on whether they are blinded or unblinded.
3. Outline what your patient should do when sensor session is over.
4. After transmitter is returned, download its data to reader, then upload data into Dexcom CLARITY from your PC.
5. Review Dexcom CLARITY reports with your patient.

G6 Pro helps you along the way by providing you with an online user guide and printed in-box materials. Remember, you can order a printed version of the user guide or save it to your desktop.

Go to dexcom.com/guides to download, or call **1.888.738.3646** to order a printed version.

Now you have an overview of the system and how you can help your patients. What's next? Preparing for you patient's visit, and inserting the sensor.

Page intentionally left blank

Chapter 5: Getting Started with G6 Pro

5.1 Introduction

In the previous chapter, you received a high-level overview of the G6 Pro system. Now it's time to learn about inserting the sensor and attaching the transmitter.

After this chapter, you'll be able to:

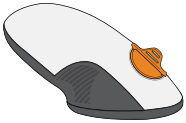
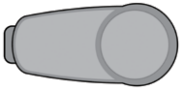
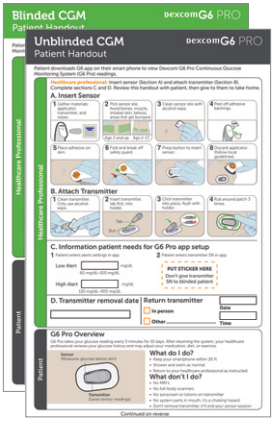
- Get ready for your patient's visit
- Insert the sensor on your patient
- Attach the transmitter
- Tell your patient about the next steps

5.2 Preparing for Patient's Visit

For a successful visit, make sure you have everything ready before your patient arrives.

Gather everything you may need:

G6 Pro Reader	
	See reader user guide for more information

G6 Sensor and Applicator	
	Don't open packaging until ready to insert the sensor
Transmitter	
	Only use transmitter and sensor inside the same box
Patient Materials	
	• Blinded CGM • Unblinded CGM (2-parts)

You provide

1. Safety Gloves
2. Alcohol wipes

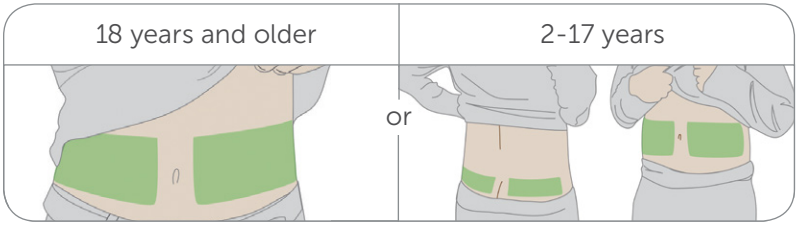
Before using, check everything. Don't use any item that's damaged or past its expiration date.

Now you're ready to insert the sensor and attach the transmitter.

5.3 Sensor Insertion

Choose Sensor Site

It's important to choose a comfortable site appropriate to your patient's age group.



People from 2 to 17 years old can use either their upper behinds or bellies. Those 18 years and older can only use their belly.

Tips

Do:

- Place at least 3 inches from an insulin pump infusion set or injection site
- If needed, shave the area so adhesive patch sticks securely
- Make sure area is clean and free of lotions, sunscreen, perfumes, and medications
- Insert into an area with some padding and avoid muscle
- Place away from waistband, muscles, scarring, tattoos, irritation, and bones

Don't:

- Use bony sites, such as over ribs

PRECAUTION

Do: Choose your patient's sensor insertion site carefully.

Choose a site:

- At least 3 inches from insulin pump infusion set or injection site
- Away from waistband, muscles, scarring, tattoos, irritation, and bones
- Unlikely to be bumped, pushed, or laid on when sleeping

Why: Inserting the sensor in these areas may affect sensor glucose readings.

Consequences: Your patient could have a severe low or high glucose event.

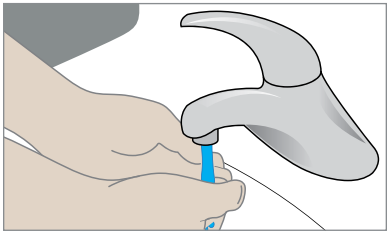
Optional: Help Patch Stay On

Are you concerned about the patch not sticking on your patient? There are two ways to help keep it on – put overpatch or medical tape (such as Blenderm™) over the adhesive patch.

To order overpatch, call Technical Support. Do not put tape over the transmitter.

Insert Sensor

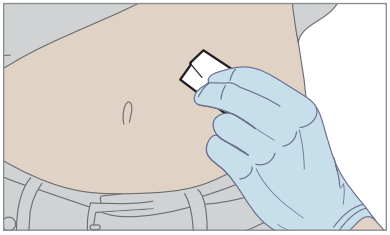
STEP 1 of 8 **Insert Sensor**



Wash and dry hands.

Put on safety gloves.

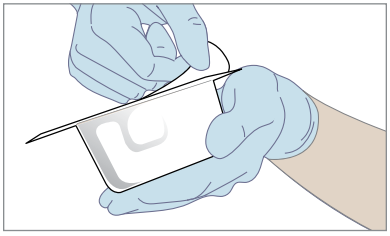
STEP 2 of 8 Insert Sensor



Clean site with alcohol wipe.

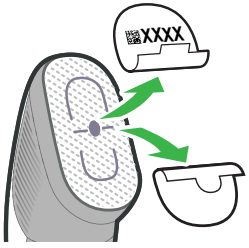
Let dry.

STEP 3 of 8 Insert Sensor



Open applicator pack.

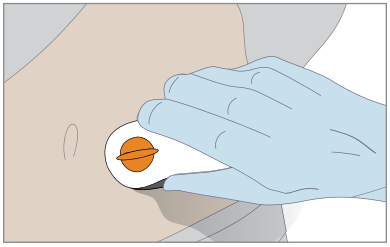
STEP 4 of 8 Insert Sensor



Remove both labels.

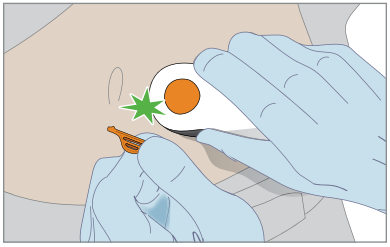
Don't touch adhesive.

STEP 5 of 8 Insert Sensor



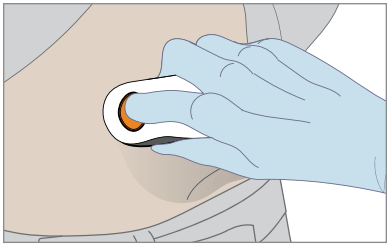
Place applicator on skin before removing safety guard.

STEP 6 of 8 Insert Sensor



Fold and break safety guard.

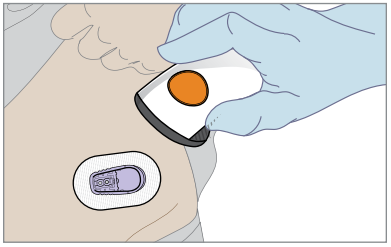
STEP 7 of 8 Insert Sensor



Press button.

STEP 8 of 8

Insert Sensor



Remove applicator.

Finished!

Once the sensor has been inserted, attach the transmitter.

Attach Transmitter

STEP 1 of 6

Attach Transmitter

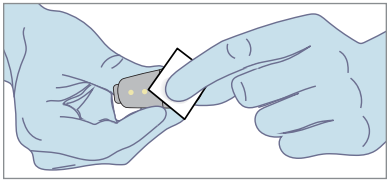
Is your patient unblinded?

Put transmitter serial number (SN) sticker on their Unblinded CGM Patient material.

The transmitter SN is for your unblinded patient's app set up.

Don't give it to your blinded patient. If you do, your blinded patient may get unblinded data without you knowing.

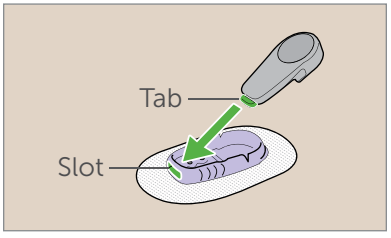
STEP 2 of 6 Attach Transmitter



Clean transmitter back.

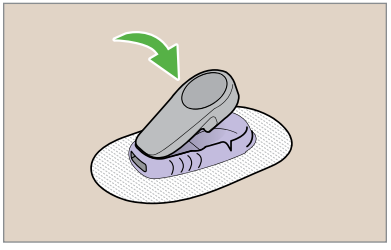
Only use alcohol.

STEP 3 of 6 Attach Transmitter



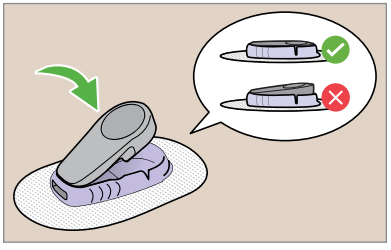
Insert tab into slot.

STEP 4 of 6 Attach Transmitter



Snap firmly into place.

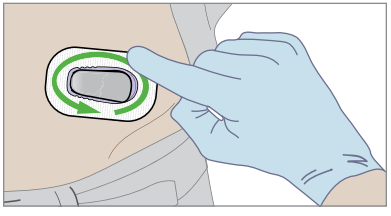
STEP 5 of 6 Attach Transmitter



Check your transmitter:

Is it flat and snug in its holder?

STEP 6 of 6 Attach Transmitter



Rub adhesive patch 3 times.

Finished!

The sensor session begins after you snap the transmitter into the transmitter holder. It doesn't matter if your patient is using the system in a blinded or unblinded mode, your next step is to use the reader to check the system status. For more information about the reader, see your Dexcom G6 Pro Reader User Guide.

5.4 Next Steps for Your Patient

The next steps for your patient depend on if they are blinded or unblinded.

Blinded

Your visit is almost done! Make sure you reviewed and completed the Blinded CGM Patient material before they leave. The Blinded CGM Patient material covers:

- System overview
- Safety statements
- Removing sensor and transmitter
- What to do with the transmitter after removal
    - Remember to tell the patient to return the sensor within 30 days of the session start. If they don't, the transmitter data is lost and you will not be reimbursed.

While the material covers removing the sensor and transmitter, you can also go to Chapter 10 for removal information. Chapters 5–9 don't pertain to blinded patients. Blinded patient information starts again at Chapter 10 and continues through the Appendices.

Unblinded

The next steps for your unblinded patient are learning about the system, the home screen, alarm and alerts, along with making treatment decisions. In other words, using the G6 Pro on a day-to-day basis.

Using the Unblinded material, review:

- System overview
- Safety statements
- Setting up the app
- Home screen
- Treatment decisions
- Removing sensor and transmitter
- What to do with the transmitter after removal
    - Remember to tell the patient to return the sensor within 30 days of the session start. If they don't the transmitter data is lost and you will not be reimbursed.
- Their return visit

Page intentionally left blank

Chapter 6: Unblinded – Using the G6 Pro

In this chapter, you'll learn what your unblinded patients need to know to use with the G6 Pro's System:

1. Setting system up
    - Compatibility
    - App
    - Set up wizard
2. Unblinded
3. Using the G6 Pro-Unblinded
    - Home screen

6.1 Setting Up System

Your unblinded patient can set up the app in your office or in their home, all they need to do is follow the in-app instructions and the unblinded patient materials. Make sure you complete the Unblinded CGM patient material by giving them the transmitter serial number (SN), and writing down their high and low alerts. Remember, your patient can go unblinded only if their smartphone and operating system are compatible with the G6 Pro.
Go to dexcom.com/compatibility.

