# OneTouch Verio**Sync**

**Blood Glucose Monitoring System** 

Owner's Booklet Instructions for use

For use with the



App on iPhone<sup>®</sup>, iPod touch<sup>®</sup> and iPad<sup>®</sup>



# **Owner's Booklet**

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# Thanks for choosing OneTouch®!

The OneTouch® Verio®Sync Blood Glucose Monitoring System is made specifically to work with the OneTouch® Reveal™ app (application)\* on the iPhone, iPad or iPod touch. One of the latest product innovations from LifeScan, the OneTouch® Verio®Sync Meter sends results wirelessly to the app using Bluetooth® (wireless RF). The app lets you review and graph your results, and helps identify patterns.

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

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

\*In this booklet, OneTouch<sup>®</sup> Reveal<sup>M</sup> app will be referred to as the "app." For details on the app, please see the app Owner's Booklet or **More > Help** in the app.

# System Requirements

The OneTouch® Verio®Sync System requires:

- The OneTouch<sup>®</sup> Reveal<sup>™</sup> app. You can download the app to your iPhone, iPod touch or iPad from the App Store<sup>™</sup> for free.
- A compatible Apple<sup>®</sup> device with iOS 4.3 and 5.1.1

Made for iPod touch (3rd and 4th generation), iPhone 4S, iPhone 4, iPhone 3GS, iPad (3rd generation), iPad 2 and iPad.

Visit www.OneTouch.com for updates on compatible Apple devices and operating systems.

For information on the app, see the OneTouch® Reveal™ App Owner's Booklet at www.OneTouch.com.

iPhone, iPod touch and iPad not included.

# Symbols

- Cautions and Warnings. Refer to the Owner's Booklet and inserts that came with your system for safety-related information.
- --- Direct current
- Consult instructions for use
- Low battery
- Empty battery
- Low battery charging
- Empty battery charging
- Last blood glucose result
- Apply blood
- Do not apply blood/Do not test
- Bluetooth<sup>®</sup> (wireless RF on)
- ✤ Airplane mode (wireless RF not on)
- Syncing with the OneTouch<sup>®</sup> Reveal<sup>™</sup> app
- **C** Control solution test result

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# Before you begin

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

**NOTE:** It is best to fully charge the battery before using the OneTouch<sup>®</sup> Verio<sup>®</sup>Sync Meter. See pages 72-79 for instructions.

# Apple Legal Notice

"Made for iPod touch", "Made for iPhone" and "Made for iPad" mean that an electronic accessory has been designed to connect specifically to iPod touch, iPhone or iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPod touch, iPhone or iPad may affect wireless performance.

Apple, iPad, iPhone, iPod, and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

# Important safety instructions

- This meter and lancing device are for single patient use only. **Do Not** share them with anyone else, including family members! **Do Not** use on multiple patients!
- After use and exposure to blood, all parts of this kit are considered biohazardous. A used kit may 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://www.fda.gov/MedicalDevices/Safety/ AlertsandNotices/ucm224025.htm.

CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.

## Intended use

The OneTouch® Verio®Sync Blood Glucose Monitoring System (BGMS) is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The system is intended to be used by a single person and should not be shared. The OneTouch® Verio®Sync BGMS is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The OneTouch® Verio®Sync BGMS is not to be used for the diagnosis of or screening of diabetes or for neonatal use. The OneTouch® Verio®Sync BGMS is also not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.

The OneTouch® Verio®Sync Meter is intended for use with the OneTouch® Verio® Control Solutions and OneTouch® Verio® Test Strips. The OneTouch® Verio® Control Solution is used to check that the meter and test strips are working together properly and that the test is performed correctly. The OneTouch® Verio®Sync BGMS communicates wirelessly with the OneTouch® Reveal™ app on commercially available mobile devices and via USB cable with LifeScan diabetes PC-based applications.

# Test principle

Glucose in the blood sample mixes with the enzyme FAD-GDH (refer to page 98) in the test strip and a small electric current is produced. The strength of this current changes with the amount of glucose in the blood sample. Your meter measures the current and calculates your blood glucose level. It then displays the blood glucose result and stores it in the meter memory.

