

Dexcom G6 Safety Statements

Indications for Use

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

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

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

Important User Information

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

Contraindication

• No MRI/CT/Diathermy – MR Unsafe

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

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

Warnings

• Read User Materials

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

- Not use the G6 correctly
- Not understand G6 information
- Affect how well it works
- Do Not Ignore Low/High Symptoms

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

• No Number, No Arrow, No CGM Treatment Decision

If your G6 does not show a number or arrow, or your G6 readings do not match your symptoms, use your meter to make diabetes treatment decisions. No number, no arrow, no treatment decision. When in doubt, get your meter out.

• Do Not Use If...

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

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

Precaution

• Avoid Sunscreen and Insect Repellent

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

Start Up Safety Statements

Warnings

• Use Meter During Startup

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

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

Precautions

• Use Correct Sensor Code

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

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

Calibration Safety Statements

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

Warnings

• Do Not Wait – Calibrate!

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

• Use Fingertips

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

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

Precautions

• Be Accurate, Be Quick.

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

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

System/Hardware/Software Safety Statements

Warnings

• Sensor Wire Breaks Off

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

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

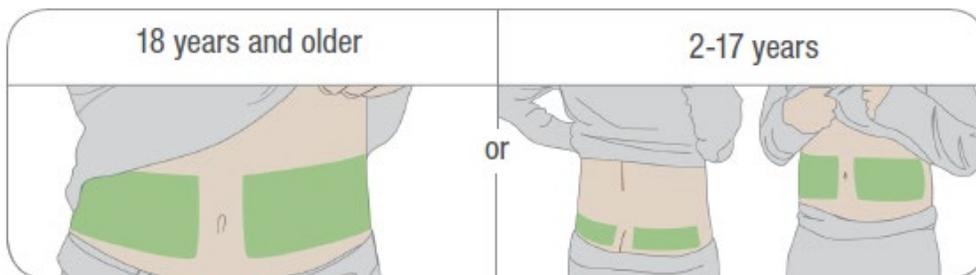
• Where to Insert: Belly or Buttocks?

All patients can use their bellies. Patients 2 to 17 years old can also choose their upper buttocks. Look for a place on your belly or upper buttocks where you have some padding.

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

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

Ages 18 and older: Insert in your belly



• Where to Store

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

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

Precautions

• Do not Use if Expired

Do not use expired sensors, because they may give incorrect results. Check the package label for the expiration date. It is in YYYY-MM-DD (Year-Month-Day) format.

• Check Package

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

• Clean and Dry Skin

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

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

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

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

• **Where to Insert: Things to Check**

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

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

Sensor placement is important. Choose a site:

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

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

Transmitter Safety Statements

Warnings

• **Inspect**

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

• **Use as Directed**

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

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

Precautions

• **Reuse – Do Not Throw Away**

When ending a session, do not throw away the transmitter. The transmitter is reusable until the G6 notifies you that the transmitter battery is about to expire. For Healthcare Professionals: Please see cleaning and disinfection instructions in Professional Use Instructions. Follow G6 instructions. If you do not, you could have a severe low or high glucose event.

System Safety Statements

Precautions

• **Treatment Decisions**

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

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

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

• **Going Through Security Check Point**

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

You can wear the G6 for the walk-through metal detector. If you do, use your meter for treatment decisions until you leave the security area. Because we have not tested every x-ray and scanner, we do not know if they damage the G6.

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

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

Receiver and Smart Device Safety Statements

Precautions

• Keep Transmitter Close to Display Device

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

• Get Alarm/Alerts on Display Device You Use

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

• Is It On?

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

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

Smart Device Safety Statements

Warnings

• Check Settings

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

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

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

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

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

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

Precautions

- Check Accessory Devices

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

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

Receiver Safety Statements

Warnings

- **Do Not Use if Damaged**

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

- **Use Cable as Directed**

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

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

Precautions

- **Test Speaker and Vibrations**

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

To make sure the speaker and vibrations work, plug in the receiver to charge. The Speaker Test screen appears for a few seconds. Follow the directions on the screen to test the speaker and vibrations. If you

hear and feel them, great! But if it does not beep and vibrate – perhaps it got wet or was dropped – contact your local Dexcom representative.

- **Keep Clean and Dry**

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

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

Dexcom Share Safety Statements

Important User Information

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

Share and Managing Your Diabetes Safety Statements

Indications for Use

- **Keep Followers Informed**

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

- **Use as Secondary Notice**

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

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

Warnings

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

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

- **Take Healthcare Professional Advice**

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

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

Share Setup and Settings Safety Statements

Warning

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

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

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

Precautions

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

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

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

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

- **Check Your Smart Device**

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

- Check Followers' Smart Devices
- Sounds on: Followers must keep their smart device volume on, or at least the keep vibration on, so they can hear and/or feel alarm/alerts. Smart device settings trump Follow app settings.
- Sharing gaps: Followers will not get your sensor information when their smart device is off, not connected to the Internet, or in Do Not Disturb or Airplane mode. When the Followers fix those issues, they will start getting the current information but they will not get the information they missed.
- Cell carrier supports simultaneous voice and data: Most cell service carriers support using voice and data at the same time. Check yours and have Followers check theirs. If it is not supported, Share will not work during phone calls. Share will restart when the call is over and send any waiting notifications.

- **Customize Share So Followers Can Support You**

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

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