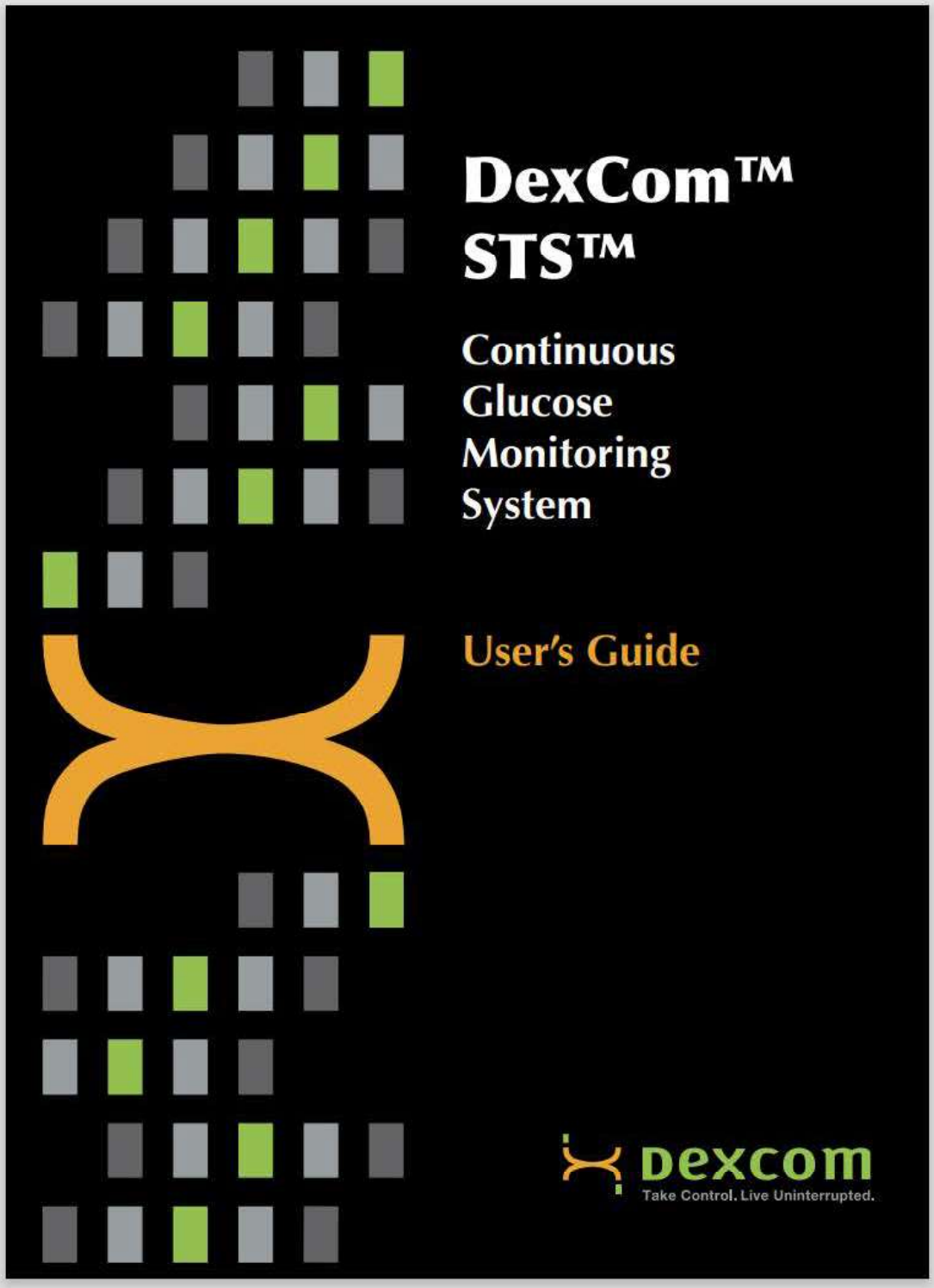
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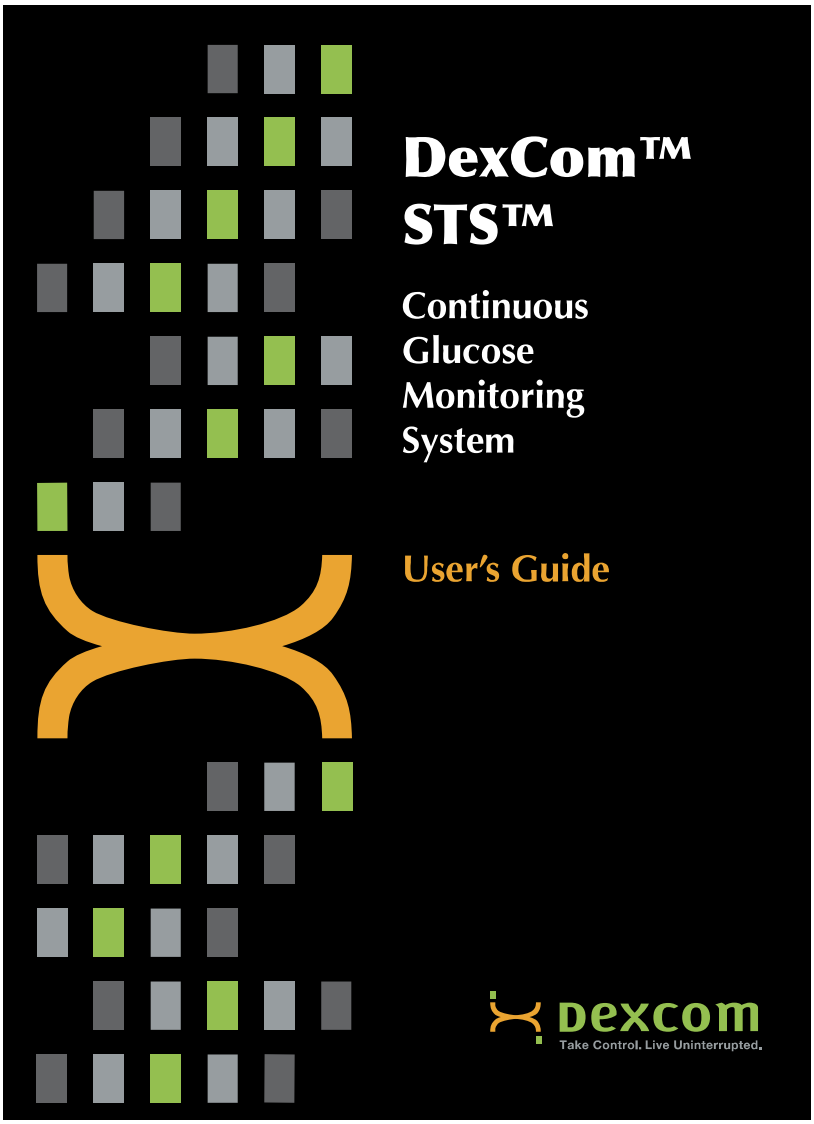
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DEXCOM EXHIBIT 1054
Dexcom v. Abbott Diabetes
IPR2023-01409


