



USER'S GUIDE

DEXCOM G4[®] PLATINUM (PEDIATRIC) CONTINUOUS GLUCOSE MONITORING SYSTEM

IMPORTANT CONTACTS AND NUMBERS

Dexcom[®] Website:	www.dexcom.com
Your Transmitter ID:	
Your Receiver ID:	
Your Healthcare Professional:	
Nearest Hospital:	

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DEXCOM G4 PLATINUM (PEDIATRIC) CONTINUOUS GLUCOSE MONITORING SYSTEM

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GLOSSARY

Alternative Site BG Testing	This is when you take a blood glucose value on your meter using a blood sample from an area on your body other than your fingertip. Do not use alternative site testing to calibrate your receiver.
Applicator	A disposable piece that comes attached to the sensor pod and inserts the sensor under the skin. There is a needle inside the applicator that you remove after you insert the sensor.
BG Meter	Blood glucose meter. You can use any commercially available meter for testing your blood glucose.
BG Value	Blood glucose value. A blood glucose value taken with your commercially available blood glucose meter.
Calibration	When you enter blood glucose values from a blood glucose meter into the receiver. Calibrations are needed for your receiver to show continuous sensor glucose readings and trend information. (Do not use alternative site testing for calibration.)
CGM	Continuous Glucose Monitoring
Commercially Available	Product that may be sold in the United States.
Default	A setting that is selected automatically, unless you choose another option.
Dexcom G4 PLATINUM (Pediatric) System	The sensor, transmitter, and receiver.
Glucose Data Gaps	Different symbols show on the trend graph instead of a sensor glucose reading to let you know that the receiver cannot provide a reading.
Glucose Trends	Trends let you see the pattern of your glucose levels. The trend graph shows where your glucose levels have been during the time shown on the screen and where your glucose levels are now.

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GLOSSARY (continued from page before)

Hypoglycemia	Low blood glucose. Same as “low.” The default low alert in your receiver is set to 80 mg/dL. Consult your health care professional to determine the appropriate hypoglycemic setting for you.
Hyperglycemia	High blood glucose. Same as “high.” The default high alert in your receiver is set to 200 mg/dL. Consult your health care professional to determine the appropriate hyperglycemic setting for you.
HypoRepeat	Optional receiver alert setting that keeps repeating the fixed low alarm every 5 seconds until your sensor glucose value rises above 55 mg/dL or you confirm it. This profile can be helpful if you want extra awareness for severe lows.
Mg/dL	Milligrams per deciliter. The standard unit of measure for sensor glucose readings in the United States.
Obstruction	Something that blocks the path between the transmitter and receiver. There are many types of things that could come between the transmitter and receiver, and Dexcom could not test them all. “Without obstruction” means that we have not tested whether items blocking the transmitter or receiver could affect the transmission range.
Profiles	Sound pattern and volume level settings for your alerts.
Range	The distance between the receiver and transmitter. Keep the two devices within 20 feet of each other without obstruction to get glucose information on your receiver.
Re-alert	A re-alert happens after the first alert is not confirmed.
Receiver	The small device that collects your glucose information from the sensor/transmitter. Your results show on the receiver screen as a sensor glucose reading (mg/dL) and as a trend.
Rise and Fall (Rate of Change) Alerts	Alerts based on how fast and how much your glucose levels rise/fall.

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GLOSSARY (continued from page before)

