### Thanks for choosing OneTouch®! **ONETOUCH** The OneTouch Ultra Plus Flex™ Blood Glucose Monitoring System is one of the latest product innovations from OneTouch® **Ultra Plus Flex**<sup>™</sup> Your OneTouch Ultra Plus Flex<sup>™</sup> Meter is designed to connect (sync) with a variety of compatible wireless devices running software applications

# Owner's Guide

Instructions for Use

# **Table of Contents**

1 Getting to know your system...... 2 Setting up your system.... 3 Taking a test.. 4 Reviewing past results......44

5 Editing Your Settings ...... 6 Caring for your system.....

8 Troubleshooting your system .....

9 Detailed information about your system...... 63

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.

that let you review and graph your results, and help identify patterns.

Every OneTouch® Meter is designed to help you test your blood glucose

This Owner's Guide offers a complete explanation of how to use your

your blood glucose level. Please keep your Owner's Guide in a safe

new meter and testing supplies. It reviews the do's and don'ts of testing

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

Meter results are sent to the compatible devices either through

BLUETOOTH® (wireless) or USB cable connection.

place; you may want to refer to it in the future.

and manage your diabetes.

Meter symbols and icons (J Meter Power

Syncing

Low Battery Battery Empty 0 Control Solution

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# Before you begin

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

===

# Direct current

BLUETOOTH® Feature On

History Mode (Past results)

Range Indicator Arrow

Apply Sample

Setting Mode

Other symbols and icons

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 Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://wayback.archive-it.org/7993/20170111013014/http://www.fda. gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. -2-

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 longterm 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

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<sup>™</sup> 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<sup>™</sup> 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.

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

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.

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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.

As your partner in diabetes care, we welcome you to contact us

(Monday to Friday, 8:00 AM - 8:00 PM Eastern Time) at

Manufactured by: Dammstrasse 19 6300 Zug

Switzerland

Meter Made in China Patent https://www.onetouch.com/patents



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Rev. Date: 03/2025

## 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<sup>™</sup> Test Strips with meters for which they are not intended may yield inaccurate results.

BLUETOOTH® wireless technology is used by some smartphones

## **BLUETOOTH®** wireless technology

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<sup>™</sup> 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<sup>™</sup> 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.

limits set forth for an uncontrolled environment. This device complies with Part 15 of the FCC Rules. Operation is subject

This equipment complies with portable FCC radio frequency exposure

to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation. NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help. These quidelines help ensure that your meter will not affect the operation of other nearby electronic devices. Additionally, other electronic devices should not affect the use of your meter. If you experience meter interference problems, try moving your meter away from the source of the interference. You can also move the electronic device or its antenna to another location to solve the

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**WARNING**: The BLUETOOTH® feature on your meter sends test results to your compatible wireless device. To prevent other people's results from being sent to your compatible

wireless device, **Do Not** let anyone else use your meter to test their blood glucose. This meter is for single patient use only. **MARNING:** In locations where cell phone use is not permitted, such as hospitals, some healthcare professional offices and airplanes, you should turn the BLUETOOTH® feature off. See "Turning the **BLUETOOTH®** feature on or off" for more information.

**Do Not** leave your meter unattended or in a public place so that others may change your personal parameters or make physical connections to it. The meter has been designed defensively to ward off malicious intent and has been tested accordingly. **BLUETOOTH®** trademark

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

# 1 Getting to know your system

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**Glucose Monitoring System** 

Your OneTouch Ultra Plus Flex™ Blood

Included with your kit:



Lancing device<sup>1</sup> Lancets\* we welcome you to contact us (Monday to Friday, 8:00 AM - 8:00 PM Eastern Time) at 1 888 567-3003 (English), 1888 567-3010 (Español), or www.OneTouch.com. **NOTE:** If another type of lancing device was included, see the separate

**NOTE:** If any item is missing or defective in your kit,

contact Customer Service. As your partner in diabetes care,

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



(vial with blue cap)

OneTouch Ultra OneTouch Ultra Plus™ Level 4 Plus™ Test Strips\* Control Solution (vial with red cap) \*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<sup>™</sup> Meter.