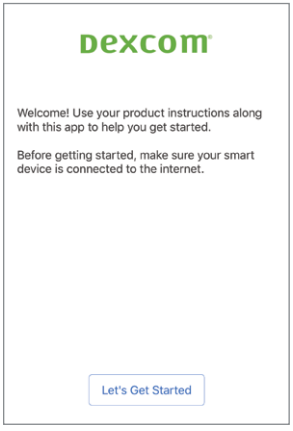
To get started, have your patient download the G6 Pro app from the app store. Once downloaded, the patient opens the app and follows the onscreen setup instructions and unblinded patient materials. They'll use the materials you filled out for them for the low/high alerts and transmitter SN. Let your patient know if their app gets closed, they won't get their sensor readings or alerts until they restart the app again.

What Patient Does: Setting Up System

STEP 1 of 4 Setting Up System

Download and open the Dexcom G6 app.

STEP 2 of 4 Setting Up System



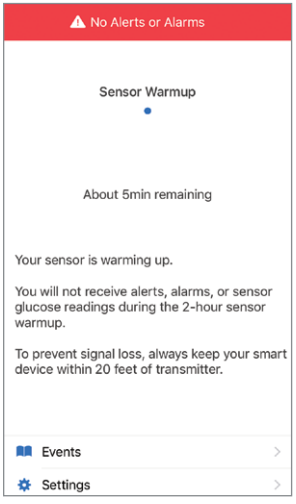
Follow onscreen instructions.

STEP 3 of 4 Setting Up System

When prompted, patient enters transmitter SN from materials.

Enters code starting with "3".

STEP 4 of 4 Setting Up System



Confirmation app setup was successful.

If still in 2-hour warmup, app screen shows countdown.

If 2-hour warmup is over, app screen shows home screen.

Finished!

After inserting the sensor, your patient will have a 2-hour sensor warmup. During this time the sensor is getting used to your patient's body. After the 2-hour warmup, your patient begins getting their sensor readings.

If your patient turns off their smart device, when they turn it back on, the app must be restarted.

6.2 Home Screen Overview

Your patient will spend most of their time viewing the home screen. It gives your patient their G6 Pro sensor glucose readings (sensor readings) and trend information. The home screen allows them to navigate to other app features.

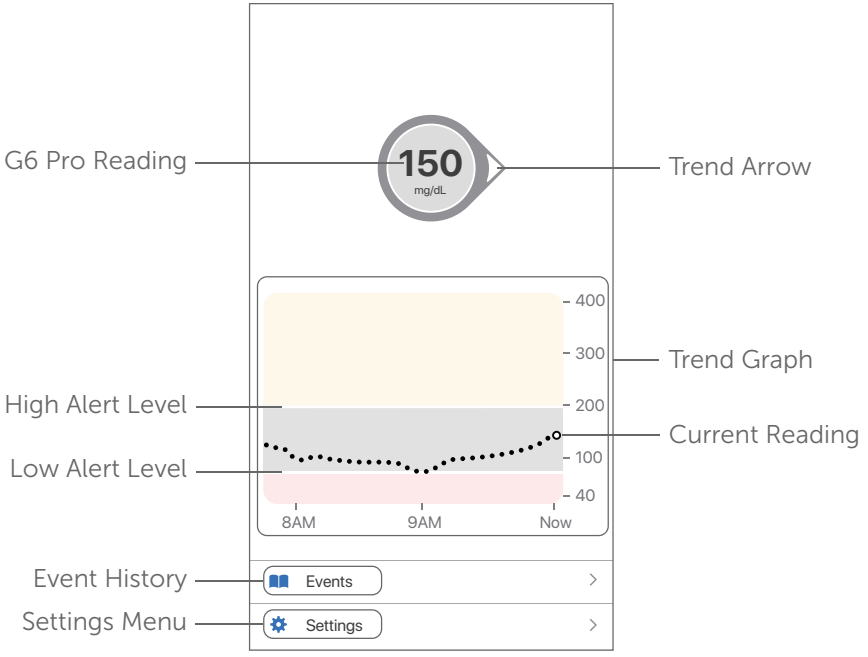
The next section labels all the home screen features, then reviews interpreting your patient's sensor readings, trend arrows, and graph, followed by navigating to other functions.

Home Screen Features

The following are home screens from the Apple app and Android app. While the sensor glucose information is the same, navigation is slightly different between the two operating systems.

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

Apple



Siri:

Your unblinded patient can ask Siri to tell them their G6 Pro readings and trend anytime their app is running! When Siri answers, their graph shows on the iPhone's lock screen. Tell patient to go to their app settings and set up a Siri shortcut.

Android


SETTINGS
Settings Menu
G6 Pro Reading
150
mg/dL
Trend Arrow
400
300
200
100
40
Trend Graph
High Alert Level
Current Reading
Low Alert Level
8AM
9AM
Now
Event History
Events

Sensor Readings, Trend Arrow, and Graph

Most Recent Reading

On the home screen, numbers and color tell your patient what their reading is now. The number is the sensor reading, updated every 5 minutes. The number's background color shows whether the sensor reading is low, high, or in the target range.

Red = Low

Yellow = High

Gray: In Target

Trend Arrows

Trend arrows show where your patient's glucose is heading.

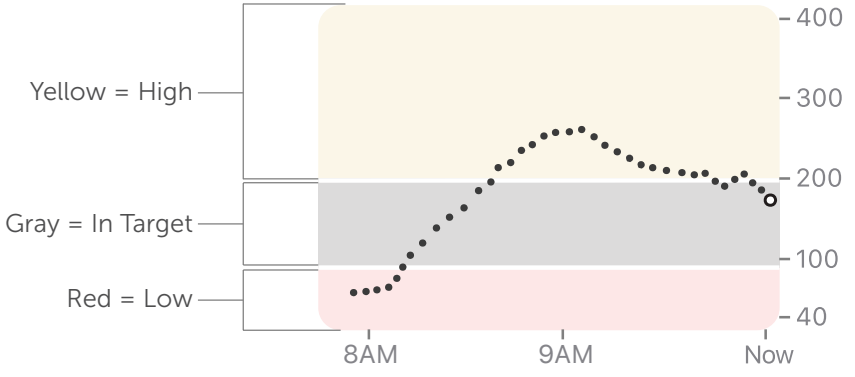
Trend Arrows	What it Means
	**Steady** Changing less than 1 mg/dL each minute
	**Slowly rising or falling** Changing 1–2 mg/dL each minute
	**Rising or falling** Changing 2–3 mg/dL each minute
	**Rapidly rising or falling** Changing more than 3 mg/dL each minute
	**No arrow** Can't determine trend

Past Readings

The dot on the right is the current sensor reading. The dots to the left are sensor readings taken earlier. A smoothing algorithm is applied to trend graph.

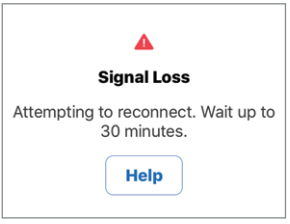
The graph's background colors also show if the sensor readings are in the target range:

- Gray: Sensor readings are in the target range
- Yellow: Sensor readings are above the High Glucose Alert setting
- Red: Sensor readings are below the Low Glucose Alert setting



Home Screen Issues

Sometimes your patient doesn't get G6 Pro readings or they won't see a number, just a message. Those are times they won't get alarm/alerts.

What You See	What It Means
	Your patient's G6 Pro reading is 40 mg/dL or below.
	Your patient's G6 Pro reading is 400 mg/dL or above.
	Error message means the G6 Pro isn't working correctly. Your patient won't get alarm/alerts or readings. (See Appendix A.)

6.3 Home Screen Navigation

Access other G6 features using the navigation icons.

App Navigation

Navigation Icon	What It Means
Settings 	Tap to: • Customize your patient's CGM, such as alert settings.
Events 	Tap to add or delete these events: • Carbohydrates • Insulin • Stress or illness • Exercise

Chapter 7: Alarm, Alerts, and Sounds

The alarm and alerts help your patient stay on track by telling them when they're outside their target range and when they're at or below 55.

The Urgent Low Alarm can't be changed or turned off, however your patient can customize alerts. From their smart device: **Menu** > **Alerts**.

Have your patient make all alerts visible on their smart phone's lock screen.

Depending on the device and its settings, the G6 Pro will make a noise, or vibrate, or a combination of both. Glucose alarm and glucose alerts will override the app's mute/silent feature.

If the patient's phone is muted, they will still get the following alerts:

- Urgent Low Alarm
- Transmitter failure
- Sensor failure

7.1 Glucose Alarm and Alerts

Urgent Low Alarm

There is only one alarm, the Urgent Low Alarm. The Urgent Low Alarm tells your patient they are at or below 55 mg/dL.

Low and High Alerts

Don't forget to write down your unblinded patient's low and high alert levels on their material.

Low Alert

This notifies your patient when their sensor readings are below their target glucose range.

High Alert

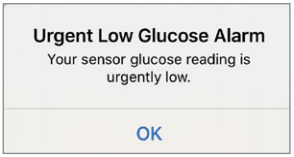
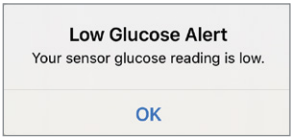
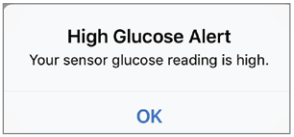
This notifies your patient when their sensor readings are above their target glucose range.

How Your Patient is Notified

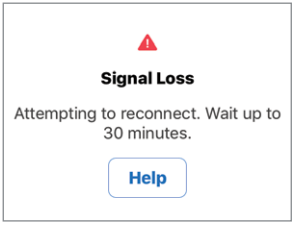
If your patient's smart device's sound is on, initially it vibrates and makes a noise. If the sound is turned off, it only vibrates. Each alert has its own vibration pattern.

For the list of sounds and vibration patterns, see Appendix I.

Low Alarm and Glucose Alerts

What Your Patient Sees	What It Means
	**Urgent Low Alarm** There is only one alarm. Sensor glucose is at or below 55. Can't change or turn off Urgent Low alarm.
	**Low Alert** Sensor glucose reading is below the set target range. On by default. Can turn off Low Glucose alert. Discuss with your patient where to set their Low Glucose alert.
	**High Glucose Alert** Sensor glucose reading is above the set target range. On by default. Can turn off High Glucose alert. Discuss with your patient where to set their High Glucose alert.

Signal Loss

What Your Patient Sees	What It Means
	App and transmitter aren't talking. Make sure your patient is within 20 feet of the app. Won't receive glucose readings or Alarm/Alerts. Tell patient: Use blood glucose (BG) meter to check glucose and make any treatment decisions.

There are many more alerts that your patient can't customize, see Appendix I.

Chapter 8: Events

8.1 Introduction

During your patient's sensor session, suggest that they keep track of exercise, their carbs, and dosing. They can either do it in a journal or use Events in G6 Pro. Keeping track of their actions or circumstances helps them see how their actions affects their glucose patterns. In this chapter, your patient can learn how to enter events.

