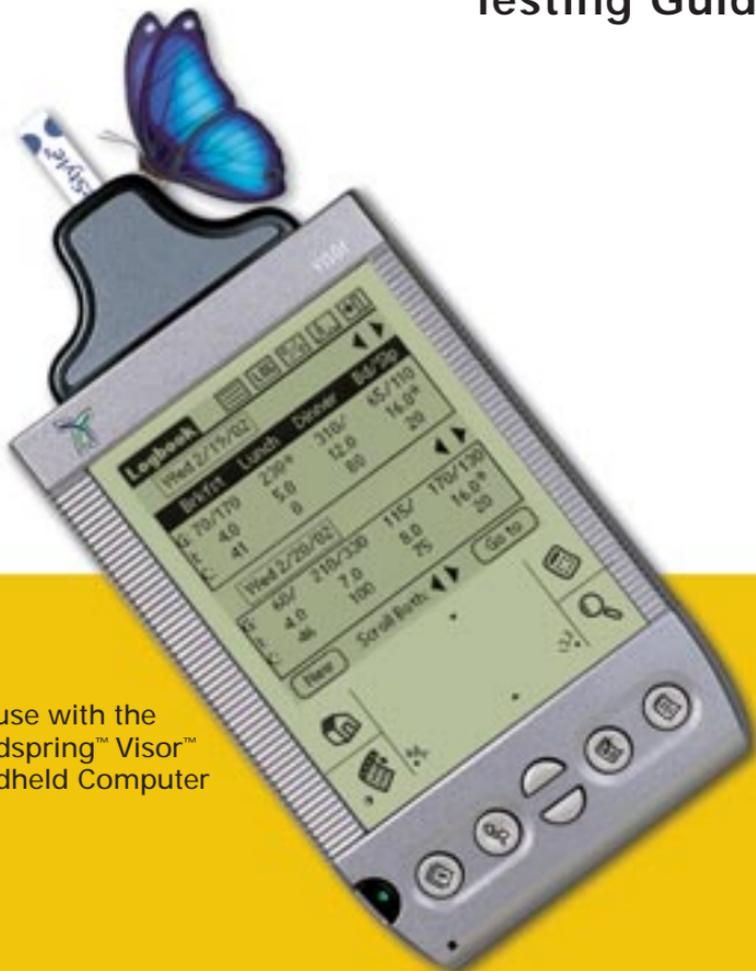**TheraSense®**
The Technology of Caring™

# Blood Glucose Testing Guide

For use with the
Handspring™ Visor™
Handheld Computer

# FreeStyle
# TRACKER™
## Diabetes Management System

## FreeStyle Tracker Diabetes Management System
## Blood Glucose Testing Guide

First, use the System Installation Guide to set up the FreeStyle Tracker System.

After the System is set up, use this Blood Glucose Testing Guide to test your blood glucose, or to perform a control solution test.

Detailed information about the material in this Guide can be found in the electronic FreeStyle Tracker System User's Guide on the CD-Rom.

## In This Guide

The FreeStyle Tracker™ System is intended for use outside the body (i.e. *in vitro* diagnostic use only).

The FreeStyle Tracker System is for measuring blood glucose from samples taken from the forearm, upper arm, hand, thigh, calf, or fingers (for more information refer to the FreeStyle Tracker System User's Guide).

The FreeStyle Tracker System should only be used with FreeStyle™ Test Strips and FreeStyle™ Control Solution. Using other brands of test strips or control solution with the FreeStyle Tracker System may produce inaccurate results.

**FreeStyle Tracker should only be used for:**

➤ Testing blood glucose (sugar)
➤ Testing only with fresh capillary whole blood samples

**FreeStyle Tracker should not be used for:**

➤ The diagnosis of diabetes
➤ Testing on newborns
➤ Testing of arterial blood

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**WARNING**

This System contains small parts that may be dangerous if swallowed. Keep away from young children.

If you are testing for hypoglycemia (low blood sugar), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.

**CAUTION**

Before using the FreeStyle Tracker System to test your blood glucose, please read all the instructions provided in this Blood Glucose Testing Guide and practice the testing procedures. Blood glucose monitoring should be done with the guidance of a health-care professional.

Most healthcare professionals recommend testing when blood glucose values are stable, before meals and before bedtime. However, when blood glucose is changing, blood from the finger-tips may show these changes sooner than blood from other sites.

