ONETOUCH®

Ultra®

Blood Glucose Monitoring System

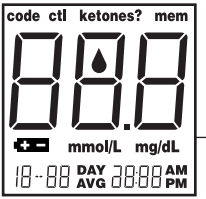
Owner's Booklet

ONETOUCH®
changes everything®

Important Safety Information

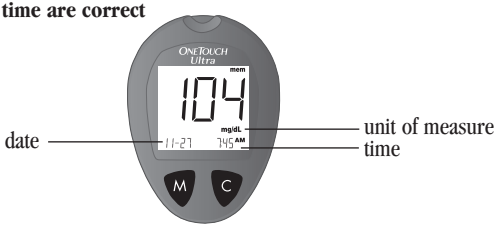
To be sure your meter is working properly, EVERY time you turn it on confirm that:

- **All segments are visible in the display check**



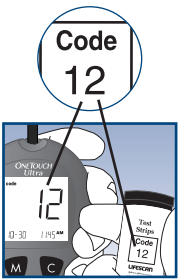
Example

- **The unit of measure is correct (mg/dL)**
- **The date and time are correct**



Example

- **The code number on the meter display matches the code number on the test strip vial**



Example

OneTouch® Ultra® System
Owner's Booklet

Read this first

Each time you turn on your meter, the unit of measure will appear on the display with the symbol. The unit of measure will also appear under every test result.

You may misunderstand your blood glucose results if your meter is set to the incorrect unit of measure. Your meter's unit of measure should be set to mg/dL.

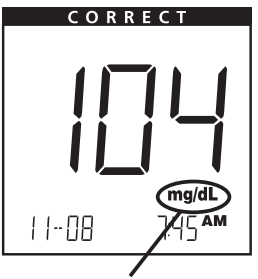


Fig. 1: mg/dL
milligrams/deciliter
no decimal point

If your meter is set to the correct unit of measure, "mg/dL" will appear on the display. Your test result will not include a decimal point (Fig. 1). **Do Not** change this setting – this is the correct unit of measure for the United States.

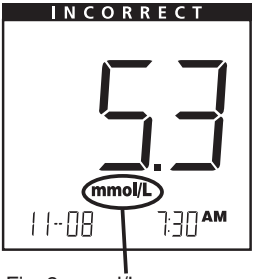


Fig. 2: mmol/L millimoles/liter decimal point

If your meter is set to the other unit of measure, "mmol/L" will appear on the display. The test result will include a decimal point (Fig. 2). Unless your doctor has told you to use this unit of measure, **Do Not** test your blood glucose. **Call LifeScan Customer Service at 1 800 227-8862 immediately for assistance.**

Always confirm that the unit of measure is in mg/dL every time you test your blood glucose level. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

Dear OneTouch® Ultra® System Owner:

You have chosen one of the best blood glucose monitoring systems available. This booklet has important information you must know about the OneTouch® Ultra® System. Please read it carefully.

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that keeping blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%.* The results you get with the OneTouch® Ultra® System can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

As the maker of OneTouch® brand blood glucose monitoring systems, LifeScan is dedicated to your health and satisfaction. You can count on:

- 24-hour customer service by highly trained professionals who are ready to answer your questions about meter operation, self-monitoring and diabetes in general
- LifeScan.com offering online access to information about our products and services as well as diabetes care
- Our OneTouch® Gold program to provide members with a monthly e-Newsletter as well as tools, information and special offers to help make living with diabetes easier. Membership is free. For more information, visit www.LifeScan.com.

We have included a warranty registration card with your system. Please complete and return it promptly to receive a gift. You may also complete product registration online at www.OneTouchWarranty.com.

We care about what you think and want to keep you informed about the latest on better living for people with diabetes. If you have any questions about your new OneTouch® Ultra® System, please call **LifeScan Customer Service at 1 800 227-8862 or visit our website at www.LifeScan.com.**

*American Diabetes Association position statement on the Diabetes Control and Complications Trial (1993).

Table of Contents

About Your New System

The OneTouch® Ultra® System uses the latest blood glucose monitoring technology. It measures the glucose content of a blood sample by means of an electrical current produced in the test strip and measured by the meter. Test results are "plasma-calibrated." This makes it easier for you and your diabetes-care team to compare your meter results with laboratory tests. If you have been using another type of meter–one that provides whole-blood results–you may notice that your test results with the OneTouch® Ultra® System are about 12 % higher.

The OneTouch® Ultra® Blood Glucose Monitoring System consists of the OneTouch® Ultra® Blood Glucose Meter, OneTouch® Ultra® Test Strips (may be sold separately), and OneTouch® Ultra® Control Solution. These products have been designed, tested, and proven to work together to produce accurate blood glucose results. **Use no other test strips or control solution other than OneTouch® Ultra® brand with your meter.**

CAUTION: If you cannot test due to a problem with your testing supplies, contact your healthcare professional or **LifeScan Customer Service at 1 800 227-8862**. Failure to test could delay treatment decisions and lead to a serious medical condition.

The OneTouch® Ultra® System is intended for use outside the body (in vitro diagnostic use). It should be used only for testing fresh capillary whole blood samples for glucose (sugar). It should not be used for the diagnosis of diabetes or for testing newborns.

CAUTION: Before using any product to test your blood glucose, read all instructions and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional. These recommendations apply to all blood glucose monitoring systems and are supported by the American Association of Diabetes Educators, the American Diabetes Association, the U.S. Food and Drug Administration, and the Advanced Medical Technology Association.

Important Information

- **Dehydration:**
  Severe dehydration resulting from excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- **Low glucose results:**
  If your test result is lower than 70 mg/dL or is shown as LO, it may mean hypoglycemia (low blood glucose). **This may require immediate treatment according to your healthcare professional's recommendations.** Although this result could be due to a test error, it is safer to treat first, and then repeat the test.
- **High glucose results:**
  If your test result is greater than 180 mg/dL or is shown as HI, it may mean hyperglycemia (high blood glucose). If you do not have symptoms, first repeat the test. Your healthcare professional can work with you to decide what actions, if any, you should take if you continue to get results higher than 180 mg/dL or if you have symptoms.
- **Repeated unexpected results:**
  If you continue to get unexpected results, check your system with control solution. See Checking the System with Control Solution on pages 13–19.

  If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this booklet, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes control program without speaking to your healthcare professional.
- **Hematocrit:**
  A hematocrit (percentage of your blood that is red blood cells) that is either very high (above 55%) or very low (below 30%) can cause false results.

WARNING: Keep the meter and testing supplies away from small children. The battery door, test strips, lancets, protective disks, and control solution cap are choking hazards.

The Complete OneTouch® Ultra® Blood Glucose Monitoring System

- OneTouch® Ultra® Meter
- Owner's Booklet
- Quick Reference Guide
- OneTouch® UltraSoft® Adjustable Blood Sampler
- Optional OneTouch® UltraClear® Cap
- OneTouch® UltraSoft® Sterile Lancets
- OneTouch® Ultra® Control Solution
- OneTouch® Ultra® Test Strips (may be sold separately)
- Carrying Case
- Warranty Registration Card
- Logbook

OneTouch®Ultra®
Blood Glucose Meter

DISPLAY
Symbols, simple messages, and test results appear here.

