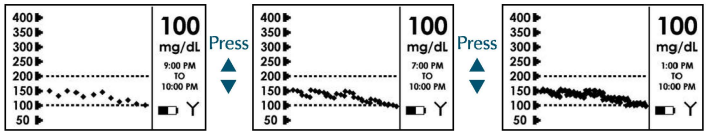
4.1 GLUCOSE TREND SCREENS

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



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

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

WARNING

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

WARNING

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

4.2 RESPONDING TO HIGH AND LOW GLUCOSE ALERTS

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

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

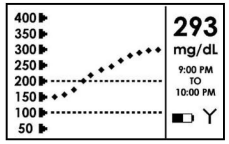


Low Glucose Alert Screen



High Glucose Alert Screen

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



1-Hour Glucose Trend Screen

- If after 5 minutes you do not respond to the first vibratory alert, the STS Receiver will beep once. It will beep loudly again after another 5 minutes if you do not respond to the second alert. You should acknowledge these alerts by pressing any STS Receiver button. The STS Receiver will not re-alert you once you acknowledge the Alert.
- If you do not acknowledge the Alert for any reason, and you are above or below the alert setting and trending up or down, the STS Receiver will re-alert you in 15 minutes.

WARNING

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

4.3 LOW GLUCOSE ALARM

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

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



Low Glucose Alarm

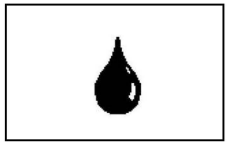
- If you do not acknowledge the vibratory alert, the STS Receiver will then sound a loud beep 5 minutes later. It will continue this vibrating/beeping until you acknowledge the alert.
- To acknowledge and turn off the alarm, press any button on the STS Receiver. If after you turn off the alarm and your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

4.4 MAINTAINING STS™ SENSOR CALIBRATION: 12-HOUR UPDATE

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

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

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



Calibration Update Screen

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

WARNING

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

4.5 MISSING STS™ GLUCOSE INFORMATION (GLUCOSE DATA GAPS)

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

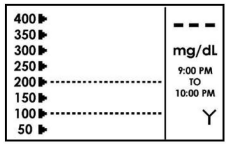
Detailed reasons for Glucose Data Gaps and what you should do to start receiving glucose readings again are described in the sections below.

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

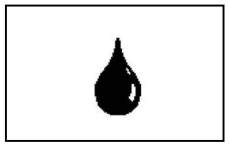
- Anytime you see a "- - -" on the STS Receiver display you should first check to see if the Antenna Icon (Y) is displayed. The STS Transmitter and STS Receiver must be within 5 feet (1.5 meters) of each other.
- If there is no Antenna, move your STS™ Receiver within range and you should receive a glucose value in the next 5 minutes.
- If there is an Antenna on the Display but no glucose values, see sections 4.5.2 and 4.5.3 for other reasons why a Glucose Data Gap may occur.

4.5.2 NOISY STS™ SENSOR GLUCOSE READINGS

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



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



Calibration Update Screen

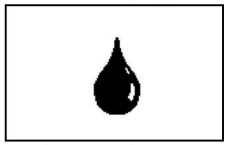
- It is recommended when you see this symbol that you take a fingerstick and upload the BG value to the STS Receiver.

NOTE

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

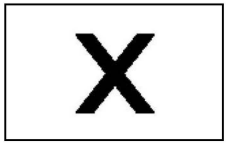
4.5.3 STS™ SENSOR GLUCOSE DATA CHECK & RE-CALIBRATION

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



Calibration Update Screen

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



Out of Calibration Screen

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

NOTE

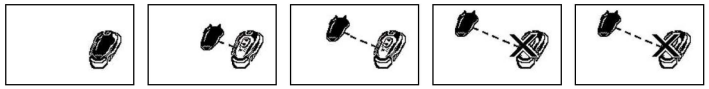
- You should check your STS Receiver in 10 minutes any time you upload BG values to make sure the calibration update was successful (no "X").
- If your DexCom STS System goes Out of Calibration, check your BG values on your meter.
- Remember that the STS Receiver will not provide you with glucose values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

