ONETOUCH

Select *Plus* Simple®

Blood Glucose Monitoring System

Owner's Guide

Instructions for Use

Simply insert a test strip to turn the meter on and begin testing.

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

IVDD (98/79/EC):

CE 0344 Blood Glucose Meter, Test Strips, and Control Solution

MDD (93/42/EEC):

CE 1639 Lancets

CE Lancing Device

LifeScan Europe GmbH
Gubelstrasse 34
6300 Zug
Switzerland

Kindly contact Customer Care at 1800 225544 or visit www.OneTouch.in.

Meter Made in China

Rev. Date: 02/2020

Lifescan™

AW 07262801A

Table of contents

Meter symbols and icons


Low battery


Battery empty


History mode (last result)


Apply sample


Range Indicator Arrow

Other symbols and icons


Cautions and Warnings: Refer to the Owner's Guide 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

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.

Before you begin

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

Intended use

The OneTouch Select Plus Simple® 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 Select Plus Simple® 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 Select Plus Simple® Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes or for neonatal use.

The OneTouch Select Plus Simple® Blood Glucose Monitoring System is not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients.

Test principle

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

1 Getting to know your system

Your OneTouch Select Plus Simple® Blood Glucose Monitoring System

Included with your kit:

OneTouch Select Plus Simple® Meter (CR2032 lithium coin cell battery included)

Lancing device

Lancets

NOTE: If any item is missing or defective in your kit, contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Guide.

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

Available separately:

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

Use only OneTouch Select® Plus Control Solutions and Test Strips with the OneTouch Select Plus Simple® Meter.

OneTouch Select® Plus Mid Control Solution*

OneTouch Select® Plus Test Strips*

Lancets*

*Lancets, OneTouch Select® Plus Control Solution and Test Strips are available separately. For availability of lancets, test strips and control solution, contact Customer Care or your 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 Select Plus Simple® Blood Glucose Monitoring System

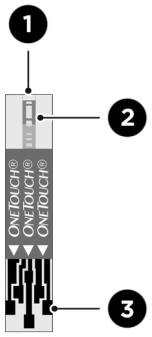
Meter

1	Test strip port
2	Battery icon
3	Last result icon
4	mg/dL is the pre-set unit of measure

5	Colour Range Indicator Bars
6	Range Indicator Arrow
7	Display
8	Serial number
9	Battery cover

Getting to know your OneTouch Select® Plus Test Strip

Test strip



1	Edge to apply sample
2	Confirmation window
3	Contact bars Insert into test strip port

The Range Indicator feature

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

A Range Indicator Arrow will appear just below your result after each test.

Range Indicator

Low	In range	High
▼	▼	▼

Colour Range Indicator Bars

(Blue)	*(Green)*	*(Red)*
Below range	In range	Above range

Example
In range result

For details about the Range Indicator, see *"Viewing your result"* in Section 2.

2 Blood glucose testing

Test your blood glucose

Preparing for a test

Have these things ready when you test:

OneTouch Select Plus Simple® Meter

OneTouch Select® Plus Test Strips

Lancing device

Sterile lancets

NOTE:

- Use only OneTouch Select® Plus Test Strips.
- Make sure your meter and test strips are about the same temperature before you test.
- **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.
- Keep test strips in a cool, dry place between 5°C and 30°C.
- **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, especially in high humidity environments.
- 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.
- **Do Not** test with a test strip that is bent or damaged.
- 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.

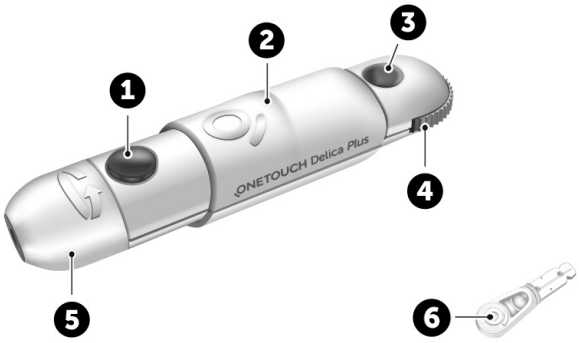
⚠***IMPORTANT:*** If another person assists you with testing, the meter, lancing device and cap should always be cleaned and disinfected prior to use by that person. See *"Cleaning and disinfection"* in Section 4.