**IMPORTANT**

The FreeStyle Tracker System is not designed to perform a blood glucose measurement while the system is placed in a Visor cradle or otherwise being charged. Remove the PDA from the HotSync Cradle or power source before doing a blood glucose measure-ment to avoid a system reset.

➤ 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 this Blood Glucose Testing Guide, call your healthcare professional.

➤ Physiologic differences in the circulation between the finger and other test sites like the forearm, upper arm, thigh, calf and hand, may result in differences in blood glucose measurements from the other test sites and your finger. Differences in blood glucose measurements between the other test sites and your finger may be observed after eating, insulin medication or exercise.

➤ Changes in blood glucose may be observed in finger blood samples sooner than blood samples from the forearm and other alternate sites. Vigorous rubbing of the alternate test sites before lancing will help to minimize the difference between finger and alternate site test results.

➤ If you are testing for hypoglycemia (low blood sugar), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.

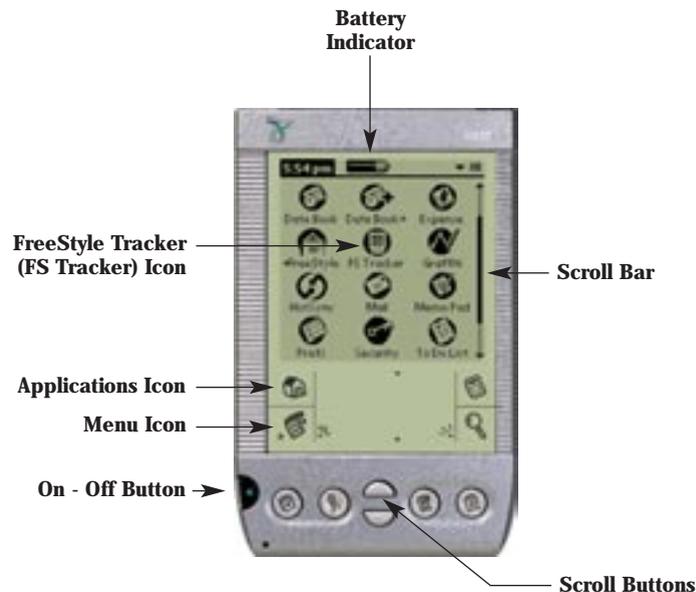**Times when you may be checking for low blood glucose include:**

➤ When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.

➤ When you have delayed a meal after taking insulin.

➤ When your healthcare professional advises you to do so.

**These are the main steps to test your blood glucose:**

**1.** Prepare the FreeStyle™ Lancing Device, then set it aside.

**2.** Remove the cover from the upper rear of the Visor™ Handheld Computer (PDA) and insert the FreeStyle Tracker™ Glucose Measurement Module (if not already inserted).

**3.** Insert a FreeStyle™ Test Strip into the Module.

**4.** Check that the test strip Cal Code displayed on the Visor PDA matches the code on the test strip vial – if not, adjust the Cal Code on the Visor PDA display.

**5.** Clean and dry the site to be lanced, then obtain a blood sample using the FreeStyle Lancing Device.

**6.** Touch the test strip (that has been inserted into the Module) to the blood droplet until you hear a single beep or see the rotating "Clock" icon.

**7.** View the result on the display

The result is automatically saved in the Logbook and Diary. When the Logbook or Diary screens are showing, you can tap on the result and then tap the Details button to view more information, or to add, change, or delete information (such as comments). The FreeStyle Tracker™ System User's Guide has more information about the Logbook and Diary.

**NOTE:** Words that are underlined (for example – Details) are on-screen commands or functions that you tap with the stylus to activate. Words that are capitalized have a special meaning or usage, or are product names.

Battery Indicator

FreeStyle Tracker (FS Tracker) Icon

Scroll Bar

Applications Icon

Menu Icon

On - Off Button

Scroll Buttons

**IMPORTANT**
This Guide applies to FreeStyle Tracker Systems using the 1.2 program version only. To check which program version your System is using, while the FreeStyle Tracker System is running tap the ▨ (Menu) icon, then tap About This Program. Do not use this Guide if it does not match the program version. Contact TheraSense Customer Service toll free at 1-888-522-5226 if you need a different version of this Guide.

