

INSTRUCTIONS FOR USE

DEXCOM™ STS™ SENSOR

STERILE DEVICE

This device is sterile unless the package has been opened or damaged. Do not use if the sterile package has been opened or damaged.

INDICATION FOR USE

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

The DexCom STS 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 DexCom STS 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 STS System results should be based on the trends and patterns seen with several sequential Sensor readings over time.

CONTRAINDICATIONS

The DexCom STS System must be removed prior to Magnetic Resonance Imaging (MRI).

Use of acetaminophen-containing medications when the STS Sensor is inserted may affect the performance of the device.

WARNINGS

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

PRECAUTIONS

- Always wash hands with soap and water before opening the STS Sensor package. After opening the package, avoid touching the adhesive area.
- Before inserting the STS Sensor, always clean the skin at the STS Sensor insertion location with a topical antimicrobial solution, such as isopropyl alcohol. Do not apply the STS Sensor until the cleaned area is dry.
- Establish a rotation schedule for choosing each new STS Sensor location. Avoid Sensor locations that are constrained by clothing, accessories, or subjected to rigorous movement during exercise.
- Avoid injecting insulin within 3 inches of the STS Sensor or 3 inches from an insulin infusion set for pump wearers.
- The STS Sensor must be covered with a water resistant bandage or tape prior to showering or bathing.
- The STS Sensor is sterile in its unopened, undamaged package. Do not use any STS Sensor if its sterile package has been previously damaged or opened.
- The STS System has currently only been tested in adult persons with type 1 and type 2 diabetes. The device has not been tested in children, adolescents or pregnant women.

PRINCIPLE OF OPERATION

The DexCom STS Sensor works through an electrochemical reaction with glucose. The enzyme on the Sensor, glucose oxidase, is used to convert glucose into an electronic signal. The STS Transmitter measures the glucose signal and continuously sends the signal to the STS Receiver wirelessly via radio frequency (RF). The STS Receiver converts the Sensor signal to a glucose reading that is displayed to the user.

REAGENTS

Glucose oxidase. The enzyme glucose is derived from a microorganism *Aspergillus niger* purified and dried according to Type VII-S guidelines. Less than 0.6 µg of glucose oxidase is used to manufacture each STS Sensor and the enzyme is cross-linked and coated entirely by an outer sensor layer, which prevents direct tissue contact with the glucose oxidase. Therefore the risk of tissue reactions from glucose oxidase is considered to be minimal.

STORAGE AND HANDLING

The STS Sensor must be stored within a temperature range of 2-25 degrees Celsius (36-77 degrees Fahrenheit). Do not freeze.

Use the STS Sensor before the expiration date shown on the package. Discard and do not use any Sensors in which the packaging is torn or the seal is broken or when the Sensor has been exposed to storage conditions outside of the specified temperature range.

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ADVERSE REACTIONS

Blistering, Redness, mild swelling at the insertion site may occur with use of the device.

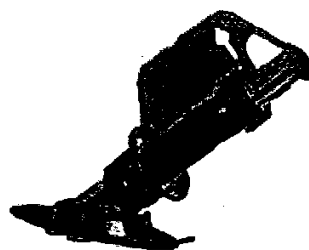
PRESCRIPTION DEVICE

Caution: U.S. federal law restricts the sale of the DexCom STS System to sale by or on order of a physician.

STS SYSTEM COMPONENTS

The STS System consists of three (3) major components.

1. **STS Sensor** – Contains the STS Applicator, Sensor Probe, and STS Sensor Pod.
 - **STS Applicator** – A disposable piece of the STS Sensor that you use to insert the Sensor Probe. There is a needle inside that STS Applicator that you remove once you have inserted the Sensor Probe underneath your skin.
 - **Sensor Probe** – The portion of the Sensor that is inserted under your skin using the STS Applicator. Measures glucose levels in your surrounding tissue fluid.
 - **STS Sensor Pod** – The small base adhered to your abdomen and holds the STS Transmitter in place. The STS Sensor Pod and STS Transmitter are all that remain on your skin during each STS Sensor wear period.
2. **STS Transmitter** – Device that snaps into the STS Sensor Pod and wirelessly sends glucose data to your STS Receiver.
3. **STS Receiver** – A pager-like device programmed to collect and process data from the STS Sensor and to display the results as a glucose values.



STS™ Sensor & STS™ Applicator



STS™ Sensor & STS™ Transmitter



STS™ Receiver

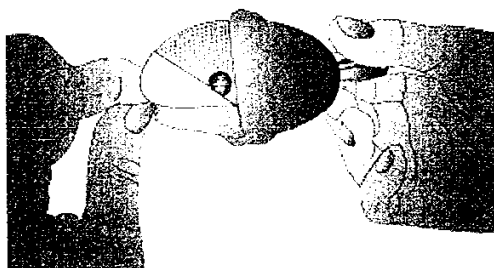
BEFORE YOU BEGIN

1. Wash your hands thoroughly.
2. Find a flat area on your abdomen (belly) where there isn't any scarring or rough patches of skin and clean that area with an isopropyl alcohol swab. Allow site to dry.
3. Make sure your Receiver is fully charged and that your Receiver and Transmitter are communicating (Antenna "Y" is visible on Receiver Screen)

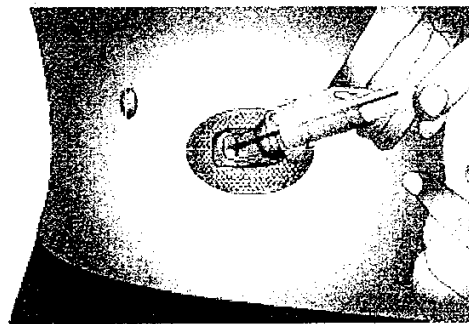
INSTRUCTIONS

These instructions describe how to insert the STS Sensor into the abdomen. Please refer to the accompanying illustrations for further assistance. The process is the same regardless of the abdominal insertion site.

Step 1. Remove the two pieces of adhesive backing from the bottom of the STS Sensor Pod and stick (adhere) the STS Pod onto the selected skin site.

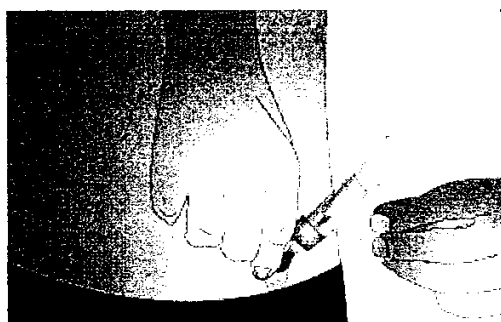


Removing the adhesive backing

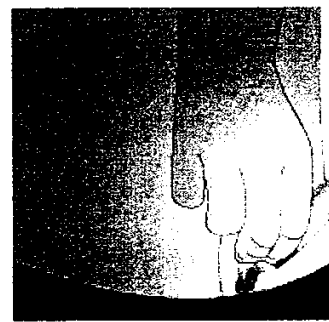


Adhering the STS Sensor on the skin

Step 2. Remove the STS Applicator Safety Lock by pulling it straight out and away from your body (using the arrow as a guide).

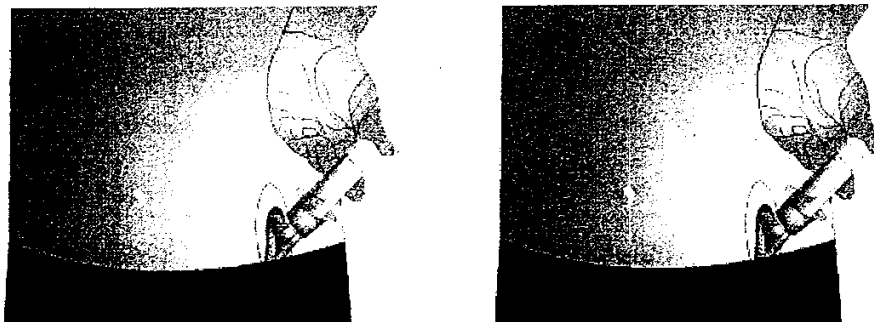


Removing the Safety Lock



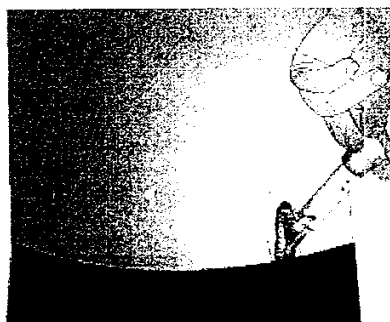
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Step 3. Holding the STS Pod with one hand and using your other hand, place two fingers under the collar and use your thumb to push the STS Applicator plunger down. This action inserts the needle and Sensor Probe.



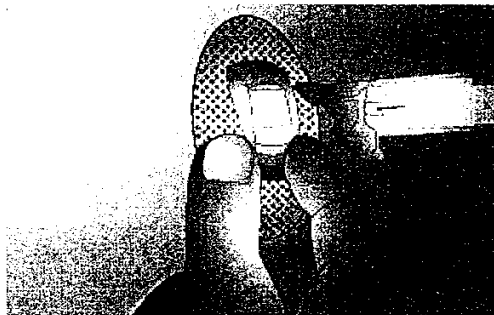
Pushing down the Plunger – Inserting the Needle and Sensor Probe

Step 4. Still holding the STS Pod with one hand, use the other hand to pull the collar of the STS Applicator back completely until you hear a click. This action pulls back (retracts) the needle and leaves the Sensor Probe underneath your skin.



Pulling back the Collar – Retracting the Needle

Step 5. Pressing the tabs on the STS Pod, pull the STS Applicator away from your body. The STS Pod will stay adhered to your skin. You can throw away the STS Applicator once it is removed.



Releasing the Applicator

Step 6. To start the continuous sensing period you must install your STS Transmitter in the STS Pod and notify the Receiver of a new STS Sensor insertion period. Detailed instructions on how to do this are located in your DexCom STS Quick Start Guide and DexCom STS User's Guide.

If you required additional information regarding use of the STS Sensor, contact DexCom Technical Support at 877-DEX-COM4 (877-339-2664).



USA:
5555 Oberlin Drive
San Diego, CA
858-200-0200
To order supplies:
877-339-2664 • www.dexcom.com

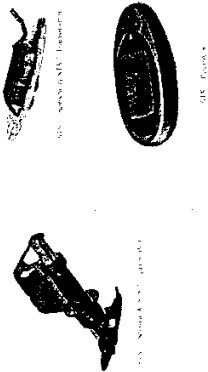
This product is covered by the following U.S. patents: 6,931,327
Other U.S. and/or foreign patents may be pending.

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LBL9551 rev. 1X

DEXCOM[®] STS[™] CONTINUOUS GLUCOSE MONITORING SYSTEM

QUICK START GUIDE

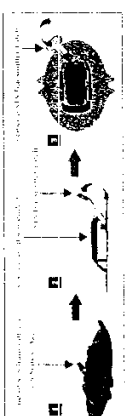


WARNING:
Treatment decisions should not be based solely on results from the DexCom STS System. You must confirm with a blood glucose meter before making therapeutic adjustments.

WARNING:
Remove all transmitters, sensors, and patches from the DexCom STS System before using the DexCom STS System for Glucose Monitoring System.

