seven® PLUS

continuous glucose monitoring system

USERS GUIDE

Dexcom™
THE GLUCOSE SENSOR COMPANY™

seven® PLUS

continuous glucose monitoring system

IMPORTANT CONTACTS AND NUMBERS

DexCom Technical Support:	1-888-SEVENGO (738-3646)
DexCom Website:	www.DexCom.com
Your Transmitter ID Number:	
Your Transmitter Expiration Date:	
Your Receiver ID:	
Your Healthcare Professional:	
Nearest Hospital:	
Other Notes:	

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SEVEN® PLUS CONTINUOUS GLUCOSE MONITORING SYSTEM

SEVEN PLUS CONTINUOUS GLUCOSE MONITORING SYSTEM KIT CONTENTS:

- Transmitter
- Receiver
- DexCom Data Manager® Accessory Software
- Receiver Charging Cable
- Receiver Case
- User's Guide
- Quick Start Guide
- CD Tutorial
- Training Checklist

NOTE: Sensors are sold separately. Commercially distributed blood glucose meter required for use. Make sure to use the correct version of Data Manager with your SEVEN PLUS. The SEVEN Sensor works with the SEVEN family of products. The SEVEN PLUS Transmitter and Receiver are not backwards compatible with the SEVEN Transmitter and Receiver.

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introduction

DexCom would like to thank you for purchasing the SEVEN PLUS Continuous Glucose Monitoring System (SEVEN PLUS)! When you use the SEVEN PLUS, 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 SEVEN PLUS 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-hours, 6-hours, 12-hours, and 24-hours. 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 with the OpenChoice™ feature on the SEVEN PLUS. The SEVEN PLUS is also directly compatible with the Lifescan® OneTouch® Ultra® Blood Glucose meter for calibration using an optional Connection Cable, which is available for purchase from DexCom Customer Support.

This User's Guide describes how to use your SEVEN PLUS from start to finish of a continuous glucose monitoring session. Important safety information, warnings, precautions, cautions, and contraindications of the SEVEN PLUS 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.

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INDICATION FOR USE

The SEVEN PLUS 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 SEVEN PLUS System is intended for use by patients at home and in health care facilities. The device is for prescription use only.

The SEVEN PLUS 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 SEVEN PLUS 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 SEVEN PLUS 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 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 SEVEN PLUS User's Guide. The Troubleshooting section (Chapter 8) contains important information on troubleshooting your SEVEN PLUS. The Technical Information section (Chapter 10) provides information on the performance characteristics of the device.

CONTRAINDICATIONS

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

WARNINGS

- This device is not designed to replace a blood glucose meter. The SEVEN PLUS must be used with a blood glucose meter.
- Treatment decisions should not be based solely on results from the SEVEN PLUS. You must confirm with 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 your blood glucose meter to check the SEVEN PLUS results.
- You should update the SEVEN PLUS' calibration every 12 hours at a minimum. The performance of the SEVEN PLUS System when calibrated less frequently than every 12 hours has not been studied.

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- Sensors 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 SEVEN and SEVEN PLUS Systems **are not approved for use** in children or adolescents, pregnant women or persons on dialysis.
- The safety and effectiveness of the SEVEN and SEVEN PLUS Systems have 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 of a 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.
- For OpenChoice Calibration 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 that occurred more than 5 minutes ago will affect device performance.

CAUTION

U.S. federal law restricts the sale of the SEVEN PLUS to sale by or on order of a physician.

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chapter one

THE SEVEN PLUS BASICS

1

1.1 GLOSSARY

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

Alternative Site Testing (BG)	This is when you take fingerstick readings from somewhere on your body other than your fingertip. Do not use alternative site testing with the SEVEN PLUS.
Applicator	A disposable 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.
Auto Upload	To transfer fingerstick readings from the OneTouch Ultra Meter to your Receiver directly with the optional Connection Cable.
BG meter	Blood Glucose Meter. You can use any FDA-cleared meter with the OpenChoice feature on your SEVEN PLUS.
BG reading	Blood Glucose reading. A fingerstick blood glucose reading taken with your FDA-cleared blood glucose meter.
Calibration	This is when you transfer fingerstick readings into the SEVEN PLUS using Auto Upload or the OpenChoice feature. Calibrations are needed for your SEVEN PLUS 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	The product has met the U.S. Food and Drug Administration's standards and may be sold legally in the United States.
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 SEVEN PLUS has 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.
OpenChoice	To transfer fingerstick readings from an FDA-cleared meter to your Receiver by hand-entering the readings using the "Enter BG" option from the menu. You should always use the same meter to calibrate your SEVEN PLUS that you routinely use to measure your blood glucose. Do not switch your BG meter in the middle of Sensor wear.
Range	The distance between the Receiver and Transmitter. Keep the 2 devices within 5 feet (1.5 meters) from each other to get glucose information on your Receiver

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Rise and Fall (Rate of Change) Alerts	Alerts based on how fast your glucose levels rise/fall.
Receiver	A cell-phone-like device, which collects your glucose information from the Transmitter. Your results are displayed on the screen as a SEVEN PLUS reading (mg/dL) and trend.
Register	To connect a OneTouch Ultra Meter to the Receiver using the Connection Cable to make sure the date and time match. This lets the Receiver accept Auto Uploads.
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. It also helps you snap the Transmitter out of the Sensor Pod after your glucose monitoring session has ended.
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.
SEVEN PLUS SYSTEM	The Sensor, Transmitter, and Receiver.
SEVEN PLUS Reading	A glucose reading shown on your Receiver. This reading is given in mg/dL units and is updated every 5 minutes.
Sensor	The SEVEN device that is inserted under the skin to continuously monitor your glucose levels.
Start-Up Period	The 2-hour “countdown” period after you tell the Receiver you have inserted a new Sensor (Glucose information cannot be provided during this time).
Status Box	The upper right corner of the Receiver Trend Graph. Once you calibrate, there will be a glucose reading or a symbol telling you why a glucose reading is not available.
Transmitter	The SEVEN PLUS device that snaps into the Sensor Pod and wirelessly sends glucose information to your Receiver.

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Transmitter ID	Transmitter ID Number that is entered into your Receiver to talk to the Transmitter.
Transmitter Latch	The small disposable piece that snaps the Transmitter into the Sensor Pod. It is removed after the Transmitter is snapped in.
Trend Arrows (Rate of Change)	Arrows on your Receiver screen that appear below your glucose reading to indicate how fast your glucose levels are changing. The SEVEN PLUS has 7 different Arrows, which show you when your glucose speed and direction change.

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1.2 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 SEVEN PLUS. This table shows what each symbol means.

	"Use By" Date		**Do Not Use If Package Is Damaged**
	Caution	LOT	**Lot Number**
	Date of Manufacture	REF	**Part Number, Catalog \Number**
	Do Not Reuse		**Lower Limit of Temperature**
SN	**Serial Number**		**Two-sided Temperature Limits**
STERILE R	**Sterilized by Radiation**		**Upper Limit of Temperature**

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	Keep Dry		**Humidity Limitation**
	Direct Current		**Type B Applied Part**
IPX 5	**Water resistant to jetting water**	IPX 7	**Temporary submersion to a depth of 1 meter for 30 minutes**
	Follow Operating Instructions	EC REP	**Authorized Representative in the European community**
	Manufacturer		

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1.3 SENSOR OVERVIEW

The Sensor is a device 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. Doing 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 wear period. The Sensor insertion site is similar to an insulin pump infusion site.

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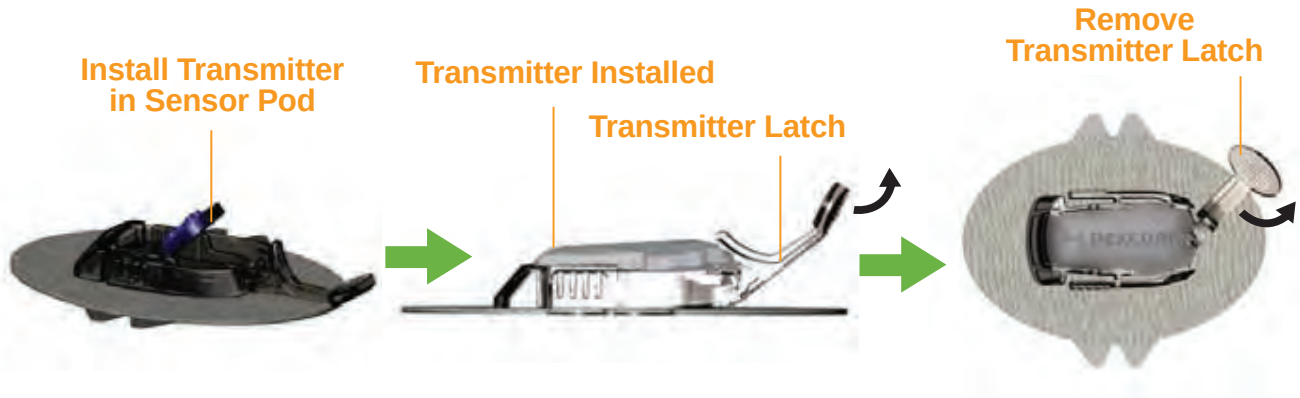
1.4 TRANSMITTER OVERVIEW

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.

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 Transmitter are within 5 feet (1.5 m) of each other. 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 2.2.2, “Setting your Transmitter ID”).

HELPFUL HINTS:

- Your Transmitter is re-used for many Sensor uses (1-year warranty).
- If you see in place of a glucose reading: This can happen even when your Transmitter and Receiver are within 5 feet of each other. Contact Technical Support at 1-888-SEVENGO (738-3646) to determine if you need to purchase a new Transmitter.
- The Receiver and Transmitter are designed and tested to withstand common electromagnetic interference, including airport security systems.



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1.5 RECEIVER OVERVIEW

The Receiver looks like a cell phone and shows your Sensor-measured glucose information. The SEVEN PLUS 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 do not know which type of unit your glucose readings are usually displayed in.

Keep the Receiver within 5 feet (1.5 m) of the Sensor and Transmitter at all times for your SEVEN PLUS to work the best. Good places to keep the Receiver are on your belt in the leather receiver case provided or in your pocket.

The Receiver is re-chargeable. The re-chargeable battery will last for about 3-5 days before you need to charge it with the Receiver Charging Cable. Your re-chargeable battery life depends on your Alert settings and how often you use the Events Menu. The Receiver will tell you when the battery charge is low. The Receiver takes 3 hours to charge fully if the battery is completely drained. To charge the Receiver, plug the charger cable provided into a standard wall outlet.

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The Receiver has 4 buttons to move you through the screens. The screens display glucose readings and trend graphs (“Trend Graphs”) and allow you to change your Receiver settings (“Menu Screens”). The Receiver is programmed 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, “Beginning a Sensor Session”).

Each Sensor must be “calibrated” before glucose readings are displayed on the Receiver. To calibrate, you can hand enter fingerstick readings (see Chapter 4, Section 4.1.1, “Using OpenChoice for Calibration”) from any FDA-cleared meter or you can calibrate with the OneTouch Ultra meter using a Connection Cable (see Chapter 4, Section 4.1.2, “Using Auto Upload for Calibration”).

HELPFUL HINTS:

- During nighttime use you may want to place the Receiver under your pillow or on your nightstand.

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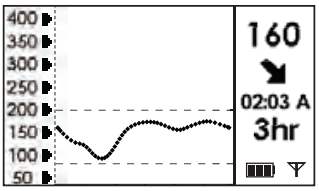
1.5.1 MOVING THROUGH THE RECEIVER SCREENS

1. Turn on the Receiver by pressing any button.

2. The Trend Graphs will appear.



a. The default screen is the 3-Hour Trend Graph, but you may see additional glucose information over time by pressing the Up ▲ and Down ▼ Arrow buttons to see the 1-Hour, 6-Hour, 12-Hour, and 24-Hour Trend Graphs.

3. From any Trend Graph, press the **OK** button to enter the Menu Screens.

a. The Up ▲ and Down ▼ Arrow buttons allow you to scroll through and highlight different Menus.

b. Press the **OK** button when the option you want is highlighted. You will then enter that Menu.

c. Press the **C** button to return to the previous Menu.

4. More information on Receiver Menus can be found in the sections listed below:

Menu	Purpose	User's Guide Reference
Trend Graph	To return to the Trend Graphs	Section 5.1
Start Sensor	To start a new Sensor. • This option only appears if a Transmitter ID has been entered and if you are not in the middle of using a Sensor	Section 3.8
Enter BG	To enter your fingerstick blood glucose readings for calibration (OpenChoice)	Section 4.1.1
Events	To enter information about meals, insulin, exercise, and health	Section 6.1

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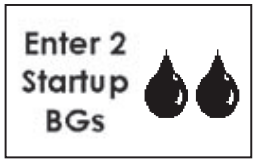
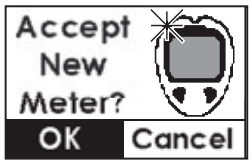
Alerts	To change the settings for Alerts and notifications from your Receiver, including High, Low, Out of Range, Rate of Change, and Other Alerts	Section 2.3
Settings	To change the time and date and Transmitter ID number and to look up your SEVEN PLUS' hardware and software numbers	Section 2.2
Shutdown	To temporarily turn off all communications between your Sensor, Transmitter and Receiver	Section 5.5
Stop Sensor	To end a Sensor wear session early • This option only appears in the middle of Sensor use	Section 7.2

1.5.2 RECEIVER SCREENS & PROMPTS

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

	**DOUBLE BLOOD DROP PROMPT:** Appears about 2 hours after you insert a new Sensor and tells you that you need to take 2 fingerstick readings on your meter and enter them to calibrate.
	SHADED-OUT BLOOD DROP PROMPT: This tells you that only 1 fingerstick reading has been successfully entered. You need to take and enter at least 1 more fingerstick reading using your meter 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 on your BG meter and enter it into the Receiver. But first check the Status Box. Only enter fingerstick readings if the Status Box shows the Single Blood Drop or a Glucose Reading. Do not enter any fingerstick readings if there are "???" or " " in the Status Box.
	LOW BATTERY NOTIFICATION: Your Receiver battery is running low and needs to be recharged. Charge the battery as soon as possible.
	**NEW METER SCREEN (Auto Upload only):** A new OneTouch Ultra meter has been plugged into your Receiver. This meter has a different serial number from the meter that was last connected to the Receiver. If you receive this screen during Auto Upload calibration, you will have to re-take any fingersticks needed for calibration and then connect the 2 devices again for Calibration Update.

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Uploading Meter	**CONNECTION SCREEN (Auto Upload only):** Your OneTouch Ultra meter is successfully transferring fingerstick readings to the Receiver using Auto-Upload with the Connection Cable.
Uploading Meter Failed	**CONNECTION FAILURE SCREEN (Auto Upload only):** Your OneTouch Ultra meter and the Receiver are not connected properly. Fingerstick readings have not been successfully transferred. This screen will only be seen when you attempt to use the Connection Cable. You should reconnect in the proper order until you see the Connection Screen or you should use OpenChoice instead.
Processing...	**METER READINGS PROCESSING SCREEN:** The blood glucose meter reading that you entered is being processed by the Receiver.
120 mg/dL Results: 1 Record Added	**RESULTS ADDED SCREEN:** The blood glucose reading you entered into the Receiver was accepted by the Receiver for calibration.
HIGH 200 mg/dL	**HIGH GLUCOSE ALERT:** Your System reading is at or above the High Glucose Alert level you set.
80 mg/dL LOW	**LOW GLUCOSE ALERT:** Your System reading is at or below the Low Glucose Alert level you set.
55 mg/dL LOW	**LOW GLUCOSE ALARM**: Your System reading is at or below the automatic Low Glucose ALARM. You cannot change this ALARM level.
Rise 2mg/dL/min or more	You can set one of these (or neither), but not both. **RISE ALERT:** Your glucose levels are rising at 2mg/dL per minute or more. OR **RAPID RISE ALERT:** Your glucose levels are rising fast at 3mg/dL per minute or more.
Rise 3mg/dL/min or more	

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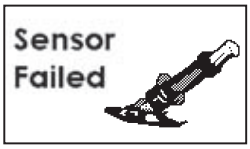
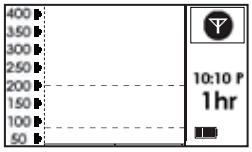
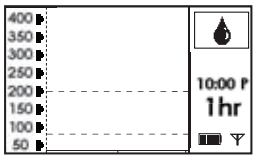
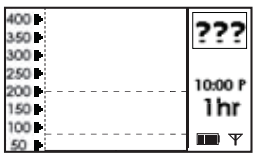
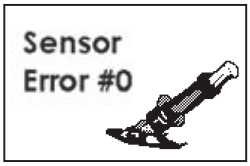
	You can set one of these (or neither), but not both. **FALL ALERT:** Your glucose levels are falling at 2mg/dL per minute or more.
	OR **RAPID FALL ALERT:** Your glucose levels are falling fast at 3 mg/dL per minute or more.
	OUT OF RANGE ALERT: The Transmitter and Receiver are not talking and you will not get readings.
	**FAILED SENSOR SCREEN:** The Sensor is not working. You will need to replace the Sensor at this time.
	TIME LOSS ALERT: The Receiver's back-up battery drained, so you need to reset the Receiver's time. The Time Loss Alert will automatically take you to the Time Setting Screen. If you were in a Sensor Session, this Alert will end your session. You must set the correct date and time and then start a new session.
	**OUT OF RANGE/NO ANTENNA:** The Receiver and Transmitter are not talking and your glucose data has not been sent to the Receiver in the last 5 minutes. If you see this screen you should make sure the Receiver and Transmitter are within 5 feet of each other. See Chapter 8 for Troubleshooting.
	**OUT OF CALIBRATION:** The SEVEN PLUS is not calibrated. If you see this screen you should take and enter an additional fingerstick reading.
	**UNKNOWN SENSOR GLUCOSE READINGS:** The Sensor is sending glucose readings that the Receiver does not understand.
	**SENSOR ERROR #0:** The Sensor cannot calibrate. If you see this screen, enter at least 1 more calibration fingerstick reading in the next 10-15 minutes. If no readings appear on the Receiver, the Sensor needs to be replaced.

