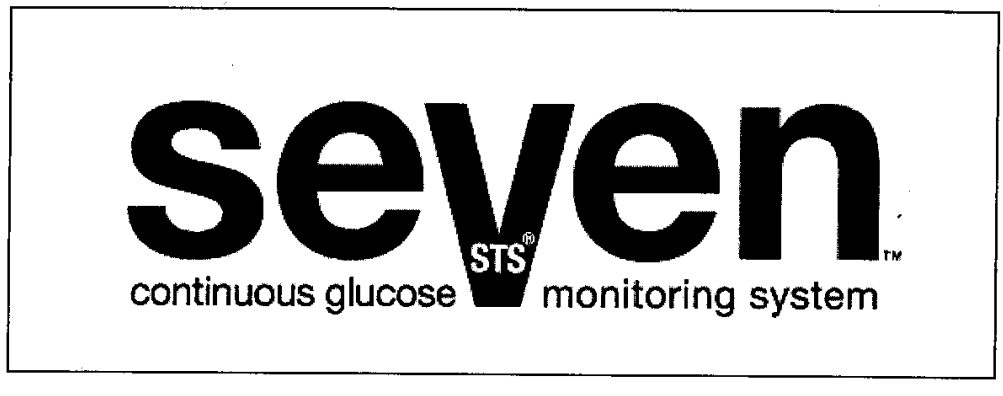

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Read this entire guide before using your STS®-7 Continuous Glucose Monitoring System. If you do not understand something or have any questions, please ask your Diabetes Management Team or another health care provider. Contraindications, warnings, precautions, and other important safety information can be found in this section, and in boxes throughout your STS-7 System User's Guide. The Troubleshooting section (Section 8) contains important information on troubleshooting your STS-7 System.

BEFORE YOU START

- Wash your hands thoroughly.
- Fully charge your STS Receiver to avoid running out of battery charge during use.
- Check that the date and time are correct on your STS Receiver.
- Place the STS Transmitter next to the STS Receiver for at least 5 minutes to make sure the two devices are communicating ("talking") with each other. There will be an Antenna Icon in the bottom right hand corner of the Trend Screens.
- Check the expiration date on the STS-7 Sensor before you start a new continuous glucose monitoring session.
- Quality check ("QC") your BG Meter per the manufacturer's instructions to make sure it is providing you the best readings for calibration.
- Clean the bottom of your STS Transmitter with a damp cloth or alcohol wipe and make sure it is dry before every use.
- Make sure that you connect (or "Register") your STS Receiver and OneTouch Ultra Blood Glucose meter before starting a new STS-7 continuous glucose monitoring session.

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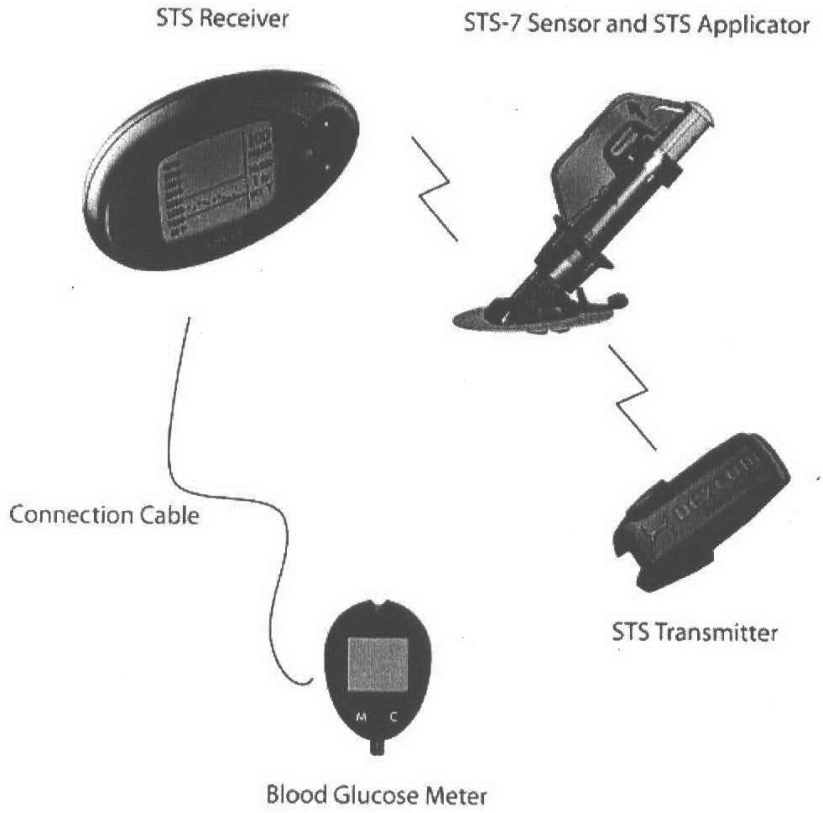

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INTRODUCTION

The STS®-7 Continuous Glucose Monitoring System provides you with real-time continuous glucose measurements every 5 minutes for up to 7 days (168 hours). These readings will help you detect trends and patterns in your glucose levels. The STS-7 System also features adjustable high and low glucose alerts to notify you when you are outside of your target glucose levels. The STS-7 System consists of three components: the STS-7 Sensor, the STS Transmitter, and the STS Receiver. The STS-7 System is only compatible with the Life Scan OneTouch Ultra Blood Glucose meter for calibration using the connection cable provided.

The STS-7 Sensor is a disposable unit that you insert into your abdomen (belly) to continuously monitor your glucose levels for up to 7 days (168 hours). The STS Transmitter is a reusable device that snaps into the STS Sensor Pod and wirelessly sends glucose information measured by your STS-7 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-7 Sensor/Transmitter. The STS Receiver displays your current glucose reading and also shows your glucose trend information from the past 1-hour, 3-hour, and 9-hour. 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.

This User's Guide describes how to use your STS-7 System from start to finish of a continuous glucose monitoring session. Important safety information, warnings, precautions, cautions, and contraindications of the STS-7 System are described in the next few pages and throughout this guide. Be sure to read this entire User's Guide before beginning your continuous glucose monitoring session.

INDICATION FOR USE

The STS-7 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 STS-7 System is intended for use by patients at home and in healthcare facilities. The device is for prescription use only. The STS-7 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 STS-7 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-7 System results should be based on the trends and patterns seen with several sequential readings over time.

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IMPORTANT SAFETY INFORMATION

Read this entire guide before using your STS®-7 Continuous Glucose Monitoring System. If you do not understand something or have any questions, please ask your Diabetes Management Team or another health care provider. Contraindications, warnings, precautions, cautions, and other important safety information can be found in this section, and in boxes throughout your STS-7 System User's Guide. The Troubleshooting section (Section 8) contains important information on troubleshooting your STS-7 System. The Technical Information Section (Section 9) provides information on the performance characteristics of the device.

CONTRAINDICATIONS

- The STS-7 System must be removed prior to Magnetic Resonance Imaging (MRI).
- Use of acetaminophen-containing medications while using the STS-7 Sensor is inserted may affect the performance of the device.

WARNINGS, PRECAUTIONS, AND CAUTIONS

WARNINGS

- This device is not designed to replace a blood glucose meter. The STS-7 System must be used with a blood glucose meter.
- Treatment decisions should not be based solely on results from the STS-7 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-7 System results.
- Update the STS-7 System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS-7 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-7 Sensor package. After opening the package, avoid touching the adhesive area.
- Before inserting the STS-7 Sensor, always clean the skin at the STS-7 Sensor insertion location with a topical antimicrobial solution, such as isopropyl alcohol. Do not apply the STS-7 Sensor until the cleaned area is dry.
- Establish a rotation schedule for choosing each new STS-7 Sensor location. Avoid STS-7 Sensor locations that are constrained by clothing, accessories, or subjected to rigorous movement during exercise.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the STS-7 Sensor.
- The STS-7 Sensor is sterile in its unopened, undamaged package. Do not use any STS-7 Sensor if its sterile package has been previously damaged or opened.
- The STS-7 Sensor has currently only been tested in adult persons with type 1 and type 2 diabetes. The device has not been tested in children or adolescents, pregnant women, or persons on dialysis.

CAUTION

U.S. federal law restricts the sale of the STS-7 System to sale by or on order of a physician.

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SECTION 1

OVERVIEW OF THE STS® SYSTEM

1.1 GLOSSARY

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

BG reading	Blood Glucose reading. A fingerstick blood glucose reading taken on your OneTouch Ultra meter or STS-7 System.
BG meter	Blood Glucose Meter. Currently, only the OneTouch Ultra meter is compatible with the STS-7 system
Calibration	Required for the STS-7 System to display continuous glucose data and trend information. Performed by uploading blood glucose readings to the STS Receiver. (Do not use alternate site testing for calibration.)
STS-7 System	The STS-7 Sensor, STS Transmitter, and STS Receiver.
Glucose Trends	Allow 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 STS-7 System has three glucose trend screens: the 1-Hour, 3-Hour, and 9-Hour Screens. Each trend screen shows glucose trends over the amount of time indicated.
mg/dL	Milligrams per deciliter. The standard unit of measure for glucose readings in the United States.
Glucose Data Gaps	When the STS Receiver does not display glucose readings sent from the STS-7 Sensor to the STS Receiver. An icon will appear instead of a glucose reading to notify you of the STS-7 Sensor issue.
Range	The distance between the STS Receiver and STS Transmitter. Keep the 2 devices 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-7 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 STS Receiver for communication.
Start-Up Period	The 2-hour period after you insert a new STS-7 Sensor (Glucose information cannot be provided during this time).
STS Applicator	A disposable piece of the STS-7 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-7 Sensor and to display the results as a glucose reading (mg/dL).
STS-7 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-7 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.

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STS Transmitter Release	The Safety Lock also serves as a tool that snaps the STS Transmitter out of the STS Sensor Pod after your glucose monitoring session has ended.
Upload	To transfer BG readings from OneTouch Ultra Meter to your STS Receiver. You transfer BG readings directly with the connection cable.

1.2 STS®-7 SENSOR OVERVIEW

The STS-7 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-7 Sensor. The glucose levels measured by the STS-7 Sensor are sent by a wireless, low-powered, radio frequency (RF) to the STS Receiver every 5 minutes for up to 7 days (168 hours).

The STS-7 Sensor consists of an STS Applicator (needle/sensor plastic 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 (26 Gauge) inside the STS Applicator. The needle is inserted about 1/2 inch 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 can be saved to remove the STS Transmitter at the end of a continuous monitoring session.

The Sensor Probe lies 1/2 inch underneath your skin and continuously measures your glucose levels for up to 7 days. The STS-7 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-7 Sensor to your STS Receiver. Once you insert your STS-7 Sensor, you will snap the STS Transmitter into the STS Sensor Pod using the STS Transmitter Latch. The STS Transmitter is used for multiple STS-7 Sensor wear periods.

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 (1.5 m) of each other. Once your STS Transmitter battery has drained, you will need to replace the Transmitter.

Your new STS Transmitter can easily be programmed to communicate with your STS Receiver (See Section 7.3).

NOTE:

- Little warning is given when your STS Transmitter battery is fully drained (you may notice an intermittent Y icon). Contact Technical Support at 1-877-DEXCOM4 (339-2664) to order a new STS Transmitter so you can continue using your STS-7 System.
- Your STS Transmitter is used for multiple STS-7 Sensor wear periods. Remove the STS Transmitter from the STS Sensor Pod and store it for your next glucose monitoring session.

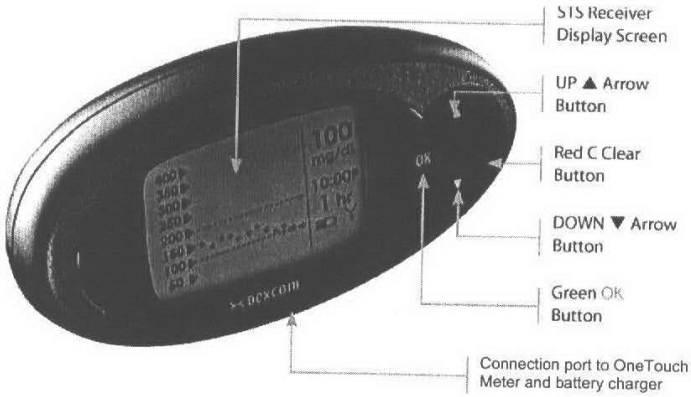
1.4 STS® RECEIVER OVERVIEW

The STS Receiver looks similar to a cell phone and communicates the glucose information measured by the STS-7 Sensor to you. Keep your STS Receiver 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 your pocket. During nighttime use you may want to place the STS Receiver under your pillow.

