



## USER'S GUIDE

# DEXCOM G4<sup>®</sup> PLATINUM CONTINUOUS GLUCOSE MONITORING SYSTEM

### IMPORTANT CONTACTS AND NUMBERS

<b>Dexcom<sup>®</sup> Website:</b>	<a href="http://www.dexcom.com">www.dexcom.com</a>
<b>Your Transmitter ID:</b>	
<b>Your Receiver ID:</b>	
<b>Your Healthcare Professional:</b>	
<b>Nearest Hospital:</b>	

© 2014 Dexcom, Inc. All rights reserved.

Dexcom, Dexcom G4, Dexcom G4 PLATINUM, Dexcom Studio, SEVEN, Stay Between the Lines and Dexcom Makes Sense 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.

# table of contents

[Page numbering will be updated after professional layout]

<b>GLOSSARY</b> .....	<b>6</b>
<b>CHAPTER 1: DEXCOM G4 PLATINUM CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM DESCRIPTION</b>	<b>9</b>
1.1 System Contents	11
1.2 Introduction	12
1.3 Sensor Overview	13
1.4 Transmitter Overview	14
1.5 Receiver Overview	15
1.6 Share Overview	
<b>CHAPTER 2: INDICATIONS FOR USE AND SAFETY STATEMENT</b> .....	<b>17</b>
2.1 INDICATIONS FOR USE	19
2.2 IMPORTANT USER INFORMATION	19
2.3 CONTRAINDICATIONS	20
2.4 WARNINGS	20
2.5 PRECAUTIONS	22
2.6 CAUTION	24
<b>CHAPTER 3: RISKS AND BENEFITS</b>	<b>25</b>
3.1 Risks	27
3.2 Benefits	28
<b>CHAPTER 4: CHARGING YOUR RECEIVER AND THE RECEIVER MAIN MENU</b>	<b>31</b>
4.1 Charging Your Receiver Battery	33
4.1.1 Charging Your Receiver Battery from an AC Power Outlet	34
4.1.2 Charging Your Receiver Battery from a Windows Compatible Computer	35
4.1.3 Knowing Your Receiver is Charged	36
4.2 Receiver Menu Options	36
<b>CHAPTER 5: DEXCOM G4 PLATINUM SYSTEM SETUP</b> .....	<b>39</b>
5.1 Setting Up the Receiver and Pairing with Your Transmitter	41
5.2 The Settings Menu	43
5.2.1 Getting to the Settings Menu	43
5.2.2 Setting Your Receiver Time and Date	43
5.2.3 Entering Your Transmitter ID	
5.2.4 Turning On Share On Your Receiver	44
5.3 Checking Information About Your Dexcom G4 PLATINUM System	45
5.4 Transmitter and Receiver Communication	46

<b>CHAPTER 6: INSERTING A SENSOR AND STARTING A SENSOR SESSION</b>	<b>49</b>
6.1 Before You Start	52
6.2 Removing the Sensor from its Packaging	53
6.3 Choosing an Insertion Site	54
6.4 Placing the Sensor	55
6.5 Sensor Insertion	56
6.6 Transmitter Attachment	58
6.7 Starting a Sensor Session	59
6.8 Sensor Startup Period	60
6.9 Taping the Sensor Pod	61
6.10 Temporary Receiver Shutdown	62
6.11 The Dexcom G4 PLATINUM System and Water	63
<b>CHAPTER 7: CALIBRATING YOUR DEXCOM G4 PLATINUM SYSTEM</b>	<b>65</b>
7.1 Calibration Overview	67
7.2 How to Calibrate	69
7.3 Startup Calibration	72
7.4 12-Hour Calibration Update	73
7.5 Other Reasons You May Need to Calibrate	73
<b>CHAPTER 8: SENSOR GLUCOSE READINGS AND TRENDS</b>	<b>75</b>
8.1 Sensor Glucose Readings	78
8.2 Rate of Change Arrows	81
8.3 Glucose Status Area Symbols	84
<b>CHAPTER 9: ALERTS, ALARM &amp; PROFILES</b>	<b>87</b>
9.1 Setting Your Alerts	89
9.1.1 Default Alert/Alarm Settings	89
9.1.2 Glucose Alerts & Alarm	91
9.1.2.1 High Glucose Alert	92
9.1.2.2 Low Glucose Alert	92
9.1.2.3 Low Glucose Alarm	93
9.1.3 Getting to the Alerts Menu	93
9.1.4 High and Low Glucose Alerts	94
9.2 Advanced Alerts	95
9.2.1 Setting a Snooze Time for Your High and Low Glucose Alerts	96
9.2.2 Rise and Fall Glucose Rate Alerts	96
9.2.3 Setting the Out of Range Alert	98
9.3 Alert Profiles	100
9.3.1 Alert Profile Options	101
9.3.2 Alert Profile Details	102
<b>CHAPTER 10: EVENTS AND DEXCOM STUDIO™ SOFTWARE</b>	<b>105</b>
10.1 Events	107

10.1.1	Selecting an Event	107
10.1.2	Setting the Date and Time for an Event	108
10.1.3	Carbohydrates	109
10.1.4	Insulin	110
10.1.5	Exercise	111
10.1.6	Health	112
10.2	Dexcom Studio Software	113
<b>CHAPTER 11: ENDING A SENSOR SESSION</b>		<b>115</b>
11.1	Automatic Sensor Shut-Off	117
11.2	Removing a Sensor	118
11.3	Transmitter Removal	119
<b>CHAPTER 12: TAKING CARE OF YOUR DEXCOM G4 PLATINUM SYSTEM</b>		<b>121</b>
12.1	Maintenance	123
12.2	Storage	123
12.3	Product Disposal	124
<b>CHAPTER 13: TROUBLESHOOTING</b>		<b>125</b>
13.1	Sensor Insertion Troubleshooting	127
13.2	Calibration Troubleshooting	128
13.2.1	Types Of Calibration Prompts	129
13.2.2	What To Do For Calibration Prompts	130
13.3	Calibration Error Troubleshooting	130
13.4	System Glucose Error	131
13.5	Sensor Inaccuracies	132
13.6	Sensor Shut-Off Troubleshooting	134
13.6.1	Early Sensor Shut-Off - Sensor Failure	134
13.6.2	Manual Sensor Shut-Off - "Stop Sensor"	135
13.7	Share Pairing Error Troubleshooting	136
13.8	Battery and Charger Troubleshooting	136
13.9	Receiver and Transmitter Communication Troubleshooting	137
13.9.1	System Recovery Check	137
13.9.2	Receiver Error Code	137
13.9.3	Low Transmitter Battery	138
13.9.4	Transmitter Failed Error Code	138
13.10	Out of Range/No Antenna	138
13.11	Alerts Are Not Working	139
<b>CHAPTER 14: TECHNICAL INFORMATION</b>		<b>141</b>
14.1	Device Performance Characteristics	143
14.2	Product Specifications	162
14.3	FCC Requirements	175
<b>CHAPTER 15: USER ASSISTANCE</b>		<b>177</b>
<b>CHAPTER 16: WARRANTY</b>		<b>181</b>
<b>CHAPTER 17: TRAVEL INFORMATION</b>		<b>189</b>

<b>CHAPTER 18: APPENDIX</b>	<b>193</b>
Appendix I, Receiver Alerts, Alarm and Prompt	195
Appendix II, Index	204
Appendix III, Symbols Used in Labeling	209

## GLOSSARY

<b>Alternative Site BG Testing</b>	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.
<b>Applicator</b>	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.
<b>BG Meter</b>	Blood glucose meter. A device used to measure how much glucose is in the blood. You can use any commercially available meter for testing your blood glucose.
<b>BG Value</b>	Blood glucose value. The measurement of glucose in the blood. A blood glucose value taken with your commercially available blood glucose meter.
<b>Bluetooth</b>	Bluetooth <sup>®</sup> wireless technology allows devices to wirelessly communicate with each other. In this case, communication between the Receiver and your iPhone / iPod touch device.
<b>Calibration</b>	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).
<b>CGM</b>	Continuous Glucose Monitoring.
<b>Commercially Available</b>	Product that may be sold in the United States.
<b>Default</b>	A setting that is selected automatically, unless you choose another option.
<b>Dexcom G4 PLATINUM System</b>	The sensor, transmitter, and receiver.
<b>Dexcom Share System</b>	Secondary notification system to the Dexcom G4 PLATINUM System. For more information, please refer to the Dexcom Share User Manual.
<b>Glucose Data Gaps</b>	Different symbols show on the trend graph instead of a sensor glucose reading to let you know that the receiver cannot provide a reading.
<b>Glucose Trends</b>	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.
<b>Hypoglycemia</b>	Low blood glucose. Same as “low.” The default low alert in your receiver is set to 80 mg/dL. Consult your healthcare provider to determine the appropriate hypoglycemic setting for you.
<b>Hyperglycemia</b>	High blood glucose. Same as “high.” The default high alert in your receiver is set to 200 mg/dL. Consult your healthcare provider to determine the appropriate hyperglycemic setting for you.