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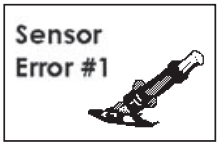	**SENSOR ERROR #1:** The Sensor is not calibrating correctly. If you see this screen, wait approximately one hour and then enter at least 1 more fingerstick reading. If no readings appear up on the Receiver, the Sensor needs to be replaced.
	ERROR CODE: The Receiver may not be working correctly. If you see this code, write the code down and use your meter to check your blood glucose readings. Notify DexCom Technical Support at 1-888-SEV-ENGO (738-3646).
	SYSTEM RECOVERY: The Receiver discovered an error that it was able to fix itself. Press the **C** button to clear this display, and your Sensor Session (Continuous Glucose Monitoring Session) will continue.
	6-HOUR SENSOR EXPIRATION NOTIFICATION: Your Continuous Glucose Monitoring Session will end in 6 hours.
	2-HOUR SENSOR EXPIRATION NOTIFICATION: Your Continuous Glucose Monitoring Session will end in 2 hours.
	30-MINUTE SENSOR EXPIRATION NOTIFICATION: Your Continuous Glucose Monitoring Session will end in 30 minutes.
	0-HOUR SENSOR EXPIRATION NOTIFICATION: Your Continuous Glucose Monitoring Session has ended. Once you clear the alert your Receiver will be notified that the Sensor has been removed. You should clear this notification and remove your Sensor at this time.

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chapter two

SEVEN PLUS SET UP

2

This chapter will help you set up your SEVEN PLUS. You will want to read this chapter before you insert and start a new Sensor.

2.1 CHARGING YOUR RECEIVER BATTERY

The Receiver battery is re-chargeable like a cellular phone. The re-chargeable battery will last for about 3-5 days before you need to charge it with the Receiver Charging Cable. Your re-chargeable battery life depends on your Alert settings and how often you use the Events Menu. The Receiver will tell you when the battery charge is low. The Receiver takes 3 hours to charge fully if the battery is completely drained. To recharge your battery, follow the instructions below:

1. Connect the Receiver Charging Cable into the port on the bottom of the Receiver. Make sure the "Push" button side of the charger cable is facing down.
2. Connect the plug into a standard power outlet.
3. The Receiver will show the symbol below of a battery charging across the Receiver screen:

4. After a few seconds, your Trend Screen will reappear with the Charging Battery symbol shown in the lower right corner next to the Antenna Symbol.
5. The battery will fully charge after 3 hours.
6. After charging is complete, press the "Push" Button on the charger to disconnect.

HELPFUL HINTS:

- Charge your 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 back-up battery might also drain. When this happens, you will need to reset your Receiver's time (see Chapter 2, Section 2.2.1, "Setting your Receiver Time and Date").
- Only use the DexCom battery charger provided in the Starter Kit. Do not use any other battery charger. You should charge the Receiver during daytime inactivity.

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2.2 THE SETTINGS MENU

The Receiver lets you set the Date and Time and the Transmitter ID. It also shows you what Software version you have.

To reach the Settings Screens, follow these steps:

1. Press any key to turn on the Receiver's display.
2. Press the **OK** button to reach the Menus.

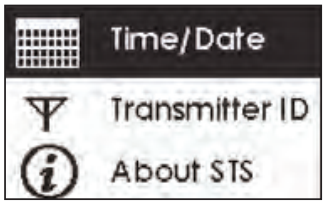
3. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you highlight "Settings."
4. Press the **OK** button to go into the Settings Menu.

5. Use the Up ▲ and Down ▼ Arrow buttons to scroll through the Settings:

   a. Time/Date b. Transmitter ID c. About STS

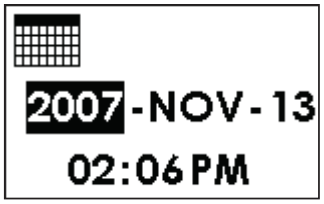
6. Press the **OK** button to enter the Settings option you want.

2.2.1 SETTING YOUR RECEIVER TIME AND DATE



1. From the Settings Menu, highlight "Time/Date" and press the **OK** button to enter the Time/Date Setting Screen.
2. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the year you want. Then press the **OK** button.

   a. You can scroll by 1 digit at a time.



3. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the month you want. Then press the **OK** button.
4. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the day you want. Then press the **OK** button.
5. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the hour you want. Then press the **OK** button.

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When you choose the hour, the AM/PM will adjust automatically (e.g. if you go from 11AM to 12PM, AM will switch to PM).

6. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the minute you want. Then press the **OK** button.

HELPFUL HINTS:

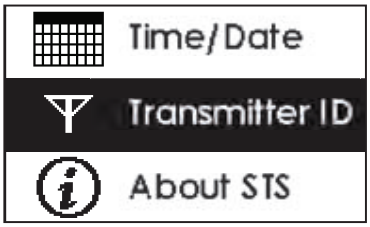
- Make sure to set the correct time on your Receiver.
- When setting the time, hold the **OK** button to cycle through the fields quickly.
- The Receiver date is set to Pacific Standard Time (PST) at the factory.
- You might need to reset the Receiver's time if the back-up battery dies. The Time Loss Alert will automatically take you to the Time/Date Setting Screen.

2.2.2 SETTING YOUR TRANSMITTER ID

Any time you use a new Transmitter or Receiver, instead of 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 5 numbers and letters 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 Settings Menu, highlight "Transmitter ID" and press the **OK** button to enter the Transmitter ID Screen.



2. The first digit will be highlighted. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the number or letter you want.
   a. The digits will "wrap" around, so you can scroll in either direction if you mistakenly pass the number or letter you want to enter.

3. Press the **OK** button to select that letter or number and move to the next.
4. Continue to follow steps 2-3 until you have entered and accepted the last letter/number by pressing the **OK** button. Press the **C** button if you make a mistake and want to go back.

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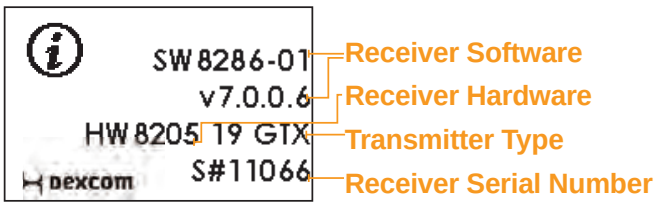
5. The Receiver will check the ID number.
   a. If the ID number is valid, the Receiver will accept it and return to the Trend Graphs.
   b. If the ID number is not valid, the Receiver will show a series of question marks and will then return to the Transmitter ID Screen so you can enter the correct ID.

2.2.3 ABOUT STS SCREEN

The "About STS" Screen shows information about the Receiver, including the software number and version, hardware number and version, Transmitter type, and Receiver serial number. ("STS" is the product family for the SEVEN PLUS.)

To reach the About Screen from the Settings Menu, highlight "About STS" and press the **OK** button to enter the About Screen.

You will see the following screen:



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2.3 SETTING YOUR ALERTS

2.3.1 FACTORY ALERT SETTINGS

The SEVEN PLUS' Alerts arrive from the factory with the following "default" settings. These default Alert Settings are provided in the below table:

	Alert Type	Default Settings	Default Prompt Sound/ Vibrate	Default Re-alert Setting
HIGH 200 mg/dL	**High Alert**	200 mg/dL	Vibe then Beep (vibrate first, then 2 high beeps and vibrate)	None (no re-alerts after pressing button)
80 mg/dL LOW	**Low Alert**	80 mg/dL	Vibe then Beep (vibrate first, then 3 low beeps and vibrate)	None (no re-alerts after pressing button)
Rise 2mg/dL/min or more Rise 3mg/dL/min or more	**Rise Alert**	Off	Disable (None)	None (no re-alerts after pressing button)
2mg/dL/min or more Fall 3mg/dL/min or more Fall	**Fall Alert**	Off	Disable (None)	None (no re-alerts after pressing button)
Rise Rate Fall Rate Other Alert	**Other Alert (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 11, Appendix 1).
Out of Range 1:56:27	**Out of Range Alert**	Off	Disable (none)	Continues to re-alert you until you come back into range.

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You can change the factory Alert Settings at any time by going to the Alerts Menu. You can reach the Alerts Menu by following these steps:

1. Press any button to turn on the Receiver display.
2. Press the **OK** button to reach the Menus.
3. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you highlight "Alerts."

4. Press the **OK** button to go into the Alerts Menu.
5. Use the Up ▲ and Down ▼ Arrow buttons to scroll through the Alerts:

a. High Alert	b. Low Alert	c. Rise Rate
d. Fall Rate	e. Other Alerts	f. Out of Range

6. Highlight the Alert you want, and press the **OK** button.
   Sections 2.3.2 – 2.3.4 will show you how to set these Alerts.

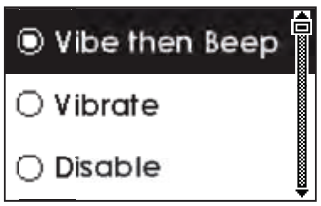
2.3.2 SETTING GLUCOSE ALERTS

High Alert, Low Alert, Rise Rate, and Fall Rate Alerts (Chapter 5, Section 5.3, "Glucose Alerts and ALARM") provide information about your glucose levels and trends.

The following steps show how to change the High Alert, Low Alert, Rise Rate, and Fall Rate Alerts settings.

1. Select the Alert you want as described in 2.3.1, "Factory Alert Settings."
2. Use the Up ▲ and Down ▼ Arrow buttons to scroll to the type of Alert notification you want to receive:
   a. Vibrate then Beep (the first alert will vibrate, then every 5 minutes the Alert will vibrate and beep)

i. High Alert sound	=	2 high tone beeps
ii. Low Alert sound	=	3 low tone beeps
iii. Rise Rate sound	=	2 high tone beeps
iv. Fall Rate sound	=	3 low tone beeps



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b. Vibrate (no sound, the Receiver will vibrate only)

c. Disable (to turn off this particular Alert notification)

3. Press the **OK** button to select the type of Alert notification you want.

   a. If you select "Disable" this will turn off this Alert type.

   b. If you select "Vibe then Beep" or "Vibrate," you will be given more Alert Setting options (depending on which Alert you are setting). Continue using the Up ▲ and Down ▼ Arrow buttons to scroll to the option you want and press the **OK** button to select the option.

4. For Low Alert and High Alert, you will then see the Snooze Time Screen. You can set the amount of time between reminder alerts after the first alert. Use the Up ▲ and Down ▼ Arrow buttons to scroll through the options for Snooze Time.

   a. You can delay these re-alerts by pressing the **C** button to "snooze" (like on an alarm clock).

   b. The High Glucose Alert and Low Glucose Alert can be set to re-alert every 30 minutes or 1, 2, 3, 4, or 5 hours by changing the Snooze settings.

   c. If the selection says "None," this means there are no re-alerts. The Receiver only alerts until you press the **C** button to stop the alert.

   d. Rise Rate and Fall Rate Alerts do not have a Snooze option.

5. Press the **OK** button to select the Snooze Time. You will then return to the Trend Graphs.

HELPFUL HINTS:

- Snooze time is the amount of time you would like to set between alerts. If you set this to "None" then the Receiver will not re-alert you of the event (such as being above your High Glucose Alert).
- Choosing "Disable" turns off this Alert type and the Receiver will not tell you if your glucose levels are high, low, or falling. The 55 mg/dl ALARM cannot be disabled.

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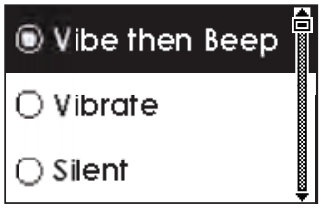
2.3.3 SETTING OTHER ALERTS

The SEVEN PLUS provides many other notifications that you can set in the "Other Alert" Menu. See Chapter 11, Appendix I for a complete list of "Other Alerts."

The default setting for all of these Alerts is "Vibe then Beep." In the "Vibe then Beep" setting, the Receiver will notify you with vibrations and a medium beep tone when these events occur. You can change the settings for all Other Alerts jointly. The following steps show how to move through the Other Alert settings.

1. Select the Alert you want as described in Section 2.3.1, "Reaching the Alerts Menus."
2. Use the Up ▲ and Down ▼ Arrow buttons to scroll to the type of Alert notification you want to receive:
   a. Vibrate then Beep (the first alert will vibrate, then every 5 minutes the Alert will vibrate and beep).
      i. The "Other Alerts" sound is one medium tone beep.
   b. Vibrate (no sound, the Receiver will vibrate only).
   c. Silent (a screen will appear, but there will be no sound or vibration).



3. Press the **OK** button to select the type of Alert notification you want. Once you press **OK** you will return to the Trend Graphs.

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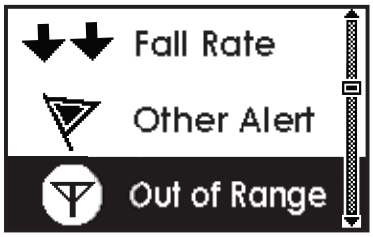
2.3.4 SETTING OUT OF RANGE ALERT



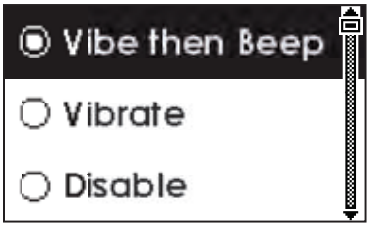
The Out of Range Alert lets you know when the Transmitter and Receiver are not talking. Typically, you should keep the Transmitter and Receiver within 5 feet (1.5 meters) of each other.

When the Transmitter and Receiver are too far apart and are not talking, you will not receive Sensor glucose readings. When this happens, the Out of Range Symbol will appear in the Status Box on your Receiver and the screen to the right will appear. The amount of time out of range will appear on the Out of Range Alert screen.

The Out of Range Alert's default setting is off ("Disable"). But, you can set the amount of time the Transmitter can be out of range before the Receiver alerts you. You can change the settings so the Alert will beep and vibrate, or vibrate only. You can set the Alert between 20 and 200 minutes. If you go out of range, the Receiver will continue to re-alert you until you come back in range again or press a Receiver button.

The following steps show how to change the Out of Range Alert settings.

1. Select the Out of Range Alert as described in 2.3.1, "Factory Alert Settings."
2. Use the Up ▲ and Down ▼ Arrow buttons to scroll to the type of Alert notification you want to receive:
   a. Vibrate then Beep (the first alert will vibrate, then every 5 minutes the Alert will vibrate and beep)
      i. The Out of Range sound is one medium tone beep.
   b. Vibrate (no sound, the Receiver will vibrate only)
   c. Disable (to turn off this particular Alert notification)



3. Press the **OK** button to select the type of Alert notification you want.
   a. If you select "Disable" you do not need to change any more settings.
   b. If you select Vibe then Beep or Vibrate, you will then set the amount of time "Out of Range" before the Receiver Alerts you. Continue using the Up ▲ and Down ▼ Arrow buttons to scroll to the time you want and press the **OK** button to select it.

You will then return to the Trend Graphs.

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2.4 AUTO UPLOAD METER REGISTRATION

Meter Registration is only required if you are using Auto Upload with a OneTouch Ultra Meter and the Connection Cable. It is not required for OpenChoice with any meter.

To register the devices connect the OneTouch Ultra Meter and Receiver following these steps:

1. Make sure the OneTouch Ultra Meter display is off (screen is blank) before connecting the Connection Cable. To turn the display off, press the M button once.
2. Using the optional Connection Cable, follow the steps below. You must do these steps in order.
   a. **First** plug the cable into the connection port of the meter. (The connection port is at the bottom of the meter).
   b. **Second** connect the wide end of the cable into the Receiver. Make sure the raised Push button on the cable is facing down.
3. After a few seconds, "PC" will appear on the OneTouch Ultra Meter screen (shown here on the right):

4. You will see the following screen below. If you would like, you can also set your Receiver to beep and vibrate when this screen appears (see Chapter 2, Section 2.3, "Setting Your Alerts").
5. Press the **OK** button to "accept" this new meter. The symbol above will disappear and the Receiver will return to the 3-Hour Glucose Trend Graph. This means your registration is complete. (Note: This process may take a few minutes to complete.)
   a. Press the Push button (facing down) on the Connection Cable to remove it.
   b. It doesn't matter if you remove the cable from the meter or the SEVEN PLUS System first.

New Meter Screen

6. Check to see that the Receiver and meter have the same time.
7. Once you have registered, all new fingerstick readings taken and uploaded from this meter will be used to calibrate your System.

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HELPFUL HINTS:

- If you use the Auto Upload feature, you must register your OneTouch meter to your Receiver the first time you use them together or after you change the time on your Receiver. You do not need to register each time you calibrate.
- Blood glucose information stored in the OneTouch Ultra Meter before registering it to your Receiver will not be used for calibration. Always register a new meter before uploading fingersticks for calibration.
- The Receiver and OneTouch Ultra meter date and time must be the same. If they are not, the fingersticks will not be accepted by the System for calibration. Anytime you change the date/time on your Receiver, connect the meter to the Receiver using the Connection Cable (without taking new fingerstick readings) to match the date/time on the devices. You can upload fingerstick readings as usual after that.

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chapter three

USING A SENSOR

3

To use your SEVEN PLUS 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 (166 hours after the 2-hour Start-Up 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 first. See Chapter 2, Section 2.1, "Charging Your Receiver Battery" 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 2.2.2, "Setting your Transmitter ID").
- ❒ Place the Transmitter next to the Receiver for at least 5 minutes to make sure they are talking with each other. There will be an Antenna Symbol in the lower right corner of the Trend Graphs when the two devices are talking.
- ❒ Check the expiration date on the Sensor, before you start, to make sure you are not using an expired Sensor. "05/09" indicates that the Sensor must be inserted before the last day in May in the year 2009.
- ❒ 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).
- ❒ Clean the bottom of the Transmitter with a damp cloth or alcohol wipe, and dry before you start a new Sensor session.
- ❒ If you are using Auto Upload from a Lifescan® OneTouch® Ultra® meter, you must connect (or "register") your meter to your Receiver before you start.
- ❒ Make sure your meter and Receiver date and time match.

