

Dear Embrace EVO[™] Owner

Thank you for choosing the Embrace EVO[™] Blood Glucose Meter to help you manage your diabetes. We designed the Embrace EVO[™] Blood Glucose Meter to be accurate and easy to use. The added convenience of the AutoCode features an innovative automatic calibration feature that eliminates the manual coding step usually required by many blood glucose meters before starting a new vial of test strips. This manual contains all of the information needed to use and maintain your new blood glucose meter. Please read carefully before use.

Please call us at 1-877-979-5454 for questions and inquiries. Hours of operation are Monday through Friday, 8am - 8pm EST. If you have any questions or need assistance outside the operational days and times, please contact your health care provider.

Intended Use

The Embrace EVO™ Blood Glucose Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

IMPORTANT:

- Dehydration – Severe dehydration may lead to inaccurate blood glucose test result. If you suspect you are severely dehydrated, contact your healthcare professional immediately.
- Hematocrit range – A hematocrit range that is higher than 55% or lower than 30% can cause inaccurate blood glucose test results.
- Not intended for use on neonates (newborns).

Important Safety Instructions

- The meter and lancing device are for single patient use. Do not share them with anyone, including other family members. Do not use on multiple patients.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

The link of public health notification and standard practice guideline are :

- “FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
- “CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010) <http://www.cdc.gov/injection-safety/Fingerstick-DevicesBGM.html>

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Embrace EVO[™] Meter





Test Strip Port

This is where you insert the test strip and the meter will turn on automatically.

Meter Display

Shows your blood glucose test results, memory values, averages, and other messages

Enter () and ▲ ▼ buttons

Press and hold Enter () for 2 seconds to turn the Meter on or off, or press Enter () to go into setup mode when not testing. Press ▲ or ▼ to enter control mode with test strip inserted, during meter setting, or to navigate the stored test values and averages.



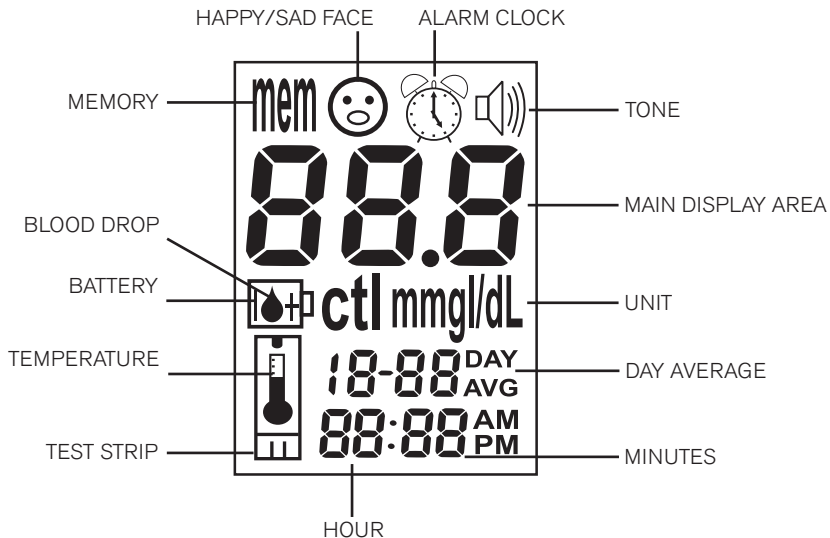
Battery Compartment

Holds one CR 2032 3V Lithium coin cell battery.

Data port

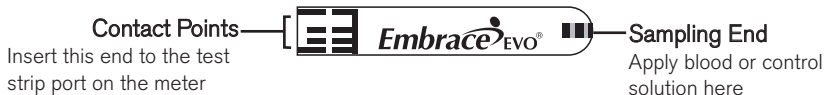
Please contact 1-877-979-5454 Monday through Friday between 8AM and 8PM (EST) for purchasing cable.

The Embrace EVO™ Meter Display Screen



- MEMORY: Indicates the number in the display area is a stored test value (see page 40)
- MAIN DISPLAY AREA: .. Displays test results, stored test values, calculated result averages, and messages.
- BATTERY: Appears when the battery is low and needs to be replaced.
- TEMPERATURE: Appears when it is either too hot or too cold to test (outside the ranges of 50°F~104°F).
- TEST STRIP: This icon will flash to prompt you to insert a test strip for testing.
- DAY AVERAGE: Displayed when viewing 7-, 14-, or 30-day averages (on page 40).
- UNIT: Unit of Measurement for your blood glucose.
- CTRL: This icon indicates a control solution test (see page 21).
- TONE: Indicates the tone is on (see page 19).
- ALARM CLOCK: Indicates the alarm function is turned on.
- HAPPY FACE: This icon indicates the meter is working properly.
- BLOOD DROP: This icon will flash to indicate the meter is ready for testing.

