

ONETOUCH[®]

UltraLink[™]

Blood
Glucose
Monitoring
System



*Wirelessly sends accurate glucose results to
MiniMed Paradigm[®] and Guardian[®] Devices[†]*

Owner's Booklet

[†] Applies to compatible Medtronic MiniMed Paradigm[®]
insulin pumps and Guardian[®] REAL-Time Systems

Welcome to the OneTouch® family!

OneTouch® is committed to creating a world without limits for people with diabetes.

The OneTouch® UltraLink™ Meter, developed by LifeScan and Medtronic Diabetes, makes it simple to get a blood glucose test result and review past results. We designed this product to make testing easy and to help you manage your diabetes.

A special wireless communication feature lets the meter automatically transmit glucose test results to compatible* Medtronic Diabetes devices.

This owner's booklet will help you learn how to use your meter properly. Please read it carefully.

If you need assistance, please contact Customer Service at 1 866 621-4846 toll free. Customer Service is available 24 hours a day, 7 days a week. If you cannot reach Customer Service, contact your health care professional for advice.

If you have **specific** questions about any partner device** from Medtronic Diabetes, you may contact the manufacturer's 24-hour line at 1 800 646-4633 (calls within the United States) or 1 818 576-5555 (calls outside the United States), or visit their website at www.medtronicdiabetes.com.

* For information on compatible Medtronic Diabetes devices, contact Medtronic directly.

** Throughout the owner's booklet, references to Medtronic Diabetes devices will be referred to as simply "partner devices."

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- Getting to know your OneTouch® UltraLink™ Blood Glucose Meter and Test Strips
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Your meter comes pre-set to automatically transmit glucose test results to your partner device. You will also need to program your meter ID into your partner device for results to be transmitted. See page 13 for instructions on where to find your meter ID and how to program it into your partner device.

Starting the test process

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NOTE: Before testing, read this owner's booklet carefully.

Insert a test strip

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



The meter will turn on, show a black start-up screen and then a code number. The first time you use the meter, the CAL CODE screen will display “—” instead of a number.

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

If the code on the meter does not match the code on the vial, press **▲** or **▼** to change the code. If the display changes to the APPLY BLOOD screen before you are ready, remove the test strip and re-start the test process.



Press **OK** when the numbers match.

The meter is ready for testing when the APPLY BLOOD screen appears.

Prepare the OneTouch® Lancing Device

Remove the blue (or black) cap and put a new lancet in the lancing device. Twist off the protective disk. Replace the cap and cock the lancing device.

**Get a drop of blood**

Hold the OneTouch® Lancing Device firmly against your finger. Press the release button.



Gently squeeze and/or massage your fingertip until a round drop of blood (● sample size) forms.

**Touch and hold the drop of blood to the narrow channel in the top edge of the test strip**

Blood will be drawn into the test strip. Keep holding the drop of blood to the top edge of the test strip until the confirmation window is full. The meter will begin to count down from 5 to 1. Then, your blood glucose level appears on the display along with the unit of measure, and the date and time of the test.

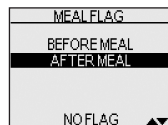


Your glucose test result will flash on the display to indicate that it is being transmitted to your partner device. The result will stop flashing after it has been received. After about 60 seconds, if the result has not been received by the partner device, the transmit feature will turn off and the result will stop flashing.

If the test results are lower than, higher than, or not what you expect, see pages 36–38.

Add a meal flag to track different types of averages

While viewing your test result, (or after it stops flashing if the PUMP COMM feature is turned on), press **▲** to get to the MEAL FLAG screen.



Press **▲** or **▼** to highlight BEFORE MEAL or AFTER MEAL.

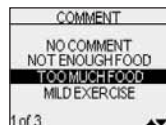
To confirm your selection, press **OK**.

The meal flag you chose will appear above the result.

If you do not wish to add a meal flag, select NO FLAG and press **OK**. This will return you to the glucose result screen.

Add a comment

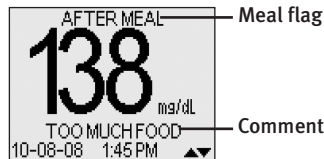
While viewing your test result, (or after it stops flashing if the PUMP COMM feature is turned on), press **▼** to get to the COMMENT screen.



Press **▲** or **▼** to highlight an appropriate comment.

To confirm your selection, press **OK**.

The comment you chose appears below the result.



- Last result
- All results
- Result averages
- Downloading results

ALL RESULTS				BEFORE MEAL AVG		
mg/dL				mg/dL		
DATE	TIME	GLUCOSE	STATUS	DAYS	NUM	AVG
09-19	2:25 PM	104	+	7	14	148
09-18	8:15 AM	90	-	14	34	140
09-17	10:23 AM	112	C	30	43	137
09-16	11:44 AM	LO				

1 of 4 MENU

⚠ WARNING: Failure to carefully follow the directions in this owner's booklet can lead to inaccurate test results.

Before you begin

Before using this product to test your blood glucose, carefully read this booklet and the inserts that come with the OneTouch® Ultra® Test Strips and OneTouch® Ultra® Control Solution. Take note of warnings and cautions throughout this booklet, 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 page 50 in the Control solution testing section.

Intended use

- The OneTouch® UltraLink™ Blood Glucose Monitoring System is intended to be used for self-testing outside the body (*in vitro* diagnostic use) for the quantitative measurement of glucose in fresh capillary whole blood obtained from the finger, forearm or palm.
- The OneTouch® UltraLink™ System is intended for use by people with diabetes in a home setting and by health care professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.
- Not for the diagnosis of diabetes
- Not for use with neonates

- Test strips for single use only
- Test strips are specific to D-glucose and do not react to other sugars that may be present in the blood
- Not for use with serum or plasma

The OneTouch® UltraLink™ Blood Glucose Monitoring System may also be used with designated partner devices. OneTouch® UltraLink™ is set up to automatically transmit each glucose result to the partner device.

See your partner device manual for instructions for setting up, using, and troubleshooting problems with your partner device.

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.

About RF

Radio frequency (RF) is a type of wireless communication. Cell phones use RF technology, as do many other devices. RF is how your OneTouch® UltraLink™ Blood Glucose Meter transmits glucose test results to your partner device.

Your OneTouch® UltraLink™ Meter comes from the factory pre-set to automatically transmit glucose test results to the partner device. You must also program the partner device to recognize the unique meter ID stored in your meter for test results to be received. This will help ensure that only results from your OneTouch® UltraLink™ Meter will be received by your partner device.

Your meter is subject to and complies with U.S. federal guidelines, Part 15 of the FCC rules for devices with RF capability. These rules state two conditions specific to the operation of the device. They are:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesirable operation.