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3

REVIEW THE SENSOR APPLICATOR

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

HELPFUL HINTS:

- Always check the expiration date on the Sensor packaging before opening the Sensor for use. Never use expired Sensors. An expiration date of "05/09" tells you the Sensor must be used before the last day in the Month of May in the year 2009.

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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 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 beltline. 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 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 uses in a row.
- You may need to shave the area where you plan to put the Sensor so that the adhesive patch sticks well.
- 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.

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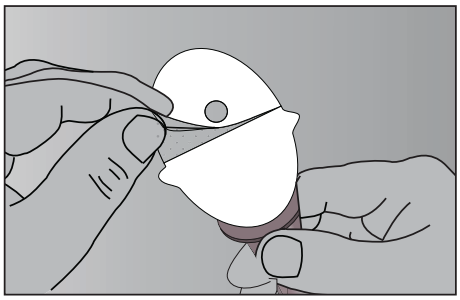
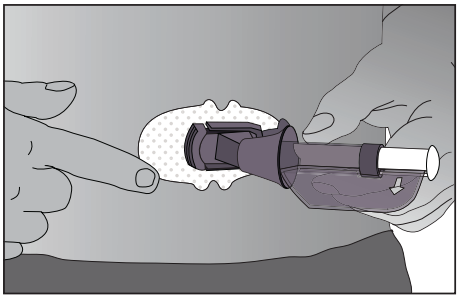
3.4 PLACING THE SENSOR

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.

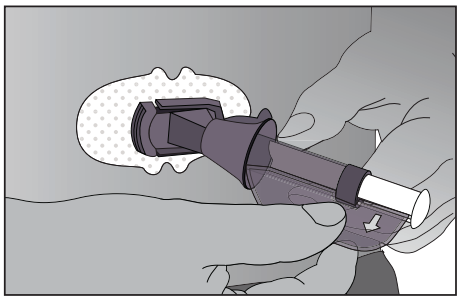


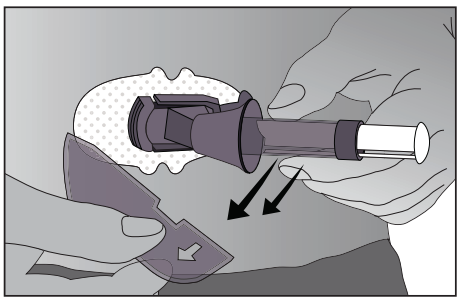
Remove the Adhesive backing



Adhere the Sensor on the skin

3. After placing the Applicator, 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

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HELPFUL HINTS:

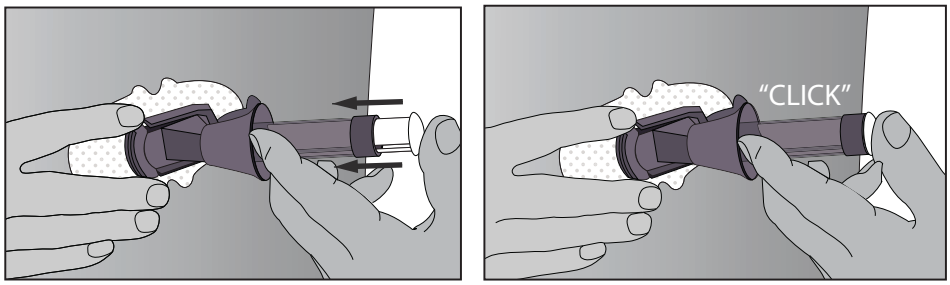
- The Safety Lock also serves as the Transmitter Key that is used later for Transmitter removal. Keep this piece to help you remove the Transmitter at the end of a continuous glucose monitoring session. When your glucose monitoring session is over, follow the steps in Chapter 7, Section 7.3, "Transmitter Removal," to remove the Transmitter.

3.5 SENSOR INSERTION

Once you have placed the Applicator on your belly and removed the Safety Lock (see Chapter 3, Section 3.4, "Placing the Sensor"), 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.

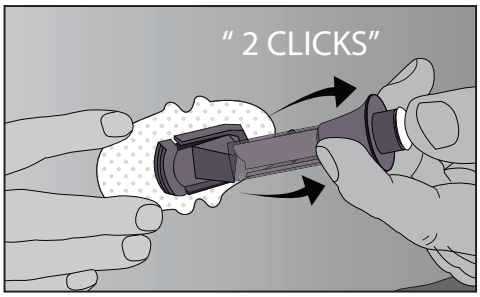
When you are pushing down on the plunger, do not pull back on the collar.



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

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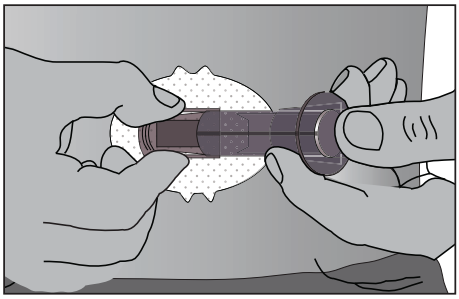
4. Squeeze the ribbed release tabs on the sides of the Sensor Pod to remove the Applicator. When you squeeze the front release tabs, the back tabs will widen, allowing you to pull off the Applicator. After this step, only the Sensor Pod will be left on your body.
   a. Make sure the Transmitter Latch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



Release the Applicator

If you have any problems with insertion, save the Sensor and Applicator and contact DexCom Technical Support at 1-888-SEVENGO (738-3646).

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.

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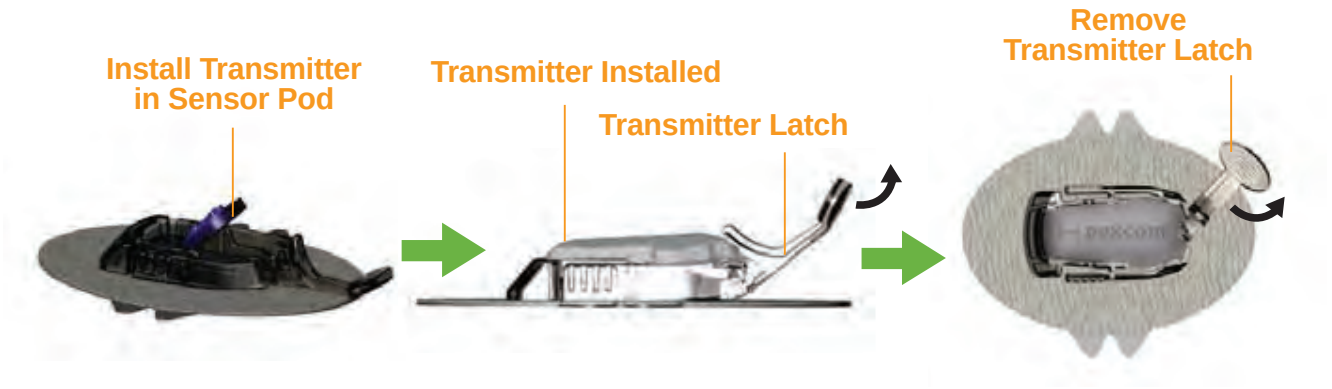
5. Remove the Transmitter Latch by holding the end of the Latch and quickly twisting off the Latch away from your body.
6. Press any button on the Receiver to check for the Antenna Symbol at the lower right corner of the screen. If the Out of Range Symbol appears in the Status Box (upper right corner) instead, move the Receiver closer to your Transmitter. (See Chapter 3, Section 3.7, “Transmitter and Receiver Communication”).



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 Chapter 3, Section 3.10, “The SEVEN PLUS and Water”).
- Make sure that you have the correct Transmitter ID Number entered into your Receiver (for all new Receivers, the Manufacturer enters this number). See Chapter 2, Section 2.2.2, “Setting your Transmitter ID”, for instructions on how to enter the Transmitter ID into your Receiver.

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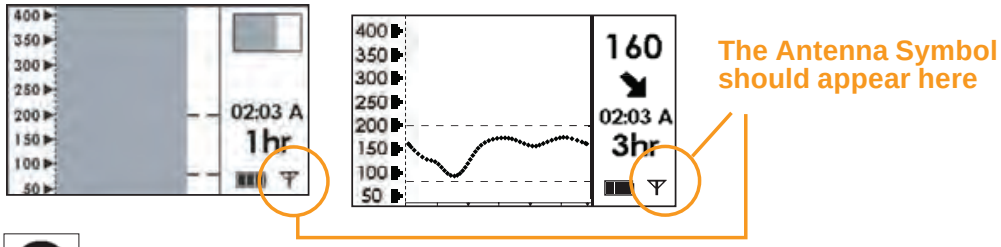
3.7 TRANSMITTER AND RECEIVER COMMUNICATION

CONTRAINDICATION: The SEVEN PLUS must be removed prior to Magnetic Resonance Imaging (MRI).

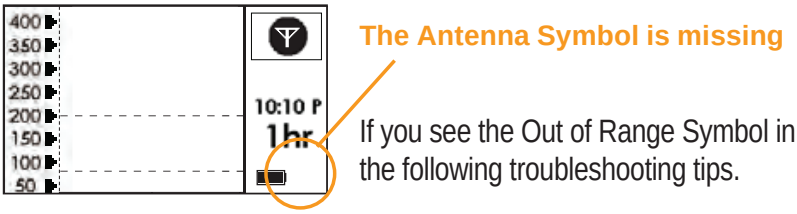
Keep your Receiver within 5 feet (1.5 m) of the Sensor/Transmitter for best communication. To check that the Receiver and Transmitter are talking, press any Receiver button to see the Glucose Trend Graphs.

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 your Status Box, then review the following troubleshooting tips.

- Is the Receiver within 5 feet (1.5 m) of your Sensor Pod/Transmitter? If the Receiver is not close enough, then move it within 5 feet of the Sensor Pod/Transmitter. Check the Status Box in 5-10 minutes to see if the Out of Range Symbol is gone, and the normal Antenna Symbol is in the lower right corner of the Receiver screen.
- If the Receiver and Transmitter are still not talking, then check to make sure the correct Transmitter ID Number is entered into your Receiver (See Chapter 2, Section 2.2.2, “Setting your Transmitter ID”).

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• If the correct Transmitter ID has been entered into your Receiver and the Receiver and Transmitter are still not talking, then contact DexCom Technical Support for further help at 1-888-SE-VENGO (738-3646).

HELPFUL HINTS:

The Transmitter and Receiver may lose communication at the following times:

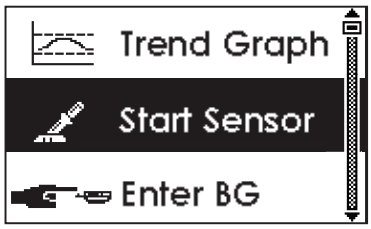
- When they are near metallic objects
- While you are lying on a waterbed
- When you are using an electric blanket

3.8 BEGINNING 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.

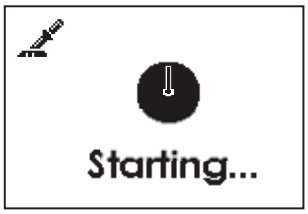
To tell the Receiver that you have inserted a new Sensor, follow the steps below.

1. Press any button to turn on the Receiver.
2. From any Trend Graph, press the **OK** button to reach the Menu Screens.



3. Use the Up ▲ and Down ▼ Arrows to scroll until you highlight "Start Sensor."

4. Press the **OK** button to confirm the start of a new Sensor, and you will see this screen:



5. Your Receiver will return to the 3-Hour Trend Graph.

6. Your 2-hour Start Up period has begun.

HELPFUL HINT

- The Start Sensor Menu option will now disappear from the menu. The option will only appear again if an active continuous glucose monitoring session ends.
- Each time you insert a new Sensor and press "**OK**" on the Start Sensor Screen, you will restart the 2-hour Start-Up period.

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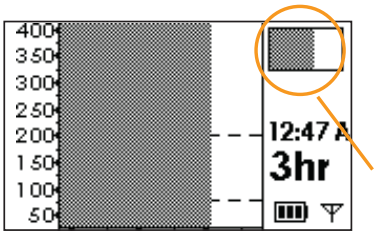
3.9 SENSOR START-UP PERIOD

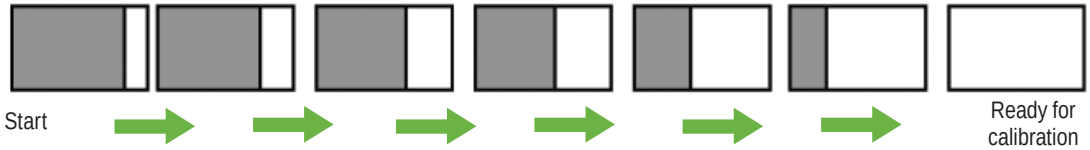
The Sensor needs a 2-hour Start-Up period. This is so the Sensor can get used to its new insertion site. During the Start-Up period, check every so often to make sure the Antenna Symbol is in the lower right corner of the Trend Graphs. Also make sure your Receiver battery is charged.



When you press any button during the Start-Up period to turn on the Receiver dislplay, your Trend Graphs and Status Box will be shaded dark gray.

A partial grey status box indicates your Sensor is still in the Start-Up period

Over time, the partial dark gray block on the screen will start to disappear to the left, indicating 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 2-hour Start-Up 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 SEVEN PLUS 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 ft 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 attached on its own. 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.

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chapter four

CALIBRATING YOUR SEVEN PLUS

4

The SEVEN PLUS System requires you to “calibrate” the Sensor glucose readings to your blood glucose meter. The purpose of calibration is so the glucose fluid your Sensor measures can be displayed to you in a reading on your Receiver that is like your blood glucose meter reading.

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

4.1 HOW TO CALIBRATE

There are two methods you can use to calibrate your System. You can either use the OpenChoice feature on your SEVEN PLUS, or you may use the Auto Upload method.

The OpenChoice feature allows you to hand enter your readings into the System, and you can use any FDA-cleared meter you choose. With Auto Upload, you must use the LifeScan One-Touch Ultra meter, and the optional Connection Cable for calibration. This Connection Cable can be purchased from DexCom Customer Support.

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

1. Start-Up Calibration 2. Calibration Update 3. Re-calibration

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

The sections in this Chapter tell you how to use OpenChoice and AutoUpload methods for calibrating your system. The sections also describe Start-Up Calibration, Calibration Update, and How to Re-calibrate in more detail.

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HELPFUL HINTS:

- If you use Auto Upload, all fingerstick readings taken with your OneTouch Ultra meter can affect calibration. Do not share your blood glucose meter with other people.
- Do not use alternative BG site testing (blood from your palm or forearm, etc.) for calibration. You must take your blood glucose from your fingertips only for calibration.

4.1.1 USING OPENCHOICE FOR CALIBRATION

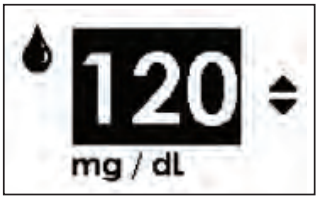
For OpenChoice Calibration you must enter the exact fingerstick reading that your blood glucose meter displays. Enter all fingerstick readings for calibration within 5 minutes. Entering incorrect fingerstick readings or fingerstick readings that occurred more than 5 minutes ago will affect device performance.

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

1. Take a fingerstick reading using your meter.
2. From any Trend Graph, press the **OK** button to reach the Menus.
3. Use the Up ▲ and Down ▼ Arrows to scroll until you highlight "Enter BG."

Note: "Enter BG" is not the first menu option at the top of the screen.

4. Press the **OK** button to select this option. You will see a screen with a blood drop and a number in mg/dL units.



   a. During initial calibration the SEVEN PLUS will default to the reading of 120mg/dL.
   b. If there has been a 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 glucose reading for calibration. Use only your BG meter reading.

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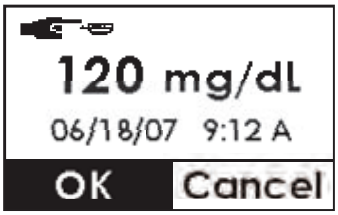
5. To enter the fingerstick reading taken from your meter, press the Up ▲ and Down ▼ Arrows until you find the correct reading. Enter a reading between 40-400 mg/dL. Also make sure this reading was taken within the past 5 minutes. Press the **OK** button to enter the reading.



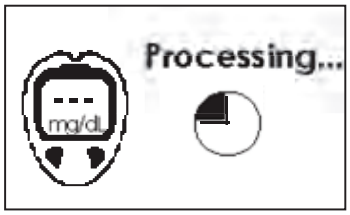
   a. Press the **OK** button to confirm the reading entered is correct.

   b. If the fingerstick reading displayed is incorrect, press the **C** button and enter in the correct reading for calibration.

   c. If you do not press any button, the Receiver will "time out" and no fingerstick reading information will be entered.

   d. Pressing the Arrow buttons lets you scroll through by 1 mg/dL. If you want to scroll faster then hold down the Arrow button.

6. Next the Glucose Readings Processing screen will appear, followed by the "Results Added" screen.



7. For Start-Up Calibration, repeat these steps for the second fingerstick reading.
8. A glucose reading will appear on the Receiver right away, and glucose readings will be updated every 5 minutes.
9. If readings do not appear immediately, see Chapter 8, Section 8.2, "Calibration Troubleshooting."

HELPFUL HINTS:

- Always check that the Receiver and meter date and time are the same.
- Make sure a blood drop or glucose reading is displayed in the Status Box on any Trend Graph before calibrating.
- 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 SEVEN PLUS will not calibrate. You will have to wait to calibrate until your blood glucose is in this range.
- Always make sure the Antenna Symbol is displayed in the lower right corner of the Trend Graph before you take fingersticks for calibration.
- You should always use the same glucose meter to calibrate the SEVEN PLUS that you routinely use to measure your blood glucose. Do not switch your BG meter in the middle of Sensor wear.

