ONETOUCH Verio Flex®

Blood Glucose Monitoring System

Owner's Booklet

Instructions for Use

ONETOUCH

Verio Flex®

Blood Glucose Monitoring System

Owner's Booklet

Thanks for choosing OneTouch®!

The OneTouch Verio Flex® Blood Glucose Monitoring System is one of the latest product innovations from OneTouch®.

Your OneTouch Verio Flex® Meter is designed to connect (sync) with a variety of compatible wireless devices running software applications that let you review and graph your results, and help identify patterns. Meter results are sent to the compatible devices either through BLUETOOTH® (wireless) or USB cable connection.

Every OneTouch® Meter is designed to help you test your blood glucose and manage your diabetes.

This Owner's Booklet offers a complete explanation of how to use your new meter and testing supplies. It reviews the do's and don'ts of testing your blood glucose level. Please keep your Owner's Booklet in a safe place; you may want to refer to it in the future.

We hope OneTouch® products and services will continue to be a part of your life.

Compatible wireless devices

Visit www.OneTouch.ca for information on which wireless devices are compatible with your OneTouch Verio Flex® Meter, and where/how to download the software application on your compatible wireless device.

Meter symbols and icons

	Meter Power
	Low Battery
	Battery Empty
	Control Solution
	Syncing
	BLUETOOTH® Feature On
	History Mode (Past results)
	Apply Sample
	Range Indicator Arrow
SET	Setting Mode

Other symbols and icons

Cautions and Warnings: Refer to the Owner's Booklet and inserts that came with your system for safety-related information.

Direct current

Before you begin

Before using this product to test your blood glucose, carefully read this Owner's Booklet, and the inserts that come with the OneTouch Verio® Test Strips, OneTouch Verio® Control Solution and the OneTouch® Delica® Plus Lancing Device.

IMPORTANT SAFETY INSTRUCTIONS:

- This meter and lancing device are for single patient use only. **Do Not** share them with anyone else, including family members! **Do Not** use on multiple patients!
- After use and exposure to blood, all parts of this kit are considered biohazardous. A used kit may potentially transmit infectious diseases even after you have performed cleaning and disinfection.

Intended use

The OneTouch Verio Flex® Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The system is intended to be used by a single patient and should not be shared.

The OneTouch Verio Flex® Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and with their healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. The OneTouch Verio Flex® Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes or for neonatal use.

Test principle

Glucose in the blood sample mixes with the enzyme FAD-GDH (see page 102) in the test strip and a small electric current is produced. The strength of this current calculates your blood glucose level. It then displays the blood glucose result and stores it in the meter memory.

Use only OneTouch Verio® Control Solution and Test Strips with the OneTouch Verio Flex® Meter. Use of OneTouch Verio® Test Strips with meters for which they are not intended may yield inaccurate results.

BLUETOOTH® wireless technology

BLUETOOTH® wireless technology is used by some smartphones and many other devices. Your OneTouch Verio Flex® Meter uses BLUETOOTH® wireless technology to pair and to send your glucose results to compatible wireless devices.

The OneTouch Verio Flex® Meter is designed to work with the OneTouch Reveal® Mobile App and many other diabetes applications on compatible wireless devices.

NOTE: Some diabetes management apps, including the OneTouch Reveal® Mobile App, may not be available in your country. Visit www.OneTouch.ca to learn if the OneTouch Reveal® Mobile App is available in your country.

Visit www.OneTouch.ca for information on which wireless devices are compatible with your OneTouch Verio Flex® Meter, and where/how to download the software application on your compatible wireless device.

When using the OneTouch Verio Flex® System, we suggest you pair your OneTouch Verio Flex® Meter with a compatible wireless device and track your results. See page 29 for pairing instructions.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

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

If you experience meter interference problems, try moving your meter away from the source of the interference. You can also move the electronic device or its antenna to another location to solve the problem.

⚠**WARNING:** The BLUETOOTH® feature on your meter sends test results to your compatible wireless device. To prevent other people's results from being sent to your compatible wireless device, **Do Not** let anyone else use your meter to test their blood glucose. This meter is for single patient use only.

⚠**WARNING:** In locations where cell phone use is not permitted, such as hospitals, some healthcare professional offices and airplanes, you should turn the BLUETOOTH® feature off. See page 27 for more information.

BLUETOOTH® trademark

The BLUETOOTH® word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by LifeScan Scotland Ltd. is under license. Other trademarks and trade names are those of their respective owners.

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1 Getting to know your system

Your OneTouch Verio Flex® Blood Glucose Monitoring System

Included with your kit:

OneTouch Verio Flex®
Meter (CR2032 lithium coin
cell battery included)

Lancing device

Lancets

NOTE: If any item is missing or defective in your kit, contact Customer Service. Contact the OneTouch® Customer Care Line at 1 800 663-5521, Monday-Friday, 9am-8pm Eastern, 6am-5pm Pacific, or visit www.OneTouch.ca.

NOTE: If another type of lancing device was included, see the separate instructions for that lancing device.

Available separately:

Items pictured below are required, but may not be included in your kit:

They are sold separately. Refer to your meter carton for a list of included items.

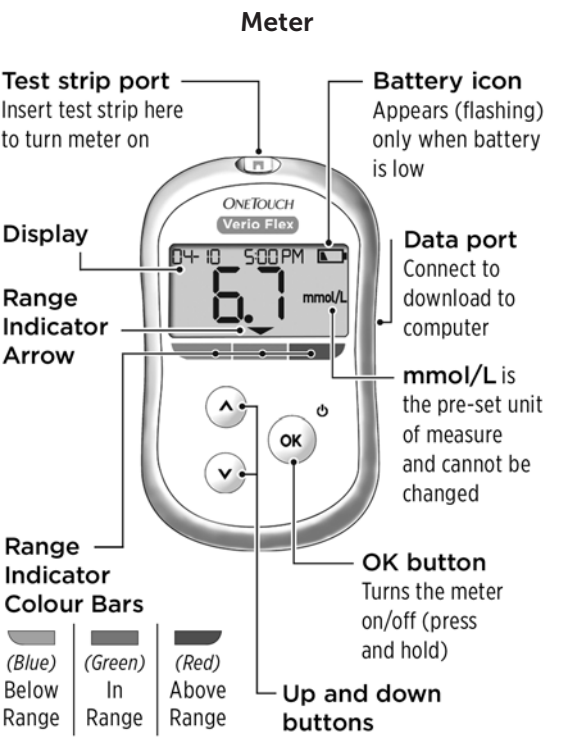
OneTouch Verio® Mid Control Solution*

OneTouch Verio® Test Strips*

*OneTouch Verio® Control Solution and Test Strips are available separately. For availability of test strips and control solution, contact Customer Service or ask your pharmacist or healthcare professional.

