

Therasense Confidential

TheraSense
Continuous Glucose Monitoring System

Therasense Confidential

July 8, 2002

Therasense Confidential

Therasense Confidential

Table of Contents

Therasense Confidential

Preface	iii
Safety and Precautions	iv
Important Information About Your Continuous Glucose Monitor	iv
Important Health Related Information	iv
Help is Available	iv
Learning the System	1
Introduction	1
The Complete System	1
Receiver	1
Transmitter	2
Sensor Support Mount and Inserter	2
FreeStyle Test Strip	3
Lancing Device	4
The Receiver/Transmitter Connection	4
Using the System	5
Operating the Receiver	5
Selecting a Menu Option	5
Replacing the Sensor	6
Removing the Old Sensor	6
Inserting a New Sensor	7
Testing Your Blood Glucose	10
When to Perform a Blood Glucose Test	10
Using the Lancing Device	13
Checking the System	15
When to Perform a Control Solution Test	15
Important Information about the Control Solution	15
How to Perform a Control Solution Test	15
Control Solution Results	17
Troubleshooting	19
Error Codes	19
Error Messages	19
Problems	21

Therasense Confidential

Therasense Confidential

Therasense Confidential

Preface

Therasense Confidential

The TheraSense Continuous Glucose Monitor is intended for use... [I still do not have an intended use statement](#). It should not be used for the diagnosis of diabetes?

The TheraSense Continuous Glucose Monitor helps people with diabetes monitor their sugar (glucose) level. The system provides glucose values on a continual basis allowing you to see patterns in your glucose levels.

The Continuous Glucose Monitor System includes:

- a sensor, which is inserted under your skin and takes glucose measurements for up to 72 hours
- a wireless transmitter that connects to the sensor and sends glucose results to a receiver
- a wireless receiver that captures and displays the glucose measurements sent by the transmitter

Glucose levels are measured and displayed every 3 minutes from a tiny sensor inserted just below the surface of your skin. The top of the sensor sits above the skin and connects to a transmitter, which sends glucose readings to a receiver that you keep with you like a pager. The receiver displays the glucose values, and also functions as a FreeStyle blood glucose meter, allowing you to perform discrete blood glucose tests using a FreeStyle Test Strip.

By getting more frequent glucose results over time, you can monitor your glucose levels more closely and gain more control of your diabetes. Understanding the continuous trend of glucose levels, rather than several isolated readings will help you and your healthcare professional to adjust your treatment plan and understand how your diet, insulin, exercise, and medication are affecting your diabetes.

Therasense Confidential

Safety and Precautions

Important Information About Your Continuous Glucose Monitor

- **Therasense Confidential** Before using the Continuous Glucose Monitor to test your glucose, read this owner's booklet and practice the testing procedures.
- Glucose monitoring should be done with the guidance of a healthcare professional.
- Do not leave a sensor inserted under your skin for more than 3 days (72 hours).
- Do not fly on an airplane while you are wearing a transmitter.
- Do not swim in salt water.
- Do not drop the receiver or allow it to get wet.
- The receiver should be used only with the FreeStyle Test Strips and Control Solution. Using other brands of test strips or control solution with the receiver can give you inaccurate results.

Important Health Related Information

- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
- Test results below 60 mg/dL (3.3 mmol/L) mean low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L) mean high blood glucose (hyperglycemia).
- If you get results below 60 mg/dL or above 240 mg/dL, and you do not have symptoms of hypoglycemia or hyperglycemia, repeat the test. If you have symptoms or continue to get results that fall below 60 mg/dL or above 240 mg/dL, follow the treatment advice of your healthcare professional.
- If you are experiencing symptoms that are not consistent with your blood glucose test results AND you have followed all instructions described in the *Continuous Glucose Monitor Owner's Booklet*, call your healthcare professional.

Help is Available

Help is available from your clinical trial site coordinator 24 hours a day, 7 days a week. Your site coordinator will provide you with contact information. You may also visit our website at www.therasense.com.

If the receiver displays an error message or if you have any questions about your TheraSense Continuous Glucose Monitor, call:

during business hours (8:00 am to 5:00 pm PST): _____

nights and weekends: _____

Therasense Confidential

Learning the System

Therasense Confidential

Introduction

The Continuous Glucose Monitor System... (Neil, still waiting for mktg literature that talks about the product features) (readings are taken from interstitial fluid, sensor is inserted under the skin and worn for 72 hours,

Would be good to have an illustration (line drawing) showing the relationship between receiver and transmitter while the transmitter is being worn with the sensor.

The Complete System

The Continuous Glucose Monitor System includes:

- a sensor, which is inserted under your skin and takes glucose measurements for up to 3 days (72 hours)
- a wireless transmitter that connects to the sensor and sends glucose results to a receiver
- a wireless receiver that captures and displays the glucose measurements sent by the transmitter

Receiver

The receiver is like a pager. You may wear it on your belt or carry it in your pocket or purse. It receives glucose readings sent from the transmitter. You can see the readings, which are updated about every 3 minutes, on the display screen. The receiver also acts as a FreeStyle blood glucose meter, allowing you to perform regular blood glucose tests using a FreeStyle test strip. Refer to “Testing Your Blood Glucose” on page 10 for information on performing a FreeStyle test with the receiver.



