G4-Global Continuous Glucose Monitoring System

CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.

USER'S GUIDE

Dexcom™
THE GLUCOSE SENSOR COMPANY™

G4-Global Continuous Glucose Monitoring System

IMPORTANT CONTACTS AND NUMBERS

DexCom Website:	www.DexCom.com
Your Transmitter ID Number:	
Your Transmitter Expiration Date:	
Your Receiver ID:	
Your Healthcare Professional:	
Nearest Hospital:	
Other Notes:	

G4-GLOBAL CONTINUOUS GLUCOSE MONITORING SYSTEM

G4-Global Receiver

G4-Global Transmitter

G4-Global Sensor and Applicator

G4-GLOBAL CONTINUOUS GLUCOSE MONITORING SYSTEM KIT CONTENTS:

- Transmitter
- Receiver
- DexCom Studio® Accessory Software
- Receiver Charging Cable
- Receiver Case
- User's Guide
- Quick Start Guide

NOTE: Sensors are sold separately. Commercially distributed blood glucose meter required for use. Make sure to use the correct version of DexCom Studio® with your G4-Global System. The G4-Global Sensor works with the G4-Global family of products. The G4-Global Sensor, Transmitter and Receiver are not backwards compatible with the SEVEN/SEVEN® PLUS Transmitter and Receiver.

The G4-Global Continuous Glucose Monitoring System is a glucose-monitoring device indicated for detecting trends and tracking patterns in adults **(age 18 and older)** with diabetes.

DexCom would like to thank you for purchasing the G4-Global Continuous Glucose Monitoring System (G4-Global System)! When you use the G4-Global System, you will see real-time continuous glucose readings every 5 minutes for up to 7 days. These readings will help you detect trends and patterns in your glucose levels. Glucose trends let you see where your glucose levels have been, which direction your levels are headed, and how fast they may be rising or falling.

The G4-Global System is made up of three technologies that all work together: the Sensor, the Transmitter, and the Receiver. The Sensor is a disposable unit that you insert into your abdomen (belly) to continuously monitor your glucose levels for up to 7 days. The Transmitter is a reusable device that snaps into the Sensor Pod. Your Transmitter will wirelessly send your Sensor-measured glucose information to your Receiver. The Receiver is a hand-held device that receives and displays your glucose information every 5 minutes.

The Receiver displays your current glucose reading and shows your glucose trend information from the past 1-hour, 3-hour, 6-hour, 12-hour, and 24-hour periods. You will also see adjustable High and Low Glucose Alerts, and a Low Glucose ALARM to tell you when you are outside of your target glucose levels. Rise and Fall (Rate of Change) Alerts will let you know when your glucose levels are changing fast.

You can use any FDA-cleared blood glucose meter for calibration on the G4-Global System.

This User's Guide describes how to use your G4-Global System from start to finish of a continuous glucose monitoring session. Important safety information, warnings, precautions, cautions, and contraindications of the G4-Global System are described in the next few pages and throughout this guide. Be sure to read this entire User's Guide before beginning a continuous glucose monitoring session.

INDICATION FOR USE

The G4-Global Continuous Glucose Monitoring System is a glucose-monitoring device indicated for detecting trends and tracking patterns in adults **(age 18 and older)** with diabetes. The G4-Global System is intended for use by patients at home and in health care facilities. The device is for prescription use only.

The G4-Global Continuous Glucose Monitoring System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The G4-Global Continuous Glucose Monitoring 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 G4-Global System results should be based on the trends and patterns seen with several sequential readings over time.

IMPORTANT SAFETY INFORMATION

Read this entire guide before using your G4-Global Continuous Glucose Monitoring System. If you do not understand something or have any questions, please ask your Diabetes Management Team or another health care provider. Contraindications, warnings, precautions, cautions, and other important safety information can be found in this section and in boxes throughout your G4-Global System User's Guide. The Troubleshooting section (Chapter 9) contains important information on troubleshooting your G4-Global System. The Technical Information section (Chapter 11, Section 11.2) provides information on the performance characteristics of the device.

CONTRAINDICATIONS

- The G4-Global System must be removed prior to Magnetic Resonance Imaging (MRI).
- Use of acetaminophen-containing medications while the Sensor is inserted may affect the performance of the device.

WARNINGS

- This device is not designed to replace a blood glucose meter. The G4-Global System must be used with a blood glucose meter.
- Treatment decisions should not be based solely on results from the G4-Global System. You must confirm results with fingerstick readings from a blood glucose meter before making therapeutic adjustments.
- Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose, use fingerstick readings from your blood glucose meter to check the G4-Global System results.
- You should update the G4-Global System calibration every 12 hours at a minimum. The performance of the G4-Global System when calibrated less frequently than every 12 hours has not been studied.
- 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.
- The G4-Global System is **not approved for use** in children or adolescents, pregnant women or persons on dialysis.
- The safety and effectiveness of the G4-Global System has not been evaluated for Sensor Probe insertion sites other than the skin of the **abdomen**.

PRECAUTIONS

- Always wash hands with soap and water before opening the Sensor package. After opening the package, avoid touching the adhesive area.
- Before inserting the Sensor, always clean the skin at the Sensor insertion location with a topical antimicrobial solution, such as isopropyl alcohol. Do not apply the Sensor until the cleaned area is dry.
- Establish a rotation schedule for choosing each new Sensor location. Avoid Sensor locations that are constrained by clothing, accessories, or subjected to rigorous movement during exercise.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches (7.62 centimeters) of the Sensor.

- The Sensor is sterile in its unopened, undamaged package. Do not use any Sensor if its sterile package has been previously damaged or opened.
- The Sensor has currently only been tested in adult persons with type 1 and type 2 diabetes. The device has not been tested in children or adolescents, pregnant women, or persons on dialysis.

CAUTION

U.S. federal law restricts the sale of the G4-Global System to sale by or on order of a physician.

table of contents

G4-GLOBAL CONTINUOUS GLUCOSE MONITORING SYSTEM:

table of contents

chapter one

THE G4-GLOBAL SYSTEM BASICS

1.1 SENSOR OVERVIEW

The Sensor is the System component that continuously measures your glucose levels. You will use a blood glucose meter to calibrate your glucose readings measured by the Sensor. The Transmitter collects the Sensor readings and sends them to the Receiver using wireless, radio frequency (RF) technology. This happens every 5 minutes for up to 7 days.

The Sensor unit has an Applicator (needle, sensor, plastic housing), Sensor Probe, and Sensor Pod. The Applicator includes a Safety Lock/Transmitter Key to keep the needle in place until you are ready to insert. After taking off the Safety Lock, you will insert the Sensor Probe just beneath the skin (subcutaneous tissue) of your belly using a small needle inside the Applicator. The needle is inserted just under the skin at an angle and carries the Sensor Probe with it. After you insert the needle and Sensor Probe, you will pull the needle back into the Applicator. This leaves the Sensor Probe behind to continuously measure your glucose levels. The Applicator, with the needle inside, is pulled off from the Sensor Pod and should be thrown away. Save the Safety Lock/Transmitter Key because you can use it to remove the Transmitter at the end of a continuous monitoring session.

The Sensor Probe lies underneath your skin at an angle and continuously measures your glucose levels for up to 7 days. The Sensor Pod and Transmitter (once snapped in) remain on your belly for the entire Sensor session. The Sensor insertion site is similar to an insulin pump infusion site.

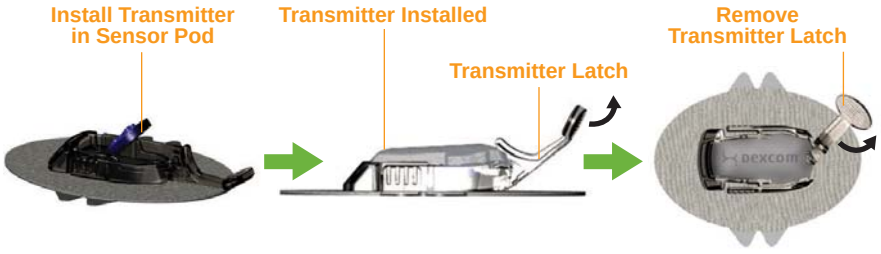
1.2 TRANSMITTER OVERVIEW

The Transmitter wirelessly sends your glucose information from the Sensor to the Receiver. Once you insert the Sensor, you will snap the Transmitter into the Sensor Pod using the Transmitter Latch. The same Transmitter is used when you change Sensors.

The Transmitter battery will last about 6 months. As the Transmitter nears the end of its battery life, it can sometimes lose communication with the Receiver. This can happen even if the Receiver and Sensor/Transmitter are within 20 feet (6 meters) of each other. The Transmitter (Low Battery) screen will first appear when there are about 2 weeks of battery life remaining. Press any Receiver button to clear the ALARM. This ALARM will reappear every day for 2 weeks, or until the Transmitter is replaced. Once the Transmitter battery has drained, you will need to replace the Transmitter because it can no longer communicate (talk) to the Receiver. You can easily set up a new Transmitter to talk with your Receiver (see Chapter 2, Section 2.4).

HELPFUL HINTS:

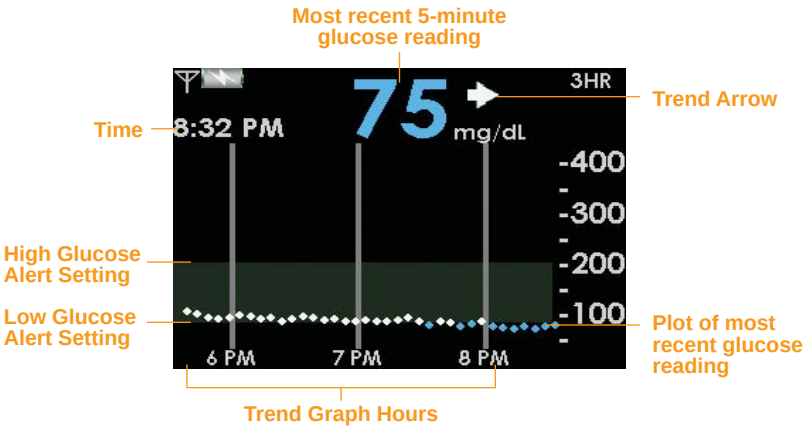
- Your Transmitter is re-used for many Sensor uses.
- If you see the Out of Range Symbol in the upper right corner of the Trend Graph, your Transmitter and Receiver are no longer talking. This can happen even when your Sensor/Transmitter and Receiver are within 20 feet (6 meters) of each other.
- The Receiver and Transmitter are designed and tested to withstand common electromagnetic interference, including airport security systems.



1.3 RECEIVER OVERVIEW

The Receiver looks like a small MP3 player and shows your Sensor-measured glucose information. The G4-Global Receiver only shows glucose readings in the milligrams per deciliter (mg/dL) unit of measure. In the United States, mg/dL is the standard unit used for glucose testing systems (i.e., blood glucose meters). Please check with your Diabetes Management Team if you have questions about the unit of measure displayed on your Receiver.

Keep the Receiver within 20 feet (6 meters) of the Sensor/Transmitter at all times for your G4-Global System to work best. Good places to keep the Receiver are on your belt in the Receiver case provided or in your pocket.

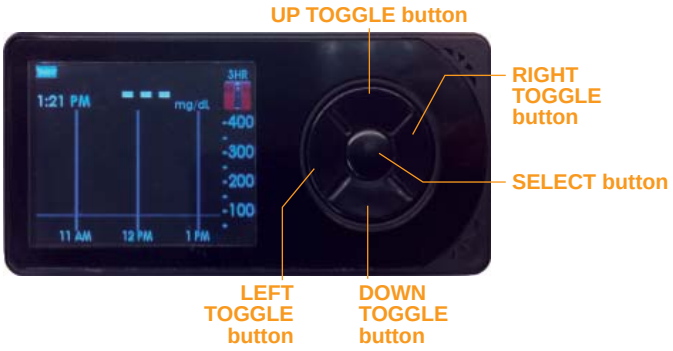


EXAMPLE: 3-Hour Trend Graph Screen

1

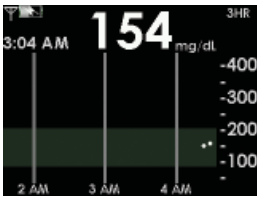
There are 5 Receiver buttons to move you through the display screens that control setup and operation. The screens display glucose readings and trend graphs (“Trend Graphs”) and allow you to change your Receiver settings (“Menu Screens”). You program your Receiver with a specific Transmitter ID Number so your Receiver and Transmitter can talk with each other. Each time you insert a new Sensor, you will need to notify the Receiver (see Chapter 3, Section 3.8).

Each Sensor must be “calibrated” before glucose readings are displayed on the Receiver. To calibrate, you manually enter fingerstick readings (see Chapter 4, Section 4.1) from any FDA-cleared meter.



1.4 MOVING THROUGH THE RECEIVER SCREENS

1. Turn the Receiver on by pressing the SELECT button.
2. The 3-Hour Trend Graph will appear.
   a. The default screen is the 3-Hour Trend Graph, but you may view glucose information for shorter or longer periods by pressing the TOP or BOTTOM TOGGLE button to see the 1-Hour, 6-Hour, 12-Hour, and 24-Hour Trend Graphs.



3. From any Trend Graph, press the SELECT button to display the Main Menu.

NOTE: Main Menu options take up more than one screen, and certain options only appear at certain times.

   a. Press the TOP or BOTTOM TOGGLE button to scroll through and highlight different Menu options.
   b. Press the SELECT button when the option you want is highlighted. You will then enter that Menu.
   c. Press the LEFT TOGGLE button to return to the previous Menu.

4. More information on Main Menu options can be found in the sections listed below:

Menu	Purpose	User's Guide Reference
Trend Graph	To display the Trend Graphs. • The 3-Hour Trend Graph is the default screen displayed whenever you turn the Receiver on.	Chapter 1
Start Sensor	To start a new Sensor session. • This option only appears if a Transmitter ID has been entered and you are not in the middle of a Sensor session.	Chapter 3
Enter BG	To enter your fingerstick blood glucose readings for calibration.	Chapter 4
Events	To enter personal information about meals, insulin, exercise, and health status.	Chapter 8
Alerts, High/low	To change the settings for notifications of High and Low Alerts from your Receiver.	Chapters 2 and 7
Alerts, Rise/Fall rate, Other, and Out of Range	To change the settings for notifications of Rise/Fall Rate (Rate of Change) Alerts, Other Alerts and Out of Range Alerts.	Chapter 8
Settings	To change the time, date and Transmitter ID number, to look up your G4-Global System hardware and software version numbers, to view Transmitter battery status, last calibration value, Sensor insertion time, and to enable Advanced features.	Chapters 2 and 7
Shutdown	To temporarily turn off all communications between your Sensor, Transmitter and Receiver.	Chapter 5
Stop Sensor	To end a Sensor session early. • This option only appears when you are in the middle of a Sensor session.	Chapter 6

See Appendix I, "Other Alerts", for a list of prompt screens that may appear on the Receiver during use.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chapter two

G4-GLOBAL SYSTEM SETUP

This chapter will help you set up your G4-Global System. You will want to read this chapter before you insert and start a new Sensor session.

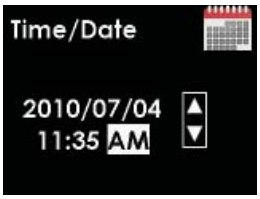
2.1 THE SETUP WIZARD

The Receiver Setup Wizard will guide you through the first-time setup of your G4-Global system.

Before setting up your Receiver, remove the Transmitter from the box.

NOTE: In order to save battery life, the Transmitter is stored in a tray with a small magnet attached. This prevents the Transmitter from turning on until it is removed from the tray. The Transmitter will turn on 10 minutes after being removed from the tray.

1. Turn your Receiver on by pressing the SELECT button on the Receiver. When you turn the Receiver on for the first time, the Setup Wizard will help you get started by prompting you to enter the following setup information:



2. Set the Time and Date

3. Enter your Transmitter ID

Your Transmitter ID can be found in any of the following locations:

- On the Transmitter card located inside your Global System Kit
- On the outside of the Transmitter box label
- Engraved on the back of the Transmitter itself

If you have difficulty locating your Transmitter ID, please contact DexCom Technical Support.

4. Set your Low and High Glucose Alert Levels

The Setup Wizard is now completed. You will now need to insert a Sensor and start a Sensor session to begin a continuous glucose monitoring session (see Chapter 3).