4.6 STS™ SYSTEM EARLY SHUTOFF SCREENS

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

4.6.1 EARLY SHUT-OFF DUE TO SENSOR NOISE

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



STS Sensor Removal Screen

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

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

4.6.2 EARLY SHUT-OFF DUE TO RECEIVER ERROR CODE

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



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

SECTION 5

ENDING YOUR STS™ SYSTEM CONTINUOUS GLUCOSE MONITORING SESSION

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

5.1 ENDING YOUR CONTINUOUS GLUCOSE MONITORING PERIOD

5.1.1 AUTOMATIC STS™ SENSOR EXPIRATION NOTIFICATION

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



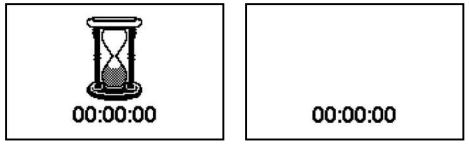
6 hour STS Sensor Expiration Notification



2 hour STS Sensor Expiration Notification



30 minute STS™ Sensor Expiration Notification (+Vibration)

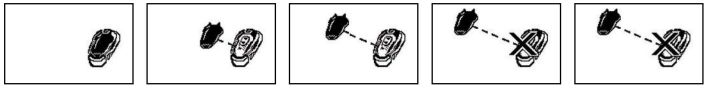


0 hour STS Sensor Expiration Notification (+Vibration)
END OF SESSION

5.1.2 MANUAL STS™ SENSOR SHUT OFF

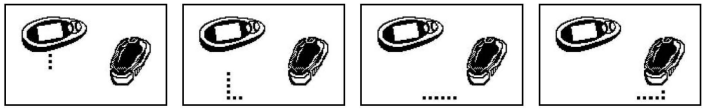
To manually end your continuous glucose monitoring period, follow the steps below:

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



STS Sensor Removal Screen

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



Confirmation Screen

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

NOTE

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

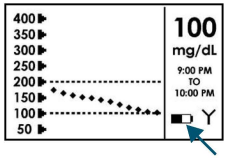
SECTION 6

MONITORING YOUR STS™ RECEIVER BATTERY

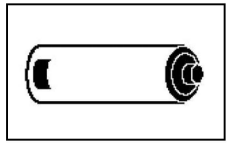
Your STS Receiver battery is rechargeable like a cellular phone. The battery should last for about 5 days before needing to be recharged. The STS Receiver will take 3 hours to fully charge when the battery is completely dead. Periodically check your STS Receiver display to make sure it has enough charge.

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.



Battery Indicator



Low Battery Alert

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

6.2 CHARGING YOUR STS RECEIVER BATTERY

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



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

SECTION 7

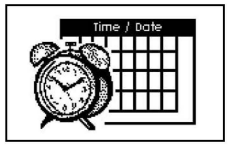
CHANGING STS™ RECEIVER SETTINGS

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

7.1 SETTING THE STS™ RECEIVER TIME

7.1.1 GETTING TO THE STS RECEIVER TIME

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

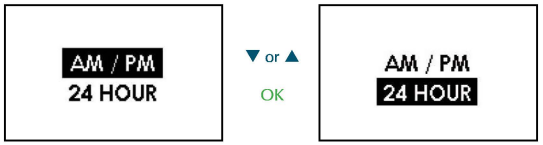


Time / Date Screen

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

7.1.2 CHOOSING THE TIME MODE

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



7.1.3 SETTING THE TIME (AM/PM MODE)

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



- When you choose the hours and minutes, the AM/PM will adjust automatically (e.g. if you go from 11:59 AM to 12:00PM, AM will automatically switch to PM).
- Note: If you pass 11:59 PM the date will automatically update to the next day or the previous day based on the arrow direction you are pressing.
- If you press C at any time, this will not set the time and return you to the STS™ Receiver Time and Date Screen.