NOTE: To conserve on battery power, the receiver screen goes blank after 10 seconds. To turn on the display, simply press the right selection button.

Therasense Confidential

Transmitter

The transmitter is a small electronic device that gets glucose readings from the sensor, inserted under your skin, and sends them to the receiver. Always keep the receiver within 10 feet of the transmitter.

Therasense Confidential

Contact points
Connect to the sensor support mount.



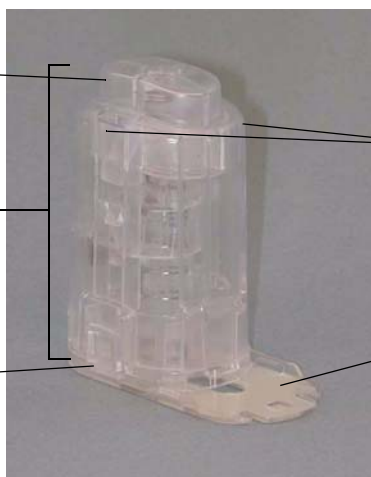
Sensor Support Mount and Inserter

The sensor is a small device that is attached to the support mount. The tiny tip of the sensor is placed just below the surface of your skin by the sensor inserter. The top of the sensor connects to the transmitter. The sensor takes the glucose readings from under the skin.

Plunger
Fires a needle into the skin, placing the tip of the sensor just below the surface of the skin.

Sensor inserter
Used to insert the sensor in the skin.

Release tabs
Releases the sensor inserter from the support mount after the sensor is inserted in the skin.



Safety tabs
Unlock the sensor inserter to prepare it for firing. Press the safety tabs when you are ready to insert the sensor into the skin.

Sensor support mount
Sticks to the skin and holds the sensor in place. The transmitter slides onto a track on top of the support mount.

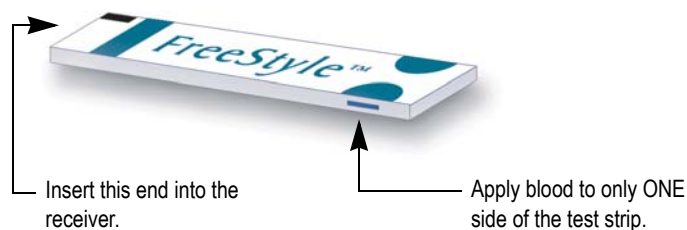
Sensor (not visible)
Located in the support mount. Measures your glucose levels. The tip of the sensor is inserted just below the surface of your skin.

Therasense Confidential

FreeStyle Test Strip

Use the FreeStyle Test Strip to run a FreeStyle blood glucose test. The receiver will prompt you to “perform a blood glucose test” each time you insert a new sensor and then periodically after that.

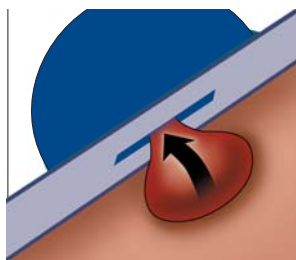
Apply blood to *only one side* of the test strip for each test.



IMPORTANT: Do not apply blood to both sides.



Gently touch one edge of the test strip to the blood sample.



The blood sample will be pulled up into the test strip.

Important Test Strip Information

For detailed information on FreeStyle Test Strips, refer to the *FreeStyle Test Strips* package insert.

- Store the test strip package in a cool, dry place below 86°F (30°C). Do not refrigerate or freeze.
- Keep away from direct sunlight and heat.
- Store test strips in their original vial only. Never transfer test strips to another vial or container. Do not store individual test strips in your carrying case. See your clinical trial site coordinator to get additional test strips.
- To ensure accurate results, use the test strips at room temperature.
- After removing a test strip from the vial, immediately replace the vial cap and close tightly.
- With clean, dry hands, you may gently touch the test strip anywhere when removing it from the vial or inserting it into the receiver.
- Do not use test strips beyond the expiration date printed on the package or you may get inaccurate results.
- Do not use test strips that are bent, cut, torn, or altered in any way.

WARNING: Keep the test strip vial away from children. The cap is a choking hazard. The cap contains a pouch filled with a drying agent that may be harmful if inhaled or swallowed and may cause skin and eye irritation.

Lancing Device

Use the lancing device to get a blood sample when you perform a FreeStyle blood glucose test.

