

ONETOUCH

Ultra Plus Flex™

Blood Glucose Monitoring System

Owner's Guide

Instructions for Use

Table of Contents

1	Getting to know your system.....	8
2	Setting up your system.....	14
3	Taking a test.....	23
4	Reviewing past results.....	44
5	Editing Your Settings	47
6	Caring for your system.....	50
7	Battery	54
8	Troubleshooting your system	57
9	Detailed information about your system.....	63

Test principle

Glucose in the blood sample mixes with the enzyme FAD-GDH (see "Technical Specifications") in the test strip and a small electric current is produced. The strength of this current calculates your blood glucose level. It then displays the blood glucose result and stores it in the meter memory.

Use only OneTouch Ultra Plus™ Control Solutions and Test Strips with the OneTouch Ultra Plus Flex™ Meter. Use of OneTouch Ultra 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 Ultra Plus Flex™ Meter uses BLUETOOTH® wireless technology to pair and to send your glucose results to compatible wireless devices.

The OneTouch Ultra Plus Flex™ Meter is designed to work with the OneTouch Reveal® Mobile App.

Visit www.OneTouch.com for information on which wireless devices are compatible with your OneTouch Ultra Plus Flex™ Meter, and where/how to download the OneTouch Reveal® Mobile App on your compatible wireless device.

When using the OneTouch Ultra Plus Flex™ System, we suggest you pair your OneTouch Ultra Plus Flex™ Meter with a compatible wireless device and track your results. See "Pairing Instructions". Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Thanks for choosing OneTouch®!

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

Your OneTouch Ultra 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.

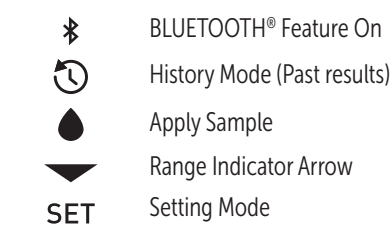
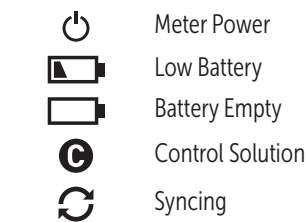
This Owner's Guide offers a complete explanation of how to use your new meter and testing supplies. It reviews the do's and don'ts of testing your blood glucose level. Please keep your Owner's Guide in a safe place; you may want to refer to it in the future.

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

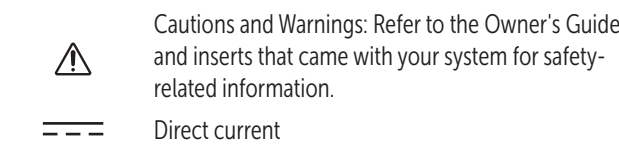
Compatible wireless devices

Visit www.OneTouch.com for information on which wireless devices are compatible with your OneTouch Ultra Plus Flex™ Meter, and where/how to download the OneTouch Reveal® Mobile App on your compatible wireless device.

Meter symbols and icons



Other symbols and icons



Before you begin

Before using this product to test your blood glucose, carefully read this Owner's Guide, and the inserts that come with the OneTouch Ultra Plus™ Test Strips and OneTouch Ultra 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 infectious or potentially infectious. A used kit may potentially transmit infectious diseases even after you have performed cleaning and disinfection.

For more information see: FDA Public Health Notification: "Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) [http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm](http://wayback.archive-it.org/7993/20170111015014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm).

CDC website on "Infection Prevention during Blood Glucose Monitoring and Insulin Administration" (2010) <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>.

Intended use

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

⚠WARNING: This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by the FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Limitations

The OneTouch Ultra Plus Flex™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. The OneTouch Ultra Plus Flex™ System is not to be used for the diagnosis or screening of diabetes or for neonatal use. The OneTouch Ultra Plus Flex™ System is not for use on critically ill patients, patients in shock, severely dehydrated patients or hyperosmolar patients (with or without ketosis). **Do Not** use the OneTouch Ultra Plus Flex™ System for alternate site testing (AST). OneTouch Ultra Plus™ Test Strips should not be used at altitudes above 10,000 feet as there may be an adverse effect on test results. Hematocrit is the percentage of red blood cells in the blood. Extremes in hematocrit may affect test results. Hematocrit levels below 20% may cause false high readings. Hematocrit levels over 60% may cause false low readings. Talk to your healthcare professional if you don't know your hematocrit level. The OneTouch Ultra Plus Flex™ Blood Glucose Monitoring System should not be used within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high glucose results with your meter. **Do Not** use the OneTouch Ultra Plus Flex™ Blood Glucose Monitoring System if you are being treated for organophosphate poisoning with Pralidoxime (PAM) as it may cause inaccurate glucose results with your meter.