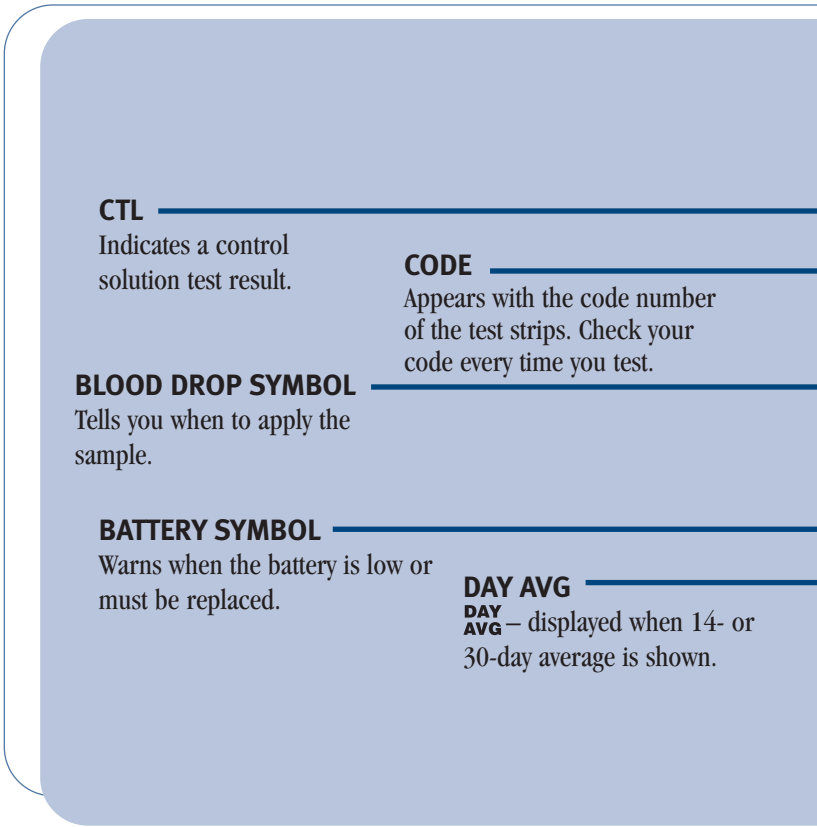
TEST PORT
The meter turns on when you insert the OneTouch® Ultra® Test Strip here.

M BUTTON
Used to enter into:
- set-up mode
- memory mode

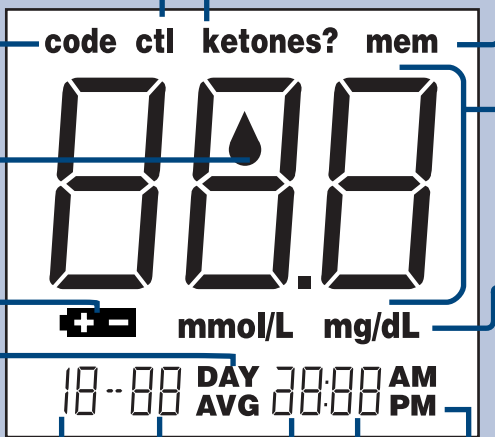
C BUTTON
Used to:
- change time, date, and code number
- mark control solution tests
- review test results in memory

DATA PORT
Used to download your test results to a computer.

OneTouch® Ultra® Meter Display



Note: mmol/L and . (decimal point) appear in display but are not used in this meter when displaying glucose results. If your meter is set to the correct unit of measure, "mg/dL" will appear on the display. Your test result will not include a decimal point. **Do Not** change this setting – this is the correct unit of measure for the United States.



KETONES?
Appears when a test result is above 240 mg/dL to suggest ketone testing.

MEM
Indicates a test result stored in memory.

TEST RESULT AREA
Test results are displayed here.

mg/dL
This is the unit of measure. Be sure this appears with the symbol before applying sample to the test strip. **WARNING: If mg/dL does not appear with the symbol, call LifeScan Customer Service at 1 800 227-8862.**

AM/PM SYMBOL
AM/PM Displayed when set to 12-hour time format.

OneTouch® Ultra® Test Strips

The OneTouch® Ultra® System measures the amount of glucose in whole blood. Blood is applied in the **TOP EDGE** of the OneTouch® Ultra® Test Strip and is automatically drawn into the reaction cell where the reaction takes place.

TOP EDGE
Apply a drop of blood to the narrow channel here in the top edge of the test strip.

CONFIRMATION WINDOW
Check here to confirm if enough blood has been applied.

CONTACT BARS
Insert this end of the test strip, contact bars facing up, into the meter. Push it all the way in until it will go no further.

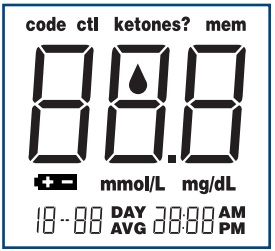
Important Test Strip Information

- Store test strip vials in a cool, dry place below 86˚F (30˚C). Keep away from direct sunlight and heat. **Do Not** refrigerate.
- Store test strips in their **original vial only**. To avoid damage or contamination, **Do Not** transfer test strips to any other place.
- After removing a test strip from the vial, replace the vial cap immediately and close it tightly.
- Use each test strip immediately after removing it from the vial.
- **Do Not** use test strips from any vial that is damaged or left open to air.
- Write the discard date (3 months after first opening the vial) on the vial label when you first open it. Discard remaining OneTouch® Ultra® Test Strips after the discard date.
- **Do Not** use test strips beyond the expiration (printed on package) or discard date, whichever comes first, because they may cause inaccurate results.
- Avoid getting dirt, food or liquids on the test strip. With clean, dry hands, you may touch the test strip anywhere on its surface.
- **Do Not** bend, cut, or alter a OneTouch® Ultra® Test Strip in any way.
- OneTouch® Ultra® Test Strips are for single use only. **Never reuse a test strip that has had either blood or control solution applied to it.**
- Apply only OneTouch® Ultra® Control Solution or a blood sample to the test strip.
- Refer to additional information in the OneTouch® Ultra® Test Strip package.

WARNING: Do Not swallow test strips. The test strip vial may contain drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

Before Testing

Checking the Meter Display



Each time you turn on the OneTouch® Ultra® Meter either by inserting a test strip or pressing the M button, all segments of the display will appear briefly. This tells you that the system is performing several self-checks to confirm that the meter is working properly.

To check that all display segments are working, with the meter off, press the M button and immediately hold the C button down.

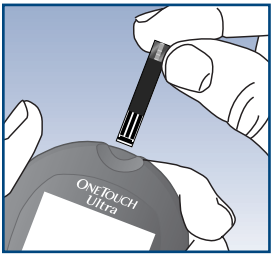
Coding the Meter

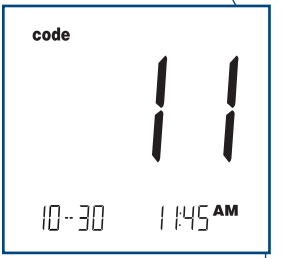
Code numbers are used to calibrate the OneTouch® Ultra® Meter with OneTouch® Ultra® Test Strips for accurate results. You must code the meter before using it for the first time and then every time you change to another vial of test strips. **Each time you test, check to be sure that the code number on the meter display matches the code number on the test strip vial.**

CAUTION: Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results. Each time you test, check to make sure the code numbers match.

STEP 1

Enter the Code Mode.





Example

Insert a test strip to turn on the meter. Push it all the way in until it will go no further. Avoid bending the test strip. The display check will appear. Then the code number is displayed for three seconds.

Note: Date and time will flash briefly.

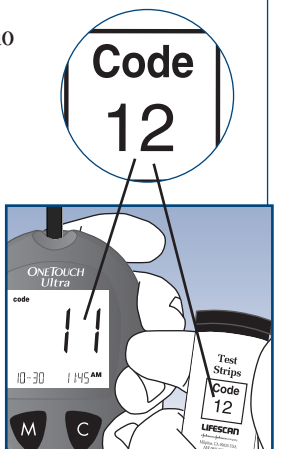
The first time you use the meter, three dashes - - - will flash, meaning that there is no code stored in the memory. Follow Step 3 to code the meter. If three dashes appear any other time, see page 50 of Display Messages and Problem-Solving Guide.