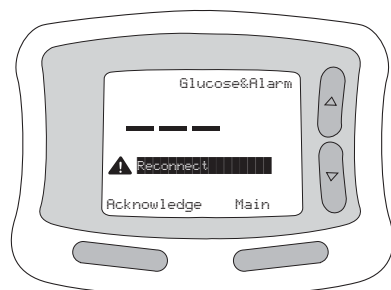


The Receiver/Transmitter Connection

The receiver and the transmitter must be kept within 10 feet of one another for glucose readings to be successfully transmitted. If the receiver is moved more than 10 feet from the transmitter, the connection will be broken and the receiver will not be able to receive glucose readings.

When the connection is broken, the following screen appears and the receiver beeps once every minute. To silence the alarm, move the receiver within 10 feet of the transmitter.

NOTE: If you hear the receiver beep, check the display screen for a message. Refer to the Troubleshooting section for information on the receiver messages.



Therasense Confidential

Using the System

Therasense Confidential

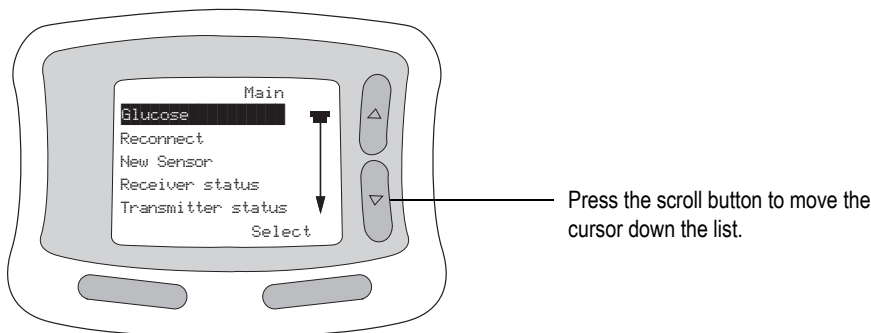
Operating the Receiver

In addition to continually displaying glucose readings, the receiver displays messages to help you use the system and to inform you of problems. Some messages prompt you to make a selection or perform a task. Use the buttons on the front of the receiver to acknowledge the information displayed and make selections.

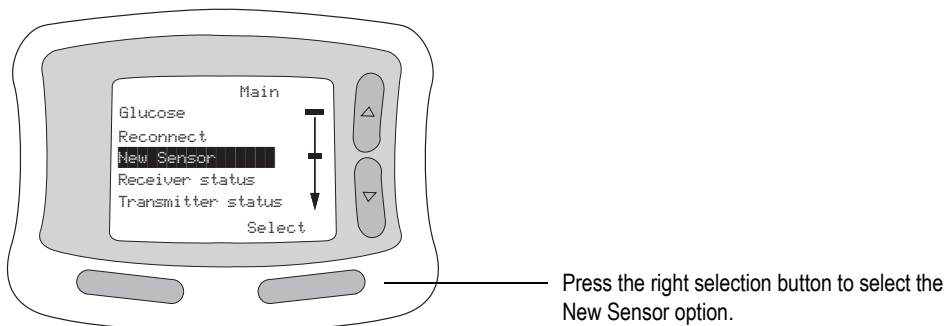
- Use the scroll buttons on the right to scroll through a list or increase or decrease a number when entering the test strip code, for example.
- Use the selection buttons on the bottom to select the option.

Selecting a Menu Option

- 1 To select an option from the main menu, use the scroll button on the right to move the cursor up or down the list.



- 2 Press a selection button on the bottom to select the option displayed on the screen just above the button. In this example, press the right button to select **New Sensor**.



Therasense Confidential

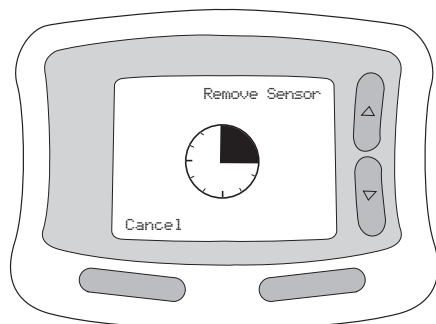
Replacing the Sensor

Once inserted, a sensor can be left in place for 3 days (72 hours). After 72 hours the receiver prompts you to remove the old sensor. After you remove the old sensor and insert a new one, the receiver will prompt you to perform a FreeStyle blood glucose test.

Therasense Confidential

Removing the Old Sensor

The receiver will prompt you to remove the used sensor.



- 1 Select **Cancel**, then choose **New Sensor** from the main menu.
- 2 Spray a small amount of adhesive remover around the edges of the support mount. (Or, moisten a cotton ball with the adhesive remover, then dab the cotton ball around the edges of the support mount.)
Allow the adhesive remover to soak under the support mount.
- 3 With the transmitter still attached to the support mount, grasp the edge of the support mount and slowly peel it off of your skin in one continuous motion.