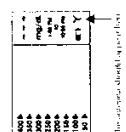
STATE OF CHARGE: STS RECEIVER IS CHARGED BEFORE YOU BEGIN.

1. INSTALLING YOUR STS TRANSMITTER

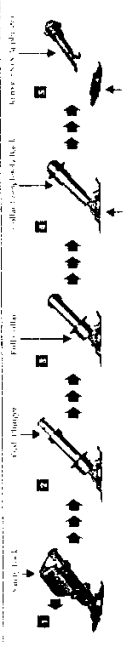


1. Place the STS Transmitter on the back of your body, away from the STS Sensor.
2. Pull the STS Transmitter Latch up and place the STS Transmitter in the place.
3. Remove the STS Transmitter Latch by pulling the end of the latch and the STS Transmitter Latch up and place the STS Transmitter in the place.

4. Press any button on the STS Receiver to check for the Antenna (you'll see a red light). If the antenna does not appear, refer to your User's Guide.



2. INSERTING A NEW STS SENSOR



1. Remove the adhesive backing from the STS Sensor Pad and place the STS Sensor on the selected site. Pull the safety lock out from the STS Applicator (pull near the arrow).
2. Place 2 fingers under the collar, with your thumb on the plunger, and push the plunger down completely.
3. Pull the collar back completely until you hear a click.
4. Press the light on the side of the STS Sensor and pull off the STS Applicator.
5. The STS Sensor Pad remains adhered to the skin after the STS Applicator is removed.

3. CALIBRATING YOUR STS SYSTEM

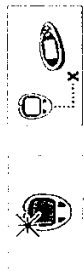
1. Dual Blood Drop Prompt: After you take 2 fingersticks using your blood glucose meter, upload the values to your STS Receiver. Upload the meter values to the STS Receiver by pushing the connection cable into the meter and the STS Receiver. The Meter Connection Cable (MCC) will support your blood glucose meter.
2. Dual Blood Drop Prompt: After you take 2 fingersticks using your blood glucose meter, upload the values to your STS Receiver. Upload the meter values to the STS Receiver by pushing the connection cable into the meter and the STS Receiver. The Meter Connection Cable (MCC) will support your blood glucose meter.



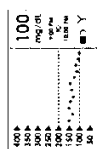
3. Remove the STS Transmitter Latch by pulling the end of the latch and the STS Transmitter Latch up and place the STS Transmitter in the place.

RECEIVER CALIBRATION/ALERT SCREENS

Checklist and/or "Low Alert" screens

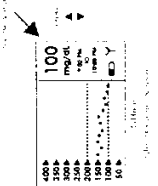


1. **Low Alert Screen:** Indicates that you have connected a new meter to the STS Receiver. Press "X" to make the meter active and connect the meter to the STS Receiver.
2. **Low Alert Screen:** Indicates that the meter and STS Receiver are not communicating properly. Press "X" to see the meter calibration screen. Take another attempt to connect the meter to the STS Receiver.



VIEWING YOUR CONTINUOUS GLUCOSE INFORMATION

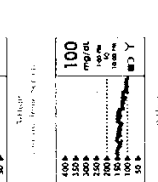
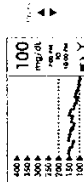
You can view glucose trends and alerts using the "Glucose" screen. Press "X" to view the "Glucose" screen.



STS RECEIVER CALIBRATION DATA SCREENS

If the STS Receiver is not displaying glucose values it could be for the following reasons:

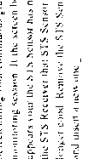
1. Your STS Receiver is not displaying glucose values. Press "X" to view the "Glucose" screen.
2. Your STS Receiver is not displaying glucose values. Press "X" to view the "Glucose" screen.



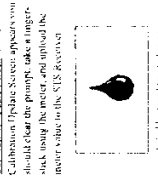
STS RECEIVER CALIBRATION DATA SCREENS

If the STS Receiver is not displaying glucose values it could be for the following reasons:

1. Your STS Receiver is not displaying glucose values. Press "X" to view the "Glucose" screen.
2. Your STS Receiver is not displaying glucose values. Press "X" to view the "Glucose" screen.

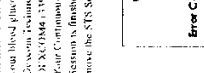


The device has vibrated and/or beep and displays one of the following screens during use. Always take a fingerstick before you make any treatment decisions.

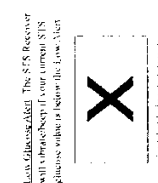


ERROR CODE

The error code indicates the STS Receiver is not functioning properly. Note the Error code, use your meter to check your glucose readings, and contact your STS Receiver manufacturer for assistance.

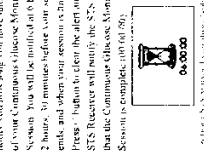


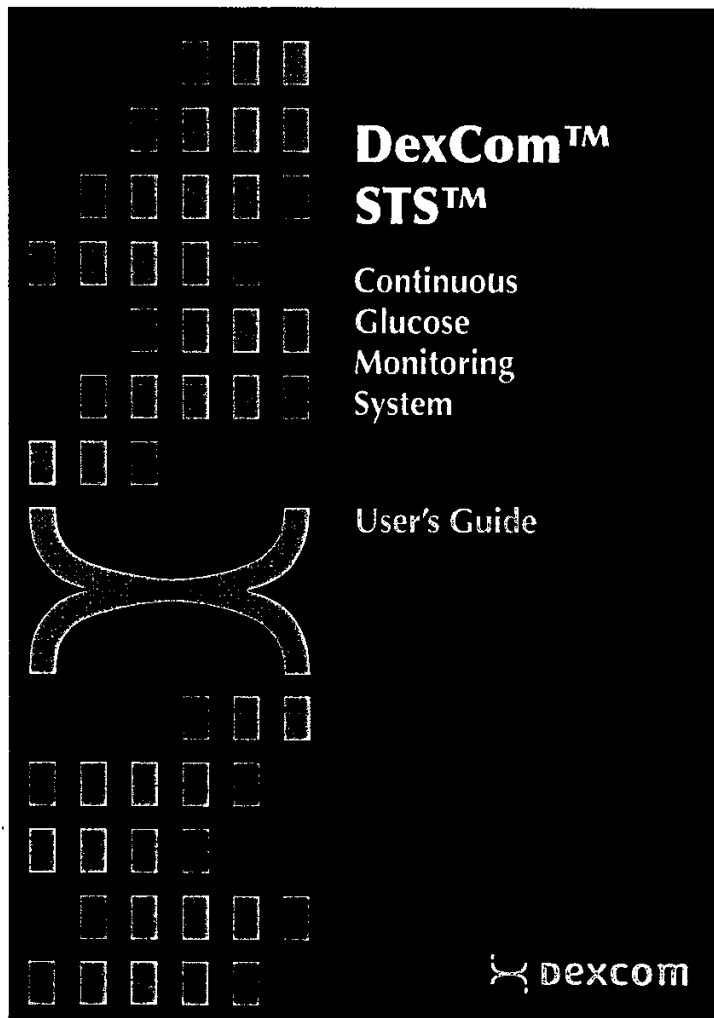
2. **Low Alert Screen:** Indicates that the STS Receiver is not displaying glucose values. Press "X" to make the meter active and connect the meter to the STS Receiver.



STS SENSOR EXPIRATION NOTIFICATION

The STS Receiver will display a screen that notifies you how long you have until the end of your Continuous Glucose Monitoring System. You will be notified at 6 hours, 2 hours, 10 minutes before your system expires, and when your system expires.





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User's Guide

CONFIDENTIAL

CONFIDENTIAL

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**DEXCOM™ STS™
CONTINUOUS GLUCOSE MONITORING SYSTEM**

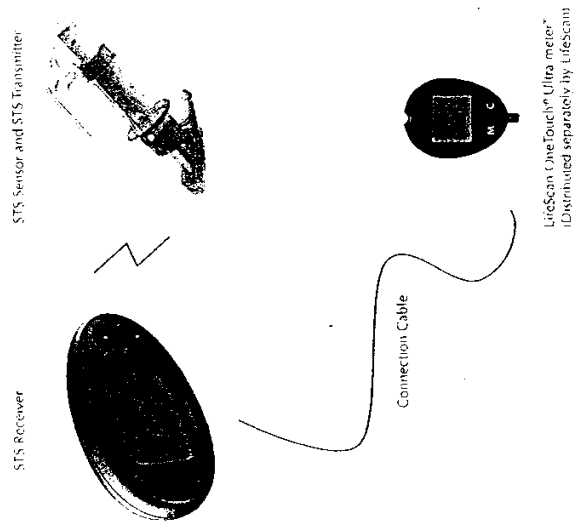


EXHIBIT 5

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INTRODUCTION

The DexCom[™] STS[™] Continuous Glucose Monitoring System provides you with real time continuous glucose measurements every 5 minutes for up to 3 days (72 hours). These readings will help you detect trends and patterns in your glucose levels. The DexCom STS System also features adjustable high and low glucose alerts to notify you when you are outside of your target glucose levels.

The DexCom STS System consists of three components: the STS Sensor, the STS Transmitter, and the STS Receiver. The DexCom STS System is currently only compatible with the LifeScan One-Touch[®] Ultra[®] Blood Glucose meter for calibration using a connection cable (Blood glucose values from the OneTouch Ultra Meter or other blood glucose meters CANNOT be manually entered in to the STS Receiver).

The DexCom STS 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 DexCom STS System is intended for use by patients at home and in healthcare facilities. The device is for prescription use only.

The DexCom STS 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 DexCom STS 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 DexCom STS System results should be based on the trends and patterns seen with several sequential readings over time.

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The STS™ Sensor is a disposable unit that you insert into your abdomen (belly) to continuously monitor your glucose levels for up to 3 days (72 hours). The STS Transmitter is a reusable device that snaps into the STS Sensor Pod and wirelessly sends glucose information measured by your STS Sensor to the STS Receiver. The STS Receiver is a hand-held device that receives and displays glucose information every 5 minutes sent by the STS Sensor/Transmitter. The STS Receiver displays your current glucose value and also shows your glucose trend information from the past 1-hour, 3 hours, and 9 hours. These trends allow you to see where your glucose levels have been and which direction your glucose levels are headed. The STS Receiver also vibrates and beeps to let you know when your glucose levels are high or low.

Clinical Studies reported 21 adverse events in 16 of 91 subjects Studied. These events consisted of 2 blisters, 2 reports of edema (swelling) and 17 reports of erythema (redness). All events were mild and required no treatment.

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

IMPORTANT SAFETY INFORMATION

READ THIS ENTIRE GUIDE BEFORE USING YOUR DEXCOM™ STS™ 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, AND OTHER IMPORTANT SAFETY INFORMATION CAN BE FOUND IN THIS SECTION, AND IN BOXES THROUGHOUT YOUR DEXCOM STS SYSTEM USER'S GUIDE. THE TROUBLESHOOTING SECTION (SECTION 8) CONTAINS IMPORTANT INFORMATION ON TROUBLESHOOTING YOUR DEXCOM STS SYSTEM.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

WARNINGS

- This device is not designed to replace a blood glucose meter. The DexCom™ STS System must be used with a blood glucose meter.
- Treatment decisions should not be based solely on results from the DexCom STS System. 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 STS System results.

