ONETOUCH Select Plus

Blood Glucose Monitoring System



Owner's Booklet

Instructions for Use

ONETOUCH Select Plus

Blood Glucose Monitoring System

Owner's Booklet

Thanks for choosing OneTouch®!

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

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

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

Meter Symbols and Icons

Low Battery

Battery Empty

Above Range Note (Blood Glucose Result)

In Range Note (Blood Glucose Result)

Below Range Note (Blood Glucose Result)

Before Meal Tag

After Meal Tag

Control Solution Result

HI Blood Glucose Result Above 33.3 mmol/L

LO Blood Glucose Result Below 1.1 mmol/L

Meter Power on/off and Meter Battery

Backlight Battery

Other symbols and icons



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

Direct current

Consult Instructions for Use

Manufacturer

Lot Number

Serial Number

Storage Temperature Limits

In Vitro Diagnostic Device

Do Not Re-use

STERILE R Sterilised by irradiation

Not for general waste

Use By Date

Contains sufficient for n tests

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Before you begin

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

IMPORTANT SAFETY INSTRUCTIONS:

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

Intended use

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

The system is intended to be used by a single patient and should not be shared.

Test principle

Glucose in the blood sample mixes with the enzyme Glucose Oxidase (see page 130) in the test strip and a small electric current is produced. The strength of this current changes with the amount of glucose in the blood sample. Your meter measures the current, calculates your blood glucose level, displays the blood glucose result, and stores it in its memory.

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

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The OneTouch Select® Plus Blood Glucose Monitoring System

Included with your kit:



OneTouch Select® Plus Meter (2 x CR2032 batteries included)



OneTouch Delica® Lancing Device



OneTouch Delica® Sterile Lancets



OneTouch Select® Plus Test Strips

A carrying case is included with your system kit.

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

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

Available separately:

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

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



OneTouch Select® Plus Mid Control Solution*



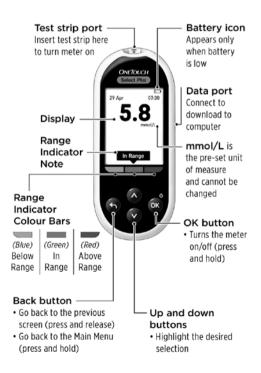
OneTouch Select® Plus Test Strips*

*OneTouch Select® Plus Control Solutions and Test Strips are available separately. For availability of test strips and control solutions, contact customer care or your healthcare professional.

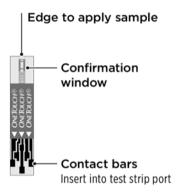
△WARNING: Keep the meter and testing supplies away from young children. Small items such as the battery door, batteries, test strips, lancets, protective covers on the lancets, and control solution vial cap are choking hazards. **Do Not** ingest or swallow any items.

Getting to know your OneTouch Select® Plus Blood Glucose Monitoring System

Meter

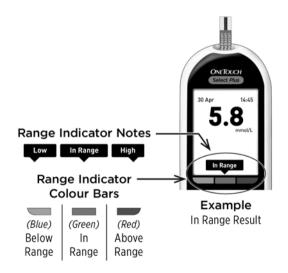


Test strip



The Range Indicator Feature

The OneTouch Select® Plus Meter automatically lets you know if your current glucose result is within, below or above your range limits. It does this by displaying a Range Indicator Note with your current glucose result. The Note also points to a corresponding Range Indicator Colour Bar below the meter display. Together, the Range Indicator Note and Colour Bar can help you understand the meaning of your glucose results.



3 Possible Range Indicator Notes



ExampleBelow Range
Result



Example In Range Result



Example Above Range Result

A Range Indicator Note will appear with your result after each test depending upon how you set your "General" low and high range limits in the meter. Your meter will use these general settings to decide which Range Indicator Note (Low, In Range or High) will appear with your result.

NOTE: These **General** Range Indicator Notes will apply to all your **untagged tests**.

The meter also provides Meal Tagging to help identify Before or After Meal tests. If you turn Meal Tagging On, you will be asked to set up additional "Mealtime" low and high range limits. Your meter will use these mealtime settings to decide which Range Indicator Note (Low, In Range or High) will appear with your result.

NOTE: These **Mealtime** Range Indicator Notes will apply to all your **Meal Tagged tests**.

Things you should know before using the Range Indicator feature:

- Your meter knows which range limit "General" or "Mealtime" to apply depending on whether your current result is untagged or meal tagged.
- Your meter comes pre-set with Meal Tagging turned Off. You will not be able to meal tag results or apply specific "Mealtime" range limits to those tagged results until you turn Meal Tagging On.
- If Meal Tagging is turned on and No Tag is selected, the lower before meal limit and upper after meal limit are used as your range to provide a range indicator note.
- The meter comes with pre-set "General" range limits and "Mealtime" range limits. You can change both these limits as needed to meet your needs.
- If you decide to change your "General" or "Mealtime" range limits, your previous Range Indicator Notes in the Results Log will not change. However, any new tests will display Range Indicator Notes which reflect your changes.

