



Intended Use

- The Optium Omega System is intended for use outside the body (in other words, *in vitro* diagnostic use only) and is for self-testing or healthcare professional use.
- The Optium Omega Meter should only be used with test strips and control solutions intended for use with the Optium Omega Meter. Using other brands of test strips and control solutions with the Optium Omega Meter can produce inaccurate results.

Do use the Optium Omega Meter for:

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

Do not use the Optium Omega Meter for:

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

WARNING:

- Patients receiving peritoneal dialysis using solutions containing icodextrin should not use the Optium Omega Blood Glucose Monitoring System.
- The Optium Omega System contains small parts that may be dangerous if swallowed.

Caution: Please read all the instructions provided in this *instructions for use* and practice the testing procedures before using the Optium Omega 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.
- The injection of solutions containing Maltose >20mg/dL or 0.6 mmol/L (present in some intravenous immunoglobulin preparations), Galactose >13 mg/dL (0.7 mmol/L), or Lactose ≥10 mg/dL (0.3 mmol/L) causes overestimation of blood glucose results.
- 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 (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), and 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 (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), 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 this *instructions for use*, call your healthcare professional.

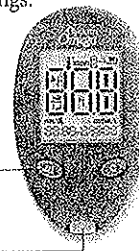
The Optium Omega Meter and How It Works

m (Mode) Button

- Move to different mode settings.
- Changes the test strip code (scrolls backward).
- Turn meter on.
- Turn meter off.

Display Screen

Displays your test results and other important information.



Test Strip Port
Insert the Top end of an Optium Omega Test Strip here

c (Configure) Button

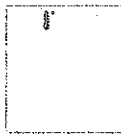
- Marks a control solution test.
- Changes the test strip code (scrolls forward), date, time, and reviews stored readings

The Optium Omega Meter Display



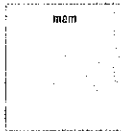
System Check Screen

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



Thermometer Symbol

Appears if your meter is out of temperature range.



Memory Symbol

Shows you test results stored in the meter memory. The meter stores your last 50 blood glucose test results.



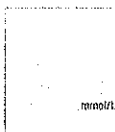
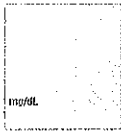
Battery Symbol

Appears when you should replace the battery.



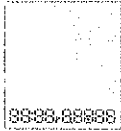
Control Solution Test Symbol

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



mg/dL or mmol/L

Indicates unit of measurement. Units are factory set and cannot be changed.



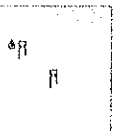
Message Area

Displays date and time.



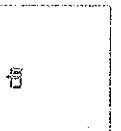
Test Result Area

Test results appear here.



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.



Test Strip Code Symbol

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

The Optium Omega Control Solution



The control solution indicated for use with the Optium Omega is a red liquid that contains a fixed amount of glucose that is used to ensure that your meter and test strips are working together properly.

Note: Please read important control solution information enclosed in the control solution package.

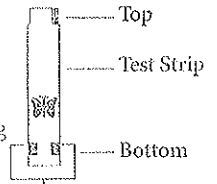
The Optim Omega Test Strip

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

Note: Please read important test strip information enclosed in the test strip package.

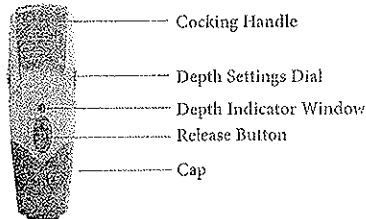
Sample Areas (dark-colored squares on test strip edge)

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





Sample Area/Test Strip Edge


The Lancing Device

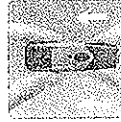



Prepare the Lancing Device


- 

Remove Cap
Snap off the cap on the lancing device at an angle.
- 

Insert Lancet
Insert a new 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
Hold the lancet firmly in place with one hand; use your other hand to twist off the rounded top.
- 

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

Set the Lancing Level
The Lancing Device offers four different settings. Move the dial to the desired setting as shown in the depth indicator window. Level 1 is the shallowest depth; Level 4 is the deepest. To lance your finger, we recommend that you start at Level 1.
- 

Cock the Handle
Pull the dark 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.