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SECTION I

OVERVIEW OF THE DEXCOM™ STS™ SYSTEM

- You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

PRECAUTIONS

- Always wash hands with soap and water before opening the STS Sensor package. After opening the package, avoid touching the adhesive area.
- Before inserting the STS Sensor, always clean the skin at the STS Sensor insertion location with a topical antimicrobial solution, such as isopropyl alcohol. Do not apply the STS Sensor until the cleaned area is dry.
- Establish a rotation schedule for choosing each new STS Sensor location. Avoid STS Sensor location that are constrained by clothing, accessories, or subjected to rigorous movement during exercise.
- Avoid injecting insulin within 3 inches of the STS Sensor or 3 inches from an insulin infusion set for pump wearers.
- The STS Sensor must be covered with a water resistant bandage or tape prior to showering or bathing.
- The STS Sensor is sterile in its unopened, undamaged package. Do not use any STS Sensor if its sterile package have been previously damaged or opened.
- The STS System has currently only been tested in adult persons with type 1 and type 2 diabetes. The device has not been tested in children, adolescents or pregnant women.

CAUTION

- U.S. federal law restricts the sale of the DexCom™ STS System to sale by or on order of a physician.

DEXCOM™ STS™

DEXCOM™ STS™

1.1 GLOSSARY

The following list of terms will help you while reading through this guide.

BG value	Blood Glucose value. A fingerstick blood glucose value taken on your LifeScan One-Touch Ultra Meter.
BG Meter	Blood Glucose Meter. Currently the only meter compatible with the DexCom™ STS™ System is the OneTouch Ultra Meter.
Calibration	Required for the DexCom STS System to display continuous glucose data and trend information. Performed by uploading One Touch Ultra meter blood glucose values to the STS Receiver. (Do not use alternate site testing for calibration.)
DexCom™ STS™ System	The STS Sensor, STS Transmitter, and STS Receiver.
Glucose Trends	Allows you to see the pattern of your glucose levels; you can see where your glucose levels have been and where your glucose levels are headed. The DexCom STS System has three (3) glucose trend screens: the 1-Hour, 3-Hour, and 9-Hour Screens. Each trend screen shows glucose trends over the specified time.
mg/dL	Milligrams per deciliter. The standard unit of measure for glucose readings in the United States.

mmol/L	Millimoles per liter. The standard unit of measure for glucose readings in many countries outside the United States.
Glucose Data Gaps	When the STS™ Receiver does not display glucose values sent from the STS Sensor to the STS Receiver.
Range	The distance between the STS Receiver and STS Transmitter. The 2 devices should be kept within 5 feet (1.7 meters) from each other for best communication.
RF	Radio Frequency Transmission of the STS Transmitter to the STS Receiver.
Sensor Probe	The portion of the STS Sensor that is inserted under your skin using the STS Applicator. Measures glucose levels in your surrounding tissue fluid.
SN #	STS Transmitter serial number that is programmed into your Receiver for communication.
Start-Up Period	The 2-hour period after you insert a new STS Sensor (Glucose information cannot be provided during this time).
STS™ Applicator	A disposable piece of the STS Sensor that you use to insert the Sensor Probe. There is a needle inside the STS Applicator that you remove once you have inserted the Sensor Probe underneath your skin.

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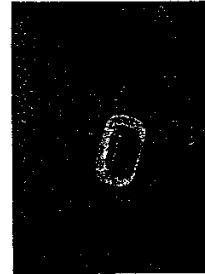
Continued 15

1.2 STS™ SENSOR OVERVIEW

The DexCom™ STS Sensor is a device that continuously measures your glucose levels. You will use a Blood Glucose(BG) meter to calibrate the readings measured by the STS Sensor. The glucose levels measured by the STS Sensor are sent by a wireless, low-powered, radio frequency (RF) to the STS Receiver every 5 minutes for up to 3 days (72-hours).

The STS Sensor consists of an STS Applicator (needle/sensor housing), Sensor Probe and STS Sensor Pod. You will insert the Sensor Probe just beneath the skin (subcutaneous tissue) of your abdomen (belly) using a small needle inside the STS Applicator. The needle is inserted about ½ inches (1.3 cm) beneath your skin and carries the Sensor Probe with it. After you insert the needle and Sensor Probe, you will pull the needle back into the STS Applicator, leaving the Sensor Probe behind to continuously measure your glucose levels. The STS Applicator is then removed from the STS Sensor Pod and should be thrown away.

The Sensor Probe lies ½ inch underneath your skin and will continuously measure your glucose levels for up to 3 days. The STS Sensor and STS Transmitter (once snapped in) are all that remain on your body for the entire wear period. The insertion site looks very similar to an insulin pump infusion site.



STS™ Receiver
A pager-like device programmed to collect and process data from the STS Sensor and to display the results as a glucose value (mg/dL or mmol/L).

STS™ Sensor
A device inserted underneath the skin to continuously monitor glucose levels.

STS™ Sensor Pod
The small base adhered to your abdomen that holds the STS Transmitter in place. The STS Sensor Pod and STS Transmitter are all that remain on your skin during each STS Sensor wear period.

STS™ Transmitter
Device that snaps into the STS Sensor Pod and wirelessly sends glucose data to your STS Receiver.

STS™ Transmitter Latch Upload
The small, disposable piece that snaps the STS Transmitter into the STS Sensor Pod. To transfer BG values from the OneTouch Ultra Meter to your STS Receiver. You transfer BG values directly with the connection cable.

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1.3 STS™ TRANSMITTER OVERVIEW

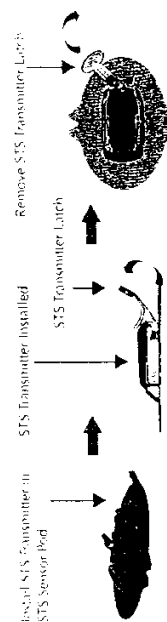
The STS Transmitter wirelessly sends glucose information collected by your STS Sensor to your STS Receiver. Once you insert your STS Sensor, you will snap the STS Transmitter into the STS Sensor Pod, using the STS Transmitter Latch. The STS Transmitter can be used for multiple STS Sensor wear periods (for approximately 6 months).

As your STS Transmitter nears the end of its useful life, it may periodically lose communication with the STS Receiver even if they are within 5 feet (1.7m) of each other. Once your STS Transmitter battery has drained, you will need to replace it.

Your new STS Transmitter can easily be programmed to communicate with your DexCom STS System (see Section 7.2).

NOTE

No warning is given when your STS Transmitter battery is about to die. Contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664) to order a new STS Transmitter so you can continue using your DexCom STS System.



1.4 STS™ RECEIVER OVERVIEW

The STS Receiver is similar to a pager or an insulin pump and communicates the glucose information measured by the STS Sensor to you. Your STS Receiver should be kept within 5 feet (1.7 m) of your STS Sensor Pod (with STS Transmitter) at all times for best communication. The best places to keep your STS Receiver are on your beltline in the carrying case provided or in the pocket of your pants. During nighttime use you may want to place the Receiver under your pillow.

The STS Receiver is rechargeable like a cell phone. The rechargeable battery should last for about 5 days before needing to be charged. However the STS Receiver will alert you when the battery charge is low. The STS Receiver takes 3 hours to fully charge if the battery was completely drained. To charge the STS Receiver, plug the charger cable provided into a standard wall outlet. If you are currently wearing a STS Sensor, remember that you should stay within 5 feet (1.7 m) of your STS Receiver to continue to receive continuous glucose information.

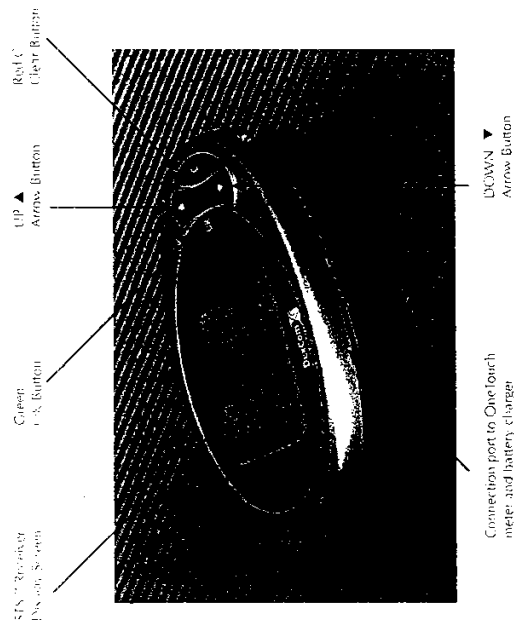
The STS Receiver has 4 buttons to guide you through its screens. The screens display Glucose values and Trend Graphs and allow you to change your STS Receiver settings. You can program your STS Receiver with a specific STS Transmitter Serial Number (SN#) so your STS Receiver and STS Transmitter can "talk" to each other. You will also notify your STS Receiver each time you insert a new STS Sensor.

Each STS Sensor must be calibrated before glucose readings can be displayed on your STS Receiver. To calibrate, you directly connect your STS Receiver to the LifeScan OneTouch Ultra Meter using the connection cable. By connecting the 2 devices, you will

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15-0000-0000-00

transfer fingerstick blood glucose values taken on your OneTouch Ultra Meter to your STS Receiver. Please note, BG values from the OneTouch Ultra Meter or other blood glucose meters CANNOT be manually entered into your STS Receiver, and you should not use alternate site testing to check your blood glucose.



1.4.1 STS™ RECEIVER SCREEN SYMBOLS

The following symbols may appear on the STS Receiver display during use:

	ANTENNA: Indicates the STS Receiver and STS Transmitter are "talking" and glucose data has been sent in the last 5 minutes.
	LOW BATTERY ALERT: Indicates the STS Receiver battery is running low and needs to be recharged. Charging should be done as soon as possible.
	CONNECTION: Indicates the BGM is successfully transferring BG values to your STS Receiver.
	CONNECTION FAILURE: Indicates the BGM and your STS Receiver are not connected properly. BG values have not been successfully transferred.
	NEW METER SCREEN: Indicates that a new meter has been plugged into the STS Receiver. This meter has a different serial number from the presently registered meter. You will have to re-take any fingersticks needed for calibration and then connect the 2 devices again for a calibration update.

 DUAL BLOOD DROP PROMPT: Appears approximately 2 hours after you insert a new STS™ Sensor and indicates that you need to take 2 fingerstick BG values on your BG meter and upload them to get into calibration.	 ERROR CODE: Indicates the STS™ Receiver is not functioning properly. If you see this code, use your meter to check your blood glucose readings and notify DexCom Technical Support at 1-877-DEXCOM4 (339-2664).
 SHADED-OUT BLOOD DROP PROMPT: Notifies you that only 1 fingerstick BG value has been successfully uploaded from the BG meter to the STS Receiver. You need to take and upload at least 1 more BG value for calibration.	 6 HOUR STS SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session will end in 6 hours.
 CALIBRATION UPDATE SCREEN: Indicates you should take a calibration fingerstick on the BG meter and upload it to the STS Receiver.	 2 HOUR STS SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session will end in 2 hours.
 OUT OF CALIBRATION SCREEN: Indicates the STS Receiver is out of calibration. You will need to take another BG fingerstick and upload it to your STS Receiver at this time.	 30 MINUTE STS SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session will end in 30 minutes.
	 0 HOUR STS SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session has ended. Once you clear the alert your STS Receiver will be notified that the STS Sensor is removed.