After this chapter, you'll be able to:

- Define an event
- Describe each type of event
- Show your patient how to add event to the app

8.2 Events Overview

An event is an action or situation that affects your patient's glucose levels. With the G6 Pro, they can track daily events so they can reflect on their effect on their glucose trends. Once entered into the app, events show in Dexcom reports generated by Dexcom CLARITY. The reports help you review how each event influenced your patient's glucose trends. You can use the reports with your patient and create a plan to manage their diabetes. Your patient needs to give you permission to view their Dexcom CLARITY report. See the Dexcom CLARITY user guide for more information.

8.3 Types of Events

G6 Pro lets your patient keep track of insulin, carbs, exercise, and health-related events.

After adding an event, it shows under the heading Events, in the app (landscape view), and in Dexcom CLARITY reports.

The next section outlines how your patient enters a long-acting insulin event.

Enter Long-acting Insulin

STEP 1 of 4 **Enter Long-acting Insulin**

From the Home screen, tap **Events**.

STEP 2 of 4 **Enter Long-acting Insulin**

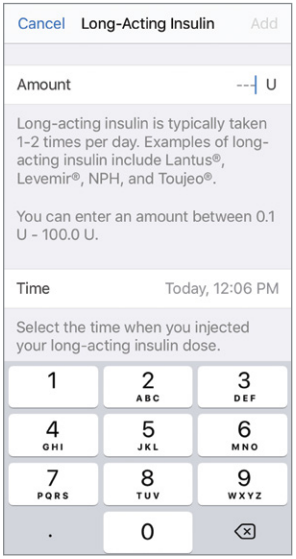
Then, tap **Add Event**.

STEP 3 of 4 **Enter Long-acting Insulin**

Tap **Long-Acting Insulin**.

STEP 4 of 4

Enter Long-acting Insulin



How much insulin did your patient give?

Enter insulin units for each dose, up to 250 units.

Can't enter the type of insulin, only dosage.

Finished!

8.4 Other Events

Dosing insulin is not the only Event your patient can enter in to the G6 Pro.

There are three other Event categories:

1. Carbs
2. Exercise
3. Health

The third category, Health, has more options:

- Illness
- Stress
- Feel High
- Feel Low
- Cycle
- Alcohol

Adding the other events is very similar to adding insulin, just follow the screen prompts.

Events Tips:

- **Carbs:** Add up all carb grams for the snack or meal, up to 250 grams
- **Exercise:** Select each exercise's intensity level and duration. Type of exercise isn't an option
- **Health-related events:**
  - Illness: Is a cold, flu, or any other temporary illness affecting your patient's well-being?
  - Stress: Under stress or feeling anxious?
  - High symptoms: Feeling high blood glucose (BG) symptoms?
  - Low symptoms: Feeling low BG symptoms?
  - Cycle: Patient on their period?
  - Alcohol: Having a glass of wine, beer, or cocktail?

For their convenience, there's no need for your patient to stop everything and enter events as they're happening. When they have a moment, your patient can enter past events.

Events are meant to be entered as individual occurrences: Don't enter daily totals; each event is entered separately.

8.5 Edit or Delete an Event

If your patient accidentally entered the wrong information, they use the Events screen to delete and re-enter incorrect events.

Delete Event

STEP 1 of 4 Delete Event

Tap **Events**.

STEP 2 of 4 Delete Event

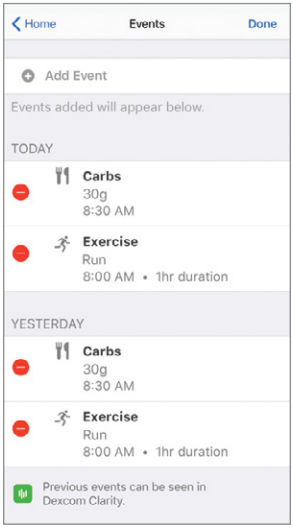
Events shows your patient their recent events, newest on the top.

Apple (shown): Tap **Edit**.

Android: Tap the pencil icon.

After tapping the edit icon (differs based on the smart device), to delete an added event, use the red icon. Follow the smart device's prompts to delete an event.

STEP 3 of 4 Delete Event

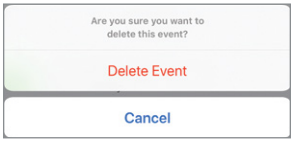


Events added have a red icon, which shows they can be deleted.

Apple (shown): Red icon is a circle on the left.

Android: Red icon is a trash can on the right.

STEP 4 of 4 Delete Event

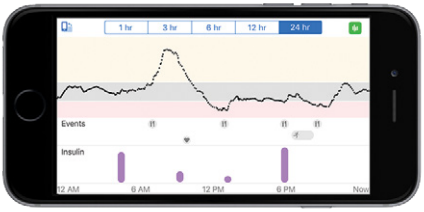


Confirm by tapping **Delete Event**.

Finished!

8.6 App: View Events

Turn smart device to landscape to view events – carbs, exercise, and health. At the bottom of the screen are the recorded insulin doses. Touch and hold a spot on the screen to see detailed information for that time.



Tap labels along top to change time scale. Touch and hold on graph to see details for that time.

Page intentionally left blank

Chapter 9: Treatment Decisions

G6 Pro gives your patient the freedom of making treatment decisions without the need to take a fingerstick. In most cases, if they have a number and an arrow, they have all the information they need.

However, there are times when they may want to use both their meter and the G6 Pro or need to use the meter instead of the G6 Pro. And sometimes, it's best not to treat, just watch and wait.

Review with your patient what works best for when making treatment decisions.

9.1 When to Use Meter and the G6 Pro

To gain confidence in the system, and if your patient wants, they can use both the meter and their G6 Pro. Using their meter, they confirm their sensor readings allowing them to see how:

- Accuracy with newly inserted sensors may vary
- Sensor readings may be different depending on the situation (meals, exercise, first day of use, etc.)

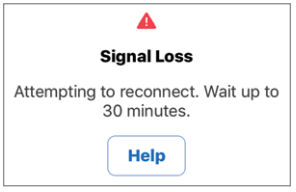
9.2 When to Use Meter Only

There are times when your patient should only rely on their meter for treatment decisions.

When in doubt: If your patient's symptoms don't match their readings, have them take a fingerstick with their meter.

When in doubt get their meter out.

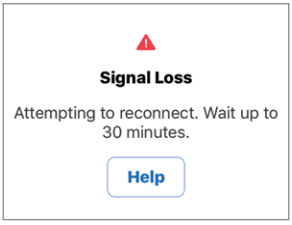
No number, no arrow, no treatment decision: Always use a meter if they don't have a number and arrow.



Treatment Decision: Meter or G6 Pro?

Meter Only

When Your Patient Sees	Notice
	Number, no arrow Not enough back to back readings • No G6 Pro treatment decision • Use meter
	Arrow, no number Below 40 or above 400 mg/dL • No G6 Pro treatment decision • Use meter

When Your Patient Sees	Notice
	No arrow, no number There's some type of system error • No G6 Pro treatment decision • Use meter

9.3 When to Watch and Wait

Whether your patient uses their meter, the G6 Pro, or both, there are times when they shouldn't treat at all, just watch and wait.

Stacking Insulin: Remind your patient not to stack insulin by taking doses too close together. Your patient doesn't want to go low; wait at least 2 hours between doses.

Sometimes, it's best to watch and wait.

9.4 Using the Trend Arrows

To make a treatment decision using the G6 Pro, your patient needs both a number and arrow. To get a trend arrow, your patient needs three back-to-back readings. No trend arrow? Their sensor reading might not be up-to-date, and your patient needs to use their meter to treat.

The trend arrows show the sensor readings are current, and their direction help dose.

An up arrow? Take a little more insulin.

A down arrow? A little less.

9.5 Practice Making Treatment Decisions

Review treatment decision scenarios with your patient. Below are some scenarios that may represent their typical day.

Ask your patient "What would you do if...?"

App Screen	Action
Your Low Alert wakes you up. You see: 	**What:** You eat an energy bar without doing a fingerstick. **Why:** You have a number and arrow, so no need for a fingerstick. An 80 mg/dL with the single down arrow means your glucose is dropping. In 15 minutes, you could be 35 mg/dL.

App Screen	Action
Sitting down for breakfast, you see: 	**What:** You dose to cover your meal. **Why:** You have a number and arrow, so no need for a fingerstick. Because of the up arrow, you take a little more insulin. 
Forty-five minutes after taking what you think was the correct dose to cover breakfast, you get a High Alert 	**What:** You decide to watch and wait and not dose again. An hour later you're back in target. **Why:** Insulin takes time to work. It's important not take insulin doses too close together, or stack insulin. Wait at least 2 hours. You don't want to go low. Sometimes it's best to watch and wait.
At lunch, you see: 	**What:** You dose to cover your meal. **Why:** You have a number and arrow, so no need for a fingerstick. Because of the down arrow, you reduce your insulin amount. 

App Screen	Action
Mid-afternoon, you see: 	**What:** If you treat, use your meter. **Why:** You have a number and no arrow. Without an arrow, you don't have a trend, and your number may not be up-to-date. You don't have enough information to make a treatment decision. No number, no arrow, no G6 Pro treatment decision.
Just before dinner, you feel a little shaky and sweaty. You see: 	**What:** Before doing anything, you take a meter reading. **Why:** Your symptoms don't match your sensor readings. You know your body, listen to it.

Showing your patient how to make treatment decisions will help them get the most out of their G6 Pro experience. And of course, if there is something wrong with their smartphone, tell your patient to use their meter if they want to measure their glucose.

In the next chapter, you'll learn what to tell your unblinded and blinded patients when their sensor session is over.

Chapter 10: Blinded/Unblinded End of Sensor Session

10.1 Introduction

This chapter reviews what your unblinded patient sees as their sensor session expires. It also reviews how both your blinded and unblinded patients remove the sensor and transmitter.

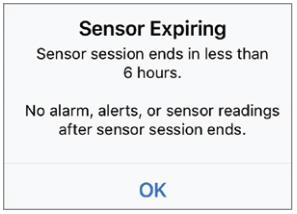
After this chapter, your patient will be able to:

- Unblinded: Identify end of sensor session notifications
- Unblinded/Blinded: Remove sensor and save transmitter.

10.2 Unblinded – End Your Sensor Session

When the 10-day sensor session is almost over, G6 Pro sends notifications letting your unblinded patient know their sensor session is ending.

Notification Example



Open app to confirm.

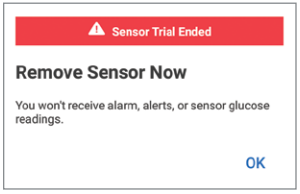
What it means:

- Notifications let your patient know their sensor session is ending soon. They get four notifications before the session ends: 24 hours, 6 hours (shown above), 2 hours, and 30 minutes before.
- Clock counts down until session ends.
- Continue to get alarm/alerts and sensor readings until session is over.
- Patient can end session early or wait.

Sensor Session Over

Open app to confirm.

App Notification



What it means:

- Sensor session is over
- Your patient won't get any more alarm/alerts or sensor readings.

Sound and Vibration Prompts

The smart device's beeps/vibrations tell your patient the sensor session is ending in 30 minutes, has just ended, or the sensor failed and the session stopped.

The initial notification is one vibration. If not confirmed in the app, the app vibrates and beeps twice, 5 minutes apart.

Once a sensor session has expired, tell your patient to remove their sensor and transmitter. After removing them, have your patient put them in a resealable bag and return everything back to your office.

10.3 Patient Materials

Each part has a section for you to complete, telling your patient when to remove the sensor and transmitter.