The Embrace EVO[™] Blood Glucose Test Strip




The Embrace EVO[™] Test Strips are glucose specific, biosensor-based test strips that can test glucose in capillary whole blood in as quickly as 6 seconds and requires very little blood sample. The test result is plasma referenced for easy comparison to lab results and has under-fill detection to alert you when there is not enough blood to perform a test, so you can be assured that each reading you get is an accurate and meaningful result.

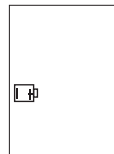
IMPORTANT:

- Be sure to use only the Embrace EVO[™] Test Strip with the Embrace EVO[™] Blood Glucose Meter. Other brands of test strips will not work with the meter.
- The Embrace EVO[™] Blood Glucose Test Strips are sensitive to moisture and light, it is important to close the vial cap of the test strip bottle tightly after each use. DO NOT leave any test strips outside the bottle while not in use.
- Carefully discard used test strips and lancets in proper waste containers.

Setting Up Your New System

Inserting (or Changing) the Battery

The battery needs to be inserted before using your Embrace EVO™ Meter for the first time or when the “” icon appears on the meter display.



Material you will need:

- One CR 2032 3V Lithium coin cell battery
- Your Embrace EVO™ Meter

Step 1.



Press firmly on the battery cover and slide in the direction of the arrow to open the cover.



Step 2.

Insert a new battery according to the direction found on the battery cover and inside the battery compartment. Slide the battery cover back into the meter firmly.

**NOTE:**

- When you change the battery, the meter automatically prompts you to check the time and date when turned on either by a Test Strip or pressing “.” If it is correct, press “” again to exit, or if the time and date are not correct, see page 13 for Setting the Clock.
- The date and stored results will not be erased when the batteries are being changed.
- Discard used batteries according to your local regulation.

Setting the Clock

Material you will need:

- Your Embrace EVO[™] Meter

Begin Set Up

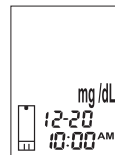
Step 1.

Press and hold “⏻” to turn on the meter.



Step 2.

The meter will run a series of self tests. “😊” will appear on the screen before entering the main mode. If error messages (Err1, Err 3, etc) appears, see Solving Problems on page 54.



Step 3.

After a flashing test strip icon appears on the meter display screen, press “▲” twice until meter display screen shows “🕒”.



Set Year

Step 4.

Press “⏻” and the current year will flash. Use the “▲” or “▼” buttons to select the correct year.

Press “⏻” button to confirm your choice and to advance to set the month.



Step 5.

The current month will flash. Use the “▲” or “▼” buttons to select the correct month.

Press “⏻” to confirm your choice and to advance to set the day.

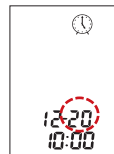


Set Day

Step 6.

The current day will flash. Use the “▲” or “▼” buttons to select the correct day.

Press “⏻” to confirm your choice and to advance to set the 12-hour or 24-hour time format.



Set 12-hour or 24-hour Time Format

Step 7.

The time format will flash. Use the “▲” or “▼” buttons to select the time format of your choice.

Press “⏻” to confirm your choice and to advance to set the hour.



Set Hour

Step 8.

The current hour will flash. Use the “▲” or “▼” buttons to select the correct hour.

Press “⏻” button to confirm your choice and to advance to set the minutes.




Set Minutes


Step 9.

The current minutes will flash. Use the “▲” or “▼” buttons to select the correct minutes. Press “⏻” to confirm your choice and exit time set up.




NOTE:

Anytime during set up, you may either press “” to exit, or insert a Embrace EVO[™] Test Strip and begin testing. The changes you have done so far will be memorized by the meter.

Begin testing (see page 28, Testing your Blood Glucose), or press and hold “” to turn off the meter.

Setting the Alarm

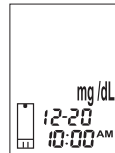
Step 1.

Press and hold “” to turn on the meter.





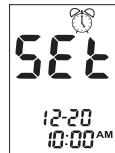
Step 2.

The meter will run a series of self tests before entering the main mode. If other error messages (Err1, Err 3, etc) appear, see Solving Problems on page 54 .



Step 3.

After a flashing test strip icon appears on the meter display screen, press “” three times until “” flashes.