**Handspring™ Visor™ Handheld Computer\*\***

**Carrying Case**

**FreeStyle Tracker™ CD Software\***

**FreeStyle Tracker™ Warranty Card\***

**FreeStyle Tracker™ Blood Glucose Testing Guide\***

**FreeStyle Tracker™ System Installation Guide\***

**FreeStyle Tracker™ Module**

**Visor Handheld Cradle\*\***

**FreeStyle™ Lancing Device and Lancets**

**Test Strip Vial and Test Strips**

**FreeStyle™ Control Solution**

\* FreeStyle Tracker Software Kit Contents
\*\* Not included in FreeStyle Tracker Monitoring Module and Software Kit

## The FreeStyle Lancing Device

**Cocking Handle**

**Depth Setting Dial**

**Depth Indicator Window**

**Release Button**

**Clear Cap (for off-finger testing)**

**Lancet**

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**IMPORTANT**

Lancing with the Clear Cap may be completed at the following test sites: forearm, upper arm, hand, thigh, calf.

## Remove the Cap

1. Snap off the Clear Cap on the lancing device, like breaking a cracker in half.

## Insert the Lancet

2. Insert a new FreeStyle™ Lancet firmly into the white lancet holder cup. (Pushing the lancet into the cup may cock the device; this is okay).

## Twist Off the Rounded Top of the Lancet

3. Hold the lancet firmly in place with one hand. Use your other hand to twist off the rounded top of the lancet. Be careful not to touch the exposed needle on the lancet.

## Replace the Cap on the Lancing Device

4. Replace the Clear Cap until it snaps or clicks into place. Be careful not to touch the exposed needle on the lancet.

## Set the Lancing Level

5. The FreeStyle™ Lancing Device offers five different depth settings. Move the Depth Setting Dial to the desired setting as shown in the Depth Indicator Window. It is recommended that you start at Level 3. Level 1 is the shallowest depth, Level 5 is the deepest.
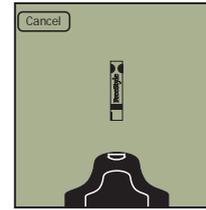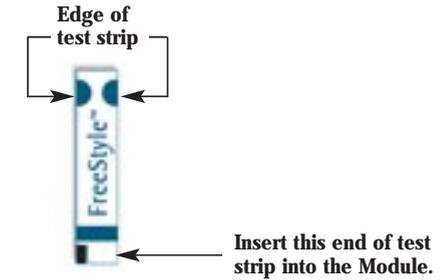
## Cocking the Handle

6. Pull the dark blue Cocking Handle out until it clicks. (You may have already cocked the handle in step 2 above; this is okay).

1. Remove the plastic cover from the top rear of the Visor PDA to expose the slot for the Module.

2. Insert the FreeStyle Tracker Glucose Measurement Module into the slot as shown.

3. "FreeStyle Tracker Diabetes Management System" will appear on the screen, indicating the System is getting ready for a glucose test.
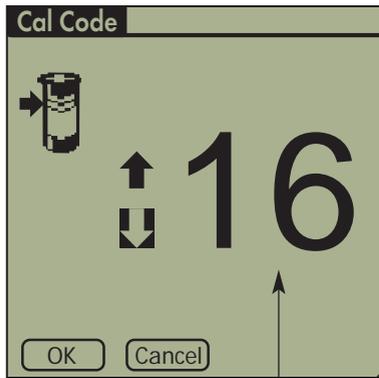
1. This screen will appear after inserting the Module

Edge of test strip



Insert this end of test strip into the Module.



2. Gently insert a new test strip as shown until it cannot go any further, and the Cal Code screen appears.

**NOTE:** If the Module is already inserted, the glucose measurement function can be started by tapping the [icon] (Measurement) icon in the top, right hand corner on the Logbook or Diary screens (see pages 20-21). Then proceed to the steps above.

1. The Cal Code screen will appear on the PDA screen after the test strip is inserted.

2. If this Cal Code number does not match the "Code" number in the blue box on the label of the test strip vial, tap the arrows on the screen to adjust to that value.

3. Tap <u>OK</u> when the values match.

**NOTE:** If you tap Cancel, the logbook screen will appear.

**NOTE:** Perform a control solution test:

➤ When you first use the FreeStyle Tracker System, before you take a blood glucose test.

➤ Each time you open a new vial of test strips.

A control solution test follows the same procedure as a blood glucose test. Substitute a drop of control solution for a drop of blood in performing the test. (For detailed information, go to page 25.)