Your Unblinded CGM patient has both the app and their materials to tell them when to remove the sensor. Your Blinded CGM patient only has their printed materials. Make sure you fill out Section C so they know when to remove the sensor.

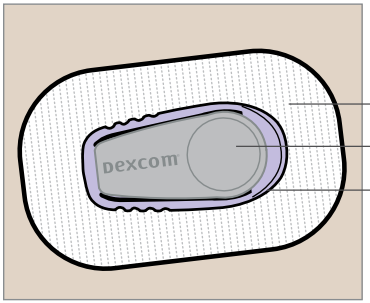
10.4 Blinded and Unblinded – Remove G6 Pro

Removing the sensor and applicator is the same for both blinded and unblinded patient. At the end of the sensor session, they simply peel off the G6 Pro.

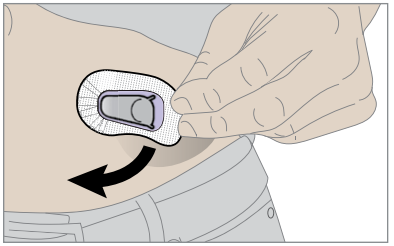
Remove Sensor

STEP 1 of 3 **Remove Sensor**

Review the parts.



STEP 2 of 3 **Remove Sensor**

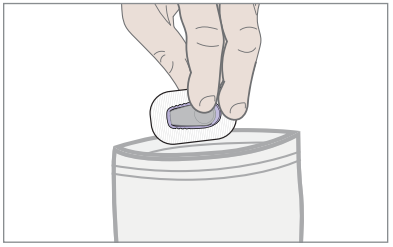


Grab edge of adhesive patch.

Peel off like a Band-Aid®.

STEP 3 of 3

Remove Sensor



Place in a sealable bag for HCP.

Once your 10-day sensor session ends, follow the instructions below to remove the patch from your body. Return to your healthcare professional (see Section D). Sensor must be returned within 30 days of starting session.

Finished!

What's Next?

Once your patient has returned their transmitter, your next step is to download its data into the optional reader, then plug reader into your PC to upload the data to Dexcom CLARITY. Once the data has been uploaded into Dexcom CLARITY, you can generate reports to review with your patient.

See the G6 Pro Reader user guide on downloading patient data, and the Dexcom CLARITY user guide on how to generate reports.

Throw away patch, with the holder and sensor attached, following your local guidelines for disposal of blood-contacting components.

Appendices

- FAQs and Troubleshooting
- Glossary
- Technical Support
- Maintenance of G6 Pro System
- Going Through Security
- Warranty
- Technical Information
- Label Symbols
- Alerts and Notifications
- Index

Page intentionally left blank

Appendix A: FAQs and Troubleshooting

Is there an error icon and no sensor reading? Or maybe the app beeped and vibrated? G6 Pro may have an issue; your patient probably won't get sensor readings until it's fixed.

Read about the issues here or tap the error icon for more information. Still have questions? Go to the FAQ section on the Dexcom website: dexcom.com/faq.

After looking at this chapter, are you still not sure what to do? If your problem isn't listed, or the solution here doesn't fix it, contact Technical Support at:

- **General:** 1.844.607.8398, 24/7 Toll Free USA
- **Healthcare Professionals:** 1.844.436.2271, 6 am–6 pm (PST), Monday–Friday

A.1 Alarm/Alerts and G6 Pro Readings

Alarm/Alerts Sound While Display Device Is Muted/ Silenced

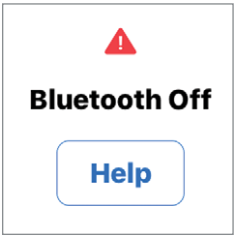
Problem
Smart device sounds even though it is muted/silenced.
Action
No action. To make sure your patient doesn't miss a high or low, alarm/alerts sound anyway. **Exception:** If an Apple smart device is silenced, no Signal Loss alert.

Cannot Hear Alarm/Alerts

Problem
Can't hear alarm/alerts on app.
Action
Display device beeps, vibrates, and displays a message when your patient first gets an alarm/alert. If your patient can't hear alarm/alerts on app, verify that the app, *Bluetooth*, volume, and notifications are on. If your patient restarts smart device, they must reopen the Dexcom app.

A.2 Error Messages

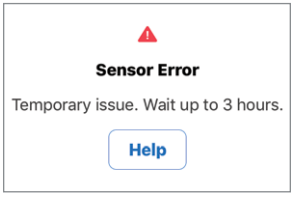
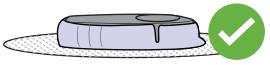
Bluetooth Off

	Problem
	Phone's *Bluetooth* is off, so the transmitter can't communicate with the app. Not getting G6 Pro readings. Display device and transmitter not connecting.
Action	
Use meter. No glucose alarm/alerts or G6 Pro readings until fixed. Turn *Bluetooth* on in phone settings. Wait up to 10 minutes for transmitter and app to communicate.	

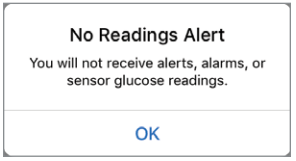
High or Low Instead of a Sensor Reading

	Problem
	Instead of displaying a sensor reading, screen shows High or Low.
Action	
Wait. The system is working correctly. When patient is above 400, system says "High." Below 40, it says "Low."	

No Readings

	Problem
	App isn't getting sensor readings. No glucose alarm/alerts or G6 Pro readings until fixed. Use meter. Tap alert to get more information.
Action	
Check transmitter: 	Is it flat and snug in its holder? Wait up to 3 hours while the system fixes itself. If not corrected after 3 hours, contact Technical Support.

No G6 Pro Readings: No Readings Alert

	Problem
	Not getting G6 Pro readings for the last 20 minutes.

Action

No glucose alarm/alerts or G6 Pro readings until fixed. Use meter.

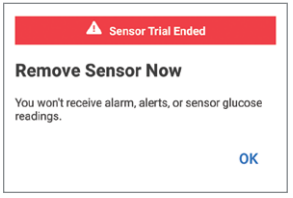
In app, tap alert to get more information.

Check transmitter: Is it snapped into the holder?

Wait up to 3 hours while the system fixes itself. If not corrected after 3 hours, contact Technical Support at:

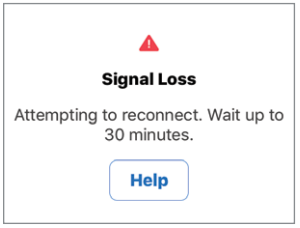
- **General:** 1.844.607.8398, 24/7 Toll Free USA
- **Healthcare Professionals:** 1.844.436.2271, 6 am–6 pm (PST), Monday–Friday

No G6 Pro Readings: Sensor Failed Alert

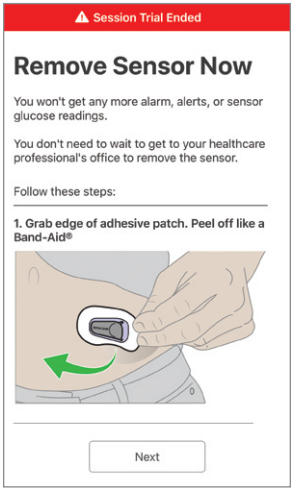
	Problem
	Not getting G6 Pro readings.

Action
No glucose alarm/alerts or G6 Pro readings. Use meter. Tap alert to get more information. If your sensor doesn't work, contact Technical Support at: • **General:** 1.844.607.8398, 24/7 Toll Free USA • **Healthcare Professionals:** 1.844.436.2271, 6 am–6 pm (PST), Monday–Friday

Signal Loss

	Problem
	Transmitter and app aren't communicating. Not getting G6 Pro readings.
Action	
Use meter. No glucose alarm/alerts or G6 Pro readings until fixed. Move smartphone within 20 feet of the transmitter. Remove barriers (like walls or metal) between smartphone and transmitter. If patient is in water, they need to keep smartphone closer than 20 feet. If that doesn't work, turn *Bluetooth* off and on. Wait 10 minutes. If that doesn't work, restart the smart device and reopen the Dexcom app. Once the problem has been fixed, older readings will show up on the trend graph.	

Transmitter Failed

	Problem
	Your patient's transmitter is no longer working.

Action
Contact Dexcom Technical Support: • **General:** 1.844.607.8398, 24/7 Toll Free USA • **Healthcare Professionals:** 1.844.436.2271, 6 am–6 pm (PST), Monday–Friday Follow steps on screen to: Remove this sensor and stop the sensor session in app.

Transmitter Not Found

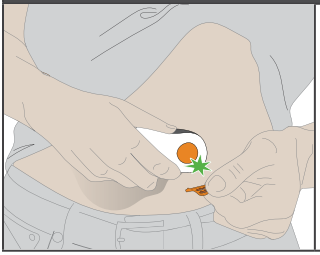
	Problem
	App isn't communicating your patient's transmitter.

Action
Check the transmitter SN: Compare the SN on materials to the SN in the app (**Settings**>**Transmitter**>**Transmitter SN**). If they don't match, re-enter the transmitter SN at **Settings**>**Transmitter**>**Pair New**. Check the transmitter: Is it flat and snug in its holder? Wait up to 3 hours while the system fixes itself. If not corrected after 3 hours, contact Customer Support for a replacement.

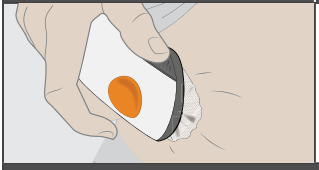
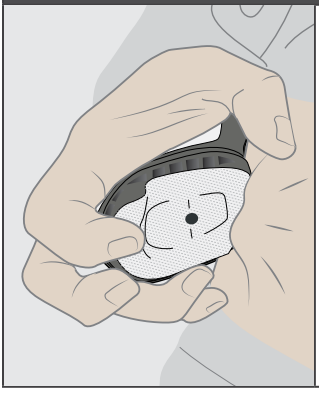
A.3 Sensor or Applicator Issues

Is the applicator stuck? Having trouble with the sensor? Review the solutions here to find a fix.

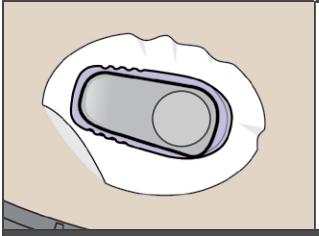
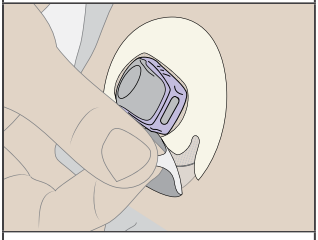
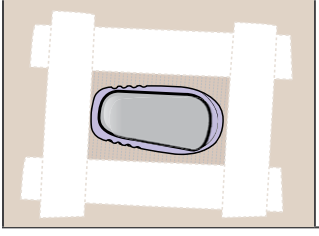
Orange Button Stuck

Problem
Can't push the applicator orange button in.
Action
 Fold and break off safety guard before pushing orange button.

Applicator's Stuck

	Problem
	Don't panic! The applicator is stuck to your patient's skin.
Action	
	Remove the applicator and adhesive patch: Gently pull the applicator up until you see the adhesive patch. Hold the front edge of patch and peel away from skin. Rock the applicator backwards, off your patient's body. Make sure the sensor isn't left on the skin. Don't try to reuse the applicator. Call Technical Support.