NOTE

- The STS Receiver date is pre-programmed at the factory.
- Your STS Receiver time can only be adjusted ± 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.

7.1.4 SETTING THE TIME (24-HOUR MODE)

• If you chose the 24-hour Time Mode:

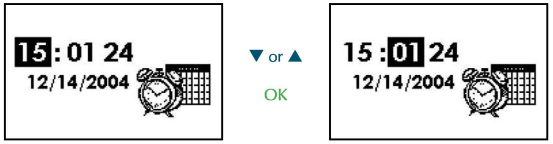


OK

•Press the Up ▲ or Down ▼ Arrows to chose the hour.

•Press the OK Button to move to the minutes.

•Press the Up ▲ or Down ▼ Arrows to choose the minutes.



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

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

NOTE

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

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

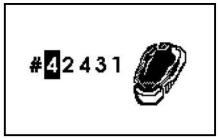
Any time you use a new STS Transmitter as part of your DexCom™ STS System, you must enter the STS Transmitter serial number (SN #) into your STS Receiver. This will begin the wireless radio-frequency (RF) communication between the two devices. To do this perform the following steps:

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



STS Transmitter Serial Number Screen

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



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

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

7.3 CHANGING YOUR GLUCOSE ALERT SETTINGS

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

7.3.1 CHOOSING GLUCOSE VALUE UNITS

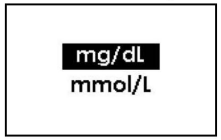
Follow the steps below to choose the type of glucose unit (mg/dL or mmol/L) you would like reported to you. Please note that if you change the alerts to the mg/dL or mmol/L units, all glucose values will be reported to you in that way.

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



Glucose Alert Screen

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



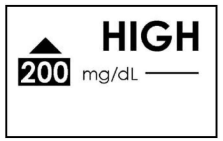
5. Press the Down ▼ or Up ▲ Arrow to select which kind of glucose unit you would like reported (mg/dL or mmol/L). Once you choose the unit you would like (highlighted unit), press the OK Button.

NOTE

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

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

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



•Use the Up ▲ or Down ▼ Arrows to increase or decrease the high glucose alert value by 20 mg/dL (i.e. 220, 240, 260 mg/dL).

•You may select high glucose alert values from 140 mg/dL to 400 mg/dL. Select the value recommended by your Diabetes Management Team by pressing the OK Button.

NOTE

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

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



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

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

NOTE

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

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

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

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



and



•Use the Up ▲ or Down ▼ Arrows to increase or decrease the high and low glucose alert values in the same manner as described above (see Section 7.3.2).

•You may select high glucose alert values from 7.8 mmol/L to 22.2 mmol/L. See the following chart to view the high alert level selection options.

- Select the value recommended by your Diabetes Management Team by pressing the OK Button.
- The chart below displays the high alert level selection options.

mmol/L
Disabled
22.2
21.1
20.0
18.9
17.8
16.6
15.5
14.4
13.3
12.2
11.1
10.0
8.9
7.8

NOTE

If you scroll above 22.2 mmol/L the display will read NO. If you press the OK Button to select this option, you will turn off the high glucose alert. You will not receive any high glucose alerts, even when your the STS™ System is in calibration.

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

mmol/L
5.0
4.4
3.9
3.3
Disabled

NOTE

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

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

SECTION 8

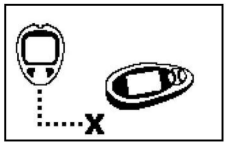
TROUBLESHOOTING

8.1 MISSING ANTENNA

- If you cannot see the Antenna Icon(Y) on your STS™ Receiver, make sure that you have your STS Receiver within 5 feet (1.5 meters) of your STS Sensor Pod and STS Transmitter.
- After checking the position of the STS Receiver wait 5 to 10 minutes to see if the Antenna Icon appears.
- If the Antenna Icon still does not appear, check to see that your STS Transmitter serial number (SN#) is correctly entered into the STS Receiver. Follow the steps found in Section 7.2.
- If none of the above options work, contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664). You may need a new STS Transmitter.

