ONETOUCH®
SelectSimple™
Blood Glucose Monitoring System

Owner's Guide.

Instructions for Use.

About your System

- Your OneTouch® SelectSimple™ Meter does not have any buttons.
- Simply insert a test strip to turn the meter on and begin testing.

Table of Contents

LifeScan Europe
Division of Cilag GmbH
International
6300 Zug
Switzerland

CE 0344

Contact customer service at 1800 225544 or 022-30845544 (07:00 AM - 11:00 PM) or visit http://www.onetouch.co.in.

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

LIFESCAN a Johnson & Johnson company

Rev. date: 10/ 2010

Included in this kit

OneTouch® SelectSimple™ Meter (Battery included)

High-Low Alarm Reference Card

Case

Lancing Device

10 Sterile Lancets

Available separately

OneTouch® Select™ Test Strips

OneTouch® Select™ Control Solution

Clear Cap

Ask for control solution where you get your test strips or contact customer service at 1800 225544 or 022-30845544 for more information. For information on how to obtain a clear cap, contact customer service at 1800 225544 or 022-30845544.

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

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™ Test Strips and OneTouch® Select™ Control Solution. Take note of warnings and cautions throughout this Owner's Guide, which are identified with ⚠. Many people find it helpful to practice the test with control solution before testing with blood for the first time. See Section C, Control solution testing.

Intended use

The OneTouch® SelectSimple™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The OneTouch® SelectSimple™ System is intended for use outside the body (in vitro diagnostic use) by people with diabetes in a home setting and/or by health care professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

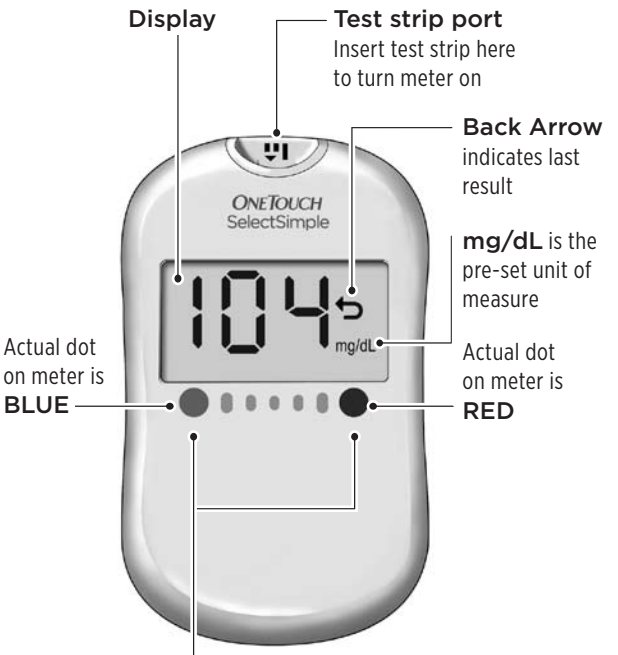
The OneTouch® SelectSimple™ Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm, or palm. It should not be used for the diagnosis of diabetes or for testing newborns.