If you have medical conditions that are associated with high uric acid level or hyperuricemia (e.g. Gout), then please check with your doctor before using the OneTouch Ultra Plus Flex™ Blood Glucose Monitoring System. Uric acid at concentrations greater than 8 mg/dL can interfere with glucose measurements.

If you take drugs containing acetaminophen (e.g. Tylenol etc.) or Dopamine at doses higher than the recommended high therapeutic level, then you may obtain inaccurate readings from the OneTouch Ultra Plus Flex™ Blood Glucose Monitoring System. Please check with your doctor if you are unsure.

As your partner in diabetes care, we welcome you to contact us (Monday to Friday, 8:00 AM - 8:00 PM Eastern Time) at 1 888 567-3003 (English), 1 888 567-3010 (Español), or www.OneTouch.com. For assistance outside of these hours, please contact your healthcare professional.

Manufactured by: LifeScan Europe GmbH
Dammstrasse 19
6300 Zug
Switzerland

Meter Made in China

Patent <https://www.onetouch.com/patents>



FILE-PF-051119 Rev01
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IP Holdings, LLC
Rev. Date: 03/2025

1 Getting to know your system

Your OneTouch Ultra Plus Flex™ Blood Glucose Monitoring System

Included with your kit:



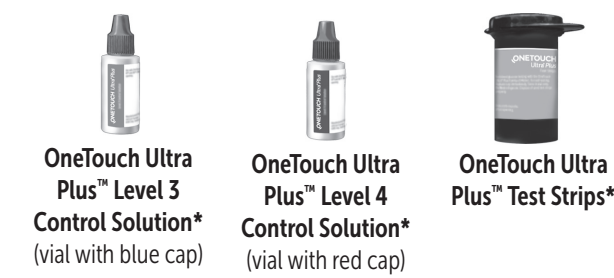
NOTE: If any item is missing or defective in your kit, contact Customer Service. As your partner in diabetes care, we welcome you to contact us (Monday to Friday, 8:00 AM - 8:00 PM Eastern Time) at 1 888 567-3003 (English), 1 888 567-3010 (Español), or www.OneTouch.com.

NOTE: 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.

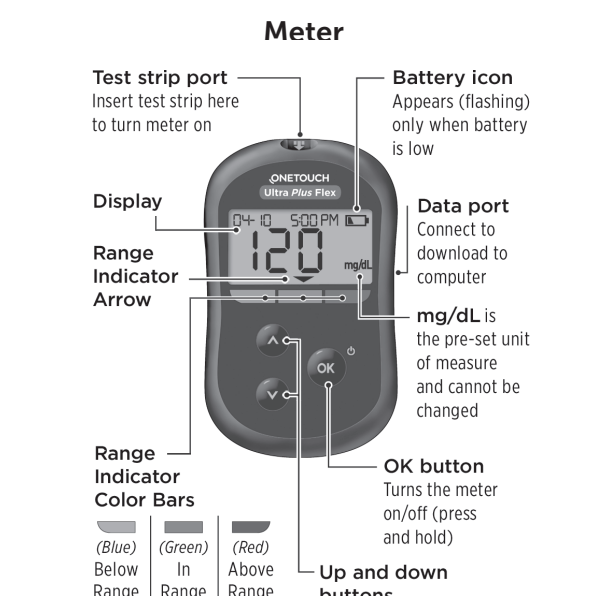


*OneTouch Ultra Plus™ Control Solution and Test Strips and OneTouch® Delica® Plus Lancing products are available separately. For availability of test strips and control solution and lancing products, contact Customer Service or ask your pharmacist or healthcare professional.

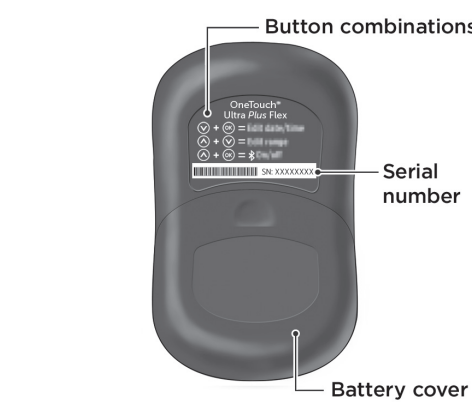
You can use either OneTouch Ultra Plus™ Level 3 Control Solution or OneTouch Ultra Plus™ Level 4 Control Solution with your OneTouch Ultra Plus Flex™ Meter.