2 Set up your system

Turn your meter on

Press and hold wuntil the start-up screen appears. Once the start-up screen is displayed, release .

The meter will also turn on when you insert a test strip.



NOTE: If you see any missing pixels within the start-up screen, there may be a problem with the meter. Call OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) during the hours of 8:30am-6pm Monday-Friday, 9am-1pm Saturday. Or visit www.LifeScan.co.uk. 800 62253 (Malta) or 800 9074 (Iceland) Monday-Friday during the hours of 9:00-16:30.

Use the display backlight to make it easy to read results

The backlight comes on automatically whenever the meter is turned on. After about 20 seconds of no activity, the backlight will dim. Pressing any button or inserting a test strip will turn the backlight back on.

First time set up

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

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

When setting up your meter you can press **5** to return to the previous screen to adjust a setting.

NOTE: You will not be able to perform a blood glucose test until you complete first time set up.

Set language

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

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



2 Set up your system

NOTE: The time and date format are pre-set. These settings cannot be changed.

Set time, date and general range limits

1. Set the time

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

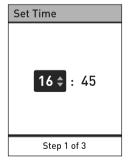
If the time is correct, press to save and continue to **Step 2** to set the date.

If you need to edit the time, press
or of to highlight **Edit** and press on.



Press ♠ or ♥ to set the hour and press ◑.

Repeat this step to set the minutes.



When the time is correct, press on to save.

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

A **Saved** screen appears to confirm that the time displayed is now stored in the meter.



2. Set the date

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

If the date is correct, press **3** to save and continue to **Step 3** to set the general range limits.

If you need to edit the date, press

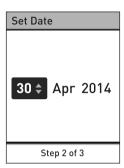
or to highlight Edit and
press ...



2 Set up your system

Press ♠ or ♦ to set the day and press ♠.

Repeat this step to set the month and year.



When the date is correct, press to save.

If you need to make an adjustment, press ♠ or ♥ to highlight Edit and press ♠, then repeat Step 2.

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



3. Set the general range limits

Your meter uses the low and high range limits set in your meter to tell you when a test result is within, below or above the range limits. The general range limits you set during first time set up will apply to all untagged glucose results unless Meal Tagging is turned On.

ACAUTION:

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

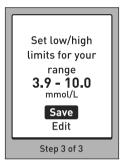
2 Set up your system

The general range limits are pre-set in the meter with a low limit of 3.9 mmol/L and a high limit of 10.0 mmol/L.

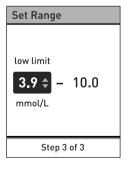
If the low and high range limits are correct, press to save.

A **Saved** screen will appear. Continue to **Setup complete**.

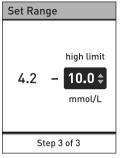
If you need to edit the pre-set limits to fit your needs, press **②** or **③** to highlight **Edit** and press **③**.



Press **②** or **②** to change the pre-set **Low Limit** to the desired value between 3.3 mmol/L and 6.1 mmol/L and press **③**.



Press **◆** or **◆** to change the pre-set **High Limit** to the desired value between 5.0 mmol/L and 16.7 mmol/L and press **●**.



When your low and high range limits are correct, press to save.

If you need to make an adjustment, press ♠ or ♠ to highlight Edit and press ♠, then repeat Step 3.



2 Set up your system

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



Setup complete

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

Press os to return to the Main Menu screen. See page 62.



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

Turn the meter off after setup

There are three ways to turn your meter off:

- Press and hold or for several seconds until the meter. turns off
- · Remove the test strip after a test.

Or.

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

Take a test

Test your blood glucose

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

Preparing for a test

Have these things ready when you test:

OneTouch Select® Plus Meter

OneTouch Select® Plus Test Strips

Lancing device

Sterile lancets

NOTE:

- Use only OneTouch Select® Plus Test Strips.
- Unlike some blood glucose meters, no separate step to code your OneTouch Select® Plus System is required.
- 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.

3 Take a test

- 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.

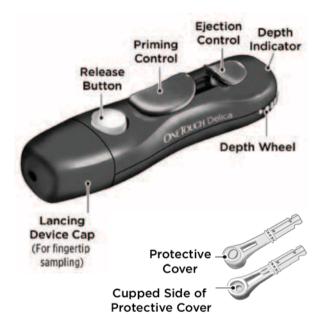
IMPORTANT: If another person assists you with testing. the meter, lancing device and cap should always be cleaned and disinfected prior to use by that person. See page 102.

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 page 126 for more information

ACAUTION:

- Do Not use the OneTouch Select® Plus System when PAM (Pralidoxime) is known or suspected to be in the patient's whole blood sample, as it may cause inaccurate 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 OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).
- If you cannot test due to a problem with your testing supplies, contact your healthcare professional. Failure to test could delay treatment decisions and lead to a serious medical condition.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.
- Do Not use test strips after the expiry date printed on the vial

OneTouch Delica® Lancing Device



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

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

NOTE:

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

ACAUTION:

To reduce the chance of infection and disease spread by plood.

