ONETOUCH Ultra® 2

Blood Glucose Monitoring System

USER GUIDE

Replaces Owner's Booklet

AW 06650204A
Rev. date: 01/2019

AW 06650204A

Contents:

Symbols

⚠ Cautions and Warnings. Refer to safety-related notes in this User Guide and inserts that came with your meter and testing supplies.

Low battery

⎓ Direct current

IVD *In vitro* diagnostic medical device

The system described herein is covered by one or more of the following U.S. patents: 5,708,247, 5,951,836, 6,241,862, 6,284,125, 7,112,265, D522,656 and D542,681. 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, 7,250,105, 7,468,125. 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.

OneTouch® Customer Care Line
Monday–Friday
9am–8pm Eastern Time
6am–5pm Pacific Time
Canada **1 800 663-5521**

Manufactured by:
LifeScan Europe GmbH
6300 Zug, Switzerland
Visit us at www.OneTouch.ca

Lifescan™

Before you begin
Before using this product to test your blood glucose, carefully read this User Guide and the inserts that come with the OneTouch Ultra® Test Strips and OneTouch Ultra® Control Solution. Take note of warnings and cautions throughout this User Guide, which are identified with ⚠. Many people find it helpful to practice the test with control solution before testing with blood for the first time. See Section 6, Control solution testing.

Intended use
The OneTouch Ultra® 2 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood. The OneTouch Ultra® 2 System is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of diabetes or for testing newborns.

Test principle
Glucose in the blood sample mixes with special chemicals in the test strip and a small electric current is produced. The strength of this current changes with the amount of glucose in the blood sample. Your meter measures the current, calculates your blood glucose level, displays the result, and stores it in its memory.

NOTE: If you have any questions about your OneTouch Ultra® 2 Blood Glucose Monitoring System, contact the OneTouch® Customer Care Line at 1 800 663-5521.

1 Getting to know your system

The OneTouch Ultra® 2 Blood Glucose Monitoring System

INCLUDED WITH YOUR KIT:

a. OneTouch Ultra® 2 Meter (batteries included)
b. Lancing Device
If another type of lancing device was included, see the separate instructions that came with that lancing device.
c. Sterile Lancet
d. Carrying Case

If any of these items are missing from your kit, contact the OneTouch® Customer Care Line at 1 800 663-5521.

AVAILABLE SEPARATELY:

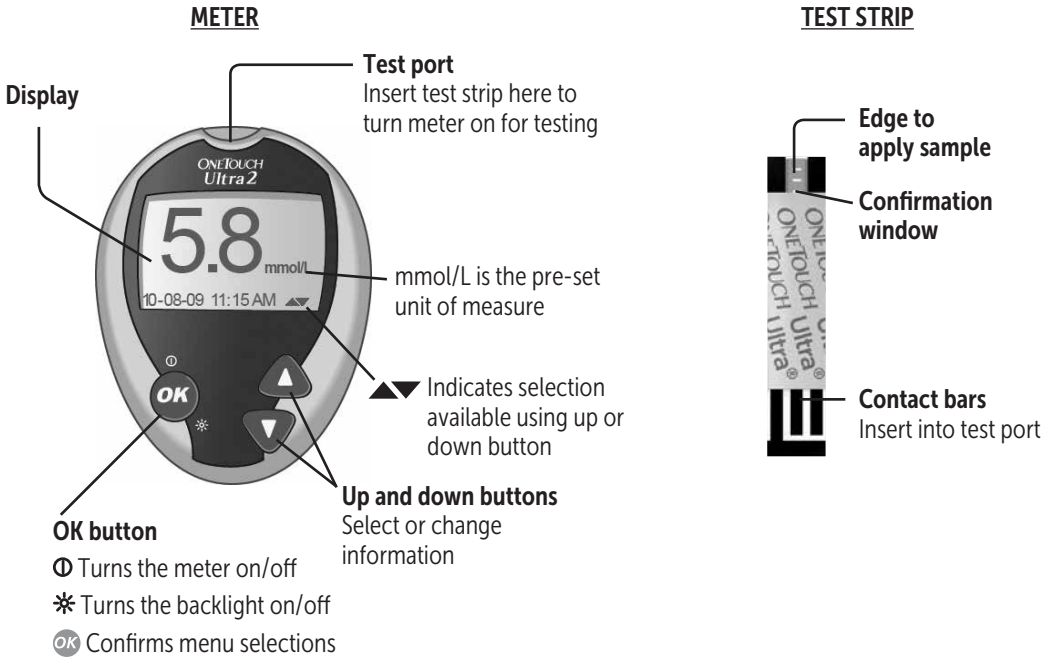
e. OneTouch Ultra® Test Strips
f. OneTouch Ultra® Control Solution

Alternate site testing (AST) Kit (not pictured).
For availability of AST Kit contact the OneTouch® Customer Care Line at 1 800 663-5521.

Ask for control solution where you buy your test strips or call the OneTouch® Customer Care Line at 1 800 663-5521.

⚠ WARNING: Keep the meter and testing supplies away from young children. Small items such as the battery door, batteries, test strips, lancets, protective covers on the lancets, and control solution vial cap are choking hazards.

Getting to know your system



Turning your meter on

To perform a test, insert a test strip as far as it will go. The meter will briefly perform system checks, then the display will turn on.

or,

With the meter turned off, press and hold OK for two seconds to access MAIN MENU. Check that the screen shows solid black for two seconds. If it does, the display is working properly. If the meter does not power on, try changing the meter battery. See *Replacing the batteries* in Section 7.

⚠ **CAUTION:** If you see any light areas within the black start-up screen, there may be a problem with the meter. Contact the OneTouch® Customer Care Line at 1 800 663-5521.

Using the meter display backlight

When the meter is already on, press and hold OK for two seconds to turn the backlight on or off.

Turning your meter off

There are several ways to turn your meter off:

- Press and hold OK for five seconds.
- Your meter will turn off by itself if left alone for two minutes.
- Go to MAIN MENU and press ▲ or ▼ to highlight METER OFF, then press OK.
- Before or after completing a test, remove the test strip. If you advance from the test result screen to the MAIN MENU by pressing OK, removing the test strip will not turn the meter off. Use one of the three methods above.