NOTE:
- When using the Setup Wizard, the Low and High Glucose Alerts are already turned on and are set to vibrate and beep. Only the Low Alert and High Alert "levels" can be adjusted in the Setup Wizard. To make other changes, see Section 2.5.
- See Sections 2.3, 2.4 and 2.5 and Chapter 7 for more information on setting the time and date, entering Transmitter ID, and Low and High Glucose Alerts from the Main Menu.

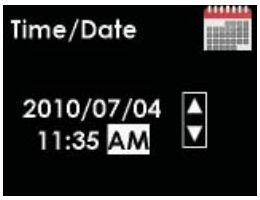
2.2 TURNING THE RECEIVER ON

1. Press the SELECT button to turn the Receiver on. The 3-Hour Trend Graph will appear.
2. Press the SELECT button to display the Main Menu.

2.3 SETTING THE TIME AND DATE

1. From the Main Menu, press the TOP or BOTTOM TOGGLE button to scroll to “Settings” and press the SELECT button. Next, scroll to “Time/Date” and press the SELECT button.

2. Check that the current date and time are correctly set in the Receiver. Press the RIGHT TOGGLE button to highlight each value in the date and time. Then, press the TOP or BOTTOM TOGGLE button to make any adjustments, and then press the RIGHT TOGGLE button to move to the next value. After choosing AM or PM, press the SELECT button. You will return to the Settings menu.



2.4 ENTERING YOUR TRANSMITTER ID

Before you can use your G4-Global System, you must enter the Transmitter ID into the Receiver. The Transmitter ID is a series of 2 letters and 5 numbers on the back of the Transmitter. Entering the ID will begin the unique wireless radio frequency (RF) communication between the Transmitter and Receiver.
To enter the Transmitter ID, perform the following steps:

1. From the Main Menu, press the TOP or BOTTOM TOGGLE button to scroll to "Settings" and press the SELECT button. Next, scroll to "Transmitter ID" and press the SELECT button.

NOTE: You can only enter your Transmitter ID when you are not in a Sensor session. During a Sensor session, "Transmitter ID" will not appear as an option on the Settings menu.

2. Starting with the first value, press the TOP or BOTTOM TOGGLE button to make any adjustment, and then press the RIGHT TOGGLE button to move to the next value. After entering the 5th number, press the SELECT button. You will return to the Settings menu.

Your Transmitter ID can be found in any of the following locations:

- On the Transmitter card located inside your Global System Kit
- On the outside of the Transmitter box label
- Engraved on the back of the Transmitter itself

If you have difficulty locating your Transmitter ID, please contact DexCom Technical Support.

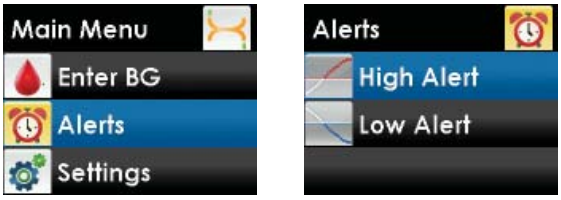
2.5 CHANGING YOUR HIGH AND LOW ALERTS

High Alerts and Low Alerts provide information about your glucose levels and trends. See Chapter 5, Section 5.3 for more information. You can turn the High Alert and/or Low Alert on or off, and choose how the Alerts are delivered (vibrate and beep, or vibrate only). You can also select the glucose value the Receiver will use to trigger a High or Low Alert.

NOTE: The High and Low Alerts are already turned on when you turn the Receiver on for the first time during Setup Wizard.

The options for setting both a High Alert and a Low Alert are the same. The following steps will show you how to change your High Alert settings.

1. From the Main Menu, press the TOP or BOTTOM TOGGLE button to scroll to “Alerts” and press the SELECT button. Next, scroll to “High Alert” or “Low Alert” and press the SELECT button.



2. On the High Alert menu (example), press the TOP or BOTTOM TOGGLE button to choose the “On/Off” option. The High Alert is currently set to “On”. If you do not want to receive this type of Alert press the SELECT button to choose “Off”.

Example-High Alert menu

3. Next, on the High Alert menu (example), press the TOP or BOTTOM TOGGLE button to choose "Type" and press the SELECT button. Then, choose "Vibrate Then Beep" or "Vibrate Only" as your Alert delivery option, and press the SELECT button.

Example-High Alert

   - Vibrate Then Beep (vibrate, then a vibrate and a beep every 5 minutes)
     - High Alert Beep (a series of tones in ascending order, followed by a few steady high tones)
     - Low Alert Beep (a series of tones in descending order, followed by a few steady low tones)
   - Vibrate Only (vibrate every 5 minutes)

NOTE: Alerts can be acknowledged by pressing any button on the Receiver.

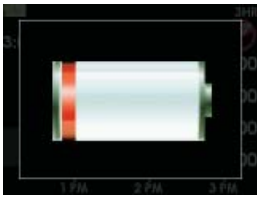
4. Next, on the High Alert menu (example), press the TOP or BOTTOM TOGGLE button to choose "Level" and press the SELECT button. Press the TOP or BOTTOM TOGGLE button to enter your Alert value (120 to 400 mg/dL in 10 mg/dL increments for a High Alert and 60 to 100 mg/dL in 5 mg/dL increments for a Low Alert). The starting value that first appears on this screen is the default value of 200 mg/dL (High Alert) and 80 mg/dL (Low Alert), or the values you set in the Setup Wizard.

Example-High Alert

You have the option to set a snooze time to re-alert you (see Chapter 8, Section 8.7, Setting a Snooze Time for Your High and Low Alerts).

2.6 CHARGING YOUR RECEIVER BATTERY

The Receiver battery is rechargeable like a cellular phone. The rechargeable battery will last for about 3-5 days before you need to charge it with the Receiver Charging Cable. Your rechargeable battery life depends on how often you turn your Receiver on, your Alert settings, and how often you enter Event information using the Events feature. The Receiver will tell you when the battery charge is low.



Low Battery

The Receiver Battery may be charged using one of the following options:

- Receiver charging cable for wall charging (cable included with kit)
- PC cable for computer charging (cable available separately)

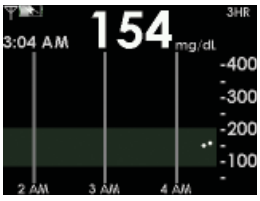
It takes about 3 hours to fully charge an empty battery with the wall charger, and about 5 hours when the Receiver is connected to a computer.

To recharge your battery, follow the instructions below:

1. Open the connection port cover on the right side of the Receiver. Plug the Receiver end of the Receiver charging or PC cable into the connection port on the Receiver.
2. Plug the other end of the cable to the wall outlet or to the USB port on your computer, depending on the cable you are using.
3. The Battery Charging screen will appear on the Receiver.

Battery Charging

4. After a few seconds the Trend Graph will reappear with the Battery Charging Symbol shown in the upper left corner next to the Antenna Symbol .



5. As the battery charges, the Battery Symbol will begin to fill in (green). When the battery is fully charged, the Battery Symbol will be completely filled in.

Start Fully Charged

6. After the charge is complete, remove the cable from the Receiver and the wall outlet or computer USB port.

HELPFUL HINTS:

- Charge your Receiver battery before each Sensor insertion. Periodically check your battery level to make sure it has enough charge.
- If your battery drains and is not charged for about 6 months, the backup battery might also drain. When this happens, you will need to reset your Receiver time and date (see Section 2.3).
- Only use the DexCom battery charger provided in the Starter Kit. Do not use any other battery charger.

chapter three

USING A SENSOR


3

To use your G4-Global Continuous Glucose Monitoring System you will need a Sensor, a Transmitter, and a Receiver. You will also need a blood glucose meter and test strips for calibration. Once inserted and calibrated, the Sensor will continuously measure and display your glucose readings for up to 7 days (167 hours after the 1-hour Startup period). The following sections will show you how to insert the Sensor and start a new continuous glucose monitoring session.

3.1 BEFORE YOU START

- ❒ Wash your hands thoroughly.
- ❒ Make sure you charge your Receiver completely. See Chapter 2, Section 2.6 for directions.
- ❒ Check that the date and time are correct on the Receiver.
- ❒ If this is a new Transmitter, make sure the correct Transmitter ID Number has been entered into your Receiver (See Chapter 2, Section 2.4).
- ❒ Check the expiration date on the Sensor, before you start, to make sure you are not using an expired Sensor. The expiration date format is YYYY-MM-DD.
- ❒ Quality check ("QC") your blood glucose meter per the manufacturer's instructions to make sure it is providing you the best readings for calibration (e.g., check the code number and use the control solution if applicable).
- ❒ Clean the bottom of the Transmitter with a damp cloth or alcohol wipe, and dry before you start a new Sensor session.
- ❒ Make sure your blood glucose meter and Receiver date and time match.

3

REVIEW THE SENSOR APPLICATOR

Review the Sensor Applicator picture below before using a new Sensor.

HELPFUL HINT: Always check the expiration date on the Sensor packaging before opening the Sensor for use. Never use expired Sensors. The expiration date format is YYYY-MM-DD.

The G4-Global Continuous Glucose Monitoring System is a glucose-monitoring device indicated for detecting trends and tracking patterns in adults **(age 18 and older)** with diabetes.

3.2 REMOVING THE SENSOR FROM ITS PACKAGING

The Sensor is sterile in its unopened, undamaged package. Do not use any Sensor if its sterile package has been previously damaged or opened.

- Carefully remove the Sensor from its packaging. Look closely at the Sensor to make sure it is not damaged.
- The Applicator is a single use, disposable unit. The Safety Lock prevents you from accidentally releasing the needle before you are ready.

3.3 CHOOSING AN INSERTION SITE

Establish a rotation schedule for choosing each new Sensor location. Avoid Sensor locations that are constrained by clothing, accessories, or subjected to rigorous movement during exercise.

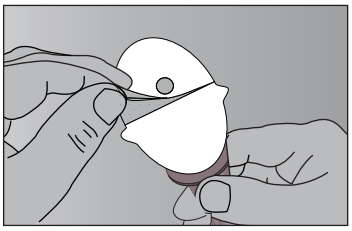
Avoid injecting insulin or placing an insulin pump infusion set within 3 inches (7.62 centimeters) of the Sensor.

Choose a site on a fatty area of 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 (i.e., pant line, seatbelts).

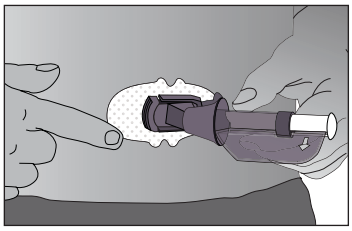
- Avoid areas with scarring, tattoos, or rough patches of skin from your insulin injections or pump.
- Choose an area that is at least 3 inches (7.62 centimeters) from where you plan to inject insulin or from where your pump infusion site is located.
- Avoid using the same spot repeatedly for Sensor 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 that the adhesive patch sticks securely.
- Make sure there are no traces of lotions, perfumes or medications on the area. Clean the area first with an alcohol swab. Make sure the area is clean and completely dry before you insert the Sensor.

3.4 PLACING THE SENSOR

1. After you have cleaned your skin, remove the adhesive backing from the Sensor Pod. Hold the Sensor by the plastic Applicator and try not to touch the sticky adhesive patch.
2. Place the Sensor on the area. You can place the Sensor flat facing to the left or right of your belly button. Make sure the Sensor is placed in the same direction shown in the picture below. You should not place the Sensor pointing in the up or down direction.

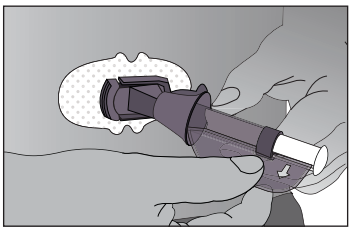


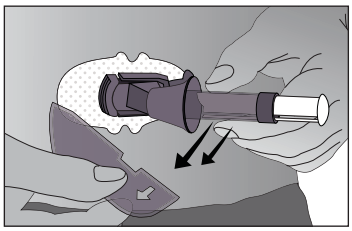
Remove the Adhesive backing



Adhere the Sensor on the skin

3. After placing the Sensor, press firmly on and around the outside of the adhesive patch to make sure it is flat.
   a. Pressing the patch to remove any wrinkles should help it stick better.
   b. Press firmly over the entire patch area.
4. Hold on to the Applicator. Then pull the Safety Lock/Transmitter Key straight out away from the applicator, in the direction the arrow shows below.





Remove the Safety Lock/Transmitter Key

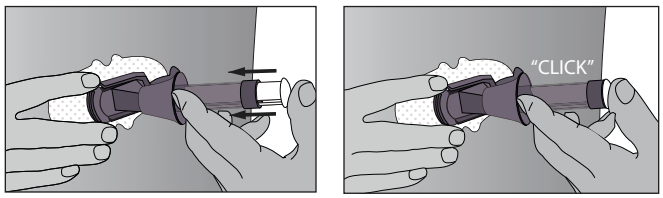
HELPFUL HINT: The Safety Lock also serves as the Transmitter Key that is used later for Transmitter removal. Keep this piece to help you remove the Transmitter at the end of a continuous glucose monitoring session. When your glucose monitoring session is over, follow the steps in Chapter 6, Section 6.4 to remove the Transmitter.

3.5 SENSOR INSERTION

Once you have placed the Applicator on your belly and removed the Safety Lock (see Section 3.4), you are ready to insert the Sensor. Follow these 4 steps to successfully insert your Sensor.

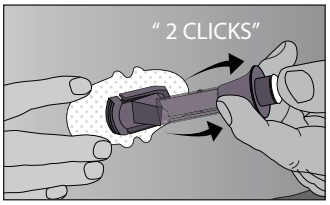
1. Hold down the Pod with one hand. With your other hand, place two fingers above the collar on the barrel of the Applicator.
2. Place your thumb on the plunger. Push the plunger down completely. This action inserts the needle and Sensor Probe under your skin.

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



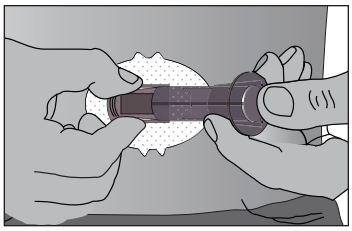
Push down the plunger – Insert the Needle and Sensor Probe

3. To remove the needle, keep holding the Sensor Pod with one hand. With your other hand, place two fingers under the collar. Then pull the collar back towards your thumb. Stop when you hear 2 "clicks" or cannot pull back any more. This step pulls the needle back into the Applicator and keeps the Sensor Probe under your skin.
   a. Remember to do this in the correct order: push plunger down, then pull collar up.



Pull back the collar - Retract the Needle

4. Squeeze the ribbed release tabs on the sides of the Sensor Pod to remove the Applicator. When you squeeze the front release tabs, the back tabs will widen, allowing you to pull off the Applicator. After this step, only the Sensor Pod will be left on your body.
   a. Make sure the Transmitter Latch is down (against your body) to remove the Applicator.



Release the Applicator

5. The used Applicator can be thrown in the trash.

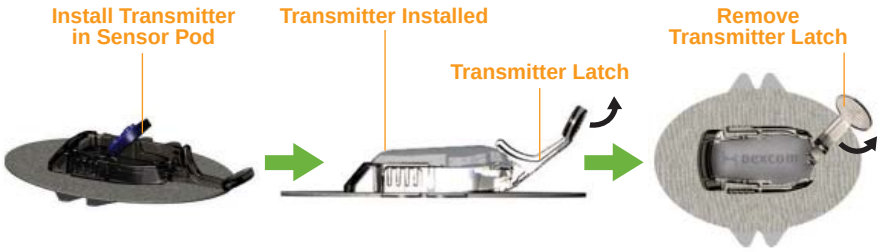
If you have any problems with insertion, save the Sensor and Applicator and contact DexCom.

3.6 TRANSMITTER ATTACHMENT

The Transmitter wirelessly sends your Sensor glucose information to the Receiver. Once you have inserted your Sensor, you will need to snap the Transmitter into the Sensor Pod. Follow the steps below to attach your Transmitter.

1. Clean and dry the bottom of the Transmitter with a damp cloth or an alcohol wipe before every use.
   a. Be careful not to touch the metal circles on the bottom of the Transmitter.
2. Place the Transmitter in the Sensor Pod with the flat side facing down.
3. Pull the Transmitter Latch over the Transmitter to snap the Transmitter into place. The Transmitter should lie flat in the Sensor Pod. You should hear 2 “clicks.”
   a. If you do not hear 2 clicks, the Transmitter might not be fully snapped in.
4. Make sure both sides of the Transmitter are secure inside the Sensor Pod.
   a. Do this by sliding your first and second fingers under the edge of the Sensor Pod (with your fingernails against your skin under the Latch).
   b. Place your thumb on top of the Transmitter.
   c. Then squeeze together to make sure the Transmitter has been snapped in.