STEP 2

Match the Code Numbers.

Compare the code number on the meter display with the code number on the test strip vial. If the two code numbers match, you may begin testing. If they do not match, follow Step 3.

CAUTION: Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results. Each time you test, check to make sure the code numbers match.



Example

STEP 3

Code the Meter.

Immediately press the C button, while the code number is displayed on meter to select the correct code. Each time you press and release the C button, the number will increase by one. To move more quickly, press and hold the C button.

Note: If the apply blood symbol is displayed before the meter is coded correctly, remove the test strip and repeat steps 1 through 3.

Note: If you scrolled past the desired code number, continue to press the C button until the correct code number appears.

After selecting the correct code number, it will flash for three seconds and then appear solid for three seconds.

CAUTION: Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results. Each time you test, check to make sure the code numbers match.

Then the symbol will appear with mg/dL, indicating that the OneTouch® Ultra® System is ready for testing.

WARNING: If mg/dL does not appear with the symbol, call LifeScan Customer Service at 1 800 227-8862.

Example

Example

Checking the System with Control Solution

Why you should do a control solution test:

- OneTouch® Ultra® Control Solution is used to check that the meter and the test strips are working together as a system and that you are performing the test correctly.
- It is very important that you do this simple check routinely to make sure you get an accurate result.

When you should do a control solution test:

- To practice the test process instead of using blood.
- When you open a new vial of test strips.
- Once a week.
- Whenever you suspect that the meter or test strips are not working properly.
- If you have had repeated unexpected blood glucose test results (as described on page 3).
- After dropping the meter.

Note: Refer to additional information in the OneTouch® Ultra® Control Solution Package.

Before you begin:

- Use only OneTouch® Ultra® Control Solution.
- Check the expiration date on the control solution vial. Record the discard date (date opened plus three months) on the vial label. **Do Not** use after expiration or discard date, whichever comes first.
- Control solution, meter, and test strips should be at room temperature (68–77˚F/20–25˚C) before testing with control solution (see Specifications section on page 60 for blood testing temperature ranges).
- Shake the vial, discard the first drop of control solution, and wipe off the tip to ensure a good sample and an accurate result.
- Store control solution tightly closed at temperatures below 86˚F (30˚C). **Do Not** refrigerate.

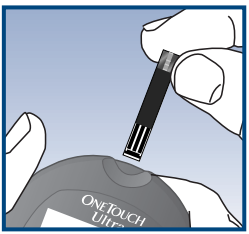
WARNING:

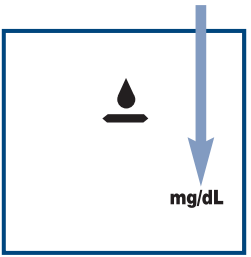
- **Do Not swallow control solution; it is not for human consumption.**
- **Do Not apply control solution to the skin or eyes as it may cause irritation.**

STEP 1

Insert a test strip into the meter.

WARNING: If mg/dL does not appear with the symbol, call LifeScan Customer Service at 1 800-227-8862.



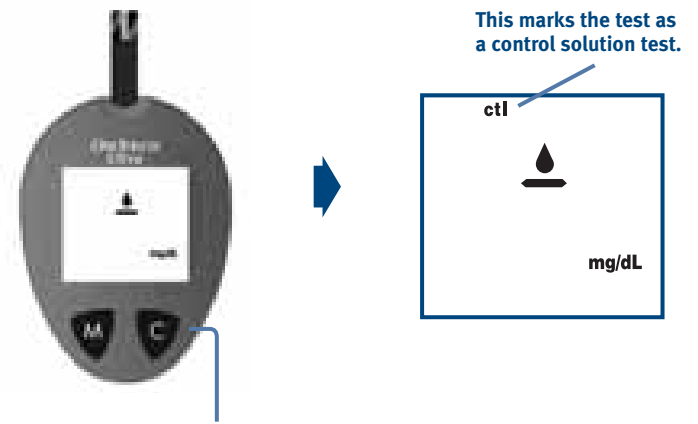


Insert a test strip, contact bars end first and facing up, into the test port. Push it all the way in until it will go no further. The meter will turn on and the display check will appear briefly.

Then the code number will appear, followed by the symbol and **mg/dL**. Be sure the meter and test strip codes match. If they do not, code the meter correctly. (See pages 10–12.)

STEP 2

Mark this test as a control solution test.



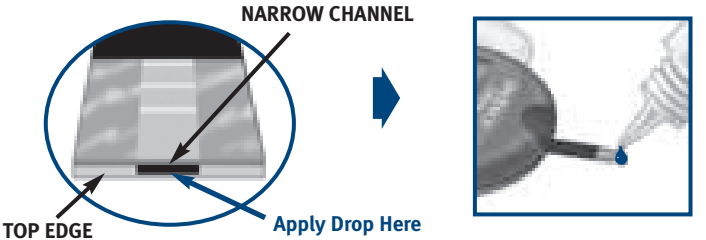
Press and release the button so **ctl** appears on the display.

Note: Mark all control solution tests with **ctl** to distinguish them from blood glucose tests in the meter memory. Marked control solution tests will not be included in your averages.

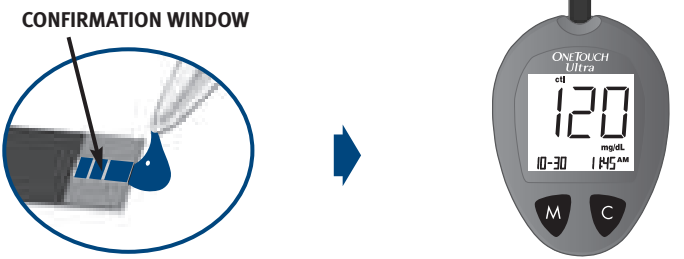
STEP 3

Apply control solution to the test strip.

To ensure an accurate control solution test, shake the vial, discard the first drop and wipe the dispenser tip before you begin.



Touch and hold a drop of control solution where the narrow channel meets the TOP EDGE of the test strip.



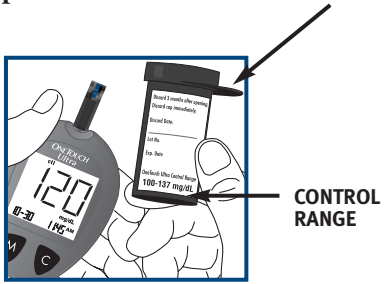
Example

The control solution will be drawn into the narrow channel. When the confirmation window is full, the meter will count down from 5 to 1.

The control solution test result will appear on the display. **ctl** will appear above your result.

STEP 4

Compare control solution result to the range printed on the TEST STRIP VIAL.



Example

CAUTION: The control solution range printed on the test strip vial is for OneTouch® Ultra® Control Solution only. It is not a recommended range for your blood glucose level.

If the results are not within the control range printed on the test strip vial, the meter and strips may not be working properly. Repeat the control solution test.

Control solution out-of-range results may be due to:

- Incorrect unit of measure.
- Error in performing the test.
- Failure to shake the control solution vial well.
- Improper meter coding.
- Test strip deterioration.
- Meter malfunction.
- Failure to discard the first drop of control solution and wipe the dispenser tip clean.
- Expired or contaminated control solution.
- The meter, test strips, or control solution are too warm or too cold.