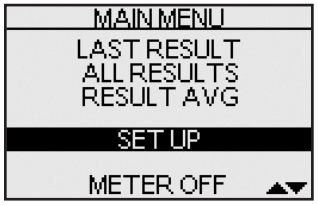
2 Setting up your meter

Setting the meter language, date and time

You can change many of the settings that came pre-set with your meter. Before using your meter for the first time or if you change the meter battery, you should check and update these settings. Make sure you complete steps 1 through 8 below to ensure your desired settings are saved.

1 Turn the meter on

With the meter turned off, press and hold OK for two seconds to access MAIN MENU.



2 Get to the LANGUAGE screen

When using the meter for the first time, or after changing the meter battery, you will automatically start in the LANGUAGE screen.

In other cases, from the MAIN MENU, press ▲ or ▼ to select SET UP and press OK. Then, press ▲ or ▼ to select METER SETTINGS and press OK.

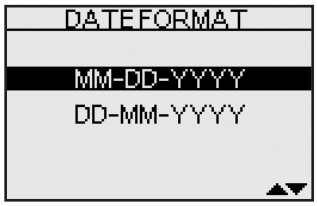
3 Choose a language

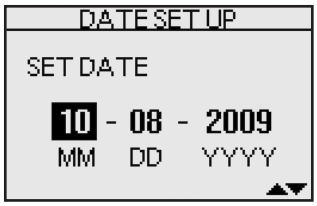
Now press ▲ or ▼ to highlight the language of your choice and press OK.

NOTE: If you select the wrong language, press OK and hold for five seconds to turn the meter off. Then, turn the meter back on and re-start from step 1.

4 Set the date format

Press ▲ or ▼ to highlight the date format—choose month first (MM-DD-YYYY) or day first (DD-MM-YYYY). To confirm your selection, press OK.



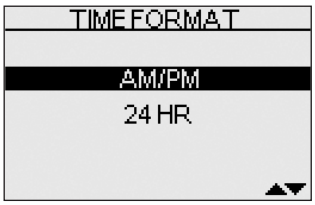


❺ Set the date

In the DATE SET UP screen, press ▲ or ▼ to change the first value and press OK.

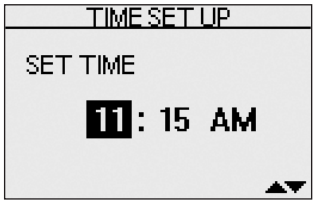
Press ▲ or ▼ to change the second value and press OK.

Press ▲ or ▼ to change the year and press OK.



❻ Set the time format

Press ▲ or ▼ to select the time format you prefer—AM/PM or 24 HR, and press OK.



❼ Set the time

Press ▲ or ▼ to set the hour and press OK. Press ▲ or ▼ to set the minutes and press OK. If you selected the AM/PM time format, press ▲ or ▼ to select AM or PM. To confirm your selection, press OK.

❽ Confirm your settings

The choice YES will be highlighted at the bottom of the screen. If your settings are correct, press OK to confirm and save the settings and return to the MAIN MENU.

⚠ WARNING: The unit of measure mmol/L must be displayed here. If your display shows mg/dL rather than mmol/L, contact the OneTouch® Customer Care Line at 1 800 663-5521. You cannot change the unit of measure. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

If you want to cancel your settings and start the settings process over again, press ▲ or ▼ to highlight NO and press OK. You will be returned to the LANGUAGE screen. Note that none of the settings you entered will be saved.

Turning the flags/comments feature off or on

Your OneTouch Ultra® 2 Meter allows you to attach optional notes to any blood glucose test result. See Section 4 Attaching flags or comments to your results for the types of meal flags and comments you can attach to a result, and the reasons for using this feature.

This feature can be turned on or off. It needs to be turned on before you can use it to attach meal flags and comments. See below.

If the flags/comments feature is left off, you will not be prompted to enter a meal flag or comment when you get a blood glucose result. Also, you will only be able to review an average for all results stored in the meter. You will not need to select a type of result average to review. See Section 5, Reviewing past results and averages for more information about result averages.

To turn the flags/comments feature off or on:

❶ **From MAIN MENU, press ▲ or ▼ to select SET UP and press OK**

❷ **From the SET UP screen, select FLAGS/COMMENTS and press OK**

❸ **Press ▲ or ▼ to highlight your response**
Select YES if you wish to change the setting, or NO if you wish to leave it as it is.

Press OK to confirm your selection and return to MAIN MENU.

Coding your meter

❶ **Check the code on the test strip vial before inserting the test strip**
Code numbers are used to calibrate your meter with the test strips you are using.

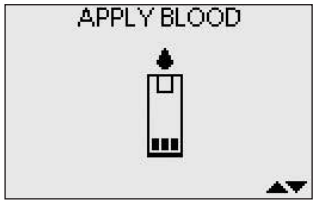
❷ Insert a test strip to turn on the meter

Remove a test strip from its vial. With clean, dry hands, you may touch the test strip anywhere on its surface. **Do Not** bend, cut or modify the test strips in any way. Use each test strip immediately after removing it from the vial. Insert the test strip into the test port as shown, with the three contact bars facing you. Push the test strip in as far as it will go.

After the black start-up screen appears, the meter will display the code from your last test. If a flashing "– –" appears instead of a code number, such as when you are first using the meter, follow the instructions in step 3 to change to a numerical code.

❸ Match the code on the meter with the code on the test strip vial

If the code on the meter does not match the code on the test strip vial, press ▲ or ▼ to match the code number on the test strip vial. The new code number will flash on the display for three seconds, then briefly stop flashing, after which the display will advance to the APPLY BLOOD screen.



If the codes already match, press OK to go to the APPLY BLOOD screen. When you do not make a change after five seconds, the display will advance to the APPLY BLOOD screen. The meter is now ready to perform a blood glucose test.

NOTE:

- If the APPLY BLOOD screen appears before you are sure the codes match, remove the test strip, and re-start from step 1.
- If you change APPLY BLOOD to APPLY CONTROL by mistake, press ▼ to change it back to APPLY BLOOD.