⚠**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. **Do Not** ingest or swallow any items.

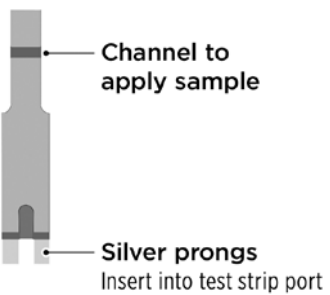
Getting to know your OneTouch Verio Flex® Blood Glucose Monitoring System



Button combinations
OneTouch®
Verio Flex
SN: XXXXXXXX
Serial
number
Battery cover

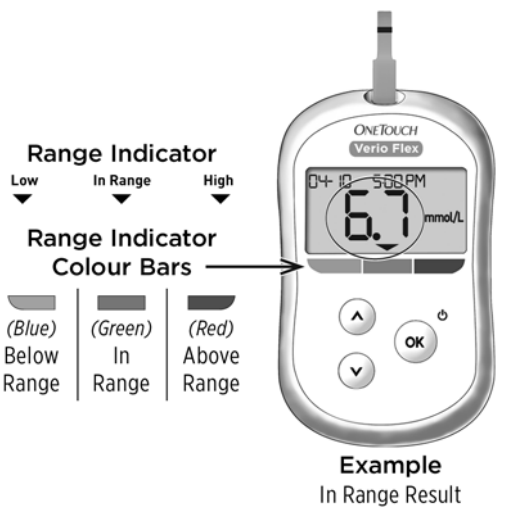
Getting to know your OneTouch Verio® Test Strip

Test strip



The Range Indicator feature

The OneTouch Verio Flex® Meter automatically lets you know if your current result is below, above or within your range limits. It does this by displaying your current result with a Range Indicator Arrow, pointing to a corresponding Range Indicator Colour Bar below the meter display. Use the Range Indicator Arrow and Colour Bar together to interpret your results.



Example
In Range Result

3 Possible Range Indicator Displays

A Range Indicator Arrow will appear just below your result after each test depending upon how you set your low and high range limits in the meter.

Example
Below Range Result

Things you should know before using the Range Indicator feature:

- The meter comes with pre-set range limits. The pre-set low range limit is 4.0 mmol/L and the pre-set high range limit is 10.0 mmol/L. You can change these limits as needed to meet your needs. See page 77 for details on the pre-set range limits and on editing your range limits.
- If you decide to change your range limits, the Range Indicator Arrows stored with previous results in meter memory will not change. However, any new tests will display Range Indicator Arrows which reflect your changes.

Example
In Range Result

Example
Above Range Result

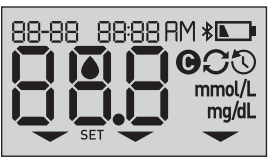
This page left blank intentionally.

2 Setting up your system

Setting up your meter

Turn your meter on

To turn your meter on, press and hold (OK) until the start-up test screen appears. Once the device is on, release (OK). You can also turn the meter on by inserting a test strip.



Every time you turn your meter on, a start-up screen will appear for a few seconds. All segments of the display should appear briefly, indicating your meter is working properly. If the meter does not power on, check the battery.

⚠CAUTION:

If you see any missing segments within the start-up screen, there may be a problem with the meter. Contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

NOTE: If you turned the meter on for the first time by inserting a test strip instead of pressing (OK), you will not be able to perform a glucose test until you complete the first time setup.

First time setup

To turn your meter on, press and hold (OK) until the start-up screen appears. Once the device is on, release (OK). The meter will now automatically prompt you to set the time and date. The SET icon will appear on the screen to indicate that the meter has entered setup mode.

Setting the time

Hour will flash

- If the hour displayed is correct, press (OK) to confirm.
- If the hour displayed is not correct, press (^) or (v) to change the hour and press (OK) to confirm.

Minutes will flash

- If the minutes displayed is correct, press (OK) to confirm.
- If the minutes displayed is not correct, press (^) or (v) to change the minutes and press (OK) to confirm.

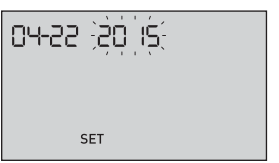
AM/PM will flash

- If the AM/PM displayed is correct, press (OK) to confirm.
- If the AM/PM displayed is not correct, press (^) or (v) to change AM/PM and press (OK) to confirm.

Setting the date

After completing the time setup, the meter will automatically move to date setup.

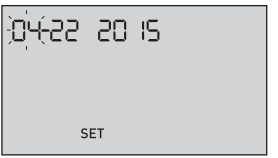
Year will flash



- If the year displayed is correct, press (OK) to confirm.
- If the year displayed is not correct, press (^) or (v) to change the year and press (OK) to confirm.

Month will flash

- If the month displayed is correct, press (OK) to confirm.
- If the month displayed is not correct, press (^) or (v) to change the month and press (OK) to confirm.



Day will flash

- If the day displayed is correct, press (OK) to confirm.
- If the day displayed is not correct, press (^) or (v) to change the day and press (OK) to confirm.

You are now ready to take a test. See the section *Testing your blood glucose* in Chapter 3.

NOTE: After completing first time setup, a screen with three dashes will appear. Once you begin testing, your last result will appear in place of the three dashes, along with the date and time the test was taken.

Adjusting the time and date settings after first time setup

You can adjust the meter's time and date settings after first time setup. Press and hold (OK) to turn the meter on, then press and hold (OK) and (∨) at the same time. The SET screen will appear. See page 76.

After adjusting the settings, your meter will exit settings mode and your last result screen will appear.

Connecting to a compatible wireless device

Turning the BLUETOOTH® feature on or off

In order to connect your meter with your compatible wireless device, the BLUETOOTH® feature will need to be turned on. The ✱ symbol will appear on the meter screen when the BLUETOOTH® feature is on. When the ✱ symbol is not present on the screen the BLUETOOTH® feature is off.

- To turn the BLUETOOTH® feature on press (OK) and (^) at the same time.
- To turn the BLUETOOTH® feature off press (OK) and (^) at the same time.

The ✱ symbol indicates the BLUETOOTH® feature is on

NOTE: The BLUETOOTH® feature will turn OFF during a blood glucose test.

Pairing Overview

Pairing allows your OneTouch Verio Flex® Meter to communicate with compatible wireless devices. The devices must be within 8 meters of each other to pair and sync. Download the OneTouch Reveal® Mobile App from the appropriate app store before pairing your meter and compatible wireless device.