5. Remove the Transmitter Latch by holding the end of the Latch and quickly twisting off the Latch away from your body.



HELPFUL HINTS:

- Make sure you hear 2 clicks when you snap the Transmitter in place (see Step 3). This helps ensure your device is water resistant (see Section 3.10).
- Make sure that you have entered the correct Transmitter ID into your Receiver. See Chapter 2, Section 2.4 for instructions on how to enter the Transmitter ID into your Receiver.

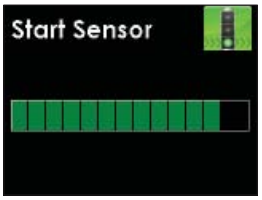
3.7 STARTING A SENSOR SESSION

After you have checked that your Transmitter and Receiver are talking, you need to tell the Receiver that you have inserted a new Sensor.

To tell the Receiver that you have inserted a new Sensor, follow the steps below.

1. Press the SELECT button to turn the Receiver on.
2. From any Trend Graph, press the SELECT button to display the Main Menu.
3. Press the TOP or BOTTOM TOGGLE button to scroll until you highlight “Start Sensor.”

4. Press the SELECT button to confirm the start of a new Sensor session. The Start Sensor Processing screen will appear to let you know your Sensor session has begun.
5. Your Receiver will then return to the 3-Hour Trend Graph.



HELPFUL HINTS:

- The Start Sensor menu option will now disappear from the Main Menu. The option will only appear again after an active Sensor session ends.
- Each time you insert a new Sensor and press SELECT to start a new Sensor session, you will start a new 1-hour Startup period.

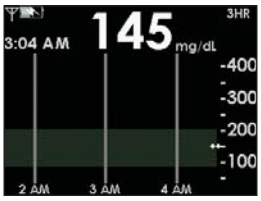
3.8 TRANSMITTER AND RECEIVER COMMUNICATION

CONTRAINDICATION: The G4-Global System must be removed prior to Magnetic Resonance Imaging (MRI).

Keep your Receiver within 20 feet (6 meters) of the Sensor/Transmitter for best communication. To check that the Receiver and Transmitter are talking, press the SELECT, LEFT or RIGHT TOGGLE button to see the Trend Graph.

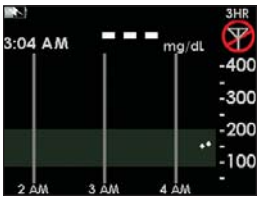
Note the difference between the two Antenna Symbols below:

This Antenna Symbol shows that the Transmitter and Receiver are talking.



This Out of Range Symbol shows the Transmitter and Receiver are not talking.

If you see the Out of Range Symbol in the upper right corner of the screen, then review the following troubleshooting tips.



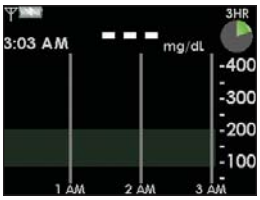
- Is the Receiver within 20 feet (6 meters) of your Sensor/Transmitter? If the Receiver is not close enough, then move it within 20 feet (6 meters) of the Sensor/Transmitter. Check in 5-10 minutes to see if the Antenna Symbol appears and the Out of Range symbol disappears.
- If the Receiver and Sensor/Transmitter are still not talking, then check to make sure the correct Transmitter ID Number is entered into your Receiver (see Chapter 2, Section 2.4).
- If the correct Transmitter ID has been entered into your Receiver and the Receiver and Transmitter are still not talking, then contact DexCom.

HELPFUL HINTS:
The Transmitter and Receiver may lose communication at the following times:
- When they are near metallic objects.
- While you are lying on a water bed.
- When you are using an electric blanket.

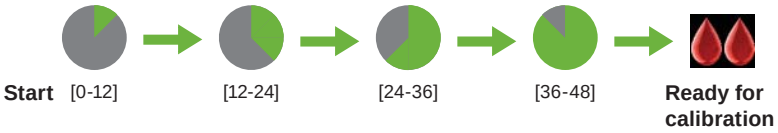
3.9 SENSOR STARTUP PERIOD

The Sensor needs a 1-hour Startup period. This is so the Sensor can get used to its new insertion site. During the Startup period, check every so often to make sure the Antenna Symbol is in the upper left corner of the Trend Graph. Also make sure your Receiver battery is fully charged.

When you press the SELECT button during the Startup period to turn the Receiver display on, your Trend Graph will include a 1-hour Countdown Symbol in the upper right hand corner.



Over time, the Countdown Symbol will fill to indicate that you are getting closer to initial calibration time. See the pictures below for an example of what this looks like.



At the end of the 1-hour Startup period the Receiver will let you know that it is time to calibrate your Sensor. Chapter 4 tells you how to calibrate your Sensor.

3.10 THE G4-GLOBAL SYSTEM AND WATER

Your Sensor (including the installed Transmitter) is water resistant when showering, bathing, or swimming. The Sensor has been tested to be water resistant when submerged for up to 3 feet (0.9 meters) for a maximum of 30 minutes. For added protection you can use a shower cover. The Receiver is not water resistant. Do not get your Receiver wet at any time.

3.11 TAPING THE SENSOR POD

The Sensor Pod should stay securely attached using its own adhesive. But, if the patch is peeling up, you can use medical tape (such as Blenderm™) 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 Needle.

chapter four

CALIBRATING YOUR G4-GLOBAL SYSTEM


4

The G4-Global System requires you to “calibrate” the Sensor glucose readings to your blood glucose meter. The purpose of calibration is to convert the measurement of glucose by the Sensor into a reading similar to the one provided by your meter.

CONTRAINDICATION: Use of acetaminophen-containing medications while the Sensor is inserted may affect the performance of the device.

4.1 CALIBRATION OVERVIEW

When calibrating, you need to manually enter your fingerstick readings into the Receiver. You can use any FDA-cleared blood glucose meter.

You will need to perform three types of calibration on your Receiver:

1. Startup Calibration 2. Calibration Update 3. Re-calibration

Startup Calibration happens at the end of the 1-hour Startup Period and takes 2 fingerstick readings. Calibration Update is a calibration that must be performed every 12 hours (about 1 fingerstick reading, 2 times per day). The Receiver will remind you when these calibrations are needed. Re-calibration may be required if one of the fingerstick readings entered for Startup Calibration or Calibration Update is not accepted by the Receiver.

The sections in this Chapter tell you how to calibrate your system. The sections also describe Startup Calibration, Calibration Update, and how to Re-calibrate in more detail.

HELPFUL HINT: Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. You must take your blood glucose readings from your fingertips only for calibration.

4

4.2 HOW TO CALIBRATE

For Calibration, you must enter the exact fingerstick reading from your meter. Readings must be between 40-400 mg/dL and must have been taken within the past 5 minutes. Entering incorrect fingerstick readings, or fingerstick readings that occurred more than 5 minutes ago, will affect device performance.

The steps below show you how to enter your fingerstick readings for calibration:

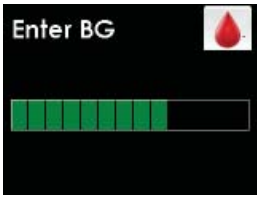
1. Take a fingerstick reading using your meter.
2. From any Trend Graph, press the SELECT button to display the Main Menu.
3. Use the TOP or BOTTOM TOGGLE button to scroll until you highlight “Enter BG.”

NOTE: “Enter BG” will be the second Main Menu option when you are not in the middle of a Sensor session.

4. 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. During initial calibration the Receiver will default to the reading of 120 mg/dL as your starting point.
   b. If there has been a glucose reading in the past 15 minutes, the Enter BG screen will display your current continuous glucose reading as your starting point. Do not use the continuous glucose reading for calibration. Use only fingerstick readings from your meter.

5. To enter the fingerstick reading taken from your meter, press the TOP or BOTTOM TOGGLE button until you find the correct reading and then press the SELECT button.
   a. Pressing the TOP or BOTTOM TOGGLE button lets you scroll by 1 mg/dL. To scroll faster, hold down the TOP or BOTTOM TOGGLE button.
6. Confirm that the fingerstick reading you entered is correct.

   a. If the fingerstick reading displayed is correct, press the LEFT TOGGLE button to highlight "OK" and then press the SELECT button.
   b. If the fingerstick reading displayed is incorrect, press the SELECT button (with "Cancel" highlighted) to return to the Enter BG screen. Repeat the steps for re-entering the correct reading.
   c. If you do not press any button, the Receiver will "time out" and no fingerstick reading will be entered.
7. The Enter BG Processing screen will appear to let you know the fingerstick reading is being processed for calibration.



8. For Startup Calibration, repeat these steps for the second fingerstick reading.
9. A glucose reading will appear on the Receiver right away, and glucose readings will be updated every 5 minutes.
10. If readings do not appear immediately, see Chapter 9, Section 9.2.

HELPFUL HINTS:

- Make sure a glucose reading is displayed at the top of the Trend Graph, or a Blood Drop Symbol is displayed in the top right corner of the Trend Graph, before calibration.
- Only fingerstick readings between 40-400 mg/dL can be used for calibration. If 1 or more of your readings entered was outside of this range, the Receiver will not calibrate. You will have to wait to until your blood glucose is in this range to calibrate.
- Always make sure the Antenna Symbol is displayed in the upper left corner of the Trend Graph before you enter fingerstick readings for calibration.
- You should always use the same meter you routinely use to measure your blood glucose to calibrate. Do not switch your meter in the middle of Sensor session.

4.3 STARTUP CALIBRATION

One (1) hour after you start the Sensor session (see Chapter 3, Section 3.7) the Receiver will tell you that you need to calibrate. The Receiver will show the Double Blood Drop Prompt. If your Alerts are set to the factory default settings, the Receiver will also vibrate and beep to tell you it is ready for calibration.

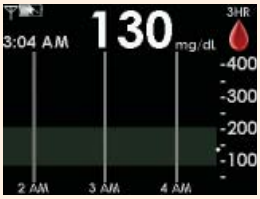
Double Blood Drop Prompt

1. You can also set your Receiver to vibrate only (see Chapter 8, Section 8.5).
2. When you see this screen, press any Receiver button to clear the display.
3. Take 2 fingerstick readings with your meter and enter them into the Receiver (see Section 4.2).

NOTE: Your fingerstick readings must be between 40 mg/dL and 400 mg/dL for calibration. The Receiver cannot use fingerstick readings outside of this range for calibration.

HELPFUL HINTS:

- If your readings are less than 40 mg/dL or greater than 400 mg/dL, you should determine if you should treat yourself first, and then calibrate when it is convenient for you.
- If you choose to clear the Double Blood Drop Prompt and calibrate later, the Blood Drop Symbol will appear in the top right corner of the Trend Graph.
- Once you clear the Double Blood Drop Prompt, it will reappear every 15 minutes until you successfully calibrate.
- Always make sure the Antenna Symbol is visible in the upper left corner before you calibrate.



4.4 CALIBRATION UPDATE

Calibration Update is required every 12 hours to make sure your Sensor readings remain accurate and are close to your blood glucose meter readings. You can enter any fingerstick readings you take during a Sensor session. If you have not entered any fingerstick readings in the past 12 hours, the Receiver will ask you for a fingerstick reading to update its calibration. The steps below show you how to enter this calibration.

You must update G4-Global System calibration every 12 hours at a minimum. The performance of the System when calibrated less frequently than every 12 hours has not been studied.

You must enter the exact fingerstick reading that your blood glucose meter displays. Enter all fingerstick readings for calibration within 5 minutes. Entering incorrect fingerstick readings, or fingerstick readings that occurred more than 5 minutes ago, will affect device performance.

1. If you see the Single Blood Drop Prompt shown to the right, clear this display by pressing any Receiver button. The Single Blood Drop Prompt will not go away until you press a button.

Single Blood Drop Prompt

2. Take a fingerstick reading at this time. Enter this reading in the Receiver to update calibration.
3. This screen will appear every 15 minutes until you enter a new fingerstick reading that is accepted for calibration.
4. If this screen reappears shortly after you have entered a new fingerstick reading, review Chapter 5, Section 5.4.

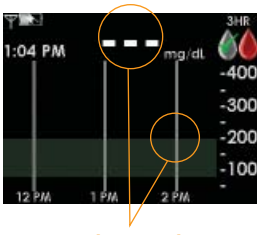
4.5 RE-CALIBRATION

When you enter a fingerstick reading for 12-Hour Update Calibration (Section 4.3), the System checks how well it is functioning compared to the blood glucose meter. During each Calibration Update attempt, the System may tell you that another fingerstick reading is needed. This Re-calibration can also be prompted during Startup Calibration. The Single Blood Drop Prompt will appear (shown to the right).

Single Blood Drop Prompt

You can clear this Screen by pressing any Receiver button. The display will return to the Trend Graph. A Blood Drop Symbol will appear on the top right of the Trend Graph screen.

This Blood Drop Symbol tells you that the System needs at least one more fingerstick reading. You will not see glucose readings or trends, or get Alerts/Low Glucose ALARM when the Blood Drop Symbol is still displayed.



No glucose data

Awaiting Fingerstick Reading (Blood Drop) Symbol

You should take another fingerstick reading and enter it into the Receiver.

1. Your System should calibrate immediately.
2. After successful Re-calibration the System will display glucose readings, trends and provide Alerts/Low Glucose ALARM again.

HELPFUL HINT: Refer to Section 8.4, “Error Code Troubleshooting,” if you see the “15 Minute Calibration Error Screen” or the “1 Hour Calibration Error Screen” on your Receiver during calibration.

15 Minute Calibration Error screen

1 Hour Calibration Error screen

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chapter five

CONTINUOUS GLUCOSE READINGS, TRENDS, ALERTS AND ALARM

This chapter will teach you how to view your G4-Global System continuous glucose readings and trend information. Once you have successfully calibrated, the G4-Global Receiver will display your glucose readings every 5 minutes. This will tell you how your glucose levels are changing.

You must update G4-Global System calibration every 12 hours at a minimum. The performance of the System when calibrated less frequently than every 12 hours has not been studied. Use of acetaminophen-containing medications while the Sensor is inserted may affect the performance of the device.

Your blood glucose meter only gives your blood glucose level at one point in time (like a still picture). However, the G4-Global System Trend Graphs and Trend (Rate of Change) Arrows will help you understand the direction your glucose level is moving (like a video camera).

The G4-Global Sensor sits in the fluid under your skin, not in your blood. The Sensor calculates a glucose reading from this fluid when you calibrate your System. So, the glucose reading you see on your Receiver may be about 5-10 minutes behind the fingerstick reading you get from your meter. If your meter reading is above 80 mg/dL, the G4-Global System readings can be 10 – 20% different from your meter readings. If your meter reading is below 80 mg/dL, the G4-Global System readings can be up to 20 mg/dL different from your meter readings.

It is important that you focus on the trends and rate of change on your Receiver, rather than the exact glucose reading. The Trend Graphs and Arrows will help you determine how fast your glucose level is rising or falling. Chapter 11, Section 11.2 tells you how closely your G4-Global System readings will be to a laboratory analyzer in the doctor's office.

Glucose Alerts and the Low Glucose ALARM are designed to help you stay within your target glucose zones. Your Low and High Glucose Alerts, and Rise and Fall (Rate of Change) Alerts can tell you when you fall outside of your target glucose range. Your Alerts are personal tools that you can set (see Chapter 2, Section 2.5), and are determined by you and your Diabetes Management Team. Your Low Glucose ALARM can tell you when your glucose levels may be reaching potentially dangerous low levels.