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

3 Testing your blood glucose

Testing with a fingertip sample

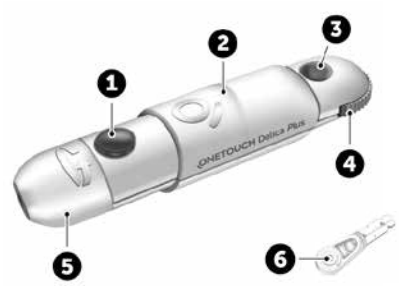
Preparing for a test

Have these things ready when you test:
OneTouch Ultra® 2 Meter
OneTouch Ultra® Test Strips
Lancing device
Sterile lancets

NOTE:
- Use only OneTouch Ultra® Test Strips.
- Make sure your meter and test strips are about the same temperature before you test.
- Testing must be done within the operating temperature range (6–44°C). For the most accurate results, try to test as close to room temperature (20–25°C) as you can (see *Detailed information about your system* in Section 8).
- Tightly close the cap on the vial immediately after use to avoid contamination and damage.
- Store unused test strips only in their original vial.
- **Do Not** open the test strip vial until you are ready to remove a test strip and perform a test. Use the test strip immediately after removing it from the vial.
- **Do Not** return the used test strip to the vial after performing a test.
- **Do Not** re-use a test strip that had blood or control solution applied to it. Test strips are for single use only.
- Write the discard date (6 months after first opening the vial) on the vial label when you first open it.

⚠ **CAUTION:**
- **Do Not** use your test strips if your vial is damaged or left open to air. This could lead to error messages or inaccurate results. Contact the OneTouch® Customer Care Line at 1 800 663-5521 immediately if the test strip vial is damaged.
- If you cannot test due to a problem with your testing supplies, contact your healthcare professional. Failure to test could delay treatment decisions and lead to a serious medical condition.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.
- **Do Not** use test strips after the expiration date (printed on the vial) or the discard date, whichever comes first, or your results may be inaccurate.

Getting to know your OneTouch® Delica® Plus Lancing Device



1 Release button
2 Slider control
3 Depth indicator
4 Depth wheel
5 Lancing device cap
6 Protective cover

The OneTouch® Delica® Plus Lancing Device uses OneTouch® Delica® or OneTouch® Delica® Plus Lancets.
- If another type of lancing device was included, see the separate instructions for that lancing device.
- The OneTouch® Delica® Plus Lancing System does not include the materials needed to perform Alternate Site Testing (AST). The OneTouch® Delica® Plus Lancing System should not be used on the forearm or palm with the OneTouch Ultra® 2 Blood Glucose Monitoring System.

Choosing the right sampling site at the right time

You can test on the fingertip or "alternate" sites like the palm with the OneTouch Ultra® 2 Meter. Fingertip testing is recommended when your blood glucose may be rapidly changing, which can occur if you've eaten, exercised, injected rapid-acting insulin or an insulin pump bolus in the last 2 hours. This is because fingertip testing may identify hypoglycemia (low blood sugar) or an insulin reaction sooner than testing with samples from other sites. You should always use a fingertip sample if you are concerned about the possibility of low blood sugar, when you are ill, under stress, or if you suffer from hypoglycemia unawareness (lack of symptoms to indicate an insulin reaction).

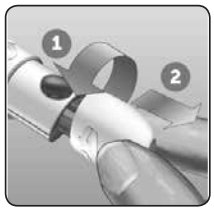
NOTE: The lancing device shown here is for fingertip testing only and is not intended for sampling "alternate" sites, like the forearm or palm. If you want to test with a forearm or palm sample, contact the OneTouch® Customer Care Line at 1 800 663-5521 to find out about obtaining an appropriate lancing device and instructions for forearm and palm testing.

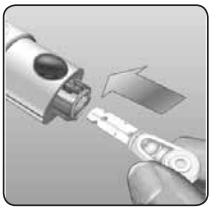
⚠ **CAUTION:** To reduce the chance of infection:
- Never share a lancet or a lancing device with anyone.
- Always use a new, sterile lancet each time you test—lancets are for single use only.
- Always keep your meter and lancing device clean (see *Caring for your system* in Section 7).
- **Do Not** use lancets after the expiration date printed on the lancet packaging.

Getting a blood sample from the fingertip

Before testing, wash your hands thoroughly with warm, soapy water. Rinse and dry.

❶ Remove the lancing device cap
Remove the cap by rotating it and then pulling it straight off the device.



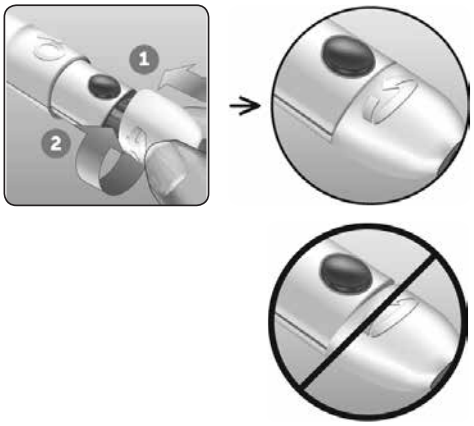


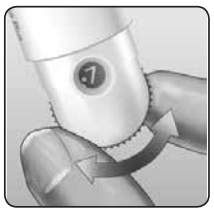
❷ Insert a sterile lancet into the lancing device
Align the lancet as shown here, so that the lancet fits into the lancet holder. Push the lancet into the device until it snaps into place and is fully seated in the holder.

Twist the protective cover one full turn until it separates from the lancet. **Save the protective cover for lancet removal and disposal.** See *Removing the used lancet*.

❸ Replace the lancing device cap
Place the cap back onto the device; turn the cap or push the cap straight on to secure it.

Ensure the cap is aligned as shown in the image.





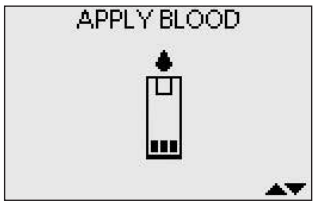
❹ Adjust the depth setting
The device has 13 puncture depth settings (each dot shown between numbers 1 to 7 on the Depth Wheel indicates an additional available depth setting). Adjust the depth by turning the depth wheel. Smaller numbers are for a shallower puncture and larger numbers for a deeper puncture.

NOTE: Try a shallower setting first and increase the depth until you find the one deep enough to get a blood sample of the proper size.

❺ Cock the lancing device
Pull the slider back until it clicks. If it does not click, it may already have been cocked when you inserted the lancet.

❻ Insert a test strip to turn the meter on
Insert a test strip into the test strip port as shown, with the three contact bars facing you.

