

ONETOUCH[®]
Verio[®]
Blood Glucose Monitoring System

**Owner's
Booklet**

Instructions for use

ONETOUCH®
Verio®

Blood Glucose Monitoring System

Owner's Booklet

Thanks for choosing OneTouch®!

The OneTouch® Verio® Blood Glucose Monitoring System is one of the latest product innovations from OneTouch®. Every OneTouch® Meter is designed to make it easy to test your blood glucose and help you 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.

Meter Symbols and Icons



Low Battery



Battery Empty



Above Range



In Range



Below Range



Low Pattern message icon



High Pattern message icon



Control solution result

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
	Consult Instructions for Use
	Manufacturer
	Lot Number
	Serial Number
	Storage Temperature Limits
	In Vitro Diagnostic Device
	Do Not Re-use
	Sterilised by irradiation
	Not for general waste
	Use By Date
	Contains sufficient for n tests

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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 and OneTouch® Verio® Control Solution.

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® 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 used for testing multiple patients. Venous whole blood samples may be used by healthcare professionals.

The OneTouch® Verio® Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch® Verio® 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 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 blood glucose result and stores it in its memory.

The OneTouch® Verio® Blood Glucose Monitoring System

Included with your kit:



OneTouch® Verio® Meter
(2 AAA batteries included)



Carrying Case



OneTouch® Delica®
Sterile Lancets



OneTouch® Delica®
Lancing Device



OneTouch® Verio®
Test Strips

NOTE: The OneTouch® Delica® Lancing Device uses ONLY OneTouch® Delica® Lancets.

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 Care or ask your pharmacist or healthcare professional.

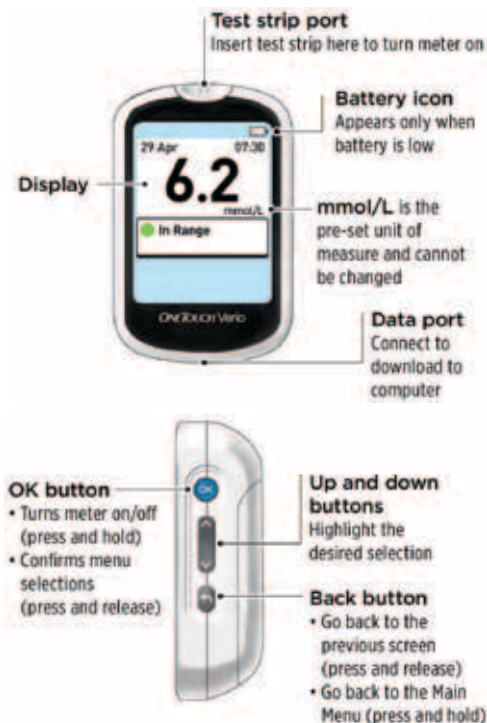
⚠WARNING: Keep the meter and testing supplies away from young children. Small items such as the battery door, batteries, test strips, lancets, protective covers on the lancets, and control solution vial cap are choking hazards. **Do Not** ingest or swallow any items.

1

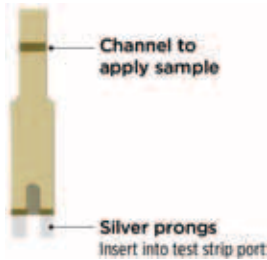
Set up your system

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

Meter



Test strip



1 Set up your system

Turn your meter on

Press and hold **OK** until the start-up screen appears. Once the start-up screen is displayed, release **OK**.



⚠CAUTION:

If you see any missing pixels within the start-up screen, there may be a problem with the meter. Call OneTouch® Customer Care on 0800 121 200 (UK) 1800 535 676 (Ireland) during the hours of 08:30 - 18:00 Monday - Friday 09:00 - 13:00 Saturday. Or visit www.LifeScan.co.uk.

Use the display backlight for better visibility




The backlight comes on automatically whenever the meter is turned on. After a few seconds of no activity, the backlight will dim. Pressing any button or inserting a test strip will turn the backlight back on.


First time setup

Before using your meter for the first time, you should check to make sure the pre-set language, time and date in the meter are correct. This ensures that the correct time and date are assigned to each of your test results.

Set Language


The first time you turn the meter on, the **Set Language** screen appears.


In the **Set Language** screen, press  or  to highlight the language you want and press .

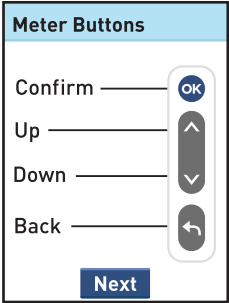
Pressing  after making your selection confirms each setting and takes you to the next screen.

Set Language
English
Slovenščina
Hrvatski
Welcome

1 Set up your system

When setting up your meter you can press  to return to the previous screen to adjust a setting.

After setting the language, the **Meter Buttons** screen appears to remind you how each meter button works. Press .



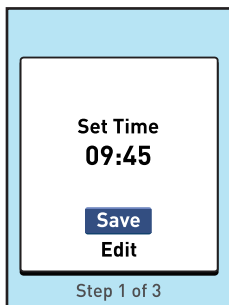
Accept pre-set time, date and range limits

Step 1: Set time

The **Set Time** screen will be displayed next.

If the time is correct, press **OK** to save.

If you need to edit the time press **▲** or **▼** to highlight **Edit** and press **OK** (see page 22).



Saved will appear to confirm that the time displayed is now stored in the meter.



1 Set up your system

Step 2: Set date

The **Set Date** screen will be displayed next.

If the date is correct, press **OK** to save.

If you need to edit the date press **▲** or **▼** to highlight **Edit** and press **OK** (see page 22).



Saved will appear to confirm that the date displayed is now stored in the meter.



Step 3: Set low and high range limits

Your low and high range limits are used by your meter to:

- Tell you when a test result is within, below or above the range limits set in the meter.
- Provide messages that let you know:
 - When you should treat a low blood glucose result.
 - Your progress staying within your blood glucose range.
 - When you have developed a pattern of blood glucose results below the low limit or above the high limit set in the meter.