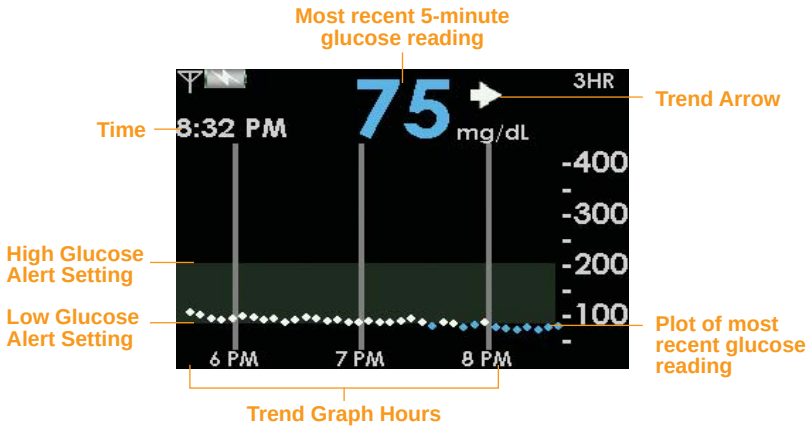
5

The G4-Global System also lets you enter information about your meals, insulin, exercise, and health. That way you and your Diabetes Management Team can view a bigger picture of your diabetes management plan. Your Diabetes Management Team can transfer this information to the DexCom Studio® Accessory Software to see how you are doing over a long period of time.

> Treatment decisions should not be based solely on results from the G4-Global System. You must confirm System readings with a fingerstick reading on a blood glucose meter before making therapeutic adjustments.
>
> You must update G4-Global System calibration every 12 hours at a minimum. The performance of the System when calibrated less frequently than every 12 hours has not been studied.

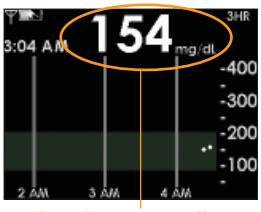
5.1 GLUCOSE READINGS

Press any button on the Receiver to display the 3-Hour Trend Graph. This is the default screen whenever you turn your Receiver on. The following information will appear:



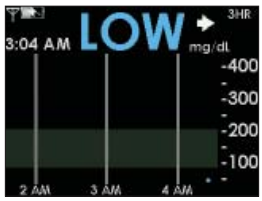
EXAMPLE: 3-Hour Trend Graph Screen

- The G4-Global System reports glucose readings from **40-400 mg/dL** and updates glucose readings every 5 minutes.

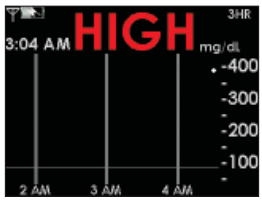


The glucose reading is in milligrams per deciliter (mg/dL) units.

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



“Low”
Less than 40 mg/dL



“High”
Greater than 400 mg/dL

- Each “dot” on the Trend Graph is a glucose reading.
- Every Trend Graph shows the current time.
- The gray zone on the Trend Graphs indicates the area in between the High Alert and Low Alert settings (see Chapter 2, Section 2.5 to change these settings).

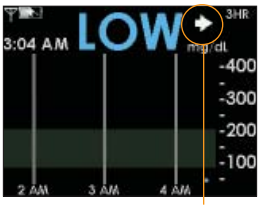
You can see Trend Graphs of your glucose information from the past 1-hour, 3-hour, 6-hour, 12-hour, and 24-hour periods by pressing the TOP or BOTTOM TOGGLE button on your Receiver. Trend Graphs show you where your glucose levels have been and where your glucose levels are headed.

(Scroll up from the 3-Hour Graph to reach the 1-Hour Graph)	
	**1-Hour Trend Graph:** The 1-Hour (1 Hr) Trend Graph shows your current glucose reading and the last 1 hour of glucose readings.
	**3-Hour Trend Graph:** The 3-Hour (3 Hr) Trend Graph shows your current glucose reading and the last 3 hours of glucose readings (this is your default Trend Graph screen).
(Scroll down from the 3-Hour Graph to reach the 6-Hour Graph)	
	**6-Hour Trend Graph:** The 6-Hour (6 Hr) Trend Graph shows your current glucose reading and the last 6 hours of glucose readings.
(Scroll down from the 6-Hour Graph to reach the 12-Hour Graph)	
	**12-Hour Trend Graph:** The 12-Hour (12 Hr) Trend Graph shows your current glucose reading and the last 12 hours of glucose readings.
(Scroll down from the 12-Hour Graph to reach the 24-Hour Graph)	
	**24-Hour Trend Graph:** The 24-Hour (24 Hr) Trend Graph shows your current glucose reading and the last 24 hours of glucose readings.

5.2 GLUCOSE TRENDS

In addition to your current glucose reading and Trend Graphs, Trend (Rate of Change) Arrows may appear to show you how your glucose readings are changing.

The Trend Arrows appear to the right of your current glucose reading.

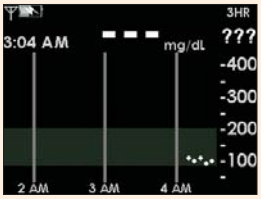


Trend Arrows appear here

This table shows the different Trend Arrows your Receiver will display:

→	**Constant:** Your glucose is steady (not increasing/decreasing more than 1 mg/dL each minute)
↗	**Slowly rising:** Your glucose is rising 1-2 mg/dL each minute
↑	**Rising:** Your glucose is rising 2-3 mg/dL each minute
↑↑	**Rapidly rising:** Your glucose is rising more than 3 mg/dL each minute
↘	**Slowly falling:** Your glucose is falling 1- 2 mg/dL each minute
↓	**Falling:** Your glucose is falling 2-3 mg/dL each minute
↓↓	**Rapidly falling:** Your glucose is falling more than 3 mg/dL each minute
no arrow	**No Rate of Change Information:** The Receiver cannot always calculate how fast your glucose is rising or falling

HELPFUL HINTS:



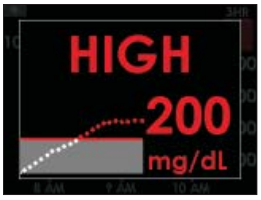
- Trend Arrows do not appear when there is Missing Glucose Information (see Section 5.4). If the ??? Symbol, the Wait Symbol, the Out of Range Symbol, or the Blood Drop Symbol appears in the upper right corner, the Trend Arrows will not appear.
- If the Trend Arrow is missing, but you are concerned that your blood glucose level may be rising or falling, take a fingerstick test on your blood glucose meter to check your readings.

5.3 GLUCOSE ALERTS AND LOW GLUCOSE ALARM

The G4-Global System lets you create your own personal settings for how you want the Receiver to tell you what is going on. The Low and High Glucose Alerts will tell you when you fall outside of your target glucose range. Rise and Fall (Rate of Change) Alerts let you know when your glucose levels are changing fast (see Chapter 8, Section 8.4). The G4-Global System also features a non-adjustable Low Glucose ALARM that will tell you when your glucose levels may be reaching potentially dangerous low levels. In addition to the Alert screens that appear on your Receiver display, you can also set High and Low Glucose Alerts to notify you with vibrations and beeps. This feature can be helpful during times when you are not able to test your blood glucose on your meter (such as sleeping, driving, exercise, or long meetings).

5.3.1 HIGH GLUCOSE ALERT

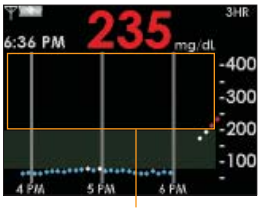
When your G4-Global System readings are at or above your High Alert level, the screen shown to the right will appear. You can also set the Receiver to beep and vibrate when this screen appears (see Chapter 2, Section 2.5). The default level is set at 200 mg/dL, but you can adjust this value.



High Glucose Alert set at 200 mg/dL

When you set the High Glucose Alert, the level is indicated by the top of the gray zone on the Trend Graphs. (If the Low Glucose Alert is not set, the High Glucose Level is indicated by a horizontal gray line.)

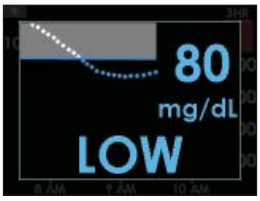
The Receiver will continue to alert you until you press any Receiver button to clear the Alert, or until your glucose readings drop below your High Glucose Alert level. You can choose to have the Receiver re-alert you every 15, 30 minutes or 1, 2, 3, 4, or 5 hours after clearing the Alert, by changing your Snooze settings (see Chapter 8, Section 8.7). Snooze settings for the High Glucose Alert are only available if Advanced features is turned on (see Chapter 8, Section 8.1).



High Glucose Alert Setting

5.3.2 LOW GLUCOSE ALERT

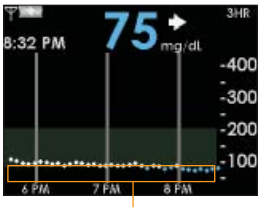
When your G4-Global System readings are at or below your Low Alert level, the screen shown to the right will appear. You can also set the Receiver to beep and vibrate when this screen appears (see Chapter 2, Section 2.5). The default level is set at 80 mg/dL, but you can adjust this value.



Low Glucose Alert set at 80 mg/dL

When you set the Low Glucose Alert, the level is indicated by the bottom of the gray zone on the Trend Graphs. (if the High Glucose Alert is not set, the Low Glucose Level is indicated by a horizontal gray line.)

The Receiver will continue to alert you until you press any Receiver button, or until your glucose readings rise above your Low Glucose Alert level. You can choose to have the Receiver re-alert you every 15, 30 minutes or 1, 2, 3, 4, or 5 hours after clearing the Alert, by changing your Snooze settings (see Chapter 8, Section 8.7). Snooze settings for the Low Glucose Alert are only available if Advanced features is turned on (see Chapter 8, Section 8.1).



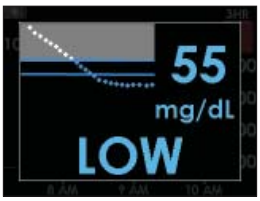
Low Glucose Alert Setting

Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose, use fingerstick readings from your blood glucose meter to check the System results.

5.3.3 LOW GLUCOSE ALARM

The G4-Global System also has an automatic Low Glucose ALARM set at 55 mg/dL. This ALARM is a feature in addition to your personal Low and High glucose Alerts. You cannot change or turn off this ALARM or its Re-ALARM settings.

- When your glucose reading is at or below 55 mg/dL the Receiver will notify you with 3 ALARMS (each 5 minutes apart) that beep/vibrate as follows:
  - 1st ALARM: Vibrate
  - 2nd ALARM: Vibrate, then a series of rapid descending tones followed by 3 constant tones. Series is repeated 3 times.
  - 3rd ALARM: Vibrate, then a series of rapid descending tones followed by 3 constant tones. Series is repeated 3 times. (louder)
- The Receiver will vibrate and beep every 5 minutes after the 3rd ALARM if your readings are still at or below 55 mg/dL, until you press any Receiver button to clear it.
- For Low Glucose ALARMs the Receiver will display the screen to the right.
- Re-ALARM: The Receiver will automatically notify you again in 30 minutes after you press any Receiver button to clear it, if your glucose readings are still at or below 55 mg/dL.



Low Glucose ALARM

5.3.4 RISE AND FALL GLUCOSE RATE ALERTS

You can activate these Alerts (see Chapter 8, Section 8.4), to have the Receiver tell you if your glucose readings are rising or falling fast.

You can set the Rise Rate (how fast you are going up) to one of two different Rise Rate levels, or choose to turn this Alert off. Depending on your selection, you will be notified if your glucose level is rising 2 mg/dL or more each minute, or 3 mg/dL or more each minute.

5

You can set the Fall Rate (how fast you are going down) to one of two different Fall Rate levels, or choose to turn this feature off. Depending on your selection, you will be notified if your glucose level is falling 2 mg/dL or more each minute, or 3 mg/dL or more each minute.

If your glucose reading rises or falls at or above/below the Alert setting you chose, the Receiver will display an Alert. You can also set the Alert to vibrate or beep (see Chapter 8, Section 8.4). Two examples are shown below:

If you set your Fall Rate to 2 mg/dL per minute and your glucose readings fall at this rate or faster, the FALLING Single Arrow screen will appear and vibrate/beep according to your settings.

Example-Fall Alert

If you set your Rise Rate to 3 mg/dL per minute and your glucose readings rise at this rate or faster, the RISING Double Arrow screen will appear and vibrate/beep according to your settings.

Example-Rapid Rise Alert

NOTE: To set Rise and Fall Glucose Rate Alerts, Advanced features must be turned on (see Chapter 8, Section 8.1).

5.4 GLUCOSE STATUS AREA ON TREND GRAPHS

This device is not designed to replace a blood glucose meter. When there is Missing Glucose Information, rely on fingerstick readings from your blood glucose meter.

Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose, confirm them with fingerstick readings from your blood glucose meter.

5.4.1 GLUCOSE STATUS AREA SYMBOLS

During your Sensor session the “Status Area” in the upper right hand corner of the Trend Graph may display any of the information below.

 **Calibration Needed**	A blood drop means your System requires you to enter another fingerstick reading. You may need to enter a fingerstick reading for your 12-hour calibration, or the Receiver might need an additional fingerstick reading to improve its calibration. (See Chapter 4, Section 4.2.)
 **Glucose Reading Error**	Three question marks mean the Receiver does not understand the Sensor signal. You should wait for more prompts and do not enter any fingerstick readings when you see this symbol. (See Section 5.4.3.)
 **RF Error**	An antenna symbol with a line through it and a circle around it, means the Sensor/Transmitter and Receiver are out of range. Make sure the Receiver and Sensor/Transmitter are within 20 feet (6 meters) of each other. (See Section 5.4.4.)

 **15 Minute Calibration Error**	Means the Sensor cannot calibrate right now. If you see this screen, enter at least 1 more calibration fingerstick reading after about 10-15 minutes. If the Sensor still cannot calibrate using this additional fingerstick reading, the Sensor needs to be replaced. (See Chapter 8, Section 8.4.)
 **1 Hour Calibration Error**	Means the Sensor is not calibrating properly. If you see this screen, wait about one hour and then enter at least 1 more fingerstick reading. If no readings display on the Receiver after this additional fingerstick, the Sensor needs to be replaced.
 **Wait**	The single hourglass means the Receiver has detected a potential problem with the Sensor signal. You should wait about 30 minutes for more prompts. Do not enter any fingerstick readings when you see this symbol.

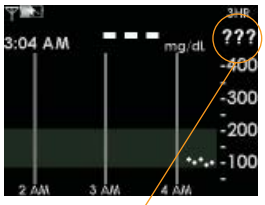
5.4.2 MISSING GLUCOSE READINGS

At certain times, a notification symbol may appear in the Status Area of the Trend Graph. These notifications are helpful in troubleshooting why glucose readings do not appear on the Receiver. The table in the previous section shows the symbols that might appear in the Status Area.

Missing Glucose Information can happen when:

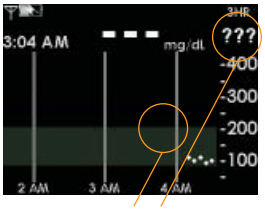
1. The System needs another fingerstick reading for calibration because the Sensor readings do not match the recent fingerstick reading you just entered.
2. The Receiver does not understand the Sensor signal.
3. The Sensor/Transmitter and Receiver are out of range. Make sure the Sensor/Transmitter and Receiver are within 20 feet (6 meters) of each other.

For calibration errors see Chapter 8. The following sections will tell you what happens when the Receiver does not understand the Sensor signal, and when your Sensor/Transmitter and Receiver are out of range. If your Receiver is not displaying glucose information, look at the Status Area on the Trend Graph.



5.4.3 SYSTEM GLUCOSE ERRORS

Sometimes the G4-Global System may tell you that it cannot provide a glucose reading. When this occurs you will see 3 question marks (???) in the Status Area.



No Glucose Data

Check the placement of your Sensor to make sure it is still sticking securely to your skin. Also make sure nothing is rubbing the Sensor Pod (i.e. clothing, seat belts, etc.).

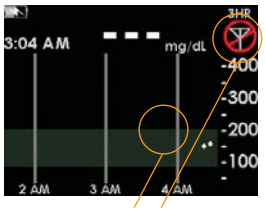
Check to see if the Transmitter is snapped in on both sides. This error can happen when the G4-Global System detects problems with the glucose signal or Sensor insertion area. Chapter 9 tells you how often you might expect to see this error. Sometimes the G4-Global System can correct the problem and continue providing glucose readings. However, if it has been 3 hours since your last glucose reading appeared, contact Technical Support.

HELPFUL HINTS:

- If you see ??? in the Status Area of the Trend Graph, it is recommended that you wait out this period of time. Do not calibrate your System during this time.
- When you see ???, taking fingerstick readings with your meter and entering them does not help the System display more glucose readings. Any fingerstick readings that you enter during ??? will be ignored by the System.
- Wait until you see a Single Blood Drop in the Status Area before entering a calibration value into your Receiver.