<b>HypoRepeat</b>	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.
<b>mg/dL</b>	Milligrams per deciliter. The standard unit of measure for sensor glucose readings in the United States.
<b>Obstruction</b>	Something that blocks the wireless 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.
<b>Profiles</b>	Sound pattern and volume level settings for your alerts.
<b>Range</b>	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.
<b>Re-Alert</b>	A re-alert happens after the first alert is not confirmed.
<b>Receiver</b>	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.
<b>Rise and Fall (Rate of Change) Alerts</b>	Alerts based on how fast and how much your glucose levels rise or fall.
<b>RF</b>	Radio-frequency transmission used to send glucose information from the transmitter to the receiver.
<b>Safety Lock</b>	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.
<b>Sensor</b>	The Dexcom G4 PLATINUM 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.
<b>Sensor Pod</b>	The small plastic base of the sensor attached to your belly that holds the transmitter in place.
<b>Snoozing</b>	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.
<b>Startup Period</b>	The 2-hour period after you tell the receiver you inserted a new sensor. Sensor glucose readings are not provided during this time.
<b>System Reading</b>	A sensor glucose reading shown on your receiver. This reading is in mg/dL units and is updated every 5 minutes.
<b>Transmitter</b>	The Dexcom G4 PLATINUM System part that snaps into the sensor pod and

	wirelessly sends glucose information to your receiver.
<b>Transmitter ID</b>	A series of numbers and/or letters that you enter into your receiver to let it communicate with the transmitter.
<b>Transmitter Latch</b>	The small, disposable piece that snaps the transmitter into the sensor pod. It is removed after the transmitter is snapped in.
<b>Trend (Rate of Change) Arrows</b>	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 CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM DESCRIPTION



Dexcom G4 PLATINUM 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](http://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 sensor, the transmitter, and the receiver. The sensor is a disposable unit that you insert under the skin of your abdomen (belly) 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.

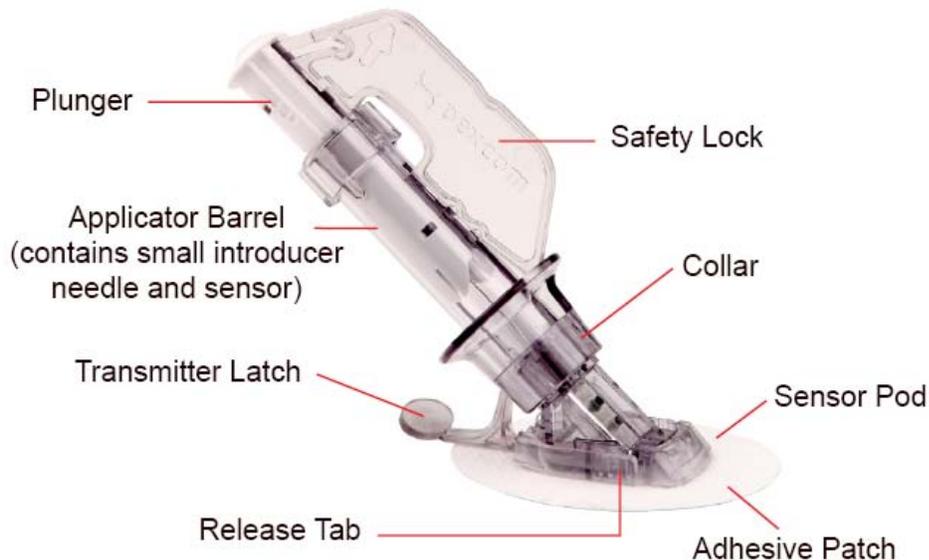
Please read this user's guide closely. It describes how to use your system.

In addition, Dexcom has a self-guided training tutorial for the Dexcom G4 PLATINUM 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 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](http://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 belly 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 the skin of your belly. 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 1.5 inches long, 0.9 inches wide and 0.5 inches thick. The 9438-05 transmitter (including sensor pod) is 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

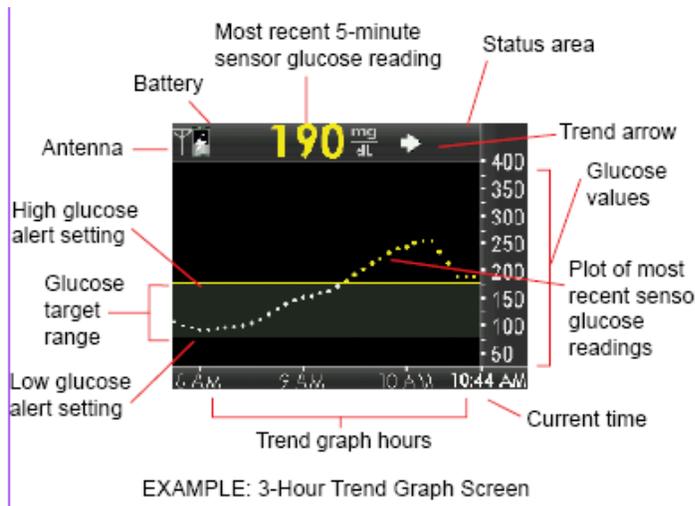


Transmitter Low Battery Screen

## 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.



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.

## 1.6 SHARE OVERVIEW

Dexcom Share™ remote monitoring system lets one person, the Sharer, transfer Dexcom G4 PLATINUM Continuous Glucose Monitoring information to another person, the Follower.

Learn more about Dexcom Share by reading the Dexcom Share User Manual.

## CHAPTER 2: INDICATIONS FOR USE AND SAFETY STATEMENT

### 2.1 INDICATIONS FOR USE

The Dexcom G4 PLATINUM Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in persons (**age 18 and older**) with diabetes. The system is intended for single patient use and requires a prescription.

The Dexcom G4 PLATINUM 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 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 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. 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 device is MR Unsafe. Do not bring any portion of the device into the MR environment. 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 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<sup>®</sup>) 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

- Thoroughly review the training materials included with your CGM system before using the Dexcom G4 PLATINUM CGM System. Incorrect use might lead to you misunderstanding the information provided by your system, or might affect system performance, and you might miss a low or high blood glucose value.

- Do not use the Dexcom G4 PLATINUM System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM 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. Using the sensor glucose readings for treatment decisions could lead to low or high blood glucose value.

- Do not ignore symptoms of high and low glucose. If your sensor glucose 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, so you do not miss a low or high blood glucose value.
- Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.
- 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**.
- The Dexcom G4 PLATINUM System **is not approved for use** in children or adolescents, pregnant women or persons on dialysis.
- It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Therefore, the use of this system in the critically ill population is not recommended.
- Sensor placement and insertion **is not approved** for sites other than the belly (abdomen).
- If your transmitter or receiver case is damaged/cracked, do not use it. 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 a low or high blood glucose value.

## 2.5 PRECAUTIONS

- Before opening the sensor package, wash 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.
- Before inserting the sensor, clean the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allow to dry. This may help prevent infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.
- Change the site where you place the sensor with each insertion. Using the same site too often might not allow the skin to heal, and 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 performance, and you might miss a low or high blood glucose value.

- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the sensor. The insulin might affect sensor performance, and you might miss a low or high blood glucose value.
- 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, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.
- 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 single arrow or double arrow, which indicates that your blood glucose is rising 2-3 mg/dL/min or more than 3 mg/dL/min. Also, do not calibrate when your receiver screen is showing the falling single arrow or double arrow, which indicates that your blood glucose is falling 2-3 mg/dL/min or more than 3 mg/dL/min. Calibrating during significant rise or fall of blood glucose may affect accuracy of sensor glucose readings.
- 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.
- 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 you might miss a low or high blood glucose value.
- 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 you might miss a low or high blood glucose value.
- 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 performance, and you might miss a low or high blood glucose value.
- 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 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 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 System. If you think a sensor has broken under your skin, contact your healthcare provider 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.<sup>1</sup>

Real-time CGM can help improve diabetes control (lower A1c values, reducing glycemic variability and time spent in low and high blood glucose ranges)<sup>1, 2, 3</sup> which can help reduce diabetes related complications.<sup>4, 5</sup> These benefits can be seen especially with using real-time CGM at least 6 days per week<sup>2</sup> and can be sustained over time.<sup>6</sup> 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.<sup>7</sup>

<sup>1</sup> 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.

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

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

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> 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.

<sup>7</sup> 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](http://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.

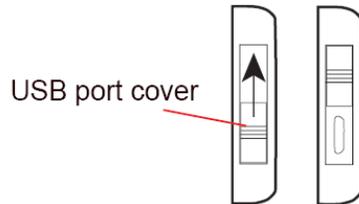
#### **WARNING**

It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Therefore, the use of this system in the critically ill population is not recommended.

#### 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
<b>Trend Graph</b>	To show the trend graphs. • The 3-hour trend graph is the default screen whenever you turn on the receiver.	Chapter 8
<b>Start Sensor</b>	To start a new sensor session. • This option only shows if you have entered a transmitter ID and you are not in the middle of a sensor session	Chapter 6
<b>Enter BG</b>	To enter your blood glucose values for calibration.	Chapter 7

<b>Profiles</b>	Profiles allow you to customize the sound and volume of alerts and alarm.	Chapter 9
<b>Events</b>	To enter personal information about meals, insulin, exercise, and health status.	Chapter 10
<b>Alerts, High/Low</b>	To change the settings for high and low alerts.	Chapter 9
<b>Settings</b>	To change the time, date and transmitter ID; to turn on the Share feature; to look up your Dexcom G4 PLATINUM System hardware and software version numbers; to view transmitter battery status, last calibration value and sensor insertion time.	Chapter 5
<b>Shutdown</b>	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
<b>Stop Sensor</b>	To end a sensor session early. <ul style="list-style-type: none"> <li>• 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.</li> </ul>	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 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 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 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.

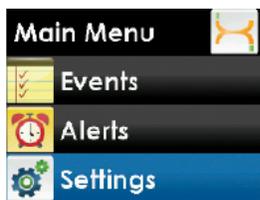
### 5.2.1 GETTING TO THE SETTINGS MENU

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** or **SELECT** 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.



Time/Date setting screen,  
year highlighted

The date format is YYYY/MM/DD.

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”):



Transmitter ID  
setting screen,  
first digit highlighted

- a. Press the **UP** or **DOWN** button to show the correct number or letter.
- b. Press the **RIGHT** 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.