Before Performing a Blood Glucose Test

1



Turn On the Meter

Insert the top of a new test strip into your meter until it stops. Press the "m" button to power the meter on.

Note: If you do not start the test within two minutes, the meter will power off. To restart your meter, press the "m" button to power the meter on again.

2



Check the Display Screen

This screen always appears when the meter is first powered on so that you can make sure the display is working properly. Do not use

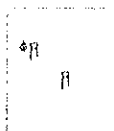
3



Set the Test Strip Code

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.

Code Number



After you set your code number, the blood drop and test strip symbols will appear on the display screen.




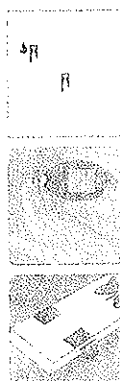
If you want to return to the code number display screen after the blood drop and test strip symbols appear, press the "c" button.

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

Blood Drop and Test Strip Symbols





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.

Performing a Blood Glucose Test

- 1  **Insert a Test Strip**
Insert the top of a new Test strip into the meter until it stops. Press the "m" to power on the meter.
- 2  **Obtain a Blood Sample**
 - a. Set the depth setting on the lancing device to its shallowest depth (1).
 - b. Lightly touch the lancing device against your fingertip.
 - c. Press the release button.
 - d. Gently squeeze your finger, if needed, until a blood drop the size of a pinhead forms (example: ).
- 3  **Apply Blood to Test Strip**
 - a. Make sure that the test strip is in the meter and the meter is powered on and the blood drop and test strip symbols are showing. 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 test strip edge per test. Do not apply blood to both edges, or you may get an inaccurate result. 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 test strip edge.



- 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  **Obtain a Result**
 - a. Do not pull the test strip away until you see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.
 - b. 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 test strip edge from which you started for up to 60 seconds from the time of the first application.
 - c. Your blood glucose test result is shown on the display screen. For meters preset to mg/dL, the mg/dL will appear to the left of the result as shown.  For meters preset to mmol/L, the "mmol/L" will appear to the right of the result as shown. 
 - d. 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.
- 5  **Test Strip and Lancing Device Disposal**
Dispose of the used test strip in a sealed container immediately.
Removing the Lancet
When you have finished testing, snap off the cap from the lancing device. 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 another test site.

Maintenance

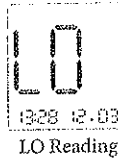
Use isopropyl alcohol or soap and water to wipe the outside of the lancing device. If you wish, remove the cap, wash it in warm water and rinse well.

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

Special Messages

LO and HI Readings

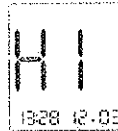
Important: Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood sugar is unusually low or high, or if you do not feel the way your results indicate, repeat the test with a new test strip. If your reading is not consistent with your symptoms, you should contact your healthcare professional and follow his or her treatment advice. The Optium Omega Meter displays test 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).

Follow your doctor's recommendations to treat hypoglycemia.



HI Reading

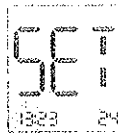
If your test result is higher than 500 mg/dL (27.8 mmol/L), HI will appear on the meter display screen. This reading indicates severe hyperglycemia (high blood glucose).

Follow your doctor's recommendation to treat hyperglycemia.

Meter Set Up

Setting Up Your Meter

- **To Enter Setup Mode**
Start with the meter off. Press and firmly hold the "m" (mode) button until the display screen appears. The first set screen is "Setting the Time".
- **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 time, date, and so on.
- **To Change Settings Within the Screen**
Press the "c" (configure) button.



Setting the Time

1. With the hour blinking, press the "c" button until the correct hour appears.
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 Time Format."



Setting the Time Format

1. With the hour mode blinking, press the "c" button to move between 12-hour and 24-hour format. The time automatically updates to the format selected.
2. Press the "m" button to move to "Setting the Date."



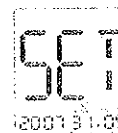
Setting the Date

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 Date Format."