The STS Receiver is rechargeable. The re-chargeable battery will 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 is completely drained. To charge the STS Receiver, plug the charger cable provided into a standard wall outlet. If you are currently wearing a STS-7 Sensor, remember to stay within 5 feet (1.5 m) of your STS Receiver to continue receiving continuous glucose information.

The STS Receiver has 4 buttons to guide you through its screens. The screens display glucose readings and trend graphs ("Trend Screens") and allow you to change your STS Receiver settings ("Settings Screens"). The STS Receiver is programmed with a specific STS Transmitter Serial Number (SN#) so your STS Receiver and STS Transmitter can "talk" (communicate) with each other. Each time you insert a new STS-7 Sensor, you will need to tell the STS Receiver (See Section 2.5) of the new STS-7 sensor insertion.

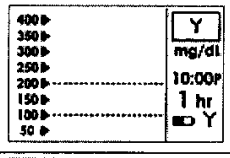
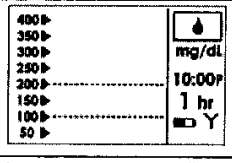
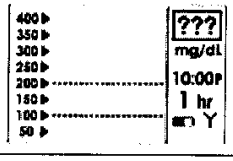
Each STS-7 Sensor must be "calibrated" before glucose readings can be displayed on your STS Receiver. To calibrate, you will directly connect your STS Receiver to the LifeScan OneTouch Ultra meter using the connection cable (See section 3.2). By connecting the 2 devices, you will transfer fingerstick blood glucose readings taken on your OneTouch Ultra Meter to your STS Receiver. Do not use alternative site testing to check your blood glucose for calibration.



1.4.1 STS® RECEIVER SCREEN SYMBOLS

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

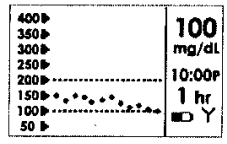
	ANTENNA: If seen in the bottom right hand side of Glucose Trend Screens. Indicates that the STS Receiver and STS Transmitter are "talking" and glucose data has been sent in the last 5 minutes.
	LOW BATTERY ALERT: Indicates the STS Receiver battery is running low and needs to be recharged. Charge the battery as soon as possible.
	CONNECTION: Indicates the BG meter is successfully transferring BG readings to your STS Receiver.
	CONNECTION FAILURE: Indicates the BG meter and your STS Receiver are not connected properly. BG readings have not been successfully transferred.
OK?	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. If you receive this screen during calibration, you will have to re-take any fingersticks needed for calibration and then connect the 2 devices again for calibration update.
	DUAL BLOOD DROP PROMPT: Appears about 2 hours after you insert a new STS-7 Sensor and indicates that you need to take 2 fingerstick BG readings on your BG meter and upload them to get into calibration.
	SHADED-OUT BLOOD DROP PROMPT: Notifies you that only 1 fingerstick BG reading has been successfully uploaded from the BG meter to the STS Receiver. You need to take and upload at least 1 more BG reading for calibration.
	CALIBRATION UPDATE SCREEN Indicates it is time for you to take a calibration fingerstick on the BG meter and upload it to the STS Receiver.
? ? ?	FAILED SENSOR SCREEN: Indicates the STS-7 Sensor is not working properly. You will need to replace your STS-7 Sensor at this time.

	NO COMMUNICATION: Indicates that the STS® Receiver and STS Transmitter are not "talking" and glucose data has not been sent in the last 5 minutes. See Section 8 for Troubleshooting.
	AWAITING CALIBRATION FINGERSTICK: Indicates a fingerstick BG reading is needed for calibration or the STS Receiver is processing a current fingerstick BG reading. See Section 3 for Calibration.
	UNKNOWN STS-7 SENSOR GLUCOSE READINGS: Indicates that the STS-7 Sensor is sending the STS Receiver glucose readings that the STS Receiver does not understand. See Section 4.5 for "Glucose Data Gaps."
Error Code: FFDE0012	ERROR CODE: Indicates the STS Receiver is not functioning properly. If you see this code, write the code down and use your meter to check your blood glucose readings. Notify DexCom Technical Support at 1-877-DEXCOM4 (339-2664).
06:00:00	6-HOUR STS-7 SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session will end in 6 hours.
02:00:00	2-HOUR STS-7 SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session will end in 2 hours.
00:30:00	30-MINUTE STS-7 SENSOR EXPIRATION NOTIFICATION Indicates that your Continuous Glucose Monitoring Session will end in 30 minutes.
00:00:00	0 HOUR STS-7 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-7 Sensor has been removed.

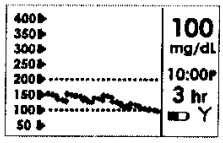
1.4.2 VIEWING THE STS® RECEIVER SCREENS

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.

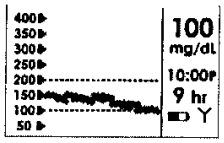
Use the Up and Down Arrow Buttons to move through screens. The button confirms any change you make to a setting, and the C Button sends you back to the previous screen or to the 1-hour trend screen if you are in the first series of a Settings Screen. The chart below shows the STS Receiver screens you can navigate through to view glucose readings or set your STS-7 System settings.



1-Hour Glucose Trend Screen



3-Hour Glucose Trend Screen

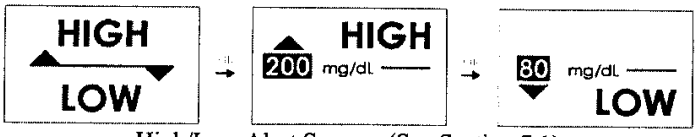


9-Hour Glucose Trend Screen

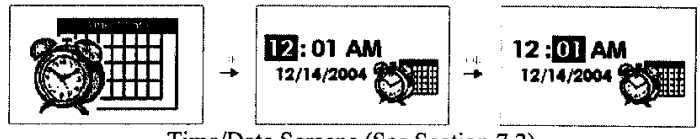
Glucose Trend Screens
(See Section 4.1)

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.

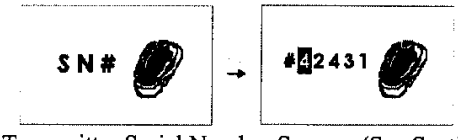
STS-7 Sensor Insertion Screens
NOTE: These screens only appear if a STS Transmitter serial number has been entered, and you are currently not in a STS-7 Continuous Monitoring Session (See Section 2.5)



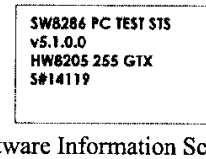
High/Low Alert Screens (See Section 7.1)



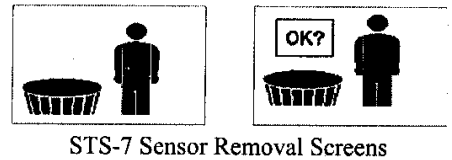
Time/Date Screens (See Section 7.2)



STS® Transmitter Serial Number Screens (See Section 7.3)



Software Information Screens

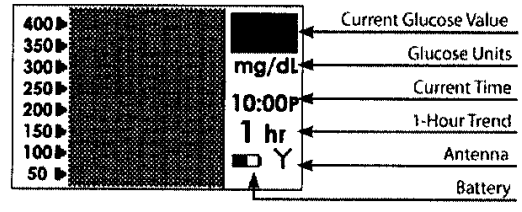


STS-7 Sensor Removal Screens
NOTE: These screens only appear if you are currently in a STS-7 Continuous Monitoring Session (See Section 5.1.2)

1.4.3 THE STS® RECEIVER DISPLAY

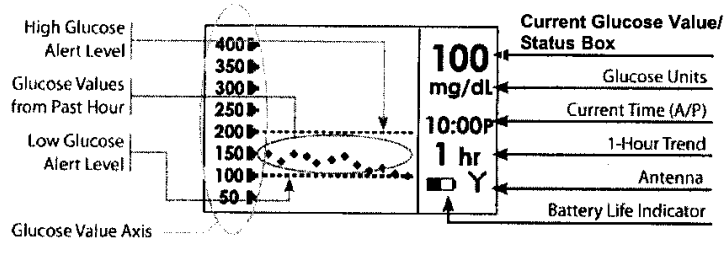
STS Receiver OFF Mode:

- STS-7 Sensor is not inserted or a session ended more than an hour ago
- The beginning of a session



STS Receiver Display Mode:

- Start-up period is over
  - If you are in the Start-up period, the STS Receiver screen will be partially shaded
- While the STS-7 System is in calibration
- STS Receiver and STS Transmitter are in range



SECTION 2

STARTING YOUR STS®-7 CONTINUOUS GLUCOSE MONITORING SESSION

To use your STS-7 Glucose Monitoring System, you will need a STS-7 Sensor, a STS Transmitter, and a STS Receiver. You will also need a meter and test strips for calibration. Once inserted and calibrated, your STS-7 Sensor will continuously measure and display your glucose readings for up to 7 days (168 hours).

At the end of the 2-hour Start-Up period, the STS-7 System will ask for 2 calibration BG readings. These two fingersticks must be taken with a BG meter and uploaded to your STS Receiver. Once calibrated, your STS Receiver will display glucose readings, trend graphs, and provide low and high glucose alerts and a low glucose ALARM.

NOTE:
The STS-7 System is currently only compatible with the OneTouch Ultra Blood Glucose Monitoring System. Calibration using other blood glucose meters is currently not possible.

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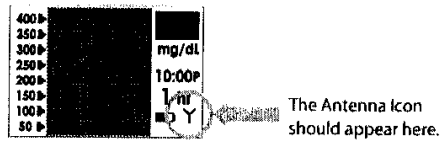
2.1 STS® TRANSMITTER AND STS RECEIVER COMMUNICATION

Keep your STS Receiver within 5 feet (1.5 m) of your STS-7 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) at the bottom right hand corner, then your STS Transmitter and STS Receiver are communicating.

If an Antenna Icon is not visible in the bottom right hand corner, 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 Icon appears on the STS Receiver display in 5-10 minutes.
- If you still do not see the Antenna Icon in the bottom right hand corner after 5-10 minutes, re-check that the correct STS Transmitter Serial Number (SN#) is programmed into your STS Receiver (See Section 7.3)
- If the correct SN# has been 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 an electric blanket

CONTRAINDICATION:
The STS-7 System must be removed prior to Magnetic Resonance Imaging (MRI).

2.2 ONETOUCH ULTRA METER – STS® RECEIVER REGISTRATION

Before using Auto Upload for calibration make sure your meter is "registered" to your STS Receiver and the STS Receiver date/time and OneTouch Ultra date/time match.

To do this you will connect the two devices in the following way.

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. Using the connection cable, **first** plug the cable into the connection port of the BG 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. (You must do these steps in order).
3. After a few seconds, "PC" will appear on the OneTouch Ultra Meter screen (shown below):

4. If you have never connected the OneTouch meter or you previously connected a different OneTouch meter, then your STS Receiver will vibrate twice and you will see the following screen:

New Meter Screen

5. Press the 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. Check to see that the STS Receiver and OneTouch Ultra meter have the same time.
7. The BG readings taken and uploaded from this meter will now be used to calibrate your STS-7 Sensor. See Section 3.2 for instructions on how to calibrate your STS-7 Sensor.

NOTE:

- Blood glucose information stored in the OneTouch Ultra Meter before registering it to your STS Receiver will not be used for calibration (See Section 3.2). You must always register a new meter before uploading fingersticks intended for calibration.
- The STS Receiver and OneTouch Ultra meter times must be within 2 minutes of each other. If they are not, the BG fingersticks will not be accepted by the STS-7 System. Therefore, after you change the time on your Receiver, connect the OneTouch Ultra meter to the STS Receiver using the upload cable (without taking new BG fingerstick readings) to synchronize the times on the devices. You can upload BG readings as usual after that.

2.3 USING A NEW STS®-7 SENSOR

The following sections will teach you how to insert your STS-7 Sensor and start a new continuous glucose monitoring session. Become familiar with the STS Applicator diagram below prior to insertion.

NOTE:
Always check the expiration date on the STS-7 Sensor packaging before opening the STS-7 Sensor for use. Do not use expired STS-7 Sensors.

2.3.1 REMOVING THE STS-7 SENSOR FROM ITS PACKAGING

- Carefully remove your STS-7 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.

QUICK TIP:
Before you insert a new STS-7 Sensor, place your STS Transmitter next to your STS Receiver for at least five minutes to make sure they are communicating. The STS Receiver will display the Antenna Icon at the bottom right hand corner of the Trend Screens.

2.3.2 CHOOSING A STS®-7 SENSOR INSERTION SITE

Choose a site on a fatty area of your abdomen (belly) to place your STS-7 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. Choose an area at least 3 inches from where you plan to inject insulin or from where your pump infusion site is located.