These guidelines help ensure that your meter will not affect the operation of other nearby devices. Additionally, other devices should not affect the use of your meter.


Other wireless devices that are in use nearby, such as a cell or mobile phone, or a wireless network, may prevent or delay the transmission of data from your meter to your partner device. Moving away from or turning off these devices may allow communication.

The meter has been tested and found to be appropriate for use at home. In most cases, it should not interfere with other home electronic devices if used as instructed. However, this meter gives off RF energy when the RF feature is turned on and in use; so, if not used correctly, your meter may interfere with your TV, radio, or other electronic devices that receive or transmit RF signals. If you experience meter interference problems, you should try moving your meter away from the source of the interference, or relocate the electronic device or its antenna to another location to resolve the problem.

If you continue to experience interference problems, contact Customer Service at 1 866 621-4846, or contact support service for the manufacturer of the device causing the interference.

In locations where cell phone use is not permitted, such as hospitals, some health care professional offices, and airplanes, you should turn the meter RF feature off.

If you plan to travel to another country, be familiar with local regulations regarding the use of RF devices. You may contact 1 866 621-4846 for more information about local regulations.

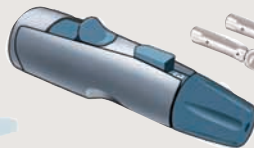
 **WARNING:** If you plan to use the RF feature on your meter to automatically transmit test results to your partner device, Do Not let anyone else use your meter to test their blood glucose. This will prevent other people's results from being transmitted to your partner device or being included in your past results and averages. If you must lend your meter to anyone else, be sure to turn the RF (PUMP COMM) feature off.



a



b



c



d



e



f



g

The OneTouch® UltraLink™ Blood Glucose Monitoring System

To test with the OneTouch® UltraLink™ System you will need the following:

- a OneTouch® UltraLink™ Meter (batteries included)
- b OneTouch® Ultra® Control Solution
- c Lancing Device
If another type of lancing device was included, see the separate instructions that came with that lancing device.
- d OneTouch® Clear Cap
- e Sterile Lancets
- f Carrying Case
- g OneTouch® Ultra® Test Strips

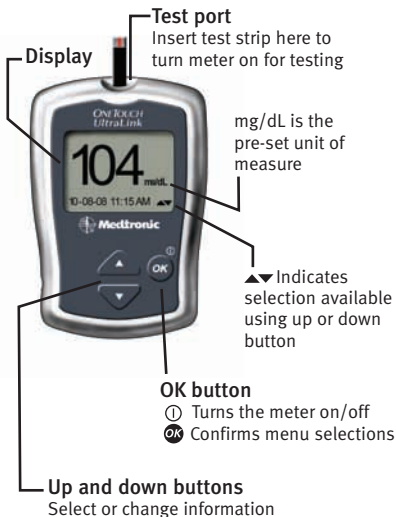
Documents in your kit include this owner's booklet, a quick reference guide, a control solution insert, a test strip insert and a warranty registration card. If any items are missing from your kit, call Customer Service.

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

Setting up your system

Getting to know your OneTouch® UltraLink™ Blood Glucose Meter and test strips

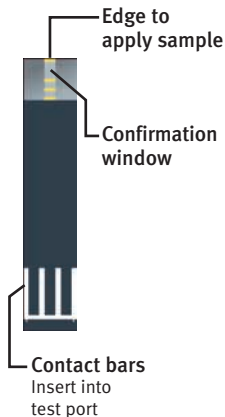
Front



Back



Test strip



Turning your meter on

There are two ways to turn 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 batteries. See pages 58–61.



CAUTION: If you see any light areas within the black start-up screen, there may be a problem with the meter. Call Customer Service.

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.

Setting the meter language, date and time

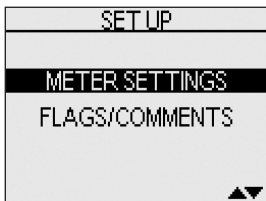
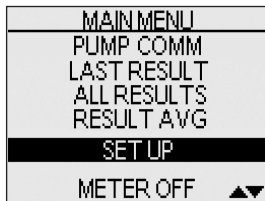
You can change many of the settings that came pre-set with your meter. Before using your meter for the first time or if you change the meter batteries, you should check and update these settings. Make sure you complete steps 1 through 8 below to ensure your desired settings are saved.

1. Turn the meter on, see page 3

2. Get to the LANGUAGE screen

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

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



The display now shows the LANGUAGE screen.

3. Choose a language

Now press ▲ or ▼ to highlight the language of your choice. To confirm your selection, press OK.

The display now shows the DATE FORMAT screen.

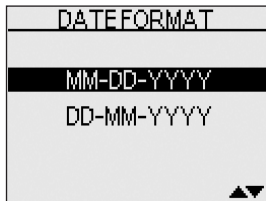
NOTE: If you select the wrong language, press OK and hold for five seconds to turn the meter off. Then, turn the meter back on and re-start from step 1.



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.

The display now shows the DATE SET UP screen.



5. Set the date

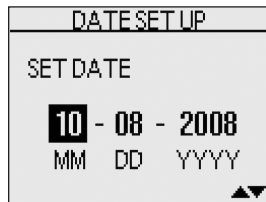
In the DATE SET UP screen, press **▲** or **▼** to change the first value. To confirm your selection, press **OK**.

Press **▲** or **▼** to change the second value.

To confirm your selection, press **OK**.

Press **▲** or **▼** to change the year. To confirm your selection, press **OK**.

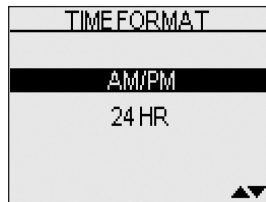
The display now shows the TIME FORMAT screen.



6. Set the time format

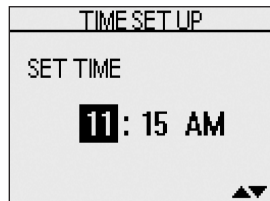
Press **▲** or **▼** to select the time format you prefer—AM/PM or 24 HR. To confirm your selection, press **OK**.

The display now shows the TIME SET UP screen.

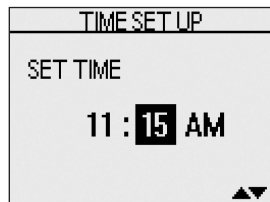


7. Set the time

Press ▲ or ▼ to set the hour. To confirm your selection, press **OK**.

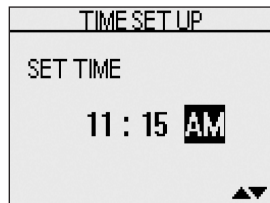


Press ▲ or ▼ to set the minutes. To confirm your selection, press **OK**.



If you have selected the AM/PM time format, AM or PM will be displayed next to the minutes.