- Make sure to wash the sample site with soap and warm water, rinse and dry before sampling.
- The lancing device is intended for a single user. Never share a lancet or lancing device with anyone.
- Always use a new, sterile lancet each time you test.
- Always keep your meter and lancing device clean (see page 102).
- The meter and lancing device are for single patient use only. **Do Not** share them with anyone, including family members! **Do Not** use on multiple patients!
- After use and exposure to blood, all parts of this kit are considered biohazardous. A used kit may transmit infectious diseases even after you have performed cleaning and disinfection.

Getting a blood sample from the fingertip

Choose a different puncture site each time you test.

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

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

1. Remove the lancing device cap

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





2. Insert a sterile lancet into the lancing device

Align the lancet as shown here, so that the lancet fits into the lancet holder. Push the lancet into the device until it snaps into place and is fully seated in the holder.

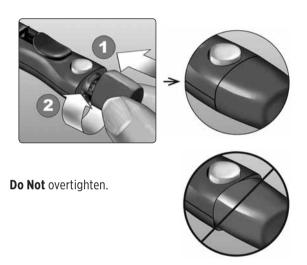


Twist the protective cover one full turn until it separates from the lancet. Save the protective cover for lancet removal and disposal. See page 52.



3. Replace the lancing device cap

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



4. Adjust the depth setting

The lancing device has seven puncture depth settings, numbered 1 through 7. Smaller numbers are for a shallower puncture and the larger numbers are for a deeper puncture. Shallower



punctures work for children and most adults. Deeper punctures work well for people with thick or callused skin. Turn the depth wheel to choose the setting.

NOTE: A shallower fingertip puncture may be less painful. Try a shallower setting first and increase the depth until you find the one deep enough to get a blood sample of the proper size.

5. Prime the lancing device

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



6. Insert a test strip to turn the meter on

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

No separate step to code the meter is required.

Contact bars



Test strip port

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



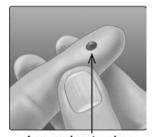
7. Puncture your finger

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



8. Get a round drop of blood

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



Approximate size

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



Applying blood and reading results

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.

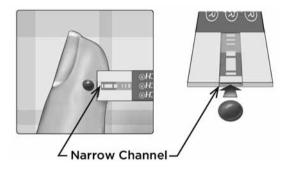


Do Not hold the meter and test strip underneath the blood drop. This may cause blood to run into the test strip port and damage the meter. Do Not allow blood to enter the Data Port.



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.



- Do Not press the test strip too firmly against the puncture site or the channel may be blocked from filling properly.
- 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.

ACAUTION:

You may get an ERROR 5 message if the blood sample does not fill the confirmation window completely. See page 119. 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.



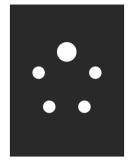
Confirmation window full





Not full

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 blood drop and wait for the meter to count down (about 5 seconds).



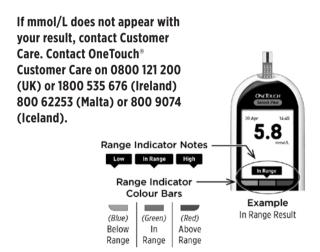
Countdown screen

ACAUTION:

Do Not make immediate treatment decisions on the Range Indicator Notes that appear with your test results. Treatment decisions should be based on the numerical result and healthcare professional recommendation and not solely on the range indicator notes.

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

When your glucose result is displayed after a test along with the date and time, the meter will display a Range Indicator Note. The Note tells you if your result is within range, below or above your general range limits set in the meter (see page 85). The Range Indicator Note will also point to the appropriate Range Indicator Colour Bar on the meter as a visual reminder



After getting a blood glucose result

Once you have your blood glucose result, you may:

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

Or,

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

Removing the used lancet

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

1. Remove the lancing device cap

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



2. Cover the exposed lancet tip

Before removing the lancet, place the lancet protective cover on a hard surface then push the lancet tip into the cupped side of the cover.





3. Eiect the lancet

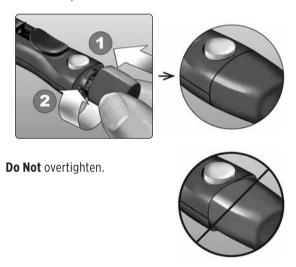
Slide the ejection control forward until the lancet comes out of the lancing device. Return the ejection control to its back position.

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



4. Replace the lancing device cap

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



It is important to use a new lancet each time you obtain a blood sample. 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.

