



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.
Hypoglycemia	Low blood glucose. Same as “low.” The default low alert in your receiver is set to 80 mg/dL. Consult your healthcare 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 healthcare 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.
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 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.

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.

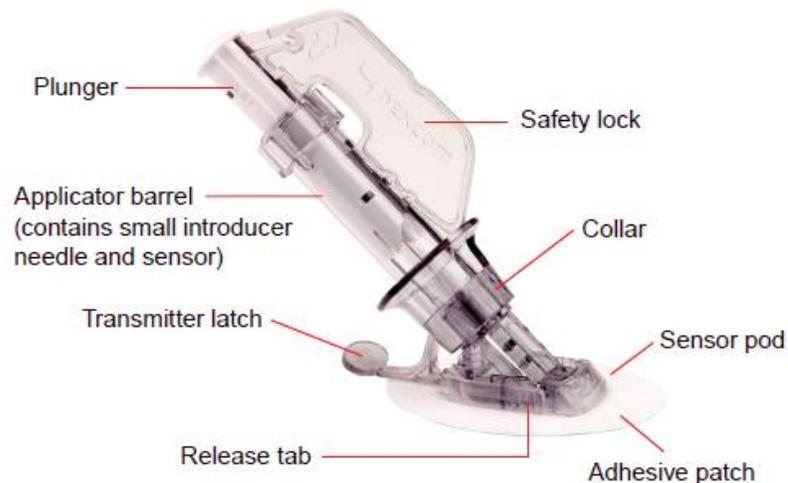
Please read this user's guide closely. It describes how to use your system.

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.



1.4 TRANSMITTER OVERVIEW

The transmitter is the gray, plastic "chip" that snaps into your sensor pod. The 9438-01 transmitter (including sensor pod) is about 1.5 inches long, 0.9 inches wide and 0.5 inches thick. The 9438-05 transmitter (including sensor pod) is about 1.5 inches long, 0.9 inches wide and 0.4 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

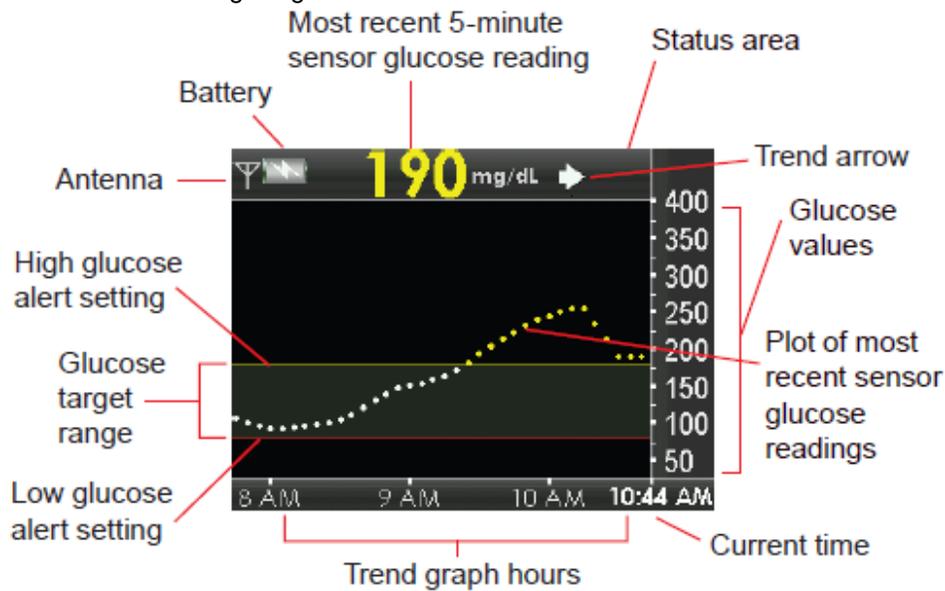


Transmitter Low Battery screen

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.

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 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.

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.
- 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 **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 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 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.

CHAPTER 3: RISKS AND BENEFITS

3.1 RISKS

There are some known risks with using real-time CGM.

You will not get sensor glucose alerts when the alert function is turned off, your transmitter and receiver are out of range, or when your receiver is not showing sensor glucose readings. You might not notice alerts if you are unable to hear them or feel the vibration. Sometimes your sensor glucose reading may be slightly different than your blood glucose meter. For example, your blood glucose meter may show a blood glucose value of 78 mg/dL, but your sensor glucose reading may show as 82 mg/dL. If your low alert is set at 80 mg/dL, your system will not alert for a low glucose at this time because 82 mg/dL is still above your low alert setting. In most cases, the sensor glucose readings will move in the right direction and will alert you of a high or low shortly after. If you do not get an alert for any reason, and you do not take frequent blood glucose measurements with your blood glucose meter, you might not be aware of low or high blood glucose levels. If this happens, and your blood glucose levels are very high or low, there is a remote chance you might need medical help.

Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain or skin irritations (redness, swelling, bruising, itching, scarring or skin discoloration). There is a low chance of this happening. In the clinical study for the Dexcom G4 PLATINUM (Pediatric) System, only slight redness and swelling occurred in a few patients. If any of these events happen, you might feel discomfort in the area the sensor is inserted.

There is a remote chance that a sensor fragment could remain under your skin if the sensor breaks while you are wearing it. This did not happen in the clinical study for the Dexcom G4 PLATINUM (Pediatric) System. If you think a sensor has broken under your skin, contact your healthcare professional and call Dexcom's Technical Support. Sensor breakage may cause some anxiety, but it is not a significant medical risk.

3.2 BENEFITS

Real-time CGM provides benefits beyond the information you get from a blood glucose meter. It provides glucose readings every five minutes for up to seven days to help you detect trends and patterns in your glucose levels. This trend information can help you see where your glucose is now as well as where your glucose may be heading and how fast you may be getting there. Understanding your glucose trends may help you take action to help avoid high or low glucose values.

Alerts and the low alarm tell you when your glucose is outside of your target glucose range and may help you avoid low and high blood sugar. Rise and fall glucose alerts can

also provide benefit by alerting you when your glucose is rapidly going down or up. This way you can be alerted to this information before you are too high or too low and take action to avoid it. Real-time CGM can help increase time in your target glucose range without increasing your time in the low or high glucose range.¹

Real-time CGM can help improve diabetes control (lower A1c values, reducing glycemic variability and time spent in low and high blood glucose ranges)^{1, 2, 3} which can help reduce diabetes related complications.^{4, 5} These benefits can be seen especially with using real-time CGM at least 6 days per week² and can be sustained over time.⁶ In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM as well as reporting a high satisfaction with CGM.⁷

¹ Garg S, Zisser H, Schwartz S, Bailey T, Kaplan R, Ellis S, Jovanovic L. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006; 29:44-50.

² JDRF CGM Study Group. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. *NEJM* 2008;359:1464-76.

³ Battelino. Effect of continuous glucose monitoring of hypoglycemia in type 1 diabetes. *Diabetes Care* 2011; 34(4): 795-800.

⁴ The Diabetes Control and Complications Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications of insulin-dependent diabetes mellitus. *N Eng J Med*. 1993; 329:997-1036.

⁵ Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents progression of diabetic microvascular complications in Japanese patients with non-insulin dependent diabetes mellitus: a randomized prospective 6-year study. *Diabetes Res Clin Pract*. 1995; 28:103-117.

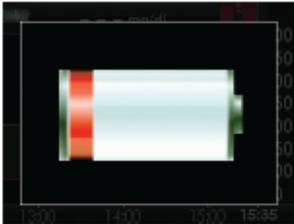
⁶ JDRF CGM Study Group. Sustained Benefit of Continuous Glucose Monitoring on A1c, Glucose Profiles, and Hypoglycemia in Adults With Type 1 Diabetes, *Diabetes Care* 2009; 32: 2047-2049.

⁷ JDRF CGM Study Group. Quality-of-Life Measures in Children and Adults With Type 1 Diabetes. *Diabetes Care* 2010; 33: 2175-2177.

CHAPTER 4: CHARGING YOUR RECEIVER AND THE RECEIVER MAIN MENU

4.1 CHARGING YOUR RECEIVER BATTERY

The receiver battery is rechargeable and will last about 3 days with normal use before you need to charge it. Your battery life depends on how often you press your receiver buttons or get alerts. The receiver will tell you when the battery charge is low.



Low battery prompt

Charge the receiver battery using one of these options:

- Section 4.1.1: an AC power outlet
- Section 4.1.2: a personal computer with Windows® operating system (to charge your receiver from your PC, Dexcom STUDIO must be installed. For system requirements and more information, see the Dexcom website (www.dexcom.com) or the Dexcom STUDIO Software User's Guide.)

Only use the Dexcom battery charger provided in the receiver kit. Do not use any other battery charger.

Charge only from a USB port on your computer or the AC power adapter. Do not use an external USB hub. An external USB hub may not provide enough power to charge the receiver.

Fully charging an empty battery takes about 3 hours with the wall charger and about 5 hours with a computer. The battery does not need to be drained to charge fully.

You may use the receiver while it is charging with an AC power outlet or PC.

Charge your receiver battery before each sensor insertion. Periodically check your battery level to make sure it has enough charge.

If your battery drains, it will keep the time and date for 3 days without being charged. After 3 days, the receiver will prompt you to reset the time and date (see Chapter 5, Section 5.2, The Settings Menu).

When the receiver is used in a healthcare facility, charging must take place away from the patient.

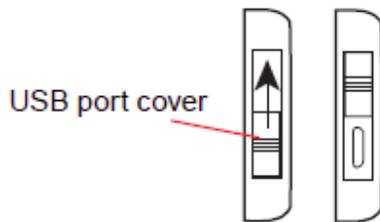
WARNING

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.

4.1.1 CHARGING YOUR RECEIVER BATTERY FROM AN AC POWER OUTLET

To recharge your battery:

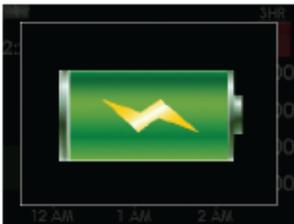
1. Plug the included USB cable into the AC power adapter.
2. Plug the AC power adapter into an AC power outlet.
3. Slide open the USB port cover on the side of the receiver to reach the port. Press down firmly with your thumb when sliding open the USB port cover.



4. Plug the micro USB end of the cable into the receiver USB port.

Keep the USB port cover on the receiver closed whenever the USB cable is not attached.

5. The battery charging screen will show on the receiver.



Battery charging screen

6. After a few seconds the trend graph will show with the battery charging symbol () in the upper left corner.



Battery charging symbol

In upper left corner of
Trend graph

4.1.2 CHARGING YOUR RECEIVER BATTERY FROM A WINDOWS COMPATIBLE COMPUTER

You must install the Dexcom STUDIO software to charge your receiver from a computer. Please see the Dexcom STUDIO installation card for driver installation instructions.

1. Plug the included USB cable into your computer.
2. Plug the other end of the USB cable into the receiver.
3. The battery charging screen shows on the receiver.



Battery charging screen

4. After a few seconds, the trend graph screen will show the battery charging symbol in the upper left corner.



Battery charging symbol
in upper left corner of
trend graph

4.1.3 KNOWING YOUR RECEIVER IS CHARGED

As the battery charges, the battery charging symbol fills in. When the battery is fully charged, the battery charging symbol is completely shaded.



Battery charging symbol fills in as battery charges

4.2 RECEIVER MENU OPTIONS

The receiver's Main Menu lets you scroll through important menu options. This table explains the purpose of each option. More information on Main Menu options can be found in the chapters listed:

Receiver Main Menu Options

Menu	Purpose	User's Guide Reference
------	---------	------------------------

Trend Graph	To show the trend graphs. <ul style="list-style-type: none"> The 3-hour trend graph is the default screen whenever you turn on the receiver. 	Chapter 8
Start Sensor	To start a new sensor session. <ul style="list-style-type: none"> This option only shows if you have entered a transmitter ID and you are not in the middle of a sensor session 	Chapter 6
Enter BG	To enter your blood glucose values for calibration.	Chapter 7
Profiles	Profiles allow you to customize the sound and volume of alerts and alarm.	Chapter 9
Events	To enter personal information about meals, insulin, exercise, and health status.	Chapter 10
Alerts, High/Low	To change the settings for high and low alerts.	Chapter 9
Settings	To change the time, date and transmitter ID; to look up your Dexcom G4 PLATINUM (Pediatric) System hardware and software version numbers; to view transmitter battery status, last calibration value and sensor insertion time.	Chapter 5
Shutdown	To temporarily turn off all communication between your transmitter and receiver during a sensor session. You will not get sensor glucose readings, and it will not extend the life of your sensor.	Chapter 6
Stop Sensor	To end a sensor session early. <ul style="list-style-type: none"> This option only shows when you are in the middle of a sensor session. You will not get sensor glucose readings, and you must dispose of your sensor if you stop the session. 	Chapter 13

See Chapter 18, Appendix I, Receiver Alerts, Alarm and Prompts, for a list of screens that may show on the receiver.

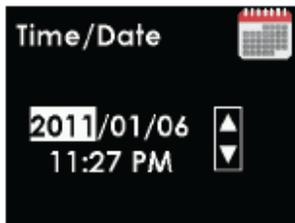
CHAPTER 5: DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM SETUP

This chapter helps you when you first set up your Continuous Glucose Monitoring system. Read this chapter before you start.

5.1 SETTING UP THE RECEIVER AND PAIRING WITH YOUR TRANSMITTER

The Setup Wizard guides you through setup the first time you turn on your receiver.

1. Remove the transmitter from its packaging. Wait 10 minutes for the transmitter to turn on before setting up the receiver.
2. Make sure your receiver is fully charged (see Chapter 4, Section 4.1, Charging Your Receiver Battery).
3. Press the **SELECT** button on the receiver to turn it on. The Setup Wizard will guide you to enter the following setup information:
 - a. Set the time and date. The date format is YYYY/MM/DD.



Time/Date setting screen

- (1) Press the **UP** or **DOWN** button to enter the current date and time.
- (2) Press the **RIGHT** or **SELECT** button to move to the next section.
- (3) Press the **SELECT** button to confirm time and date.

- b. Enter your transmitter ID.



Transmitter ID setting screen

- (1) Press the **UP** or **DOWN** button to enter your transmitter ID.
 - (2) Press the **RIGHT** or **SELECT** button to move to the next space.
 - (3) Press the **SELECT** button after you enter the last number or letter to confirm the transmitter ID.

Your transmitter ID is a unique code with 5 numbers and/or letters found in the following locations:

- On the transmitter box label
- On the bottom of the transmitter

c. Set your low and high glucose alert values. Your low and high glucose alerts are pre-set to 80 mg/dL and 200 mg/dL but can be changed.



Low Alert setting screen



High Alert setting screen

(1) Press the **UP** or **DOWN** button to select your alert level. The low alert can be changed in steps of 5 mg/dL, and the high alert can be changed in steps of 10 mg/dL.

(2) Press the **SELECT** button to confirm your alert level.

- You can also change your alert levels in the Alerts menu.
- The unit of measure (mg/dL) is not adjustable.
- If you need to change the time, date or transmitter ID after you complete the Setup Wizard see Section 5.2, The Settings Menu.

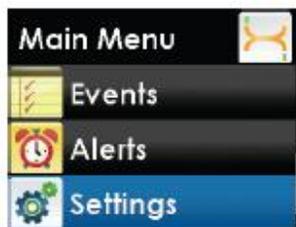
The Setup Wizard is now complete. To start using your Dexcom G4 PLATINUM (Pediatric) CGM System you must insert a sensor (see Chapter 6, Inserting a Sensor and Starting a Sensor Session).

5.2 THE SETTINGS MENU

The Settings menu lets you change the time, date or transmitter ID. The Setup Wizard only works the first time you turn on your receiver, but you can always use the Settings menu.

5.2.1 GETTING TO THE SETTINGS MENU

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph shows.
2. Press the **SELECT** button to see the Main Menu.
3. From the Main Menu, press the **UP** or **DOWN** button to scroll to “Settings” and press the **SELECT** button. The Settings menu shows:



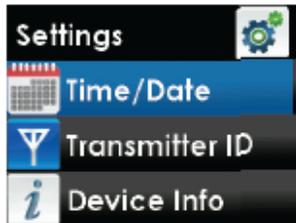
Main Menu, Settings highlighted



Settings Menu

5.2.2 SETTING YOUR RECEIVER TIME AND DATE

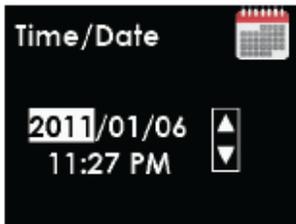
1. From the Settings menu, press the **UP** or **DOWN** button to scroll to “Time/Date,” and press the **SELECT** button.



Settings menu, Time/Date highlighted

2. Press the **RIGHT** button to highlight each value in the date and time.
3. Press the **UP** or **DOWN** button to make any changes.
4. Press the **RIGHT** button to move to the next value.

The date format is YYYY/MM/DD.



Time/Date setting screen, year highlighted

5. Press the **SELECT** button after choosing “AM” or “PM.” You will return to the Settings menu.

You might need to reset the receiver’s time and date if the rechargeable battery drains. If this happens, the receiver will alert you and automatically take you to the Time/Date setting screen.

5.2.3 ENTERING YOUR TRANSMITTER ID

Any time you switch to a new transmitter and/or receiver you must enter the transmitter ID into your receiver. The transmitter ID is a series of 5 numbers and/or letters that can be found in the following locations:

- On the transmitter box label
- On the bottom of the transmitter

If you cannot find your transmitter ID, please contact Dexcom Technical Support (see Chapter 15, User Assistance).

You can only set your transmitter ID when you are not in a sensor session. During a sensor session, “Transmitter ID” will not be an option on the Settings menu.

To enter the transmitter ID follow these steps:

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to “Transmitter ID” and press the **SELECT** button.



Settings menu, Transmitter ID highlighted

2. Start with the first number or letter (do not enter “SN”):
 - a. Press the **UP** or **DOWN** button to show the correct number or letter.



Transmitter ID setting screen, first digit highlighted

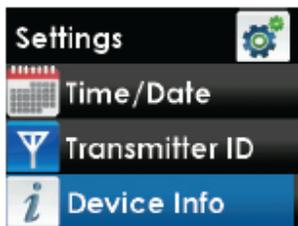
- b. Press the **RIGHT** or **SELECT** button to move to the next value and repeat step a.
 - c. Continue repeating steps a and b to enter the whole transmitter ID.
 - d. Press the **SELECT** button after you enter the last number or letter. You will return to the Settings menu.

NOTE: The “Transmitter ID” menu option is marked with an antenna symbol as a graphical flag; it does not tell you whether the transmitter and receiver are communicating. The “Transmitter ID” menu option only shows when you are not in a sensor session. See Section 5.4 for the antenna symbol that shows whether the transmitter and receiver are communicating.

5.3 CHECKING INFORMATION ABOUT YOUR DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM

You can check your receiver for information about your CGM system at any time.

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to “Device Info.”



Settings menu, Device Info highlighted

2. Press the **SELECT** button. Information about your sensor session and system will show.



Device Info screen

3. Scroll down to see all of the Device Info:

- Insertion Time
- Last Calibration
- Transmitter Battery
- Transmitter ID
- Serial Number
- Part Number
- Part Revision
- Software Number
- Software Revision

4. Press the **LEFT** button to return to the Settings menu.

5.4 TRANSMITTER AND RECEIVER COMMUNICATION

When you are in a sensor session, you can check that the receiver and transmitter are communicating.

CONTRAINDICATION

MR 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.

PRECAUTION

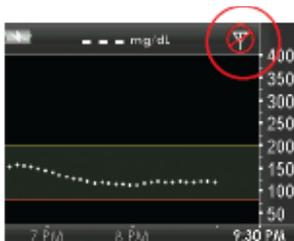
Avoid separating the transmitter and receiver by more than 20 feet. The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc.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

Press the **SELECT**, **LEFT** or **RIGHT** button to see the trend graph. This antenna symbol  shows that the transmitter and receiver are communicating.



Antenna symbol appears in upper left of trend graph

This out of range symbol  shows the transmitter and receiver are not communicating.



Out of range symbol appears in upper right of trend graph

CHAPTER 6: INSERTING A SENSOR AND STARTING A SENSOR SESSION

You need a sensor, a transmitter, and a receiver to use your Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System. You also need a blood glucose meter and test strips for calibration. The blood glucose meter and test strips are not provided in the Dexcom G4 PLATINUM (Pediatric) System. The sensor continuously measures and displays your sensor glucose readings for up to 7 days. The following sections will show you how to insert the sensor and start a new continuous glucose monitoring session.

Please review the tutorial on the disc in your kit. The tutorial is also available online at www.dexcom.com.

WARNING

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 **1.877.339.2664** or **1.858.200.0200**.

For patients undergoing an MRI with a retained wire broken off from a Dexcom G4 PLATINUM Sensor, in-vitro MRI testing did not detect any safety hazards. There was no significant migration or heating of the wire and imaging artifacts were limited to the area around the wire.

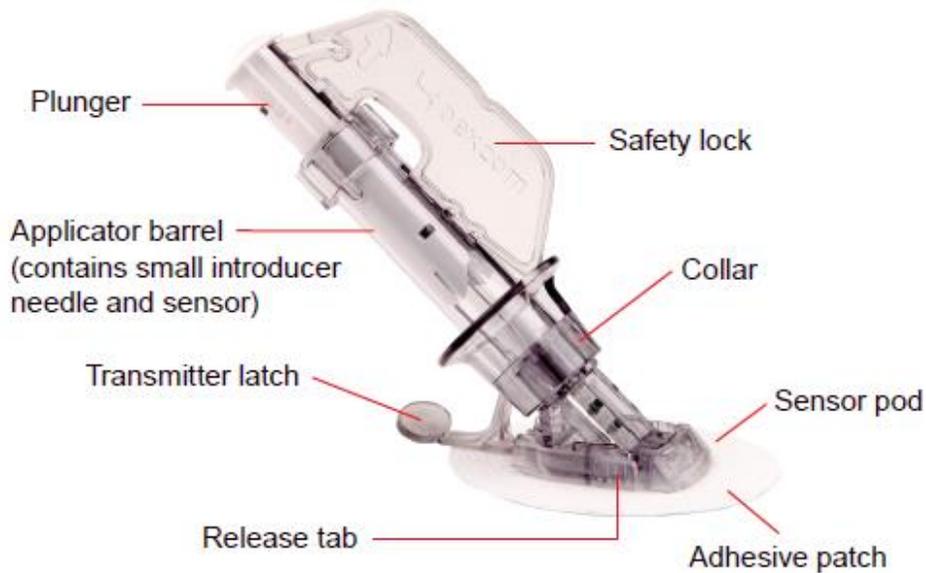
6.1 BEFORE YOU START

- Make sure the correct transmitter ID has been entered into your receiver (see Chapter 5, Section 5.2, The Settings Menu). You do not need to re-enter the transmitter ID each time you start a sensor session.
- Check the expiration date on the sensor package label. The format is YYYY-MM-DD. Insert sensors on or before the end of the expiration date calendar day.
- Follow your blood glucose meter's manufacturer's instructions to make sure you are getting accurate blood glucose values for calibration.
- Wipe the bottom of the transmitter with a damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth, and air dry for 2-3 minutes.
- Make sure your blood glucose meter and receiver date and time match.

WARNING

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.

Review the sensor applicator picture before using a new sensor.



6.2 REMOVING THE SENSOR FROM ITS PACKAGING

PRECAUTION

Do not use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.

- Wash your hands thoroughly, and dry them.
- Carefully remove the sensor from its packaging. Look closely at the sensor to make sure it is not damaged.
- The applicator is for single use and is disposable.
- The safety lock prevents you from releasing the needle accidentally before you are ready.

6.3 CHOOSING AN INSERTION SITE

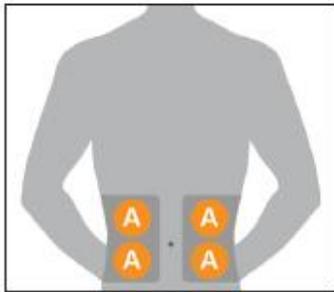
PRECAUTIONS

- 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.

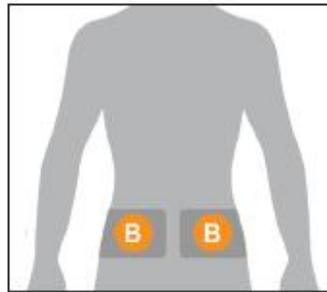
Review the tutorial disc for more help to learn how to insert your sensor.

Choose a site to place the sensor. Insert in the belly (front of body, option A) or the upper buttocks (back of body, option B).

No other sensor insertion sites have been tested and we do not know how well the sensor will work in other sites.



Front of body, sensor site option A



Back of body, sensor site option B

The ideal sensor insertion site for you may be based on your body type, activity, sensitivities, and other personal and physical traits. You can choose a site above or below your belt line. The best areas to insert your sensor are usually flat and “pinchable.” Avoid sensor insertion where something may rub or press against the sensor. For example, avoid sensor insertion along the waist band and seat belt strap, in or near the belly button, on the upper buttocks near the waist/belt or too low on the buttocks where you sit.

PRECAUTION

Avoid using the same spot repeatedly for sensor 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.

- Choose an area at least 3 inches from your insulin pump infusion set or injection site.
- You may need to shave the area where you plan to put the sensor so the adhesive patch sticks securely.
- Make sure there are no traces of lotions, perfumes or medications on the skin where you place the sensor.

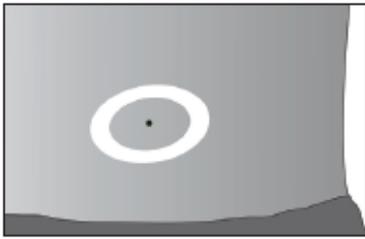
For more help on ideal sensor insertion sites for you, contact your healthcare professional.

6.4 PLACING THE SENSOR

WARNINGS

• 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.

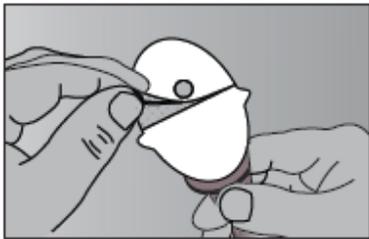
1. Clean your skin at the sensor placement site with an alcohol wipe. Make sure the area is clean and completely dry before you insert the sensor.



Step 1. (Optional) Use skin prep in doughnut shape, and insert in clean skin at center

NOTE: Skin preparation or adhesive products (Mastisol[®], Skin Tac[™]) are optional. If you use an optional skin preparation or adhesive product, place it on the skin in a “doughnut” shape where you will place the sensor adhesive patch. Insert the sensor through the clean skin at the center of the doughnut where it is free of skin preparation or adhesive products. Let dry (skin may feel slightly sticky).

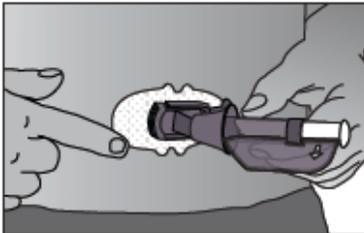
2. Remove the adhesive backing from the sensor pod one half at a time, using the white tabs on the backing. Hold the sensor by the applicator barrel, and try not to touch the sticky adhesive patch.



Step 2. Remove the adhesive backing

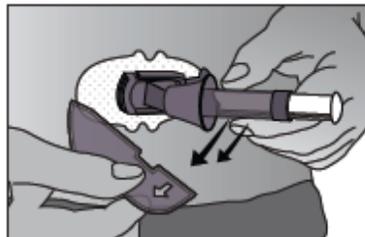
3. Place the sensor horizontally, NOT vertically, on your skin.

4. Move your fingers around the adhesive patch to secure the tape to your skin.



Step 3 and 4. Adhere the sensor on the skin

5. Hold the applicator, and pull the safety lock straight out away from the applicator, in the direction of the arrows in the picture.



Step 5. Remove the safety lock

6. Save the safety lock to help you remove the transmitter at the end of your sensor session. The safety lock can be used for transmitter removal but is not required. When your glucose monitoring session is over, follow the steps in Chapter 11, Section 11.3, Transmitter Removal, with or without the safety lock.

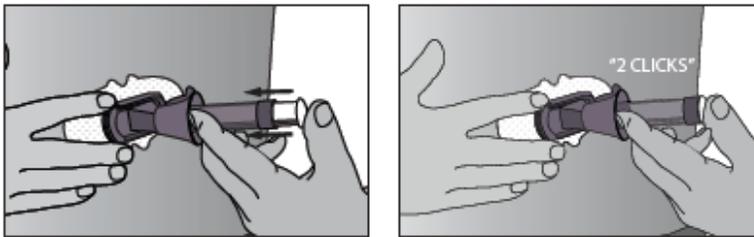
NOTE: Contact your healthcare professional for specific questions regarding the use of medical tape, barrier wipes and/or other adhesives as it relates to your use of Dexcom CGM.

6.5 SENSOR INSERTION

You are ready to insert the sensor after you place the applicator on your skin and remove the safety lock. To insert your sensor follow these steps:

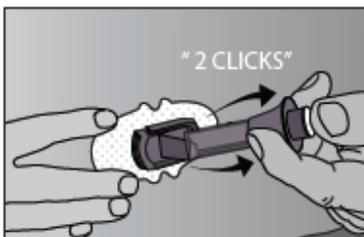
1. Place the fingers of one hand at the edge of the white adhesive (at the opposite side of the sensor from the transmitter latch). You may pinch up on your skin using this hand. Do not pinch up in the middle section of the plastic base.
2. While still pinching, use your other hand to place two fingers above the collar on the applicator barrel so they are resting above the collar.
3. Place your thumb on the white plunger. Push the plunger down completely, making sure it is flush against the applicator barrel. You should hear **2 clicks**. This inserts the needle and sensor under your skin.

When you are pushing down on the plunger, do not pull back on the collar.



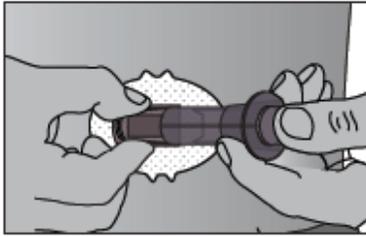
Steps 1-3. Push down the plunger – insert the needle and sensor

4. Keep pinching up on your skin with one hand. With your other hand, place two fingers under the collar. Keep your thumb lightly on top of the white plunger, and pull the collar back towards your thumb until you hear **2 clicks** or cannot pull back any more. This leaves the sensor under your skin and removes the needle from your body.



Step 4. Pull back the collar – retract the needle

5. Squeeze the center of the ribbed release tabs on the sides of the sensor pod to remove the applicator barrel. Only the sensor pod will be left on your body.



Step 5. Release the applicator barrel

- Make sure the transmitter latch is down (against your body) before squeezing the tabs to remove the applicator barrel.
- Squeeze the center of the ribbed part of the release tabs.
- While squeezing the tabs, rock the applicator barrel forward and out away from your body.

If you have any problems with insertion, save the sensor and applicator and contact Dexcom Technical Support (see Chapter 15, User Assistance).

6.6 TRANSMITTER ATTACHMENT

You must snap the transmitter into the sensor pod after you insert your sensor. Follow these steps to attach your transmitter.

1. Wipe and dry the bottom of the transmitter with a damp cloth or an alcohol wipe before every use.

Do not touch the metal circles on the bottom of the transmitter with your skin.

Do not scratch the bottom of the transmitter as scratches may compromise the waterproof seal.

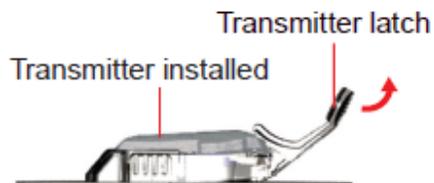
2. Place the transmitter in the sensor pod (with the flat side down, and the narrower side away from the transmitter latch).



Install transmitter in sensor pod

3. Snap in the transmitter:

- a. With one hand, you may want to pinch up on your skin at the front edge of the white adhesive.
- b. Place one finger on the transmitter to keep it in place.
- c. With your other hand, pull the transmitter latch up and forward, over the transmitter, to snap it into place. The transmitter should lie flat in the sensor pod.



Side view of transmitter in sensor pod

- Make sure you hear **2 clicks** when you snap the transmitter in place. If it is not fully snapped in, this may lead to a poor connection and let fluids to get under the transmitter. This can lead to inaccurate sensor glucose readings.

- d. Release your pinch on the adhesive edge at this time.
 - e. Make sure the transmitter is secure by sliding your fingers under each long side of the sensor pod and pressing down on the transmitter with your thumb of the same hand, like you are pinching it.
4. Hold the sides of your sensor pod with one hand. Remove the transmitter latch with your other hand by quickly twisting off the latch away from your body.



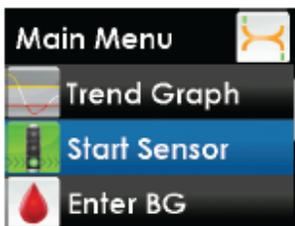
Twist transmitter latch up or down

5. Do not remove the transmitter from the sensor pod while the pod is attached to your skin.

6.7 STARTING A SENSOR SESSION

Follow the steps below to tell the receiver that you inserted a new sensor.

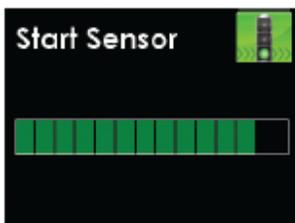
1. Press the **SELECT** button to turn on the receiver.
2. From any trend graph, press the **SELECT** button to see the Main Menu.
3. Press the **DOWN** button to highlight “Start Sensor.”



Main Menu, Start Sensor highlighted

- The “Start Sensor” menu option will disappear from the Main Menu after you select it. The option will only come back after an active sensor session ends. If you do not see the “Start Sensor” option on your menu screen, you can continue your current session or stop the session (refer to Chapter 13, Section 13.6, Sensor Shut-off Troubleshooting).

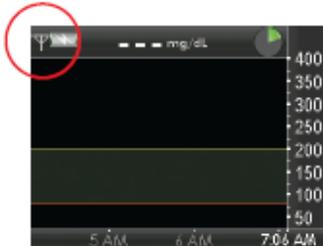
4. Press the **SELECT** button to confirm the start of a new sensor session. The Start Sensor “thinking” screen lets you know your sensor 2-hour startup has begun.



Start Sensor “thinking” screen

5. Press **SELECT** to confirm this message. Your receiver returns to the 3-hour trend graph.

6. Check your receiver 10 minutes after starting your sensor session to make sure your receiver and transmitter are communicating. The antenna symbol  should be in the upper left corner of trend graph. If the out of range symbol  shows in the upper right corner of the trend graph, see Chapter 13, Section 13.9, Out of Range/No Antenna.



Antenna symbol should appear in upper left of trend graph

7. You will not get sensor glucose readings or alerts until your 2-hour startup period ends and you complete your first calibrations. See Chapter 7, Section 7.3, Startup Calibration.

6.8 SENSOR STARTUP PERIOD

The sensor needs a 2-hour startup period to adjust to being under the skin.

Your trend graph shows a 2-hour countdown symbol  in the upper right corner.

1. Press **SELECT** during the startup period to turn the on receiver display and see this symbol.



Countdown symbol appears in upper right of trend graph

The countdown symbol  fills in over time to show that you are getting closer to the first calibration time.

You will not get sensor glucose readings, alerts and alarm during the countdown.