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NARNING: 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



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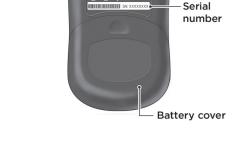
04-22 (20 15)

SET

)04<del>,</del>22 20 (5)

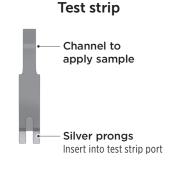
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**Test Strip** 

Getting to know your OneTouch Ultra Plus™



# The Range Indicator feature

The OneTouch Ultra Plus Flex<sup>™</sup> 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

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Example Below Range In Range Result Result

• The meter comes with pre-set range limits. The pre-set low range your range limits" for details on the pre-set range limits and on editing your range limits.

## Setting up your meter 200 To turn your meter on, press and hold

Example Above Range Result Things you should know before using the Range Indicator feature:

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 • 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

# Setting up your system

# Turn your meter on

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

test until you complete the first time setup.

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.

mmol/L mg/dL

## **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 1888 567-3003. **NOTE:** If you turned the meter on for the first time by inserting a test strip instead of pressing ox, you will not be able to perform a glucose

## First time setup Io turn your meter on, press and hold ox

appears. Once the device is on, release or. 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.

# Hour will flash

· If the hour displayed is correct, press ok to confirm. · If the hour displayed is not correct,

press or to change the hour and press or to confirm. Minutes will flash

## · If the minutes displayed is correct, press ox to confirm

• If the minutes displayed is not correct,

press or to change the minutes and press ox to confirm.

## AM/PM will flash • If the AM/PM displayed is correct,

press or to confirm.

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

## Month will flash • If the month displayed is correct, press

5,45,PM

5:45 PM

press or to change the month and press or to confirm.

Setting the date

Year will flash

ok to confirm.

ok to confirm.

Day will flash

• If the year displayed is correct, press

• If the year displayed is not correct,

and press or to confirm.

press or to change the year

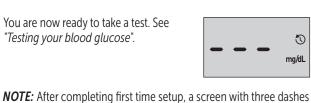
• If the month displayed is not correct,

• If the day displayed is correct, press ok to confirm. If the day displayed is not correct,

press or to change the day and press or to confirm.

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your last result screen will appear.



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## 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 or to turn the meter on, then press and hold ox and vat the same time. The SET screen will appear. See "Editing time and date".

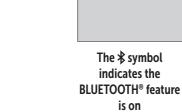
After adjusting the settings, your meter will exit settings mode and

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

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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®

To turn the BLUETOOTH® feature off press on and on at the same



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

### Connecting to a compatible wireless device **Pairing Overview** Turning the BLUETOOTH® feature on or off

App from the appropriate app store before pairing your meter and compatible wireless device.

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 Your OneTouch Ultra Plus Flex<sup>™</sup> Meter can be paired with multiple compatible wireless devices. To pair multiple compatible wireless

# **Pairing Instructions** 1. Start by turning your meter on using the w button

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

Multiple OneTouch Ultra Plus Flex™ Meters can be paired with your compatible wireless device. For example, your compatible wireless

device.

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



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

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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

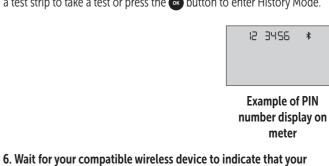


will display a six digit PIN number

# **CAUTION:**

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

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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

1. Open the OneTouch Reveal® Mobile App on your compatible 2. Press and hold to turn the meter on and make sure the BLUETOOTH® feature is ON as indicated by (\*)

ready to send results to the OneTouch Reveal<sup>®</sup> Mobile App.

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

# to notify you that the meter is communicating with the app.

Syncing Data

After syncing, the Sync symbol will disappear, the "Syncing Data"

screen and you can proceed with testing.

# Turning the meter off

There are three ways to turn your meter off:

• 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.

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considered infectious or potentially infectious. A used kit may

transmit infectious diseases even after you have performed

• 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

• **Do Not** use lancets after the expiration date printed on the

cleaning and disinfection.

lowest penetration depth.

Preparing your lancing

1. Remove the lancing device cap

pulling it straight off the device.

Remove the cap by rotating it and then

lancet packaging.