Avoid using the same spot repeatedly for STS-7 Sensor insertion.

You may need to shave the area where you plan to put the STS-7 Sensor so that 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. Make sure the area is clean and dry prior to insertion.

PRECAUTION:
Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the STS-7 Sensor.

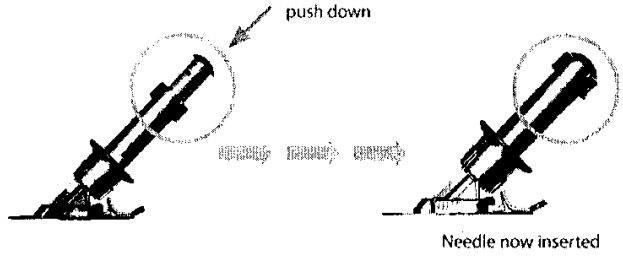
2.3.3 PLACING THE STS-7 SENSOR

1. After you have cleaned the skin site, remove the adhesive backing from the STS Sensor Pod. Hold the STS-7 Sensor by the STS Applicator area, making sure not to touch the sticky adhesive.
2. Place the STS-7 Sensor on the site you selected, pointing towards your belly button. You can place the STS-7 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:

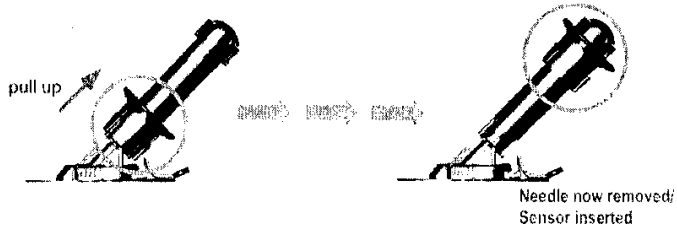
NOTE:
The Safety Lock also serves as the STS Transmitter Release. Keep the Safety Lock / STS Transmitter Release with your BG meter or in a safe place. When your glucose monitoring session is over, follow the steps in Section 5.2 to remove your STS Transmitter.

2.3.4 STS®-7 SENSOR INSERTION

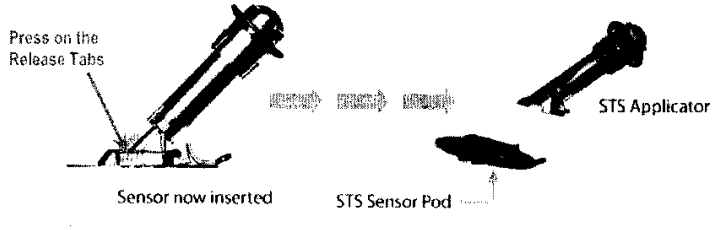
1. After placing the STS Applicator on your abdomen and removing the Safety Lock, place two fingers under the collar (making sure not to squeeze the applicator) and place your thumb on the plunger. Push the plunger down completely. This action inserts the needle and sensor underneath your skin.



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.



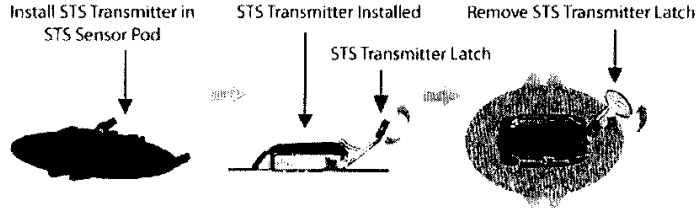
3. Remove the STS Applicator by pressing the release tabs on the sides of the STS Sensor Pod. Once you feel the back tabs open, pull off the STS Applicator so that only the STS Sensor Pod remains adhered to your body.



2.4 STS® TRANSMITTER ATTACHMENT

The STS Transmitter wirelessly sends your STS-7 Sensor glucose information to your STS Receiver. Once you have inserted the STS-7 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 and dry 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.
5. Ensure both sides of the STS Transmitter are secure in the STS Pod.



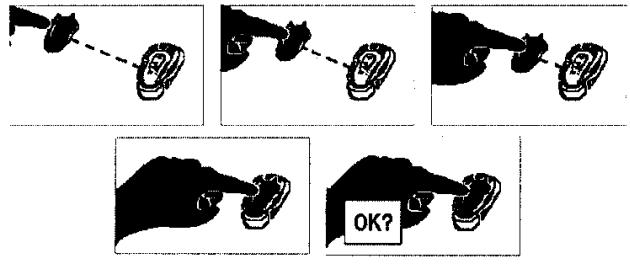
NOTE:
Make sure that you have the correct STS Transmitter Serial Number (SN#) entered into your STS Receiver. The SN# is printed on a sticker located on the top of a STS Transmitter when you first receive it. See Section 7.3 for instructions on how to enter the SN# into your STS Receiver.

2.5 STARTING A NEW STS®-7 CONTINUOUS GLUCOSE MONITORING SESSION

After you have checked that your STS-7 System is communicating, you need to tell your STS Receiver that you have inserted a new STS-7 Sensor.

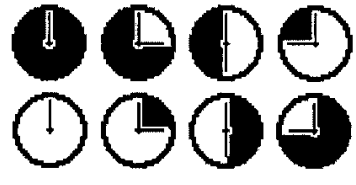
To indicate that you have inserted a new STS-7 Sensor and to begin the 2-hour Start-Up Period you must do the following:

1. Scroll down through the Receiver Settings Screens to the STS-7 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 get to the STS Receiver Setting screens.
3. You will arrive at the STS Sensor Insertion Screen, shown below.



STS-7 Sensor Insertion Screen

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



Confirmation Screen

5. After the STS Receiver has successfully processed the new STS Sensor Insertion, the STS Receiver will return to the grayed out 1-hour Trend Screen and the 2-hour Start-Up period will begin.

NOTE

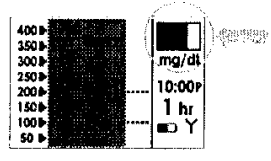
- Each time you insert a new STS-7 Sensor and press " " on the STS Sensor Insertion screen, you will restart the 2-hour Start-up period.
- You must insert a new STS-7 Sensor every time you press " " on the STS Sensor Insertion screen.
- The STS-7 Sensor Insertion Screen will only appear again after you have ended an active continuous glucose monitoring session (see Section 5).

2.6 STS®-7 SENSOR START UP PERIOD

The STS-7 Sensor requires a two hour Start-Up period to "equilibrate" (adjust) to its new biological environment. The Start-Up period will last 2 hours from the time you have confirmed the STS Sensor insertion.

During the Start-Up period, periodically check to see that the Antenna Icon (Y) is visible in the bottom right hand corner of the Trend Screens and that your STS Receiver battery is charged.

When you press any button during the Start-Up period, your Trend graphs will be shaded dark gray. Over time, the dark gray screen will start to disappear indicating that you are getting closer to initial calibration time. An example of this change is shown below.



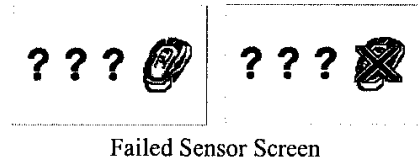
A partial gray status box indicates your STS-7 Sensor is still in the Start-Up period

At the end of the 2 hour Start-Up period the STS receiver will provide prompt you to notify you that it is time to calibrate your STS-7 Sensor. Section 3 describes how to calibrate your STS-7 Sensor.

QUICK TIP:
Your 3-hour Trend Screen is the best indicator of how much time you have left in the Start-Up Period.

2.6.1 PROBLEMS DURING THE START-UP PERIOD

During the Start-Up period you may see the Failed Sensor Screen.



Failed Sensor Screen

If you see this screen, the STS-7 Sensor is not working properly or you may have dislodged the STS-7 Sensor or STS Transmitter. You will need to replace your STS-7 Sensor. To replace your STS-7 Sensor, remove your STS Sensor Pod by gently peeling up the adhesive patch from your skin (this will pull out the Sensor Probe). Remove the STS Transmitter from the STS Sensor Pod (See Section 5.2). Clean and dry 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-7 Sensor, go through a new 2-hour Start-Up Period, and calibrate your STS-7 Sensor before you can receive more continuous glucose information.

NOTE:
If you have dislodged the STS-7 Sensor or Transmitter you will have to replace your STS-7 Sensor.

SECTION 3

STS®-7 SENSOR CALIBRATION

The STS-7 System uses the LifeScan OneTouch Ultra meter to calibrate your STS-7 Sensor readings. The OneTouch Ultra meter transfers the fingerstick blood glucose (BG) readings through the connection cable.

The STS-7 System requires 2 BG fingerstick readings at the first calibration prompt. The STS Receiver will prompt you for these readings about 2 hours after you insert a new STS-7 Sensor (See Section 3.1).

After initial calibration, if you have not uploaded another BG reading in 12 hours the STS Receiver will request a new BG reading for calibration update.

WARNING:
Update the STS-7 System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS-7 System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

NOTE:

- All fingerstick BG readings taken with your OneTouch Ultra meter are evaluated for calibration. Do not share your blood glucose meter with other people.

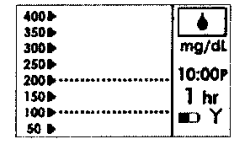
3.1 THE STS®-7 SYSTEM CALIBRATION PROMPT (THE END OF THE START UP PERIOD)

Two (2) hours after STS-7 Sensor insertion (See Section 2.5), your STS Receiver will prompt you to calibrate your STS-7 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 follow the steps provided in Section 3.2 to calibrate your STS-7 System.

If you choose to silence the Double Blood Drop Prompt and calibrate at a later time, the Trend Screen will display a Blood Drop in the upper right hand corner. This indicates that BG fingerstick readings are still needed for calibration.



- Your blood glucose reading must be between 40 mg/dL and 400 mg/dL to calibrate. If you take fingersticks outside of this range, the STS-7 System will not calibrate. Treat yourself first and then try calibrating the STS-7 Sensor at a later time.
- Always check that the STS Receiver and BG meter time are the same. The STS Receiver and OneTouch Ultra meter must be within 2 minutes of each other for calibration. If they are not, connect the OneTouch Ultra meter to the STS Receiver before taking BG fingersticks for calibration.
- If you use more than 1 OneTouch Ultra meter during a continuous glucose monitoring period, any BG fingersticks you take using the "non-registered" meter will not be used for calibration. You will have to register the meter first, and then take BG readings with the new meter for calibration. (See section 2.2).

3.2 AUTO UPLOAD CALIBRATION

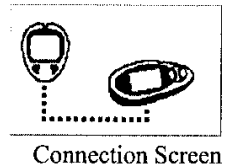
3.2.1 UPLOAD BG READINGS TO YOUR STS® RECEIVER FOR CALIBRATION USING THE AUTO UPLOAD CABLE

The steps below will guide you through Auto Upload Calibration:

1. Take 2 fingersticks with your OneTouch Ultra meter.
2. Make sure that 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 you STS Receiver and STS Transmitter are communicating (the Y is in the bottom right hand corner of the Trend Screen).
3. Using the connection cable, **first** plug the cable into the connection port of the BG 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. (You must do these steps in order).
4. After a few seconds, "PC" will appear on the OneTouch Ultra meter screen (shown below):

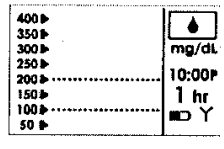
NOTE:
It is important that you follow steps 1-4 for Auto Upload in that exact order for successful BG reading transfer and calibration of the STS-7 System.

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



Connection Screen

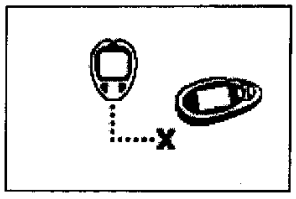
6. The 1-Hour Trend Screen with a Blood Drop in the upper right hand corner ("Status Box") shown below will appear once the upload is complete. The Blood Drop icon will be replaced by a glucose reading once the STS-7 Sensor successfully calibrates.



7. Disconnect the cable from the BG meter and the STS Receiver (the order that you disconnect does the cable does not matter).
8. A glucose reading will appear on the STS Receiver in about 15 minutes, and glucose readings will be updated every 5 minutes.
9. If it has been more than 20 minutes, see Section 3.3 "Calibration Troubleshooting."

3.3 CALIBRATION TROUBLESHOOTING

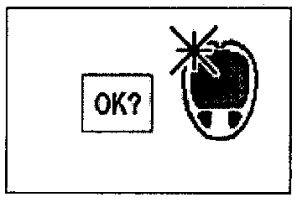
The following prompts may appear during or shortly after your first calibration attempt of the STS®-7 System. Review the following troubleshooting methods to ensure successful calibration.