Countdown symbol fills in during sensor startup

If you see the out of range symbol  at the top of the screen during the 2-hour startup, review the following troubleshooting tips:

- Make sure your receiver and transmitter are within 20 feet of each other without obstruction. Check in 10 minutes to see if the antenna symbol shows in the upper left corner of the receiver screen.
- If the receiver and transmitter are still not communicating, check the device information screen to make sure the correct transmitter ID is entered into your receiver (see Chapter 5, Section 5.2, The Settings Menu).

- If the correct transmitter ID is in your receiver and the receiver and transmitter are still not communicating, contact Dexcom Technical Support (see Chapter 15, User Assistance).

At the end of the 2-hour startup period the receiver lets you know it is time to calibrate your sensor. Chapter 7, Calibrating Your Dexcom G4 PLATINUM (Pediatric) System, tells you how to calibrate your sensor.

6.9 TAPING THE SENSOR POD

The sensor pod should stay on your skin using its own adhesive. But, if the patch is peeling up, you can use medical tape (such as Blenderm™, Tegaderm™, Smith & Nephew IV3000®, 3M™ tape) for extra support. If you use tape, only tape over the white adhesive patch on all sides for even support. Do not tape over the transmitter or any of the plastic parts of the sensor pod. Do not tape under the sensor pod or leave any substance on the skin where you insert the sensor.

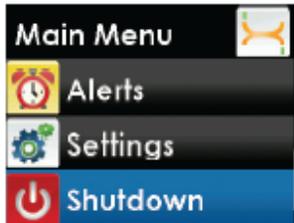


The right way to use tape for extra support

6.10 TEMPORARY RECEIVER SHUTDOWN

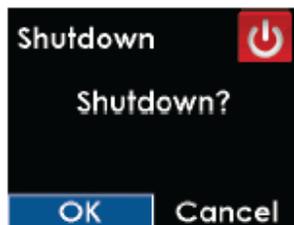
There may be times when you want to shut down your receiver temporarily. Shutdown stops all communication between the transmitter and receiver and turns the receiver off. You will not receive sensor glucose readings or **any** alerts or alarm while the receiver is shut down, but your current sensor session will continue. Follow these steps to shut down your receiver:

1. From the Main Menu, scroll to highlight “Shutdown.” Press the **SELECT** button.



Main Menu, Shutdown highlighted

2. Confirm that you want to shut down your receiver.
 - a. If you want to shut down, press the **LEFT** button to highlight “OK,” and then press the **SELECT** button.



Shutdown screen OK highlighted

- b. If you want to cancel the shutdown, press the **SELECT** button (with “Cancel” highlighted) to return to the Main Menu.

To turn the receiver back on and resume communication with the transmitter, press the **SELECT** button. It may take up to 20 seconds for the display to turn back on.

Remember that your alerts and low glucose alarm will not work when the receiver is shut down.

Shutting down the receiver does not extend the sensor life beyond 7 days. Your sensor session will stop 7 days after you started the sensor session.

6.11 THE DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM AND WATER

Your sensor is water resistant when showering, bathing or swimming if the transmitter is fully snapped in. The sensor has been tested to be water resistant when submerged for up to 8 feet and up to 24 hours.

Keep the receiver dry. Do not spill fluids on it or drop it into fluids. **Keep the micro USB port cover closed to help prevent fluid from getting inside the receiver.** Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub or water bed.

If your receiver gets wet, make sure the speaker and vibrate mode are still working. You can do this using the Try It option in the profiles menu. See Chapter 9, Section 9.3, Alert Profiles.

CHAPTER 7: CALIBRATING YOUR DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM

You must calibrate Dexcom G4 PLATINUM (Pediatric) System sensor glucose readings to your blood glucose meter.

CONTRAINDICATION

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.

7.1 CALIBRATION OVERVIEW

Your receiver needs calibrations to display continuous sensor glucose readings and trend information. There are important times when you **must** calibrate:

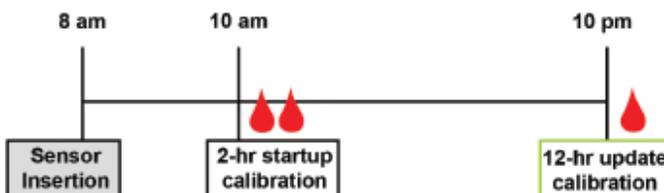
1. 2-hour startup: 2 hours after you insert your sensor
2. 12 hour update: every 12 hours after the 2-hour startup calibration
3. More information needed or other reasons

When calibrating, you must enter your blood glucose values into the receiver by hand. You can use any commercially available blood glucose meter. You must calibrate with accurate blood glucose meter values to get accurate sensor glucose readings.

On the first day of your sensor session, you must enter 2 blood glucose values into your receiver. You must enter 1 blood glucose value calibration 12 hours after your startup calibration. You must enter 1 blood glucose value every 12 hours. The receiver will remind you when it needs these calibrations. You may be prompted to enter additional blood glucose values as needed.

Example Minimum Calibration Schedule During Seven-Day Sensor Session

Monday (Day One of Sensor Session):



Tuesday - Sunday (Days 2-7 Sensor Session):



Example Minimum Calibration Schedule During Seven-Day Sensor Session

PRECAUTION

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 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.

7.2 HOW TO CALIBRATE

You must enter the exact blood glucose value from your meter for each calibration. Blood glucose values must be between 40-400 mg/dL and must have been taken within the past 5 minutes.

- Make sure either a sensor glucose reading or a calibration needed symbol  shows at the top of the trend graph before calibrating.
- Your sensor can be calibrated if your meter glucose is 40 mg/dL or above. For safety reasons, if your blood glucose is low, first treat your low blood sugar.
- Always make sure the antenna symbol  is in the upper left corner of the trend graph before you enter blood glucose values for calibration.
- Always use the same meter to calibrate that you routinely use to measure your blood glucose. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy vary between blood glucose meter brands.
- The accuracy of the blood glucose meter value used for calibration may affect the accuracy of sensor glucose readings.

WARNING

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.

PRECAUTION

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.

PRECAUTION

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.

Only use blood glucose values between 40-400 mg/dL for calibration. If the blood glucose value you enter is outside of this range, the receiver will not calibrate. You must wait until your blood glucose is in this range to calibrate.

These steps show you how to enter your blood glucose values for calibration:

1. Wash and dry your hands, make sure your glucose test strips are not expired and have been stored properly, and make sure your meter is properly coded (if required).
2. Take a blood glucose measurement using your meter.
 - Carefully apply the blood sample to the test strip following your meter or test strip instructions.
3. From any trend graph, press the **SELECT** button to see the Main Menu.
4. Use the **UP** or **DOWN** button to scroll until you highlight “Enter BG.”
 - “Enter BG” will be the second Main Menu option when you are in the middle of a sensor session.



Main Menu, Enter BG highlighted

5. Press the **SELECT** button to choose this option. You will see a screen with a blood drop and a number in mg/dL units.

- a. When the receiver does not have a recent sensor glucose reading the default is 120 mg/dL.

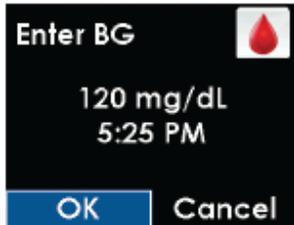


Enter BG screen, default is 120 mg/dL

b. If there has been a sensor glucose reading in the past 15 minutes, the Enter BG screen shows your current sensor glucose reading. **Do not use the current sensor glucose reading for calibration.** Use only blood glucose values from your meter.

6. Use the **UP** or **DOWN** button to scroll until you see the correct blood glucose value, and then press the **SELECT** button.

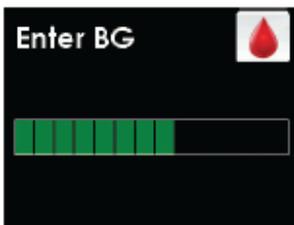
7. **Confirm that the blood glucose value you entered is correct. Entering incorrect values may affect the sensor accuracy.**



Enter BG screen, OK highlighted to confirm

- a. Press the **SELECT** button if the blood glucose value displayed is correct.
- b. If the blood glucose value shown is incorrect, press the **RIGHT** button to highlight "Cancel" then press the **SELECT** button to return to the Enter BG screen. Repeat the steps to enter the correct blood glucose value.
- c. If you do not press the **SELECT** button, the receiver will "time out" and no blood glucose value will be recorded for calibration.

8. The Enter BG "thinking" screen lets you know the blood glucose value is being used for calibration.



Enter BG "thinking" screen

9. For 2-hour startup calibration, repeat these steps for the second blood glucose value.

A sensor glucose reading appears on the receiver right away, and sensor glucose readings are updated every 5 minutes.

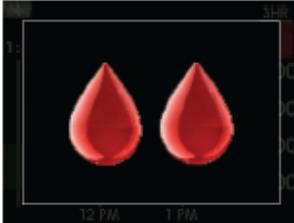
If readings do not appear immediately, see Chapter 13, Section 13.2, Calibration Troubleshooting.

PRECAUTION

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.

7.3 STARTUP CALIBRATION

Two hours after you start the sensor session (see Chapter 6, Section 6.7, Starting a Sensor Session) the receiver tells you that you need to calibrate by showing the startup calibration prompt. This means you need to calibrate with 2 separate blood glucose values from your meter. **You will not see sensor glucose readings until the receiver accepts the blood glucose values.**



Startup calibration prompt

1. When you see this screen, press the **SELECT** button to clear it.
 - a. The startup calibration symbol will stay at the top of the trend graph until you calibrate.
 - b. The system will re-alert you every 15 minutes until you enter the blood glucose values.
 - c. If you do not clear the prompt, the system will re-alert you every 5 minutes.
2. Take 2 separate blood glucose measurements with your meter, and enter the blood glucose values into the receiver (see Chapter 7, Section 7.2, How to Calibrate).

7.4 12-HOUR CALIBRATION UPDATE

Calibrate your system at least every 12 hours after your first calibration (2-hour startup calibration) to make sure your sensor glucose readings remain accurate and close to your blood glucose meter values. You can enter blood glucose values earlier than 12 hours if you want. If you have not entered any blood glucose values in the past 12 hours, the receiver will ask you to enter a blood glucose value to update its calibration.

WARNING

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.

The following steps show you how to enter this calibration.

1. When you see this screen, press the **SELECT** button to clear it.



Calibration prompt

- a. The calibration needed symbol will stay at the top of the trend graph until you calibrate.
 - b. The system will re-alert every 15 minutes until you enter the blood glucose values.
2. Take 1 blood glucose measurement with your meter, and enter the blood glucose value into the receiver. If this screen reappears soon, see Chapter 13, Section 13.2, Calibration Troubleshooting.

7.5 OTHER REASONS YOU MAY NEED TO CALIBRATE

You may need to calibrate when your system did not accept the last calibration or your blood glucose value is very different from the sensor glucose reading.

When you see this calibration prompt it means it is time to calibrate with a single blood glucose value.



Calibration prompt

Take 1 blood glucose measurement with your meter, and enter the blood glucose into the receiver. If this screen reappears soon, see Chapter 13, Section 13.2.1, Types of Calibration Prompts.

These screens show calibration errors (see Chapter 13, Section 13.3, Calibration Error Troubleshooting).



Wait 15 minutes calibration error screen Wait 1 hour calibration error screen

CHAPTER 8: SENSOR GLUCOSE READINGS AND TRENDS

This chapter teaches you how to view your sensor glucose readings and trend information. The trend graph provides additional information that your blood glucose meter does not. It shows your current glucose value, the direction it is changing and how fast it is changing. The trend graph can also show you where your glucose has been over time.

CONTRAINDICATION

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.

Your blood glucose meter and sensor measure glucose from two different types of body fluids: blood and interstitial fluid. Therefore, readings from your blood glucose meter and sensor may not match.

The greatest benefit you get from using your Dexcom G4 PLATINUM (Pediatric) System will come from the trending information. It is important that you focus on the trends and rate of change on your receiver, rather than the exact sensor glucose reading.

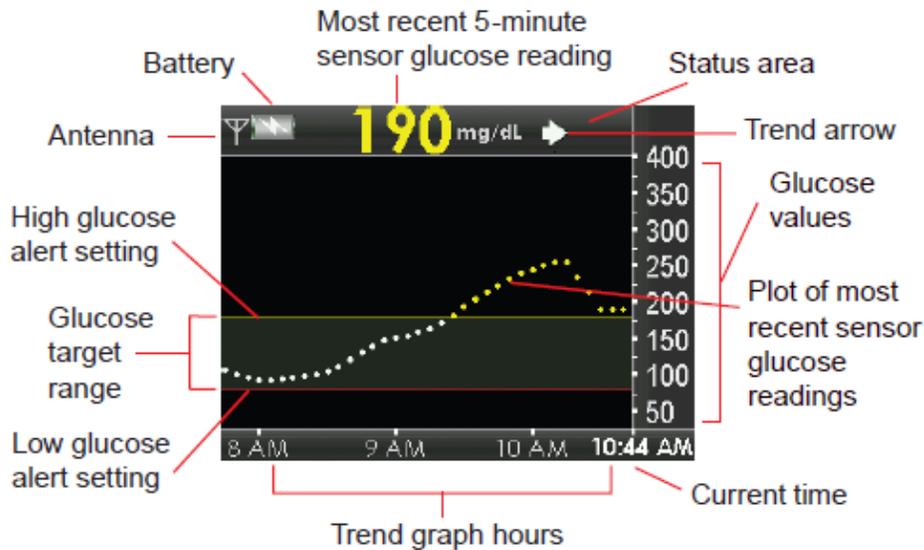
If you have trouble reading your receiver in bright sunlight, find a shady spot.

WARNING

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.

8.1 SENSOR GLUCOSE READINGS

Press the **SELECT** button to wake up the receiver screen and see the home screen (the 3-hour trend graph). The 3-hour trend graph shows the following:



EXAMPLE: 3-Hour Trend Graph Screen

- Each “dot” on the trend graph is a sensor glucose reading reported every 5 minutes.
 - The trend graph shows the current time.
 - The status area shows needed calibration updates, calibration errors and sensor glucose reading issues.
 - Your high alert setting shows as a yellow line across the trend graph.
 - Your low alert setting shows as a red line across the trend graph.
 - The gray zone highlights your target glucose range, based on your high and low glucose alert settings.
 - Your current sensor glucose reading is red if it is low and yellow if it is high, based on your high and low glucose alert settings.
 - If your low glucose alert is not set and your glucose is 55 mg/dL or lower, your glucose value is red.
 - If your sensor glucose readings are in between your high and low glucose alert settings, the glucose value is white.
 - The dots on your trend graph change colors based on your high and low alert settings.

You can view your past glucose information on the 1, 3, 6, 12, and 24 hour trend graphs by pressing the **UP** or **DOWN** button.

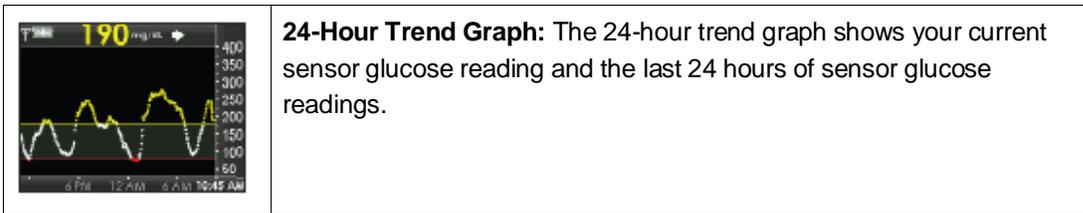
- Your system only reports glucose information between 40-400 mg/dL. Your trend graph shows a flat line or dots at 400 or 40 mg/dL when your glucose is outside this range.



The sensor glucose reading is in
 Milligrams per deciliter (mg/dL) unit

Which Trend Graph Do You See?

<i>(Scroll up from the 3-hour graph to reach the 1-hour graph)</i>	
	<p>1-Hour Trend Graph: The 1-hour trend graph shows your current sensor glucose reading and the last 1 hour of sensor glucose readings.</p>
	<p>3-Hour Trend Graph: The 3-hour trend graph shows your current sensor glucose reading and the last 3 hours of sensor glucose readings.</p>
<i>(Scroll down from the 3-hour graph to reach the 6-hour graph)</i>	
	<p>6-Hour Trend Graph: The 6-hour trend graph shows your current sensor glucose reading and the last 6 hours of sensor glucose readings.</p>
<i>(Scroll down from the 6-hour graph to reach the 12-hour graph)</i>	
	<p>12-Hour Trend Graph: The 12-hour trend graph shows your current sensor glucose reading and the last 12 hours of sensor glucose readings.</p>
<i>(Scroll down from the 12-hour graph to reach the 24-hour graph)</i>	



The receiver displays “LOW” when the most recent sensor glucose reading is less than 40 mg/dL and “HIGH” when the most recent sensor glucose reading is greater than 400 mg/dL.



Trend graph reading LOW Trend graph reading HIGH

8.2 RATE OF CHANGE ARROWS

Your rate of change arrows add detail about the direction and speed of glucose change over the last 15-20 minutes.

The trend arrows show to the right of your current sensor glucose reading.



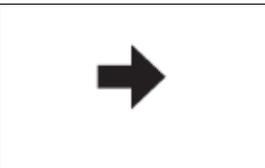
Rate of change arrow appears in upper right of trend graph

Do not overreact to the rate of change arrows. Consider recent insulin dosing, activity, food intake, your overall trend graph and your blood glucose value before taking action.

If there are missed communications between the sensor and receiver during the last 15-20 minutes, an arrow may not display.

This table shows the different trend arrows your receiver displays:

Trend Arrows

	<p>Constant: Your glucose is steady (not increasing/decreasing more than 1 mg/dL each minute). Your glucose could increase or decrease by up to 15 mg/dL in 15 minutes.</p>
---	--

	Slowly rising: Your glucose is rising 1-2 mg/dL each minute. If it continued rising at this rate, your glucose could increase up to 30 mg/dL in 15 minutes.
	Rising: Your glucose is rising 2-3 mg/dL each minute. If it continued rising at this rate, your glucose could increase up to 45 mg/dL in 15 minutes.
	Rapidly rising: Your glucose is rising more than 3 mg/dL each minute. If it continued rising at this rate, your glucose could increase more than 45 mg/dL in 15 minutes.
	Slowly falling: Your glucose is falling 1-2 mg/dL each minute. If it continued falling at this rate, your glucose could decrease up to 30 mg/dL in 15 minutes.
	Falling: Your glucose is falling 2-3 mg/dL each minute. If it continued falling at this rate, your glucose could decrease up to 45 mg/dL in 15 minutes.
	Rapidly falling: Your glucose is falling more than 3 mg/dL each minute. If it continued falling at this rate, your glucose could decrease more than 45 mg/dL in 15 minutes.
No arrow	No rate of change information: The receiver cannot calculate how fast your glucose is rising or falling at this time.

Trend arrows show to the right of your sensor glucose reading. They tell you more about your glucose's speed and direction.

Trend arrows do not show when there are glucose data gaps (see Chapter 13, Section 13.4, System Glucose Error). If the glucose reading error symbol , the wait symbol , the out of range symbol , or the calibration needed symbol  show at the top of the trend graph, the trend arrows will not show.



Trend graph with out of range symbol in upper right and glucose data gaps

If the trend arrow is missing, but you are concerned that your blood glucose level may be rising or falling, take a blood glucose measurement test on your blood glucose meter.

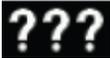
WARNING

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.

8.3 GLUCOSE STATUS AREA SYMBOLS

The “status area” at the top of the trend graph may show any of the status symbols below during your sensor session. You will not get sensor glucose readings during the time a status symbol shows except during the regular 12-hour calibration prompt.

Status Symbols

 Calibration Needed	This symbol means you need to enter a calibration. This prompt will show when it is time for your 12-hour calibration update or any other time an additional calibration is needed (see Chapter 7, Section 7.2, How to Calibrate).
 Additional Startup Calibration Needed	This symbol means you need to enter one more blood glucose value in order to calibrate the system and start getting sensor glucose readings.
 Glucose Reading Error	This symbol means the receiver does not understand the sensor signal but is likely to recover. This symbol is related to the sensor only. You should wait for more prompts and do not enter any blood glucose values when you see this symbol (see Chapter 13, Section 13.4, System Glucose Error for more information).
 Out of Range	This symbol means the receiver and sensor/transmitter are not communicating. Make sure the receiver and sensor/transmitter are within 20 feet of each other without obstruction (see Chapter 1, Section 1.4, Transmitter Overview).

 <p>Wait 15 Minutes Calibration Error</p>	<p>This symbol means the sensor cannot calibrate right now. If you see this screen, enter at least one more calibration blood glucose value after about 10-15 minutes. If the sensor still cannot calibrate after that, the sensor needs to be removed and a new sensor needs to be inserted.</p>
 <p>Wait 1 Hour Calibration Error</p>	<p>This symbol means the sensor is not calibrating correctly. If you see this screen, wait a minimum of one hour and then enter one more blood glucose value. If no readings display on the receiver after this, the sensor needs to be removed and a new sensor needs to be inserted.</p>
 <p>Wait</p>	<p>This symbol means the receiver has detected a potential significant problem with the sensor signal and may result in a sensor failure. You should wait about 30 minutes for more prompts. Do not enter any blood glucose values when you see this symbol.</p>

Status symbols show in the upper right of your trend graph.

CHAPTER 9: ALERTS, ALARM & PROFILES

This chapter teaches you about your Dexcom G4 PLATINUM (Pediatric) CGM System's many alerts and alarm and how to set them.

9.1 SETTING YOUR ALERTS

9.1.1 DEFAULT ALERT/ALARM SETTINGS

The following alerts and alarm are preset on your receiver.

Default Alert/Alarm Settings

What will I see on the receiver screen?	What does this mean?	What is the default setting?	How will the receiver notify me?	Will the receiver re-notify me?
	High Glucose Alert Your most recent sensor glucose reading is at or above the high alert setting.	On at 200 mg/dL	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes until confirmed or your glucose value drops below the alert level.	No, unless you have turned on the high alert snooze feature.
	Low Glucose Alert Your most recent sensor glucose reading is at or below the low alert setting.	On at 80 mg/dL	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes until confirmed or your glucose value goes above the alert level.	No, unless you have turned on the low alert snooze feature.
	Low Glucose Alarm Your most recent sensor glucose reading is at or below 55 mg/dL.	On	Vibrates 4 times and then vibrates/beeps 4 times every 5 minutes until confirmed or your glucose value goes above 55 mg/dL.	Yes, every 30 minutes after each confirmation until your blood glucose value comes back into range.

	<p>Out of Range Alert The sensor/transmitter and Receiver are not communicating to each other.</p>	<p>Off</p>	<p>The alert will not notify you. You must change the settings to receive this alert.</p>	<p>No</p>
	<p>Rise/Fall Alert Single Arrow Your glucose is rising/falling at or above a rate of 2 mg/dL/min (at least 30 mg/dL in 15 minutes).</p>	<p>Off</p>	<p>The alert will not notify you. You must change the settings to receive this alert.</p>	<p>No</p>
	<p>Rise/Fall Alert Double Arrow Your glucose is rising/falling at or above a rate of 3 mg/dL/min (at least 45 mg/dL in 15 minutes).</p>	<p>Off</p>	<p>The alert will not notify you. You must change the settings to receive this alert.</p>	<p>No</p>

This table describes the receiver alerts and alarm and explains how the receiver will notify you in the default setting.

Your receiver may alert you at other times you need to take action, such as low battery, failed sensor, etc. See Chapter 18, Appendix I, for a detailed list of these other alerts.

9.1.2 GLUCOSE ALERTS AND ALARM

The Dexcom G4 PLATINUM (Pediatric) System lets you create personal settings for how you want the receiver to tell you what is going on. The low and high glucose alerts tell you when your sensor glucose readings are outside your target glucose range. Rise and fall (rate of change) alerts let you know when your glucose levels are changing fast (see Chapter 9, Section 9.2, Advanced Alerts). The Dexcom G4 PLATINUM (Pediatric) System also has a 55 mg/dL low glucose alarm that cannot be changed or turned off. This safety feature tells you your glucose level may be dangerously low. You can set high and low glucose alerts to vibrate and beep. This feature can help during sleeping, driving, exercising or during meetings.

When you have both your high and low alerts turned on, a gray zone on your trend graph shows your target range.

Please select your alert settings in consultation with your healthcare professional. The sensor glucose readings may differ from your blood glucose measurement. If your sensor glucose readings are higher than your blood glucose, sometimes your low alert may not vibrate and/or beep when your blood glucose is actually low, depending on your alert profile setting. Selecting a higher level for the low alert setting will reduce the missed low alerts but may cause more false alerts. It is important you discuss your alert settings with your healthcare professional.

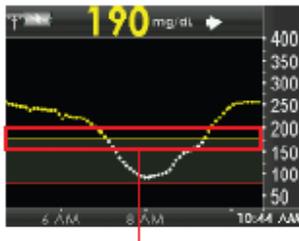
9.1.2.1 HIGH GLUCOSE ALERT

When your sensor glucose readings are at or above your high alert level, this screen shows your high glucose alert level. Your receiver vibrates and/or beeps depending on your profile setting (see Chapter 9, Section 9.3, Alert Profiles). This level shows as a yellow line on the trend graph.



High glucose alert set at 200 mg/dL

The receiver continues to alert until you press the **SELECT** button to clear the alert or until your sensor glucose readings drop below your high glucose alert level. You can have the receiver re-alert after clearing the alert (to change your snooze settings see Chapter 9, Section 9.2, Advanced Alerts).



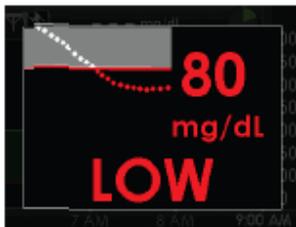
High glucose alert setting

9.1.2.2 LOW GLUCOSE ALERT

WARNING

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.

When your sensor glucose readings are at or below your low alert level, this screen shows your low glucose alert level. Your receiver vibrates and/or beeps depending on your profile setting. This level shows as a red line on the trend graph.



Low glucose alert set at 80 mg/dL



Low glucose alert setting

The receiver continues to alert until you press the **SELECT** button to clear the alert or until your sensor glucose readings rise above your low glucose alert level. You can have the receiver re-alert after clearing the alert (to change your snooze settings see Chapter 9, Section 9.2, Advanced Alerts).

9.1.2.3 LOW GLUCOSE ALARM

The Dexcom G4 PLATINUM (Pediatric) System also has a fixed low alarm at 55 mg/dL. This is different than your low glucose alert. You cannot change or turn off this alarm or its re-alarm settings.



Low glucose alarm

- The receiver displays the low glucose alarm screen.
- Re-alarm: The receiver automatically alerts again 30 minutes after you press the **SELECT** button to clear it, if your sensor glucose readings are still at or below 55 mg/dL.

- Your receiver does not alert if you have a sensor glucose reading outside your target range and you calibrated in the last 5 minutes.
- The receiver alerts if your sensor glucose reading stays outside your target range after five minutes.

9.1.3 GETTING TO THE ALERTS MENU

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph shows.
2. Press the **SELECT** button to see the Main Menu.
3. From the Main Menu, press the **UP** or **DOWN** button to scroll to “Alerts,” and press the **SELECT** button. The Alerts menu shows.



Trend graph



Main Menu, Alerts highlighted



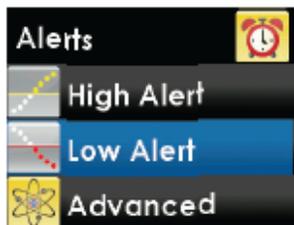
Alerts menu, High Alert highlighted

9.1.4 HIGH AND LOW GLUCOSE ALERTS

The steps for setting both the high alert and the low alert are the same.

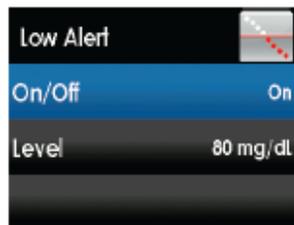
The following steps show you how to change your high and low alert settings.

1. From the Alerts menu, press the **UP** or **DOWN** button to select “High Alert” or “Low Alert” and press the **SELECT** button.



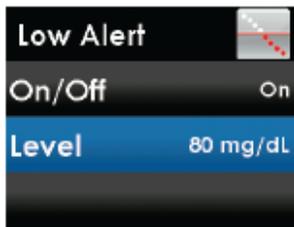
Alerts menu, Low Alert highlighted

2. Highlight “On/Off,” and then press the **SELECT** button to set this option. A check mark shows next to the current setting.



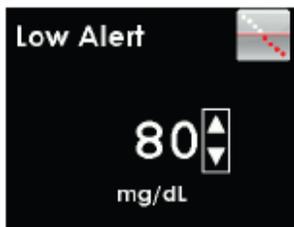
Low Alert menu, On/Off highlighted, On selected

3. Press the **LEFT** button to return to the last screen.
4. Press the **DOWN** button to highlight “Level.” The number that shows is your current glucose alert level.



Low Alert menu, Level highlighted

5. To change this number, press the **SELECT** button, and then press the **UP** or **DOWN** button to select your glucose alert level.



Low Alert setting screen, 80 mg/dL selected

- Your high glucose alert value can be set between 120 and 400 mg/dL in 10 mg/dL steps.
- Your low glucose alert value can be set between 60 and 100 mg/dL in 5 mg/dL steps.

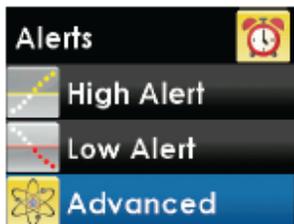
6. Press **the SELECT button to confirm your alert level.**

7. You will return to the Alerts menu when you finish.

9.2 ADVANCED ALERTS

Advanced alerts include the high and low snooze, rise and fall rate, and out of range alerts. All advanced alerts follow the following steps.

1. Press the **SELECT** button to turn on the receiver.
2. Press the **SELECT** button to enter the Main Menu.
3. Press the **UP** or **DOWN** button to highlight "Alerts," and press the **SELECT** button.
4. From the Alerts menu, press the **UP** or **DOWN** button to select "Advanced," and press the **SELECT** button.

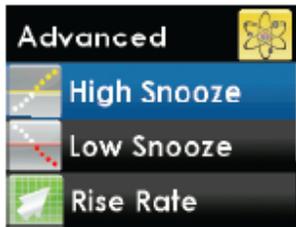


Alerts menu, Advanced highlighted

9.2.1 SETTING A SNOOZE TIME FOR YOUR HIGH AND LOW GLUCOSE ALERTS

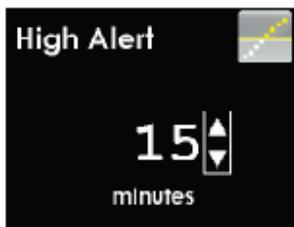
The snooze feature lets you delay your high and low glucose re-alerts. You have the option to set a snooze time for every 15 minutes for up to 5 hours.

1. Press the **UP** or **DOWN** button to highlight “High Snooze” or “Low Snooze” and press the **SELECT** button.



Advanced menu, High Snooze highlighted

2. Press the **UP** or **DOWN** button to select the amount of time (in 15 minute steps) between the first alert and re-alerts. Press the **SELECT** button.



High Alert setting screen, 15 minutes selected

- If you set the amount of time to zero there will be no re-alerts.

3. Press the **LEFT** button to return to the Alerts menu when you finish.

9.2.2 RISE AND FALL GLUCOSE RATE ALERTS

Rate alerts tell you when your glucose levels are rising (rise alert) or falling (fall alert) and by how much. You can choose for your receiver to alert when your sensor glucose reading is rising or falling 2 mg/dL or more per minute, or 3 mg/dL or more per minute.

Please select your alert settings in consultation with your healthcare professional. The sensor glucose readings may differ from your blood glucose measurement. If your sensor glucose readings are changing slower than your blood glucose is actually changing, sometimes your rise or fall glucose rate alerts may not vibrate and/or beep when your blood glucose is actually rising or falling. Selecting the 2 mg/dL level setting instead of the 3 mg/dL level setting will reduce the missed alerts but may cause more false alerts. It is important you discuss your alert settings with your healthcare professional.

If you set your fall rate to 2 mg/dL per minute and your sensor glucose readings fall at this rate or faster, the “FALLING single arrow” screen shows, and the receiver vibrates or beeps in line with your profile settings.



Fall alert

If you set your rise rate to 3 mg/dL per minute and your sensor glucose readings rise at this rate or faster, the “RISING double arrow” screen shows, and the receiver vibrates or beeps in line with your profile settings.



Rapid rise alert

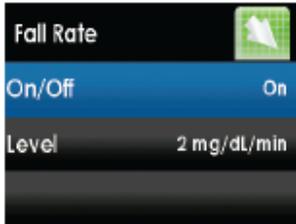
These steps show how to change your rise or fall rate alert settings.

1. Press the **UP** or **DOWN** button to choose “Rise Rate” or “Fall Rate,” and press the **SELECT** button.



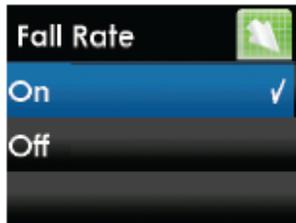
Alerts menu, Fall Rate highlighted

2. Highlight “On/Off” and then press the **SELECT** button.



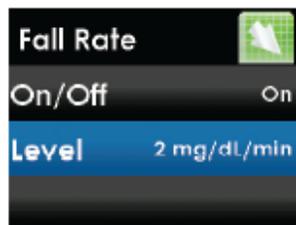
Fall Rate menu, On/Off highlighted

3. Press the **UP** or **DOWN** button to choose “On” or “Off.” Then, press the **SELECT** button to select “On” or “Off.”



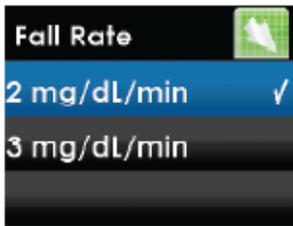
Fall Rate menu, On selected

4. Press the **LEFT** button to go back to the last screen. Highlight “Level” and then press the **SELECT** button.



Fall Rate menu, Level highlighted

5. Choose “2 mg/dL/min” (2 mg/dL or more per minute) or “3 mg/dL/min” (3 mg/dL or more per minute). Press the **SELECT** button.



Fall Rate menu, 2 mg/dL/min selected

6. Press the **LEFT** button to return to the Alerts menu when you finish.

9.2.3 SETTING THE OUT OF RANGE ALERT

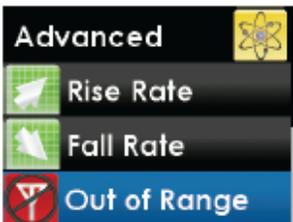
The out of range alert lets you know when the transmitter and receiver are not communicating with each other. Keep the transmitter and receiver within 20 feet of each other without obstruction. When the transmitter and receiver are too far apart, you will not get sensor glucose readings.

The out of range symbol  in the upper right corner of the trend graph and the Out of Range alert screen show when the transmitter and receiver are not communicating. The amount of time out of range shows on the Out of Range alert screen. It will continue to re-alert until they are back in range.



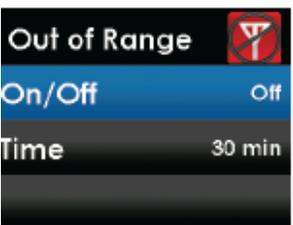
Out of Range alert screen

1. Press the **UP** or **DOWN** button to choose "Out of Range," and press the **SELECT** button.



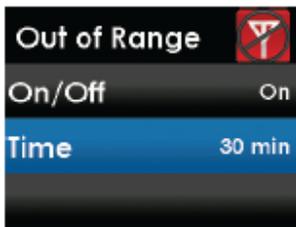
Advanced menu, Out of Range highlighted

2. Press the **UP** or **DOWN** button to choose "On/Off." Then, press the **SELECT** button to select "On." If you do not want to get out of range alert press the **SELECT** button again to choose "Off."



