

# ONETOUCH

## Ultra Plus Flex™

Blood Glucose Monitoring System

# Owner's Guide

### Instructions for Use

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### 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

- 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

### Before you begin

Before using this product to test your blood glucose, carefully read this Owner's Guide, and the inserts that came 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.

## 1 Getting to know your system

### Your OneTouch Ultra Plus Flex™ Blood Glucose Monitoring System

#### Included with your kit:



### 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 hypotensive 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](http://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

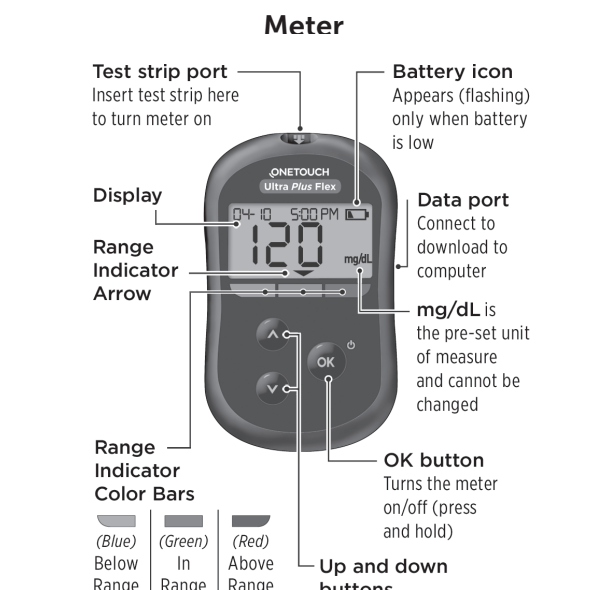
Patent <https://www.onetouch.com/patents>



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IP Holdings, LLC  
Rev. Date: 03/2025

**⚠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



\*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.

### First time setup

To 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.

##### AM/PM will flash

- If the AM/PM displayed is correct, press to confirm.
- If the AM/PM displayed is not correct, press or to change AM/PM 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.

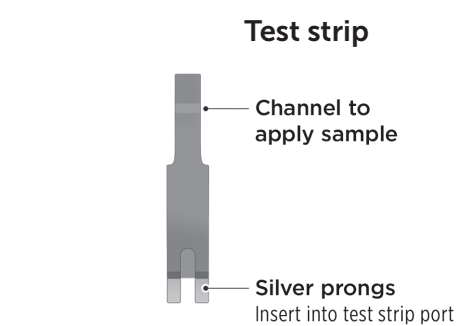
## –5–

### 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.



### Getting to know your OneTouch Ultra Plus™ Test Strip



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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 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.

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

### 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.

### 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

- Start by turning your meter on using the button
- 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

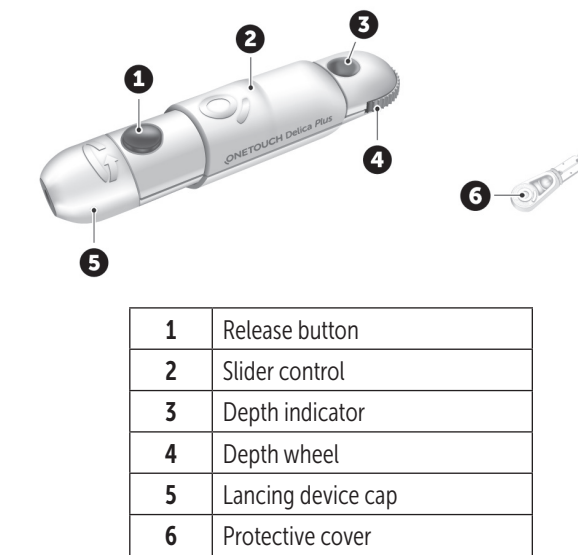


#### 5. When prompted by the OneTouch Reveal® Mobile App, the meter will display a six digit PIN number

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

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### 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.

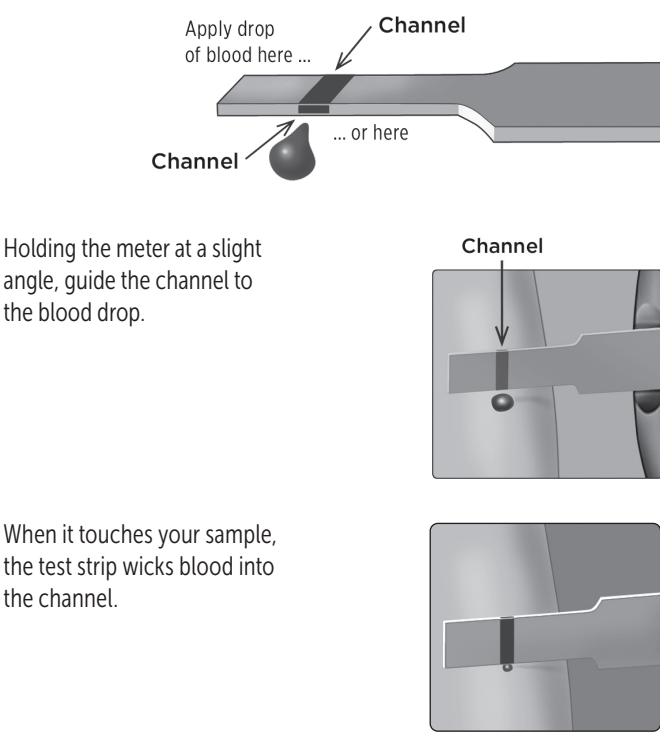
### Applying blood and reading results

#### Applying the sample

##### 1. Apply the sample to the test strip

You can apply blood to either side of the test strip. Apply your sample to the opening of the channel.