CONNECTION FAILURE SCREEN

If you see this screen (with an "X" between the dotted lines), the BG reading upload failed. In this case, clear the alert by pressing any STS Receiver button. No additional BG fingersticks are required. Disconnect the devices and review the following:

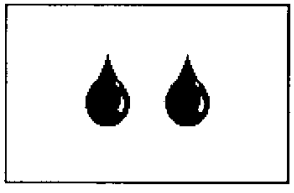
- Make sure that the OneTouch Ultra Meter screen is always blank before you connect the 2 devices.
- Make sure you plug the connection cable into the meter first and into the STS Receiver second.
- Do not disconnect the cable while uploading or before you see the 1-Hour Trend Screen appear.



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 STS-7 System. See Section 2.2 for instructions on how to do this.
- You will have to take 2 additional BG fingersticks and upload them.



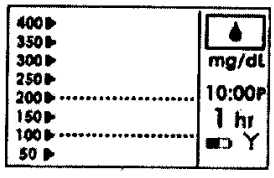
REPEAT DOUBLE BLOOD DROP PROMPT

If initial calibration is not successful, the STS Receiver will continue to provide the Double Blood Drop Prompt every 15 minutes for up to 3 hours after the STS-7 Sensor Start-Up Period. Make sure you have followed the instructions in Section 3 (STS-7 Sensor Calibration) and the instructions for how to address the Connection Failure Screen and New Meter Screen. If you have followed these steps and you still receive the Double Blood Drop Prompt, then one of the following errors has occurred:

- Both BG fingerstick readings you took and uploaded for your first calibration attempt were outside of the 40-400 mg/dL range, **or**
- The STS Receiver and STS Transmitter were not communicating with each other at the time you took the 2 BG fingersticks uploaded for calibration, **or**
- The STS Receiver could not understand "???" your sensor signal at the time you uploaded the BG fingerstick readings for calibration.

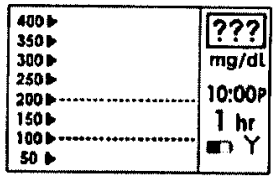
If you get prompted by the REPEAT DOUBLE BLOOD DROP PROMPT follow the steps below:

1. Clear the Screen by pressing any STS® Receiver button.
2. Check the upper right hand corner of the STS Receiver for the current STS Receiver status and determine what to do based on the STS Receiver Status Icon displayed:
   a. If the "Awaiting Fingerstick Reading" Icon (shown below) is displayed, take 2 more BG fingersticks (readings must be within 40-400 mg/dL) and upload those readings to the STS Receiver.



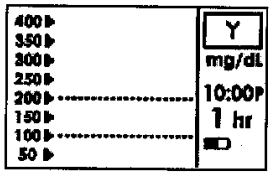
"Awaiting Calibration Fingerstick" Icon

   b. If the "???"Icon (shown below) is displayed your Receiver cannot understand the sensor signal. Do not take any additional fingersticks for calibration at this time. Wait until you are prompted with the Double Blood Drop Screen again and review Steps 1 and 2.

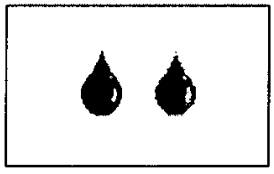


"???" Icon

   c. If the "No Communication" Icon (shown below) is displayed, do not take any additional fingersticks for calibration at this time. Move the Receiver and Transmitter so that they are within 5 feet of each other and wait at least 5 minutes. If you are still having problems with communication review Section 4.6.1 also. When you are prompted with the Double Blood Drop Prompt again, review Steps 1 and 2 to calibrate.



"No Communication" Icon

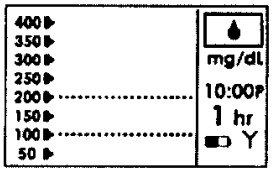


SHADED-OUT DOUBLE BLOOD DROP PROMPT
Shaded-out Blood Drop Prompt indicates that 1 more BG fingerstick is needed for calibration. The STS® Receiver will continue to provide the Shaded-Out Blood Drop Prompt every 15 minutes for up to 3 hours after the STS-7 Sensor Start-Up Period until a minimum of 2 BG fingersticks are successfully taken and uploaded to the STS Receiver.

To complete calibration after receiving the SHADED-OUT BLOOD DROP PROMPT follow the steps below:

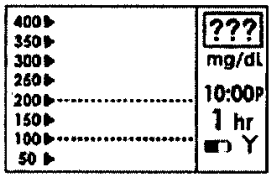
1. Clear the Screen by pressing any STS Receiver button.
2. Check the upper right hand corner of the STS Receiver for the current STS Receiver status and determine what to do based on the STS Receiver Status Icon displayed:

   a. If the "Awaiting Calibration Fingerstick" Icon (shown below) is displayed, take 1 more BG fingerstick (reading must be within 40-400 mg/dL) and upload that reading to the STS Receiver.



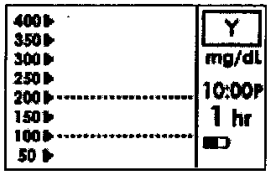
"Awaiting Calibration Fingerstick" Icon

   b. If the "???"Icon (shown below) is displayed your Receiver cannot understand the sensor signal. Do not take any additional fingersticks for calibration at this time. Wait until you are prompted with the Double Blood Drop Screen again and review Steps 1 and 2.



"???" Icon

c. If the "No Communication" Icon (shown below) is displayed, do not take any additional fingersticks for calibration at this time. Move the Receiver and Transmitter so that they are within 5 feet of each other and wait at least 5 minutes. If you are still having problems with communication review Section 4.6.1 also. When you are prompted with the Double Blood Drop Prompt again, review Steps 1 and 2 to calibrate.

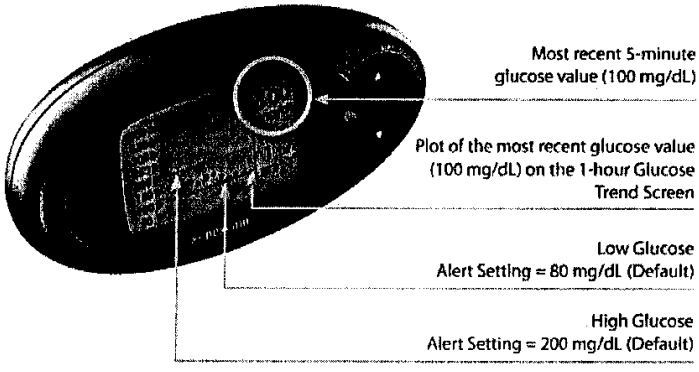


"No Communication" Icon

NOTE:
If you are still having trouble with STS®-7 calibration (*e.g.* receiving multiple prompts) following these steps, contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664) for further assistance.

VIEWING YOUR CONTINUOUS GLUCOSE INFORMATION

This section will educate you on how to view STS®-7 System continuous glucose trend information. Once you have successfully calibrated, the STS-7 System will provide you with continuous glucose information every 5 minutes, and Low and High Glucose Alerts and the Low Glucose ALARM will notify you when you fall outside of your target glucose range. Press any button on the STS Receiver and the following glucose information will be shown to you:

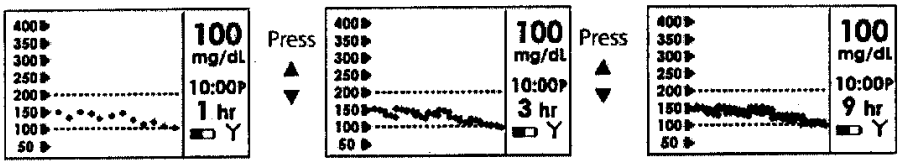


After successful calibration, the STS Receiver will update your glucose reading every 5 minutes. You will be provided with glucose readings from 40 mg/dL to 400 mg/dL and you can check your STS-7 Sensor glucose reading at any time by pressing any STS Receiver button. In addition to displaying individual glucose readings, your STS-7 System will alert you when your glucose levels fall outside of your programmed alert levels. The default high and low glucose alerts are set at 80
mg/dL and 200 mg/dL but can be changed to fit your personal diabetes goals (See Section 7.1).

WARNING:
Update the STS-7 System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS-7 System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

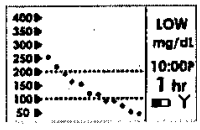
4.1 GLUCOSE TREND SCREENS

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

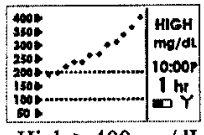


1-Hour Glucose Trend Screen | 3-Hour Glucose Trend Screen | 9-Hour Glucose Trend Screen

- The STS-7 System reports glucose readings from **40 to 400 mg/dL** and updates glucose readings every 5 minutes.
- The STS-7 System reads "**LOW**" when <40 mg/dL and "**HIGH**" when >400 mg/dL



"Low" < 40 mg/dL



High > 400 mg/dL

- Each "dot" on the glucose trend screen represents a glucose reading.
- The current time is on each Glucose Trend Screen ("A" is AM and "P" is PM).
- The "dashed lines" on the Glucose Trend Screens are the High Alert and Low Alert Settings (see Section 7.1 to change these settings)
- The 1-hour Trend Screen (**1 hr**) shows your current glucose reading and the last 1 hour of glucose readings.
- The 3-hour Trend Screen (**3 hr**) shows your current glucose reading and the last 3 hours of glucose readings.
- The 9-hour Trend Screen (**9 hr**) shows your current glucose reading and the last 9 hours of glucose readings.

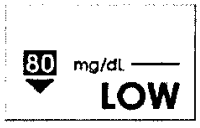
WARNING:

- Treatment decisions should not be based solely on results from the STS-7 System. You must confirm with a blood glucose meter before making therapeutic adjustments.
- Update the STS-7 System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS-7 System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

4.2 HIGH AND LOW GLUCOSE ALERTS

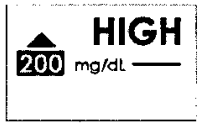
One of the benefits of the STS®-7 System is your ability to set High and Low Glucose Alerts that tell you when your glucose readings are out of your "target range" (See Section 7.1). This feature can be helpful during periods of time when you may not test your blood glucose (such as sleeping, driving, exercise, or long meetings).

- When your STS-7 glucose readings are at or below your Low Alert setting the STS Receiver will notify you for up to 15 minutes:
  - 1st 5-minute Alert: "Vibrate"
  - 2nd 5-minute Alert: "Vibrate" "Beep"
  - 3rd 5-minute Alert: "Vibrate" "Beep" "Beep"
- For Low Alerts the STS Receiver will display the following screen with the notification:



Low Glucose Alert Screen

- For High Alerts the STS Receiver will display the following screen with the notification:



High Glucose Alert Screen

- Press any STS Receiver Button to stop the Low Alert notification (vibrating/beeping).
- Once you press a Receiver button to acknowledge the alert, the STS Receiver will not notify you until your glucose readings rise above or fall below your High and Low Alert settings again.

DEFAULT ALERT SETTINGS:

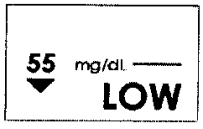
- HIGH Alert = 200 mg/dL
- LOW Alert = 80 mg/dL

Default settings can be changed or turned off (see section 7.1)

4.3 LOW GLUCOSE ALARM (≤55 mg/dL)

In addition to your personal glucose alert settings, your STS® Receiver also has an automatic Low Glucose ALARM set at 55 mg/dL. **You cannot change or turn off this ALARM.**

- When your STS-7 glucose readings are at or below 55mg/dL the STS Receiver will notify you for up to 15 minutes:
  - 1st 5-minute Alert: "Vibrate"
  - 2nd 5-minute Alert: "Vibrate" "Beep"
  - 3rd 5-minute Alert: "Vibrate" "Beep" "Beep"
- For Low ALARMs the STS Receiver will display the following screen with the notification:



Low Glucose ALARM

- Press any STS Receiver Button to stop the Low Alert notification (vibrating/beeping).
- The STS Receiver will automatically notify you again in 30 minutes if your glucose readings are still at or below 55 mg/dL.

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-7 System results.

4.4 THE STS®-7 SYSTEM AND WATER

The STS-7 Sensor (including the installed STS Transmitter) is water resistant, so it is not necessary to remove or cover the STS-7 Sensor when showering, bathing, or swimming. When submerging the STS-7 Sensor during bathing or swimming the STS-7 Sensor is water resistant up to a depth of 3 ft (1 meter) for up to 30 minutes. The STS-7 Sensor performance has not been tested in elevated water temperatures, such as those in a Jacuzzi or hot tub. It is recommended that you avoid STS-7 Sensor exposure to Jacuzzis and hot tubs.