Out of Range menu, On/Off highlighted

3. Press the **UP** or **DOWN** button to choose "Time," and press the **SELECT** button.



Out of Range menu, Time highlighted

4. Press the **UP** or **DOWN** button to choose the amount of time out of range after which the receiver will alert. Press the **SELECT** button.

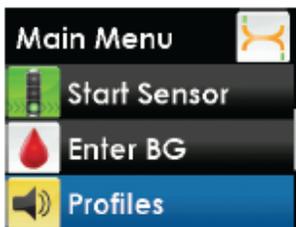


Out of Range setting screen, 20 minutes selected

5. Press the **LEFT** button to return to the Alerts menu when you finish.

9.3 ALERT PROFILES

The Dexcom G4 PLATINUM (Pediatric) System lets you set profiles to choose the way you want your alerts to act. This feature is found under the Profiles option on the Main Menu. You can set your profile to the sound pattern and volume that fits your needs.



Main Menu, Profiles highlighted

Your profile options are:

1. Vibrate
2. Soft
3. Normal
4. Attentive
5. HypoRepeat

For each profile option, the first alert is vibration only.

Regardless of which alert profile you chose, if you confirm the first vibrate alert, you will not get a sound alert.

When you choose your profile setting this setting applies to all alerts, alarm and prompts.

Within each profile setting, each alert has its own unique sound pattern, tone and volume level. This lets you to easily identify each alert and alarm and its meaning.

The fixed low alarm at 55 mg/dL cannot be turned off or adjusted.

The soft, normal, attentive and HypoRepeat profiles have the following alert sequence:

- The first alert is vibrate only.
- If the alert is not confirmed in five minutes, the system vibrates and beeps.
- If the alert is not confirmed in five more minutes, the system vibrates and beeps louder. This continues at the same volume every five minutes until confirmed.

For the HypoRepeat profile only:

- If the alert is confirmed and your sensor glucose readings continue to be at or below 55 mg/dL your system repeats the alert sequence in 30 minutes.

Press the **SELECT** button to confirm any alert.

9.3.1 ALERT PROFILE OPTIONS



Vibrate profile: when you want to silence the receiver and be alerted by vibration. The only exception to this is the fixed low alarm at 55 mg/dL, which alerts you as a vibration first, followed by beeps 5 minutes later if not confirmed.



Soft profile: when you need your alert to be less noticeable. This profile sets all the alerts and alarm to lower volume beeps.



Normal profile: the default profile when you receive your system. This profile sets all alerts and alarms to higher volume beeps.



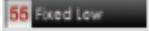
Attentive profile: when you need your alert to be the most noticeable. This profile sets all the alerts and alarm to loud and highly distinctive melodies.



“HypoRepeat” profile: very similar to the normal profile, but it continuously repeats the fixed low alarm every 5 seconds until your sensor glucose reading rises above 55 mg/dL or is confirmed. This profile can be helpful if you want extra alerts for severe low sensor glucose readings.

The “Try It” feature is found under the Profiles menu and lets you hear an example of each alert and alarm.

9.3.2 ALERT PROFILE DETAILS

PROFILE TYPE	VIBRATE 	SOFT 	NORMAL 	ATTENTIVE 	HYPOREPEAT 
High Alert 	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + ascending melody	2 long vibrates + 2 medium beeps
Low Alert 	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + descending melody	3 short vibrates + 3 medium beeps
Rise Alert 	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 1 short ascending melody	2 long vibrates + 2 medium beeps
Fall Alert 	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + 2 short descending melodies	3 short vibrates + 3 medium beeps
Out of Range Alert 	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 3 short repeating melodies	1 long vibrate + 1 medium beep
Fixed Low 	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 2 long descending melodies + pause + 4 low beeps	4 short vibrates + 4 low beeps + pause + repeat sequence
All Other Alerts	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 short melody	1 long vibrate + 1 medium beep

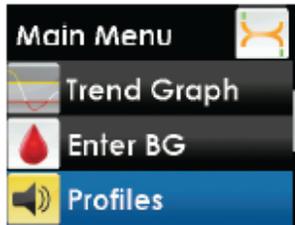
These steps show you how to select the profile you want.

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph will show.



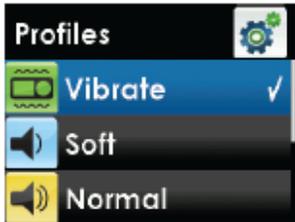
Trend graph

2. Press the **SELECT** button to see the Main Menu.
3. Press the **UP** or **DOWN** button to scroll to “Profiles,” and press the **SELECT** button. The Profiles menu will show.



Main Menu, Profiles highlighted

4. Press the **UP** or **DOWN** button to scroll to the profile you want to set, and press the **SELECT** button.



Profiles menu, Vibrate highlighted

5. Press the **LEFT** button to return to the Main Menu when you finish.

CHAPTER 10: EVENTS

The Events feature lets you record information that may help you and your healthcare professionals better understand your glucose patterns and trends. You can enter details about carbohydrates, insulin, exercise, and health issues. You can view these events with your trends and patterns using the Dexcom STUDIO software.

10.1 EVENTS

Event markers can be downloaded and viewed in the Dexcom STUDIO software but cannot be viewed on your receiver.

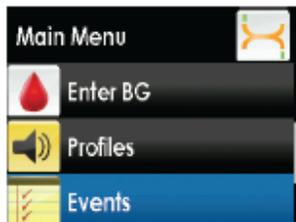
10.1.1 SELECTING AN EVENT

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph will show.
2. Press the **SELECT** button to see the Main Menu.



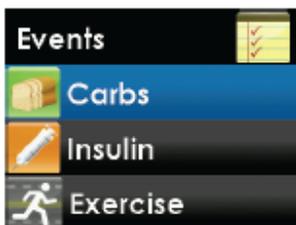
Trend graph

3. Press the **UP** or **DOWN** button to scroll to “Events,” and press the **SELECT** button. The Events menu will show.



Main Menu, Events highlighted

4. Press the **UP** or **DOWN** button to choose the event you want: “Carbs,” “Insulin,” “Exercise” or “Health.” Press the **SELECT** button.



Events menu, Carbs highlighted

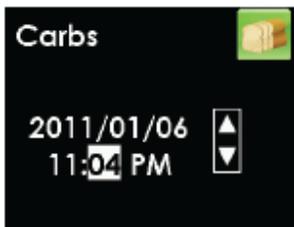
10.1.2 SETTING THE DATE AND TIME FOR AN EVENT

When you enter an event, you must check that the date and time for that event are correct. The default is the current date and time stored in the receiver. The date format is YYYY/MM/DD.

If you change the date or time for any event, it only applies to that event and will not change the current date and time in your receiver.

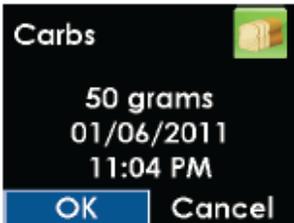
To change the date and time for an event:

1. Press the **RIGHT** button to highlight each value in the date and time.
2. Press the **UP** or **DOWN** button to make any changes, and then press the **RIGHT** button to move to the next value.
3. Press the **SELECT** button after choosing “AM” or “PM.”



Carbs setting screen, minutes highlighted

4. Press the **SELECT** button to confirm the entry.

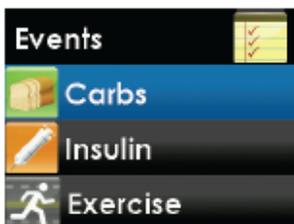


Carbs setting screen, OK highlighted

10.1.3 CARBOHYDRATES

The Carbs event lets you enter the amount of carbohydrates you have taken, up to 250 grams.

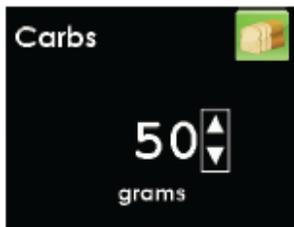
1. From the Events menu press the **UP** or **DOWN** button to choose “Carbs,” and press the **SELECT** button.



Events menu, Carbs highlighted

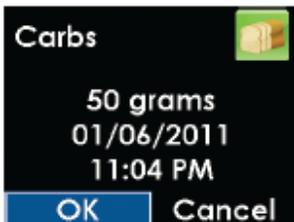
2. Press the **UP** or **DOWN** button to enter your carb amount (0-250 grams), and press the **SELECT** button.

- The number that shows on this screen is the last number you entered or the default amount of 50 grams.



Carbs setting screen, 50 grams selected

3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.
4. Press the **LEFT** or **RIGHT** button to choose either "OK" to confirm or "Cancel" to discard this entry, and then press the **SELECT** button. You will return to the Events menu.

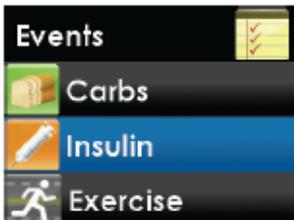


Carbs setting screen, OK highlighted

10.1.4 INSULIN

The Insulin event lets you enter the amount of insulin you have taken, up to 250 units. You can only enter an insulin amount, not the type of insulin.

1. From the Events menu press the **UP** or **DOWN** button to choose "Insulin," and press the **SELECT** button.



Events menu, Insulin highlighted

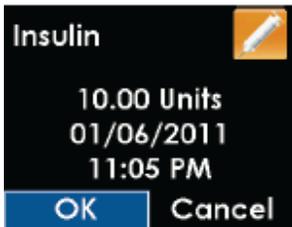
2. Press the **UP** or **DOWN** button to enter your insulin amount (0-250 units), and press the **SELECT** button.
 - The number that shows on this screen is the last number you entered or the default amount of 10 units.



Insulin setting screen, 10 units highlighted

3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.

4. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.

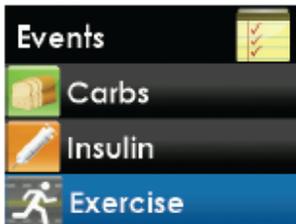


Insulin setting screen, OK highlighted

10.1.5 EXERCISE

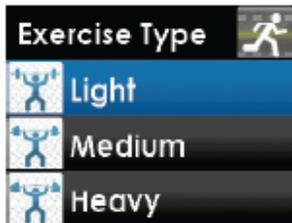
The Exercise event lets you enter intensity (light, medium, or heavy) and duration (up to 360 minutes).

1. From the events menu press the **UP** or **DOWN** button to choose “Exercise,” and press the **SELECT** button.



Events menu, Exercise highlighted

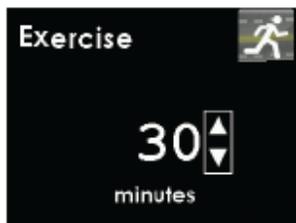
2. Press the **UP** or **DOWN** button to choose your exercise intensity level, and press the **SELECT** button.



Exercise Type menu, Light highlighted

3. Press the **UP** or **DOWN** button to enter your exercise duration (0-360 minutes), and press the **SELECT** button.

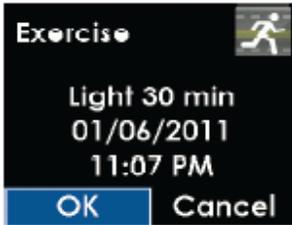
- The number that shows on this screen is the default amount of 30 minutes.



Exercise setting screen, 30 minutes selected

4. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.

5. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.

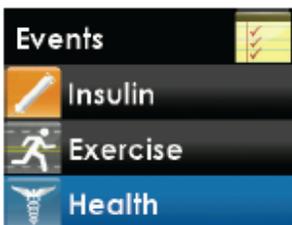


Exercise setting screen, OK highlighted

10.1.6 HEALTH

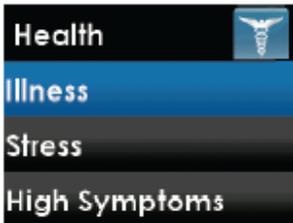
The Health event lets you enter episodes of illness, stress, high symptoms, low symptoms, cycle (menstrual) or alcohol consumption.

1. From the Events menu press the **UP** or **DOWN** button to choose “Health,” and press the **SELECT** button.



Events menu, Health highlighted

2. Press the **UP** or **DOWN** button to choose your health event, and press the **SELECT** button.



Health menu, Illness highlighted

3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.

4. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.



Health setting screen, OK highlighted

10.2 DEXCOM STUDIO SOFTWARE

The Dexcom STUDIO software is optional. This software lets you view trends, track patterns and create custom charts to display your glucose trends.

You can change the date ranges to view long- or short-term patterns and trends. You can use data from current and older downloads and save or print files for you and your healthcare professionals to review.

For system requirements and more information, see the Dexcom website (www.dexcom.com) or the Dexcom STUDIO Software User's Guide.

CHAPTER 11: ENDING A SENSOR SESSION

PRECAUTION

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.

Your sensor gives you sensor glucose readings for up to seven days. The performance of a sensor has not been tested beyond seven days.

Information for the end of a sensor session:

- Do not remove the transmitter from the sensor pod while the pod is attached to your skin.
- Consult your local waste management authorities for instructions to dispose of blood contacting parts (sensor and applicator).
- In some cases, your sensor session may end before you have finished a full 7-day period. If this happens, see Chapter 13, Section 13.6, Sensor Shut-Off Troubleshooting.
- **Glucose alerts and alarm do not work after the sensor session ends.**

11.1 AUTOMATIC SENSOR SHUT-OFF

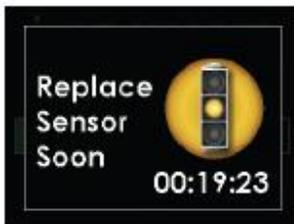
The receiver tells you how much time you have left until your sensor session is complete. The Replace Sensor screen shows at 6 hours, 2 hours and 30 minutes before your 7-day sensor session ends.



6-hour Replace Sensor



2-hour Replace Sensor



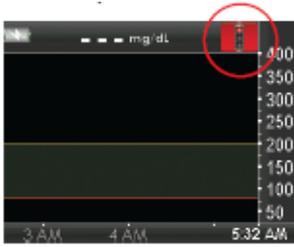
30-minute Replace Sensor



Replace Sensor

You can set these alerts with the profiles setting (see Chapter 9, Section 9.3.2, Alert Profile Details, "All Other Alerts"). After the 6-hour, 2-hour, and 30-minute reminders, you continue to receive sensor glucose readings. Press **SELECT** to clear these screens. You must remove your sensor after the Replace Sensor Now screen (00:00:00) shows.

Sensor glucose readings do not show on the receiver after your sensor session ends. The trend graphs show that the sensor session has ended with a red stoplight symbol at the top.



Trend graph with red stoplight in upper right

You must remove your sensor and insert a new sensor.

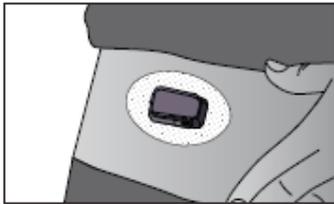
11.2 REMOVING A SENSOR

WARNING

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 **1.877.339.2664** or **1.858.200.0200**.

When you remove the sensor, make sure to pull out the sensor pod while the transmitter is still attached.

1. Gently peel up the sensor pod adhesive patch from your skin. This will pull out your sensor.



Keep the transmitter in the sensor pod Peel up the sensor pod adhesive patch



Completely remove the adhesive patch

11.3 TRANSMITTER REMOVAL

PRECAUTION

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.

Do not remove the transmitter while the sensor pod is still attached to the body.

After the sensor pod is off your body, you must remove the transmitter to reuse it. Use either of these two transmitter removal methods:

Method 1

The safety lock that you removed from the applicator (see Chapter 6, Section 6.4, Placing the Sensor), can be used as a tool to remove the transmitter.

1. Place the sensor pod/transmitter on a flat surface.
2. Hold the rounded edge of the safety lock.
3. Make sure the jagged edge of the safety lock is facing down, with the arrow pointing up, as shown:



Method 2

Use your fingers to spread out the tabs at the back of the sensor pod (end closest to the sensor pod tab wings). The transmitter will “pop” out of the sensor pod.

CHAPTER 12: TAKING CARE OF YOUR DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM

12.1 MAINTENANCE

Transmitter

- Wipe the outside of the transmitter with a damp cloth or isopropyl alcohol wipe between uses.
- Keep the transmitter protected when not in use.

Receiver

- Do not spill fluid on the receiver or submerge the receiver in liquid.
- Keep the receiver in its carrying case or otherwise protected.
- Charge the receiver when the battery gets low.
- **Keep the micro USB port cover closed to help prevent fluid from getting inside the receiver.**

Accessories

- Insert cables only as directed. Do not force cables in place.
- Look at cables for signs of wear and tear.
- Only use Dexcom-supplied parts (including cables and chargers). Use of non-Dexcom supplied parts may affect safety and performance.

There is no repair service available for your Dexcom G4 PLATINUM (Pediatric) CGM System. If you experience problems with your system contact Dexcom Technical Support (see Chapter 15, User Assistance).

12.2 STORAGE

Sensor

- Keep the sensor in its sterile packaging until you are ready to use it.
- Do not insert sensors past the expiration date. The expiration date format is YYYY-MM-DD. Insert sensors on or before the end of the calendar day printed on the sensor package label.
- Store at temperatures between 36° F - 77° F. Storing outside this temperature may result in reduced sensor response to glucose and may cause inaccurate CGM readings. You may store your sensors in the refrigerator if it is within this temperature range. Sensors should not be stored in a freezer.

•
Store at humidity levels between 15% - 85% relative humidity.

Transmitter

- Keep the transmitter protected when not in use.
- Store at temperatures between 32° F - 113° F.
- Store at humidity levels between 10% - 95% relative humidity.

Receiver

- Keep the receiver protected when not in use.
- Fully charge the battery before storing for over 3 months.

- Store at temperatures between 32° F - 113° F.
- Store at humidity levels between 10% - 95% relative humidity.

12.3 PRODUCT DISPOSAL

Consult your local waste management authorities for instructions to dispose of devices containing electronic waste (transmitter and receiver) and blood contacting parts (sensor and applicator).

CHAPTER 13: TROUBLESHOOTING

This chapter provides helpful tips and instructions to fix issues you may have while using your Dexcom G4 PLATINUM (Pediatric) CGM System.

If any of the troubleshooting steps in this chapter do not fix your issue, contact Dexcom Technical Support (see Chapter 15, User Assistance).

13.1 SENSOR INSERTION TROUBLESHOOTING

Sensor insertion difficulties

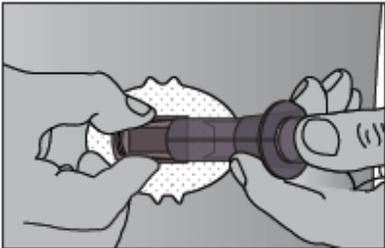
• **I am having trouble taking out the safety lock:**

- Make sure to pull the safety lock straight out away from your body. Use the arrows on the safety lock as a guide.

• **I am not able to pull the collar up:**

- Make sure the white plunger is completely pressed down before pulling the collar up.
- Use force when pulling the collar up.

• **I am not able to remove the applicator barrel from the sensor pod:**



Release the applicator barrel

- Make sure the collar is pulled all the way up. When pulling the collar up you should hear 2 “clicks.” You may need to use extra force to pull the collar as close to the top of the applicator as possible.

- Make sure the transmitter latch is flat against the adhesive on your body before squeezing the release tabs.

- Use force when squeezing the ribbed release tabs on the sides of the sensor pod.
- Lift the applicator in a curving movement away from your body.

• **I am not able to remove the transmitter latch:**

- Hold the sensor pod with one hand and twist the transmitter latch with the other hand to remove it.
- Do not try to snap it straight off.

Sensor pod is not sticking long enough

- Make sure your skin is clean, clear of any cream or lotion, and completely dry before you insert the sensor.

- Shave your skin before you insert the sensor if hair is preventing the sensor pod from sticking.

- You may use medical tape (such as Blenderm, Tegaderm, IV 3000, 3M tape) over the white adhesive patch of the sensor pod, but do not place the tape over the transmitter or the plastic parts of the sensor pod.

13.2 CALIBRATION TROUBLESHOOTING

Calibration prompts may show during your sensor session. Review the following troubleshooting tips for calibration.

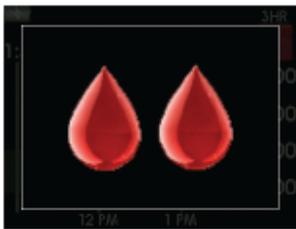
- Do not calibrate if the out of range symbol  shows in the status area.
- Do not calibrate if the glucose reading error symbol  shows in the status area.
- Do not calibrate if your blood glucose value is below 40 or above 400 mg/dL.
- Before you take a blood glucose value for calibration, wash your hands, make sure your glucose test strips have been stored properly and are not expired and make sure that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions that came with your meter or test strips.
- Make sure you have not taken any medications containing acetaminophen (such as Tylenol).
- See Chapter 7, Calibrating Your Dexcom G4 PLATINUM (Pediatric) System, for further information.

13.2.1 TYPES OF CALIBRATION PROMPTS

This section describes the three calibration symbols. The next section describes what to do when you see one of these symbols.

Startup calibration prompt

This prompt means the receiver's 2-hour startup period is complete. You need to enter two blood glucose values to calibrate the system.

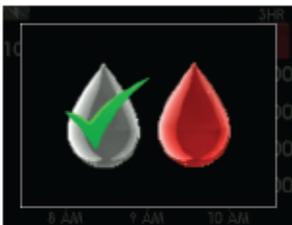


Startup calibration prompt

The receiver shows the 2-hour startup calibration prompt screen every 15 minutes until the receiver accepts the blood glucose values.

Additional startup calibration prompt

This prompt means you need to enter one more blood glucose value to calibrate the system.



Additional startup calibration prompt

The receiver shows the additional startup calibration prompt screen every 15 minutes until the receiver accepts the blood glucose value.

Calibration prompt

This prompt means you need to enter one blood glucose value. It shows when it is time for your 12-hour calibration update or any other time you need to calibrate.



Calibration prompt

The receiver shows this prompt screen every 15 minutes until the receiver accepts the blood glucose value.

13.2.2 WHAT TO DO FOR CALIBRATION PROMPTS

1. When you see a calibration prompt, press the **SELECT** button to clear the prompt.
2. Check the status area at the top of the screen.



Prompt in status area

- a. If the startup calibration symbol  shows, take 2 more blood glucose values and enter them into your receiver.
- b. If the additional startup calibration symbol  shows, take 1 more blood glucose value and enter it into your receiver.
- c. If the calibration needed symbol  shows, take 1 more blood glucose value and enter it into your receiver.

13.3 CALIBRATION ERROR TROUBLESHOOTING

This screen means you recently entered a calibration blood glucose value, and the sensor is having trouble calibrating. If you press the **SELECT** button to clear this screen, this symbol  shows in the status area.



Wait 15 minutes calibration error screen

If you see this screen, wait 15 minutes and then enter 1 more calibration blood glucose value. Wait 15 more minutes. If this error screen still shows, enter 1 more blood glucose value. Wait another 15 minutes. If this error screen still shows, the sensor needs to be replaced.

This screen also means you recently entered a calibration blood glucose value and the sensor is having trouble calibrating. If you press the **SELECT** button to clear the screen, this symbol  shows in the status area.



Wait 1 hours calibration error screen

If you see this screen, wait at least 1 hour and then enter 1 more calibration blood glucose value. Wait 15 minutes. If this error screen still shows, enter 1 more blood glucose value. Wait another 15 minutes. If this error screen still shows, the sensor needs to be replaced.

13.4 SYSTEM GLUCOSE ERROR

The system may tell you that it cannot provide a sensor glucose reading. When this happens you will see either the glucose reading error symbol **???** or the wait symbol  in the status area. These symbols mean the receiver does not understand the sensor signal temporarily. These symbols are related to the sensor only.



No glucose date **???**



No glucose date 

Wait for more prompts, and **do not enter** any blood glucose values when you see these symbols. The system will not use a blood glucose value for calibration when these symbols show (see Chapter 8, Section 8.3, Glucose Status Area Symbols).

Often, the system can correct the problem and continue providing sensor glucose readings. If it has been at least 3 hours since your last sensor glucose reading, contact Technical Support (see Chapter 15, User Assistance).

If you see these system glucose error symbols often, follow these troubleshooting tips before inserting another sensor:

- Make sure your sensor is not expired.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (i.e. clothing, seat belts, etc.).
- Make sure you selected a good insertion site (see Chapter 6, Section 6.3, Choosing an Insertion Site).
- Make sure your insertion site is clean and dry before sensor insertion.
- Wipe the bottom of the transmitter with a damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2-3 minutes.

13.5 SENSOR INACCURACIES

Inaccuracies are usually related to your sensor only and not your receiver or transmitter. Your sensor glucose readings are meant to be used for trending purposes only. Your blood glucose meter and sensor measure your glucose from two different types of body fluids: blood and interstitial fluid. Therefore, your readings from your blood glucose meter readings and sensor may not match.

WARNINGS

- 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.

PRECAUTION

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.

If the difference between your sensor glucose reading and blood glucose value is greater than 20% of the blood glucose value for sensor glucose readings > 80 mg/dL or greater than 20 points for sensor glucose readings < 80 mg/dL, wash your hands and take another blood glucose measurement. If the difference between this second blood glucose measurement and the sensor is still greater than 20% for sensor glucose readings > 80 mg/dL or greater than 20 points for sensor glucose readings < 80 mg/dL, recalibrate your sensor using the second blood glucose value. The sensor glucose reading will correct over the next 15 minutes. If you see differences between your sensor glucose readings and blood glucose values outside of this acceptable range, follow the troubleshooting tips below before inserting another sensor:

- Make sure your sensor is not expired.

- Make sure you do not calibrate when the **???** or  is shown.
- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration as alternative site readings may be different than those from a blood glucose value. Use a blood glucose value only from your fingers for calibration.
- Use only blood glucose values between 40-400 mg/dL for calibration. If one or more of your values is outside of this range, the receiver will not calibrate.
- Use the same meter you routinely use to measure your blood glucose to calibrate. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy vary between blood glucose meter brands.
- Before taking a blood glucose measurement for calibration, wash your hands, make sure your glucose test strips have been stored properly and are not expired and make sure that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your meter or test strips.
- Make sure you are using your blood glucose meter following the manufacturer's instructions to get accurate blood glucose values for calibration.
- Make sure you have not taken any medications containing acetaminophen (such as Tylenol) to ensure you are getting accurate blood glucose values for calibration.

13.6 SENSOR SHUT-OFF TROUBLESHOOTING

In some cases your sensor session may stop or need to be stopped before the end of a full 7-day period. You must remove your sensor.

13.6.1 EARLY SENSOR SHUT-OFF – SENSOR FAILURE

The receiver may detect issues with your sensor where it cannot determine your sensor glucose reading. The sensor session ends and the receiver shows the “Sensor Failed” screen. If you see this screen, it means your CGM session has ended. Press the **SELECT** button to clear this screen.



Sensor Failed screen

Remove your sensor and insert a new sensor.

To help improve future sensor performance:

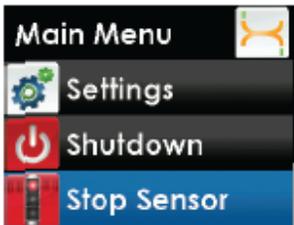
- Make sure your sensor is not expired.
- Make sure your transmitter is snapped in.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure nothing is rubbing the sensor pod (i.e., clothing, seat belts, etc.).
- Make sure you have selected a good insertion site (see Chapter 6, Section 6.3, Choosing an Insertion Site).
- Make sure your insertion site is clean and dry prior to sensor insertion.

13.6.2 MANUAL SENSOR SHUT-OFF – “STOP SENSOR”

There may be times that you will want to stop your sensor session before the end of the seven days. Some of these times may include removing the sensor early due to:

- Calibration issues that cannot be resolved
- **???** symbol that does not resolve
- Sensor adhesion issues
- Lifestyle needs

When you are in an active sensor session, you will see the “Stop Sensor” option but not the “Start Sensor” option on the Main Menu.

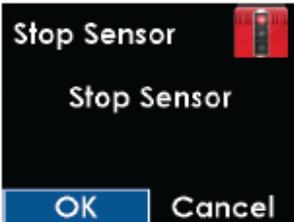


Main Menu, Stop Sensor highlighted

When you are not in an active sensor session, you will see the “Start Sensor” option but not the “Stop Sensor” option on the Main Menu.

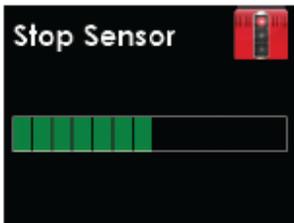
Stop your sensor session if you remove your sensor before the end of the full 7 day period.

1. To end your sensor session, select “Stop Sensor” from the Main Menu.
2. Press the **SELECT** button with “OK” highlighted to confirm.



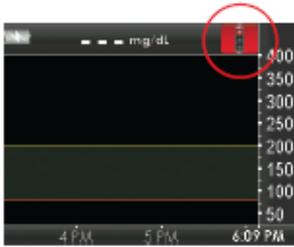
Stop Sensor screen, OK highlighted

3. The Stop Sensor “thinking” screen will show to let you know the sensor session is stopping.



Stop Sensor “thinking” screen

4. Once the session has stopped, a red stoplight symbol () shows in the upper right of the trend graph.



Trend graph with red spotlight in upper right

13.7 BATTERY AND CHARGER TROUBLESHOOTING

Only use the Dexcom cable and battery charger to charge your receiver.

A full charge can take up to 5 hours and will last about 3 days, depending on how often you turn on your receiver, use the alerts, and enter events.

If your receiver does not show the battery charging symbol when plugged into the charger, make sure that both ends of the USB cable are fully inserted into the receiver port and wall charger or computer.

If your battery drains and is not charged for a few weeks it may not turn on. If your receiver does not turn on, first try to charge it (see Chapter 4, Section 4.1, Charging Your Receiver Battery). If your receiver still does not turn on you may need to reset the receiver:

1. Connect the receiver to the charger before resetting.
2. Insert the end of a paperclip into the small circular hole on the back of the receiver and push down. The receiver will vibrate and show the thinking screen.
3. Charge your receiver.
4. You may need to reset the time and date (see Chapter 4, Section 4.1, Charging Your Receiver Battery and Chapter 5, Section 5.2, The Settings Menu).

13.8 RECEIVER AND TRANSMITTER COMMUNICATION TROUBLESHOOTING

13.8.1 SYSTEM RECOVERY CHECK

This screen means the system found an error that it was able to fix. Press the **SELECT** button to clear this display, and continue your sensor session.



System Check screen

13.8.2 RECEIVER ERROR CODE

This screen shows an error code that means the receiver may not be working properly. Write down the error code and contact Dexcom Technical Support (see Chapter 15, User Assistance). Continue to check your blood glucose value using your blood glucose meter.



Receiver Error Code screen

No alert sound or vibration will warn you that you are no longer getting sensor glucose readings.

13.8.3 TRANSMITTER LOW BATTERY

This screen shows when the transmitter nears the end of its battery life (see Chapter 1, Section 1.4, Transmitter Overview). It will first show when there is about 1 week of battery life left. When the transmitter battery drains low enough, the transmitter and receiver will stop communicating. Replace your transmitter as soon as possible after you see this screen. Contact Dexcom Sales Support (see Chapter 15, User Assistance) to order a new transmitter.



Transmitter Low Battery screen

13.8.4 TRANSMITTER FAILED

This screen means that the transmitter is not working. If you get this alert during a sensor session, your sensor session automatically stops. Contact Dexcom Technical Support (see Chapter 15, User Assistance). Continue to check your blood glucose value using your blood glucose meter.



Transmitter Failed screen

13.9 OUT OF RANGE/NO ANTENNA

PRECAUTION

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.

This screen means your receiver and transmitter are not communicating and you are not getting sensor glucose readings.



Out of Range alert screen

- Your receiver and transmitter only communicate when you are in an active sensor session.
- Each time you start a new sensor session, wait 10 minutes for your receiver and transmitter to start communicating.
- You may sometimes experience loss of communication for 10 minutes at a time. This is normal.
- If you see the out of range symbol in the status area for more than 10 minutes, move your receiver and transmitter within 20 feet of each other without obstruction. Wait 10 minutes and communication should be restored.

- You must enter your transmitter ID correctly into your receiver to receive sensor glucose readings (see Chapter 5, Section 5.2, The Settings Menu). Make sure you have removed your sensor and stopped your sensor session before checking or changing your transmitter ID. “Transmitter ID” will not appear as an option on the Settings menu during a sensor session.

If you are still having trouble getting system readings, contact Dexcom Technical Support (see Chapter 15, User Assistance).

13.10 ALERTS ARE NOT WORKING

1. Make sure you have not turned off the sound and/or vibrations for the alerts. Chapter 9, Section 9.1, Setting Your Alerts explains how to change these alert options.
2. Check that you have turned on and set the level for your advanced alerts (see Chapter 9, Section 9.2, Advanced Alerts).
3. Remember, the first alert is vibrate only. See Chapter 18, Appendix I, Receiver Alerts, Alarm and Prompts sequence tables for how the alerts, alarm and prompts work.

If your receiver gets wet or is dropped, make sure the speaker and vibrations still work. You can do this with the Try It option in the Profiles menu (see Chapter 9, Section 9.3.1, Alert Profile Options).

CHAPTER 14: TECHNICAL INFORMATION

14.1 DEVICE PERFORMANCE CHARACTERISTICS

NOTE: We recommend that you review the information in this chapter with your healthcare professional to understand how well the Dexcom G4 PLATINUM (Pediatric) System performs.

The Dexcom G4 PLATINUM (Pediatric) System (the System) uses a glucose sensor to continuously measure and monitor your glucose levels. The sensor is “calibrated” using a commercially available blood glucose meter; and once calibrated the System reports glucose readings up to every 5 minutes. The System was evaluated in a clinical study in which System readings were compared to blood glucose values to assess its performance and how well the System readings compare to a laboratory test method that measures blood glucose values. Additionally, subjects performed self-monitoring blood glucose meter tests at home to assess the System performance in a real use environment.

Although the performance characteristics of the System are presented below, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors (CGMs), such as the Dexcom G4 PLATINUM (Pediatric) System.

Clinical Study Overview

The System performance for children and adolescents was evaluated in two separate prospective clinical studies: the **Original** Pediatric Receiver Software Study (**SW10050**) and the **Software 505** Pediatric Receiver Software Study (**SW10505**). Differences between the studies include the number of subjects enrolled, the number of Systems worn by each participant, the SMBG meter used, the length of time subjects were evaluated in a controlled clinic environment and whether or not subjects ages 13-17 had their glucose levels intentionally manipulated during the study. An overview of each study is provided below. Both sets of study data are presented in the tables that follow and are labeled as **Original** Pediatric Study or **Software 505** Pediatric Study from this point forward.

The **Original** Pediatric Study enrolled 176 subjects, with 16% of subjects younger than 6-years old, and the **Software 505** Pediatric Study enrolled 79 subjects, with 20% of subjects younger than 6-years old. All subjects had Type 1 or Type 2 diabetes mellitus and required insulin or oral medication to manage their diabetes. In the **Original** Pediatric Study, about 99% of subjects had Type 1 diabetes and 1% had Type 2 diabetes. In the **Software 505** Pediatric Study, all subjects had Type 1 diabetes. Sensors were inserted in either the abdomen or upper buttocks. Both studies included subjects between ages 2 to 17.