If the code on the meter does not match the code on the test strip vial, see *Coding your meter* in Section 2.

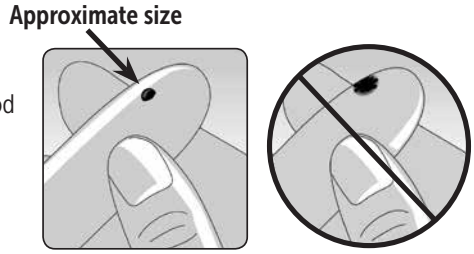


When the APPLY BLOOD screen appears on the display, you can apply your blood sample.

❼ Puncture your finger
Hold the lancing device firmly against the side of your finger. Press the release button. Remove the lancing device from your finger.

❽ Get a round drop of blood
Gently squeeze and/or massage your fingertip until a round drop of blood forms.

NOTE: If the blood smears or runs, **Do Not** use that sample. Dry the area and gently squeeze another drop of blood or puncture a new site.



Applying blood and reading results

Once you have a blood sample and your meter shows the APPLY BLOOD screen, you are ready to obtain a blood glucose result. If your meter does not show the APPLY BLOOD screen, remove the unused test strip and re-start the test process. See *Getting a blood sample from the fingertip* in Section 3.

Fingertip

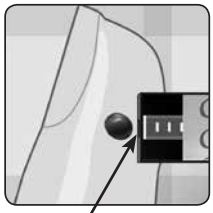
❶ Prepare to apply the sample
Keeping your finger extended and steady, move the meter and test strip toward the blood drop.

Do Not apply blood on the top of the test strip.

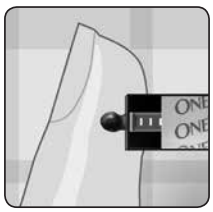
Do Not hold the meter and test strip underneath the blood drop. This may cause blood to run into the test port and damage the meter.

❷ Apply the sample

Line up the test strip with the blood drop so that the narrow channel on the edge of the test strip is almost touching the edge of the blood drop.



Narrow channel

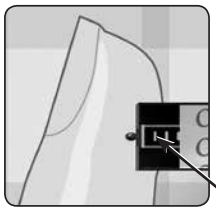


Gently touch the channel to the edge of the blood drop.

Be careful not to push the test strip against your fingertip or the test strip may not fill completely.

- **Do Not** smear or scrape the drop of blood with the test strip.
- **Do Not** apply more blood to the test strip after you have moved the drop of blood away.
- **Do Not** move the test strip in the meter during a test.

⚠ **CAUTION:** You may get an ERROR 5 message or an inaccurate result if the blood sample does not fill the confirmation window completely. See *Troubleshooting* in Section 8. Discard the test strip and re-start the test process.



Confirmation window full

❸ Wait for the confirmation window to fill completely

The blood drop will be drawn into the narrow channel and the confirmation window should fill completely.

When the confirmation window is full, this means you have applied enough blood. Now you can move the test strip away from the blood drop and wait for the meter to count down from 5 to 1.

Full

Not full

❹ Read your result on the meter

Your blood glucose level appears on the display, along with the unit of measure, and the date and time of the test. Blood glucose results are automatically stored in the meter's memory.

(Example)

⚠ WARNING: If mmol/L does not appear with the test result, contact the OneTouch® Customer Care Line at 1 800 663-5521. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

⚠ **CAUTION:** If you test at the low end of the operating range (6°C) and your glucose is high (over 10.0 mmol/L), 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.

Error messages

If you get an ERROR message on your screen rather than a result, see *Troubleshooting* in Section 8.

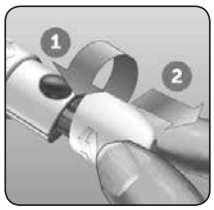
After getting a result

Once you have read your result, you may:

- Attach notes to this result if the flags/comments feature is on, see Section 4, Attaching flags or comments to your results, or
- Review your meter memory by pressing OK to go to MAIN MENU, see Section 5, Reviewing past results and averages, or
- Turn the meter off by removing the test strip.

Removing the used lancet

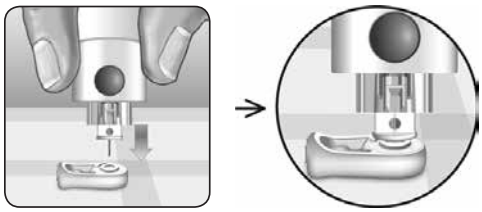
NOTE: This lancing device has an ejection feature, so you do not have to pull out the used lancet.



❶ Remove the lancing device cap

Remove the cap by rotating it and then pulling it straight off the device.

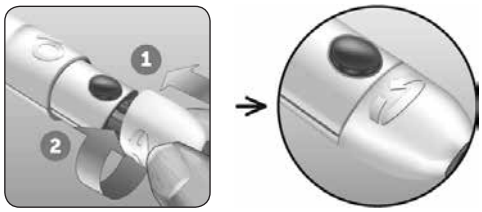
❷ Cover the exposed lancet tip
Before removing the lancet, place the lancet protective cover on a hard surface then push the lancet tip into the flat side of the disk.



❸ Eject the lancet
Holding the lancing device directed downwards, push the slider forward until the lancet comes out of the lancing device. If the lancet fails to eject properly, cock the device then push the slider control forward until the lancet comes out.

❹ Replace the lancing device cap
Place the cap back onto the device; turn the cap or push the cap straight in to secure it.

Ensure the cap is aligned as shown in the image.



It is important to use a new lancet each time you obtain a blood sample. **Do Not** leave a lancet in the lancing device. This will help prevent infection and sore fingertips.

Disposing of the used lancet and test strip
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 healthcare professional's recommendations or local regulations for proper disposal.

Interpreting unexpected test results

Refer to the following cautions whenever your test results are lower or higher than what you expect.

⚠ **CAUTION:**

Low glucose results

- If your test result is lower than 4.0 mmol/L or is shown as LOW GLUCOSE, it may mean hypoglycemia (low blood glucose). Treat this condition immediately, according to your healthcare professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do another test.

- If you test at the low end of the operating range (6°C) and your blood glucose is high, you may get an inaccurate low result. Re-test in a warmer environment with a new test strip.

Dehydration and low glucose results

- You may get false low glucose results if you are severely dehydrated. If you think you are severely dehydrated, contact your healthcare professional immediately.