8.2 PROBLEMS UPLOADING BG VALUES TO YOUR STS RECEIVER

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



Connection Failure Screen

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

8.3 TIME DIFFERENCE BETWEEN BG METER AND STS™ RECEIVER

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

8.4 ERROR CODE

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



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

SECTION 9

TECHNICAL INFORMATION

9.1 DEVICE PERFORMANCE CHARACTERISTICS

Performance Characteristics

NOTE

You should 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™ System or STS works.

The STS System uses a glucose Sensor to continuously monitor your glucose levels. The STS Sensor is "calibrated" using your OneTouch® Ultra® blood glucose meter. Once calibrated, the STS System reports glucose values every 5 minutes. In a clinical study, STS values 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 System are given below, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors such as the STS System. Performance may be best understood by viewing graphs called time-elapsed plots. In these plots, the values from the STS 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 100-102, Figures 2-4. They are examples of good, average and poor STS 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 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 System may be idealized.

- The mean Hemoglobin A1c among the 91 participants was 7.6%. Many people with diabetes have higher A1c levels, indicating poorer control of their glucose levels.
- Subjects saw, on average, 6 to 7 fingerstick results per day. This enables subjects to control their glucose levels better.
- 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 System.
- OneTouch Ultra meters used in the study were well maintained. Because the OneTouch Ultra meter is used to calibrate the STS 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 System.

Clinical Study Results

To evaluate performance of the STS System, 91 participants were enrolled in a clinical study conducted at 4 centers. All participants had Type 1 or Type 2 diabetes mellitus, and required insulin to manage their diabetes. About 80% of participants had Type 1 diabetes and about 20% had Type 2 diabetes. Subjects ranged in age from 18 to 79 years of age.

Participants used the STS System for approximately nine days (each participant wore 3 Sensors for 3 days.) STS Receivers were calibrated approximately 3 times per day using the Lifescan One-Touch Ultra meter. Approximately half of the participants used the STS System in a controlled clinic environment for 2 of the 9 days. The remainder of the study took place at home.

While using the STS System in the clinic, 14 participants also 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 System were paired with YSI readings in order to characterize how well STS System results agreed with blood glucose results. For the remainder of the study, STS results were paired with OneTouch Ultra blood glucose meter results when participants were at home. (One OneTouch meter was used to calibrate STS, while a second OneTouch meter was used to collect the comparison blood glucose results.)

Agreement and Accuracy

Agreement between the STS System and blood glucose levels is characterized using matched pairs of STS and YSI results. Each YSI measurement was paired with the STS measurement that was closest in time to it. Agreement between matched pairs was estimated by calculating the percent difference between the STS reading and the YSI reading. For example, if the YSI reading is 100 mg/dL and the STS reading is 90 mg/dL, there is a 10% difference between the two. The mean absolute percent difference is the average of all of the “distances” between STS readings and YSI readings viewed as percentages.

The bias was also calculated. Bias is defined as the average difference between the STS System glucose values and the true glucose value provided by YSI values. Agreement and Bias are summarized in Table 1 below:

Table 1. STS Sensor-Meter agreement during 3-day of use

Number of paired glucose measurements	676
Mean Absolute Percent Difference (±SD)	26% (± 21%)
Bias	Approximately +11% across the measuring range

The agreement of the STS System to blood glucose levels was also assessed by calculating the percentage of STS System values that were within 20%, 30%, and 40% of the YSI reading. For values less than 80 mg/dL the difference was calculated according to the percent falling within 20, 30, and 40 mg/dL. The total number of data pairs considered in this analysis 676. Results are shown in Table 2.