Press ▲ or ▼ to set AM or PM. To confirm your selection, press **OK**.



The display now shows the SETTINGS screen.

8. 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 mg/dL must be displayed here. If your display shows mmol/L rather than mg/dL, contact Customer Service. 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® UltraLink™ Meter allows you to attach optional notes to any blood glucose test result. See pages 40–43 for the types of meal flags and comments you can attach to a result, and the reasons for using this feature.

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

If you do not wish to track separate result averages for before and after meals, nor attach comments to any test result, you may turn this feature off. See page 10.

If you turn off the flags/comments feature, you will not see ▲▼ on the test result screen after you complete a blood glucose test. You will be able to review the ALL RESULTS AVG screen, but not before- or after-meal averages. See page 46 for more information about result averages.

To turn the flags/comments feature off or on:

1. From MAIN MENU, press ▲ or ▼ to select SET UP

To confirm your selection, press **OK**.

2. From the SET UP screen, select FLAGS/COMMENTS

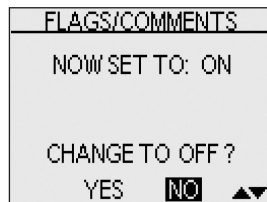
To confirm your selection, press **OK**.



3. 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.



Automatic transmission of blood glucose test results to your partner device

Blood glucose test results will be transmitted automatically to your partner device when:

- the PUMP COMM feature is turned on, *and*
- your meter and partner device are paired (“linked”).

Turning the PUMP COMM (partner device communication) feature on and off

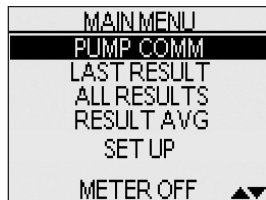
The PUMP COMM feature allows your meter to automatically transmit glucose test results to your partner device using a wireless (RF) link.

The meter comes pre-set with the PUMP COMM feature turned on. If you turn the PUMP COMM feature off, your test results will not be transmitted automatically, and you will need to manually enter test results into your partner device.

To turn the **PUMP COMM** feature off or on:

1. From **MAIN MENU**, press **▲** or **▼** to select **PUMP COMM**

To confirm your selection, press **OK**.

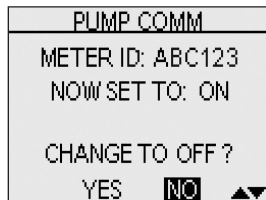


2. Press **▲** or **▼** to highlight your response

Your unique meter ID will be displayed on the top line of the screen. The current PUMP COMM setting will be displayed underneath.

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.



To confirm the PUMP COMM feature is set the way you want, select PUMP COMM from the **MAIN MENU** and press **OK**.

Pairing (linking) your meter and partner device

Programming your meter ID links your partner device to the meter. If you do not “link” the meter to your partner device, you will enter your blood glucose test results manually. Each meter has its own unique ID. This helps ensure only partner devices with your unique meter ID can automatically receive blood glucose test results from your meter. **Partner devices without your unique meter ID cannot receive your blood glucose test results.**

Your unique meter ID is stored in the meter memory. To display the ID on your meter, you must complete step 1 in the previous section. The ID also appears on both labels on the back side of the meter.



IMPORTANT: See your partner device manual for instructions for programming your meter ID into your partner device.


Starting the test process


Have these things ready when you test your blood glucose level:

- OneTouch® UltraLink™ Meter
- OneTouch® Ultra® Test Strips
- Lancing device
- Sterile lancets with protective disks
- OneTouch® Ultra® Control Solution

NOTE:

- Use only OneTouch® Ultra® Test Strips with your OneTouch® UltraLink™ Meter.
- Make sure your meter and test strips are about the same temperature before you test.
- Testing must be done within the operating temperature range (43–111°F). For the most accurate results, try to test as close to room temperature (68–77°F) as you can.
- OneTouch® Ultra® Test Strips are for single use only. Never re-use a test strip that had either blood or control solution applied to it.

 **CAUTION:** If you cannot test due to a problem with your testing supplies, contact your health care professional or Customer Service. Failure to test could delay treatment decisions and lead to a serious medical condition.

 **CAUTION:** The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

1. 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.



2. Insert a test strip to turn on the meter

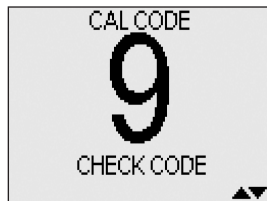
Start with the meter off. If you have turned the meter on to change settings or review past results, turn it off. Remove a test strip from its vial and immediately replace the vial cap and close it tightly. With clean, dry hands, you may touch the test strip anywhere on its surface.

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. 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.

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.



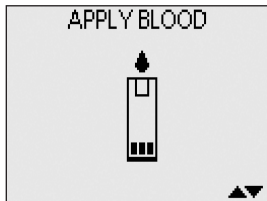
3. Match the code on the meter with the code on the test strip vial

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.



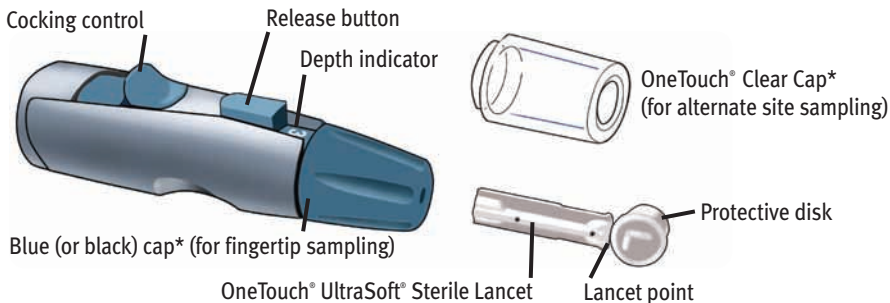
⚠ CAUTION: Matching the code on the meter and the code on the test strip vial is essential to obtaining accurate results. Each time you test, check to make sure the code numbers match.

NOTE:

- If the APPLY BLOOD screen appears before you are sure the codes match, remove the test strip, and re-start from step 1, see page 15.
- If you change APPLY BLOOD to APPLY CONTROL by mistake, press **▼** to change it back to APPLY BLOOD.

Getting a blood sample

Overview of the OneTouch® Lancing Device



**The blue (or black) cap and OneTouch® Clear Cap are also used for depth adjustment.*

⚠ CAUTION: To reduce the chance of infection:

- Make sure to wash the puncture site with soap and water before sampling.
- Never share a lancet or a lancing device with anyone.
- Always use a new, sterile lancet—lancets are for single use only.
- Keep your meter and lancing device clean. See pages 57–58.


NOTE: If you do not have a OneTouch® Lancing Device, please refer to the instructions that came with your lancing device.