High glucose results

- If your test result is higher than 10.0 mmol/L, it may mean hyperglycemia (high blood glucose) and you should consider re-testing. Talk to your healthcare professional if you are concerned about hyperglycemia.

- HIGH GLUCOSE is displayed when your blood glucose level is higher than 33.3 mmol/L. You may have severe hyperglycemia (very high blood glucose). Re-test your blood glucose. If the result is HIGH GLUCOSE again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional immediately.

Repeated unexpected glucose results

- If you continue to get unexpected results, check your system with control solution. See Section 6, Control solution testing.

- If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this User Guide, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes control program without speaking to your healthcare professional.

Unusual red blood cell count

- 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.

4 Attaching flags or comments to your results

Attaching flags or comments to your results

Your OneTouch Ultra® 2 Meter allows you to attach optional notes to any blood glucose test result. There are two kinds of notes and different reasons to apply them.

Note type	*Recommendation*	*Benefit*
Meal Flag	Add a meal flag to every blood glucose result.	Allows you to link the effects of food to your blood glucose result. Provides you with separate averages for before-meal and after-meal tests.
Comment	Select an appropriate comment whenever you test under conditions that you or your healthcare professional feel are worth noting.	Helps track possible reasons for test results.

We suggest you talk to your healthcare professional to see how meal flags and comments may help you manage your diabetes.

You can attach these notes just after a blood glucose test before you remove your used test strip from your meter. You can also modify notes when reviewing a past result.

You will not be able to add a meal flag or comment to a result marked as a control solution test.

This feature can be turned on or off. It needs to be turned on before you can use it. See *Turning the flags/ comments feature off or on* in Section 2 for instructions.

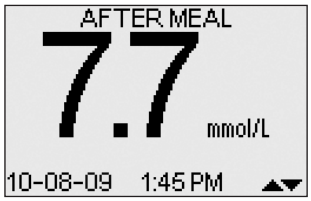
Add or change a meal flag

If the flags/comments feature is turned on, the up arrow at the bottom right corner of the result screen will flash when a result is first displayed to remind you to enter a meal flag. To add or change a meal flag:

❶ While viewing a result, press △ to display the MEAL FLAG screen

❷ Press △ or ▽ to highlight BEFORE MEAL or AFTER MEAL
If you decide not to assign a flag to this result, select NO FLAG.

❸ To confirm your selection, press OK
The meal flag you chose will appear above the result on the result screen.



NOTE: Testing after a meal can show how the food you ate affects your blood glucose. These results can be flagged as AFTER MEAL and are usually obtained two hours after the start of the meal. Your healthcare professional may suggest another time period or other use for this feature.

Add or change a comment

The down arrow at the bottom right corner of the result screen will flash after you enter a meal flag for a new result to remind you to consider entering a comment. To add or change a comment:

❶ While viewing a result, press ▽ to display the COMMENT screen

❷ Press △ or ▽ to highlight an appropriate comment

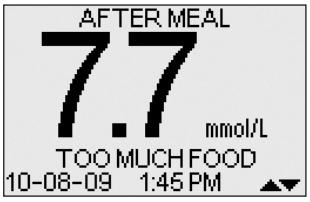
The available choices are:

NO COMMENT	STRESS
NOT ENOUGH FOOD	ILLNESS
TOO MUCH FOOD	FEEL HYPO
MILD EXERCISE	MENSES (period)
HARD EXERCISE	VACATION
MEDICATION	OTHER

Highlight NO COMMENT if you decide not to add a comment, or if you want to erase a previously entered comment from the result.

Use OTHER when the available choices do not apply. You may want to write down what OTHER means to you so you can discuss it with your healthcare professional.

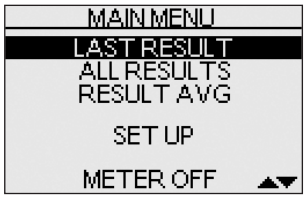
❸ To confirm your selection, press OK
The comment you chose will appear below the result.



5 Reviewing past results and averages

Reviewing past results and averages

If you have just completed a test, press OK to get to the MAIN MENU screen. If your meter is off, press OK and hold to turn it on. From the MAIN MENU screen you can choose:

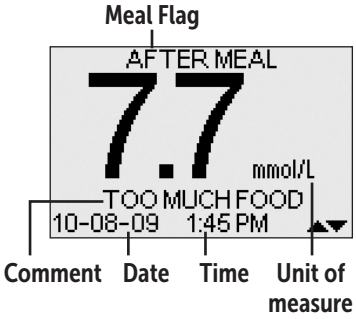


- LAST RESULT to view your most recent result,
- ALL RESULTS to review up to 500 of your most recent results four at a time, or
- RESULT AVG to select one of three types of result averages.

Press ▲ or ▼ to highlight LAST RESULT, ALL RESULTS, or RESULT AVG and press OK.

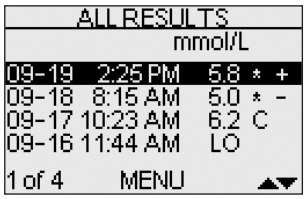
Last result

The meter will display your most recent result. Press OK to return to MAIN MENU. If you wish to add or change a meal flag or comment for this result, see Section 4, Attaching flags or comments to your results.



All results

The meter will display four results at a time, in the order the tests were done, starting with the most recent. For each test result, the meter will display the date and time of the test. Results may also contain the following symbols:



HI if the result was above 33.3 mmol/L,
LO if the result was below 1.1 mmol/L,
***** if a comment has been chosen for the result,
C if the result is from a control solution test,
– if the result is flagged BEFORE MEAL, and
+ if the result is flagged AFTER MEAL.

The meter stores a maximum of 500 blood glucose or control solution test results. When the memory is full, the oldest result is dropped as the newest is added.

To view details of an individual result, press ▲ or ▼ to highlight the result you want, then press OK. If you wish to add or change a meal flag or comment for this result, see Section 4, Attaching flags or comments to your results. To return to the list of all results from an individual result, press OK.

To view more recent results, continue to press ▲ after the top result on the display is highlighted. If you press ▲ when the most recent result is highlighted, you will see the oldest stored results.

To view older results, press ▼ after MENU is highlighted. Pressing and holding ▲ or ▼ allows you to move more quickly through the results. To return to the main menu, highlight MENU, then press OK.