5.4.4 OUT OF RANGE/NO ANTENNA

- When you see the Out of Range Symbol in the Status Area, this means the Receiver has “missed” the last glucose reading sent by the Transmitter.
- If you see this Symbol, make sure the Receiver is within 20 feet (6 meters) of the Sensor/Transmitter. If not, move the Receiver closer and wait at least 5 minutes.
- Once you have moved the Receiver closer and waited 5-10 minutes, the Out of Range Symbol in the Status Area should disappear. The Antenna Symbol should reappear in the upper left corner, and you should receive a glucose reading.



No Glucose Data

- If you are still having trouble receiving System readings because of this problem, contact DexCom Technical Support.

HELPFUL HINTS:

- You can set an Out of Range Alert to notify you when the Receiver and Sensor/Transmitter are not talking (see Chapter 8, Section 8.6). You can also set the amount of time the Transmitter can be out of range before the Receiver alerts you.
- The Sensor/Transmitter and Receiver may lose communication during the following circumstances: while you are lying on a waterbed, while you are near other metallic objects, or when you are using an electric blanket.

5.5 TEMPORARY SENSOR SHUT DOWN

There may be times when you want to temporarily shut down your Receiver. Shutdown will stop all communication between the Transmitter and Receiver, and will turn the Receiver off. You will not receive glucose readings or any Alerts/ Low Glucose ALARMs while the Receiver is shut down, but your current Sensor session will remain in progress. Follow these steps to shut down your Receiver:

1. From the Main Menu, scroll to and highlight "Shutdown". Press the SELECT button.

2. Confirm that you want to shutdown your Receiver.
   a. If you want to shutdown, press the LEFT TOGGLE 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.

3. 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.

HELPFUL HINTS:

- Remember that your Alerts and Low Glucose ALARM will not work when the Receiver is shut down.
- Your Sensor session will stop 7 days after you start the Sensor session. Shutting down the Receiver does not extend Sensor life beyond 7 days.

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chapter six

COMPLETING YOUR CONTINUOUS GLUCOSE MONITORING SESSION

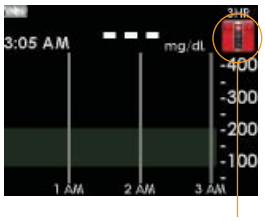

6

At the end of your Sensor session (or wear period), you will need to remove the Sensor. Gently peel up the adhesive patch from your skin (this will pull out your Sensor Probe). Then remove the Transmitter from the Sensor and keep it for your next continuous glucose monitoring session (see Section 6.4).

6.1 REMOVING A SENSOR

Your Sensor session will end on time when the Sensor expires (after 7 days). You can also choose to end the session early, or it might end early (less than 7 days) due to a Sensor failure.

Once your Sensor session has ended, glucose readings will no longer be shown on the Receiver. The Trend Graphs will indicate that the Sensor session has ended by displaying a red Stoplight Symbol in the upper right corner.



A Stop Sign indicates that your Sensor session has ended

HELPFUL HINT: Remember to save your Transmitter after each Sensor removal. The same Transmitter is used for each session until you have reached the end of the Transmitter battery life. The Sensor can be thrown in the trash.

6.2 AUTOMATIC SENSOR SHUT-OFF

The Receiver will tell you how much time you have remaining until your G4-Global Sensor session is complete. The Sensor Expiration screen will appear at 6 hours, 2 hours and 30 minutes before your 7-day session ends.

You can to set the Receiver to vibrate and/or beep with these displays if you choose (see Chapter 8, Section 8.5). After the 6-hour, 2-hour, and 30-minute reminders, you will still continue to receive glucose readings. You can clear any of these screens by pressing any button on the Receiver. You must remove your Sensor after the final Sensor Expiration screen (00:00:00) appears.

6-hour Sensor Expiration Notification

2-hour Sensor Expiration Notification

30-minute Sensor Expiration Notification

Sensor Expiration Notification End of session

Once the Replace Sensor Now screen appears, press any button on the Receiver to clear this notification.

6.3 EARLY SENSOR SHUT-OFF

In some cases your Sensor session may end before you have completed a full 7-day period. You should review Chapter 11, Section 11.2 in this User's Guide to determine how often you should expect this to happen. Examples of why this may occur are described below.

6.3.1 EARLY SHUT-OFF – SENSOR FAILURE

During a session the Receiver may detect a series of issues with your Sensor signal where it can no longer determine your glucose reading (see Chapter 9, Section 9.3). At this time the CGM session will end and show the screen to the right.

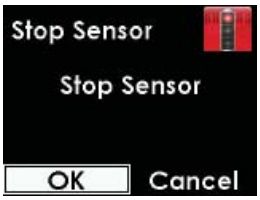
If you see this screen then your continuous glucose monitoring session has ended. Press any button on the Receiver to clear this screen.

Sensor Failed Screen

6.3.2 MANUAL SENSOR SHUT-OFF – "STOP SENSOR"

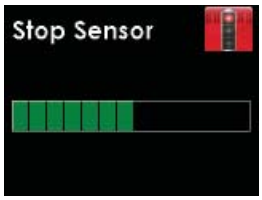
To manually end your Sensor session, select "Stop Sensor" from the Main Menu. This option will only appear if you are in the middle of an active Sensor session (you have already started a Sensor session and the Sensor has not expired or failed). See Chapter 6, and Chapter 9, Section 9.3.

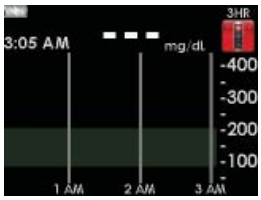
With "OK" highlighted, press the SELECT button to confirm that you want to stop the Sensor session.



6

The Stop Sensor processing screen will appear to let you know the Sensor session is stopping. Once the session has stopped, a Red Stoplight Symbol will appear in the upper right corner of the Trend Graph.





HELPFUL HINTS:

- If you removed your Sensor before stopping the Sensor session on the Receiver, the Sensor Failed screen will appear automatically. You must press SELECT before inserting a new Sensor. Look closely at the Sensor to make sure it is not damaged.
- You cannot reverse the decision to stop a Sensor session after pressing the SELECT button. Press the LEFT TOGGLE button to return to the Main Menu if you do not want to stop the Sensor session.

6.4 TRANSMITTER REMOVAL

When you are ready to remove the Sensor, make sure to pull out the Sensor Pod with the Transmitter still inside. Once the Sensor Pod is off your body, you will need to remove the Transmitter. To do this you can use either of the two methods below:

Method 1

The Safety Lock/Transmitter Key once removed from the Applicator (see Chapter 3, Section 3.5) can be used as a tool to remove the Transmitter.

1. Place the Sensor Pod on a table.
2. Hold the rounded edge of the Transmitter Key.
3. Make sure the jagged edge of the Transmitter Key is facing down (the direction away from the removal arrow) as shown below:

4. Insert the jagged edges so that they “hug” the Transmitter wings in the Sensor Pod. Press the Transmitter Key down until you cannot press down anymore, and the Transmitter wings will “pop” out of the Sensor Pod.
5. Remove the Transmitter and store it in a cool, dry place until your next glucose monitoring session.

Method 2

If you did not save the Transmitter Key, you can simply use your pointer finger on each hand and spread out the tabs at the back of the Sensor Pod (end closest to the wings). The Transmitter wings will “pop” out of the Sensor Pod.

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chapter seven

BASIC SETTINGS


7

7.1 THE SETTINGS MENU

7.1.1 GETTING TO THE SETTINGS MENU

1. Press any button to turn on the Receiver. The 3-Hour Trend Graph will appear.

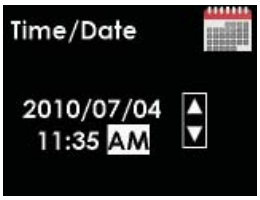
2. Press the SELECT button to display the Main Menu.

3. From the Main Menu, press the TOP or BOTTOM TOGGLE button to scroll to “Settings” and press the SELECT button. The Settings menu will appear.

7.1.2 SETTING YOUR RECEIVER TIME AND DATE

1. From the Settings menu, press the TOP or BOTTOM TOGGLE button to scroll to “Time/Date” and press the SELECT button.

2. Check that the current date and time are correctly set in the Receiver. Press the RIGHT TOGGLE button to highlight each value in the date and time. Then, press the TOP or BOTTOM TOGGLE button to make any adjustments and then press the RIGHT TOGGLE button to move to the next value. After choosing AM or PM, press the SELECT button. You will return to the Settings menu.



HELPFUL HINTS:

- The date in the Receiver is set at the factory to Pacific Standard Time (PST).
- Make sure to set the correct date and time on your Receiver.
- When setting values for the time or date, press and hold the TOP or BOTTOM TOGGLE button to scroll through the fields more quickly.
- You might need to reset the Receiver's time and date if the rechargeable battery is drained. If this happens, the Time Loss Alert will automatically take you to the Time/Date Setting Screen.

7.1.3 ENTERING YOUR TRANSMITTER ID

Any time you switch to a new Transmitter and/or Receiver (as a replacement to the Transmitter and Receiver that came in your kit) you must enter the Transmitter ID into your Receiver. The Transmitter ID is a series of 2 letters and 5 numbers on the back of the Transmitter. Entering the ID will begin the unique wireless radio frequency (RF) communication between the Transmitter and Receiver.

NOTE: You can only set your Transmitter ID when you are not in a Sensor session. During a Sensor session, "Transmitter ID" will not appear as an option on the Settings menu.

To enter the Transmitter ID, perform the following steps:

1. From the Settings menu, press the TOP or BOTTOM TOGGLE button to scroll to "Transmitter ID" and press the SELECT button.

2. Starting with the first number (do not enter the first 2 letters), press the TOP or BOTTOM TOGGLE button to make any adjustment and then press the RIGHT TOGGLE button to move to the next value. After entering the 5th number, press the SELECT button. You will return to the Settings menu.

Your Transmitter ID can be found in any of the following locations:

- On the Transmitter card located inside your G4-Global System Kit
- On the outside of the Transmitter box label
- Engraved on the back of the Transmitter itself

If you have difficulty locating your Transmitter ID, please contact DexCom Technical Support.

7.1.4 CHECKING INFORMATION ABOUT YOUR RECEIVER

At any time you can check your Receiver for information about your G4-Global System.

1. From the Settings menu, press the TOP or BOTTOM TOGGLE button to scroll to “Device Info” and press the SELECT button.

2. Information about your Sensor session and System will appear. Scroll down to see all the information. Press the LEFT TOGGLE button to return to the Settings menu.

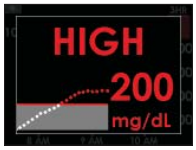
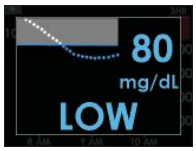
Device Info:

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

7.2 SETTING YOUR ALERTS

7.2.1 FACTORY ALERT SETTINGS

The G4-Global System is shipped from the factory with the following “default” settings for Alerts. (See the table below.)

Screen	Alert Type	Default Setting	Default Prompt Vibrate/Beep	Default Re-alert Setting
	High Alert	On- 200 mg/dL	Vibe then Beep (vibrate first, then 2 high beeps and vibrate)	None (no Re-alerts after pressing any Receiver button to clear)
	Low Alert	On- 80 mg/dL	Vibe then Beep (vibrate first, then 3 low beeps and vibrate)	None (no Re-alerts after pressing any Receiver button to clear)
 	Rise Alert	Off	Disabled (None)	None (no Re-alerts after pressing any Receiver button to clear)

Screen	Alert Type	Default Setting	Default Prompt Vibrate/Beep	Default Re-alert Setting
 	Fall Alert	Off	Disabled (None)	None (no Re-alerts after pressing any Receiver button to clear)
	Other Alerts (See Chapter 11, Appendix 1 for a detailed list of all “Other Alerts.”)	On	Vibe then Beep (vibrate first, then medium beep tone)	Depends on the Alert Type (See Chapter 12, Appendix 1)
	Out of Range Alert	Off	Disabled (None)	Continues to Re-alert you until you come back into range.

7.2.2 GETTING TO THE ALERTS MENU

1. Press the SELECT button to turn on the Receiver. The 3-Hour Trend Graph will appear.

2. Press the SELECT button to display the Main Menu.

3. From the Main Menu, press the TOP or BOTTOM TOGGLE button to scroll to "Alerts" and press the SELECT button. The Alerts menu will appear.

7.2.3 SETTING GLUCOSE ALERTS

The High Alert, Low Alert, Rise Rate Alert, and Fall Rate Alert (see Chapter 5) provide information about your glucose levels and trends. The following will show you how to change the High Alert, Low Alert, Rise Rate Alert, and Fall Rate Alert settings.

NOTE: To receive Rise Rate and Fall Rate Alerts, Advanced Features must be turned on (see Chapter 8, Section 8.1).

High and Low Glucose Alerts

NOTE: The options for setting both a High Alert and a Low Alert are the same.

The following steps will show you how to change your High Alert Settings.

1. From the Alerts menu, press the TOP or BOTTOM TOGGLE button to select “High Alert” or “Low Alert” and press the SELECT button.

2. On the High Alert menu (example), press the TOP or BOTTOM TOGGLE button to choose “On/Off”. The High Alert is currently set to “On”. If you do not want to receive this type of Alert press the SELECT button to choose “Off”.

Example-High Alert menu

3. Next, on the High Alert menu (example), press the TOP or BOTTOM TOGGLE button to choose “Type” and press the SELECT button. Then, choose “Vibrate Then Beep” or “Vibrate Only” as your alert delivery option, and press the SELECT button.

Example-High Alert

   - Vibrate Then Beep (vibrate, then a vibrate and a beep every 5 minutes)
     - High Alert Beep (a series of tones in ascending order, followed by a few steady high tones)
     - Low Alert Beep (a series of tones in descending order, followed by a few steady low tones)
   - Vibrate Only (vibrate every 5 minutes)

NOTE: Alerts can be acknowledged by pressing any button on the Receiver.

4. Next, on the High Alert menu (example), press the TOP or BOTTOM TOGGLE button to choose “Level” and press the SELECT button. Press the TOP or BOTTOM TOGGLE button to enter your Alert value (120 to 400 mg/dL in 10 mg/dL increments for a High Alert and 60 to 100 mg/dL in 5 mg/dL increments for a Low Alert). The starting value that first appears on this screen is the default value of 200 mg/dL (High Alert) and 80 mg/dL (Low Alert), or the values you set in the Setup Wizard.

Example-High Alert

You have the option to set a snooze time to re-alert you (see Chapter 8, Section 8.7).

7

Rise and Fall Rate Alerts

NOTE:
- The options for setting both a Rise Rate Alert and a Fall Rate Alert are the same.
- To use the Rise and Fall Rate Alerts feature, Advanced Features must be turned on. (See Chapter 8, Section 8.1.)

The following steps will show you how to change your Fall Rate Alert settings.

1. From the Alerts menu, press the TOP or BOTTOM TOGGLE button to select "Rise Rate" or "Fall Rate" and press the SELECT button.
2. On the Fall Rate menu (example), press the TOP or BOTTOM TOGGLE button to choose "On/Off". Then, press the SELECT button to select "On". If you do not want to receive this type of Rate Alert press the SELECT button to choose "Off".

Example-Fall Rate menu

3. Next, on the Fall Rate menu (example), press the TOP or BOTTOM TOGGLE button to choose "Type" and press the SELECT button. Then, choose "Vibrate Then Beep" or "Vibrate Only" as your alert delivery option and press the SELECT button.

Example-Fall Rate

   - Vibrate Then Beep (vibrate, then a vibrate and a beep every 5 minutes)
     - Rise Rate Beep (a series of rapid ascending tones, repeated 3 times)
     - Fall Rate Beep (a series of rapid descending tones, repeated 3 times)
   - Vibrate Only (vibrate every 5 minutes)

NOTE: Alerts can be acknowledged by pressing any button on the Receiver.

4. Next, on the Fall Rate menu (example), press the TOP or BOTTOM TOGGLE button to choose "Level" and press the SELECT button. Then, choose whether the alerts should be delivered when your glucose levels are falling either "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.

Example-Fall Rate

When finished, press the LEFT TOGGLE button to return to the Alerts menu.

NOTE: When you choose "2 mg/dL/min" for your Rise or Fall Rate Alert, one arrow will appear on the screen when you receive an Alert. Two arrows (meaning Rapid) will appear when you select "3 mg/dL/min" for your Rise or Fall Rate Alert.