Data from the Adult Study has also been provided. The **Original** Adult Study enrolled 72 subjects, and the **Software 505** Adult Study enrolled 51 subjects. All subjects had Type 1 or Type 2 diabetes mellitus, and required insulin or oral medication to manage their diabetes. In the **Original** Adult Study, 83% of subjects had Type 1 diabetes, and 17% of subjects had Type 2 diabetes. In the **Software 505** Adult Study, 86% of subjects had Type 1 diabetes, and 14% of subjects had Type 2 diabetes. Both studies included subjects greater than 18 years of age.

Subjects in all studies used the System for seven days. In the **Original** Pediatric Study, all subjects wore 2 sensors; in the **Software 505** Pediatric Study, all subjects wore 1 sensor only. Throughout the 7-day wear period, the sensors were calibrated with an average of 2 fingersticks per day (approximately once every 12 hours), using self-monitoring blood glucose (SMBG) meter values. The **Original** Pediatric Study used the LifeScan[®] OneTouch[®] Verio[®] IQ meter; the **Software 505** Pediatric Study used Bayer's CONTOUR[®] NEXT USB meter. In the **Original** Adult Study, subjects used the LifeScan[®] OneTouch[®] Ultra[®] 2 meter and in the **Software 505** Adult Study, subjects used Bayer's CONTOUR[®] NEXT USB meter.

For the Pediatric study, all subjects were evaluated in a controlled clinic environment on Day 1, Day 4 or Day 7 of the 7-day wear period. While using the System in the clinic, all subjects provided at least two fingerstick measurements per hour, and subjects ages 6-17 also provided venous blood for comparison to a

reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the “YSI.” In the **Original** Pediatric Study, subjects’ glucose levels were not intentionally manipulated during this study; in the **Software 505** Pediatric Study, subjects ages 13-17 had their glucose levels intentionally manipulated during the clinic session. Readings from the System were reported every 5 minutes and paired with YSI values collected every 15 minutes in order to characterize how well the System readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, and the System performance was also paired with the comparative meter results, referred to as the “SMBG.”

For the **Original** Adult Study, all subjects were evaluated in a controlled clinic environment on all three clinic days: Day 1, Day 4, and Day 7 of the 7-day wear period. In the **Software 505** Adult Study, subjects were evaluated in one of the three clinic days so there are fewer data samples than in the **Original** Study.

CHECKING YOUR RECEIVER SOFTWARE VERSION

You can check your receiver for information about your CGM system at any time.

1. From the Settings menu, press the UP or DOWN button to scroll to “Device Info.”



2. Press the SELECT button. Information about your sensor session and system will show.

Settings menu,
Device Info

3. Scroll down to see:

- Serial Number
- Part Number
- Part Revision
- Software Number
- Software Revision



Device Info screen

4. Press the LEFT button to return to the Settings menu.

Agreement Relative to YSI

Agreement between the System and blood glucose values is characterized using paired System and YSI values. The System and YSI results were compared by pairing the YSI blood glucose value to a System glucose reading that occurred immediately after the YSI was collected.

The agreement of the System to blood glucose value was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and greater than 40% of the YSI values. For readings

less than or equal to 80 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL, the absolute percent difference (%) from the YSI values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30% or greater than 40 mg/dL or 40% were then calculated in Table 1-A (Pediatric Study) and Table 1-B (Adult Study). Tables 1-A and 1-B are categorized within CGM glucose ranges. When you see a CGM reading on your receiver, these tables show you how likely that reading matches your blood glucose level (measured by YSI in the study).

Original Pediatric Study (SW10050): The total number of data pairs considered in the analysis was 2922. Of these, 68% of the System readings fall within ± 20 mg/dL of the YSI blood glucose values ≤ 80 mg/dL and within $\pm 20\%$ of YSI blood glucose values > 80 mg/dL.

Software 505 Pediatric Study (SW10505): The total number of data pairs considered in the analysis was 2262. Of these, 91% of the System readings fall within ± 20 mg/dL of the YSI blood glucose values ≤ 80 mg/dL and within $\pm 20\%$ of YSI blood glucose values > 80 mg/dL.

Original Adult Study (SW10050): The total number of data pairs considered in the analysis was 9152. Of these, 82% of the System readings fall within ± 20 mg/dL of the YSI blood glucose values ≤ 80 mg/dL and within $\pm 20\%$ of YSI blood glucose values > 80 mg/dL.

Software 505 Adult Study (SW10505): The total number of data pairs considered in the analysis was 2263. Of these, 93% of the System readings fall within ± 20 mg/dL of the YSI blood glucose values ≤ 80 mg/dL and within $\pm 20\%$ of YSI blood glucose values > 80 mg/dL.

Table 1-A. System Agreement to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	2922	55%	68%	85%	7%
	Software 505	2262	81%	91%	96%	2%
40-60	Original	19	63%	74%	79%	21%
	Software 505	86	54%	74%	91%	3%
61-80	Original	76	61%	82%	92%	4%
	Software 505	142	77%	82%	90%	3%
81-180	Original	1155	56%	69%	84%	6%
	Software 505	805	78%	88%	97%	1%
181-300	Original	1380	55%	68%	85%	7%
	Software 505	957	89%	96%	99%	1%
301-350	Original	206	48%	62%	80%	11%
	Software 505	209	81%	91%	94%	5%
351-400	Original	86	48%	61%	79%	12%
	Software 505	63	64%	81%	83%	8%

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 1-B. System Agreement to YSI within CGM Glucose Ranges (Adult)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	9152	71%	82%	92%	3%
	Software 505	2263	86%	93%	98%	1%
40-60	Original	512	67%	78%	88%	6%
	Software 505	120	89%	94%	98%	0%
61-80	Original	781	73%	85%	94%	2%
	Software 505	226	91%	96%	99%	0%
81-180	Original	3853	67%	78%	91%	3%
	Software 505	738	84%	92%	98%	1%
181-300	Original	2784	72%	84%	93%	4%
	Software 505	798	86%	93%	98%	1%
301-350	Original	775	82%	91%	97%	2%
	Software 505	229	86%	94%	98%	1%
351-400	Original	447	74%	84%	91%	5%
	Software 505	152	80%	92%	97%	0%

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505)

Agreement When CGM Reads “LOW” or “HIGH”

The System reports glucose readings between 40 and 400 mg/dL. When the System determines the glucose reading is below 40 mg/dL, it displays “LOW” in the Receiver Status Box. When the System determines that the glucose reading is above 400 mg/dL, it displays “HIGH” in the Receiver Status Box. Because the System does not display glucose readings below 40 mg/dL or above 400 mg/dL, the comparisons to the actual blood glucose readings (as determined by the YSI analyzer) when CGM is classified as “LOW” or “HIGH” are included separately in Tables 2-A and 2-B. The tables include the numbers and the cumulative percentages when YSI values were less than certain glucose readings (for “LOW”), and when YSI values were greater than certain glucose readings (for “HIGH”).

Original Pediatric Study (SW10050): When the System displayed “LOW” (13 occasions), 0% (0 out of 13) of the YSI values were less than 80 mg/dL. When the System displayed “HIGH” (70 occasions), 99% (69 out of 70) of the YSI values were greater than 240 mg/dL, and 97% (68 out of 70) of the YSI values were greater than 280 mg/dL.

Software 505 Pediatric Study (SW10505): When the System displayed “LOW” (16 occasions), 94% (15 out of 16) of the YSI values were less than 80 mg/dL, and 63% (10 out of 18) of the YSI values were less than 70 mg/dL. When the System displayed “HIGH” (24 occasions), 96% (23 out of 24) of the YSI values were greater than 240 mg/dL, and 92% (22 out of 24) of the YSI values were greater than 280 mg/dL.

Original Adult Study (SW10050): When the System displayed “LOW” (155 occasions), 92% (142 out of 155) of the YSI values were less than 80 mg/dL, and only 79% (123 out of 155) of the YSI values were less than 70 mg/dL. When the System displayed “HIGH” (248 occasions), 99% (246 out of 248) of the YSI values were greater than 240 mg/dL, and 96% (238 out of 248) of the YSI values were greater than 280 mg/dL.

Software 505 Adult Study (SW10505): When the System displayed “LOW” (18 occasions), 100% (18 out of 18) of the YSI values were less than 80 mg/dL, and 94% (17 out of 18) of the YSI values were less than 70 mg/dL. When the System displayed “HIGH” (45 occasions), 100% (45 out of 45) of the YSI values were greater than 240 mg/dL, and 100% (45 out of 45) of the YSI values were greater than 280 mg/dL.

Table 2-A. Number and Percentage of YSI Values When CGM Readings are “LOW” or “HIGH” (Pediatric)

CGM Readings	Study ¹	CGM-YSI pairs	YSI mg/dL					Total
			< 55	< 60	< 70	< 80	≥ 80	
“LOW”	Original	n	0	0	0	0	13	13
		Cumulative Percent	0%	0%	0%	0%	100%	
	Software 505	n	3	5	10	15	1	16
		Cumulative Percent	19%	31%	63%	94%	6%	

CGM Readings	Study ¹	CGM-YSI pairs	YSI mg/dL					Total
			> 340	> 320	> 280	> 240	≤ 240	
“HIGH”	Original	n	38	51	68	69	1	70
		Cumulative Percent	54%	73%	97%	99%	1%	
	Software 505	n	14	19	22	23	1	24
		Cumulative Percent	58%	79%	92%	96%	4%	

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 2-B. Number and Percentage of YSI Values When CGM Readings are “LOW” or “HIGH” (Adult)

CGM Readings	Study ¹	CGM-YSI pairs	YSI mg/dL					Total
			< 55	< 60	< 70	< 80	≥ 80	
“LOW”	Original	n	66	84	123	142	13	155
		Cumulative Percent	42%	54%	79%	92%	8%	
	Software 505	n	11	16	17	18	0	18
		Cumulative Percent	61%	89%	94%	100%	0%	
CGM Readings	Study ¹	CGM-YSI pairs	YSI mg/dL					Total
			> 340	> 320	> 280	> 240	≤ 240	
“HIGH”	Original	n	189	220	238	246	2	248
		Cumulative Percent	76%	89%	96%	99%	1%	
	Software 505	n	40	43	45	45	0	45
		Cumulative Percent	89%	96%	100%	100%	0%	

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Concurrence of System and Laboratory Reference

Tables 3-A (**Original** Pediatric Study), 3-B (**Software 505** Pediatric Study), 3-C (**Original** Adult Study), and 3-D (**Software 505** Adult Study) are categorized by ranges of CGM glucose readings. These tables describe, for each range of CGM glucose readings, what percentage of paired YSI values were in the same glucose range (shaded) or in glucose ranges above and below the paired CGM readings. For example, based on the **Software 505** Pediatric Study, when CGM readings are within 81 to 120 mg/dL, you can expect your blood glucose levels are within 81 to 120 mg/dL 69% of time.

Table 3-A. Concurrence of CGM Readings and YSI Values (Original Pediatric Study)

CGM (mg/dL)	YSI (mg/dL) Row percentage of matched pairs in each CGM glucose range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	0%	0%	0%	54%	31%	15%	0%	0%	0%	0%	0%	13
40-60	0%	21%	58%	16%	5%	0%	0%	0%	0%	0%	0%	19
61-80	0%	21%	45%	30%	4%	0%	0%	0%	0%	0%	0%	76
81-120	0%	1%	20%	66%	12%	1%	0%	0%	0%	0%	0%	338
121-160	0%	0%	1%	36%	54%	7%	1%	0%	0%	0%	0%	511
161-200	0%	0%	0%	4%	40%	48%	6%	1%	0%	0%	0%	596
201- 250	0%	0%	0%	1%	9%	44%	41%	5%	0%	0%	0%	658
251- 300	0%	0%	0%	0%	2%	7%	50%	36%	3%	0%	2%	432
301- 350	0%	0%	0%	0%	0%	2%	18%	59%	21%	0%	0%	206
351- 400	0%	0%	0%	0%	0%	0%	3%	28%	50%	16%	2%	86
> 400	0%	0%	0%	0%	0%	0%	1%	14%	41%	36%	7%	70

Table 3-B. Concurrence of CGM Readings and YSI Values (Software 505 Pediatric Study)

CGM (mg/dL)	YSI (mg/dL) Row percentage of matched pairs in each CGM glucose range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	25%	63%	6%	0%	0%	0%	0%	0%	0%	0%	16
40-60	0%	33%	60%	6%	1%	0%	0%	0%	0%	0%	0%	86
61-80	0%	8%	64%	26%	2%	0%	0%	0%	0%	0%	0%	142
81-120	0%	1%	15%	69%	13%	1%	1%	0%	0%	0%	0%	314
121-160	0%	0%	0%	15%	66%	18%	1%	0%	0%	0%	0%	313
161-200	0%	0%	0%	1%	18%	66%	15%	0%	0%	0%	0%	355
201- 250	0%	0%	0%	0%	1%	17%	68%	14%	0%	0%	0%	444
251- 300	0%	0%	0%	0%	0%	0%	26%	58%	16%	0%	0%	336
301- 350	0%	0%	0%	0%	0%	0%	4%	40%	46%	9%	0%	209
351- 400	0%	0%	0%	0%	0%	0%	3%	14%	62%	21%	0%	63
> 400	0%	0%	0%	0%	0%	0%	4%	13%	29%	38%	17%	24

Table 3-C. Concurrence of CGM Readings and YSI Values (Original Adult Study)

CGM (mg/dL)	YSI (mg/dL)											Number of Paired CGM-YSI
	Row percentage of matched pairs in each CGM glucose range											
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	48%	37%	7%	1%	0%	0%	0%	0%	0%	0%	155
40-60	4%	49%	36%	11%	1%	0%	0%	0%	0%	0%	0%	512
61-80	0%	22%	51%	24%	1%	0%	0%	0%	0%	0%	0%	781
81-120	0%	2%	17%	66%	13%	1%	0%	0%	0%	0%	0%	1706
121-160	0%	0%	1%	25%	60%	13%	2%	0%	0%	0%	0%	1492
161-200	0%	0%	0%	2%	28%	53%	16%	2%	0%	0%	0%	1240
201- 250	0%	0%	0%	0%	3%	21%	51%	21%	3%	1%	0%	1181
251- 300	0%	0%	0%	0%	0%	4%	19%	49%	24%	3%	0%	1018
301- 350	0%	0%	0%	0%	0%	0%	3%	28%	51%	16%	1%	775
351- 400	0%	0%	0%	0%	0%	0%	3%	10%	43%	38%	7%	447
> 400	0%	0%	0%	0%	0%	0%	1%	6%	21%	57%	15%	248

Table 3-D. Concurrence of CGM Readings and YSI Values (Software 505 Adult Study)

CGM (mg/dL)	YSI (mg/dL)											Number of Paired CGM-YSI
	Row percentage of matched pairs in each CGM glucose range											
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	83%	11%	0%	0%	0%	0%	0%	0%	0%	0%	18
40-60	2%	74%	22%	3%	0%	0%	0%	0%	0%	0%	0%	120
61-80	0%	19%	68%	13%	0%	0%	0%	0%	0%	0%	0%	226
81-120	0%	0%	19%	72%	8%	1%	0%	0%	0%	0%	0%	347
121-160	0%	0%	0%	17%	72%	11%	0%	0%	0%	0%	0%	246
161-200	0%	0%	0%	0%	25%	59%	16%	0%	0%	0%	0%	286
201- 250	0%	0%	0%	0%	0%	16%	70%	13%	1%	0%	0%	376
251- 300	0%	0%	0%	0%	0%	2%	16%	61%	14%	7%	0%	281
301- 350	0%	0%	0%	0%	0%	0%	2%	28%	59%	10%	1%	229
351- 400	0%	0%	0%	0%	0%	0%	0%	4%	47%	45%	5%	152
> 400	0%	0%	0%	0%	0%	0%	0%	0%	20%	38%	42%	45

Accuracy Relative to YSI

Accuracy between matched pairs was also estimated by calculating the percent difference between the System reading and the YSI value. For example, if the YSI value is 100 mg/dL and the System reading is 90

mg/dL, a 10% difference between the System and the YSI is reported. The System and YSI values were compared by pairing the System reading that fell immediately after the YSI value was collected.

In the example above, the System reading is less than the YSI value, so the percent difference reading is negative. The mean percent difference is the average of all positive and negative percent differences between the two devices; it tells you if the System reads higher or lower on average than the YSI within each glucose range.

Another estimate used to show the accuracy of the System is the absolute percent difference. The absolute percent difference tells you the percent difference or “distance” between the System and YSI values, but does not tell you whether the System is reading, on average, higher or lower than the YSI laboratory standard. The mean absolute percent difference is the average “distance” (regardless if positive or negative) between System readings and YSI values.

Accuracy measures in differences for both the **Original** Pediatric and **Software 505** Pediatric Studies are based on 2922 and 2262 paired glucose results, respectively; the data are summarized in Table 4-A. Table 4-A is categorized within CGM glucose ranges.

Original Pediatric Study (SW10050): Overall, on average, the System reads 13.5% different (Mean Percent Difference) than the reference and 17.4% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the System reads 11.6% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the System reads about 13.5% or less than the YSI blood glucose values.

Software 505 Pediatric Study (SW10505): Overall, on average, the System reads 1.8% different (Mean Percent Difference) than the reference and 10.4% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the System reads 1.2% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the System reads about 7.9% or less than the YSI blood glucose values.

Accuracy measures in differences for both the **Original** and **Software 505** Adult Studies are based on 9152 and 2263 paired glucose results, respectively; the data are summarized in Table 4-B. Table 4-B is categorized within CGM glucose ranges.

Original Adult Study (SW10050): Overall, on average, the System reads 2.9% different (Mean Percent Difference) than the reference and 13.3% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the System reads 1.7% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the System reads about 9.8% or less than the YSI blood glucose values.

Software 505 Adult Study (SW10505): Overall, on average, the System reads 2.5% different (Mean Percent Difference) than the reference and 9.0% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the System reads 2.4% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the System reads about 7.0% or less than the YSI blood glucose values.

Table 4-A. System Difference to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Ranges (mg/dL) ¹	Study ²	Number of Paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	2922	13.5%	11.6%	17.4%	13.5%
	Software 505	2262	1.8%	1.2%	10.4%	7.9%
*40-60	Original	19	-18.1	-9.1	19.2	9.1
	Software 505	86	-15.3	-13.2	16.1	13.2
*61-80	Original	76	-3.7	-2.3	13.4	10.6
	Software 505	142	-4.8	-1.0	11.8	7.7
81-180	Original	1155	11.9%	9.7%	17.0%	13.0%
	Software 505	805	1.9%	0.7%	10.6%	8.1%
181-300	Original	1380	14.8%	12.4%	17.4%	13.3%
	Software 505	957	2.2%	1.0%	8.1%	6.5%
301-350	Original	206	19.2%	15.9%	19.4%	15.9%
	Software 505	209	7.8%	6.5%	11.0%	7.9%
351-400	Original	86	18.5%	15.5%	19.1%	15.5%
	Software 505	63	14.9%	11.6%	15.2%	11.6%

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

* For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).

Table 4-B. System Difference to YSI within CGM Glucose Ranges (Adult)

CGM Glucose Ranges (mg/dL) ¹	Study ²	Number of Paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	9152	2.9%	1.7%	13.3%	9.8%
	Software 505	2263	2.5%	2.4%	9.0%	7.0%
*40-60	Original	512	-10	-8.2	13.5	9.7
	Software 505	120	-3.3	-2.1	6.9	4.8
*61-80	Original	781	-2.4	-0.4	11.4	8.6
	Software 505	226	0.8	1.4	6.7	5.4
81-180	Original	3853	4.8%	3.0%	13.8%	9.8%
	Software 505	738	3.9%	4.1%	9.6%	8.2%
181-300	Original	2784	2.1%	0.0%	11.9%	9.2%
	Software 505	798	0.6%	0.4%	8.0%	6.1%
301-350	Original	775	3.8%	2.8%	9.8%	7.9%
	Software 505	229	4.1%	3.4%	8.0%	5.8%
351-400	Original	447	10.4%	7.7%	12.8%	9.1%
	Software 505	152	7.2%	6.3%	9.2%	7.2%

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

* For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).

Low and High Glucose Alerts

The ability of the System to detect high and low glucose levels is assessed by comparing System results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The System and YSI values were compared by pairing the System reading that occurred immediately after the YSI value was collected. We suggest that you ask your doctor what alert settings would be best for you.

Table 5-A. Hypoglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric, Ages 6-17)

Hypoglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	0%	100%	0%	100%
	Software 505	22%	78%	75%	25%
60	Original	11%	89%	25%	75%
	Software 505	42%	58%	78%	23%
70	Original	47%	53%	50%	50%
	Software 505	68%	32%	75%	25%
80	Original	55%	45%	55%	45%
	Software 505	86%	14%	91%	9%
90	Original	69%	31%	62%	38%
	Software 505	90%	10%	93%	7%
100	Original	75%	25%	62%	38%
	Software 505	91%	9%	93%	7%

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 5-B. Hypoglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5)

Hypoglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	3%	97%	57%	43%
	Software 505	25%	75%	100%	0%
60	Original	11%	89%	62%	38%
	Software 505	20%	80%	100%	0%
70	Original	29%	71%	77%	23%
	Software 505	20%	80%	100%	0%
80	Original	35%	65%	85%	15%
	Software 505	61%	39%	100%	0%
90	Original	51%	49%	89%	11%
	Software 505	78%	22%	100%	0%
100	Original	64%	36%	91%	9%
	Software 505	82%	18%	100%	0%

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 5-C. Hypoglycemic Alert Evaluation (Adult)

Hypoglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	50%	50%	71%	29%
	Software 505	71%	29%	68%	32%
60	Original	64%	36%	75%	25%
	Software 505	85%	15%	83%	17%
70	Original	79%	21%	83%	17%
	Software 505	92%	8%	91%	9%
80	Original	87%	13%	86%	14%
	Software 505	95%	5%	90%	10%
90	Original	90%	10%	89%	11%
	Software 505	96%	4%	94%	6%

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Tables 5-A, 5-B and 5-C. Table 5-A represents the alert evaluation within 15 minutes of the YSI value for a sub-set of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 5-B represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric study. Table 5-C represents the hypoglycemic alert evaluation within 15 minutes of the YSI value in the adult study.

Hypoglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the percent of time the device alarmed when the blood glucose level was at or below the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the percent of time the device alarmed when the blood glucose level was above the alert setting within 15 or 30 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 the **Original** Pediatric Study, if your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 47% of the time and not be below 70

mg/dL approximately 53% of the time within the 15 minute period before or after your alarm sounds. Based on the **Software 505** Pediatric Study, if your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 68% of the time and not be below 70 mg/dL approximately 32% of the time within the 15 minute period before or after your alarm sounds.

In the adult study, the alarm would sound approximately 79% of the time when the blood sugar would go below 70 mg/dL for the **Original** Adult Study and 92% of the time for the **Software 505** Adult Study.

Hypoglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hypoglycemia or how often it misses such an event. The Hypoglycemia Detection Rate is the percent of time the blood glucose level was at or below the alert setting and device alarmed within 15 or 30 minutes before or after the blood glucose was at or below the alert settings. The Hypoglycemia Missed Detection Rate is the percent of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or below the alert setting.

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 the **Original** Pediatric Study, if your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 50% of the time and not to sound approximately 50% of the time within the 15 minute period before or after your blood sugar goes below 70 mg/dL. Based on the **Software 505** Pediatric Study, if your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 75% of the time and not to sound approximately 25% of the time within the 15 minute period before or after your blood sugar goes below 70 mg/dL.

In the Adult Study, the alarm would sound 83% of the time when the blood sugar went below 70 mg/dL for the **Original** Adult Study and 91% of the time for the **Software 505** Adult Study.

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Tables 6-A, 6-B and 6-C. Table 6-A represents the alert evaluation within 15 minutes of the YSI value for a sub-set of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 6-B represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric study. Table 6-C represents the hyperglycemic alert evaluation within 15 minutes of the YSI value in the Adult Study.

Hyperglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the percent of time the device alarmed when the blood glucose level was at or above the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the percent of time the device alarmed when the blood glucose level was below the alert setting within 15 or 30 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 the **Original** Pediatric Study, if your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 71% of the time and not be above 200 mg/dL approximately 29% of the time within the 15 or 30 minute period before or after your alarm sounds. Based on the **Software 505** Pediatric Study, if your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 94% of the time and not be above 200 mg/dL approximately 6% of the time within the 15 or 30 minute period before or after your alarm sounds.

In the adult study if the alarm sounded, the blood sugar was at or above 200 mg/dL approximately 92% of the time for the **Original** Adult Study and 96% of the time for the **Software 505** Adult Study.

Hyperglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hyperglycemia or how often it misses such an event. The Hyperglycemia Detection Rate is the percent of time the blood glucose level was at or above the alert setting and the device alarmed within 15 or 30 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the percent of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or above the alert setting.

For example, if you set your High Glucose alert to 200 mg/dL, how often will your alarm alert you if your blood glucose goes at or above 200 mg/dL? Based on the **Original** Pediatric Study, if your blood sugar goes above 200 mg/dL, you can expect your alarm to sound 98% of the time and not to sound approximately 2% of the time within the 15 minute period before or after your blood sugar goes above 200 mg/dL. Based on the **Software 505** Pediatric Study, if your blood sugar goes above 200 mg/dL, you can expect your alarm to sound 97% of the time and not to sound approximately 3% of the time within the 15 minute period before or after your blood sugar goes above 200 mg/dL.

In the Adult Study, the alarm would sound 97% of the time when the blood sugar went above 200 mg/dL for the **Original** Adult Study and 98% of the time for the **Software 505** Adult Study.

Table 6-A. Hyperglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric, Ages 6-17 years)

Hyperglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	91%	9%	98%	2%
	Software 505	98%	2%	99%	1%
140	Original	87%	13%	99%	1%
	Software 505	97%	3%	98%	2%
180	Original	75%	25%	99%	1%
	Software 505	94%	6%	98%	2%
200	Original	71%	29%	98%	2%
	Software 505	94%	6%	97%	3%
220	Original	67%	33%	97%	3%
	Software 505	93%	7%	96%	4%
240	Original	62%	38%	96%	4%
	Software 505	88%	12%	94%	6%
300	Original	43%	57%	93%	7%
	Software 505	69%	31%	84%	16%

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 6-B. Hyperglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 years)

Hyperglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	92%	8%	98%	2%
	Software 505	97%	3%	99%	1%
140	Original	90%	10%	98%	2%
	Software 505	98%	2%	100%	0%
180	Original	87%	13%	96%	4%
	Software 505	99%	1%	93%	7%
200	Original	85%	15%	96%	4%
	Software 505	98%	2%	93%	7%
220	Original	81%	19%	95%	5%
	Software 505	100%	0%	97%	3%
240	Original	80%	20%	95%	5%
	Software 505	99%	1%	98%	2%
300	Original	71%	29%	90%	10%
	Software 505	95%	5%	96%	4%

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 6-C. Hyperglycemic Alert Evaluation (Adult)

Hyperglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	95%	5%	98%	2%
	Software 505	98%	2%	100%	0%
140	Original	94%	6%	97%	3%
	Software 505	97%	3%	99%	1%
180	Original	92%	8%	97%	3%
	Software 505	97%	3%	99%	1%
200	Original	92%	8%	97%	3%
	Software 505	96%	4%	98%	2%
220	Original	91%	9%	95%	5%
	Software 505	94%	6%	98%	2%
240	Original	91%	9%	94%	6%
	Software 505	93%	7%	95%	5%
300	Original	82%	18%	86%	14%
	Software 505	86%	14%	90%	10%

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Calibration Stability

The System must be calibrated every 12 hours. To demonstrate performance of the System over a 12-hour calibration period, Systems were evaluated to verify that performance remains consistent over the 12-hour calibration period. Systems were evaluated in 2-hour increments after calibration. Performance was estimated at each 2-hour interval and stratified by glucose values by calculating the percentage of System readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30% and greater than 40 mg/dL or 40% of the YSI values in Table 7-A and 7-B.

Table 7-A. Percentage of System Readings¹ within YSI Values with Data Stratified in 2-Hour Increments after Calibration (Pediatric)

<u>Time from Calibration</u>	<u>Study²</u>	<u>Number of paired CGM-YSI</u>	<u>Percent within 15/15% YSI</u>	<u>Percent within 20/20% YSI</u>	<u>Percent within 30/30% YSI</u>	<u>Percent greater than 40/40% YSI</u>
<u>0-2 hours</u>	<u>Original</u>	<u>648</u>	<u>65%</u>	<u>75%</u>	<u>87%</u>	<u>7%</u>
	<u>Software 505</u>	<u>545</u>	<u>83%</u>	<u>91%</u>	<u>97%</u>	<u>1%</u>
<u>2-4 hours</u>	<u>Original</u>	<u>649</u>	<u>51%</u>	<u>67%</u>	<u>86%</u>	<u>7%</u>
	<u>Software 505</u>	<u>460</u>	<u>72%</u>	<u>89%</u>	<u>96%</u>	<u>2%</u>
<u>4-6 hours</u>	<u>Original</u>	<u>630</u>	<u>51%</u>	<u>61%</u>	<u>80%</u>	<u>10%</u>
	<u>Software 505</u>	<u>428</u>	<u>77%</u>	<u>88%</u>	<u>95%</u>	<u>2%</u>
<u>6-8 hours</u>	<u>Original</u>	<u>409</u>	<u>52%</u>	<u>68%</u>	<u>85%</u>	<u>5%</u>
	<u>Software 505</u>	<u>325</u>	<u>88%</u>	<u>92%</u>	<u>94%</u>	<u>3%</u>
<u>8-10 hours</u>	<u>Original</u>	<u>296</u>	<u>53%</u>	<u>69%</u>	<u>84%</u>	<u>7%</u>
	<u>Software 505</u>	<u>305</u>	<u>86%</u>	<u>93%</u>	<u>97%</u>	<u>1%</u>
<u>10-12 hours</u>	<u>Original</u>	<u>253</u>	<u>58%</u>	<u>74%</u>	<u>89%</u>	<u>5%</u>
	<u>Software 505</u>	<u>198</u>	<u>89%</u>	<u>94%</u>	<u>98%</u>	<u>0%</u>
<u>12-14 hours</u>	<u>Original</u>	<u>37</u>	<u>32%</u>	<u>38%</u>	<u>65%</u>	<u>22%</u>
	<u>Software 505</u>	<u>1</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>0%</u>

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 7-B. Percentage of System Readings¹ within YSI Values with Data Stratified in 2-Hour Increments after Calibration (Adult)

<u>Time from Calibration</u>	<u>Study²</u>	<u>Number of paired CGM-YSI</u>	<u>Percent within 15/15% YSI</u>	<u>Percent within 20/20% YSI</u>	<u>Percent within 30/30% YSI</u>	<u>Percent greater than 40/40% YSI</u>
<u>0-2 hours</u>	<u>Original</u>	<u>1929</u>	<u>78%</u>	<u>88%</u>	<u>96%</u>	<u>2%</u>
	<u>Software 505</u>	<u>469</u>	<u>93%</u>	<u>97%</u>	<u>99%</u>	<u>0%</u>
<u>2-4 hours</u>	<u>Original</u>	<u>1516</u>	<u>69%</u>	<u>81%</u>	<u>91%</u>	<u>4%</u>
	<u>Software 505</u>	<u>389</u>	<u>90%</u>	<u>97%</u>	<u>99%</u>	<u>0%</u>
<u>4-6 hours</u>	<u>Original</u>	<u>1547</u>	<u>69%</u>	<u>79%</u>	<u>91%</u>	<u>5%</u>
	<u>Software 505</u>	<u>383</u>	<u>85%</u>	<u>91%</u>	<u>97%</u>	<u>2%</u>
<u>6-8 hours</u>	<u>Original</u>	<u>1520</u>	<u>68%</u>	<u>79%</u>	<u>92%</u>	<u>3%</u>
	<u>Software 505</u>	<u>380</u>	<u>79%</u>	<u>90%</u>	<u>97%</u>	<u>2%</u>
<u>8-10 hours</u>	<u>Original</u>	<u>1555</u>	<u>71%</u>	<u>82%</u>	<u>92%</u>	<u>4%</u>
	<u>Software 505</u>	<u>347</u>	<u>83%</u>	<u>92%</u>	<u>98%</u>	<u>0%</u>
<u>10-12 hours</u>	<u>Original</u>	<u>1068</u>	<u>65%</u>	<u>77%</u>	<u>91%</u>	<u>4%</u>
	<u>Software 505</u>	<u>295</u>	<u>80%</u>	<u>90%</u>	<u>98%</u>	<u>0%</u>
<u>12-14 hours</u>	<u>Original</u>	<u>17</u>	<u>65%</u>	<u>76%</u>	<u>82%</u>	<u>12%</u>
	<u>Software 505</u>	<u>0</u>	<u>--</u>	<u>--</u>	<u>--</u>	<u>--</u>

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Sensor Stability Relative to YSI

Sensors can be worn for up to 7 days. To verify sensor performance over time, 176 subjects were evaluated with the **Original** Pediatric System across the 7-day wear period while 79 subjects were evaluated with the **Software 505** Pediatric System across the 7-day wear period in the pediatric studies. Performance was estimated by calculating the percentage of System readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30% and greater than 40 mg/dL or 40% of the YSI values at the beginning (Day 1), middle (Day 4) and end (Day 7) of the System lifecycle. The average and median of the absolute percent differences are included in Table 8-A showing consistent accuracy and sensor stability over the 7-day life of the sensor.

In the Adult studies, 72 subjects were evaluated with the **Original** Adult system across the 7-day wear period while 50 subjects were evaluated with the **Software 505** Adult system across the 7-day wear period. The Adult Study results are displayed in Table 8-B.

Table 8-A. Sensor Stability Relative to YSI (Accuracy over Time¹)- (Pediatric)

Day of Wear	Study ²	Number of paired CGM-YSI	Mean Absolute Percent Differences	Median Absolute Percent Differences	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent greater than 40/40% YSI
Day 1	Original	1016	21.2	15.8	48%	61%	78%	15%
	Software 505	740	12.7	8.5	75%	83%	91%	4%
Day 4	Original	810	16.0	13.9	52%	66%	87%	3%
	Software 505	795	8.1	6.7	89%	97%	100%	0%
Day 7	Original	1096	15.1	11.3	63%	76%	89%	4%
	Software 505	727	10.4	8.4	80%	91%	98%	1%

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 8-B. Sensor Stability Relative to YSI (Accuracy over Time¹)- (Adult)

Day of Wear	Study ²	Number of paired CGM-YSI	Mean Absolute Percent Differences	Median Absolute Percent Differences	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent greater than 40/40% YSI
Day 1	Original	3023	16.7%	13.2%	59%	71%	86%	6%
	Software 505	680	10.7%	7.9%	77%	84%	96%	2%
Day 4	Original	3108	11.4%	8.2%	77%	87%	95%	2%
	Software 505	777	8.0%	6.4%	89%	96%	99%	0%
Day 7	Original	3021	11.9%	8.9%	76%	87%	95%	2%
	Software 505	806	8.5%	7.2%	90%	97%	99%	0%

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Precision of System Readings

In the **Original** Pediatric Study, all subjects wore two Systems. This was to look at how similarly two Systems function on the same subject (sensor precision). Precision was evaluated by comparing the glucose readings from the two Systems worn on the same subject at the same time. Results showed that

System readings from the two sensors generally agreed with each other within 10% (absolute percent difference) with a 7% coefficient of variation. Only one System was worn in the **Software 505** Pediatric Study so precision data was not collected in this study.