RF	Radio-frequency transmission used to send glucose information from the transmitter to the receiver.
Safety Lock	The safety lock keeps the needle inside the applicator before you are ready to insert the sensor. It also helps you snap the transmitter out of the sensor pod after your sensor session ends.
Sensor	The Dexcom G4 PLATINUM (Pediatric) System part that includes an applicator and wire. The applicator inserts the wire under your skin, and the wire measures glucose levels in your tissue fluid.
Sensor Pod	The small plastic base of the sensor attached to your skin that holds the transmitter in place.
Snoozing	The option to delay your alert for a set amount of time. A snooze time can be set for high and low glucose re-alerts.
Startup Period	The 2-hour period after you tell the receiver you inserted a new sensor. Sensor glucose readings are not provided during this time.
System Reading	A sensor glucose reading shown on your receiver. This reading is in mg/dL units and is updated every 5 minutes.
Transmitter	The Dexcom G4 PLATINUM (Pediatric) System part that snaps into the sensor pod and wirelessly sends glucose information to your receiver.
Transmitter ID	A series of numbers and/or letters that you enter into your receiver to let it communicate with the transmitter.
Transmitter Latch	The small, disposable piece that snaps the transmitter into the sensor pod. It is removed after the transmitter is snapped in.
Trend (Rate of Change) Arrows	Arrows on trend graphs that show how fast your glucose levels are changing. There are 7 different arrows that show when your glucose speed and direction change.



chapter one

DEXCOM G4 PLATINUM (PEDIATRIC) CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM DESCRIPTION





CHAPTER 1: DEXCOM G4® PLATINUM (PEDIATRIC) CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM DESCRIPTION



**Dexcom G4 PLATINUM
(Pediatric) Receiver**



**Dexcom G4 PLATINUM
Transmitter**



**Dexcom G4 PLATINUM
Sensor**

1.1 SYSTEM CONTENTS:

- sensor
- transmitter
- receiver
- receiver USB charging/download cable
- AC power adapter - MT21255
- receiver case
- user's guide
- quick start guide
- training checklist
- tutorial disc
- Dexcom STUDIO™ software (available for download online at www.dexcom.com)

Sensors are sold separately. Commercially distributed blood glucose (BG) meter required for use.



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PRECAUTION

The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver are not compatible with the SEVEN®/SEVEN® PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work. Also, make sure to use the correct version of Dexcom STUDIO with your system.

1.2 INTRODUCTION

When you use the system, you will see continuous sensor glucose readings updated every 5 minutes for up to 7 days. These readings will help you notice trends and patterns in your glucose levels.

The system includes the Dexcom G4 PLATINUM Sensor, the Dexcom G4 PLATINUM Transmitter, and the Dexcom G4 PLATINUM (Pediatric) Receiver. The sensor is a disposable unit that you insert under your skin to continuously monitor your glucose levels for up to 7 days. The transmitter is a reusable device that wirelessly sends your sensor's glucose information to your receiver. The receiver is a hand-held device that receives and displays your glucose information.

Please read this user's guide closely. It describes how to use your system.

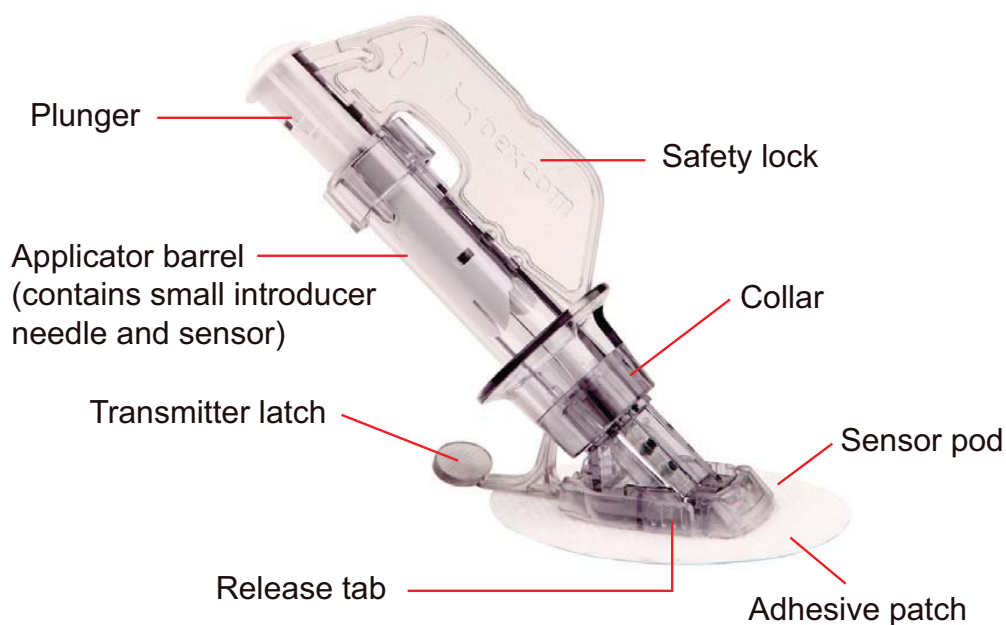
In addition, Dexcom® has a self-guided training tutorial for the Dexcom G4 PLATINUM (Pediatric) CGM System. Some people have found this to be an effective method of product training. Please review the tutorial on the disc and discuss with your healthcare professional to decide if the Dexcom G4 PLATINUM (Pediatric) System Tutorial is a good training option for you. The tutorial disc can only be used with your computer and cannot be used in DVD players. The tutorial is also found on the Dexcom website – www.dexcom.com.