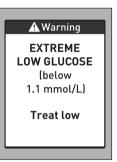
Interpreting unexpected test results

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

ACAUTION:

Low blood glucose resultsIf your blood glucose result is

below 3.9 mmol/L or is shown as **EXTREME LOW GLUCOSE**, (meaning the result is less than 1.1 mmol/L), it may mean hypoglycaemia (low blood glucose). This may require immediate treatment according to your healthcare professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do



another test. **ACAUTION:**

Dehydration and low blood glucose results

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

ACAUTION:

High blood glucose results

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

EXTREME HIGH GLUCOSE is

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



ACAUTION:

Repeated unexpected blood glucose results

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

If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this Owner's Booklet, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes management programme without speaking to your healthcare professional.

ACAUTION:

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.

Test with control solution

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 yial 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.

ACAUTION:

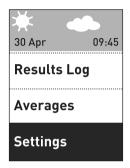
- Do Not swallow or ingest control solution.
- Do Not apply control solution to the skin or eyes as it may cause irritation.
- Do Not use control solution after the expiry date (printed on the vial label) or the discard date, whichever comes first, or your results may be inaccurate.

Do a control solution test

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

Performing a control solution test

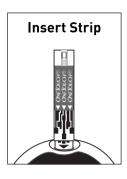
- 1. Press and hold to turn the meter on and display the Main Menu
- 2. Highlight Settings on the Main Menu and press ®



3. Highlight Control Test and press ©



Wait for the Insert Strip screen to appear on the display.



4. Insert a test strip

Make sure the contact bars are facing you.

Contact bars



Test strip port

Wait for the **Apply Control Solution** screen to appear on the display.



5. 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.



6. 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.



7. Read your result

The meter will count down and display your result along with the date, time, unit of measure, and Control Solution.

Because **Control Test** was selected, the meter marks the result as a control solution test.



△CAUTION: Make sure you select Control Test from the Settings screen before you begin a control solution test. An Error 6 screen may appear if you applied control solution to the test strip without following the steps beginning on page 62. See page 121 for more information.

8. Check 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 range printed on the test strip vial.



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

Out-of-range results may be due to:

- Not following the instructions beginning on page page 62.
- Control solution is contaminated, expired, or past its discard date
- Test strip or test strip vial is damaged or expired.
- Meter, test strips and/or control solution were not all at the same temperature when the control solution test was performed.
- Control solution was not at room temperature (20-25°C).
- A problem with the meter.
- Dirt or contamination in the small well on the top of the control solution cap (see Step 5).

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

ACAUTION:

- 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. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).
- The control solution ranges printed on the test strip vial are for control solution tests only and are not recommended ranges for your blood glucose level.

9. Cleaning

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

Take a test 3

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Review past results and averages

Review your past results

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

1. Get to the Results Log

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

*			
30 Apr	09:45		
Results Log			
Averages			
Settings			

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

NOTE: The Meal Tagging symbols that appear in the example screen to the right will not appear next to your result until Meal Tagging is turned On, and you begin tagging your results.

Results Log				
mmol/		L		
Tue, 30 Apr				
15:45 🖜	5.8			
Mon, 29 Apr				
18:45 🛣	10.1			
Sun, 28 Apr		•		

2. Scroll through your results

Press to move backward and ♠ to move forward through your results. Pressing and holding • or \textcal{\texccal{\textcal{\tiny}\textcal{\tiny}\textcal{\textcal{\textcal{\textcal{\textcal{\textcal{\texic quickly.

To display the details of a particular result, press @ with that result highlighted.



4 Review past results and averages

The following symbols may appear with your result. Some of these symbols may only appear when displaying results in the **Results Log**.

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

if the result is from a control solution test (see

page 59)

if the glucose result was above the high limit

if the glucose result was within range

if the glucose result was below the low limit

if the glucose result was tagged Before Meal

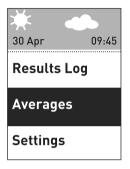
if the glucose was tagged After Meal

Press **6** to return to the **Results Log** screen.

View your averages

Get to the **Averages** screen

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



For each of the 7, 14, 30 and 90 day periods leading up to the current date, the meter displays the averages of those results. These averages include ALL your results, including Meal Tagged and untagged results.

Averages		
7 Days	6.4 mmol/L	
14 Days	6.8 mmol/L	
30 Days	6.7 mmol/L	
90 Days	6.1 mmol/L	
Page 1 of 3		

4 Review past results and averages

If Meal Tagging is turned On, you can view your Before Meal and After Meal Averages for the same time periods. Press ❖ or ❖ to display your Before Meal and After Meal Averages. Only those results tagged Before Meal or After Meal will be included in these averages.

Press to return to the Main Menu screen.

Before Meal Avgs		
7 Days	6.4 mmol/L	
14 Days	6.2 mmol/L	
30 Days	6.2 mmol/L	
90 Days	№ 5.6 mmol/L	
Page 2 of 3		

After Meal Avgs			
7 Days	Ì	6.4 mmol/L	
14 Days	Ì	10.0 mmol/L	
30 Days	Ì	11.1 mmol/L	
90 Days	Ì	10.3 mmol/L	
Page 3 of 3			

NOTE:

- Averages are calculated only when there are at least 2 glucose results for the time period being averaged.
- An EXTREME HIGH GLUCOSE result is always counted as 33.3 mmol/L, and an EXTREME LOW GLUCOSE result is always counted as 1.1 mmol/L.
- The meter calculates averages based on the 7, 14, 30 and 90 day periods ending on the current date setting. If you change your date setting, your averages may change too.