⚠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.

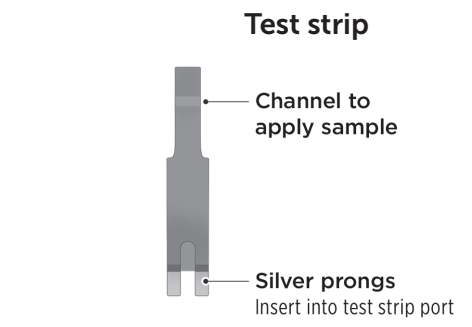
Getting to know your OneTouch Ultra Plus Flex™ Blood Glucose Monitoring System



–5–



Getting to know your OneTouch Ultra Plus™ Test Strip



The Range Indicator feature

The OneTouch Ultra 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 Color Bar below the meter display. Use the Range Indicator Arrow and Color Bar together to interpret your results.



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.



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 70 mg/dL and the pre-set high range limit is 180 mg/dL. 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

To turn your meter on, press and hold **OK** until the start-up test screen appears. Once the device is on, release **OK**. 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 Service. Contact us at 1 888 567-3003.

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

First time setup

To turn your meter on, press and hold **OK** until the start-up screen appears. Once the device is on, release **OK**. 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 **OK** to confirm.
- If the hour displayed is not correct, press **Left** or **Right** to change the hour and press **OK** to confirm.

Minutes will flash

- If the minutes displayed is correct, press **OK** to confirm.
- If the minutes displayed is not correct, press **Left** or **Right** to change the minutes and press **OK** to confirm.

AM/PM will flash

- If the AM/PM displayed is correct, press **OK** to confirm.
- If the AM/PM displayed is not correct, press **Left** or **Right** to change AM/PM and press **OK** 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 **OK** to confirm.
- If the year displayed is not correct, press **Left** or **Right** to change the year and press **OK** to confirm.

Month will flash

- If the month displayed is correct, press **OK** to confirm.
- If the month displayed is not correct, press **Left** or **Right** to change the month and press **OK** to confirm.

Day will flash

- If the day displayed is correct, press **OK** to confirm.
- If the day displayed is not correct, press **Left** or **Right** to change the day and press **OK** to confirm.

You are now ready to take a test. See "Testing your blood glucose".

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 **OK** to turn the meter on, then press and hold **Left** and **Right** 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 **Bluetooth** symbol will appear on the meter screen when the BLUETOOTH® feature is on. When the **Bluetooth** symbol is not present on the screen the BLUETOOTH® feature is off.

- To turn the BLUETOOTH® feature on press **Left** and **Right** at the same time.
- To turn the BLUETOOTH® feature off press **Left** and **Right** at the same time.

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

Pairing Overview

Pairing allows your OneTouch Ultra Plus Flex™ Meter to communicate with compatible wireless devices. The devices must be within 26 feet 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.

Multiple OneTouch Ultra 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".

Your OneTouch Ultra 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 **OK** button
2. The BLUETOOTH® feature is turned on by pressing **Left** and **Right** together

The **Bluetooth** 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



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 **OK** button to enter History Mode.

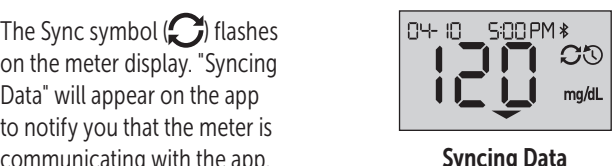
6. Wait for your compatible wireless device to indicate that your meter and compatible wireless device are paired

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 **OK** to turn the meter on and make sure the BLUETOOTH® feature is ON as indicated by (B)

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



After syncing, the Sync symbol will disappear, the "Syncing Data" message will disappear on the app, and the app will display a list of any new results sent from the meter.

NOTE: Inserting a test strip during the transmission will cancel the transfer of all results. The flashing **Bluetooth** symbol appears on the screen and you can proceed with testing.