Step 4.

Press “⏻” to enter the alarm setting. Use the “▲” or “▼” buttons to turn ON/OFF alarm 1.

**Step 5-Turn OFF the alarm**

Press “⏻” while the screen display shows alarm Off, then the screen will advance to set alarm 2. Repeat the above for alarm 3.

**Step 6-Turn ON the alarm**

Press “⏻” while the screen display shows alarm On, The screen will advance to set the alarm hour. The alarm hour will flash. Use the “▲” or “▼” buttons to select the correct alarm hour.



Press “⏻” to confirm your choice and to advance to set the alarm minutes. The alarm minutes will flash. Use the “▲” or “▼” buttons to select the correct alarm minutes.

Press “⏻” to confirm your choice and to advance to set the alarm 2. Repeat the above for alarm 3.



Turning ON/OFF Tone Sound

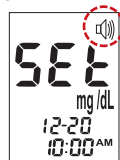
The Embrace EVO[™] Meter comes with beeper sound ON as preset. Turning off the tone may cause you to miss many important cues from your meter – such as confirmation or error messages.

Step 1.

Press “⏻” button to confirm your choice to advance to turning the Tone on or off.

Step 2.

Use the “▲” or “▼” buttons until meter display screen shows “🔊”, and the Tone ON/OFF icon will flash.



Step 3.

Press the “⏻” button to select Tone setting. Use the “▲” or “▼” buttons to turn on/off the tone.

**Step 4.**

Press the “⏻” to exit once you have made your selection.

**NOTE:**

Anytime during set up, you may either press “⏻” to exit, or insert a Embrace EVO™ Test Strip and begin testing. The changes you have done so far will be memorized by the meter.

Begin testing by inserting a Embrace EVO™ Test Strip (see page 28, Testing Your Blood Glucose), or press “⏻” to return to the start of set up, or press and hold “⏻” button to turn off the meter.

Control Solution Testing

Performing a Control Solution Test

The purpose of the control solution testing is to validate the performance of the Embrace EVO™ Blood Glucose Meter using the testing solution with a known range of glucose.

For purchasing information please contact us at 1-877-979-5454 between 8am and 8pm (EST) Monday through Friday.

You should perform control solution testing when:

- Using the Meter for the first time
- You open a new bottle of Embrace EVO™ Blood Glucose Test Strips
- You left the cap on the test strip vial open for a while
- You dropped the Meter
- You suspect your Embrace EVO™ Meter and Embrace EVO™ Test Strips are not working properly
- The blood glucose test results do not reflect how you feel
- You want to practice the testing procedure

IMPORTANT:

- Use only the Embrace EVO[™] Glucose Control Solution (Level 1 and Level 2) with the Embrace EVO[™] Test Strips. Other brands of control solution will produce an inaccurate result.
- Always check the expiration date. DO NOT use control solutions if expired.
- Mark the newly opened bottle of control solution with the date opened; discard any unused control solution three months after opening.
- DO NOT FREEZE. Store the control solutions at room temperature 59°F~86°F.

Materials you will need:

- Embrace EVO[™] Glucose Control Solution (Level 1 and Level 2)
- Your Embrace EVO[™] Meter
- A new Embrace EVO[™] Blood Glucose Test Strip

Step 1.

Insert a Embrace EVO[™] Blood Glucose Test Strip into the meter with the blood sample reaction zone facing up. Make sure the test strip contact points are inserted all the way into the meter. Close the test strip bottle immediately after you take out a strip.



IMPORTANT:

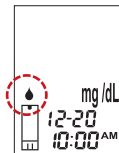
- Do not use a Test Strip that has expired. Check the expiration date that is printed on the test strip bottle and its package.
- Use each Test Strip immediately after removing it from the bottle.
- After removing a test strip from the bottle, replace the bottle cap immediately and close it tightly.
- Do not use wet or damaged Test Strips.
- Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place.
- Record the “date opened” on the test strip bottle label when you first open it. Three months after first opened date, discard the bottle and any remaining Test Strips.
- Make sure you are testing in an environment that is between 50°F~104°F, and allow 10 to 15 minutes for it to reach the new temperature before use. Your meter will not begin testing if it detects it is outside this temperature range.
- This is an auto coding meter. You do not need to insert a code card.
- Must insert test strip in the top of meter.
- Must see a flashing blood drop icon if the test strip has been inserted in the top.

Step 2:

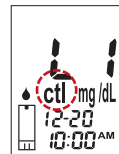
The “ 😊 ” will appear, and then the meter will enter the main mode with flashing test strip icon on the bottom-left side. If error messages (Err 1, Err 3, etc) appears, see Solving Problems on page 53 for Trouble Shooting.