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:

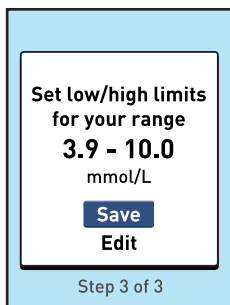
Be sure to talk to your healthcare professional about the low and high range limits that are right for you. When selecting or changing your limits, you should consider factors such as your lifestyle and diabetes therapy. Never make significant changes to your diabetes care plan without consulting your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

1 Set up your system

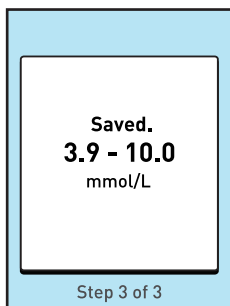
The meter is pre-set with a low limit of 3.9 mmol/L and a high limit of 10.0 mmol/L.

If the low and high range limits are correct, press **OK** to save.

If you need to edit the pre-set limits to fit your needs press **▲** or **▼** to highlight **Edit** and press **OK** (see page 22).



Saved will appear to confirm the low and high limits displayed are now stored in the meter.



Setup complete appears on the screen. Your meter is now ready for use.

After a few seconds, the Main Menu will appear on the screen. See page 34.






NOTE: If the meter was turned on by inserting a test strip, the **Apply Blood** screen appears instead of the Main Menu. See page 46.

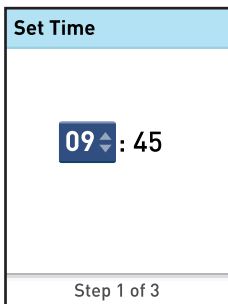
1 Set up your system

Edit pre-set time, date and range limits




Step 1: Edit the time

To change the time press  or  to set the hour and press .

Repeat this step to set the minutes.



When the time is correct, press .

If you need to make an adjustment, press  or  to highlight **Edit** and press , then repeat **Step 1**.






Set up your system **1**

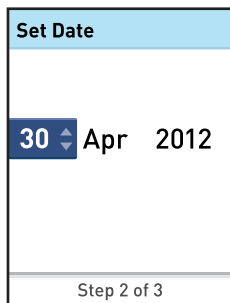
Saved will appear to confirm that the time displayed is now stored in the meter.



Step 2: Edit the date

To change the date press  or  to set the day and press .

Repeat this step to set the month and year.



1 Set up your system

When the date is correct, press **OK**.




If you need to make an adjustment, press **▲** or **▼** to highlight **Edit** and press **OK**, then repeat **Step 2**.



Saved will appear to confirm that the date displayed is now stored in the meter.





Step 3: Edit your low and high range limits

To change the pre-set **Low Limit** press  or  to the desired value between 3.3 mmol/L and 6.1 mmol/L and press .




Set Range

Low Limit

3.9   - **10.0**



mmol/L

Step 3 of 3

To change the pre-set **High Limit** press  or  to the desired value between 6.7 mmol/L and 16.7 mmol/L and press .

Set Range

High Limit

4.2 - **10.0**  

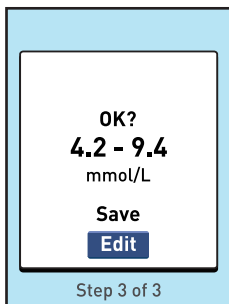
mmol/L

Step 3 of 3

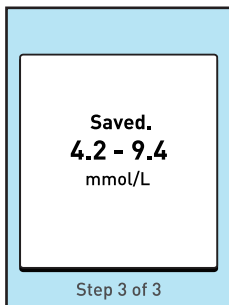
1 Set up your system

When your low and high range limits are correct, press **OK**.

If you need to make an adjustment, press **▲** or **▼** to highlight **Edit** and press **OK**, then repeat **Step 3**.



Saved will appear to confirm that the low and high limits displayed are now stored in the meter.



Setup complete appears on the screen. Your meter is now ready for use.

After a few seconds, the Main Menu will appear on the screen. See page 34.






NOTE: If the meter was turned on by inserting a test strip, the **Apply Blood** screen appears instead of the Main Menu. See page 46.

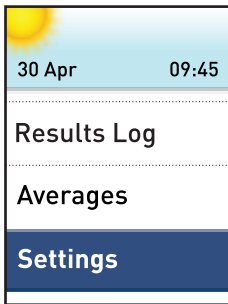
1 Set up your system

Adjust meter settings after first time setup

You can adjust the meter settings at any time. When you turn your meter on, the Main Menu is displayed after the start-up screen. A blue bar highlights the current selection on the meter display.

1. Get to the Settings screen

From the Main Menu, press  or  to highlight **Settings** and press .



2. Select the setting

Select the specific setting you want to modify and press **OK**.

To change your low or high limits, highlight **Tool Settings** and press **OK**, then select **Range** and press **OK**.



Settings
Time / Date
Language
Tool Settings
Meter Info


NOTE: For information on **Messages**, see page 68.

Once the setting you want to modify is displayed, the first entry on the screen will be highlighted.

1 Set up your system

3. Press  or  to change to your desired value, then press .

To skip a highlighted entry, simply press . Each time you press , the next entry on the screen will be highlighted.

For example, if you want to change the time, highlight **Time/Date** on the **Settings** screen and press .

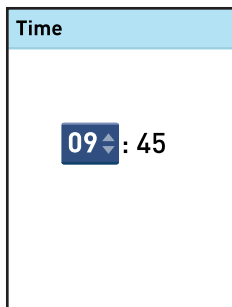
4. Next, highlight **Time** and press .

Time / Date
Time: 09:45
Date: 30 Apr 2012

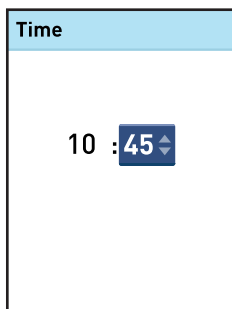
Example
Time Setting Change

The current time set in the meter is displayed.

5. Press  or  to change the hour and press .



6. Repeat this step to change the minutes.



1 Set up your system

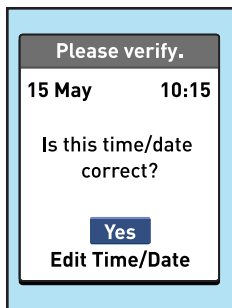
Once you have advanced through every entry on the setting screen, **Saved** will be displayed to confirm that your changes have been stored in the meter.



NOTE: To help ensure that the time and date in your meter are set correctly, once every 6 months a screen will prompt you to confirm the time and date set in the meter.