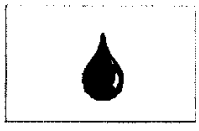
The STS Receiver is not water resistant. Do not get your Receiver wet at any time.

4.5 STS-7 SENSOR RECALIBRATION/ 12-HOUR UPDATE

Upload any fingerstick BG readings you take during STS-7 Sensor wear. These BG readings will update your STS-7 System calibration.

If you have not uploaded any fingerstick BG readings in the past 12 hours, the STS Receiver will request a fingerstick BG reading to update its calibration as follows:

- The Calibration Update Screen will appear to notify you to update STS-7 System Calibration (Note: The STS Receiver will not vibrate at this time).
- If you see the reminder symbol below, 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.



Calibration Update Screen

- Take a fingerstick at this time. Upload this reading to your STS Receiver to update your STS-7 Sensor calibration.
- This screen will reappear every 15 minutes until you upload a new BG fingerstick reading.
- If this screen re-appears shortly after you have uploaded a new BG fingerstick reading, review the "Calibration Troubleshooting" section of this User's Guide (Section 3.3).

WARNING:
Update the STS-7 System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS-7 System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

4.6 MISSING STS™-7 GLUCOSE INFORMATION (GLUCOSE DATA GAPS)

At times your STS-7 System will not display glucose information or provide alerts. These Glucose Data Gaps can happen when:

1. The Transmitter and Receiver are out of range.
2. The STS Receiver does not understand the STS-7 Sensor signal.
3. The STS-7 System needs another BG fingerstick readings for calibration because the STS-7 Sensor readings do not match your blood glucose meter readings.

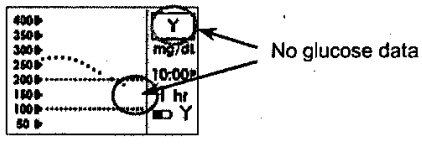
Reasons for "Glucose Data Gaps" and what to do to receive new STS-7 readings are described in the Sections below.

WARNING:

- This device is not designed to replace a blood glucose meter. Especially during Glucose Data Gaps, rely on your blood glucose meter.
- Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose confirm them using your blood glucose meter.

4.6.1 MISSING GLUCOSE READINGS – NO "Y"

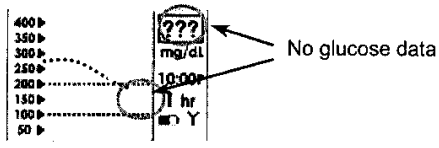
- Anytime you see the Antenna Icon "Y" in the Status Box instead of a glucose reading the STS Receiver has "missed" the last glucose reading sent by the Transmitter to the Receiver.



- Make sure your STS Receiver is within 5 feet of the STS Transmitter/STS Sensor Pod. If it is not, move your STS Receiver closer and wait at least 5 minutes. The "Y" icon in the Status Box should go away and you will receive a STS-7 glucose reading in the next 5-10 minutes.
- If you are still having trouble receiving STS-7 readings because of this problem, contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664).

4.6.2 MISSING GLUCOSE READINGS – "???"

During continuous glucose monitoring your STS® System may get a reading that it does not understand. When this occurs you will see 3 question marks (???) in the STS Receiver Status Box.

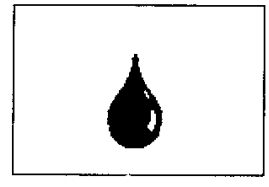


- Check the placement of your STS-7 Sensor to make sure it is still sticking well to your skin and that nothing is rubbing the STS-7 Sensor Pod (i.e. clothing, seat belts, etc.).
- The (???) can also happen because your glucose readings are rapidly rising or rapidly falling.
- The STS Receiver can tell if there are "Major" or "Minor" issues with your Sensor signal where it cannot calculate a STS-7 glucose reading. Minor sensor issues can be resolved (go away) and the STS-7 System will be able to give you more glucose readings.
- A series of "Major" issues with your Sensor can cause the STS Receiver to automatically turn off before the end of a full 7-day session (see Section 4.7). If you see the "Failed Sensor" Screen you will need to replace your STS-7 Sensor and start a new continuous glucose monitoring session.
- Glucose readings will be displayed again once the STS-7 System determines it is okay to do so.

- When you see "???" in the status box of the Receiver Trend Screen, taking BG fingersticks with your meter and uploading them <u>does not help</u> the STS-7 System display more glucose readings. Any BG fingersticks that you take during "???" will be ignored by the STS-7 System.

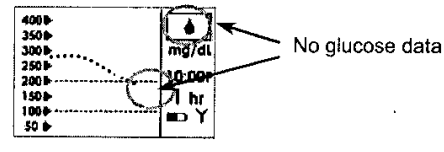
4.6.3 MISSING GLUCOSE READINGS – "[ ]" DURING CALIBRATION UPDATE/RECALIBRATION

- When you take and upload a BG fingerstick for calibration (Section 4.5), the STS®-7 System checks how well it is functioning compared to the BG meter. The calibration update process takes about 15 minutes. During your first calibration update attempt, the STS-7 System may determine that another BG reading is needed. The Calibration Update Screen will appear again (shown below) and the STS Receiver will vibrate.



Calibration Update Screen

- Clear this Screen by pressing any button. The display will return to the 1-hour Trend Screen. You will see a blood drop icon in the Status Box instead of a glucose reading.



Awaiting Calibration Fingerstick Icon

- The blood drop icon indicates that the STS-7 System requires at least one more BG fingerstick reading to start displaying glucose readings and providing alerts again.
- Take another BG fingerstick and upload this information to the Receiver. After you do this, your STS-7 System will take about 15 minutes to update calibration. The blood drop symbol will remain in the upper right corner during the 15-minute period.
- After successful re-calibration your STS-7 System will display glucose readings, trends and provide Alerts and ALARMs again.

NOTE:

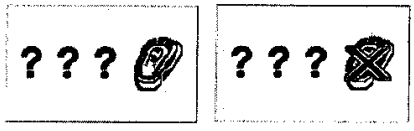
If you have not received any glucose readings in the past hour and have attempted re-calibration by taking and uploading at least 3 BG fingersticks then contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664) as there may be a problem with your STS-7 Sensor.

4.7 STS®-7 SYSTEM EARLY SHUT-OFF

In some cases your STS-7 System Continuous Glucose Session may end before the end of a full 7-day period (See Section 9.1, Table 10). Examples of why this may occur are described below.

4.7.1 EARLY SHUT-OFF – SENSOR FAILURE

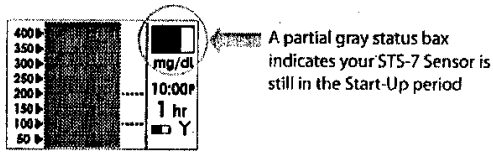
During use you STS Receiver may detect a series of "Major" issues with your Sensor signal where it can no longer calculate STS-7 glucose readings (See Section 4.6.2). At this time the STS-7 System will automatically turn off and display the following screen:



Failed Sensor Screen

If you see this screen then your STS-7 continuous glucose monitoring session has ended. Press any button on the STS Receiver to clear this screen.

STS-7 glucose readings will not be displayed and the STS Receiver screen will indicate that the STS-7 Session has ended by displaying the gray rectangle at the upper right corner.



Remove your STS Sensor Pod by gently peeling up the adhesive patch from you skin (this will pull out the Sensor Probe). Remove the STS Transmitter from the STS Sensor Pod and store it for your next glucose monitoring session (See Section 5.2).

To start a new STS-7 continuous glucose monitoring session, insert a new STS-7 Sensor, notify the STS Receiver and then calibrate at the end of the Start-Up Period.

NOTE:
Remember to save your STS Transmitter after each STS-7 Sensor removal. The same Transmitter is used for each STS-7 session until you have reached the end of the STS Transmitter battery life.

4.7.2 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-7 System Continuous Glucose monitoring session has ended. Note the code that appears on the screen, if any, and contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664).

ENDING YOUR STS®-7 SYSTEM CONTINUOUS GLUCOSE MONITORING SESSION

At the end of your STS-7 Sensor wear period, you can simply remove your STS Sensor Pod by gently peeling up the adhesive patch from your skin (this will pull out your sensor probe). Remove the STS Transmitter from the STS Sensor Pod and keep it for your next glucose monitoring session.

5.1 CONTINUOUS GLUCOSE MONITORING PERIOD END

5.1.1 AUTOMATIC STS-7 SENSOR EXPIRATION NOTIFICATION

Your STS Receiver will notify you of how much time you have remaining until your STS-7 Continuous Glucose Monitoring Session is complete. The Expiration Screen will appear 6 hours and 2 hours before your 7-Day (168-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-7 Sensor when the 0 hour Screen appears.

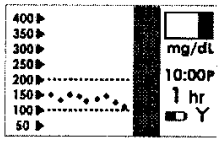
6 hour STS-7 Sensor Expiration Notification

2 hour STS-7 Sensor Expiration Notification

30 minute STS-7 Sensor Expiration Notification (+Vibration)

0 minute STS-7 Sensor Expiration Notification (+Vibration)
END OF SESSION

Once the 0 hour Screen appears, press any of the STS® Receiver buttons to clear this notification. Glucose readings will no longer be displayed and the STS Receiver screen will indicate that the STS-7 Session has ended by displaying the gray rectangle at the upper right corner.

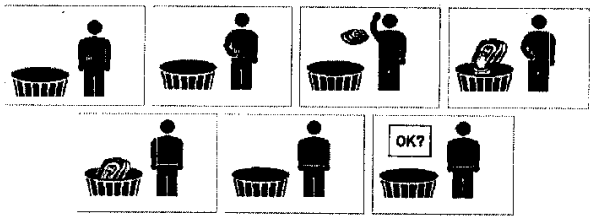


Over time the STS Receiver display will continue to "gray out" if a new STS-7 Sensor is not inserted.

5.1.2 MANUAL STS-7 SENSOR SHUT-OFF

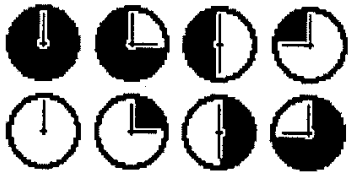
To manually end your continuous glucose monitoring session, follow the steps below:

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 5 times to arrive at the STS-7 Sensor Removal Screen, shown below. Once you see this screen, press the button to indicate removal of your STS-7 Sensor.



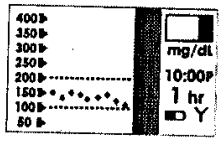
STS-7 Sensor Removal Screen

4. After you see the series of screens below, you have successfully removed your STS-7 Sensor.



Confirmation Screen

5. The STS® Receiver will default to the 1-Hour Trend Screen. Glucose readings will no longer be displayed and the STS Receiver screen will indicate that the STS-7 Session has ended by displaying the gray rectangle at the upper right corner.



Over time, the STS Receiver display will continue to "gray out" if a new STS-7 Sensor is not inserted.

NOTE:

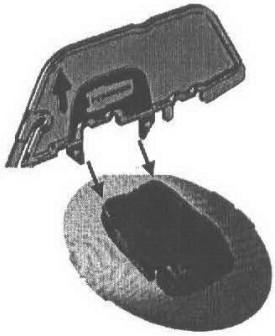
- If you removed your STS-7 Sensor before notifying the STS Receiver, the Failed Sensor Screen will appear automatically (See Section 4.7.1). You must press before inserting a new STS-7 Sensor.
- Your STS Transmitter is used for each STS-7 Sensor session. Remove the STS Transmitter from the STS Sensor Pod and store it for your next glucose monitoring session.

5.2 STS® TRANSMITTER REMOVAL

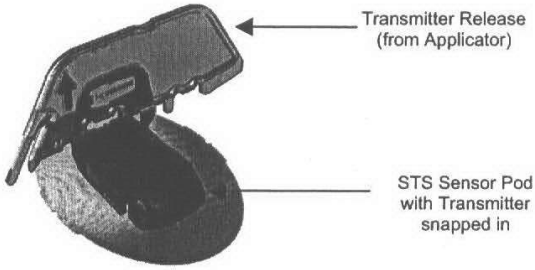
After pulling out the STS-7 Sensor with the STS Transmitter still in the STS Sensor Pod, you will need to remove the STS Transmitter. To do this you can use either of the two methods:

Method 1

- The Safety Lock/STS Transmitter Release (Section 2.2.3) detached from the STS Applicator can be used as a tool to remove the STS Transmitter. Place the STS Sensor Pod on a table. Hold the rounded edge of the STS Transmitter Release perpendicular to the STS Sensor Pod length. Make sure the jagged edge of the STS Transmitter Release is facing down (the direction away from the removal arrow) as shown below:



- Insert the jagged edges so that they "hug" the STS Transmitter wings in the STS Sensor Pod. Press the STS Transmitter Release down until you cannot press down anymore, and the STS Transmitter wings will "pop" out of the STS Sensor Pod.