NOTE: Some diabetes management apps, including the OneTouch Reveal® Mobile App, may not be available in your country. Visit www.OneTouch.ca to learn if the OneTouch Reveal® Mobile App is available in your country.

Multiple OneTouch Verio Flex® Meters can be paired with your compatible wireless device. For example, your compatible wireless device can be paired with a meter at home and another at work. To pair multiple meters, repeat the pairing instructions for each meter. See page 29 for pairing instructions.

Your OneTouch Verio Flex® Meter can be paired with multiple compatible wireless devices. To pair multiple compatible wireless devices, repeat the pairing instructions for each compatible wireless device.

Pairing Instructions

1. Start by turning your meter on using the (OK) button

2. The BLUETOOTH® feature is turned on by pressing (OK) and (^) together

The ᛒ symbol will appear to indicate that the BLUETOOTH® feature is on.

3. Open the OneTouch Reveal® Mobile App and follow instructions to pair meter with your compatible wireless device

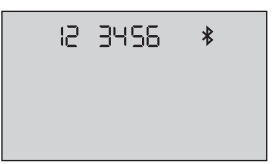
4. Look for "OneTouch" and the last 4 characters of the meter serial number on the compatible wireless device display to correctly identify your meter

5. When prompted by the OneTouch Reveal® Mobile App, the meter will display a six digit PIN number

Enter the PIN number into your compatible wireless device using the keypad on your compatible wireless device.

⚠CAUTION:

Make sure the PIN you enter on your compatible wireless device matches the PIN on your meter display. If a PIN number unexpectedly appears on your meter display, cancel the PIN request by either inserting a test strip to take a test or press the (OK) button to enter History Mode.



Example of PIN number display on meter

6. Wait for your compatible wireless device to indicate that your meter and compatible wireless device are paired

Syncing to send results wirelessly to the OneTouch Reveal® Mobile App

After pairing the meter with your compatible wireless device, you are ready to send results to the OneTouch Reveal® Mobile App.

1. Open the OneTouch Reveal® Mobile App on your compatible wireless device

2. Press and hold (OK) to turn the meter on and make sure the BLUETOOTH® feature is ON as indicated by (✱)

If needed, press (OK) and (^) at the same time to turn the BLUETOOTH® feature on.

The Sync symbol (🔄) flashes on the meter display. "Syncing Data" will appear on the app to notify you that the meter is communicating with the app.

Syncing Data

After syncing, the Sync symbol will disappear, the "Syncing Data" message will disappear on the app, and the app will display a list of any new results sent from the meter.

NOTE: Inserting a test strip during the transmission will cancel the transfer of all results. The flashing symbol appears on the screen and you can proceed with testing.

Turning the meter off

There are three ways to turn your meter off:

- Press and hold OK for several seconds until the meter turns off.
- Remove the test strip.
- Your meter will turn off by itself if left alone for two minutes.

NOTE: Following a glucose test, the meter will still be available for BLUETOOTH® connection for up to 4 hours. See page 71 for more details.

3 Taking a test

Testing your blood glucose

Preparing for a blood glucose test

NOTE: Many people find it helpful to practice testing with control solution before testing with blood for the first time. See page 60.

Have these things ready when you test:

OneTouch Verio Flex® Meter

OneTouch Verio® Test Strips

Lancing device

Sterile lancets

NOTE:

- Use only OneTouch Verio® Test Strips.
- Unlike some blood glucose meters, no separate step to code your OneTouch Verio Flex® System is required.
- Testing must be done within operating temperature range (6-44°C).
- Make sure your meter and test strips are about the same temperature before you test.
- Keep test strips in a cool, dry place between 5°C and 30°C.

- **Do Not** test if there is condensation (water build-up) on your meter. Move your meter and test strips to a cool, dry spot and wait for the meter surface to dry before testing.
- **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.
- 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** return the used test strip to the vial after performing a test.
- **Do Not** re-use a test strip that had blood, control solution, or any contaminants applied to it. Test strips are for single use only.
- With clean, dry hands, you may touch the test strip anywhere on its surface. **Do Not** bend, cut or modify the test strip in any way.
- When you first open a vial of test strips, record the discard date on the label. Refer to the test strip insert or vial label for instructions on determining the discard date.

- Comparing your blood glucose test results taken with this meter to your results taken from a different meter is not recommended. Results may differ between meters and are not a useful measure of whether your meter is working properly. To check your meter accuracy, you should periodically compare your meter results to those obtained from a lab. See page 98 for more information.

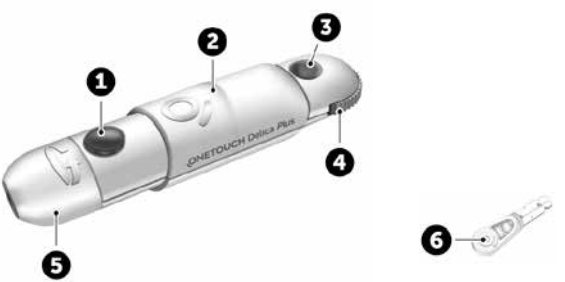
IMPORTANT: If another person assists you with testing, the meter should always be cleaned prior to use by that person. See page 80.

⚠CAUTION:

- The OneTouch Verio Flex® Blood Glucose Monitoring System should not be used for patients within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high results.
- **Do Not** use the OneTouch Verio® Family of Meters when PAM (Pralidoxime) is known or suspected to be in the patient's whole blood sample.

- **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 Customer Service immediately if the test strip vial is damaged. Contact OneTouch® Customer Care at 1 800 663-5521.
- 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

NOTE:

- 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 Verio Flex® Blood Glucose Monitoring System has not been evaluated for Alternate Site Testing (AST). Use only fingertips when testing with the system.

Lancing precautions

⚠CAUTION:

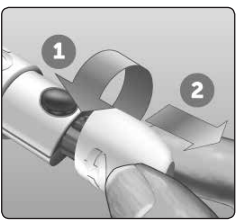
To reduce the chance of infection and disease spread by blood:

- Make sure to wash the sample site with soap and warm water, rinse and dry before sampling.
- The lancing device is intended for a single user. Never share a lancet or lancing device with anyone.
- Always use a new, sterile lancet each time you test.
- Always keep your meter and lancing device clean (See page 80).
- The meter and lancing device are for single patient use only. **Do Not** share them with anyone, including family members! **Do Not** use on multiple patients!
- After use and exposure to blood, all parts of this kit are considered biohazardous. A used kit may transmit infectious diseases even after you have performed cleaning and disinfection.
- **Do Not** use lancets after the expiration date printed on the lancet packaging.