Example-Fall Rate Alert

Example-Rapid Rise Alert

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chapter eight

ADVANCED FEATURES
BEYOND THE BASICS

Advanced features allows you to do the following:

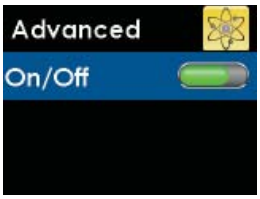
- Enter events related to your carbohydrate consumption, insulin usage, exercise and overall health. Event information can be downloaded to a PC along with your glucose readings and viewed using the DexCom Studio® Accessory Software.
- Expand and customize the Alerts feature so that the Receiver can:
  - notify you when and how fast your glucose levels are rising or falling
  - deliver other Alerts according to your preference
  - notify you when your Sensor/Transmitter and Receiver are out of range

8.1 ACTIVATING ADVANCED FEATURES

To use the Receiver's Advanced features, the Advanced features setting must be turned on.

1. From the Main Menu, press the TOP or BOTTOM TOGGLE button to scroll to "Settings" and press the SELECT button. Next, scroll to "Advanced" and press the SELECT button.

2. On the "Advanced" screen, press the SELECT button to turn Advanced features On (or Off). Press the LEFT TOGGLE button to return to the Settings screen.



8

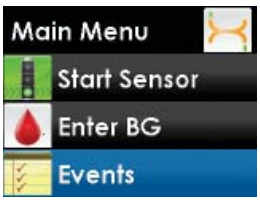
8.2 DIABETES EVENTS

With the G4-Global System you can enter meal, insulin, physical activity, and health information. This information can help you and your Diabetes Management Team review your glucose trends and patterns and may help you make better decisions about your diabetes management plan. These events can be downloaded to a PC along with your glucose readings and reviewed later with the DexCom Studio® Accessory Software.

8.2.1 SELECTING AN EVENT

When Advanced features is turned on, “Events” will appear as an option on the Main Menu.

1. Press the TOP or BOTTOM TOGGLE button to choose “Events” and press the SELECT button.



From the Events menu you can choose “Carbs”, “Insulin”, “Exercise” or “Health”.

8.2.2 SETTING THE DATE AND TIME FOR AN EVENT

When you enter an event you will be prompted to check that the date and time for that event are correct. The default date and time for events you enter is the current date and time stored in the Receiver.

1. To change the date and time for an event, press the RIGHT TOGGLE button to highlight each value in the date and time. Then, press the TOP or BOTTOM TOGGLE button to make any adjustments and then press the RIGHT TOGGLE button to move to the next value. After choosing AM or PM, press the SELECT button. You will advance to the Event confirmation screen.

NOTE: 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.

8.2.3 CARBOHYDRATES

The Carbs Event lets you enter the amount of carbohydrates you have consumed, up to 250 grams for any particular date and time.

1. Press the TOP or BOTTOM TOGGLE button to choose “Carbs” and press the SELECT button.

2. Press the TOP or BOTTOM TOGGLE button to enter your carb amount (0-250 grams), and press the SELECT button. The number that first appears on this screen will be the last number you entered or the default amount of 50 grams.

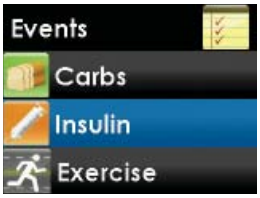
4. Check that the date and time for this entry are correct.

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

8.2.4 INSULIN

The Insulin Event lets you enter the amount of insulin you have taken, up to 250 units for any particular date and time. You can only enter an insulin amount, not the type of insulin taken.

1. Press the TOP or BOTTOM TOGGLE button to choose “Insulin” and press the SELECT button.



2. Press the TOP or BOTTOM TOGGLE button to enter your insulin amount (0-250 units), and press the SELECT button. The number that first appears on this screen will be the last number you entered or the default amount of 10 units.

3. Check that the date and time for this entry are correct.

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

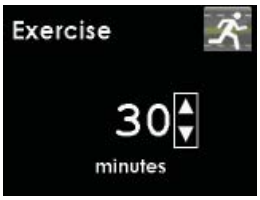
8.2.5 EXERCISE

The Exercise Event lets you enter the intensity (Light, Medium, or Heavy) and duration (up to 360 minutes), for any particular date and time.

1. Press the TOP or BOTTOM TOGGLE button to choose “Exercise” and press the SELECT button.

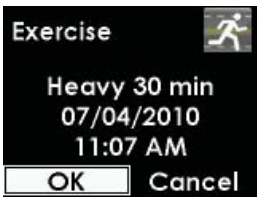
2. Press the TOP or BOTTOM TOGGLE button to enter your exercise intensity level, and press the SELECT button.

3. Press the TOP or BOTTOM TOGGLE button to enter your exercise duration (0-360 minutes), and press the SELECT button. The number that first appears on this screen is the default amount of 30 minutes.



4. Check that the date and time for this entry are correct.

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



8.2.6 HEALTH

The Health Event lets you enter episodes of Illness, Stress, High Symptoms, Low Symptoms, Cycle (menstrual) or Alcohol consumption, for any particular date and time.

1. Press the TOP or BOTTOM TOGGLE button to choose “Health” and press the SELECT button.

2. Press the TOP or BOTTOM TOGGLE button to enter your health event, and press the SELECT button.

3. Check that the date and time for this entry are correct.

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

8.3 DEXCOM STUDIO SOFTWARE

The DexCom Studio® Accessory Software comes with your G4-Global System. This software allows you to view trends and track patterns and create customizable charts to display your glucose trends.

Change the date ranges to view long- or short-term patterns and trends. Plus, you can use data from current and previous G4-Global System downloads and save or print files that you can take to your next doctor visit.

For system requirements refer to the DexCom website (www.dexcom.com). The DexCom Studio® Help File gives you more information on how to use this software.

NOTE: To receive Rise and Fall Rate Alerts, Advanced Features must be turned on.

8.4 RISE AND FALL GLUCOSE RATE ALERTS

Rate Alerts notify you when your glucose levels are rising (Rise Alert) or falling (Fall Alert), and by how much. You can turn the Rise and/or Fall Rate Alert on or off, and choose how the Alerts are delivered (vibrate and beep, or vibrate only). You can also choose whether the Alert should be delivered when your glucose is either rising or falling 2 mg/dL or more per minute, or 3 mg/dL or more per minute.

When Advanced features is turned on, “Rise Rate” and “Fall Rate” will appear as additional options on the Alerts menu. The options for setting both a Rise Rate Alert and Fall Rate Alert are the same.

The following steps will show you how to change your Fall Rate Alert settings.

1. Press the TOP or BOTTOM TOGGLE button to choose “Rise Rate” or “Fall Rate” and press the SELECT button.

2. On the Fall Rate menu (example), press the TOP or BOTTOM TOGGLE button to choose “On/Off”. Then, press the SELECT button to select “On”. If you do not want to receive this type of Rate Alert press the SELECT button to choose “Off”.

Example-Fall Rate menu

3. Next, on the Fall Rate menu (example), press the TOP or BOTTOM TOGGLE button to choose “Type” and press the SELECT button. Then, choose “Vibrate Then Beep” or “Vibrate Only” as your alert delivery option and press the SELECT button.

Example-Fall Rate

- Vibrate Then Beep (vibrate, then a vibrate and a beep every 5 minutes)
  - High Alert Beep (a series of tones in ascending order, done in pairs)
  - Low Alert Beep (a series of tones in descending order, done in pairs)
- Vibrate Only (vibrate every 5 minutes)

NOTE: Alerts can be acknowledged by pressing any button on the Receiver.

4. Next, on the Fall Rate menu (example), press the TOP or BOTTOM TOGGLE button to choose “Level” and press the SELECT button. Then, choose whether the alerts should be delivered when your glucose levels are falling either “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.

Example-Fall Rate

When finished, press the LEFT TOGGLE button to return to the Alerts menu.

NOTE: When you choose “2 mg/dL/min” for your Rise or Fall Rate Alert, one arrow will appear on the screen when you receive the Alert. Two arrows (meaning Rapid) will appear when you select “3 mg/dL/min” for your Rise or Fall Rate Alert.

Example-Fall Alert

Example-Rapid Rise Alert

8.5 SETTING OTHER ALERTS

The G4-Global System provides many other notifications. See Chapter 12, Appendix I for a complete list of these “Other Alerts.”

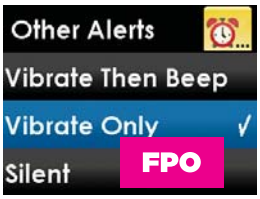
When Advanced features is turned on, “Other Alerts” will appear as an additional option on the Alerts menu. The default “Type” for all of the “Other Alerts” is “Vibrate Then Beep”, a setting that will notify you with vibrations and a series of rapid ascending then descending tones, when these Alerts occur. This setting can be changed to “Vibrate Only” or “Silent”.

1. Press the TOP or BOTTOM TOGGLE button to choose “Other Alerts” and press the SELECT button.

2. “Type” is highlighted. Press the SELECT button.

3. Press the TOP or BOTTOM TOGGLE button to change “Vibrate Then Beep” to “Vibrate Only” or “Silent” option and press the SELECT button.

When finished, press the LEFT TOGGLE button to return to the Alerts menu.



8.6 SETTING THE OUT OF RANGE ALERT

The Out of Range Alert lets you know when the Sensor/Transmitter and Receiver are not talking to each other. Typically, you should keep the Sensor/Transmitter and Receiver within 20 feet (6 meters) of each other. When the Sensor/Transmitter and Receiver are too far apart and are not talking, you will not receive glucose readings from the Sensor.

When this happens, the Out of Range Symbol will appear in the upper right corner of the Trend Graph and the screen to the right will appear. The amount of time the devices are out of range will appear on the Out of Range Alert screen.

When Advanced features is turned on, “Out of Range” will appear as an additional option on the Alerts menu.

The default setting for the Out of Range Alert is off (“disabled”). But if you choose to turn this Alert on, you can then set the Alert to either “Vibrate Then Beep” or “Vibrate Only”. “Vibrate Then Beep” notifies you with vibrations and a series of 3 ascending tones, repeated 3 times, followed by 5 buzzers. You can also set the amount of time (between 20 and 200 minutes) the Transmitter can be out of range before the Receiver alerts you. If you go out of range, the Receiver will continue to re-alert you until you come back in range again, or press any button on the Receiver.

1. Press the TOP or BOTTOM TOGGLE button to choose “Out of Range” and press the SELECT button.

2. On the Out of Range menu, press the TOP or BOTTOM TOGGLE button to choose “On/Off”. Then, press the SELECT button to select “On”. If you do not want to receive Out of Range Alerts press the SELECT button to choose “Off”.

3. Next, on the Out of Range menu, press the TOP or BOTTOM TOGGLE button to choose “Type” and press the SELECT button. Then, choose “Vibrate Then Beep” or “Vibrate Only” as your alert delivery option and press the SELECT button.

4. Next, on the Out of Range menu, press the TOP or BOTTOM TOGGLE button to choose “Time” and press the SELECT button. Then, press the TOP or BOTTOM TOGGLE button to choose the elapsed time, after which the Receiver will alert you and continue to re-alert you until you are back in range. Press the SELECT button.

When finished, press the LEFT TOGGLE button to return to the Alerts menu.

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

You have the option to set a snooze time (every 15 minutes up to 5 hours) in between High and Low glucose Re-alerts.

NOTE: To set a snooze time for your High and Low Alerts, Advanced Features must be turned on.

TOGGLE button to choose “Snooze” and press the SELECT button.

Example-High Alert

2. Press the TOP or BOTTOM TOGGLE button to select the amount of time (in 15 minute increments) in between the first Alert and Re-alerts. Press the SELECT button. If you set the amount of time to zero there will be no Re-alerts.

When finished, press the LEFT TOGGLE button to return to the Alerts menu.

Example-High Alert

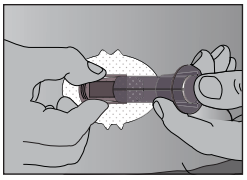
chapter nine

TROUBLESHOOTING

9.1 SENSOR INSERTION TROUBLESHOOTING

Sensor Insertion Difficulties

- **I am having trouble taking out the Safety Lock/Transmitter Key:**
  - Make sure to pull straight out using the arrows on the Safety Lock as a guide.
  - Do not wiggle back and forth.
- **I am not able to pull the Collar up:**
  - Make sure the plunger is completely pressed down before pulling the collar up.
  - When pulling the Collar up you should hear 2 clicks.
  - Try using more force when pulling the collar up.
- **I am not able to remove the Applicator from the Sensor Pod:**
  - Pull the Collar all the way up. It should be very close to the top of the Applicator.
  - Make sure the Transmitter Latch is down before squeezing the Release Tabs.
  - Then squeeze the ribbed Release Tabs (on the side), and lift the Applicator away from your body.



Release the Applicator

- **Removing the Transmitter Latch is difficult:**
  - Hold the Sensor Pod down with one hand and twist the Latch with the other hand to remove it.
  - Do not try to snap it straight off.

Sensor Pod is Not Sticking Long Enough

- Do not use any cream or lotion on your skin where you attach the Sensor Pod.
- Clean the skin and make sure it is completely dry before you attach the Sensor Pod. Do not leave any substance on the skin where the Needle inserts.
- You may use medical tape (such as Blenderm™) 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.

The G4-Global Continuous Glucose Monitoring System is a glucose-monitoring device indicated for detecting trends and tracking patterns in adults **(age 18 and older)** with diabetes.

9.2 CALIBRATION TROUBLESHOOTING

Prompts may appear during or shortly after you try to calibrate your System. Review the following troubleshooting tips so that your calibration is successful.

- Make sure you have inserted a Sensor and started a Sensor session
- Do not use expired Sensors
- Store Sensors at room temperature (see Chapter 9 for Maintenance and Storage of your System)
- Make sure your meter readings are between 40 and 400 mg/dL before you calibrate
- Quality check your blood glucose meter per the manufacturer's instructions

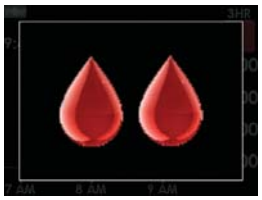
9.2.1 BLOOD DROP PROMPTS

9.2.1.1 TYPES OF BLOOD DROP PROMPTS

This section describes the three blood drop symbols you will see. The next section (Section 9.2.1.2) describes what to do when you see one of these symbols.

Repeat Double Blood Drop Prompt

If Startup calibration is not successful, the Receiver will continue to display this screen until you correct the problem. If you have followed these steps and you still receive the Double Blood Drop Prompt, then one of the following errors has occurred:



Double Blood Drop Prompt

- Both fingerstick readings you took and entered for your first calibration were outside of the 40-400 mg/dL range, **or**
- The Receiver and Transmitter were not talking (Out of Range Symbol appears in the Status Area) with each other at the time you took the 2 fingersticks entered for calibration, **or**
- The Receiver could not understand (??? appears in the Status Area) your Sensor signal at the time you entered the fingerstick readings for calibration.

Additional Startup Blood Drop Prompt

The Additional Startup Blood Drop Prompt (with 1 checked) means you need 1 more fingerstick reading for Startup Calibration.

This screen will appear and the Receiver will make a medium tone and vibrate once (if set to “Vibe then beep”). The Receiver will continue to show the Additional Startup Blood Drop Prompt screen every 15 minutes until the fingerstick reading is successfully entered into the Receiver.

Additional Blood Drop Prompt

Single Blood Drop Prompt

The Single Blood Drop Prompt means you need 1 more fingerstick reading to calibrate. This symbol will appear when it is time for the 12-Hour Calibration Update or if the Receiver needs another fingerstick reading for Re-calibration.

Single Blood Drop Prompt

- 12-Hour Update: The screen will prompt you again every 15 minutes until a new fingerstick reading is successfully entered.
- Additional fingerstick needed: The Receiver will vibrate and will make a sound. The Receiver will notify you two more times (to enter a fingerstick), or until a new fingerstick reading is successfully entered.

9.2.1.2 STATUS AREA SYMBOLS DURING BLOOD DROP PROMPTS

If you are prompted repeatedly by the Double Blood Drop screen, Additional Startup Blood Drop screen (1 checked), or the Single Blood Drop screen, make sure you first check the Status Area on your Receiver before you take another fingerstick reading. Then follow the steps below:

1. Clear the prompt from the Screen by pressing any button on the Receiver.
2. Check the Status Area in the upper right corner of your Receiver. You will decide what to do based on the symbol that is shown in the Status Area:

   a. If the Double Blood Drop Prompt Symbol is displayed:

   - Take 2 more fingerstick readings if you are prompted by the Double Blood Drop.

