

DECLARATION OF NATHANIEL E FRANK-WHITE

1. I am a Records Request Processor at the Internet Archive. I make this declaration of my own personal knowledge.
2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.
3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.
4. The archived data made viewable and browseable by the Wayback Machine is obtained by use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.
5. The Internet Archive assigns a URL on its site to the archived files in the format `http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]` aka an "extended URL". Thus, the extended URL `http://web.archive.org/web/19970126045828/http://www.archive.org/` would be the URL for the record of the Internet Archive home page HTML file (`http://www.archive.org/`) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.
6. Attached hereto as Exhibit A are true and accurate copies of screenshots of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.



7. Attached hereto as Exhibit B are true and accurate copies of the Internet Archive's records of the archived files for the URLs and the dates specified in the following table.

Folder	URL
1	http://web.archive.org/web/20071023144033/http://www.abbottdiabetescare.com/static/content/document/ART03162-Rev-C.pdf
2	http://web.archive.org/web/20071023143201/http://www.abbottdiabetescare.com/static/content/document/ART06705-Rev-A.pdf
3	http://web.archive.org/web/20071023143138/http://www.abbottdiabetescare.com/static/content/document/ART06690-Rev-B-EN.pdf
4	http://web.archive.org/web/20100326114949/http://www.abbottdiabetescare.com/static/content/document/ART00903-Rev-C.pdf
5	http://web.archive.org/web/20071023143813/http://www.abbottdiabetescare.com/static/content/document/ART03978-Rev-A.pdf
6	http://web.archive.org/web/20070204032520/http://www.bayerdiabetes.com:80/us/prodServ/custService/pdf/BREEZE_eng.pdf
7	http://web.archive.org/web/20040217213153/http://www.lifescan.com/pdf/ultra_quick_start.pdf
8	http://web.archive.org/web/20070421182818/http://www.lifescan.com:80/pdf/ultra_ob.pdf
9	http://web.archive.org/web/20040205060705/http://www.lifescan.com/pdf/99183_otb.pdf

8. I declare under penalty of perjury that the foregoing is true and correct.

DATE: March 9, 2022

Nathaniel E Frank-White
Nathaniel E Frank-White



Owner's Booklet



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Toll Free at 1-888-522-5226

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Testing Your Blood Glucose

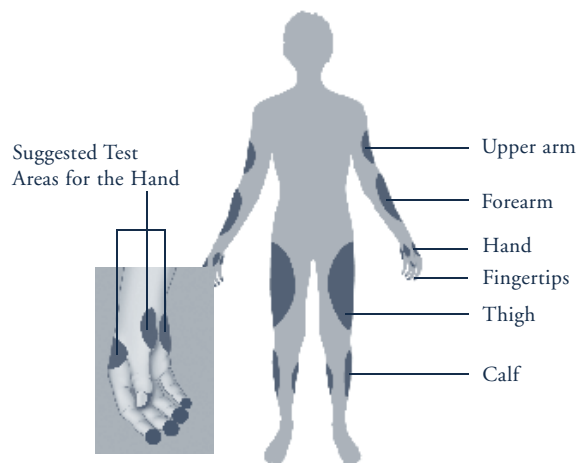
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The FreeStyle® System Uses the World's Smallest Sample So You Can Test on a Variety of Locations

Test On or Off Your Fingers



The FreeStyle Meter gives you the freedom to obtain a blood sample for testing your glucose level from different areas of your body. You may test your blood glucose from your forearm, upper arm, thigh, calf, hand, as well as fingers. The human figure above shows the areas where you can test with the FreeStyle System. Avoid moles, veins, bones and tendons.

WARNING: We recommend that you test on your fingers or palm (at the base of the thumb) if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Important Information About Your FreeStyle® Blood Glucose Monitoring System

How the FreeStyle System Should Be Used

- The FreeStyle System is intended for use outside the body (in other words, *in vitro* diagnostic use only).
- The FreeStyle System is used for measuring blood glucose (also known as *blood sugar*) from samples taken from the forearm, upper arm, hand, thigh, calf, or fingers (refer to page 1 for more information).
- The FreeStyle Meter should only be used with FreeStyle Test Strips and FreeStyle Control Solution. Using other brands of test strips and control solutions with the FreeStyle Meter can produce inaccurate results.

Do use the FreeStyle Meter for:

- Testing blood glucose.
- Testing only with fresh capillary whole blood samples.

Do not use the FreeStyle Meter for:

- The diagnosis of diabetes.
- Testing on newborns.
- Testing of arterial blood.

WARNING: Keep the FreeStyle System away from young children as it contains small parts that may be dangerous if swallowed.