## 5.2.4 TURNING ON SHARE ON YOUR RECEIVER

Please see the Pairing Receiver section in Chapter Two of your Dexcom Share User Manual to learn how to turn on the Share feature on your Receiver *with Share*.

## 5.3 CHECKING INFORMATION ABOUT YOUR DEXCOM G4 PLATINUM 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.
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



Device Info screen

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

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 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

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 you might miss a low or high blood glucose value.

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 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 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](http://www.dexcom.com).

### WARNING

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.

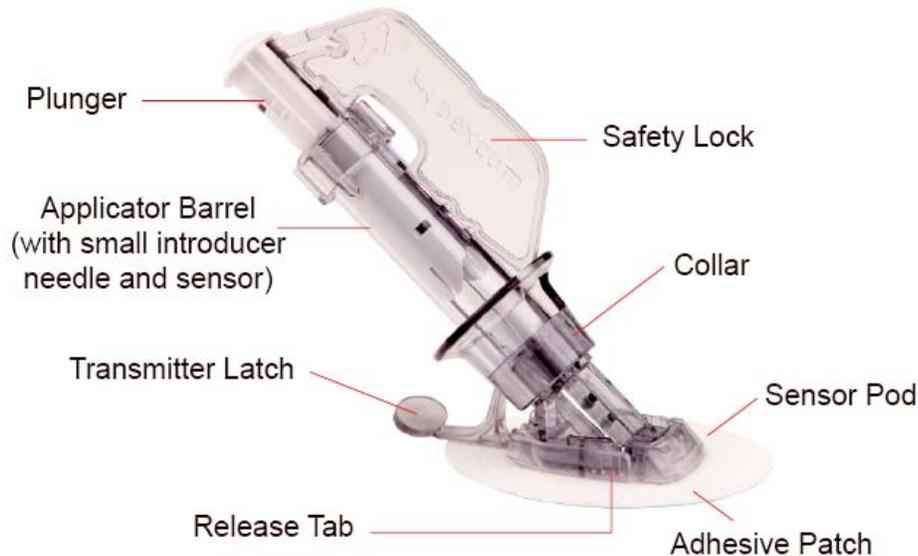
### 6.1 BEFORE YOU START

- 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 a low or high blood glucose value.

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

### PRECAUTION

- 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 performance, and you might miss a low or high blood glucose value.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the sensor. The insulin might affect sensor performance, and you might miss a low or high blood glucose value.

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

Choose a site on your belly to place the sensor. You can choose a site above or below your belt line. The best areas to insert your sensor are usually flat, “pinchable,” and free from where rubbing can occur, such as along the waist band and seat belt strap.

- Choose an area at least 3 inches from your insulin pump infusion set or injection site.

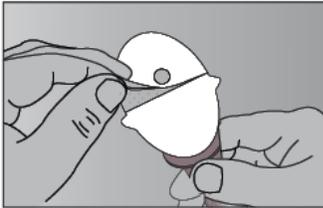
- Avoid using the same spot repeatedly for sensor insertion. Never use the same site for 2 sensor sessions in a row.
- You may need to shave the area where you plan to put the sensor so the adhesive patch sticks securely.
- Make sure there are no traces of lotions, perfumes or medications on the area.

## 6.4 PLACING THE SENSOR

### WARNING

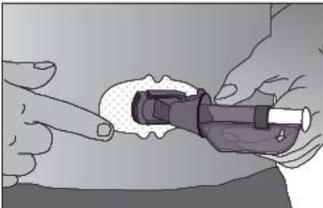
Do not use the Dexcom G4 PLATINUM System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose readings. Using the sensor glucose readings for treatment decisions could lead to low or high blood glucose value.

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.
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.



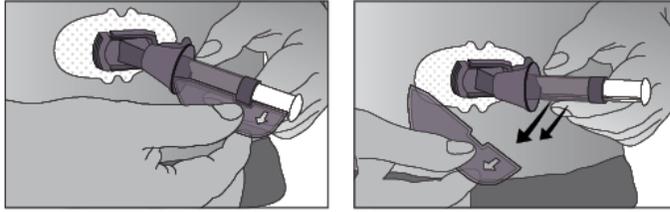
Step 2. Remove the adhesive backing

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

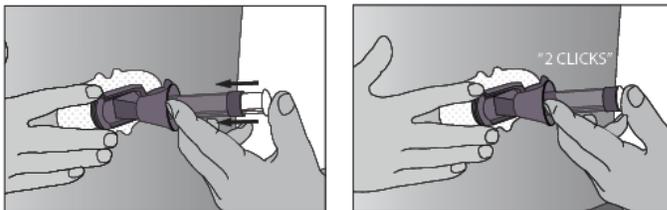
6. Save the safety lock to help you remove the transmitter at the end of your sensor session. The safety lock can be used for transmitter removal but is not required. When your glucose monitoring session is over, follow the steps in Chapter 11, Section 11.3, Transmitter Removal, with or without the safety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

## 6.5 SENSOR INSERTION

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

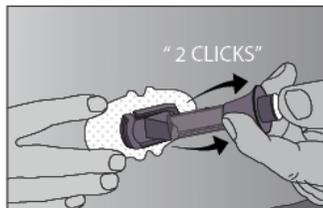
1. Place the fingers of one hand at the edge of the white adhesive (at the opposite side of the sensor from the transmitter latch). You may pinch up on your skin using this hand. Do not pinch up in the middle section of the plastic base.
2. While still pinching, use your other hand to place two fingers 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.**



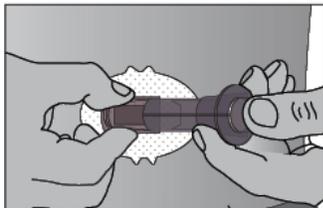
Steps 1-3. Push down the plunger - insert the needle and sensor

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.

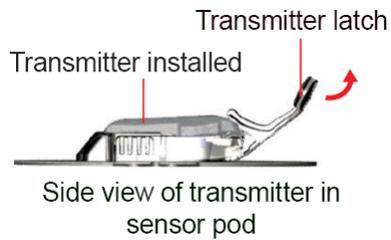
2. Place the transmitter in the sensor pod (with the flat side down, and the narrower side away from the transmitter latch).



**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.



- 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.



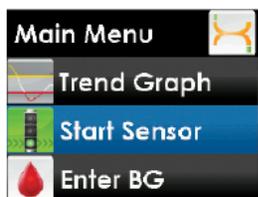
Twist transmitter latch up or down

**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.

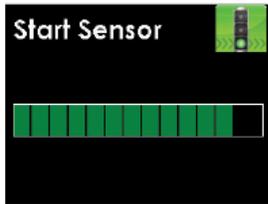
1. Press the **SELECT** button to turn on the receiver.
2. From any trend graph, press the **SELECT** button to see the Main Menu.
3. Press the **DOWN** button to highlight “Start Sensor.”



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. 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.



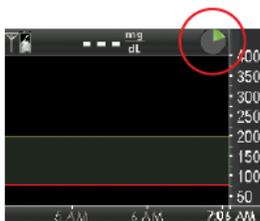
Antenna symbol should appear in upper left of trend graph

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.

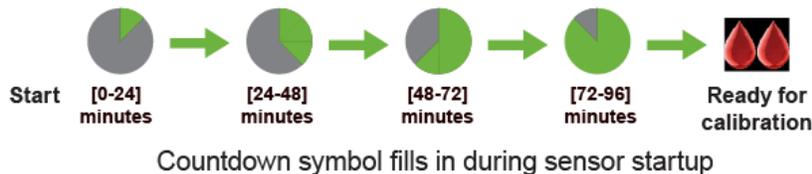
Your trend graph shows a 2-hour countdown symbol  in the upper right corner.



Countdown symbol appears in upper right of trend graph

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

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.



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 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, IV 3000, 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.

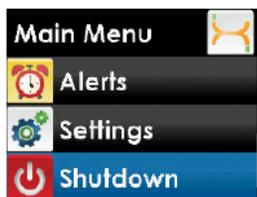


The right way to use tape for extra support

## 6.10 TEMPORARY RECEIVER SHUTDOWN

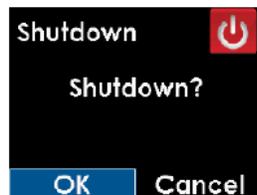
There may be times when you want to shut down your receiver temporarily. Shutdown stops all communication between the transmitter and receiver and turns the receiver off. You will not receive sensor glucose readings or **any** alerts or alarm while the receiver is shut down, but your current sensor session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



Shutdown screen,  
OK highlighted

- a. If you want to shut down, press the **LEFT** button to highlight "OK," and then press the **SELECT** button.
- 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 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 SYSTEM

You must calibrate Dexcom G4 PLATINUM 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:

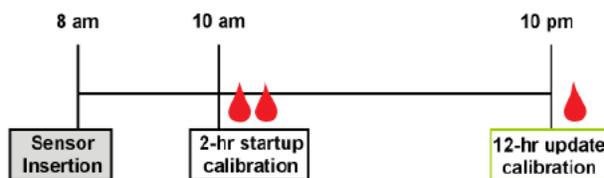
1. 2-hour startup: 2 hours after you insert your sensor
2. 12 hour update: every 12 hours after the 2-hour startup calibration
3. More information needed or other reasons

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.

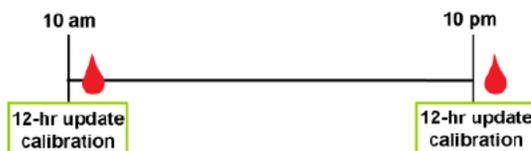
On the first day of your sensor session, you must enter 2 blood glucose values into your receiver. You must enter 1 blood glucose value calibration 12 hours after your startup calibration. You must enter 1 blood glucose value every 12 hours. The receiver will remind you when it needs these calibrations. 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 performance, and you might miss a low or high blood glucose value.