In the **Original** Adult Study, 36 subjects wore two Systems. Results showed that System readings from the two sensors generally agreed with each other within 9% (absolute percent difference) with a 7% coefficient of variation. Only one System was worn in the **Software 505** Adult Study so precision data was not collected in this study.

Sensor Life

Sensors may be worn for up to 7 days (168 hours). To estimate how long a sensor will work over 7 days, 351 sensors were evaluated in the **Original** Pediatric Study to determine how many days/hours of readings each sensor provided. Eighty-five percent (85%) of the sensors lasted until Day 7 (145-168 hours). For the **Software 505** Pediatric Study, 77 sensors were evaluated to determine how many days/hours of readings each sensor provided. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours).

In the **Original** Adult Study, 108 sensors were evaluated to determine how many days/hours of readings each sensor provided. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours). There were 6 (6%) sensors that ended early, four of which lasted more than 3 days. For the **Software 505** Adult Study, 51 sensors were evaluated to determine how many days/hours of readings each sensor provided. Ninety-eight percent (98%) of the sensors lasted until Day 7 (145-168 hours). There was 1 (2%) sensor that ended early, which lasted until day 5 of the sensor wear.

Number of Readings Provided

The System is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, the System may not display a glucose reading and readings are “skipped.” Tables 9-A and 9-B estimate the number of readings you can expect to receive from the System over the entire 7-day period after calibration. For the **Original Pediatric** Study, 86% of Systems provided between 1,518 and 1,992 valid glucose readings (or more than 75% of the expected number of readings). Adjusted within each system wear-day, the **Original** Pediatric System provided an average of 95% of all expected glucose readings as seen in Table 10-A.

For the **Software 505** Pediatric Study, 91% of Systems provided between 1,623 and 1,990 valid glucose readings (or more than 75% of the expected number of readings). Adjusted within each system wear-day, the **Software 505** Pediatric System provided an average of 95% of all expected glucose readings (288) as seen in Table 10-A.

For the **Original** Adult Study, 94% of Systems provided between 1,811 and 1,992 valid glucose readings (or more than 75% of the expected number of readings). Adjusted within each system wear-day, the **Original** Adult System provided an average of 97% of all expected glucose readings (288) as seen in Table 10-B.

For the **Software 505** Adult Study (SW10505), 96% of Systems provided between 1,497 and 1,992 valid glucose readings (or more than 75% of the expected number of readings). Adjusted within each system wear-day, the **Software 505** Adult System provided an average of 98% of all expected glucose readings (288) as seen in Table 10-B.

Table 9-A. Number of Readings Provided by Each Sensor Over 7-Days (Pediatric)

<u>% of Total Possible Readings Provided</u>	<u>Study¹</u>	<u>Total Readings Provided (Min-Max)</u>	<u>% of Systems Providing that Number of Readings</u>
<u>0-25%</u>	<u>Original</u>	<u>103-427</u>	<u>3%</u>
	<u>Software 505</u>	<u>60-223</u>	<u>4%</u>
<u>26-50%</u>	<u>Original</u>	<u>569-954</u>	<u>3%</u>
	<u>Software 505</u>	<u>877-891</u>	<u>3%</u>
<u>51-75%</u>	<u>Original</u>	<u>1006-1484</u>	<u>9%</u>
	<u>Software 505</u>	<u>1131-1342</u>	<u>3%</u>
<u>76-100%</u>	<u>Original</u>	<u>1518-1992</u>	<u>86%</u>
	<u>Software 505</u>	<u>1623-1990</u>	<u>91%</u>

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 9-B. Number of Readings Provided by Each Sensor Over 7-Days (Adult)

<u>% of Total Possible Readings Provided</u>	<u>Study¹</u>	<u>Total Readings Provided (Min-Max)</u>	<u>% of Systems Providing that Number of Readings</u>
<u>0-25%</u>	<u>Original</u>	<u>167-491</u>	<u>2%</u>
	<u>Software 505</u>	<u>0</u>	<u>0%</u>
<u>26-50%</u>	<u>Original</u>	<u>719-914</u>	<u>4%</u>
	<u>Software 505</u>	<u>856-856</u>	<u>2%</u>
<u>51-75%</u>	<u>Original</u>	<u>1267-1267</u>	<u>1%</u>
	<u>Software 505</u>	<u>1253-1253</u>	<u>2%</u>
<u>76-100%</u>	<u>Original</u>	<u>1811-1992</u>	<u>94%</u>
	<u>Software 505</u>	<u>1497-1992</u>	<u>96%</u>

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 10-A. System Readings within Wear Days (Pediatric)

Statistic	Study ¹	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days ²
Mean	Original	97%	96%	96%	95%	94%	94%	92%	95%
	Software 505	96%	96%	95%	96%	93%	95%	93%	95%
Median	Original	99%	99%	99%	99%	99%	99%	98%	99%
	Software 505	99%	98%	99%	99%	97%	97%	98%	98%
STD	Original	6%	10%	9%	12%	14%	14%	17%	12%
	Software 505	9%	6%	12%	10%	15%	7%	12%	11%

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

² A total of 108 sensors were included with the **Original** Study and 77 sensors were included with the **Software 505** study.

Table 10-B. System Readings within Wear Days (Adult)

Statistic	Study ¹	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days ²
Mean	Original	98%	98%	98%	98%	97%	99%	95%	97%
	Software 505	98%	99%	98%	98%	96%	99%	97%	98%
Median	Original	100%	100%	100%	100%	100%	100%	100%	100%
	Software 505	99%	100%	100%	100%	100%	100%	100%	100%
STD	Original	5%	3%	9%	8%	10%	3%	11%	8%
	Software 505	3%	2%	8%	11%	15%	2%	13%	9%

¹ Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

² A total of 108 sensors were included with the **Original** Study and 51 sensors were included with the **Software 505** Study.

Agreement and Accuracy Relative to SMBG

During the study, agreement between the System and blood glucose values is also characterized using paired System and SMBG results (Tables 11-12). The System and SMBG values were compared by pairing the comparative SMBG value to a System glucose reading that occurred immediately after the SMBG was collected. These results characterize the performance subjects expect during real-time use of the System in their daily diabetes management when comparing the System readings to their home blood glucose meter results.

Tables 11-A and 11-B are categorized within CGM glucose ranges. For readings less than or equal to 80 mg/dL the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, or greater than 40 mg/dL or 40% were then calculated. For example, if the CGM reads 100 mg/dL, it is between 81-180 mg/dL range and you can expect the CGM readings to be within 20% of the SMBG values 74% of the time for the **Original** Pediatric System and 84% time for the **Software 505** Pediatric System. For the adult system, CGM readings would be within 20% of the SMBG values 78% of the time for the **Original** Adult System and 85% time for the **Software 505** Adult System if CGM read 100 mg/dL.

Table 11-A. System Agreement to SMBG within CGM Glucose Ranges (Pediatric)

CGM Glucose Ranges ¹ (mg/dL)	Study ²	Number of paired CGM-SMBG	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent greater than 40/40% SMBG
Overall	Original	16318	64%	76%	89%	5%
	Software 505	4264	73%	84%	94%	2%
40-60	Original	487	44%	55%	68%	19%
	Software 505	240	54%	71%	86%	7%
61-80	Original	1340	59%	70%	85%	7%
	Software 505	399	64%	76%	92%	2%
81-180	Original	7084	62%	74%	90%	5%
	Software 505	1650	72%	84%	95%	2%
181-300	Original	5627	69%	80%	90%	5%
	Software 505	1526	79%	89%	97%	2%
301-350	Original	1176	65%	77%	90%	4%
	Software 505	319	72%	83%	94%	2%
351-400	Original	604	58%	72%	86%	6%
	Software 505	130	69%	79%	86%	8%

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 11-B. CGM System Agreement to SMBG within CGM Glucose Ranges (Adult)

CGM Glucose Ranges¹ (mg/dL)	Study²	Number of paired CGM-SMBG	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent greater than 40/40% SMBG
Overall	Original	7508	69%	81%	94%	2%
	Software 505	2992	77%	87%	96%	1%
40-60	Original	731	75%	84%	92%	4%
	Software 505	221	73%	80%	87%	7%
61-80	Original	968	78%	86%	95%	1%
	Software 505	336	77%	85%	95%	1%
81-180	Original	3141	65%	78%	93%	2%
	Software 505	1362	74%	85%	96%	1%
181-300	Original	1960	68%	81%	94%	3%
	Software 505	826	80%	90%	97%	1%
301-350	Original	450	77%	88%	98%	1%
	Software 505	161	83%	93%	99%	0%
351-400	Original	258	75%	85%	95%	2%
	Software 505	86	90%	93%	98%	1%

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

² Both sets of study data are presented and are labeled as **Original (SW10050)** or **Software 505 (SW10505)**.

Tables 12-A and 12-B are categorized within CGM glucose ranges. Overall, the System in the **Original** Pediatric Study reads, on average, 2.2% higher (Mean Percent Difference) than SMBG values and 15.3% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the System reads 0.9% or less than the SMBG values and the Median Absolute Percent Difference shows that half of the time the System reads about 11.1% or less different than SMBG values.

Overall, the System in the **Software 505** Pediatric Study reads, on average, 0.7% lower (Mean Percent Difference) than SMBG values and 12.5% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the System reads -1.1% or less than the SMBG values and the Median Absolute Percent Difference shows that half of the time the System reads about 9.5% or less different than SMBG values.

In the adult studies, the System in the **Original** Adult Study reads, on average, 0.4% lower (Mean Percent Difference) than SMBG values and 14.0% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the System reads -1.4% or less than the SMBG values and the Median Absolute Percent Difference shows that half of the time the System reads about 11.0% or less different than SMBG values.

Overall, the System in the **Software 505** Adult Study reads, on average, 2.6% lower (Mean Percent Difference) than SMBG values and 11.3% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the System reads lower in 2.7% or less.

Table 12-A. System Difference to SMBG within CGM Glucose Ranges (Pediatric)

<u>CGM Glucose Ranges¹</u> <u>(mg/dL)</u>	<u>Study²</u>	<u>Number of Paired</u> <u>CGM-SMBG</u>	<u>Mean Percent</u> <u>Difference</u>	<u>Median</u> <u>Percent</u> <u>Difference</u>	<u>Mean Absolute</u> <u>Percent</u> <u>Difference</u>	<u>Median</u> <u>Absolute</u> <u>Percent</u> <u>Difference</u>
<u>Overall</u>	<u>Original</u>	<u>16318</u>	<u>2.2%</u>	<u>0.9%</u>	<u>15.3%</u>	<u>11.1%</u>
	<u>Software 505</u>	<u>4264</u>	<u>-0.7%</u>	<u>-1.1%</u>	<u>12.5%</u>	<u>9.5%</u>
<u>*40-60</u>	<u>Original</u>	<u>487</u>	<u>-22.1</u>	<u>-17.0</u>	<u>23.9</u>	<u>18.0</u>
	<u>Software 505</u>	<u>240</u>	<u>-15.9</u>	<u>-14.0</u>	<u>16.9</u>	<u>14.0</u>
<u>*61-80</u>	<u>Original</u>	<u>1340</u>	<u>-11.8</u>	<u>-8.0</u>	<u>17.0</u>	<u>11.0</u>
	<u>Software 505</u>	<u>399</u>	<u>-7.8</u>	<u>-6.0</u>	<u>13.7</u>	<u>10.0</u>
<u>81-180</u>	<u>Original</u>	<u>7084</u>	<u>1.1%</u>	<u>-1.0%</u>	<u>15.4%</u>	<u>11.4%</u>
	<u>Software 505</u>	<u>1650</u>	<u>-1.2%</u>	<u>-2.6%</u>	<u>12.1%</u>	<u>9.5%</u>
<u>181-300</u>	<u>Original</u>	<u>5627</u>	<u>5.7%</u>	<u>3.4%</u>	<u>13.5%</u>	<u>9.5%</u>
	<u>Software 505</u>	<u>1526</u>	<u>1.7%</u>	<u>0.9%</u>	<u>10.1%</u>	<u>7.7%</u>
<u>301-350</u>	<u>Original</u>	<u>1176</u>	<u>9.6%</u>	<u>7.2%</u>	<u>14.2%</u>	<u>10.4%</u>
	<u>Software 505</u>	<u>319</u>	<u>6.7%</u>	<u>5.9%</u>	<u>11.8%</u>	<u>8.9%</u>
<u>351-400</u>	<u>Original</u>	<u>604</u>	<u>12.7%</u>	<u>10.2%</u>	<u>16.1%</u>	<u>11.9%</u>
	<u>Software 505</u>	<u>130</u>	<u>12.0%</u>	<u>8.9%</u>	<u>15.7%</u>	<u>10.6%</u>

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

* For CGM ≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).

Table 12-B. CGM System Difference to SMBG within CGM Glucose Ranges (Adult)

<u>CGM Glucose Ranges¹</u> <u>(mg/dL)</u>	<u>Study²</u>	<u>Number of Paired</u> <u>CGM-SMBG</u>	<u>Mean Percent</u> <u>Difference</u>	<u>Median</u> <u>Percent</u> <u>Difference</u>	<u>Mean Absolute</u> <u>Percent</u> <u>Difference</u>	<u>Median</u> <u>Absolute</u> <u>Percent</u> <u>Difference</u>
<u>Overall</u>	<u>Original</u>	<u>7508</u>	<u>-0.4%</u>	<u>-1.4%</u>	<u>14.0%</u>	<u>11.0%</u>
	<u>Software 505</u>	<u>2992</u>	<u>-2.6%</u>	<u>-2.7%</u>	<u>11.3%</u>	<u>8.6%</u>
<u>*40-60</u>	<u>Original</u>	<u>731</u>	<u>-9.3</u>	<u>-8.0</u>	<u>11.7</u>	<u>8.0</u>
	<u>Software 505</u>	<u>221</u>	<u>-10.3</u>	<u>-6.0</u>	<u>13.0</u>	<u>8.0</u>
<u>*61-80</u>	<u>Original</u>	<u>968</u>	<u>-1.0</u>	<u>1.0</u>	<u>10.7</u>	<u>8.0</u>
	<u>Software 505</u>	<u>336</u>	<u>-4.0</u>	<u>-2.0</u>	<u>10.1</u>	<u>7.0</u>
<u>81-180</u>	<u>Original</u>	<u>3141</u>	<u>1.4%</u>	<u>0.0%</u>	<u>14.2%</u>	<u>11.0%</u>
	<u>Software 505</u>	<u>1362</u>	<u>-2.6%</u>	<u>-3.1%</u>	<u>11.4%</u>	<u>8.9%</u>
<u>181-300</u>	<u>Original</u>	<u>1960</u>	<u>-0.7%</u>	<u>-2.8%</u>	<u>13.0%</u>	<u>10.3%</u>
	<u>Software 505</u>	<u>826</u>	<u>-1.4%</u>	<u>-2.0%</u>	<u>9.5%</u>	<u>7.4%</u>
<u>301-350</u>	<u>Original</u>	<u>450</u>	<u>-0.7%</u>	<u>-2.6%</u>	<u>10.5%</u>	<u>8.6%</u>
	<u>Software 505</u>	<u>161</u>	<u>-0.0%</u>	<u>0.0%</u>	<u>8.3%</u>	<u>6.0%</u>
<u>351-400</u>	<u>Original</u>	<u>258</u>	<u>5.0%</u>	<u>3.0%</u>	<u>11.9%</u>	<u>8.6%</u>
	<u>Software 505</u>	<u>86</u>	<u>3.9%</u>	<u>3.2%</u>	<u>8.1%</u>	<u>6.7%</u>

Sensor Stability Relative to SMBG

Sensors can be worn for up to 7 days. Performance was estimated by calculating the percentage of system readings within various percentages of the SMBG values at each day of the sensor wear period (Table 13). The average and median of the absolute percent differences are included in the tables.

Table 13. Sensor Stability Relative to SMBG (Accuracy¹ over Time) - Pediatric

Day of Wear	Study ²	Number of paired CGM-SMBG	Mean Absolute Percent Differences	Median Absolute Percent Differences	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent greater than 40/40% SMBG
Day 1	Original	3216	18.8%	14.2%	53%	65%	81%	10%
	Software 505	893	14.8%	10.7%	64%	79%	91%	5%
Day 2	Original	2148	16.2%	12.4%	60%	74%	87%	6%
	Software 505	436	13.2%	10.4%	69%	81%	95%	3%
Day 3	Original	1977	15.2%	11.0%	63%	76%	89%	5%
	Software 505	441	13.8%	11.3%	66%	77%	91%	2%
Day 4	Original	2830	14.0%	10.9%	66%	79%	91%	4%
	Software 505	850	10.7%	8.5%	79%	91%	97%	1%
Day 5	Original	1768	15.4%	10.7%	67%	78%	90%	5%
	Software 505	374	11.4%	8.7%	74%	86%	96%	1%
Day 6	Original	1704	14.3%	9.8%	68%	79%	90%	4%
	Software 505	410	12.3%	9.2%	72%	80%	93%	2%
Day 7	Original	2675	12.4%	9.2%	72%	83%	94%	3%
	Software 505	860	11.3%	8.6%	79%	90%	96%	2%

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

² Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Adverse Events

No serious adverse events or device-related serious adverse events occurred during the studies. Mild to moderate skin irritation, such as erythema or edema, occurred at the sensor needle insertion area or the adhesive area. No infection, bruising, or bleeding occurred at the sensor needle insertion area or the adhesive area.

Potential Options To Address FDA's Labeling Request (P120005/S031)

Dexcom would appreciate feedback regarding the inclusion of adult SW505 Data (P120005/S018) to the Pediatric user's guide. We have included several layout options below.

Different versions of Table 1- *System Agreements to YSI within CGM Glucose Ranges* have been laid out below for your review.

Option 1- Keep tables with original pediatric and SW505 data in printed user's guide as submitted, add directions to access original and SW505 adult data on the web.

Pros: Simple tables are easiest to comprehend; fewer tables. Most relevant data to pediatric subjects is available in the printed User's Guide. All adult data is available on the web. User has ability to zoom and scroll larger tables more easily on the web.

Cons: One additional step to access adult data; requires internet access

Option 2- Separate pediatric and adult tables containing both original and SW505 values:

Pros: Easy to understand; clearly delineates populations

Cons: May display unnecessary original adult data, generates additional tables. May be hard to compare data in tables that span multiple pages.

Table 1-A. System Agreement to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	2922	55%	68%	85%	7%
	Software 505	2262	81%	91%	96%	2%
40-60	Original	19	63%	74%	79%	21%
	Software 505	86	54%	74%	91%	3%
61-80	Original	76	61%	82%	92%	4%
	Software 505	142	77%	82%	90%	3%
81-180	Original	1155	56%	69%	84%	6%
	Software 505	805	78%	88%	97%	1%
181-300	Original	1380	55%	68%	85%	7%
	Software 505	957	89%	96%	99%	1%
301-350	Original	206	48%	62%	80%	11%
	Software 505	209	81%	91%	94%	5%
351-400	Original	86	48%	61%	79%	12%
	Software 505	63	64%	81%	83%	8%

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

² BOTH SETS OF STUDY DATA ARE PRESENTED AND ARE LABELED AS ORIGINAL (SW10050) OR SOFTWARE 505 (SW10505).

Table 1-B. System Agreement to YSI within CGM Glucose Ranges (Adult Studies)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	9152	71%	82%	92%	3%
	Software 505	2263	86%	93%	98%	1%
40-60	Original	512	67%	78%	88%	6%
	Software 505	120	89%	94%	98%	0%
61-80	Original	781	73%	85%	94%	2%
	Software 505	226	91%	96%	99%	0%
81-180	Original	3853	67%	78%	91%	3%
	Software 505	738	84%	92%	98%	1%
181-300	Original	2784	72%	84%	93%	4%
	Software 505	798	86%	93%	98%	1%
301-350	Original	775	82%	91%	97%	2%
	Software 505	229	86%	94%	98%	1%
351-400	Original	447	74%	84%	91%	5%
	Software 505	152	80%	92%	97%	0%

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

² BOTH SETS OF STUDY DATA ARE PRESENTED AND ARE LABELED AS **ORIGINAL** (SW10050) OR **SOFTWARE 505** (SW10505)

Option 3- One table containing original and SW505 data for both Peds and Adults:

Pros: Generates the least amount of tables.

Cons: Table too large to be displayed on one page in printed user’s guide, confusing. Font would be smaller than FDA has previously recommended. Provides data not applicable to the use population.

Table 1. System Agreement to YSI within CGM Glucose Ranges

CGM Glucose Range ¹ (mg/dL)	Study Population	Study ²	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Pediatric	Original	2922	55%	68%	85%	7%
		Software 505	2262	81%	91%	96%	2%
	Adult	Original	9152	71%	82%	92%	3%
		Software 505	2263	86%	93%	98%	1%
40-60	Pediatric	Original	19	63%	74%	79%	21%
		Software 505	86	54%	74%	91%	3%
	Adult	Original	512	67%	78%	88%	6%
		Software 505	120	89%	94%	98%	0%
61-80	Pediatric	Original	76	61%	82%	92%	4%
		Software 505	142	77%	82%	90%	3%
	Adult	Original	781	73%	85%	94%	2%
		Software 505	226	91%	96%	99%	0%
81-180	Pediatric	Original	1155	56%	69%	84%	6%
		Software 505	805	78%	88%	97%	1%
	Adult	Original	3853	67%	78%	91%	3%
		Software 505	738	84%	92%	98%	1%
181-300	Pediatric	Original	1380	55%	68%	85%	7%
		Software 505	957	89%	96%	99%	1%
	Adult	Original	2784	72%	84%	93%	4%
		Software 505	798	86%	93%	98%	1%
301-350	Pediatric	Original	206	48%	62%	80%	11%
		Software 505	209	81%	91%	94%	5%

351-400	Adult	Original	775	82%	91%	97%	2%
		Software 505	229	86%	94%	98%	1%
	Pediatric	Original	86	48%	61%	79%	12%
		Software 505	63	64%	81%	83%	8%
	Adult	Original	447	74%	84%	91%	5%
		Software 505	152	80%	92%	97%	0%

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

² All sets of study data are presented and are labeled as **Original Pediatric** (SW10050), **Software 505 Pediatric** (SW10505), **Original Adult** (SW10050) or **Software 505 Adult** (SW10505).

Option 4- One table with both adult and peds SW505 data as well as original peds

Pros: Three studies displayed in one table.

Cons: Most confusing since it appears that the original adult data is missing. Table too large to be displayed on one page in printed user’s guide. Font would be smaller than FDA has previously recommended. Provides data not applicable to the use population.

Table 1. System Agreement to YSI within CGM Glucose Ranges

CGM Glucose Range ¹ (mg/dL)	Study Population	Study ²	Number of paired CGM-YSI	Percent within 15/15%	Percent within 20/20%	Percent within 30/30%	Percent Greater than 40/40%
				YSI	YSI	YSI	YSI
Overall	Pediatric	Original	2922	55%	68%	85%	7%
		Software 505	2262	81%	91%	96%	2%
	Adult	Software 505	2263	86%	93%	98%	1%
40-60	Pediatric	Original	19	63%	74%	79%	21%
		Software 505	86	54%	74%	91%	3%
	Adult	Software 505	120	89%	94%	98%	0%
61-80	Pediatric	Original	76	61%	82%	92%	4%
		Software 505	142	77%	82%	90%	3%
	Adult	Software 505	226	91%	96%	99%	0%
81-180	Pediatric	Original	1155	56%	69%	84%	6%
		Software 505	805	78%	88%	97%	1%
	Adult	Software 505	738	84%	92%	98%	1%
181-300	Pediatric	Original	1380	55%	68%	85%	7%
		Software 505	957	89%	96%	99%	1%
	Adult	Software 505	798	86%	93%	98%	1%
301-350	Pediatric	Original	206	48%	62%	80%	11%
		Software 505	209	81%	91%	94%	5%
	Adult	Software 505	229	86%	94%	98%	1%
351-400	Pediatric	Original	86	48%	61%	79%	12%
		Software 505	63	64%	81%	83%	8%
	Adult	Software 505	152	80%	92%	97%	0%

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

² All sets of study data are presented and are labeled as **Original Pediatric** (SW10050), **Software 505 Pediatric** (SW10505), **Software 505 Adult** (SW10505).

Dexcom Recommendation:

In reviewing your labeling request, Dexcom recommends the following 2 options:

1. Option 1: The combination of a printed user's guide containing Pediatric Study data from both the original study and that with SW505, as well as directions on how to access the website for all Adult Data, would be easiest for users to understand. Thus, Dexcom believes that this is the ideal solution. This option would greatly reduce user confusion and most effectively communicate the data to the user since only the data from the use population is available. This option also avoids the addition of numerous tables or tables that span multiple pages.
2. Option 2: Taking into consideration both the number and size of tables that are necessary to effectively communicate data from three or four studies, this option uses a consistent format to the adult User's Guide and avoids the addition of jumbo tables which would span multiple pages.



MEMO

Date: February 19, 2015
To: Seth Carmody, Ph.D., DHHS/FDA/CDRH/OMPT/CDRH/OIR/DCTD/DDDB
Cc: File P120005/S031
From: Andrew Balo
RE: 180-Day Supplement P120005/S031, FDA Questions/Request for Information

On February 13, 2015, Seth Carmody sent the following comments regarding P120005/S031 to Andrew Balo via email. The FDA comments and Dexcom's responses to these comments are detailed below.

1) FDA Question:

In reviewing the clinical summaries, raw data, and labeling I did not see data for the true alert rate (hypo and hyper) for CGM-SMBG (2-5 years of age). The tables would be similar to table 5-C and 6-C in the final labeling from P120005/S002. Please provide these tables or indicate where they can be found at your earliest convenience.

Dexcom Response:

Please find below a hypoglycemic alert and detection rate table in reference to SMBG for ages 2-5 years (now table 5-B), as well as a hyperglycemic alert and detection rate table in reference to SMBG for ages 2-5 years (now table 6-B). These tables are similar to tables 5-C and 6-C as contained in P120005/S002 and have been designed to reflect data from both the original and 505 software versions.

These tables have been incorporated into the Low and High Alert Section of the User's Guide, and the revised section is contained in Attachment 2.

Table 5-B. Hypoglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Ages 2-5)

Hypoglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	3%	97%	57%	43%
	SOFTWARE 505	25%	75%	100%	0%
60	Original	11%	89%	62%	38%
	SOFTWARE 505	20%	80%	100%	0%
70	Original	29%	71%	77%	23%
	SOFTWARE 505	20%	80%	100%	0%
80	Original	35%	65%	85%	15%
	SOFTWARE 505	61%	39%	100%	0%
90	Original	51%	49%	89%	11%
	SOFTWARE 505	78%	22%	100%	0%
100	Original	64%	36%	91%	9%
	SOFTWARE 505	82%	18%	100%	0%

¹ BOTH SETS OF STUDY DATA ARE PRESENTED AND ARE LABELED AS ORIGINAL (SW10050) OR SOFTWARE 505 (SW10505).

Table 6-B. Hyperglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Ages 2-5 years)

Hyperglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	92%	8%	98%	2%
	Software 505	97%	3%	99%	1%
140	Original	90%	10%	98%	2%
	Software 505	98%	2%	100%	0%
180	Original	87%	13%	96%	4%
	Software 505	99%	1%	93%	7%
200	Original	85%	15%	96%	4%
	Software 505	98%	2%	93%	7%
220	Original	81%	19%	95%	5%
	Software 505	100%	0%	97%	3%
240	Original	80%	20%	95%	5%
	Software 505	99%	1%	98%	2%
300	Original	71%	29%	90%	10%
	Software 505	95%	5%	96%	4%

¹ BOTH SETS OF STUDY DATA ARE PRESENTED AND ARE LABELED AS **ORIGINAL** (SW10050) OR **SOFTWARE 505** (SW10505).

ATTACHMENT 1

FDA Email P120005/S031
February 13, 2015

From: <Carmody>, Seth <Seth.Carmody@fda.hhs.gov>
Date: Friday, February 13, 2015 at 12:58 PM
To: Andy Balo <abalo@dexcom.com>
Subject: true alert rates (2-5 years old)

Andy,

In reviewing the clinical summaries, raw data, and labeling I did not see data for the true alert rate (hypo and hyper) for CGM-SMBG (2-5 years of age). The tables would be similar to table 5-C and 6-C in the final labeling from P120005/S002. Please provide these tables or indicate where they can be found at your earliest convenience.

Thank you,
Seth

ATTACHMENT 2

Updated Low and High Glucose Alert Section from
LBL012867, G4 PLATINUM (Pediatric) User's Guide

Low and High Glucose Alerts

The ability of the System to detect high and low glucose levels is assessed by comparing System results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The System and YSI values were compared by pairing the System reading that occurred immediately after the YSI value was collected. We suggest that you ask your doctor what alert settings would be best for you.

Table 5-A. Hypoglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Ages 6-17)

Hypoglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	0%	100%	0%	100%
	SOFTWARE 505	22%	78%	75%	25%
60	Original	11%	89%	25%	75%
	SOFTWARE 505	42%	58%	78%	23%
70	Original	47%	53%	50%	50%
	SOFTWARE 505	68%	32%	75%	25%
80	Original	55%	45%	55%	45%
	SOFTWARE 505	86%	14%	91%	9%
90	Original	69%	31%	62%	38%
	SOFTWARE 505	90%	10%	93%	7%
100	Original	75%	25%	62%	38%
	SOFTWARE 505	91%	9%	93%	7%

¹ BOTH SETS OF STUDY DATA ARE PRESENTED AND ARE LABELED AS ORIGINAL (SW10050) OR SOFTWARE 505 (SW10505).

Table 5-B. Hypoglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Ages 2-5)

Hypoglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	3%	97%	57%	43%
	SOFTWARE 505	25%	75%	100%	0%
60	Original	11%	89%	62%	38%
	SOFTWARE 505	20%	80%	100%	0%
70	Original	29%	71%	77%	23%
	SOFTWARE 505	20%	80%	100%	0%
80	Original	35%	65%	85%	15%
	SOFTWARE 505	61%	39%	100%	0%
90	Original	51%	49%	89%	11%
	SOFTWARE 505	78%	22%	100%	0%
100	Original	64%	36%	91%	9%
	SOFTWARE 505	82%	18%	100%	0%

¹ BOTH SETS OF STUDY DATA ARE PRESENTED AND ARE LABELED AS ORIGINAL (SW10050) OR SOFTWARE 505 (SW10505).

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Tables 5-A and 5-B. Table 5-A represents the alert evaluation within 15 minutes of the YSI value for a sub-set of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 5-B represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric study.

Hypoglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the percent of time the device alarmed when the blood glucose level was at or below the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the percent of time the device alarmed when the blood glucose level was above the alert setting within 15 or 30 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 the ORIGINAL Study, if your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 47% of the time and not be below 70 mg/dL approximately 53% of the time within the 15 minute period before or after your alarm sounds. Based on the

SOFTWARE 505 Study, if your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 68% of the time and not be below 70 mg/dL approximately 32% of the time within the 15 minute period before or after your alarm sounds.

Hypoglycemia Detection Rate

The detection rate shows how often the device recognizes and alerts you to an episode of hypoglycemia or how often it misses such an event. The hypoglycemia detection rate is the percent of time the blood glucose level was at or below the alert setting and device alarmed within 15 or 30minutes before or after the blood glucose was at or below the alert settings. The hypoglycemia missed detection rate is the percent of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 or 30minutes before or after the blood glucose was at or below the alert setting.

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 the **original** study, if your blood sugar goes below 70 mg/dl, you can expect your alarm to sound 50% of the time and not to sound approximately 50% of the time within the 15 minute period before or after your blood sugar goes below 70 mg/dl. Based on the **software 505** study, if your blood sugar goes below 70 mg/dl, you can expect your alarm to sound 75% of the time and not to sound approximately 25% of the time within the 15 minute period before or after your blood sugar goes below 70 mg/dl.

Table 6-A. Hyperglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Ages 6-17 years)

Hyperglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	91%	9%	98%	2%
	SOFTWARE 505	98%	2%	99%	1%
140	Original	87%	13%	99%	1%
	SOFTWARE 505	97%	3%	98%	2%
180	Original	75%	25%	99%	1%
	SOFTWARE 505	94%	6%	98%	2%
200	Original	71%	29%	98%	2%
	SOFTWARE 505	94%	6%	97%	3%
220	Original	67%	33%	97%	3%
	SOFTWARE 505	93%	7%	96%	4%
240	Original	62%	38%	96%	4%
	SOFTWARE 505	88%	12%	94%	6%
300	Original	43%	57%	93%	7%
	SOFTWARE 505	69%	31%	84%	16%

¹ BOTH SETS OF STUDY DATA ARE PRESENTED AND ARE LABELED AS ORIGINAL (SW10050) OR SOFTWARE 505 (SW10505).

Table 6-B. Hyperglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Ages 2-5 years)

Hyperglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	92%	8%	98%	2%
	Software 505	97%	3%	99%	1%
140	Original	90%	10%	98%	2%
	Software 505	98%	2%	100%	0%
180	Original	87%	13%	96%	4%
	Software 505	99%	1%	93%	7%
200	Original	85%	15%	96%	4%
	Software 505	98%	2%	93%	7%
220	Original	81%	19%	95%	5%
	Software 505	100%	0%	97%	3%
240	Original	80%	20%	95%	5%
	Software 505	99%	1%	98%	2%
300	Original	71%	29%	90%	10%
	Software 505	95%	5%	96%	4%

¹ BOTH SETS OF STUDY DATA ARE PRESENTED AND ARE LABELED AS ORIGINAL (SW10050) OR SOFTWARE 505 (SW10505).

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Tables 6-A and 6-B. Table 6-A represents the alert evaluation within 15 minutes of the YSI value for a sub-set of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 6-B represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric study.

Hyperglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the percent of time the device alarmed when the blood glucose level was at or above the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the percent of time the device alarmed when the blood glucose level was below the alert setting within 15 or 30 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 the **ORIGINAL** Study, if your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 71% of the time and not be above 200 mg/dL approximately 29% of the time within the 15 or 30 minute period before or after your alarm sounds. Based on the **SOFTWARE 505** Study, if your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 94% of the time and not be above 200 mg/dL approximately 6% of the time within the 15 or 30 minute period before or after your alarm sounds.

Hyperglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hyperglycemia or how often it misses such an event. The Hyperglycemia Detection Rate is the percent of time the blood glucose level was at or above the alert setting and the device alarmed within 15 or 30 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the percent of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or above the alert setting.

For example, if you set your High Glucose alert to 200 mg/dL, how often will your alarm alert you if your blood glucose goes at or above 200 mg/dL? Based on the **ORIGINAL** Study, if your blood sugar goes above 200 mg/dL, you can expect your alarm to sound 98% of the time and not to sound approximately 2% of the time within the 15 minute period before or after your blood sugar goes above 200 mg/dL. Based on the **SOFTWARE 505** Study, if your blood sugar goes above 200 mg/dL, you can expect your alarm to sound 97% of the time and not to sound approximately 3% of the time within the 15 minute period before or after your blood sugar goes above 200 mg/dL.

CHAPTER 15: USER ASSISTANCE

Dexcom Website:
www.dexcom.com

Dexcom Address:
6340 Sequence Drive
San Diego, CA 92121

TECHNICAL SUPPORT

For Dexcom product questions and troubleshooting issues¹¹.