Caution: Please read all the instructions provided in this *Owner's Booklet* and practice the testing procedures before using the FreeStyle System. Blood glucose monitoring should be done with the guidance of a healthcare professional.

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 do not have symptoms of hypoglycemia or hyperglycemia (refer to pages 35 and 36), 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 *and* you have followed all instructions described in the *FreeStyle Owner's Booklet*, call your healthcare professional.
- Intravenous therapy solutions such as some immunoglobulin preparations and peritoneal dialysis solutions containing icodextrin or compounds of Galactose ≥ 13 mg/dL or Maltose ≥ 20 mg/dL may cause overestimation of blood glucose results.

Important Health-Related Information

- Changes in blood glucose may be observed in finger or palm (at the base of the thumb) 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 or palm (at the base of the thumb) and alternate site test results.
- Physiologic differences in the circulation between the finger or palm (at the base of the thumb) and other test sites like the forearm, upper arm, hand, thigh, and calf may result in differences in blood glucose measurements from these test sites and your finger or palm (at the base of the thumb). Differences in blood glucose measurement between the other test sites and your finger or palm (at the base of the thumb) may be observed after eating, insulin medication, or exercise.

WARNING: We recommend that you test on your fingers or palm (at the base of the thumb) if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

The FreeStyle® Meter and FreeStyle Test Strip

Getting Started with the FreeStyle Meter

TheraSense has developed and tested your FreeStyle Meter, FreeStyle Test Strips, and FreeStyle Control Solution to provide precise and accurate results.

These items are included in your FreeStyle Blood Glucose Monitoring System:

1. Getting Started Guide
2. Owner's Booklet
3. Quick Reference Guide
4. FreeStyle Control Solution
5. FreeStyle Test Strips (10 Count)
6. FreeStyle Meter
7. FreeStyle Lancing Device
8. Finger Cap (for Lancing Device)
9. Sterile Lancets (10 Count)
10. Carrying Case
11. Daily Log
12. Warranty Registration Card (not shown)
13. One pre-installed #2032 battery, 3 volt lithium (not shown)
14. User Instructional Video (not shown). Please call TheraSense Customer Service to receive your free copy



FreeStyle® Blood Glucose Monitoring System



The FreeStyle® Meter and How It Works

Data Port

Allows you to transfer data from the meter's memory to a computer or upload to a secure, protected website designed for diabetes data management. Refer to "Transferring Data" on page 45 for more information.

Display Screen

Displays your test results and other important information.

m (Mode) Button

The "m" button is used to:

- Move to different screens such as memory and setup.
- Changes the code (scrolls backward).

Sample Target Areas (dark-colored half-circles on test strip)

Apply blood or control solution to one edge of the strip only. Insert printed side up (with the dark-colored rectangle going into the meter).

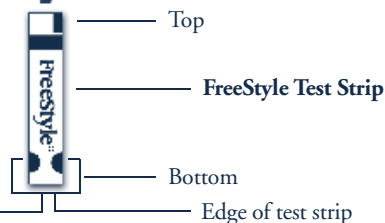
c (Configure) Button

The "c" button is used to:

- Mark a test result as control solution.
- Changes the test strip code (scrolls forward), date, time, unit of measurement, sound options, and reviews stored readings.

Test Strip Port

Insert the **Top** end of a new FreeStyle Test Strip here. The meter powers on when you insert the test strip.



The FreeStyle® Meter Display

Memory Mode Symbol

Shows you a test result stored in the meter memory. The meter stores your last 250 blood glucose test results.

Check Owner's Booklet Symbol

Appears when the meter detects LO or HI blood glucose, out of temperature range results, low battery, data cable inserted and error messages.

Note: Always refer to *FreeStyle Owner's Booklet* when this appears.

Message Area

Date, time, number of tests, and software version appear here.



System Check Screen

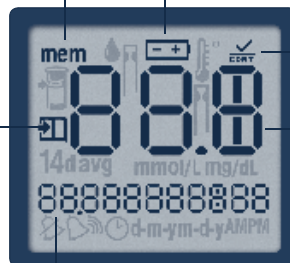
This screen always appears when meter is first powered on so that you can make sure the display is working properly.

Battery Symbol

Appears when you should replace the battery.

Control Solution Test Result Symbol

Shows that you have marked a test result as a control solution test.



Test Result Area

Test results appear here. A decimal point appears only when the unit of measurement is in millimoles per liter (mmol/L).

The FreeStyle® Meter Display

Check and Set Test Strip Code Symbol

Appears when you should check and set the test strip code.