Preparing your lancing device

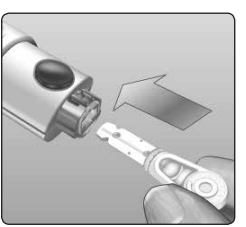
1. Remove the lancing device cap

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

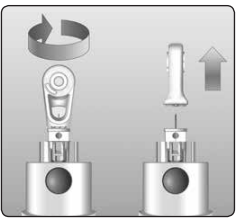


2. Insert a sterile lancet into the lancing device

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.



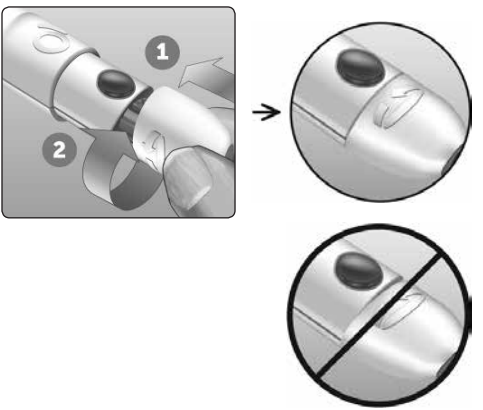
Twist the protective cover one full turn until it separates from the lancet. **Save the protective cover for lancet removal and disposal.** See page 57.



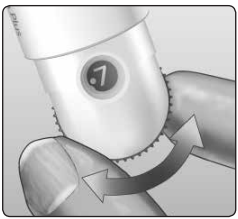
3. Replace the lancing device cap

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.



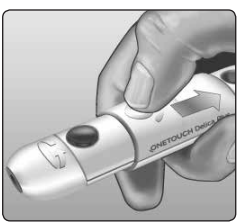
4. Adjust the depth setting



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.

5. 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.

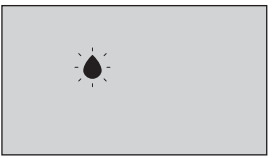
Preparing the meter

1. Insert a test strip to turn the meter on

Insert a test strip into the test strip port with the gold side of the test strip and the two silver prongs facing you.

NOTE: No separate step to code the meter is required.

The flashing blood drop icon (🩸) appears on the display. You can now apply your blood sample to the test strip.



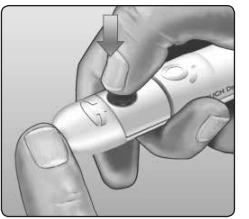
Sampling blood from the fingertip

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

Before testing, wash your hands and the sample site with warm, soapy water. Rinse and dry completely. Contaminants on the skin may affect results.

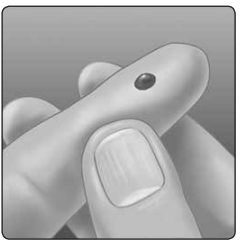
1. Puncture your finger

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



2. 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

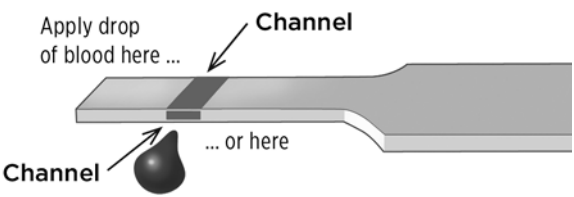
Applying the sample

1. Apply the sample to the test strip

You can apply blood to either side of the test strip.

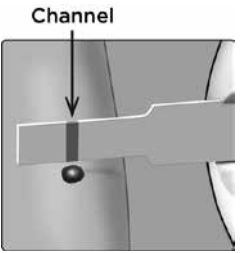
Apply your sample to the opening of the channel.

Be sure to apply your sample immediately after you get a drop of blood.

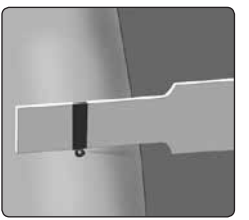


3 Taking a test

Holding the meter at a slight angle, guide the channel to the blood drop.



When it touches your sample, the test strip wicks blood into the channel.

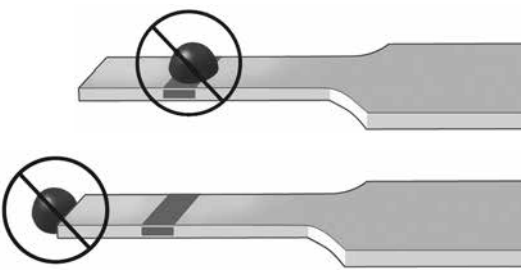


2. Wait for the channel to fill completely

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

The channel turns red and the meter will count down from 5 to 1.

Blood should **not** be applied on the top of the test strip or to the top edge of the test strip.



NOTE:

- **Do Not** smear or scrape the sample with the test strip.
- **Do Not** press the test strip too firmly against the puncture site or the channel may be blocked from filling properly.
- **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 or you may get an error message or the meter may turn off.
- **Do Not** remove the test strip until the result is displayed or the meter will turn off.

Viewing your result

Your result appears on the display, along with the unit of measure, and the date and time of the test. After your glucose result appears, the meter will also display a Range Indicator Arrow below your glucose result to indicate if your result is below, above or within your range limits (see page 19). The arrow will point to the appropriate Range Indicator Colour Bar on the meter as a visual reminder.

Example
Below Range Result

Example
In Range Result

Example
Above Range Result

⚠**CAUTION:**

Do Not make immediate treatment decisions based on the Range Indicator feature. Treatment decisions should be based on the numerical result and healthcare professional recommendation and not solely on where your result falls within your range limits.

⚠**WARNING:** Confirm that the unit of measure mmol/L is displayed. If your display shows mg/dL rather than mmol/L, stop using the meter and contact Customer Service.

Interpreting unexpected results

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

⚠CAUTION:

Low results

If your result is below 4.0 mmol/L or is shown as **LO** (meaning the result is less than 1.1 mmol/L), it may mean hypoglycemia (low blood glucose). This may require immediate treatment according to your healthcare professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do another test.

NOTE: When your glucose result is below 1.1 mmol/L, both the **LO** and the Range Indicator Arrow will flash on the meter screen.

⚠CAUTION:

Dehydration and low results

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

⚠CAUTION:

High results

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

NOTE: When your glucose result is above 33.3 mmol/L, both the **HI** and the Range Indicator Arrow will flash on the meter screen.