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4.1.2 USING AUTO UPLOAD FOR CALIBRATION

If you choose to use Auto Upload for calibration you must make sure your meter is "registered" to your Receiver (see Chapter 2, Section 2.4, "Auto Upload Meter Registration"). Also make sure the Receiver date/time and OneTouch Ultra date/time match. You should register your meter during the Start-Up period.

Auto Upload is when you use the OneTouch Ultra Meter and the Connection Cable that is available for purchase from DexCom Customer Support. You need to use the OpenChoice feature for all other meters. The steps below will show you how to use Auto Upload Calibration:

1. Check to see that the Receiver and OneTouch Ultra meter have the same date and time.
2. Take a fingerstick reading using your meter (take 2 fingerstick readings for Start-Up Calibration).
3. Make sure the OneTouch Ultra Meter display is off (screen is blank) before connecting. To turn the display off, press the M button once.
4. Using the optional Connection Cable, follow the steps below. You must follow these steps in order for successful fingerstick reading transfer and calibration of the System.
   a. **First** plug the cable into the connection port of the OneTouch Ultra Meter. (The connection port is at the bottom of the meter).
   b. **Second** connect the wide end of the cable into the Receiver. Make sure the raised "push" button on the cable is facing down.
5. After a few seconds, "PC" will appear on the OneTouch Ultra Meter screen (shown to the right):

6. The Receiver will display the Connection Screen. The Connection Screen tells you that fingerstick readings from the meter are successfully being uploaded to the Receiver.

Connection Screen

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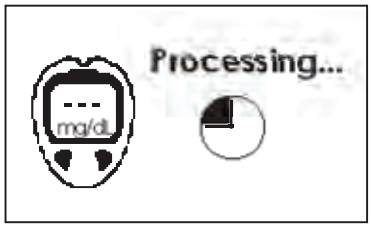
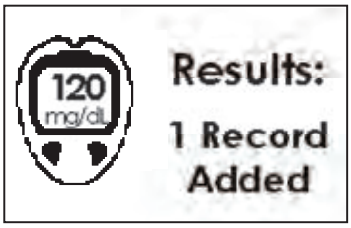
7. The processing screen will appear, followed by the results screen.





8. Once you see the Results Screen, then press the Push button on the Connection Cable to disconnect the cable from the OneTouch Ultra Meter and the Receiver (the order that you disconnect the cable does not matter).
9. After you are done, press the **C** button to return to the 3-Hour Trend Graph.

HELPFUL HINTS:

- Always check that the Receiver and meter date and time are the same.
- All fingerstick readings taken with your OneTouch Ultra meter might be used for calibration. Do not share your blood glucose meter with other people.
- If you use more than 1 OneTouch Ultra meter during SEVEN PLUS use, any fingersticks you take using the "non-registered" meter will not be used for calibration even if you attach this meter with the connection cable. You will have to register the meter first and then take fingerstick readings with the new meter for Auto Upload calibration.

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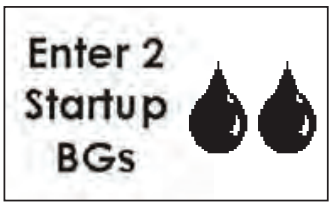
4.2 START-UP CALIBRATION

Two (2) hours after you start the Sensor (see Chapter 3, Section 3.8, “Beginning a Sensor Session”) the Receiver will tell you that you need to calibrate the Sensor. The Receiver will show the screen shown to the right. If your Alerts are set to the factory default settings, the Receiver will also vibrate to tell you it is ready for calibration.

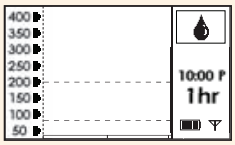


Double Blood Drop Prompt

1. You can set your Receiver to beep and vibrate instead when this screen appears (see Chapter 2, Section 2.3, Setting your Alerts).
2. When you see this screen, press the **C** button to clear the display.
3. Take 2 fingersticks with your meter and enter these meter readings. You can use the Open-Choice Feature or the Auto Upload method to calibrate.
4. Your blood glucose readings must be between 40 mg/dL and 400 mg/dL for calibration.The SEVEN PLUS 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 and then calibrate when it is convenient for you.
- Always check that the Receiver and blood glucose meter date and time are the same.
- If you choose to silence the Double Blood Drop Prompt and calibrate later, the Trend Graph will show a Blood Drop in the Status Box (upper right corner). This means that fingerstick readings are still needed for calibration (see inset image).



- 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 lower right corner before you calibrate.

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4.3 CALIBRATION UPDATE

> ⚠ You must update SEVEN PLUS calibration every 12 hours at a minimum. The performance of the System when calibrated less frequently than every 12 hours has not been studied.
>
> For OpenChoice Calibration 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.

Calibration Update is required every 12 hours to make sure your Sensor readings remain accurate or are close to your BG meter readings. You can enter any fingerstick readings you take during Sensor wear. 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.

1. If you see the reminder symbol show to the right, clear this display by pressing any Receiver button. The Calibration Update Screen will not go away until you press a button.

Calibration Update Screen

2. Take a fingerstick 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 (using OpenChoice or Auto Upload).
4. If this screen re-appears shortly after you have entered a new fingerstick reading, review Chapter 5, Section 5.4, “Glucose Status.”

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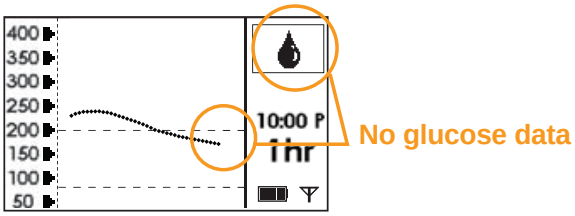
4.4 RE-CALIBRATION (BLOOD DROP IN STATUS BOX " 💧 ")

When you take and enter a fingerstick for 12-Hour Update Calibration (Section 4.3, "Calibration Update"), 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 Start-Up Calibration. The Calibration Update Screen will appear (shown to the right).

Calibration Update Screen

You can clear this Screen by pressing the **C** button. The display will return to the Trend Graph. A blood drop symbol in the Status Box will appear.



Awaiting Fingerstick Reading (Blood Drop) Symbol

This Status Box Symbol tells you that the System needs at least one more fingerstick reading. You won't see glucose readings or get Alerts/Alarm when the Blood Drop is still in the Status Box.

You should take another fingerstick and enter this information to the Receiver.

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

HELPFUL HINTS:

- Refer to Section 8.4, "Error Code Troubleshooting," if you see "Sensor Error #0" or "Sensor Error #1" on your Receiver during calibration.
- If you have not received any glucose readings in the past hour, and have attempted Re-Calibration by taking and entering at least 3 fingersticks that are 15 minutes apart each, then contact DexCom Technical Support at 1-888-SEVENGO (738-3646). There may be a problem with your Sensor.

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chapter five

CONTINUOUS GLUCOSE READINGS, TRENDS, ALERTS AND ALARM

5

This chapter will teach you how to view your SEVEN PLUS continuous glucose trend information. Once you have successfully calibrated, the SEVEN PLUS will show you continuous glucose information every 5 minutes. This will tell you how your glucose levels are changing.

> ⚠ You must update SEVEN PLUS 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 fingerstick blood glucose meter only tells you your blood glucose level at one point in time (like a still picture). However, the SEVEN PLUS Trend Graphs and Trend Arrows (Rate of Change) will help you understand the direction your glucose level is moving (like a video camera).

The SEVEN 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 blood glucose meter. The SEVEN PLUS System readings can be 10-20% 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 blood glucose is rising or falling. Chapter 10, Section 10.1, “Device Performance Characteristics” tells you how closely your SEVEN PLUS readings will be to a laboratory analyzer in the doctor’s office.

Glucose Alerts and the Low ALARM are designed to help you stay within your target glucose zones. Your Low and High Glucose Alerts, and Rapid Rise and Rapid Fall 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 2.3, “Setting your Alerts”) and are determined by you and your diabetes healthcare team. Your Low Glucose ALARM can tell you when your glucose levels may be reaching potentially dangerous low levels.

In addition to Alerts and the ALARM, you can also enter information about your meals, insulin, exercise, and health. That way you and your diabetes care team can receive a bigger picture of your diabetes management plan. You can see this information on an every 5-minute basis by looking at your trend screen.Your diabetes healthcare team can transfer this information to the Data Manager software to see how you are doing over a long period of time.

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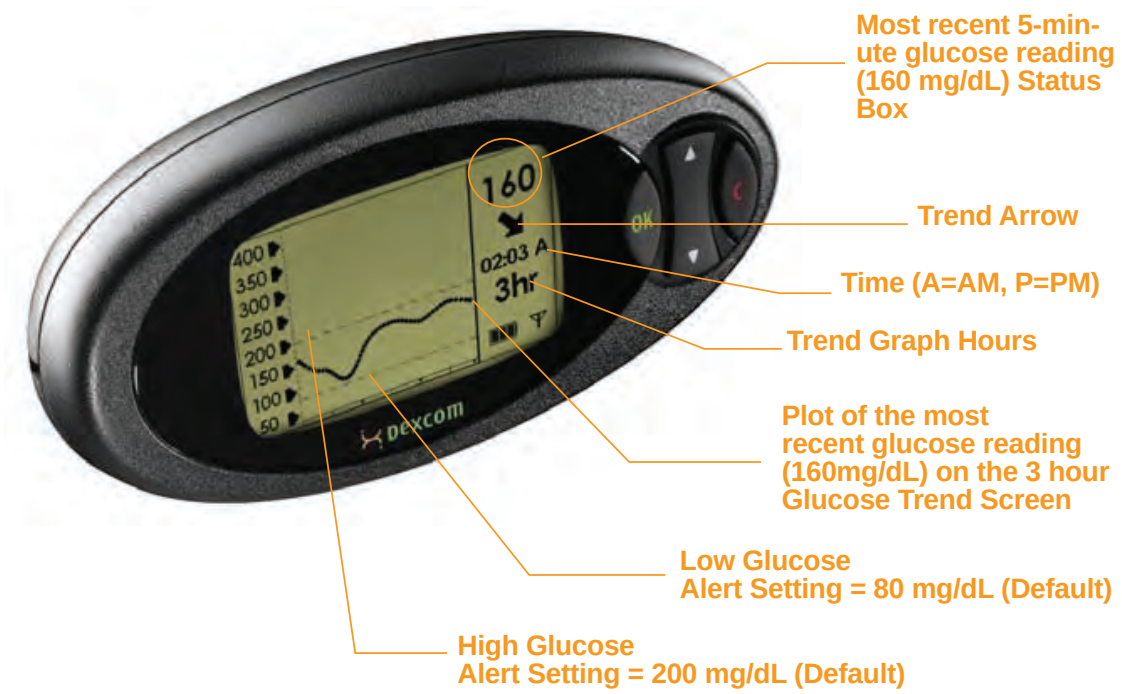
5

5.1 GLUCOSE READINGS

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

Press any button on the Receiver and the following glucose information will be shown to you:



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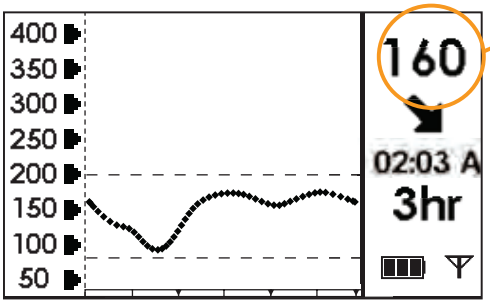
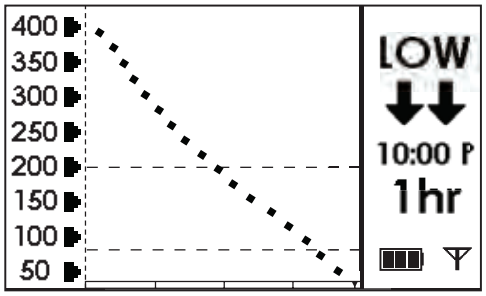
- The SEVEN PLUS reports glucose readings from **40-400 mg/dL** and updates glucose readings every 5 minutes.

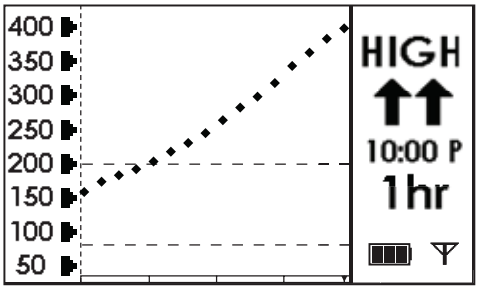


The glucose reading is in milligrams per deciliter (mg/dL) units.

The System reads "LOW" when the glucose reading is less than 40 mg/dL, and "HIGH" when the glucose reading is greater than 400 mg/dL.



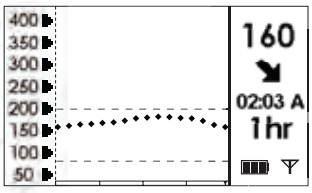
"Low"- Less than 40 mg/dL



"High"-Greater than 400 mg/dL

- Each "dot" on the glucose Trend Graph is a glucose reading.
- Each Glucose Trend Graph shows the current time ("A" is AM and "P" is PM).
- The "dashed lines" on the Glucose Trend Graphs are the High Alert and Low Alert Settings (see Chapter 2, Section 2.3, "Setting your Alerts," 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 Up ▲ and Down ▼ Arrows on your Receiver. These Glucose 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 Glucose Trend Graph:** The 1-hour Trend Graph (**1 hr**) shows your current glucose reading and the last 1 hour of glucose readings.

(continued on next page)

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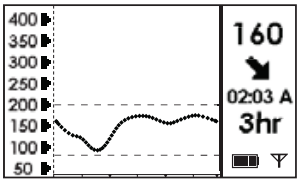
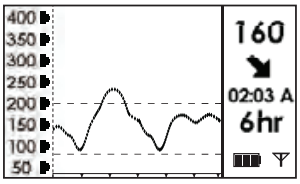
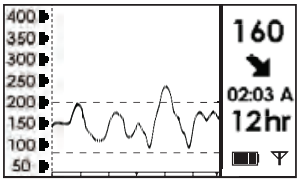
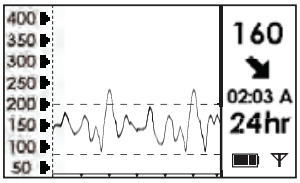
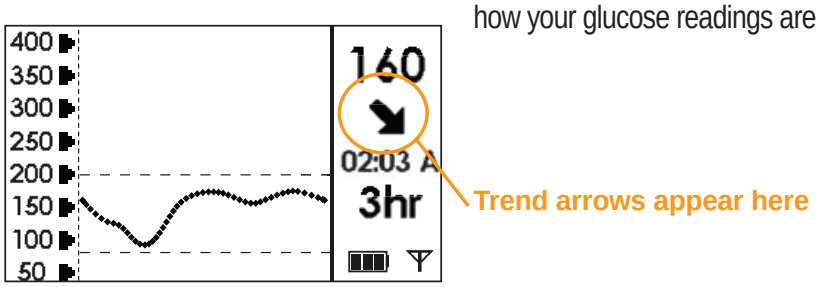
	**3-Hour Glucose Trend Graph:** The 3-hour Trend Graph (**3 hr**) shows your current glucose reading and the last 3 hours of glucose readings (this is your default trend screen).
(Scroll down from the 3-Hour Graph to reach the 6-Hour Graph)	
	**6-Hour Glucose Trend Graph:** The 6-hour Trend Graph (**6 hr**) 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 Glucose Trend Graph:** The 12-hour Trend Graph (**12 hr**) 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 Glucose Trend Graph:** The 24-hour Trend Graph (**24 hr**) 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 Arrows may appear to show you how your glucose readings are changing.



The Trend Arrows appear on the upper right corner of the Trend Graphs, just below your current glucose reading in the Status Box.

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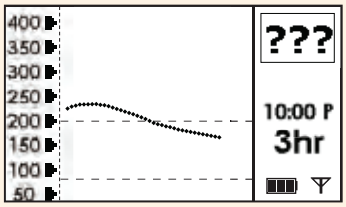
This table shows the different Trend Arrows your Receiver will display:

➡	**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:



- The Trend Arrows do not appear during Missing Glucose Information (see Chapter 5, Section 5.4, "Glucose Status"). If the "???" Symbol, the Out of Range Symbol, or the blood drop Calibration Update Symbol appears in the Status Box, the Rise and Fall Arrows will not appear.

- If the Rate of Change Arrow is missing, but you are concerned that your blood glucose level may be rising or falling, take a fingerstick and use your blood glucose meter to check your readings.

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5.3 GLUCOSE ALERTS AND ALARM

The SEVEN PLUS 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, and Rise and Fall Alerts let you know when your glucose levels are changing fast. The SEVEN PLUS also features a non-adjustable Low Glucose ALARM that will tell you when your glucose levels may be reaching potentially dangerous low levels.

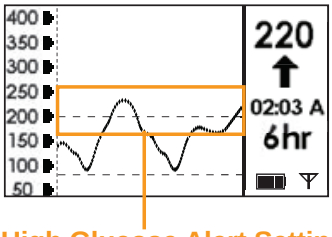
With the SEVEN PLUS, you can set High and Low Glucose Alerts that help tell you when your glucose readings are out of your "target range." The High and Low Glucose Alerts also have different tones (high and low beeps) to notify you. This feature can be helpful during times when you may not test your blood glucose (such as sleeping, driving, exercise, or long meetings).

5.3.1 HIGH GLUCOSE ALERT

When your SEVEN PLUS glucose readings are at or above your High Alert level the screen shown to the right will appear. You can set the Receiver to beep and vibrate when this screen appears (see Chapter 2, Section 2.3, "Setting your Alerts"). The default is set at 200 mg/dL, but you can change this.

High Glucose Alert set at 200 mg/dL

When you set the High Glucose Alert, it will appear as a dashed line on your Glucose Trend Graphs.