14-Day Average Symbol

Appears with a glucose reading that equals the average value of the readings from the last 14 days (refer to page 43).

Sound Level Symbols

Indicates whether the meter sound prompt (beep) is set to high, low, or off.

Blood Drop and Test Strip Symbols

These symbols work together in an animation to tell you when the meter is ready for you to apply blood or control solution.

Thermometer Symbol

Appears if your meter is out of temperature range for getting an accurate reading.

mg/dL (U.S. Standard) or mmol/L

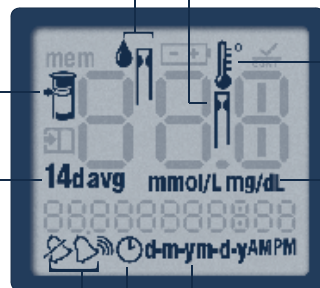
The units of measurement used for your test result.

Date Setup Symbol

d-m-ym-d-y appears in Set mode when setting the date format.

Time Setup Symbol

A clock symbol appears in Set mode when setting the time in the time format (12-hour versus 24-hour).



The FreeStyle® Test Strip

Apply blood or control solution to only **one edge** of the test strip per test.

Important: Use only one edge of the test strip per test. Do not apply blood to both edges. Test strips may be used only once. Discard used test strips.



The Test Strip Does the Work

The test strip acts like a sponge and pulls the blood into the strip through the edge.



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

Important Test Strip Information

- The FreeStyle® System has an operating range of 40° to 104° F (5° to 40° C).
- Store the test strip package in a cool, dry place between 37° to 86° F (3° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight and heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle 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 meter.
- 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.

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

The FreeStyle® Control Solution

All About FreeStyle Control Solution

What is FreeStyle Control Solution?

It is a red liquid that contains a fixed amount of glucose and has three important uses:

- To practice testing without having to use your own blood.
- To ensure that your meter and test strips are working together properly.
- To check that you are following the correct testing procedure.



What is the best way to check my FreeStyle Meter?

Perform a test using the FreeStyle Control Solution. A control solution test follows the same procedure as a blood glucose test, except that you use a sample of control solution instead of a drop of blood (refer to pages 19 to 21 for information on performing a control solution test).

How does the control solution test tell me my meter is working properly?

If the meter reading is within the control solution acceptable range, the meter is working properly.

When should I perform a control solution test?

- When you first get your meter, before doing a blood glucose test.
- When you open and begin using a new vial of test strips.

- When you suspect that your meter 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 meter is dropped, damaged, or exposed to liquids.
- When your healthcare professional advises you to do so.

How do I know if my control solution has expired?

FreeStyle® Control Solution is good for three months after opening the bottle, or until the expiration date printed on the label, whichever comes first. Count forward three months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle.

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

Ensuring Accurate Control Solution Results.

- Use only FreeStyle® Control Solution with your FreeStyle Meter. The use of other brands of control solution with the FreeStyle Meter 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 level.
- 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 performed between 59° to 104°F (15° to 40°C).

Caution: Results from FreeStyle Control Solution tests do not reflect your blood glucose level.

How do I Know if the control solution test results are accurate?

- The control solution test results should fall within the range printed on the test strip vial label.

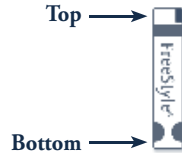
Important: *The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.*

- If control solution results are out of this range, **repeat the test.**
- Out of range test results may be caused by:
 - Expired or bad control solution.
 - Expired or bad test strip.
 - Error in performing test.
 - Watered-down control solution.
 - Code on test strip vial does not match code set in meter.
 - Meter malfunction.
 - Control solution test done outside 59° to 104°F (15° to 40°C).

If your control solution test results continue to fall outside the range printed on the test strip vial:

1. The FreeStyle® System may not be working properly.
2. Do not use the FreeStyle System to test your blood glucose.
3. Call TheraSense Customer Service.

Performing a Control Solution Test



Insert only the Top end of test strip into the meter (with the dark-colored rectangle going into the meter).

1



Grasp the bottom of the test strip with the name “FreeStyle” facing up.

Insert the top of the test strip into your meter until it stops. This will power on the meter.

2



The code number on the display should match the code number on the side of your test strip vial. They must always match, or your results will be inaccurate. (Refer to “Setting the Test Strip Code” on pages 27 and 28.)

Wait for the meter to display the Blood Drop and Test Strip symbols.

Note: Be ready to adjust the code on the meter to match the code number on the test strip vial.

3



Gently touch only **one edge** of the test strip to the control solution.