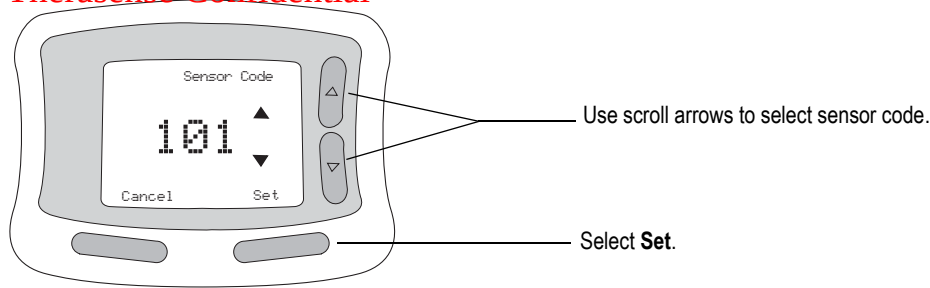


- 4 Slide the transmitter off the support mount and discard the support mount. It cannot be reused. Do not discard the transmitter.
- 5 Gently wash the contact points on the transmitter with soapy water. Rinse thoroughly. Shake the transmitter to remove excess water, then blot the contact points on a soft cloth or lint-free paper towel or tissue. Set it aside.
- 6 If necessary, use the adhesive remover, baby oil, or a wet, soapy wash cloth to remove any adhesive residue left on your skin.

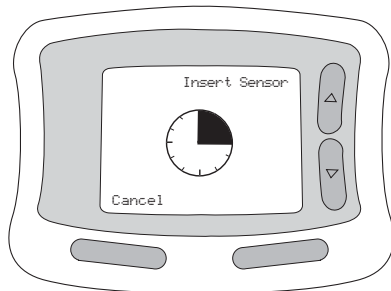
Therasense Confidential

- 7 The receiver can detect that the sensor has been removed and will automatically prompt you for the code number of the new sensor. The code number can be found on the foil package. Use the scroll arrows to display the correct code, then select **Set**.

Therasense Confidential



- 8 When the code number has been set, the receiver prompts you to insert the new sensor. Refer to “Inserting a New Sensor” in the following section for information.



Inserting a New Sensor

Before inserting a new sensor, be sure you have the following materials:

- sensor inserter (in its unopened, foil package)
- transmitter
- receiver
- soap and water

- 1 Select an insertion site. You can insert the sensor at one of the following sites:
- on the middle of your abdomen at least 2 inches away from your navel and above the belt line
 - on the backside of your upper arm

NOTE: Avoid areas where the edges of clothing may catch or rub against the sensor. Avoid inserting the sensor in the same place as it was previously inserted.

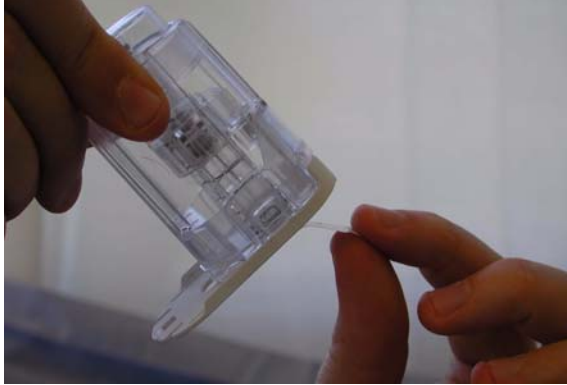
- 2 Wash your hands thoroughly with soap and water.
- 3 Clean the insertion site with soap and water. Be sure to thoroughly rinse and dry the area.
- 4 Carefully disable the safety mechanism by squeezing the safety tabs on the sides of the plunger. You may find it easier to press one safety tab at a time.

CAUTION! Once the safety tabs are pressed, the sensor inserter will fire if the plunger is depressed. Be careful not to press the plunger until you have correctly placed the sensor inserter on the skin and are ready to insert the sensor.

Therasense Confidential

GRAPHIC squeezing safety tabs/pulling pin
Therasense Confidential

- 5 Remove the adhesive backing at the bottom of the support mount.



- 6 Place the sensor inserter, adhesive-side down, on the skin at the insertion site. Hold it firmly in place to ensure it sticks to the skin.
If inserting the sensor on your arm, position the sensor support mount so that it runs lengthwise down your arm.

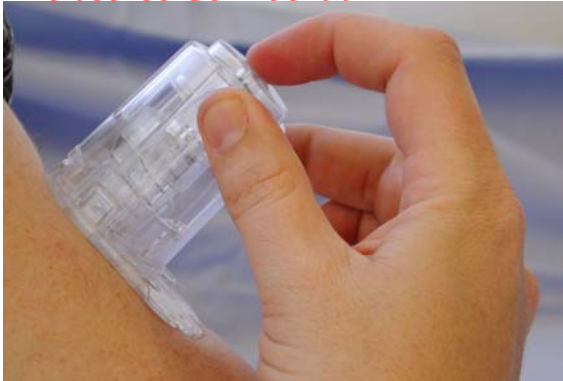


Therasense Confidential

- 7 Press the plunger on the top of the sensor inserter. A needle will quickly penetrate your skin to place the sensor, then withdraw leaving the sensor in place.