Be sure to apply your sample immediately after you get a drop of blood.



## 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
- NOTE:**
- 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".

#### 5. Cock the lancing device

Push 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 blue side of the test strip and the two silver prongs facing you.

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

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.

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## –32–



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**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.

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**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**

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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.

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**3. Wipe dry with a clean, sterile gauze**

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

- 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.
- Do Not** squeeze the germicidal wipe into test strip port.
- Do Not** spray cleaning solution on the meter and lancing device.
- Do Not** immerse the meter and lancing device in any liquid.

The cleaning and disinfection instructions for the lancing device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient.

The OneTouch Ultra Plus Flex™ System withstood cleaning and disinfection cycles well in excess of LifeScan's recommendation. See "Cleaning and Disinfecting Cycles" for more details.

Examples of damage to the meter may include fogged display, cracked housing or lens, illegible labels, button not working or meter malfunction (such as repeated error messages). Examples of damage to the lancing device and cap may include cracking, illegible depth setting numbers and lancing device malfunction (such as failure to load, cock or release).

**Do Not** use your meter or lancing device if you see evidence of such damage. If you have questions about cleaning or disinfecting, or if you see evidence of physical damage, contact Customer Service. As your partner in diabetes care, we welcome you to

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**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**t 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**

**Er 1**

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Technical specifications	
<b>Assay method</b>	FAD-GDH (flavin adenine dinucleotide dependent glucose dehydrogenase)
<b>Automatic shutoff</b>	Two minutes after last action
<b>Battery ratings</b>	3.0 V d.c. (CR2032 lithium coin cell battery), 
<b>Battery type</b>	One replaceable 3.0 Volt CR2032 lithium coin cell battery (or equivalent)
<b>BLUETOOTH® Technology</b>	Frequency band: 2.4-2.4835 GHz Maximum power: 0.4 mW Operating Range Distance: minimum 26.25 feet (unobstructed) Operating Channels: 40 Channels Security Encryption: 128-bit AES (Advanced Encryption Standard)
<b>Calibration</b>	Plasma-equivalent
<b>Data port type</b>	Compatible with USB 2.0
<b>Memory</b>	500 test results
<b>Operating ranges</b>	Temperature: 50-104°F Relative humidity: non-condensing 10-90% Altitude: up to 10,000 feet Hematocrit: 20-60%

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**⚠CAUTION:**

**High results**

- 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.

- 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.

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

**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.

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**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.

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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.

**Cleaning and Disinfecting Cycles**

The meter, lancing device and cap can be cleaned daily for 3 years and have been tested up to 2879 cleaning cycles.

The meter, lancing device and cap can be disinfected weekly for 3 years, and have been tested up to 412 cleaning and disinfection cycles.

**7 Battery**

**Replacing the battery**

Your OneTouch Ultra Plus Flex™ Meter uses one CR2032 lithium coin cell battery.

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

**IMPORTANT:** Use only one CR2032 lithium coin cell battery with your meter. **Do Not** use rechargeable batteries. Use of an incorrect battery type may result in your meter providing fewer tests than normal. If the meter does not turn on, you may need to replace the battery. See below for instructions.

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**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 "Applying the control solution". If this message continues to appear, 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  symbol appears on the display. If this message continues to appear, contact Customer Service. Contact us at 1 888 567-3003.

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**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.

**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.

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**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.

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

**NOTE:** After replacing the battery, you will be prompted to set time and date, as if you are turning the meter on for the first time.

**1. Remove the old battery**

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

**2. Insert the new battery**

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

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**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.

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**Lay User Accuracy**

User Accuracy of the system was assessed at 4 clinical sites. 169 patients tested their blood using the OneTouch Ultra Plus Flex™ System where results were compared to the YSI 2300 Glucose Analyzer laboratory instrument.

**Fingertip Results for Low Glucose Concentrations <75 mg/dL**

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

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
75.0% (15/20)	90.0% (18/20)	95% (19/20)

**Fingertip Results for High Glucose Concentrations ≥75 mg/dL**

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

Within ±5%	Within ±10%	Within ±15%	Within ±20%
63.1% (94/149)	88.6% (132/149)	96.0% (143/149)	100.0% (149/149)

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**4. Replace the lancing device cap**

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

Ensure the cap is aligned as shown in the image.

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

**Disposing of the used lancet and test strip**

Discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used lancets and test strips may be considered 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.

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- 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**

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## 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.

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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**

**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.

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**What it means**

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

**What to do**

Replace the meter battery soon.