Specifically, apply the control solution to the test strip edge next to one of the dark-colored half-circles.

If the sound prompt is on, your meter will beep when the test strip is full. A short line then moves clockwise around the display screen while the sample is processing.

Important: Do not apply control solution to both edges.

If the sound prompt is on, your meter will beep twice and the result will appear on the display screen in about 7 seconds. To mark the result as a control solution result, press and hold the “c” button on the FreeStyle® Meter for two seconds.

Wait for the control solution symbol (☑) to appear at the top of the display screen and the date and time on the bottom of the display screen.

If you have marked a test as a control solution test by mistake, you can unmark it by pressing and holding the “c” button again for two seconds.

Pressing the “m” button for two seconds will save the test result and allow you to enter the meter memory.

4



Compare your control solution test results to the range printed on your test strip vial label.

Your control solution results should fall within the range printed on the side of your test strip vial.

If your test results do not fall within range, refer to page 18.

To power off the meter, remove the test strip.

Important: Be sure to discard used test strips. (Test strips may be used only once.)

Testing Your Blood Glucose



Important: To ensure accurate results, wash your hands and test site (for example, your forearm) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

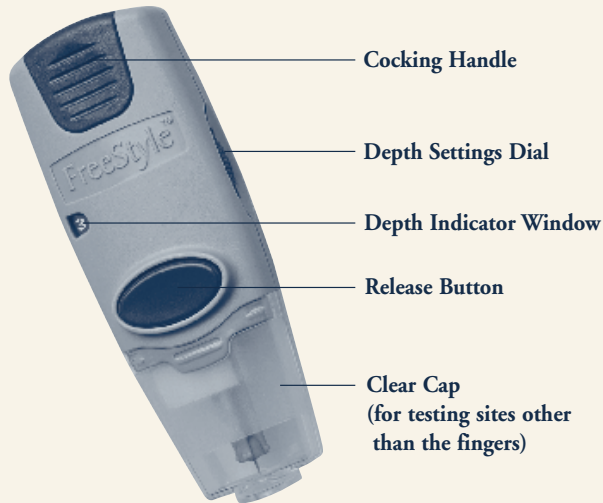
- With the FreeStyle® Meter, you can test your blood glucose on your forearm, fingers, upper arm, hand, thigh, or calf.
- Testing with the FreeStyle Meter requires a very small sample size, just 3/10 microliter of blood; about the size of a pinhead (example: ●).
- Most healthcare professionals recommend testing when blood glucose values are stable: before meals and before bedtime. However, when blood glucose is changing, blood from the fingertips or palm (at the base of the thumb) may show these changes sooner than blood from other sites.

WARNING: We recommend that you test on your fingers or palm (at the base of the thumb) if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

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.

The FreeStyle® Lancing Device



23

Using the Lancing Device

1



Remove Cap

Snap off the cap on the lancing device at an angle.

2



Insert Lancet

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.)

3



Twist Off the Rounded Top

Hold the lancet firmly in place with one hand; use your other hand to twist off the rounded top.

24

4



Replace Cap

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

Important: Lancing with the clear cap may be completed at the following test sites: forearm, upper arm, hand, thigh, and calf. Step 2 on page 29 shows an example of lancing on the forearm. Testing on other sites (except for fingers) is similar.

Use the blue cap for finger tests.

5



Set the Lancing Level

The FreeStyle® Lancing Device offers five different settings. Move the dial to the desired setting as shown in the depth indicator window. We recommend that you start at Level 3.

Level 1 is the shallowest depth; Level 5 is the deepest.

To lance your finger, we recommend that you set the depth setting on the lancing device to its shallowest depth (1).