**Important System and Test Strip Information**

➤ The FreeStyle Tracker System has an operating range of 50-95°F (10-35°C).

➤ 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 or heat.

➤ Store your test strips in their original vial only; never transfer them to another vial or any other container.

➤ 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 Module.

➤ Do not use test strips beyond the expiration date printed on the package as this may cause inaccurate results.

➤ Do not bend, cut, or alter FreeStyle Test Strips in any way.

➤ Never store individual test strips in your carrying case.

For detailed storage and usage information, refer to the FreeStyle Test Strip package insert.

**WARNING**
Keep the test strip vial away from children. The cap is a choking hazard. The cap or vial contains drying agents to protect the test strips. Drying agents may be harmful if inhaled or swallowed and may cause skin or eye irritation.

**1.** Wash your hands and the test site with soap and warm water. Dry both well. Make sure that there is no cream or lotion where you will lance.

**2.** To bring fresh blood to the surface, rub the area vigorously until you feel it getting warm.

**3.** Using the FreeStyle Lancing Device (prepared earlier – starting on page 10), press the Clear Cap of the lancing device against the test site.

**NOTE:** Do not take a sample where veins or moles can be seen. Also, avoid tendons or bony areas.

**4.** Press the Release Button. DO NOT LIFT UP. Continue to hold the lancing device against the test site, gradually increasing the pressure for several seconds.

**5.** While holding the lancing device on the test site, look through the Clear Cap. The blood sample should be the size of a pin head (example ● ).

**6.** Lift the lancing device straight up. Be careful not to touch the blood sample on the test site.

**NOTE:** It is possible you may experience bruising at the test site. To test at other sites, see the information on page 23.
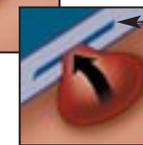
**To Apply the Blood Sample to the Test Strip:**

**CAUTION**
➤ Use only **ONE** edge of the test strip per test.
➤ **DO NOT** "press" the test strip against the test site.
➤ **DO NOT** scrape the blood onto the test strip.
➤ **DO NOT** apply blood to the flat side of the test strip.
➤ **DO NOT** apply blood to test strip when the test strip is out of the Module.
➤ **DO NOT** put blood or foreign objects into the strip port.
➤ Use the test strip only **ONCE**.

**1.** Bring the test strip (that has been inserted into the Module) to the blood sample at a slight angle.

**2.** Gently touch only one edge of the test strip to the blood sample. Do not lift the strip up. Wait until you hear a single beep, or see the Processing screen displayed. This means that enough blood was absorbed.

**Edge of test strip**

**Edge of test strip**

**IMPORTANT**
**DO NOT** apply blood to both edges.

16

17

**CAUTION**

If blood is applied to both edges of the test strip you may get an inaccurate reading. If you have performed a test using both sides of the test strip, redo the blood glucose test with a new test strip and a fresh blood sample.

**3.** A clock animation on the screen labeled "Processing" indicates that the test is under way.

**Inadequate Blood Sample**

If the FreeStyle Tracker System has not beeped or the Processing screen does not appear, the sample may be too small. You can continue to fill the test strip for up to sixty seconds. Just be sure you fill the test strip only from the same edge from which you started.

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**The Result screen will appear when the test has been completed (signaled by 2 beeps).**



Cal Code used for this test

Test result

Date and time of test

Unit of measure

Tap New to start a new test

Tap Logbook to view this result in the Logbook display.

Tap Details to add more information to the result

Tap Control if this test was done using control solution. A √, will be displayed below the Cal Code.

**CAUTION**

Low or high blood glucose readings (displayed as "Lo" or "Hi") can indicate a potentially serious medical condition. The FreeStyle Tracker System displays results between 20 and 500 mg/dL (1.1 and 27.8 mmol/L).

**This concludes the blood glucose test.**

➤ Discard the used test strip.

➤ Test strips may only be used once.

➤ To remove the lancet, see page 24.