Turning the meter off

There are three ways to turn your meter off:

- Press and hold **OK** for several seconds until the meter turns off.
- Remove the test strip.
- Your meter will turn off by itself if left alone for two minutes.

NOTE: Following a glucose test, the meter will still be available for BLUETOOTH® connection for up to 4 hours. See "Sending your results to the app" for more details.

3 Taking a test

Testing your blood glucose

Preparing for a blood glucose test

NOTE: Many people find it helpful to practice testing with control solution before testing with blood for the first time. See "Control solution testing precautions".

Have these things ready when you test:

- OneTouch Ultra Plus Flex™ Meter
- OneTouch Ultra Plus™ Test Strips
- Lancing device
- Sterile lancets
- Use only OneTouch Ultra Plus™ Test Strips.
- Unlike some blood glucose meters, no separate step to code your OneTouch Ultra Plus Flex™ System is required.
- Testing must be done within operating temperature range (50–104°F) and 10–90% non-condensing relative humidity.
- Make sure your meter and test strips are about the same temperature before you test.
- Keep test strips in a cool, dry place between 41°F and 86°F and below 65% relative humidity. See "Storing your system" for full storage instruction.
- **Do Not** test if there is condensation (water build-up) on your meter. Move your meter and test strips to a cool, dry spot and wait for the meter surface to dry before testing.

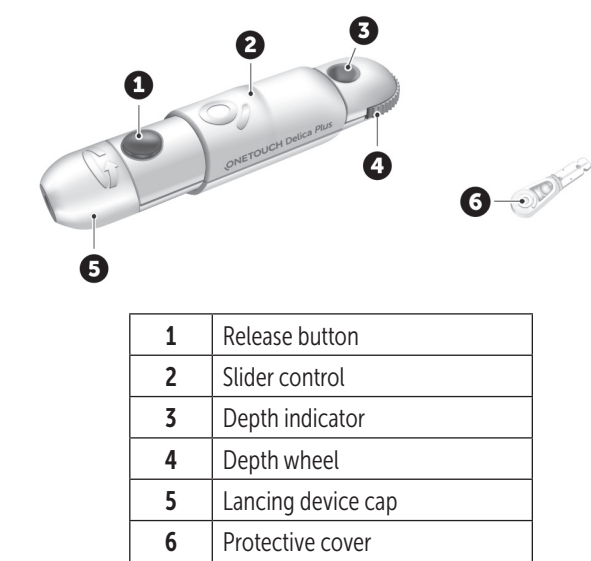
- **Do Not** open the test strip vial until you are ready to remove a test strip and perform a test. Use the test strip immediately after removing it from the vial.
- Tightly close the cap on the vial immediately after use to avoid contamination and damage.
- Store unused test strips only in their original vial.
- **Do Not** return the used test strip to the vial after performing a test.
- **Do Not** re-use a test strip that had blood, control solution, or any contaminants applied to it. Test strips are for single use only.
- With clean, dry hands, you may touch the test strip anywhere on its surface. **Do Not** bend, cut or modify the test strip in any way.
- When you first open a vial of test strips, record the discard date on the label. Refer to the test strip insert or vial label for instructions on determining the discard date.
- 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.

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

⚠CAUTION:

- **Do Not** use your test strips if your vial is damaged or left open to air. This could lead to error messages or inaccurate results. Contact Customer Service immediately if the tightly closed vial is damaged. Contact us at 1 888 567-3003.
- 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 expiration date (printed on the vial) or the discard date, whichever comes first, or your results may be inaccurate.

Getting to know your OneTouch® Delica® Plus Lancing Device



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 Ultra 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 Ultra Plus Flex™ Blood Glucose Monitoring System.
- Keep the lancing device away from young children. Patients younger than 18 years old should be supervised by adults when using the OneTouch® Delica® Plus Lancing Device and OneTouch® Delica® Plus lancets. The lancing device, cap, lancets and lancet protective covers are choking hazards.

Lancing precautions

⚠CAUTION:

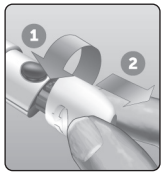
- To reduce the chance of infection and disease spread by blood:
- Make sure to wash the sample site with soap and warm water, rinse and dry before and after sampling. Contaminants on the skin may affect results.
- The lancing device is intended for a single user. Never share a lancet or lancing device with anyone.
- Always use a new, sterile lancet each time you test. Used lancet blades must be safely discarded after a single use.
- Always keep your meter and lancing device clean, disinfect reusable components according to manufacturer's instructions between each use. (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! Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested.

- After use and exposure to blood, all parts of this kit are considered infectious or potentially infectious. A used kit may transmit infectious diseases even after you have performed cleaning and disinfection.
- **Do Not** use lancets after the expiration date printed on the lancet packaging.
- Risk of injury. If the penetration depth is too deep, the puncture can injure children. Before using the lancing device for the first time on children, ask your healthcare professional. Start with the lowest penetration depth.

Preparing your lancing device

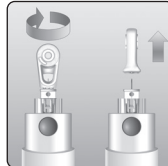
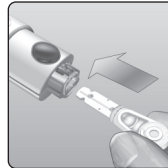
1. Remove the lancing device cap

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



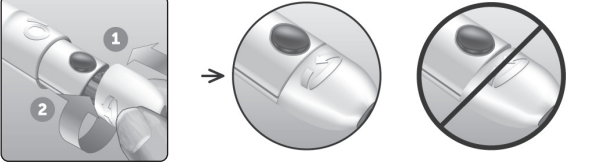
2. Insert a sterile lancet into the lancing device

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.



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.



–29–

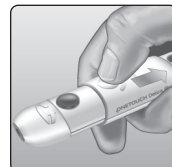
4. Adjust the depth setting

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

Hold 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

Interpreting unexpected results

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

⚠CAUTION:

Low results

If your result is below 70 mg/dL or is shown as **LO** (meaning the result is less than 20 mg/dL), it may mean hypoglycemia (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.

NOTE: When your glucose result is below 20 mg/dL, both the **LO** and the Range Indicator Arrow will flash on the meter screen.

⚠CAUTION:

Dehydration and low results

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



If your result is above 180 mg/dL, it may mean hyperglycemia (high blood glucose) and you should consider re-testing. Talk to your healthcare professional if you are concerned about hyperglycemia.

If **HI** is displayed when your result is over 600 mg/dL, you may have severe hyperglycemia (very high blood glucose). Re-test your blood glucose level. If the result is **HI** again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional immediately.

NOTE: When your glucose result is above 600 mg/dL, both the **HI** and the Range Indicator Arrow will flash on the meter screen.

⚠CAUTION:

Repeated unexpected results

- If you continue to get unexpected results, check your system with control solution.
- If you are experiencing symptoms that are not consistent with your results and you have followed all instructions in this Owner's Guide, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes management program without speaking to your healthcare professional.

Usual red blood cell count

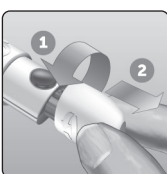
A hematocrit (percentage of your blood that is red blood cells) that is either very high (above 60%) or very low (below 20%) can cause false results.

Removing the used lancet

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

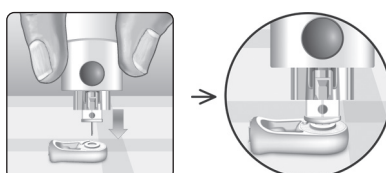
1. Remove the lancing device cap

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



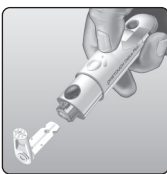
2. Cover the exposed lancet tip

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



3. Eject the lancet

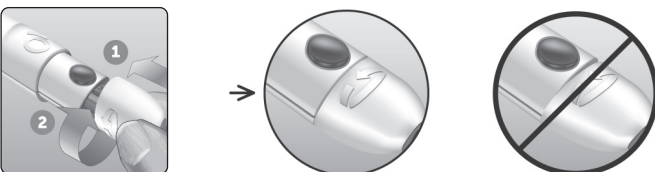
Holding the lancing device directed downwards, push the slider forward until the lancet comes out of the lancing device. If the lancet fails to eject properly, cock the device then push the slider control forward until the lancet comes out.



4. Replace the lancing device cap

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

Ensure the cap is aligned as shown in the image.



It is important to use a new lancet each time you obtain a blood sample. **Do Not** leave a lancet in the lancing device. This will help prevent infection and sore fingertips.

Discarding 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 infectious or potentially infectious 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.

Testing with control solution

Control solution testing precautions

OneTouch Ultra 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:

- Use only OneTouch Ultra Plus™ Level 3 Control Solution or OneTouch Ultra Plus™ Level 4 Control Solution with your OneTouch Ultra Plus Flex™ Meter. Either level can be used to check your system.
- When you first open a new vial of control solution, record the discard date from 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.