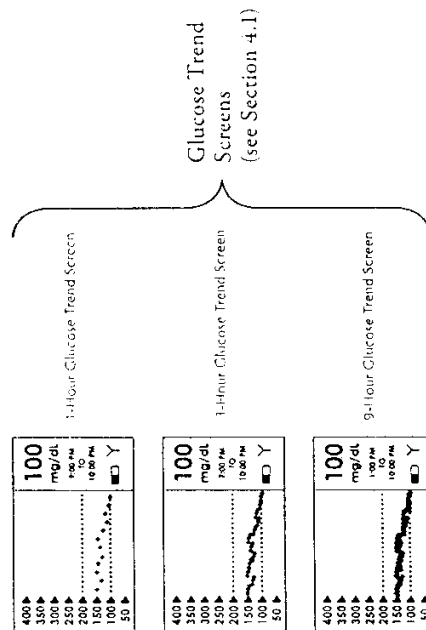
23-100-0000-001

23-100-0000-001

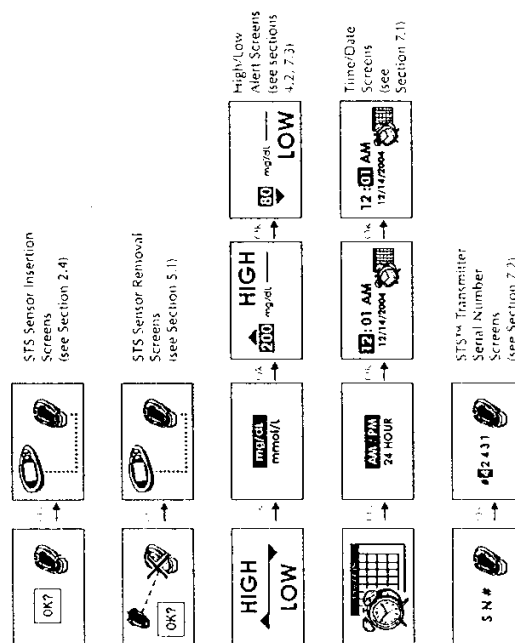
1.4.2 VIEWING THE STS™ RECEIVER SCREENS

By default, the STS Receiver's Liquid Crystal Display (LCD) screen is turned off to save battery power. However, you can press any STS Receiver button to display the 1-hour Trend Screen.

Use the Up ▲ and Down ▼ Arrow Buttons to move through screens. The OK button confirms any change you make to a setting, and the C Button sends you back to the previous screen or to the 1-hour trend screen if you are in the first series of a setting screen. The chart below shows the STS Receiver screens you can navigate through to view glucose readings or set your STS System settings.



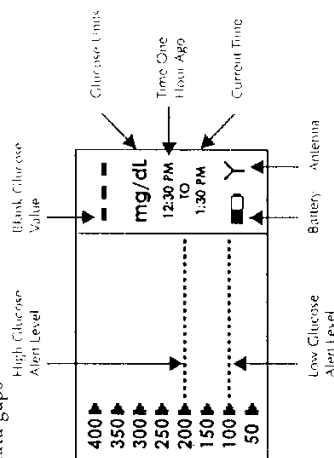
Settings Screens (see Section 7)
To get to these screens, once you get to the 9-hr Screen, you must hold down the Down ▼ arrow for at least 7 Seconds.



1.4.3 STS™ RECEIVER SCREEN DISPLAYS

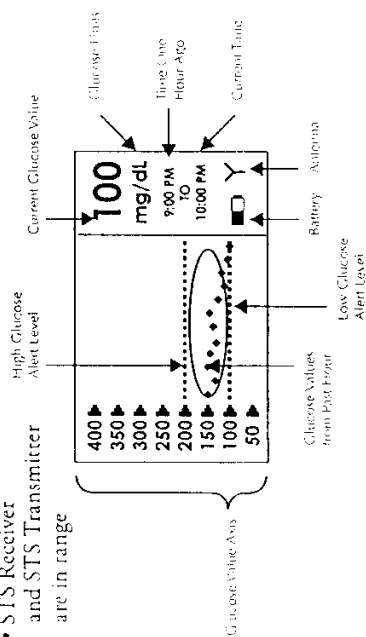
STS Receiver Non-Display Mode:

- During Start-up period
- During Glucose data gaps



STS Receiver Display Mode:

- In Calibration
- STS Receiver and STS Transmitter are in range



SECTION 2

STARTING YOUR STS™ CONTINUOUS GLUCOSE MONITORING SESSION

To use your DexCom™ STS Glucose Monitoring System, you will need a STS Sensor, a STS Transmitter, and a STS Receiver. You will also need a LifeScan OneTouch Ultra meter and OneTouch Ultra test strips for calibration. Once inserted and calibrated, your STS Sensor will continuously measure and display your glucose values for up to 3 days (72 hours).

At the end of the 2-hour Start-Up period, the DexCom STS System will ask for 2 calibration BG values. These two fingersticks must be taken using the OneTouch Ultra meter and uploaded to your STS Receiver using the connection cable. Once calibrated, your STS Receiver will display glucose values, trend graphs, and provide low and high glucose alerts.

BEFORE YOU START

- Wash your hands thoroughly.
- You should fully charge your STS Receiver to avoid the battery dying during use.
- Check that the SN# entered into the STS Receiver is the same SN# number located on the top label of the STS Transmitter, place this information on the STS Transmitter / STS Receiver Card for future reference.

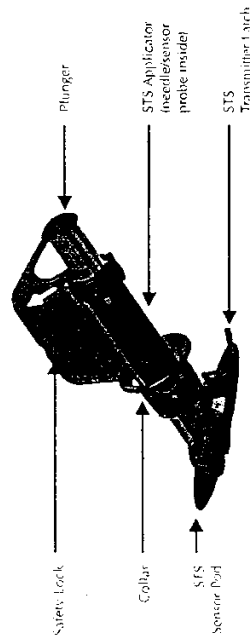
- Place the STS Transmitter and STS Receiver next to each other to make sure they are communicating (you see the Antenna Icon).
- Register your OneTouch Ultra meter to your STS™ Receiver before each session.
- Check the expiration date on the STS Sensor before every time you start a new STS continuous glucose monitoring session.
- You should "QC" your OneTouch Ultra meter per the manufacturer's instructions to make sure it is providing you the best readings for calibration.
- You should clean the bottom of your STS Transmitter with a damp cloth or alcohol wipe before every use.
- Make sure you have enough water resistant bandages or medical tape for showers, bathing, etc..., for three days of use.

2.1 INSERTING A NEW STS™ SENSOR

The following sections will teach you how to insert your STS Sensor and start a new continuous glucose monitoring session. You should become familiar with the STS Applicator diagram below prior to insertion.

NOTE

Always check the expiration date on the STS Sensor packaging before you open the STS Sensor for use.



2.1.1 REMOVING AN STS SENSOR FROM ITS PACKAGING

- Carefully remove your STS Sensor from its packaging and examine it to make sure it is not damaged.
- The STS Applicator is a single use, disposable unit. The safety lock prevents you from accidentally releasing the needle before you are ready.

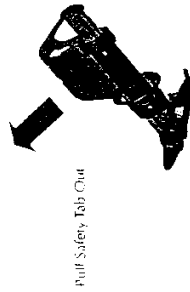
2.1.2 CHOOSING AND PREPARING A SITE FOR STS™ SENSOR INSERTION

- Choose a site on fatty area of your abdomen (belly) to put your STS Sensor. You can choose a site above or below your beltline. The best areas are usually flat, "pinchable", and relatively free from where rubbing can occur (i.e. pant line, seatbelts).
- Avoid areas with scarring or rough patches of skin from your insulin injections or pump. The area you choose should be at least 3 inches (7 cm) from where you plan to inject insulin or from where your pump is located.
- Avoid using the same spot repeatedly for STS Sensor insertion.
- You may need to shave the area where you plan to put the STS so the adhesive patch sticks well.
- Make sure there are no traces of lotions, perfumes or medications by using an alcohol swab to clean the area. The area should be clean and dry prior to insertion.

2.1.3 ADHERING THE STS SENSOR

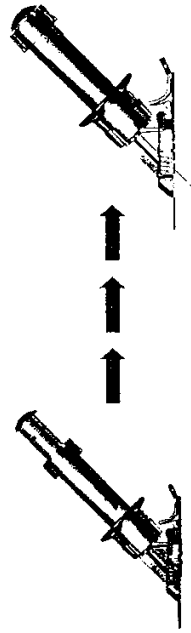
1. After you have cleaned the skin site, remove the adhesive backing from the STS Sensor Pod. Hold the STS Sensor by the STS Applicator area, making sure not to touch the sticky adhesive.
2. Place the STS Sensor on the site you selected, horizontal to your mid-line. You can place the STS Sensor facing towards or away from your belly button. Press firmly on and around the adhesive to make sure it is flat.

3. Once you have stuck the adhesive to your abdomen (belly), pull the Safety Lock out from the STS Applicator. Pull near the arrow on the Safety lock, as shown below:



2.1.4 INSERTING YOUR STS™ SENSOR

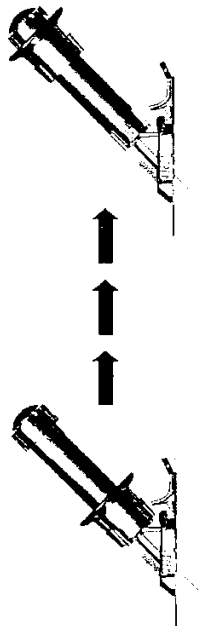
1. After adhering the STS Applicator to your abdomen and removing the Safety Lock, place two fingers under the collar (making sure not to squeeze the applicator) and place your thumb on the plunger. Push the plunger down completely. This action inserts the needle and sensor underneath your skin.



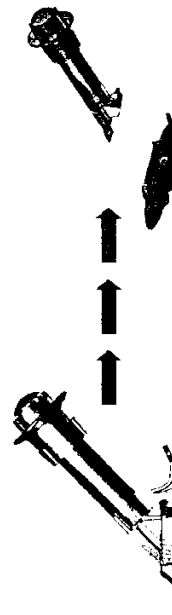
30-100-00000

CONTINUED

2. After you have pushed the plunger down, pull the collar back until you hear a click or cannot pull back any further. This step pulls the needle back into the STS Applicator and leaves the sensor underneath your skin.



3. Remove the STS Applicator by pressing the tabs on the sides of the STS Sensor Pod. Once you feel the back tabs open, pull off the STS Applicator so that only the STS Pod remains adhered to your body.

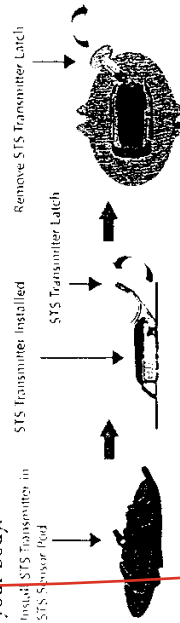


2.2 INSTALLING YOUR STS™ TRANSMITTER

The STS Transmitter wirelessly sends your STS Sensor glucose information to your STS Receiver. Once you have inserted the STS Sensor, you will need to snap the STS Transmitter into the STS Sensor Pod. To do this, you must perform the following steps:

1. Clean the bottom of the STS Transmitter with a damp cloth or an alcohol wipe before every use.
2. Place the STS Transmitter in the STS Sensor Pod with the flat side facing down.
3. Pull the STS Transmitter Latch over the STS Transmitter to snap the STS Transmitter into place so it lies flat in the STS Sensor Pod.