## 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

Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

## 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 single arrow or double arrow, which indicates that your blood glucose is rising 2-3 mg/dL/min or more than 3 mg/dL/min. Also, do not calibrate when your receiver screen is showing the falling single arrow or double arrow, which indicates that your blood glucose is falling 2-3 mg/dL/min or more than 3 mg/dL/min. Calibrating during significant rise or fall of blood glucose may affect accuracy of sensor glucose readings.

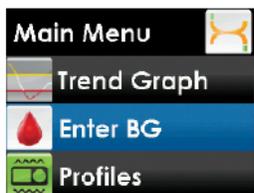
## PRECAUTION

To calibrate the system, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.

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”.



Main Menu,  
Enter BG highlighted

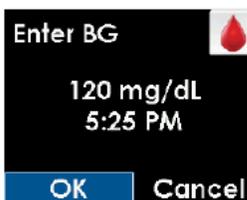
- “Enter BG” will be the second Main Menu option when you are in the middle of a sensor session.
5. Press the **SELECT** button to choose this option. You will see a screen with a blood drop and a number in mg/dL units.
    - a. When the receiver does not have a recent sensor glucose reading the default is 120 mg/dL.



Enter BG screen,  
default is 120 mg/dL

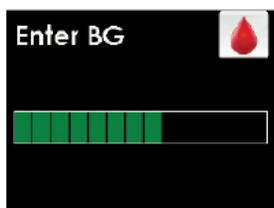
- b. If there has been a sensor glucose reading in the past 15 minutes, the Enter BG screen shows your current sensor glucose reading. **Do not use the current sensor glucose reading for calibration.** Use only blood glucose values from your meter.
6. Use the **UP** or **DOWN** button to scroll until 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, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.

## **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**

Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

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 startup 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 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.**

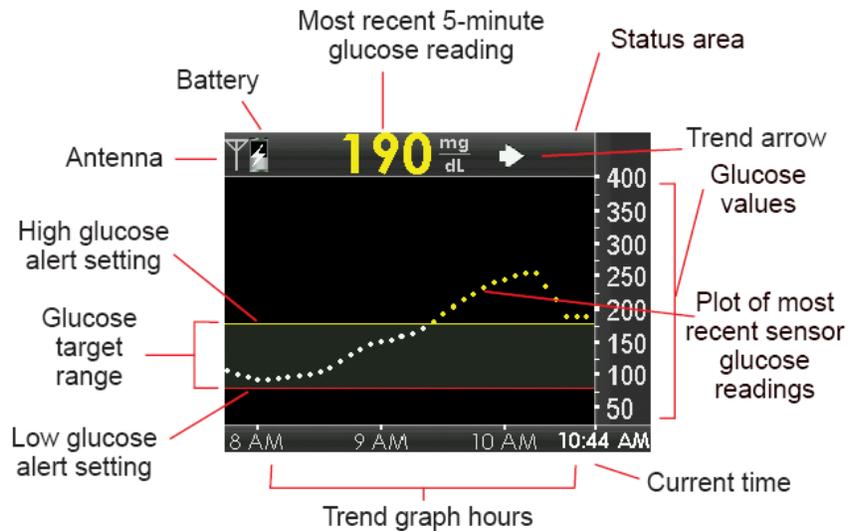
If you have trouble reading your receiver in bright sunlight, find a shady spot.

### WARNING

Do not use the Dexcom G4 PLATINUM System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM 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. Using the sensor glucose readings for treatment decisions could lead to low or high blood glucose value.

## 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.

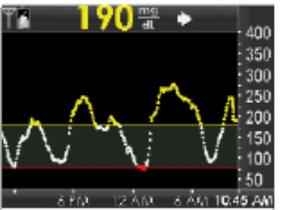
- Your system only reports glucose information between 40-400 mg/dL. Your trend graph shows a flat line or dots at 400 or 40 mg/dL when your glucose is outside this range.



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

### Which Trend Graph Do You See?

(Scroll up from the 3-hour graph to reach the 1-hour graph)

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

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

	<b>Constant:</b> 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.
	<b>Slowly rising:</b> 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.
	<b>Rising:</b> 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.
	<b>Rapidly rising:</b> 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.

	<b>Slowly falling:</b> 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.
	<b>Falling:</b> 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.
	<b>Rapidly falling:</b> 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.
<b>No arrow</b>	<b>No rate of change information:</b> 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 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, so you do not miss a low or high blood glucose value.

## 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

 <p>Calibration Needed</p>	<p>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).</p>
 <p>Additional Calibration Needed</p>	<p>This symbol means you need to enter one more blood glucose value in order to calibrate the system and start getting sensor glucose readings.</p>
 <p>Glucose Reading Error</p>	<p>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 <b>do not enter</b> any blood glucose values when you see this symbol (see Chapter 13, Section 13.4, System Glucose Error for more information).</p>
 <p>Out of Range</p>	<p>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>
 <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

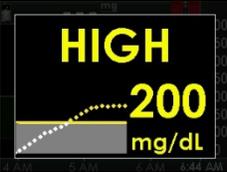
This chapter teaches you about your Dexcom G4 PLATINUM CGM System's many alerts and alarm and how to set them.

### 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?
	<b>High Glucose Alert</b> Your most recent sensor glucose reading is at or above the high alert setting.	On at 200 mg/dL	Vibrates two times then vibrates/beeps two 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.
	<b>Low Glucose Alert</b> Your most recent sensor glucose reading is at or below the low alert setting.	On at 80 mg/dL	Vibrates three times then vibrates/beeps three 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.
	<b>Low Glucose Alarm</b> Your most recent sensor glucose reading is at or below 55 mg/dL.	On	Vibrates 4 times, then vibrates/beeps 4 times every five 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><b>Out of Range Alert</b> The sensor/transmitter and receiver are not communicating to each other.</p>	Off	The alert will not notify you. You must change the settings to receive this alert.	No
	<p><b>Rise/Fall Alert Single Arrow</b> Your glucose is rising/falling at or above a rate of 2 mg/dL/min (at least 30 mg/dL in 15 minutes).</p>	Off	The alert will not notify you. You must change the settings to receive this alert.	No
	<p><b>Rise/Fall Alert Double Arrow</b> Your glucose is rising/falling at or above a rate of 3 mg/dL/min (at least 45 mg/dL in 15 minutes).</p>	Off	The alert will not notify you. You must change the settings to receive this alert.	No

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 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 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.

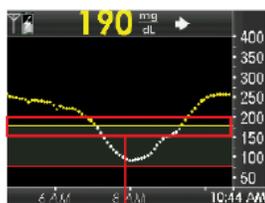
When you have both your high and low alerts turned on, a gray zone on your trend graph shows your target range.

### 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

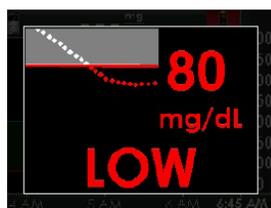


High glucose alert setting

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).

### 9.1.2.2 LOW GLUCOSE ALERT

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 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.

- The receiver displays the low glucose alarm screen.

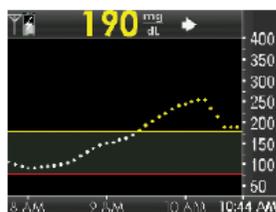


Low glucose alarm

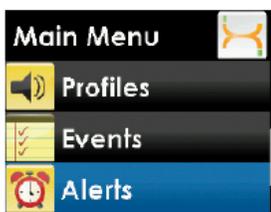
- Re-alarm: The receiver automatically alerts again 30 minutes after you press the **SELECT** button to clear it, if your sensor glucose readings are still at or below 55 mg/dL.
- Your receiver does not alert if you have a sensor glucose reading outside your target range and you calibrated in the last 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

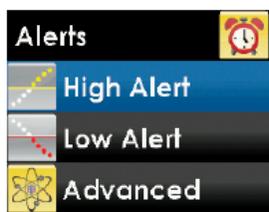
1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph shows.
2. Press the **SELECT** button to see the Main Menu.
3. From the Main Menu, press the **UP** or **DOWN** button to scroll to “Alerts,” and press the **SELECT** button. The Alerts menu shows.



Trend graph



Main Menu,  
Alerts highlighted

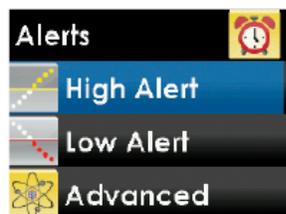


Alerts menu,  
High Alert highlighted

### 9.1.4 HIGH AND LOW GLUCOSE ALERTS

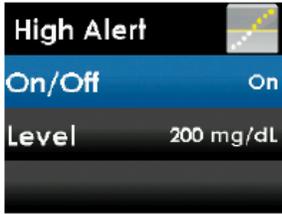
The steps for setting both the high alert and the low alert are the same. The following steps show you how to change your high and low alert settings.

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



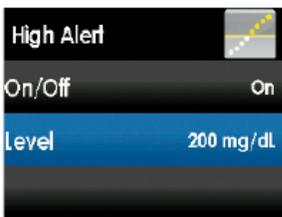
Alerts menu,  
High Alert highlighted

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



High 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 high glucose alert level.



High Alert menu,  
Level highlighted

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



High Alert setting screen,  
200 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. Press the **LEFT** button to 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

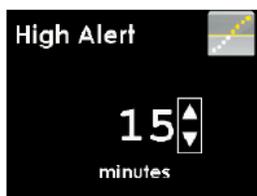
The snooze feature lets you delay your high and low glucose re-alerts. You have the option to set a snooze time for every 15 minutes for up to 5 hours.

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.