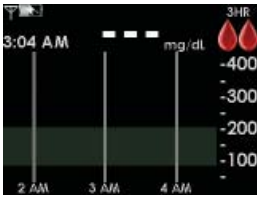
   b. If the Additional Startup Blood Drop Prompt Symbol is displayed:

   - Take 1 more fingerstick reading if you are prompted by the Additional Startup or Single Blood Drop. (Readings must be within 40-400 mg/dL).0

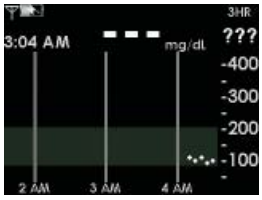
   c. If the “Single” Blood Drop Symbol prompt is displayed:

   - Enter your fingerstick readings into the Receiver.

   d. If ??? is displayed, your Receiver cannot understand your Sensor signal. Do not take any more fingerstick readings for calibration at this time. Wait until you see one of the Blood Drop Prompts and review Steps 1 and 2.



Double Blood Drop Prompt

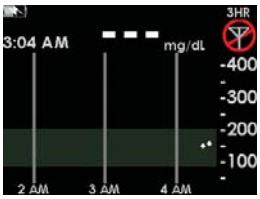


“Unknown Glucose Reading” Symbol

e. If the Out of Range Symbol is displayed, do not take any more fingerstick readings for calibration at this time. Move the Receiver and Transmitter so that they are within 20 feet (6 meters) of each other and wait at least 5 minutes.

1. Make sure your Transmitter ID is entered into the Receiver (see Chapter 2, Section 2.4)
2. Make sure your Transmitter is fully snapped in

If you are still having problems with communication review Chapter 5, Section 5.4.4. When you are prompted with any of the Blood Drop Prompt screens again, review the steps at the beginning of this section to calibrate.



Out of Range Symbol

HELPFUL HINT: If you are still having trouble with G4-Global System calibration (e.g., receiving repeated prompts) following these steps, contact DexCom Technical Support at 1-888-SEVENGO (738-3646) for help.

9.3 SENSOR FAILED TROUBLESHOOTING

In some cases your Sensor session may stop before the end of a full 7-day period. Follow the guidelines below to have the best results with your System.

- Do not use expired Sensors
- Store Sensors at room temperature (see Chapter 10, Section 10.2)
- Quality check your blood glucose meter
- Make sure your Transmitter is snapped in fully
- Make sure your Sensor Pod is not dislodged or peeling up

During use your System may detect problems that make your Sensor unable to calculate glucose readings (see Chapter 5, Section 5.4.3). At this time the Sensor session will stop automatically and the following screen will appear.

Sensor Failed Screen

9.4 CALIBRATION ERROR TROUBLESHOOTING

The screen to the right means your Sensor cannot calibrate. If you see this screen, enter at least 1 more calibration fingerstick reading after about 10-15 minutes. If no readings are displayed after this additional fingerstick, the Sensor may need to be replaced.

15 Minute Calibration Error Screen

If you clear this screen by pressing any button on the Receiver, you will see this symbol ( ) in the Status Area.

The screen to the right tells you that the Sensor is not calibrating correctly. If you see this screen, wait approximately one hour. Then, enter at least 1 more calibration fingerstick reading. If no readings are displayed after this additional fingerstick, the Sensor may need to be replaced.

1-Hour Calibration Error Screen

If you clear this screen by pressing any button on the Receiver, you will see this symbol ( ) in the Status Area.

Receiver Error Code

An error code displayed on your Receiver means the Receiver may not be working properly. An example is shown to the right:

Receiver Error Code Screen

Note any code that may appear on the screen, and contact DexCom Technical Support at 1-888-SEVENGO (738-3646). Continue to check blood glucose readings using your meter.

System Recovery Check

This screen indicates that the System discovered an error that it was able to fix itself. Press any button on the Receiver to clear this display, and your continuous monitoring session will continue.

System Recovery Check Screen

9.5 RECEIVER AND CABLES TROUBLESHOOTING

Battery and Charging Difficulties

1. Remember to charge your Receiver battery.
   a. The charge will last approximately 3-5 days, depending on how often you turn on your Receiver, use the Alerts, and enter Events.
   b. Make sure you are not pressing buttons by mistake if you carry the Receiver in your pocket or bag.
   c. Check the Battery image on your Trend Graphs to see how much charge is left in the battery.
   d. The Receiver takes about 3 hours to charge fully if using the wall charger, and about 5 hours to charge fully using the USB charger.
2. Make sure the Charging Cable is fully inserted in the Receiver and in the electrical outlet.
   a. Pull the cable out carefully.
   b. Only use DexCom cables.
3. If your battery drains and is not charged for a few weeks, the time and date may be lost. When this happens, you will need to reset your Receiver's time and date (see Chapter 2, Section 2.3).
4. Only use the DexCom battery charger.

Alerts Not Working

1. Make sure you have not disabled the sound and/or vibrations for the Alerts. Chapter 2, Section 2.5 explains how to change these Alert options.
2. Check to be sure that Advanced Features is turned on. If not, you will not receive Rise and Fall Rate Alerts.
3. Remember “Vibe then Beep” will vibrate during the first alert and then will beep during the re-alert. If you do not hear a sound during the first alert, this is normal.

9.6 RECEIVER AND TRANSMITTER COMMUNICATION TROUBLESHOOTING

This screen will appear once the Transmitter nears the end of its battery life (see Chapter 1, Section 1.2). Contact DexCom to order a new Transmitter.

Low Transmitter Battery Screen

The screen to the right tells you that the Transmitter is not working correctly. If you get this alert during a Sensor session in progress, your Sensor session will automatically stop. Note this alert and contact DexCom Technical Support at 1-888-SEVENGO (738-3646). Continue to check blood glucose readings using your meter.

Transmitter Failed Screen

chapter ten

TAKING CARE OF YOUR G4-GLOBAL SYSTEM


10

10.1 MAINTENANCE

The G4-Global Receiver requires minimal maintenance. Keep the following tips in mind:

Sensor and Transmitter

- Insert the Sensor only as directed.
- Snap the Transmitter completely into the Sensor Pod in the correct alignment.
- Calibrate the G4-Global Receiver every 12 hours as directed.
- Do not wear the Sensor/Transmitter in water deeper than 3 feet and do not wear the Sensor/Transmitter in water for over 30 minutes.
- Remove the Sensor and Transmitter as directed.
- Wipe the Transmitter clean with a wet cloth or alcohol wipe between uses.
- Keep the Transmitter clean and protected when not in use.

Receiver

- Do not get the Receiver wet.
- Keep the Receiver in its carrying case or otherwise protected.
- Charge the Receiver when the battery gets low.

Accessories

- Insert cables only as directed. Only use cables intended for use with the G4-Global Receiver. Do not force cables in place.
- Observe cables for signs of wear and tear.
- Maintain your fingerstick blood glucose meter as directed by the manufacturer.
- Only use DexCom-supplied parts (including cables and chargers). Use of other parts might degrade safety.

10

10.2 STORAGE

Sensor

- Keep the Sensor in its sterile packaging until you are ready to use it.
- Do not insert Sensors past the expiration date printed on the Sensor packaging.
- Storage Temperature should be 36°-77° F (2°-25° C) for the length of its shelf life. You may store your Sensors in the refrigerator if it is within this temperature range.

Transmitter

- Keep the Transmitter clean and protected when not in use.
- Transmitter Warranty is 6 months.
- Storage Temperature should be 32°- 113° F (0°- 45° C).

Receiver

- Keep the Receiver clean and protected when not in use.
- Receiver Warranty is 1 year.
- Storage Temperature should be 32°- 113° F (0°- 45° C).
- Store at Humidity levels between 10-95% Relative Humidity.

10.3 CLEANING AND DISINFECTING

WARNING: Review all contraindications, warnings, precautions and detailed procedures in the User's Guide before using the G4-Global System.

PRECAUTION:

- Always disinfect and clean the Transmitter after removing it from the body/ patient.
- Always clean and/or disinfect the Receiver while it is DISCONNECTED from any cables or electrical outlets.

NOTE:
- Always clean the Receiver and Transmitter after each use.
- Do NOT use bleach or acetone to clean the Receiver and Transmitter.

For Single-Patient Use

Cleaning

1. Use an alcohol wipe, or equivalent to clean the outside of the Receiver and Transmitter. Avoid using wipes that contain adhesive properties. (e.g. Smith + Nephew IV Prep™).

NOTE: Do NOT get the DexCom Receiver wet. Ensure the wipe is slightly damp, but not wet enough to leave drops of liquid on the Receiver surface (particularly the openings and buttons).

2. Place the Receiver and Transmitter on a clean, dry cloth and air dry for 2-3 minutes.

For Multi-Patient Use

Preparation

1. Use precaution when handling products worn by another person.
2. Wash hands thoroughly.
3. Wear personal protective equipment as appropriate (gloves, protective goggles, gowns, etc.).

Disinfection

4. Wipe down the outer surface of each component with Steris® Coverage® Spray TB Plus, or equivalent sterilant.
5. Allow contact time for 3 minutes at room temperature (20°C/68°F).

Cleaning

6. Use an alcohol wipe, or equivalent, to clean the outside of the Receiver and Transmitter. Avoid using wipes that contain adhesive properties (e.g. Smith + Nephew IV Prep™).

NOTE: Do NOT get the DexCom Receiver wet. Ensure the wipe is slightly damp, but not wet enough to leave drops of liquid on the Receiver surface (particularly the openings and buttons).

7. Verify that any signs of bodily fluids have been wiped away. The presence of bodily fluids is rare.
8. Place the Receiver and Transmitter on a clean, dry cloth and air dry for 2-3 minutes.
9. When completely dry, place the Receiver and Transmitter in a sealed bag with the cleaning method and date. For example:

NOTE: Include the following information in the Multi-Patient Use Disinfection and Cleaning Record: Device Information, Date of Disinfection and Cleaning, Method of Disinfection (e.g. disinfectant), and Method of Cleaning (e.g. 70% or 99% IPA).

10. Dispose of gloves as biohazard waste and wash your hands immediately after completing disinfection and cleaning of Receiver and Transmitter.

chapter eleven

STUDY RESULTS

Section 11.1

Placeholder for G4-Global Receiver Pivotal Study Results

Section 11.1

Placeholder for G4-Global Receiver Pivotal Study Results

Section 11.1
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Placeholder for G4-Global Receiver Pivotal Study Results

Section 11.1

Placeholder for G4-Global Receiver Pivotal Study Results

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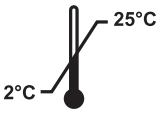
Section 11.1

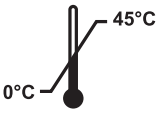
Placeholder for G4-Global Receiver Pivotal Study Results

11.2 PRODUCT SPECIFICATIONS

Sensor

Glucose Range	40-400 mg/dL (2.2 – 22.2 mmol/L)	
Sensor Life	Up to 7 days	
Calibration	FDA-cleared blood glucose meter	
Calibration Range	40-400 mg/dL (2.2 – 22.2 mmol/L)	
Operational Conditions	Humidity: Maximum 95 % Relative	
Storage Condition	Temperature: 2°-25° C (36°-77° F)	
Moisture Protection	IPX 5: water resistance to jetting water IPX 8: temporary submersion to a depth of 8 feet (2.44 meters) for 24 hours	
Sterilization	Sterile by radiation	

Transmitter

Dimensions (including Sensor Pod)	Length: 1.5 inches (3.8 cm) Width: 0.9 inches (2.3 cm) Thickness: 0.5 inches (1.3 cm)	
Weight (including Sensor Pod)	0.4 ounces (10 grams)	
Communication Range	20 ft (6m)	
Frequency Range	2.425 - 2.477 GHz	
Power Supply	Silver Oxide Batteries	
Operational Conditions	Temperature: 10°- 42° C (50°- 108° F) Humidity: Maximum 95% Relative	
Storage Conditions	Temperature: 0°- 45° C (32°- 113° F)	
Limited Warranty	6 months	
Moisture Protection	IPX 5: water resistance to jetting water IPX 8: temporary submersion to a depth of 8 feet (2.44 meters) for 24 hours	
Protection Against Electrical Shock	Type B Applied Part	

PARAMETER	PERFORMANCE CHARACTERISTICS
Frequency Allocation	2.4 GHz ISM Band
TX/RX Frequencies	2.424 999 877 GHz 2.449 993 677 GHz 2.474 737 539 GHz 2.477 236 919 GHz
Bandwidth	270.833 kHz
Maximum Output Power	1.25 mW EIRP
Modulation	Minimum Shift Key
Data Rate	49.987 Kbits/Sec
Total Packet	224 bits
Transmit Duty Cycle	4.48 ms every 5 minutes at each of the four TX frequencies.
Data Detection Range	20 ft (6m)
Average Number of Collisions due to Coexistence. 20 DexCom Transmitters within 20 feet over a 24 hr period (288 transmissions each)	Total of 2 collisions, if collision occurs, no glucose value is received

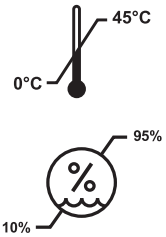
11

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the Transmitter should assure that it is used in such an environment

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Electromagnetic Environment Guidance Electrostatic Discharge (ESD) **IEC 61000-4-2**	± 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 %
Electrical Fast Transient /burst **IEC 61000-4-4**	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable- Battery Operated	
Surge **IEC 61000-4-5**	± 1 kV differential mode ± 2 kV common mode	Not Applicable- Battery Operated	
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines **IEC 61000-4-11**	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 sec	Not Applicable- Battery Operated	
Power Frequency **(50/60 Hz) Magnetic Field** **IEC 61000-4-8**	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

Receiver

Reading Frequency	Every 5 minutes	
Dimensions	Length: 4.5 inches (11.4 cm) Width: 2.3 inches (5.8 cm) Thickness: 0.85 inches (2.2 cm)	
Weight	4.0 ounces (113.39 g)	
Communication Range	20 ft (6m)	
Memory Storage	30 days of user data, 7 days of tech support	
Re-Chargeable Battery Use	3 to 5 days	
Charging Time	3 hours wall outlet, 5 hours USB	
Storage/Operating Conditions	Temperature: 0°- 45° C (32°- 113° F) Humidity: 10-95 % Relative	
Operating Pressure	10.2 to 21.8 psi	
Moisture Protection	None	
Limited Warranty	1 year	

11

Guidance and Manufacturer's Declaration- Electromagnetic Immunity

The Receiver is intended for use in the electromagnetic environment specified below. The customer or the user of the Receiver should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
Electromagnetic Environment Guidance Electrostatic Discharge (ESD) **IEC 61000-4-2**	± 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%
Electrical Fast Transient /burst **IEC 61000-4-4**	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Main power quality should be that of a typical commercial or hospital environment
Surge **IEC 61000-4-5**	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Main power quality should be that of a typical commercial or hospital environment
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines **IEC 61000-4-11**	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 sec	Main power quality should be that of a typical commercial or hospital environment

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
Power Frequency **(50/60 Hz) Magnetic Field** **IEC 61000-4-8**	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: UT is the a.c. main voltage prior to application of the test level

Guidance and Manufacturer's Declaration- Electromagnetic Immunity

The Receiver is intended for use in the electromagnetic environment specified below. The customer or the user of the Receiver should assure that it is used in such an environment.

Electromagnetic Environment Guidance
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. Recommended Separation Distance $d = 1.2\ P^{1/2}$ $d = 1.2\ P^{1/2}$ 80 MHz to 800 MHz $d = 2.3\ P^{1/2}$ 800 MHz to 2.5 GHz
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*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000- 4-6	3 Vrms 150 k Hz to 80 MHz	3 V	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).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with following symbol:
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 measure field strength in the location in which the Receiver is used exceeds the applicable RG compliance level above, the Receiver should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as reorienting or relocating the Receiver.

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and 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.

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 0.1 1 10 100	0.12 0.38 1.2 3.8 12	0.12 0.38 1.2 3.8 12	0.23 0.73 2.3 7.3 23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) 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.