Choosing the right sampling site at the right time

The OneTouch® UltraLink™ Meter allows you to sample blood from your fingertip, forearm or palm. At times, results obtained at the forearm or palm may be different from a fingertip measurement. Talk to your health care professional before you begin using your forearm or palm for sampling.

If you are testing:	Use blood sample from your:
Routinely before meals	Fingertip, forearm, or palm
Prior to or more than two hours after: <ul style="list-style-type: none"> • a meal • a rapid-acting insulin injection or insulin pump bolus • exercise 	Fingertip, forearm, or palm
When your blood glucose is changing rapidly, such as: <ul style="list-style-type: none"> • within two hours after a meal • within two hours after a rapid-acting insulin injection or insulin pump bolus, or • during or within two hours after exercise 	Fingertip
When you are concerned about the possibility of hypoglycemia (low blood sugar)	Fingertip
When the AST site results do not agree with the way you feel, during illness or during times of stress	Fingertip

IMPORTANT: Be sure to read your partner device manual carefully and consult with your health care professional before using alternate site blood glucose results obtained from your meter with the partner device. For example, calibrating continuous glucose monitoring systems.

 **CAUTION:** Do **Not** test on your forearm or palm when:

- You think your blood glucose is rapidly falling, such as within two hours of exercise or a rapid-acting insulin injection or insulin pump bolus. Testing with a fingertip sample may identify hypoglycemia or an insulin reaction sooner than testing with a forearm or palm sample.
- It has been less than two hours after a meal, a rapid-acting insulin injection or insulin pump bolus, physical exercise, or you think your glucose level is changing rapidly.
- You are concerned about the possibility of hypoglycemia or an insulin reaction, such as when driving a car. This is especially important if you suffer from hypoglycemia unawareness (lack of symptoms to indicate an insulin reaction).

Remember: Consult with your health care professional before using your forearm or palm for testing.

Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.

If bruising occurs at an alternate site or you have difficulty getting a sample, consider sampling from a fingertip instead. You may want to review the choice of sites with your health care professional.

Preparing your sample site

Before you test your blood glucose, wash your hands and forearm (if applicable) thoroughly with warm, soapy water. Rinse and dry.



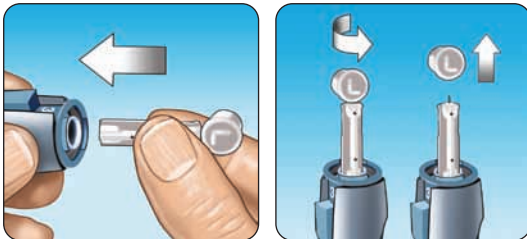
Lancing and sampling from your fingertip

1. Remove the blue (or black) cap by snapping it off



2. Insert a sterile lancet into the OneTouch® Lancing Device

Insert the lancet into the holder and push in firmly. Twist the protective disk until it separates from the lancet and save the disk for later use. **Do Not** twist the lancet.



3. Replace the blue (or black) cap by snapping it back on

4. Adjust the depth setting

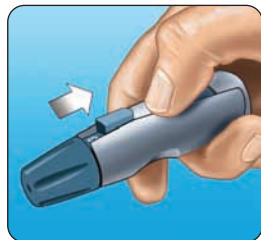
The OneTouch® Lancing Device has nine puncture depth settings, numbered 1 through 9. The smaller numbers are for a shallower puncture, and the larger numbers are for a deeper puncture. Shallower punctures work for children and most adults. Deeper punctures work well for people with thick or callused skin. Twist the blue (or black) cap until the correct setting appears.



NOTE: A shallower puncture may be less painful. Try a shallower setting first and increase the depth until you find the one deep enough to get a sufficient blood drop (● sample size) for testing.

5. Cock the OneTouch® Lancing Device

Slide the cocking control back until it clicks. If it does not click, it may have been cocked when you inserted the lancet.



6. Puncture your finger

Hold the OneTouch® Lancing Device firmly against the side of your finger. Press the release button. Remove the OneTouch® Lancing Device from your finger.



7. Get a round drop of blood

Gently squeeze and/or massage your fingertip until a round drop of blood (● sample size) forms.



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



Lancing and sampling from an alternate site

Sampling from your palm or forearm allows you to use your fingertips less often. You may find that obtaining a blood sample from an alternate site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different than getting a sample from your fingertips.

Forearm sampling

Choose a fleshy area of the forearm away from bone, visible veins and hair. Sometimes there is less blood flow to the forearm than to the fingertips. To help you get a large enough drop of blood, you may gently massage or apply warmth to the site to increase blood flow.



Forearm

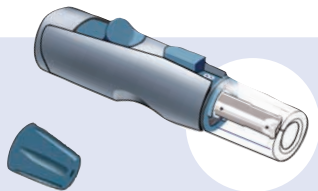
Palm sampling

Choose a fleshy area on the palm below your thumb or pinky finger. Select a spot with no visible veins and away from deep lines which may cause your blood sample to smear.



Palm

IMPORTANT: Be sure to read your partner device manual carefully and consult with your health care professional before using alternate site blood glucose results obtained from your meter with the partner device. For example, calibrating continuous glucose monitoring systems.



Blue (or black) cap for fingertip sampling only

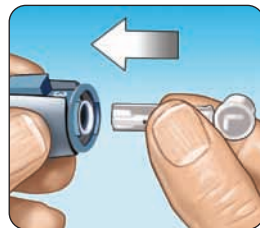
The OneTouch® Clear Cap is used for forearm and palm sampling only. Replace the blue (or black) cap with the OneTouch® Clear Cap.

1. Remove the blue (or black) cap by snapping it off

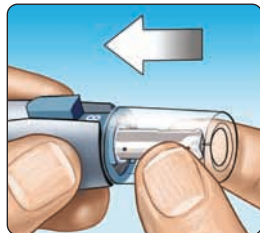


2. Insert a sterile lancet into the OneTouch® Lancing Device

Insert the lancet into the holder and push in firmly. Twist the protective disk until it separates from the lancet and save the disk for later use. **Do Not** twist the lancet.



3. Install the OneTouch® Clear Cap on the OneTouch® Lancing Device by snapping it on



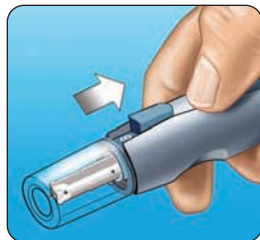
4. Adjust the depth setting

You may have to adjust the OneTouch® Lancing Device to a deeper setting to get a large enough drop of blood from your forearm or palm. Twist the OneTouch® Clear Cap toward the larger numbers to increase the depth.



5. Cock the OneTouch® Lancing Device

Slide the cocking control back until it clicks. If it does not click, it may have been cocked when you inserted the lancet.