Adhesive Patch Won't Stick

	Problem
	The adhesive patch is peeling off.
Action	
Overpatch 	Put overpatch or medical tape (such as Blenderm™) over the adhesive patch. To order overpatch, call Technical Support. Do not put tape over the transmitter. Prevent peeling before inserting the sensor by: • Using adhesive products (such as Mastisol®, Skin Tac™, etc.) under the patch. • Thoroughly rubbing the patch onto skin.
Medical Tape 	

Adhesive Backing Won't Come Off

Problem
Backing won't come off the patch
Action
Lift the backing by the tab

Stopping Sensor Session

Problem
Your patient needs to end their sensor session early because of: • Personal reasons • Error notifications telling them to end sensor session • Error or wait screens that won't go away • Sensor coming out of body

Action	
	To end the sensor session early in the app, go to Stop Sensor in the Settings menu. After you've stopped your sensor, you can remove it.

Stopping sensor problems

Make sure:

- Sensor hasn't expired
- You selected a good insertion site
- Nothing is rubbing against transmitter holder, like a seatbelt or waistband
- Insertion site is clean and dry before sensor insertion
- Transmitter is snapped securely in transmitter holder
- Transmitter holder isn't dislodged and patch isn't peeling

Water and Your System

	Problem
	Your patient wants to swim, take a shower, or jump in the hot tub, but they're worried about getting water on the system.
Action	
Once snapped into place, the transmitter is water resistant. Swim, shower, or take a bath without worrying about the system.	

A.4 Accuracy

G6 Pro Readings Do Not Match Symptoms

	Problem
	G6 Pro readings don't match how you feel
Action	
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. *Tips for Accuracy* Many factors can contribute to a difference between the meter value and the G6 Pro reading. • Different fluids: Remember that the meter measures blood and the G6 Pro measures interstitial fluid. • Clean hands for fingerstick: The most common reason is hands that weren't perfectly clean for the fingerstick. Start over. Patient should wash their hands thoroughly with soap and water and dry them. Then test again. • Newly inserted sensor: For some patients and some sensors, the accuracy they experience with each newly inserted sensor may vary. They should take a fingerstick if their symptoms don't match their G6 Pro readings. • Meter strips: The meter strips weren't stored correctly or are expired.	

A.5 App

Can’t Download App

Problem
Patient got a new smart device and can’t download the Dexcom app
Action
Check dexcom.com/compatibility for a list of smart devices that work with the G6 Pro app. If it’s a compatible device, stop sensor session on the current smart device. Install the app on the new smart device. Follow the app screens to get the app set up on the new smart device. Your patient’s glucose history and settings will display on the new smart device.

Appendix B: Glossary

A1C	Blood test used to diagnose type 1 or 2 diabetes and to gauge how well you're managing your diabetes. A1C reflects your average blood sugar level for the past 2 to 3 months.
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. Don't 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 Pro 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.
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 safety statement outlining specific situations where the G6 shouldn't be used because it may be harmful to you. The risk of use clearly outweighs any possible benefit.
Default	A manufacturer's preset option for a device setting.
Hyperglycemia	High BG. Same as "high" or high blood sugar. Hyperglycemia is characterized by an excess of glucose in the bloodstream. It's important to treat hyperglycemia. If left untreated, hyperglycemia can lead to serious complications.
Hypoglycemia	Low BG. Same as "low" or low blood sugar. Hypoglycemia is characterized by a low level of glucose in the bloodstream. It's important to treat hypoglycemia. If left untreated, hypoglycemia can lead to serious complications.
Indications	How, for what purposes, and under what circumstances you should use the G6.
iOS	Operating system used for Apple smart devices.
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. Don't install the G6 Pro app on a jailbroken or rooted smart device. It may not work correctly.
mg/dL	Milligrams per deciliter. The standard unit of measure for BG readings in the United States.
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.

Peripheral Device	Hardware connected to your smart device. For example, a *Bluetooth* headset, Apple watch, or other smart watch.
Precaution	A safety statement regarding any special care to be exercised by you or your HCP 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 Glucose Reading	A BG measurement taken by the G6. Typically referred to as "G6 Pro readings" in these instructions.
Sensor Session	The 10-day monitoring period after inserting a new sensor. During this time frame, your glucose is being monitored and reported every 5 minutes, with data being sent to your display device(s).
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. Doesn't 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.

Appendix C: Technical Support

User Assistance

Dexcom Website:

dexcom.com

Dexcom Address:

6340 Sequence Drive San Diego, CA 92121

Technical Support

For Dexcom product questions and troubleshooting issues, contact Technical Support at:

- **General:** 1.844.607.8398, 24/7 Toll Free USA
- **Healthcare Professionals:** 1.844.436.2271, 6 am–6 pm (PST), Monday–Friday

Page intentionally left blank

Appendix D: Maintenance of G6 Pro System

D.1 Applicator/Sensor

- Keep in sterile packaging until ready for use
- Don't start a sensor past the Use By Date:
  - May provide inaccurate G6 Pro sensor readings
  - May be unsterile
  - Use-by date is on package in year-month-day (YYYY-MM-DD) format
- Don't use lotion, sunscreen, insect repellent, or similar substances on sensor

D.2 Transmitter

- Keep in box until ready for use, then check transmitter and don't start if damaged
- Use-by date is on package in year-month-day (YYYY-MM-DD) format
- Transmitter is single use, it can't be transferred to another person
- Transmitter is water resistant
  - Don't use lotion, sunscreen, insect repellent, or similar substances on transmitter
  - Clean outside of transmitter only with isopropyl alcohol; let dry before use

D.3 Storage

Storing system correctly helps prevent system failures.

G6 Pro System Components

- Store between 36°F and 86°F
  - Storing outside this range may cause inaccurate readings
  - May be stored in refrigerator if within temperature range
  - Store in cool, dry place; don't store in a parked car on a hot day or in a freeze
- To keep system working safely, do not change any system component
  - Only use the transmitter and sensor from the same package

Sensor

- Store in sterile packaging until ready for use

Transmitter

- Keep protected when not in use

D.4 System Disposal

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

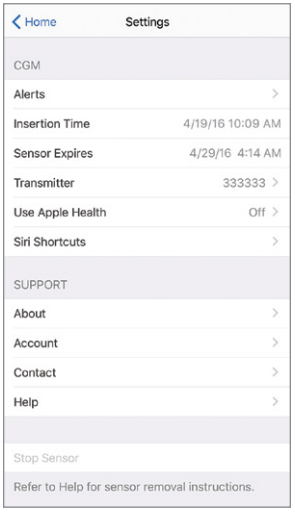
D.5 Checking System Information

Your patient can check their app for information about their CGM system any time.

STEP 1 of 2 Check CGM Settings

Tap **Settings**.

STEP 2 of 2 Check CGM Settings



To update and/or check:

- CGM information: Insertion date and time, transmitter SN, when sensor expires
- Transmitter software version
- Support: Online help, account, and contact information

Finished!

Page intentionally left blank

Appendix E: Going Through Security

Patient should tell the Security Officer they're wearing a continuous glucose monitor and want to be hand-wanded or get a full-body pat-down with a visual inspection of the sensor and transmitter. Have patient tell the Security Officer they can't remove the sensor because it's inserted under the skin.

Security Equipment to Use

Hand-wanding, pat-downs, visual inspection, and walk-through metal detectors: If your patient is wearing a G6 Pro, use any of these screening methods.

Security Equipment to Avoid

The G6 Pro hasn't been tested in advanced imaging technology (AIT) body scanners or X-ray baggage scanners.

Body scanners: Your patient shouldn't go through an AIT scanner, when wearing their G6 Pro.

X-Ray machines: Your patient shouldn't put their system components through x-ray machines.

In a Plane

Your patient can use their smart device to get sensor glucose information while in the plane. After switching to airplane mode, turn the smart device's *Bluetooth* on.

For More Information

Contact your airline for their policies.

Visit the TSA's website at tsa.gov.

Email: TSA-ContactCenter@tsa.dhs.gov

Phone: **1.866.289.9673**

Appendix F: Warranty

F.1 Dexcom Transmitter Limited Warranty

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

The G6 Pro System uses the Dexcom G6 transmitter and sensor applicator.

What Is Covered and for How Long?

Dexcom, Inc. ("Dexcom") provides a limited warranty to the original purchaser ("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 (the "Date of First Use") and expiring 30 days thereafter; provided, that, the Date of First use occurs within five (5) months of the date of shipment (or disbursement) of the transmitter to Purchaser ("Warranty Period").

Note: If Purchaser 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 isn't subject to any other warranty.

What Isn't Covered?

This Limited Warranty is based on the Purchaser properly using the continuous glucose monitoring system in a timely manner and in accordance with the documentation provided by Dexcom. Purchaser is 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" the continuous glucose monitoring system or cell phone and taking other unauthorized actions may put the user at risk, cause the continuous glucose monitoring system to malfunction, are not permitted and void the Limited Warranty.

This Limited Warranty doesn't 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 ID 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 cell phones or smart devices and connection to the internet.
- A transmitter that has been taken apart physically or that has had any of its software accessed in any unauthorized manner.
- Water damage to transmitter beyond specifications listed in the G6 Pro User Guide.

Options to get the User Guide:

- Download or view: dexcom.com/guides
- Online request form to receive a free printed copy: dexcom.com/guides
- Request a free copy by mail
- Request a free copy by phone:

  Toll free: **1.888.738.3646**

  Toll: **1.858.200.0200**

Dexcom's Obligations Under the Limited Warranty

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

To return, the transmitter must be sent to an authorized Dexcom Technical Support Department. Make sure to adequately package the transmitter for shipping.

The return package needs to include:

- Transmitter
- Sales receipt or comparable substitute proof of sale showing the date of purchase
- Transmitter's serial number
- Seller's name and address
- Purchaser's name and address for Dexcom to ship the replacement

Call Dexcom Technical Support Department for delivery information or help:

Dexcom Technical Support Phone Numbers:

- **General:** 1.844.607.8398, 24/7 Toll Free USA
- **Healthcare Professionals:** 1.844.436.2271, 6 am–6 pm (PST), Monday–Friday

Upon receipt by Dexcom of a defective transmitter covered by this Limited Warranty, Dexcom will promptly replace the defective transmitter.

If Dexcom determines the transmitter isn't covered by this Limited Warranty, Purchaser must pay all shipping charges for the transmitter's return by Dexcom.

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 Continuous Glucose Monitoring System or any feature or service provided by Dexcom for use with any Dexcom Continuous Glucose Monitoring System.

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 can't be transferred to anyone else, and 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

The device performance described in this section are from studies conducted for the Dexcom G6 CGM System (G6). The performance of the G6 is relevant because the G6 Pro uses the same sensor and transmitter.

NOTE: We recommend that you review the information in this chapter with your patient to understand how well the Dexcom G6 systems perform.

G.1 Device Performance Characteristics

The G6 uses a glucose sensor to continuously measure and monitor your patient's glucose levels. After the sensor warmup is complete, the G6 reports glucose readings every 5 minutes. The G6's performance was evaluated in clinical studies in which G6 Pro 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 (40–400 mg/dL). 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 Pro readings to YSI blood glucose values. For blood glucose values less than or equal to 70 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 70 mg/dL, 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 20 mg/dL 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 your patient sees a CGM reading on their mobile application, these tables show how likely their readings match their 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 Pro readings fall within $\pm$ 20 mg/dL of the YSI blood glucose values < 70 mg/dL and within $\pm$ 20% of YSI blood glucose values $\geq$ 70 mg/dL.