If they are correct, press **OK**. If not correct, press **▲** or **▼** to highlight **Edit Time/Date** and press **OK**. Follow the steps in page 28 to adjust the time and date. Once the time and date are set correctly, press **▲** or **▼** to highlight **Done** and press **OK**. After a few seconds, the Main Menu will appear on the screen.

If you turned the meter on by inserting a test strip, the **Apply Blood** screen will be displayed.






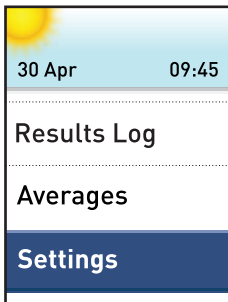
1 Set up your system

Check the meter serial number and software version

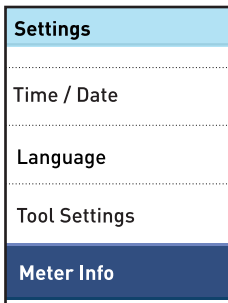
The meter serial number and software version are stored in your meter. You can check this information at any time.

1. Get to the Meter Info screen

From the Main Menu, press  or  to highlight **Settings** and press .



2. Select Meter Info and press



The meter information is displayed.

Meter Info
Serial #: 12345678
Software: 0X40000_000
Units: mmol/L

3. Press to return to the Settings screen

Turn the meter off after setup.

There are two ways to turn your meter off:

- Press and hold  for several seconds until the meter turns off.

Or,

- Your meter will turn off by itself if left alone for two minutes.

2 Take a test

Test your blood glucose

NOTE: Many people find it helpful to practise testing with control solution before testing with blood for the first time. See page 59.

Preparing for a test

Have these things ready when you test:

OneTouch® Verio® 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® System is required.
- 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 or control solution 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.

IMPORTANT: If another person assists you with testing, the meter, lancing device and cap should always be cleaned and disinfected prior to use by that person. See page 92.

2 Take a test

⚠CAUTION:

- The OneTouch® Verio® 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® System 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 Care immediately if the test strip vial is damaged. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).
- 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 expiry date (printed on the vial) or the discard date, whichever comes first, or your results may be inaccurate.

OneTouch® Delica® Lancing Device



NOTE: The OneTouch® Delica® Lancing Device uses ONLY OneTouch® Delica® Lancets.

If the lancing device shown here is different from the device included in your kit, please see the separate insert for your lancing device.

2 Take a test

NOTE:

- The OneTouch® Verio® Blood Glucose Monitoring System has not been evaluated for Alternate Site Testing (AST). Use only fingertips when testing with the system.
- The OneTouch® Delica® Lancing System does not include the materials needed to perform Alternate Site Testing (AST). The OneTouch® Delica® Lancing System should not be used on the forearm or palm with the OneTouch® Verio® Blood Glucose Monitoring System.

⚠CAUTION:

To reduce the chance of infection:

- 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 92).
- 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!

Getting a blood sample from the fingertip

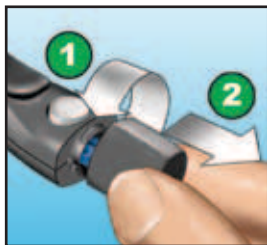
Choose a different puncture site each time you test.

Repeated punctures in the same spot may cause soreness and calluses.

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

1. Remove the lancing device cap

Remove the cap by turning it counterclockwise and then pulling it straight off of the device.



2 Take a test

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.

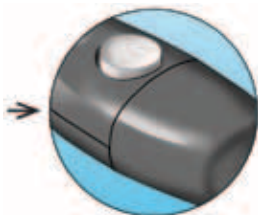


Twist the protective cover one full turn until it separates from the lancet. **Save the protective cover for lancet removal and disposal.** See page 56.

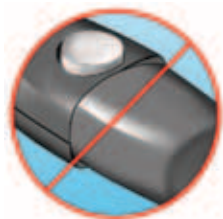


3. Replace the lancing device cap

Place the cap back onto the device; turn clockwise to secure the cap.



Do Not overtighten.



2 Take a test

4. Adjust the depth setting

The lancing device has seven puncture depth settings, numbered 1 through 7.

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. Turn the depth wheel to choose the setting.



NOTE: A shallower fingertip puncture may be less painful. 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.

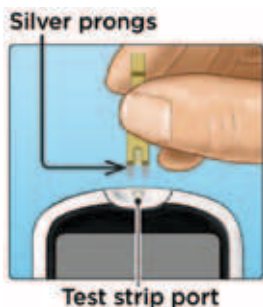
5. Prime the lancing device

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

**6. Insert a test strip to turn the meter on**

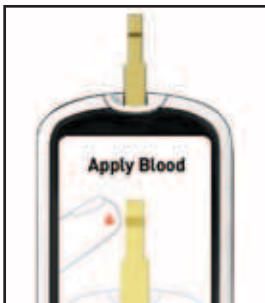
Insert a test strip into the test strip port with the gold side of the test strip and the two silver prongs facing you.

No separate step to code the meter is required.



2 Take a test

When the **Apply Blood** screen appears on the display, you can apply your blood sample to either side of the test strip.



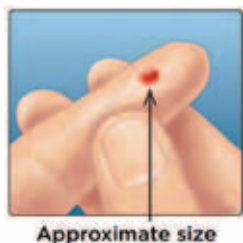
7. Puncture your finger

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



8. Get a round drop of blood

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



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.



2 Take a test

Applying blood and reading results

1. Apply the sample to the test strip

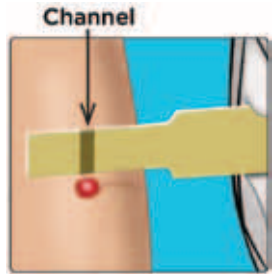
You can apply blood to either side of the test strip.

Apply your sample to the opening of the channel.

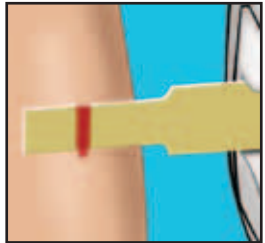
Be sure to apply your sample immediately after you get a drop of blood.



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.



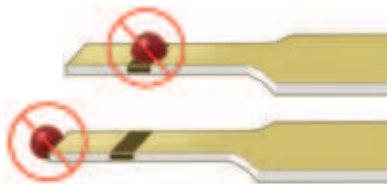
2 Take a test

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.