High Glucose Alert Setting

The Receiver will continue to alert until you press a button or until your glucose readings drop below your High Glucose Alert setting. At the default setting, the Receiver will not re-alert you after you have pressed a button to clear the alert. But, you can choose to have the Receiver re-alert you every 30 minutes or 1, 2, 3, 4, or 5 hours after pressing a button. You can do this by changing your Snooze settings (see Chapter 2, Section 2.3, "Setting your Alerts").

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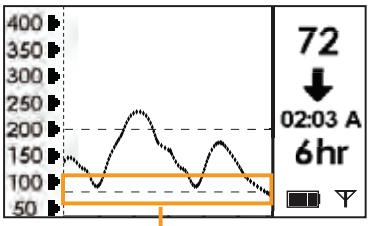
5.3.2 LOW GLUCOSE ALERT

When your SEVEN PLUS glucose readings are at or below your Low Alert level, the following screen will appear. You can set the Receiver to beep and vibrate when this screen appears (see Chapter 2, Section 2.3, “Setting your Alerts”). The default is set at 80 mg/dL, but you can change this.

Low Glucose Alert set at 80 mg/dL

When you set the Low Glucose Alert, it will appear as a dashed line on your Glucose Trend Graphs.



Low Glucose Alert Setting

The Receiver will continue to alert until you press a button or until your glucose readings rise above your Low Glucose Alert setting. At the default setting, the Receiver will not re-alert you after you have pressed a button to clear the alert. But, you can choose to have the Receiver re-alert you every 30 minutes or 1, 2, 3, 4, or 5 hours after pressing a button. You can do this by changing your Snooze settings (see Chapter 2, Section 2.3, “Setting your Alerts”).

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

5.3.3 LOW GLUCOSE ALARM

The Receiver also has an automatic Low Glucose ALARM set at 55 mg/dL. This ALARM is a feature in addition to your personal glucose alerts. **You cannot change or turn off this ALARM or its re-Alert settings.**

- When your SEVEN PLUS glucose reading is at or below 55mg/dL the Receiver will notify you with 4 low beeps and vibration in this order:
  - 1st 5-minute ALARM: “Vibrate”
  - 2nd 5-minute ALARM: “Vibrate” “Beep” “Beep” “Beep” “Beep”
  - 3rd 5-minute ALARM: “Vibrate” “Beep” “Beep” “Beep” “Beep” (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 the **C** button.

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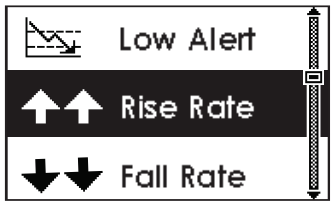
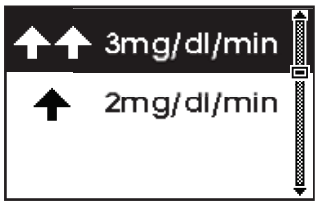
- For Low ALARMs the Receiver will display the Low Glucose ALARM screen (see image on right).
- Re-ALARM: The Receiver will automatically notify you again in 30 minutes after you press the **C** button if your glucose readings are still at or below 55 mg/dL.

Low Glucose ALARM

5.3.4 RISE AND FALL GLUCOSE RATE ALERTS

You can activate these Alerts (see Chapter 2, Section 2.3, "Setting your Alerts"), to have the Receiver tell you if your glucose levels are rising or falling fast.





You can choose to set one of the two Receiver Rise Rates (how fast you are going up) or none. You can be notified if your glucose level is rising 2 or more mg/dL each minute, or 3 or more mg/dL each minute.

You can choose to set one of the two Receiver Fall Rates (how fast you are going down) or none. You can choose to be notified if your glucose level is falling 2 or more mg/dL each minute, or 3 or more mg/dL each minute.

If your glucose level rises or falls at the Alert setting you chose, it will display an Alert to you. You can set the Alert to vibrate or beep (see Chapter 2, Section 2.3, "Setting your Alerts"). Two examples are shown below:

If you set your Fall Rate to 2 mg/dL per minute and your glucose levels fall at this level or faster, the Single Arrow Screen will appear and alert according to your settings.

If you set your Rise Rate to 3 mg/dL per minute and your glucose levels rise at this level or faster, the Double Arrow Screen will appear and alert according to your settings.

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5.4 GLUCOSE STATUS

This device is not designed to replace a blood glucose meter. During Missing Glucose Information, rely on 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 using your blood glucose meter.

5.4.1 GLUCOSE STATUS BOX SYMBOLS

During your Sensor Session the Status Box in the upper right hand corner can display any of the information below.

157 **Glucose Reading**	Once the Receiver is calibrated, your glucose readings will appear in the Status Box in mg/dL units. Your glucose readings are updated every 5 minutes.
Calibration Needed	A blood drop tells you your System requires another fingerstick reading entry. You might be due for your 12-hour calibration or the Receiver might need an additional fingerstick to improve its calibration. (See Section 4.4)
??? **Glucose Reading Error**	Three question marks mean the Receiver cannot understand the Sensor signal. You should wait for more prompts and do not enter any fingersticks when you see this symbol. (See Section 5.4.3)
RF Error	A white antenna in a black circle, means the Transmitter and Receiver are out of range. Make sure the Receiver and Transmitter are within 5 feet of each other. (See Section 5.4.4).
Err0 **Sensor Error #0**	Means the Sensor cannot calibrate right now. If you see this screen, enter at least 1 more calibration fingerstick reading in the next 10-15 minutes. If the Sensor still cannot calibrate after this additional fingerstick, the Sensor needs to be replaced. (See Section 8.4)
Err1 **Sensor Error #1**	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. (See Section 8.4)

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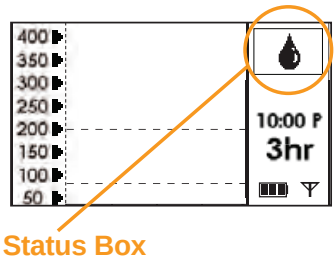
5.4.2 MISSING GLUCOSE READINGS

Glucose readings usually appear in the Status Box. At certain times, a notification symbol can appear in the Status Box instead of the glucose readings. These notifications are helpful in troubleshooting. The table in this section shows the symbols that might appear in the Status Box.

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 Transmitter and Receiver are out of range. Make sure the Transmitter and Receiver are within 5 feet 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 Transmitter and Receiver are out of range.



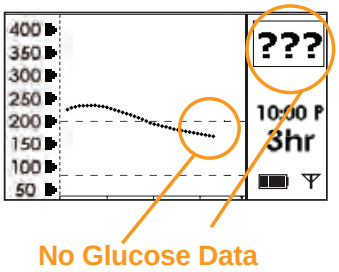
If your Receiver is not displaying glucose information, look at the Status Box in the upper right corner of any Trend Graph.

5.4.3 SYSTEM GLUCOSE ERRORS

Sometimes the SEVEN PLUS may tell you that it cannot provide a glucose reading. When this occurs you will see 3 question marks (???) in the Receiver Status Box.

Check the placement of your Sensor to make sure it is still sticking well 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.



Oftentimes this error happens when the SEVEN PLUS detects problems with the glucose signal or insertion area. Section 10.1 tells you how often you might expect seeing this error. Sometimes the SEVEN PLUS can fix the issue and start providing glucose readings. However, if it has been 3 hours, contact Technical Support.

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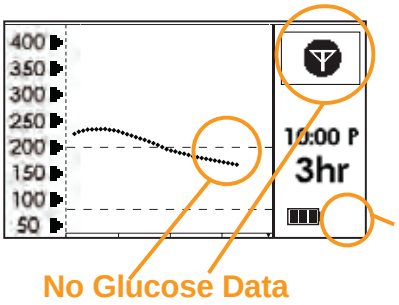
HELPFUL HINTS:

- If you see the "???" in the Status Box of the Receiver 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 fingersticks with your meter and entering them does not help the System display more glucose readings. Any fingersticks that you take during "???" will be ignored by the System.
- Wait until you see a single blood drop in the Status Box 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 Box instead of a glucose reading, 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 5 feet of the Transmitter/Sensor Pod. If it is not, move the Receiver closer and wait at least 5 minutes.

NOTE: The Antenna Symbol in the lower right corner will disappear.

- Once you have moved the Receiver closer and waited 5-10 minutes, the Out of Range Symbol in the Status Box should go away. The Antenna Symbol should reappear in the lower right corner, and you should receive a glucose reading in the Status Box.
- If you are still having trouble receiving System readings because of this problem, contact DexCom Technical Support at 1-888-SEVENGO (738-3646).

HELPFUL HINTS:

- You can set an Out of Range Alert to notify you when the Receiver and Transmitter are not talking (see Chapter 2, Section 2.3.4, "Setting Out of Range Alert"). You can set the amount of time the Transmitter can be out of range before the Receiver alerts you.
- The Transmitter and Receiver may lose communication during the following circumstances: While you are lying on a waterbed, while they are near metallic objects, or when you are using an electric blanket.

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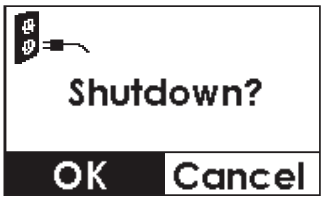
5.5 TEMPORARY SENSOR SHUT DOWN

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 while the Receiver is shut down, but your current continuous monitoring session will remain in progress. Follow these steps to shut down your Receiver:

1. Press any button to turn the Receiver's display on.
2. Press the **OK** button to reach the Options Menu.
3. Use the Up ▲ and Down ▼ Arrow buttons to scroll until "Shutdown" is highlighted.
4. Press the **OK** button. The Shutdown confirmation screen will appear.



5. Press the **OK** button to confirm that you want to shut down.
6. The Receiver will power down. No data will be collected and no Alerts/ALARMS will sound or appear.
7. Hold down any key to turn the Receiver on again.

HELPFUL HINTS:

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

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chapter six

DIABETES MANAGEMENT TOOLS

6

6.1 DIABETES EVENTS

With the SEVEN PLUS you can enter meal, insulin, health, and activity 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 reviewed later with the DexCom Data Manager software.

6.1.1 HOW TO ENTER AN EVENT

1. Press any key to turn on the Receiver's display.
2. Press the **OK** button to reach the Options Menu.
3. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you highlight "Events." (see screen shown to the right).

4. Press the **OK** button to go into the Events Menu.
5. Use the Up ▲ and Down ▼ Arrow buttons to scroll through the different type of Events:
   a. Carbohydrates b. Insulin c. Exercise d. Health
6. Highlight the event you want, and press the **OK** button to enter the Events option you want.
7. In the individual Events Menus, use Up ▲ and Down ▼ Arrow buttons to scroll through the options you want to select (e.g., grams of carbohydrates, type of exercise), and press the **OK** button to select the option.
8. At the time setting screens for each event:
   - You will see the current date and time. Press **OK** if you would like to use this time stamp.
   - If you would like to change this entry, use the Up ▲ and Down ▼ Arrow buttons to highlight "edit". Press **OK**.

   a. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the year you want. Then press the **OK** button.
      i. You can scroll by 1 digit at a time.

   b. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the month you want. Then press the **OK** button.

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c. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the day you want. Then press the **OK** button.

d. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the hour you want. Then press the **OK** button. When you choose the hour, the AM/PM will adjust automatically (e.g. if you go from 11AM to 12PM, AM will switch to PM).

e. Use the Up ▲ and Down ▼ Arrow buttons to scroll until you select the minute you want. Then press the **OK** button.

9. You will see an event summary screen.

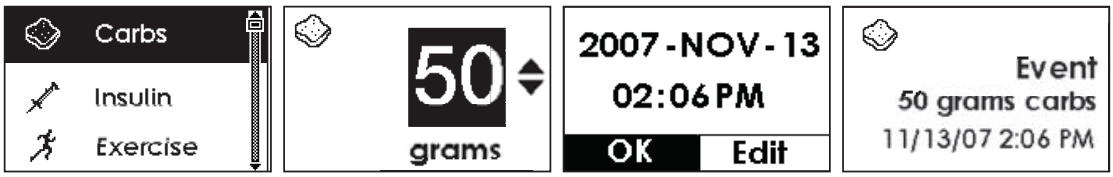
   a. Press the **OK** button to confirm.

Press the **C** button if the information is incorrect and you want to back-up.

6.1.2 CARBOHYDRATES

You can enter the carbohydrates you eat by using the Carbs Menu.

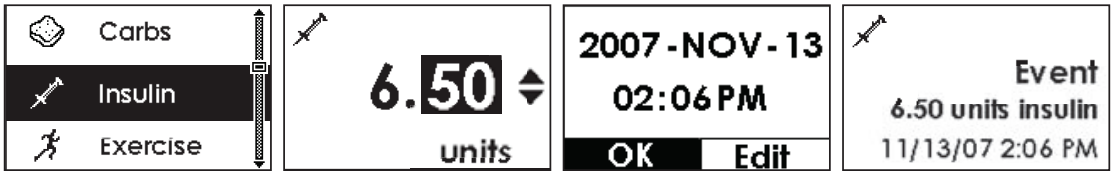
- You can enter 0-200 grams.
- When you enter this menu, you will either see the last number of Carbohydrates grams you entered or you will see 50 grams (default).



6.1.3 INSULIN

You can enter the insulin you take by using the Insulin Menu.

- You can enter 0-250 units.
- When you enter this menu, you will either see the last Insulin units you entered or you will see 10 units (default).
- You cannot set different types of insulin.



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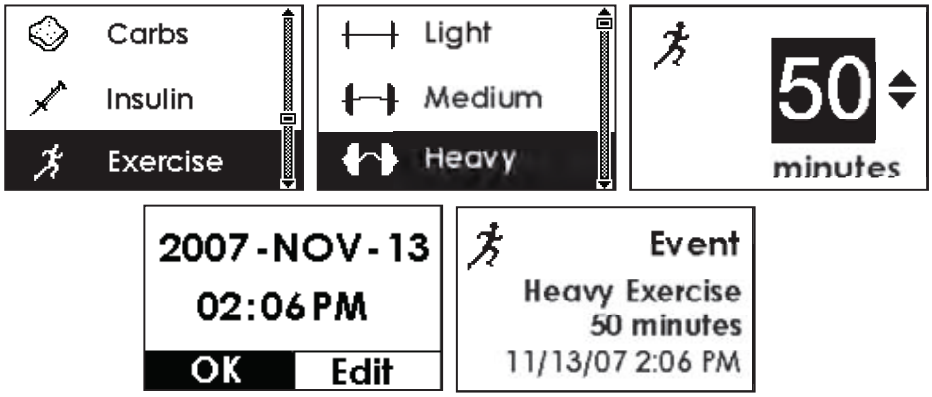
6.1.4 EXERCISE

You can enter any exercise you participate in by using the Exercise Menu.

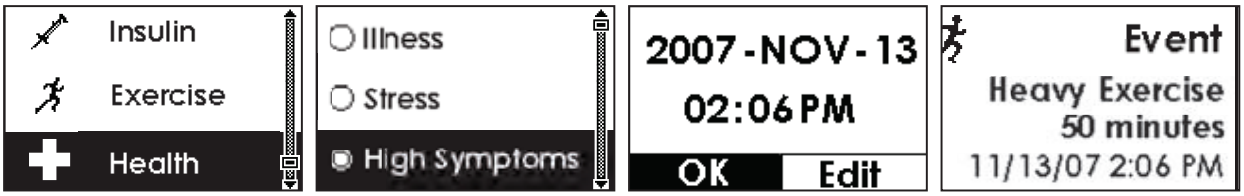
- You can select Light, Medium, or Heavy Exercise Intensity.
- You can enter 0-360 minutes for the duration of your exercise. The default is always 30 minutes.



6.1.5 HEALTH

You can enter instances of changes in your health using the Health Menu.

- You can select Illness, Stress, High Symptoms, Low Symptoms, Cycle, or Alcohol.



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6.2 DATA MANAGER SOFTWARE

The DexCom Data Manager® computer software comes with your SEVEN PLUS. This software allows you to view trends and track patterns.

The software creates 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 SEVEN PLUS Receiver downloads and save or print files that you can take to your next doctor visit.

For system requirements you may contact Customer Support at 1-888-SEVENGO (738-3646) or refer to the DexCom website (www.dexcom.com). The Data Manager Help File gives you more information on how to use this software.

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chapter seven

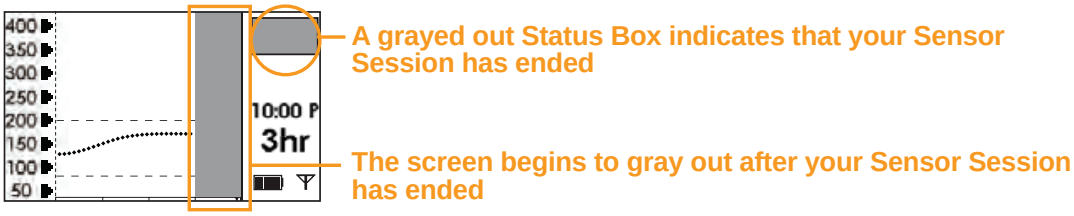
COMPLETING YOUR CONTINUOUS GLUCOSE MONITORING SESSION

7

At the end of your Sensor Session, or wear period, you will need to remove the Sensor Pod. Gently peel up the adhesive patch from your skin (this will pull out your Sensor Probe). Then remove the Transmitter from the Sensor Pod and keep it for your next glucose monitoring session (see Chapter 7, Section 7.3, “Transmitter Removal”).

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

Once your Sensor use has ended, glucose readings will no longer be shown on the screen. The Receiver screen will indicate that the Sensor Session has ended by displaying the gray rectangle in the Status Box.



Over time the Receiver display (Trend Graph area) will continue to “gray out” until a new Sensor is inserted.

HELPFUL HINTS:

- 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.