Step 3:

Wait for the flashing blood drop and test strip icons on the left of the meter display screen.

**Step 4:**

Press the “▼” button once to enter Level 1 Control Solution Testing, twice to enter Level 2 Control Solution Testing. A “ctl” and Level 1 (or Level 2) will appear next to the test strip icon on the meter display screen, indicating that the meter is in Control Solution Testing. If you decide not to do a control solution test, press the “▲” or “▼” button until the “ctl” disappears from the meter display.



Step 5:

Squeeze a drop of Glucose Control Solution (Level 1 and Level 2) onto a clean, dry, non-absorbent surface. Do not apply Control Solution to the test strip directly from the bottle. Replace the bottle cap on the control solution bottle immediately after use.

Step 6:

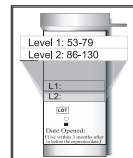
While holding the meter, touch the control solution to the edge of the sampling end of the test strip, and the control solution will be automatically pulled into the reaction area of the test strip.

**Step 7:**

The screen will begin to count down. After 6 seconds, the control solution testing result will appear on the meter display screen.

**Step 8:**

Compare the reading on the screen to the control range printed on the test strip bottle or its package. If the reading does not fall within the control range printed on the test strip bottle or its package, see Control Solution



Trouble Shooting on page 27.

NOTE:

- Control Solution Testing results will be stored into the meter's memory and indicated by "ctl" icon.
- Control solution testing result will not be used for calculating averages.
- Replace the bottle cap on the control solution bottle immediately after use.

Step 9:

Manually remove the used test strip and discard it into a proper waste basket. The meter will time-out after 1.5 minutes of inactivity.

IMPORTANT:

- Do not reuse test strips.

Control Solution Trouble Shooting

If your control solution testing is out of range (too high or too low), it may be caused by the following:

Possible Causes

- Wrong brand of Control Solution being used
- Expired or contaminated control solution or damaged test strips
- Meter malfunction
- Control solution not at room temperature

What you can do ...

- Make sure you are using Embrace EVO[™] Glucose Control Solution (Level 1 and Level 2).
- Make sure the testing environment is between 50°F~104°F.
- Check the expiration and open bottle date on both Control Solution and test strips. Repeat the test using a new test strip. If the result is still out of range, use a new bottle of control solution and retest.
- Please call us at 1-877-979-5454 for questions and inquiries. Our hours of operation are Monday through Friday between 8am and 8pm (EST). All other times, please contact your healthcare provider.

Testing Your Blood Glucose


Materials you will need:

- Your Embrace EVO™ Meter
- A new Embrace EVO™ Blood Glucose Test Strip
- Lancing device with a sterile, unused lancet
- Clear cap for Alternative Site Testing (AST) on palm and forearm (optional)

Before you test for the first time, make sure:

Set up your meter properly and run a control test. See Setting Up Your New System on page 11, and Control Solution Testing on page 21 for details.

Wash your hands and testing site thoroughly with soap plus warm water, and dry well.

You must be in an area between the temperature ranges of 50°F~104°F. Your meter will not test outside of this range and will display . Move the meter into an area that is between 50°F~104°F, and let it sit for 10 to 15 minutes before testing again.

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected appropriately when testing is conducted by the second person.

Preparing Your Lancing Device

Caution:

- The lancets are for single use only. Always use a new, sterile lancet each time you test.
- DO NOT share your lancing device or lancets with other people. Sharing or reusing lancets can lead to disease transmission.
- Dispose of properly in biohazard waste.
- When performing a blood glucose test, use a new sterile lancet every time. If alcohol wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

Step 1:

Wash hands with soap and warm water and dry thoroughly. Warm water stimulates blood flow to the fingers making it easier to obtain a sample.

Step 2:

Hang the arm down at the side for 10 to 15 seconds. Massage the wrist, palm, and then fingers. This can stimulate the blood flow to the finger more quickly.

Step 3:

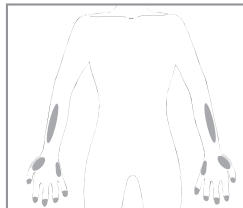
Hold the lancing device or lancet against the side of the finger and lance the finger. Follow manufacturer's instruction for how the lancing device or lancet should be used.

TIP:

- To avoid soreness, select a site on the side of your fingertips. To avoid calluses, choose a different site each time for obtaining the blood sample.