DexCom™
STS™
Continuous
Glucose
Monitoring
System
User's Guide
dexcom
Take Control. Live Uninterrupted.

User's Guide

DEXCOM™ STS™
CONTINUOUS GLUCOSE MONITORING SYSTEM



TABLE OF CONTENTS

INTRODUCTION 9

IMPORTANT SAFETY INFORMATION 11

SECTION 1

OVERVIEW OF THE DEXCOM™ STS™ SYSTEM 13
1.1 Glossary 14
1.2 STS Sensor Overview 17
1.3 STS Transmitter Overview 18
1.4 STS Receiver Overview 19
1.4.1 STS Receiver Screen Symbols 21
1.4.2 Viewing the STS Receiver Screens 24
1.4.3 STS Receiver Screen Displays 26

SECTION 2

STARTING YOUR STS CONTINUOUS GLUCOSE MONITORING SESSION 27
2.1 Inserting a New STS Sensor 29
2.1.1 Removing the STS Sensor from its Packaging 29
2.1.2 Choosing and Preparing a Site for STS Sensor Insertion 30
2.1.3 Adhering Your STS Sensor 30
2.1.4 Inserting Your STS Sensor 31
2.2 Installing Your STS Transmitter 33
2.3 Checking that Your STS Transmitter and STS Receiver are Communicating 35
2.4 Telling Your STS Receiver You Have Inserted a New STS Sensor 37
2.5 STS Sensor Start-Up Period 38
2.6 Registering a Meter to your STS Receiver 40

SECTION 3

HOW TO CALIBRATE THE STS SENSOR 42
3.1 Receiving the Calibration Prompt (The End of the Start Up Period) 43
3.2 How To Upload BG Values to Your STS Receiver for Calibration 45
3.3 Calibration Trouble Shooting 48

SECTION 4

VIEWING YOUR CONTINUOUS GLUCOSE INFORMATION 50
4.1 Glucose Trend Screens 52
4.2 Responding to High and Low Glucose Alerts 54
4.3 Low Glucose Alarm 56
4.4 Maintaining STS Sensor Calibration: 12-Hour Update 57
4.5 Missing STS Glucose Information (Glucose Data Gaps) 58
4.5.1 Receiver And Transmitter Are “Out of Range” 58
4.5.2 Noisy STS™ Sensor Glucose Readings 59
4.5.3 STS Sensor Glucose Data Check & Re-Calibration 60
4.6 STS System Early Shutoff Screens 62
4.6.1 Early Shut-off Due to Sensor Noise 62
4.6.2 Early Shut-off Due to Receiver Error Code 63

SECTION 5

ENDING YOUR STS CONTINUOUS GLUCOSE MONITORING PERIOD 64
5.1 Ending Your Continuous Glucose Monitoring Session 65
5.1.1 Automatic STS Sensor Expiration Notification 65
5.1.2 Manual STS Sensor Expiration Notification 67

SECTION 6

MONITORING YOUR STS RECEIVER BATTERY 68
6.1 Low Battery Alert 69
6.2 Charging Your STS Receiver Battery 70

SECTION 7

CHANGING STS RECEIVER SETTINGS 71
7.1 Setting the Receiver Time 72
7.1.1 Getting to the STS Receiver Time 72
7.1.2 Choosing the Time Mode 72
7.1.3 Setting the Time (AM/PM Mode) 73
7.1.4 Setting the Time (24-hour Mode) 74
7.2 How To Enter a New STS Transmitter Serial Number (SN#) 75
7.3 Changing Your Glucose Alert Settings 76
7.3.1 Choosing Glucose Value Units 76
7.3.2 Setting High and Low Glucose Alert Levels (mg/dL Units) 78
7.3.3 Setting High and Low Glucose Alerts(mmol/L Units) 79

SECTION 8

TROUBLESHOOTING 81
8.1 Missing Antenna 82
8.2 Problems Uploading BG Values to Your STS Receiver 82
8.3 Time Difference Between Blood Glucose Meter and STS Receiver 84
8.4 Error Codes 84

SECTION 9

TECHNICAL INFORMATION 85
9.1 Device Performance Characteristics 86
9.2 Product Specifications 103
9.3 FCC Requirements 111

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 OneTouch® 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.

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.

- 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.

SECTION 1

OVERVIEW OF THE DEXCOM™ STS™ SYSTEM

1.1 GLOSSARY

The following list of terms will help you while reading though 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 (1.5 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.

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

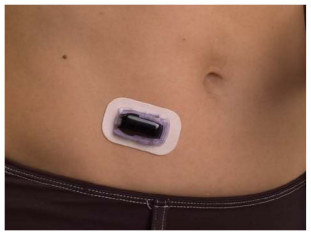
1.2 STS™ SENSOR OVERVIEW

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.