⚠**CAUTION:**

Repeated unexpected results

- If you continue to get unexpected results, check your system with control solution.
- If you are experiencing symptoms that are not consistent with your results and you have followed all instructions in this Owner's Booklet, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes management program without speaking to your healthcare professional.

Unusual red blood cell count

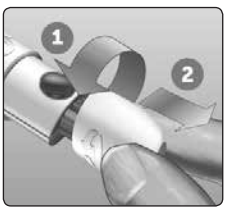
A hematocrit (percentage of your blood that is red blood cells) that is either very high (above 60%) or very low (below 20%) can cause false results.

Removing the used lancet

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

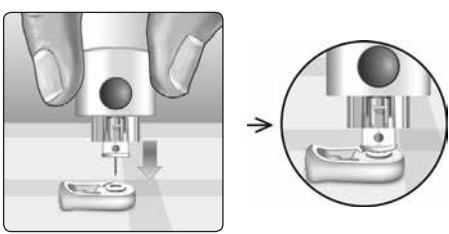
1. Remove the lancing device cap

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



2. 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.



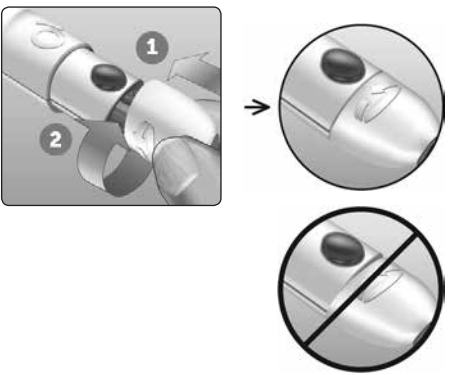
3. Eject the lancet

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.

4. 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

Discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used lancets and test strips may be considered biohazardous waste in your area. Be sure to follow your healthcare professional's recommendations or local regulations for proper disposal.

Wash hands thoroughly with soap and water after handling the meter, test strips, lancing device and cap.

Testing with control solution

Control solution testing precautions

OneTouch Verio® Control Solution is used to check that the meter and test strips are working together properly and that the test is performing correctly. (Control solution is available separately.)

NOTE:

- Use only OneTouch Verio® Control Solution with your OneTouch Verio Flex® Meter.
- When you first open a new vial of control solution, record the discard date on the vial label. Refer to the control solution insert or vial label for instructions on determining the discard date.
- Tightly close the cap on the control solution vial immediately after use to avoid contamination or damage.

See page 34 for more information on testing.

⚠CAUTION:

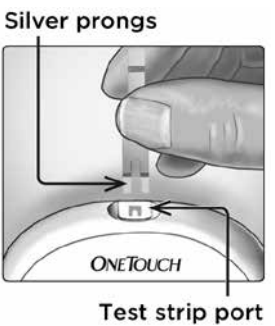
- **Do Not** swallow or ingest control solution.
- **Do Not** apply control solution to the skin, eyes, ears or nose as it may cause irritation.
- **Do Not** use control solution after the expiration date (printed on the vial label) or the discard date, whichever comes first, or your results may be inaccurate.

When to do a control solution test

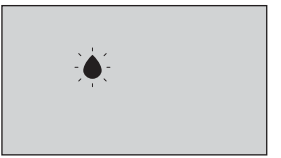
- When you open a new vial of test strips.
- If you suspect that the meter or test strips are not working properly.
- If you have had repeated unexpected blood glucose readings.
- If you drop or damage the meter.

Preparing your meter for a control solution test

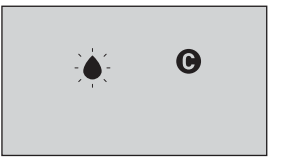
1. Insert a test strip to turn the meter on



2. Wait for the flashing blood drop icon (💧) to appear on the display



3. Press and hold ^ or v until the control solution icon (Ⓒ) appears on the display

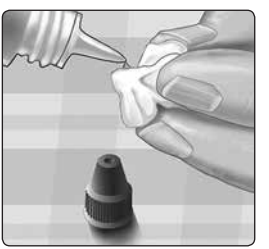


Preparing the control solution

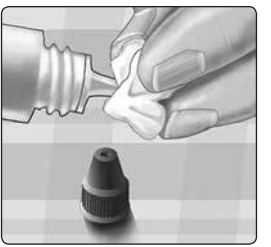
1. Before removing the cap, shake the vial gently

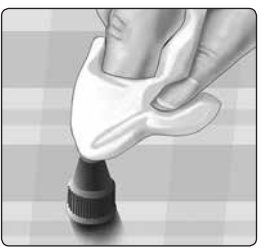
2. Remove the vial cap and place it on a flat surface with the top of the cap pointing up

3. Squeeze the vial to discard the first drop

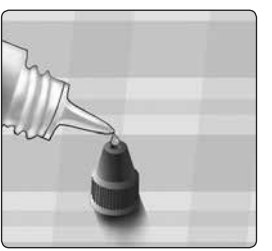


4. Wipe both the tip of the control solution vial and the top of the cap with a clean, damp tissue or cloth





5. Squeeze a drop into the small well on the top of the cap or onto another clean, non-absorbent surface



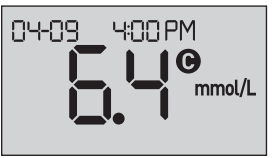
Applying the control solution

1. Hold the meter so that the side edge of the test strip is at a slight angle to the drop of control solution

2. Touch the channel on the side of the test strip to the control solution

3. Wait for the channel to fill completely

Viewing your control solution result



After the control solution is applied, the meter will count down until the test is complete. Your result is displayed along with the date, time, unit of measure, and C (for control solution) and stored in the meter.

Control solution results can be seen when reviewing past results on the meter.

⚠**CAUTION:** Make sure you press and hold ^ or v until the control solution icon C appears before you begin a control solution test. Invalid results may be logged into your history if you applied control solution to the test strip without following the steps beginning on page 62.

Checking if the result is in range

Compare the result displayed on the meter to the range printed **on your OneTouch Verio® Control Solution vial**. If your control solution result falls outside the expected range, repeat the test with a new test strip.

Example range
OneTouch Verio® Mid Control Solution Control Range 5.7-7.7 mmol/L

⚠CAUTION:

The range printed on the control solution vial is for control solution tests only **and is not a recommended range for your blood glucose level.**

Causes of out-of-range results

Out-of-range results may be due to:

- Not following the instructions for performing a control solution test.
- Control solution is contaminated, expired, or past its discard date.
- Test strip or test strip vial is damaged, expired, or past its discard date.
- Meter, test strips and/or control solution were not all at the same temperature when the control solution test was performed.
- A problem with the meter.
- Dirt or contamination in the small well on the top of the control solution cap.