Charging Cable*

AC Input	110-240 V, 50-60 Hz
Length	6.6 FT (2 M)

***** There is a separate USB cable and USB power supply.

11.3 FCC REQUIREMENTS

The Transmitter covered by this User's Guide has been certified under FCC ID: PH29433

Although the Transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from the Transmitter 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 twelve

APPENDIX

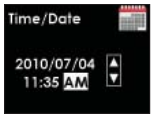

12

APPENDIX I, OTHER ALERTS

This table describes the Other Alerts, how to clear them and when you will be re-alerted by the Receiver.

Screen	Alert Title	Description	Re-Alert	Clearing Alerts	Re-Alert After Clear
	Low Battery	The Receiver battery is low. Charge your Receiver as soon as possible when you see the Low Battery Alert.	2 times in the next 10 minutes	Press any Receiver button	Every 60 minutes
	Single Blood Drop Prompt	The Receiver needs a calibration fingerstick reading. Take a fingerstick reading and enter it into the Receiver.	None	Press any Receiver button	Every 15 minutes
	Double Blood Drop Prompt	You must enter two additional fingerstick readings for Startup Calibration.	Every 5 minutes	Press any Receiver button	Every 15 minutes
	Additional Blood Drop Prompt	You must enter one additional fingerstick reading for Startup Calibration.	Every 5 minutes	Press any Receiver button	Every 15 minutes

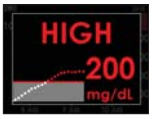
Screen	Alert Title	Description	Re-Alert	Clearing Alerts	Re-Alert After Clear
	Wait 15 minutes to calibrate	The Sensor is not calibrating properly (see Section 8.4, “Error Code Troubleshooting for instructions on what to do is you see this screen).	Every 5 minutes	Press any Receiver button	Every 15 minutes until you fix the problem, or your glucose level changes enough to fix the problem itself
	Wait 1 Hour to calibrate				
	Sensor Expiration	Your Sensor session will soon expire, and you will need to change your Sensor soon. There will be no sound when the 6-hour and 2-hour screens display. The 30-minute screen will be set to your “Other Alert” options.	None for 6-hour and 2-hour. 2 times in the next 10 minutes for 30-minute	Press any Receiver button	None
	Sensor Expiration	The Sensor session is complete. You should change your Sensor at this time.	2 times in the next 10 minutes	Press any Receiver button	None

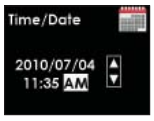
Screen	Alert Title	Description	Re-Alert	Clearing Alerts	Re-Alert After Clear
	Sensor Failed	The Sensor is not working properly (see Section 8.3, “Sensor Failed Troubleshooting”).	2 times in the next 10 minutes	Press any Receiver button	None
	Receiver Error	There is a problem with the Receiver. Write down the code on the screen, and contact DexCom.	None. The Receiver will beep and vibrate for 5 seconds and then will be silent.	Cannot clear alert	None
	System Recovery	There was a problem with the Receiver, but it was able to fix itself.	Every 5 minutes	Press any Receiver button	None
	Time Loss	The Receiver backup battery has drained, and you will need to reset the Receiver time and date. The Time Loss Alert automatically takes you to the Time/Date Setting screen.	None	Enter the time and date	None

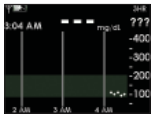
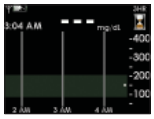
12

APPENDIX II, RECEIVER SCREENS & PROMPTS

The following prompt screens may appear on the Receiver during use:

	**DOUBLE BLOOD DROP PROMPT:** Appears about 1 hour after you insert a new Sensor, and tells you that you need to take 2 fingerstick readings on your meter and enter them for calibration.
	**DOUBLE BLOOD DROP PROMPT, (1 CHECKED):** This tells you that only 1 fingerstick reading has been successfully entered. You need to take at least 1 more fingerstick reading on your meter and enter it for calibration.
	**SINGLE BLOOD DROP PROMPT:** This screen appears during Calibration Update or Re-Calibration. This means it is time for you to take a fingerstick reading on your meter and enter it into the Receiver. Only enter fingerstick readings if the Single Blood Drop Symbol or your current glucose reading is displayed on the Trend Graph. Do not enter any fingerstick readings if ???, or appear in the upper right corner of the Trend Graph.
	**RECEIVER LOW BATTERY NOTIFICATION:** Your Receiver battery is running low and needs to be recharged. Charge the battery as soon as possible.
	**ENTER BG PROCESSING SCREEN:** The meter reading that you entered is being processed for calibration by the Receiver.
	**HIGH GLUCOSE ALERT:** Your glucose reading is at or above the High Glucose Alert level you set.
	**LOW GLUCOSE ALERT:** Your glucose reading is at or below the Low Glucose Alert level you set.

	**LOW GLUCOSE ALARM**: Your System reading is at or below the factory Low Glucose ALARM level (55 mg/dL). You cannot change this ALARM level.
 	**RISE ALERTS:** Either the Rise Alert or Rapid Rise Alert may appear, depending on the Rise Alert level you set. **Rise Alert:** Your glucose levels are rising at 2 mg/dL per minute or more. OR **Rapid Rise Alert:** Your glucose levels are rising fast at 3 mg/dL per minute or more.
 	**FALL ALERTS:** Either the Fall Alert or the Rapid Fall Alert may appear, depending on the Fall Rate Alert level you set. **Fall Alert:** Your glucose levels are falling at 2 mg/dL per minute or more. OR **Rapid Fall Alert:** Your glucose levels are falling fast at 3 mg/dL per minute or more.
	**OUT OF RANGE ALERT:** The Transmitter and Receiver are not talking and you will not receive glucose readings.
	**SENSOR FAILED SCREEN:** The Sensor is not working. You will need to replace the Sensor at this time.
	**TIME/DATE LOSS ALERT:** The Receiver backup battery is drained, so you need to reset the Receiver time and date. The Time Loss Alert will automatically take you to the Time/Date Setting Screen. If you were in the middle of a Sensor Session, this Alert will end your session. You must recharge the Receiver battery. Then, you must set the correct date and time and start a new session.

	**OUT OF RANGE/NO ANTENNA:** The Receiver and Transmitter are not talking and your glucose readings have not been sent to the Receiver in the last 5 minutes. If you see this screen (with no Antenna Symbol in the upper left hand corner) you should make sure the Receiver and Transmitter are within 20 feet (6m) of each other. See Chapter 8 for Troubleshooting.
	**UNKNOWN SENSOR GLUCOSE READINGS:** ??? appears in the upper right corner of the Trend Graph. The Sensor is sending glucose readings that the Receiver does not understand.
	**15 MINUTE CALIBRATION ERROR:** The Sensor cannot calibrate. If you see this screen, enter at least 1 more fingerstick reading for calibration after about 10-15 minutes. If no glucose readings appear on the Receiver, the Sensor needs to be replaced.
	**1 HOUR CALIBRATION ERROR:** The Sensor is not calibrating correctly. If you see this screen, wait approximately 1 hour and then enter at least 1 more fingerstick reading for calibration. If no glucose readings appear up on the Receiver, the Sensor needs to be replaced.
	**WAIT:** The Single Hourglass Symbol in the upper right hand corner means the Receiver has detected a potential problem with the Sensor signal. You should wait about 30 minutes for more prompts. Do not enter any fingerstick readings for calibration when you see this symbol.
	**ERROR CODE:** The Receiver may not be working correctly. If you see this code, write the code down for troubleshooting and use your meter to check your blood glucose readings.
	**SYSTEM RECOVERY:** The Receiver discovered an error that it was able to fix itself. Press any Receiver button to clear this display. Your Sensor session will continue.
	**6-HOUR SENSOR EXPIRATION NOTIFICATION:** Your Sensor session will end in 6 hours.

	**2-HOUR SENSOR EXPIRATION NOTIFICATION:** Your Sensor session will end in 2 hours.
	**30-MINUTE SENSOR EXPIRATION NOTIFICATION:** Your Sensor session will end in 30 minutes.
	**0-HOUR SENSOR EXPIRATION NOTIFICATION:** Your Sensor session has ended. Once you clear the Alert, your Receiver will be notified that the Sensor has been removed. You should clear this notification by pressing any Receiver button, then remove your Sensor at this time.

12

GLOSSARY

The following list of terms will help you while reading though this guide:

Alternative Site Testing (BG)	This is when you obtain a glucose reading on your meter using a blood sample from an area on your body other than your fingertip. Do not use alternative site testing for entering blood glucose readings into the G4-Global Receiver.
Applicator	A disposable component piece that comes attached to the Sensor Pod, and inserts the Sensor Probe under the skin. There is a needle inside the Applicator that you remove once you have inserted the Sensor Probe.
BG meter	Blood Glucose meter. You can use any FDA-cleared meter for obtaining fingerstick readings to enter into your G4-Global Receiver.
BG reading	Blood Glucose reading. A fingerstick blood glucose reading taken with your FDA-cleared blood glucose meter.
Calibration	This is when you enter fingerstick readings from a blood glucose meter into the G4-Global Receiver. Calibrations are needed for your G4-Global Receiver to display continuous glucose readings and trend information. (Do not use alternative site testing for calibration.)
Default	A setting that is selected automatically unless another option is chosen.
FDA-cleared System	The product has met the U.S. Food and Drug Administration's standards and may be sold legally in the United States.
G4-Global System	The Sensor, Transmitter, and Receiver.
G4-Global Reading	A glucose reading shown on your Receiver. This reading is given in mg/dL units and is updated every 5 minutes.
Glucose Data Gaps	This can happen when the Receiver does not display a glucose reading that is sent from the Transmitter. A symbol will appear instead of a glucose reading to let you know that the Receiver cannot display a reading.
Glucose Trends	Trends let you see the pattern of your glucose levels; you can see where your glucose levels have been and where your glucose levels are headed. The G4-Global Receiver displays five glucose Trend Graphs: the 1-Hour, 3-Hour, 6-Hour, 12-Hour, and 24-Hour Graphs. Each Trend Graph shows glucose trends over the amount of time shown on the screen.

mg/dL	Milligrams per deciliter. The standard unit of measure for glucose readings in the United States.
Range	The distance between the Receiver and Transmitter. Keep the 2 devices within 20 feet (6 meters) from each other to get glucose information on your Receiver
Rise and Fall (Rate of Change) Alerts	Alerts based on how fast your glucose levels rise/fall, and by how much.
Receiver	An MP3-like device, which collects your glucose information from the Sensor/Transmitter. Your results are displayed on the Receiver screen as a glucose reading (mg/dL) and as a trend.
RF	Radio-Frequency transmission used to send glucose information from the Transmitter to the Receiver.
Safety Lock/ Transmitter Key	The Safety Lock keeps the needle inside the Applicator before you are ready to insert the Sensor Probe. It also helps you snap the Transmitter out of the Sensor Pod after your Sensor session has ended.
Sensor	The G4-Global System component that is inserted under the skin to continuously measure your glucose levels.
Sensor Pod	The small base of the Sensor attached to your belly that holds the Transmitter in place. The Sensor Pod and Transmitter are all that remain on your skin during each Sensor use.
Sensor Probe	The part of the Sensor that is inserted under your skin with the Applicator. It measures the glucose levels in your surrounding tissue fluid.
Startup Period	The 1-hour “startup” period after you tell the Receiver you have inserted a new Sensor (glucose readings cannot be provided during this time).
Transmitter	The G4-Global System component that snaps into the Sensor Pod and wirelessly sends glucose information to your Receiver.
Transmitter ID	Transmitter ID Number that is entered into your Receiver to enable it to talk to the Transmitter.

Transmitter Latch	The small disposable component that snaps the Transmitter into the Sensor Pod. It is removed after the Transmitter is snapped in.
Trend (Rate of Change) Arrows	Arrows on Trend Graphs that indicate if and how fast your glucose levels are changing. The are 7 different arrows that show when your glucose speed and direction change.

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 G4-Global System. This table shows what each symbol means.

	**"Use By" Date**		**Lot Number**
	**Caution**		**Part Number, Catalog Number**
	**Date of Manufacture**		**Lower Limit of Temperature**
	**Do Not Reuse**		**Two-sided Temperature Limits**
	**Serial Number**		**Upper Limit of Temperature**
	**Sterilized by Radiation**		**Keep Dry**
	**Do Not Use if Package is Damaged**		**Direct Current**

IPX 5	Water resistant to jetting water		Type B Applied Part
IPX 8	Temporary submersion to a depth of 8 feet (2.44 meters) for 24 hours		Follow Operating Instructions
	Manufacturer	EC REP	Authorized Representative in the European community
	Humidity Limitation		

:: ADDITIONAL INFORMATION

Receiver INPUT: 5 VDC, 750 mA

Rated supply voltage range: 100-240 VAC (AC supply)

Phases and current: 0.3A (AC supply)

Rated frequency range: 50-60 Hz (AC supply)

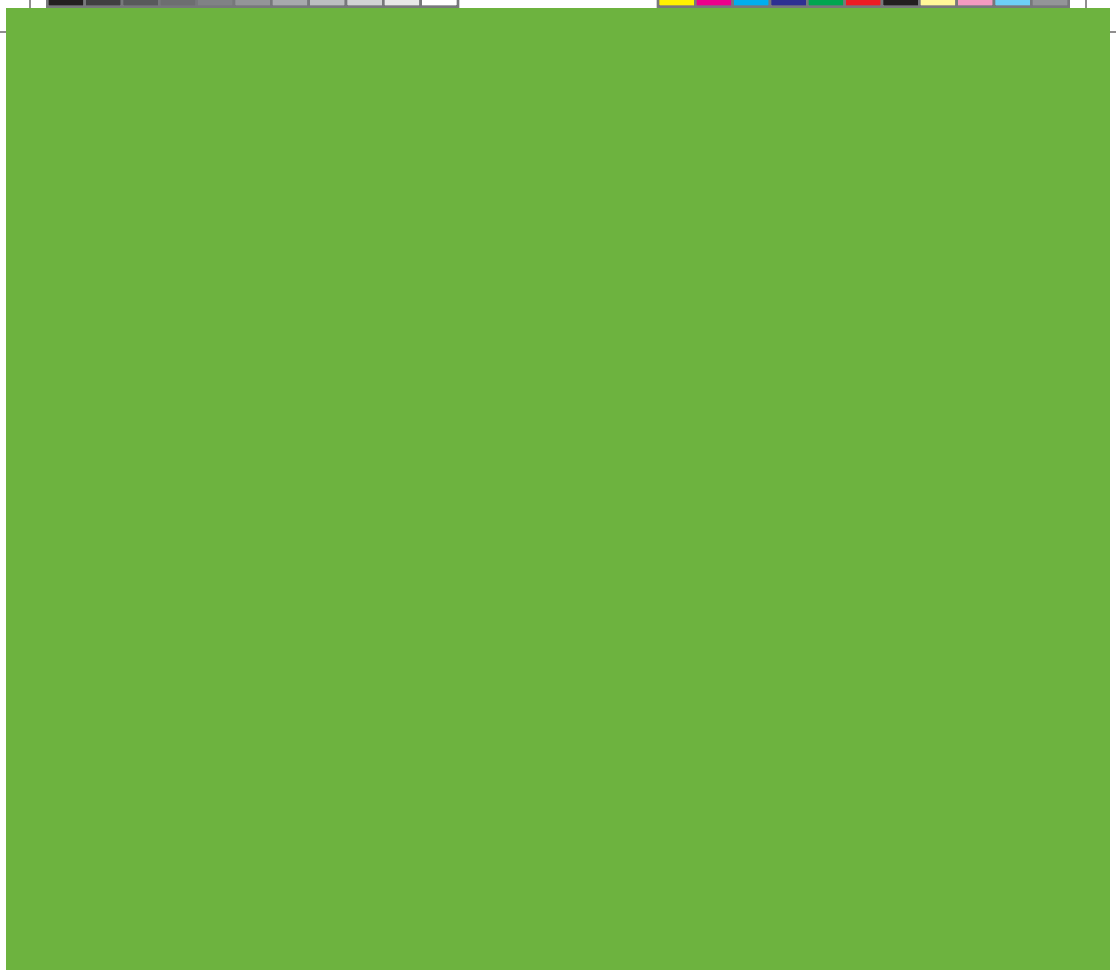
index

R

S

T

W



dexcom™
THE GLUCOSE SENSOR COMPANY™

DexCom, INC
6340 Sequence Drive,
San Diego, CA 92121 USA
+1.858.200.0200
www.DexCom.com

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