- Remove the STS Transmitter and store it in a cool, dry place until your next glucose monitoring session.

Method 2

- If you did not save the STS Transmitter Release, you can simply use your forefinger on each hand and spread out the tabs at the back of the STS Sensor Pod (end closest to the wings). The STS Transmitter wings will "pop" out of the STS Sensor Pod.

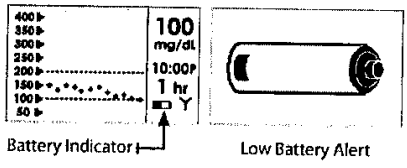
STS® RECEIVER BATTERY

Your STS Receiver battery is rechargeable like a cellular phone. The battery will last for about 5 days before needing to be recharged. The STS Receiver will take 3 hours to charge when the battery has completely drained.

NOTE:
Typically the Receiver only needs to be charged every 5 days. However, this can vary by how often you check Receiver Trend Screens or receive Alerts or ALARMs. Periodically check your STS battery level to make sure it has enough charge.

6.1 LOW BATTERY ALERT

- The Battery indicator is located next to the Antenna Icon (Y) on the bottom right side of the screen. This indicator tells you how much charge is left in the battery.
- When the STS Receiver's battery is low, the STS Receiver will flash a large Low Battery Alert across the screen. Press the C Button to clear the alert.



NOTE:
Charge your STS Receiver as soon as possible when you see the Low Battery Alert so you can continue receiving glucose readings.

6.2 CHARGING THE STS RECEIVER BATTERY

- To charge the STS Receiver battery, connect the charger cable 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 will last approximately 5 days before recharging is necessary.

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 of all STS Receiver screens.

7.1 GLUCOSE ALERT SETTINGS

The default setting for the high glucose alert is 200 mg/dL. The default setting for the low glucose alert is 80 mg/dL. Set these alerts at settings that will help monitor when your glucose levels are too high or too low. Work with your Diabetes Management Team to help you choose your appropriate glucose alert settings.

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

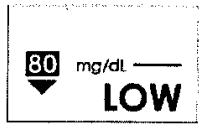
- Press the Down ▼ Arrow 3 times until you come to the 9-hour Glucose Trend Screen.
- Hold the Down ▼ Arrow for at least 7 seconds until you come to Settings Screens.
- Scroll down until you arrive at the Glucose Alert Screens:

- Once you are at the glucose alert screen, press to begin setting your alert levels. You will see the following High Glucose Alert Screen:

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

NOTE:
If you scroll above 400 mg/dL the display will read NO. If you press the Button to select this option, you will turn off the high glucose alert. You will not receive any high glucose alerts at this Alert setting.

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



- Use the Up ▲ or Down ▼ Arrows to increase or decrease the low glucose alert level by 10 mg/dL.
- You may select low glucose alert levels from 60 mg/dL to 90 mg/dL.
- Select the level recommended by your Diabetes Management Team by pressing the Button.

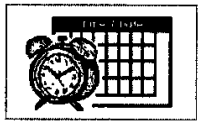
NOTE:
If you scroll below 60 mg/dL the display will read NO. If you press the Button to select this option, you will turn off the low glucose alert. You will not receive any low glucose alerts at this Alert setting. (For safety, there is a Low Glucose ALARM set at 55 mg/dL that you cannot turn off. See section 4.3).

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

7.2 HOW TO SET THE STS® RECEIVER TIME

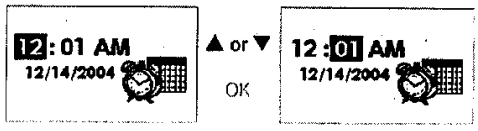
7.2.1 STS RECEIVER TIME SCREEN

- 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 until you arrive at the Time/Date Screen.
- Press the Button on the STS Receiver to begin setting the time.



7.2.2 SETTING THE TIME (AM/PM MODE)

- Once you select the Time/Date Screen and press , the Time Set Screen will appear in the format you selected.
- Press the Up ▲ or Down ▼ Arrows to choose the hour.
- Press the Button to move to the minutes.
- Press the Up ▲ or Down ▼ Arrows to choose 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 12:00 PM, 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

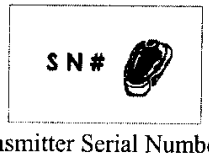
NOTE:

- The STS® Receiver date is preset to Pacific Standard Time (PST) at the factory.
- Your STS Receiver time can only be adjusted ± 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 replaced.

7.3 ENTERING A NEW STS® TRANSMITTER SERIAL NUMBER (SN#)

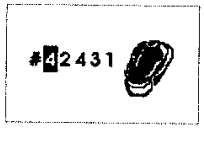
Any time you use a new STS Transmitter or new STS Receiver as part of your STS-7 System, you must enter the STS Transmitter Serial Number (SN #) into your STS Receiver. This will begin the wireless radio-frequency (RF) communication between the two devices. To do this perform the following steps:

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 until you arrive at the STS Transmitter Serial Number Screen:



STS Transmitter Serial Number Screen

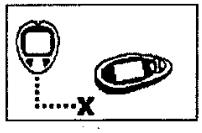
4. Press the Button to display the entry screen for the STS Transmitter SN#:
5. The SN# is printed on a removable label located on top of the STS Transmitter.
6. To enter your SN#, press the Up ▲ or Down ▼ Arrows until you arrive at the first number or letter.



7. Press the Button to enter that number or letter and to move to the next number or letter.
8. Once you have entered all of the numbers or letters, press the 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 the SN# will not be changed.

8.1 PROBLEMS UPLOADING BG READINGS TO YOUR STS® RECEIVER WITH THE AUTO UPLOAD CABLE

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



Connection Failure Screen

- Make sure you have done the following during upload:
  - The meter must be "OFF" prior to performing the upload (no display). If necessary, press the M button once to turn the meter off, and then reconnect the two devices.
  - Do not push any meter buttons while performing the upload.
  - The connection cable is plugged into the connection port properly. Remember to plug the cable into the meter first and then into the STS Receiver.
  - The Antenna Icon (Y) is present in the bottom right hand corner of the STS Receiver.
- If you are still unable to successfully transfer readings 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 BG meter 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.

8.2 TIME DIFFERENCE BETWEEN BG METER AND STS® RECEIVER

- Each time you connect the STS Receiver to your OneTouch Ultra meter your STS Receiver will automatically update the date and time on your meter so that they are "synchronized" or "match".
- If you update the Date and/or Time on your STS Receiver, the meter date and time will be updated the next time you connect the OneTouch Ultra meter to the STS Receiver using the upload cable.
- If you notice that there is a time difference between the STS Receiver and meter often, contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664). There may be a problem with one of the devices.
- Never change the time or date on the OneTouch Ultra meter. Always change the date and time on the STS Receiver and then register the meter with the STS Receiver.

NOTE:
The STS Receiver and OneTouch Ultra meter times must be within 2 minutes of each other for calibration. If they are not, the uploaded BG fingersticks will not be accepted by the STS-7 System. Any time you change the time on your Receiver, connect the OneTouch Ultra meter to the STS Receiver using the upload cable (without taking new BG fingerstick readings) to "synchronize" the times on the devices. You can upload BG readings as usual after that.

8.3 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 (sometimes an error code will not be available).
- Contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664). You may need to replace your STS Receiver.
- Continue to check BG readings on your meter.

TECHNICAL INFORMATION

SECTION 9.1 DEVICE PERFORMANCE CHARACTERISTICS

NOTE:
We recommend that you have the information in this chapter reviewed by your healthcare provider. We also suggest that you review this information with them in order to understand how well the STS®-7 System Performs.

The STS-7 System uses a glucose Sensor Probe to continuously monitor your glucose levels. The STS-7 Sensor is "calibrated" using your OneTouch® Ultra® blood glucose meter. Once calibrated, the STS-7 System reports glucose readings every 5 minutes. In a clinical study, STS-7 readings were compared to blood glucose measurements in order to assess its performance. Clinical Study findings are presented below.

Although presentations to characterize performance of the STS-7 System are given below, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors such as the STS-7 System. Performance may be best understood by viewing graphs called time-elapsed plots. In these plots, the values from the STS-7 System were recorded over time and were overlaid with values taken at the same time with a reliable laboratory method. Three representative time-elapsed plots are presented on pages 59-60 Figures 2-4. They are examples of good, average and poor STS-7 System performance.

Users and healthcare providers should consider that performance in this study might be idealized. Participants enrolled in the clinical study, and certain conditions of the study tend to result in above average glucose control. This, in turn, may result in the appearance that the STS-7 System agrees with blood glucose levels better than it does under typical conditions. Monitors that measure glucose in interstitial fluid often show better agreement to blood glucose levels when glucose levels are not changing rapidly or when glucose levels are not extremely low or high. The following are some examples of why performance of the STS-7 System may be idealized.

- The average Hemoglobin A1c among the 72 participants was 7.6%. Many people with diabetes have higher A1c levels, indicating poorer control of their glucose levels.
- Subjects took, on average, 6 fingerstick results per day. This enabled subjects to control their glucose levels better than with fewer fingerstick results per day.
- While subjects participated in the clinic portion of the study, they were more limited in their activities than someone at home. They were also provided with all their meals. Subjects who are more active, or with poor eating habits, may create more challenging conditions for the STS-7 System.
- OneTouch Ultra meters used in the study were well maintained. Because the OneTouch Ultra meter is used to calibrate the STS-7 System, performance may be poorer if the meter is not well maintained. It is important to carry out quality-control checks on the meter and code the meter according to the manufacturer's instructions to optimize performance of the STS-7 System.

CLINICAL STUDY RESULTS

To evaluate performance of the STS®-7 System, 72 participants were enrolled in a clinical study conducted at 5 centers. All participants had Type 1 or Type 2 diabetes mellitus, and required insulin to manage their diabetes. About 75% of participants had Type 1 diabetes and about 25% had Type 2 diabetes. Subjects ranged in age from 18 to 71.

Participants used the STS-7 System for approximately seven days (each participant wore 1 or 2 Sensors for 7 days.) STS Receivers were calibrated approximately 2-3 times per day, on average, over the 7-day period using the Lifescan OneTouch Ultra meter. Throughout the 7-day wear period, the STS Receiver was calibrated the most on day 1, with an average of 4 fingersticks per day, and was calibrated with an average of 2 fingersticks per day for days 2-7.

All participants used the STS-7 System in a controlled clinic environment on Day 1, Day 4, or Day 7 of the 7-day wear period. The remainder of the study took place at home. While using the STS-7 System in the clinic, 69 of the 72 participants had their blood glucose measured every 20 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus glucose analyzer. This instrument is referred to as the "YSI." Readings from the STS-7 System were paired with YSI readings in order to characterize how well STS-7 System results agreed with blood glucose results. For the remainder of the study, participants used the STS-7 System at home and results were paired with OneTouch Ultra blood glucose meter results (1 OneTouch meter was used to calibrate the STS-7 System, while a different OneTouch meter was used to collect the comparison blood glucose results). During Initial Calibration, participants were able to calibrate on the first attempt 98% of the time. Two-percent (2%) of the time one more attempt was required for calibration. For Re-Calibration and Calibration Updates 98% of the time participants only needed one attempt to update calibration. One-percent (1%) of participants required a second attempt, and less than one-percent (<1%) of participants needed 3-5 additional attempts for re-calibration.

AGREEMENT

Agreement between the STS-7 System and blood glucose levels is characterized using paired STS-7 System and YSI results. The STS-7 and YSI values were compared by pairing the STS-7 value that fell within 2.5 to 7.5 minutes after the YSI value was collected.

The agreement of the STS-7 System to blood glucose levels was assessed by calculating the percentage of STS-7 System values that were within 20%, 30%, and greater than 40% of the YSI readings. For values less than or equal to 80 mg/dL the difference in mg/dL between the two glucose values was calculated. For values greater than 80 mg/dL the percent difference (%) from the YSI value was calculated. The percentages of total values within 20 mg/dL or 20%, 30 mg/dL or 30%, or greater than 40 mg/dL or 40% were then calculated. The total number of data pairs considered in this analysis was 2,318. Results are shown in Table 1.

Table 1. Percentage of STS®-7 System Results Falling Within 20, 30, and Greater Than 40 Percent of the Paired YSI Results, at Various Glucose Concentrations

YSI Readings (mg/dL)	Number of Paired Readings	% of STS-7 Readings Within 20%*	% of STS-7 Readings Within 30%*	% of STS-7 Readings Greater than 40%* of YSI
40-60*	36	86%	94%	6%
61-80*	70	68%	91%	5%
81-180	1087	69%	85%	6%
181-300	850	74%	91%	3%
301-350	127	72%	97%	0%
351-400	48	69%	94%	0%
Overall	2,318	71%	89%	4%

* For the 40-60 and 61-80 mg/dL range the difference is presented as the difference in mg/dL between the STS-7 Sensor and YSI, rather than the percent.