⚠CAUTION:

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

Cleaning the control solution cap

Clean the top of the control solution cap with a clean, damp tissue or cloth.

4 Reviewing past results

Reviewing past results on your meter

Your meter stores your most recent 500 blood glucose and control solution test results and displays them in the order the tests were taken. The (🕘) symbol will appear on your screen when in History Mode.

1. When the meter is off, press and hold (OK) to turn History Mode on

The (🕘) symbol indicates you are viewing your past results.

The (▼) symbol indicates if the result was below, above or within range at the time of the test, by pointing to the appropriate colour bar.

2. Scroll through your results by pressing (˅) to move backwards and (˄) to move forward through your results

Using the meter without syncing to an app

The meter can be used without a compatible wireless device or the app. You can still test your blood glucose and review up to 500 results on the meter.

Sending your results to the app

If the BLUETOOTH® feature on the meter is turned on, indicated by the BLUETOOTH® symbol (), the meter will automatically send the latest result to any paired compatible wireless device. The compatible wireless device must have the app running and have already been paired to the meter before sending a result.

NOTE: The compatible wireless device must have the app open and have already been paired to the meter before sending a result. See page 28.

NOTE: If the BLUETOOTH® feature on the meter is **turned off**, or the meter is out of range, the result is not sent to the compatible wireless device. The result is saved in the meter memory with the current date and time, and will be sent to the app the next time you sync. The sent results are also stored in the meter. To sync, the app must be open and running on your compatible wireless device.

To ensure that glucose test results are successfully sent to the app, turn on the BLUETOOTH® feature and check the following:

- The compatible wireless device and meter are both turned on, and the app is running.
- The meter is correctly paired with your compatible wireless device.
- The BLUETOOTH® feature on both devices is running (indicated by) and the devices are within 8 meters of each other.
- The meter will attempt to transmit results up to 4 hours after a test, even if the meter appears to be off. This is indicated by the BLUETOOTH® symbol () remaining on the meter screen.

Example

If you are still unable to send results to the compatible wireless device, please call Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

NOTE: Inserting a test strip during the transmission will cancel the transfer of all results. The symbol appears on the screen and you can proceed with testing.

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

Connect only to a computer certified to UL 60950-1 ( ).

To transfer meter data, follow the instructions provided with the diabetes management software product to download the results from the meter. You will need a standard micro USB interface cable to connect your OneTouch Verio Flex® Meter to a computer to download results (not included).

Once the command to start the download is sent from the computer to the meter, the meter display will show the flashing Sync symbol (🔄) indicating that the meter is in communication mode.

Do Not insert a test strip while the meter is connected to a computer.

If you are unable to download your results to a computer, please call Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

5 Editing Your Settings

Editing time and date

You can adjust the meter's time and date settings after first time setup. Press and hold (OK) to turn the meter on, then press and hold (OK) and (v) at the same time. The SET screen will appear, and the hour will flash.

For instructions on adjusting the time and date, see page 23.

After adjusting the settings, you will exit settings mode and your last glucose result screen will appear. The adjusted time and date will be displayed once a new glucose test has been completed and the result appears on the screen.

NOTE: You will not be able to perform a blood glucose test until you finish editing the time and date.

NOTE: The OneTouch Reveal® Mobile App on your compatible wireless device checks and updates the time and date in your meter each time you sync. Check the time and date often on your compatible wireless device to be sure they are correct. See the App instructions for more information.

Editing your range limits

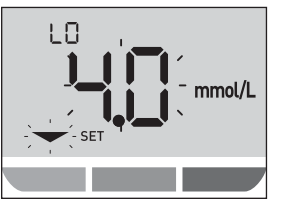
Your meter uses low and high range limits to tell you when your result is below, above or within your set range. The meter comes with pre-set range limits that can be changed. The pre-set low range limit is 4.0 mmol/L and the pre-set high range limit is 10.0 mmol/L. To edit the pre-set range limits press and hold ^ and v at the same time. The SET screen will appear with the current low range limit displayed, and the number and range indicator arrow will flash.

NOTE: The low and high range limits you set apply to all glucose test results. This includes tests taken before or after mealtimes, medications and around any other activities that may affect your blood glucose.

⚠CAUTION:

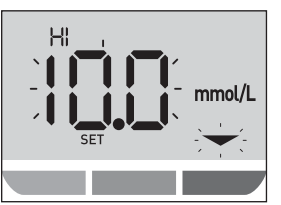
Be sure to talk to your healthcare professional about the low and high range limits that are right for you. When selecting or changing your limits, you should consider factors such as your lifestyle and diabetes therapy. Never make significant changes to your diabetes care plan without consulting your healthcare professional.

1. Review the pre-set low range limit displayed



- To accept the pre-set low range limit, press (OK).
- To edit the pre-set low range limit, press (^) or (v) to change the value between 3.3 mmol/L-6.1 mmol/L, and then press (OK).

2. Review the pre-set high range limit displayed



- To accept the pre-set high range limit, press (OK).
- To edit the pre-set high range limit, press (^) or (v) to change the value between 5.0 mmol/L-16.7 mmol/L, and then press (OK).

Your meter will exit settings mode and your last result screen will appear.

NOTE: If you change your range limits, this will only affect whether future test results are displayed as below, above or within your range limits. Changing your range limits does not affect how past results are displayed.

NOTE: You will not be able to perform a glucose test until you finish editing the range limits.

NOTE: You can use the OneTouch Reveal® Mobile App on your compatible wireless device to change the range limits stored in your meter. See the instructions that came with the app for more information.

6 Caring for your system

Storing your system

Store your meter, test strips, control solution and other items in your carrying case. Keep in a cool, dry place between 5°C and 30°C. **Do Not** refrigerate. Keep all items away from direct sunlight and heat.

Cleaning and disinfection

Cleaning and disinfection are different and both should be performed. Cleaning is part of your normal care and maintenance and should be performed prior to disinfection, but cleaning does not kill germs. Disinfection is the only way to reduce your exposure to disease. For cleaning information, see page 80 and for disinfecting information, see page 82.

Cleaning your meter, lancing device and cap

The meter, lancing device and cap should be cleaned whenever they are visibly dirty and before disinfection. Clean your meter at least once per week. For cleaning obtain regular strength liquid dish soap and a soft cloth. Prepare a mild detergent solution by stirring 2.5 mL of regular strength liquid dish soap into 250 mL of water.