Important Information on Alternative Site Testing (AST)

The Embrace EVO[™] Blood Glucose Meter can test for blood glucose from sites other than your fingertip such as palm and forearm (alternative site testing, or AST). Alternative site testing can be less painful than fingertip testing, but because of the physiological difference between your fingertip and palm and forearm ⁽¹⁾, AST result may be significantly different than results from fingertip testing under certain conditions. You should consult with your doctor or healthcare professional before using AST.



DO AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since last meal)
- 2 hours or more after taking insulin.
- 2 hours or more after exercise.

Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs)

Alternative site measurements should never be used for insulin dosing calculations.

AST SHOULD NOT be used when:

- You have Hypoglycemic unawareness (not able to tell if you have low blood sugar).
- Within 2 hours of a meal, exercise, or medication.
- You will be operating machinery or driving a car.
- You are sick.
- You think your blood glucose is low.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.

Consult with your healthcare professional to decide if AST is right for you.

NOTE:

- If results from AST do not agree with how you feel, use fingertip testing instead.

1. Shu M, Osamu F, Kazuhiro H, Yoshihito A: Hypoglycemia Detection Rate Differs Among Blood Glucose Monitoring Sites. Diabetes Care 28(3):708–709, 2005

Performing a Blood Glucose Test

Step 1:

Take out a Embrace EVO[™] Test Strip from the test strip bottle and close the bottle immediately. Insert the test strip to turn on the meter.



IMPORTANT:

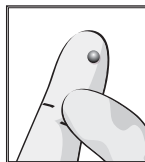
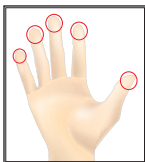
- Check the expiration date printed on the test strip bottle and its package. Do not use expired test strips.
- Use each test strip immediately after removing it from the bottle.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place.
- Record the “date opened” on the bottle label. Discard the bottle and any remaining test strip after three months from date of opening.
- Must insert test strip in the top of meter.
- Must see a flashing blood drop icon if the test strip has been inserted in the top of meter.

Step 2:

Wait for the flashing blood drop and test strip icons to appear on the left of the meter display screen.

Step 3- obtain blood sample**For Fingertip Testing:**

Hold the lancing device (use the white cap) against the center of your fingertip and press the release button to create a puncture.

**TIP:**

- Gently massage your hand and finger toward the puncture site to form a drop of blood (approximately: 0.8 μ L). Do not “milk,” or squeeze around the puncture site.
- Lance the side of your fingertip to avoid soreness. To avoid calluses, choose a different lancing site each time.

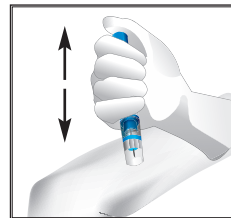
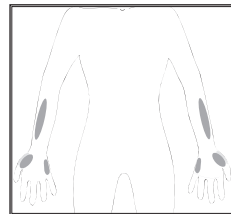
Step 3- continued

For Testing on Palm and Forearm:

Hold the lancing device (**use the clear cap**) against the test site (base of palm or forearm). Avoid a test site that has veins, moles, excessive hair, or bone. Press the lancing device firmly against the test site and press the release button. Do not lift up.

For forearm test sites, apply and release pressure (“Pumping”) for a few seconds while keeping the lancing device in constant contact with the skin. Palm testing (at the base of the thumb) does not require pumping.

When the blood is about the size of a pen tip (approximately: 0.8 μ l) lift the lancing device straight up without smearing the blood.



IMPORTANT:

- If results from AST do not agree with how you feel, use fingertip testing instead.

Step 4:

Gently bring the test strip and touch the drop of blood at a slight angle. The test strip acts like a straw to pull the blood in. Keep the test strip in the blood drop until the meter beeps to indicate the test strip has enough blood to test.

**Step 5:**


The screen will start to count down. After 6 seconds, your glucose testing result will appear on the meter display screen. Your test result will be automatically stored into the meter memory.

CAUTION:

- If you see “HI” or “LO” displayed, your blood glucose level may be above 600 mg/dL or below 20 mg/dL. Test again using fingertip testing, DO NOT test on palm or forearm. If you still receive the same result, call your physician or healthcare professional immediately.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device or test strips.

- Clean and disinfect the meter and lancing device after the test see page 44 for cleaning and disinfection.

Step 6:

Remove the used test strip and throw it into a proper wastebasket. The meter will time-out after 1.5 minutes of inactivity. Press “” to reactivate the meter.

Step 7:

Remove the used lancet from your lancing device according to instructions and discard it into a proper wastebasket.