4 Review past results and averages

Result averages provide information from past results. **Do Not** use result averages to make immediate treatment decisions. Always consult your healthcare professional before making significant changes to your diabetes care plan.

∧CAUTION:

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

Download results to a computer

OneTouch® Diabetes Management Software can store all of your records and help you spot patterns for planning meals, exercise, insulin dosing, and medication. To learn more about OneTouch® Diabetes Management Software and to order the software, visit www.LifeScan.co.uk or contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).

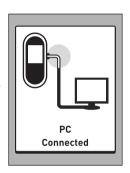
Connect only to a computer certified to UL 60950-1.

To transfer meter data, follow the instructions provided with the OneTouch® Diabetes Management Software to download the results from the meter. You will need a standard micro USB interface cable to connect your One Touch Select® Plus Meter to a computer to download results (not included).

Once the meter has been connected to the computer. the meter display will show PC Connected indicating that the meter is in communication mode.

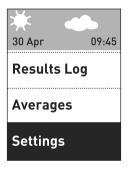
Do Not insert a test strip while the meter is connected to a computer.

Do Not change the batteries when connected to a PC.



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

From the Main Menu, press **△** or **✓** to highlight **Settings** and press **③**.



Select the specific setting you want to modify and press .



Set time and date

1. Edit the time

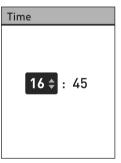
Highlight Time/Date on the **Settings** screen and press **©**. Next, highlight **Time** and press ОК



The current time set in the meter is displayed. Press \triangle or \bigcirc to change the hour and press .

Repeat this step to change the minutes.

A **Saved** screen appears to confirm that the time displayed is now stored in the meter



2. Edit the date

Highlight **Date** on the **Time/Date** screen and press **3**.



The current date set in the meter is displayed. Press ♠ or ♥ to change the day and press ♠.

Repeat this step to change the month and year.

A **Saved** screen appears to confirm that the date displayed is now stored in the meter.



NOTE: To help ensure that the time and date in your meter are set correctly, once every 6 months, and every time you change the batteries, a screen will prompt you to confirm the time and date set in the meter. If they are correct, press . See page 108 for information on changing the hatteries



If not correct, press \triangle or \bigcirc to highlight **Edit** and press Representation in the state of Once the time and date are set correctly, press \(\Oldsymbol{O} \) or \(\Oldsymbol{O} \) to highlight **Done** and press **a**. After a few seconds, the Main Menu will appear on the screen.

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

Set range limits

Range limits are defined by a low and high limit and are set by you in the meter. Your meter uses the low and high range limits to tell you when a test result is within, below or above the range limits. When you select **Range** on the **Settings** screen, you will be able to edit your "General" range limits.

△CAUTION:

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

NOTE: If you decide to change your "General" range limits, your previous Range Indicator Notes in the Results Log will not change. However, any new tests will display Range Indicator Notes which reflect your changes.

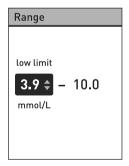
Edit your general range limits

Highlight Range on the Settings screen and press .

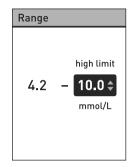


The current general range limits set in the meter are displayed.

Press ♠ or ♥ to change the Low Limit to the desired value between 3.3 mmol/L and 6.1 mmol/L. Then press .



Press **◆** or **♦** to change the **High Limit** to the desired value between 5.0 mmol/L and 16.7 mmol/L. Then press **●**.



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



Turn Meal Tagging On/Off

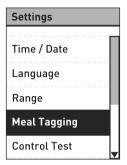
Your OneTouch Select® Plus Meter lets you attach a Before Meal or After Meal tag to your current glucose result. To add tags. Meal Tagging must be turned On.

- A Before Meal glucose test is taken just before the start of your meal.
- An After Meal glucose test is typically taken one or two hours after the start of your meal.

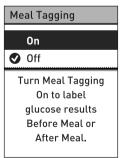
We suggest you talk to your healthcare professional to see how meal tags may help you manage your diabetes.

Use care when adding tags to your glucose results. Incorrect tagging can cause the information displayed in averages to be inaccurate and/or misinterpreted.

Highlight **Meal Tagging** on the **Settings** screen and press **a**.



A check mark will indicate whether Meal Tagging is currently turned Off or On.



When you turn Meal Tagging On. you will be prompted to check vour Before Meal and After Meal range limits that will apply only to those glucose results that are tagged Before Meal and After Meal Press on to continue and make any adjustments to your Before Meal or After Meal limits



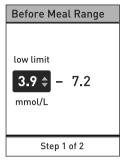
The pre-set Before Meal range limits are 3.9 mmol/L and 7.2 mmol/L (Low and High Limits), and the pre-set After Meal range limits are 6.7 mmol/L and 10.0 mmol/L (Low and High Limits).