**The Logbook screen contains the following information:**

**The Diary screen contains the following information:**

Date

Time Periods

G: blood glucose test results.
70/170 in the Breakfast Time
Period means 70 was the
"Pre Breakfast" result, 170 was
the "Post Breakfast" result

An * here indicates this is the
earliest of multiple entries - tap
it to view the additional entries
in the Diary

I: the sum of insulin entries
in a Time Period

C: the sum of carbohydrate
entries in a Time Period

Tap New to make
a new entry

Tap the date,
◀ ▶, or the scroll
buttons to change
the date displayed

Tap Today to bring
the lower Logbook
chart to today's date

An * here indicates this is the
sum of two or more entries -
tap it to view the separate
entries in the Diary

Tap any entry in the
Logbook screen or tap the
▤ icon to go to the
Diary screen

Event values

Event type

Time Period

Date and time
of event

Tap an item to highlight
it, then tap Details
to see more information
related to the
highlighted event
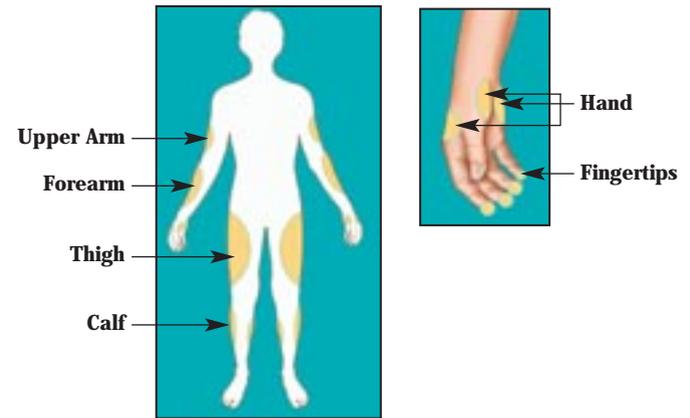
Tap New to make
a new Diary entry

Tap Go to to
view events
from other
dates

Tap these
Next / Previous
arrows to move
forward or back
in time in the
Diary

This icon indicates
there is a comment
with this event

20

21

| Icons and Terms | Explanation |
|---|---|
| **ICONS** | |
| ▤ | Go to the Diary screen |
| LOG | Go to the Logbook screen |
| % | Go to the Statistics screens |
| 📈 | Go to the Line Graph / Pie Chart / Modal Day screens |
| 🩸 | Go to the Glucose Measurement screen |
| **TIME PERIODS** | |
| <B | Pre Breakfast |
| >B | Post Breakfast |
| <L | Pre Lunch |
| >L | Post Lunch |
| <D | Pre Dinner |
| >D | Post Dinner |
| Bd | Bedtime |
| Slp | Sleep |
| **EVENT TYPES** | |
| Gluc | Blood glucose test result (automatic) |
| Gluc* | Blood glucose test result (manual entry) |
| Cntl | Control solution test result |
| Insu | Insulin units taken |
| Meal | Carbohydrates consumed |
| Meds | Medication taken |
| Hlth | State of Health |
| Exer | Exercise or physical activity performed |
| Prof | Basal Profile change |
| Temp | Temporary basal rate change |
| Note | Additional comments entered |
| * | In the Logbook, this indicates that there are multiple entries for this item – tap the item to view the other entries |



**Lancing with the Clear Cap may be completed at the following test sites:**

➤ Forearm
➤ Upper arm
➤ Hand
➤ Thigh
➤ Calf

An example of lancing the forearm is shown on page 16. Testing at other sites is similar, except for the fingers.

**IMPORTANT**

It is possible you will experience bruising at the listed test sites above. If bruising does occur, you can lance your finger or another site instead. Should you choose to lance your finger, a special dark blue Finger Cap is also provided with your FreeStyle Lancing Device. To test your finger, see the instructions on lancing your finger in the electronic FreeStyle Tracker™ System User's Guide.

**WARNING**

If you are testing for hypoglycemia (low blood sugar), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.

## How to Remove the Lancet

**1.** When you have finished testing your blood, remove the Clear Cap of the lancing device.

**2.** Hold the lancet over a sharps container or a puncture-proof container with a lid.



**3.** Pinch the white clip that holds the lancet until the lancet falls out.

## Maintenance

Use isopropyl alcohol or soap and water to wipe the outside of the Lancing Device.

If you wish, remove the Clear Cap. Wash it in warm water and rinse well.

**Do not immerse the body of the lancing device in water or any liquid.**

## When should I perform a Control Solution test?

➤ When you first get your FreeStyle Tracker™ System, before doing a blood glucose test.

➤ When you first begin using a new vial of test strips.

➤ When you suspect that your FreeStyle Tracker System or Test Strips are not working properly.

➤ When you think your test results are not accurate, or if your test results are not consistent with how you feel.