Table 2. Percentage of STS Results Falling Within 20, 30, and 40 Percent of the Paired YSI Result, Stratified According to Glucose Concentration

YSI Readings (mg/dL)	Number of Paired Readings	% of STS Readings Within 20%*	% of STS Readings Within 30%*	% of STS Readings Within 40%*
40-80*	140	56	74	88
81-120	133	44	63	75
121-240	314	46	67	86
241-350**	89	65	81	93

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

** There were no YSI readings above 350 mg/dL observed in these studies.

Performance above 300 mg/dL is characterized by comparing STS results to OneTouch results. This information is presented in Table 3, below:

Table 3. Percentage of STS Results Falling Within 20, 30, and 40 Percent of the Paired OneTouch Meter Result, Stratified According to Glucose Concentration

Blood Glucose Meter Readings (mg/dL)	Number of Paired Readings	% of STS Readings Within 20%*	% of STS Readings Within 30%*	% of STS Readings Within 40%*
>300-350	121	84	98	100
>350-375	32	91	100	100
>375-400	12	83	83	100

The STS System reports glucose concentrations between 40 and 400 mg/dL. When STS determines the glucose level is below 40 mg/dL, it indicates "LOW." If STS determines that the glucose level is above 400 mg/dL, it indicates "HIGH." The ability of the STS 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 20 occasions STS indicated the glucose level was less than 40 mg/dL. Of these, 4 times the glucose level was below 40 mg/dL. The actual range of glucose concentrations was 18-90 mg/dL compared to YSI.
- There were 37 occasions when STS indicated the glucose level was above 400 mg/dL. Of these, 3 times the glucose level was above 400 mg/dL. The actual range of glucose concentrations was 245-445 mg/dL compared to YSI.

The Clarke Error Grid was used to determine if STS results are "clinically accurate". The Clarke Error Grid divides a correlation plot into 5 zones, which are described in Table 4.

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

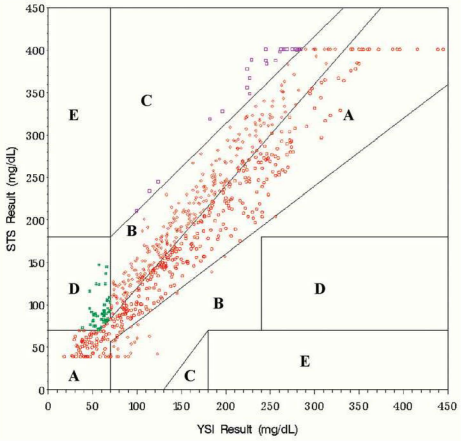
Table 4. Clarke Error Grid Description

Zone	Description
A	Clinically Accurate, would lead to correct treatment decisions
B	Would lead to small corrections that would keep a normal glucose level state or would cause no treatment decision
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 erroneous and "dangerous" treatment decisions

Figure 1 is a correlation plot. Each YSI result (on the horizontal axis) is matched up with its corresponding STS result (on the vertical axis). A point is recorded where the two values intersect. There are 733 paired data points recorded.

The measuring range of the YSI is 0-900 mg/dL while the measuring range of the STS System is 40-400 mg/dL. In the graph below, if STS indicated "LOW" then the reading is recorded as 40 mg/dL. If STS indicated "HIGH" then the reading is recorded as 400 mg/dL.

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



The percentage of STS System results in the above graph are presented in Table 5 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 5. Stratified Clarke Error Grid Analysis

YSI Readings (mg/dL)	Number of Paired Readings	A+B %	A %	B %	C %	D %	E %
<=80 mg/dL	156	69%	52%	17%	0%	31%	0%
81-120 mg/dL	137	99%	44%	55%	2%	N/A	N/A
121-240 mg/dL	314	98 %	46%	51%	3%	N/A	0%
>240 mg/dL	126	87%	57%	29%	14%	0%	0%
Total (40-400 mg/dl)	733	90%	49%	41%	4%	7%	0%