IMPORTANT:

- You should consult your health care provider for instructions on how to properly dispose the used test strip.

Understanding Your Blood Glucose Test Results

Blood glucose values will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for adults without diabetes are⁽²⁾:

- less than 100 mg/dL before meals.
- less than 140 mg/dL after meals.

It is important to consult with your physician or healthcare professional to determine an appropriate target range for you.

What to do if you get a high or low reading

If the Meter displays results that are HI or LO, or you get a result that is more than 250 mg/dL or below 50 mg/dL AND you feel ill:

- Treat your diabetes according to the instruction from your doctor and/or consult with your healthcare provider.

If the Meter displays results that are "HI" or "LO," or you get a result that is more than 250 mg/dL or below 50 mg/dL AND you DO NOT feel ill:

- Test your meter with a control solution, refer to page 21, Control Solution Testing.
- Test again using fingertip.

If you still get a high or low reading, contact your healthcare professional.

IMPORTANT:

- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with blood glucose meters.

Reference:

2. American Diabetes Association Position Statement: Standards of Medical Care in Diabetes—2010. Diabetes Care 2010; 33 (Suppl.1):S11–S61.


Viewing Stored Readings and 7-, 14-, and 30-Day Average from Memory

Your Embrace EVO™ Meter automatically stores up to 300 test and control results with date and time. In addition, the meter also provides 7-, 14-, and 30-day average to help you better track your efforts in controlling your blood glucose level. You will need to set your meter date and time before using the memory and day averaging function, see page 11, Setting Up Your New System. The meter will not memorize any test or control results if the date and time are not set.

Material you will need:

- Your Embrace EVO™ Meter

Step 1:

Turn on the meter by pressing and holding “” button.

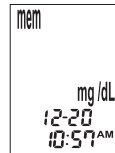


Step 2:

The “ 😊 ” will appear on the screen, and then the meter will display the main mode. If error messages (Err 1, Err 3, etc) appear, see Solving Problems on page 54 for trouble shooting.

Step 3:

After the flashing test strip icon appears, press the “ ▲ ” button once, and the “**mem**” will appear at the upper left corner of the display screen. Press “ ⏻ ” to select the “**mem**” mode.



Step 4:

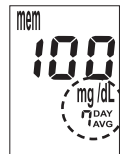
Press “ ▲ ” to view your result, from the most recent to the oldest.


When less than 300 results are stored in the meter’s memory, “**nil**” will appear after the last recorded test result.

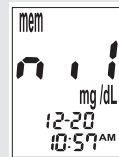
Step 5:

For 7-Day, 14-Day, or 30-Day Average results, continue to press the “▼” button until you see the 7-Day, 14-Day, or 30-Day Average icon according to your choice.


When your 30-day average is displayed, you can press “▲” to go back to view your averages and stored readings.

**NOTE:**

- Control testing results will be flagged by a “ctl” icon next to the “” icon in addition to the “**mem**” icon. Control testing results will not be included in the day averages.
- When there are no memorized results stored in the meter, the display screen will show “**nil**”.
- When there is no day average data available, the display screen will show 4 dashes.



- If the meter's memory already has 300 test results, adding a new test result will cause the oldest one to be deleted.
- Memorized test results and day averages will not be erased when changing batteries.

After you finish viewing memory or days averages, either begin testing by inserting a Embrace EVO[™] Blood Glucose Test Strip (see page 28 , Testing Your Blood Glucose), or press and hold the “” button to turn off the meter.

Caring for the Meter

Caring for your Embrace EVO™ Meter is easy. Follow these simple guidelines to keep your Embrace EVO™ Meter working properly.

NOTE:

- Do not get water inside the Embrace EVO™ Meter. Never immerse the meter or hold it under running water.
- Do not use glass or household cleaners on the meter.
- Do not try to clean the test strip holder.
- Do not contaminate the strip holder with blood or control solution.
- Handle the meter with care; severe shock, such as dropping the meter, could damage the electronics.

Cleaning and disinfection procedures for meter and lancing device

Cleaning and disinfection are different and both should be performed. Cleaning is part of your normal care and maintenance, but cleaning does not kill germs effectively. After use

and exposure to blood, all parts of this kit can potentially transmit infectious diseases. Disinfection is the only way to reduce your exposure to disease.

You should disinfect areas where there are both high concentrations of dangerous germs and a possibility that they will be spread to others. That is because disinfectants have ingredients that destroy bacteria and other germs. While surfaces may look clean, many infectious germs may be lurking around. Given the right conditions some germs can live on surfaces for hours and even for days.