1.3 SENSOR OVERVIEW

The sensor is the piece that comes in a sterile, sealed sensor pouch. The sensor is made up of an applicator, a sensor pod, and a sensor wire. You remove the applicator after insertion. The sensor pod stays on your skin for the entire sensor session, up to 7 days. The pod is made of plastic and an adhesive patch. The sensor wire is thin and flexible, and inserts just under your skin. It is attached to the sensor pod, and is made of silver and platinum metal with polymer membranes. You discard the sensor at the end of the session.

See Chapter 14 for Product Specifications.





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1.4 TRANSMITTER OVERVIEW

The transmitter is the gray, plastic “chip” that snaps into your sensor pod. The transmitter (including sensor pod) is about 1.5 inches long, 0.9 inches wide and 0.5 inches thick. Once snapped into the sensor pod, the transmitter wirelessly sends your glucose information to the receiver. The transmitter and sensor are water resistant when properly connected. Do not throw away your transmitter. It is reusable.

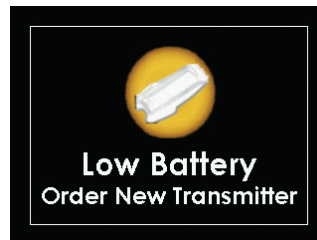
The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water, so the range is much less if you are in a pool, bathtub or water bed.

The transmitter battery will last at least 6 months. Once you see the transmitter low battery screen, replace the transmitter as soon as possible. Your transmitter battery may drain as quickly as one week after this alert appears.

See Chapter 14 for Product Specifications.