4. Remove the STS Transmitter Latch by holding down the STS Sensor Pod with one hand, then holding the latch with your thumb and forefinger and quickly twisting your wrist away from your body.



QUICK TIP

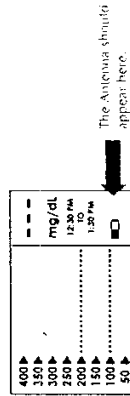
You can place your STS Transmitter next to your STS Receiver before you snap it in to make sure they are communicating before you insert a new sensor. When the STS Transmitter and STS Receiver are next to each other the STS Receiver should display the Antenna Icon.

FIGURE 3-1

FIGURE 3-2

2.3 CHECKING THAT YOUR STS™ TRANSMITTER AND STS™ RECEIVER ARE COMMUNICATING

You should keep your STS Receiver within 5 feet (1.7 m) of your STS Sensor/STS Transmitter for best communication. To check that your STS Receiver and STS Transmitter are communicating ("talking"), press any STS Receiver button to see the 1-hour Glucose Trend Screen:



If you can see the Antenna Icon (Y), then your STS Transmitter and STS Receiver are communicating. You are ready to notify your STS Receiver that you have inserted a new STS Sensor and begin your continuous glucose monitoring session (Section 2.4). If an antenna has not appeared then you should review the following:

- Is the STS Receiver within 5 feet (1.7 m) of your STS Sensor Pod/STS Transmitter? If the STS Receiver is not close enough, move it within that range and re-check to see if the Antenna appears on the STS Receiver display in 5-10 minutes.
- If you still do not see the Antenna Icon after 5-10 minutes, re-check that the correct STS Transmitter Serial number (SN#) is programmed into your STS Receiver (see Section 7.2 to do this).
- If you make sure that the correct SN# is entered into your STS™ Receiver and you still do not see the antenna icon please contact DexCom Technical Support for further assistance 1-877-DEX-COM4 (339-2664).

NOTE

Make sure that you have the correct STS Transmitter serial number (SN#) entered into your STS Receiver. The SN# is printed on a sticker located on the top of a STS Transmitter when you first receive it. You should place that sticker on the STS Transmitter / STS Receiver Card provided for future reference. See Section 7.2 for instructions on how to enter the SN# into your STS Receiver.

NOTE

The STS Transmitter and STS Receiver may lose communication during the following circumstances:

- Near metallic objects
- While lying on a waterbed
- During use of electric blanket

CONTRAINDICATION

The DexCom[™] STS System must be removed prior to Magnetic Resonance Imaging (MRI).

2.4 TELLING YOUR STS[™] RECEIVER YOU HAVE INSERTED A NEW STS[™] SENSOR

You are now on your way to beginning your continuous glucose monitoring session! After you have checked that your DexCom[™] STS System is communicating, you need to tell your STS Receiver that you have inserted a new STS Sensor.

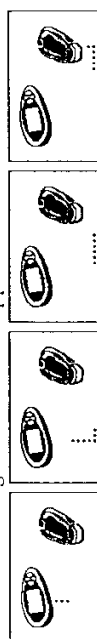
To indicate that you have inserted a new STS Sensor and to begin the Start-Up Period you must do the following:

1. Scroll down through the Receiver Settings Screens to the STS Sensor Insertion Screen by pressing the Down ▼ Arrow 3 times until you come to the 9-hour Glucose Trend Screen.
2. At the 9-hour Screen, hold the Down ▼ Arrow for at least 7 seconds to see the STS Sensor Insertion Screens, shown below.



STS Sensor Insertion Screen

3. Press the OK button to confirm insertion and then you will see the following series of screens appear:



Confirmation Screen

After completion of the above series of screens the STS Receiver will return to the 1-hour Trend Screen and the Start-Up period will begin.

NOTE

You must tell your STS Receiver each time you insert a new STS Sensor or the STS Receiver will not begin its Start-Up period for calibration.

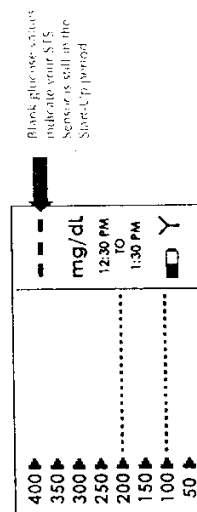
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2.5 STS™ SENSOR START-UP PERIOD

The STS Sensor requires a two hour Start-Up period to adapt to its new biological environment (equilibrates). The Start-Up period lasts 2 hours from the current time displayed on the 1-hour Trend Screen once you have confirmed STS Sensor insertion.

During the Start-Up period you should periodically check to see that the Antenna Icon (Y) is visible and that your STS Receiver battery is charged.

Pressing any of the STS Receiver buttons during the Start-Up period will display the following screen:



At the end of the 2 hour Start-Up period the STS Receiver will provide a vibratory prompt to notify you that it is time to calibrate your STS Sensor. Section 3 describes how to calibrate your STS Sensor.

During the Start-Up period you may see the STS™ Sensor Removal Screen.



STS Sensor Removal Screen

If you see this screen, the STS Sensor is not working properly or you may have dislodged the STS Sensor. You will need to replace your STS Sensor. In order to replace your STS Sensor, simply remove your STS Sensor Pod by gently peeling up the adhesive patch from your skin, which will pull out the Sensor Probe. Remove the STS Transmitter from the STS Sensor Pod and clean the bottom of the STS Transmitter with a damp cloth or alcohol swab before your next use. To begin a new session, you must insert a new STS Sensor, go through a new Start-Up period and calibrate your STS Sensor.

NOTE

- The STS Receiver is only compatible with the LifeScan One-Touch Ultra Blood Glucose Meter. Please refer to the LifeScan OneTouch Ultra meter Owner's Booklet for complete information about using this meter.
- All BG values used for STS Sensor calibration must be uploaded using the connection cable.
- BG values **CANNOT** be manually entered into your STS Receiver.
- Alternate site BG testing is not approved for calibration of the DexCom™ STS System.

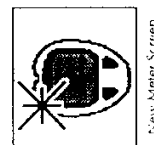
2.6 REGISTERING A METER TO YOUR STS™ RECEIVER

If you are connecting the OneTouch Ultra Meter to your STS Receiver for the first time or are using a different meter since your last STS Receiver connection, you will have to register the meter so it can be used for calibration. You can do this by simply connecting the 2 devices as follows:

1. Make sure the OneTouch Ultra meter display is off (screen is blank) before connecting. To turn it off, press the M button once.
2. Plug the meter into your STS Receiver using the connection cable. First plug the cable into the connection port of the meter. (The connection port is at the bottom of the meter). Then connect the wide end of the cable into the STS 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 below):



4. Your STS Receiver will vibrate twice and you will see the following screen:



5. Press the (OK) button to accept this new meter. The symbol will then disappear and the STS™ Receiver will return to the 1-Hour Glucose Trend Screen to indicate that registration is complete. (Note: This process may take a few minutes to complete.)
6. BG values uploaded from this meter will now be used to calibrate your STS Sensor. See Section 3 for instructions on how to calibrate your STS Sensor.

NOTE

- Blood glucose information stored in the OneTouch Ultra meter before registering it to your STS Receiver will not be used for calibration. You must always register a meter for the first time before uploading fingersticks intended for calibration.
- If you use more than 1 OneTouch Ultra meter during a continuous glucose monitoring period any fingersticks you take on the non-registered meter will not be used for calibration. You will have to register the meter first, and then take BG values with the new meter for calibration.

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SECTION 3

HOW TO CALIBRATE YOUR STS™ SENSOR

The DexCom™ STS System uses the LifeScan OneTouch Ultra meter to calibrate your STS Sensor readings. You can directly connect these 2 devices using the connection cable.

The DexCom STS System requires 2 fingerstick BG values at the first calibration prompt. The STS Receiver will prompt you for these values about 2 hours after you insert a new STS Sensor (see Section 2.4). The STS Receiver will also request 1 fingerstick BG value if you have not uploaded another BG value within 12 hours. These additional BG values will update the calibration throughout your STS Sensor wear period.

WARNING

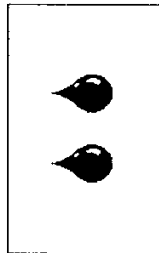
You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

NOTE

Always check your STS Receiver for the Antenna Icon while you upload fingerstick BG values.

3.1 RECEIVING THE CALIBRATION PROMPT (THE END OF THE START UP PERIOD)

Two (2) hours after STS™ Sensor insertion (see Section 2.4), your STS Receiver will prompt you to calibrate your STS Sensor by vibrating and displaying the following screen on the STS Receiver:



Dual Blood Drop Prompt

After you see this prompt, press the C Button to clear the display and do the following:

1. Take 2 BG fingersticks using your OneTouch Ultra meter.
(Note: If you are not familiar with using this meter, please see the LifeScan OneTouch Ultra meter Owner's booklet for complete instructions).
2. Then upload these 2 BG values from your meter to your STS Receiver.

If you do not upload 2 fingerstick BG values for calibration immediately after you see this prompt, the STS Receiver will vibrate/beep and display the "Dual Blood Drop Screen" every 15 minutes for the next 3 hours. If it is not convenient for you to calibrate at this time you can continue to silence the prompt by pressing the "C" button on the STS Receiver.

3.1.1.1.1.1.1.1

HELPFUL HINTS:

- Prior to taking any fingersticks for calibration, make sure the STS Transmitter and STS Receiver are communicating (the Y is displayed).
- Make sure you have previously registered your OneTouch Meter to your STS Receiver.
- Your blood glucose value must be between 40 mg/dl and 400 mg/dl (2.2 and 22.2 mmol/L) to calibrate. If you take fingersticks outside of this range the STS System will not calibrate. You should treat yourself first and then try calibrating the STS Sensor at a later time.

3.2 HOW TO UPLOAD BG VALUES TO YOUR STS™ RECEIVER FOR CALIBRATION

Once you have taken at least 2 fingersticks, you can calibrate your STS Sensor by uploading the fingerstick BG values from the OneTouch Ultra meter to your STS Receiver. The following steps will guide you through your upload:

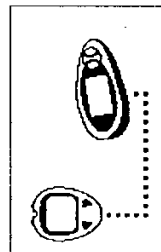
1. Make sure the OneTouch Ultra meter display is off (screen is blank) before connecting. To turn it off, press the M button once. Check your STS Receiver to make sure that your STS Receiver and STS Transmitter are communicating (the Y is visible).
2. Plug the meter into your STS Receiver using the connection cable. First plug the cable into the connection port of the meter. (The connection port is at the bottom of the meter). Then connect the wide end of the cable into the STS Receiver. Make sure the raised Push button on the cable is facing down (toward the back of the STS Receiver).
3. After a few seconds, "PC" will appear on the OneTouch Ultra meter screen (shown below):



10-1000-0000

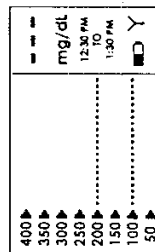
10-1000-0000

4. The STS™ Receiver will display the Connection Screen below. The following screen indicates that BG values from the meter are successfully being uploaded to your STS Receiver for calibration:



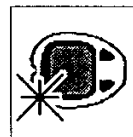
Connection Screen

5. The 1-Hour Trend Screen will appear once the upload is complete:



6. Disconnect the cable from the BGM and STS Receiver (The order that you disconnect the cable does not matter).
7. Press the M button on the OneTouch Ultra meter to see that the date and time are the same as the STS Receiver. The current time on the STS Receiver will be displayed on any trend screen at the bottom-most time stamp. If they do not match, re-connect the 2 devices to set the date and time on the meter and take 2 new fingerstick values to upload.
8. A glucose value should appear on the STS Receiver in about 15 minutes, and glucose values will be updated every 5 minutes.