If the Before Meal range limits are correct, press on to save.

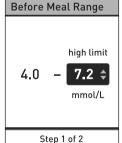
If you need to make adjustments, press \bullet or \bullet to highlight **Edit** and press .

Before Meal: set low/high range limits 3.9 - 7.2mmol/L Save Fdit Step 1 of 2

Press ◆ or ◆ to change the **Low Limit** to the desired value between 3.3 mmol/L and 6.1 mmol/L. Then press ◆.



Press ◆ or ◆ to change the **High Limit** to the desired value between 5.0 mmol/L and 12.0 mmol/L. Then press ◆.



A **Saved** screen appears to confirm that your Before Meal range limits are stored in the meter



If the After Meal range limits are correct, press or to save.

If you need to make adjustments. press or to highlight Edit and press . Then follow the previous steps above for setting and saving the After Meal range limits



NOTE: The After Meal I ow limit can be set between 5.0 mmol/L and 6.7 mmol/L. The After Meal High limit can be set between 6.6 mmol/L and 16.7 mmol/L.

When you are finished setting and saving your mealtime range limits, a **Saved** screen appears to confirm that Meal Tagging is On.



NOTE: If Meal Tagging is turned On and you choose to turn it Off, you will be prompted to confirm or edit your general range limits that will apply to all untagged glucose results.

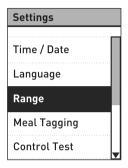
Follow the instructions on page 85 to edit your general range limits.



Edit your mealtime range limits

Meal Tagging must be turned On to be able to edit mealtime range limits. See page 87.

Highlight **Range** on the **Settings** screen and press .

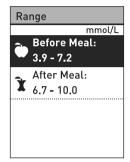


NOTE: If you decide to change your "Mealtime" range limits, your previous Range Indicator Notes in the Results Log will not change. However, any new tests will display Range Indicator Notes which reflect your changes.

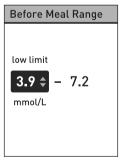
Edit your Before Meal and After Meal range limits.

Highlight **Before Meal** on the **Range** screen and press **®**.

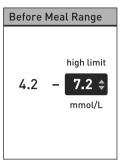
The current Before Meal range limits set in the meter are displayed.



Press ♠ or ♥ to change the **Low Limit** to the desired value between 3.3 mmol/L and 6.1 mmol/L. Then press ♠.



Press or to change the High Limit to the desired value between 5.0 mmol/L and 12.0 mmol/L. Then press .

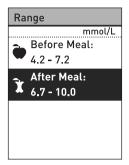


A **Saved** screen appears to confirm that the Before Meal range limits displayed are now stored in the meter.



Highlight **Range** on the **Settings** screen and press **3**. Next, highlight **After Meal** on the **Range** screen and press **3**.

Follow the previous steps for changing the After Meal range limits



NOTE: The After Meal Low limit can be set between 5.0 mmol/L and 6.7 mmol/L. The After Meal High limit can be set between 6.6 mmol/L and 16.7 mmol/L.

Attaching tags to your glucose results

When Meal Tagging is turned On, you can tag your glucose results. After your glucose result appears on the display after a test, your tagging options appear below your result (**Before Meal**, **After Meal**, and **No Tag**).

Press ♠ or ♥ to highlight

Before Meal (♠) or After Meal
(♠) and press ♠. If you do not want to tag this result, highlight

No Tag and press ♠, or press ♠ to return to the Result screen.



NOTE:

- You can edit the meal tag that appears below your result while your result is still displayed (see next page). Simply press to return to the **Meal Tagging** screen above and repeat the instructions for tagging your result.
- You can tag an EXTREME HIGH result but not an EXTREME LOW result.
- You cannot edit a meal tag while reviewing the result in the Results Log.

The selected **Before Meal** (*****) or **After Meal** (*****) icon will appear below your result.

The Range Indicator feature on your meter automatically displays the appropriate Range Indicator Note and points to the corresponding Range Indicator Colour Bar. Your meter applies either Before Meal or After Meal range limits to your result, depending on whether you attached a Before Meal or After Meal tag.



Check the meter serial number, software version, and last meter error

The meter serial number, software version, and information about the last meter error are stored in your meter. You can check this information at any time and use it for troubleshooting.

 Press ♠ or ♠ to scroll to and highlight Meter Info on the Settings screen



2. Press to display the meter information



Press

to scroll down and display information about the last error that occurred on the meter.



6 Care and maintenance

Storing your system

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

Cleaning and disinfection

Cleaning and disinfection are different and both should be performed. Cleaning is part of your normal care and maintenance and should be performed prior to disinfection, but cleaning does not kill germs. Disinfection is the only way to reduce your exposure to disease. For cleaning information, see page 103 and for disinfecting information, see page 105.