- **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.

3. Read your result on the meter

Your blood glucose result appears on the display, along with the unit of measure, and the date and time of the test.

If mmol/L does not appear with the blood glucose result, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).



Example

⚠ CAUTION:

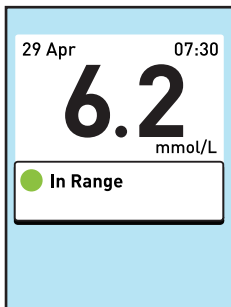
If **Ⓢ Control solution** appears on the screen when testing your blood glucose, repeat the test with a new test strip. If the problem persists, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).

2 Take a test

Know whether your current glucose test result is within, below or above your range

When your blood glucose result is displayed after a test, the meter will display a colour-coded dot to tell you if your result is within range, below your low limit or above your high limit set in the meter. See page 19 and page 28.

-  **In Range**
-  **Below Range**
-  **Above Range**




Example
In Range Result


The OneTouch® Verio® Meter scans your test results and displays messages to let you know how you are progressing and help you better manage your diabetes. These messages are automatically displayed on the screen with your test result when certain conditions are met. See page 68 for more information on messages.

After getting a blood glucose result

Once you have your blood glucose result, you may:

- Press and hold  to return to the Main Menu.

Or,

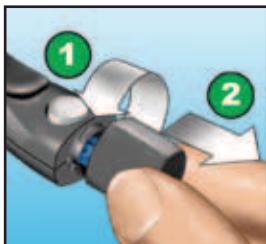
- Press and hold  for several seconds until the meter turns off. The meter will also automatically turn off if left alone for two minutes.

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

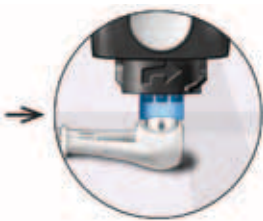
Remove the cap by turning it counterclockwise and then pulling it straight off of the device.



2 Take a test

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 cupped side of the cover.



3. Eject the lancet

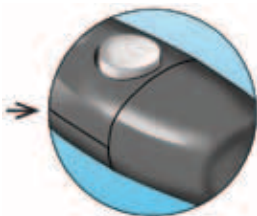
Slide the ejection control forward until the lancet comes out of the lancing device. Return the ejection control to its back position.

If the lancet fails to eject properly, prime the device again and then slide the ejection control forward until the lancet comes out.

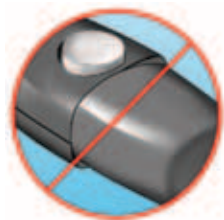


4. Replace the lancing device cap

Place the cap back onto the device; turn clockwise to secure the cap.



Do Not overtighten.



It is important to use a new lancet each time you obtain a blood sample. This will help prevent infection and sore fingertips.

2 Take a test

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.

Interpreting unexpected test results

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

⚠CAUTION:

Low blood glucose results

If your blood glucose result is below 3.9 mmol/L or is shown as **EXTREME LOW GLUCOSE**, (meaning the result is less than 1.1 mmol/L), it may mean hypoglycaemia (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.

⚠CAUTION:**Dehydration and low blood glucose results**

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

High blood glucose results

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

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

2 Take a test

⚠CAUTION:

Repeated unexpected blood glucose results

If you continue to get unexpected results, check your system with control solution. See page 59.

If you are experiencing symptoms that are not consistent with your blood glucose 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 programme without speaking to your healthcare professional.

Unusual red blood cell count

A haematocrit (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.

Test with control solution

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® 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.

2 Take a test

⚠CAUTION:

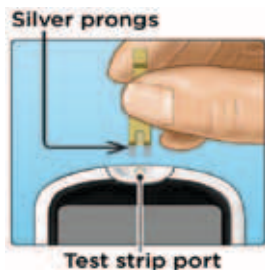
- **Do Not** swallow or ingest control solution.
- **Do Not** apply control solution to the skin or eyes as it may cause irritation.
- **Do Not** use control solution after the expiry date (printed on the vial label) or the discard date, whichever comes first, or your results may be inaccurate.

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.

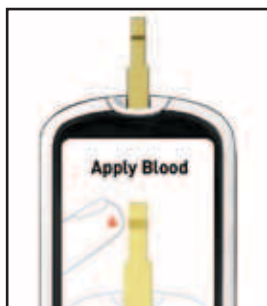
Performing a control solution test

1. Insert a test strip to turn the meter on



Wait for the **Apply Blood** screen to appear on the display.

NOTE: The same **Apply Blood** screen that appears during a blood glucose test also appears during a control solution test.



2 Take a test

2. Prepare the control solution

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

Squeeze the vial to discard the first drop.



Example
OneTouch® Verio® Mid
Control Solution

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



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



3. Apply the control solution

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



Touch the channel on the side of the test strip to the control solution. Wait for the channel to fill completely.



2 Take a test

4. Read your result

The meter will count down from 5 to 1. Your result is displayed along with the date, time, unit of measure, and **C Control solution**.

The meter automatically marks the result as a control solution test.



Example

⚠CAUTION:

If the words **Control solution** do not appear on the screen, this result will be included in your averages and your averages will change too. Repeat the test with a new test strip. If the problem persists, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).

5. Check 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.



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


2 Take a test

Out-of-range results may be due to:


- Not following the instructions beginning on page 61.
- 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 (see Step 2).

After getting a control solution result

Once you have a control solution result, you may:

- Press and hold  to return to the Main Menu.

Or,

- Press and hold  for several seconds until the meter turns off. The meter will also automatically turn off if left alone for two minutes.

6. Cleaning

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

Control solution results can be seen when reviewing past results, but are not included in result averages.

⚠ 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 Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).
- The control solution range printed on the control solution vial is for control solution tests only **and is not a recommended range for your blood glucose level.**

3 View messages that appear with your test results

The OneTouch® Verio® Meter scans your test results and automatically displays messages that can help you and your healthcare professional make changes to your diabetes care plan when necessary.

These messages can make it easy for you to:

- know when to take action,
- view your progress in managing your diabetes, and
- see if your glucose is regularly running above or below your range at about the same time of day.