The proper disinfection of Embrace EVO™ blood glucose monitoring equipment is using DISPATCH® Hospital Cleaner Disinfectant Towels With Bleach, it is pre-moistened disposable towels for use in healthcare and other areas where control of cross contamination is required. Only Dispatch wipes have been validated for use in cleaning and disinfection of the meter.

Cleaning and disinfection frequency: The Meter and Lancing Device should be cleaned when it appears dirty or contaminated with blood. It should be cleaned using the Dispatch wipe prior to each disinfection stop according to the validated cycle of 1825 times. Clean-

ing and Disinfection was validated for a cycle of $365 \times 5 = 1825$ times is equivalent to one cleaning plus one disinfection per day over 5 years.

Cleaning and disinfecting your meter

Clean and disinfect your meter at least 1 time per week using DISPATCH[®] hospital cleaner disinfectant towels with bleach, with EPA registration number 56392-8. Other wipes with EPA Reg. No. 56392-8 may also be used.

1. Wash hands with soap and water.
2. Inspect for blood, debris, dust, or lint anywhere on the meter.
3. Clean or disinfect meter.
 - To clean the Embrace EVO™ meter, blood/body fluids must be thoroughly cleaned from surface and objects before disinfecting. Dispense a new towel (DISPATCH[®]) from its package. Wipe surface with towel (DISPATCH[®]) until completely wet. You should wipe all external areas of the meter including both front and back surfaces. Avoid wetting the test strip holder. Discard used towel in a sealed container where it will not be touched by others.

- To disinfect the Embrace EVO[™] meter, dispense a fresh towel (DISPATCH[®]) from its package. Wipe surface with towel (DISPATCH[®]) until completely wet. You must wipe all external areas of the meter including both front and back surfaces and allow 1 minute contact at room temperature. Avoid wetting the test strip holder. Wipe dry or allow to air dry. Oily substances must be removed prior to disinfection. Discard used towel in a sealed container where it will not be touched by others.



NOTE:

- If the meter is being operated by a second person who is providing testing assistance to the user, the meter should be cleaned and disinfected prior to use by the second person.
- Avoid alcohol and ammonia. Even though these two ingredients are excellent disinfectants, they are not safe for your meter or lancet device. Alcohol damages the LED readout and ammonia corrodes the metal parts.
- User should wash hands thoroughly with soap and water after handling the meter, lancet device, and test strip.
- Keep DISPATCH[®] out of reach of children.
- Do not flush towels down toilet.
- Do not get water inside the meter or hold it under running water.
- Do not use glass or household cleaners on the meter.
- Do not try to clean the test strip holder.
- Avoid wetting the test strip holder.
- Only DISPATCH[®] hospital cleaner disinfectant towel should be used to clean and disinfect your meter.

Cleaning and disinfecting your Lancing Device

Clean and disinfect your Lancing Device at least 1 time per week with DISPATCH® hospital cleaner disinfectant towels with bleach, with EPA registration number 56392-8. Other wipes with EPA Reg. No. 56392-8 may also be used. Cleaning and Disinfection was validated for a cycle of $365 \times 5 = 1825$ times is equivalent to one cleaning plus one disinfection per day over 5 years. The lancing device has a 5-year use life.

1. Inspect for blood, debris, dust, or lint anywhere on the lancing device.
2. Clean or disinfect lancing device.
3. To clean the lancing device and AST endcap, blood/body fluids must be thoroughly cleaned from surface and objects before disinfecting. Dispense a new towel (DISPATCH®) from its package. Wipe surface with towel (DISPATCH®) until completely wet. Discard used towel in a sealed container where it will not be touched by others.
4. To disinfect the lancing device and AST endcap, dispense a fresh towel (DISPATCH®) from its package. Wipe surface with towel (DISPATCH®) until completely wet. You must wipe surface with towel (DISPATCH®) until completely wet and allow 1 minute contact at room temperature. Wipe dry or allow to air dry. Oily substances must be removed prior to disinfection. Discard used towel in a sealed container where it will not be touched by others.



5. Wash hands with soap and water.

NOTE:

- If the meter is being operated by a second person who is providing testing assistance to the user, the lancing device should be decontaminated prior to use by the second person.
- The lancing device is for patient self-monitoring by a single person only. It must not be used to collect blood from more than one person as this poses an infection risk.
- Keep DISPATCH[®] out of reach of children.
- User should wash hands thoroughly with soap and water after handling the lancing device.
- Only DISPATCH[®] Hospital Cleaner Disinfectant Towel should be used to do cleaning and disinfection with the lancing device.