# Testing your blood glucose

3 Taking a test

solution before testing with blood for the first time. See "Control solution testing precautions". Have these things ready when you test:

## OneTouch Ultra Plus™ Test Strips Lancing device Sterile lancets

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

OneTouch Ultra Plus Flex™ Meter

- 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.
- 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.

• **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

• 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

determining the discard date.

the label. Refer to the test strip insert or vial label for instructions on

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

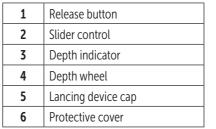
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• Comparing your blood glucose test results taken with this meter

## **ACAUTION:** • **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 test strip 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.

**Lancing Device** 



# 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<sup>™</sup> Blood Glucose Monitoring System
- fingertips when testing with the system.
- 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.





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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

· 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:**

Monitoring System.

# 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 • 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.
- 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,

• Always keep your meter and lancing device clean, disinfect reusable

particularly in settings where multiple patients are tested. -27-2. Wait for the channel to fill completely

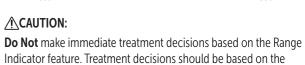
## The blood drop will be drawn into the narrow channel. The channel should fill completely.

edge of the test strip.

# **⚠CAUTION**:



Viewing your result



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Your result appears on the display, along with the unit of measure,

and the date and time of the test. After your glucose result appears,

the meter will also display a Range Indicator Arrow below your

displayed. If your display shows mmol/L rather than mg/dL, stop

using the meter and contact Customer Service.

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# Preparing for a blood glucose test

## NOTE: Use only OneTouch Ultra Plus<sup>™</sup> Test Strips.

- (50-104°F) and 10-90% non-condensing relative humidity.
- 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.
- -23-2. Insert a sterile lancet into the lancing



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. Ensure the cap is aligned as shown in the image.



## dot shown between numbers 1 to 7 on the Depth Wheel indicates an additional available depth setting). Adjust the depth by turning the depth

4. Adjust the depth setting

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.

The device has 13 puncture depth settings (each



1. Puncture your finger Hold the lancing device firmly against the

2. Get a round drop of blood until a round drop of blood forms.

NOTE: If the blood smears or runs, Do Not use that sample. Dry the area and gently



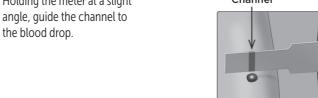
# Enter the PIN number into your compatible wireless device using the keypad on your compatible wireless device.

-20-Getting to know your OneTouch® Delica® Plus

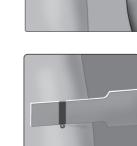


# NOTE: • The OneTouch® Delica® Plus Lancing Device uses

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the channel.



**Do Not** apply more blood to the test strip after you have moved the drop of blood away.

will turn off.

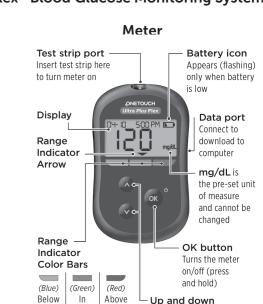
Do Not remove the test strip until the result is displayed or the meter

LifeScan Europe GmbH



IP Holdings, LLC

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



Range Range Range

# Button combinations

which reflect your changes.

Pairing allows your OneTouch Ultra Plus Flex<sup>™</sup> 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

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devices, repeat the pairing instructions for each compatible wireless

# 5. When prompted by the OneTouch Reveal® Mobile App, the meter



# has not been evaluated for Alternate Site Testing (AST). Use only

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

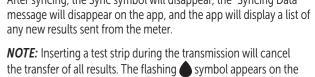




# Setting the time 645 RM

until the start-up screen

The Sync symbol (C) flashes on the meter display. "Syncing Data" will appear on the app



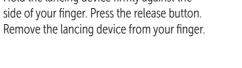
 Press and hold or for several seconds until the meter turns off. Remove the test strip.

-17--18--19-• The OneTouch® Delica® Plus Lancing System does not include • After use and exposure to blood, all parts of this kit are

# • **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.

# -25-

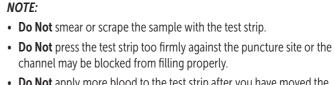
## Sampling blood from the fingertip Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses. Before testing, wash your hands and the sample site with warm,







When it touches your sample, the test strip wicks blood into



Example

Above Range

Result

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**NOTE:** Many people find it helpful to practice testing with control

• 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

Align the lancet as shown here, so that the lancet fits into the lancet holder. Push the

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

1. Insert a test strip to turn the

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 on

meter is required.