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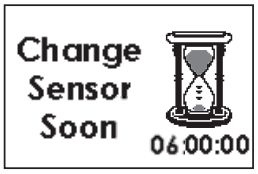
7.1 AUTOMATIC SENSOR SHUT-OFF

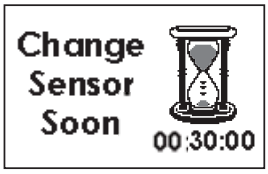
The Receiver will tell you how much time you have remaining until your SEVEN Sensor session is complete. The Expiration Screen will appear 6 hours and 2 hours before your 7-Day session ends.

At 30-minutes and 0-hours before your 7-day session ends, the Receiver will display the Expiration Screen. You can set the Receiver to vibrate and/or beep with these 30-minute or 0-hour displays if you choose (see Chapter 2, Section 2.3, "Setting your Alerts"). After the 6-hour, 2-hour, and 30-minute reminders you will still continue to receive System readings. You can clear all of these screens by pressing the **C** 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 (+ vibration if set)

Sensor Expiration Notification (+ vibration if set) End of session

Once the Final Expiration Screen appears, press the C button to clear this notification.

7.2 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 10, "Technical Information," of this User's Guide to determine how often you should expect this to happen. Examples of why this may occur are described on the next page.

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7.2.1 EARLY SHUT-OFF – SENSOR FAILURE

During use the Receiver may detect a series of issues with your Sensor signal where it can no longer determine what your glucose reading is (see Chapter 8, Section 8.3, “Sensor Failed Troubleshooting”). At this time the System will automatically turn off and show the screen to the right:

If you see this screen then your continuous glucose monitoring session has ended. Press the **C** button to clear this screen.

Failed Sensor Screen

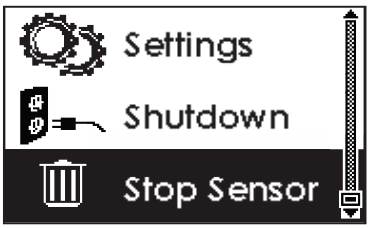
HELPFUL HINT

- If you removed your Sensor before telling the Receiver, the Failed Sensor Screen will show up automatically. You must press **OK** before inserting a new Sensor.

7.2.2 MANUAL SENSOR SHUT-OFF – “STOP SENSOR”

To manually end your Sensor session, use the Stop Sensor Menu. This Menu title will only appear during a Sensor wear period. You must have already started a Sensor with the Start Sensor Menu, and the Sensor Session must not have expired (Chapter 7, ”Completing Your Continuous Glucose Monitoring Session”) or failed (Chapter 8, Section 8.3, “Sensor Failed Troubleshooting”).

Press the **OK** button to confirm that you want to stop the Sensor.



HELPFUL HINT

- You cannot reverse this decision after the final **OK**. Press the **C** button if you do not want to stop the Sensor wear period.

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7.3 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 (Chapter 3, Section 3.5, "Sensor Insertion") 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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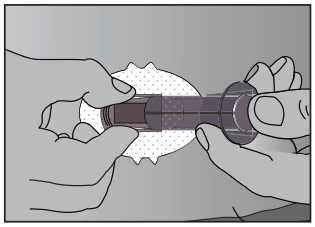
chapter eight

TROUBLESHOOTING

8.1 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.

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8.2 CALIBRATION TROUBLESHOOTING

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

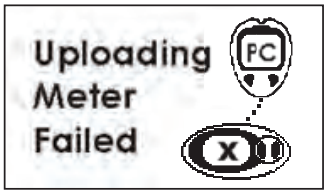
- Make sure you have inserted a Sensor and Started a Sensor Session
- Do not use expired Sensors
- Store Sensors at room temperature (see Chapter 9 for Maintenance and Storage of your System)
- Make sure your meter readings are between 40 and 400mg/dL before you calibrate
- Quality check your blood glucose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

8.2.1 CONNECTION FAILURE AND NEW METER SCREENS (AUTO UPLOAD ONLY)

You should see these two notification screens only if you are using the OneTouch Ultra Meter with the Connection Cable.

Connection Failure Screen

If you see this screen to the right, (with an "X" on the Receiver screen), the fingerstick reading transfer failed. First clear the alert by pressing the **C** button. No additional fingersticks are required. Disconnect the devices and review the following:



Connection Failure Screen

1. Make sure that the meter screen is always blank before you connect the 2 devices.
2. Make sure you plug the Connection Cable into the meter first and into the Receiver second.
3. Do not disconnect the cable while uploading or before you see the Trend Graph appear.
4. Re-try upload using the proper step order.

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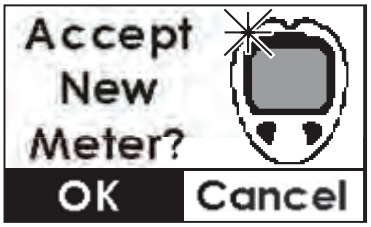
New Meter Screen

You will see this screen if you have connected a new/ different meter to your Receiver. Your Receiver will vibrate.



New Meter Screen

1. You will be asked to register the meter with your System. See Chapter 4, Section 4.1.2, “Using Auto Upload for Calibration”.
2. You will have to take 2 additional fingersticks and upload them.

8.2.2 BLOOD DROP PROMPTS

8.2.2.1 TYPES OF BLOOD DROP PROMPTS

This section describes the three blood drop symbols you will see. The next section (Section 8.2.2.2, “Status Box Symbols During Blood Drop Prompts”) describes what to do when you see one of these symbols.

Repeat Double Blood Drop Prompt

If Start-Up calibration is not successful, the Receiver will continue to display this screen until you correct the problem. Make sure you have followed the instructions in Section 4.1.1, “Using OpenChoice for Calibration” and the instructions for how to address the Connection Failure Screen and New Meter Screen (if using Auto Upload). 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 in Status Box) with each other at the time you took the 2 fingersticks entered for calibration, **or**
- The Receiver could not understand (“???” in Status Box) your Sensor signal at the time you entered the fingerstick readings for calibration.

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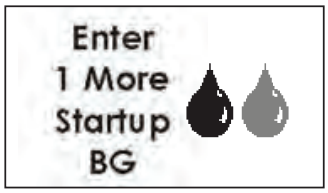
Shaded-Out Blood Drop Prompt

The Shaded-Out Blood Drop Prompt means you need 1 more fingerstick for Start-Up Calibration.



Shaded-out Blood Drop Prompt

This symbol 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 Shaded-Out Blood Drop Prompt every 15 minutes until you successfully take the fingerstick and enter it into the Receiver.

Single Blood Drop Prompt

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

Single Bolld Drop Prompt

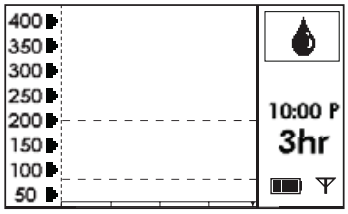
- 12-Hour Update: The symbol will prompt you again every 15 minutes until a new fingerstick is successfully entered.
- Additional fingerstick needed: The Receiver will vibrate and will make a sound. The Receiver will notify you two more times (to enter a fingerstick), or until a new fingerstick is successfully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

8.2.2.2 Status Box Symbols During Blood Drop Prompts

If you are prompted by the Repeat Double Blood Drop, Shaded-Out Blood Drop, or Single Blood drop, make sure you first check the Status Box on your Receiver before you take another fingerstick. Then follow the steps below:

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

   a. If the "Awaiting Fingerstick Reading" Blood Drop Symbol (shown to the right) is displayed:



Awaiting Fingerstick Reading (Blood Drop) Symbol

- Take 2 more fingersticks if you are prompted by the Double Blood Drop.
- 1 more fingerstick if you are prompted by the Shaded-Out or Single Blood Drop. (Readings must be within 40-400 mg/dL).
- Enter your fingerstick readings into the Receiver.

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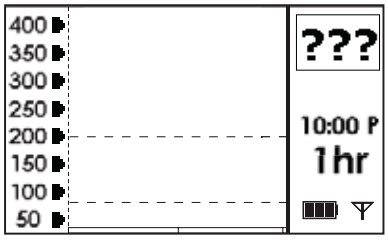
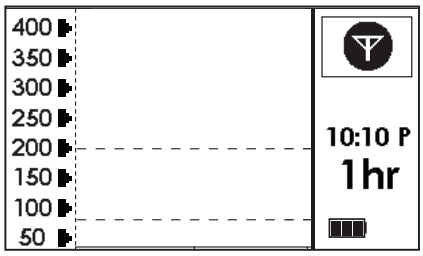
b. If the "???" Symbol (shown to the right) is displayed, your Receiver cannot understand your Sensor signal. Do not take any more fingersticks for calibration at this time. Wait until you see the Awaiting Fingerstick Reading (Blood Drop) Screen again and review Steps 1 and 2.



"Unknown Glucose Reading" Symbol

c. If the "No Communication" Symbol (shown below) is displayed, do not take any more fingersticks for calibration at this time. Move the Receiver and Transmitter so that they are within 5 feet of each other and wait at least 5 minutes.

1. Make sure your Transmitter ID is entered into the Receiver (Section 2.2.2)
2. Make sure your Transmitter is fully snapped in



Out of Range Symbol

If you are still having problems with communication review Chapter 5, Section 5.4.4, "Out of Range/No Antenna." When you are prompted with either Blood Drop Prompt again, review the steps at the beginning of this section to calibrate.

HELPFUL HINTS:

- If you are still having trouble with SEVEN PLUS calibration (e.g., receiving multiple prompts) following these steps, contact DexCom Technical Support at 1-888-SEVENGO (738-3646) for help.

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8.3 SENSOR FAILED TROUBLESHOOTING

In some cases your Sensor Session may stop before the end of a full 7-day period. You should review Chapter 10 of this User's Guide to see how often you should expect this to happen to you. Follow the user guidelines below to have the best results with your System.

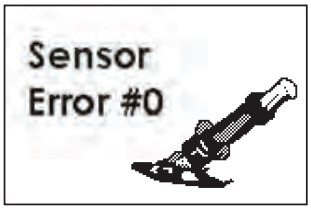
- Do not use expired Sensors
- Store Sensors at room temperature (see Chapter 9 for Maintenance and Storage)
- Quality check your blood glucose meter
- Make sure your Transmitter is snapped in fully
- Make sure your Sensor Pod is not dislodged or peeling up

During use your Receiver may detect a series of problems that make your Sensor unable to calculate System Glucose Readings (see Chapter 5 Section 5.4.3, "System Glucose Errors"). At this time the System will automatically turn off and display the following screen:

Failed Sensor Screen

8.4 ERROR CODE TROUBLESHOOTING

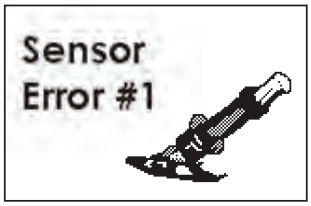
The screen to the right means your Sensor cannot calibrate. If you see this screen, enter at least 1 more calibration fingerstick reading in the next 10-15 minutes. If you still do not see readings after you enter 2 more fingersticks in the Receiver, the Sensor may need to be replaced.



Sensor Error #0 Screen

If you clear this screen by pressing the **C** button, you will see this error code (shown to the left) in the Status Box.

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



Sensor Error #1 Screen

If you clear this screen by pressing the **C** button, you will see this error code (shown to the left) in the Status Box.

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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 the code that appears on the screen, if any, and contact DexCom Technical Support at 1-888-SEVENGO (738-3646). Continue to check BG readings using your meter.

System Recovery Check

This screen indicates there was a problem with the Receiver, but the System was able to fix itself. Press the **C** button to clear this display, and your continuous monitoring session will continue.

System Recovery Check Screen

8.5 RECEIVER AND CABLES TROUBLESHOOTING

Battery and Charging Difficulties

1. Remember to charge your Receiver's battery.
   a. The charge will last approximately 3-5 days, depending on how often you turn on your Receiver's screens, 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.
2. Make sure the Charging Cable is fully inserted in the Receiver and in the electrical outlet.
   a. If your cable has a Push button, press this to release the cable. Do not pull out without pressing the button.
   b. Pull the cable out carefully so you do not bend the prongs.
   c. Only use DexCom cables.
3. If your battery drains and is not charged for about 6 months, the back-up battery might also drain. When this happens, you will need to reset your Receiver's time (see Chapter 2, Section 2.2.1, "Setting your Receiver Time and Date").
4. Only use the DexCom battery charger.

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Alerts Not Working

1. Make sure you have not disabled the sound and/or vibrations for the Alerts. Chapter 2, Section 2.3, “Setting your Alerts” explains how to change these Alert options.
2. 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.

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chapter nine

TAKING CARE OF YOUR SEVEN PLUS

9

9.1 MAINTENANCE

The SEVEN PLUS 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 SEVEN PLUS 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 SEVEN PLUS. Do not force cables in place.
- Remove cables carefully by pressing “Push” buttons (if available) made for easy removal.
- 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.

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9.2 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 (the last day of the month if only the month and year are printed).
- 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 1 year.
- 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 10-85% Relative Humidity.

9.3 CLEANING

Cleaning the Receiver (Single-patient Use):

1. Wipe the outside of the Receiver with a dry or wrung-out, slightly damp cloth.
2. The Receiver is not waterproof. Do not use a soaking wet cloth.
3. Disinfect with an Isopropyl alcohol wipe if desired.
4. Do not use soap, nail polish remover, or paint thinner. Only use Isopropyl alcohol and water.

Cleaning the Transmitter (Single-patient Use):

1. Wipe the Transmitter clean with a wet cloth or Isopropyl alcohol wipe between uses.
2. The Transmitter is water resistant when snapped into the Sensor Pod, but do not soak the Transmitter in liquid.
3. Do not use soap, nail polish remover, or paint thinner. Only use Isopropyl alcohol and water.

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chapter ten

TECHNICAL INFORMATION

10

10.1 DEVICE PERFORMANCE CHARACTERISTICS

NOTE: The Performance Characteristics section of this User's Guide has changed to reflect the recent study done. The overall results of the trial showed that this next-generation SEVEN System will provide you more continuous glucose readings, and you should expect more of your Sensors to provide data for the entire 7-day use period. Note that the data described in the Performance Section also showed a difference from this generation SEVEN device to the original SEVEN device in performance in the low glucose region (40-80 mg/dL).

Our study showed that at 50 mg/dL blood glucose, the device reported glucose to be as high as 64 mg/dL and at 80 mg/dL blood glucose; the device reported glucose to be as high as 90 mg/dL. Because the performance of the Next-Generation SEVEN System varies from the original, it is important that you assess how the new generation device performs for you, especially in the low range. You should review the performance of this device with your healthcare provider to understand how well the Next-Generation SEVEN System performs.

The SEVEN PLUS uses a glucose Sensor to continuously measure and monitor your glucose levels. The Sensor is "calibrated" using your OneTouch® Ultra® blood glucose meter (Auto Upload) or a FDA-cleared blood glucose meter (using the OpenChoice™ feature). Once calibrated, the SEVEN PLUS reports glucose readings up to every 5 minutes. In a clinical study, SEVEN PLUS readings were compared to blood glucose measurements in order to assess its performance or how well the SEVEN PLUS measurements compare to a laboratory method that measures blood glucose levels. Clinical Study findings are presented below.

Although presentations to characterize performance of the SEVEN PLUS are given below, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors such as the SEVEN PLUS. Performance may be best understood by viewing graphs called "time-elapsed plots". In these plots, the readings from the SEVEN PLUS were recorded over time and were overlaid with readings taken at the same time with a reference laboratory method. Three representative time-elapsed plots are presented in this section (see Figures 2-3). They are examples of excellent, average and poor SEVEN PLUS performance.

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Participants enrolled in the clinical study and certain conditions of the study tend to result in above average glucose control. This, in turn, may result in the appearance that the SEVEN PLUS agrees with blood glucose levels better than it does under typical conditions. The following are some examples of why performance of the SEVEN PLUS might be idealized in this study.

- The average Hemoglobin A1c among the 53 participants was 7.4%. Many people with diabetes have higher A1c levels, indicating poorer control of their glucose levels.
- While subjects participated in the clinic portion of the study, they were more limited in their activities than someone at home. They were also provided with all their meals. Subjects who are more active, or with poor eating habits, may create more challenging conditions for the SEVEN PLUS.
- Blood Glucose meters used in the study were well maintained. Because the meter is used to calibrate the SEVEN PLUS, performance may be poorer if the meter is not well maintained. It is important to carry out quality-control checks on the meter and code the meter according to the manufacturer's instructions to optimize performance of the SEVEN PLUS.

Clinical Study Results

To evaluate performance of the SEVEN PLUS, 53 participants were enrolled in a clinical study conducted at 3 clinics. All participants had Type 1 or Type 2 diabetes mellitus, and required insulin to manage their diabetes. About 81% of participants had Type 1 diabetes and about 19% had Type 2 diabetes. Subjects ranged in age from 23 to 72 years old.

Participants used the SEVEN PLUS for approximately 7 days (each participant wore 1 or 2 Sensors for 7 days.) Receivers were calibrated approximately 2 times per day, on average, over the 7-day period using the Lifescan® OneTouch® Ultra meter. Throughout the 7-day wear period, the Receiver was calibrated the most on day 1, with an average of 3 fingersticks per day (2 to start up and 1 in the evening), and was calibrated with an average of 2 fingersticks per day for days 2-7 (approximately every 12 hours).

All participants used the SEVEN PLUS in a controlled clinic environment on Day 1, Day 4, or Day 7 of the 7-day wear period. The remainder of the study took place at home. While using the SEVEN PLUS in the clinic 49 of the 53 participants had their blood glucose measured every 15 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus glucose analyzer. This instrument is referred to as the "YSI." Readings from the SEVEN PLUS were paired with YSI readings in order to characterize how well SEVEN PLUS results agreed with blood glucose results. For the remainder of the study, participants used the SEVEN PLUS at home and results were paired with OneTouch Ultra blood glucose meter results. During Start-Up Calibration (see Chapter 4), all participants (100%) were able to calibrate successfully after the 2 hour Start-up period. For Calibration Updates/Re-Calibration (see Chapter 4) 97% of the time participants only needed one attempt to update calibration. Two-percent (2%) of Calibration Updates required a second attempt, and less than one-percent (<1%) of Calibration Updates needed more than three attempts.