View messages that appear with your test results **3**

The following types of messages may be displayed on the screen with your test result:

- **Treat Low Result** - a prompt that tells you to treat a low blood glucose result.
- **Progress Notes** - informs you about the progress you are making in managing your diabetes and how often your blood glucose results are in range.
- **Pattern Messages** - help guide you back in range by letting you know when your results have been repeatedly above or below the range set in your meter at about the same time of day.
- **7 Day Average** - the average of all blood glucose results over the past 7 days.

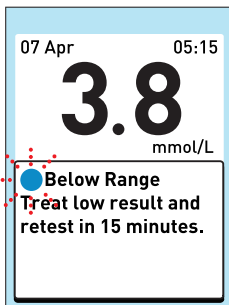
For the Treat Low Result, Progress Notes and Pattern messages to appear, each message type must be turned on (see page 81). The 7 Day Average message is always on and cannot be turned off.

3 View messages that appear with your test results

View a Treat Low Result message

Your meter can prompt you to treat a low blood glucose level whenever your current test result is below the low limit set in the meter (see page 19 and page 28).

When appropriate, the **Treat Low Result** message automatically appears below your test result and the blue dot will blink.



NOTE: The **Treat Low Result** message must be turned on for this message to be displayed (see page 81).

⚠CAUTION:

A **Treat Low Result** message may not appear every time your result is below the low limit. **If your result is below the low limit and is also part of a low pattern, a Low Pattern message (see page 74) will appear instead of the Treat Low Result message.** Whenever a **Low Pattern** message is displayed, you should follow your healthcare professional's advice for treating a low blood glucose result.

View messages that appear with **3** your test results

View a **Progress Note**

The OneTouch® Verio® Meter helps you see your success in achieving in-range results with two types of Progress Notes: a Consistency message and an Achievement message.

When appropriate, Progress Notes appear below your test result.

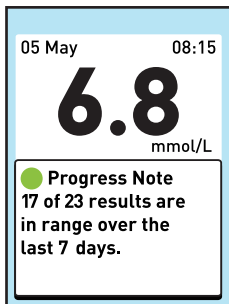
3 View messages that appear with your test results

Consistency Message

This type of Progress Note lets you know how many of your results have been within range over a 7 day period.

A Consistency message is displayed when:

- Your current result is in range, and
- You have tested at least 2 times in the past 7 days, and
- 70% or more of your results over the past 7 days have been in range, and
- No other Consistency message has been displayed during the past 7 days.



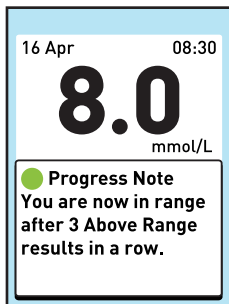
Example
Consistency Message

The OneTouch® Verio® Meter scans your results over the last 7 days and displays a Consistency message only when these 4 criteria are met. The meter will continue to scan your results over future 7 day periods and display a Consistency message when appropriate.

View messages that appear with your test results **3**

Achievement Message

The Achievement message is displayed when an in-range glucose result follows a series of 3 or more consecutive results that were above the high limit set in your meter.



NOTE:

- The **Progress Note** (Consistency and Achievement) message must be turned on for these messages to be displayed (see page 81).
- If a blood glucose result triggers both an Achievement and a Consistency message, only the Achievement message will be displayed.

3 View messages that appear with your test results

View a Pattern message

Low and High Pattern messages appear when the meter identifies a pattern of glucose results that fall outside the low and high limits you set on page 19 and page 28.

Pattern messages provide information from past results and may help you to identify a need to consider making therapy or lifestyle adjustments. Always consult your healthcare professional before making significant changes to your diabetes care plan.

Every time you test your blood glucose, your OneTouch® Verio® Meter searches for any new patterns that have developed over the past 5 days. Patterns are identified based on whether results were below/above the low/high limits set in your meter, and the time of day the tests were taken. For a group of results to be considered a pattern, the time of day for those results must be within 3 hours of each other.

When appropriate, Pattern messages automatically appear below your test result.

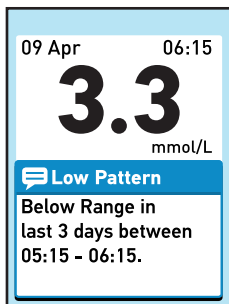
NOTE: Pattern messages must be turned on for these messages to be displayed (see page 81).

View messages that appear with your test results **3**

A **Low Pattern** message appears when your meter spots 2 results that are:

- Below the low limit,
- Over 5 consecutive days, and
- From the same time of day (within 3 hours)

A **Low Pattern** message indicates that your current test result is below the low limit set in your meter. Whenever a **Low Pattern** message is displayed, you should follow your healthcare professional's advice for treating a low blood glucose result.



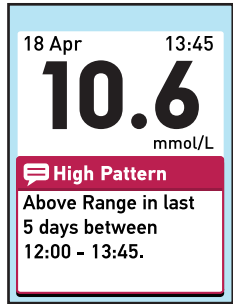
Example
Low Pattern Message

3 View messages that appear with your test results

A **High Pattern** message appears when your meter spots 3 results that are:

- Above the high limit,
- Over 5 consecutive days, and
- From the same time of day (within 3 hours)

Once a result is included in a Pattern message, it will not be included in future Pattern messages.



Example
High Pattern Message

View messages that appear with your test results **3**

NOTE: To be sure that Low/High Pattern messages appear whenever appropriate:

- Pattern messages must be turned on (see page 81).
- Be sure the time and date are set correctly and update if you change time zones, or if the time changes to or from daylight saving time.
- Test your blood glucose using only this meter. Using different meters may cause you to miss patterns.
- Test when you are feeling high or low.

3 View messages that appear with your test results



CAUTION:



- **Do Not** use Pattern messages to make immediate and/or significant changes to your diabetes care plan without first consulting your healthcare professional.
- **Do Not** wait for Pattern messages to treat low or high results. Always use your current result for immediate treatment decisions.
- Low and High Pattern messages are based on the low and high limits you set in the meter (see page 19 and page 28). These Messages are different from **EXTREME HIGH GLUCOSE** and **EXTREME LOW GLUCOSE** Warnings that appear whenever your blood glucose level is above 33.3 mmol/L or below 1.1 mmol/L.
- Changing your low/high limits will affect your Pattern messages. When you change either limit, only blood glucose results taken after the change will be used to detect new Low/High Patterns.
- **Do Not** allow other people to use your meter as your patterns may be affected.