Averages

If the flags/comments feature is left off, selecting RESULT AVG from the MAIN MENU will lead directly to the ALL RESULTS AVG screen. If the flags/comments feature is on, the meter will display the three types of averages you can access:

- the average of all test results,
- the average of before-meal results, and
- the average of after-meal results.

To select the type of result average you want to see, press ▲ or ▼ to highlight your choice, then press OK.

The meter will display each of your 7-, 14-, and 30-day averages. The top of the display shows which type of average you are looking at. For each of the 7-, 14-, and 30-day periods leading up to the current date, the meter will display the number of results obtained (NUM) and the average of those results (AVG).

In result averages, a HIGH GLUCOSE result is counted as 33.3 mmol/L, and a LOW GLUCOSE result as 1.1 mmol/L. Control solution results are not part of your averages. From any screen showing averages, press OK to go back to the previous screen.

To return to the main menu from the RESULT AVG screen, press ▽ until MENU is highlighted, then press OK.

BEFORE MEAL AVG
mmol/L

DAYS	NUM	AVG
7	14	8.2
14	34	7.8
30	43	7.6

NOTE:

- Result averages provide information from past results. **Do Not** use result averages to make immediate treatment decisions.
- If you change your date setting, your averages may change too. The meter calculates averages based on the 7-, 14-, and 30-day periods ending on the current date setting.
- If you do not have results in the past 7-, 14-, and 30-day periods, the NUM and AVG columns will show 0. Also, if you do not use the meal flag feature, then the NUM and AVG columns will show 0 on the BEFORE MEAL and AFTER MEAL average screens.

AFTER MEAL AVG
mmol/L

DAYS	NUM	AVG
7	0	0.0
14	0	0.0
30	0	0.0

To see averages for different parts of the day or over a different number of days, you can use diabetes management software and your home computer. See *Downloading results to a computer* in this Section.

Downloading results to a computer

Your meter can work with diabetes management software, which provides a visual way to track key factors that affect your blood sugar.

❶ Obtain the required software and cable

For order information and to learn more about diabetes management tools available to you, contact the OneTouch® Customer Care Line at 1 800 663-5521, Monday-Friday, 9am-8pm Eastern, 6am-5pm Pacific, or visit www.OneTouch.ca.

❷ Install the software on a computer

Follow the installation instructions provided with the Software. If using a OneTouch® Interface Cable (USB format), install the software driver.

⚠ WARNING: To avoid a possible shock, Do Not insert a test strip when the meter is connected to a computer with the OneTouch® Interface Cable.

❸ Get ready to transfer readings

Connect the OneTouch® Interface Cable to the COM or USB port on your computer.

Make sure the meter is turned off. If you insert the cable while the meter is already on, the meter will not respond to computer commands. Then connect the other end of the OneTouch® Interface Cable to the meter data port.

❹ Transfer data

Follow the instructions provided with the diabetes management software product to download the results from the meter.

Once the command to start the download is sent from the computer to the meter, the meter display will show "PC" indicating that the meter is in communication mode. You will not be able to perform a test when the meter is in communication mode.

6 Control solution testing

When to test with control solution

OneTouch Ultra® Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly.

- Do a control solution test:
  - whenever you open a new vial of test strips.
  - if you suspect the meter and test strips are not working properly.
  - if you have had repeated unexpected blood glucose results.
  - if you drop or damage the meter.

NOTE:

- Use only OneTouch Ultra® Control Solution with your OneTouch Ultra® 2 Meter.
- Control solution tests must be done at room temperature (20–25°C). Make sure your meter, test strips, and control solution are at room temperature before testing.
- Write the discard date (3 months after first opening the vial) on the vial label when you first open it.

⚠ **CAUTION: 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.

How to test with control solution

Start with the meter off. If you have turned the meter on to change settings or review past results, turn it off.

❶ Check the code on the test strip vial before inserting the test strip

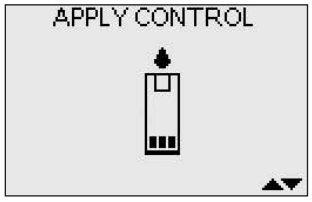
❷ Insert a test strip to turn on the meter

Make sure the three contact bars are facing you. Push the test strip in as far as it will go. **Do Not** bend the test strip.

❸ Match the code on the meter with the code on the test strip vial

If the code on the meter does not match the code on the test strip vial, press △ or ▽ to match the code number on the test strip vial. The new code number will flash on the display for three seconds, then briefly stop flashing, after which the display will advance to the APPLY BLOOD screen.

If the codes already match, press OK to go to the APPLY BLOOD screen. When you do not make a change after five seconds, the display will advance to the APPLY BLOOD screen.



❹ Mark the test as a control solution test

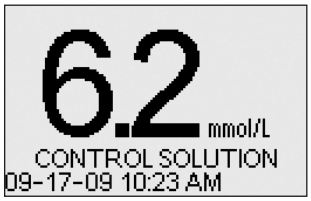
Press △ to change APPLY BLOOD to APPLY CONTROL. You must mark the test before you apply control solution. Once you have completed the test, you cannot change the marking.

The meter is now ready to perform a control solution test.

❺ Prepare and apply control solution

Shake the control solution vial before each test. Remove the cap and squeeze the vial to discard the first drop. Then wipe the tip with a clean tissue or cloth. Hold the vial upside down and gently squeeze a hanging drop.

Touch and hold the hanging drop of control solution where the narrow channel meets the **TOP EDGE** of the test strip. Make sure the confirmation window fills completely. Control solution should not be applied to the flat face of the test strip.



❻ Read your result

When the confirmation window is full, the meter will count down from 5 to 1.

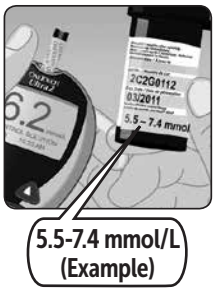
Your control solution result will then appear on the display, along with the date, time, unit of measure, and the words CONTROL SOLUTION. The control solution results can be viewed in the list of past results, but are not counted in your result averages.

❼ Check if the result is in range

Compare the result displayed on the meter to the control solution range printed **on the test strip vial**. Each vial of test strips may have a different control solution range. If the results you get are not within this range, the meter and test strips may not be working properly. Repeat the control solution test.