6. Puncture your forearm or palm

Firmly press and hold the lancing device against your forearm or palm for a few seconds. **Wait until the skin surface under the OneTouch® Clear Cap changes color (as blood collects beneath the skin).** This tells you there is enough blood flow for a good sample. Then press the release button while continuing to apply pressure. Keep holding the lancing device against your skin until a round drop of blood forms under the cap.



Forearm



Palm

7. Remove the OneTouch® Lancing Device

Carefully lift the lancing device away from your skin.

Do Not smear the blood sample.

NOTE:

- You may need to wait a little longer to get a large enough drop of blood from the forearm or palm. **Do Not** squeeze the site excessively.
- If the sample drop of blood runs or spreads due to contact with hair or with a line in your palm, **Do Not** use that sample. Try puncturing again in a smoother area.
- Remember: You may have to adjust the lancing device to a deeper setting to get a large enough drop of blood.

IMPORTANT: Be sure to read your partner device manual carefully and consult with your health care professional before using alternate site blood glucose results obtained from your meter with the partner device. For example, calibrating continuous glucose monitoring systems.

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 page 14.

1. Prepare to apply the sample

Keeping your finger extended and steady, move the meter and test strip toward the blood drop.



Fingertip

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.



When applying a drop of blood from your forearm or palm, keep your palm or forearm steady and bring the top edge of the test strip to the drop of blood with your other hand.



Forearm

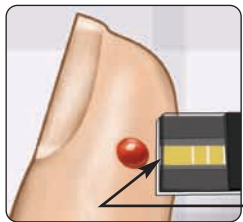


Palm

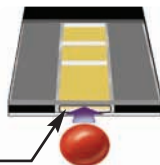
IMPORTANT: Be sure to read your partner device manual carefully and consult with your health care professional before using alternate site blood glucose results obtained from your meter with the partner device. For example, calibrating continuous glucose monitoring systems.

2. Apply the sample

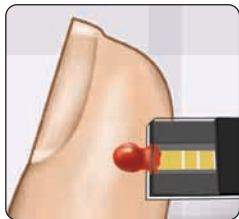
Line up the test strip with the blood drop so that the narrow channel on the edge of the test strip is almost touching the edge of the blood drop.



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.



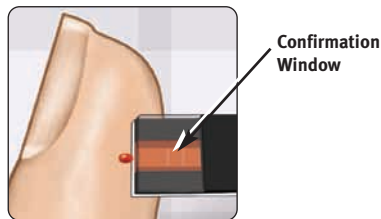
NOTE:

- **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 page 68. Discard the test strip and re-start the test process.

3. 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

4. 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)

5. Check that the result has been transmitted to your partner device

The blood glucose result will begin flashing on the display if the PUMP COMM feature is turned on. This indicates that your result is being transmitted to your partner device. The result will stop flashing after it has been received. After about 60 seconds, if the result has not been received by the partner device, the transmit feature will turn off and the result will stop flashing.



6. Confirm that a blood glucose test result has been received by your partner device

When the partner device is idle (at the Home Screen), it will beep or vibrate when it receives a blood glucose test result from the meter. The result will appear on the partner device screen. See your partner device manual for more information.

After getting a result

Once you have read your result (and it has been transmitted to the partner device when the PUMP COMM feature is turned on), you may:

- Attach notes to this result if the flags/comments feature is on, see page 40, or
- Review your meter memory by pressing **OK** to go to MAIN MENU, see page 44, or
- Turn the meter off by removing the test strip.

NOTE:

- Your result may only flash for a few seconds before it is received by your partner device.
- See your partner device manual for instructions on how to manually enter your glucose result into the partner device if it was not automatically transmitted.
- While the result is flashing, your meter will only respond to pressing the **OK** button for five seconds. This will cancel the transmission of your result to your partner device but only if the result has not already been transmitted.
- If you remove the test strip while the result is flashing, the meter will stay on until the result is received by the partner device. Then the meter will turn off. Leave the test strip in the meter if you plan to add meal flags or comments to your result.
- If the result does not flash, check to be sure the PUMP COMM feature is turned on. If the result is not received by the partner device, refer to the Troubleshooting section for instructions.
- WARNINGS/ERRORS, LOW GLUCOSE and HIGH GLUCOSE test results, and control solution test results are **Not** transmitted to your partner device.

⚠ WARNING: If mg/dL does not appear with the test result, call Customer Service. 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 (43°F) 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.

Error messages

If you get an ERROR message on your screen rather than a result, see pages 63–69.

Unexpected test results

Refer to these cautions **⚠** whenever your test results are lower than, higher than, or not what you expect.

⚠ CAUTION: 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 health care professional immediately.

⚠ CAUTION: Low glucose results

If your test result is lower than 70 mg/dL or is shown as LOW GLUCOSE, it may mean hypoglycemia (low blood glucose). This may require immediate treatment according to your health care professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do another test.

⚠ CAUTION: High glucose results

If your test result is higher than 180 mg/dL, it may mean hyperglycemia (high blood glucose). If you are uncertain about this test result, consider re-testing. Your health care professional can work with you to decide what actions, if any, you should take if your results are higher than 180 mg/dL.

If your meter displays HIGH GLUCOSE, you may have a very high blood glucose level (severe hyperglycemia) exceeding 600 mg/dL. Re-check your glucose level. If the result is HIGH GLUCOSE again, this may indicate a severe problem with your blood glucose control and it is important you obtain and follow instructions from your health care professional without delay.

⚠ CAUTION: Repeated unexpected glucose results

If you continue to get unexpected results, check your system with control solution. See Control solution testing, pages 50–55.

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 health care professional. Never ignore symptoms or make significant changes to your diabetes control program without speaking to your health care professional.

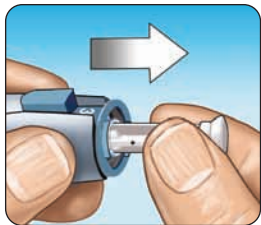
⚠ CAUTION: Unusual red blood cell count

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.

Removing the used lancet

Remove the lancing device cap by snapping it off. **Cover the exposed lancet tip before removing the lancet.**

Place the lancet protective disk on a hard surface. Push the lancet tip into the disk. Remove the lancet and place it in a container for sharp objects. Replace the cap.



Disposing of the used lancet and test strip

Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your health care professional's recommendations or your local regulations for proper disposal.

Attaching flags or comments to your results

Your meter allows you to attach optional notes to your blood glucose 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 results. 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 health care professional feel are worth noting.	Helps track possible reasons for test results.

You can attach these notes just after a blood glucose test, or after the result has been transmitted to the partner device if the PUMP COMM feature is turned on. In both cases you must attach the notes 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.