Dexcom Technical Support Phone Numbers:

1.877.339.2664 or 1.858.200.0200

(24 hours, 7 days a week)

Dexcom Technical Support E-mail:

TechSupport@dexcom.com

Dexcom Technical Support Fax:

1.877.633.9266

SALES SUPPORT

For help with first-time orders, re-orders, tracking shipments, and locating a Dexcom representative in your area.

Dexcom Sales Support Phone Numbers:

1.877.339.2664 or 1.858.200.0200

Dexcom Sales Support E-mail:

CustomerService@dexcom.com

Dexcom Sales Support Fax:

1.877.633.9266

¹¹ Dexcom Technical Support does not offer medical advice.

CHAPTER 16: WARRANTY

Dexcom G4 PLATINUM (Pediatric) System Limited Warranty

1. What is Covered and for How Long?

Dexcom, Inc. (“Dexcom”) provides a limited warranty to the original purchaser that the Dexcom G4 PLATINUM (Pediatric) Receiver is free from defects in material and workmanship under normal use (“Limited Warranty”) for the period commencing upon the date of shipment and continuing for the following specified period of time after that date (“Warranty Period”):

Dexcom G4 PLATINUM (Pediatric) Receiver: 1 Year

NOTE: If you received this receiver as a replacement for an in-warranty receiver, any remaining warranty on the original receiver shall transfer to this replacement receiver, and this warranty page shall be void.

2. What is Not Covered?

This Limited Warranty is conditioned upon proper use of the product by the purchaser. This Limited Warranty does not cover: (a) 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; (b) equipment that has the ID number removed or made illegible; (c) all surfaces and other externally exposed parts that are scratched or damaged due to normal use; (d) malfunctions resulting from the use of the product in conjunction with accessories, products or ancillary or peripheral equipment not furnished or approved by Dexcom; (e) defects or damage from improper testing, operation, maintenance, installation or adjustment; (f) installation, maintenance, and service of products; or (g) equipment that has been disassembled; or (h) water damage to the receiver (receiver is not water resistant, do not get the receiver wet at any time).

3. What are Dexcom’s Obligations Under the Limited Warranty?

During the Warranty Period, Dexcom will replace, at Dexcom’s sole option, without charge to purchaser, any defective Dexcom G4 PLATINUM (Pediatric) Receiver. Purchaser must return the product to an authorized Dexcom Customer Support Department in an adequate container for shipping, accompanied by purchaser’s sales receipt or comparable substitute proof of sale showing the date of purchase, the ID number of the product, and the seller’s name and address. To obtain assistance on where to deliver the Dexcom G4 PLATINUM (Pediatric) Receiver, call Dexcom Customer Support Department at **1.877.339.2664** or **1.858.200.0200**. Upon receipt, Dexcom will promptly replace the defective product. If Dexcom determines that any product is not covered by this Limited Warranty, purchaser must pay all shipping charges for the return of such product.

4. What are the Limits on Dexcom’s Warranty and Liability Obligations?

THE LIMITED WARRANTY OF DEXCOM DESCRIBED ABOVE IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, AND DEXCOM

EXPRESSLY EXCLUDES AND DISCLAIMS ALL SUCH OTHER WARRANTIES, 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 G4 PLATINUM (PEDIATRIC) SYSTEM. THIS LIMITATION SHALL APPLY EVEN IF DEXCOM OR ITS AGENT HAS BEEN ADVISED OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF THIS LIMITED REMEDY. THIS LIMITED WARRANTY SHALL NOT EXTEND TO ANYONE OTHER THAN THE ORIGINAL PURCHASER OF THIS PRODUCT 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 WHICH PURCHASER ACKNOWLEDGES IS AND WILL ALWAYS BE CONSTRUED TO BE LIMITED BY ITS TERMS OR AS LIMITED AS THE LAW PERMITS.

Dexcom G4 PLATINUM Transmitter Limited Warranty

1. What Is Covered And For How Long?

Dexcom, Inc. ("Dexcom") provides a limited warranty to the original purchaser that the Dexcom G4 PLATINUM Transmitter is free from defects in material and workmanship under normal use ("Limited Warranty") for the period commencing upon the date of shipment and continuing for the following specified period of time after that date ("Warranty Period"):

Dexcom G4 PLATINUM Transmitter: 6 Months

NOTE: If you received this transmitter as a replacement for an in-warranty transmitter, any remaining warranty on the original transmitter shall transfer to this replacement transmitter, and this warranty page shall be void.

2. What Is Not Covered?

This Limited Warranty is conditioned upon proper use of the product by the purchaser. This Limited Warranty does not cover: (a) 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; (b) equipment that has the ID number removed or made illegible; (c) all surfaces and other externally exposed parts that are scratched or damaged due to normal use; (d) malfunctions resulting from the use of the product in conjunction with accessories, product or ancillary or peripheral equipment not furnished or approved by Dexcom; (e) defects or damage from improper testing, operation, maintenance, installation or adjustment; (f) installation, maintenance, and service of products; (g) equipment that has been disassembled, or (h) water damage to the transmitter beyond the specifications listed in the Dexcom G4 PLATINUM (Pediatric) CGM System User's Guide, a copy of which was included with your Dexcom G4 PLATINUM (Pediatric) CGM System and may be found at www.dexcom.com.

3. What Are Dexcom's Obligations Under The Limited Warranty?

During the Warranty Period, Dexcom will replace, at Dexcom's sole option, without charge to purchaser, any defective Dexcom G4 PLATINUM Transmitter. Purchaser must return the product to an authorized Dexcom Customer Support Department in an adequate container for shipping, accompanied by purchaser's sales receipt or comparable substitute proof of sale showing the date of purchase, the ID number of the product, and the seller's name and address. To obtain assistance on where to deliver the Dexcom G4 PLATINUM Transmitter, contact Dexcom Customer Support Department at **1.877.339.2664** or **1.858.200.0200**. Upon receipt, Dexcom will promptly replace the defective product. If Dexcom determines that any product is not covered by this Limited Warranty, purchaser must pay all shipping charges for the return of such product.

4. What Are The Limits on Dexcom's Warranty And Liability Obligations?

THE LIMITED WARRANTY OF DEXCOM DESCRIBED ABOVE IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, AND DEXCOM EXPRESSLY EXCLUDES AND DISCLAIMS ALL SUCH OTHER WARRANTIES, 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 G4 PLATINUM (PEDIATRIC) CGM SYSTEM. THIS LIMITATION SHALL APPLY EVEN IF DEXCOM OR ITS AGENT HAS BEEN ADVISED OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF THIS LIMITED REMEDY. THIS LIMITED WARRANTY SHALL NOT EXTEND TO ANYONE OTHER THAN THE ORIGINAL PURCHASER OF THIS PRODUCT AND STATE 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 WHICH PURCHASER ACKNOWLEDGES IS AND WILL ALWAYS BE CONSTRUED TO BE LIMITED BY ITS TERMS OR AS LIMITED AS THE LAW PERMITS.

CHAPTER 17: TRAVEL INFORMATION

It is safe for you to go through the metal detector or be "handwanded" while wearing your Dexcom sensor and transmitter. If you're concerned or uncomfortable about going through the walk-through metal detector, the Transportation Security Administration (TSA) states that you should notify the Security Office that you're wearing a continuous glucose monitor and would like a full-body pat-down and a visual inspection of your Dexcom sensor and transmitter instead. Advise the Security Office that the sensor cannot be removed because it is inserted under the skin.

Instead of putting your Dexcom G4 PLATINUM (Pediatric) System through the x-ray, request that the TSA officer perform a visual inspection. This must be requested before the screening process begins. Your Dexcom G4 PLATINUM (Pediatric) System components that are not attached to your body (e.g., receiver,

extra sensors) should be ready in a separate bag when you approach the Security Officer. For other medical supplies, such as medications, meters and strips, check the manufacturer’s instructions or the TSA website.

You may keep the receiver on before take-off, while in flight and after landing. The Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System is safe for use on U.S. commercial airlines. The Dexcom G4 PLATINUM Transmitter is an M-PED with emission levels that meet RTCA/DO160, Section 21, Category M. Per FAA Advisory, Circular #91-21, 1B, dated 8/25/06. Any M-PED that meets this standard in all modes may be used onboard the aircraft without any further testing by the operator. This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI).

Visit the TSA’s website if you have any questions or concerns.

www.tsa.gov

E-mail: TSA-ContactCenter@dhs.gov

Phone: Call 1.866.289.9673

CHAPTER 18: APPENDIX

APPENDIX I: RECEIVER ALERTS, ALARM AND PROMPTS

The following tables describe the alarm, alerts and prompts and how the receiver notifies you.

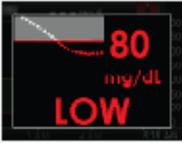
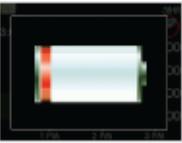
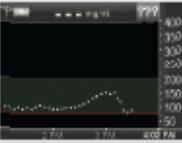
Prompt - Shows on screen only. Silent, no vibrate or beep.

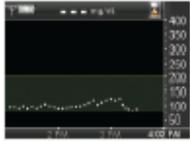
Alert - Notifies with vibrate and beep depending on your profile settings.

Alarm - Low 55 - Notifies with vibrate and beep. Cannot be changed.

Receiver Alerts, Alarm and Prompts

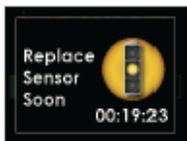
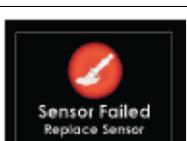
What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Low glucose alarm	Your most recent sensor glucose reading is at or below 55 mg/dL.	Vibrates 4 times and then vibrates/beeps 4 times every 5 minutes until confirmed or your glucose value goes above 55 mg/dL.	Yes, every 30 minutes after each confirmation until your blood glucose value comes back into range.
	High glucose alert	Your most recent sensor glucose reading is at or above the high alert setting.	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes until confirmed or your glucose	No, unless you have turned on the high snooze feature. See Chapter 9,

			value drops below the alert level.	Section 9.2, Advanced Alerts.
	Low glucose alert	Your most recent sensor glucose reading is at or below the low alert setting.	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes until confirmed or your glucose value goes above the alert level.	No, unless you have turned on the low snooze feature. See Chapter 9, Section 9.2, Advanced Alerts.
	Low battery alert	The receiver battery is low. Charge your receiver as soon as possible when you see this alert.	Vibrates 1 time at 20% battery capacity left.	Yes, at 10% battery capacity left.
	Out of Range alert	The transmitter and receiver are not communicating and you will not receive sensor glucose readings.	Vibrates 1 time and then vibrates/beeps every 5 minutes until the receiver and transmitter are back in range.	No unless you have turned on the out of range alert.
	Glucose reading error prompt	The sensor is sending sensor glucose readings that the receiver does not understand. You will not receive	Symbol in status area only.	N/A

		sensor glucose readings.		
	Wait prompt	The receiver has detected a potential problem with the sensor signal. You should wait about 30 minutes for more prompts. Do not enter any blood glucose values during this time. You will not receive sensor glucose readings.	Symbol in status area only.	N/A
	Wait 15 minutes calibration error alert	The sensor cannot calibrate. Wait 15 minutes then enter 1 more blood glucose value. Wait 15 more minutes. If error screen still appears enter 1 more blood glucose value. Wait 15 minutes. If no sensor glucose readings appear on the	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	No

		receiver, the sensor needs to be replaced.		
	Wait 1 hour calibration error alert	The sensor cannot calibrate. Wait a minimum of 1 hour then enter 1 more blood glucose value for calibration. If no sensor glucose readings appear on the receiver, the sensor needs to be replaced.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	No
	12 hour calibration prompt	The receiver needs a blood glucose value entered to calibrate.	Prompt screen only.	Yes, every 15 minutes.
	Calibration prompt	The receiver needs a blood glucose value entered to calibrate. Sensor glucose readings will not be displayed at this time.	Vibrates 1 time then vibrates/beeps every 5 minutes until confirmed.	Yes, every 15 minutes.

	Startup calibration prompt	The receiver needs 2 blood glucose values entered to calibrate.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	Yes, every 15 minutes.
	Additional startup calibration prompt	The receiver needs 1 additional blood glucose value to complete startup calibration.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	Yes, every 15 minutes.
	Enter BG processing screen prompt	The receiver is processing the blood glucose value you entered.	Prompt screen only.	N/A
	Rise alert	Your glucose levels are rising at 2 mg/dL per minute or more.	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes or until confirmed (2 repeats max).	No
	Rapid rise alert	Your glucose levels are rising fast at 3 mg/dL per minute or more.	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes or until confirmed (2 repeats max).	No
	Fall alert	Your glucose levels are falling at 2 mg/dL per minute or more.	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes or until confirmed (2 repeats max).	No

	Rapid fall alert	Your glucose levels are falling fast at 3 mg/dL per minute or more.	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes or until confirmed (2 repeats max).	No
	6-hour sensor expiration prompt	Your sensor session will end in 6 hours.	Prompt screen only.	N/A
	2-hour sensor expiration alert	Your sensor session will end in 2 hours.	Prompt screen only.	No
	30-minute sensor expiration alert	Your sensor session will end in 30 minutes.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	No
	End of session sensor expiration alert	Your sensor session has ended.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	No
	Sensor failed alert	The sensor is not working properly.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	Yes, 2 re-alerts in the next 10 minutes for 30 minutes.
	Receiver error code alert	Your receiver is not working properly. Record the error code and call	Vibrates 1 time (4 seconds) + 4 beeps.	No

		Dexcom Technical Support.		
	System recovery check alert	There was a system error and the receiver fixed it.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	No
	Set time/date prompt	Backup battery has drained, time/date need to be reset.	Vibrates 1 time.	No
	Transmitter low battery alert	Transmitter battery is low. Replace the transmitter as soon as possible.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	Yes, once a day.
	Transmitter failed alert	The transmitter has failed. Replace the transmitter immediately.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	No

Important alerts that can be checked by the user:

- **Out of range alert** - You can test this alert by moving the receiver more than 20 feet away for 30 minutes or more.
- **30-minute sensor expiration alert** - You will see this alert in the normal course of using a sensor for seven days.
- **0-hour sensor expiration alert** - You will see this alert in the normal course of using a sensor for seven days.

Other alerts and alarms cannot be safely checked by the user.

APPENDIX II: INDEX

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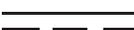
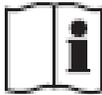
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APPENDIX III: SYMBOLS USED IN LABELING

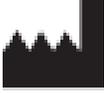
The following symbols may be found on the sensor, transmitter, and receiver package labels. These symbols tell you about the proper and safe use of the Dexcom G4 PLATINUM (Pediatric) CGM System. Some of these symbols may not have meaning in your region, and are listed for informational purposes only. This table shows what each symbol means.

Symbols

	"Use By" Date		Lot Number
	Caution		Part Number, Catalog Number
	Date of Manufacture		Sterile by Radiation
	Do Not Reuse		Two-sided Temperature Limits
	Serial Number		Temporary submersion
	Class II Equipment		Vertically falling drops
	Alternating Current		Direct Current
	Type BF Applied Part		Follow Operating Instructions

(continued on next page)

Symbols (continued from page before)

	Manufacturer		Authorized Representative in the European Community
	Two-Sided Humidity Limitation		Non-ionizing Radiation
	European Union WEEE Directive 2006-66-EC		Marking Certifies that the device meets the European Council Directive 93/42/EEC
	Electrical Equipment Designed Primarily for Indoor Use		Do Not Use if Package is Damaged
	Input	SB	Ship By Date
	Keep Dry	Rx Only	Prescription Required



Inserting the Sensor (continued)

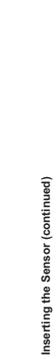
- h. Place the fingers of one hand at the edge of the white adhesive (at the bottom) and the other hand at the top of the transmitter lath. You may pinch up on your skin along this hand.
- i. While still pinching, use your other hand to place two fingers above the transmitter lath and pull down on the white purger and pull down completely. You should hear 2 clicks.
- j. Move your 2 fingers from above the collar to below the collar. Keep your thumb lightly on top of the white transmitter lath. You may pinch up on your skin along this hand. You may hear 2 clicks or cannot pull back any more. You might feel pressure as you pull back the collar. You may hear 2 clicks, as shown in the picture.
- k. Make sure the transmitter lath is down against your skin. Gently separate the collar from the transmitter lath. Push the collar forward and out away from your body.



Initial transmitter in sensor pod



Transmitter lath



Side view of transmitter in sensor pod

Setting Your Alert Profile (continued)

- *Alerting can be used when you want your alert to be noticeable. Alerts at all the alerts and alarms to read and with distinctive melodies.
- *Hypoglycemia can be used when you want extra alerts for severe low sensor glucose readings. This profile is like the normal profile, but it will keep repeating the fixed low alarm every 5 seconds until you hear 2 or 4 and your sensor glucose reading rises above 65 mg/dL.
- a. Press the **TV** feature under the Profiles option in the Main Menu to hear an example of each alert profile.
 - b. Follow these steps to set your alert profile:
 - a. From any trend graph, press the **SELECT** button to get to the Profiles menu.
 - b. Press the **DOWN** button to highlight "Profiles". Press the **SELECT** button.
 - c. Press the **UP** or **DOWN** button to highlight the alert profile you want to use.
 - d. Press the **SELECT** button. **A** will appear to the right of the profile you select.
- NOTE:** No matter what profile you set, all alerts and alarms will notify you by vibrating first. There will be no beep if you confirm the alert or alarm after the first vibration.



Profile menu



Profile menu

Setting Up Your Device (continued)

- Setup Wizard:**
Press the **SELECT** button to turn the receiver on. The Setup Wizard will walk you through the steps to set your Time/Date, Transmitter ID and Low/High Alerts.
- The Setup Wizard will only start when you set up your Dexcom G4 PLATINUM (Pediatric) Receiver for the first time.
- Setting the Time/Date:**
- a. Press the **UP** or **DOWN** button to enter each number or value.
 - b. Press the **RIGHT** or **SELECT** button to move to the next screen.
 - c. After setting the AM/PM, press the **SELECT** button to accept changes.
- Setting Your Transmitter ID:**
Your transmitter ID makes it possible for your transmitter and receiver to communicate with each other.
- a. Find the transmitter ID on the back of your transmitter.
 - b. Press the **UP** or **DOWN** button to enter the letter or number in each space.
 - c. Press the **RIGHT** or **SELECT** button to move to the next space.
 - d. After entering the last space, press the **SELECT** button to accept changes.
- NOTE:** You can only enter your transmitter ID when you are not in an active sensor session.



Setup Wizard



Setup Wizard

Getting to Know the CGM Device (continued)

- Dexcom G4 PLATINUM Transmitter (DO NOT THROW AWAY!)**
- The transmitter is the grey "chip" that snaps into your sensor pod. The transmitter battery will last at least 6 months. The Transmitter Low Battery screen will first show when the transmitter is low on battery. You will see the transmitter low battery screen as soon as possible after you see the Transmitter Low Battery screen.
- Dexcom G4 PLATINUM Sensor Applicator (Disposable)**
- The applicator is the grey "chip" that snaps into your sensor pod. The applicator battery will last at least 6 months. The Transmitter Low Battery screen will first show when the transmitter is low on battery. You will see the transmitter low battery screen as soon as possible after you see the Transmitter Low Battery screen.



Transmitter



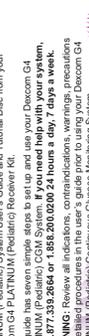
Sensor

Getting to Know the CGM Device (continued)

- Dexcom G4 PLATINUM Receiver (DO NOT THROW AWAY!)**
- The receiver is the grey "chip" that snaps into your sensor pod. The receiver battery will last at least 6 months. The Transmitter Low Battery screen will first show when the transmitter is low on battery. You will see the transmitter low battery screen as soon as possible after you see the Transmitter Low Battery screen.
- Dexcom G4 PLATINUM Sensor Applicator (Disposable)**
- The applicator is the grey "chip" that snaps into your sensor pod. The applicator battery will last at least 6 months. The Transmitter Low Battery screen will first show when the transmitter is low on battery. You will see the transmitter low battery screen as soon as possible after you see the Transmitter Low Battery screen.



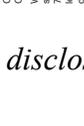
Receiver



Sensor

Getting to Know the CGM Device (continued)

- Dexcom G4 PLATINUM Receiver (continued)**
- The receiver is the grey "chip" that snaps into your sensor pod. The receiver battery will last at least 6 months. The Transmitter Low Battery screen will first show when the transmitter is low on battery. You will see the transmitter low battery screen as soon as possible after you see the Transmitter Low Battery screen.



Receiver



Sensor

Inserting the Sensor (continued)

- d. Hold the transmitter lath against your hand. Remove the transmitter lath with the other hand quickly twisting off the lath away from your body.
- Step 5**
Starting Your Sensor Session
- Once you have inserted the sensor and attached the transmitter, you need to start the sensor session on your receiver.
- a. From any trend graph, press the **SELECT** button to go to the Main Menu.
 - b. Press the **DOWN** button to highlight "Start Sensor".
 - c. Press the **SELECT** button. The Start Sensor "thinking" screen will appear. You will know your sensor 2-hour starting period has begun.



Start Sensor



Start Sensor

Inserting the Sensor (continued)

- a. Choose the site for the sensor. Avoid areas that are likely to be bumped or pushed or areas of your skin that are likely to be rubbed or irritated (such as the armpits, the upper buttocks (back of body, option B), or the lower buttocks (back of body, option A)).
- b. Clean your skin at the sensor placement site with an alcohol wipe. Let dry.
- c. If you use an optional skin preparation or adhesive product, place it on the skin in a "roughnut" shape where you will place the sensor adhesive. The adhesive product should be applied to the skin (skin may feel slightly tacky).
- d. Remove the sensor from its packaging.
- e. Peel the adhesive backing from the sensor pod one half at a time.
- f. Place the sensor horizontally, NOT vertically, on your skin. The adhesive backing and the adhesive patch will be on the back of the sensor. Press the sensor to secure the tape to your skin.
- g. Hold the applicator, and pull the transmitter lath out of the applicator in the direction of the arrows in the picture. Save the safety lock to use with the transmitter later at the end of your sensor session.



Step 6



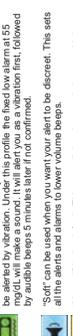
Step 7

Setting Up Your Device (continued)

- Setting Your Low/High Glucose Alert Levels:**
The low and high alert level defaults are 80 mg/dL and 200 mg/dL, but can be changed. Press the **UP** or **DOWN** button to change your low alert level between 60-100 mg/dL.
- a. Press the **UP** or **DOWN** button to change your low alert level between 60-100 mg/dL.
 - b. Press the **SELECT** button to accept your level.
- NOTE:** There is also a non-adjustable 55 mg/dL low alarm. Your receiver will show the 5-hour trend graph (home screen) after you finish the Setup Wizard.



Alert Level



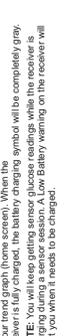
Alert Level

Setting Up Your Device (continued)

- Setting Your Alert Profile**
You can choose receiver "alert profiles" with different sounds and volumes to fit your needs.
- Your alert profile options are:
- Normal: The default. This sets all the alerts and alarms to higher volume beeps.
 - Soft: Can be used when you want your alert to be discreet. This sets all the alerts and alarms to lower volume beeps.
 - Volume Beeps: This sets all the alerts and alarms to higher volume beeps.



Alert Profile



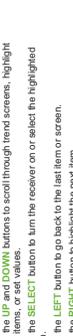
Alert Profile

Setting Up Your Device (continued)

- Charging Your Receiver:**
Charging the receiver will allow you to use the receiver for up to 10 hours before you begin. A full charge can take up to 5 hours and will last about 3 days. Open the USB port cover to charge your receiver. The USB port cover closes when receiver is not being charged.
- There are two ways you can charge your receiver:
- a. Plug the USB cable into the AC power adapter. Then plug the adapter into an AC power outlet (such as a wall outlet).
 - b. Plug the USB cable into your computer, and plug the other end of the cable into your receiver.
- NOTE:** The receiver will not charge if the USB cable is plugged into the wrong port. The receiver will not charge if the USB cable is plugged into the wrong port. The receiver will not charge if the USB cable is plugged into the wrong port.



Receiver



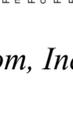
Receiver

Setting Up Your Device (continued)

- Charging Your Receiver:**
Charging the receiver will allow you to use the receiver for up to 10 hours before you begin. A full charge can take up to 5 hours and will last about 3 days. Open the USB port cover to charge your receiver. The USB port cover closes when receiver is not being charged.
- There are two ways you can charge your receiver:
- a. Plug the USB cable into the AC power adapter. Then plug the adapter into an AC power outlet (such as a wall outlet).
 - b. Plug the USB cable into your computer, and plug the other end of the cable into your receiver.
- NOTE:** The receiver will not charge if the USB cable is plugged into the wrong port. The receiver will not charge if the USB cable is plugged into the wrong port. The receiver will not charge if the USB cable is plugged into the wrong port.



Receiver



Receiver

7 Simple Steps to Start



Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring (CGM) System Training Checklist

WARNING: Review all Indications, Contraindications, Warnings, Precautions, and detailed procedures in the User's Guide before using the Dexcom G4 PLATINUM (Pediatric) CGM System.

Use this checklist as a guide, along with your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide (QSG) and Tutorial to get started with using your Dexcom G4 PLATINUM (Pediatric) System.

Patient Name: _____ Patient E-mail: _____
 Trained by: Self-Training/Tutorial Diabetes Center/Doctor's Office Dexcom Staff _____
 Date: _____ Physician Name: _____

<p>■ Step 1</p>	<p>Getting To Know Your Device</p> <p>Receiver Transmitter Sensor/Sensor Applicator</p> <ul style="list-style-type: none"> • Charge receiver • Do the appropriate quality checks for the blood glucose meter per the manufacturer's instructions 	 Dexcom G4 PLATINUM (Pediatric) Receiver  Dexcom G4 PLATINUM Sensor and Applicator  Dexcom G4 PLATINUM Transmitter
<p>■ Step 2</p>	<p>Setting Up Your Device</p> <ul style="list-style-type: none"> • Remove transmitter from tray and wait 10 minutes for it to be activated • Complete Setup Wizard: <ul style="list-style-type: none"> > Set time/date, transmitter ID and low/high glucose alerts High alert: _____ Low alert: _____ 	 Settings menu, Time/Date highlighted
<p>■ Step 3</p>	<p>Setting Your Alert Profile</p> <ul style="list-style-type: none"> • Vibrate • Soft • Normal (default setting) • Attentive • HypoRepeat 	 Profiles menu, Vibrate highlighted
<p>■ Step 4</p>	<p>Inserting Your Sensor</p> <ul style="list-style-type: none"> • Locate appropriate placement site • Clean insertion site and back of transmitter • Follow steps to: <ol style="list-style-type: none"> 1. Insert sensor 2. Remove sensor applicator 3. Attach transmitter 4. Remove transmitter latch 	 Sensor site insertion
<p>■ Step 5</p>	<p>Starting Your Sensor Session</p> <ul style="list-style-type: none"> • Follow steps to start sensor session. No sensor glucose readings during 2-hour startup period • Approximately 10 minutes after sensor session has started, check Y is in upper left corner of trend graph 	 Main Menu, Start Sensor highlighted
<p>■ Step 6</p>	<p>Calibrating</p> <ul style="list-style-type: none"> • Follow steps for startup calibration and update calibration • Review user's guide for more information 	 Startup calibration prompt
<p>■ Step 7</p>	<p>Ending Your Sensor Session</p> <ul style="list-style-type: none"> • Your sensor session will stop 7 days after you started the sensor session • Remove sensor and transmitter together from body • Remove transmitter from sensor pod. Keep transmitter • Dispose of sensor according to your local community guidelines 	 Replace Sensor Now screen

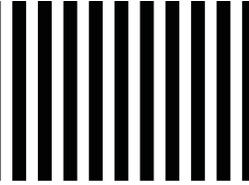
CONTRAINDICATIONS

- 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.

WARNINGS

- 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.
- ~~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.~~

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DEXCOM, INC.
6340 SEQUENCE DR.
SAN DIEGO, CA 92121-9942



RETURN THIS CHECKLIST TO DEXCOM

Please sign, complete, and return this checklist to Dexcom via fax (1.866.348.6030), e-mail (fieldclinicaltraining@dexcom.com), or US mail by using the Business Reply Card. If sending by mail, please fold this document so the Business Reply Card is face up and the back of the postcard is blank. Seal the edges of the postcard with tape.

Individuals who return a signed copy of this form within 14 days of training will be eligible to participate in a monthly drawing for a free box of sensors!

Individuals are limited to a one-time prize redemption for a box of sensors. Health care professionals who purchase the Dexcom G4 PLATINUM (Pediatric) System are not eligible to participate. Winners will be notified by e-mail.

TECHNICAL SUPPORT

Dexcom Technical Support is available 24 hours/7 days a week/365 days a year at **1.877.339.2664** or **1.858.200.0200**.



Dexcom, Inc. | 6340 Sequence Drive | San Diego, CA 92121
Technical Support: 1.877.339.2664/1.858.200.0200 | www.dexcom.com

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LBL012949 Rev X01

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~~MT22023~~ ~~MT23000~~ Dexcom G4 PLATINUM (Pediatric) “Seven Simple Steps to Start” Device Training Tutorial

REVISION: ~~October 31~~ November 24, 2014

Section	Voice-over	Visuals
1 Introduction (Title screen)	[None]	<p>[Text - upper right-hand corner of screen]</p> <p>LBL012911 Rev X01, MT23000 Rev X01; Dexcom G4 PLATINUM (Pediatric) CGM System Tutorial Content Version X01</p> <p>Dexcom G4 Platinum (Pediatric) logo</p> <p>Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System</p> <p>7- Simple Steps Tutorial logo</p>  <p>“Start Your Training” button</p> <p>If you’ve already reviewed the introduction, click here to skip. [This text is on bottom of all screens in Introduction]</p> <p>Tool to check your screen size to be sure the viewer is using the tutorial at “full screen” Check your screen size. You should be able to see all 4 corner arrows fully, otherwise please maximize this window before continuing.</p> <p>[Text - lower-left corner of screen]</p> <p>© 20154 Dexcom, Inc. All rights reserved.</p> <p>Dexcom, Dexcom G4, Dexcom G4 PLATINUM, Dexcom STUDIO, SEVEN, Stay Between the Lines and The Glucose Sensor Company are either registered trademarks or trademarks of Dexcom, Inc. in the United States and/or other countries. All other product or company names that may be mentioned in this publication are tradenames, trademarks or registered trademarks of their respective owners.</p>
1a	[None]	<p>INDICATIONS FOR USE</p> <p>The Dexcom G4 PLATINUM (Pediatric) Continuous</p>



		<p>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.</p> <p>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.</p> <p>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.</p> <p>IMPORTANT USER INFORMATION</p> <p>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.</p> <p>CONTRAINDICATIONS</p> <ul style="list-style-type: none">• 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. <p>WARNINGS</p> <ul style="list-style-type: none">• 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
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		<p>system accuracy. This could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.</p> <ul style="list-style-type: none">• 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.• 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 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
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		<p>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.</p> <ul style="list-style-type: none">• 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. <p>PRECAUTIONS</p> <ul style="list-style-type: none">• 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
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		<p>so the sensor adhesive will stick better.</p> <ul style="list-style-type: none">• Avoid using the same spot repeatedly for sensor 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
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		<p>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.</p> <ul style="list-style-type: none"> • 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 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. <p>CAUTION</p> <p>U.S. (Federal) law restricts the sale of the Dexcom G4 PLATINUM (Pediatric) System to sale by or on order of a physician.</p>
<p>1b</p>	<p>Please read your Dexcom G4 PLATINUM (Pediatric) User's Guide in addition to reviewing this tutorial. The User Guide has the most complete and detailed information on how to use your CGM System as well as sensor</p>	<p>Please read your Dexcom G4® PLATINUM (Pediatric) User's Guide in addition to reviewing this tutorial. The User's Guide has the most complete and detailed information on how to use your CGM System.</p> <p>○ 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.</p>



accuracy and performance data.

The Dexcom G4 PLATINUM (Pediatric) System will be referenced as the Dexcom G4 PLATINUM System throughout this tutorial.

The performance of the Dexcom G4 PLATINUM was assessed in two independent clinical studies. Table 1 summarizes the overall accuracy of the CGM system in the pediatric and adult population. Table 2 summarizes the alert performance in various hypoglycemic ranges in these two separate populations.

Table 3 shows the overall accuracy of the Dexcom G4 PLATINUM (Pediatric) CGM system when compared to reference blood glucose values from a blood glucose meter. This data more accurately represents the performance you can expect from the Dexcom G4 PLATINUM (Pediatric) system in daily life.

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.
- Review the Dexcom G4 PLATINUM (Pediatric) CGM System accuracy and performance data in the User's Guide to better understand the performance expectation of this CGM system and the potential differences in performance between adults and pediatrics.

The Dexcom G4 PLATINUM (Pediatric) System and components ~~may~~ will be referenced as the Dexcom G4 PLATINUM System and components throughout this tutorial.

Table 1: Overall Accuracy

Studies	CGM to YSI		
	Number of Matched Pairs	MARD (%)	% 20/20
Pediatric Study (2 to 17 years old)	2922	17%	68%
Adult Study (18 or more years old)	9152	13%	82%

Table 2: Hypoglycemic Alert Rate

Hypoglycemic Alert Levels mg/dL (mmol/L)	Pediatric Study (2 to 17 years old)		Adult Study (18 or more years old)	
	True Alert Rate	Hypoglycemic Detection Rate	True Alert Rate	Hypoglycemic Detection Rate
55 (3.1)	0%	0%	50%	71%
60 (3.3)	11%	25%	64%	75%
70 (3.9)	47%	50%	76%	83%
80 (4.4)	55%	55%	87%	88%
90 (5.0)	89%	62%	90%	89%
100 (5.6)	75%	62%	93%	90%

Reference values from YSI (Yellow Springs Instrument).

When compared to the adult population, the Dexcom G4 PLATINUM CGM System had larger differences between the sensor glucose readings and actual blood glucose in the pediatric population. In addition, fewer low glucose events were detected by the CGM system in the pediatric population than in the adult population.

Table 3: Overall Accuracy

Studies	CGM to SMBG		
	Number of Matched Pairs	MARD (%)	% 20/20
Pediatric Study (2 to 17 years old)	16318	15%	76%
Adult Study (18 or more years old)	7508	14%	81%

Correlation between SMBG values and the Dexcom G4 PLATINUM (Pediatric) CGM System was similar in the adult and pediatric population.