➤ When your FreeStyle Tracker System is dropped, damaged, or exposed to liquids.

➤ When your healthcare professional advises you to do so.

## Precautions when using Control Solution

➤ Use only FreeStyle brand control solution with your FreeStyle Tracker System. Use of other brands of test strips or control solution with the FreeStyle Tracker System may produce inaccurate results.

➤ Replace the cap on the control solution bottle immediately after using.

➤ Results from FreeStyle Control Solution tests do not reflect your blood glucose levels.

➤ FreeStyle Control Solution is good for 3 months after opening the bottle, or until the expiration date printed on the label, whichever occurs first.

➤ Do not use control solution past the expiration date or you may get inaccurate results.

➤ Do not add water or any liquid to control solution.

➤ Control solution tests are specified to be accurate only when used between 59-104°F (15-40°C).

## How do I know if my Control Solution has expired?

On the date you open a new control solution vial, count forward 3 months. This is your discard date. Write this date on the side of the control solution vial.

**Example:** You open the control solution on January 15th. Count forward 3 months to April 15th. This is the discard date that you record on the vial.

### IMPORTANT
The control solution range printed on the test strip vial label is a target range for control solution only. It is not a target range for your blood glucose level.

## If the control solution results are out of this range, REPEAT THE TEST.

Out of range test results may be caused by:
- Expired control solution
- Expired or bad test strip
- Error in performing the test
- Diluted or watered-down control solution
- Code on the test strip vial does not match the Cal Code set on the FreeStyle Tracker PDA screen
- System malfunction
- The control solution test being done outside the temperature range of 59-104°F (15-40°C)

## If your control solution test results continue to fall outside the range printed on the test strip vial, the FreeStyle Tracker System may not be working properly.
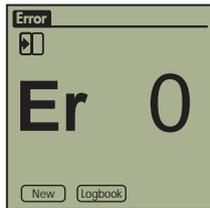
- IF SO, DO NOT USE THE FREESTYLE TRACKER SYSTEM TO TEST YOUR BLOOD.
- CALL THERASENSE CUSTOMER SERVICE AT 1-888-522-5226.

| System Does Not Work During a Glucose Test ||
|---|---|
| **PROBABLE CAUSE** | **WHAT TO DO** |
| Batteries are dead. | Replace the batteries. |
| Batteries are installed incorrectly, or there are no batteries in the system. | Check that both batteries are installed correctly. (Refer to PDA instructions.) |
| Test strip is inserted upside down, wrong end in or incompletely inserted into the FreeStyle Tracker Module. | Insert the test strip correctly with the name "FreeStyle" facing up, and the **edge** of the test strip clearly visible. (See page 13.) |
| Defective Module or test strips. | Call TheraSense Customer Service. |
| Blood or foreign objects put into test strip port. | Call TheraSense Customer Service. |

| Test Does Not Start After Applying The Blood Sample ||
|---|---|
| **PROBABLE CAUSE** | **WHAT TO DO** |
| Blood sample too small. | Repeat the test using a new test strip and a larger blood sample. |
| Defective test strip. | Repeat the test with a new test strip. |
| Sample applied after automatic shutoff (2 minutes). | Repeat the test using a new test strip. Wait until you see the "Blood Drop and Test Strip" animation on the PDA screen before you apply blood. |
| Defective system or test strips. | Call TheraSense Customer Service. |

The following Error Messages may be displayed if there is a problem with the System or a measurement result. Possible causes for the error are listed, followed by actions you can take to resolve the problem.
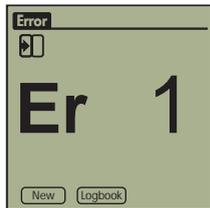
### Error 0

**Possible Cause**
➤ Problem with the Module or
➤ Problem with the PDA or
➤ Module not properly inserted into the PDA

**What You Should Do:**

**1.** Unplug the Module and plug it back into the PDA. Then retest using control solution and a new test strip. If the control solution test works, retest using blood and a new test strip.

**2.** If the retest using control solution does not work, or if the error persists, call TheraSense Customer Service.

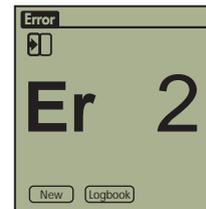### Error 1

**Possible Cause**
➤ Sample too small or
➤ Problem with the test strip or
➤ Problem with the system or
➤ VERY low blood glucose (less than 20 mg/dL).