Preparing the meter



Test strip port

soapy water. Rinse and dry completely. Contaminants on the skin may affect results.

The flashing blood drop icon ( appears on the display. You can now

apply your blood sample to the test

Gently squeeze and/or massage your fingertip

squeeze another drop of blood or puncture

a new site.





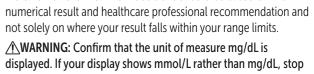
Applying the sample



5 to 1.

**Do Not** move the test strip in the meter during a test or you may get an error message or the meter may turn off.

The channel turns red and the meter will count down from glucose result to indicate if your result is below, above or within your range limits (see "The Range Indicator feature"). The arrow Blood should **not** be applied on the top of the test strip or to the top will point to the appropriate Range Indicator Color Bar on the meter as a visual reminder.



-30--31--32--33-



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.

-35-

## 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

the Range Indicator Arrow will flash on the meter screen.

**ACAUTION:** 

High results

**NOTE:** This lancing device has an ejection feature, so you do not have 04-11 . 7:15 PM to pull out the used lancet. 

## 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

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

Removing the used lancet

Unusual red blood cell count



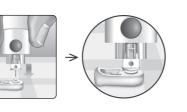


## 2. Cover the exposed lancet tip Before removing the lancet, place the lancet protective cover on a hard

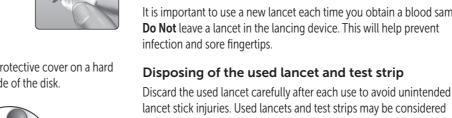
A hematocrit (percentage of your blood that is red blood cells) that is

either very high (above 60%) or very low (below 20%) can cause false





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. -37-



# infectious or potentially infectious waste in your area. Be sure to follow your healthcare professional's recommendations or local regulations for

# 3. Eject the lancet

Holding the lancing device directed



Wash hands thoroughly with soap and water after handling the meter,

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• Dirt or contamination in the small well on the top of the control

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.

Place the cap back onto the device; turn the cap or push the cap straight

4. Replace the lancing device cap

Ensure the cap is aligned as shown in the image.

in to secure it.

proper disposal.

test strips, lancing device and cap.



meter and test strips are working together properly and that the test is performing correctly. (Control solution is available separately.) Use only OneTouch Ultra Plus<sup>™</sup> Level 3 Control Solution or

OneTouch Ultra Plus™ Control Solution is used to check that the

Testing with control solution

Control solution testing precautions

- OneTouch Ultra Plus™ Level 4 Control Solution with your OneTouch Ultra Plus Flex<sup>™</sup> Meter. Either level can be used to check
- 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.
- Do Not swallow or ingest control solution. • **Do Not** apply control solution to the skin, eyes, ears or nose as it
- Do Not use control solution after the expiration date (printed on the
- may be inaccurate.

- When you open a new vial of test strips.
- When to do a control solution test

vial label) or the discard date, whichever comes first, or your results

Sending your results to the app

running on your compatible wireless device.

on the BLUETOOTH® feature and check the following:

• The BLUETOOTH® feature on both devices is running

meter before sending a result.

"Pairing Overview".

the app is running.

prior to use by that person.

1. Use a Clorox® Germicidal Wipe to

wipe the outside of the meter and

To clean your meter, hold it with the

test strip port pointed down. Be sure to

Wipe the outside of the lancing device

2. Wipe dry with a clean, sterile gauze

squeeze out any excess liquid before you

disinfecting.

lancing device

wipe the meter.

• If you suspect that the meter or test strips are not working properly.

Using the meter without syncing to an app

-39-

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

If the BLUETOOTH® feature on the meter is turned on, indicated by the

BLUETOOTH<sup>®</sup> 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

**NOTE:** The compatible wireless device must have the app open and

**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

To ensure that glucose test results are successfully sent to the app, turn

• The compatible wireless device and meter are both turned on, and

The meter is correctly paired with your compatible wireless device.