1.3 STS™ TRANSMITTER OVERVIEW

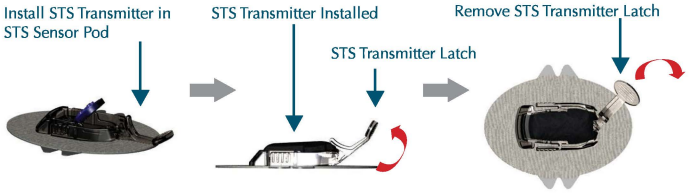
The STS Transmitter wirelessly sends glucose information collected by your STS Sensor to your STS Receiver. Once you insert your STS Sensor, you will snap the STS Transmitter into the STS Sensor Pod, using the STS Transmitter Latch. The STS Transmitter can be used for multiple STS Sensor wear periods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

As your STS Transmitter nears the end of its useful life, it may periodically loose communication with the STS Receiver even if they are within 5 feet(1.5m) 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 (1.5 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 re-chargeable 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 (1.5 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

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.

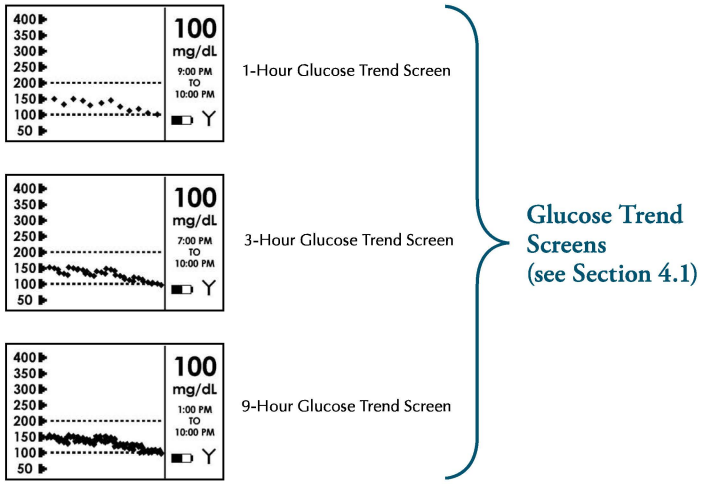
	DUAL BLOOD DROP PROMPT: Appears approximately 2 hours after you insert a new STS™ Sensor and indicates that you need to take 2 fingerstick BG values on your BG meter and upload them to get into calibration.
	SHADED-OUT BLOOD DROP PROMPT: Notifies you that only 1 fingerstick BG value has been successfully uploaded from the BG meter to the STS Receiver. You need to take and upload at least 1 more BG value for calibration.
	CALIBRATION UPDATE SCREEN: Indicates you should take a calibration fingerstick on the BG meter and upload it to the STS Receiver.
	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.

	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).
	6 HOUR STS SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session will end in 6 hours.
	2 HOUR STS SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session will end in 2 hours.
	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.

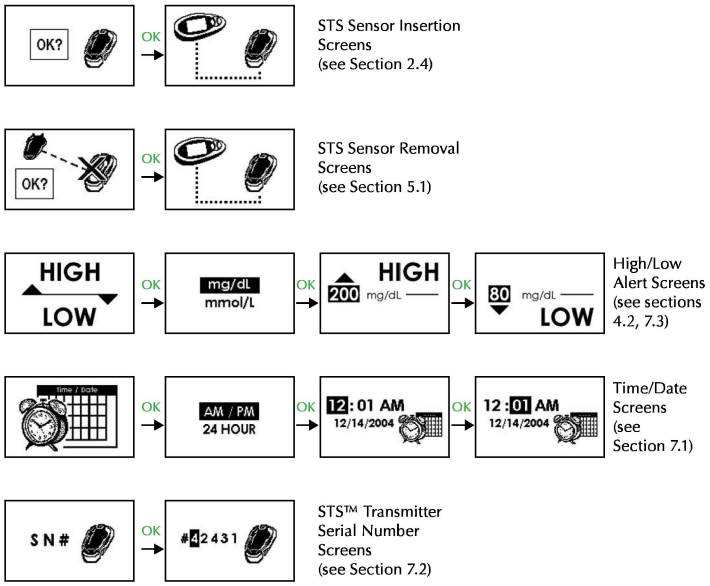
1.4.2 VIEWING THE STS™ RECEIVER SCREENS

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.