Out-of-range results may be due to:

- not following the instructions detailed in steps 1-7,
- expired or contaminated control solution,
- expired or damaged test strip,
- use of a test strip or control solution past its discard date, or
- a problem with the meter.

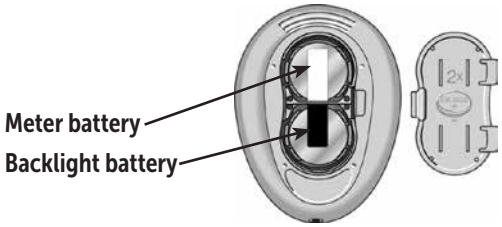


⚠ **CAUTION:** The control solution range printed on the test strip vial is for OneTouch Ultra® Control Solution only. It is not a recommended range for your blood glucose level.

⚠ **CAUTION:** If you continue to get control solution test results that fall outside the range printed on the test strip vial, **Do Not** use the meter, the test strips, or the control solution. Contact the OneTouch® Customer Care Line at 1 800 663-5521.

Replacing the batteries

Your OneTouch Ultra® 2 Meter uses two 3.0 Volt CR 2032 lithium batteries (or equivalent). Replacement batteries can be found in most stores where batteries are sold. Your meter comes with two batteries already installed–one that powers the meter only and one that powers the backlight.



Low meter battery

The meter shows a battery icon ( ) in the upper right corner of the display or a low battery message to indicate the condition of the **meter** battery only. When the battery icon first appears, there is enough power for a minimum of 100 more tests. You should replace the meter battery as soon as possible.

When your meter displays the LOW BATTERY screen message, there is not enough battery power remaining to perform a test. You must install a new battery before using your meter.

Low backlight battery

Replace the backlight battery when you can no longer see the backlight coming on. There will not be any icon on the meter display to indicate a low backlight battery. Note that the meter will provide accurate blood glucose results even when the backlight battery needs to be replaced.

Replacing the batteries

❶ Remove the old battery

Start with the meter off. Open the battery door and pull up on the battery ribbon. The white ribbon is for the meter battery, and the black ribbon is for the backlight battery.

⚠ WARNING: CHEMICAL BURN HAZARD. DO NOT INGEST BATTERY. This product contains a coin/button cell battery. If swallowed, it can quickly cause severe internal burns and can lead to death. Keep new and used batteries away from children. If you think batteries might have been swallowed, seek immediate medical attention.

⚠ WARNING: To avoid a possible shock, Do Not change either battery while the meter is connected to a computer with the OneTouch® Interface Cable.

❷ Insert the new battery

With the "+" side facing up toward you, place the battery in the compartment within the fold of the ribbon. Push the battery until it snaps into the battery clasp. Insert the two battery door tabs into the matching holes on the meter, and push down until you hear the door click into place.

If the meter does not power on after you have replaced the meter battery, check that the battery is correctly installed with the "+" side up. If the meter still does not power on, contact the OneTouch® Customer Care Line at 1 800 663-5521.

❸ Check your meter settings
Removing the meter battery will not affect your stored results. However, you may need to re-set your meter settings. See *Setting the meter language, date and time* in Section 2.

❹ Dispose of batteries
Please recycle or dispose of used batteries using your local battery collection systems and in compliance with your local environmental laws and regulations.

Caring for your system

Your OneTouch Ultra® 2 Blood Glucose Monitoring System does not need any special maintenance.

Storing your system
Store your meter, test strips, control solution and other items in your carrying case after each use. Store each item in a cool, dry place below 30°C, but **Do Not** refrigerate. Keep all items away from direct sunlight and heat.

Tightly close the cap on the test strip vial and/or control solution vial immediately after use to avoid contamination or damage. Store test strips only in their original vial.

Checking for expiration or damage to test strips and control solution
Expiration dates for test strips and control solutions are printed on their vial labels. When you first open a new vial of test strips or control solution, record the discard date on the label. Refer to the test strip or control solution vial for instructions on determining the discard date.

⚠ **CAUTION: Do Not** use the test strips or control solution after the expiration date printed on the vial or the discard date, whichever comes first, or your results may be inaccurate.

Cleaning your meter
To clean your meter, wipe the outside with a soft cloth dampened with water and mild detergent. **Do Not** use alcohol or another solvent to clean your meter.

Do Not get any liquids, dirt, dust, blood, or control solution inside the meter through the test port or the data port. Never spray cleaning solution on the meter or immerse it in any liquid.

Cleaning your lancing device and clear cap
To clean these items, wipe them with a soft cloth dampened with water and mild detergent. **Do Not** immerse the lancing device in any liquid.

To disinfect these items, prepare a solution of one part household bleach to nine parts water. Wipe the lancing device with a soft cloth dampened with this solution. Immerse the **caps only** in this solution for 30 minutes. After disinfecting, rinse briefly with water and allow both to air dry.*

*Follow manufacturer's instruction for handling and storage of bleach.

8 Troubleshooting and detailed information about your system

Troubleshooting

The OneTouch Ultra® 2 Meter displays messages when there are problems with the test strip, with the meter, or when your blood glucose levels are higher than 33.3 mmol/L or lower than 1.1 mmol/L. Messages do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message.

In this section, screens that display "SEE OWNER'S BOOKLET" mean you should refer to this User Guide.

Message	What it means	What to do
WARNING LOW GLUCOSE BELOW 1.1 mmol/L	You may have a very low blood glucose level (severe hypoglycemia), lower than 1.1 mmol/L.	**This may require 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 do another test.
WARNING HIGH GLUCOSE ABOVE 33.3 mmol/L	You may have a very high blood glucose level (severe hyperglycemia), over 33.3 mmol/L.	Re-check your glucose level. If the result is HIGH GLUCOSE again, obtain and follow instructions from your healthcare professional without delay.
WARNING TEMPERATURE ERROR OUT OF OPERATING RANGE SEE OWNER'S BOOKLET	Meter is too hot (above 44°C) or too cold (below 6°C) to work correctly.	Wait a few minutes and insert a new test strip. If you do not get another TEMPERATURE ERROR message, the meter is now within the operating range.
WARNING ERROR 1 METER PROBLEM CALL CUSTOMER SERVICES	There is a problem with the meter.	**Do Not** use the meter. Contact the OneTouch® Customer Care Line at 1 800 663-5521.
WARNING ERROR 2 METER OR STRIP PROBLEM RETEST WITH A NEW STRIP	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; see Section 3, Testing your blood glucose. If this message continues to appear, contact the OneTouch® Customer Care Line at 1 800 663-5521.
WARNING ERROR 3 METER WAS NOT READY RETEST WITH A NEW STRIP	The sample was applied before the meter was ready.	Repeat the test with a new test strip. Apply a blood or control solution sample only after APPLY BLOOD or APPLY CONTROL appears on the display. If this message continues to appear, contact the OneTouch® Customer Care Line at 1 800 663-5521.