(indicated by \*) and the devices are within 26 feet of each other.

\*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

lancing device and cap should always be cleaned and then disinfected

wipes. Clorox® is a registered trademark of the Clorox Company.

**IMPORTANT:** If another person assists you with testing, the meter,

Cleaning your meter, lancing device and cap

week. Be sure to clean the meter, lancing device and cap before

The meter, lancing device and cap should be cleaned at least once per

have already been paired to the meter before sending a result. See

• If you drop or damage the meter.

• If you have had repeated unexpected blood glucose readings.

3. Squeeze the vial to discard the first drop

of the cap pointing up

2. Wait for the flashing blood

3. Press and hold or or

until the control solution icon

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

(**(C)**) appears on the display

display

drop icon ( ) to appear on the

Test strip port

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

Applying the control solution

1. Hold the meter so that the side edge

of the test strip is at a slight angle to the

clean, non-absorbent surface

drop of control solution



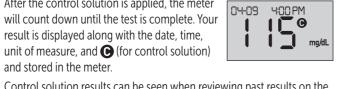
and stored in the meter.

3. Wait for the channel to fill completely

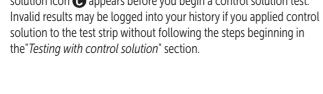
2. Touch the channel on the side of the test strip to the control

Viewing your control solution result

After the control solution is applied, the meter



Control solution results can be seen when reviewing past results on the **^CAUTION:** Make sure you press and hold **^** or **▽** until the control solution icon **©** appears before you begin a control solution test.



Checking if the result is in range

Each vial of test strips has both of control solution you used.



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

# **ACAUTION:**

and is not a recommended range for your blood glucose level. Causes of out-of-range results

- Control solution is contaminated, expired, or past its discard date.
- Test strip or test strip vial is damaged, expired, or past its discard date.
- temperature when the control solution test was performed.

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

Cleaning the control solution cap

4 Reviewing past results

· A problem with the meter.

solution cap.

**∴**CAUTION:

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 on 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

Caring for your system

Storing your system

and humidity, may cause inaccurate readings.

is the only way to reduce your exposure to disease.

purchase options contact Customer Service.

Contact us at 1 888 567-3003.

Cleaning and disinfection

lancing device and cap".



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Once opened, store your meter, test strips, control solution, lancing

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.

Cleaning and disinfection are different. Both should be performed

maintenance, but does not kill germs. You should clean your meter,

For cleaning information, see "Cleaning your meter, lancing device

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

-50-

and cap" and for disinfecting information, see "Disinfecting your meter,

lancing device and cap before disinfecting. After use and exposure to

blood, all parts of this kit may transmit infectious diseases. Disinfection

at least once per week. Cleaning is part of your normal care and

Exposure to temperatures outside the storage limits, as well as moisture

device and lancets in your carrying case. Keep in a cool, dry place

-45-

test, even if the meter appears to be off. This is indicated by the BLUETOOTH® symbol (\*) remaining on the meter screen.

• The meter will attempt to transmit results up to 4 hours after a

-40-

Preparing your meter for a control solution test

1. Insert a test strip to turn the meter Silver prongs



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.

transfer of all results. The symbol appears on the screen and you can proceed with testing.

**NOTE:** Inserting a test strip during the transmission will cancel the

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

(Español), or www. One Touch. com. Connect only to a computer certified to IEC 62368-1.

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Disinfecting your meter, lancing device

The meter, lancing device and cap should be disinfected at least

once per week. Be sure to clean the meter, lancing device and cap

and cap

before disinfecting.

1. First, clean your meter, lancing device

Follow step 1 of "Cleaning your meter,

2. Use a new Clorox® Germicidal

Wipe to wipe the outside of the

meter, lancing device and cap

Be sure to squeeze out any excess

liquid before you wipe the meter.

Hold the meter with the test strip

Allow the surface of the meter,

lancing device and cap to remain

until the surface is damp

port pointed down.

damp for 1 minute.

and cap prior to disinfecting

lancing device and cap".

PM Eastern Time) at 1 888 567-3003 (English), 1 888 567-3010

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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<sup>™</sup> 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

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**

3. Wipe dry with a clean, sterile gauze

• **Do Not** use alcohol or any other solvent.