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 40-400 mg/dL, inclusive.

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

CGM Glucose Range[1] (mg/dL)	Number of paired CGM-YSI	Percent within 15 mg/dL YSI	Percent within 20 mg/dL YSI	Percent within 40 mg/dL YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mg/dL)	MARD (%)
<54	383	84.3	90.6	98.4				-6.9	13.8
54-69	1,537	89.6	95.1	99.5				-0.5	11.5
70-180	9,453				73.9	86.6	99.3	-2.8	10.9
181-250	4,093				80.2	92.1	99.9	-10.0	9.3
>250	3,863				91.1	97.7	100.0	-3.8	7.1

[1]CGM readings are within 40-400 mg/dL, inclusive.

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

CGM Glucose Range[1] (mg/dL)	Number of paired CGM-YSI	Percent within 15 mg/dL YSI	Percent within 20 mg/dL YSI	Percent within 40 mg/dL YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mg/dL)	MARD (%)
<54	90	48.9	62.2	85.6				-20.0	26.0
54-69	262	85.5	88.5	96.6				-5.9	13.3
70-180	3,144				79.8	90.8	99.5	-0.3	9.7
181-250	1,360				83.4	93.5	99.9	-1.2	8.9
>250	916				89.3	95.9	99.9	9.2	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 40-400 mg/dL, inclusive.

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

CGM Glucose Range[1] (mg/dL)	Number of paired CGM-YSI	Percent within 15 mg/dL YSI	Percent within 20 mg/dL YSI	Percent within 40 mg/dL YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mg/dL)	MARD (%)
<54	60	40.0	51.7	80.0				-24.1	28.9
54-69	177	87.0	88.1	96.0				-6.3	13.4
70-180	1,910				80.5	91.0	99.5	-1.1	9.7
181-250	775				81.9	95.0	100.0	-2.3	9.1
>250	574				89.2	96.5	99.8	8.0	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 40-400 mg/dL, inclusive.

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

CGM Glucose Range[1] (mg/dL)	Number of paired CGM-YSI	Percent within 15 mg/dL YSI	Percent within 20 mg/dL YSI	Percent within 40 mg/dL YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mg/dL)	MARD (%)
<54	30	66.7	83.3	96.7				-11.7	20.1
54-69	85	82.4	89.4	97.6				-5.2	13.2
70-180	1,234				78.8	90.4	99.4	0.9	9.7
181-250	585				85.3	91.6	99.8	0.1	8.5
>250	342				89.5	94.7	100.0	11.1	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 40-400 mg/dL, inclusive.

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

YSI Glucose Range (mg/dL)	Number of paired CGM-YSI	Percent within 15 mg/dL YSI	Percent within 20 mg/dL YSI	Percent within 40 mg/dL YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mg/dL)	MARD (%)
<54	483	88.2	95.9	99.8				6.0	15.8
54-69	1,783	88.8	96.1	99.9				4.0	12.4
70-180	8,713				76.8	89.0	99.6	-0.8	10.3
181-250	3,940				83.0	92.7	99.8	-7.2	8.8
>250	4,410				83.4	93.3	99.8	-13.5	8.6

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

YSI Glucose Range (mg/dL)	Number of paired CGM-YSI	Percent within 15 mg/dL YSI	Percent within 20 mg/dL YSI	Percent within 40 mg/dL YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mg/dL)	MARD (%)
<54	47	95.7	100.0	100.0				5.0	11.8
54-69	309	86.1	95.1	100.0				2.8	13.7
70-180	3,099				79.9	90.4	98.8	1.7	9.8
181-250	1,401				84.9	93.3	99.8	-0.8	9.0
>250	916				85.2	94.0	100.0	-3.3	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-H. G6 Accuracy to YSI within YSI Glucose Ranges (Pediatrics*, Abdomen; n=99)

YSI Glucose Range (mg/dL)	Number of paired CGM-YSI	Percent within 15 mg/dL YSI	Percent within 20 mg/dL YSI	Percent within 40 mg/dL YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mg/dL)	MARD (%)
<54	28	100.0	100.0	100.0				4.2	11.3
54-69	201	90.0	96.0	100.0				3.0	12.8
70-180	1,904				79.3	89.5	98.5	0.4	10.2
181-250	761				84.9	94.9	99.6	-1.4	9.1
>250	602				85.4	95.8	100.0	-3.9	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-I. G6 Accuracy to YSI within YSI Glucose Ranges (Pediatrics*, Buttocks; n=66)

YSI Glucose Range (mg/dL)	Number of paired CGM-YSI	Percent within 15 mg/dL YSI	Percent within 20 mg/dL YSI	Percent within 40 mg/dL YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mg/dL)	MARD (%)
<54	19	89.5	100.0	100.0				6.2	12.6
54-69	108	78.7	93.5	100.0				2.4	15.2
70-180	1,195				80.8	92.0	99.2	3.8	9.3
181-250	640				84.8	91.4	100.0	-0.1	8.8
>250	314				84.7	90.4	100.0	-2.1	7.8

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

Agreement When CGM Reads "LOW" or "HIGH"

The G6 reports glucose readings between 40 and 400 mg/dL. When the G6 determines the glucose reading is below 40 mg/dL, it displays "LOW" in the Mobile Application Status Box. When the G6 determines that the glucose level is above 400 mg/dL, it displays "HIGH" in the Mobile Application Status Box. Because the System does not display glucose values below 40 mg/dL or above 400 mg/dL, 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 80 mg/dL. When the G6 displayed "HIGH" (54 occasions), 100% (54 out of 54) of the YSI values were greater than 280 mg/dL.

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

CGM Readings	CGM-YSI Pairs	YSI (mg/dL)					Total
		< 55	< 60	< 70	< 80	≥ 80	
"LOW"	n	65	80	95	117	22	139
	Cumulative Percent	47%	58%	68%	84%	16%	
CGM Readings	**CGM-YSI Pairs**	**YSI (mg/dL)**					**Total**
		> 340	> 320	> 280	> 250	≤ 250	
"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 81 to 120 mg/dL, you can expect your blood glucose levels are within 81 to 120 mg/dL 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 81 to 120 mg/dL, you can expect your CGM readings to be within 81 to 120 mg/dL 78% of time.

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

CGM Glucose Range [1] (mg/dL)	YSI (mg/dL)											
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	Total
<40	13.5%	56.7%	24.0%	3.8%	1.9%	.	.	.	.	.	.	104
40- 60	1.2%	67.8%	27.9%	2.7%	0.2%	0.1%	.	.	.	.	.	917
61- 80	0.1%	21.3%	61.4%	16.9%	0.3%	0.1%	.	.	.	.	.	2,275
81- 120	.	0.4%	13.6%	70.3%	15.1%	0.6%	0.0%	.	.	.	.	3,782
121- 160	.	.	0.0%	14.2%	64.3%	20.1%	1.3%	0.0%	0.0%	.	.	3,026
161- 200	.	.	.	0.1%	14.5%	56.7%	26.9%	1.5%	0.2%	0.0%	.	2,597
201- 250	.	.	.	.	0.2%	12.1%	59.4%	25.4%	2.9%	0.0%	.	2,869
251- 300	.	.	.	.	.	0.1%	13.7%	59.1%	25.3%	1.9%	.	2,268
301- 350	.	.	.	.	.	.	0.2%	22.3%	63.4%	13.7%	0.5%	1,212
351- 400	.	.	.	.	.	.	.	0.8%	43.9%	52.5%	2.9%	383
>400	.	.	.	.	.	.	.	.	5.9%	76.5%	17.6%	34

[1]CGM readings are within 40 to 400 mg/dL, inclusive.

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

CGM Glucose Range [1] (mg/dL)	YSI (mg/dL)											
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	Total
<40	2.9%	22.9%	28.6%	42.9%	2.9%	.	.	.	.	.	.	35
40- 60	0.6%	37.9%	43.5%	13.7%	3.7%	0.6%	.	.	.	.	.	161
61- 80	.	11.5%	65.8%	20.4%	1.9%	0.4%	.	.	.	.	.	485
81- 120	.	0.2%	12.5%	76.3%	10.5%	0.6%	.	.	.	.	.	1,282
121- 160	.	.	.	13.6%	71.9%	13.6%	0.9%	.	.	.	.	1,013
161- 200	.	.	.	0.2%	18.6%	59.4%	20.2%	1.6%	.	.	.	1,087
201- 250	.	.	.	.	0.1%	19.2%	63.8%	15.7%	1.2%	.	.	828
251- 300	.	.	.	.	.	0.2%	28.1%	59.6%	11.8%	0.4%	.	544
301- 350	.	.	.	.	.	.	1.0%	32.8%	56.4%	9.8%	.	287
351- 400	.	.	.	.	.	.	.	5.9%	52.9%	38.8%	2.4%	85
>400	.	.	.	.	.	.	.	.	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.*

[1]CGM readings are within 40 to 400 mg/dL, inclusive.

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

CGM Glucose Range [1] (mg/dL)	YSI glucose range (mg/dL)										
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400
<40	51.9%	5.0%	1.1%	0.1%	0.1%	.	.	.	.	.	.
40- 60	40.7%	52.7%	11.7%	0.7%	0.1%	0.0%	.	.	.	.	.
61- 80	7.4%	41.0%	63.7%	11.0%	0.2%	0.1%	.	.	.	.	.
81- 120	.	1.3%	23.4%	75.8%	19.7%	1.0%	0.0%	.	.	.	.
121- 160	.	.	0.0%	12.2%	66.9%	24.8%	1.4%	0.0%	0.1%	.	.
161- 200	.	.	.	0.1%	13.0%	59.9%	25.3%	1.7%	0.4%	0.2%	.
201- 250	.	.	.	.	0.2%	14.1%	61.9%	30.6%	5.1%	0.2%	.
251- 300	.	.	.	.	.	0.1%	11.3%	56.2%	35.9%	9.6%	.
301- 350	.	.	.	.	.	.	0.1%	11.3%	48.0%	38.0%	26.1%
351- 400	.	.	.	.	.	.	.	0.1%	10.5%	46.0%	47.8%
>400	.	.	.	.	.	.	.	.	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

[1]CGM readings are within 40 to 400 mg/dL, inclusive.

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

CGM Glucose Range [1] (mg/dL)	YSI glucose range (mg/dL)										
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400
<40	50.0%	6.3%	1.8%	1.2%	0.1%	.	.	.	.	.	.
40- 60	50.0%	48.0%	12.5%	1.8%	0.6%	0.1%	.	.	.	.	.
61- 80	.	44.1%	57.1%	7.9%	0.8%	0.2%	.	.	.	.	.
81- 120	.	1.6%	28.6%	78.0%	12.4%	0.8%	.	.	.	.	.
121- 160	.	.	.	11.0%	67.3%	14.5%	1.0%	.	.	.	.
161- 200	.	.	.	0.2%	18.7%	67.6%	24.1%	3.0%	.	.	.
201- 250	.	.	.	.	0.1%	16.6%	57.8%	22.8%	3.5%	.	.
251- 300	.	.	.	.	.	0.1%	16.8%	56.8%	22.7%	2.7%	.
301- 350	.	.	.	.	.	.	0.3%	16.5%	57.4%	37.8%	.
351- 400	.	.	.	.	.	.	.	0.9%	16.0%	44.6%	20.0%
>400	.	.	.	.	.	.	.	.	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.*

[1] CGM readings are within 40 to 400 mg/dL, inclusive.