"I understand the performance expectations of the



		<p>Dexcom G4 PLATINUM (Pediatric) CGM system and the importance to read and thoroughly review the Dexcom G4 PLATINUM (Pediatric) User's Guide for the most complete review of the device and the accuracy and performance expectations of this CGM system."</p> <p>1 button on screen: "I AGREE" button</p>
<p>2</p>	<p>Hello, I'm Lynn Jones, a Nurse Practitioner and Certified Diabetes Educator. I use the Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System regularly in my practice, and today, I'm going to walk you through the simple, basic steps you'll need to get your new System up and running.</p>	<p>[Dexcom G4 PLATINUM (Pediatric) logo]</p> <p>[7 Simple Steps Tutorial logo]</p>  
<p>3</p>	<p>First off, I want to congratulate you on making the Dexcom G4 PLATINUM (Pediatric) System part of your life! Your decision to use continuous glucose monitoring, or CGM, as a tool for your daily diabetes self-management is an important one, and will prove to be one of the best decisions you've made! Welcome to the world of CGM with the Dexcom G4 PLATINUM (Pediatric) System!</p>	<p>[Various graphic's showing children with their CGM device.]</p> 



<p>4</p>	<p>The Dexcom G4 PLATINUM System will provide you with glucose readings every five minutes for up to seven days. But it does so much more than that. It can show you your glucose level trends and patterns, helping you to see your glucose levels in a whole new way!</p>	<p>The Dexcom G4® PLATINUM (Pediatric) System Components</p>



		<p>SENSOR / SENSOR APPLICATOR RECEIVER TRANSMITTER</p>
<p>5</p>	<p>With CGM, you'll be getting a more complete picture than you were with your blood glucose meter alone. You'll be seeing the direction and speed of your glucose changes. This additional information will be a powerful tool in helping you make more informed decisions about food, insulin and overall diabetes management.</p>	
<p>6</p>	<p>One important thing to note: Your blood glucose meter and Dexcom G4 PLATINUM System Sensor measure glucose from two different types of body fluids: blood, and interstitial fluid. Therefore, readings from your blood glucose meter and Sensor may not match. This is normal. I recommend to my patients that they focus on the trend information from their Dexcom G4 PLATINUM System, not the glucose value.</p>	<p>BLOOD GLUCOSE METER DEXCOM G4 PLATINUM (Pediatric) RECEIVER</p>



7	<p>It's important to remember that your Dexcom G4 PLATINUM CGM System is a supplement to—NOT a replacement for—your traditional blood glucose meter. All of your diabetes treatment decisions, like how much insulin to take, if you need to treat a low glucose value with fast-acting carbohydrate, etc., need to be based on blood glucose values from your blood glucose meter. It's important to make sure to take a fingerstick blood glucose measurement before you make any treatment decisions.</p>	<p>Your Dexcom G4 PLATINUM (Pediatric) System Is a Supplement to—NOT a Replacement for—Your Traditional Blood Glucose Meter.</p> <p>All of your diabetes treatment decisions, like how much insulin to take, if you need to treat a low glucose value with fast-acting carbohydrate, etc., need to be based on blood glucose values from your blood glucose meter.</p> <p>It's important to make sure to take a fingerstick blood glucose measurement before you make any treatment decisions.</p>
7a	[No audio-Pop-up box]	<p>"I understand that all insulin treatment decisions need to be based on the blood glucose values from my blood glucose meter, NOT solely on my Dexcom G4 PLATINUM (Pediatric) Sensor glucose readings."</p> <p>2 buttons on screen: "Review Information Again" button and "I AGREE" button</p>
8	<p>Let's go over some important information and contraindications that you should know about the Dexcom G4 PLATINUM System:</p> <ul style="list-style-type: none"> Remove the Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver before Magnetic Resonance Imaging or (MRI), 	<p>Contraindications</p> <ul style="list-style-type: none"> 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



	<p>Computed Tomography or (CT) scan, or diathermy treatment.</p> <ul style="list-style-type: none"> • The Dexcom G4 PLATINUM 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 may 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. <p>Some common over the counter medications that contain acetaminophen are Tylenol, Tylenol cold and flu, Excedrin, etc.</p> <p>Consult your healthcare provider if you are concerned that a medication you are taking may contain acetaminophen.</p>	<p>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.</p> <ul style="list-style-type: none"> • 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.  <p>Common Over-the-Counter Medications That Contain Acetaminophen</p>
8a	[No audio-Pop-up box]	<p>"I understand the contraindications for the Dexcom G4 PLATINUM (Pediatric) CGM System."</p> <p>2 buttons on screen: "Review Information Again" button and "I AGREE" button</p>
9	<p>Today, we're going to cover seven simple and easy steps designed to help you set up and begin using your Dexcom G4 PLATINUM System. These steps usually take about 40 minutes to complete.</p>	<p>[Dexcom G4 PLATINUM (Pediatric) logo and 7 Simple Steps Tutorial logo]</p> <p>Step 1: Getting To Know Your CGM Device</p> <p>Step 2: Setting Up Your Device</p> <p>Step 3: Setting Your Alert Profile</p> <p>Step 4: Inserting Your Sensor</p> <p>Step 5: Starting Your Sensor Session</p> <p>Step 6: Calibrating</p> <p>Step 7: Ending Your Sensor Session</p>
10	<p>Remember, as you get started with your System, or at any time in the future, you</p>	<p>Dexcom Technical Support 1-877-339-2664</p>

	<p>can call Dexcom’s Technical Support for assistance. The number is 1-877-339-2664, and there are people available to help you 24 hours a day, 7 days a week, 365 days a year.</p>	<p><u>24 hours a day, 7 days a week</u> (00+ 1-858-200-0200 for US users while traveling internationally)</p>
<p>11</p>	<p>Also, before you begin to use your Dexcom G4 PLATINUM (Pediatric) System, or any time you have questions, you can review the Quick Start Guide, User’s Guide, and/or Training Checklist in your Dexcom G4 PLATINUM (Pediatric) Starter Kit.</p> <p>This training follows the same steps as are presented in the Quick Start Guide, so you may want to have the Quick Start Guide out for your reference.</p>	<p>Questions?</p> <p>Your training documents may not look identical to the examples shown here.</p>  <p>USER'S GUIDE TRAINING CHECKLIST QUICK START GUIDE</p>
<p>12</p>	<p>Finally, it’s important that Dexcom document that you’ve completed this self-guided training and receive the information you need to use your Dexcom G4 PLATINUM (Pediatric) System. Please take the time to complete your Dexcom G4 PLATINUM (Pediatric) Training Checklist, seal it, and mail it back. The Checklist already has pre-paid postage on the back for your convenience.</p>	<p>Your training documents may not look identical to the examples shown here.</p> <p>TRAINING CHECKLIST</p> 



12a	Now, let's dive into Step 1: Getting to Know Your Device.	
13	[None]	<p>[Dexcom G4 PLATINUM (Pediatric) logo and 7 Simple Steps Tutorial logo]</p> <p>How to Navigate Through the Dexcom G4 PLATINUM (Pediatric) System Tutorial</p>
13a	<p>Before we officially get started, let's take a minute to talk about how to use this online tutorial.</p> <p>This tutorial is designed to guide you through each of the basic steps <i>while</i> you are setting up the Dexcom G4 PLATINUM System. It is interactive, meaning you can start and stop it, and you can move forward and back within the steps.</p> <p>Pause the tutorial whenever you need to, in order to complete each task as it is discussed. And, complete all of the tasks in each step before moving onto the next step. If you don't feel comfortable with any part of a step, just review that part before moving on.</p>	<p>This tutorial is designed to guide you while you are setting up the Dexcom G4 PLATINUM (Pediatric) System.</p> <ul style="list-style-type: none"> • The program is interactive • Pause to complete each task • Complete each task before moving on to the next step <p>Use your mouse to explore the orange highlighted areas on this screen and learn how to interact with the program</p> <p>“Continue With Program” button</p>
13b	<p>Take a minute to become more familiar with the controls at the bottom of the screen.</p> <p>You can also access any step you have previously reviewed, or any future step</p>	<p>[Text for buttons revealed with roll-over actions from the user:]</p> <ul style="list-style-type: none"> - BOTTOM-FAR LEFT: The Rewind button allows you to step backward to previous points in the program content. - BOTTOM-MIDDLE: The Play button allows



	<p>in the Dexcom G4 PLATINUM tutorial by clicking on the step you want on the menu at the top of the screen.</p>	<p>you to pause and play the program content. It acts just like the pause and play on a VCR or DVD player.</p> <ul style="list-style-type: none">- BOTTOM-RIGHT: The Fast-Forward button allows you to step forward to future points in the program content.- TOP MAIN NAV BAR: This is the Main Program Navigation. Use these buttons to jump to any Step in the program.- TOP COMPLETION BAR: This progress bar will fill-in as you complete the program.- TOP INTRODUCTION BUTTON: Click the Introduction button to review the video Introduction again.- TOP Important User Information button: Click the Important User Information button to quickly access User Information about this Dexcom System.
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Section	Voice-over	Visuals
14 Step 1: Getting to Know CGM Your Device	[No VO]	<p>[7 Simple Steps Tutorial logo and Dexcom G4 PLATINUM (Pediatric) logo]</p> <p>Step 1: Getting to Know Your CGM Device</p>
15a	<p>After completing this step, you will have:</p> <ul style="list-style-type: none"> • Learned more about your receiver, transmitter, sensor, and sensor applicator • Charged your receiver (or at least started to charge it) • Prepared your transmitter for use • Checked that your sensor is not expired • Learned why it's important to perform appropriate quality checks on your blood glucose meter 	<p>After completing this step, you will have:</p> <ul style="list-style-type: none"> • Learned more about your Receiver, Transmitter, and Sensor/Applicator • Charged your Receiver • Prepared your Transmitter for use • Checked that your Sensor is not expired • Learned why it's important to perform appropriate quality checks on your blood glucose meter <p>Step 1 in this tutorial is designed to help you become more familiar with your Dexcom G4 PLATINUM (Pediatric) System. DO NOT press any buttons until we start Step 2.</p>
16	<p>Your Dexcom G4 PLATINUM System is made up of three components that all work together: the receiver, the transmitter, and the sensor. Do not take the transmitter out of the tray until you are ready to start using your Dexcom CGM system.</p> <p>If you've been a past Dexcom CGM user, note the receiver, transmitters and sensors from your previous Dexcom System are not compatible or interchangeable with the Dexcom G4 PLATINUM System.</p>	 <p>RECEIVER TRANSMITTER SENSOR APPLICATOR SENSOR</p> <p>Do not take the transmitter out of the tray until you are ready to start using your Dexcom CGM System</p>



	<p>Before using your system, there are a few things you need to do:</p>	
<p>17</p>	<p>First, make sure to charge your receiver completely, as it is recommended that it be fully charged before you begin. You can charge your receiver one of two ways: by using a wall charger, or by using a USB cable connected to your computer. A full charge can take up to 3 hours with the wall charger, or 5 hours when using your computer.</p>	<div data-bbox="889 457 1312 745" data-label="Image"> </div> <p>1. Charge your Receiver completely.</p> <p>Wall Charger 3 hours</p> <p>USB Cable 5 hours</p> <div data-bbox="883 1131 1318 1446" data-label="Image"> </div> <p>(You must install Dexcom STUDIO software before charging from your computer.)</p>
<p>18</p>	<p>The battery symbol will begin to fill in as the receiver charges. When the receiver is fully charged, you'll see the battery symbol fully shaded green.</p>	<div data-bbox="906 1598 1295 1822" data-label="Image"> </div> <p>When your battery is charged, your battery</p>



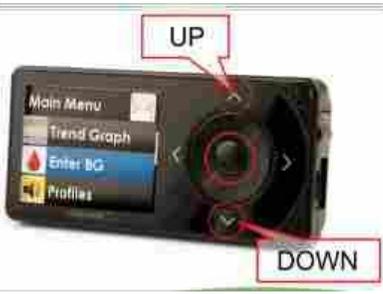
		charging icon will be fully shaded green.
19	[No VO]	The program is paused so you can charge your receiver. When finished, click the Play button to the left.
20	Second: Take the transmitter out of tray and clean the bottom of your transmitter with a damp cloth or alcohol wipe, and dry. You should do this each time you start a new sensor session.	<p>This is an example of the Dexcom G4 PLATINUM Transmitter. The information on the back of your Transmitter may not look identical to what is shown here.</p>  <p>2. Clean the bottom of your Transmitter.</p>
21	[No VO]	The program is paused so you can clean your Transmitter. When finished, click the Play button to the left.
22	Third: check the expiration date on the sensor packaging to make sure you are not using an expired sensor. The expiration date is shown in a year – month – day format. Your sensor must be inserted on or before the end of the day printed on the sensor packaging.	<p>This Sensor package label is an example and may not be identical to the label on your Sensor package.</p> 

		 <p>3. Check the Sensor packaging to make sure you are not using an expired Sensor.</p>
23	[No VO]	<p>The program is paused so you can check your Sensor expiration date. When finished, click the Play button to the left.</p>
24	<p>And finally, you'll want to do the appropriate quality checks for your blood glucose meter per the manufacturer's instructions. This is an important step. Making sure a patient's blood glucose meter is accurately reading their levels is KEY to making sure my patients have the best—and most accurate—experience with CGM.</p> <p>As you'll learn, your Dexcom G4 PLATINUM System is calibrated by your fingerstick blood glucose readings. Making sure those fingerstick readings are accurate is important to having your Dexcom G4 PLATINUM System work its best.</p> <p>So, take the time to make sure your blood glucose meter is coded, and that test strips have been stored properly and are not outdated. You should check your test strips with control solution per</p>	 <p>It is important to make sure your blood glucose meter is accurate and to calibrate using blood glucose values from your fingertips only.</p>



	<p>the manufacturer's instructions.</p> <p>Note: Some meters may not need to be coded; see your meter's manufacturer's instructions for care.</p> <p>In addition to making sure your meter is accurate, you need to have the best fingerstick technique when you calibrate your Dexcom G4 PLATINUM Sensor. Most importantly, remember to wash your hands before taking a fingerstick blood glucose measurement.</p>	 <p>Perform quality checks recommended by the manufacturer.</p> 
25	[No VO – Pop-up box]	<p>The program is paused so you can quality check your blood glucose meter. When finished, click the Play button to the left.</p>
26	<p>So, we've prepared your Dexcom G4 PLATINUM System components for use. Let's move on to better understanding your device.</p>	
28	First, your receiver. Your receiver is a	Sensor glucose readings in mg/dL



	<p>small, handheld device that shows your sensor glucose readings in milligrams per deciliter, the direction and speed of your glucose levels, and your glucose trends and patterns.</p>	<p>Direction and speed of glucose levels Glucose trends and patterns</p> 
<p>29</p>	<p>To turn your receiver on, you can press the SELECT button, the LEFT button, or the RIGHT button. Note the UP and DOWN buttons do not turn your receiver on. Once your receiver is on, the display light is automatically turned on .</p>	<p>Reminder DO NOT press any buttons until we start Step 2.</p>  <p>SELECT</p>
<p>30</p>	<p>If you want to access the Main Menu, you'll press the SELECT button.</p> <p>To scroll through items, highlight items, and set values, you'll use the UP and DOWN buttons.</p>	 <p>SELECT</p> <hr/>  <p>UP DOWN</p>
<p>31</p>	<p>To select an option that's highlighted, you'll use the SELECT button.</p>	<p>SELECT</p>



	<p>To confirm changes in settings, you'll also use the SELECT button.</p>	
<p>32</p>	<p>To go back to a previous Menu option or screen, you'll use the LEFT button.</p>	<p>LEFT</p> 
<p>33</p>	<p>To move to the next screen, you'll use the RIGHT button.</p>	<p>RIGHT</p> 
<p>34</p>	<p>Now, let's talk a little about the transmitter.</p> <p>The transmitter wirelessly sends your glucose information to the receiver. The transmitter and sensor are water resistant when properly connected.</p>	<p>This is an example of the Dexcom G4 PLATINUM Transmitter. The information on the back of your Transmitter may not look identical to what is shown here.</p>  <p>The Transmitter is water resistant when securely snapped into the Sensor Pod.</p>  <p>Do NOT throw away the Transmitter!</p>

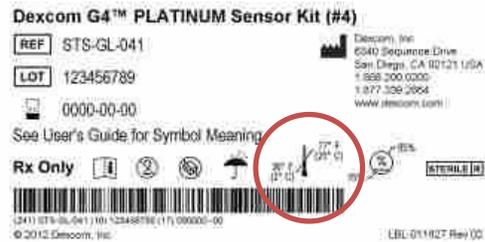


<p>35</p>	<p>Keep in mind that your transmitter is NOT DISPOSABLE! You will reuse the transmitter with each new sensor session.</p>	
<p>36</p>	<p>Another important point is that your transmitter needs to be within approximately 20 feet of your receiver for your transmitter and receiver to communicate. Even during the initial warm-up period that starts each new sensor session, you should keep your transmitter and receiver within this distance in order to get the best communication and minimize loss of CGM readings.</p>	<div style="text-align: center;">  <p>Transmitter must be within 20 feet of the Receiver.</p> </div> <p>Transmitter must be within 20 feet of the Receiver.</p> <div style="text-align: center;">  <p>Loss of CGM readings</p> </div>
<p>37</p>	<p>Some additional things to remember about your transmitter:</p> <ul style="list-style-type: none"> - The Dexcom G4 PLATINUM Continuous Glucose Monitoring System is safe for use on U.S. commercial airlines. This device can withstand exposure to common electrostatic or (ESD) and electromagnetic interference or (EMI). - The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well 	<ul style="list-style-type: none"> • “The Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System is safe for use on US commercial airlines. This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI) • 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

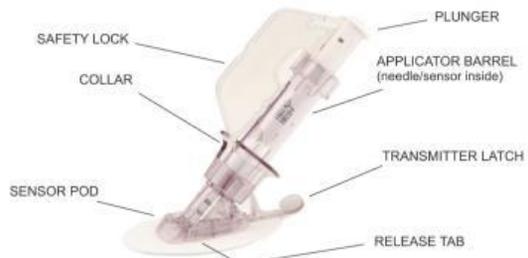


	<p>through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc.”</p> <p>And speaking of water, your sensor and the attached transmitter are water resistant when showering, bathing, or swimming. The sensor has been tested to be water-resistant when submerged up to 8 feet for a maximum of 24 hours.</p> <p>The receiver is NOT water resistant. Do not get your receiver wet at any time.</p>	 <p>Your Sensor and attached Transmitter are water resistant when showering, bathing, or swimming.</p>  <p>The Receiver is NOT water resistant. Do not get your Receiver wet at any time.</p>
<p>38</p>	<p>Your transmitter battery will last about 6 months, after which you will need to replace your transmitter. Your system will let you know when it's time for your transmitter to be replaced by showing you the “Low Battery” warning. This screen will first appear when there is about 1 week of battery life left.</p>	 <p>To order a replacement Transmitter, call Dexcom Customer Service at 877-339-2664 (00+1-858-200-0200 for US users while traveling internationally)</p>
<p>39</p>	<p>Finally, let's talk about the sensor and sensor applicator.</p> <p>The sensor is the part of your device that is placed under the skin on your belly and continuously measures your glucose levels.</p>	

Sensors should be stored at room temperature – between 36 to 77° F.



This Sensor package label is an example and may not be identical to the label on your Sensor package.



40

The parts of the sensor applicator are labeled in this picture.

We'll talk more about the sensor and sensor applicator when we go over how to insert the sensor in Step 4. For now, there are two things you should keep in mind:

- Sensor/Sensor Applicator ARE disposable
- Contact your local waste management authorities for proper disposal of your Sensors
 - If you have problems with your Sensor, keep your Sensor until after you speak with Dexcom Technical Support at 877-339-2664, 24 hours a day, 7 days a week (00+ 1-858-200-0200 for US users while traveling internationally)

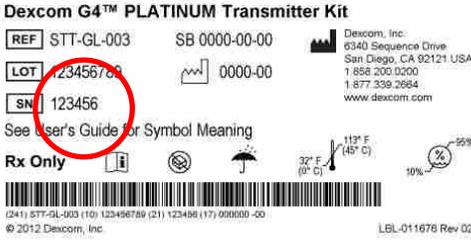


	<p>One: Unlike the transmitter, the sensor and sensor applicator ARE disposable.</p> <p>Two: If you have problems with your sensor session, you'll want to keep your sensor until you speak with Dexcom Technical Support .</p>	<p>- Sensor identification information can be found on the Sensor/Sensor Pod</p>
<p>41</p>	<p>Step 1 Tasks Completed:</p> <p>If you are not fully comfortable with any of these tasks, please review Step 1 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 1], your Dexcom G4 PLATINUM (Pediatric) User's Guide, or call your local Dexcom Technical Support Representative.</p> <p>Please review and check this list before moving on to the next step.</p> <p>If you need to review any of the tasks in Step 1 again, choose to “replay” the task on the list. You will then be taken to that specific task to review again.</p>	<p>If you are not fully comfortable with any of these tasks, please review Step 1 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 1], your Dexcom G4 PLATINUM (Pediatric) User's Guide and/or call Dexcom Technical Support at 1-877-339-2664, <u>24 hours a day, 7 days a week</u>.</p> <p>Step 1 Tasks Completed:</p> <ul style="list-style-type: none"> • I am now more familiar with my Receiver, my Transmitter, and my Sensor/Applicator • I have charged my Receiver • I know how to prepare my Transmitter for use • I have checked that my Sensor has not expired • I know the importance of making sure that my blood glucose meter is working properly, and I know how to perform the appropriate quality checks <p>To continue to the next step, check each box above (by clicking on the box) and then click “Continue With Program. ” To review any of these tasks before continuing, click the “Replay” button next to that task.</p> <p>“Continue With Program” button</p>



Section	Voice-over	Visuals
42 Step 2: Setting Up Your Device	It's time to focus on what you need to do to set up your Dexcom G4 PLATINUM (Pediatric) Receiver the first time you use your System.	[7 Simple Steps Tutorial logo and Dexcom G4 PLATINUM (Pediatric) logo] Step 2: Setting Up Your Device
43	<p>After completing this step, you will have:</p> <ul style="list-style-type: none"> • Activated your transmitter • Set the time and date on your receiver • Set your unique transmitter ID into your receiver to make sure your transmitter and receiver talk only to each other • Set your individualized high and low glucose alert levels on your receiver • Learned more about your 3-Hour trend graph screen, which is the home screen 	<p>After completing this step, you will have:</p> <ul style="list-style-type: none"> • Activated your Transmitter • Set the time and date on your Receiver • Set your unique Transmitter ID into your Receiver to make sure your Transmitter and Receiver talk only to each other • Set your individualized High and Low Glucose Alert levels on your Receiver • Learned more about your 3-Hour Trend Graph screen (Home screen) <p>Start interacting with your Dexcom G4 PLATINUM (Pediatric) System now.</p>
44	Before setting up your receiver, remove your transmitter from its tray and wait 10 minutes for it to be activated.	   <p style="text-align: center;">TRANSMITTER</p>
45	[No VO – Pop-up box]	The program is paused so you can activate

		your Transmitter. When finished, click the Play button to the left.
46	<p>The first thing you're going to need to do is turn your receiver on. You do this by pressing the SELECT button.</p> <p>When you turn your receiver on for the first time, the device's Setup Wizard will help you get started by prompting you to enter the following information:</p>	
47	<p>First: the time and date. To set the time and date, press the RIGHT button to highlight each value, and to move to the next value.</p>	<p>[Show visual of patient setting time and date.]</p>  <p>1. Set Time and Date.</p>
48	<p>Press the UP/DOWN buttons to adjust each value.</p>	
49	<p>After setting the AM/PM value, press the SELECT button to accept changes and move on to the next step in the Setup Wizard—setting your transmitter ID.</p>	
50	<p>[No VO – Pop-up box]</p>	<p>The program is paused so you can set the time and date on your Receiver. When finished, click the Play button to the left.</p>
51	<p>Your unique transmitter ID makes it possible for your transmitter to talk only to your receiver.</p>	

	<p>The ID can be found in the following locations:</p> <ul style="list-style-type: none"> • On the outside of the transmitter box label, and • Engraved on the back of the transmitter itself <p>If you have difficulty locating your transmitter ID, contact Dexcom Technical Support.</p>	<p>2. Set your unique Transmitter ID.</p>  <p>The label is located on the bottom of the box This Transmitter label is an example and may not be identical to the label on your Transmitter box.</p>  <p>This is an example of the Dexcom G4 PLATINUM Transmitter. The information on the back of your Transmitter may not look identical to what is shown here.</p> <p>2. Set your unique Transmitter ID.</p>
<p>52</p>	<p>Enter each transmitter ID letter or number into the receiver, one at a time. Start with the first letter or number. Press the UP or DOWN buttons to adjust each value.</p>	 <p>2. Set your unique Transmitter ID.</p>

53	Press the RIGHT or SELECT button to move to the next field.	 <p>2. Set your unique Transmitter ID.</p>
54	<p>After entering the last value, press the SELECT button.</p> <p>Note: You can only enter your transmitter ID BEFORE you activate your sensor. During a sensor session, “Transmitter ID” will not appear as an option on your device.</p>	 <p>Enter your Transmitter ID BEFORE you activate your Sensor.</p> <p>Enter your Transmitter ID BEFORE you activate your Sensor.</p>
55	[No VO – Pop-up box]	The program is paused so you can enter your Transmitter ID. When finished, click the Play button to the left.
56	<p>For the final step in your initial set-up, we will set your low and high glucose alert levels. These levels allow your receiver to alert you when your sensor readings trend above or below your individualized alert levels.</p> <p>These alerts are not meant to be your target levels, but the levels at which you want to be alerted so that you can take action before you get too low or too high.</p> <p>The alerts are defaulted to be turned on, and set at 80 milligrams per</p>	<p>Low and High Glucose Alerts</p>   <ul style="list-style-type: none"> • NOT target levels, but levels at which you want to be alerted so you can take action before you get too low or too high

	<p>deciliter for low, and 200 milligrams per deciliter for high. These can be individualized based on your needs, personal experience or suggestions from your healthcare provider.</p>	<ul style="list-style-type: none"> • Default settings: <ul style="list-style-type: none"> ○ Low: 80 mg/dL ○ High: 200 mg/dL
57	<p>To set your Low Glucose Alert level, press the UP and DOWN buttons to adjust your Low Alert value.</p>	
58	<p>Press SELECT to accept this value.</p>	
59	<p>Repeat these steps to set your High Alert value.</p>	
60	<p>As you use the Dexcom G4 PLATINUM System, you may need to change the High and Low Glucose Alerts you initially set up. You can change or individualize these alerts whenever you want to, or whenever or your healthcare provider suggests changing them, to best meet your needs.</p> <p>Again, alerts on your Dexcom G4 PLATINUM System can be set based</p>	 <p>Summary of Low and High Glucose Alerts</p> <ul style="list-style-type: none"> • Alerts can be set based on your individual needs • Alerts are confirmed by pressing the SELECT button



	<p>on your individual needs. Alerts are confirmed by pressing the SELECT button. We will discuss Alert Profiles in Step 3.</p>	<ul style="list-style-type: none"> Alert profiles will be discussed in Step 3
60	<p>You and your healthcare professional may decide to change the low-glucose alert setting from the default of 80 mg/dL. Check with your blood-glucose meter when or if you have signs and symptoms of low-glucose. Press the SELECT button to confirm you have read and understand this message.</p>	<p>"I understand not to rely solely on CGM alerts to detect low-glucose. I should take a fingerstick blood-glucose measurement with my blood-glucose meter whenever I have signs or symptoms of low-glucose. It is recommended to consult with my healthcare professional to determine the best low-glucose alert setting for me."</p> <p>2 buttons on screen: "Review Information Again" button and "I AGREE" button</p>
61	[No VO – Pop-up box]	<p>The program is paused so you can enter your personal High and Low Alert levels if you choose to. When finished, click the Play button to the left.</p>
62	<p>After initial setup, when you turn your receiver on, your Home screen, which is the 3-Hour Trend Graph screen, will appear.</p> <p>Your Dexcom G4 PLATINUM alert settings will be displayed on your Trend Graphs:</p> <ul style="list-style-type: none"> Your Low Alert setting is seen as a red line across the trend graph Your High Alert setting is seen as a yellow line across the trend graph <p>You will also see the following on your trend graphs:</p> <ul style="list-style-type: none"> A gray zone that highlights your target glucose range. The size of 	 <p>[Interactive animation on screen timed to v/o:]</p> <ul style="list-style-type: none"> - Low Alert - High Alert - Target Glucose Range - Current Glucose Reading when in an active 7-day Sensor session - WHITE - RED - YELLOW

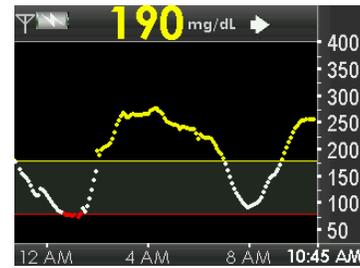
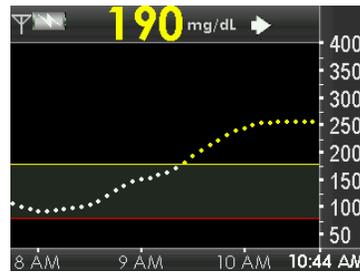
your gray zone will depend on your High and Low Glucose Alert settings.

- Your glucose reading as a numerical value, when you are in an active sensor session; in other words: once you have started your 7-day sensor session. This number will be white if it's in your target glucose range, red if it's low (based on your settings), and yellow if it's high. The dots on your trend graph will also change color based on your Low and High Alert settings.

Note: If your low glucose alert is not set and your glucose level is 55 milligrams per deciliter or lower, your glucose value will be red.



You can view your past glucose information through the 1, 3, 6, 12, and 24-hour Trend Graphs.



	<p>Access these Trend Graphs by pressing the UP or DOWN buttons.</p>	
<p>63</p>	<p>Step 2 Tasks Completed:</p> <p>If you are not fully comfortable with any of these tasks, please review Step 2 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 2], your Dexcom G4 PLATINUM (Pediatric) User's Guide, or call your local Dexcom Technical Support Representative.</p> <p>Please review and check this list before moving on to the next step.</p> <p>If you need to review any of the tasks in Step 2 again, choose to "replay" the task on the list. You will then be taken to that specific task to review again.</p>	<p>If you are not fully comfortable with any of these tasks, please review Step 2 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 2], your Dexcom G4 PLATINUM (Pediatric) User's Guide and/or call Dexcom Technical Support at 1-877-339-2664, 24 hours a day, 7 days a week.</p> <p>Step 2 Tasks Completed:</p> <ul style="list-style-type: none"> • I have activated my Transmitter • I have set the current time and date on my Receiver • I have entered my unique Transmitter ID into my receiver • My personal High and Low Glucose Alert levels are set on my receiver • I know more about my Trend Graph screens <p>To continue to the next step, check each box above (by clicking on the box) and then click "Continue With Program." To review any of these tasks before continuing, click the "Replay" button next to that task.</p> <p>"Continue With Program" button</p>

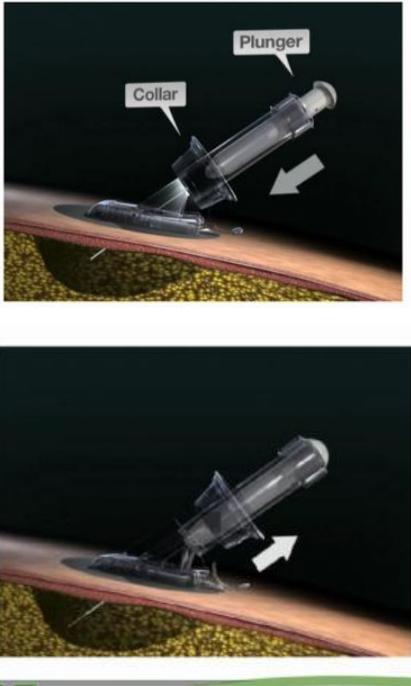
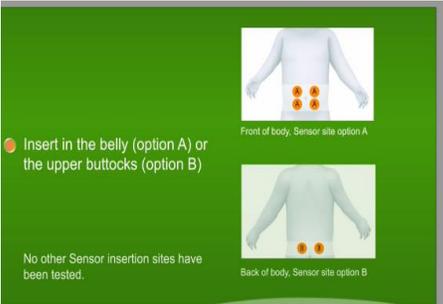
Section	Voice-over	Visuals
64 Step 3: Setting Your Alert Profile	Another task you will want to complete upfront is setting your Alert Profile.	[7 Simple Steps Tutorial logo and Dexcom G4 PLATINUM (Pediatric) logo] Step 3: Setting Your Alert Profile
65	After completing this step, you will have: <ul style="list-style-type: none"> Chosen an Alert Profile that is right for you 	After completing this step, you will have: <ul style="list-style-type: none"> Chosen an Alert Profile that is right for you
66	Your Dexcom G4 PLATINUM System allows you to choose the way you want your alerts and alarms to behave. This customizable feature is found under the “Profiles” option on the Main Menu, as shown on screen.	 <p>[Highlight “Profiles” on menu screen]</p>
67	<p>You can set your profile to the sound pattern and volume that best fit your needs. As you go about your daily activities, you can quickly and easily change the way your system alerts you by changing your Alert Profile.</p> <p>Your Alert Profile options are:</p> <ol style="list-style-type: none"> Vibrate. With this option, your Dexcom G4 PLATINUM System vibrates instead of making a sound Soft, which is a discreet, less noticeable alert Normal. This is the default Alert Profile option. Beeps are heard at medium volume Attentive, which is the most 	 <p>Alert Profile Options</p> <ol style="list-style-type: none"> Vibrate – silent Soft – discreet; less noticeable Normal – default profile; medium volume beeps Attentive – most noticeable; loud and distinctive melodies HypoRepeat – Normal profile with additional repetitive vibrate and beep

	noticeable option, with loud and distinctive melodies, and 5. HypoRepeat, which is the normal profile with additional repetitive vibrating and beeping sequences.	sequence
68	<p>Within each profile setting, each alert has its own unique sound pattern, tone and volume level; this allows you to easily identify each alert and alarm.</p> <p>When choosing your Alert Profile setting, keep in mind this setting will apply to ALL alerts, alarms and prompts.</p> <p>No matter what Alert Profile you choose, a vibration will be your first signal that you have an alert or alarm.</p>	<p style="text-align: center;">Alert Profile Tips</p> <ul style="list-style-type: none"> • Within each profile setting, each alert has its own unique sound pattern, tone, and volume level for easy identification of each alert and alarm • Your Alert Profile setting will apply to all alerts, alarms, and prompts • A vibration will be your first signal that you have an alert or alarm <p>For more information about Alert Profiles and how you will be notified about the various alerts and alarms, refer to your Dexcom G4 PLATINUM (Pediatric) User’s Guide.”</p>
69	<p>To help you decide which Alert Profile is best for you, you can use the “Try It” feature, which is an option under the “Profiles” menu. This allows you to hear an example of the sounds associated with each profile.</p>	 <p style="text-align: center;">Read the Dexcom G4 PLATINUM (Pediatric) User’s Guide for more details on the Alert Profiles for the Dexcom G4 PLATINUM (Pediatric) System.</p>
70	[No VO – Pop-up box]	The program is paused so you can choose your preferred Alert Profile. When finished, click the Play button to the left.
71	Step 3 Tasks Completed:	If you are not fully comfortable with this