See "Testing your blood glucose" for more information on testing.

⚠CAUTION:

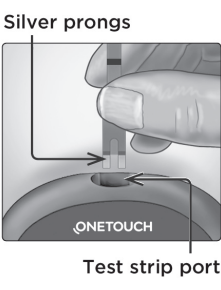
- Do Not** swallow or ingest control solution.
- Do Not** apply control solution to the skin, eyes, ears or nose as it may cause irritation.
- Do Not** use control solution after the expiration date (printed on the vial label) or the discard date, whichever comes first, or your results may be inaccurate.

When to do a control solution test

- When 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 readings.
- If you drop or damage the meter.

Preparing your meter for a control solution test

1. Insert a test strip to turn the meter on



Test strip port

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



3. Press and hold or until the control solution icon appears on the display

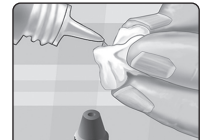


Preparing the control solution

1. Before removing the cap, shake the vial gently

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

3. Squeeze the vial to discard the first drop



- The meter will attempt to transmit results up to 4 hours after a test, even if the meter appears to be off. This is indicated by the BLUETOOTH® symbol (⌘) remaining on the meter screen.



Example

If you are still unable to send results to the compatible wireless device, please call Customer Service. Contact us at 1 888 567-3003.

NOTE: Inserting a test strip during the transmission will cancel the transfer of all results. The blood drop symbol appears on the screen and you can proceed with testing.

Downloading results to a computer

Your meter can work with diabetes management software, which provides a visual way to track key factors that affect your blood sugar. To learn more about diabetes management tools available to you, contact Customer Service. As your partner in diabetes care, we welcome you to contact us (Monday to Friday, 8:00 AM - 8:00 PM Eastern Time) at 1 888 567-3003 (English), 1 888 567-3010 (Español) or www.OneTouch.com.

Contact only to a computer certified to IEC 62368-1.

–35–

–36–

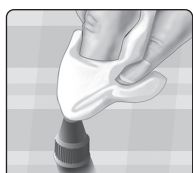
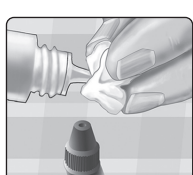
–37–

–38–

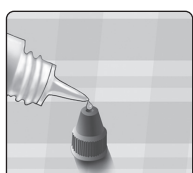
–39–

–40–

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

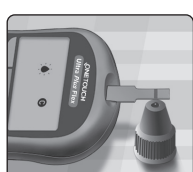


5. Squeeze a drop into the small well on the top of the cap or onto another clean, non-absorbent surface



Applying the control solution

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



2. Touch the channel on the side of the test strip to the control solution



3. Wait for the channel to fill completely

Viewing your control solution result

After the control solution is applied, the meter will count down until the test is complete. Your result is displayed along with the date, time, unit of measure, and (for control solution) and stored in the meter. Control solution results can be seen when reviewing past results on the meter.

⚠CAUTION: Make sure you press and hold or until the control solution icon appears before you begin a control solution test. Invalid results may be logged into your history if you applied control solution to the test strip without following the steps beginning in the "Testing with control solution" section.



Checking if the result is in range

Each vial of test strips has both OneTouch Ultra Plus™ Level 3 Control Solution and OneTouch Ultra Plus™ Level 4 Control Solution ranges printed on its label. Compare the result displayed on the meter to either the OneTouch Ultra Plus™ Level 3 Control Solution or OneTouch Ultra Plus™ Level 4 Control Solution range printed on the test strip vial, depending on the type of control solution you used.



Example range
OneTouch Ultra Plus™
Level 3 Control Solution
Control Range
102-138 mg/dL
OneTouch Ultra Plus™
Level 4 Control Solution
Control Range
298-403 mg/dL

⚠CAUTION:

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

Causes of out-of-range results

Out-of-range results may be due to:

- Not following the instructions for performing a control solution test.
- Control solution is contaminated, expired, or past its discard date.
- Test strip or test strip vial is damaged, expired, or past its discard date.
- Meter, test strips and/or control solution were not all at the same temperature when the control solution test was performed.

- A problem with the meter.
- Dirt or contamination in the small well on the top of the control solution cap.