**What You Should Do:**

**1.** If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your doctor's recommendation for treating hypoglycemia (low blood glucose).

**2.** Retest using control solution and a new test strip. If the control solution test works, retest using blood and a new test strip.

**3.** If the retest using control solution does not work, or the error persists, call TheraSense Customer Service.
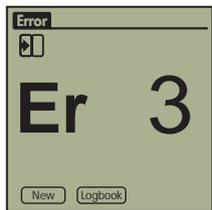
### Error 2

**Possible Cause**
➤ Problem with the test strip or
➤ Problem with the system or
➤ VERY high glucose (above 500 mg/dL).
➤ HI control solution applied when temperature is too cold (condensation). (This applies only to control solution that is labeled as HI).

**What You Should Do:**

1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your doctor's recommendation for treating hyperglycemia (high blood glucose).

2. Retest using control solution and a new test strip. If the control solution test works, retest using blood and a new test strip.

3. If the retest using control solution does not work, or the error persists, call TheraSense Customer Service.

## Error 3

| | **Possible Cause** |
|---|---|
| Error<br><br>**Er 3**<br><br>New  Logbook | ➤ Incorrect test procedure, e.g. putting blood on the test strip before inserting the test strip in the Module, blood applied before the "Blood Drop and Test Strip" animation or<br>➤ Problem with the test strip or<br>➤ Problem with the System. |

**What You Should Do:**

**1.** Be sure you see the "Blood Drop and Test Strip" animation on the PDA screen before you apply blood or control solution.

**2.** Retest using control solution and a new test strip. If the control solution test works, retest using blood and a new test strip.

**3.** If the retest using control solution does not work, or if the error persists, call TheraSense Customer Service.
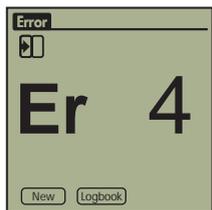
## Error 4

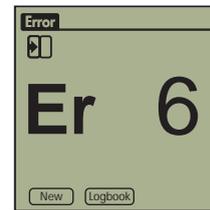| | **Possible Cause** |
|---|---|
| Error<br><br>**Er 4**<br><br>New  Logbook | ➤ Problem with the test strip or<br>➤ System malfunction. |

**What You Should Do:**

1. Retest using control solution and a new test strip. If the control solution test works, retest using blood and a new test strip.

**2.** If the retest using control solution does not work, or if the error persists, call TheraSense Customer Service.

## Error 5

Error 5 is not used with the FreeStyle Tracker System.

## Error 6

| | **Possible Cause** |
|---|---|
| Error<br><br>**Er 6**<br><br>New  Logbook | ➤ A button on the system was pushed when applying blood sample or control solution |

**What You Should Do**

**1.** Retest using a new test strip. Do not touch any buttons when applying blood or control solution to the test strip.

**2.** If the error persists, call TheraSense Customer Service.

Avoid getting dirt, dust, blood, control solution, water, or any liquid inside the FreeStyle Tracker Module through the test strip port and the Module connector port.

Store the System in the carrying case after each use.

| Specifications | |
| --- | --- |
| **FREESTYLE TRACKER SYSTEM TESTING SPECIFICATIONS** | |
| Result Range | 20 to 500 mg/dL (1.1 - 27.8 mmol/L) |
| Calibration | Plasma equivalent |
| Sample | Whole blood, capillary |
| Sample Size | 300 nanoliters (0.3 microliters) |
| Test Time | Average of 15 seconds |
| Assay Method | Coulometric Electrochemical Sensor |
| Measurement Units | Either mg/dL or mmol/L |
| Module Memory Backup | 250 most recent blood glucose and control solution tests |
| PDA Logbook Memory | 2,500 glucose tests and other entered events |
| Automatic Shut-off | 2 minutes and user adjustable |
| PDA Power Source | 2 replaceable AAA batteries, or rechargeable PDA battery |
| AAA Battery Life | 2 - 4 weeks |
| Operating Temperature | 50 - 95 °F (10 - 35 °C) |
| Operating Relative Humidity | 5-90% |
| Hematocrit | 0-60% |

**TheraSense**®
The Technology of Caring™

**1360 South Loop Road**
**Alameda, CA 94502**

www.freestyletracker.com
Toll Free 1-888-522-5226