Test principle

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

A. GETTING TO KNOW YOUR SYSTEM

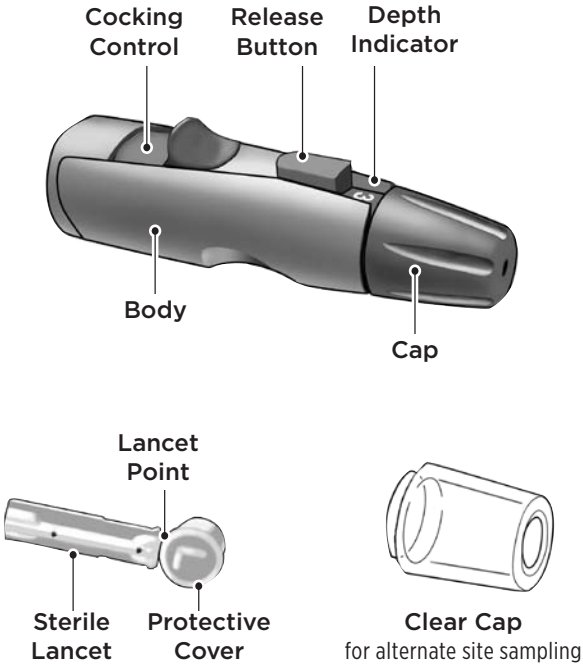
Meter



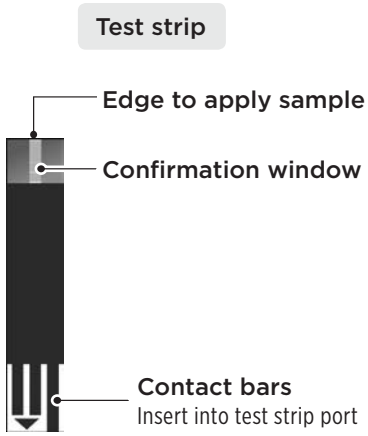
Glucose Range Dots
correspond to three pre-set glucose ranges

This will help identify if your blood glucose test result is "LOW", "HIGH", or "VERY HIGH"

Lancing Device

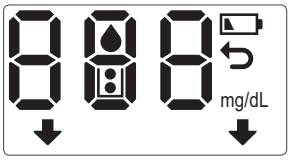


NOTE: If another type of lancing device and/or lancet are included, see the separate instructions that came with the device.



Things to know about testing with the OneTouch® SelectSimple™ System

- The meter does not require any additional set up.
- The meter turns on whenever you insert a test strip. Every time you insert a test strip, a start-up test screen will appear for 2 seconds. All segments of the display should appear briefly on the start-up test screen to let you know the meter is working properly.



- Whenever you insert a test strip, the meter will display your last result (blood glucose or control solution test) before prompting you to apply blood. If this is the first time using the meter or after installing a new battery, three dashes (- - -) will appear instead.
- At times, the meter will beep to alert you to certain conditions, such as when to apply blood to the test strip or if your test result is “LOW”, “HIGH”, or “VERY HIGH”.
- The meter does not require coding. It is pre-set to Code 25.

⚠ CAUTION:

- If any information is missing from the start-up test screen, there may be a problem with the meter. Contact customer service at 1800 225544 or 022-30845544.
- If the meter does not turn on after inserting the test strip:
  1) Make sure that the test strip is inserted with the contact bars facing you and the arrow pointing down, see Testing with a fingertip sample in Section B.
  2) Be sure that the battery is properly installed, see Inserting/replacing battery in Section D.
  3) Make sure you are using the correct test strip. Use only OneTouch® Select™ Test Strips (Code 25 only).
- If the meter still does not turn on, contact customer service at 1800 225544 or 022-30845544.

Getting your meter and test strip ready for testing

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

- OneTouch® SelectSimple™ Meter
- OneTouch® Select™ Test Strips
- Lancing device
- Sterile lancets with protective covers
- OneTouch® Select™ Control Solution

NOTE:

- Use only OneTouch® Select™ Test Strips (Code 25 only) with your OneTouch® SelectSimple™ Meter.
- Make sure your meter and test strips are about the same temperature before you test.
- Testing must be done within the operating temperature range 10–44°C. For the most accurate results, try to test as close to room temperature 20–25°C as you can.
- Tightly close the cap on the vial immediately after use to avoid contamination and damage.
- Store unused test strips only in their original vial.
- Write the discard date (6 months after first opening the vial) on the vial label when you first open it.
- **Do Not** return the used test strip to the vial after performing a test.

NOTE: *(continued)*

- **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.
- OneTouch® Select™ Test Strips are for single use only. Never re-use a test strip that had either blood or control solution applied to it.

⚠ CAUTION:

- If you cannot test due to a problem with your testing supplies, contact your healthcare professional or customer service at 1800 225544 or 022-30845544. 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.

⚠ CAUTION: To reduce the chance of infection:

- Make sure to wash the lancing site with soap and water before sampling.
- Never share a lancet or a lancing device with anyone.
- Always use a new, sterile lancet — lancets are for single use only. Attempted reuse of this single use device will affect safety, performance and effectiveness, and expose user to unnecessary risks.
- Keep your meter and lancing device clean. See Caring for your system in Section D.

B. TESTING YOUR BLOOD GLUCOSE

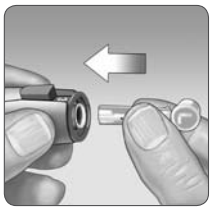
Testing with a fingertip sample

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

1. Snap off the lancing device cap

2. Insert a sterile lancet

Firmly push the lancet into the holder.