- **Do Not** use alcohol or any other solvent.
- **Do Not** allow liquids, dirt, dust, blood or control solution to enter the test strip port or the data port. (See page 16.)
- **Do Not** spray cleaning solution on the meter or immerse it in any liquid.

1. Holding the meter with the test strip port pointed down, use a soft cloth dampened with water and mild detergent to wipe the outside of the meter and lancing device

Be sure to squeeze out any excess liquid before you wipe the meter. Wipe the outside of the cap.

2. Wipe dry with a clean, soft cloth

Disinfecting your meter, lancing device and cap

The meter, lancing device and cap should be disinfected periodically. Clean your meter, lancing device and cap prior to disinfecting. For disinfecting, obtain regular household bleach (*containing a minimum* of 5.5% sodium hypochlorite as the active ingredient)*. Prepare a solution of 1 part household bleach and 9 parts water or obtain equivalent (0.55% sodium hypochlorite*) wipes.

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

1. Hold the meter with the test strip port pointed down

Use a soft cloth dampened with this solution or a 0.55% equivalent sodium hypochlorite wipe to wipe the outside of the meter and lancing device until the surface is damp. Be sure to squeeze out any excess liquid before you wipe the meter.

2. After wiping, cover the surface you are disinfecting with the soft cloth dampened with the bleach solution or 0.55% equivalent sodium hypochlorite wipe for 1 minute

Then wipe with a clean, damp, soft cloth.

Wash hands thoroughly with soap and water after handling the meter, lancing device and cap.

If you see signs of wear, please contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

7 Battery

Replacing the battery

Your OneTouch Verio Flex® Meter uses one CR2032 lithium coin cell 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.

IMPORTANT: Use only one CR2032 lithium coin cell battery with your meter. **Do Not** use rechargeable batteries. Use of an incorrect battery type may result in your meter providing fewer tests than normal.

If the meter does not turn on, you may need to replace the battery. See below for instructions.

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

NOTE: After replacing the battery, you will be prompted to set time and date, as if you are turning the meter on for the first time.

1. Remove the old battery

Start with the meter turned off. Remove the battery cover by pressing and sliding it downward.

Pull up on the battery ribbon to lift the battery out of the compartment.

Do Not remove the battery while the meter is connected to a computer.

2. Insert the new battery

Insert one CR2032 lithium coin cell battery on top of the battery ribbon, with the plus (+) side up.

If the meter does not power on after you have replaced the meter battery, check that the battery is correctly installed. If the meter still does not power on, contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

3. Replace battery cover by sliding it upwards onto the meter

4. Check your meter settings

Removing the meter battery will not affect your stored results. However, you will need to check your date and time settings.

5. Dispose of battery

Dispose of the battery according to your local environmental regulations.

8 Troubleshooting your system

Error and other messages

The OneTouch Verio Flex® Meter displays messages when there are problems with the test strip, with the meter or when your glucose levels are above 33.3 mmol/L or below 1.1 mmol/L. Improper use may cause an inaccurate result without producing an error message.

NOTE: If the meter is on but does not operate (locks-up), contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

What it means

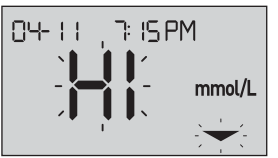
You may have a very low blood glucose level (severe hypoglycemia), below 1.1 mmol/L.

NOTE: When your glucose result is below 1.1 mmol/L, both the **LO** and the Range Indicator Arrow will flash on the meter screen.

What to do

This may require immediate treatment. Although this message could be due to a test error, it is safer to treat first and then do another test. Always treat according to your healthcare professional's recommendations.

What it means



You may have a very high blood glucose level (severe hyperglycemia), over 33.3 mmol/L.

NOTE: When your glucose result is above 33.3 mmol/L, both the **HI** and the Range Indicator Arrow will flash on the meter screen.

What to do

Re-test your blood glucose level. If the result is **HI** again, obtain and follow instructions from your healthcare professional right away.

What it means

Meter is too hot (above 44°C) to perform a test.

What to do

Move the meter and test strips to a cooler area. Insert a new test strip when the meter and test strips are within the operating range (6-44°C). If you do not get another **HI .t** message, you can proceed with testing.

If this message continues to appear, contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

What it means

Meter is too cold (below 6°C) to perform a test.

What to do

Move the meter and test strips to a warmer area. Insert a new test strip when the meter and test strips are within the operating range (6-44°C). If you do not get another **LO.t** message, you can proceed with testing.

If this message continues to appear, contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

Error Screens

If there is a problem with your meter, the following error screens may appear. Along with an error number, there is also an error code in the upper left corner of your meter screen. If you cannot resolve the error with your meter, contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521. They will refer to the error number and code to help troubleshoot the problem.

Example Error Screen Code

What it means

There is a problem with the meter.

What to do

Do Not use the meter. Contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

What it means

Error message could be caused either by a used test strip or a problem with the meter or test strip.

What to do

Repeat the test with a new test strip; see page 47 or page 65. If this message continues to appear, contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

What it means

The sample was applied before the meter was ready.

What to do

Repeat the test with a new test strip. Apply a blood or control solution sample only after the flashing symbol appears on the display. If this message continues to appear, contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

What it means

One of the following may apply:

- Not enough blood or control solution was applied or more was added after the meter began to count down.
- The test strip may have been damaged or moved during testing.
- The sample was improperly applied.
- There may be a problem with the meter.

What to do

Repeat the test with a new test strip; see page 47 or page 65. If the error message appears again, contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

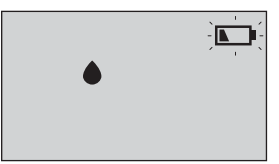
What it means

The meter has detected a problem with the test strip. Possible cause is test strip damage.

What to do

Repeat the test with a new test strip; see page 47 or page 65. If the error message appears again, contact Customer Service. Contact OneTouch® Customer Care at 1 800 663-5521.

What it means



Meter battery power is low but there is still enough battery power to perform a test. The flashing low battery ( ) icon will continue to appear until the battery is replaced.

What to do

Replace the meter battery soon.

What it means

There is not enough battery power to perform a test.

What to do

Replace the battery immediately.

What it means

No result in memory, such as the first time use or when you have chosen to delete all the results after downloading to a computer.

What to do

Contact Customer Service to report this occurrence, **unless** this is your first use of the meter. You can still perform a blood glucose test or control solution test and get an accurate result. Contact OneTouch® Customer Care at 1 800 663-5521.