NOTE: Once the plunger is pressed, the sensor inserter cannot be reused.

Therasense Confidential



- 8 While holding the sensor inserter at the site, firmly squeeze the release tabs at the base of the inserter, then lift the sensor inserter straight up and out of the support mount. Make sure the support mount remains on your skin.

NOTE: A small drop of blood appearing at the sensor site is normal.



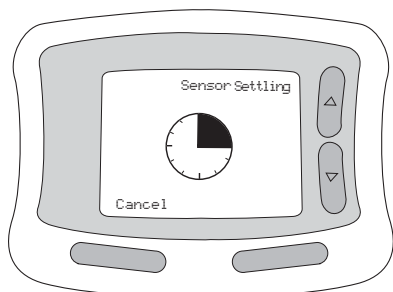
- 9 Discard the sensor inserter.
- 10 Firmly slide the transmitter onto the support mount and push it until it clicks into place. It is important to get a tight connection.



Therasense Confidential

IMPORTANT: Make sure you keep the receiver within 10 feet of the transmitter. The receiver must be kept close to the transmitter so that glucose readings taken by the sensor can be sent to the receiver. If you move more than 10 feet from the receiver, the receiver will begin to beep once each minute.

- 11 **Therasense Confidential** When the sensor has been correctly inserted and the transmitter is in place, the receiver beeps once, displays the Sensor Settling screen, beeps twice, then displays the main menu.



- 12 In approximately 1 hour after you insert the sensor, the receiver will prompt you to perform a blood glucose test. Proceed to “Testing Your Blood Glucose” in the following section when you see this prompt.

Testing Your Blood Glucose

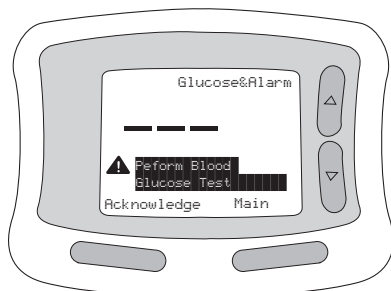
Before performing a blood test, be sure you have the following materials:

- receiver
- Free Style Test Strips
- FreeStyle Lancing Device
- sterile lancets
- soap and water

When to Perform a Blood Glucose Test

The receiver will prompt to perform a blood glucose test after you insert a new sensor. You will also need to perform a test at various other times throughout the day.

- when the receiver prompts you to perform a blood glucose test at 1, 4, and 24 hours after a new sensor insertion
- before each meal
- 1 and 2 hours after each meal
- before you go to bed
- at midnight

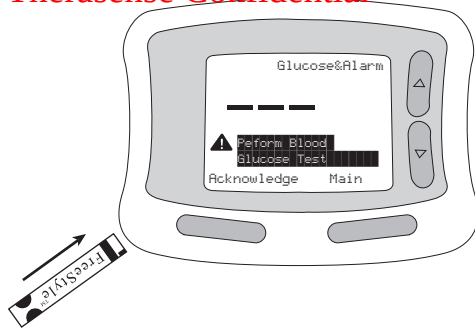


Therasense Confidential

- 1 Insert a test strip into the receiver. Push the test strip until it stops.

NOTE: If you do not start the test within 2 minutes of inserting the test strip, the receiver will automatically turn off. To restart the receiver, take out the unused test strip and reinsert it into the receiver.

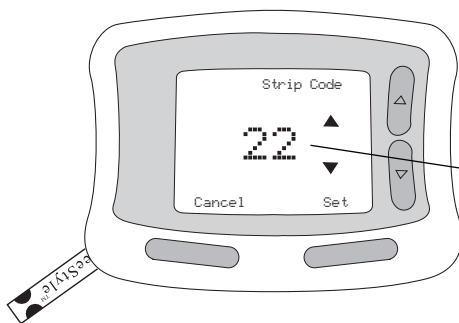
Therasense Confidential



- 2 When the receiver detects the test strip, the strip code number appears on the display. Compare the code number on the display to the code number shown on the test strip vial. Make sure the code numbers match.

- If the code numbers match, select **Set** and proceed to step 4.
- If the code numbers do not match, proceed to step 3 to change the code number on the receiver.

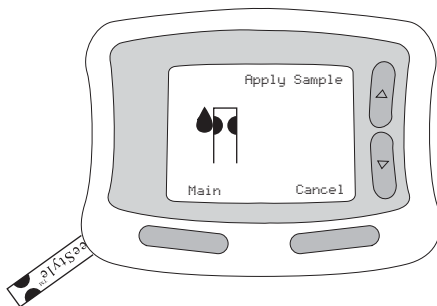
IMPORTANT: To ensure accurate results, make sure the code number shown on the receiver screen matches the code number on the test strip vial.



Make sure test strip code numbers match.