NOTE: For alternate site testing, use only OneTouch® UltraSoft® Lancets.

3. Twist off the protective cover and save it for later use

Replace the blue cap by snapping it back on.

4. Adjust the depth setting

Twist the lancing device cap until the desired setting appears. Smaller numbers are for shallower punctures, which may be less painful.

Shallower punctures work for children and most adults. Deeper punctures work well for people with thick or callused skin.

5. Cock the lancing device

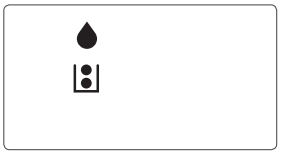
Slide the cocking control back until it clicks.

If it does not click, that's okay. It may have been cocked when you inserted the lancet.

6. Insert a test strip to turn the meter on

Insert a test strip into the test strip port as shown, with the contact bars facing you and the arrow pointing down.

After the start-up test screen, your last result (blood glucose or control solution test) will appear on the display, and the back arrow icon will blink.



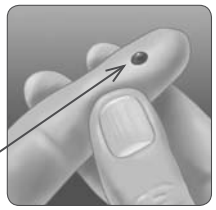
After your last result is displayed, your meter will beep and an icon appears showing a drop with a test strip that fills. This indicates that your meter is ready for you to apply a blood sample. You have 2 minutes to apply a blood sample before the meter turns off.

7. Lance your finger

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

8. Get a round drop of blood

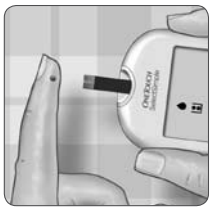
Gently squeeze your finger until you get a round drop of blood.



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

Applying blood and reading results

1. Prepare to apply the sample



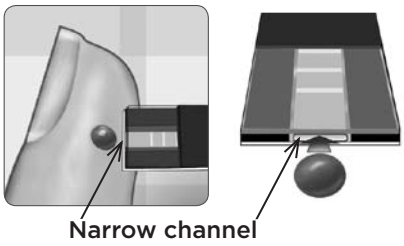
Keeping your finger extended and steady, move the meter and test strip toward the blood drop.

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

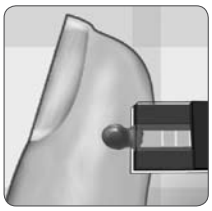
Do Not hold the meter and test strip underneath the blood drop. This may cause blood to run into the test strip port and damage the meter.

2. Apply the sample

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



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



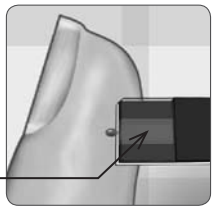
Be careful not to push the test strip against your fingertip or the test strip may not fill completely.

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

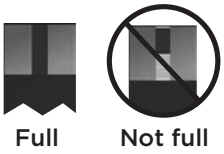
⚠ CAUTION:
You may get an ERROR 5 message or an inaccurate result if the blood sample does not fill the confirmation window completely. See Troubleshooting in Section E. Discard the test strip and re-start the test process.

3. Wait for the confirmation window to fill completely

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



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



See Step 4 below, left.

Applying blood and reading results

(continued)

4. Read your result on the meter

After the meter counts down, your blood glucose level appears on the display along with the unit of measure.

In this example, the test result is 104 mg/dL. The meter will beep once but no arrow will appear below your result.

Example 1

If your test result is "LOW", "HIGH", or "VERY HIGH", an arrow will appear below your result and point to one of two colour dots. The meter will also beep.

In this example, the test result is 64 mg/dL. A blinking arrow will point to the BLUE DOT on your meter, and the meter will beep twice each time the arrow blinks. This represents a "LOW" result, below 70 mg/dL.

Example 2

See the next section for more information on "LOW", "HIGH", and "VERY HIGH" results.

Knowing when your test result is "LOW", "HIGH", or "VERY HIGH"

Your meter has two colour dots below the display. Each dot corresponds to a pre-set "LOW", "HIGH", and "VERY HIGH" glucose range.

The combination of an arrow (blinking/not blinking) pointing to one of the two colour dots and the meter beeping, will tell you if your result is "LOW", "HIGH", or "VERY HIGH".