The list of things you should look for as signs of deterioration after disinfection

Meter:

- Control solution out of range
- Clouding of the LCD display
- Corroding of the plastic housing
- Corroding of the buttons

Lancing Device:

- Corroding of the plastic housing of Lancing Device and clear AST cap
- Corroding of the depth setting
- Corroding of the buttons

If these signs of deterioration are noted, you should stop using the device and call customer service at 1-877-979-5454 between 8AM and 8PM (EST), Monday through Friday.

Purchase information for Dispatch Hospital Cleaner Disinfectant towels with Bleach

Dispatch[®] is the product of Caltech, the catalog number is CLH69150

To find a local distributor in your area call Customer Service at 800.234.7700, Mon-Fri 8:30am - 5:00pm EST

You can also purchase the Dispatch on the web site below:

<http://cgi.ebay.com/>

<http://www.amazon.com/>



If you need assistance or have questions about cleaning and disinfection of the meter, please contact customer service at 1-877-979-5454 between 8AM and 8PM (EST), Monday through Friday.




Storage and Precautions

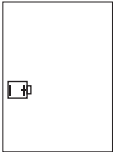


- The meter and the test strips are designed to be used within the temperature ranges between 50°F~104°F.
- Avoid leaving the meter in extremely hot or cold place, such as near a heat source or in an extremely hot or cold car.
- Do not store or use the meter or test strips where they may be exposed to high humidity levels, such as in a bathroom or kitchen.
- Always close bottle cap immediately after removing a test strip and make sure it is closed tightly.

Solving Problems

This section details the significant display screen messages and error codes you will encounter when using your Embrace EVO™ Meter and Embrace EVO™ Test Strips.

Message	What it Means	What Should You Do
	The meter electronic or test strip is damaged	<ul style="list-style-type: none">• Remove the battery, reinsert it and turn on the meter again.• Remove the test strip and insert a new test strip again.• If problem persists, call us at 1-877-979-5454 between 8AM and 8PM (EST), Monday through Friday.
	Used or contaminated test strip	Repeat the test with a new test strip. Wait until you see the flashing blood drop icon before you add blood or control solution sample.

Message	What it Means	What Should You Do
	Not enough sample on the test strip to start	Remove the Test Strip and repeat the test with a new test strip. See Testing Your Blood Glucose on page 29.
	Test result is higher than 600 mg/dL	Wash and dry your hands and repeat the test using a new test strip. If the result is still "HI" , contact your physician or health-care professional immediately.
	Test result is lower than 20 mg/dL	Wash and dry your hands and repeat the test using a new test strip. If the result is still "LO" , contact your physician or health-care professional immediately.

Message	What it Means	What Should You Do
	Battery is low.	Change the battery according to instructions on page 11, Inserting (or Changing) the Battery.
	There are no memorized results in the meter	Check if the date and time on your meter is set up. See Setting Up Your New System on page 11. Start testing your blood glucose, see Testing Your Blood Glucose on page 29.
	Temperature out of range	Move the meter into an area that is between 50°F~104°F, and allow 10 to 15 minutes for it to reach the new temperature.

Product Warranty

Omnis Health, LLC warrants the Embrace EVO[™] Meter to be free of defects in workmanship and materials under normal use for a period of five (5) years from the date of purchase to the consumer.

The liability of Omnis Health, LLC is limited to repair or replacement and in no event shall Omnis Health, LLC be liable for any collateral or consequential damages or loss.

Instruments subjected to misuse, abuse, neglect, unauthorized repair or modification will be excluded from this warranty.

This guarantee specifically excludes expendables and consumables.

All warranty claims must be directed to the Omnis Health, LLC authorized dealer responsible for the sale of the system.

The warranty applies only to the original purchaser of the system.

Specifications

Test Strips:	Embrace EVO™ Test Strips
Test Range:	20 ~ 600 mg/dL
Calibration:	Plasma
Blood Sample Size:	Minimum 0.8μL
Hematocrit Range:	30~55%
Display Type:	LCD screen
Memory:	300 blood test results with date and time
Result Averaging:	7, 14, and 30 days averaging
Dimension:	76L x 45W x 13H (mm)
Weight:	29g
Battery:	1 x CR 2032 3V Lithium coin cell battery
Battery Life:	1000 tests of continuous use or one year
Automatic Power-off:	After 1.5 minutes of nonuse
Operating Temperature:	50°F ~ 104°F
Relative Humidity:	20-85%
Storage Condition:	Meter at 39°F ~ 122°F Test Strips at 41°F ~ 86°F