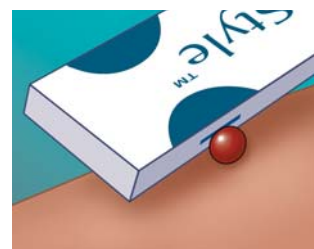


- 3 If the code number on the receiver screen does not match the code number on the test strip vial, use the scroll buttons to the right of the display screen to change the code number on the receiver. Select **Set** when the code numbers match.
- 4 The receiver prompts you to apply a sample and displays a test strip and blood drop. Wash the testing site with soap and water. Be sure there is no cream or lotion where you will lance. Lance your forearm or finger to get a blood sample. Refer to “Using the Lancing Device” on page 13.



Therasense Confidential

- 5 Apply blood to the test strip.
 - Bring the test strip to the blood sample at a slight angle.
 - Gently touch one edge of the test strip to the blood sample on your arm. The blood will be pulled into the test strip.
 - A single beep means that enough sample was applied.



CAUTION!

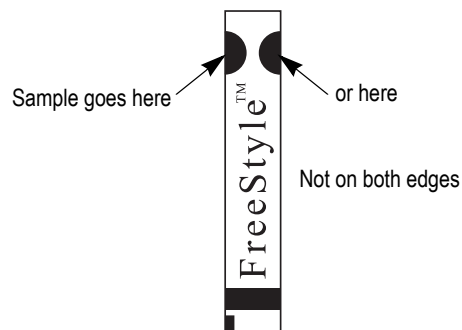
Do not press the test strip down hard against your arm.

Do not scrape the blood.

Do not apply blood to the flat side of the test strip.

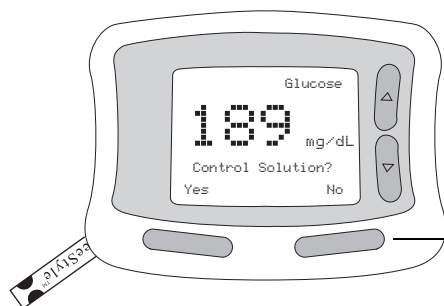
Do not apply blood to both edges of the test strip.

NOTE: If after 5 seconds, your meter has not beeped, the blood sample may be too small. You can continue to fill the test strip for up to 60 seconds as long as you continue to apply blood to the same edge with which you started.



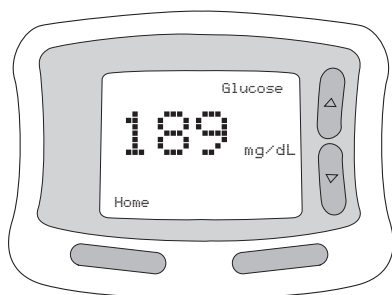
A clock appears as the receiver measures the glucose result. The time it takes depends on your blood glucose level. The higher your glucose value, the longer it takes. Normal blood glucose levels will take an average of 15 seconds.

- 6 The test is complete when you hear 2 beeps. The receiver prompts you to indicate if the result is a control solution result. Select **No**.



Select **No** indicating this is not a result from a control solution test.

- 7 Remove and discard the test strip.



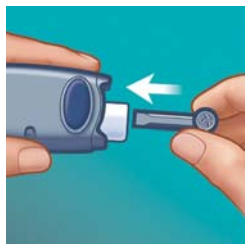
Therasense Confidential

Using the Lancing Device

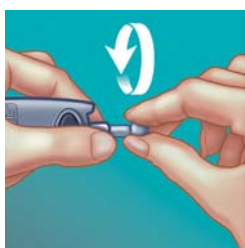
- 1 Snap off the clear cap.



- 2 Insert a new lancet into the white lancet holder cup.



- 3 Hold the lancet firmly in place with one hand while you use your other hand to twist off the round disk on the top of the lancet.



- 4 Replace the clear cap on the lancing device. It will snap into place. Be careful not to touch the exposed needle on the lancet.



5 Select a depth setting.

The lancing device has five depth settings—1 is for a shallow puncture and 5 is for the deepest puncture. Turn the settings dial to the desired setting as shown in the depth indicator window. If this is your first time lancing, start at level 3.



6 Pull the dark blue cocking handle out until it clicks.

If the handle is already out, you may have cocked the device in step 2 when you inserted the lancet.



7 Rub the test site until you feel it getting warm. This will bring blood to the surface of the skin.



8 Lance your skin by pressing the clear cap down against your skin and pressing the release button. DO NOT LIFT UP.



9 Continue to hold the lancing device on your arm and gradually increase pressure for several seconds. Look through the clear cap on your arm. The blood sample should be about the size of a pinhead or about this big ←

10 Lift the lancing device straight up. Be careful not to smear the blood sample.

11 Gently touch one edge of the test strip to the blood sample. Refer to step 5 on page 12 for information on applying blood to the test strip.

Therasense Confidential

- 12 To remove the lancet from the lancing device:
- Remove the clear cap of the lancing device.
 - Hold the lancet over a puncture-proof container.
 - Pinch the white clip that holds the lancet. The lancet will fall out.