**What it means**

There is not enough battery power to perform a test.

**What to do**

Replace the battery immediately.

**What it means**


No result in memory, such as the first time use or when you have chosen to delete all the results after downloading to a computer.

**What to do**

Contact Customer Service to report this occurrence, **unless** this is your first use of the meter. You can still perform a blood glucose test or control solution test and get an accurate result. Contact us at 1 888 567-3003.

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**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.

–56–

**What it means**

There is not enough battery power to perform a test.

**What to do**

Replace the battery immediately.

**What it means**

No result in memory, such as the first time use or when you have chosen to delete all the results after downloading to a computer.

**What to do**

Contact Customer Service to report this occurrence, **unless** this is your first use of the meter. You can still perform a blood glucose test or control solution test and get an accurate result. Contact us at 1 888 567-3003.

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Regression Statistics			
Samples were tested on each of three test strip lots. Results indicate that the OneTouch Ultra Plus Flex™ System compares well with a laboratory method.			
# of Subjects	# of Tests	Slope	Intercept (mg/dL)
169	169	1.02	-1.29
95% CI Slope			
1.01 to 1.04	-5.66 to 3.08	13.6	0.99
Precision			
Within Run Precision (300 Venous Blood Samples Tested per Glucose Level) Data generated using the OneTouch Ultra Plus Flex™ Meter.			
Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
40	34.98	0.86	2.46
90	98.81	1.89	1.91
130	139.26	2.95	2.11
200	222.32	4.28	1.92
350	382.15	8.14	2.13

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**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 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.

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.

**Using the meter without syncing to an app**

The meter can be used without a compatible wireless device or the app. You can still test your blood glucose and review up to 500 results on the meter.


**Sending your results to the app**

If the BLUETOOTH® feature on the meter is turned on, indicated by the BLUETOOTH® symbol , the meter will automatically send the latest result to any paired compatible wireless device. The compatible wireless device must have the app running and have already been paired to the meter before sending a result.

**NOTE:** The compatible wireless device must have the app open and have already been paired to the meter before sending a result. See "Pairing Overview".

**NOTE:** If the BLUETOOTH® feature on the meter is **turned off**, or the meter is out of range, the result is not sent to the compatible wireless device. The result is saved in the meter memory with the current date and time, and will be sent to the app the next time you sync. The sent results are also stored in the meter. To sync, the app must be open and running on your compatible wireless device.

To ensure that glucose test results are successfully sent to the app, turn on the BLUETOOTH® feature and check the following:

- The compatible wireless device and meter are both turned on, and the app is running.
- The meter is correctly paired with your compatible wireless device.
- The BLUETOOTH® feature on both devices is running (indicated by ) and the devices are within 26 feet of each other.

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\*Other products, such as Clorox® Disinfecting Wipes, have not been tested and should not be used. Only Clorox® Germicidal Wipes should be used. Follow manufacturer's instruction for handling and storage of wipes. Clorox® is a registered trademark of the Clorox Company.

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

**Cleaning your meter, lancing device and cap**

The meter, lancing device and cap should be cleaned at least once per week. Be sure to clean the meter, lancing device and cap before disinfecting.

**1. Use a Clorox® Germicidal Wipe to wipe the outside of the meter and lancing device**

To clean your meter, hold it with the test strip port pointed down. Be sure to squeeze out any excess liquid before you wipe the meter.

Wipe the outside of the lancing device cap.

**2. Wipe dry with a clean, sterile gauze**

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**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.

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**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.

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**9 Detailed information about your system**

**Comparing meter results to laboratory results**

Results obtained from the OneTouch Ultra Plus Flex™ 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 Ultra Plus Flex™ Meter is considered accurate when it is within 15 mg/dL of a laboratory method when the glucose concentration is lower than 75 mg/dL and within 15% of a laboratory method when the glucose concentration is 75 mg/dL 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 70 mg/dL higher than a lab test using blood drawn from a vein.<sup>1</sup>
- Your hematocrit is above 60% or below 20%.
- You are severely dehydrated.

For additional information, refer to the OneTouch Ultra Plus™ Test Strip Insert.

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

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Glucose Level Ranges (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 2 (25-49)	36.87	0.97	2.62
Level 3 (102-138)	117.98	2.19	1.86
Level 4 (298-403)	352.08	7.92	2.25

Results show that the greatest variability observed between test strips when tested with blood is 0.86 mg/dL SD or less at glucose levels less than 75 mg/dL or 2.13% CV or less at glucose levels at 75 mg/dL or above.

Total Precision (600 Control Solution Tests per Glucose Level)  
Data generated using the OneTouch Ultra Plus Flex™ Meter.

Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
40	34.98	0.86	2.46
90	98.81	1.89	1.91
130	139.26	2.95	2.1



<b>Lifescan</b> <sup>®</sup> Description: Owners Guide UHF USen (LED)		Art Agency: GPL Inveness		Job No.: N/A	
File Name: FILE-PF-051119		MC Rev.: 01		Contact: David Latham	
GPS Reference No.: N/A		JDE Item No.: N/A		Rev. Date: 07-Mar-25	
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				Outline	
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