You can choose not to attach a meal flag or comment after a blood glucose test. If you do not want to use this feature at all, you can turn it off so the meter will not prompt you to add notes or to select a type of result average to review. See page 9 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. If the PUMP COMM feature is turned on, the up arrow will flash after the result has been transmitted to the partner device. The flashing arrow is to remind you to enter a meal flag.

To add or change a meal flag:

1. While viewing a result, press ▲ to display the MEAL FLAG screen

Wait for the test result to stop flashing if the PUMP COMM feature is turned on.

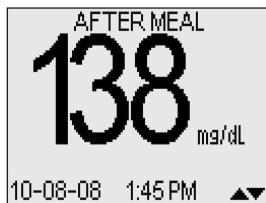
2. Press ▲ or ▼ to highlight BEFORE MEAL or AFTER MEAL

If you decide not to assign a flag to this result, select NO FLAG.



3. 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 health care 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:

1. While viewing a result, press ▼ to display the COMMENT screen

2. 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

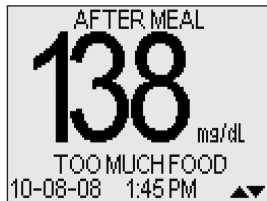


Highlight NO COMMENT if you decide not to add a comment, or if you want to erase a previously entered comment from the result.

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 health care professional.

3. To confirm your selection, press OK

The comment you chose will appear below the result.



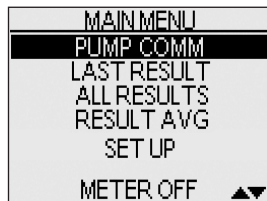
Reviewing past results and averages

If you have just completed a test, press **OK** to get to the MAIN MENU screen. If your meter is off, press and hold **OK** 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.

To confirm your selection, press **OK**.



Last result

The meter will display your most recent result. This result will include the unit of measure and the date and time of the test. If the result was marked as CONTROL SOLUTION or with either a meal flag or comment, these notes will be shown as well. Press **OK** to return to MAIN MENU. If you wish to add or change a meal flag or comment for this result, see pages 41–43.

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 600 mg/dL,
- LO** if the result was below 20 mg/dL,
- *** 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.

ALL RESULTS		
mg/dL		
09-19	2:25 PM	104 * +
09-18	8:15 AM	90 * -
09-17	10:23 AM	112 C
09-16	11:44 AM	LO
1 of 4	MENU	▲▼

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 pages 41–43. 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.

Result averages

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.

RESULT AVG		
ALL RESULTS AVG		
BEFORE MEAL AVG		
AFTER MEAL AVG		
MENU		▲▼

If you have turned the flags/comments feature off, selecting RESULT AVG from the MAIN MENU will lead directly to the ALL RESULTS AVG screen.

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).

BEFORE MEAL AVG		
		mg/dL
DAYS	NUM	AVG
7	14	148
14	34	140
30	43	137

In result averages, a HIGH GLUCOSE result is counted as 600 mg/dL, and a LOW GLUCOSE result as 20 mg/dL. 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** to confirm your selection.

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		
		mg/dL
DAYS	NUM	AVG
7	0	0
14	0	0
30	0	0

To see averages for different parts of the day or over a different number of days, you can use OneTouch® Diabetes Management Software and your home computer. See the next section, on page 48.

Downloading results to a computer

You can use your meter with OneTouch® Diabetes Management Software (DMS) for storing your records and to help you spot patterns for planning meals, exercise, and medication. OneTouch® DMS puts information downloaded from the meter into charts and graphs.

1. Obtain the required software and cable

For order information and to learn more about OneTouch® Diabetes Management Software, visit www.OneTouchDiabetesSoftware.com.

2. 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:

- **The use of electronic devices may result in the build up of electrostatic discharge (ESD) which can impact their use.**
- **To avoid a possible shock, Do Not insert a test strip or change the batteries when the meter is connected to a computer with the OneTouch® Interface Cable.**

NOTE: For downloading instructions to Medtronic CareLink™ Personal software, refer to www.carelink.medtronicdiabetes.com.

3. 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.

Interface Cable



4. Transfer data

Follow the instructions provided with the OneTouch® DMS 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.




Control solution testing

OneTouch® Ultra® Control Solution is used to check that the meter and the test strips are working together properly and that you are performing the test correctly.

Do a control solution test:

- Whenever you open a new vial of test strips.
- If you suspect that the meter or test strips are not working properly.
- If you have had repeated unexpected blood glucose results.
- If you drop or damage the meter.

NOTE: Results marked as control solution tests are not transmitted to your partner device.

 **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.

NOTE:

- Use only OneTouch® Ultra® Control Solution with your OneTouch® UltraLink™ Meter.

- For information on second level of control solution, contact Customer Service at 1 866 621-4846, 24 hours a day, 7 days a week. If you cannot reach Customer Service, contact your health care professional for advice.
- Control solution tests must be done at room temperature (68–77°F). Make sure your meter, test strips, and control solution are at room temperature before testing.

Performing a control solution test

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

1. Check the code on the test strip vial before inserting the test strip



2. Insert a test strip to turn on the meter

Remove a test strip from its vial and immediately replace the vial cap and close it tightly. 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.



3. 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.



4. 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.

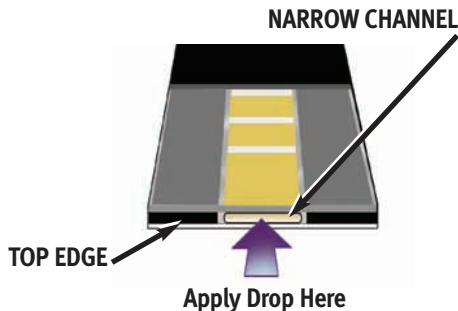


⚠ WARNING: Be sure to correctly mark every control solution test or the result will be mistakenly transmitted to your partner device.

5. 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.

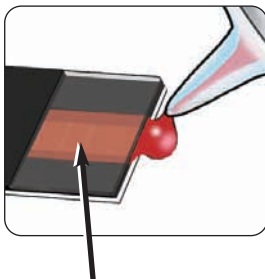


6. Read your result

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.



CONFIRMATION WINDOW



7. 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 on pages 51–54,
- 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. Call Customer Service.

Caring for your system

Your OneTouch® UltraLink™ 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 86°F, 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

Test strips and control solution have expiration dates printed on their vials. When you first open a test strip or control solution vial, you must record the discard date (date opened plus three months) in the space provided on the label.

⚠ 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.

⚠ CAUTION: Do Not use your test strips if your vial is damaged or left open to air. This could lead to error messages or tests that read higher than the actual value. Call Customer Service immediately if the test strip vial is damaged.