In this example, the test result is 185 mg/dL. An arrow will point to the RED DOT and the meter will beep once. This represents a "HIGH" result, above 180 mg/dL.

BLUE ● DOT	RED ● DOT	RED ● DOT
20 to 69 mg/dL LOW	**180 to 239 mg/dL HIGH**	**240 to 600 mg/dL VERY HIGH**
Arrow blinks for 15 seconds. Meter beeps twice each time the arrow blinks.	Arrow appears but does not blink. Meter beeps once.	Arrow blinks for 15 seconds. Meter beeps once every other time the arrow blinks.

⚠ WARNING:

The unit of measure mg/dL must be displayed here. If your display shows mmol/L rather than mg/dL, contact customer service at 1800 225544 or 022-30845544 (07:00 AM – 11:00 PM) or visit http://www.onetouch.co.in. You cannot change the unit of measure. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

⚠ CAUTION:

- If your blood glucose is high and you test when the temperature is at the low end of the operating range 10°C, the result on your meter may be lower than your actual glucose level. Re-test in a warmer environment with a new test strip as soon as possible.
- **Do Not** make immediate treatment decisions based on whether your results fall within one of these pre-set ranges.
- Treatment decisions should be made based on the numerical result and your healthcare professional's recommendations.
- Consult with your healthcare professional as to how the pre-set ranges defined by the two dots on your meter apply to your personal target range.

Error Messages

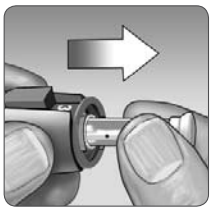
If you get an ERROR message on your screen rather than a result, see Troubleshooting in Section E.

After getting a result

Remove the test strip from the meter and the meter will turn off.

Removing the used lancet

Remove the lancing device cap by snapping it off. Cover the exposed lancet tip before removing the lancet. Place the lancet protective cover on a hard surface. Push the lancet tip into the cover. Remove the lancet and place it in a container for sharp objects. Replace the cap.



Disposing of the used lancet and test strip

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

Interpreting unexpected test results

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

⚠ CAUTION:

Low glucose results

- If your test result is lower than 70 mg/dL, it may mean hypoglycaemia (low blood glucose). Treat this condition immediately, according to your healthcare professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do another test.
- The Error 7 screen is displayed when your blood glucose level is lower than 20 mg/dL. You may have severe hypoglycaemia (very low blood glucose). If you re-test your blood glucose and the Error 7 screen appears again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional immediately.
- If your blood glucose is high and you test when the temperature is at the low end of the operating range 10°C, the result on your meter may be lower than your actual glucose level. Re-test in a warmer environment with a new test strip as soon as possible.

Dehydration and low glucose results

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

High glucose results

- If your test result is higher than 180 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.
- The Error 8 screen is displayed when your blood glucose level is higher than 600 mg/dL. You may have severe hyperglycaemia (very high blood glucose). Re-test your blood glucose. If the Error 8 screen appears again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional immediately.

Repeated unexpected glucose results

- If you continue to get unexpected results, check your system with control solution. See Section C, Control solution testing.
- If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this Owner's Guide, contact your healthcare professional. Never ignore symptoms or make significant changes to your diabetes control 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 55%) or very low (below 30%) can cause false results.

Testing with a forearm or palm sample

The OneTouch® SelectSimple™ Meter lets you obtain a blood sample from your forearm or palm. Getting a drop of blood from these "alternate sites" may be less painful than a fingertip sample.

If you are testing:	Use blood sample from your:
Routinely before meals. Prior to or more than two hours after: • a meal • exercise • a rapid-acting insulin injection or insulin pump bolus	Fingertip, forearm, or palm
When your blood glucose is changing rapidly, such as: • within two hours after a meal • within two hours after a rapid-acting insulin injection or insulin pump bolus, or • during or within two hours after exercise	Fingertip

⚠ CAUTION:
Talk to your healthcare professional before using your forearm or palm for testing.

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

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

Getting a blood sample

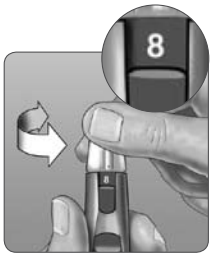
Getting a blood sample from your forearm or palm is different than getting a sample from your fingertips. Follow these instructions to get a sufficient blood drop for testing.