Checking the System

When to Perform a Control Solution Test

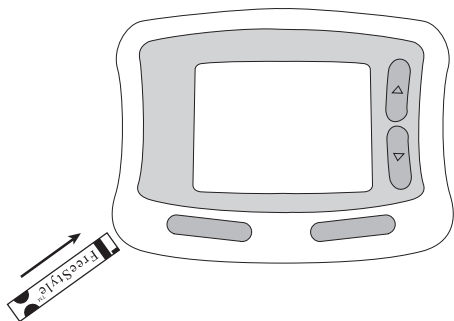
- When you open a new vial of test strips
- If you suspect that your meter or test strips are not working properly
- If you think your test result is not accurate, or if your test results are not consistent with how you feel
- If you drop your receiver or expose it to liquids
- When your healthcare professional advises you to do so

Important Information about the Control Solution

- Use only FreeStyle brand control solution. Use of other brands may produce inaccurate results.
- Replace the cap on the control solution vial immediately.
- Results from a control solution test do not reflect your glucose levels.
- Discard the control solution 3 months after you open the vial. Write the discard date on the vial when you first open. The discard date is 3 months from the day you open the vial.
- Do not use the control solution past the expiration date or you may get inaccurate results.
- Do not add water or any liquid to the control solution

How to Perform a Control Solution Test

- 1 Insert a test strip into the receiver. Push the test strip until it stops.

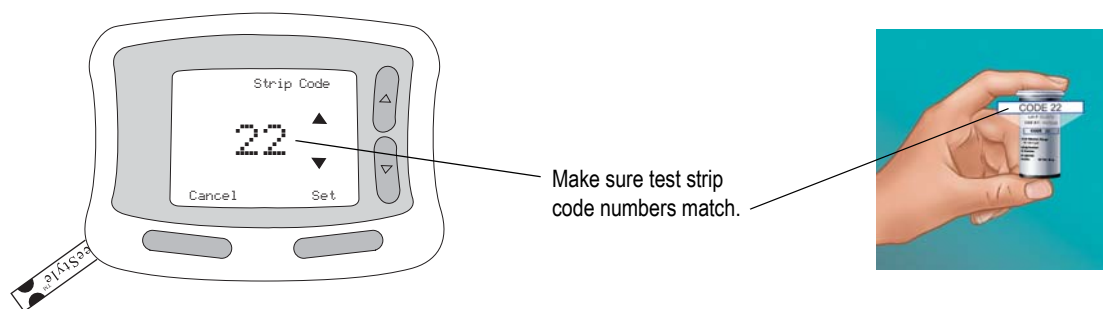


- 2 The receiver automatically turns on and displays the test strip code number. Compare the code on the display to the code number shown on the test strip vial. Make sure the code numbers match.

Therasense Confidential

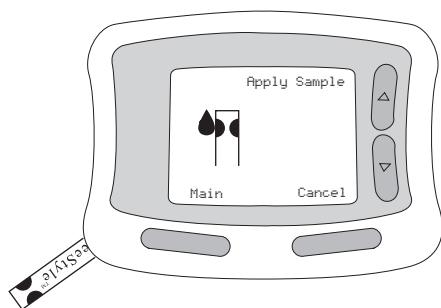
- If the code numbers match, select **Set** and proceed to step 4.
- If the code numbers do not match, proceed to step 3 to change the code number on the receiver.

IMPORTANT: To ensure accurate results, make sure the code number shown on the receiver screen matches the code number on the test strip vial.

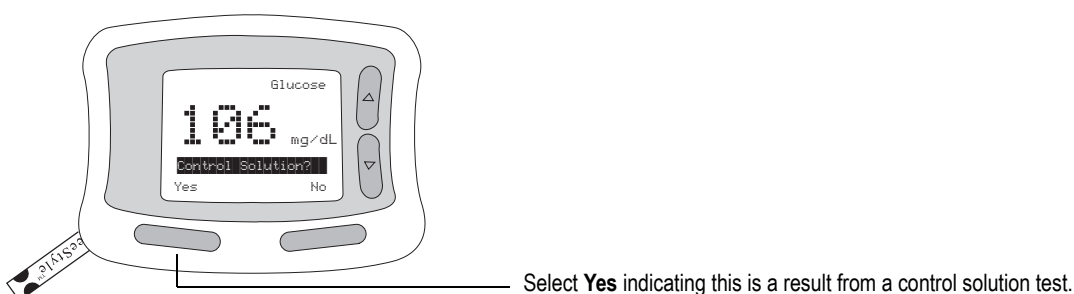


- 3 If the code number on the receiver screen does not match the code number on the test strip vial, use the scroll buttons to the right of the display screen to change the code number on the receiver. Select **Set** when the code numbers match.

The receiver prompts you to apply a sample and displays a test strip and blood drop.