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

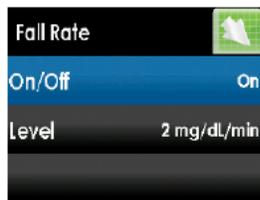
These steps show how to change your rise or fall rate alert settings.

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.



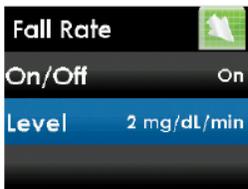
Fall Rate menu,  
On/Off highlighted

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



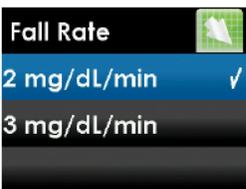
Fall Rate menu,  
On selected

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.



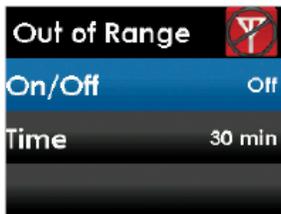
Out of Range  
alert screen

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 alerts 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.

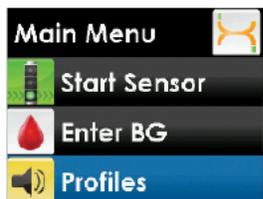


Out of Range setting screen,  
20 minutes selected

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

## 9.3 ALERT PROFILES

The Dexcom G4 PLATINUM 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 to hear an example of each alert and alarm.

### 9.3.2 ALERT PROFILE DETAILS

PROFILE TYPE	VIBRATE 	SOFT 	NORMAL 	ATTENTIVE 	HYPOREPEAT 
<b>High Alert</b> 	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
<b>Low Alert</b> 	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
<b>Rise Alert</b> 	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
<b>Fall Alert</b> 	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
<b>Out of Range Alert</b> 	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
<b>Fixed Low</b>	4 short	4 short	4 short vibrates	4 short vibrates	4 short vibrates

	vibrates + 4 medium tone beeps	vibrates + 4 medium tone beeps	+ 4 medium tone beeps	+ 2 long descending melodies + pause + 4 low beeps	+ 4 low beeps + pause + repeat sequence
<b>All Other Alerts</b>	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

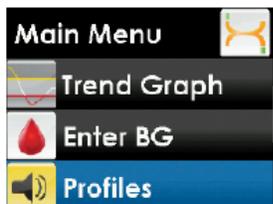
These steps show you how to select the profile you want.

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



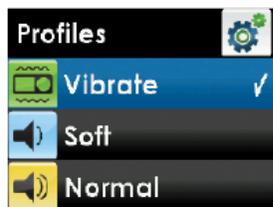
Trend graph

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

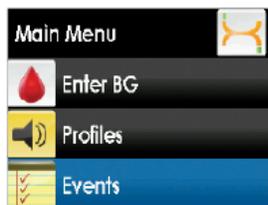
1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph will show.



Trend graph

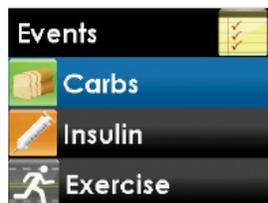
2. Press the **SELECT** button to see the Main Menu.

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

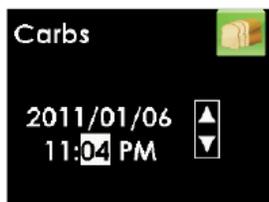
#### 10.1.2 SETTING THE DATE AND TIME FOR AN EVENT

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.

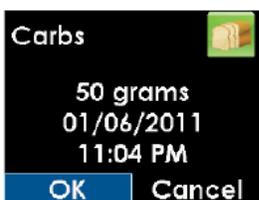
To change the date and time for an event:

1. Press the **RIGHT** button to highlight each value in the date and time.



Carbs setting screen,  
minutes highlighted

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

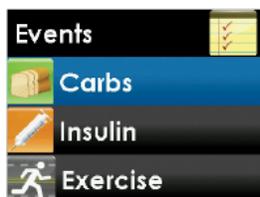


Carbs setting screen,  
OK highlighted

### 10.1.3 CARBOHYDRATES

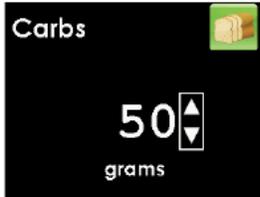
The Carbs event lets you enter the amount of carbohydrates you have taken, up to 250 grams.

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



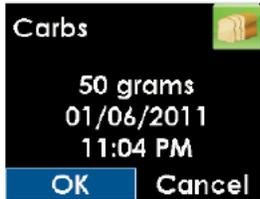
Events menu,  
Carbs highlighted

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.

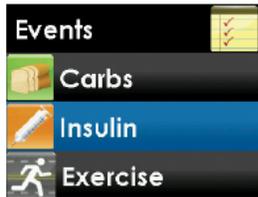


Carbs setting screen,  
OK highlighted

## 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

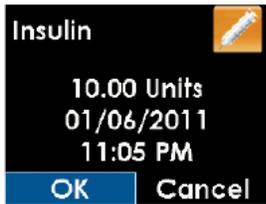
2. Press the **UP** or **DOWN** button to enter your insulin amount (0-250 units), and press the **SELECT** button.
  - The number that shows on this screen is the last number you entered or the default amount of 10 units.



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.

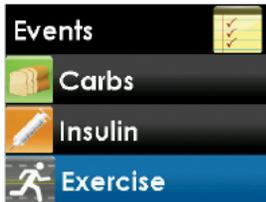


Insulin setting screen,  
OK highlighted

## 10.1.5 EXERCISE

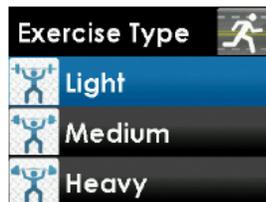
The exercise event lets you enter intensity (light, medium, or heavy) and duration (up to 360 minutes).

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



Events menu,  
Exercise highlighted

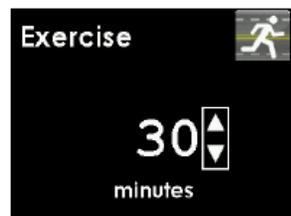
2. Press the **UP** or **DOWN** button to choose your exercise intensity level, and press the **SELECT** button.



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](http://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:

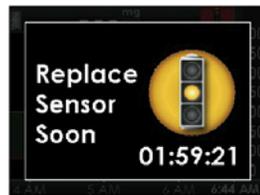
- Do not remove the transmitter from the sensor pod while the pod is attached to your skin.
- Consult your local waste management authorities for instructions to dispose of blood contacting parts (sensor and applicator).
- In some cases, your sensor session may end before you have finished a full 7-day 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

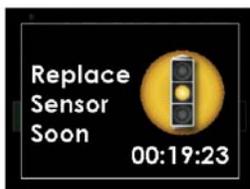
The receiver tells you how much time you have left until your sensor session is complete. The Replace Sensor screen shows at 6 hours, 2 hours and 30 minutes before your 7-day sensor session ends.



6-hour Replace Sensor



2-hour Replace Sensor



30-minute Replace Sensor

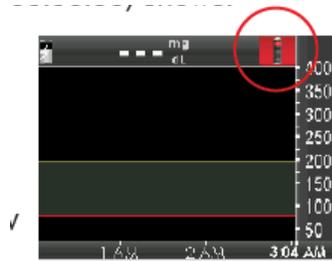


Replace Sensor  
end of session

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.

You must remove your sensor and insert a new sensor.



Trend graph with red stoplight in upper right

## 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 24 hours a day, 7 days a week.**

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 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 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 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:**

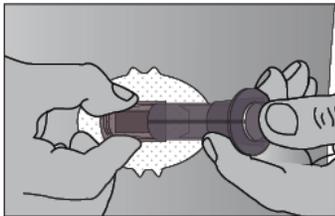
- Make sure to pull the safety lock straight out away from your body. Use the arrows on the safety lock as a guide.

- **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:**

- 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.



Release the applicator barrel

- 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 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.

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

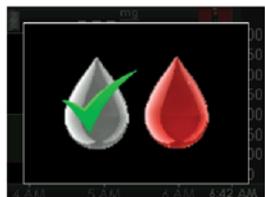


Startup calibration prompt

#### Additional startup calibration prompt

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

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

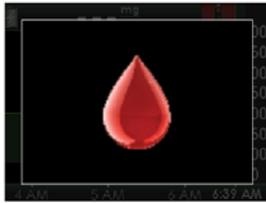


Additional startup calibration prompt

#### 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.

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



Calibration prompt

## 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.

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.



Wait 1 hour  
calibration error screen

## 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.

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).



No glucose data (  )



No glucose data (  )

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 icons 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.

### WARNING

Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

### PRECAUTION

To calibrate the system, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.

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.

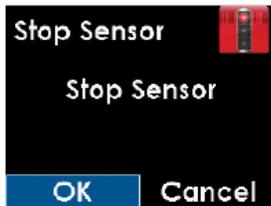


Main Menu,  
Stop Sensor highlighted

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.

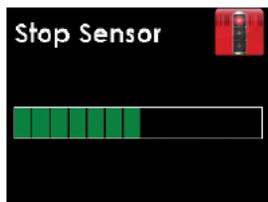
Stop your sensor session if you remove your sensor before the end of the full 7 -day period.

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.



## 13.7 SHARE PAIRING ERROR TROUBLESHOOTING

This screen means you recently turned Share “On,” and your Receiver is having trouble connecting with your iPhone or iPod touch. If you press the “Ok” button to clear this screen, you will be taken back to the Share menu and Share will be turned “Off.” Turn Share “On” to try pairing again. For more information on how to troubleshoot your Dexcom Share System, refer to the Dexcom Share User Manual.