Message	What it means	What to do
WARNING **ERROR 4** STRIP PROBLEM SEE OWNER'S BOOKLET	***One of the following may apply:*** You may have high glucose and have tested in an environment near the low end of the system's operating temperature range (6–44°C). *or*,	If you tested in a cool environment, repeat the test in a warmer environment with a new test strip; see Section 3, Testing your blood glucose.
	There may be a problem with the test strip. For example, it may have been damaged or moved during testing. *or*,	If you tested in a normal or warm environment, repeat the test with a new test strip; see Section 3, Testing your blood glucose.
	The sample was improperly applied. *or*, There may be a problem with the meter.	If you applied the sample incorrectly, review blood application (see Section 3, Testing your blood glucose) or control solution testing (see Section 6, Control solution testing) and repeat the test with a new test strip. If this message continues to appear, contact the OneTouch® Customer Care Line at 1 800 663-5521.
WARNING **ERROR 5** STRIP PROBLEM OR SAMPLE TOO SMALL RETEST WITH A NEW STRIP	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 information on blood application (see Section 3, Testing your blood glucose) or control solution testing (see Section 6, Control solution testing).
5.8 mmol/L 10-08-09 11:15 AM	Meter battery is low but still has enough power to perform a test.	When the battery icon first appears, there is enough power for a minimum of 100 more tests. Test results will still be accurate, but replace the battery as soon as possible.
WARNING **LOW BATTERY** REPLACE BATTERY NOW! SEE OWNER'S BOOKLET	Meter battery does not have enough power to perform a test.	Replace meter battery.

Message	What it means	What to do
———	No result in memory, such as the first time use of the meter *or,* your meter was unable to recall this result. This result will not be included in result averages.	You can still perform a blood glucose test and get an accurate result. Contact the OneTouch® Customer Care Line at 1 800 663-5521 to report this occurrence, **unless** this is your first use of the meter.
ALL RESULTS mmol/L 09-19 2:25 PM 5.8 * + --- 09-17 10:23 AM 6.2 C 09-16 11:44 AM LO 1 of 4 MENU ▲▼	Your meter was unable to recall this result. This result will not be included in result averages.	You can still perform a blood glucose test and get an accurate result, but contact the OneTouch® Customer Care Line at 1 800 663-5521 to report this occurrence.

Detailed information about your system

Comparing meter and laboratory results

Test results with the OneTouch Ultra® 2 Meter are plasma-calibrated. This helps you and your healthcare professional to compare your meter results with laboratory tests. If you have been using another type of meter–one that provides whole blood-calibrated results–you may notice that your test results with the OneTouch Ultra® 2 Meter are approximately 12% higher.

OneTouch Ultra® 2 Meter test results and laboratory test results both are expressed in plasma-equivalent units. However, your meter result may differ 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® 2 Meter glucose value is considered accurate when it is within ±20% of the laboratory measurement. There are some specific situations that could cause a difference of more than ±20%:

- You have eaten recently. The blood glucose level from blood obtained from a fingertip can be up to 3.9 mmol/L higher than blood drawn from a vein (venous sample) used for a lab test.[1]
- Your hematocrit (percentage of your blood that is red blood cells) is high (above 55%) or low (below 30%).
- You are severely dehydrated.
- You tested at a temperature near the low end of the operating range (6°C) and you get a high glucose result (i.e., greater than 10.0 mmol/L). In this situation, repeat the test in a warmer environment with a new test strip as soon as possible.

For accuracy and precision data and for important information on limitations, see the insert that comes with your test strips.

1. Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R. (ed.), *Tietz Textbook of Clinical Chemistry*. Philadelphia: W.B. Saunders Company (1994), 959.

To maximize your chances of an accurate comparison between meter and laboratory results, follow a few basic guidelines:

Before going to the lab

- Perform a control solution test to make sure the meter is working properly.
- **Do Not** eat for at least eight hours before you test your blood.
- Take your meter with you to the lab.

While at the lab

- Conduct your meter test within 15 minutes of the lab test.
- Use only fresh, capillary blood obtained from the fingertip.
- Follow all instructions in this User Guide for performing a blood glucose test with your meter.

Technical specifications

Reported result range	1.1–33.3 mmol/L
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Test time	5 seconds
Assay method	Glucose oxidase biosensor
Meter power source	One replaceable 3.0 Volt CR 2032 lithium battery (or equivalent)
Backlight power source	One replaceable 3.0 Volt CR 2032 lithium battery (or equivalent)
Unit of measure	mmol/L
Memory	500 blood glucose or control solution test results
Automatic shutoff	2 minutes after last action
Size	7.92 x 5.72 x 2.29 cm
Weight	Approximately 42.5 grams, with batteries
Operating ranges	Temperature: 6–44°C Relative humidity: 10–90% Altitude: up to 3048 meters Hematocrit: 30–55%
Battery ratings	2 x 3.0 V d.c., 60 mA (2 x CR 2032 batteries) ⎓ direct current

Electrical and safety standards

This meter complies with CISPR 11: 2003, Class B (Radiated Only). Emissions of the energy used are low and not likely to cause interference in nearby electronic equipment. The meter has been tested for immunity to Level 3 electrostatic discharge as specified in IEC 61000-4-2. This meter has been tested for immunity to radio frequency interference over the frequency range 80 MHz to 2.5 GHz at 3V/m as specified in IEC 61000-4-3.

Degree of protection rating: IP32

C US CAN/CSA C22.2 61010-1:04, UL 61010-1:04, IEC 61010-1 and IEC 61010-2-101.

Guarantee

LifeScan guarantees that the OneTouch Ultra® 2 Meter will be free of defects in material and workmanship for three years, valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable.