

ONETOUCH

Select Plus Flex™

Blood Glucose Monitoring System

Owner's Guide

Instructions for Use

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Thanks for choosing OneTouch®!

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

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

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

This Owner's Guide 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 Guide in a safe place; you may want to refer to it in the future.

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

Compatible wireless devices

Visit www.myOneTouch.co.uk for information on which wireless devices are compatible with your OneTouch Select Plus Flex™ Meter, and where/how to download the software application on your compatible wireless device.

Meter symbols and icons

Meter Power

Low Battery

Battery Empty

Control Solution

Syncing

BLUETOOTH® Feature On

History Mode (Past results)

Apply Sample

Range Indicator Arrow

Setting Mode

Other symbols and icons

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

Direct current

Consult Instructions for Use

Manufacturer

Lot Number

Serial Number

Storage Temperature Limits

In Vitro Diagnostic Device

Do Not Re-use

Sterilised by irradiation

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

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

The OneTouch Select Plus Flex™ Blood Glucose Monitoring System is not for use on critically ill patients, patients in shock, dehydrated patients or hypersomolar patients.

Test principle

Glucose in the blood sample mixes with the enzyme Glucose Oxidase (see "Technical Specifications") 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.

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

BLUETOOTH® wireless technology

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

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

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):

Lancets

RED (2014/53/EU):

Blood Glucose Meter

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LifeScan

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

Visit www.myOneTouch.co.uk for information on which wireless devices are compatible with your OneTouch Select Plus Flex™ Meter, and where/how to download the software application on your compatible wireless device.

When using the OneTouch Select Plus Flex™ System, we suggest you pair your OneTouch Select Plus Flex™ Meter with a compatible wireless device and track your results. See "Pairing Instructions" for pairing instructions.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

Your meter is subject to and complies with applicable Worldwide Radio regulations and guidelines. Generally, these rules state two conditions specific to the operation of the device:

1. This device may not cause harmful interference.

2. This device must accept any interference received, including interference that may cause undesirable operation.

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

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

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

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

Do Not leave your meter unattended or in a public place so that others may change your personal parameters or make physical connections to it.

The meter has been designed defensively to ward off malicious intent and has been tested accordingly.

BLUETOOTH® trademark

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

1 Getting to know your system

3

OneTouch Select Plus Flex™ Meter (CR2032 lithium coin cell battery included)

4

Lancing device

5

Lancets

6

OneTouch Select® Plus Test Strips*

Included with your kit:

OneTouch Select® Plus Mid Control Solution*

OneTouch Select® Plus Test Strips*

Lancets*

*Lancets: OneTouch Select® Plus Control Solution and Test Strips are available separately. For availability of lancets, test strips and control solution, contact Customer Care or your healthcare professional.

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

Getting to know your OneTouch Select Plus Flex™ Blood Glucose Monitoring System

Meter

Test strip port

Display

Range Indicator Arrow

Range Indicator Colour Bars

Battery icon

Data port

mmol/L is the pre-set unit of measure and cannot be changed

OK button

Up and down buttons

Button combinations

Serial number

Battery cover

Getting to know your OneTouch Select® Plus Test Strip

Test strip

Edge to apply sample

Confirmation window

Contact bars

Insert into test strip port

The Range Indicator feature

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

Range Indicator

Low

In Range

High

Range Indicator Colour Bars

Below Range

In Range

Above Range

Example

In Range Result

3 Possible Range Indicator Displays

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

Example

Below Range Result

Example

In Range Result

Example

Above Range Result

Things you should know before using the Range Indicator feature:

The meter comes with pre-set range limits. The pre-set low range limit is 3.9 mmol/L and the pre-set high range limit is 10.0 mmol/L. You can change these limits as needed to meet your needs. See "Editing your range limits" for details on the pre-set range limits and on editing your range limits.

If you decide to change your range limits, the Range Indicator Arrows stored with previous results in meter memory will not change. However, any new tests will display Range Indicator Arrows which reflect your changes.

2 Setting up your system

Setting up your meter

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

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

⚠ CAUTION: If you see any missing segments within the start-up screen, there may be a problem with the meter. Contact Customer Care. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

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

First time setup

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

Setting the time

Hour will flash

If the hour displayed is correct, press to confirm.

If the hour displayed is not correct, press or to change the hour and press to confirm.

Minutes will flash

If the minutes displayed is correct, press to confirm.

If the minutes displayed is not correct, press or to change the minutes and press to confirm.

Setting the date

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

Year will flash

If the year displayed is correct, press to confirm.

If the year displayed is not correct, press or to change the year and press to confirm.

Month will flash

If the month displayed is correct, press to confirm.

If the month displayed is not correct, press or to change the month and press to confirm.

Day will flash

If the day displayed is correct, press to confirm.

If the day displayed is not correct, press or to change the day and press to confirm.

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

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

Adjusting the time and date settings after first time setup

You can adjust the meter's time and date settings after first time setup. Press and hold to turn the meter on, then press and hold and at the same time. The SET screen will appear. See "Editing time and date".

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

Connecting to a compatible wireless device

Turning the BLUETOOTH® feature on or off

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

• To turn the BLUETOOTH® feature on press and at the same time.

• To turn the BLUETOOTH® feature off press and at the same time.

The symbol indicates the BLUETOOTH® feature is on

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

Pairing Overview

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

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

Multiple OneTouch Select Plus Flex™ Meters can be paired with your compatible wireless device. For example, your compatible wireless device can be paired with a meter at home and another at work. To pair multiple meters, repeat the pairing instructions for each meter. See "Pairing Instructions" for pairing instructions.

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

Pairing Instructions

1. Start by turning your meter on using the button

2. The BLUETOOTH® feature is turned on by pressing and together

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

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

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

Serial number

Example of PIN number display on meter

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

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

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

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

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

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

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

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

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

3 Taking a test

Testing your blood glucose

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 "Control solution testing precautions".

Preparing for a test

Have these things ready when you test:

OneTouch Select Plus Flex™ Meter

OneTouch Select® Plus Test Strips

Lancing device

Sterile lancets

NOTE:

• Use only OneTouch Select® Plus Test Strips.

• Make sure your meter and test strips are about the same temperature before you test.

• **Do Not** test if there is condensation (water build-up) on your meter. Move your meter and test strips to a cool, dry spot and wait for the meter surface to dry before testing.

• Keep test strips in a cool, dry place between 5°C and 30°C.

• **Do Not** open the test strip vial until you are ready to remove a test strip and perform a test. Use the test strip immediately after removing it from the vial, especially in high humidity environments.

- Tightly close the cap on the vial immediately after use to avoid contamination and damage.
- Store unused test strips only in their original vial.
- **Do Not** return the used test strip to the vial after performing a test.
- **Do Not** re-use a test strip that had blood or control solution applied to it. Test strips are for single use only.
- **Do Not** test with a test strip that is bent or damaged.
- With clean, dry hands, you may touch the test strip anywhere on its surface. **Do Not** bend, cut or modify the test strip in any way.

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

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

⚠ CAUTION:

- **Do Not** use the OneTouch Select Plus Flex™ 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).
- 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.

Getting to know your OneTouch® Delica® Plus Lancing Device

1

Release button

2

Slider control

3

Depth indicator

4

Depth wheel

5

Lancing device cap

6

Protective cover

NOTE:

• The OneTouch® Delica® Plus Lancing Device uses OneTouch® Delica® or OneTouch® Delica® Plus Lancets.

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

• The OneTouch Select Plus Flex™ Blood Glucose Monitoring System has not been evaluated for Alternate Site Testing (AST). Use only fingertips when testing with the system.

• The OneTouch® Delica® Plus Lancing System does not include the materials needed to perform Alternate Site Testing (AST). The OneTouch® Delica® Plus Lancing System should not be used on the forearm or palm with the OneTouch Select Plus Flex™ Blood Glucose Monitoring System.

Lancing precautions

The OneTouch® Delica® Plus Lancing Device is mainly used for blood micro sampling for self-monitoring of blood glucose with OneTouch® Delica® Lancets and OneTouch® Delica® Plus Lancets.

⚠ CAUTION:

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

• Make sure to wash the sample site with soap and warm water, rinse and dry before sampling.

• The lancing device is intended for a single user. Never share a lancet or lancing device with anyone.

• Always use a new, sterile lancet each time you test.

• Always keep your meter and lancing device clean. (See "Cleaning and disinfection".)

• The meter and lancing device are for single patient use only. **Do Not** share them with anyone, including family members! **Do Not** use on multiple patients!

• After use and exposure to blood, all parts of this kit are considered biohazardous. A used kit may transmit infectious diseases even after you have performed cleaning and disinfection.

• **Do Not** use lancets after the expiry date printed on the lancet packaging.

If a serious incident occurs while using the OneTouch® Delica® Plus Lancing Device, please contact Customer Care immediately. Call OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland). Lines open 9am-5pm Monday - Friday. www.myOneTouch.co.uk. You should also contact your local competent authority. Contact information for your country can be found at: <https://ec.europa.eu/growth/sectors/medical-devices/contacts>

A serious incident is one that did or could have led to the following:

- The death of a patient, user, or other person;
- The temporary or permanent serious deterioration of a patient's, user's, or other person's state of health; or
- A serious public health threat.

Preparing your lancing device

1. Remove the lancing device cap

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

2. Insert a sterile lancet into the lancing device

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

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

3. Replace the lancing device cap

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

Ensure the cap is aligned as shown in the image.

4. Adjust the depth setting

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

are for a shallower puncture and larger numbers for a deeper puncture.

NOTE: Try a shallower setting first and increase the depth until you find the one deep enough to get a blood sample of the proper size.

5. Cock the lancing device

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

Preparing the meter

1. Insert a test strip to turn the meter on

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

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

Contact bars

Test strip port

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

Sampling blood from the fingertip

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

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

1. Puncture your finger

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

2. Get a round drop of blood

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

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

Applying blood and reading results

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.

Applying 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.

Narrow Channel

Confirmation window full

Full

Not Full

⚠ CAUTION:

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

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

Countdown Screen

Viewing your result

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

Example

Below Range Result

Example

In Range Result

Example

Above Range Result

07311301A_SPF_O3_mmol_EMEA_en_LED_R2.indd 1

1/12/24 11:30 AM

LifeScan [®]		Description: OG SPF mmol EMEA en (LED)		Art.Agency: Accolad		Job No.: 84789	
File Name: AW07311301		MC Rev.: A		Agency Contact: Henry Umeh			
CPS Reference No.: For CPS number refer to the DMS object under Links & Attachments				JDE Item No.: N/A		Rev. Date: 12-Jan-24	
ADS No./Rev.: DEV-REC-0000561 Rev 10		ADS ID: GLUD-09		Deline No./Rev.: N/A		No. of Covers: N/A <input checked="" type="checkbox"/>	
Language Sequence: English				Inside No. of pages: N/A <input checked="" type="checkbox"/>			
				No. of sides: 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/>			
Spot Colors		Process Colors		Uncoated Area		Special Instructions	
PMS	N/A <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> CMYK <input type="checkbox"/> Black <input checked="" type="checkbox"/> N/A <input type="checkbox"/>	<input type="checkbox"/> Uncoated Area <input checked="" type="checkbox"/> N/A <input checked="" type="checkbox"/>	<input type="checkbox"/>		N/A <input checked="" type="checkbox"/>	<input type="checkbox"/> Deline <input checked="" type="checkbox"/>
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