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

Low and High Glucose Alerts

The ability of the STS System to detect high and low glucose levels is assessed by comparing STS results to YSI results at low and high glucose concentrations, and when the alert sounds. There were 733 pairs of matched STS and YSI results evaluated. We suggest that you ask your doctor what settings are 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, if you set the STS Low Glucose Alert to 70 mg/dL, the STS System will alert when glucose levels drop below 70 mg/dL 57% of the time. Additionally, 24% of the time when the alert sounds, the glucose level will actually be above 70 mg/dL. If you set the STS the Low Glucose Alert to 90 mg/dL, the STS System will alert when glucose levels drop below 90 mg/dL 68% of the time. At this alert level, 9% of the time when the alarm sounds, the glucose level will actually be above 90 mg/dL.

Table 6. Hypoglycemic Alert Evaluation

STS Alert Level	True Alert Rate*	False Alert Rate**
60 mg/dL	54%	36%
70 mg/dL	57%	24%
80 mg/dL	62%	13%
90 mg/dL	68%	9%

*True Alert Rate is the % of time when the glucose level was at or below the alert setting and the alert would have sounded.
**False Alert Rate is the % of time when the device would have sounded but the blood glucose level was above the alert level.

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 High Glucose Alert to 200 mg/dL, the STS System will alert when glucose levels rise above 200 mg/dL 98% of the time. Additionally, 31% of the time when the alert sounds, the glucose level will actually be below 200 mg/dL.

Table 7. Hyperglycemic Alert Evaluation

STS Alert Level	True Alert Rate*	False Alert Rate**
140 mg/dL	99%	21%
180 mg/dL	98%	24%
200 mg/dL	98%	31%
240 mg/dL	96%	43%
300 mg/dL	97%	67%

*True Alert Rate is the % of time when the glucose level was at or above the alert setting and the alert would have sounded.
**False Alert Rate is the % of time when the device would have sounded but the blood glucose level was below the alert setting.

Calibration Stability

The STS System should be calibrated every 12 hours. To demonstrate performance of the STS System over a 12-hour calibration period 91 Sensors were evaluated to verify that performance remains consistent over the 12 hour calibration period, a portion of STS Systems are evaluated in 3 hour increments after calibration. Performance is assessed by comparing the % of STS Sensor readings falling within 20, 30, and 40 % of the One-Touch reading in each 3 hour period. Minimal deterioration in performance is noted. See Table 8, below.

Table 8. Percentage of STS Readings Falling Within 20, 30, and 40% of OneTouch Readings With Data Stratified in Three Hour Increments After Calibration

Time After Calibration (hours)	% of STS Readings Within 20%*	% of STS Readings Within 30%*	% of STS Readings Within 40%*
0-3	62	79	89
3-6	63	79	88
6-9	59	81	91
9-12	58	74	85

*The difference from the OneTouch is measured in mg/dl if the meter reading is less than 80 mg/dL.

The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

Sensor Stability

STS Sensors may be worn up to 72 hours. To verify that sensors perform consistently over the 72 hour period, 91 Sensors were evaluated in 12 hour increments after insertion. Performance is assessed by comparing the % of STS results falling within 20, 30, and 40% of the OneTouch result in each 12 hour increment after the STS Sensor is inserted.

Table 9. Percentage of STS Readings Falling Within 20, 30, and 40% of OneTouch Readings With Data Stratified in 12 Hour Increments After Sensor Insertion

Time After Insertion (hours	% of STS Results Falling Within 20%*	% of STS Results Falling Within 30%*	% of STS Results Falling Within 40%*
0-12	64	82	91
12-24	63	79	88
24-36	59	76	86
36-48	63	79	88
48-60	58	77	87
60-72	62	81	91

*The difference from the SMBG reading is measured in mg/dL if the meter reading is less than 80 mg/dL or in percent if the meter reading is 80 mg/dL or higher.