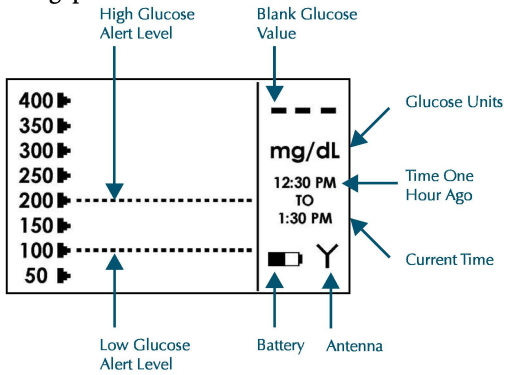
Settings Screens (see Section 7)
To get to these screens, once you get to the 9-hr Screen, you must hold down the Down ▼ arrow for at least 7 Seconds.



1.4.3 STS™ RECEIVER SCREEN DISPLAYS

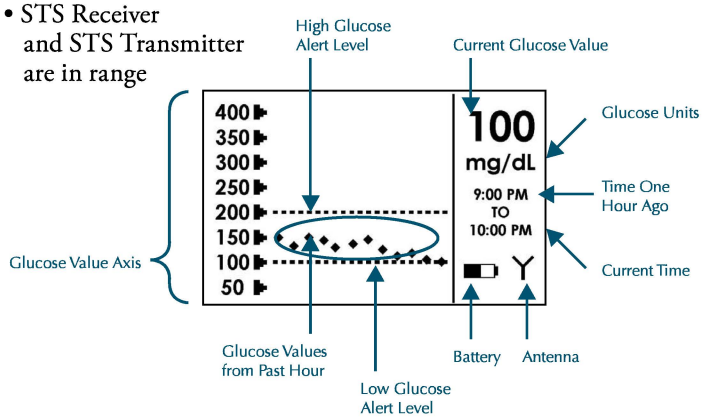
STS Receiver Non-Display Mode:

- 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.

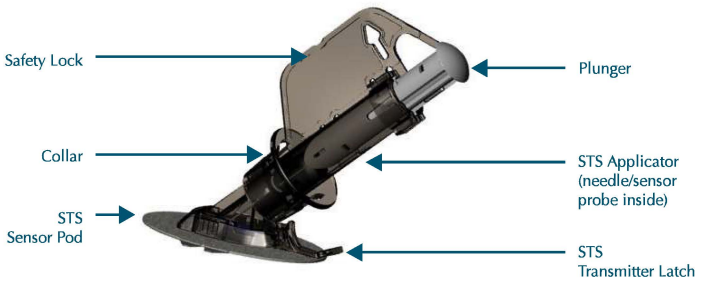
- Place the STS Transmitter and STS Receiver next to each other to make sure they are communicating (you see the Antenna Icon).
- Register your OneTouch Ultra meter to your STS™ Receiver before each session.
- Check the expiration date on the STS Sensor before every time you start a new STS continuous 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

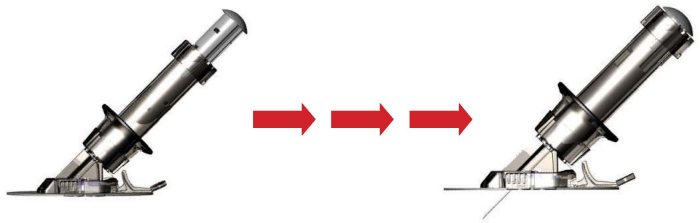
1. After you have cleaned the skin site, remove the adhesive backing from the STS Sensor Pod. Hold the STS Sensor by the STS Applicator area, making sure not to touch the sticky adhesive.
2. Place the STS Sensor on the site you selected, horizontal to your mid-line. You can place the STS Sensor facing 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:

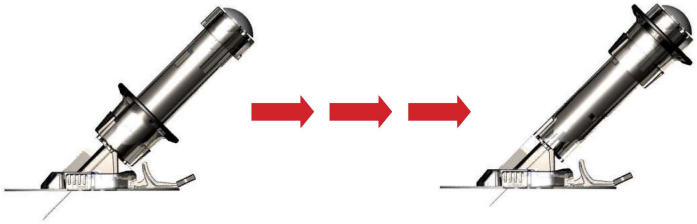


2.1.4 INSERTING YOUR STS™ SENSOR

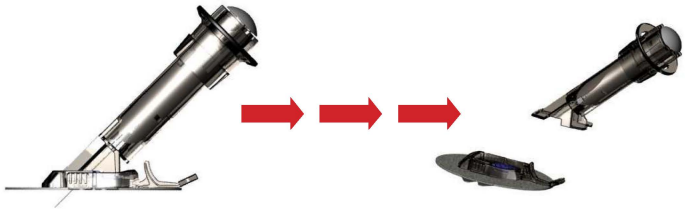
1. After adhering the STS Applicator to your abdomen and removing the Safety Lock, place two fingers under the collar (making sure not to squeeze the applicator) and place your thumb on the plunger. Push the plunger down completely. This action inserts the needle and sensor underneath your skin.



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.



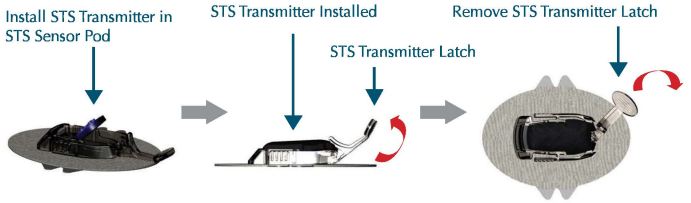
3. Remove the STS Applicator by pressing the tabs on the sides of the STS Sensor Pod. Once you feel the back tabs open, pull off the STS Applicator so that only the STS Pod remains adhered to your body.



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.

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.

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

You should keep your STS Receiver within 5 feet (1.5 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 (1.5 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-DEXCOM4 (339-2664).

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

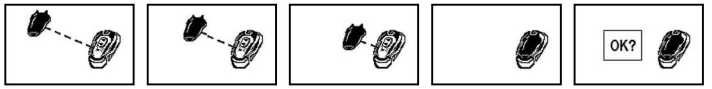
The DexCom™ STS System must be removed prior to Magnetic Resonance Imaging (MRI).

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.

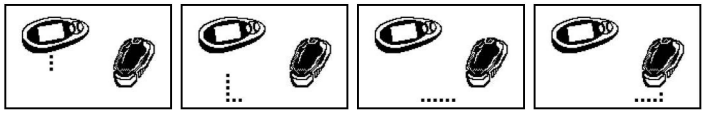
To indicate that you have inserted a new STS Sensor and to begin the Start-Up Period you must do the following:

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

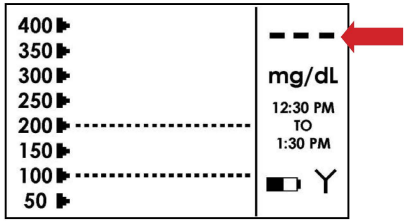
You must tell your STS Receiver each time you insert a new STS Sensor or the STS Receiver will not begin its Start-Up period for calibration.

2.5 STS™ SENSOR START-UP PERIOD

The STS Sensor requires a two hour Start-Up period to adapt to its new biological environment (equilibrater). 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.

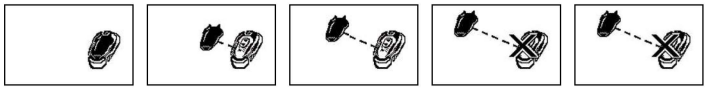
Pressing any of the STS Receiver buttons during the Start-Up period will display the following screen:



Blank glucose values indicate your STS Sensor is still in the Start-Up period

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 Srceen.



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.