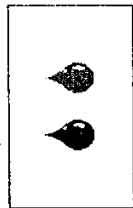
IF YOU SEE ANY OF THE FOLLOWING 3 SCREENS DURING OR AFTER UPLOAD, SEE SECTION 3.3, CALIBRATION TROUBLESHOOTING:



New Meter Screen



Connection Failure Screen

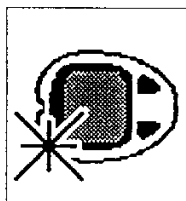


Shaded Out Blood Drop Prompt

NOTES

- BG values CANNOT be manually entered into the STS Receiver.
- Only BG values between 40 - 400mg/dL (2.2 - 22.2mmol/L) can be used for calibration. If 1 or more of your values are outside this range, you will have to re-calibrate.
- Always make sure the STS Receiver Antennae Icon (Y) is visible.
- Never change the date and time on your OneTouch Ultra meter. Your STS Receiver will do this automatically each time you connect the two devices.

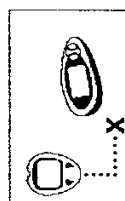
3.3 CALIBRATION TROUBLESHOOTING



NEW METER SCREEN

You will see this screen if you are connecting a new/different OneTouch Ultra Meter to your STS™ Receiver for the first time. Your STS Receiver will vibrate twice.

- You will be asked to register the meter with your DexCom STS System. See Section 2.6 for instructions on how to do this.

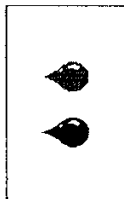


CONNECTION FAILURE SCREEN

If you see this screen (with an "X" between the dotted lines), the BG value upload failed. In this case you should clear the alert by pressing any STS Receiver button and disconnect the devices and review the following:

- Make sure that the OneTouch Ultra meter screen is always blank before you connect the 2 devices.
- Make sure you plug the connection cable into the meter first and the STS Receiver second.
- Do not disconnect the cable while uploading or before you see the 1-Hour Trend Screen appear.

SHADED-OUT BLOOD DROP PROMPT



The Shaded-Out Blood Drop Prompt indicates that you should take one more BG fingerstick and upload it to your STS™ Receiver and may appear for the following reasons:

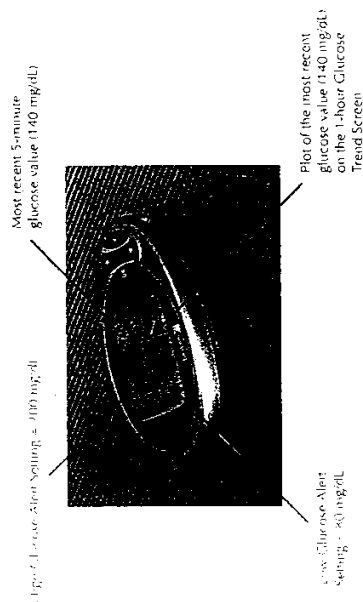
- One of the BG values you uploaded was outside of the 40-400mg/dL (2.2 -22.2 mmol/L) range required for calibration. (For safety, your STS Sensor will not initially calibrate on extreme glucose values).
- Only one BG value was successfully uploaded to your STS Receiver.
- Your STS Transmitter and STS Receiver may have been out of range. Check to see if you have an Antenna Icon and take another fingerstick.

The STS Receiver will prompt you to remind you a second fingerstick is required for successful calibration every 15 minutes for the next 3 hours.

SECTION 4

VIEWING YOUR CONTINUOUS GLUCOSE INFORMATION

This section will educate you on how to view and understand Glucose Trend information provided to you by your STS™ System. Once you have uploaded at least 2 BG values (between 40-40mg/dL or 2.2-22.2mmol/L) to your STS Receiver (calibrated), wait at least 15 minutes to check the STS Receiver display for glucose information. If your STS Sensor has successfully calibrated, you should see the following display by pressing any button on the STS Receiver:



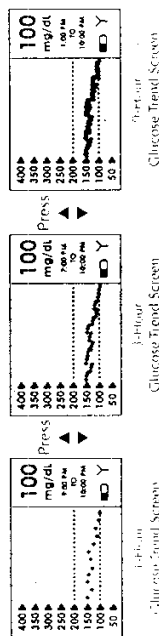
After successful calibration, the STS™ Receiver will update your glucose value every 5 minutes. You will be provided with glucose readings from 40 mg/dL (2.2 mmol/L) to 400 mg/dL (22.2 mmol/L) and you can check your STS Sensor glucose value at any time by pressing any STS Receiver button. In addition to discrete glucose values, your STS System will alert you when your glucose levels are outside of your programmed alert levels. The default high and low glucose alerts are set at 80 mg/dL (4.4 mmol/L) and 200 mg/dL (11.1 mmol/L) but can be changed to fit your personal diabetes goals (see Section 7.3.2).

WARNING

You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

4.1 GLUCOSE TREND SCREENS

You can see glucose trend graphs of your glucose information from the past 1-hour, 3-hour and 9-hour periods by pressing the Down ▼ and Up ▲ Arrows on your STS™ Receiver. The Glucose Trend Screens allow you to see where your glucose levels have been and where your glucose levels are headed.



- Each "dot" on a glucose trend graph represents a past glucose reading.
- You can tell which screen you are viewing by looking at the time. The bottom time is always the most current time. The top time is the time the graph starts (e.g., 1 hour earlier, 3 hours earlier, or 9 hours earlier).
- The dashed lines on the graph represent the high and low glucose alert settings (see Section 7.3).
- Glucose values between 40 mg/dL and 400 mg/dL (2.2 mmol/L and 22.2 mmol/L) will be displayed on the STS Receiver.
- For glucose values less than 40 mg/dL (2.2 mmol/L) the value displayed will be "Low"
- For glucose values greater than 400 mg/dL (22.2 mmol/L) the value displayed will be "High"

WARNING

Treatment decisions should not be based solely on results from the DexCom STS System. You must confirm with a blood glucose meter before making therapeutic adjustments.

WARNING

You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

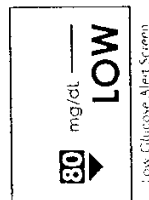
ST-0000000000

ST-0000000000

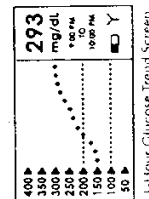
4.2 RESPONDING TO HIGH AND LOW GLUCOSE ALERTS

One of the benefits of the DexCom[™] STS[™] System is your ability to select high and low glucose alerts that will tell you when your glucose values are out of your target range (see Section 7.3). This feature is especially helpful during extended periods of time when you may not test your blood glucose (such as sleeping, driving, exercise, or long meetings).

- When your STS Sensor glucose values are below your Low Alert setting and trending down, the STS Receiver will vibrate and display the Low Alert Screen.
- When the STS Sensor glucose values are above your High Alert setting and trending up, the STS Receiver will vibrate and display the High Alert Screen.
- Examples of the STS Receiver Screens are shown below:



- Press any button on the STS Receiver to acknowledge the glucose alert and the 1 Hour Glucose Trend Screen will show your current glucose value (outside of the alert setting).



- If after 5 minutes you do not respond to the first vibratory alert, the STS Receiver will beep once. It will beep loudly again after another 5 minutes if you do not respond to the second alert. You should acknowledge these alerts by pressing any STS Receiver button. The STS Receiver will not re-alert you once you acknowledge the Alert.

- If you do not acknowledge the Alert for any reason, and you are above or below the alert setting and trending up or down, the STS Receiver will re-alert you in 15 minutes.

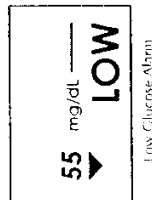
WARNING

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 STS System results.

4.3 LOW GLUCOSE ALARM

In addition to your personal glucose alert settings, your STS™ Receiver also has an automatic low glucose alarm set at 55mg/dL (3.1 mmol/L). You cannot change or turn off the Low Glucose Alarm.

- When the STS Sensor detects a glucose level below 55 mg/dL (3.1 mmol/L) your STS Receiver will vibrate to notify you of a very low glucose value by displaying the following screen:



- If you do not acknowledge the vibratory alert, the STS Receiver will then sound a loud beep 5 minutes later. It will continue this vibrating/beeping until you acknowledge the alert.
- To acknowledge and turn off the alarm, press any button on the STS Receiver. If after you turn off the alarm and your glucose is still ≤ 55 mg/dL (3.1 mmol/L) in the next 30 minutes, the STS Receiver will alarm you again and continue to do so until your glucose levels rise above 55 mg/dL (3.1 mmol/L).
- You may want to take a fingerstick at this time to determine if you should make any treatment decisions.
- If the glucose value that initiated the alert is below 40mg/dL (2.2 mmol/L), the STS Receiver will display LOW only (no glucose value displayed).

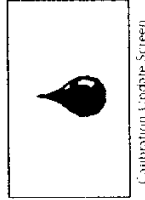
Figure 3-10

4.4 MAINTAINING STS™ SENSOR CALIBRATION: 12-HOUR UPDATE

You should upload any fingerstick BG values you take during STS Sensor wear. These BG values will update your STS System calibration.

However, if you have not uploaded any fingerstick BG values for at least 12 hours, the STS Receiver will request a fingerstick BG value to update its calibration as follows:

- The Calibration Update Screen will appear to notify you of the requirement to update the STS System calibration (Note: The STS Receiver will not vibrate at this time.)



- If you see this reminder symbol, clear this display by pressing any STS Receiver button. The Calibration Update Screen will not go away until you acknowledge it by pressing a button.
- It is recommended that you take a fingerstick at this time using the OneTouch Ultra Blood Glucose meter. Upload this value to your STS Receiver to update your STS Sensor calibration.

WARNING

You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

Figure 3-11

4.5 MISSING STS™ GLUCOSE INFORMATION (GLUCOSE DATA GAPS)

At times your DexCom STS System will not display glucose information, or provide alerts. These Glucose Data Gaps can happen if the two devices are out of Range, if the STS Sensor readings are "noisy", or if the STS System determines that another fingerstick is needed for calibration because the STS Sensor values are not matching your current blood glucose value.

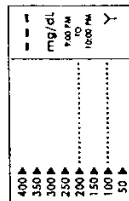
Detailed reasons for Glucose Data Gaps and what you should do to start receiving glucose readings again are described in the sections below.