The STS-7 System reports glucose concentrations between 40 and 400 mg/dL. When the STS-7 determines the glucose level is below 40 mg/dL, it indicates "LOW." If the STS-7 System determines that the glucose level is above 400 mg/dL, it indicates "HIGH." The ability of the STS-7 System to accurately report these occurrences is assessed by looking at the actual glucose concentrations (as determined by the YSI analyzer) when "LOW" or "HIGH" is reported.

- On 34 occasions the STS-7 System indicated the glucose value was less than 40 mg/dL or "LOW". Of these, 3 times the YSI glucose value was below 40 mg/dL. When the STS read less than 40 mg/dL, the actual range of glucose values the YSI read at these times was 36-74 mg/dL.
- There were 13 occasions when STS-7 System indicated the glucose value was above 400 mg/dL or "HIGH." Of these, 7 times the YSI glucose value was above 400 mg/dL. The actual range of glucose values the YSI read at these times was 302-494 mg/dL.

LOW AND HIGH GLUCOSE ALERTS

The ability of the STS-7 System to detect high and low blood glucose levels is assessed by comparing STS-7 System results to YSI results at low and high glucose levels (concentrations), and determining if the alert would have sounded. The STS-7 and YSI values were compared by pairing the STS-7 value that fell within 2.5 to 7.5 minutes after the YSI value was collected. There were 2,346 pairs of paired STS-7 System and YSI results evaluated. We suggest that you ask your doctor what Alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in the table below. For example, the data in the table shows that if you set the STS-7 Low Glucose Alert to 70 mg/dL, the STS-7 System will alert you 68% of the time when your actual blood glucose levels are at or below 70 mg/dL (True Alert Rate). The table also shows that at the same Alert setting (70 mg/dL), the Low Alert will not alert you 32% of the time ("Missed Alert Rate***").

Also at the 70 mg/dL alert level, 63% of the time the STS®-7 will falsely alert you that your glucose level is at or less than 70 mg/dL when your glucose level will actually be above 70 mg/dL.

If you set the STS-7 Low Glucose Alert to 90 mg/dL, the STS-7 System will alert you 85% of the time when your glucose levels are at or below 90 mg/dL. The table also shows that at the same Alert setting (90 mg/dL), the Low Alert will not alert you 15% of the time ("Missed Alert Rate***"). Also at the 90 mg/dL alert level, 36% of the time the STS-7 will falsely alert you that your glucose level is at or less than 90 mg/dL when your glucose level will actually be above 90 mg/dL.

Table 2.Hypoglycemic Alert Evaluation

STS-7 Alert Level	True Alert Rate*	False Alert Rate**	Missed Alert Rate***
60 mg/dL	64 %	79 %	36 %
70 mg/dL	68 %	63 %	32 %
80 mg/dL	76 %	45 %	25 %
90 mg/dL	85 %	36 %	15 %

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

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

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

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in the table below. For example, if you set the STS-7 High Glucose Alert to 200 mg/dL, the STS-7 System will alert when your glucose levels rise above 200 mg/dL 79% of the time (True Alert). Additionally, 8% of the time when the alert sounds, the glucose level will actually be below 200 mg/dL (False Alert).

Table 3. Hyperglycemic Alert Evaluation

Alert Setting	True Alert Rate*	False Alert Rate**	Missed Alert Rate***
140 mg/dl	84 %	4 %	16 %
180 mg/dl	76 %	8 %	24 %
200 mg/dl	79 %	8 %	21 %
220 mg/dl	70 %	11 %	30 %
240 mg/dl	60 %	14 %	40 %
300 mg/dl	53 %	22 %	47 %

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

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

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

Performance of High and Low Glucose Alerts at night comparing the STS®-7 to YSI data has not been established with the STS-7 Sensor. During use of the device at home, the STS-7 the High Alert was set at 200 mg/dL and the Low Alert was set at 80 mg/dL. The STS-7 data was compared to the OneTouch Ultra data collected during home use. Analysis of the home use data showed that when the STS-7 was above 200 mg/dL, 18% the OneTouch Ultra meter readings were actually below 200 mg/dL (False High Alert). When the STS-7 read below 80 mg/dL, the OneTouch Ultra was actually reading above 80 mg/dL 34% of the time (False Low Alerts).

ACCURACY

Accuracy between matched pairs was also estimated by calculating the percent difference between the STS-7 System reading and the YSI reading. The STS-7 and YSI values were compared by pairing the STS-7 value that fell within 2.5 to 7.5 minutes after the YSI value was collected. For example, if the YSI reading is 100 mg/dL and the STS-7 System reading is 90 mg/dL, there is a 10% difference between the STS-7 System and the YSI Laboratory machine.

In the above example the STS-7 reading is less than YSI reading and so the percent difference value is negative. Another estimate used to tell you the accuracy of the STS-7 is the absolute percent difference. The absolute percent difference tells you the overall percent difference or "distance" between the STS-7 and YSI readings, but does not tell you if the STS-7 is reading higher or lower than the YSI laboratory standard. The mean percent difference is the average of all of the positive and negative percent differences between the two devices compared and therefore tells you if the STS-7 on average reads higher or lower than the YSI at each glucose range. The mean absolute percent difference is the average "distance" (regardless if positive or negative) between STS-7 readings and YSI readings.

These accuracy measures are summarized in Table 4 below and are based on 2,323 paired glucose measurements:

Table 4. STS-7 System and YSI Blood Glucose Accuracy by Glucose Concentration

Glucose Range (mg/dL)	Number of Paired Readings	Mean Percent Difference	Mean Absolute Percent Difference
Overall (40-400 mg/dL)	**2,323**	**-8%**	**17%**
40-60	36	10%	23%
61-80	172	3%	23%
81-180	1,077	-8%	17%
181-300	865	-10%	15%
301-350	119	-10%	14%
351-400	47	-13%	14%

Table 4 shows that that the STS®-7 on average reads 3-10% higher than the YSI at glucose levels of 40-80 mg/dL and reads 10-13% lower, on average than the YSI at glucose concentrations of 301-400 mg/dL (Mean Percent Difference). The STS-7 reads on average 23% different than the YSI at glucose levels of 40-80 mg/dL and on average, 14% different than the YSI readings at glucose levels of 301-400 mg/dL (Mean Absolute Percent Difference).

CLARKE ERROR GRID ANALYSES

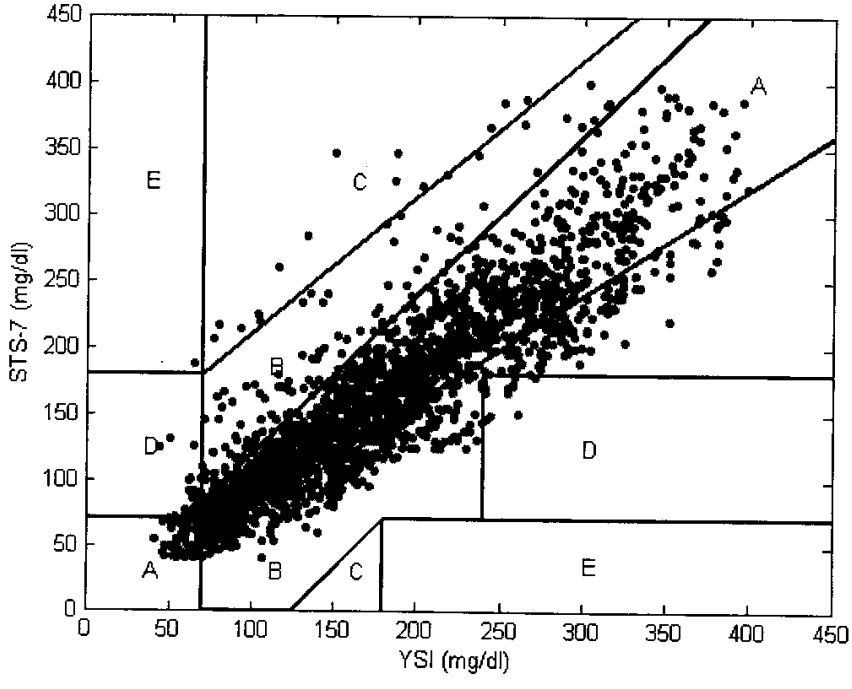
The Clarke Error Grid was used to determine if STS-7 System results are "clinically accurate". The Clarke Error Grid divides a correlation plot into 5 zones, which are described in the table below.

Table 5. Clarke Error Grid Description

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

Results in zones A and B are considered clinically acceptable, while results in zones C, D, and E are potentially dangerous. They may result in clinically significant errors. The Clarke Error Grid zones are labeled on a correlation plot in Figure 1. Each YSI result (on the horizontal axis) is matched up with its corresponding STS-7 System result (on the vertical axis). A point is recorded where the two values intersect. These results are based on 2,318 paired data points recorded.

Figure 1. Clarke Error Grid, STS-7 System Results Compared to YSI Results



The percentage of STS®-7 System results in the above graph are presented in Table 6 below according to the percentage of points falling within each zone (A-E). Results are further broken down (stratified) according to the range of glucose concentration.

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

Glucose Range (mg/dl)	Total YSI – STS-7 Pairs	A %	B %	C %	D %	E %
40-75	149	69%	15%	0%	15%	1%
76-180	1144	68%	31%	1%	N/A*	N/A*
181-300	850	73%	25%	1%	1 %	0%
301-400	175	71%	29%	N/A*	0%	0%
Overall	2318	70%	27%	1%	2%	0%

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

The Continuous Error Grid was also used to determine if the STS-7 System results are "clinically accurate". The Continuous Error Grid looks at how closely the STS-7 values match to the YSI Analyzer and also how closely the STS-7 glucose rate of change (how fast the glucose rises or falls) compared to the actual blood glucose rate of change measured by the YSI. The data is evaluated in 3 zones: clinically accurate readings, benign errors, and clinically inaccurate readings. See the table below for the STS-7 System accuracy by glucose range. There were 2,173 paired points evaluated.

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

	Hypoglycemia (YSI<= 70 mg/dl) (4% of the data)	**Euglycemia** (70< YSI <=180 mg/dl) (51% of the data)	**Hyperglycemia** (YSI >180 mg/dl) (45% of the data)
Accurate Readings	76%	97%	94%
Benign Errors	0%	2%	3%
Inaccurate Readings	24%	1%	3%

CALIBRATION STABILITY

Calibrate the STS®-7 System every 12 hours. To demonstrate performance of the STS-7 System over a 12-hour calibration period, 94 STS-7 Sensors were evaluated to verify that performance remains consistent over the 12-hour calibration period. STS-7 Systems were evaluated in 4 hour increments after calibration. Performance was estimated at each 4-hour interval and stratified by glucose concentrations by calculating the percentage of STS-7 readings within 20%, 30% and greater than 40% of the YSI readings. See the table below.

Table 8. Percentage of STS-7 readings within 20%, 30% and >40% of the YSI Laboratory reading with data stratified in 4-hour increments after calibration and by glucose concentration (Day 1, 4, and 7)

Time from Calibration and YSI Glucose Range (mg/dL)	Number of Paired Readings	% of Readings within 20% of YSI	% of Readings within 30% of YSI	% of Readings greater than 40% of YSI
40-75 mg/dL				
0-4 hours	47	77%	94%	2%
4-8 hours	62	73%	90%	6%
8-12 hours	36	64%	92%	0%
76-180 mg/dL				
0-4 hours	520	64%	81%	6%
4-8 hours	371	73%	89%	5%
8-12 hours	260	72%	85%	5%
181-350 mg/dL				
0-4 hours	434	78%	92%	2%
4-8 hours	333	67%	90%	1%
8-12 hours	210	73%	92%	5%
351-400 mg/dL				
0-4 hours	21	90%	95%	0%
4-8 hours	34	68%	91%	0%
8-12 hours	18	28%	100%	0%

Calibration cycles across days 1, 4, and 7 were evaluated and there were no significant differences noted. There is minimum data to support updating calibration less frequently than every 12 hours. It is recommended to calibrate the STS-7 System a minimum of every 12 hours.

SENSOR STABILITY

STS-7 Sensors may be worn for up to 168 hours. To verify that sensors perform consistently over the 168-hour period, 94 Sensors were evaluated at Day 1, Day 4, and Day 7 of the lifecycle. Performance was estimated by calculating the percentage of STS-7 readings within 20%, 30% and >40% of the YSI readings at the beginning (Day 1), middle (Day 4) and end (Day 7) of STS-7 lifecycle. Results are shown in the table below.