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 (≥ 2 mg/dL/min), how often is reference glucose also rising? The answer is 71.3% of the time for adults and 67.1% for pediatrics.
2. When the G6 CGM rate of change is rapidly falling (≤ 2 mg/dL/ min), how often is reference glucose also falling? The answer is 98.0% of the time.
3. When the G6 CGM rate of change is stable (≥ -1 mg/dL/min and ≤ 1 mg/dl/ min), how often is glucose changing rapidly (≥ 2 mg/dL/min or ≤ 2 mg/dL/ min)? The answer is only 1.9% of the time.

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

CGM Rate Range (mg/dL/ min)	YSI glucose range (mg/dL)						CGM-YSI Pairs (n)
	<-2	[-2,-1)	[-1,-0)	[0,1]	(1,2]	>2	
<-2	53.3%	35.0%	9.9%	1.5%	0.0%	0.2%	463
[-2,-1)	7.4%	56.9%	32.5%	2.9%	0.3%	0.0%	2,077
[-1,0)	0.4%	9.5%	76.9%	12.5%	0.6%	0.1%	7,986
[0,1]	0.1%	1.0%	26.2%	60.6%	10.6%	1.6%	5,199
(1,2]	0.0%	0.4%	3.1%	26.8%	52.9%	16.8%	1,734
>2	0.1%	0.1%	0.8%	5.6%	22.1%	71.3%	1,367

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

CGM Rate Range (mg/dL/ min)	YSI glucose range (mg/dL)						CGM-YSI Pairs (n)
	<-2	[-2,-1)	[-1,-0)	[0,1]	(1,2]	>2	
<-2	47.9%	37.0%	12.8%	1.9%	0.0%	0.5%	211
[-2,-1)	6.6%	55.5%	33.8%	3.4%	0.6%	0.1%	686
[-1,0)	0.5%	8.9%	73.7%	15.8%	1.0%	0.0%	2,048
[0,1]	0.0%	0.8%	25.5%	62.9%	10.0%	0.8%	1,666
(1,2]	0.0%	0.4%	4.4%	35.9%	48.0%	11.4%	546
>2	0.0%	0.5%	1.7%	7.1%	23.6%	67.1%	423

** 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 Pro 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 70 mg/dL 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 70 mg/dL approximately 85.5% of the time and above 70 mg/dL 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 55 mg/dL, and an alert was provided, glucose was <70 mg/dL 85% of the time within 15 minutes of the alert. (Data not presented in table.)

When the hypoglycemic alert rate was set at 60 mg/dl, and an alert was provided, glucose was <70 mg/dl 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 70 mg/dL, how often will your alarm alert you if your blood glucose goes below 70 mg/dL? Based on results for pediatrics in the G6 Study (Table 5-B), when your blood sugar goes below 70 mg/dL, 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 70 mg/dL.

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

Hypoglycemic Alert Level (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
55	1,408	66.6	33.4	642	63.9	36.1
60	2,370	74.6	25.4	1,158	74.1	25.9
70	5,079	85.5	14.5	2,365	86.0	14.0
80	8,187	89.1	10.9	3,372	92.7	7.3
90	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 (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
55	358	31.6	68.4	66	68.2	31.8
60	521	44.1	55.9	119	73.1	26.9
70	1,054	68.0	32.0	369	81.6	18.4
80	1,794	80.5	19.5	671	88.1	11.9
90	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 200 mg/dL 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 200 mg/dL approximately 96% of the time and not be above 200 mg/dL 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 240 mg/dL and your blood sugar rises above 240 mg/dL, 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 240 mg/dL, 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 (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	37,061	97.5	2.5	12,664	97.6	2.4
140	32,148	97.2	2.8	11,175	96.8	3.2
180	23,424	96.6	3.4	8,455	95.2	4.8
200	19,586	96.0	4.0	7,265	93.6	6.4
220	15,689	95.6	4.4	6,143	91.2	8.8
240	12,279	94.6	5.4	5,007	88.7	11.3
300	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 (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	11,683	97.3	2.7	3,930	97.8	2.2
140	10,113	96.2	3.8	3,388	97.7	2.3
180	6,821	93.4	6.6	2,366	94.7	5.3
200	5,190	93.3	6.7	1,874	91.2	8.8
220	4,096	90.4	9.6	1,453	91.7	8.3
240	3,068	86.9	13.1	1,093	90.2	9.8
300	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.*

Sensor Stability

Sensors can be worn for up to 10 days. Performance was estimated by calculating the percentage of G6 Pro readings within 15 mg/dL or 15% (15/15%), 20 mg/dL or 20% (20/20%), and 40 mg/dL 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 70 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 70 mg/dL, 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 40-400 mg/dL, 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	2167	9.9	81.2	92.1	99.8
Middle	1268	9.1	83.1	93.7	99.8
End	2337	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 40-400 mg/dL, 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.*

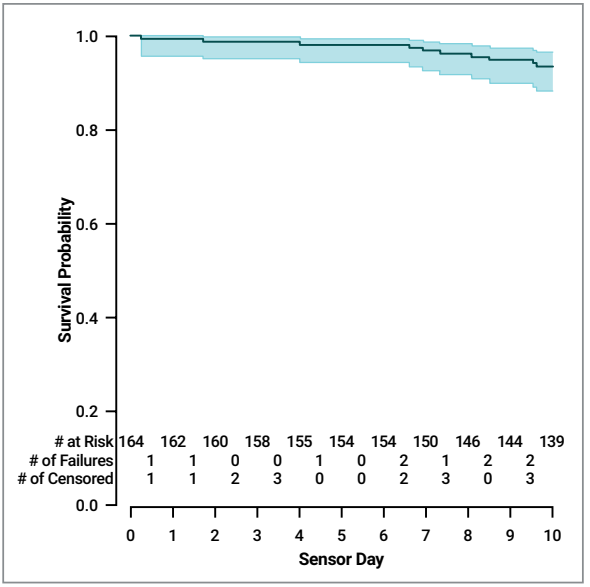


Figure 1-A. Kaplan Meier Curve of Sensor Life (Adults; N = 164)
Note: "# of Censored" refers to sensors excluded from the survival analysis due to reasons not related to the device (e.g., subject dropped out of study)

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.*

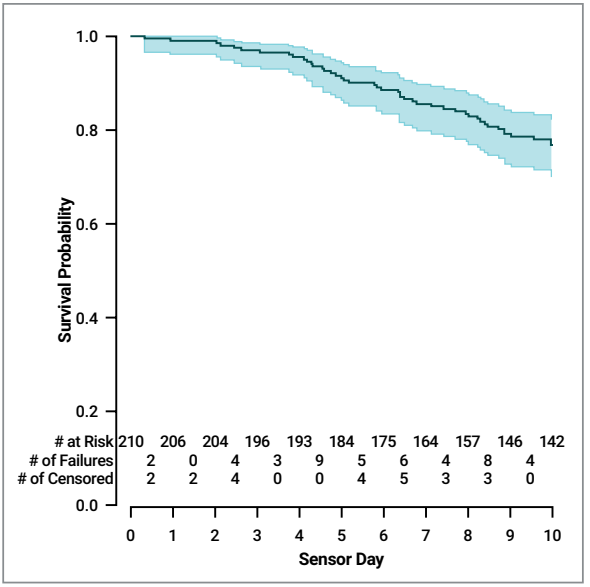


Figure 1-B. Kaplan Meier Curve of Sensor Life (Pediatrics; N = 210)
Note: "# of Censored" refers to sensors excluded from the survival analysis due to reasons not related to the device (e.g., subject dropped out of study)

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 (mg/dL)	14.0	14.5	16.4	9.4
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 Pro readings to YSI blood glucose values. For glucose value less than or equal to 70 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For glucose value greater than 70 mg/dL, the absolute difference (%) relative to the YSI values was calculated. The percentages of total readings within 20 mg/dL 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 $\pm$ 20 mg/dL of the YSI blood glucose values < 70 mg/dL and within $\pm$ 20% of YSI blood glucose values $\geq$ 70 mg/dL 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 (95% LB)
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 12 inches to any part of the G6 CGM system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Sensor Product Specifications

Glucose Range	40–400 mg/dL
Sensor Useful Life	Up to 10 days
Storage and Transport Conditions	Temperature: 36°F–86°F Store sensors in a cool, dry place
Sterilization	Sterile by radiation

Transmitter Product Specifications

Electrical Safety Class	Internally Powered
Battery Longevity (Typical)	1 month
Battery Charging Time	Non-rechargeable
Operational Conditions	Ambient Temperature: 50°F–107.6°F Humidity: 10%–95% RH
Maximum Enclosure Temperature	109°F
Storage and Transport Conditions	Temperature: 32°F–113°F Humidity: 10%–95% RH
Operating Altitude	-1,300 feet to 13,800 feet
Ingress Protection	IP28: Protection against insertion of large objects and immersion in water for up to 8 feet for 24 hours
Protection Against Electrical Shock	Type BF applied part
TX/RX Frequencies	2.402–2.480 GHz
Bandwidth	1.07 MHz
Maximum Output Power	1.0 mW EIRP
Modulation	Gaussian Frequency-Shift Keying
Data Rate	1 Mbps
Data Communication Range	20 feet

Electromagnetic Immunity and Emissions Declaration and Guidance

The transmitter is 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
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
Surge **IEC 61000-4-5**	N/A
Voltage Dips and Interruptions **IEC 61000-4-11** **IEC 60601-1-11**	N/A
Conducted Fields Disturbance **IEC 61000-4-6**	N/A

Immunity Test	Transmitter Compliance Level
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 healthcare environment as control over the EMC environment cannot be guaranteed. An interference event can be recognized by gaps in G6 Pro readings or gross inaccuracies. The user is encouraged to try to mitigate these effects by one of the following measures:

If the G6 Pro 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 70 mg/dL, CGM should read within ± 30 points. If the meter shows 70 mg/dL and above, the CGM should read ± 30%. Example: a 202 mg/dL sensor reading and a 188 mg/dL glucose meter value = a 7% 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 patient's 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.1.

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.1.

Electromagnetic Emissions Specifications

Emissions Test	Compliance
Radio Frequency Emissions CISPR 11/FCC part 15	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 FCC Compliance Statements

This G6 CGM transmitter complies with Part 15 of the FCC Rules. 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 FCC ID

Transmitter Part Number	9445-20
FCC ID	PH29688

Appendix H: Label Symbols

Symbols may be found on the sensor and transmitter package labels. These symbols tell you about the proper and safe use of the G6 Pro. For a listing of what they mean, see below. You may also reference the Symbols Glossary at dexcom.com/symbols.