⚠CAUTION:

If you continue to get control solution results that fall outside the range printed on the test strip vial, **Do Not** use the meter, test strips, or control solution. Contact Customer Service. Contact us at 1 888 567-3003.

Cleaning the control solution cap

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

4 Reviewing past results

Reviewing past results on your meter

Your meter stores your most recent 500 blood glucose and control solution test results and displays them in the order the tests were taken. The symbol will appear on your screen when in History Mode.

1. When the meter is off, press and hold to turn History Mode on

The symbol indicates you are viewing your past results.

The symbol indicates if the result was below, above or within range at the time of the test, by pointing to the appropriate color bar.

2. Scroll through your results by pressing to move backwards and to move forward through your results



–44–

–45–

–46–

To transfer meter data, follow the instructions provided with the diabetes management software product to download the results from the meter. You will need a standard micro USB interface cable to connect your OneTouch Ultra Plus Flex™ Meter to a computer to download results (not included).

Once the command to start the download is sent from the computer to the meter, the meter display will show the flashing Sync symbol indicating that the meter is in communication mode.

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

If you are unable to download your results to a computer, please call Customer Service. Contact us at 1 888 567-3003.



5 Editing your settings

Editing time and date

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, and the hour will flash.

For instructions on adjusting the time and date, see "First time setup".

After adjusting the settings, you will exit settings mode and your last glucose result screen will appear. The adjusted time and date will be displayed once a new glucose test has been completed and the result appears on the screen.

NOTE: You will not be able to perform a blood glucose test until you finish editing the time and date.

NOTE: The OneTouch Reveal® Mobile App on your compatible wireless device checks and updates the time and date in your meter each time you sync. Check the time and date often on your compatible wireless device to be sure they are correct. See the App instructions for more information.

Editing your range limits

Your meter uses low and high range limits to tell you when your result is below, above or within your set range. The meter comes with pre-set range limits that can be changed. The pre-set low range limit is 70 mg/dL and the pre-set high range limit is 180 mg/dL. To edit the pre-set range limits press and hold and at the same time. The SET screen will appear with the current low range limit displayed, and the number and range indicator arrow will flash.

NOTE: The low and high range limits you set apply to all glucose test results. This includes tests taken before or after meals, medications and around any other activities that may affect your blood glucose.

⚠CAUTION:

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

1. Review the pre-set low range limit displayed

- To accept the pre-set low range limit, press.
- To edit the pre-set low range limit, press or to change the value between 60 mg/dL-110 mg/dL, and then press.



2. Review the pre-set high range limit displayed

- To accept the pre-set high range limit, press.
- To edit the pre-set high range limit, press or to change the value between 90 mg/dL-300 mg/dL, and then press.



Your meter will exit settings mode and your last result screen will appear.

NOTE: If you change your range limits, this will only affect whether future test results are displayed as below, above or within your range limits. Changing your range limits does not affect how past results are displayed.

NOTE: You will not be able to perform a glucose test until you finish editing the range limits.

NOTE: You can use the OneTouch Reveal® Mobile App on your compatible wireless device to change the range limits stored in your meter. See the instructions that came with the app for more information.

6 Caring for your system

Storing your system

Once opened, store your meter, test strips, control solution, lancing device and lancets in your carrying case. Keep in a cool, dry place between 41°F and 86°F and below 65% relative humidity. Keep away from direct sunlight and heat. **Do Not** store the test strip vial in rooms where the air is humid such as the kitchen, laundry room or bathroom. Exposure to temperatures outside the storage limits, as well as moisture and humidity, may cause inaccurate readings.

Cleaning and disinfection

Cleaning and disinfection are different. Both should be performed at least once per week. Cleaning is part of your normal care and maintenance, but does not kill germs. You should clean your meter, lancing device and cap before disinfecting. After use and exposure to blood, all parts of this kit may transmit infectious diseases. Disinfection is the only way to reduce your exposure to disease.

For cleaning information, see "Cleaning your meter, lancing device and cap" and for disinfecting information, see "Disinfecting your meter, lancing device and cap".

For cleaning and disinfecting, Clorox® Germicidal Wipes® containing 0.55% sodium hypochlorite as the active ingredient have been shown to be safe for use with the OneTouch Ultra Plus Flex™ System and can be obtained from retail websites offering disinfection products, e.g., www.officedepot.com or www.staples.com. For more information on purchase options contact Customer Service. Contact us at 1 888 567-3003.