Table 9. STS®-7 Sensor Stability (Accuracy Over Time)

Day of Wear and YSI Glucose Range (mg/dL)	Number of Paired Readings	% of Readings within 20% of YSI	% of Readings within 30% of YSI	% of Readings greater than 40% of YSI
Day 1				
40-75*	36	69%	89%	11%
76-180	416	52%	77%	9%
181-350	401	75%	93%	1%
350-400	29	69%	100%	0%
Day 4				
40-75*	33	82%	91%	3%
76-180	346	69%	81%	7%
181-350	325	62%	89%	3%
350-400	16	75%	94%	0%
Day 7				
40-75*	76	68%	93%	0%
76-180	389	85%	95%	2%
181-350	251	86%	94%	3%
350-400	28	54%	89%	0%

*For the low glucose range (40-75 mg/dL), the value shown is the percent within 20 mg/dL, 30 mg/dL or greater than 40 mg/dL).

PRECISION OF STS-7 SYSTEM READINGS

In the same study, 28 of the subjects wore two STS-7 Systems. This was done to look at how similar two STS-7 Systems on the same person function (Sensor Precision). Precision was evaluated by comparing the glucose readings from the two STS-7 Systems. Results showed that STS-7 Systems generally agreed with each other within 16%.

SENSOR LIFE

STS®-7 Sensors may be used for up to 168 hours. Looking only at the STS-7 Sensors that were not replaced during the course of the study, 97 STS-7 Sensors were evaluated to estimate how many sensors continued to work for up to168 hours. Of those 97 STS-7 Sensors there were no insertion problems. Table 10, below, displays how long you can expect a STS-7 Sensor to last. For example, 75% of the sensors lasted between 145-168 hours.

Table 10. Estimated STS-7 Sensor Life

Number of Days of Use (Hours)	Percentage of STS-7 Sensors
1 (24 hours)	8%
2 (48 hours)	1%
3 (72 hours)	4%
4 (96 hours)	4%
5 (120 hours)	2%
6 (144 hours)	6%
7 (168 hours)	75%

Of the 24 sensors that did not last beyond 144 hours, 14 of them became nonfunctional because of device failure (Early Sensor Shutoff), 7 of them fell off the insertion site, 2 terminated early because the STS Pod came unglued from the adhesive, and 1 STS-7 Sensor stopped functioning because of an STS Transmitter Connection Issue.

NUMBER OF READINGS PROVIDED

The STS-7 System is capable of providing a reading every 5 minutes, or 288 readings per day. For a variety of reasons, this does not always happen. Sometimes sensors fail to provide readings after calibration and readings are "skipped." Table 11, below, estimates the number of readings you can expect to receive from the STS-7 System over the entire 7-day period. For example, 69% of STS-7 devices provided between 1,537 and 1,992 readings.

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

% of Total Possible Readings Provided	Total Readings Provided	% of STS-7 Devices Providing that number of readings
0-25%	5-504	12%
26-50%	654-974	6%
51-75%	1039-1494	12%
76-100%	1537-1992	69%

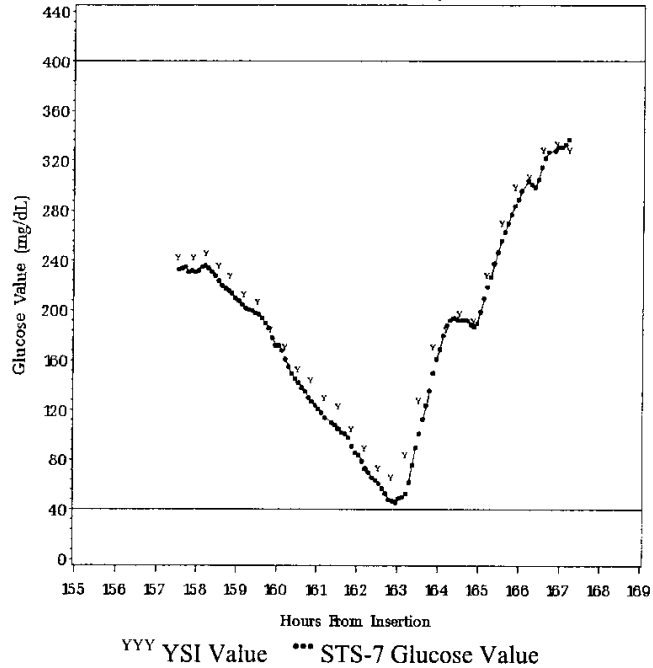
Approximately 7% of readings were lost because the STS Transmitter was more than 5 feet away from the STS Receiver. Other readings were lost because the STS-7 System detected signal problems and therefore did not display a value. The average amount of time a subject went without getting readings was about 15 minutes (or there was a data gap of three readings in a row).

TIME-ELAPSED PLOTS

Examples of STS®-7 Continuous Glucose Monitoring System overlaid with the corresponding YSI readings over time are presented below. The horizontal axis represents time, with the matching STS-7 System and YSI readings plotted above the point in time when the measurements were taken. The circles (•) on the graph represent the STS-7 System data, connected by a line. The "Y" represents the YSI reading.

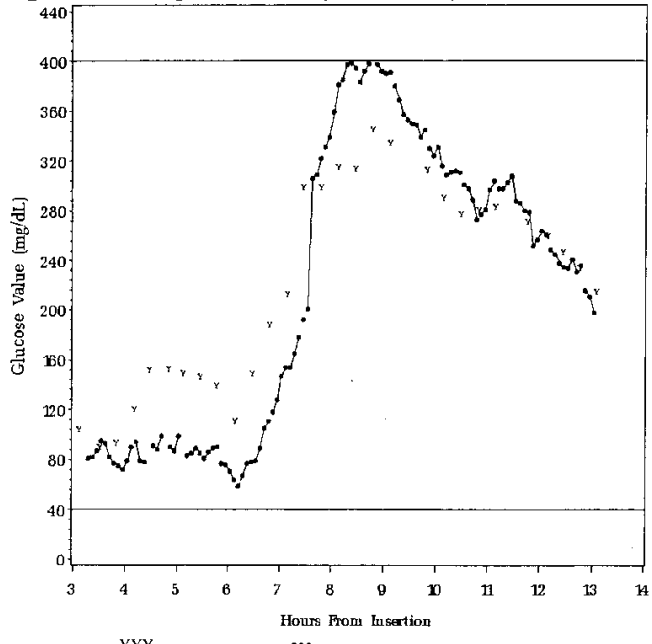
There are three Figures presented. Figure 2 is an example of when the STS-7 System performed well, Figure 3 represents a period when the STS-7 System performed in an average manner, and Figure 4 represents when the STS-7 System performed poorly.

Figure 2. Example of "Good" STS-7 System Performance



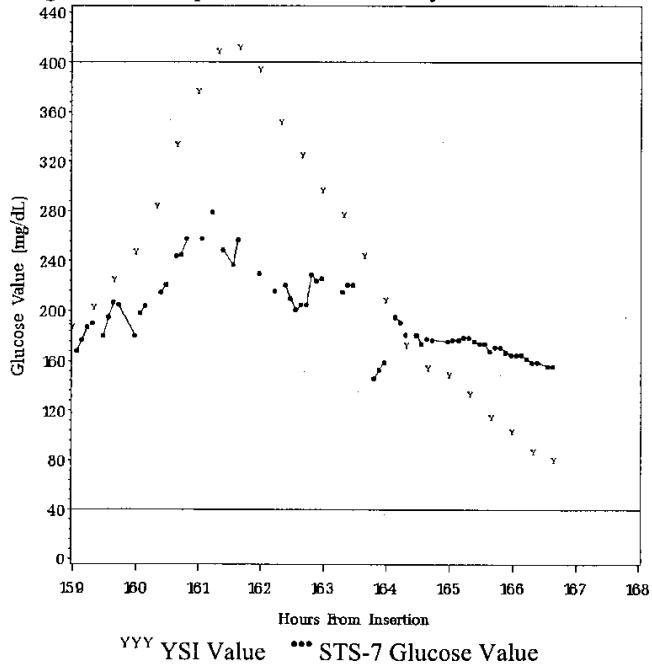
YYY YSI Value ••• STS-7 Glucose Value

Figure 3. Example of "Average" STS-7 System Performance



YYY YSI Value ••• STS-7 Glucose Value

Figure 4. Example of "Poor" STS-7 System Performance



YYY YSI Value ••• STS-7 Glucose Value

ADVERSE EVENTS

No adverse events related to use of the device were reported during the seven-day trial. Overall 89% of patients reported no symptoms of irritation and 11% reported at least one symptom at any insertion site. See Table 11 below for the types of irritation looked for and reported on during the trial.

Table 11. Summary of Irritation Events

Symptoms Reported	% of Patient Reported Events at the STS-7 Sensor Insertion Sites
Redness (Erythema)	10%
Swelling (Edema)	0%
Bruising	1%
Infection	0%

ABBOTT Exhibit 2001
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IPR2023-01251

9.2 PRODUCT SPECIFICATIONS

STS®-7 SENSOR

Glucose Range	40-400 mg/dL (2.2 – 22.2 mmol/L)
Sensor Life	Up to 7 days
Calibration	OneTouch Ultra Blood Glucose
Calibration Range	40-400 mg/dL (2.2 – 22.2 mmol/L)
Operational Conditions	Humidity: Maximum 95 % Relative
Storage Condition	Temperature: 2°-25° C (36°-77° F)
Shelf Life	4 Months
Moisture Protection	IPX 5: water resistance to jetting water IPX 7: temporary submersion to a depth of 3 feet (1 meter) for 30 minutes

STS TRANSMITTER

Dimensions (including STS Sensor Pod)	Length: 1.5 inches (3.8 cm) Width: 0.9 inches (2.3 cm) Thickness: 0.4 inches (1.0 cm)
Weight (including STS Sensor Pod)	.24 ounces (6.7 grams)
Communication Range	5 ft (1.5 m)
Frequency	402-405 MHz
Power Supply	Silver Oxide Batteries
Operational Conditions	Temperature: 10°- 42° C (50°- 108° F) Humidity: Maximum 95 % Relative
Storage Conditions	Temperature: 0°- 45° C (32°- 113° F)
Limited Warranty	1 year
Moisture Protection	IPX 5: water resistance to jetting water IPX 7: temporary submersion to a depth of 3 feet (1 meter) for 30 minutes

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The STS® Transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the STS Transmitter should assure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**STS Transmitter Compliance Level**	**Electromagnetic Environment Guidance**
Electromagnetic Environment Guidance Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical Fast Transient /burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable-Battery Operated	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not Applicable-Battery Operated	
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	Not Applicable-Battery Operated	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power Frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial of hospital environment

Reading Frequency	Every 5 minutes
Dimensions	Length: 4.5 inches (11.4 cm) Width: 2.3 inches (5.8 cm) Thickness: 0.85 inches (2.2 cm)
Weight	3.5 ounces (100 g)
Communication Range	5 ft (1.5 m)
Memory Storage	30 days
Battery Life	5 days
Storage/Operating Conditions	Temperature: 0°- 45° C (32°- 113° F) Humidity: 10-85 % Relative
Power Supply	Rechargeable Battery
Charging Time	3 hours
Limited Warranty	1 year
Moisture Protection	None

Guidance and Manufacturer's Declaration- Electromagnetic Immunity
The STS® Receiver is intended for use in the electromagnetic environment specified below. The customer or the user of the STS Receiver should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	STS Receiver Compliance Level	Electromagnetic Environment Guidance
Electromagnetic Environment Guidance Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical Fast Transient /burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	Main power quality should be that of a typical commercial or hospital environmental.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power Frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial of hospital environment

Note: U_T is the a.c. mains voltage prior to application of the test level

Guidance and Manufacturer's Declaration- Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the STS Receiver, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\ P^{1/2}$ $d = 1.2\ P^{1/2}$ 80 MHz to 800 MHz $d = 2.3\ P^{1/2}$ 800 MHz to 2.5 GHz
Conducted RF IEC 61000-4-6	3 Vrms 150 k Hz to 80 MHz	3 V	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

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

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and STS® Receiver

The STS Receiver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the STS Receiver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the STS Receiver as recommended below, according to the maximum output power of the communications equipment.

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

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

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[illegible]

Length	**1.0 FT (30 CM)**

[illegible]

Length	**6.6 FT (2 M)**

9.3 FCC REQUIREMENTS

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

PH29402

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

The STS Transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although the STS Transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from the STS Transmitter will be free from interference.

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