6



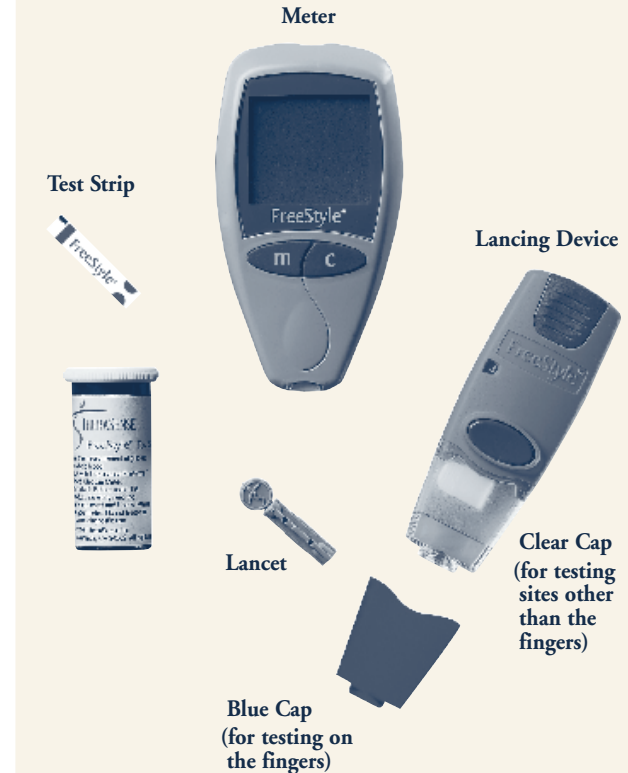
Cock the Handle

Pull the dark blue cocking handle out until it clicks.

(You may have already cocked the handle in step 2; this is okay.)

You are now ready to perform a blood glucose test (refer to page 27).

Blood Glucose Testing Components



Performing a Blood Glucose Test

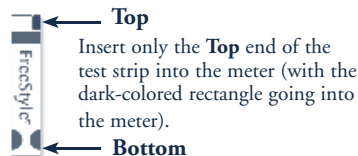
Before performing a blood glucose test, prepare the lancing device (refer to pages 24 and 25 for more information).

1



Prepare Your Meter

- Insert a new test strip into the meter until it stops. The meter will power on.

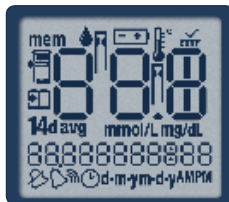


Note: If you do not start the test within two minutes, the meter will power off. To restart your meter, take out the unused test strip and reinsert it into the meter.

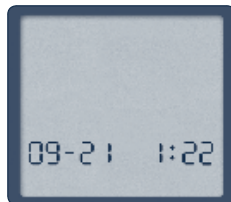
Setting the Test Strip Code

When the meter powers on, four display screens appear in the following order:

1. System Check



2. Date and Time



3. Code Number



4. Blood Drop and Test Strip Symbols



Note: To ensure accurate test results, make sure the code number on your meter always matches the number in the box outlined in blue, located on the side of the test strip vial.

- When you see the word “COdE” and a code number on the display screen, use the “c” (configure) button to scroll forward or the “m” (mode) button to scroll backward until the number matches the number on your test strip vial. The FreeStyle® Meter has a total of 50 codes.
- After you set your code number, the Blood Drop and Test Strip symbols will appear on the display screen.
- If you want to return to the code number display screen after the Blood Drop and Test Strip symbols appear, press the “c” button.

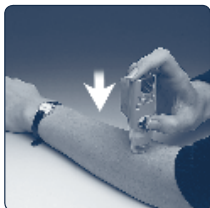
Caution: Take care to not press the “c” or “m” buttons when you are holding the meter while performing the blood test. If you do, you might change the code and get an incorrect reading or an Error 6.



Lancing Your Forearm, Upper Arm, Hand, Thigh, or Calf

For instructions on lancing your finger, refer to page 30.

To bring fresh blood to the surface of the test site, rub the test site vigorously for a few seconds until you feel it getting warm.



Lance the test site with the lancing device:

- Hold the clear cap down against the top of your test site. Depress the release button. **Do not lift up.**
- Continue to hold the lancing device and **gradually** increase pressure for several seconds.
- While holding the lancing device on your test site, look through the clear cap; the blood sample should be about the size of a pinhead (**example:** ●).
- Lift the lancing device straight up; be careful not to smear the blood sample on your test site.



Important: Avoid lancing areas with obvious veins or moles to avoid excess bleeding.

Important: Avoid lancing areas where tendons or bones stick out (for example, hand bones and ankle bones).



Lancing Your Finger

- Stimulate blood flow by keeping your hand warm or by lowering your hand to waist level and by gently massaging your finger.
- Set the depth setting on the lancing device to its shallowest depth (1).
- Lightly touch the lancing device (with the blue cap) against the side of your fingertip.
- Depress the release button, then place the lancing device on the table or desk near you.
- Gently squeeze your finger, if needed, until a blood drop the size of a pinhead forms (**example:** ●).

3



Filling the Test Strip with Blood

a. Make sure that the test strip is in the meter and the meter is powered on. (If the meter is powered off, take out the test strip and reinsert into the meter.) Leave the test strip in the meter. You are now ready to apply the blood sample.

b. Bring the test strip to the blood sample at a slight angle.

Important: Use only one edge of the test strip per test. Do not apply blood to both edges. Test strips may be used only once. Discard used test strips.

c. The test strip acts like a sponge and pulls the blood into the strip through the edge.

