

DEXCOM™ STS™-7 CONTINUOUS GLUCOSE MONITORING SYSTEM

Transmitter model number 9400-02



STS™ -7 Sensor & STS™ Applicator



STS™ -7 Sensor & STS™ T2 Transmitter



STS™ R2 Receiver

www.DexCom.com

Technical Support at
1-877-(DEXCOM4) 339-2664.



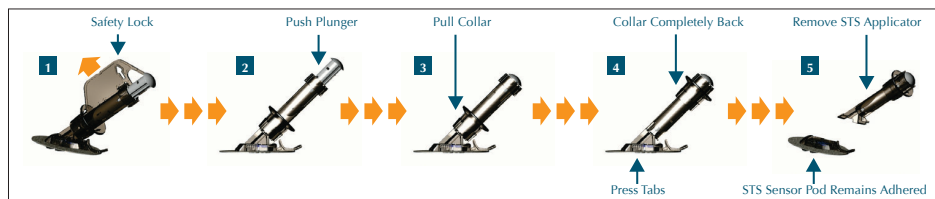
WARNING

Treatment decisions should not be based solely on results from the DexCom STS-7 System. You must confirm with a blood glucose meter before making therapeutic adjustments.

***MAKE SURE YOUR STS R2 RECEIVER IS CHARGED BEFORE YOU BEGIN.**

STARTING CONTINUOUS GLUCOSE MONITORING

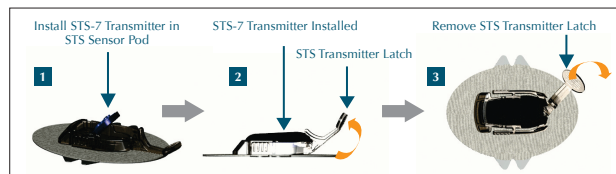
STEP 1 INSERTING A NEW STS™ -7 SENSOR



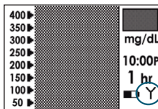
Choose a site on your abdomen (belly) to put the STS-7 Sensor that is a flat area and where you don't have any scarring or rough patches of skin and clean the site with an alcohol swab.

1. Remove the adhesive backing from the STS Sensor Pod and place the STS-7 Sensor on the selected site. Pull the safety lock out from the STS Applicator (pull near the arrow).
2. Place 2 fingers under the collar, with your thumb on the plunger, and push the plunger down completely.
3. Pull the collar back completely until you hear a click.
4. Press the tabs on the sides of the STS-7 Sensor and pull off the STS Applicator.
5. The STS Sensor Pod remains adhered to the skin after the STS Applicator is removed.

STEP 2 INSTALLING YOUR STS™ T2 TRANSMITTER



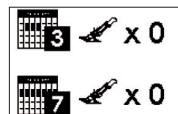
1. Place the STS T2 Transmitter into the STS Sensor Pod with the flat side facing down.
2. Pull the STS Transmitter Latch up onto the STS T2 Transmitter to snap it into place.
3. Remove the STS Transmitter Latch by holding the end of the latch and quickly twisting off the latch away from your body.
4. Press any buttons on the STS R2 Receiver to check for the Antenna Icon (Y) at the bottom right hand corner of the screen. If the Antenna Icon appears in the upper right hand corner of the screen, refer to your User's Guide



STEP 3 ENTERING A STS LICENSE CODE

1. Press the Down ▼ Arrow 3 times until you come to the 9-hour Glucose Trend Screen. Then hold the Down ▼ Arrow for at least 7 seconds until you see the STS License Code Screen (If you have already inserted a STS-7 Sensor, press the Down ▼ Arrow 1 more time to get to the STS License Code Screen):
2. Use the Up ▲ and Down ▼ Arrows to enter the STS License Code found in your shipment and press the OK button to confirm the STS License Code.

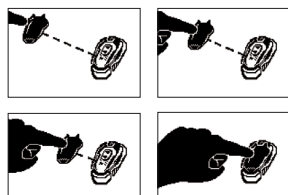
#00000



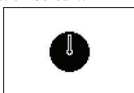
Press the OK button.