Batch/Lot Number

Bluetooth

Catalog Number

Caution

Consult Instructions for Use

Date of Manufacture

Do Not Reuse

Do Not Use if Package is Damaged

IP28: Protection Against Insertion of Large Objects and Immersion in Water

Keep Away from Heat

Keep Dry

Manufacturer

MR Unsafe

PN

Part Number

Rx Only

Prescription Required

SN

Serial Number

STERILE R

Sterile by Radiation

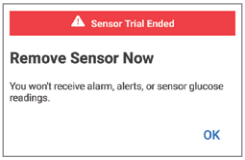
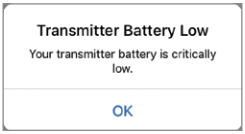
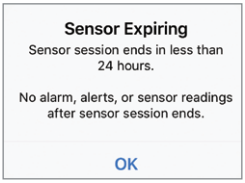
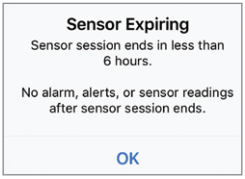
Temperature Limitation

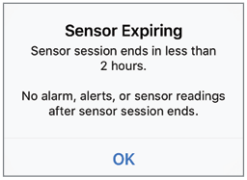
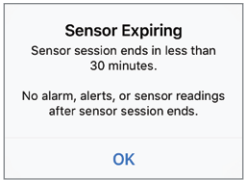
Type BF Applied Part

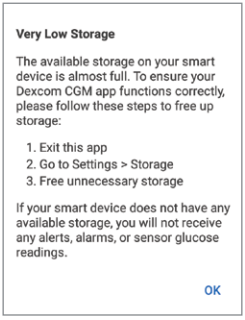
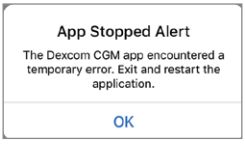
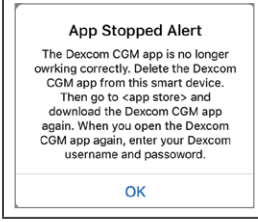
Use By Date

Appendix I: Alerts and Notifications

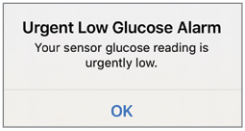
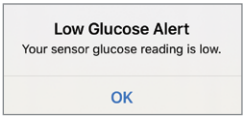
I.1 App: System Alerts

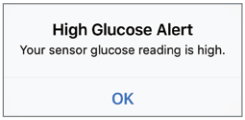
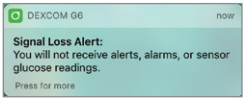
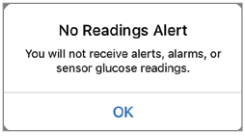
Screen	Default On	Default Sound	Default Vibration	Change Settings	Override Mute
	YES	Fixed Alert Beep	YES	NO	YES
	YES	Fixed Alert Beep	YES	NO	NO
	YES	Silent Alert	NO	NO	NO
	YES	Silent Alert	NO	NO	NO

Screen	Default On	Default Sound	Default Vibration	Change Settings	Override Mute
	YES	Silent Alert	NO	NO	NO
	YES	Fixed Alert Beep	YES	NO	NO
	YES	Silent Alert	NO	NO	NO

Screen	Default On	Default Sound	Default Vibration	Change Settings	Override Mute
	YES	Silent Alert	NO	NO	NO
	YES	Fixed Alert Beep	YES	NO	YES
	YES	Fixed Alert Beep	YES	NO	YES
	YES	Fixed Alert Beep	YES	NO	YES

I.2 App: Glucose and No Data Alerts

Screen	Default On	Default Sound	Default Vibration	Editable Settings	Override Mute
	YES	Urgent Low	YES	Notify Below (default is 55 mg/dL) Repeat (default is 30 minutes) Sound (default is Urgent Low)	YES
	YES	Low Alert	YES	Enable/ Disable (default is enabled) Notify Below (default is 80 mg/dL) Repeat (default is Never) Sound (default is Low Alert)	YES

Screen	Default On	Default Sound	Default Vibration	Editable Settings	Override Mute
	YES	High Alert	YES	Enable/ Disable (default is enabled) Notify Above (default is 200 mg/dL) Repeat (default is Never) Sound (default is High Alert)	YES
	YES	Signal Loss Alert	NO	Enable/ Disable Sound (default is Signal Loss Alert)	Android YES Apple NO
	YES	Signal Loss Alert	YES	Enable/ Disable (default is disabled) Sound (default is Signal Loss Alert)	YES

Page intentionally left blank

Appendix J: Extend Your App

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

Not seeing any data? Open the app.

On their Apple smart device, they can set up Siri to tell them their G6 Pro readings.

Does your patient use health apps? Your patient can share glucose information with the apps for a more complete picture.

J.1 Today View (Apple)

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

To add G6

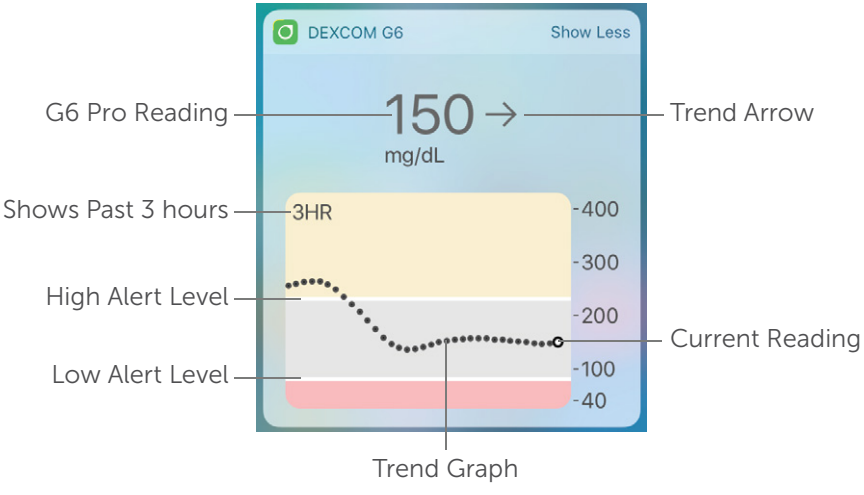
1. Scroll to the bottom
2. Tap **Edit**

See smart device instructions for details.

Images below are representational only, your patient's screen may look different.

Today View

Tap **Show More** to show your patient's graph.

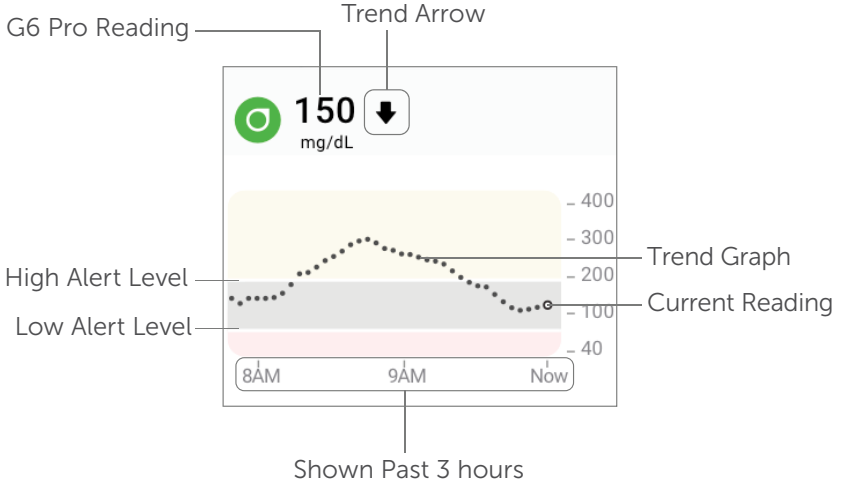


J.2 Quick Glance (Android)

Check G6 on the lock screen or swipe down from the top.

Quick Glance

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



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

J.3 Smart Watches

Check G6 on your patient's Apple or Android smart watch.

Suggested Use

Using a smart watch with the system may change how your patient gets alarm/alerts.

- Smart watch only communicates with the smart device, not the transmitter.
- No alarm/alerts or G6 Pro readings on the smart watch unless it's connected to a smart device.

Make sure your patient understands how they get notifications when a watch is connected.

- Must wear the watch to see alerts and feel their vibrations.
- In smart device settings, make sure notifications are sent to both smart device and watch.
- Don't disable or block notifications from the app.

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

Go to dexcom.com/compatibility to make sure your patient's smart watch works with G6 Pro.

Apple Watch Setup (iPhone)

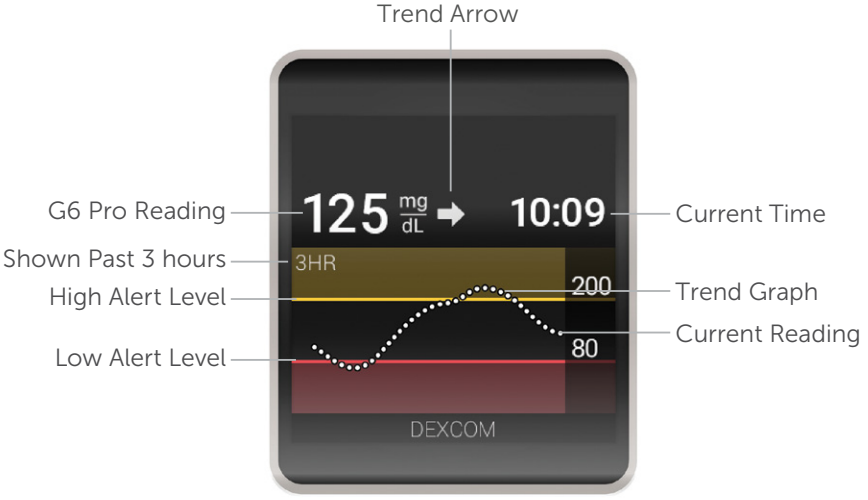
To install the app, use the Watch app on your iPhone.

See smart watch instructions for details about installing apps.

Android Wear Setup

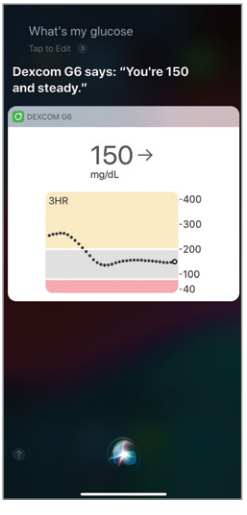
Using the Dexcom G6 watch face, check G6 information. See smart watch instructions for details.

Android Wear



J.4 Siri (Apple)

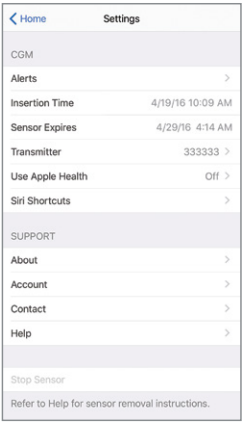
Use app settings to set up a Siri shortcut. Ask Siri to announce G6 Pro readings and trend anytime your app is running! When Siri answers, graph shows on lock screen.

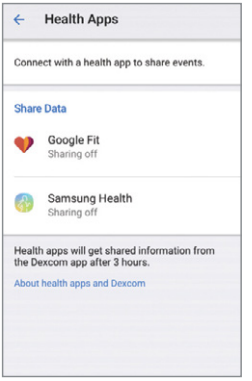


J.5 Health Apps

Send glucose information to health apps, like Apple Health and Android's Samsung Health and Google Fit.

Use **Settings** > **Health Apps** to start. Once you set up the health app, the last 30 days of glucose information (except the last 3 hours) is sent to the health app. Subsequently, new glucose information – delayed by 3 hours – is sent.





Page intentionally left blank

Index

Dexcom

Dexcom, Inc.
6340 Sequence Drive
San Diego, CA 92121 USA
Phone: **1.858.200.0200**

Tech Support:

- **General:** 1.844.607.8398, 24/7 Toll Free USA
- **Healthcare Professionals:** 1.844.436.2271, 6 am–6 pm (PST), Monday–Friday

Web: dexcom.com

MT25847 / LBL017179 Rev 005, Rev Date: 02/2020