⚠ CAUTION:
Before testing, make sure to wash the puncture site with soap and water. Rinse and dry thoroughly.

The clear cap is for forearm and palm sampling only. Replace the blue cap with the clear cap. For more information on how to obtain a clear cap, contact customer service at 1800 225544 or 022-30845544.

1. Insert a sterile lancet and snap on the clear cap

2. Adjust the depth setting



You may need a deeper setting to get a sufficient sample for testing.

Twist the clear cap toward the larger numbers to increase the depth.

Be sure to cock the lancing device.

3. Choose a sample site

- Choose a spot away from bone, veins, and hair. Massage the site to increase blood flow.
- Select a spot with no visible veins and avoid deep lines, which may cause your blood sample to smear.

Forearm

Palm

4. Lance your forearm or palm

- Firmly press and hold the lancing device against your forearm or palm for a few seconds.
- Wait until the skin surface under the clear cap changes colour (as blood collects beneath the skin). This tells you there is enough blood flow for a good sample.

Forearm or Palm

- Then press the release button while continuing to apply pressure.

Forearm

Palm

- Keep holding the lancing device against your skin until a round drop of blood forms under the cap.
- When sampling from your forearm or palm, make sure the drop of blood is sufficient (● approximate size) before you release pressure and remove the lancing device.

Forearm or Palm

5. Remove the lancing device

Carefully lift the lancing device away from your skin. **Do Not** smear the blood sample.

If the drop of blood runs or spreads due to contact with hair or a line in your palm, **do not** use the sample. Try lancing again in a smoother area.

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

---

6. Apply the sample to the test strip

Keep your forearm or palm steady and use your other hand to bring the top edge of the test strip to the drop of blood.

Forearm

Palm

- See Testing with a fingertip sample in Section B for more information on applying the blood sample to the test strip.
- See Interpreting unexpected test results in Section B for more information on unexpected test results.
- See Testing with a fingertip sample in Section B for information on disposing the used lancet.

C. CONTROL SOLUTION TESTING

When to test with control solution

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

Do a control solution test:
- to practice the test process instead of using blood,
- whenever you open a new vial of test strips,
- if you suspect the meter or test strips are not working properly,
- if you have had repeated unexpected blood glucose results as described in Applying blood and reading results in Section B, or
- if you drop or damage the meter.

NOTE:
- Use only OneTouch® Select™ Control Solution with your OneTouch® SelectSimple™ Meter.
- Control solution is available separately. Ask for control solution where you get your test strips or contact customer service at 1800 225544 or 022-30845544.
- Control solution tests must be done at room temperature 20–25°C. Make sure your meter, test strips, and control solution are at room temperature before testing.

⚠ CAUTION:
Do Not swallow control solution; it is not for human consumption. **Do Not** apply control solution to the skin or eyes as it may cause irritation.

How to test with control solution

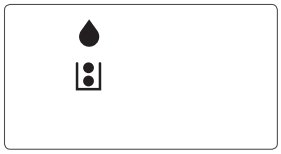
1. Insert a test strip to turn the meter on

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

2. Wait for the meter to prompt you to apply a control solution sample

After the start-up test screen, your last result (blood glucose or control solution test) will appear on the display, and the back arrow icon will blink.

After your last result is displayed, your meter will beep and an icon appears showing a drop with a test strip that fills. This indicates that your meter is ready for you to apply a control solution sample. You have 2 minutes to apply a control solution sample before the meter turns off.



3. Prepare the control solution

Before removing the cap, shake the vial gently. 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.

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.

4. Apply the control solution

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

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

5. Read your result

When the confirmation window is full, the meter will count down from 5 to 1. Your control solution result will then appear on the display along with the unit of measure.

NOTE: If the HIGH/LOW alarm is activated during control solution testing, do not be concerned or take any action. The HIGH/LOW alarm should not be used to evaluate control solution results.

6. Check if the result is in range

OneTouch® Select™
105–158 mg/dL
(Example Range)

Compare your result to the range on the test strip vial.

Each vial of test strips has a OneTouch® Select™ Control Solution range printed on its label. Compare the result displayed on the meter to the OneTouch® Select™ Control Solution range printed **on the test strip vial** depending on the type of control solution you used.