	<p>If you are not fully comfortable with any of these tasks, please review Step 3 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 3], your Dexcom G4 PLATINUM (Pediatric) User's Guide, or call your local Dexcom Technical Support Representative.</p> <p>Please review and check this list before moving on to the next step.</p> <p>If you need to review any of the tasks in Step 3 again, choose to "replay" the task on the list. You will then be taken to that specific task to review again.</p>	<p>task, please review Step 3 again.</p> <p>You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 3], your Dexcom G4 PLATINUM (Pediatric) User's Guide and/or call Dexcom Technical Support at 1-877-339-2664, <u>24 hours a day, 7 days a week</u>.</p> <p>[bullet below has a replay button and a check box the user has to check. Box must be checked before the user can continue.]</p> <p>Step 3 Task Completed:</p> <ul style="list-style-type: none">• I have set my Alert Profile <p>To continue to the next step, check the box above (by clicking on the box) and then click "Continue With Program." To review again before continuing, click the "Replay" button.</p> <p>"Continue With Program" button</p>
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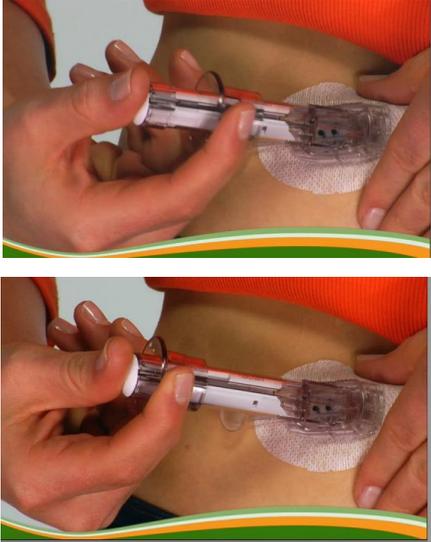
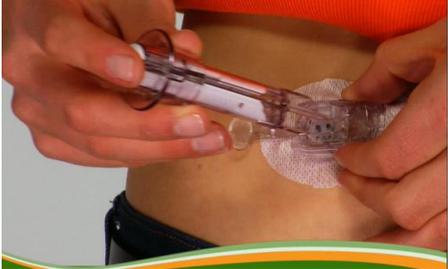
<p>72 Step 4: Inserting the sensor</p>	<p>Now that your initial set-up is done, it's time to learn how to insert a new sensor.</p>	<p>[Text] [7 Simple Steps tutorial logo and Dexcom G4 PLATINUM (Pediatric) logo] Step 4: Inserting the Sensor</p>
<p>73</p>	<p>After completing this step, you will have:</p> <ul style="list-style-type: none"> • Chosen a placement site for your sensor • Inserted your sensor • Attached your transmitter • Learned the options for skin preparation or adhesive products 	<p>After completing this step, you will have:</p> <ul style="list-style-type: none"> • Chosen a placement site for your Sensor • Inserted your Sensor • Attached your Transmitter • Learned options for skin preparation or adhesive products (optional)
<p>74</p>	<p>Before starting this process, you should have a sensor Applicator, your transmitter, alcohol wipes and skin preparation or adhesive products if needed, for example, (Skin Tac or Mastisol) ready to go.</p> <p>Your first sensor insertion may not feel natural, but once you have done it once or twice, it should become more familiar.</p> <p>The process of inserting the sensor is as follows: On the applicator barrel, the white plunger inserts the introducer needle and sensor under your skin. When the collar is pulled back completely, the introducer needle is removed and the tiny, flexible sensor remains under your skin.</p>	<p>[Visual of sensor and transmitter]</p> <ul style="list-style-type: none"> • Sensor Applicator • Transmitter • Alcohol Wipes • Skin preparation or adhesive products if needed 

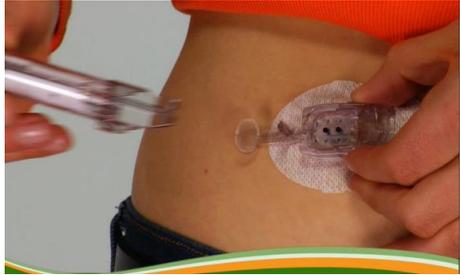
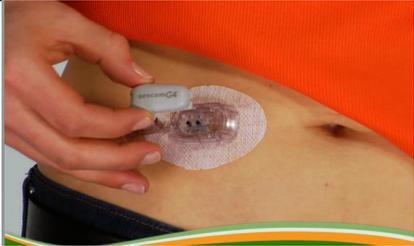
		
75a	<p>First, wash your hands with soap and water before opening the sensor package. After opening the package, avoid touching the adhesive area. Next, choose a site to place your sensor. Your site placement options are:</p> <ul style="list-style-type: none"> • Insert in the belly (option A) or the upper buttocks (option B). 	<ul style="list-style-type: none"> • Wash your hands with soap and water before opening the sensor package • After opening the package, avoid touching the adhesive area • Choose a site to place your sensor.  <p>Insert in the belly (option A) or the upper buttocks (option B)</p> <p>[Text under image of front of child:] Front of body, Sensor site option A</p>

	No other sensor insertion sites have been tested.	<p>[Text under image of back of child:] Back of body, Sensor site option B</p> <p>No other Sensor insertion sites have been tested.</p>
75b	<p>When you choose which site to place your sensor, here are a few things to keep in mind:</p> <p>The best areas to insert your sensor are usually flat and “pinchable”.</p> <p>The placement site should be out of the way of your waistband.</p> <p>Avoid areas that are likely to be bumped, pushed or pressed against or areas of your skin with scarring, tattoos, or irritation.</p> <p>Place the sensor at least 3 inches away from your insulin pump infusion set or injection site.</p> <p>Make sure there are no traces of lotions, perfumes or medications on the skin where you place the sensor.</p> <p>Change the site where you place your sensor with each new sensor.</p> <p>The ideal sensor insertion site for you may be based on your body type, activity, sensitivities, and other personal traits. For more help on choosing the ideal sensor insertion sites for you, contact your healthcare provider.</p>	<p>Choosing the Ideal Sensor Placement Site:</p> <ul style="list-style-type: none"> • Choose a flat and ‘pinchable’ area • Avoid areas around your waistband or areas you put pressure on while sleeping or sitting • Avoid areas on your skin with scarring, tattoos, or irritation • Place at least 3 inches away from your insulin pump infusion set or injection site. • Avoid using lotions, perfumes and ointments on the skin where you place the Sensor • Avoid using the same spot repeatedly for Sensor placement <p>The ideal Sensor insertion site for you may be based on your body type, activity, sensitivities, and other personal traits. For more help on choosing the ideal Sensor insertion sites for you, contact your healthcare provider.</p> <p>PRECAUTION: Avoid using the same spot repeatedly for sensor insertion. Rotate your sensor placement sites, and do not use the same site for two sensor sessions in a row. Using the same site may cause scarring or skin irritation.</p>
75c	[No audio]	The program is paused so you can collect

		<p>your materials, wash your hands and choose a site to place your sensor. When finished, click the Play button to the left.</p>
75d	<p>Once you have chosen your site to place your sensor, you'll then clean the placement site on your body with alcohol, and let it dry.</p> <p>To help the sensor stick to your body, you can also use skin preparation or adhesive products, for example (Skin Tac or Mastisol). These products are optional and should be used prior to inserting your sensor on your body. If you choose to use a skin preparation or adhesive product, place it on the skin in a "doughnut" shape where you will place the sensor adhesive patch. The center area of the doughnut should be free of skin preparation or adhesive products and is where you will insert your sensor. Let the skin preparation or adhesive product dry before inserting your sensor.</p>	<ul style="list-style-type: none"> When inserting a Sensor, you'll first clean the placement site with alcohol, and let it dry.  <ul style="list-style-type: none"> If needed, you'll then apply the skin preparation or adhesive product to your chosen Sensor placement site and let dry.  <p>[Show adhesive product animating on belly, to the left of belly button, to depict how to apply adhesive.]</p> <p>Do not place adhesive in the center area. Allow the adhesive product to dry before inserting the Sensor.</p>
756e	[No VO]	<p>The program is paused so you can clean your placement site and apply the skin preparation or adhesive if needed. When finished, click the Play button to the left.</p>
76	In real-time, the sensor insertion	

	happens very quickly. Let's see how quick an actual Dexcom G4 PLATINUM sensor insertion can be...	
77	Once the placement site is clean and the optional skin preparation or adhesive product has been placed on your skin and dry, remove the adhesive tabs from the bottom of the sensor Pod.	
78	Place the sensor horizontally on the placement site on your body, NOT vertically. Rotate your fingers around the adhesive to secure the adhesive tape to the body.	
79	Remove the Safety Lock by pulling straight out. Save the Safety Lock, as you'll be using it to remove your transmitter from your sensor after your sensor session is done.	 
80	Using the thumb and forefinger on your non-dominant hand, you may want to pinch up on the tips of the white adhesive on your skin at the base of the sensor pod.	

81	With your dominant hand, place 2 fingers above the sensor applicator collar.	
82	Put your thumb on the plunger and push down completely. You should hear 2 clicks.	
83	Using your thumb as a base, move your fingers from above the collar to below the collar, and pull the collar up completely towards your thumb until you hear 2 clicks or cannot pull back any more. You might feel pressure as you pull back the collar, but continue to pull it back completely, as shown.	
84	Make sure the transmitter latch is flush against the skin.	
85	While still holding the sensor applicator, use your other hand to squeeze the ribbed tabs on the sides of the sensor Pod. Rock the sensor applicator forward and out, away from your body.	

		
87	[No VO]	The program is paused so you can insert your sensor. When finished, click the Play button to the left.
88	Once your sensor has been inserted, it's time to attach the transmitter. First, if you haven't already done so, clean your transmitter with an alcohol wipe and let it dry.	 <p>This is an example of the Dexcom G4 PLATINUM Transmitter. The information on the back of your transmitter may not look identical to what is shown here.</p> 
89	Once it's dry, place your transmitter into the sensor pod (flat side down, thinner side away from the transmitter latch).	

		
90	<p>With one hand, you may want to pinch up on your skin at the front tips of the white adhesive. Use a finger to hold the transmitter in place. With your other hand, move the transmitter latch forward until you hear 2 clicks. This may take some force.</p>	  
91	<p>To remove the transmitter latch, hold the sides of the sensor pod with one hand and the transmitter latch with the other. Twist off the latch.</p> <p>Your sensor insertion is now complete. You are now ready to go on to the next step.</p>	 <p>Your sensor insertion is now complete. You are now ready to go on to the next step.</p>
92	[No VO – Pop-up box]	<p>The program is paused so you can attach your transmitter. When finished, click the Play button to the left.</p>
93	Step 4 Tasks Completed:	Step 4 Tasks Completed:



	<p>If you are not fully comfortable with any of these tasks, please review Step 4 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 4], your Dexcom G4 PLATINUM (Pediatric) User's Guide, or call your local Dexcom Technical Support Representative.</p> <p>Please review and check this list before moving on to the next step.</p> <p>If you need to review any of the tasks in Step 4 again, choose to "replay" the task on the list. You will then be taken to that specific task to review again.</p>	<p>If you are not fully comfortable with any of these tasks, please review Step 4 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 4], your Dexcom G4 PLATINUM (Pediatric) User's Guide, and/or call Dexcom Technical Support at 1-877-339-2664, 24 hours a day, 7 days a week.</p> <p>Step 4 Tasks Completed:</p> <ul style="list-style-type: none">• I have chosen a placement site for my Sensor• I have inserted my Sensor• I have attached my Transmitter <p>To continue to the next step, check each box above (by clicking on the box) and then click "Continue With Program." To review any of these tasks before continuing, click the "Replay" button next to that task.</p> <p>"Continue with program" button</p>
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Section	Voice-over	Visuals
94 Step 5: Starting Your Sensor Session	Once a new sensor has been inserted, it's time to start your sensor session.	<p>[Dexcom G4 PLATINUM (Pediatric) logo]</p> <p>Step 5: Starting Your Session</p>
95	After completing this step, you will have: <ul style="list-style-type: none"> Started your sensor session Confirmed your transmitter and receiver are talking to each other 	After completing this step, you will have: <ul style="list-style-type: none"> Started your Sensor session Confirmed your Transmitter and Receiver are talking to each other
96	Press your receiver's SELECT button to get to the Main Menu.	Press your Receiver's SELECT button to get to the Main Menu. 
96b	Press the DOWN button to highlight "Start Sensor." Press the SELECT button to confirm the start of a new Sensor session. The "Start Sensor Processing" screen will appear to let you know the 2-hour startup period has begun.	 <p>Press the DOWN button to highlight "Start Sensor."</p> 
97	[No VO – Pop-up box]	The program is paused so you can start your Sensor session. When finished, click the Play button to the left.

<p>98</p>	<p>To confirm that your receiver and transmitter are talking, Check your receiver approximately 10 minutes after starting your sensor session. The antenna symbol should appear in the upper left corner of the trend graph screen.</p>	<p>Antenna Symbol 10 Minutes</p> 
<p>99</p>	<p>If the Out of Range symbol appears in the upper right corner, see the User's Guide or the Troubleshooting section on the back of the Quick Start Guide.</p>	<p>Out of Range Symbol Countdown Symbol</p> 
<p>100</p>	<p>So that you'll know how much time is left in the startup period, a Countdown symbol will appear and gradually fill in over 2 hours. During this initial 2-hour warm-up, your Dexcom G4 PLATINUM System will not display any Sensor glucose readings, and no alerts or alarms will be activated.</p>	 <p>During the initial 2-hour warm-up:</p> <ul style="list-style-type: none"> • Your Dexcom G4 PLATINUM (Pediatric) System will not display any sensor glucose readings • No alerts or alarms will be activated

		
101	[No VO – Pop-up box]	<p>The program is paused so you can confirm that your Receiver and Transmitter are communicating. You may have to wait 5–10 minutes. When finished, click the Play button to the left.</p>
102	<p>Step 5 Tasks Completed: If you are not fully comfortable with any of these tasks, please review Step 5 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 5], your Dexcom G4 PLATINUM (Pediatric) User’s Guide, or call your local Dexcom Technical Support Representative.</p> <p>Please review and check this list before moving on to the next step.</p> <p>If you need to review any of the tasks in Step 5 again, choose to “replay” the task on the list. You will then be taken to that specific task to review again.</p>	<p>If you are not fully comfortable with either of these tasks, please review Step 5 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 5], your Dexcom G4 PLATINUM (Pediatric) User’s Guide and/or call Dexcom Technical Support at 1-877-339-2664, 24 hours a day, 7 days a week.</p> <p>Step 5 Tasks Completed:</p> <ul style="list-style-type: none"> • I have started my Sensor session • My Transmitter and Receiver are talking to each other <p>To continue to the next step, check each box above (by clicking on the box) and then click “Continue With Program.” To review either of these tasks before continuing, click the “Replay” button next to that task.</p> <p>“Continue With Program” button</p>

Section	Voice-over	Visuals
103 Step 6: Calibrating	Once the startup period is over, it's time to calibrate your device.	<p>[Dexcom G4 PLATINUM logo]</p> <p>Step 6: Calibrating</p>
104	After completing this step, you will have: <ul style="list-style-type: none"> • Learned what calibration is and why it's important • Know how to recognize calibration prompts • Entered calibration values from your blood glucose meter • Learned some tips for calibration 	After completing this step, you will have: <ul style="list-style-type: none"> • Learned what calibration is and its importance • Know how to recognize calibration prompts • Entered calibration values from your blood glucose meter • Learned some tips for calibration
105A	First, let's talk a little about what calibration is.	Calibration
105B	Think of getting a new sensor as being a little like getting a new watch. When you get a new watch, you don't just let it run and take the time it displays as correct.	
105C	Instead, you look at a watch or clock you already have, and set that time on the NEW watch. In other words, you adjust or standardize your NEW watch to a known reference (a clock or watch you already have).	 <p>Set the NEW watch to a standardized time.</p>

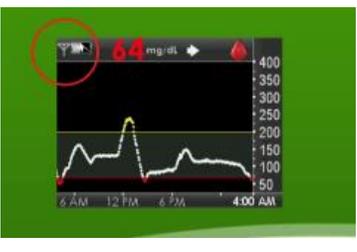
105D	<p>It's the same thing when you get a new sensor. The new sensor doesn't automatically know what your glucose levels are, just as a new watch doesn't automatically know what time it is.</p>	
105E	<p>You have to "teach" your new sensor your blood glucose values by entering in a KNOWN glucose VALUE from your blood glucose meter—just as you would adjust a new watch to the current time. This is how you calibrate your sensor.</p>	 <p>"Teach" the new Sensor using a known blood glucose value.</p>
105F	<p>Calibration is a VERY important part of making sure your Dexcom G4 PLATINUM System is working its best. So be sure to make every calibration count. And, calibrate smart by using the best fingerstick technique with your blood glucose meter (wash your hands, use your fingertips, etc).</p> <p>UNLIKE a new watch, where you generally just set the time once, your sensor needs to be calibrated throughout its life. This is because its readings can change over time...like a watch over time running a little too fast or too slow. You'll need to calibrate your sensor to make sure that it is providing you with the most accurate sensor glucose readings over the whole time that you are using it. We'll go over the calibration schedule a little later in this step.</p>	<p style="text-align: center;">Calibration</p> <ul style="list-style-type: none"> • Every calibration counts! • Calibrate smart using the best fingerstick technique • Calibrate over the life of your Sensor

106	<p>Your initial startup calibration is done by taking 2 fingerstick readings with your blood glucose meter and entering the exact values into your receiver within 5 minutes of them being taken. The initial startup calibration with each new sensor is the ONLY time you need to enter 2 consecutive blood glucose values.</p>	<p>Calibration</p> <ul style="list-style-type: none"> Your initial startup calibration is done by taking 2 fingerstick readings with your blood glucose meter and entering the exact values into your Receiver within 5 minutes of them being taken The initial startup calibration with each new Sensor is the ONLY time you need to enter 2 consecutive blood glucose values
107	<p>If you plan on downloading data from your receiver and glucose meter, make sure the times and dates on the two devices match.</p>	<p>Calibration</p> <p>Note: Make sure the times and dates on your blood glucose meter and Receiver match.</p>
108	<p>After the 2-hour startup period, the Double Blood Drop prompt will appear on your receiver to let you know it is time to enter your initial startup calibrations. Press SELECT to clear this alert.</p>	
109	<p>[No VO – Pop-up box]</p>	<p>The program is paused to wait for the 2-hour startup period to finish. When finished, click the Play button to the left.</p>

110	Next, wash and dry your hands.	
111	Perform a fingerstick blood glucose reading with your blood glucose meter. [Production: please have the following pop up here – No V/O]	
112	[No VO – Pop-up box]	The program is paused so you can perform your fingerstick blood glucose reading. When finished, click the Play button to the left.
113	Enter the exact blood glucose value into your Dexcom G4 PLATINUM (Pediatric) Receiver within 5 minutes of performing the fingerstick. To enter the value, press SELECT to get to the Main Menu. Press the down button to highlight "Enter BG". Press SELECT to choose this option.	
114	Initially, the default glucose setting will be at 120 milligrams per deciliter. Press the UP or DOWN buttons to enter the exact blood glucose value from your blood glucose meter into the receiver. Press SELECT.	

		
115	Confirm the calibration value is correct. If yes, press the SELECT button to accept the calibration entry.	
116	[No VO – Pop-up box]	The program is paused so you can enter your fingerstick value from your blood glucose meter. When finished, click the Play button to the left. 
117	Perform another fingerstick to get a second blood glucose value, and then repeat the previous steps to enter your second calibration value.	Calibration <ul style="list-style-type: none"> Perform another fingerstick to get a second blood glucose value, and then repeat the previous steps to enter your second calibration value 
118	[No VO – Pop-up box]	The program is paused so you can test a second time with your blood glucose meter and enter your second fingerstick

		<p>reading. When finished, click the Play button to the left.</p>
<p>119</p>	<p>Throughout your seven day sensor session, the calibration prompt will appear to let you know it is time to update your calibration by entering one fingerstick blood glucose value. Calibration must occur at:</p> <ul style="list-style-type: none"> ○ Startup – 2 hours after your sensor insertion ○ 12 hour calibration – every 12 hours after your initial startup calibration. <p>You can calibrate more frequently if desired.</p> <p>In some cases, during your sensor session you may be prompted to enter additional calibration updates if needed.</p>	 <p>Calibration must occur at:</p> <ul style="list-style-type: none"> ○ Startup – 2 hours after your Sensor insertion ○ 12 hour calibration – every 12 hours after your initial startup calibration 
<p>120</p>	<p>Before we move on, let's go over some calibration tips that are important for you to remember:</p> <ul style="list-style-type: none"> • In order to obtain the most accurate readings on your Dexcom G4 PLATINUM System, proper calibration is required using accurate blood glucose values • Use a blood glucose value obtained only from a fingerstick for all entered calibrations • Make sure a glucose reading is displayed at the top of the Trend Graph—or a Blood Drop Symbol is 	 <p>Calibration Tips</p> <ul style="list-style-type: none"> • In order to obtain the most accurate readings on your Dexcom G4 PLATINUM (Pediatric) System, proper calibration is required using accurate blood glucose values • Use a blood glucose value obtained only from a fingerstick for calibration

<p>displayed in the top right corner of the Trend Graph—before entering a calibration</p> <ul style="list-style-type: none"> • Only fingerstick readings between 40 and 400 milligrams per deciliter can be used for calibration. If one or more of your readings entered was outside of this range, the receiver will not calibrate. You will have to wait until your blood glucose is in this glucose range to calibrate. • Always make sure the Antenna Symbol is displayed in the upper left corner of the Trend Graph before you enter blood glucose values for calibration • You should always use the same meter you routinely use to measure your blood glucose to calibrate. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy may vary between brands • Enter your blood glucose value into the receiver within 5 minutes of performing the fingerstick. • Do not calibrate if any acetaminophen-containing medications are active in your body. If you take any acetaminophen-containing medications, ask your healthcare provider or pharmacist how long 	<ul style="list-style-type: none"> • Make sure a glucose reading is displayed at the top of the Trend Graph—or a Blood Drop Symbol is displayed in the top right corner of the Trend Graph—before calibration  <ul style="list-style-type: none"> • Only fingerstick blood glucose readings between 40 and 400 mg/dL can be used for calibration. If one or more of your readings entered was outside of this range, the Receiver will not calibrate. You will have to wait until your blood glucose is in this range to calibrate <p>Always make sure the Antenna Symbol is displayed in the upper left corner of the Trend Graph before you enter blood glucose values for calibration</p>  <ul style="list-style-type: none"> • You should always use the same meter you routinely use to measure your blood glucose to calibrate. Do not switch your meter in the middle of a Sensor session. Blood glucose meter and strip accuracy may vary
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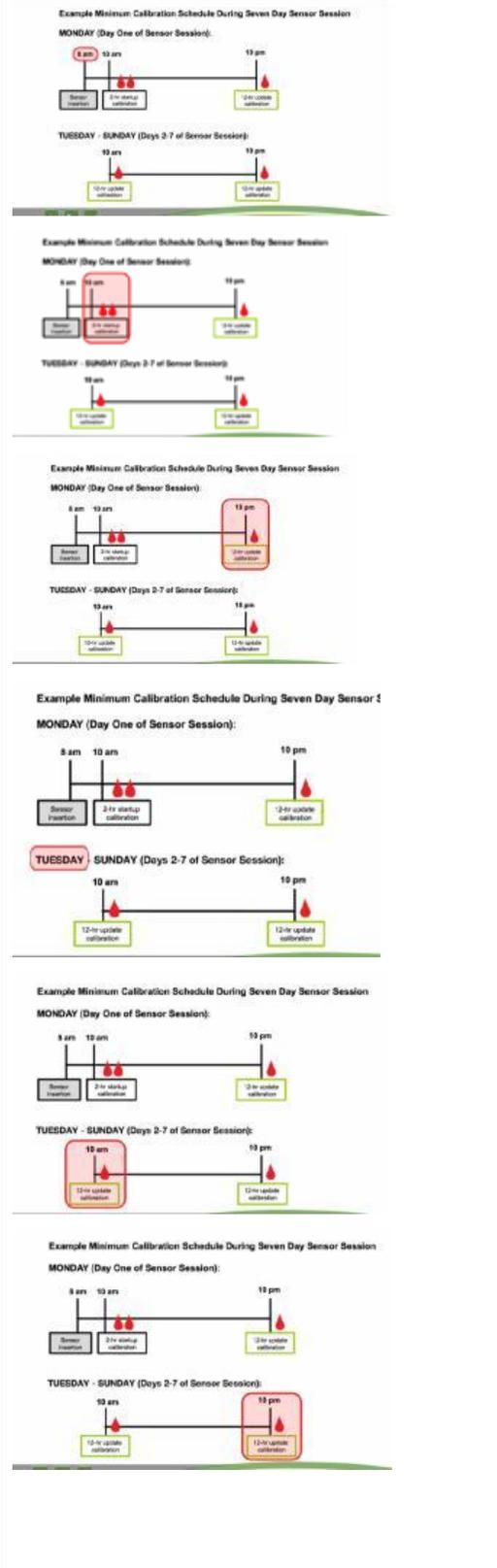
	<p>these medications are active in your body.</p>	<p>between brands</p> <ul style="list-style-type: none"> • Enter your blood glucose value into the Receiver within 5 minutes of performing the fingerstick • Do not calibrate if any acetaminophen-containing medications are active in your body. If you take any acetaminophen-containing medications, ask your healthcare provider or pharmacist how long these medications are active in your body
<p>121</p>	<p>WARNING: Your sensor readings may be inaccurate if you calibrate less often than recommended.</p> <p>Let's walk through an example of the minimum calibration schedule during a seven-day sensor session.</p> <p>Let's say you insert your sensor and start your sensor session on Monday morning at 8 am. This would be considered Day One of your sensor session.</p> <p>At 10 am on Monday, you would receive the 2-hour startup calibration prompt, letting you know you need to do your two initial startup calibrations. You would take 2 fingerstick blood glucose readings with your blood glucose meter, and enter each value into your receiver.</p>	<p>WARNING: 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.</p> <p>Example Minimum Calibration Schedule During Seven Day Sensor Session</p> <p>MONDAY (Day One of Sensor Session):</p> <p>Example Minimum Calibration Schedule During Seven-Day Sensor Session</p> <p>Monday (Day One of Sensor Session):</p>  <p>Tuesday - Sunday (Days 2-7 Sensor Session):</p>  <p>TUESDAY – SUNDAY (Days 2-7 of Sensor Session):</p>

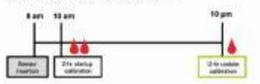
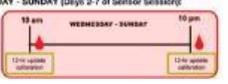
At 10 pm—12 hours after your startup calibration—you would receive the 12-hour update calibration prompt. You would take one fingerstick blood glucose reading with your blood glucose meter and enter the exact value into your receiver.

Tuesday would be Day Two of your sensor session. At 10 am Tuesday morning, the 12-hour update calibration prompt would notify you that it is time to enter another calibration. You would again take **one** fingerstick blood glucose reading with your blood glucose meter and enter that exact value into your receiver.

Late Tuesday evening—10 pm—the 12-hour update calibration prompt would alert you. You would again take **one** fingerstick blood glucose reading with your blood glucose meter and enter that exact value into your receiver.

Wednesday through Sunday, or Days 3 through 7 of your sensor session, you would continue with the same calibration schedule as on Tuesday—entering one fingerstick blood glucose value at 10 am, and another at 10 pm.



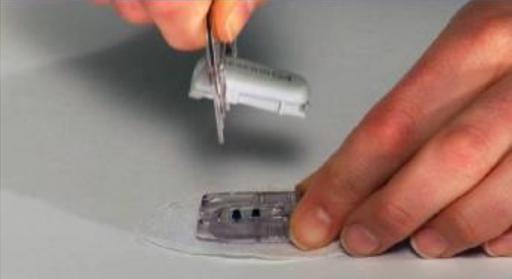
		<p>Example Minimum Calibration Schedule During Seven Day Sensor Session</p> <p>MONDAY (Day One of Sensor Session):</p>  <p>TUESDAY - SUNDAY (Days 2-7 of Sensor Session):</p>  <p>Example Minimum Calibration Schedule During Seven Day Sensor Session</p> <p>MONDAY (Day One of Sensor Session):</p>  <p>TUESDAY - SUNDAY (Days 2-7 of Sensor Session):</p>  <p>For more information on calibrating your Dexcom G4 PLATINUM (Pediatric) System, such as how the calibration prompts will alert you, see the Dexcom G4 PLATINUM (Pediatric) User's Guide</p>
121a	[No audio – pop-up box]	<p>"I understand that, in order to obtain the most accurate readings with my Dexcom G4 PLATINUM (Pediatric) System, I need to calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate."</p> <p>"Review Information Again" button and "I AGREE" button</p>
122	<p>Step 6 Tasks Completed:</p> <p>If you are not fully comfortable with any of these tasks, please review Step 6 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 6], your Dexcom G4 PLATINUM (Pediatric) User's Guide or call your local Dexcom Technical Support Representative.</p>	<p>If you are not fully comfortable with any of these tasks, please review Step 6 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 6], your Dexcom G4 PLATINUM (Pediatric) User's Guide and/or call Dexcom Technical Support at 1-877-339-2664, 24 hours a day, 7 days a week.</p>

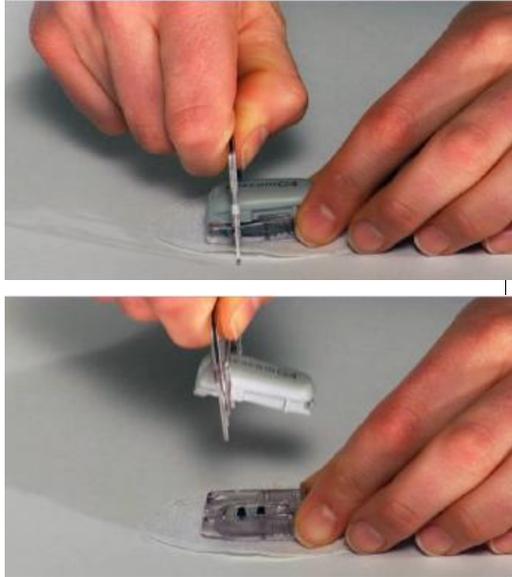


	<p>Please review and check this list before moving on to the next step.</p> <p>If you need to review any of the tasks in Step 6 again, choose to “replay” the task on the list. You will then be taken to that specific task to review again.</p>	<p>Step 6 Tasks Completed:</p> <ul style="list-style-type: none">• I understand what calibration means and why it’s so important• I know what the calibration prompts look like• I have entered fingerstick values from my blood glucose meter into my receiver for initial calibration• I have learned some tips about calibrating <p>To continue to the next step, check each box above (by clicking on the box) and then click “Continue With Program.” To review any of these tasks before continuing, click the “Replay” button next to that task.</p> <p>“Continue With Program” button</p>
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Section	Voice-over	Visuals
123 Step 7: Ending Your Sensor Session	Finally, let's talk about ending a sensor session.	[Text] [7 Simple Steps tutorial logo and Dexcom G4 PLATINUM (Pediatric) logo] Step 7: Ending Your Sensor Session
124	<p>After completing this step, you will have:</p> <ul style="list-style-type: none"> • Learned the sensor expiration prompts • Learned how to remove the sensor and transmitter from your body • Learned how to remove the transmitter from the sensor pod <p>You must remove the sensor and transmitter from your body by peeling both of them off TOGETHER. DO NOT try to detach the transmitter from the Sensor Pod before removing both the transmitter and sensor from your body.</p> <p>At the end of your first sensor session, you may want to come back to this step of the tutorial and review it again before moving forward.</p>	<p>After completing this step, you will have:</p> <ul style="list-style-type: none"> • Learned the Sensor expiration prompts • Learned how to remove the Sensor and Transmitter from your body • Learned how to remove the Transmitter from the Sensor Pod <p>The Sensor and Transmitter MUST be removed from your body by peeling them off TOGETHER. DO NOT try to detach the Transmitter from the Sensor Pod before removing from your body.</p>
125	<p>The sensor automatically shuts off after 7 days (the receiver will alert you before this happens).</p> <p>When you see this screen, it's time to</p>	

	<p>remove your sensor and transmitter.</p>	
<p>126</p>	<p>To remove your sensor and transmitter, keep the sensor and transmitter attached to each other, and peel the Sensor Pod from your body, similar to removing a bandage. The sensor and transmitter need to be removed together. Do NOT remove the transmitter from the sensor pod prior to removing the sensor from your body.</p>	 <p>The Sensor and Transmitter need to be removed together.</p> <p>Do NOT remove the Transmitter from the Sensor Pod prior to removing the Sensor from your body.</p>
<p>127</p>	<p>[No VO – Pop-up box]</p>	<p>The program is paused so you can remove the Sensor and Transmitter from your body. Remove them TOGETHER. When finished, click the Play button to the left.</p>

128	<p>Once you've removed the sensor pod and transmitter from your body, you will need to take the transmitter out of the sensor pod. You can do this manually or by using the safety lock.</p> <p>If you did not keep the safety lock, you can use your fingers to spread out the back tabs of the sensor pod. The transmitter will then pop out.</p>	<p>Removing the Transmitter</p> <p>Take the Transmitter out of the Sensor Pod</p>  <ul style="list-style-type: none">You can do this manually or by using the Safety Lock  
129	<p>To use the safety lock to remove the transmitter, insert the jagged edges of the safety lock so they "hug" the transmitter wings in the sensor pod.</p>	  

130	<p>Press the safety lock down until you cannot press any more, then pull up. The transmitter will pop out of the Sensor base.</p>	
131	<p>DO NOT throw away your transmitter. However, you will throw away your sensor. You can now insert a new sensor and start a new sensor session.</p>	<p>Do NOT throw away your Transmitter! Throw away your Sensor per your local guidelines.</p>  <p>You can now insert a new Sensor and start a new Sensor session.</p> 
132	[No VO – Pop-up box]	<p>The program is paused so you can take the Transmitter out of the Sensor Pod. When finished, click the Play button to the left.</p>
133	Step 7 Tasks Completed:	If you are not fully comfortable with any



	<p>If you are not fully comfortable with any of these tasks, please review Step 7 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 7], your Dexcom G4 PLATINUM (Pediatric) User's Guide—or call your local Dexcom Technical Support Representative.</p> <p>Please review and check this list before moving on to reviewing the Dexcom G4 PLATINUM (Pediatric) Important User Information.</p> <p>If you need to review any of the tasks in Step 7 again, choose to "replay" the task on the list. You will then be taken to that specific task to review again.</p>	<p>of these tasks, please review Step 7 again. You can also consult your Dexcom G4 PLATINUM (Pediatric) Quick Start Guide [Step 7], your Dexcom G4 PLATINUM (Pediatric) User's Guide and/or call Dexcom Technical Support at 1-877-339-2664, 24 hours a day, 7 days a week.</p> <p>Step 7 Tasks Completed:</p> <ul style="list-style-type: none">• I know the Sensor expiration prompts• I have learned how to remove or have removed the Sensor and transmitter from my body TOGETHER AS ONE UNIT• I have learned how to remove or have removed the Transmitter from the Sensor pod <p>To continue to the next step, check each box above (by clicking on the box) and then click "Continue With Program." To review any of these tasks before continuing, click the "Replay" button next to that task.</p> <p>"Continue With Program" button</p>
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Section	Voice-over	Visuals
134 Conclusion	[None]	[None] [7 Simple Steps Tutorial logo and Dexcom G4 PLATINUM logo]
135	This concludes our review of the seven basic steps needed to get up and running with your Dexcom G4 PLATINUM Continuous Glucose Monitoring System.	Conclusion of Your Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System Review
136	Remember, as you get started with your System, or at any time in the future, you can call Dexcom Technical Support for assistance. There are people available to help you 24 hours a day 7 days a week, 365 days a year. Also, the Quick Start Guide and User's Guide in your Starter Kit may help answer any questions you may have.	<p>Dexcom Technical Support 1-877-339-2664 (00+ 1-858-200-0200 for US users while traveling internationally), 24 hours a day, 7 days a week</p>  <p>QUICK START GUIDE USER'S GUIDE</p> <p>Your training documents may not look identical to the examples shown here.</p>
137	Remember, this self-guided training has focused only on setting up your Dexcom G4 PLATINUM System. For any questions or concerns regarding how to use the glucose trend information, how to use alert settings, and other diabetes management questions, please talk with your healthcare provider. Thank you for spending this time with me, and good luck using your System! Welcome to the Dexcom family!	<p>For any questions or concerns regarding how to use the glucose trend information and/or alert settings, and other diabetes management questions, please talk with your healthcare provider.</p> <p>Welcome to the Dexcom Family!</p>  <p>Welcome to the Dexcom Family!</p> 