Transmitter

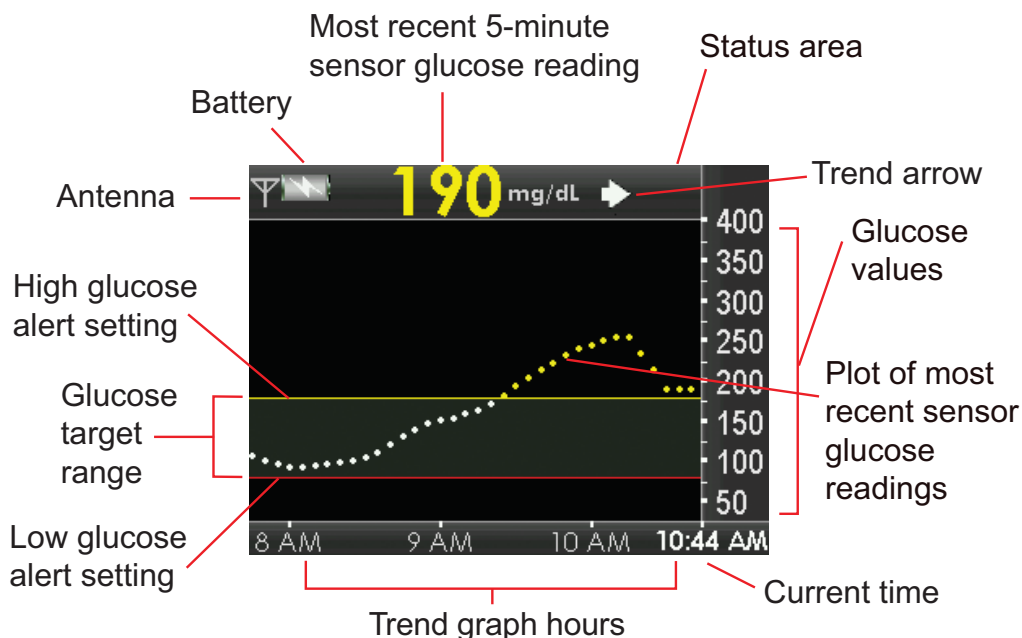


Transmitter Low Battery screen

1.5 RECEIVER OVERVIEW

The receiver is the small hand-held device that looks like a cell phone. It is about 4 inches long, 1.8 inches wide and 0.5 inches thick. It shows your sensor glucose readings, trend graph, direction and rate of change arrow.

Do not spill fluids on the receiver or drop the receiver into fluids. Keep the micro USB port door closed to help prevent fluid and dust from getting inside the receiver.



EXAMPLE: 3-Hour Trend Graph Screen

The trend graph screen on your receiver shows your sensor glucose readings, trend graph, direction and rate of change arrow

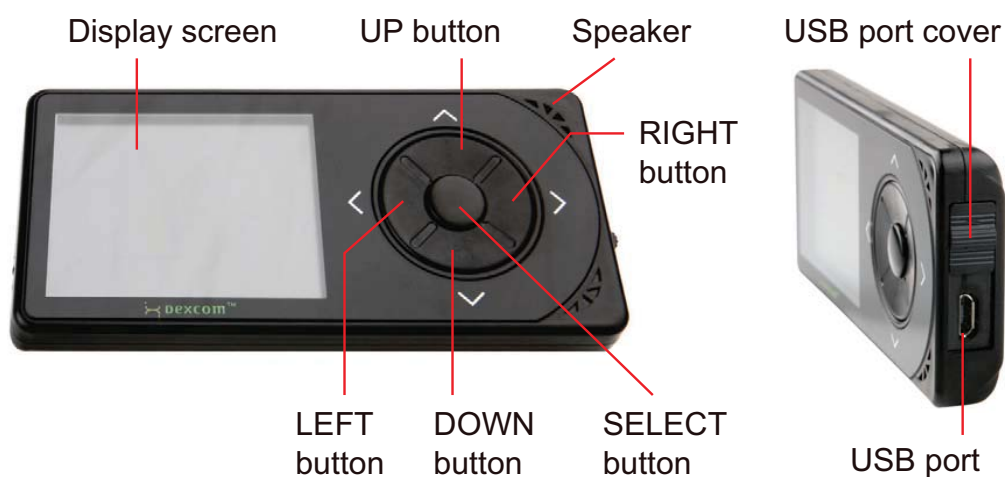
There are five receiver buttons to move you through the screens. The trend graph screens show sensor glucose readings, trend graphs and trend arrows. The receiver menu screens let you change your receiver settings.

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Your receiver and transmitter wirelessly pair together to communicate securely and only with each other.

You will need a commercially available blood glucose meter to use with your system.

See Section 14 for Product Specifications.



Receiver buttons:

- Press the **UP** and **DOWN** buttons to scroll through trend screens, highlight menu items, or set values.
- Press the **SELECT** button to turn the receiver on or select the highlighted option.
- Press the **LEFT** button to go back to the last item or screen.
- Press the **RIGHT** button to highlight the next item.



chapter two

INDICATIONS FOR USE AND SAFETY STATEMENT





CHAPTER 2: INDICATIONS FOR USE AND SAFETY STATEMENT

2.1 INDICATIONS FOR USE

The Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in persons ages 2 to 17 years with diabetes. The system is intended for single patient use and requires a prescription.

The Dexcom G4 PLATINUM (Pediatric) System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Dexcom G4 PLATINUM (Pediatric) System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom G4 PLATINUM (Pediatric) System results should be based on the trends and patterns seen with several sequential readings over time.