View messages that appear with your test results 3

Reviewing results that create low and high patterns

You can review the individual results that combine to create a Low or High Pattern by reviewing the **Results Log** in your meter (see page 86).

The  icon will appear beside each result that is part of a **Low Pattern**. The  icon will appear beside each result that is part of a **High Pattern**.

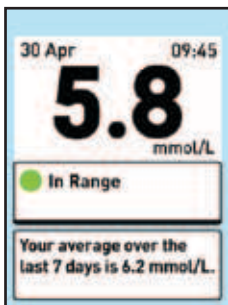
Results Log	
mmol/L	
30 Apr 11:52	 10.1
29 Apr 22:45	5.4
29 Apr 07:30	6.4
28 Apr 10:12	 24.7

Blinking icons will appear next to the results that are part of your most recent pattern.

3 View messages that appear with your test results

View a 7 Day Average message

Your 7 Day Average will be shown when there is no **Treat Low Result, Progress Note or Pattern** message displayed with your glucose result. Your 7 Day average will appear below your test result.






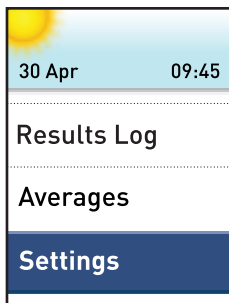
NOTE: Your 7 Day average message only appears with a result that is in your range (In Range ●) and when there have been at least 2 glucose tests taken during the most recent 7 day period.

View messages that appear with your test results 3

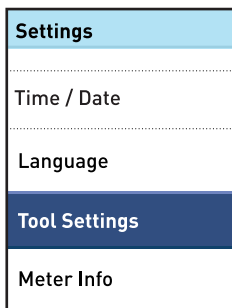
Turn Messages off (or on)

1. Get to the Messages On/Off screen

From the Main Menu, press  or  to highlight **Settings** and press .



Press  or  to highlight **Tool Settings** and press .



3 View messages that appear with your test results

Press  or  to highlight **Messages On/Off** and press .

Tool Settings
Range: 4.2 – 9.4 mmol/L
Messages On/Off





2. Select the type of message you want to turn off (or on)

Press  or  to highlight **Treat Low Result, Progress Note** or **Pattern** and press .


Messages On/Off
Treat Low Result: On
Progress Note: On
Pattern: On

View messages that appear with your test results **3**


3. Turn the Message off (or on)

Press  or  to highlight **Off** if you do not want to receive this type of message (**Treat Low Result** message example) and press . If you want to keep this message type on, press  with **On** highlighted.

You will return to the **Messages On/Off** screen.

Treat Low Result
 On
Off
Turn On to get Treat Low Result messages when below range.

Example
Treat Low Result
message **On**

Treat Low Result
 On
Off
Turn Off to stop Treat Low Result messages when below range.

Example
Treat Low Result
message **Off**

3 View messages that appear with your test results

IMPORTANT: For the **Treat Low Result**, **Progress Note** and **Pattern Message** to appear with your results, each message type must be turned on.

Repeat Steps 2 and 3 to turn the **Progress Note** and **Pattern Message Off** (or **On**).

4. When finished, press and hold  to return to the Main Menu

**View messages that appear with
your test results** **3**




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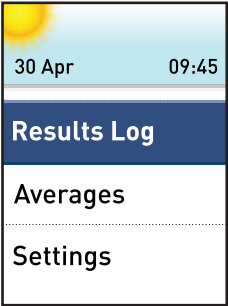
4 Review past results and averages

Your meter stores your most recent 500 blood glucose and control solution test results and displays them in several ways.

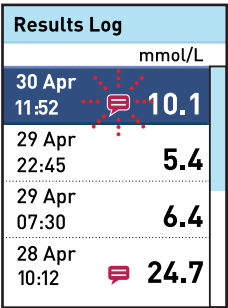
Review your past results

1. Get to the Results Log





From the Main Menu, press  or  to highlight **Results Log** and press .




Up to four results are displayed on the screen, starting with the most recent.



2. Scroll through your results

Press  to move backward and  to move forward through your results. Pressing and holding  or  allows you to move more quickly.


Press  to return to the Main Menu.


The following symbols may also appear:

HI if the blood glucose result was above 33.3 mmol/L

LO if the blood glucose result was below 1.1 mmol/L

 if the result is from a control solution test (see page 59)

 if the blood glucose result is part of a low pattern (see page 74)

 if the blood glucose result is part of a high pattern (see page 74)

NOTE: The pattern icon () will blink when the result is part of your most recent pattern.

4 Review past results and averages




Other notes will appear in the **Results Log** to indicate when you have made changes to your low and high range limits.

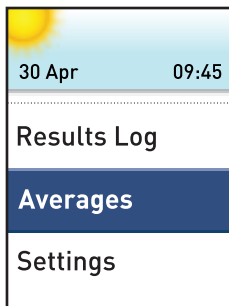
Results Log	
	mmol/L
26 Apr 22:45	6.1
Range changed to: 4.4 - 8.3	
25 Apr 21:36	6.7
25 Apr 08:25	3.4

Example
Range (low/high
limits) change


View your averages

1. Get to the Averages screen

From the Main Menu, press  or  to highlight **Averages** and press .



For each of the 7, 14, 30 and 90 day periods leading up to the current date, the meter displays the number of results and the average of those results.

Press  to return to the Main Menu.

Averages	
	mmol/L
7 Days	
57 Results	6.4
14 Days	
133 Results	8.9
30 Days	
242 Results	10.6
90 Days	
500 Results	7.2

NOTE: Averages are calculated only when there are at least 2 blood glucose results for the time period being averaged.

4 Review past results and averages

If you do not have results in the past 7, 14, 30 and 90 day periods, the number next to **Results** will be zero and dashes will appear in the mmol/L column.

In result Averages, Progress Notes and Low/High Pattern messages, an **EXTREME HIGH GLUCOSE** result is always counted as 33.3 mmol/L, and an **EXTREME LOW GLUCOSE** result is always counted as 1.1 mmol/L. (See page 56 for more information on low and high blood glucose results.)