Share unsuccessful pairing prompt

If you are not using the Share feature, you should leave Share turned “Off”.

## 13.8 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).

## 13.9 RECEIVER AND TRANSMITTER COMMUNICATION TROUBLESHOOTING

### 13.9.1 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

### 13.9.2 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.**

### 13.9.3 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

### 13.9.4 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

## 13.10 OUT OF RANGE/NO ANTENNA

### PRECAUTION

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 you might miss a low or high blood glucose value.

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).

## 13.11 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 speakers 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

[Section 14.1 will be updated to reflect the labeling changes approved for P120005/S018]

### 14.1 DEVICE PERFORMANCE CHARACTERISTICS

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

The Dexcom G4 PLATINUM 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 real use environment.

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

#### CLINICAL STUDY OVERVIEW

The System performance was evaluated in two separate prospective clinical studies: the **Original** Receiver Software Study (SW10050) and the **Advanced** 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, and the number of clinic days each subject participated in 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** Study or **Advanced** Study from this point forward.

The **Original** Study enrolled 72 subjects, and the **Advanced** 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** Study, 83% of subjects had Type 1 diabetes, and 17% of subjects had Type 2 diabetes. In the **Advanced** 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.

## 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.
3. Scroll down to see:

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

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



Subjects in both studies used the System for seven days. In the **Original** Study, thirty-six subjects each wore 2 sensors; in the **Advanced** Study, all subjects wore 1 sensor only. Throughout the 7-day wear period, the sensor was calibrated with an average of 2 fingersticks per day (approximately once every 12 hours). In the **Original** Study, subjects used the LifeScan<sup>®</sup> OneTouch<sup>®</sup> Ultra<sup>®</sup>2 meter and in the **Advanced** Study, subjects used Bayer's CONTOUR<sup>®</sup> NEXT USB meter.

In the **Original** 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 **Advanced** Study, subjects were evaluated in one of the three clinic days so there are fewer data samples than in the **Original** Study. While using the System in the clinic, subjects had their blood glucose measured every 15 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus<sup>™</sup> Glucose Analyzer. This instrument is referred to as the “YSI.” Readings from the System were reported every 5 minutes and paired with YSI values 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.”

**Table 1. System Agreement to YSI within CGM Glucose Ranges**

CGM Glucose Range <sup>1</sup> (mg/dL)	Study <sup>2</sup>	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%
	Advanced	2263	86%	93%	98%	1%
40-60	Original	512	67%	78%	88%	6%
	Advanced	120	89%	94%	98%	0%
61-80	Original	781	73%	85%	94%	2%
	Advanced	226	91%	96%	99%	0%
81-180	Original	3853	67%	78%	91%	3%
	Advanced	738	84%	92%	98%	1%
181-300	Original	2784	72%	84%	93%	4%
	Advanced	798	86%	93%	98%	1%
301-350	Original	775	82%	91%	97%	2%
	Advanced	229	86%	94%	98%	1%
351-400	Original	447	74%	84%	91%	5%
	Advanced	152	80%	92%	97%	0%

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

<sup>2</sup> Both sets of study data are presented and are labeled as **Original** (SW10050) or **Advanced** (SW10505).

### 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. TABLE 1 IS CATEGORIZED WITHIN CGM GLUCOSE RANGES. WHEN YOU SEE A CGM READING ON YOUR RECEIVER, THIS TABLE SHOWS YOU HOW LIKELY THAT READING MATCHES YOUR BLOOD GLUCOSE LEVEL (MEASURED BY YSI IN THE STUDY).

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

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

**Table 2. Number and Percentage of YSI Values When CGM Readings are “Low” or “High”**

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

<sup>1</sup> Both sets of study data are presented and are labeled as **Original** (SW10050) or **Advanced** (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 Dexcom G4 PLATINUM System determines that the glucose level is above 400 mg/dL, it displays “HIGH” in the Receiver Status Box. Because the System does not display glucose values below 40 mg/dL or above 400 mg/dL, the comparisons to the actual blood glucose levels (as determined by the YSI analyzer) when CGM is classified as “LOW” or “HIGH” are included separately in Table 2. The table includes the numbers and the cumulative percentages when YSI values were less than certain glucose levels (for “LOW”), and when YSI values were greater than certain glucose levels (for “HIGH”).

**ORIGINAL 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.

**ADVANCED 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 3-A. Concurrence of CGM Readings and YSI Values (Original 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-B. Concurrence of CGM Readings and YSI Values (Advanced 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

**Concurrence of System and Laboratory Reference**

Tables 3-A and 3-B are categorized by ranges of CGM glucose readings. This table describes, 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 **Advanced** 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 72% of time.

## 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** and **Advanced** Studies are based on 9152 and 2263 paired glucose results, respectively; the data are summarized in Table 4. Table 4 is categorized within CGM glucose ranges.

**Original 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.

**Advanced 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. System Difference to YSI within CGM Glucose Ranges**

CGM Glucose Ranges <sup>1</sup> (mg/dL)	Receiver Software <sup>2</sup>	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%
	Advanced	2263	2.5%	2.4%	9.0%	7.0%
*40-60	Original	512	-10.0	-8.2	13.5	9.7
	Advanced	120	-3.3	-2.1	6.9	4.8
*61-80	Original	781	-2.4	-0.4	11.4	8.6
	Advanced	226	0.8	1.4	6.7	5.4
81-180	Original	3853	4.8%	3.0%	13.8%	9.8%
	Advanced	738	3.9%	4.1%	9.6%	8.2%
181-300	Original	2784	2.1%	0.0%	11.9%	9.2%
	Advanced	798	0.6%	0.4%	8.0%	6.1%
301-350	Original	775	3.8%	2.8%	9.8%	7.9%
	Advanced	229	4.1%	3.4%	8.0%	5.8%
351-400	Original	447	10.4%	7.7%	12.8%	9.1%
	Advanced	152	7.2%	6.3%	9.2%	7.2%

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

<sup>2</sup> Both sets of study data are presented and are labeled as **Original** (SW10050) or **Advanced** (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.

### The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Table 5.

#### Hypoglycemia Alert Rate

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

For example, if you set the Low Glucose Alert to 70 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be low? Based on the **ORIGINAL** Study, if your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 79% of the time and not be below 70 mg/dL approximately 21% of the time within the 15 minute period before or after your alarm sounds. Based on the **ADVANCED** Study, if your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 92% of the time and not be below 70 mg/dL approximately 8% 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 % of time the blood glucose level was at or below the alert setting and device alarmed within 15 minutes before or after the blood glucose was at or below the alert settings. The Hypoglycemia Missed Detection Rate is the % of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 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** Study, if your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 83% of the time and not to sound approximately 17% of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL. Based on the **ADVANCED** Study, if your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 91% of the time and not to sound approximately 9% of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL.

**Table 5. Hypoglycemic Alert Evaluation**

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

<sup>1</sup> Both sets of study data are presented and are labeled as **Original** (SW10050) or **Advanced** (SW10505).

## The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Table 6.

### Hyperglycemia Alert Rate

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

For example, if you set the High Glucose alert to 200 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be high? Based on the **ORIGINAL** Study, if your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 92% of the time and not be above 200 mg/dL approximately 8% of the time within the 15 minute period before or after your alarm sounds. Based on the **ADVANCED** Study, if your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 96% of the time and not be above 200 mg/dL approximately 4% of the time within the 15 minute period before or after your alarm sounds.

### Hyperglycemia Detection Rate

The Detection Rate 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 % of time the blood glucose level was at or above the alert setting and the device alarmed within 15 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the % of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 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 97% of the time and not to sound approximately 3% of time within the 15 minute period before or after your blood sugar goes above 200 mg/dL. Based on the **ADVANCED** 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 time within the 15 minute period before or after your blood sugar goes above 200 mg/dL.

**Table 6. Hyperglycemic Alert Evaluation**

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

<sup>1</sup> Both sets of study data are presented and are labeled as **Original** (SW10050) or **Advanced** (SW10505).

**Table 7. Percentage of System Readings<sup>1</sup> within YSI Values with Data Stratified in 2-Hour Increments after Calibration**

Time from Calibration	Study <sup>2</sup>	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
0-2 hours	Original	1929	78%	88%	96%	2%
	Advanced	469	93%	97%	99%	0%
2-4 hours	Original	1516	69%	81%	91%	4%
	Advanced	389	90%	97%	99%	0%
4-6 hours	Original	1547	69%	79%	91%	5%
	Advanced	383	85%	91%	97%	2%
6-8 hours	Original	1520	68%	79%	92%	3%
	Advanced	380	79%	90%	97%	2%
8-10 hours	Original	1555	71%	82%	92%	4%
	Advanced	347	83%	92%	98%	0%
10-12 hours	Original	1068	65%	77%	91%	4%
	Advanced	295	80%	90%	98%	0%
12-14 hours	Original	17	65%	76%	82%	12%
	Advanced	0	--	--	--	--

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

<sup>2</sup> Both sets of study data are presented and are labeled as **Original** (SW10050) or **Advanced** (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%, 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values in Table 7.

**Table 8. Sensor Stability (Accuracy<sup>1</sup> over Time)**

Day of Wear	Study <sup>2</sup>	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%
	Advanced	680	10.7%	7.9%	77%	84%	96%	2%
Day 4	Original	3108	11.4%	8.2%	77%	87%	95%	2%
	Advanced	777	8.0%	6.4%	89%	96%	99%	0%
Day 7	Original	3021	11.9%	8.9%	76%	87%	95%	2%
	Advanced	806	8.5%	7.2%	90%	97%	99%	0%

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

<sup>2</sup> Both sets of study data are presented and are labeled as **Original** (SW10050) or **Advanced** (SW10505).