NOTE: 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 *"Comparing meter results to laboratory results"* in Section 7.

⚠CAUTION:

- **Do Not** use the OneTouch Select Plus Simple® System when PAM (Pralidoxime) is known or suspected to be in the patient's whole blood sample, as it may cause inaccurate results.
- A haematocrit (percentage of your blood that is red blood cells) that is either very high (above 55%) or very low (below 30%) can cause false results.
- **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 information for Customer Care is listed at the end of this Owner's Guide.
- 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.
- **Do Not** use test strips after the expiry date printed on the vial.

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

Lancing precautions

⚠CAUTION:

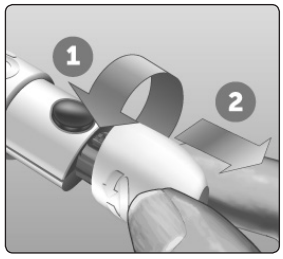
To reduce the chance of infection and disease spread by blood:

- 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 *"Cleaning and disinfection"* in Section 4).
- **Do Not** use lancets after the expiry date printed on the lancet packaging.

Preparing your lancing device

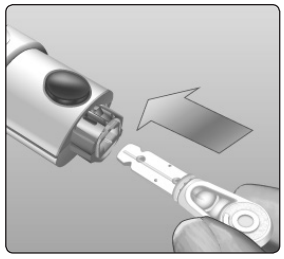
1. Remove the lancing device cap

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

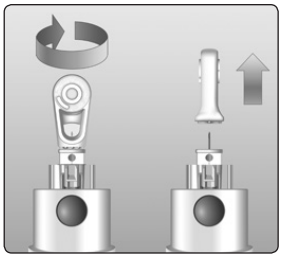


2. Insert a sterile lancet into the lancing device

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.



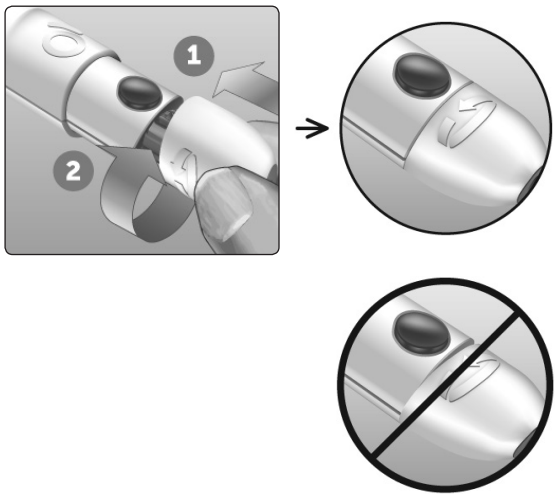
Twist the protective cover one full turn until it separates from the lancet. **Save the protective cover for lancet removal and disposal.** See *"Removing the used lancet".*



3. Replace the lancing device cap

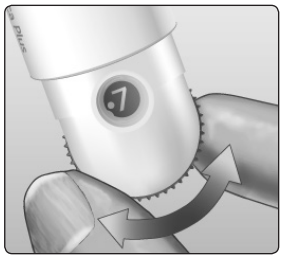
Place the cap back onto the device; turn the cap or push the cap straight on to secure it.

Ensure the cap is aligned as shown in the image.



4. Adjust the depth setting

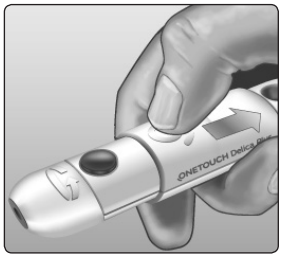
The device has 13 puncture depth settings (each dot shown between numbers 1 to 7 on the Depth Wheel indicates an additional available depth setting). Adjust the depth by turning the depth wheel. Smaller numbers are for a shallower puncture and larger numbers for a deeper puncture.



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

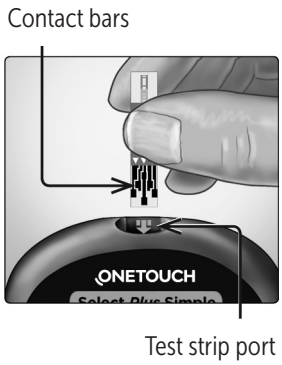
Pull the slider back until it clicks. If it does not click, it may already have been cocked when you inserted the lancet.