Cleaning your meter, lancing device and cap

The meter, lancing device and cap should be cleaned when they are visibly dirty and before disinfection. Clean your meter at least once per week.

The meter and lancing device should be cleaned whenever they are visibly dirty. For cleaning obtain regular strength liquid dish soap and a soft cloth. Prepare a mild detergent solution by stirring 2.5 mL of regular strength liquid dish soap into 250 mL of water.

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



6 Care and maintenance

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

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



2. Wipe dry with a clean, soft cloth



Disinfecting your meter, lancing device and cap

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

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

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

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



6 Care and maintenance

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



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

If you see signs of wear, please contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).

Care and maintenance 6

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7 Batteries

Your OneTouch Select® Plus Meter uses 2x CR2032 lithium batteries. One battery powers the meter only and the other powers the backlight. See page 123, for information on when to change the meter batteries.

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

Do Not change the batteries when connected to a PC.

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

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

Replacing the batteries

1. Remove the old batteries

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



Pull up firmly on the plastic battery ribbons. The plastic battery ribbon with the (1) symbol is for the meter battery, and the plastic tab with the -☆- symbol is for the backlight battery.



7 Batteries

2. Insert the new batteries

With the "+" side facing up toward you, place each battery in the compartment within the fold of the plastic battery tab.

Push each battery in until it snaps into the battery clasp.



Replace the 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 with the "+" side up. If the meter still does not power on, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).



Batteries 7

3. Check your meter settings

You will be prompted to set the time and date whenever you change the batteries. See page 24.

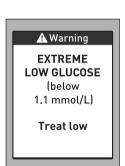
4. Dispose of batteries

Dispose of batteries according to your local environmental regulations.

8 Troubleshooting

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

NOTE: If the meter is on but does not operate (locks-up), contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).



What it means

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

What to do

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



What it means

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

What to do

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

A Warning

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

What it means

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

What to do

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

A Warning

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

What it means

Meter is too cold (below 10°C) to work correctly.

What to do

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

Meter problem. Contact Customer Care.

What it means

There is a problem with the meter.

What to do

Do Not use the meter Contact Customer Care Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).

Error 2

Meter or strip problem. Retest with a new strip.

What it means

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

What to do

Repeat the test with a new test strip; see page 32 or page 59. If this message continues to appear, contact Customer Care Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).

Meter was not ready. Retest with a new strip.

What it means

The sample was applied before the meter was ready.

What to do

Repeat the test with a new test strip. Apply a blood or control solution sample only after Apply Blood or Apply Control **Solution** appears on the display. If this message continues to appear, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).

Strip problem. Retest with a new strip.

What it means

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

What to do

Repeat the test with a new test strip; see page 32 or page 59. If the error message appears again, contact Customer Care Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).

Strip fill problem. Retest with a new strip.

What it means

One of the following may apply:

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

What to do

Repeat the test with a new test strip; see page 32 or page 59. If the error message appears again, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).

There are two Error 6 screens:

Perform blood test again with a new strip.

What it means

The meter has detected a problem with the test strip. Possible cause is that you did not apply a blood sample to the test strip when prompted by the meter.

What to do

Repeat the test with a new test strip; see page 32. If the error message appears again, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).

Perform control solution test again with a new strip.

What it means

The meter has detected a problem with the test strip. Possible cause is that you did not apply a control solution sample to the test strip when prompted by the meter.

What to do

Repeat the test with a new test strip; see page 59. If the error message appears again, contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland).

8 Troubleshooting



What it means

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

What to do

Once the meter Low Battery icon is displayed, it will continue to appear until you replace the meter battery. Test results will still be accurate, but replace the batteries as soon as possible (see page 108).



What it means

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

What to do

Press or to continue but replace the meter battery as soon as possible.



What it means

There is not enough meter battery power to perform a test.

What to do

Replace the meter battery immediately.

8 Troubleshooting

Results Log
No Results
1

What it means

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

What to do

Contact Customer Care to report this occurrence, **unless** this is your first use of the meter. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) 800 62253 (Malta) or 800 9074 (Iceland). You can still perform a blood glucose test and get an accurate result.

Troubleshooting 8

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9 Detailed information about your system

Comparing meter results to laboratory results

Results obtained from the OneTouch Select® Plus Meter and laboratory tests are reported in plasma-equivalent units. However, your meter result may differ from your lab result due to normal variation. A result from your OneTouch Select® Plus Meter is considered accurate when it is within 0.83 mmol/L of a laboratory method when the glucose concentration is lower than 5.5 mmol/L, and within 15% of a laboratory method when the glucose concentration is 5.5 mmol/L or higher.

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

- You have eaten recently. This can cause a result from fingertip testing to be up to 3.9 mmol/L higher than a lab test using blood drawn from a vein.¹
- Your haematocrit is above 55% or below 30%.
- · You are severely dehydrated.
- For additional information, refer to the OneTouch Select® Plus Test Strip Insert.