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Agreement

Agreement between the SEVEN PLUS and glucose levels is characterized using paired SEVEN PLUS and YSI results. The SEVEN PLUS and YSI readings were compared by pairing the YSI blood glucose reading to a SEVEN PLUS glucose reading that occurred approximately 5 minutes after the YSI reading was collected.

The agreement of the SEVEN PLUS to blood glucose levels was assessed by calculating the percentage of SEVEN PLUS readings that were within 20%, 30%, and greater than 40% of the YSI readings. For readings less than or equal to 80 mg/dL the difference in mg/dL between the two glucose readings was calculated. For readings greater than 80 mg/dL the percent difference (%) from the YSI reading was calculated. The percentages of total readings within 20 mg/dL or 20%, 30 mg/dL or 30%, or greater than 40 mg/dL or 40% were then calculated. The total number of data pairs considered in this analysis was 1,827. Results are shown in Table 1.

Table 1. Percentage of SEVEN PLUS Results Falling Within 20, 30, and Greater Than 40 Percent of the Paired YSI Results, at Various Glucose Concentrations

YSI Readings (mg/dL)	Number of Paired Readings	% of SEVEN PLUS Readings Within 20%*	% of SEVEN PLUS Readings Within 30%*	% of SEVEN PLUS Readings Greater than 40%* of YSI
40-400	**1827**	**76%**	**90%**	**5%**
40-80	277	73%	87%	6%
81-180	801	74%	89%	5%
181-300	563	81%	93%	3%
301-400	186	75%	95%	2%

* For the 40-80 mg/dL range the absolute difference is presented as the difference in mg/dL between the SEVEN PLUS and YSI, rather than the percent.

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The SEVEN PLUS reports glucose concentrations between 40 and 400 mg/dL. When the SEVEN PLUS determines the glucose level is below 40 mg/dL, it displays “LOW” in the Receiver Status Box. When the SEVEN PLUS determines that the glucose level is above 400 mg/dL, it displays “HIGH” in the Receiver Status Box. The ability of the SEVEN PLUS to accurately report these occurrences is assessed by looking at the actual blood glucose concentrations (as determined by the YSI analyzer) when “LOW” or “HIGH” are reported.

- On 19 occasions, the SEVEN PLUS indicated the glucose reading was less than 40 mg/dL and displayed “LOW”. Of these, the YSI blood glucose readings were never below 40 mg/dL and ranged between 43 mg/dL up to 141 mg/dL.
- On 39 occasions, the SEVEN PLUS indicated the glucose reading was greater than 400 mg/dL and displayed “HIGH”. Of these, the paired YSI glucose reading was also above 400 mg/dL twelve (12) times. When the SEVEN PLUS read more than 400 mg/dL, the range of the YSI blood glucose readings at that time was 264-438 mg/dL.

LOW AND HIGH GLUCOSE ALERTS

The ability of the SEVEN PLUS to detect high and low glucose levels (concentrations) is assessed by comparing SEVEN PLUS results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The SEVEN PLUS and YSI readings were compared by pairing the SEVEN PLUS reading that occurred approximately 5 minutes after the YSI reading was collected. There were 1,827 pairs of paired SEVEN PLUS and YSI results evaluated. We suggest that you ask your doctor what Alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in the table on the next page. For example, the data in the table shows that if you set the Low Glucose Alert to 70 mg/dL, the SEVEN PLUS will alert you of a blood glucose measurement of 70 mg/dL or lower 57% of the time within 5 minutes of reaching that blood glucose level (True Alert Rate). The table also shows that at the same Alert setting (70 mg/dL), the Low Alert may not alert you 44% of the time (“Missed Alert Rate***”) within 5 minutes of the blood glucose reading. Also at the 70 mg/dL alert level, 46% of the time the SEVEN PLUS may falsely alert you that your glucose level is at or less than 70 mg/dL when your actual blood glucose level is above 70 mg/dL.

If you set the Low Glucose Alert to 90 mg/dL, the SEVEN PLUS should alert you 73% of the time within 5 minutes of when your glucose levels are at or below 90 mg/dL. The table also shows that at the same Alert setting (90 mg/dL), the Low Alert may not alert you within ~5

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minutes of the low blood glucose event 27% of the time ("Missed Alert Rate***"). Also at the 90 mg/dL alert level, 25% of the time the SEVEN PLUS may falsely alert you that your glucose level is at or less than 90 mg/dL when your actual blood glucose reading is above 90 mg/dL at that time.

Table 2. Hypoglycemic Alert Evaluation

SEVEN PLUS Alert Level	True Alert Rate*	False Alert Rate**	Missed Alert Rate***
60 mg/dL	59 %	61 %	41%
70 mg/dL	57%	46 %	44 %
80 mg/dL	64 %	29 %	36 %
90 mg/dL	73 %	25 %	27 %

* True Alert Rate is the % of time when the blood glucose level was at or below the alert setting and the alert sounded.

** False Alert Rate is the % of time when the device alarmed but the blood glucose level was above the alert setting.

*** Missed Alert Rate is the % of time when the device failed to alarm when the blood glucose level was at or below the alert setting.

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in the table below. For example, if you set the High Glucose Alert to 200 mg/dL, the SEVEN PLUS should alert you 81% of the time within 5 minutes when your blood glucose levels rise above 200 mg/dL (True Alert). Additionally, 7% of the time when the alert sounds, the glucose level may actually be below 200 mg/dL (False Alert) at this time.

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Table 3. Hyperglycemic Alert Evaluation

Alert Setting	True Alert Rate*	False Alert Rate**	Missed Alert Rate***
140 mg/dl	92 %	6 %	8 %
180 mg/dl	84 %	6 %	16 %
200 mg/dl	82 %	7 %	18 %
220 mg/dl	80 %	8 %	20 %
240 mg/dl	77 %	8 %	23 %
300 mg/dl	59 %	27 %	41 %

* True Alert Rate is the % of time when the blood glucose level was at or above the alert setting and the alert sounded.

** False Alert Rate is the % of time when the device alarmed but the blood glucose level was below the alert setting.

*** Missed Alert Rate is the % of time when the device failed to alarm when the blood glucose level was at or above the alert setting.

Performance of High and Low Glucose Alerts at night comparing the SEVEN PLUS to YSI data has not been established with the SEVEN Sensor. During use of the SEVEN PLUS at home, the High Alert was set to 200 mg/dL and the Low Alert was set to 80 mg/dL. Subjects were asked to take a fingerstick each time a high or low glucose alert sounded. The SEVEN PLUS and Meter readings were compared by pairing the SEVEN PLUS reading that occurred on average 5 minutes after the fingerstick meter reading was taken during home use. Analysis of the home use data showed that when the SEVEN PLUS was above 200 mg/dL, 77% of the OneTouch Ultra meter readings were above 200 mg/dL (True High Alert). When the SEVEN PLUS read below 80 mg/dL, 73% of the time the OneTouch Ultra readings were below 80 mg/dL (True Low Alerts). The SEVEN PLUS notified the subject that their glucose levels were falsely below the Low Alert level 27% of the time and notified the subject that their glucose levels were falsely above the High Alert level 23% of the time.

Accuracy

Accuracy between matched pairs was also estimated by calculating the percent difference between the SEVEN PLUS reading and the YSI reading. The SEVEN PLUS and YSI readings were compared by pairing the SEVEN PLUS reading that fell approximately 5 minutes after the YSI reading was collected. For example, if the YSI reading is 100 mg/dL and the SEVEN PLUS reading is 90 mg/dL, a 10% difference between the SEVEN PLUS and the YSI Laboratory machine is reported.

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In the above example the SEVEN PLUS reading is less than the YSI reading and so the percent difference reading is negative. The mean percent difference is the average of all of the positive and negative percent differences between the two devices compared and, therefore, tells you if the SEVEN PLUS on average reads higher or lower than the YSI at each glucose range. Another estimate used to tell you the accuracy of the SEVEN PLUS is the absolute percent difference. The absolute percent difference tells you the overall percent difference or "distance" between the SEVEN PLUS and YSI readings, but does not tell you if the SEVEN PLUS is reading on average higher or lower than the YSI laboratory standard. The mean absolute percent difference is the average "distance" (regardless if positive or negative) between SEVEN PLUS readings and YSI readings. These accuracy measures are summarized in Table 4 below and are based on 1,827 paired glucose measurements:

Table 4. SEVEN PLUS and YSI Blood Glucose Accuracy by Glucose Concentration

Glucose Range (mg/dL)	Number of Paired Readings	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall (40-400 mg/dL)	**1827**	**-1%**	**-3%**	**16%**	**13%**
40-80	277	13%	12%	25%	20%
81-180	801	-1%	-2%	15%	13%
181-300	563	-6%	-7%	13%	12%
301-400	186	-9%	-9%	13%	10%

Table 4 shows that the SEVEN PLUS, on average, reads 13% higher than the YSI at glucose levels of 40-80 mg/dL and reads 9% lower, on average, than the YSI at glucose concentrations of 301-400 mg/dL (Mean Percent Difference). The SEVEN PLUS reads, on average, 25% different than the YSI at glucose levels of 40-80 mg/dL and, on average, 13% different than the YSI readings at glucose levels of 301-400 mg/dL (Mean Absolute Percent Difference). The Median Percent Difference shows that 50% of the time the SEVEN PLUS reads approximately 3% less than the YSI System and the Median Absolute Difference shows that 50% of the time the SEVEN PLUS reads about 13% different then YSI blood glucose readings taken within 5 minutes.

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Clarke Error Grid Analysis

The Clarke Error Grid was used to determine if SEVEN PLUS results are “clinically accurate.” The Clarke Error Grid divides a correlation plot into 5 zones, which are described in the table below.

Zone	Description
A	Clinically Accurate, would lead to correct treatment decisions
B	Would lead to benign decisions or no treatment
C	Would lead to overcorrection of normal glucose levels
D	Would lead to failure to be aware of and treatment of high or low glucose levels
E	Would lead to inaccurate and “dangerous” treatment decisions

Results in zones A and B are considered “clinically acceptable”, in which you would most likely make accurate treatment decisions or decide not to do treatment with the readings provided, while results in zones C, D, and E can lead to dangerous treatment errors. The Clarke Error Grid zones are labeled on a correlation plot in Figure 1. Each YSI result (on the horizontal axis) is matched up with its corresponding SEVEN PLUS result (on the vertical axis). A point is recorded where the two readings intersect. These results are based on 1,827 paired data points recorded.

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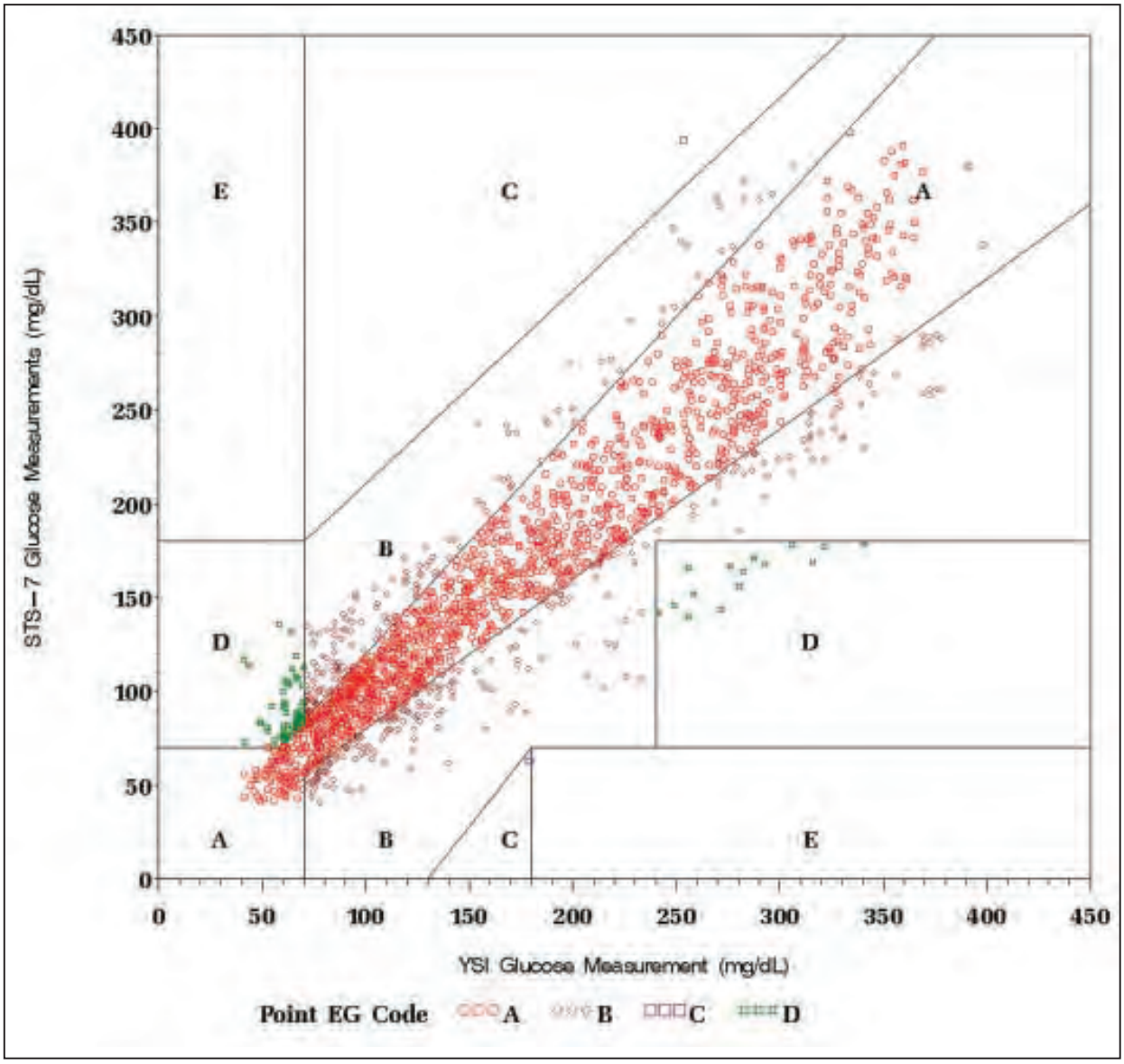
Figure 1.

Clarke Error Grid, SEVEN PLUS Results Compared to YSI Results

Point Error Grid Regions for All Site



The percentage of SEVEN PLUS results in the above graph are presented in Table 6 on the next page according to the percentage of points falling within each zone (A-E). Results are further broken down (stratified) according to therange of glucose concentration.

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Table 6. Clarke Error Grid Analysis, Stratified by YSI Glucose Concentrations

Glucose Range (mg/dl)	Total YSI – SEVEN PLUS Pairs	A %	B %	C %	D %	E %
40-400	**1,827**	**73%**	**23%**	**0%**	**4%**	**0%**
40-80	277	57%	22%	0%	21%	0%
81-180	801	73%	27%	0%	N/A*	N/A*
181-300	563	81%	17%	0%	2%	0%
301-400	186	75%	23%	N/A*	2%	0%

* N/A means that the Clarke Error Grid does not consider the possibility of these zones in that glucose range.

The Continuous Error Grid was also used to determine if the SEVEN PLUS results are "clinically acceptable." The Continuous Error Grid looks at how closely the SEVEN PLUS readings match to the YSI Analyzer and also how closely the SEVEN PLUS glucose rate of change (how fast the glucose rises or falls) compares to the actual blood glucose rate of change measured by the YSI. The data is evaluated in 3 zones: clinically accurate readings, benign errors, and clinically inaccurate readings. See the table below for the SEVEN PLUS accuracy by glucose range. There were 1,827 paired points evaluated.

Table 7. Continuous Error Grid Combined Point and Rate Rating Table

	Hypoglycemia (YSI<= 70 mg/dl) (8% of the data)	Euglycemia (70< YSI <=180 mg/dl) (51% of the data)	Hyperglycemia (YSI >180 mg/dl) (41% of the data)
Accurate Readings	61%	97%	94%
Benign Errors	1%	2%	2%
Inaccurate Readings	39%	1%	5%

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Calibrations Stability

The SEVEN PLUS must be calibrated every 12 hours. To demonstrate performance of the SEVEN PLUS over a 12-hour calibration period, 71 Sensors were evaluated to verify that performance remains consistent over the 12-hour calibration period. SEVEN PLUSs were evaluated in 3-hour increments after calibration. Performance was estimated at each 3-hour interval and stratified by glucose concentrations by calculating the percentage of SEVEN PLUS readings within 20%, 30% and greater than 40% of the YSI readings. See the table below.

Table 8. Percentage of SEVEN PLUS readings within 20%, 30% and 40% of the YSI Laboratory reading with data stratified in 3-hour increments after calibration across days 1, 4 and 7.

Time from Calibration and YSI Glucose Range (40-400 mg/dL)	Number of Paired Readings	% of Readings within 20% of YSI	% of Readings within 30% of YSI	% of Readings within 40% of YSI
0-3 hours	1031	77%	91%	96%
3-6 hours	345	75%	91%	96%
6-9 hours	235	71%	88%	94%
9-12 hours	187	77%	88%	91%

Sensor Stability

Sensors can be worn for up to 7 days. To verify that sensors perform consistently over the 7-day period, 71 Sensors were evaluated across the 7-day wear period. Performance was estimated by calculating the percentage of SEVEN PLUS readings within 20%, 30% and >40% of the YSI readings at the beginning (Day 1), middle (Day 4) and end (Day 7) of the SEVEN PLUS lifecycle. Results are shown in the table below.