If the result you get is not within the appropriate range, the meter and test strips may not be working properly. Repeat the control solution test.

7. Cleaning

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

Out-of-range results may be due to:

- not following the instructions detailed in steps 1–7,
- expired or contaminated control solution,
- expired or damaged test strip,
- use of a test strip or control solution past its discard date,
- a problem with the meter, or
- control solution test was performed outside the correct temperature range 20–25°C.

NOTE:

It is important to compare your control solution result with the correct range printed on the test strip vial or your result may appear to be out of range.

IMPORTANT:

The next time you test, your last test result (which appears on the display when you insert a test strip) is from a control solution test, and not a blood glucose test.

⚠ CAUTION:

The control solution range printed on the test strip vial is for OneTouch® Select™ Control Solution only. It is not a recommended range for your blood glucose level.

⚠ CAUTION:

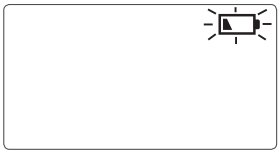
If you continue to get control solution results that fall outside the range printed on the test strip vial, **Do Not** use the meter, the test strip, or the control solution. Contact customer service at 1800 225544 or 022-30845544.

D. CARING FOR YOUR SYSTEM

Inserting/replacing the battery

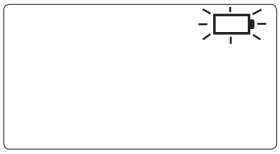
Your OneTouch® SelectSimple™ Meter uses one 3.0 Volt CR 2032 lithium battery (or equivalent). Replacement batteries can be found in most stores where batteries are sold.

A blinking, partially-filled battery icon will appear by itself on the display when battery power is very low. There is enough battery power to complete a few more tests, but you should replace the battery as soon as possible.



The icon will continue to blink on all other screens until you replace the battery.

A blinking, empty battery icon will appear by itself on the display when there is not enough battery power to complete a test or view your last result.



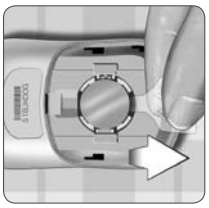
You must replace the battery to continue using the meter.

1. Remove the battery door

Start with the meter off. Place your thumb or forefinger on the battery door, and push to the side to remove the battery door from the back of the meter.

2. Remove the old battery

Pull up on the plastic tab.



3. Insert the new battery

With the "+" side facing up toward you, place the battery over the narrow part of the plastic tab in the compartment. Fold the wider part of the plastic tab over the top of the battery, and push the battery until it snaps into place. Slide the battery door back into position until it clicks into place.

If the meter does not power on after you have replaced the battery, check that the battery is correctly installed with the "+" side up. If the meter still does not power on, contact customer service at 1800 225544 or 022-30845544.

4. Dispose of batteries according to your local environmental regulations

Caring for your system

Your OneTouch® SelectSimple™ Blood Glucose Monitoring System does not need any special maintenance.

Storing your system

Store your meter, test strips and control solution in your case after each use. Store each item in a cool, dry place below 30°C, but **Do Not** refrigerate. Keep all items away from direct sunlight and heat. Tightly close the cap on the test strip vial and/or control solution vials immediately after use to avoid contamination or damage. Store test strips only in their original vial.

Checking for expiration or damage to test strips and control solutions

Test strips and control solutions have expiry dates printed on their vials. When you first open a test strip or control solution vial, you must record the discard date in the space provided on the label:

- Test Strips: date opened plus six (6) months
- Control Solutions: date opened plus three (3) months

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

⚠ CAUTION:
Do Not use your test strips if your vial is damaged or left open to air. This could lead to error messages or inaccurate test results. Contact customer service at 1800 225544 or 022-30845544 immediately if the test strip vial is damaged.

Cleaning your meter

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

To disinfect the meter, prepare a solution of one part household bleach to nine parts water. Wipe the meter with a soft cloth dampened with this solution. After disinfecting, allow the meter surface to remain wet for approximately 5 to 10 minutes and wipe dry with a soft cloth.

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

Cleaning your lancing device and clear cap

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

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

If your lancing device is different than the one shown in this Owner's Guide, check the instructions for your lancing device for information on its care and maintenance.