2.2 IMPORTANT USER INFORMATION

Please review your product instructions before using your continuous glucose monitoring system. Indications, contraindications, warnings, precautions, cautions, and other important user information can be found in your product instructions. Discuss with your healthcare professional how you should use your sensor trend information to help manage your diabetes. Your product instructions contain important information on troubleshooting your system and on the performance characteristics of the device.

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2.3 CONTRAINDICATIONS

- Remove the Dexcom G4 PLATINUM sensor, transmitter, and receiver before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. The Dexcom G4 PLATINUM (Pediatric) System has not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the device so that it might not display sensor glucose readings or provide alerts, and you might miss a low or high blood glucose value.
- Taking medications with acetaminophen (such as Tylenol®) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

2.4 WARNINGS

- Do not use the Dexcom G4 PLATINUM (Pediatric) CGM System until you have thoroughly reviewed the training materials. Incorrect use might lead you to misunderstand the CGM information or affect system accuracy. This could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not use the Dexcom G4 PLATINUM (Pediatric) System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM (Pediatric) System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose readings. Solely relying on the sensor glucose alerts and readings for treatment decisions could result in



you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

- Do not ignore symptoms of high and low glucose. If your sensor glucose alerts and readings do not match your symptoms, measure your blood glucose with a blood glucose meter even if your sensor is not reading in the high or low range. Solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decision.
- In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.
- Do calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate and glucose alerts to become unreliable. This could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not ignore sensor fractures. Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to our Technical Support department at



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1.877.339.2664 or 1.858.200.0200.

- Do not use the Dexcom G4 PLATINUM (Pediatric) System in pregnant women or persons on dialysis. The system **is not approved for use** in pregnant women or persons on dialysis and has not been evaluated in these populations. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not use the Dexcom G4 PLATINUM (Pediatric) System in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not insert the sensor in sites other than the belly (abdomen) or upper buttocks. Other sites have not been studied and are not approved. Use in other sites might cause sensor glucose readings to be inaccurate and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not expect alerts from the Dexcom G4 PLATINUM (Pediatric) System until after the 2-hour startup. You will NOT get any sensor glucose readings or alerts until after the 2-hour startup ends AND you complete the startup calibration. During this time you might miss severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.



- Do not use your transmitter or receiver if it is damaged/cracked. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.
- Store the sensor at temperatures between 36° F - 77° F for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not allow young children to hold the sensor, transmitter or transmitter kit box without adult supervision. The sensor and transmitter include small parts that may pose a choking hazard. Keep the transmitter kit box away from young children; it contains a magnet that should not be swallowed.

2.5 PRECAUTIONS

- Do not open the sensor package until you have washed your hands with soap and water, and let them dry. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.
- Do not insert the sensor until you have cleaned the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allowed the skin to dry. Inserting into unclean skin might lead to infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.
- Avoid using the same spot repeatedly for sensor



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insertion. Rotate your sensor placement sites, and do not use the same site for two sensor sessions in a row. Using the same site might cause scarring or skin irritation.

- Avoid inserting the sensor in areas that are likely to be bumped, pushed or compressed or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the sensor. The insulin might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.
- To calibrate the system, do enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Do not enter sensor glucose readings for calibration. Entering incorrect blood glucose values, blood glucose values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing



the rising or falling single arrow or double arrow, which indicates that your blood glucose is rapidly rising or falling. Calibrating during significant rise or fall of blood glucose may affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

- The system accuracy may be affected when your glucose is changing at a significant rate (e.g., 2-3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal.
- Avoid separating the transmitter and receiver by more than 20 feet. The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Keep the USB port cover on the receiver closed whenever the USB cable is not attached. If water gets into the USB port, the receiver could become damaged and stop displaying readings or providing alerts and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not



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represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor accuracy and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

- Do not discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.
- The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver are not compatible with the SEVEN/SEVEN PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work. Also make sure to use the correct version of Dexcom STUDIO with your system.

2.6 CAUTION

U.S. (Federal) law restricts the sale of the Dexcom G4 PLATINUM (Pediatric) System to sale by or on order of a physician.