NOTE: The meter calculates averages based on the 7, 14, 30 and 90 day periods ending on the current date setting. If you change your date setting, your averages may change too.

Result averages provide information from past results.

Do Not use result averages to make immediate treatment decisions. Always consult your healthcare professional before making significant changes to your diabetes care plan.

⚠CAUTION:

Do Not allow other people to use your meter as it may affect your averages.

Downloading results to a computer

OneTouch® Diabetes Management Software (DMS) can store all of your records and help you spot patterns for planning meals, exercise, insulin dosing and medication. Contact us to learn more about OneTouch® DMS and to order the software. Call OneTouch® Customer Care on 0800 121 200 (UK) 1800 535 676 (Ireland) during the hours of 08:30 - 18:00 Monday - Friday 09:00 - 13:00 Saturday. Or visit www.LifeScan.co.uk.

To transfer meter data, follow the instructions provided with the OneTouch® DMS to download the results from the meter. You will need a standard micro USB interface cable to connect your OneTouch® Verio® 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 **PC Connected** indicating that the meter is in communication mode.

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



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 93 and for disinfecting information, see page 95.

Cleaning your meter, lancing device and cap

The meter and lancing device should be cleaned whenever they are visibly dirty. 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 12.)
- **Do Not** spray cleaning solution on the meter or immerse it in any liquid.



5 Care and maintenance

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.

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.

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

Hold the meter with the test strip port pointed down.

Use a soft cloth dampened with this solution 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.



After wiping, cover the surface you are disinfecting with the soft cloth dampened with the bleach solution for 1 minute.

5 Care and maintenance

Then wipe with a clean, damp, soft cloth and allow to air dry.



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

If you see signs of wear, please contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).

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6

Batteries

Your OneTouch® Verio® Meter uses two AAA alkaline batteries. See Troubleshooting, page 110 and page 111, for information on when to change the meter batteries.

If the meter does not turn on, check the batteries.

IMPORTANT: Use only AAA alkaline batteries with your meter. **Do Not** use rechargeable batteries. Use of an incorrect battery type or the replacement of only one battery may result in your meter providing fewer tests than normal.

⚠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.

Replacing the batteries

1. Remove the old batteries

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



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



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

6 Batteries

2. Insert the new batteries

Insert two AAA alkaline batteries on top of the battery 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, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).



3. Check your meter settings

Removing the meter batteries will not affect your stored results. However, you may need to check your meter settings. See page 28.

4. Dispose of batteries

Dispose of batteries according to your local environmental regulations.

7

Troubleshooting

The OneTouch® Verio® 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 Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).



Warning

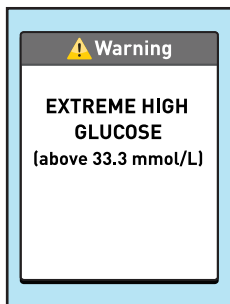
**EXTREME LOW
GLUCOSE**
(below 1.1 mmol/L).
Treat low result
and retest in
15 minutes.

What it means

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

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 hyperglycaemia), over 33.3 mmol/L.

What to do

Re-test your blood glucose level.

If the result is **EXTREME HIGH GLUCOSE** again, obtain and follow instructions from your healthcare professional right away.

7 Troubleshooting



Warning

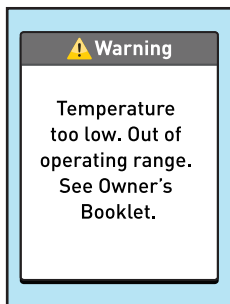
Temperature too high. Out of operating range.
See Owner's Booklet.

What it means

Meter is too hot (above 44°C) to work correctly.

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 **Temperature too high** message, you can proceed with testing.



What it means

Meter is too cold (below 6°C) to work correctly.

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 **Temperature too low** message, you can proceed with testing.

7 Troubleshooting



Error 1

Meter problem.
Contact Customer
Service.

What it means

There is a problem with the meter.

What to do

Do Not use the meter. Contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).



Error 2

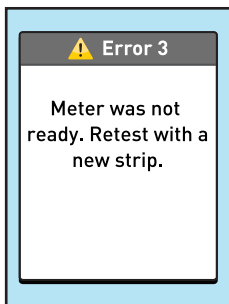
Meter or strip
problem. Retest
with a new strip.

What it means

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

What to do

Repeat the test with a new test strip; see page 48 or page 59. If this message continues to appear, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).



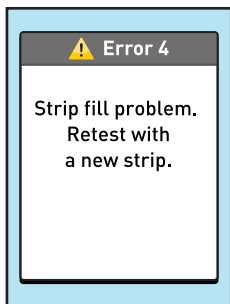
What it means

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 **Apply Blood** appears on the display. If this message continues to appear, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).

7 Troubleshooting



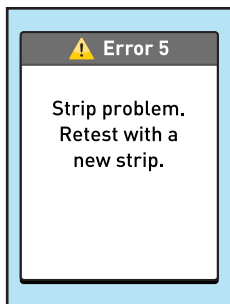
What it means

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 48 or page 59. If the error message appears again, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).



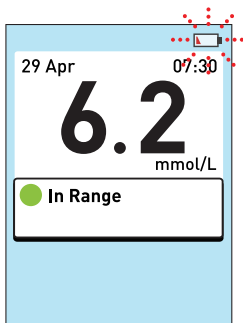
What it means

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 48 or page 59. If the error message appears again, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI).

7 Troubleshooting

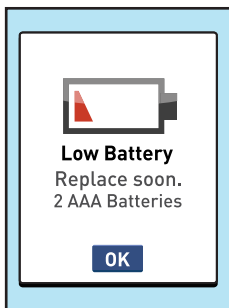


What it means

Battery power is low but there is still enough power to perform a test.

What to do

Once the Low Battery icon is displayed, it will continue to appear until you replace the batteries. Test results will still be accurate, but replace the batteries as soon as possible (see page 98).

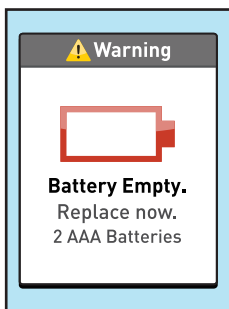


What it means

Battery power is low but there is still enough power to perform a test.

What to do

Press **OK** to continue but replace the batteries as soon as possible.



What it means

There is not enough battery power to perform a test.