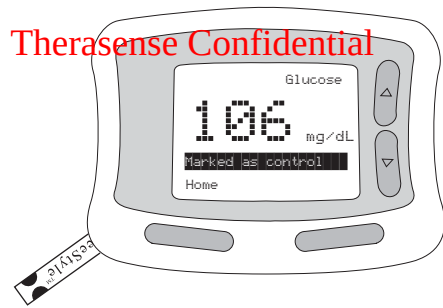


- 4 Apply the control solution as follows:
 - turn the vial to the side and gently squeeze it to bring a drop to the vial tip
 - touch one edge of the test strip to the control solution
 - a beep means that enough sample was applied
- 5 The test result is complete when you hear 2 beeps. The receiver prompts you to indicate if the result is a control solution result. Select **Yes**.



Therasense Confidential

- 6 The receiver displays the result marked as a control solution. Compare the control solution result to the range printed on the test strip vial.



- 7 Record the result in your log book.
- 8 Remove and discard the test strip.

Control Solution Results

Compare the control solution result to the range printed on the test strip vial.

- The control result should fall within the range printed on the test strip vial.
- If the control solution result falls outside this range, repeat the control test with a new test strip.

IMPORTANT: If the control solution result continues to fall outside the range printed on the test strip vial, the receiver may not be working properly.

- Do not use the system to test your blood.
- Call your clinical trial site coordinator.

Out-of-range control results may be caused by:

- expired control solution
- expired or damaged test strip
- error in performing the test
- code number on receiver does not match code number on test strip vial
- receiver malfunction

Therasense Confidential

Therasense Confidential

Troubleshooting

Therasense Confidential

Error Codes

Error Code	What It Means	What To Do
Er1	1. Not enough blood was applied to test strip. 2. Problem with test strip. 3. Problem with meter. 4. Very low blood glucose (less than 20 mg/dL)	1. If you have symptoms such as weakness or sweating, follow your doctor's advice. 2. If meter beeps, call your clinical trial coordinator for help. 3. If meter does not beep, run a control solution test. If control solution test works, repeat blood test using new test strip. If control solution test does not work, call your clinical trial coordinator.
Er2	1. Incorrect procedure (for example, a used test strip was inserted). 2. Problem with test strip. 3. Problem with meter. 4. Very high blood glucose (greater than 500 mg/dL)	1. If you have symptoms such as thirst or blurry vision, follow your doctor's advice. 2. If in doubt about your symptoms, test again with a new test strip.
Er3	1. Incorrect procedure (for example, blood was applied to test strip before test strip was inserted). 2. Problem with test strip. 3. Problem with meter.	1. Be sure you see "Apply Sample" on display before you apply sample. 2. Test with control solution. If out of range or error persists, call your clinical trial coordinator.
Er4	Receiver Malfunction.	Call your clinical trial coordinator for a replacement.
Er5	Faulty or damaged test strip.	Try another test strip or clean the test strip port.

Error Messages

Error Code	What It Means	What To Do
Failed Sensor	The receiver has detected a damaged or irregular sensor.	Be sure the sensor was inserted correctly, the support mount is securely in place, and the transmitter is firmly inserted.
Cal expire soon		

Therasense Confidential

Error Code	What It Means	What To Do
Cannot Find PC for Data Upload	The receiver cannot establish communication with a PC. not for clinicals	
File System Error		
High glucose		
History log full		
Impending high		
Impending low		
Log cleared		
Log data corrupted		
Low glucose		
New Sensor Time Out	The receiver has not detected a new sensor.	Insert a new sensor and attach the transmitter to the support mount. If you have already done so, make sure the transmitter is pushed firmly into the support mount.
No glucose data		
No Sensor Detected	The transmitter was not correctly installed into the support mount.	
Perform blood glucose test See Help #25	The receiver will prompt you to perform a blood test in approximately 1, 4, and 24 hours after a new sensor is inserted.	Perform a blood test using a test strip. Refer to “Testing Your Blood Glucose” on page 10.
Reconnect to Tx See Help #23	The receiver cannot detect the transmitter.	Be sure the receiver and transmitter are within 10 feet of one another.
Replace the sensor See Help #24	Once inserted a sensor is good for 72 hours, after that you need to replace it with a new sensor.	Remove the sensor and insert a new one. Refer to “Replacing the Sensor” on page 6.
Sensor expire soon		
Stabilize Conditions See Help #26	The transmitter temperature is above X°F or below X°F or changing rapidly.	
System Time Error		
Reestablish link		
Rx battery low	The receiver battery power is low.	Replace the batteries.

Therasense Confidential

Error Code	What It Means	What To Do
Tx battery low Therasense Confidential	The transmitter battery is very low.	Change the battery.
Tx Link Failure	The receiver has linked to an unidentified transmitter.	Turn off any transmitters not in use. Reestablish the link.
Upload Failure		

Problems

Problems	What To Do
The support mount is not sticking to your skin.	1. Make sure your skin is clean and thoroughly dry before placing the support mount on the skin. 2. Place an over-bandage over the transmitter after connecting the transmitter to the support mount.