Precision of STS System Readings

A separate study of 20 subjects, wearing two STS Systems each was also conducted. This study was designed to look at how similar two STS Systems on the same person function (Sensor Precision). Precision was evaluated by comparing the glucose readings from the two STS Systems. Results showed that STS Systems generally agreed with each other within 21%.

Sensor Life

Sensors may be used for up to 72 hours. Ninety-one sensors were evaluated to estimate how many sensors continued to work up to 72 hours. Table 10, below, displays how long you can expect a sensor to last. For example, 75% of the sensors lasted between 65 and 72 hours.

Table 10. Estimated Sensor Life

Hours of Use	Percentage of Sensors
4-18 hours	8%
20-35 hours	6%
45-64 hours	11%
65-72 hours	75%

Of the 24 sensors that did not last beyond 64 hours, approximately two-thirds of them became nonfunctional because of device failure and one-third of them fell off the inserted site. Almost all STS failures occurred in the first two days.

Number of Readings Provided

The STS 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 or readings are skipped. Table 11 below, estimates the number of readings you can expect to get from the STS System per day. For example, 47% of STS devices provided between 251 and 288 readings per day.

Table 11. Number of Readings Provided by Each Sensor per Day

Range of Readings Provided per Day	% of STS Devices Providing that number of readings
0-1	10%
36-151	10%
168-220	11%
221-250	22%
251-288	47%

Approximately 17% of readings were lost because the Transmitter was more than 5 feet away from the Receiver. Most other results were lost because an error was detected during calibration, causing a delay in obtaining results. (The error may be operator related or because of an algorithm problem.)

Time-Elapsed Plots

Example of STS continuous glucose monitoring overlaid with the corresponding YSI readings over time are presented below. The horizontal axis represents time, with the matching STS and YSI readings plotted above the point in time when the measurements were taken. The circles (•) on the graph represent the STS data, connected by a line. The "Y"s represent the YSI reading.