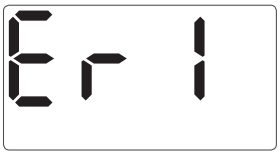
E. TROUBLESHOOTING AND DETAILED INFORMATION ABOUT YOUR SYSTEM

Troubleshooting

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

What it means

Error message indicates there is a problem with the meter.



What to do

Do Not use the meter. Contact customer service at 1800 225544 or 022-30845544.

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 Section B, Testing your blood glucose. If this message continues to appear, contact customer service at 1800 225544 or 022-30845544.

What it means

Error message indicates that the blood or control solution 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 blinking blood drop icon appears on the display. If this message continues to appear, contact customer service at 1800 225544 or 022-30845544.

One of the following may apply:

What it means

You may have high glucose and have tested in an environment near the low end of the system's operating temperature range 10–44°C.

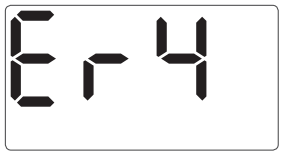
What to do

Make sure you are testing within the operating range 10–44°C, and repeat test with a new test strip; see Section B, Testing your blood glucose. If this error message appears again, contact customer service at 1800 225544 or 022-30845544.

OR

What it means

There may be a problem with the test strip. For example, it may have been damaged or moved during testing.



What to do

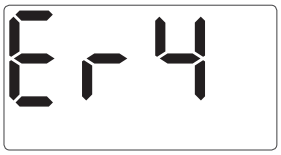
Make sure you are testing within the operating range 10–44°C, and repeat test with a new test strip; see Section B, Testing your blood glucose. If this error message appears again, contact customer service at 1800 225544 or 022-30845544.

Error 4 continues to the right

One of the following may apply:

What it means

There may be a problem with the meter.



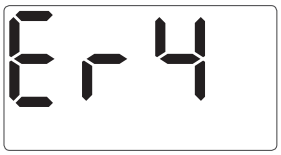
What to do

If this error message appears again, contact customer service at 1800 225544 or 022-30845544.

OR

What it means

The sample was improperly applied.



What to do

If you applied the sample incorrectly, review blood application (see Section B, Testing your blood glucose) or control solution testing (see Section C, Control solution testing) and repeat the test with a new test strip. If the error message appears again, contact customer service at 1800 225544 or 022-30845544.

Error 4 begins to the left

What it means

The meter has detected a problem with the test strip. Possible causes are test strip damage or an incompletely filled confirmation window.

What to do

Repeat the test with a new test strip. Refer to blood application (see Section B, Testing your blood glucose) or control solution testing (see Section C, Control solution testing).

NOTE: **There is no Error 6 message.**

What it means

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

What to do

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

What it means

You may have a very high blood glucose level (severe hyperglycaemia), above 600 mg/dL.

What to do

Re-check your glucose level. If an Er 8 message appears again, obtain and follow instructions from your healthcare professional without delay.

What it means

The meter has detected that the temperature is above or below the system operating range. **Do Not** perform a test until the meter and test strips reach a temperature within the operating range of 10–44°C.

What to do

Repeat the test after the meter and test strips have reached a temperature within the operating range.

Troubleshooting

What it means

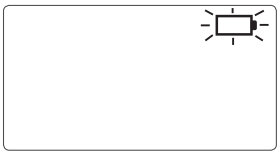
The meter battery power is very low. There is only enough battery power to complete a few more tests.

What to do

Replace the battery as soon as possible.

What it means

Battery is dead. You will not be able to use your meter until you replace the battery.



What to do

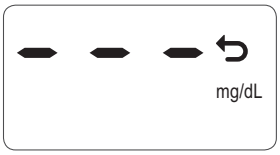
Replace the battery now.

What it means

No last result is stored, such as the first time use of the meter, or if you have installed a new battery.

OR

Your meter was unable to recall the last result.



What to do

You can still perform a blood glucose test and get an accurate test result. Contact customer service at 1800 225544 or 022-30845544 to report this occurrence if this is **not** your first time use of the meter, or if you have **not** installed a new battery.

Detailed information about your system

Comparing meter and laboratory results

Test results with the OneTouch® SelectSimple™ Meter are plasma-calibrated. This helps you and your healthcare professional to compare your meter results with laboratory tests. If you have been using another type of meter — one that provides whole blood-calibrated results — you may notice that your test results with the OneTouch® SelectSimple™ Meter are approximately 12% higher. OneTouch® SelectSimple™ Meter test results and laboratory test results both are expressed in plasma-equivalent units. However, your meter result may differ from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way.