4.5.1 STS RECEIVER AND STS TRANSMITTER ARE "OUT OF RANGE"

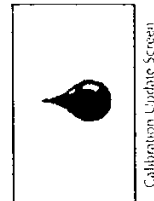
- Anytime you see a " - - - " on the STS Receiver display you should first check to see if the Antenna Icon (Y) is displayed. The STS Transmitter and STS Receiver must be within 5 feet (1.7 meters) of each other.
- If there is no Antenna, move your STS™ Receiver within range and you should receive a glucose value in the next 5 minutes.
- If there is an Antenna on the Display but no glucose values, see sections 4.5.2 and 4.5.3 for other reasons why a Glucose Data Gap may occur.

4.5.2 NOISY STS™ SENSOR GLUCOSE READINGS

- During your continuous monitoring session, your STS Sensor may send the STS Receiver "noisy" glucose readings that the STS Receiver will not display. If this occurs, the antenna will be visible (Y symbol), but you will see a " - - - " on the STS Receiver Display.



- If this happens, you may want to check the placement of your STS Sensor to make sure it is still adhered to your skin properly and that nothing is rubbing the STS Sensor (i.e. clothing, seat belts).
- This may also occur due to rapid increases or decreases in your glucose levels.
- Once the "noise" stops, your STS Receiver will display glucose values again and provide High and Low Glucose alerts. However, your STS Receiver may also display the following screen:



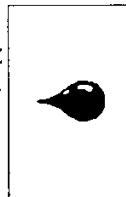
- It is recommended when you see this symbol that you take a fingerstick and upload the BG value to the STS Receiver.

NOTE

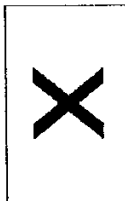
Your STS System will count how many "noisy" values you have during your 3-day glucose monitoring session. If it counts 20 "noisy" events, then the STS Receiver will end your glucose monitoring session and you will see the STS Sensor Removal Screen the next time you turn on the STS Receiver display. If you see the STS Sensor Removal Screen, you will have to insert a new STS Sensor and calibrate after the Start-Up period.

4.5.3 STS™ SENSOR GLUCOSE DATA CHECK & RE-CALIBRATION

- When you update calibration by uploading a fingerstick BG value the Calibration Update Screen may appear.



- If this screen appears the fingerstick you uploaded was not processed correctly and you should upload another fingerstick. There will be a vibratory alert and beep for this alert.
- If you do not respond to the Calibration Update Screen by uploading a fingerstick BG value, the Out of Calibration Screen may appear in the next 10 minutes.



- This screen appears if the last fingerstick you uploaded does not closely match your STS System glucose readings. It prevents you from missing clinically important information (i.e. when your glucose levels are high or low).
- When you see the Out of Calibration Screen, you must take a new fingerstick BG value and upload it to your STS Receiver to continue your glucose monitoring session.

NOTE

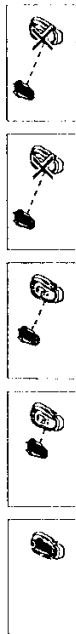
- You should check your STS Receiver in 10 minutes any time you upload BG values to make sure the calibration update was successful (no "X").
- If your DexCom STS System goes Out of Calibration, check your BG values on your meter.
- Remember that the STS Receiver will not provide you with glucose values or alerts while it is out of calibration.

4.6 STS™ SYSTEM EARLY SHUTOFF SCREENS

In some cases your STS System Continuous Glucose Session may end before the end of a full 3-day period. Cases when this may occur are described below.

4.6.1 EARLY SHUT-OFF DUE TO SENSOR NOISE

If your Receiver detects more than 20 incidences of "noise" (see Section 4.5.2), then the STS System will cease displaying glucose values using the current STS Sensor inserted and will display the following screen:



STS Sensor Removal Screens

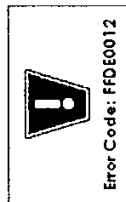
If you see this screen, then your current STS Continuous Glucose monitoring session has ended. You can simply remove your STS Sensor Pod by gently peeling up the adhesive patch from your skin, which will pull out the Sensor Probe. Remove the STS Transmitter from the STS Sensor Pod and store it for your next glucose monitoring session. To receive anymore continuous information, you must insert a new STS Sensor, go through a new Start-Up period and calibrate the new STS Sensor.

You should also clean the bottom of your STS Transmitter with a damp cloth or alcohol wipe before your next use.

FIGURE 4-11

4.6.2 EARLY SHUT-OFF DUE TO RECEIVER ERROR CODE

An error code displayed on the STS Receiver indicates that the STS Receiver is not functioning properly. An example is displayed below:



If you see this screen, then your current STS System Continuous Glucose monitoring session has ended. You should note the code that appears on the screen and contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664).

FIGURE 4-12

SECTION 5

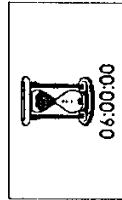
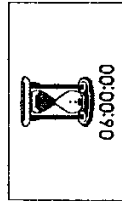
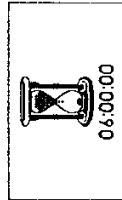
ENDING YOUR STS™ SYSTEM CONTINUOUS GLUCOSE MONITORING SESSION

At the end of your 3-day (72 hour) STS Sensor wear period, you can simply remove your STS Sensor Pod by gently peeling up the adhesive patch from your skin which will pull out your sensor probe. Remove the STS Transmitter from the STS Sensor Pod and keep for your next glucose monitoring session.

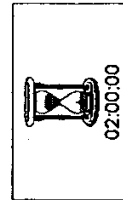
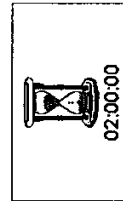
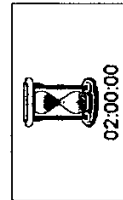
5.1 ENDING YOUR CONTINUOUS GLUCOSE MONITORING PERIOD

5.1.1 AUTOMATIC STS™ SENSOR EXPIRATION NOTIFI- CATION

Your STS Receiver will notify you how much time you have remaining until your STS Continuous Glucose Monitoring Session is complete. The Expiration Screen will simply appear 6 hours and 2 hours before your 72-hour session ends. At the 30 minute and 0 hour Expiration Screen, the STS Receiver will display the Expiration Screen and will also vibrate. You can clear all of these screens by pressing any button on the STS Receiver. You can remove your STS Sensor when the 0 hour Screen appears.



6 hour STS Sensor Expiration Notification



2 hour STS Sensor Expiration Notification

01-10-2015

01-10-2015

5.1.2 MANUAL STS™ SENSOR SHUT OFF

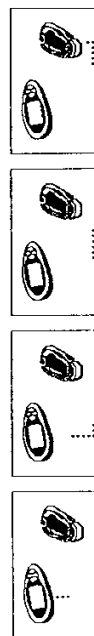
To manually end your continuous glucose monitoring period, follow the steps below:

1. Press the Down ▼ Arrow 3 times until you see the 9-hour Glucose Trend Screen.
2. Hold the Down ▼ Arrow for at least 7 seconds to get to the STS Receiver Settings screens.
3. Press the Down ▼ Arrow 1 time to arrive at the STS Sensor Removal Screen, shown below. Once you see this screen, press the OK button to indicate removal of your STS Sensor.



STS Sensor Removal Screen

4. After you see the series of screens below, you have successfully removed your STS Sensor.

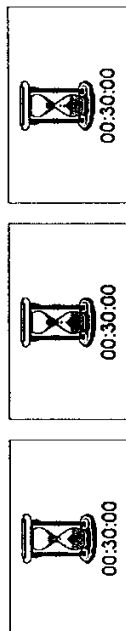


Confirmation Screen

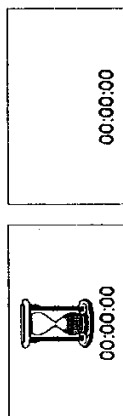
5. The STS Receiver will clear to the default 1-Hour Trend Screen.

NOTE

If you removed your STS Sensor before telling the STS Receiver, the STS Sensor Removal Screen will appear automatically. You must press OK before inserting a new STS Sensor.



30 minute STS™ Sensor Expiration Notification (+Vibration)

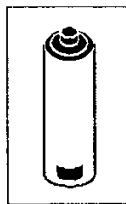


0 hour STS Sensor Expiration Notification (+Vibration)
END OF SESSION

SECTION 6

6.1 LOW BATTERY ALERT

-
- | Time | Concentration (mg/dl) |
|----------|-----------------------|
| 9:00 PM | 100 |
| 9:15 PM | 150 |
| 9:30 PM | 200 |
| 9:45 PM | 250 |
| 10:00 PM | 350 |



Battery Indicator

Low Battery Alert

NOTE

You should charge your STS Receiver as soon as possible when you see the Low Battery Alert so you can continue to receive glucose readings.

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6.2 CHARGING YOUR STS RECEIVER BATTERY

- To charge the STS Receiver battery, connect the charger cable provided into the port on the bottom of your STS Receiver. Make sure the "Push" button side of the charger cable is facing down.
- Connect the plug into a standard power outlet.
- The STS Receiver will display the animated symbol below of a battery charging across the STS Receiver Screen:



- After a few seconds, the 1-hour Glucose Trend Screen will reappear with the animated Battery indicator displayed in the lower right corner next to the Antenna Icon (Y).
- The battery will fully charge after 3 hours and should last approximately 5 days before recharging is necessary.

SECTION 7

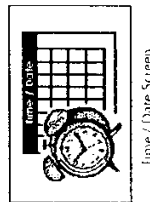
CHANGING STS™ RECEIVER SETTINGS

You can reach all of the STS Receiver Settings Screens by scrolling down to the 9-Hour Glucose Trend Screen and holding the Down ▼ Arrow for at least 7 seconds. Please refer to Section 1.4.2 for an overview on the order of all STS Receiver screens.

7.1 SETTING THE STS™ RECEIVER TIME

7.1.1 GETTING TO THE STS RECEIVER TIME

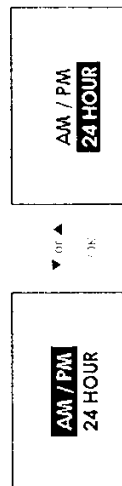
- Press the Down ▼ Arrow 3 times to get to the 9-hour glucose trend screen.
- Hold the Down ▼ Arrow again for at least 7 seconds to get to the Settings Screens.
- Press the Down ▼ Arrow 3 more times to view the Time/Date Screen:



- Press the OK Button on the STS Receiver to begin setting the time.

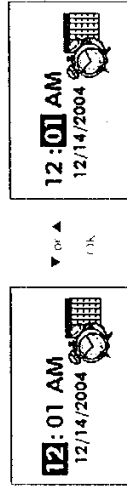
7.1.2 CHOOSING THE TIME MODE

- You can choose what time format you would like displayed.
- Choose an AM/PM (12-hour) format or a 24-hour clock format by pressing the Down ▼ Arrow or Up ▲ Arrow.
- Press the OK Button once you have selected the time format you prefer.



7.1.3 SETTING THE TIME (AM/PM MODE)

- Once you select the time format and press OK, the Time Set Screen will appear in the format you selected.
- Press the Up ▲ or Down ▼ Arrows to choose the hour.
- Press the OK Button to move to the minutes.
- Press the Up ▲ or Down ▼ Arrows to choose the minutes.