Prepare the meter and view the last result

1. Insert a test strip to turn the meter on

Insert a test strip into the test strip port with the contact bars facing you.



A start-up screen will appear for a few seconds. All segments shown here should appear briefly on the display, indicating your meter is working properly.

⚠CAUTION:

If any segments shown here are missing in the start-up screen, there may be a problem with the meter. Contact Customer Care.

If the meter does not power on, check the battery. See *"Replacing the battery"* in Section 5.

Your last result will then appear and the last result icon will blink (). If this is your first time using the meter, dashes will appear instead of a result. See *"Error and other messages"* in Section 6.

Next, the flashing blood drop icon () will appear on the display. You can now apply your blood sample to the test strip.

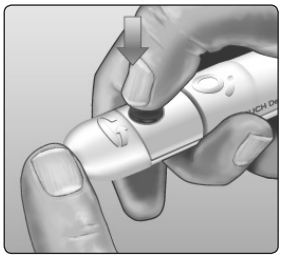
Sampling blood from the fingertip

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.

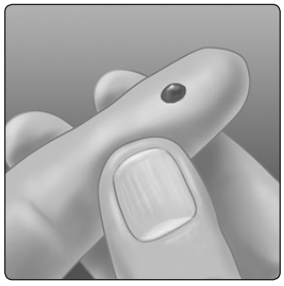
1. Puncture your finger

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

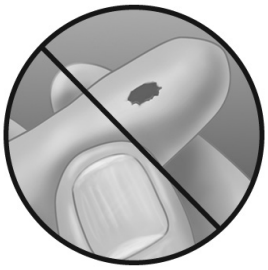


2. Get a round drop of blood

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

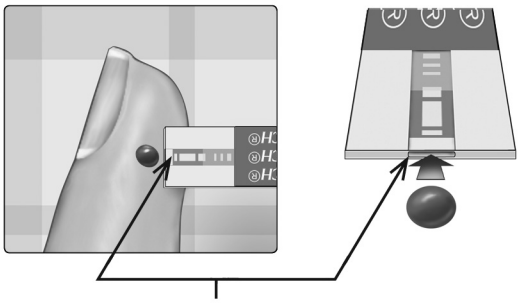


NOTE: If the blood smears or runs, **Do Not** use that sample. Dry the area and gently squeeze another drop of blood or puncture a new site.

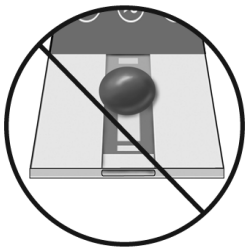


Applying the sample

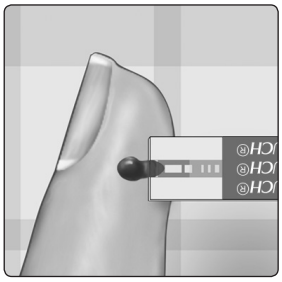
Line up the test strip with the blood drop.



NOTE: **Do Not** apply blood on the top of the test strip.

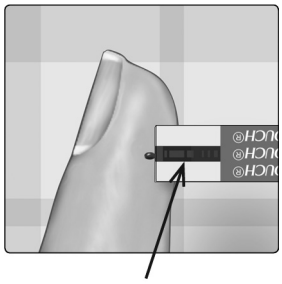


Gently touch the channel to the edge of the blood drop.

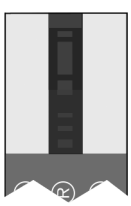


Wait for the confirmation window to fill completely.

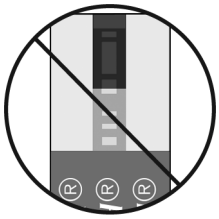
The blood drop will be drawn into the channel and the confirmation window should fill completely.



Confirmation window full



Full



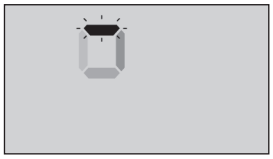
Not full

⚠CAUTION:

You may get an error message or an inaccurate result if the blood sample does not fill the confirmation window completely. Discard the used strip and re-start the test process with a new test strip.