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 OneTouch® Lancing Device and OneTouch® Clear Cap

To clean these items, wipe them with a soft cloth dampened with water and mild detergent. **Do Not** immerse the OneTouch® Lancing Device in any liquid.

To disinfect these items, prepare a solution of one part household bleach to ten parts water. Wipe the OneTouch® 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.

Batteries

Your OneTouch® UltraLink™ Meter uses two AAA alkaline batteries. Replacement batteries can be found in most stores where batteries are sold. Your meter comes with two batteries already installed. Batteries should last a minimum of two months at an average of four tests per day with the PUMP COMM feature turned on.



IMPORTANT: Use only AAA alkaline batteries with your meter. **Do Not** use rechargeable batteries. Use of an incorrect battery type may result in your meter providing fewer tests than normal from when the battery icon or the LOW BATTERY screen first appears.

⚠ WARNING: Certain batteries may cause leaking which can damage the meter or cause the batteries to lose power sooner than normal. Replace leaking batteries immediately.

Low meter batteries

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 batteries.

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



Replacing batteries

1. Remove the old batteries

Start with the meter off. Remove the battery cover by squeezing the tab on the side of the cover. Pull up on the battery ribbon to lift both batteries out of the compartment.



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

2. Insert the new batteries

Insert two AAA alkaline batteries on top of the black ribbon. Plus (+) and minus (–) signs will guide you in placing the batteries.



If the meter does not power on after you have replaced the meter batteries, check that the batteries are correctly installed. If the meter still does not power on, call Customer Service.

3. Check your meter settings

Removing the meter batteries will not affect your stored results. However, you may need to re-set your meter settings. See pages 4–8.

4. Replace the cover


Insert the two battery cover tabs into the matching holes, and push down until you hear the cover click into place.



5. Dispose of batteries according to your local environmental regulations

NOTE: When the PUMP COMM feature is turned on the meter will use more battery power.


Troubleshooting

 **WARNING:** Failure to carefully follow the directions in this owner's booklet can lead to inaccurate test results.

RF communications problems

If a glucose test result on your meter was not received by your partner device, be sure to check the following:

- The PUMP COMM feature on your meter is turned on.
- The meter option feature on your partner device is turned on.
- Your meter ID is entered correctly into your partner device.
- Your meter and partner device are within RF range. If not, try moving the devices closer together.
- If there are other devices nearby that might be affecting the RF link. If so, try turning off those devices or move to another location.

 **CAUTION:** Changes or modifications not expressly approved by LifeScan could void the user's authority to operate the equipment.

IMPORTANT: If your glucose result was not transmitted to your partner device, you can manually enter your glucose result into the partner device. See your partner device manual for:

- manually entering your glucose results,
- troubleshooting RF communication,
- other problems with your partner device.

Understanding error and other messages

The OneTouch® UltraLink™ Meter displays messages when there are problems with the test strip, with the meter, or when your blood glucose levels are higher than 600 mg/dL or lower than 20 mg/dL. Messages do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message.


NOTE: WARNINGS/ERRORS, LOW GLUCOSE and HIGH GLUCOSE test results, and control solution test results, are **Not** transmitted to your partner device.

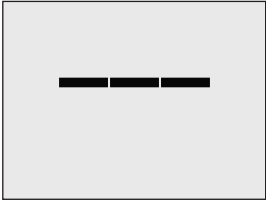
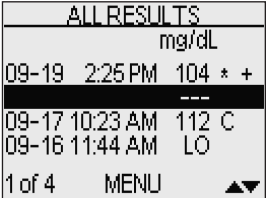
Message	What it means	What to do
<div> <div>WARNING</div> <div> LOW GLUCOSE BELOW 20 mg/dL </div> <div>▲▼</div> </div>	You may have a very low blood glucose level (severe hypoglycemia), lower than 20 mg/dL.	<p>This may require immediate treatment according to your health care professional's recommendations.</p> <p>Although this message could be due to a test error, it is safer to treat first and then do another test.</p>
<div> <div>WARNING</div> <div> HIGH GLUCOSE ABOVE 600 mg/dL </div> <div>▲▼</div> </div>	You may have a very high blood glucose level (severe hyperglycemia), over 600 mg/dL.	Re-check your glucose level. If the result is HIGH GLUCOSE again, obtain and follow instructions from your health care professional without delay.
<div> <div>WARNING</div> <div> TEMPERATURE ERROR OUT OF OPERATING RANGE SEE OWNER'S BOOKLET </div> </div>	Meter is too hot (above 111°F) or too cold (below 43°F) 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.

Message	What it means	What to do
<div> <div>WARNING</div> <div> ERROR 1 METER PROBLEM CALL CUSTOMER SERVICES </div> </div>	There is a problem with the meter.	Do Not use the meter. Contact Customer Service.
<div> <div>WARNING</div> <div> ERROR 2 METER OR STRIP PROBLEM RETEST WITH A NEW STRIP </div> </div>	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 pages 30–36. If this message continues to appear, contact Customer Service.

Message	What it means	What to do
<div> <div>WARNING</div> <div> ERROR 3 METER WAS NOT READY RETEST WITH A NEW STRIP </div> </div>	<p>The sample was applied before the meter was ready.</p>	<p>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 Customer Service.</p>
<div> <div>WARNING</div> <div> ERROR 4 STRIP PROBLEM SEE OWNER'S BOOKLET </div> </div>	<p><i>One of the following may apply:</i></p> <p>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).</p> <p><i>or,</i></p>	<p>If you tested in a cool environment, repeat the test in a warmer environment with a new test strip; see pages 30–36. If the message appears again, contact Customer Service.</p>

Message	What it means	What to do
<div> <div>WARNING</div> <div> ERROR 4 STRIP PROBLEM SEE OWNER'S BOOKLET </div> </div>	<p>There may be a problem with the test strip. For example, it may have been damaged or moved during testing.</p> <p><i>or,</i></p> <p>The sample was improperly applied.</p> <p><i>or,</i></p> <p>There may be a problem with the meter.</p>	<p>If you tested in a normal or warm environment, repeat the test with a new test strip; see pages 30–36. If the error message appears again, contact Customer Service.</p> <p>If you applied the sample incorrectly, review pages on blood application (see pages 30–36) or control solution testing (see pages 50–55) and repeat the test with a new test strip. If the error message appears again, contact Customer Service.</p> <p>If the error message appears again, contact Customer Service.</p>

Message	What it means	What to do
<div> <div>WARNING</div> <div>ERROR 5</div> <div>STRIP PROBLEM OR SAMPLE TOO SMALL</div> <div>RETEST WITH A NEW STRIP</div> </div>	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 pages 30–36) or control solution testing (see pages 50–55).
<div> <div> <div>104 mg/dL</div> <div>10-08-08 11:15 AM</div> </div> <div></div> </div>	Meter batteries are low but still have enough power to perform a test.	When the battery icon first appears, there is enough power for about 25 more tests if using alkaline batteries. Test results will still be accurate, but replace the batteries as soon as possible.
<div> <div>WARNING</div> <div>LOW BATTERY</div> <div>REPLACE BATTERY NOW!</div> <div>SEE OWNER'S BOOKLET</div> </div>	Meter batteries do not have enough power to perform a test.	Replace meter batteries.