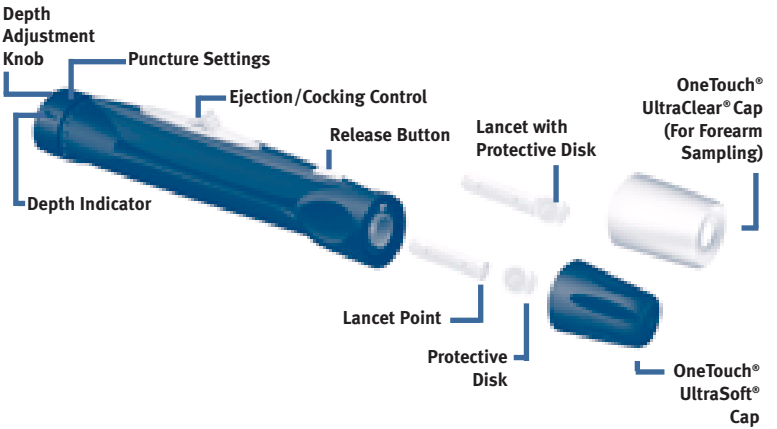
CAUTION: If you continue to get control solution test results that fall outside of the range printed on the vial, the system may not be working properly. **Do Not** use the meter. Call **LifeScan Customer Service at 1 800 227-8862.**

Testing Your Blood

Read this section and the test strip package insert carefully before testing. Make sure you have all items needed to test.

- OneTouch® Ultra® Meter
- OneTouch® Ultra® Test Strips
- Lancing Device
- Sterile Lancets with protective disks

Preparing the OneTouch® UltraSoft® Adjustable Blood Sampler (Sampler)



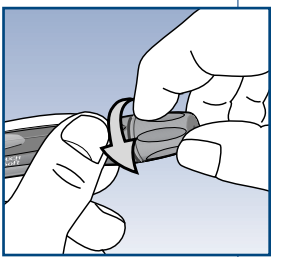
CAUTION: To reduce the chance of infection:

- Never share a lancet or the **Sampler** with anyone.
- Always use a new, sterile lancet. Lancets are for single use only.
- Keep the OneTouch® Ultra® Meter and **Sampler** clean.
- Make sure to wash the puncture site with soap and water before testing.

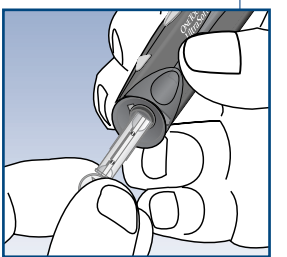
STEP 1

Insert a Lancet.

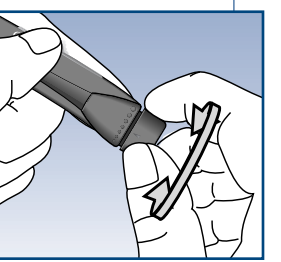
Turn the OneTouch® UltraSoft® Cap counter-clockwise to remove it.



Insert the lancet into the lancet holder and push down firmly until it is fully seated. **Do Not** twist the lancet. Twist the protective disk until it separates from the lancet. Replace the OneTouch® UltraSoft® Cap. Turn it clockwise until it is snug.



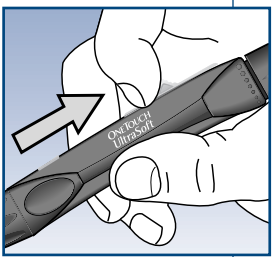
Adjust the puncture depth setting if necessary. Twist the depth adjustment knob toward the smaller bumps for a shallower puncture or toward the larger bumps for a deeper puncture.

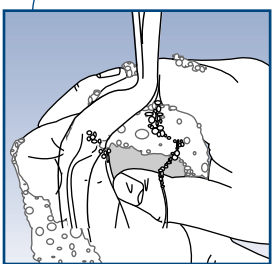


STEP 2

Cock the Sampler.

Slide the ejection/cocking control back until it clicks. If it does not click, the **Sampler** may have been cocked when the lancet was inserted. The **Sampler** is now ready for use.





STEP 3

Wash Your Hands and the Puncture Site.

To reduce the chance of infection, use warm, soapy water. Rinse and dry thoroughly.

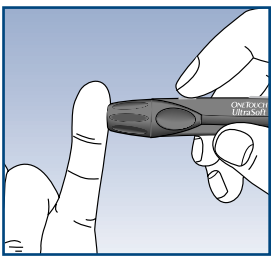
Fingertip Blood Sampling

The OneTouch® Ultra® System requires a very small blood drop to perform a test. You may obtain it from a **fingertip** or **forearm.** (See page 25 for information on obtaining a blood sample from the forearm.) Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.

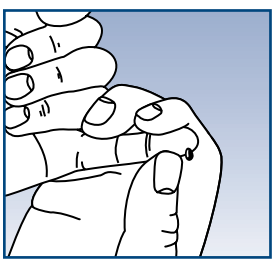
STEP 1

Position the Sampler.

Hold the **Sampler** firmly against the side of your finger. Press the release button.



Note: **Do Not** use OneTouch® UltraClear® Cap on your finger.



STEP 2

Massage the Fingertip.

Massaging the fingertip gently will help you obtain a round drop of blood. **Do Not** squeeze excessively on the puncture site. The blood sample must be at least one microliter (1 µL) in volment (● actual size) or you may get an Er5 message (see page 57) or an inaccurate test result. **Do Not** smear the blood sample. Proceed with your blood glucose test.

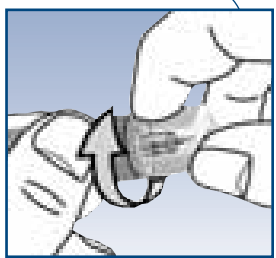
Forearm Blood Sampling

The forearm has fewer nerve endings than the fingertip so you may find that obtaining a blood sample from the forearm may be much less painful than using the fingertip. The technique for forearm sampling is different from fingertip sampling. Also there are differences between forearm samples and fingertip samples that you should understand. Please read the important information on page 27 carefully.

STEP 1

Install the OneTouch® UltraClear® Cap.

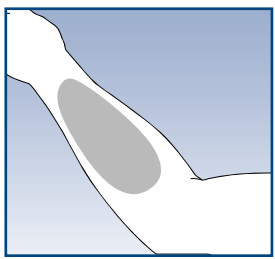
To aid in obtaining a blood sample from the forearm, replace the OneTouch® UltraSoft® Cap on the **Sampler** with the OneTouch® UltraClear® Cap. If necessary, set the **Sampler** for a deeper puncture.



STEP 2

Choose the Puncture Site.

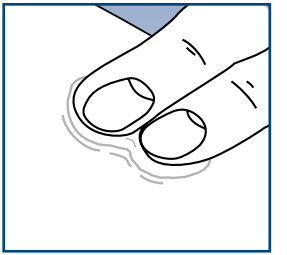
Select a soft, fleshy area on your forearm that is clean and dry, away from bone, and free of visible veins and hair.

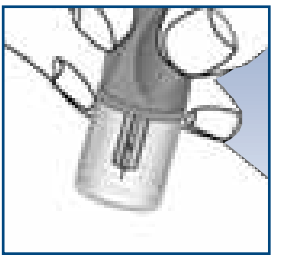


STEP 3

Massage the Area.

To increase blood flow to the puncture site, massage the area gently. For individuals who experience difficulty in getting sufficient blood for a test, rubbing the area more vigorously or applying heat briefly may be helpful.





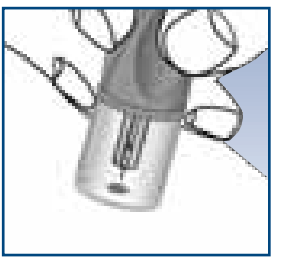
STEP 4

Position the Sampler.

Press and hold the **Sampler** against the forearm for a few seconds. Press the release button.

STEP 5

Allow Blood Drop to Form.



Continue holding the **Sampler** against the skin for a few seconds until the blood drop forms. Allow enough blood to form under the OneTouch® UltraClear® Cap until you have a blood sample (● actual size) that is sufficient to fill the confirmation window of the test strip. If you must massage the area to obtain more blood, **Do Not** squeeze the site excessively.

If bruising occurs, you may choose to lance a fingertip instead. If you are having difficulty obtaining blood from the forearm, call **LifeScan Customer Service at 1 800 227-8862**.

Important information about forearm testing

- Under certain conditions, blood glucose test results obtained using samples taken from your forearm may differ significantly from fingertip samples.
- The conditions in which these differences are more likely to occur are when your blood glucose is changing rapidly such as following a meal, an insulin dose, or physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than forearm samples.
- When your blood glucose is falling, testing with a fingertip sample may identify a hypoglycemic (low blood sugar) level sooner than a test with a forearm sample.
- Use forearm samples only for testing prior to, or more than two hours after meals, insulin doses, or physical exercise.
- Testing performed within two hours after meals, insulin doses, or physical exercise, or whenever you feel that your glucose levels may be changing rapidly, should be done with a fingertip sample.
- You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin reactions) such as when driving a car, particularly if you suffer from hypoglycemic unawareness (lack of symptoms to indicate an insulin reaction), as forearm testing may fail to detect hypoglycemia.

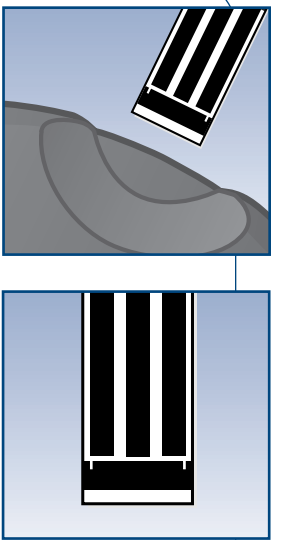
What you should do:

- Use forearm or fingertip samples for testing prior to, or more than two hours after meals, insulin doses, or physical exercise.
- Routine testing before meals can be done either at the fingertip or the forearm.
- Consult your healthcare professional before you begin using the forearm for testing.

STEP 1

Insert Test Strip.

Insert a test strip, contact bars end first and facing up, into the test port. Push it in until it will go no further. The meter will turn on and the display check will appear briefly. Then the code number will appear, followed by the symbol with mg/dL. Check to make sure the code number on the meter display matches the code number on the test strip vial. **Always confirm that the unit of measure is mg/dL when you test your blood glucose level.**



Insert This End

WARNING: If mg/dL does not appear with the symbol, call LifeScan Customer Service at 1 800 227-8862. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

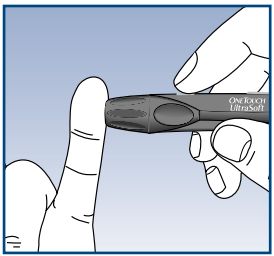
Be sure the meter and test strip codes match. If they do not, code the meter correctly. (See pages 10–12.)

CAUTION: Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results. Each time you test, check to make sure the code numbers match.

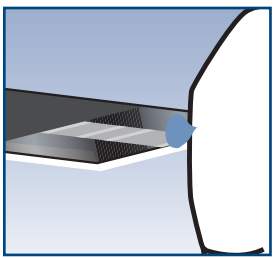
STEP 2

Apply Sample.

Obtain a round drop of blood using the **Sampler**. **The blood sample must be at least 1 µL in volume** (● actual size) to fill the confirmation window.

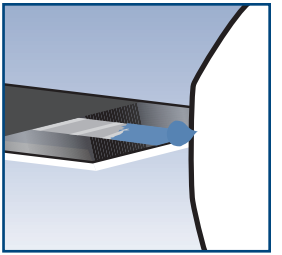


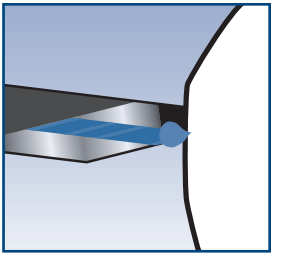
When the ▲ symbol appears on the display, **touch and hold the drop of blood to the narrow channel in the top edge of the test strip.**



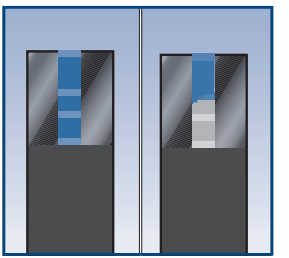
- **Do Not** apply sample to the front or back of the test strip.
- **Do Not** push your finger against the test strip.
- **Do Not** apply a smeared sample.

Hold the blood drop to the top edge of the test strip **until the confirmation window is full before the meter begins to count down.** If the confirmation window does not fill completely before the meter begins to count down, **Do Not** add more blood to the test strip; discard the test strip and retest. If you have trouble filling the test strip, call **LifeScan Customer Service at 1 800 227-8862** for assistance.





If the confirmation window is not full, you may get an Er5 message (see page 57) or an inaccurate test result.



Good Sample **Sample Too Small**

Note: If you do not apply a blood sample within two minutes after the symbol appears, the meter will turn itself off. You must remove the test strip and insert it back into the meter to restart the test procedure.

STEP 3

Accurate Results in Just 5 Seconds.

Your blood glucose test result will appear after the meter counts down from 5 to 1. Blood glucose test results are automatically stored in the meter memory. You may also record them in the logbook provided with your system. Turn the meter off by removing the test strip. Dispose of used test strip in a sealed container.

Example
Plasma-Calibrated Result

WARNING: If mg/dL does not appear with the test result, call LifeScan Customer Service at 1 800 227-8862.

CAUTION: If you tested at the low end of the operating range (43°F/6°C) and your glucose is high (over 180 mg/dL), the reading on your meter may be lower than your actual glucose. In this situation, repeat the test in a warmer environment with a new test strip as soon as possible.

Discarding used test strips and lancets

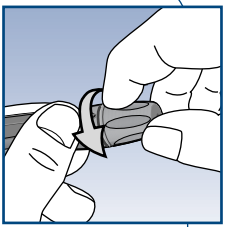
It is important to discard the used lancet carefully after each use to avoid unintended lancet stick injuries.

Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations for proper disposal.

STEP 1

Remove the OneTouch® UltraSoft® Cap from the Sampler.

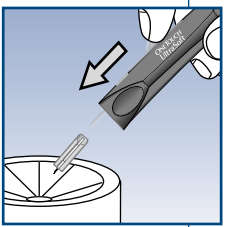
Twist the OneTouch® UltraSoft® Cap counter-clockwise. (Optional: Replace the protective disk on the used lancet by placing it on a hard surface and pushing the lancet tip into the disk.)



STEP 2

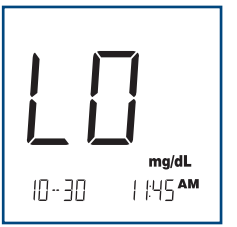
Eject the Lancet.

Point the **Sampler** down and away. Push the release button to ensure that the **Sampler** is not cocked. Push forward on the ejection/cocking control and eject the lancet directly into a container for sharp objects. Return the ejection/cocking control to the middle position. Replace the OneTouch® UltraSoft® Cap.

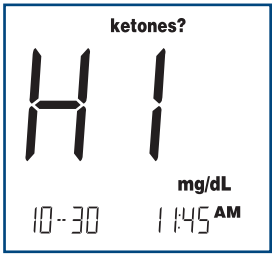


Special Messages

The OneTouch® Ultra® Meter displays results between 20 and 600 mg/dL. If your blood glucose test result is lower than 20 mg/dL, LO will appear on the meter display. **This may mean severe hypoglycemia (low blood glucose) that requires immediate treatment according to your healthcare professional's recommendations.** Although this message could be due to a test error, it is safer to treat first, and then repeat the test.



If your blood glucose test result is above 600 mg/dL, HI will appear on the meter display. **This may mean severe hyperglycemia (high blood glucose). You should recheck your blood glucose level. If HI again appears on the display, call your healthcare professional immediately.**



When your blood glucose test result is above 240 mg/dL or reads HI, "**ketones?**" will appear on the meter display. **This message does not mean that the system detected ketones but that testing with a ketone test strip may be advisable. Consult your healthcare professional about when and how to test for ketones.**

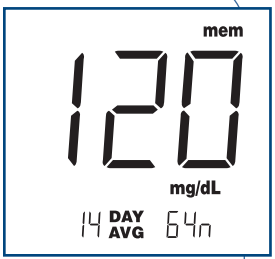
Example

Using the Meter Memory

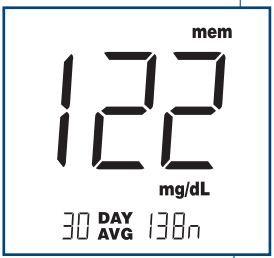
Your OneTouch® Ultra® Meter stores the 150 most recent blood glucose and control solution test results with date and time in its memory. It also provides you with 14- and 30-day averages of your blood glucose test results. If your 14-day and 30-day test result averages are not what you expect, you should not rely on them. Review the test results in memory with these easy steps.

STEP 1

Enter the Memory Mode.



You may enter the memory mode either with the meter turned off or immediately after completing a test. Press the M button. **mem** and the 14-day average will appear with the number of blood glucose tests performed in this period (e.g. 64n means that 64 tests were performed within the period). After three seconds, the 30-day average will appear. (If you are using the meter for the first time, - - - indicates there are no test results in memory.)



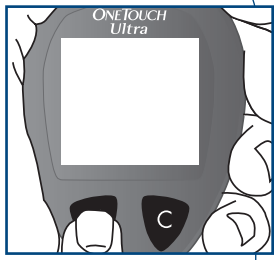
These averages are calculated from the blood glucose results obtained during the last 14 and 30 calendar days. A HI result will be included in your averages as 600 mg/dL and a LO result as 20 mg/dL. Results marked as control solution tests will not be included in your averages. If your 14-day and 30-day test result averages are not what you expect, you should not rely on them.

STEP 2

Recall Test Results.

The most recent test result with date and time will appear. Press and release the C button and the next most recent test result will appear. The meter will recall up to your last 150 test results in order from the most recent to the oldest. If memory is not full, - - - will appear for memory locations that are empty. When the memory is full, the oldest result is dropped and the newest is added. To move through the tests more quickly, press and hold the C button. Marked control solution tests will appear as **ctl**.

STEP 3



Exit the Memory Mode.

Press the M button to turn off the meter.

Downloading Test Results to a Personal Computer

Transferring test results with date and time from the meter memory to your personal computer requires OneTouch® Diabetes Management Software with the accompanying OneTouch® Interface Cable. (OneTouch® Diabetes Management Software is available separately.)

Note to users of OneTouch® Diabetes Management Software: **Do Not** transfer data from a meter that has experienced a loss of power. Call **LifeScan Customer Service at 1 800 227-8862** for more information.

STEP 1

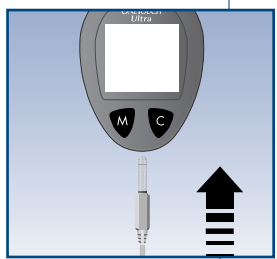
Install OneTouch® Diabetes Management Software.

Follow the instructions provided in the OneTouch® Diabetes Management Software User's Manual.

STEP 2

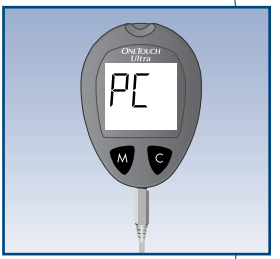
Connect the OneTouch® Interface Cable.

Make sure the meter is turned off. Connect the OneTouch® Interface Cable to your computer and (with the meter turned off) to the meter data port.



Note: While in the communication mode, you will be unable to perform a blood glucose test. If the meter is in either memory or setting mode, it will not respond to computer commands.

STEP 3



Transfer Data.

Follow the instructions in the OneTouch® Diabetes Management Software User's Manual to initiate the data transfer command. PC will appear on the meter display when the first command is received, indicating that the meter is in the communication mode. If the command is not received within two minutes, the meter will turn itself off. Pressing the M button will also turn the meter off.

To learn more about OneTouch® Diabetes Management Software or to obtain a OneTouch® Interface Cable separately, call **LifeScan Data Management Line at 1 800 382-7226 or visit us at www.LifeScan.com.**

Comparing Meter and Laboratory Results

OneTouch® Ultra® Meter test results and laboratory test results are both expressed in plasma-equivalent units. However, your meter result may differ somewhat from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. Your OneTouch® Ultra® Meter glucose value should agree with a laboratory measurement within ±20% most of the time under normal conditions. A result within that range is considered accurate when testing with the OneTouch® Ultra® Meter. However, results can differ by more than ±20% in some situations. See the OneTouch® Ultra® Test Strip package insert for typical accuracy and precision data and for important information on Limitations of Procedure.

To make an accurate comparison between meter and laboratory results, follow these guidelines:

Before going to the lab:

- Perform a control solution test to make sure the meter is working properly.
- It is best to fast for at least eight hours before doing comparison tests.
- Take your meter with you to the lab.

While at the lab:

- Make sure that the meter test and the lab test are performed within 15 minutes of each other.
- Wash your hands before obtaining a blood sample.
- Use only fresh capillary blood obtained from the fingertip.

You may still have a variation from the laboratory result because blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication, or experienced stress.[1] In addition, if you have eaten recently, the blood glucose level from a fingerstick can be up to 70 mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.[2] Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the percentage of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (severe dehydration) may also cause a meter result to be different from a laboratory result.

References

1. Surwit, R.S., and Feinglos, M.N.: *Diabetes Forecast* (1988), April, p. 49–51.
2. Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R. (ed.), *Tietz Textbook of Clinical Chemistry.* Philadelphia: W.B. Saunders Company (1994), p. 959.

Meter Set-up

You may need to update the meter settings when you first receive your meter or when you replace the battery.

Follow these instructions. If you need assistance, call LifeScan Customer Service at 1 800 227-8862.

Meter on

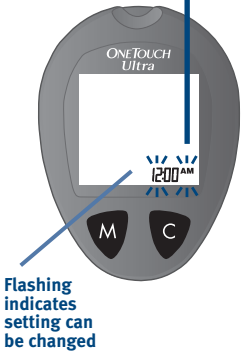
STEP 1

Enter the meter set-up.

- Start with the meter off.
- Press and continue to hold the M button until **ONLY** the time appears on the bottom right of the display.
- Release the M button.

Note: You must move through all the settings to save changes.

If you use the 12-hour format, the AM or PM will change each time you reach 12:00. Be sure the AM/PM setting is correct when you set the hour.



STEP 2

Set the hour.

Press and release the C button to change the hour. If you go past the desired hour, press and release the C button until you scroll through to the desired hour.

To scroll faster, hold the C button down.

Press and release the M button to move to the next step.

STEP 3

Set the minutes.

Press and release the C button to change to the desired minutes.

Press and release the M button to move to the next step.

STEP 4

Set the AM/PM or 24-hour time format.

or

Press and release the C button to choose between AM/PM and 24-hour formats.

Press and release the M button to move to the next step.

STEP 5

Set the year.

Press and release the C button to change to the desired year.

Press and release the M button to move to the next step.

STEP 6

Set the month.

Press and release the C button to change to the desired month.

Press and release the M button to move to the next step.

STEP 7

Set the day.

Press and release the C button to change to the desired day.

Press and release the M button.

Continue to the next page.

If your meter has shut off after setting the day, you have completed the meter set-up and saved your changes.

If either mg/dL or mmol/L is flashing on the display, continue below.

STEP 8

Set the unit of measure to mg/dL.

Press and release the C button until mg/dL appears on the display.

Press and release the M button to save your entry, save your changes, and shut the meter off.

WARNING: The mg/dL unit of measure is the standard in the United States. If mg/dL does not appear, call LifeScan Customer Service at 1 800 227-8862.

Note: The 14- and 30-day averages in the meter memory are calculated from results obtained during the 14 and 30 calendar days preceding the current date and time settings. When the date and time are changed, the averages may change. If your 14-day and 30-day test averages are not what you expect, do not rely on them.

Caring for Your OneTouch® Ultra® System

Meter

Your OneTouch® Ultra® Meter does not require special maintenance or cleaning. Take care to avoid getting dirt, dust, blood, control solution, or liquids inside the meter through the test port or data port. LifeScan recommends that you store the meter in its carrying case after each use.

A cloth dampened with water and mild detergent can be used to wipe down the outside of the meter. Your OneTouch® Ultra® Meter is a precision instrument. Please handle it with care.

Do Not use alcohol or any other solvent to clean your meter.

OneTouch® UltraSoft® Adjustable Blood Sampler

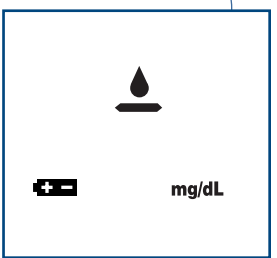
Clean the **Sampler** and Caps (OneTouch® UltraSoft® and OneTouch® UltraClear®) with soap and water. To disinfect the **Sampler**, prepare a disinfectant solution of one part household bleach to 10 parts water. Dampen a cloth with this solution and wipe the **Sampler** thoroughly. **Soak only the cap or caps** for at least 30 minutes in the disinfectant solution. **Do Not** soak the **Sampler** in liquid. Rinse the **Sampler** and caps with water and dry thoroughly.

Battery

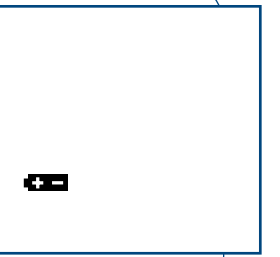
Your OneTouch® Ultra® Meter comes with a pre-installed 3.0 V (#2032 or equivalent) lithium battery. The battery will provide you with enough power to perform about 1,000 tests. When replacing the battery, use only a 3.0 V (#2032 or equivalent) lithium battery.

The meter will alert you when the power is getting low by displaying two different messages:

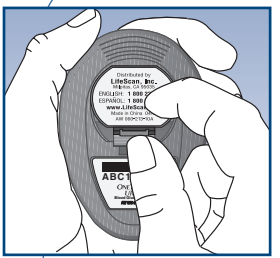
The symbol appears on the display with mg/dL when the meter is turned on and all other display messages are functional. From the time the symbol first appears, there is enough power left for about 50 tests. The test results will be accurate, but it is time to change the battery.



When the symbol appears on the display by itself, it means that the battery will not provide enough power for a test. You must change the battery.



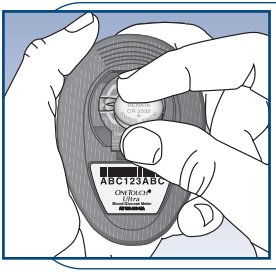
To replace the battery, make sure that the meter is turned off. Turn the meter over and locate the battery compartment.



STEP 1

Open the Battery Compartment.

Push up on the tab and pull the battery compartment cover toward you.



STEP 2

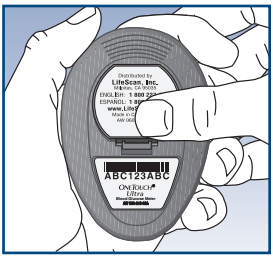
Remove the Old Battery.

Pull upward on the clear plastic tab. Insert one 3.0 V (#2032 or equivalent) lithium battery, making sure the positive "+" side of the battery is facing up.

STEP 3

Place the Cover.

Place the cover over the battery compartment. Push down until you hear the tab click into place.



STEP 4

Check the Time, Date, and Unit of Measure.

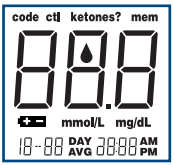
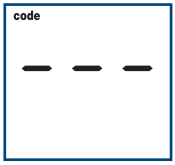
After replacing the battery, turn the meter on by inserting a test strip or pressing the M button. If the meter is in setting mode, confirm that the time, time format and date are set correctly. If they are not, use the M and C buttons to reset the meter before testing. See Meter Set-up, pages 40–45. Also, be sure to confirm the unit of measure is mg/dL.

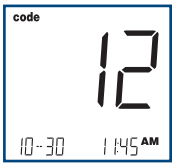
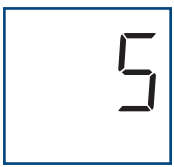
WARNING: The mg/dL unit of measure is the standard in the United States. If mg/dL does not appear, call LifeScan Customer Service at 1 800 227-8862.

Note: Replacing the battery does not affect previous test results stored in memory. However, the time and date settings may need to be updated. **Always confirm the unit of measure is mg/dL.**

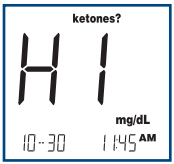
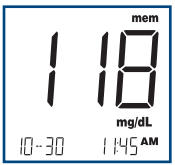
Display Messages and Problem-Solving Guide

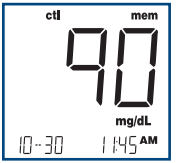
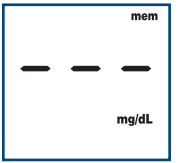
Following is a summary of all display messages. These messages help to identify certain problems but do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message or a symbol. In the event of a problem, refer to the information under ACTION. Assistance is available from **LifeScan Customer Service 24 hours a day, seven days a week. Call LifeScan Customer Service at 1 800 227-8862.**

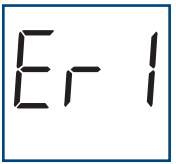
MESSAGE	WHAT IT MEANS	ACTION
	Display check. Appears whenever the meter is turned on. To verify that all segments are present on the display, with the meter off, press the M button and immediately hold the C button down. Compare the meter display with page 10.	If segments are missing, call **LifeScan Customer Service at 1 800 227-8862** for further action. Missing segments can lead to misinterpretation of test results.
	1. This message appears immediately after the display check if your meter has not been coded. 2. If this message appears at any time after the first time the meter was coded, the code number has been lost. The test results stored in the meter memory may be out of order.	1. See Coding the Meter, pages 10–12. 2. **Do Not** rely on the 14- and 30-day averages. It is important to call **LifeScan Customer Service at 1 800 227-8862.**

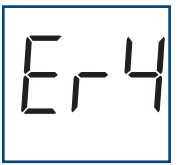
MESSAGE	WHAT IT MEANS	ACTION
 *Example*	This is the code number stored in the meter.	Make sure that this code number matches the code number on the vial of the test strips you are using. **CAUTION:** Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results. Each time you test, check to make sure the code numbers match.
	The system is ready to accept a blood sample.	You may now apply the blood sample. **WARNING: If mg/dL does not appear with the symbol, call LifeScan Customer Service at 1 800 227-8862 for assistance.**
	The system is ready to accept a control solution test sample.	You may now apply the control solution.
	Five-second countdown. The meter is calculating the result. After the countdown, the meter will display the test result.	None required.

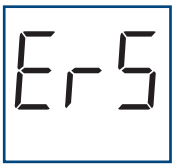
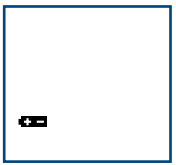
MESSAGE	WHAT IT MEANS	ACTION
 *Example*	A blood glucose test result in mg/dL.	None required. **WARNING: If mg/dL does not appear with the test result, call LifeScan Customer Service at 1 800 227-8862 for assistance.**
 *Example*	A blood glucose test result with a suggestion to check your ketone levels.	Follow the instructions of your healthcare professional regarding ketone testing.