## Sensor Stability

Sensors can be worn for up to 7 days. To verify sensor performance over time, 72 subjects were evaluated with the **Original** System across the 7-day wear period while 50 subjects were evaluated with the **Advanced** System across the 7-day wear period. 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% , 40 mg/dL or 40% 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 showing consistent accuracy and sensor stability over the 7-day life of the sensor.

## Precision of System Readings

In the **Original** Study, 36 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 9% (absolute percent difference) with a 7% coefficient of variation. Only one System was worn in the **Advanced** 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, 108 sensors were evaluated with the **Original** Study 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 **Advanced** 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.

**Table 9. Number of Readings Provided by Each Sensor Over 7-Days**

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

<sup>1</sup> BOTH SETS OF STUDY DATA ARE PRESENTED AND ARE LABELED AS **ORIGINAL** (SW10050) OR **ADVANCED** (SW10505).

**Table 10. System Readings Within Wear Days**

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

<sup>1</sup> Both sets of study data are presented and are labeled as **Original** (SW10050) or **Advanced** (SW10505).

<sup>2</sup> A total of 108 sensors were included with the **Original** Study and 51 sensors were included with the **Advanced** Study.

### 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.” Table 9 estimates the number of readings you can expect to receive from the System over the entire 7-day period after calibration. For the **Original** 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** System provided an average of 97% of all expected glucose readings (288) as seen in Table 10.

For the **Advanced** 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 **Advanced** System provided an average of 98% of all expected glucose readings (288) as seen in Table 10.

**Table 11. CGM System Agreement to SMBG within CGM Glucose Ranges**

CGM Glucose Ranges <sup>1</sup> (mg/dL)	Study <sup>2</sup>	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%
	Advanced	2992	77%	87%	96%	1%
40-60	Original	731	75%	84%	92%	4%
	Advanced	221	73%	80%	87%	7%
61-80	Original	968	78%	86%	95%	1%
	Advanced	336	77%	85%	95%	1%
81-180	Original	3141	65%	78%	93%	2%
	Advanced	1362	74%	85%	96%	1%
181-300	Original	1960	68%	81%	94%	3%
	Advanced	826	80%	90%	97%	1%
301-350	Original	450	77%	88%	98%	1%
	Advanced	161	83%	93%	99%	0%
351-400	Original	258	75%	85%	95%	2%
	Advanced	86	90%	93%	98%	1%

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

<sup>2</sup> Both sets of study data are presented and are labeled as **Original** (SW10050) or **Advanced** (SW10505).

### 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. 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.

Table 11 is 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%, 40 mg/dL or 40% 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 78% of the time for the **Original** System and 85% time for the **Advanced** System.

**Table 12. CGM System Difference to SMBG within CGM Glucose Ranges**

CGM Glucose Ranges <sup>1</sup> (mg/dL)	Study <sup>2</sup>	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	<b>Original</b>	7508	-0.4%	-1.4%	14.0%	11.0%
	<b>Advanced</b>	2992	-2.6%	-2.7%	11.3%	8.6%
*40-60	<b>Original</b>	731	-9.3	-8.0	11.7	8.0
	<b>Advanced</b>	221	-10.3	-6.0	13.0	8.0
*61-80	<b>Original</b>	968	-1.0	1.0	10.7	8.0
	<b>Advanced</b>	336	-4.0	-2.0	10.1	7.0
81-180	<b>Original</b>	3141	1.4%	0.0%	14.2%	11.0%
	<b>Advanced</b>	1362	-2.6%	-3.1%	11.4%	8.9%
181-300	<b>Original</b>	1960	-0.7%	-2.8%	13.0%	10.3%
	<b>Advanced</b>	826	-1.4%	-2.0%	9.5%	7.4%
301-350	<b>Original</b>	450	-0.7%	-2.6%	10.5%	8.6%
	<b>Advanced</b>	161	-0.0%	0.0%	8.3%	6.0%
351-400	<b>Original</b>	258	5.0%	3.0%	11.9%	8.6%
	<b>Advanced</b>	86	3.9%	3.2%	8.1%	6.7%

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

<sup>2</sup> Both sets of study data are presented and are labeled as **Original** (SW10050) or **Advanced** (SW10505).

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

Table 12 is categorized within CGM glucose ranges. Overall, the System in the **Original** 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 **Advanced** 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 than the SMBG values and the Median Absolute Percent Difference shows that half of the time the System reads about 8.6% or less different than SMBG values.

## Adverse Events

No serious adverse events or device-related serious adverse events occurred during either study. Mild or very slight skin irritation, such as erythema or edema, occurred in low frequency around the adhesive area. No infection, bruising, or bleeding occurred at the sensor needle insertion area or the adhesive area.

## 14.2 PRODUCT SPECIFICATIONS

### Sensor Product Specifications

<b>Glucose Range</b>	40 - 400 mg/dL
<b>Sensor Life</b>	Up to 7 days
<b>Calibration</b>	Commercially available blood glucose meter
<b>Calibration Range</b>	40 - 400 mg/dL
<b>Storage Condition</b>	Temperature: 36° F - 77° F Humidity: 15% - 85% RH
<b>Sterilization</b>	Sterile by radiation

### Transmitter Product Specifications

<b>Part Number</b>	9438-01	9438-05
<b>Dimensions (including sensor pod)</b>	Length: 1.5 inches Width: 0.9 inches Thickness: 0.5 inches	Length: 1.5 inches Width: 0.9 inches Thickness: 0.4 inches
<b>Weight (including sensor pod)</b>	0.4 ounces	0.3 ounces
<b>Power Supply</b>	Silver oxide batteries (not replaceable)	
<b>Operational Conditions</b>	Temperature: 50° F - 108° F Humidity: 10% - 95% RH	
<b>Storage Conditions</b>	Temperature: 32° F - 113° F Humidity: 10% - 95% RH	
<b>Operating Altitude</b>	-500 to 12000 feet	
<b>Limited Warranty</b>	6 months	

<b>Moisture Protection</b>	IP28: temporary submersion
<b>Protection Against Electrical Shock</b>	Type BF applied part

### Transmitter Performance Characteristics

Parameter	Performance Characteristics
<b>TX/RX Frequencies</b>	2.424 999 877 GHz 2.449 993 677 GHz 2.474 737 539 GHz 2.477 236 919 GHz
<b>Bandwidth</b>	334.7 kHz
<b>Maximum Output Power</b>	1.25 mW EIRP
<b>Modulation</b>	Minimum Shift Key
<b>Data Rate</b>	49.987 Kbits/Sec
<b>Total Packet</b>	224 bits
<b>Transmit Duty Cycle</b>	4.48 ms every 5 minutes at each of the four TX frequencies.
<b>Data Detection Range</b>	20 feet

The Dexcom G4 PLATINUM 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).

### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter (P/N 9438-01 and P/N 9438-05) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

### Transmitter Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
<b>Electrostatic Discharge (ESD) IEC 61000-4-2</b>	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the

			relative humidity should be at least 30%
<b>Electrical Fast Transient /burst</b>	± 2 kV for power supply lines	Not applicable	
<b>IEC 61000-4-4</b>	± 1 kV for input/output lines	Battery operated	
<b>Surge IEC 61000-4-5</b>	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable Battery operated	
<b>Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11</b>	< 5% $U_T$ (> 95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles < 5% $U_T$ (> 95% dip in $U_T$ ) for 5 sec	Not applicable Battery operated	
<b>Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8</b>	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**NOTE:**  $U_T$  is the a.c. mains voltage prior to application of the test level.

### Receiver Product Specifications

<b>Part Number</b>	MT22495
<b>Reading Frequency</b>	Every 5 minutes
<b>Dimensions</b>	Length: 4.0 inches Width: 1.8 inches Thickness: 0.5 inches
<b>Weight</b>	2.4 ounces
<b>Receiver Input</b>	5V DC, 1A

<b>Power Supply</b>	MT21255
<b>Communication Range</b>	20 feet
<b>Memory Storage</b>	30 days of glucose data, 7 days of tech support data
<b>Re-Chargeable Battery Use</b>	3 days
<b>Charging Time</b>	3 hours wall outlet, 5 hours powered USB
<b>Charging Temperature Condition</b>	Temperature: 32° F - 104° F
<b>Storage/Operating Conditions</b>	Temperature: 32° F - 113° F Humidity: 10% - 95% RH
<b>Operating Altitude</b>	-500 to 12000 feet
<b>Moisture Protection</b>	IP22: vertically falling drops
<b>Limited Warranty</b>	1 year
<b>Control Classification</b>	Class II equipment

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The receiver (P/N MT22495) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the receiver should ensure that it is used in such an environment.

### Receiver Electromagnetic Immunity Specifications

<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Receiver Compliance Level</b>	<b>Electromagnetic Environment Guidance</b>
<b>Electrostatic Discharge (ESD)</b> <b>IEC 61000-4-2</b>	± 6 kV Contact ± 8 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
<b>Electrical Fast Transient /burst</b> <b>IEC 61000-4-4</b>	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
<b>Surge</b> <b>IEC 61000-4-5</b>	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
<b>Voltage Dips, Short</b>	< 5% U <sub>T</sub>	< 5% U <sub>T</sub>	Mains power quality

<b>Interruptions and Voltage Variations on Power Supply Input Lines</b>	(> 95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles	(> 95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles	should be that of a typical commercial or hospital environment.
<b>IEC 61000-4-11 IEC 60601-1-11</b>	70% $U_T$ (30% dip in $U_T$ ) for 25 cycles 85% $U_T$ (15% dip in $U_T$ ) for 5 sec < 5% $U_T$ (> 95% dip in $U_T$ ) for 5 sec	70% $U_T$ (30% dip in $U_T$ ) for 25 cycles 85% $U_T$ (15% dip in $U_T$ ) for 5 sec < 5% $U_T$ (> 95% dip in $U_T$ ) for 5 sec	
<b>Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8</b>	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**NOTE:**  $U_T$  is the a.c. mains voltage prior to application of the test level.

### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Dexcom G4 PLATINUM System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the Dexcom G4 PLATINUM System should ensure that it is used in such an environment.

### System Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
<b>Conducted RF IEC 61000- 4-6 (Receiver only)</b>	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the receiver, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended Separation Distance</b> $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz
<b>Radiated RF IEC 61000-4-3</b>	3 V/m 80 MHz to 2.5 GHz	20 V/m 80 MHz to 2.4 GHz  10 V/m 2.4 GHz to 2.5 GHz	

			<p><math>d = 1.2 \sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.3 \sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup> should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with following symbol:</p> 
--	--	--	---

**NOTE 1:** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Dexcom G4 PLATINUM System is used exceeds the applicable RF compliance level above, the Dexcom G4 PLATINUM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Dexcom G4 PLATINUM System.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

### Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

The Dexcom G4 PLATINUM System is intended for use in the electromagnetic environment specified below. The customer or the user of the Dexcom G4 PLATINUM System should ensure that it is used in such an environment.

### Electromagnetic Emissions Specifications

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The Dexcom G4 PLATINUM System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely

		to cause any interference in nearby electronic equipment.
<b>RF emissions CISPR 11</b>	Class B	The Dexcom G4 PLATINUM System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
<b>Harmonic emissions IEC 61000-3-2</b>	Not applicable	
<b>Voltage fluctuations/flicker emissions IEC 61000-3-3</b>	Not applicable	

### Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Receiver

The receiver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the receiver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the receiver as recommended below, according to the maximum output power of the communications equipment. Portable and mobile RF equipment include: baby monitors, Bluetooth wireless headsets, wireless routers, microwave ovens, laptops with internal wi-fi adapters, GSM cell phones, RFID scanners and hand-held security metal detector often used by security screeners.

#### Minimum Recommended Distance Between Transmitter and Receiver

Rated maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 P^{1/2}$	80 MHz to 800 MHz $d = 1.2 P^{1/2}$	800 MHz to 2.5 GHz $d = 2.3 P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in feet can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

**NOTE 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

### USB Charging/Download Cable\* Specifications

<b>Dexcom P/N</b>	MT20655
<b>Input/Output</b>	5V DC, 1A
<b>Type</b>	USB A to USB micro B

<b>Length</b>	3 feet
---------------	--------

\* The power supply/charger can be connected to the USB charging/download cable for charging using an AC power outlet.

### Power Supply/Charger Specifications

<b>Dexcom P/N</b>	MT21255
<b>Class</b>	II
<b>Input:</b>	AC Input 100-240 Vac, 50/60Hz, 0.2A, 0.2A rms at 100Vac
<b>DC Output:</b>	5V DC, 1A (5.0 Watts)

## 14.3 FCC REQUIREMENTS

The transmitter covered by this user's guide has been certified under FCC ID: PH29433. The receiver has been certified under FCC ID: PH29495.

Although the transmitter and receiver have been approved by the Federal Communications Commission, there is no guarantee that they will not receive interference or that any particular transmission from the transmitter or receiver will be free from interference.

### Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

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

### Warning (Part 15.21)

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

### FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

## 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 issues<sup>8</sup>.

**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

<sup>8</sup> Dexcom Technical Support does not offer medical advice

## **CHAPTER 16: WARRANTY**

### **Dexcom G4 PLATINUM 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 Receiver with Share 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 Receiver with Share: 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 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 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 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 CGM System User's Guide, a copy of which was included with your Dexcom G4 PLATINUM CGM System and may be found at [www.dexcom.com](http://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 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 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 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 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](http://www.tsa.gov)

E-mail: [TSA-ContactCenter@dhs.gov](mailto:TSA-ContactCenter@dhs.gov)

Phone: Call 1.866.289.9673

## CHAPTER 18: APPENDIX

### APPENDIX I, RECEIVER ALERTS, ALARM AND PROMPTS

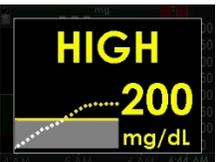
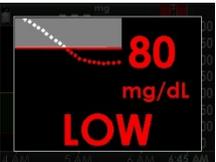
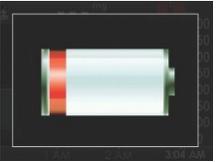
The following tables describe the alarm, alerts and prompts and how the receiver notifies you.

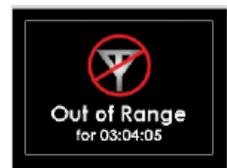
**Prompt** - Shows on screen only. Silent, no vibrate or beep.

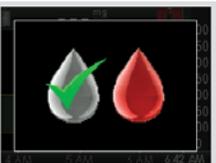
**Alert** - Notifies with vibrate and beep depending on your profile settings.

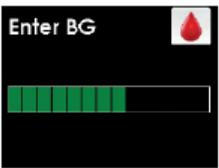
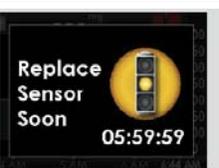
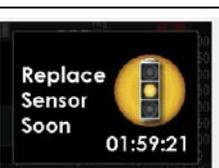
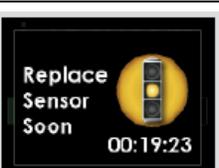
**Alarm** - Low 55 - Notifies with vibrate and beep. Cannot be changed.

#### 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 four times and then vibrates/beeps four 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 two times and then vibrates/beeps two times every 5 minutes until confirmed or your glucose value drops below the alert level.	No, unless you have turned on the high snooze feature. See Chapter 9, Section 9.2, Advanced Alerts.
	Low glucose alert	Your most recent sensor glucose reading is at or below the low alert setting.	Vibrates three times and then vibrates/beeps three 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 one 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.
	Unknown sensor prompt	The sensor is sending sensor glucose readings that the receiver does not understand. You will not receive sensor glucose readings.	Symbol in status area only.	N/A
	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	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	No

		glucose readings appear on the 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 and 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	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	Yes, every 15 minutes.

		calibration.		
	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.	Vibrate 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 Dexcom Technical Support.	Vibrates 1 time (4 seconds) + 4 beeps.	No
	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 then vibrates/beeps every 5 minutes (2 repeats max).	No
	Share unsuccessful pairing prompt	Your Receiver is having trouble connecting with your iPhone or iPod touch via Bluetooth.	Prompt screen only.	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

### A

Alarm, Low Glucose	93
Alerts	89
Glucose Alerts	91
High	92
Low	92
Setting	94
Not Working	139
Out of Range	138
Setting	98
Profiles	100
Setting	103
Rise and Fall (Rate of Change)	96
Setting	97
Alternative Site Testing (BG)	6
Antenna Symbol	47
Missing	138
Arrows, Trend (Rate of Change)	81

### B

Battery, Receiver	33
Charging	33
Troubleshooting	136
Battery, Transmitter	138
Benefits	28
Blood Glucose (BG) Meter	6
Blood Glucose (BG) Value	6
Bluetooth	##

### C

Calibration	67
Calibration Update	73
How to Calibrate	69
Prompts	129
Re-Calibration	73
Startup Calibration	72
Troubleshooting	128
Charging, Receiver	33

Troubleshooting	136
Contact Information, Dexcom	179
Sales Support	179
Technical Support	179
Website	179
Contents, Dexcom G4 PLATINUM CGM System Kit	11
<b>D</b>	
Device Information	45
Dexcom Studio Software	113
<b>E</b>	
Events, Diabetes	107
Carbohydrates	109
Exercise	111
Health	112
Insulin	110
<b>G</b>	
Glucose Data Gaps	6
Glucose Trends	6
<b>M</b>	
Maintenance, System	123
Menu Options	36
<b>R</b>	
Radio-Frequency (RF)	8
Range	7
Receiver	7
Charging your	33
Menu Options	36
Overview	15
Pairing with Transmitter	44
Prompts and Notifications	195
Trend Screen, viewing	78
Settings	43
Temporary Shut Down	62
Risks	27

## S

Safety Information	19
Caution	24
Contraindications	20
Important User Information	19
Indications for Use	19
Warnings	20
Precautions	22
Sensor	8
Applicator	6, 13
Automatic Shut-Off	117
Expiration Date	52
Failed	134
Insertion	51
Insertion Site	54
Overview	13
Pod	8, 13
Removing from Package	53
Sensor Failure	134
Starting a Session	59
Start-up Period	60
Stop Sensor (Manual Sensor Shut-Off)	135
Troubleshooting	127
Wire	13
Settings, Alerts	89
Settings, Receiver	43
Device Information	45
Date and Time	43
Transmitter ID	44
Setup Wizard	41
Share	##
Specifications, Product	162
Startup Period	60
Status Area	78
Symbols	84
Troubleshooting	128
Storage, System	123
Symbols, Labeling	209

## **T**

Tape	61
Transmitter	8
Attaching to Sensor	58
ID Number	8
Setting	44
Latch	8, 58
Overview	14
Pairing with receiver	44
Removal	119
Safety-Lock	8
Removing	56, 127
Using	119
Trend screen, receiver	78

## **W**

Warranty	181
Water Resistance	63

## 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 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
	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	<b>SB</b>	Ship By Date
	Keep Dry		MR Unsafe
	Bluetooth		

# Dexcom®



Dexcom, Inc.

6340 Sequence Drive  
 San Diego, CA 92121 USA  
 1.858.200.0200  
 1.877.339.2664  
[www.dexcom.com](http://www.dexcom.com)

LBL012528 Rev X02 MT22690

Stay Between the Lines