STEP 4 HOW TO START YOUR CONTINUOUS GLUCOSE MONITORING SESSION

1. Press the Down ▼ Arrow 3 times until you come to the 9-hour Glucose Trend Screen. Then hold the Down ▼ Arrow for at least 7 seconds until you see the STS Sensor Insertion Screen (If you have already entered a STS License Code).



2. Press the OK button to confirm Sensor Insertion and you will see the following Confirmation Screen:



3. Your Start-Up Period begins once you press the OK button.

STEP 5 CALIBRATING YOUR STS™-7 SYSTEM

1. **Dual Blood Drop Prompt:** After 2 hours the STS R2 Receiver will vibrate and display the Dual Blood Drop Prompt to alert you to calibrate the STS-7 Sensor. Press the C Button to clear the prompt.



1. Dual Blood Drop Prompt

2. **Meter Connection Screen:** After you take 2 fingersticks using your blood glucose meter, upload the values to your STS R2 Receiver. Upload the meter values to the STS R2 Receiver by plugging the connection cable into the meter first (the meter must be off) and then into the STS R2 Receiver. The Meter Connection Screen ("PC") will appear on your blood glucose meter.



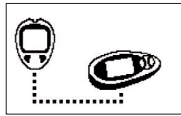
2. Meter Connection Screen

Confidential

Draft Under FDA Review

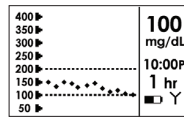
STEP 5 CALIBRATING YOUR STS™-7 SYSTEM (CONTINUED)

3. **Receiver Connection Screen:** The Receiver Connection Screen will appear on the STS R2 Receiver while the BG values are being transferred from the meter to the STS R2 Receiver.



3. Receiver Connection Screen

4. **1-Hour Trend Screen:** Once the upload is complete the 1-Hour Trend Screen will appear. Disconnect the cable from the meter and STS R2 Receiver. A glucose value should appear in about 15 minutes and glucose values will be updated every 5 minutes.



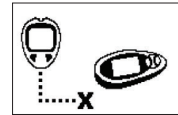
4. 1-Hour Trend Screen

RECEIVER CALIBRATION ALERT SCREENS

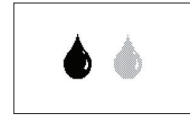
DURING CALIBRATION YOU MAY SEE THE FOLLOWING SCREENS:



1. New Meter Screen



2. Connection Failure Screen



3. Shaded-Out Blood Drop Prompt

1. **New Meter Screen:** Indicates that you have connected a new meter to the STS R2 Receiver. Press **OK**. You must re-take the fingersticks and connect the meter to the STS R2 Receiver.
2. **Connection Failure Screen:** Indicates the meter and STS R2 Receiver are not connected properly. If you see this screen the meter values will not be transferred successfully. Clear the alert by pressing

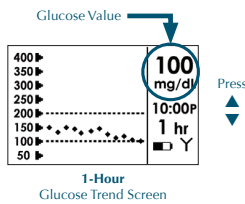
any button and disconnect the cable from the STS Receiver. Make sure the meter is off and reconnect the cable to the STS R2 Receiver (the cable must be plugged into the meter first).

3. **Shaded-Out Blood Drop Prompt:** Notifies you that 1 more fingerstick is needed for calibration. Take another fingerstick and upload it to your STS R2 Receiver.

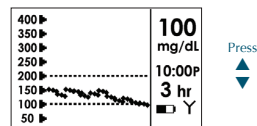
CONTINUOUS MONITORING

VIEWING YOUR CONTINUOUS GLUCOSE INFORMATION

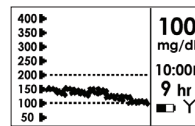
You can view glucose trends and patterns using the 1-hour, 3-hour, and 9-hour Glucose Trends Screens. (See screens below).



1-Hour Glucose Trend Screen



3-Hour Glucose Trend Screen



9-Hour Glucose Trend Screen

STS™ R2 RECEIVER ALERT SCREENS

The device may vibrate and/or beep and display one of the following screens during use: Always take a fingerstick before you make any treatment decisions.