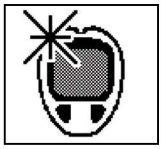
2.6 REGISTERING A METER TO YOUR STS™ RECEIVER

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:



New Meter 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.

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

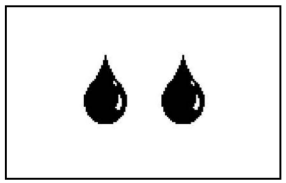
You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

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.

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.

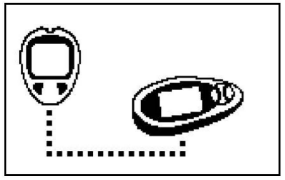
3. 2 HOW TO UPLOAD BG VALUES TO YOUR STS™ RECEIVER FOR CALIBRATION

Once you have taken at least 2 fingersticks, you can calibrate your STS Sensor by uploading the fingerstick BG values from the One-Touch 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):

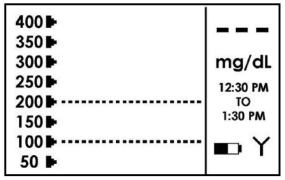


4. The STS™ Receiver will display the Connection Screen below. The following screen indicates that BG values from the meter are successfully being uploaded to your STS Receiver for calibration:



Connection Screen

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

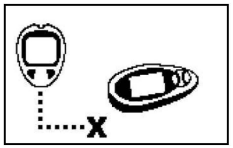


6. Disconnect the cable from the BGM and STS Receiver (The order that you disconnect the cable does not matter).
7. Press the M button on the OneTouch Ultra meter to see that the date and time are the same as the STS Receiver. The current time on the STS Receiver will be displayed on any trend screen 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.

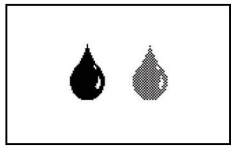
IF YOU SEE ANY OF THE FOLLOWING 3 SCREENS DURING OR AFTER UPLOAD, SEE SECTION 3.3, CALIBRATION TROUBLESHOOTING:



New Meter Screen



Connection Failure Screen

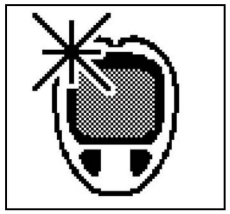


Shaded-Out Blood Drop Prompt

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.

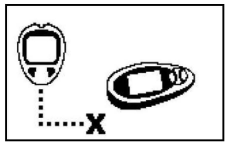
3.3 CALIBRATION TROUBLESHOOTING



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.

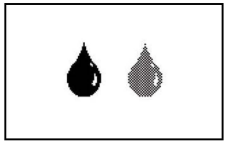
- You will be asked to register the meter with your DexCom STS System. **See Section 2.6 for instructions on how to do this.**



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:

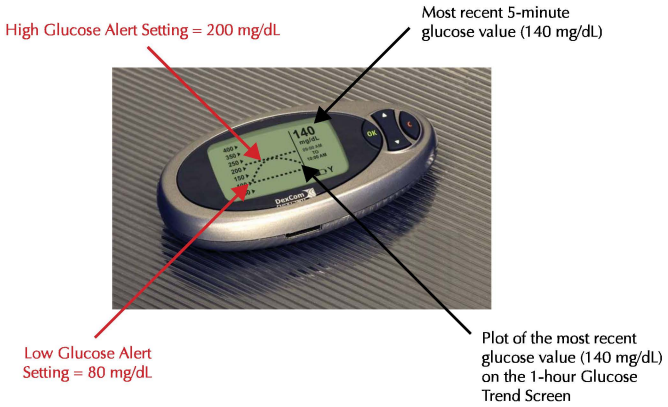
- One of the BG values you uploaded was outside of the 40-400mg/dL (2.2 -22.2 mmol/L) range required for calibration. (For safety, your STS Sensor will not initially calibrate on extreme glucose values).
- Only one BG value was successfully uploaded to your STS Receiver.
- Your STS Transmitter and STS 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 calibrate a minimum of every 12 hours has not been studied.