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

Figure 2. Example of "Good" STS Performance

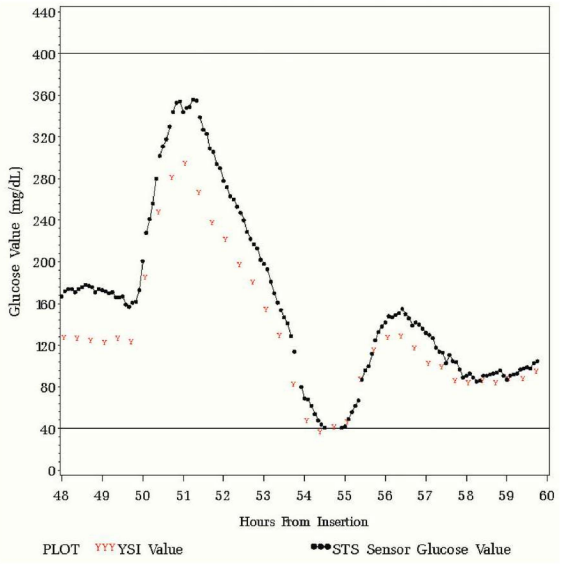


Figure 3. Example of "Average" STS Performance

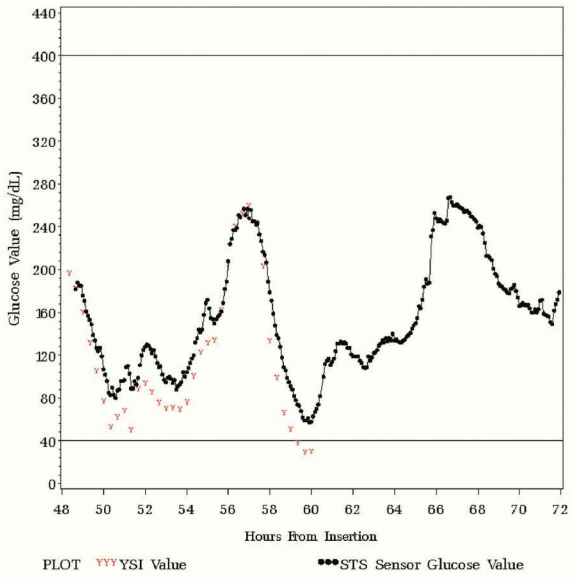
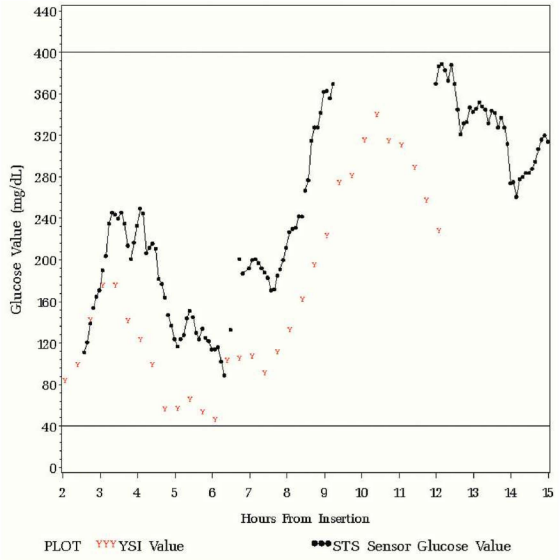


Figure 4. Example of "Poor" STS Performance



Adverse Events

Twenty-one (21) adverse events were reported in 16 of 91 study participants. These events consisted of 2 blisters, 2 reports of edema (swelling), and 17 reports of erythema (redness). All were mild and required no treatment.

9.2 PRODUCT SPECIFICATIONS

STS™ SENSOR

Glucose Range	40-400 mg/dl (2.2 – 22.2 mmol/l)
Sensor Life	Up to 3 days
Calibration	Blood Glucose Measurement-Fingerstick Value
Calibration Range	40-400 mg/dl (2.2 – 22.2 mmol/l)
Operational Conditions Humidity	Humidity: Maximum 95 % Relative
Storage Conditions	Temperature: 2°-25° C (36°-77° F)
Shelf Life	6 Months

STS TRANSMITTER

Dimensions (including STS Sensor Pod)	Length: 1.8 inches (4.6 cm) Width: 1.2 inches (3.0 cm) Thickness: 0.4 inches (1.0 cm)
Weight (including STS Sensor Pod)	.32 ounces (9 grams)
Communication Range	5 ft (1.5 m)
Frequency	402-405 MHz
Power Supply	Lithium Battery
Display	Liquid Crystal Display (LCD)
Operational Conditions Humidity	Temperature: 10°- 42° C (50°- 108° F) Humidity: Maximum 95 % Relative
Storage Conditions	Temperature: 0°- 45° C (32°- 113° F)
Limited Warranty	6 months

PARAMETER	PERFORMANCE CHARACTERISTICS
Frequency Allocation	MICS Band
TX/RX Frequency	402.142MHz
Bandwidth	300kHz
Maximum Output Power	25uW EIRP
Modulation	On-Off Key
Data Rate	8192 bits/Sec
Total Packet	48 bits
Transmit Duty Cycle	5.86ms every 5 minutes
Data Corruption Detection CRC	
Range	5ft
Probability of Transmission Overlap due to Coexistence - 20 DexCom STS Tramsnitters - within 15 feet	<1% probability of Transmission Overlap; if overlap 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

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

STS™ RECEIVER

Reading Frequency	Every 5 minutes
Dimensions	Length: 4.5 inches (11.4 cm) Width: 2.3 inches (5.8 cm) Thickness: 0.85 inches (2.2 cm)
Weight	3.5 ounces (100g)
Communication Range	5 ft (1.5 m)
Battery Life	5 days
Memory Storage	30 days
Storage/Operating Conditions	Temperature: 0°- 45° C (32°- 113° F) Humidity: 10-85 % Relative Humidity
Power Supply	Rechargeable Battery
Charging Time	3 hours
Limited Warranty	6 months

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