1. **Calibration Update Screen:** If the Calibration Update Screen appears you should clear the prompt, take a fingerstick using your meter, and upload the meter value to the STS R2 Receiver.



1. Calibration Update Screen

2. **Low Glucose Alert:** The STS R2 Receiver will vibrate/beep if your current STS-7 Sensor glucose value is below the Low Alert setting. Press any button on the STS R2 Receiver to acknowledge the alert; if you do not the STS R2 Receiver will continue to alert you for the next 10 minutes. The Factory Low Alert setting is 80 mg/dL. You should work with your diabetes management team to determine the best alert setting for you. (Take a fingerstick before you make any treatment decisions.)



2. Low Glucose Alert

3. **High Glucose Alert:** The STS R2 Receiver will beep/vibrate if your current STS-7 Sensor glucose value is above the High Alert setting. Press any button on the STS R2 Receiver to acknowledge the alert; if you do not the STS R2 Receiver will continue to alert you for the next 10 minutes. The Factory High Alert setting is 200 mg/dL. You should work with your diabetes management team to determine the best alert setting for you. (Take a fingerstick before you make any treatment decisions.)



3. High Glucose Alert

4. **Low Glucose Alarm:** In addition to your personal glucose alert settings, your STS R2 Receiver will beep/vibrate if your glucose falls below 55 mg/dL. Press any button to acknowledge the alert if you do not the STS R2 Receiver will continue to alert you every 5 minutes.

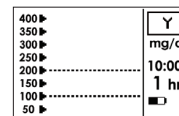


4. Low Glucose Alarm

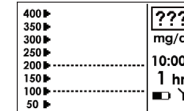
STS™ R2 RECEIVER GLUCOSE DATA GAPS

If the STS-7 System is not displaying glucose values it could be for the following reasons:

1. Your STS™ T2 Transmitter and STS R2 Receiver are not communicating. The Antenna Icon will appear in the upper right hand corner of the screen (there is no Antenna Icon (Y) in the bottom right hand corner of the screen). Make sure your STS R2 Receiver and STS T2 Transmitter are within 5 ft. of each other.



2. Your STS-7 Sensor is sending the STS R2 Receiver "noisy" glucose readings that the STS R2 Receiver will not display.



Once the "noise" stops, your STS R2 Receiver will display glucose values again.

3. If you upload a fingerstick to update calibration you may see the Calibration Update Screen due to the fingerstick not closely matching your STS-7 System glucose readings. Take a fingerstick and upload it to the STS R2 Receiver to update calibration.

STS™ RECEIVER EARLY SHUT-OFF SCREENS

You may see the STS Sensor Removal Screen during your continuous glucose monitoring session. If the screen below appears your the STS-7 Sensor has notified the STS R2 Receiver that STS-7 Sensor is no longer good. Remove the STS-7 Sensor and insert a new one.



STS Sensor Removal

ERROR CODE

The error code indicates the STS R2 Receiver is not functioning properly. Note the Error code, use your meter to check your blood glucose readings, and contact Dexcom Technical Support at 1-877-DEXCOM4 (339-2664) immediately. Your Continuous Glucose Monitoring Session is finished and you should remove the STS-7 Sensor.



ENDING YOUR CONTINUOUS GLUCOSE MONITORING SESSION

STS™-7 SENSOR EXPIRATION NOTIFICATION

The STS R2 Receiver will display screens that notify you how long you have until the end of your Continuous Glucose Monitoring Session. You will be notified at 6 hours, 2 hours, 30 minutes before your session ends, and when your session is finished.



6 hour STS Sensor Expiration Notification



2 hour STS Sensor Expiration Notification



30 minute STS Sensor Expiration Notification



0 hour STS Sensor Expiration Notification

Confidential

Draft Under FDA Review

© DexCom 2006 All rights reserved

FCC REQUIREMENTS

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

PH29402

The STS T2 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 T2 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 T2 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 T2 Transmitter will be free from interference.