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

- You have eaten recently. After meals, the blood glucose level from a fingertip can be up to 70 mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.[1]
- Your haematocrit (percentage of blood that is red blood cells) is high (above 55%) or low (below 30%).
- You are suffering from severe dehydration.
- Your blood glucose is high and you tested when the temperature was at the low end of the operating range (10°C), so the result on your meter may be lower than your actual glucose level. Re-test in a warmer environment with a new test strip as soon as possible.

For important information on limitations, see the insert that comes with your test strips. To maximise your chances of an accurate comparison between meter and laboratory results, follow a few basic guidelines:

Before going to the lab

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

While at the lab

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

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.

Technical specifications

Reported result range	20–600 mg/dL
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Test time	5 seconds
Assay method	Glucose oxidase biosensor
Meter power source	One replaceable 3.0 Volt CR 2032 lithium battery (or equivalent)
Unit of measure	mg/dL
Memory	Last glucose or control solution test result only
Automatic shutoff	2 minutes after last action
Size	86 mm x 51 mm x 15.5 mm
Weight	Approximately 43 grams, with battery
Operating ranges	Temperature: 10–44°C Altitude: up to 3,048 meters Relative humidity: 10–90% Haematocrit: 30–55%
Battery ratings	One 3.0 V d.c., 3 mA (one CR 2032 battery) ⎓ direct current

Electrical and safety standards

The meter has been tested for ESD immunity to Level 4 electrostatic discharge as specified in IEC 61000-4-2. This meter has been tested for immunity to radio frequency interference over the frequency range 80 MHz to 1 GHz and 1.4 GHz to 2.5 GHz at 3 V/m, and 2.5 GHz to 2.7 GHz at 1 V/m as specified in IEC 61326-1:2005. Degree of protection rating: Minimum of IP20. This meter complies with CISPR 11:2009, Class B (Radiated Only). Emissions of the energy used are low and are not likely to cause interference in nearby electronic equipment.

Guarantee

LifeScan guarantees that the OneTouch® SelectSimple™ 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.

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 75 mg/dL, and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher. Samples from 100 diabetic patients at 1 clinical centre were tested using both the OneTouch® SelectSimple™ System and the YSI Model 2300 Glucose Analyser (laboratory test).

System Accuracy Results for Glucose Concentrations <75 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL†
69% (58/84)	98.8% (83/84)	100% (84/84)

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

† ISO 15197 Minimum Acceptable Accuracy Requirements.

System Accuracy Results for Glucose Concentrations ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%†
45.9% (237/516)	86.2% (445/516)	99.4% (513/516)	99.6% (514/516)

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

System Accuracy Results across the entire Glucose Range
Within ±15 mg/dL or ±20%
99.7% (598/600)

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

Therefore, 99.7% of the total results obtained with the OneTouch® SelectSimple™ System achieved the goal suggested by the diabetes experts.

Regression Statistics

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

Summary of Regression Analysis			
Number of Subjects	Number of Tests	Slope	Intercept (mg/dL)
100	600	0.959	-0.785

95% CI Slope	95% CI Intercept (mg/dL)	Std. Error ($S_{y.x}$) (mg/dL)	R^2
0.951 to 0.967	-2.488 to 0.917	11.054	0.989

Precision Within Run Precision/Repeatablity (100 Venous Blood Tests)			
Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
40	39.0	1.64	4.20
100	102.2	2.26	2.21
130	122.9	2.92	2.38
200	205.6	3.65	1.77
300	312.2	4.36	1.40

Total Precision (200 control solution tests)			
Glucose Level (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Low	45.4	1.35	2.96
Normal	117.1	2.52	2.15
High	343.0	7.64	2.23

Symbols

 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

 Contains sufficient for <n> tests

 Do not re-use

 Expiry Date

 In Vitro Diagnostic Medical Device

 Serial Number

 Lot Number

 Sterilised by irradiation

 Manufacturer

 Upper limit of temperature

 Separate collection of batteries

Display screen icons

 Apply blood to test strip

 Last blood glucose or control solution result

 Low battery power, change battery as soon as possible

 Empty battery, change battery now