9 Detailed information about your system

Comparing meter results to laboratory results

Results obtained from the OneTouch Verio Flex® Meter and laboratory tests are reported in plasma-equivalent units. However, your meter result may differ from your lab result due to normal variation. A result from your OneTouch Verio Flex® Meter is considered accurate when it is within 0.83 mmol/L of a laboratory method when the glucose concentration is lower than 5.55 mmol/L and within 15% of a laboratory method when the glucose concentration is 5.55 mmol/L or higher.

Meter results can be affected by factors that do not affect lab results in the same way. Specific factors that may cause your meter result to vary from your lab result may include:

- You have eaten recently. This can cause a result from fingertip testing to be up to 3.9 mmol/L higher than a lab test using blood drawn from a vein.[1]
- Your hematocrit is above 60% or below 20%.
- You are severely dehydrated.

For additional information, refer to the OneTouch Verio® Test Strip Insert.

[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.

Guidelines for obtaining an accurate meter to lab comparison

Before going to the lab:

- Perform a control solution test to make sure your meter is working properly.
- **Do Not** eat for at least 8 hours before you test your blood.
- Take your meter and testing supplies with you to the lab.

Testing with your OneTouch Verio Flex® Meter at the lab:

- Test within 15 minutes of the lab test.
- Use only a fresh, capillary blood sample from your fingertip.
- Follow all instructions in this Owner's Booklet for performing a blood glucose test.

Comparing your meter results to those taken from another meter

Comparing your blood glucose test results taken with this meter to your results taken from a different meter is not recommended. Results may differ between meters and are not a useful measure of whether your meter is working properly.

Technical specifications

Assay method	FAD-GDH (flavin adenine dinucleotide dependent glucose dehydrogenase)
Automatic shutoff	Two minutes after last action
Battery ratings	3.0 V d.c. (CR2032 lithium coin cell battery), ⎓
Battery type	One replaceable 3.0 Volt CR2032 lithium coin cell battery (or equivalent)
BLUETOOTH® Technology	Frequency band: 2.4-2.4835 GHz Maximum power: 0.4 mW Operating Range Distance: minimum 8 meters (unobstructed) Operating Channels: 40 Channels Security Encryption: 128-bit AES (Advanced Encryption Standard)
Calibration	Plasma-equivalent
Data port type	Compatible with USB 2.0

Memory	500 test results
Operating ranges	Temperature: 6-44°C Relative humidity: non-condensing 10-90% Altitude: up to 3048 meters Hematocrit: 20-60%
Reported result range	1.1-33.3 mmol/L
Sample	Fresh capillary whole blood
Sample volume	0.4 µL
Size	52.0(W) x 86.0(L) x 16.0(T) mm
Test time	5 seconds
Unit of measure	mmol/L
Weight	Approximately 50 grams

System Accuracy

Diabetes experts have suggested that 95% of glucose meter results should agree within 0.83 mmol/L of a laboratory method when the glucose concentration is lower than 5.55 mmol/L, and within 15% of a laboratory method when the glucose concentration is 5.55 mmol/L or higher.

Samples from 100 patients were tested using both the OneTouch Verio Flex® System and the YSI 2300 Glucose Analyzer laboratory instrument.

System Accuracy Results for Glucose Concentrations <5.55 mmol/L

Percent (and number) of meter results that match the laboratory test

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
82.0% (123/150)	98.0% (147/150)	100% (150/150)

System Accuracy Results for Glucose Concentrations ≥5.55 mmol/L

Percent (and number) of meter results that match the laboratory test

Within ±5%	Within ±10%	Within ±15%
62.9% (283/450)	94.7% (426/450)	99.3% (447/450)

System Accuracy Results for Glucose Concentrations between 2.1 mmol/L and 25.9 mmol/L

Within ±0.83 mmol/L or ±15%
99.5% (597/600)

NOTE: Where 2.1 mmol/L represents the lowest glucose reference value and 25.9 mmol/L represents the highest glucose reference value (YSI value).

Regression Statistics

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

# of Subjects	# of Tests	Slope	Intercept (mmol/L)
100	600	1.01	-0.02

95% CI Slope	95% CI Intercept (mmol/L)	Std. Error ($S_{y.x}$) (mmol/L)	R^2
1.00 to 1.01	-0.12 to 0.08	0.64	0.99

User Performance Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 167 lay persons showed the following results:

93.1% within ±0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L, and 98.6% within ±15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

97.6% of the total number of samples were within ±0.83 mmol/L or ±15% of the medical laboratory values.

Precision

Within Run Precision (300 Venous Blood Samples Tested per Glucose Level)

Data generated using the OneTouch Verio Flex® Meter.

Target Glucose (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (%)
2.2	2.0	0.05	2.26
5.0	4.9	0.10	1.95
7.2	7.1	0.14	1.95
11.1	11.1	0.22	1.98
19.4	19.1	0.34	1.79

Results show that the greatest variability observed between test strips when tested with blood is 0.10 mmol/L SD or less at glucose levels less than 5.55 mmol/L, or 1.98% CV or less at glucose levels at 5.55 mmol/L or above.

Total Precision (600 Control Solution Tests per Glucose Level)

Data generated using the OneTouch Verio Flex® Meter.

Glucose Level Ranges (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (%)
Low (1.39-2.72)	2.06	0.05	2.48
Mid (5.67-7.67)	6.53	0.13	2.05
High (16.56-22.39)	19.37	0.46	2.38

Guarantee

LifeScan guarantees that the OneTouch Verio Flex® 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: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 electrostatic discharge as specified in IEC 61326-2-6. This meter complies with immunity to radio frequency interference as specified in IEC 61326-1 and 61326-2-6.

The meter meets the requirements for immunity to electrical interference at the frequency range and test level specified in international standard ISO 15197.

Do Not use the equipment where aerosol sprays are being used, or when oxygen is being administered.

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Notes

Notes

Contents covered by one or more of the following U.S. patents: 6,179,979, 6,193,873, 6,284,125, 6,716,577, 6,749,887, 6,797,150, 6,863,801, 6,872,298, 7,045,046, 7,498,132, 7,846,312,8,449,740 and 8,529,751. Use of the monitoring device included herein is protected under one or more of the following U.S. patents: 6,413,410, 6,890,421, 8,163,162, 7,749,371, 8,449,740 and 8,529,751. 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 Verio® Test Strip. No test strip supplier other than LifeScan, Inc. is authorised 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.

Contact the OneTouch® Customer Care Line at 1 800 663-5521, Monday-Friday, 9am-8pm Eastern, 6am-5pm Pacific, or visit www.OneTouch.ca.

Meter Made in China

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Lifescan™

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