Message	What it means	What to do
	<p>No result in memory, such as the first time use of the meter or after a download of all data to a computer.</p> <p>or,</p> <p>Your meter was unable to recall this result. This result will not be included in result averages.</p>	<p>You can still perform a blood glucose test and get an accurate result. Contact Customer Service to report this occurrence if this is not:</p> <ol style="list-style-type: none"> 1. Your first time use of the meter, or 2. After you just downloaded results from your meter.
	<p>Your meter was unable to recall this result. This result will not be included in result averages.</p>	<p>You can still perform a blood glucose test and get an accurate result, but contact Customer Service to report this occurrence.</p>

Detailed information about your system

Comparing meter and laboratory results

Test results with the OneTouch® UltraLink™ Meter are plasma-calibrated. This helps you and your health care 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® UltraLink™ Meter are approximately 12% higher.

OneTouch® UltraLink™ 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® UltraLink™ Meter glucose value is considered accurate when it is within $\pm 20\%$ of the laboratory measurement. There are some specific situations that could cause a difference of more than $\pm 20\%$:

- You have eaten recently. The blood glucose level from blood obtained from a fingertip can be up to 70 mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.¹

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.

- 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 (43°F) and you get a high glucose result (i.e., greater than 180 mg/dL). 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.

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 owner's booklet for performing a blood glucose test with your meter.

Technical specifications

Reported result range	20–600 mg/dL
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Test time	5 seconds
Radio Frequency (RF)	916.5MHz
Assay method	Glucose oxidase biosensor
Meter power source	Two replaceable AAA alkaline batteries. Expected battery life is a minimum of 2 months at an average of 4 tests per day with the PUMP COMM feature turned on.
Unit of measure	mg/dL
Memory	500 blood glucose or control solution test results
Automatic shutoff	2 minutes after last action
Size	3.5 x 2.4 x 1.0 inches
Weight	Approximately 3 ounces, with batteries

Operating ranges

Temperature: 43–111°F
Relative humidity: 10–90%
Altitude: up to 10,000 feet
Hematocrit: 30–55%

Battery ratings

2 x 1.5 V d.c., 40 mA
(2 x AAA alkaline batteries)
— — — direct current

**Wireless (RF)
operating range**

Maximum 4 feet*
*Your partner device must be within 4 feet of your meter to receive a blood glucose test result.

**Separation distance
from other wireless
(RF) devices**

Minimum 12 inches**
**The use of a cell phone within 12 inches of your meter or partner device may interfere with the transmission of blood glucose test results to the partner device. Other types of wireless devices that are in use nearby may also prevent or delay the transmission of test results. Moving away from or turning off these interfering devices may allow communication.

**Expected delay
(latency range) in
wireless (RF)
communication**

Minimum 3 seconds
Maximum 60 seconds

Symbols



Cautions and Warnings. Refer to safety-related notes in the owner's booklet and inserts that came with your meter and testing supplies.



Low battery



Direct current

System accuracy

Analytical Performance Characteristics

The accuracy of the OneTouch® UltraLink™ Blood Glucose Monitoring System was assessed by comparing blood glucose test results on 135 subjects, with those obtained using a YSI Model 2300 Glucose Analyzer. Six results were obtained for each subject (each tested in duplicate with test strips from 3 separate lots). The following results were obtained:

System Accuracy Results for Glucose Concentrations <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL[†]
85/150 (56.7%)	137/150 (91.3%)	149/150 (99.3%)

System Accuracy Results for Glucose Concentrations ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%[†]
234/660 (35.5%)	464/660 (70.3%)	608/660 (92.1%)	653/660 (98.9%)

System Accuracy Results across the entire Glucose Range

Within ±15 mg/dL or ±20%
802/810 (99.0%)

These results indicate that the OneTouch® UltraLink™ Blood Glucose Monitoring System meets the ISO 15197 requirements for accuracy.

† ISO 15197 Minimum Acceptable Accuracy Requirements:

- 95% of individual glucose results must fall within ± 15 mg/dL of the YSI reference at glucose concentrations < 75 mg/dL
- 95% of individual glucose results must fall within $\pm 20\%$ of the YSI reference at glucose concentrations ≥ 75 mg/dL

Regression Statistics

# of Subjects	# of Tests	Slope (mg/dL)	Intercept (mg/dL)	95% CI Slope	95% CI Intercept	Std. Error ($S_{y,x}$)	R ²
135	810	0.970	-2.77	(0.960, 0.979)	(-4.75, -0.80)	14.98	0.981

Samples were tested in duplicate on each of three test strip lots. Results indicate that the OneTouch® UltraLink™ Meter compares well with a laboratory method.

Precision

Within Run Precision (100 venous blood tests)			
Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard deviation (mg/dL)	Coefficient of variation (%)
40	50.78	1.56	3.07
100	108.84	2.26	2.08
130	136.12	2.26	1.66
200	210.08	3.01	1.43
300	305.66	4.07	1.33

Total Precision (200 control solution tests)			
Glucose level (mg/dL)	Mean Glucose (mg/dL)	Standard deviation (mg/dL)	Coefficient of variation (%)
Low	47.52	1.42	2.99
Normal	116.22	2.23	1.92
High	339.71	6.61	1.95

Results show that the greatest variability observed (of two lots tested) is 3.1% or less.

OUR COMMITMENT TO YOU:

Our goal is to provide you with quality health care products and dedicated customer service. If you are not fully satisfied with this product or need assistance, contact your authorized LifeScan representative at 1 866 621-4846 toll free. Customer Service is available 24 hours a day, 7 days a week. If you cannot reach Customer Service, contact your health care professional for advice.

Guarantee

LifeScan guarantees that the OneTouch® UltraLink™ 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.

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 80MHz to 2.5GHz at 3V/m as specified in IEC 61000-4-3.

Degree of protection rating: IP11



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

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Notes

[illegible]

Notes

Reminders

Time of day *Your target ranges
from your health care professional*

Before breakfast

Before lunch or dinner

1 hour after meals

2 hours after meals

Between 2 a.m. and 4 a.m.

Patent information

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, and 7,112,265. 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, and 7,250,105. 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.

1 866 621-4846

Customer Service is available 24 hours a day, 7 days a week. If you cannot reach Customer Service, contact your health care professional for advice.

Or

Visit us at www.LifeScan.com



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