• **Do Not** allow liquids, dirt, dust, blood or

• **Do Not** squeeze the germicidal wipe into

• **Do Not** spray cleaning solution on the

meter and lancing device.

control solution to enter the test strip port

meter, lancing device and cap.

or the data port.

test strip port.

You can adjust the meter's time and date settings after first time setup. Press and hold or to turn the meter on, then press and hold ox and vat the same time. The SET screen will appear, and the hour will flash.

For instructions on adjusting the time and date, see "First time 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. -47-

Wash hands thoroughly with soap and water after handling the

Do Not immerse the meter and lancing device in any liquid.

The cleaning and disinfection instructions for the lancing device

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.

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

**Do Not** use your meter or lancing device if you see evidence of

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See "Cleaning and Disinfecting Cycles" for more details.

are intended only to reduce the risk of local use site infection; they

Be sure to talk to your healthcare professional about the low and

**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

-42-

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 **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 A and V 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 mealtimes, medications and around any other activities that may affect your

# **CAUTION:**

or www.OneTouch.com

7 Battery

below for instructions.

What it means

What to do

What to do

What it means

The sample was applied before

There is a problem with the meter.

Contact us at 1 888 567-3003.

**Do Not** use the meter. Contact Customer Service.

Replacing the battery

blood glucose.

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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The meter, lancing device and cap can be disinfected weekly for 3 years,

Your OneTouch Ultra Plus Flex<sup>™</sup> Meter uses one CR2032 lithium coin cell

**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

IMPORTANT: Use only one CR2032 lithium coin cell battery with your

meter. **Do Not** use rechargeable batteries. Use of an incorrect battery

If the meter does not turn on, you may need to replace the battery. See

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type may result in your meter providing fewer tests than normal.

have been swallowed, seek immediate medical attention.

and have been tested up to 412 cleaning and disinfection cycles.

contact us (Monday to Friday, 8:00 AM - 8:00 PM Eastern Time) at

1888 567-3003 (English), 1888 567-3010 (Español),

Cleaning and Disinfecting Cycles

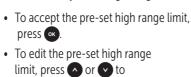
The meter, lancing device and cap can be cleaned daily for

3 years and have been tested up to 2879 cleaning cycles.

# To accept the pre-set low range limit,

- press ok.
- limit, press or to change the value between
- 60 mg/dL-110 mg/dL, and then press ox. 2. Review the pre-set high range limit displayed

press ok.



mg/dL

90 mg/dL-300 mg/dL, and then press ok.

**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

**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<sup>®</sup> Mobile App on your

> If the meter does not power on after you have replaced the meter battery, check that the battery is correctly installed.

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



you will need to check your date and time settings.

# Dispose of the battery according to your local environmental

regulations.

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# 8 Troubleshooting your system

-51-

## **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 1888 567-3003.

# What it means

meter screen

(severe hypoglycemia), below 20 mg/dL.



**NOTE:** When your glucose result is below 20 mg/dL, both

to lab comparison

working properly.

Meter at the lab:

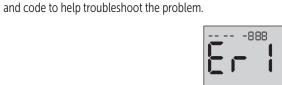
blood glucose test.

Before going to the lab:

Contact us at 1 888 567-3003.

perform a test.

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.



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**Technical specifications** 

Assay method

**Automatic shutoff** 

**Battery ratings** 

**Battery type** 

**BLUETOOTH®** 

**Technology** 

Calibration

Memory

Data port type

**Operating ranges** 



the meter was ready. What to do



1888 567-3003. -60-

Repeat the test with a new test strip; see "Applying the sample" or

contact Customer Service. Contact us at 1 888 567-3003.

"Applying the control solution". If this message continues to appear,

Contact us at 1 888 567-3003.

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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

## What it means Meter battery power is low but

What to do Replace the meter battery soon.

What it means

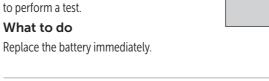
What it means

there is still enough battery power

to perform a test. The flashing low

battery ( ) icon will continue to

appear until the battery is replaced.



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 us at 1888 567-3003.