Detailed information 9 about your system

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.

¹Sacks, D.B.: "Carbohydrates," Burtis, C.A., and Ashwood E.R. (ed.). Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

9 Detailed information about your system

Guidelines for obtaining accurate meter to lab comparisons:

Before going to the lab:

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

Testing with your OneTouch Select® Plus Meter at the lab:

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

9 Detailed information about your system

Technical Specifications

Assay method	Glucose oxidase biosensor
Automatic shutoff	Two minutes after last action
Battery ratings	Two 3.0 V d.c., (2x CR2032 batteries),
Battery type	2 replaceable 3.0 Volt CR 2032 lithium batteries (or equivalent)
Biological source:	Aspergillus Niger
Calibration	Plasma-equivalent
Memory	500 test results
Operating ranges	10-44°C Relative humidity: Non-condensing 10-90% Altitude: up to 3048 metres Haematocrit: 30-55%
Reported result range	1.1-33.3 mmol/L
Sample	Fresh capillary whole blood
Sample volume	1.0 μL
Size	43.0(W) x 101.0(L) x 15.6(T) mm
Test Time	Average test time 5 seconds
Unit of measure	mmol/L
Weight	Approximately 200 grams

Detailed information 9 about your system

System Accuracy

Diabetes experts have suggested that glucose meters should agree within 0.83 mmol/L of a laboratory method when the glucose concentration is lower than 5.55 mmol/L, and within 15% of a laboratory method when the glucose concentration is 5.55 mmol/L or higher. Samples from 100 patients were tested using both the OneTouch Select® Plus System and the YSI 2300 Glucose Analyser laboratory instrument.

System Accuracy Results for Glucose Concentrations < 5.55 mmol/L

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

Within	Within	Within
±0.28 mmol/L	±0.56 mmol/L	±0.83 mmol/L
72.0%	94.6%	98.2%
(121/168)	(159/168)	(165/168)

9 Detailed information about your system

System Accuracy Results for Glucose Concentrations ≥5.55 mmol/L

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

Within ±5%	Within ±10%	Within ±15%
72.7%	98.6%	100.0%
(314/432)	(426/432)	(432/432)

System Accuracy Results for Glucose Concentrations between 1.2 mmol/L and 25.9 mmol/L

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

NOTE: Where 1.2 mmol/L represents the lowest glucose reference value and 25.9 mmol/L represents the highest glucose reference value (YSI value).

Regression Statistics

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

# of Subjects	# of Tests	Slope	Intercept (mmol/L)
100	600	0.97	0.12

95% CI Slope	95% CI Intercept (mmol/L)	Std. Error (S _{y.x}) (mmol/L)	R ²
0.97 to 0.98	0.05 to 0.19	0.45	0.99

9 Detailed information about your system

Precision

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

Data generated using the OneTouch Select® Plus Meter.

Target Glucose (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (%)
2.2	2.50	0.09	3.59
3.6	3.90	0.10	2.56
6.7	7.06	0.16	2.25
11.1	11.57	0.29	2.52
19.4	19.55	0.40	2.07

Results show that the greatest variability observed between test strips when tested with blood is 0.10 mmol/L SD or less at glucose levels less than 5.55 mmol/L, or 2.52% CV or less at glucose levels at 5.55 mmol/L or above.

Total Precision (600 Control Solution Tests per Glucose Level)

Data generated using the OneTouch Select® Plus Meter.

Glucose Level Ranges (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (%)
Low (1.67-2.78)	2.61	0.06	2.49
Mid (5.33-7.99)	6.15	0.11	1.83
High (15.54-23.31)	20.40	0.31	1.52

9 Detailed information about your system

User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 165 lay persons showed the following results:

 100% within ±0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L, and 97.7% within ±15% of the medical, laboratory values at glucose concentrations at or above 5.55 mmol/L

98.2% of the <u>total number of</u> samples were within ± 0.83 mmol/L or $\pm 15\%$ of the medical laboratory values

Guarantee

LifeScan guarantees that the OneTouch Select® Plus 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.

Detailed information 9 about your system

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. This meter complies with immunity to radio frequency interference as specified in IFC 61326-1 or 61326-2

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

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

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

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

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Contents covered by one or more of the following U.S. patents: 5,708,247, 5,951,836, 6,241,862, 6,284,125, 7,112,265, 7,462,265, 7,807,031, and 8,398,664. Use of the monitoring device included herein is protected under one or more of the following U.S. patents: 6,413,410, 6,733,655, 7,250,105, 7,468,125, 8,066,866 and 8,093,903. Purchase of this device does not act to grant a use license under these patents. Such a license is granted only when the device is used with OneTouch* Select* *Plus* Test Strip. No test strip supplier other than LifeScan is authorized to grant such a license. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.

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

IVDD (98/79/EC):



Blood Glucose Meter, Test Strips, and Control Solution

MDD (93/42/EEC):

Lancing System

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