If the meter does not power on after you have replaced the meter battery, check that the battery is correctly installed. If the meter still does not power on, contact Customer Service. Contact us at 1 888 567-3003.

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



Battery cover

4. Check your meter settings

Removing the meter battery will not affect your stored results. However, you will need to check your date and time settings.

5. Dispose of battery

Dispose of the battery according to your local environmental regulations.

8 Troubleshooting your system

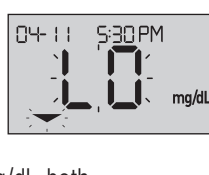
Error and other messages

The OneTouch Ultra Plus Flex™ Meter displays messages when there are problems with the test strip, with the meter or when your glucose levels are above 600 mg/dL or below 20 mg/dL. 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 Service. Contact us at 1 888 567-3003.

What it means

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



NOTE: When your glucose result is below 20 mg/dL, both the **LO** and the Range Indicator Arrow will flash on the meter screen.

What to do

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

What it means

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



NOTE: When your glucose result is above 600 mg/dL, both the **HI** and the Range Indicator Arrow will flash on the meter screen.

What to do

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

What it means

Meter is too hot (above 104°F) to perform a test.



What to do

Move the meter and test strips to a cooler area. Insert a new test strip when the meter and test strips are within the operating range (50-104°F). If you do not get another **HI** message, you can proceed with testing.

If this message continues to appear, contact Customer Service. Contact us at 1 888 567-3003.

What it means

Meter is too cold (below 50°F) to perform a test.



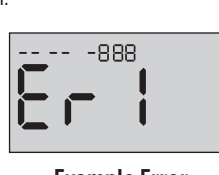
What to do

Move the meter and test strips to a warmer area. Insert a new test strip when the meter and test strips are within the operating range (50-104°F). If you do not get another **LO** message, you can proceed with testing.

If this message continues to appear, contact Customer Service. Contact us at 1 888 567-3003.

Error Screens

If there is a problem with your meter, the following error screens may appear. Along with an error number, there is also an error code in the upper left corner of your meter screen. If you cannot resolve the error with your meter, contact Customer Service. Contact us at 1 888 567-3003. They will refer to the error number and code to help troubleshoot the problem.



Example Error Screen Code

What it means

There is a problem with the meter.



What to do

Do Not use the meter. Contact Customer Service. Contact us at 1 888 567-3003.

What it means

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



What to do

Repeat the test with a new test strip; see "Applying the sample" or "Preparing your meter for a control solution test". If the error message appears again, contact Customer Service. Contact us at 1 888 567-3003.

What it means

The sample was applied before the meter was ready.



What to do

Repeat the test with a new test strip. Apply a blood or control solution sample only after the flashing blood drop symbol appears on the display. If this message continues to appear, contact Customer Service. Contact us at 1 888 567-3003.

What it means

One of the following may apply:

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

What to do

Repeat the test with a new test strip; see "Test your blood glucose" or "Preparing your meter for a control solution test". If the error message appears again, contact Customer Service. Contact us at 1 888 567-3003.



What it means

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



What to do

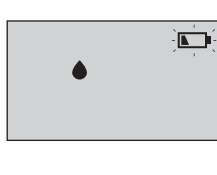
Repeat the test with a new test strip; see "Test your blood glucose" or "Preparing your meter for a control solution test". If the error message appears again, contact Customer Service. Contact us at 1 888 567-3003.

What it means

Meter battery power is low but there is still enough battery power to perform a test. The flashing low battery icon will continue to appear until the battery is replaced.

What to do

Replace the meter battery soon.



What it means

Lifescan [®] Description: Owners Guide UPF USen (LED)				Art Agency: GPL Inverness				Job No.: N/A													
File Name: LIFE-PPF-051119				MC Rev: 01				Contact: David Latham													
CPS Reference No.: N/A				JDE Item No.: N/A				Rev. Date: 07-Mar-25													
ADS No./Rev: DEV-REC-0000561 Rev 12				ADS ID: GUID-09				Outline No./Rev.: N/A													
Language Sequence: English				No. of Covers: ☒				☒													
Inside No. of pages: ☒				No. of sides: 1 ☐ 2 ☒				☒													
Spot Colors				Process Colors				Uncoated Area				Special Instructions				Dieline					
PMS		N/A ☒		 CMYK		 Black		N/A ☐		 Uncoated Area		N/A ☐		 Dieline		N/A ☒		 Gloss		 Matte	
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