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

When the confirmation window is full, this means you have applied enough blood. The Countdown screen will appear. Now you can move the test strip away from the drop of blood and wait for the meter to count down (about 5 seconds).



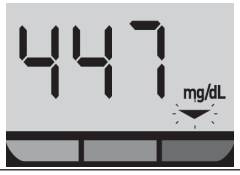
Countdown screen

Viewing your result

Your result appears on the display, along with the unit of measure.

After your blood glucose result appears, the meter will display a Range Indicator Arrow below your glucose result to indicate if your result is below, above or within the meter's range limits (see *"The Range Indicator feature"* in Section 1). The arrow will point to the appropriate Colour Range Indicator Bar on the meter as a visual reminder.

NOTE: When testing with blood, if the Range Indicator Arrow is not shown along with your blood glucose reading, the meter has detected a problem with the test strip. Repeat the test with a new test strip.

	Below range	In range	Above range	Above range
Colour Bar:	Blue	Green	Red	Red
Range Indicator Arrow:	Blinks	Does not blink	Does not blink	Blinks
Screen:				
Blood glucose range:	20 mg/dL to 69 mg/dL	70 mg/dL to 179 mg/dL	180 mg/dL to 239 mg/dL	240 mg/dL to 600 mg/dL

⚠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 the meter's range limits.

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

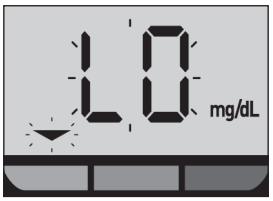
NOTE: If you get an error message instead of a result, see *"LO and HI blood glucose messages"* in Section 6.

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 70 mg/dL or is shown as **LO** (meaning the result is less than 20 mg/dL), 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:

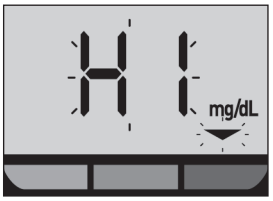
Dehydration and low results

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 179 mg/dL, it may mean hyperglycaemia (high blood glucose) and you should consider re-testing. Talk to your healthcare professional if you are concerned about hyperglycaemia.
- **HI** is displayed when your result is over 600 mg/dL. You may have severe hyperglycaemia (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.



⚠**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 Guide, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes management programme without speaking to your healthcare professional.

Turning the meter off

There are two ways to turn your meter off:

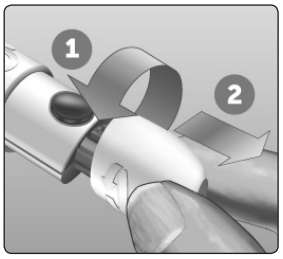
- Remove the test strip.
- Leave your meter alone for two minutes and it will turn off by itself.

Removing the used lancet

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

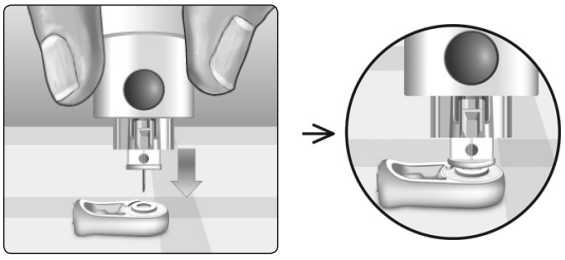
1. Remove the lancing device cap

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



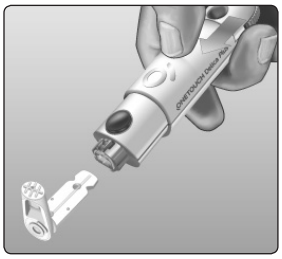
2. Cover the exposed lancet tip

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

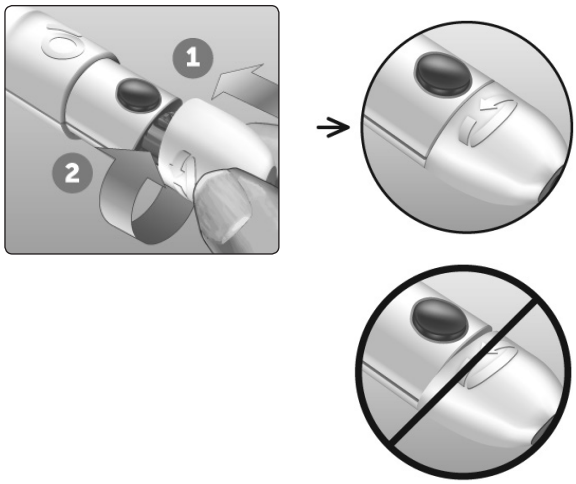
Holding the lancing device directed downwards, push the slider forward until the lancet comes out of the lancing device. If the lancet fails to eject properly, cock the device then push the slider control forward until the lancet comes out.



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.

3 Control solution testing

Control solution testing precautions

OneTouch Select® Plus 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:

- 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.
- **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, especially in high humidity environments.
- Control solution tests must be done at room temperature (20-25°C). Make sure your meter, test strips and control solutions are at room temperature before testing.

⚠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

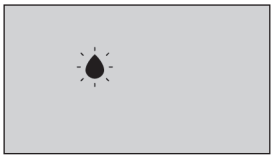
- If you suspect that the meter or test strips are not working properly.
- If you have had repeated unexpected blood glucose results.
- If you drop or damage the meter.

Preparing your meter for a control solution test

1. Insert a test strip to turn the meter on

Insert the test strip with the test strip port and contact bars facing you.

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

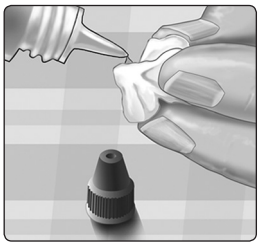


Preparing the control solution

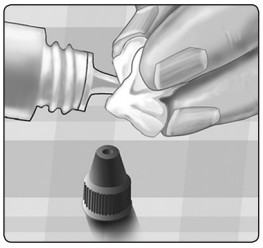
1. Before removing the cap, shake the vial gently

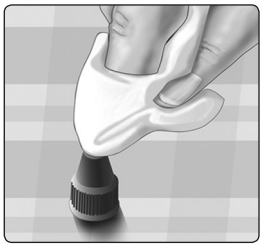
2. Remove the vial cap and place it on a flat surface with the top of the cap pointing up

3. Squeeze the vial to discard the first drop

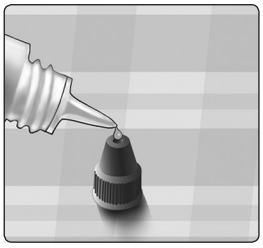


4. Wipe both the tip of the control solution vial and the top of the cap with a clean, damp tissue or cloth



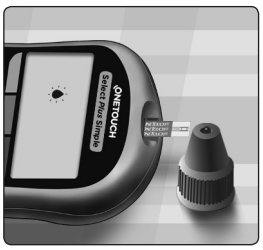


5. Squeeze a drop into the small well on the top of the cap or onto another clean, non-absorbent surface



Applying the control solution

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



2. Touch the channel on the top edge 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 unit of measure. Your meter will not display a Range Indicator Arrow with a control solution result.

NOTE: Your meter does not store a control solution result after it is turned off. When you turn your meter on, your last blood glucose result will appear along with the History Mode icon ( ).

Checking if the result is in range

Each vial of test strips has the OneTouch Select® Plus Mid Control Solution range printed on its label. Compare the result displayed on the meter to the OneTouch Select® Plus Mid Control Solution range printed on the test strip vial.

Example range
OneTouch Select® Plus
Mid Control Solution
Control Range
102-138 mg/dL

If your control solution result falls outside the expected range, repeat the test with a new test strip.

⚠CAUTION:

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

Causes of out-of-range control solution 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 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 test strip vial, **Do Not** use the meter, test strips, or control solution. Contact Customer Care.

Cleaning the control solution cap

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

4 Caring for your system

Storing your system

Store your meter, test strips, control solution and other items 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.

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. (See *"Getting to know your OneTouch Select Plus Simple® Blood Glucose Monitoring System"* in Section 1.)
- **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

Be sure to squeeze out any excess liquid before you wipe the meter.

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.

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

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

2. After wiping, cover the surface you are disinfecting with the soft cloth dampened with the bleach solution 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 Care.

5 Battery

Replacing the battery

Your OneTouch Select Plus Simple® Meter uses one CR2032 lithium coin cell battery.

⚠***IMPORTANT:*** Use only one CR2032 lithium coin cell battery with your meter. **Do Not** use rechargeable batteries. The meter will not function if an incorrect battery type is installed.

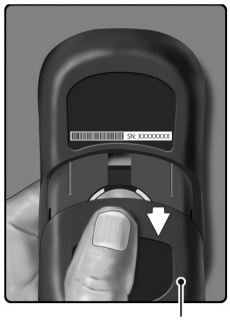
If the meter does not turn on, you may need to replace the battery. See below for instructions.

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

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

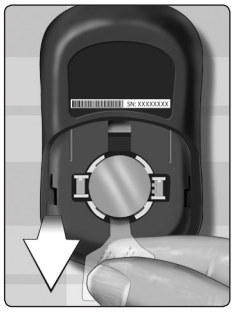
1. Remove the old battery

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



Battery cover

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

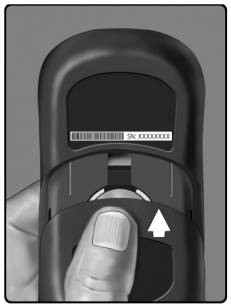


2. Insert the new battery

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

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

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 Care.



4. Dispose of battery

Dispose of the battery according to your local environmental regulations.

LO and HI blood glucose messages

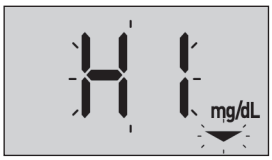
What it means

You may have a very low blood glucose level (severe hypoglycaemia), below 20 mg/dL.

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 600 mg/dL.

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.

Temperature messages

What it means

The 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 (10-44°C). If you do not get another **HI .t** message, you can proceed with testing.

What it means

The meter is too cold (below 10°C) to perform a test.

What to do

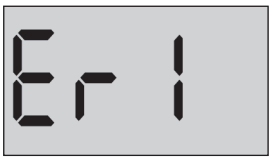
Move the meter and test strips to a warmer area. Insert a new test strip when the meter and test strips are within the operating range (10-44°C). If you do not get another **LO.t** message, you can proceed with testing.

If you continue to get **HI .t** or **LO.t** messages, contact Customer Care.

Error and other messages

What it means

There is a problem with the meter.



What to do

Do Not use the meter. Contact Customer Care.

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. If this message continues to appear, contact Customer Care.

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 Care.

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. If the error message appears again, contact Customer Care.

What it means

One of the following may apply:

- Not enough blood or control solution was applied.
- Blood or control solution 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. If the error message appears again, contact Customer Care.

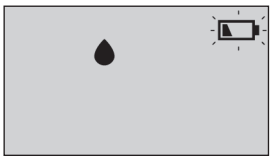
What it means

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. If the error message appears again, contact Customer Care.

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

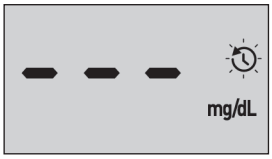
Replace the battery immediately.

What it means

No result in memory, such as the first time use of the meter.

or

Your meter was unable to recall the last result.



What to do

Contact Customer Care 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.

7 Detailed information about your system

Comparing meter results to laboratory results

If you wish to check your meter's accuracy, compare it to a lab result. See *"Guidelines for obtaining an accurate meter to lab comparison"*. Results obtained from the OneTouch Select Plus Simple® Meter and laboratory tests are reported in plasma-equivalent units. However, your meter result may differ from your lab result for any of several reasons. Your meter measures glucose (sugar) in capillary blood, but the lab measures glucose in venous blood. When your blood sugar is changing because you have eaten, exercised, or taken medication, the difference between venous and capillary blood may be greater than when you are fasting. For example, if you have eaten recently, a result from fingertip testing may be up to 70 mg/dL higher than a lab test using blood drawn from a vein.[1] Therefore, when comparing a meter to a lab, it is important to fast for at least 8 hours. (It is OK to drink water.)

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:

- Your haematocrit is above 55% or below 30%.
- You are severely dehydrated.

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

According to an international standard[2] a result from your OneTouch Select Plus Simple® Meter is considered accurate when it is within 15 mg/dL of a laboratory method when the glucose concentration is lower than 100 mg/dL and within 15% of laboratory method when the glucose concentration is 100 mg/dL or higher.

[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.

[2]ISO 15197:2013. *In vitro diagnostic test systems —Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.*

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 Select Plus Simple® 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 Guide 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	Glucose Oxidase biosensor
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
Biological source	Aspergillus Niger
Calibration	Plasma-equivalent
Memory	Last glucose test result only
Operating ranges	Temperature: 10-44°C Relative humidity: non-condensing 10-90% Altitude: up to 3048 metre Haematocrit: 30-55%
Reported result range	20-600 mg/dL
Sample	Fresh capillary whole blood
Sample volume	1.0 µL
Size	52(W) x 86(L) x 16(T) millimetres
Test time	Average test time is 5 seconds
Unit of measure	mg/dL
Weight	Approximately 50 grams

System Accuracy

Diabetes experts have suggested that glucose meters should agree within 15 mg/dL of a laboratory method when the glucose concentration is lower than 100 mg/dL, and within 15% of a laboratory method when the glucose concentration is 100 mg/dL or higher. Samples from 100 patients were tested using both the OneTouch Select Plus Simple® System and the YSI 2300 Glucose Analyzer laboratory instrument.

System Accuracy Results for Glucose Concentrations <100 mg/dL

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

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
61.3% (103/168)	94.6% (159/168)	99.4% (167/168)

System Accuracy Results for Glucose Concentrations ≥100 mg/dL

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

Within ±5%	Within ±10%	Within ±15%
69.0% (298/432)	95.4% (412/432)	99.1% (428/432)

System Accuracy Results for Glucose Concentrations Between 39.9 mg/dL and 451 mg/dL

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

Within ±15 mg/dL or ±15%
99.2% (595/600)

NOTE: Where 39.9 mg/dL represents the lowest glucose reference value and 451 mg/dL represents the highest glucose reference value (YSI value).

User Performance Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 160 lay persons showed the following results:

96.6% within ±15 mg/dL of the medical laboratory values at glucose concentrations below 100 mg/dL, and 94.7% within ±15% of the medical laboratory values at glucose concentrations at or above 100 mg/dL.

95.0% of the total number of samples were within ±15 mg/dL or ±15% of the medical laboratory values.

Regression Statistics

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

# of Subjects	# of Tests	Slope	Intercept (mg/dL)
100	600	1.00	-2.19

95% CI Slope	95% CI Intercept (mg/dL)	Std. Error ($S_{y.x}$) (mg/dL)	R^2
0.99 to 1.00	-3.64 to -0.73	9.19	0.99

Precision

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

Data generated using the OneTouch Select Plus Simple® Meter.

Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
25	25.43	1.50	5.88
40	40.33	1.56	3.86
65	63.01	2.11	3.35
120	117.43	3.07	2.61
200	196.55	4.42	2.25
350	349.25	7.83	2.24
560	562.88	11.61	2.06

Results show that the greatest variability observed between test strips when tested with blood is 2.11 mg/dL SD or less at glucose levels less than 100 mg/dL, or 2.61% CV or less at glucose levels at 100 mg/dL or above.

Total Precision (600 Control Solution Tests per Glucose Level)

Data generated using the OneTouch Select Plus Simple® Meter.

Glucose Level Ranges (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
20 - 30	25.74	1.13	4.41
30 - 50	46.19	1.29	2.80
96 - 144	111.93	2.27	2.03
280 - 420	362.94	6.09	1.68
420 - 600	546.34	10.27	1.88

Guarantee

LifeScan guarantees that the OneTouch Select Plus Simple® 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.

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 include 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.

Customer care

Kindly contact Customer Care at 1800 225544 or visit www.OneTouch.in.

Contents covered by one or more of the following U.S. patents: 8,066,866, 8,093,903 and 8,486,245. Purchase of this device does not act to grant a use licence under these patents. Such a licence is granted only when the device is used with OneTouch Select® Plus Test Strip. No test strip supplier other than LifeScan is authorised to grant such a licence. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.