Edge of test strip

STOP

- **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 the test strip when the test strip is out of the meter.
- **Do not** put blood or foreign objects into the test strip port.

4



Waiting for Result

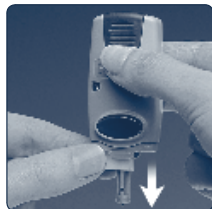
- Do not lift the test strip up until you hear **one** beep **or** see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.
- If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same edge of the test strip from which you started for up to 60 seconds from the time of the first application.
- The test result is complete when you hear **two** beeps. Your blood glucose test result is shown on the display screen.
- The time that the meter takes depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result. Results appear in an average of 7 seconds.



Important:

- Use only one edge of the test strip per test.
- If blood is applied to both edges, you can get an inaccurate result.
- If you have performed a test using both edges of the test strip, repeat the blood glucose test using a new test strip and a fresh blood sample.

5



Removing the Lancet

When you have finished testing, snap off the cap from the lancing device. Hold the lancet over a sharps container or a puncture-proof container with a lid. Pinch the white clip that holds the lancet until the lancet falls out.

Potential Bruising

It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance your finger or another site instead of your arm. Refer to page 1 for instructions on testing other sites.

Maintenance

Use isopropyl alcohol or soap and water to wipe the outside of the lancing device. If you wish, remove the cap, wash it in warm water and rinse well.

Important: Do not immerse the body of the lancing device in water or any other liquid.



LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle® Meter displays results from 20 to 500 mg/dL (1.1 to 27.8 mmol/L).



LO Reading

If your test result is lower than 20 mg/dL (1.1 mmol/L), LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).

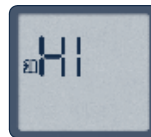
LO Reading *with* Symptoms

If you have a LO reading and have symptoms such as weakness, sweating, nervousness, headache, or confusion, **then** follow your doctor's recommendations to treat hypoglycemia.

LO Reading *without* Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, **then** retest with a new test strip. If you still get a LO reading, follow your doctor's recommendation to treat hypoglycemia.

LO and HI Readings



HI Reading

If your test is above 500 mg/dL (27.8 mmol/L), HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).

HI Reading *with* Symptoms

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, **then** follow your doctor's recommendation to treat hyperglycemia.

HI Reading *without* Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, **then** retest with a new test strip. If you still get a HI reading, follow your doctor's recommendation to treat hyperglycemia.

Appendices

Meter Screen Displays

Setting Up Your Meter

- **To Enter Setup Mode**

Start with the meter off (and no test strip inserted). Press and firmly hold the “m” (mode) button until the set display screen appears.

- **To Exit at Any Time**

Press and hold the “m” button until the meter powers off.

- **To Move Through the Screens**

Press the “m” button to move through all the setup screens such as sound level, time, date, and so on.

Press the “c” (configure) button to change setting within a setup screen.

Example: Use the “m” button to bring up the blinking unit of measurement display screen. Press the “c” button to select the desired Unit of Measurement; mg/dL (U.S. Standard) or mmol/L.

Setting the Sound



OFF



LOW



HIGH

There are three sound volume options to let you know when the test strip is full, when the reading is done, and when an error occurs: Off, Low, and High (default setting).

1. Press the “c” button until the desired sound level appears.
2. Press the “m” button to move to “Setting the Time.”

Setting the Time



HOUR



MINUTE

1. With the hour blinking, press the “c” button until the correct hour appears. If using the 12-hour time format, be sure to press the “c” button until the correct choice between “AM” and “PM” is seen.
2. Press the “m” button to move to minute setting.
3. With the minute blinking, press the “c” button until the correct minute appears.
4. Press the “m” button to move to “Setting the Date.”

Setting the Date



MONTH



DAY



YEAR

1. With the month blinking, press the “c” button until the correct month appears.
2. Press the “m” button to move to the day setting.
3. With the day blinking, press the “c” button until the correct day appears.
4. Press the “m” button to move to the year setting.
5. With the year blinking, press the “c” button until the correct year appears.
6. Press the “m” button to move to “Setting the Unit of Measurement.”

Setting the Unit of Measurement



1. To select milligrams per deciliter (mg/dL) or millimoles per liter (mmol/L), press the “c” button until the correct Unit of Measurement appears.
2. Press the “m” button to move to “Setting the Time Format.”

Setting the Time Format



You may select the 12-hour (AM/PM) time format or the 24-hour (00:00 to 23:59) time format.