Year-Month-
Day



Year-Day-
Month

Setting the Date Format

1. With the date blinking, press the "c" button to select month-day or day-month format. The date automatically updates to the format selected.
2. Press the "m" button to move to the "Setting the Time Format."

Meter Memory

Access and Exit Memory

To Access

Start with the meter off. Press the "m" button and release; when the meter turns on three display screens will appear in the following order:

1. System Check Screen
2. Code Number
3. Blood Drop and Test Strip

When the blood drop and test strip symbols are displayed, press and hold the "m" button and release.

To Exit at Any Time

Press the "m" button until the meter powers off.

Test Results

The meter stores the last 50 test results with time and date. You may scroll through all of the test results by pressing and holding the "c" button. The first test result you see is the most recent. LO and HI readings are included in your memory.

As you continue to push the "c" button the meter will scroll back to older test results. Eventually it will scroll to the most recent test result.



Temperature

A test 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.



Blood Glucose Test

A test result without a control solution symbol 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 a control solution symbol indicates that you have marked this reading as a control solution test.

The date and time of the control solution reading will appear on the bottom of the screen.

Error Messages

Error 1

Possible Causes

- Sample is too small.
- Problem with the test strip.

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 your local customer care office.

Error 2

Possible Causes

- Problem with the test strip.
- Problem with the meter.
- Very high glucose (above 500 mg/dL or 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 your local customer care office.

Error 3

Possible Causes

- Incorrect test procedure. For example, putting blood on the test strip before turning on 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 your local customer care office.

Error 4

Possible Causes

- Problem with test strip.
- Problem with the meter.

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 your local customer care office.

Error 5

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 your local customer care office.

Meter Maintenance

Battery

Your Meter comes with one #2032, 3 volt, lithium battery installed. The 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.

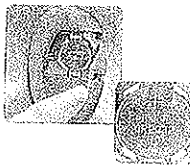
Important: When this symbol appears, you should replace the battery immediately.

- To avoid losing the time and date settings, replace the battery *immediately after* removing the old battery.
- If you lose the current time and date during the battery removal, you must reset the time and date.
- If the time and date settings are not reset, test results will be displayed with a time of 12:00 a.m. (00:00) and a date of 00-00.
- Removing the battery does not affect the meter's memory log or previously-stored user settings (for example, the calibration code and date format).



Replacing the Battery

Turn the meter over. Slide the battery door to the right to open. Remove the old battery by pulling battery tab.



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



To close, slide the battery door in until it snaps into place. Be sure to discard the old battery in compliance with your local government's regulations.

Caring for Your Meter

Avoid getting dirt, dust, blood, control solution, water or any other liquid in the meter's test strip port. 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: Never immerse the meter in water or any other liquid.

Troubleshooting

ISSUE: Meter does not power on after pressing the on button









Probable Cause	What to Do
The battery is dead.	Replace the battery and reset the date and time (if necessary).
The battery is installed incorrectly.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
There is no battery in the meter.	Install battery.
Defective meter or test strips.	Call your local customer care office.
Blood or foreign objects put into test strip port.	Call your local customer care office.

ISSUE: Test does not start after applying the blood sample

Probable Cause	What to Do
Blood sample is too small.	You may add blood to the same test strip edge from which you started from for up to 60 seconds from the time of the first application. If necessary, perform another 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.
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. Make sure the test strip is fully inserted.
Defective meter or test strips.	Call your local customer care office.

Optium Omega System 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	Preset to mg/dL (milligrams per deciliter) or mmol/L (millimols per liter)
Meter Storage Temp.	-4° to 140° F (-20° to 60° C)
Memory	50 blood glucose and control solution tests with date and time
Operating Relative Humidity	5% to 90% (non-condensing)
Operating Temperature	40° to 104° F (4° 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	0.3 microliter (300 nanoliters)
Size	Width 2.00" x Length 3.30" x Thickness 0.63" (at thickest point)
Test Time	Average of 5 seconds
Weight	1.43 oz. (including battery)

	European Authorized Representative		Manufactured by
	In vitro diagnostic medical device		CE Mark reg. IVDD 98/79/EC
	Catalog number		Recycle
	Consult instructions for use		Environmental friendly