Table 9. SEVEN PLUS System Sensor Stability (Accuracy Over Time)

Day of Wear (40-400 mg/dl)	Number of Paired Readings	% of Readings within 20% of YSI	% of Readings within 30% of YSI	% of Readings within 40% of YSI
Day 1	637	77%	91%	3%
Day 4	635	80%	94%	3%
Day 7	533	70%	86%	8%

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Precision of SEVEN PLUS System Readings

In the same study, 18 of the subjects wore two SEVEN PLUS'. This was done to look at how similarly two SEVEN PLUS' on the same person function (Sensor Precision). Precision was evaluated by comparing the glucose readings from the two SEVEN PLUS' worn on the same subject at the same time. Results showed that SEVEN PLUS readings from the two sensors generally agreed with each other within 15%.

Sensor Life

During the trial there were no Sensor insertion problems and Sensors may be worn for up to 7 days (168 hours). To estimate how long a SEVEN Sensor will work over 7 days, the 71 Sensors were evaluated to determine how many Days (hours) of readings each Sensor provided. Table 10, below, displays how long you can expect a Sensor to last after insertion. For example, 89% of the sensors lasted more than 6 and up to the full 7 days (144-168 hours).

Table 10. Estimated SEVEN Sensor Life

Number of Days of Use (Hours)	Percentage of Sensors
1 (24 hours)	1%
2 (48 hours)	1%
3 (72 hours)	6%
4 (96 hours)	0%
5 (120 hours)	0%
6 (144 hours)	3%
7 (168 hours)	89%

There were 6 Sensors that did not last at least 6 days or more than 144 hours. Five (5) of those sensors became non-functional due to an Early Sensor Shut-off, and 1 Sensor ended before 6 days because the subject bumped the Sensor and it fell off.

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Number of Readings Provided

The SEVEN PLUS is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, this does not always happen. Sometimes sensors cannot provide readings after calibration and readings are "skipped" (see Chapter 5). Table 11, below, estimates the number of readings you can expect to receive from the SEVEN PLUS over the entire 7-day period. For example, 87% of SEVEN PLUS devices provided between 1,557 and 1,992 readings (or at least 76% of the expected number of readings).

Table 11. Number of Readings Provided by Each Sensor Over 7-Days

% of Total Possible Readings Provided	Total Readings Provided	% of SEVEN PLUS Devices Providing that number of readings
0-25%	261	1%
26-50%	521-782	7%
51-75%	1005-1477	4%
76-100%	1557-1992	87%

Approximately 7% of readings were lost because the Transmitter and Receiver were not communicating. Approximately 1% of the time the SEVEN PLUS required additional calibration readings to start displaying glucose readings again. Over 7 days of use, on average, subjects experienced 3 periods of time where the Receiver could not display glucose readings and displayed "???" instead. These periods lasted on average for 1 hour. A small percentage of subjects (<10%) experienced a period of missing glucose readings (or "???") for more than 4 hours. However, per the Sensor Life data above, 89% of the Sensors were able to "recover" from these periods of signal problems and begin displaying continuous glucose readings again.

Time-Elapsed Plots

Examples of SEVEN PLUS Continuous Glucose Monitoring System overlaid with the corresponding YSI readings over time are presented on the next page. The horizontal axis represents time, with the matching SEVEN PLUS and YSI readings plotted above the point in time when the measurements were taken. The circles (•) on the graph represent the SEVEN PLUS data. The "Y" represents the YSI reading.

There are three Figures presented. Figure 2 is an example of when the SEVEN PLUS performed well, Figure 3 represents a period when the SEVEN PLUS performed in an average manner, and Figure 4 represents when the SEVEN PLUS performed poorly.

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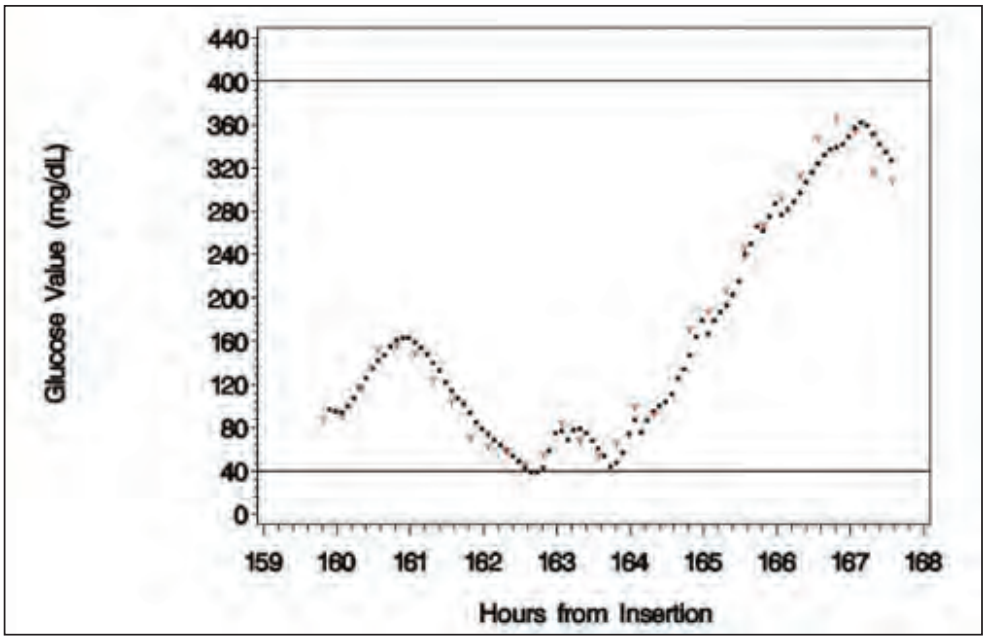
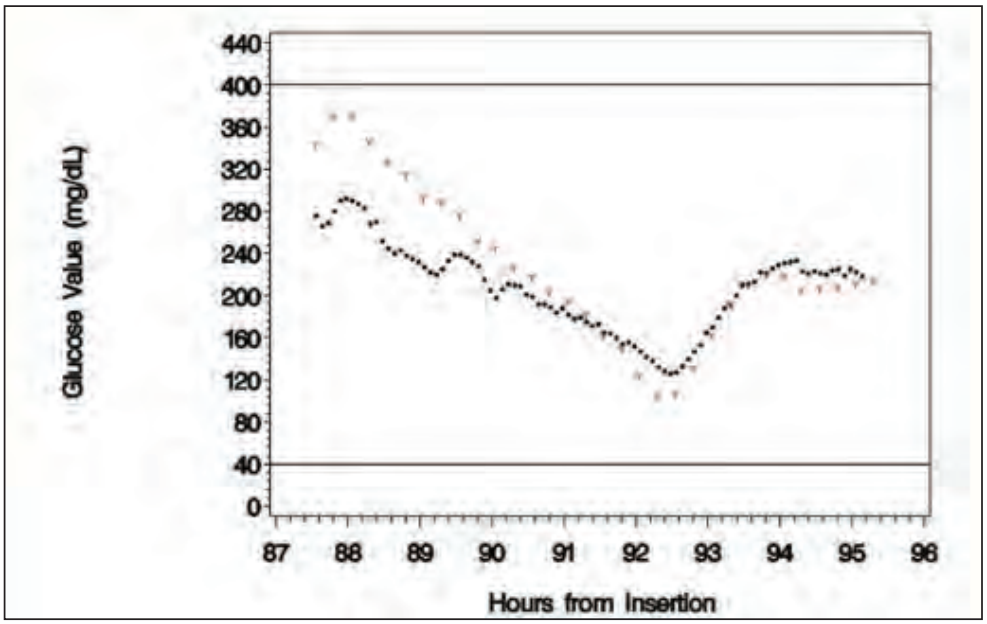
Figure 2. Example of "Good" SEVEN PLUS Performance



YYY YSI Reading ··· SEVEN PLUS Glucose Reading

Figure 3. Example of " Average" SEVEN PLUS Performance



YYY YSI Reading ··· SEVEN PLUS Glucose Reading

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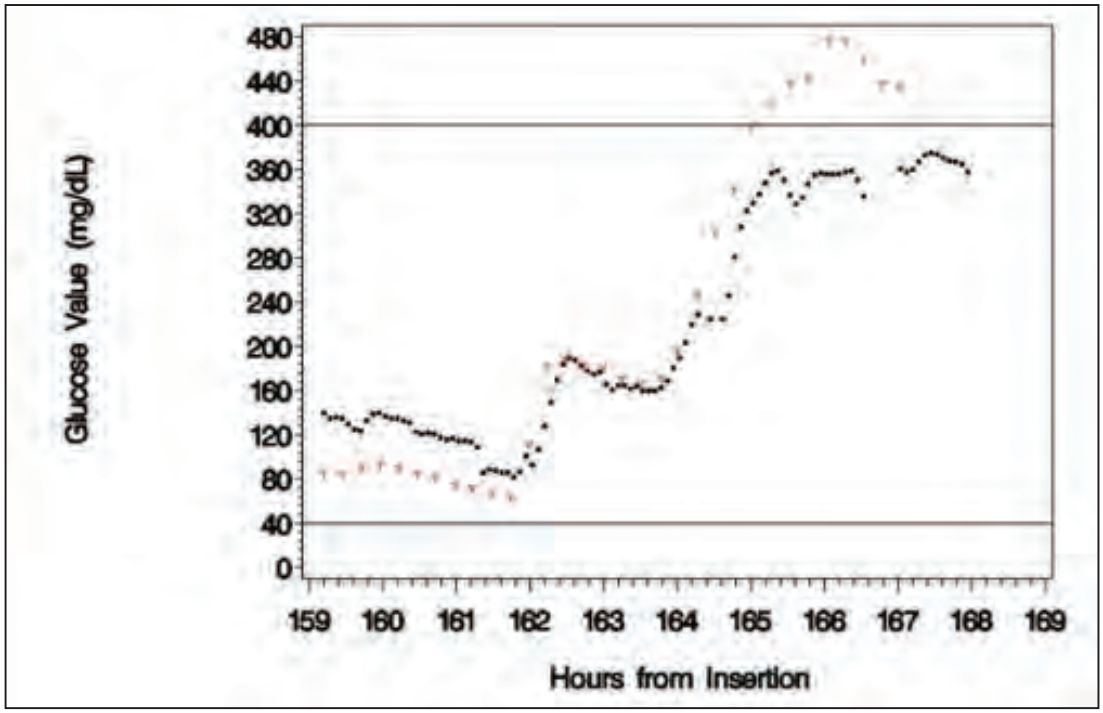
Figure 4. Example of "Poor" SEVEN PLUS Performance



YYY YSI Reading ···SEVEN PLUS Glucose Reading

Adverse Events

Overall 92% of patients reported no symptoms of irritation and 8% reported at least one symptom at any insertion site. During the trial irritation such as mild redness, mild swelling, mild bruising was seen. Although bleeding was not seen in this study, other studies using the same sensor showed a small percentage of persons who had bleeding after needle insertion. See Table 12 below for the types of irritation looked for and reported on during this trial:

Table 12. Summary of Irritation Events

Symptoms Reported	% of Patient Reported Events at the Sensor Insertion Sites
Redness (Erythema)	6%
Swelling (Edema)	1%
Bruising	1%
Infection	0%

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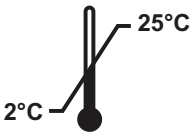
10.2 PRODUCT SPECIFICATIONS

Sensor

Glucose Range	40-400 mg/dL (2.2 – 22.2 mmol/L)	
Sensor Life	Up to 7 days	
Calibration – Auto Upload	OneTouch Ultra Blood Glucose Meter	
Calibration – OpenChoice	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 7: temporary submersion to a depth of 3 feet (1 meter) for 30 minutes	IPX 5 IPX 7
Sterilization	Sterile by election beam	STERILE R

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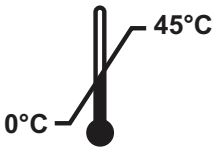
Transmitter

Dimensions (including Sensor Pod)	Length: 1.5 inches (3.8 cm) Width: 0.9 inches (2.3 cm) Thickness: 0.4 inches (1.0 cm)	
Weight (including Sensor Pod)	0.24 ounces (6.7 grams)	
Communication Range	5 ft (1.5 m)	
Frequency	402-405 MHz	
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	1 year	
Moisture Protection	IPX 5: water resistance to jetting water IPX 7: temporary submersion to a depth of 3 feet (1 meter) for 30 minutes	IPX 5 IPX 7

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PARAMETER	PERFORMANCE CHARACTERISTICS
Frequency Allocation	MICS Band
TX/RX Frequency	402.142 MHz
Bandwidth	300 kHz
Maximum Output Power	25 uW EIRP
Modulation	On-Off Key
Data Rate	8192 bits/Sec
Total Packet	76 bits
Transmit Duty Cycle	9.28 ms every 5 minutes
Data Detection Range	5 ft
Average Number of Collisions due to Coexistence. 20 DexCom Transmitters within 15 feet over a 24 hr period (288 transmissions each)	Total of 4 collisions, if collision occurs, no glucose value is received

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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

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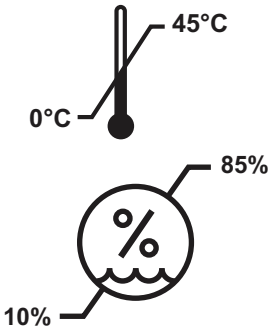
Receiver

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	3.5 ounces (100 g)	
Communication Range	5 ft (1.5 m)	
Memory Storage	30 days	
Re-Chargeable Battery Use	3 to 5 days	
Charging Time	3 hours	
Storage/Operating Conditions	Temperature: 0°- 45° C (32°- 113° F) Humidity: 10-85 % Relative	
Moisture Protection	None	
Limited Warranty	1 year	

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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 environmental.
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

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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	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 k Hz to 80 MHz	3 V	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 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). 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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

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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.

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance 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.

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Charging Cable

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

10.3 FCC REQUIREMENTS

The Transmitter covered by this User's Guide has been certified under FCC ID: PH29402

The Transmitter is authorized by rule under the Medical Implant Communications Service (part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e. transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation.

The Transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. 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.

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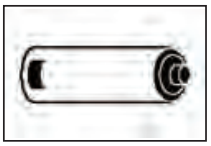
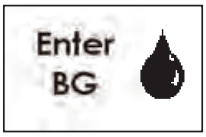
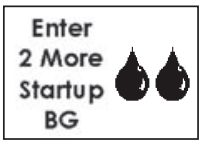
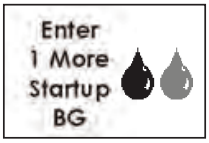
chapter eleven

APPENDIX I, OTHER ALERTS

This table shows the Other Alerts. You can also learn how to clear the Alert and when you will be re-alerted by the Receiver for the event:

Screen	Alert Title	Description	Re-Alert	Clearing Alerts	Re-Alert After Clear
	Low Battery Alert	The Receiver's 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 **C** button or charge the Receiver	Every 60 minutes
	"Enter BG" Single Blood Drop Alert	The Receiver needs a calibration fingerstick. Take a fingerstick and enter the reading into the Receiver.	None	Press **C** button	Every 15 minutes
	"Enter 2 More Startup BGs" Repeat Double Blood Drop Alert	You must enter two additional fingerstick readings for Start-Up calibration.	Every 5 minutes	Press **C** button	Every 15 minutes
	"Enter 1 More Startup BG" Shaded-Out Blood Drop Alert	You must enter one additional fingerstick reading for Start Up Calibration.	Every 5 minutes	Press **C** button	Every 15 minutes

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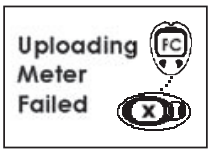
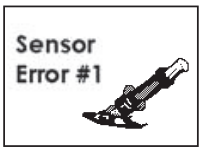
Screen	Alert Title	Description	Re-Alert	Clearing Alerts	Re-Alert After Clear
	Failed Meter Communication Alert	There was a problem with communication between the OneTouch Ultra Meter and the Receiver using the Connection Cable.	Every 5 minutes	Press **C** button and reconnect the OneTouch Ultra Meter.	None
	Sensor Error #0 and #1 Alerts	The Sensor is not calibrating properly (see Section 8.4, "Error Code Troubleshooting," for instructions on what to do if you see this screen).	Every 5 minutes	Press **C** button	Every 15 minutes until you fix the problem or your glu-cose level changes enough to fix the problem itself
	Sensor Expiration Alerts	Your Sensor 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 **C** button	None

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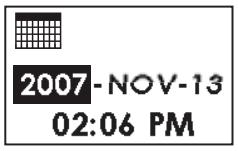
Screen	Alert Title	Description	Re-Alert	Clearing Alerts	Re-Alert After Clear
	Sensor Expiration Alerts	You have worn the Sensor for 7 days. You should change your Sensor at this time.	2 times in the next 10 minutes	Press **C** button	None
	Sensor Failed Alert	The Sensor is not working properly (see Section 8.3, "Sensor Failed Troubleshooting").	2 times in the next 10 minutes	Press **C** button	None
	Receiver Error Alert	There is a problem with the Receiver. Write down the code on the screen, and contact DexCom Technical Support at 1-888-SEVENGO (738-3646).	None. The Receiver will beep and vibrate for 5 seconds and then will be silent.	Cannot clear alert	None. Cannot clear the alert.
	System Recovery Alert	There was a problem with the Receiver that it was able to fix itself.	Every 5 minutes	Press **C** button	None
	Time Loss Alert	The Receiver's back-up battery has drained, and you will need to reset the Receiver's time. The Time Loss Alert automatically takes you to the Time Setting Screen.	None	Enter the time	None

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:: 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)

	Type B applied part
STERILE R	**Sensor is sterilized by electron beam**
	Do not reuse the Sensors
	Follow operating instructions
Sensor and Transmitter are subject to IPX5 and IPX7:	
IPX 5	**Water resistant to jetting water**
IPX 7	**Temporary submersion to a depth of 1 meter for 30 minutes**
Receiver is not water resistant	
	Do not get the Receiver wet

DexCom, Inc. | 6340 Sequence Drive | San Diego, CA 92121 USA
Technical Support 1-888-SEVENGO (738-3646) | www.DexCom.com

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