MESSAGE	WHAT IT MEANS	ACTION
	You may have a very high blood glucose level, exceeding 600 mg/dL.	You should retest your glucose level and if HI appears again, call your healthcare professional immediately.
	You may have a very low blood glucose level, lower than 20 mg/dL.	**Treat this condition immediately according to your healthcare professional's recommendations.** Although this message could be due to a test error, it is safer to treat first, and then repeat the test.
	A blood glucose test result stored in the memory.	None required.

MESSAGE	WHAT IT MEANS	ACTION
	A control solution test result stored in the memory.	None required.
	There is no test result stored in this place in the memory.	None required.
	Average of results from the last 14 days (64n means that 64 tests were performed within the period). The 30-day average appears with a 30 before the DAY AVG on the screen.	If your 14-day and 30-day test result averages are not what you expect, you should not rely on them.

MESSAGE	WHAT IT MEANS	ACTION
	Error message that indicates that there is a problem with the meter.	**Do Not** use the meter. Call **LifeScan Customer Service at 1 800 227-8862** for a replacement meter.
	Error message could be caused either by a used test strip or a problem with the meter.	Repeat the test with a new test strip. Refer to pages 8–9 for test strip information. If the error message persists, call **LifeScan Customer Service at 1 800 227-8862.**
	Error message that indicates that the blood or control solution sample was applied before the symbol appeared on the display.	Repeat the test with a new test strip. Apply blood or control solution sample only after the symbol appears on the display. Refer to pages 29–30 for information on sample application.

MESSAGE	WHAT IT MEANS	ACTION
	Error message that indicates one of the following conditions may be present:	
	1. You may have high glucose and have tested in an environment near the low end of the system's operating temperature range (43–111°F / 6–44°C).	1. If you tested in a cool environment, repeat the test in a warmer environment with a new test strip. If the error message appears again, call **LifeScan Customer Service at 1 800 227-8862**.
	2. There may be a problem with the test strip. For example, it may have been damaged or moved during testing.	2. If you were testing in a normal or warm environment, repeat the test with a new test strip. (See pages 8–9 for test strip information.) If the error message appears again, call **LifeScan Customer Service at 1 800 227-8862.**
	3. The sample was improperly applied.	3. If you applied the blood incorrectly, review pages 29–30 on blood application and repeat the test with a new test strip. If the error message appears again, call **LifeScan Customer Service at 1 800 227-8862.**

MESSAGE	WHAT IT MEANS	ACTION
Error 4 continued	4. There may be a problem with the meter.	4. If the error message appears again, call **LifeScan Customer Service at 1 800 227- 8862.**
	Error message that indicates that the meter has detected a problem with the test strip. Possible causes are test strip damage or an incompletely filled confirmation window.	Repeat the test with a new test strip. Refer to pages 29–30 for information on sample application.
	The symbol appears on the display with the unit of measure. The power is getting low. It is time to change your battery.	Test results will still be accurate, but replace the battery as soon as possible.
	The symbol appears on the display by itself. The power is too low to perform a test.	Replace the battery at once. The meter will not operate.

MESSAGE	WHAT IT MEANS	ACTION
	Flashing time means the meter has lost power and entered the setting mode.	You must reset the time, time format and date. See Meter Set-up, pages 40–45. Confirm that your meter is set in mg/dL. If not, call **LifeScan Customer Service at 1 800 227-8862.** Note to users of OneTouch® Diabetes Management Software: **Do Not** transfer data from a meter that has experienced a loss of power. Call **LifeScan Customer Service at 1 800 227-8862** for more information.
	The meter has detected that the temperature is below the system operating range. **Do Not** perform a test until the meter and test strips reach a temperature within the operating range of 43–111°F (6–44°C).	Repeat the test after the meter and test strips have reached a temperature within the operating range.
	The meter has detected that the temperature is above the system operating range. **Do Not** perform a test until the meter and test strips reach a temperature within the operating range of 43–111°F (6–44°C).	Repeat the test after the meter and test strips have reached a temperature within the operating range.

If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
No power	Replace the battery.
No battery or battery incorrectly installed	Check that the battery is correctly installed with the positive "+" side up.
Test strip inserted incorrectly or incompletely	Insert the test strip correctly with the contact bars end first and facing up. Push it in until it will go no further.
Defective meter or test strip	Call **LifeScan Customer Service at 1 800 227-8862**.

If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample	Repeat the test with a new test strip and a larger sample, making sure blood is placed to the narrow channel in the top edge of the test strip.
Defective test strip	Repeat the test with a new test strip.
Sample applied after automatic shutoff (two minutes after last user action)	Repeat the test with a new test strip; apply sample only when the symbol appears on the display.
Defective meter	Call **LifeScan Customer Service at 1 800 227-8862**.

Specifications

Result Range: 20 to 600 mg/dL

Calibration: Plasma-equivalent

Sample: Fresh capillary whole blood

Sample Size: Minimum 1 microliter

Test Time: 5 seconds

Assay Method: Glucose oxidase biosensor

Power Source: One replaceable 3.0 V (#2032 or equivalent) lithium battery

Battery Life: About 1,000 tests (about one year at three tests per day)

Glucose Units: mg/dL

Memory: 150 blood glucose and control solution tests

Automatic Shutoff: Two minutes after last user action

Size: 3.12″ x 2.25″ x 0.85"

Approximate Weight: 1.5 ounces with battery

Operating Ranges:

Temperature 43–111°F/6–44°C

Relative Humidity 10–90%

Hematocrit 30–55%

Guarantee

The makers guarantee that the OneTouch® Ultra® Meter shall be free of defects in material and workmanship for a period of three years. This guarantee is valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable.

PRODUCT SAFETY INFORMATION

The OneTouch® Ultra® system complies with the following standard:

UL (Underwriters Laboratories Standard) UL 60601-1

- Internally powered equipment. Battery operated with one replaceable 3.0 V lithium battery.
- This unit is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Continuous mode of operation.
- Type BF applied part degree of protection against electrical shock. This is a level of electrical safety protection for the user suitable for this medical device.

Index

Times of Day	Glucose Ranges for People Without Diabetes, mg/dL	Your Target Ranges, mg/dL
Before breakfast	70–105	_____
Before lunch or dinner	70–110	_____
1 hour after meals	Less than 160	_____
2 hours after meals	Less than 120	_____
Between 2 and 4 AM	Greater than 70	_____

Source: Krall, L.P., and Beaser, R.S.: *Joslin Diabetes Manual.* Philadelphia: Lea and Febiger (1989), p. 138.

Meter Serial No. _____

Important phone numbers:
LifeScan Customer Service (24 hours a day, 7 days a week):
English 1 800 227-8862 **Español 1 800 381-7226**

_____ _____
Healthcare Professional Pharmacist

_____ _____
Diabetes Educator Other

ONETOUCH®
changes everything®

LifeScan Customer Service toll-free numbers:
(24 hours a day, 7 days a week)

U.S.A. English 1 800 227-8862
Español 1 800 381-7226

Visit us online at:
English www.LifeScan.com
Español www.onetouchenespanol.com

The system described herein is covered by one or more of the following U.S. patents: 6,045,567, 6,156,051, 6,197,040, 6,284,125, and D428,150. Use of the monitoring device included herein is protected under one or more of the following U.S. patents: 6,413,410, 6,733,655. Purchase of this device does not act to grant a use license under these patents. Such a license is granted only when the device is used with OneTouch® Ultra® Test Strips. No test strip supplier other than LifeScan is authorized to grant such a license. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.

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