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a vein.1

# Comparing meter results to laboratory results Results obtained from the OneTouch Ultra Plus Flex<sup>™</sup> Meter and

· You are severely dehydrated. For additional information, refer to the OneTouch Ultra Plus™ Test Strip

• Your hematocrit is above 60% or below 20%.

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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

Level 2 (25-49) 36.87 0.97 2.62   Level 3 117.98 2.19 1.86
(102-138)
Level 4 352.08 7.92 2.25 (298-403)

600 mg/dL.

What to do

obtain and follow instructions from your healthcare professional

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**NOTE:** When your glucose result is above 600 mg/dL, both the **HI** 

and the Range Indicator Arrow will flash on the meter screen.

**Re-test your blood glucose level.** If the result is **HI** again,

You may have a very high blood glucose

level (severe hyperglycemia), over

What it means Meter is too hot (above 104°F) to

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 .t message, you can proceed with testing. If this message continues to appear, contact Customer Service.

What it means

Meter is too cold (below 50°F) to

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 1888 567-3003. They will refer to the error number



Sample volume  $0.4 \, \mu L$ 3.38 (H) x 2.05 (W) x 0.63 (D) inches 5 seconds

**Fingertip Results for Glucose** Concentrations < 75 mg/dL Percent (and number) of meter results that match the laboratory test

Fingertip Results for Glucose Concentrations >75 mg/dL

## User Accuracy of the system was assessed at 4 clinical sites. 169 patients tested their blood using the OneTouch Ultra Plus Flex™ System where

method.

# of Subjects

169 -1.29 95% CI Slope 95% CI Std. Error  $\mathbb{R}^2$  $(S_{v,x})$ Intercept

(mg/dL)

1.01 to 1.04	-5.66 to 3.08	13.6	0.99
Precision			
	sion (300 Venou	us Blood Samples	Tested per Glu
Data generated (	using the OneTo	uch Ultra Plus Fle	ex™ Meter.

## 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

## 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

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

(mg/dL)	(mg/dL)	(mg/dL)	
Level 2 (25-49)	36.87	0.97	2.62
Level 3 (102-138)	117.98	2.19	1.86
Level 4	352.08	7.92	2.25

## valid from the date of purchase (or the date of acquisition if you received a free meter) with proof of purchase (or acquisition). The guarantee extends only to the original purchaser and is not

Service is listed at the end of this Owner's Guide.

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# interference as specified in IEC 61326-1 and 61326-2-6.

interference at the frequency range and test level specified in international standard ISO 15197. **Do Not** use the equipment where aerosol sprays are being used, or when oxygen is being administered.

-70-

**CAUTION:** Repeated unexpected results

over 600 mg/dL. You may have severe

• 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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OneTouch Ultra Plus™ Level 3 Control Solution and OneTouch Ultra Plus<sup>™</sup> 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



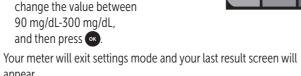
# The range printed on the test strip vial is for control solution tests only

Out-of-range results may be due to: Not following the instructions for performing a control solution test.

• Meter, test strips and/or control solution were not all at the same

-43-1. Review the pre-set low range limit displayed

• To edit the pre-set low range



compatible wireless device to change the range limits stored in your meter. See the instructions that came with the app for more information.

-49-

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

**MARNING**: Certain batteries may cause leaking which can

and date, as if you are turning the meter on for the first time.

1. Remove the old battery

sliding it downward.

out of the compartment.

connected to a computer.

2. Insert the new battery

What it means

What to do

What it means

damage.

What to do

One of the following may apply:

began to count down.

side up.

Start with the meter turned off.

Pull up on the battery ribbon to lift the battery

Do Not remove the battery while the meter is

Insert one CR2032 lithium coin cell battery

on top of the battery ribbon, with the plus (+)

-55-

• Not enough blood or control solution was

• The sample was improperly applied.

The meter has detected a problem with

the test strip. Possible cause is test strip

appears again, contact Customer Service.

• There may be a problem with the meter.

applied or more was added after the meter

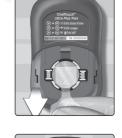
• The test strip may have been damaged or moved during testing.

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.

Remove the battery cover by pressing and



Battery cove



# Removing the meter battery will not affect your stored results. However,

# 5. Dispose of battery

# If the meter still does not power on, contact Customer Service. Contact us at 1 888 567-3003.

Battery cover

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.

the **LO** and the Range Indicator Arrow will flash on the

perform a test. What to do

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Guidelines for obtaining an accurate meter

• Perform a control solution test to make sure your meter is

• **Do Not** eat for at least 8 hours before you test your blood.

• Take your meter and testing supplies with you to the lab.

Testing with your OneTouch Ultra Plus Flex™

• Use only a fresh, capillary blood sample from your fingertip.

• Follow all instructions in this Owner's Guide for performing a

Comparing your meter results to those taken

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

(such as failure to load, cock or release).

**Error Screens** If there is a problem with your meter, the following error screens



Sample Size Test time

mg/dL Unit of measure Weight Approximately 1.76 ounces

20-600 mg/dL Reported result range Fresh capillary whole blood

results were compared to the YSI 2300 Glucose Analyzer laboratory Instrument.

Lay User Accuracy

## **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

(mg/dL)

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

You may have a very low blood glucose level

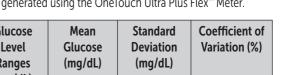
# Detailed information about your system

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concentration is lower than 75 mg/dL and within 15% of a laboratory method when the glucose concentration is 75 mg/dL or higher.

to be up to 70 mg/dL higher than a lab test using blood drawn from

<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.



Level 3 (102-138)	117.98	2.19	1.86
Level 4 (298-403)	352.08	7.92	2.25

**Limited Guarantee** 

**Electrical and safety standards** This meter complies with CISPR 11:Class B (Radiated Only). Emissions of the energy used are low and not likely to cause interference in nearby electronic equipment. The meter has been tested for immunity to electrostatic discharge as specified in IEC 61326-2-6. This meter complies with immunity to radio frequency

The meter meets the requirements for immunity to electrical

10-90% Altitude: up to 10,000 feet

Hematocrit: 20-60% -65-

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

FAD-GDH (flavin adenine dinucleotide dependent glucose dehydrogenase) Two minutes after last action 3.0 V d.c. (CR2032 lithium coin cell battery), <del>\_\_\_\_</del>

One replaceable 3.0 Volt CR2032

Frequency band: 2.4-2.4835 GHz

minimum 26.25 feet (unobstructed)

Operating Channels: 40 Channels

Security Encryption: 128-bit AES

(Advanced Encryption Standard)

Relative humidity: non-condensing

Plasma-equivalent

500 test results

Compatible with USB 2.0

Temperature: 50-104°F

lithium coin cell battery (or

Maximum power: 0.4 mW

Operating Range Distance:

equivalent)

Within ±5% | Within ±10%

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

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

Within ±15%

Within ±20%

63.1% 88.6% 96.0% 100.0% (94/149)(132/149)(143/149)(149/149)

# 4. Check your meter settings



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.

> # of Tests Slope Intercept (mg/dL) 169 1.02

Glucose Level

from another meter Comparing your blood glucose test results taken with this meter to your results taken from a different meter is not recommended. Results may differ between meters and are not a useful measure of

whether your meter is working properly.

• Test within 15 minutes of the lab test.

transferable. If the meter stops working or a defect occurs on any part, contact Customer Service. Contact information for Customer

LifeScan guarantees that the OneTouch Ultra Plus Flex™ Meter will be free of defects in material and workmanship for three years,

-66--67--68--69-

Lifescan Description: Owners Guide UPF USen (LED)		Art Agency: GPL Inverness Job No.: N/A				
File Name: FILE-PF-051119	lame: FILE-PF-051119 MC Rev.: 01		Contact: David Latham			
CPS Reference No.: N/A		JDE Item No.: N/A	Re	Rev. Date: 07-Mar-25		
ADS No./Rev.: DEV-REC-0000561 Rev 12 ADS ID: GUD-09 Dieline No./Rev.: N/A		No. of Covers:	N/A	A 🗹		
Language Sequence: English		Inside No. of pages:	N/A	A 🗹		
		No. of sides: 1 2 2				
Spot Colors	Process Colors	Uncoated Area		Special Instructions		Dieline
PMS N/A	CMYK Black N/A	Uncoated Area		N/A		Dieline N/A
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