What to do

Replace both batteries immediately.

7 Troubleshooting

Results Log




No Results

What it means

No result in memory, such as the first time use of the meter or after downloading all data to a computer.

What to do

Contact Customer Care to report this occurrence, **unless** this is your first use of the meter. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI). You can still perform a blood glucose test and get an accurate result.

Results Log		
		mmol/L
30 Apr 11:52		10.1
29 Apr 10:45		---
29 Apr 07:30		6.4
28 Apr 10:12		24.7

What it means

Your meter was unable to recall this result. This result will not be included in result averages.

What to do

Contact Customer Care to report this occurrence. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (ROI). You can still perform a blood glucose test and get an accurate result.

8 Detailed information about your system

Comparing meter results to laboratory results

Results obtained from the OneTouch® Verio® 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® Meter is considered accurate when it is within $\pm 20\%$ of the lab result.

Meter results can be affected by factors that do not affect lab results in the same way, which may cause a difference of more than $\pm 20\%$. Specific factors that may cause your meter result to vary from your lab result by more than $\pm 20\%$ 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 haematocrit is above 60% or below 20%.
- You are severely dehydrated.
- For additional information, refer to the OneTouch® Verio® Test Strip Insert.

¹Sacks, 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 comparisons:

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® 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.

8 Detailed information about your system

Technical Specifications

Assay method	FAD-GDH (glucose dehydrogenase)
Automatic shutoff	Two minutes after last action
Battery ratings	2 x 1.5V d.c. (2 x AAA alkaline batteries), == direct current
Battery type	Two replaceable AAA alkaline batteries
Calibration	Plasma-equivalent
Memory	500 test results
Operating ranges	Temperature: 6-44°C Relative humidity: non-condensing 10-90% Altitude: up to 3048 meters Haematocrit: 20-60%
Reported result range	1.1-33.3 mmol/L
Sample	Fresh capillary whole blood
Sample volume	0.4 µL
Size	2.52 x 5.18 x 8.00 cm
Test time	5 seconds
Unit of measure	mmol/L
Weight	Approximately 85 grams

Analytical Performance Characteristics

System Accuracy

Diabetes experts have suggested that glucose meters 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.

This level of accuracy has been demonstrated in studies with the OneTouch® Verio® Family of Blood Glucose Monitoring Systems (data on file). Samples from 100 patients were tested using both the OneTouch® VerioVue™ System and the YSI 2300 Glucose Analyzer laboratory instrument. This data is representative of system accuracy for the OneTouch® Verio® Family of Blood Glucose Monitoring Systems as performance of the systems is equivalent (data on file).

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
35.1% (59/168)	84.5% (142/168)	99.4% (167/168)

8 Detailed information about your system

System Accuracy Results for Glucose Concentrations ≥ 5.55 mmol/L

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

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
65.0% (281/432)	94.2% (407/432)	99.3% (429/432)

System Accuracy Results for Glucose Concentrations between 1.7 mmol/L and 24.9 mmol/L

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

Within ± 0.83 mmol/L or $\pm 15\%$
99.3% (596/600)

NOTE: Where 1.7 mmol/L represents the lowest glucose reference value and 24.9 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® System compares well with a laboratory method.

Number of Subjects	Number of Tests	Slope	Intercept (mmol/L)
100	600	0.97	0.32

95% CI Slope	95% CI Intercept (mmol/L)	Std. Error ($S_{y,x}$) (mmol/L)	R ²
0.96 to 0.98	0.23 to 0.41	0.56	0.99

User Performance Evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 172 lay persons showed the following results:

88.9% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L, and 98.5% within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

This data is representative of all lay-user OneTouch® Verio® Family Blood Glucose Monitoring Systems as performance of the systems is equivalent. This clinical accuracy data was generated using the OneTouch® VerioVue™ Meter (Data on file).

8 Detailed information about your system

Precision

This precision data was generated using the OneTouch® VerioVue™ Meter. This data is representative of all lay user OneTouch® Verio® Family Blood Glucose Monitoring Systems as performance of the systems is equivalent (data on file).

Within Run Precision (300 venous blood tests per glucose level)

Target Glucose (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (%)
2.2	2.7	0.06	2.11
5.6	6.1	0.11	1.89
7.2	7.9	0.15	1.89
11.1	12.1	0.21	1.73
19.4	20.7	0.45	2.17

Results show that the greatest variability observed between test strips when tested with blood is 2.17% or less.

Detailed information **8** about your system

Total Precision (600 results at each control solution level)

Glucose Level Ranges (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (%)
Low (1.7-2.8)*	2.12	0.05	2.47
Mid (5.3-8.0)*	6.47	0.12	1.79
High (15.6-23.3)*	18.91	0.40	2.11

NOTE: ISO 15197:2013(E) stipulates the following glucose ranges for intermediate precision: 1.7-2.8 mmol/L, 5.3-8.0 mmol/L and 15.6-23.3 mmol/L. Testing was carried out to meet the target mid-points of these requirements.

8 Detailed information about your system

Guarantee

LifeScan guarantees that the OneTouch® Verio® 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 Level 3 electrostatic discharge as specified in IEC 61000-4-2. This meter complies with immunity to radio frequency interference over the frequency range 80 MHz to 2.5 GHz at 3V/m as specified in IEC 61000-4-3.

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

Use of this meter near electrical or electronic equipment that are sources of electromagnetic radiation, may interfere with proper operation of this meter. It is advisable to avoid testing in close proximity to sources of electromagnetic radiation.

Common sources of electromagnetic radiation includes mobile phones, walkie talkies or garage door openers.

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

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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, and 7,846,312. Use of the monitoring device included herein is protected under the following U.S. patent: 6,413,410, 6,890,421, 8,163,162, 7,749,371. Purchase of this device does not act to grant a use license under this patent. Such a license is granted only when the device is used with OneTouch® Verio® Test Strip. 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.

If you have questions about the use of any OneTouch® product, contact Customer Care on 0800 121 200 (UK) 1800 535 676 (ROI).


If you cannot reach Customer Care, contact your healthcare professional for advice.

LifeScan self-test blood glucose monitoring devices conform to the following EU Directives:

IVDD (98/79/EC):

 Blood Glucose Meter, Test Strips, and Control Solution
0344

MDD (93/42/EEC):

 Lancing System
0120

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