1. Press the “**c**” button to select the preferred time format. The time will automatically update to the time format selected. (If using the 12-hour time format, AM or PM will also appear.)
2. Press the “**m**” button to move to “Setting the Date Format.”

Setting the Date Format



You may select m-d-y or d-m-y (for example, Sept. 21 2003 can be displayed as 9-21-2003 or 21-09-2003).

1. Press the “**c**” button to select the preferred date format.
2. Press the “**m**” button to move to the “Software Version Display.”

Software Version Display



This is the software version programmed in your FreeStyle® Meter. It is for display only, and cannot be changed.

The picture to the left is an example. Your meter may have a different number.

Write the software version shown on your meter display on page 67.

TheraSense Customer Service may ask you to provide this number when you call with questions or concerns regarding your FreeStyle Meter.

To exit the software version display screen, press the “**m**” button and continue to press the “**m**” button for a few seconds until the meter powers off.

Viewing Your Meter Memory

Getting In and Out of Memory

- **To Enter**

Start with the meter off (and no test strip inserted). Press the “m” button and release; the first memory screen to appear will be your 14-day average.

- **To Exit at Any Time**

Press and hold the “m” button until the meter powers off.

14-Day Average

The first memory display screen you see is your 14-day average. This includes all the readings from the last 14 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)



14d avg = your 14-day average

n = indicates the number of results
included in your 14-day average.

Working the Memory

The meter stores the last 250 test readings with time and date. You may scroll through all of the readings by pressing and holding the “c” button. The first reading you see is the most recent result. As you continue to push the “c” button the meter will scroll back to older readings. Eventually it will scroll to the most recent reading again.

Blood Glucose Test



A result without a control solution symbol (✓CONT) indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.

Control Solution Test



A value with (✓CONT) indicates that you have marked this reading as a control solution test (refer to page 20). This result is **not** included in your 14-day average. The date and time of the control solution reading will appear on the bottom of the screen.

Special Notes



Temperature: A result with a thermometer symbol indicates that the reading was taken outside of the meter's specified operating temperature range and may be less accurate. This value is included in your 14-day average.

LO Reading: A LO reading (under 20 mg/dL [1.1 mmol/L]) is included in the memory; it is **not** included in your 14-day average. Values under 20 mg/dL are recorded in memory as LO.

HI Reading: A HI reading (over 500 mg/dL [27.8 mmol/L]) is included in the memory; it is **not** included in your 14-day average. Values over 500 mg/dL are recorded in memory as HI.

Transferring Data



The data port allows you to download test results from the meter's memory to a computer or upload to a secure, protected website designed for diabetes data management. (Requires Freestyle Data Cable, and Freestyle data management software or other software programs that accept Freestyle data.)

You will see the word "PC" on the display screen when the Freestyle Data Cable is inserted into the data port. The meter will display "PC" until the cable is removed from the data port.

For more information, please go to our website or call TheraSense Customer Service.

Note: You will not be able to perform a test when the cable is inserted in the data port.

45 Call Customer Service Toll Free at 1-888-522-5226 www.therasense.com

Error Messages

Error 1



Possible Causes

- Sample is too small.
- Problem with the test strip.
- Problem with the meter.
- **Very** low blood glucose (less than 20 mg/dL [1.1 mmol/L]).

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.
2. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, 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 Causes

- Problem with the test strip.
- Problem with the meter.
- **Very** high glucose (above 500 mg/dL [27.8 mmol/L]).
- HIGH control solution applied when temperature is too cold.
(This applies only to control solution that is labeled as HIGH.)

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.
2. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, 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 Causes

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter, or blood applied before the Blood Drop and Test Strip symbols display.
- Problem with the test strip.
- Problem with the meter.

What You Should Do

1. Be sure you see the Blood Drop and Test Strip symbols on the display screen before you apply blood or control solution.
2. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, 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 Causes

- Problem with test strip.
- Meter malfunction.

What You Should Do

1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, 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.

Note: Error 5 is not used.

Error 6



Possible Causes

A button on the meter was pushed when applying blood sample or control solution.

What You Should Do

1. Retest using a new test strip. Do not touch the “m” or the “c” button while applying blood or control solution to the test strip.
2. If the error persists, call TheraSense Customer Service.

Battery

Your FreeStyle® Meter comes with one #2032, 3 volt, lithium battery installed. Each battery provides enough power to perform about 1,000 tests. If your battery runs low, the battery symbol () appears on every display screen until you change the battery.