- When you choose the hours and minutes, the AM/PM will adjust automatically (e.g. if you go from 11:59 AM to 12:00PM, AM will automatically switch to PM).

- Note: If you pass 11:59 PM the date will automatically update to the next day or the previous day based on the arrow direction you are pressing.

- If you press C at any time, this will not set the time and return you to the STS™ Receiver Time and Date Screen.

NOTE

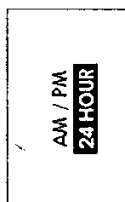
- The STS Receiver date is pre-programmed at the factory.
- Your STS Receiver time can only be adjusted $\pm$ 24 hours from the factory set time/date. If you need to adjust the time more than 24 hours there may be a problem with the STS Receiver. Please contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664) to determine if your STS Receiver needs to be re-placed.

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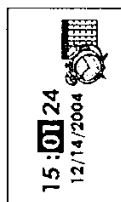
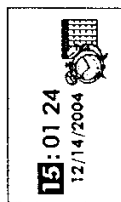
72

7.1.4 SETTING THE TIME (24-HOUR MODE)

- If you chose the 24-hour Time Mode:



- Press the Up ▲ or Down ▼ Arrows to chose the hour.
- Press the OK Button to move to the minutes.
- Press the Up ▲ or Down ▼ Arrows to choose the minutes.



- Note: If you pass 23:59 the date will automatically update to the next day or the previous day based on the arrow direction you are pressing.

- If you press C at any time, this will return you to the STS™ Receiver Time and Date Screen and will not set the time.

NOTE

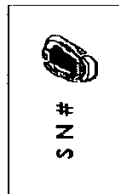
- The STS Receiver date is pre-programmed at the factory.
- Your STS Receiver time can only be adjusted $\pm$ 24 hours from the factory set time/date. If you need to adjust more the time more than 24 hours there may be a problem with the STS Receiver. Please contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664) to determine if your STS Receiver needs to be replaced.

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7.2 HOW TO ENTER A NEW STS™ TRANSMITTER SERIAL NUMBER (SN#)

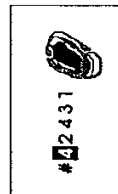
Any time you use a new STS Transmitter as part of your DexCom™ STS System, you must enter the STS Transmitter serial number (SN #) into your STS Receiver. This will begin the wireless radio-frequency (RF) communication between the two devices. To do this perform the following steps:

1. Press the Down ▼ Arrow 3 times until you come to the 9-hour Glucose Trend Screen.
2. Hold the Down ▼ Arrow for at least 7 seconds until you come to the Settings Screens.
3. From this screen, press the Down ▼ Arrow 4 more times until you arrive at the STS Transmitter Serial Number Screen:



STS Transmitter Serial Number Screen

4. Press the OK Button to display the entry screen for the STS Transmitter SN#:



5. The 5-digit SN# is located on the STS Transmitter packaging. The SN# is also printed on a removable label located on top of the STS Transmitter. After entering the SN # into your STS Receiver, remove the sticker and place it on the STS Transmitter / STS Receiver Card for future reference.

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6. To enter your SN#, press the Up ▲ or Down ▼ Arrows until you arrive at the first number.
7. Press the OK Button to enter that number and to move to the next number.
8. Once you have entered all of the numbers, press the OK Button once more to confirm the STS™ Transmitter serial number.
9. If you press C at any time, this will return you to the STS Transmitter Serial Number Screen and not change the SN#.

7.3 CHANGING YOUR GLUCOSE ALERT SETTINGS

The default setting for the high glucose alert is 200 mg/dL (11.1 mmol/L). The default setting for the low glucose alert is 80 mg/dL (4.5 mmol/L). These alerts should be set at values that will help monitor when your glucose levels are too high or too low. You should work with your Diabetes Management Team to help you choose your appropriate glucose alert settings.

7.3.1 CHOOSING GLUCOSE VALUE UNITS

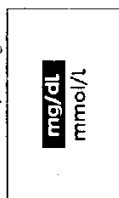
Follow the steps below to choose the type of glucose unit (mg/dL or mmol/L) you would like reported to you. Please note that if you change the alerts to the mg/dL or mmol/L units, all glucose values will be reported to you in that way.

1. Press the Down ▼ Arrow 3 times until you come to the 9-hour Glucose Trend Screen.
2. Hold the Down ▼ Arrow for at least 7 seconds until you come to Settings Screens.
3. Press the Down ▼ Arrow 2 more times to get to the Glucose Alert Screens:



Glucose Alert Screen

4. After you press OK, you will see the glucose unit screen which will allow you to choose your glucose unit values:



5. Press the Down ▼ or Up ▲ Arrow to select which kind of glucose unit you would like reported (mg/dL or mmol/L). Once you choose the unit you would like (highlighted unit), press the OK Button.

NOTE

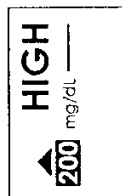
- Your DexCom™ STS™ System can display glucose readings in two different units of measure. In the United States, milligrams per deciliter (mg/dL) are the standard unit used for glucose testing systems (i.e. blood glucose meters). In many other parts of the world, the standard unit for glucose readings is millimoles per liter (mmol/L). Please check with your Diabetes Management Team if you do not know which type of unit your glucose readings are usually displayed in.
- Because the DexCom STS System can be set to display glucose readings in either of these 2 units of measure, it is important to check the unit displayed on the STS Receiver EVERY time you view a glucose reading. This will allow you to make sure that you are receiving readings according to your desired unit setting (mg/dL or mmol/L).

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7.3.2 SETTING HIGH AND LOW GLUCOSE ALERT LEVELS (mg/dL UNITS)

- If you choose mg/dL as your glucose units, you will see the following High Glucose Alert Screen:



- Use the Up ▲ or Down ▼ Arrows to increase or decrease the high glucose alert value by 20 mg/dL (i.e. 220, 240, 260 mg/dL).
- You may select high glucose alert values from 140 mg/dL to 400 mg/dL. Select the value recommended by your Diabetes Management Team by pressing the OK Button.

NOTE

If you scroll above 400 mg/dL the display will read NO. If you press the OK Button to select this option, you will turn off the high glucose alert. You will not receive any high glucose alerts, even when your STS™ System is in calibration.

- Once you press OK to select your high glucose alert value, you will see the Low Glucose Alert Screen:



- Use the Up ▲ or Down ▼ Arrows to increase or decrease the low glucose alert value by 10 mg/dL.

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- You may select low glucose alert values from 60 mg/dL to 90 mg/dL. Select the value recommended by your Diabetes Management Team by pressing the OK Button.

NOTE

If you scroll below 60 mg/dL the display will read NO. If you press the OK Button to select this option, you will turn off the low glucose alert. You will not receive any low glucose alerts, even when your STS™ System is in calibration. (For safety, there is a low glucose alarm set at 55 mg/dL that you cannot turn off. See section 4.3).

- Press the OK Button after you set the low glucose alert to confirm the both high and low alert settings and then you will return to the Glucose Alert Screen.

7.3.3 SETTING HIGH AND LOW GLUCOSE ALERTS (MMOL/L UNITS) SETTINGS

- If you choose mmol/L as your glucose units, you will see the following High Glucose Alert screens:



- Use the Up ▲ or Down ▼ Arrows to increase or decrease the high and low glucose alert values in the same manner as described above (see Section 7.3.2).
- You may select high glucose alert values from 7.8 mmol/L to 22.2 mmol/L. See the following chart to view the high alert level selection options.

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- Select the value recommended by your Diabetes Management Team by pressing the OK Button.

- The chart below displays the high alert level selection options.

mmol/L	NOTE
Disabled	
22.2	
21.1	If you scroll above 22.2 mmol/L the display will read NO. If you press the OK Button to select this option, you will turn off the high glucose alert. You will not receive any high glucose alerts, even when your the STS™ System is in calibration.
20.0	
18.9	
17.6	
16.6	
15.5	
14.4	
13.3	
12.2	
11.1	
10.0	
8.9	
7.8	

- You may select low glucose alert values 3.3 mmol/L to 5.0 mmol/L. See the following chart to view the low alert level selection options.

mmol/L	NOTE
5.0	
4.4	If you scroll below 3.3 mmol/L the display will read NO. If you press the OK Button to select this option, you will turn off the low glucose alerts, even when the STS System is in calibration. (For safety, there is a low glucose alarm set at 3.1 mmol/L that cannot be turned off. See section 4.3).
3.9	
3.3	
Disabled	

- Press the OK Button after you set the low glucose alert to confirm the both high and low alert settings and you will return to the Glucose Alert Screen.

80-1040-01

SECTION 8 TROUBLESHOOTING

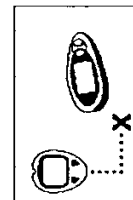
80-1040-01

8.1 MISSING ANTENNA

- If you cannot see the Antenna Icon(Y) on your STS™ Receiver, make sure that you have your STS Receiver within 5 feet (1.7 meters) of your STS Sensor Pod and STS Transmitter.
- After checking the position of the STS Receiver wait 5 to 10 minutes to see if the Antenna Icon appears.
- If the Antenna Icon still does not appear, check to see that your STS Transmitter serial number (SN#) is correctly entered into the STS Receiver. Follow the steps found in Section 7.2.
- If none of the above options work, contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664). You may need a new STS Transmitter.

8.2 PROBLEMS UPLOADING BG VALUES TO YOUR STS RECEIVER

- If the OneTouch Ultra Meter and STS Receiver have trouble communicating with each other, the following symbol will be displayed:



Connection Failure Screen

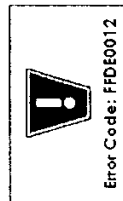
- Make sure you have done the following during upload:
 - » The meter should be "OFF" prior to performing the upload (no display). If necessary, press the M button once to turn the meter off and reconnect the two devices.
 - » DO not accidentally push meter buttons while performing the upload.
 - » Connection cable is plugged in properly. Remember to plug it into the meter first and then to the STS Receiver.
 - » The Antenna Icon (Y) is present.
- If you are still unable to successfully transfer values to the STS™ Receiver:
 - » Press the M button on the BG meter to view its display and to ensure the meter is functioning.
 - » If the BG meter has no display, replace the meter's battery. (Note: The meter's battery should last at least a year.)
- If the BGM still fails to function after replacing the meter's battery, replace the meter.
- Press one of the STS Receiver buttons and check to see that it is functioning.
- If the STS Receiver's display does not appear, plug the STS Receiver into the charger to make sure that the battery is charged.
- If you still do not see a display, contact DexCom Technical Support 1-877-DEXCOM4 (339-2664) for further help.

8.3 TIME DIFFERENCE BETWEEN BG METER AND STS™ RECEIVER

- The time on the blood glucose meter is matched to the STS Receiver every time you connect the OneTouch Ultra meter to your STS Receiver.
- If you notice that a time difference between the meter time and the STS Receiver time occurs often, contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664). Your STS Receiver may need to be replaced.
- DO NOT attempt to change the Ultra Meter time.

8.4 ERROR CODE

The STS Receiver may display Error Codes like the one below. This indicates that the STS Receiver is not functioning properly.



- If an error occurs, note the error code number (if applicable).
- Contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664). You may need to replace your STS Receiver.
- Continue to check BG values on your meter.

SECTION 9

TECHNICAL INFORMATION