Important: *When this symbol appears, you should replace the battery immediately.*

- To avoid losing the time and date settings, replace the battery **within one minute** of removing the old battery.
- If you take more than one minute to replace the battery, you must reset the time and date to get the correct 14-day average.
- Removing the battery does not affect the meter's memory log or previously-stored user settings (for example, unit of measurement, calibration code, and date format).
- If the time and date settings are not reset, test results will be stored in memory with a time of 12:00 a.m. (00:00) and a date of 00-00.

Replacing the Battery

1



Turn the meter over. Press in the battery door clip to open. Swing door out and then off the meter.



2



Install the battery with the positive (+) sign facing up towards you.



3



To close, angle the bottom of battery door onto meter and press down until it snaps gently into place.

Note: If you cannot find a replacement battery, call TheraSense Customer Service.

Setting the Time and Date after Replacing the Battery

Even if you lose your time and date settings, you can conduct a blood glucose test at any time by inserting a test strip into the meter. When you are finished with your test, you should reset the time and date settings by following the instructions for Option 1, Option 2, or Option 3.

Option 1 – Powering On the Meter with the “m” Button



1. Press and release the “m” button. The setup screen appears.
2. Enter the correct time and date by following the instructions for “Setting Up Your Meter” on pages 37 to 42.

Important: You must begin the setup process within five seconds.

If you do not begin the setup process within five seconds, the meter automatically displays the 14-day average screen. You may now scroll through all of the readings in the memory. Refer to “Working the Memory” on page 44.



Option 2 – Powering On the Meter by Inserting a Test Strip



1. Push the test strip into the meter until it stops. The meter powers on. The setup screen appears.
2. Enter the correct time and date by following the instructions for “Setting Up Your Meter” on pages 37 to 42.

Important: *You must begin the setup process within five seconds.*

If you do not begin the setup process within five seconds, the meter automatically displays the Code Number screen followed by the Blood Drop and Test Strip Symbols screens (shown below). This indicates that the meter is now ready to conduct a blood glucose test. Refer to “Performing a Blood Glucose Test” on page 27.



Option 3 – Powering On the Meter to Enter the Setup Mode



1. Press and firmly hold the “m” button until the setup screen appears.
2. Enter the correct time and date by following the instructions for “Setting Up Your Meter” on pages 37 to 42.

Note: Once you begin the setup process using any of the three options above, you may update all of your meter’s settings.

Troubleshooting

Meter does not power on after inserting a test strip.

Probable Cause	What to Do
The battery is dead.	Replace the battery and reset the date and time (refer to pages 51 and 52).
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you (refer to page 51). Note: If the battery has been installed incorrectly or has been out of the meter for more than one minute, reset the date and time (refer to page 52).
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the test strip with the printed side up and the top of the strip in the meter (refer to page 8).
Defective meter 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 (two minutes).	Repeat the test using a new test strip. Wait until you see the Blood Drop and Test Strip symbols on the display screen before you apply the blood sample (refer to page 31).
Defective meter or test strips.	Call TheraSense Customer Service.

Caring for Your Meter

- Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip and data ports.
- Store the meter in the carrying case after each use.

Cleaning the Meter

Clean the outside of the meter using a cloth dampened with one of the following:

- Mild detergent/mild soap and water
- 70% isopropyl alcohol
- A mix of one part household bleach, nine parts water

Important: Avoid getting water or any other liquid into the test strip and data port. **Never** immerse the meter in water or any other liquid solution.

Meter Specifications

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	1,000 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	Either mg/dL or mmol/L
Memory	250 blood glucose and control solution tests with date and time
Operating Relative Humidity	5% to 90%
Operating Temperature	40° to 104° F (5° to 40° C)
Power Source	One #2032 battery, 3 volt lithium replaceable
Result Range	20 to 500 mg/dL (1.1 to 27.8 mmol/L)
Sample	Whole blood, capillary
Sample Size	300 nanoliters (1/3 or 0.3 microliter)
Size	Width 2.03" x Length 3.82" x Thickness 0.98" (at thickest point)
Test Time	Average of 7 seconds
Weight	2.04 oz. (including battery)

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Time of Day	Plasma glucose range (mg/dL) for people without diabetes	Your target range (mg/dL)
Fasting and before meal	Less than 110	_____ mg/dL
2 hours after meals	Less than 140	_____ mg/dL
Bedtime	Not specified	_____ mg/dL
Between 2AM and 4AM	Not specified	_____ mg/dL

Source: ADA Clinical Practice Recommendations 2003 .

Meter Serial No. () – () _____ – _____
(Found on the back of your meter)

Software Version No. _____

Important phone numbers:

TheraSense Customer Service: Toll Free 1-888-522-5226
(24-hours a day, 7-days a week)

Physician

Pharmacist

Diabetes Educator

Other