## About Bluetooth®

Bluetooth<sup>®</sup> is a type of wireless (RF) communication. Cell phones use Bluetooth<sup>®</sup> technology as do many other devices. Your OneTouch<sup>®</sup> Verio<sup>®</sup>Sync Meter uses Bluetooth<sup>®</sup> to pair with the Apple device and to send results to the app.

# **▲ CAUTION**

Before testing, you must first pair your meter with the Apple device and initially sync with the app. This will ensure that results from your meter are sent wirelessly to the app on your Apple device. See pages 18-25. Your meter is subject to and complies with U.S. federal guidelines, Part 15 of the FCC rules for devices with RF capability. These rules state two conditions specific to the operation of the device. They are:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesirable operation.

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

With the exception of your iPhone, other electronic wireless devices that are in use nearby, such as a cell phone or a wireless network, may prevent or delay the transmission of data from your meter to the app. Moving away from or turning off these electronic devices may allow communication.

The meter has been tested and found to be appropriate for use at home. In most cases, it should not interfere with other home electronic devices if used as instructed. However, this meter gives off RF energy when Bluetooth<sup>®</sup> is on. If not used correctly, your meter may interfere with your TV, radio, or other electronic devices that receive or transmit RF signals. If you experience meter interference problems, try moving your meter away from the source of the interference. You can also move the electronic device or its antenna to another location to solve the problem.

If you continue to experience interference, contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time), or visit www.OneTouch.com. Or, contact support service for the manufacturer of the electronic device causing the interference.

In locations where cell phone use is not permitted, such as hospitals, some healthcare professional offices, and airplanes, you should set the meter to "Airplane" mode (Bluetooth<sup>®</sup> off). See Step 1 on page 20 for more information.

# **▲ WARNING**

The Bluetooth<sup>®</sup> feature on your meter sends test results to your Apple device. To prevent other people's results from being sent to the Apple device, **Do Not** let anyone else use your meter to test their blood glucose. This meter is for single patient use only.

## Bluetooth® Trademark

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

# The OneTouch<sup>®</sup> Verio<sup>®</sup>Sync Blood Glucose Monitoring System

Included with your kit:



The following item is sold separately.



- OneTouch<sup>®</sup> Verio<sup>®</sup>Sync Meter (with internal rechargeable battery)
- B Carrying case
- G AC adapter
- OneTouch<sup>®</sup> Delica<sup>®</sup> Sterile Lancets
- Mini USB cable
- OneTouch<sup>®</sup> Delica<sup>®</sup> Lancing Device
- G OneTouch<sup>®</sup> Verio<sup>®</sup> Level 3 Control Solution
- OneTouch<sup>®</sup> Verio<sup>®</sup> Test Strips

The following item is sold separately.

OneTouch<sup>®</sup> Verio<sup>®</sup> Level 4 Control Solution\*

You can use either OneTouch® Verio® Level 3 Control Solution or OneTouch® Verio® Level 4 Control Solution with your OneTouch® Verio®Sync Meter.

\*For availability of test strips and control solutions, ask your pharmacist or healthcare professional.

## **▲ WARNING**

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

# Setting up your system

#### Getting to know your OneTouch® Verio®Sync Blood Glucose Monitoring System



# Setting up your system

Test strip



# Turning your meter on

1. Press and hold the meter button until the meter comes on



# **▲** CAUTION

If you see any missing segments within the start-up screen, there may be a problem with the meter. Contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).

Next, the Last Result screen appears. The arrow ( $\backsim$ ) indicates that this is the Last Result screen. The three dashes (---) mean that no results are currently stored in the meter. The airplane symbol ( $\rightarrow$ -) indicates that Bluetooth<sup>®</sup> is not on. When Bluetooth<sup>®</sup> is on (\$), your meter will automatically attempt to sync ( $\mathfrak{C}$ ) any unsent blood glucose readings.



# Using the display backlight and test strip port light

The backlight and test strip port light come on automatically when the meter is turned on or a test strip is inserted. The backlight will dim and the test strip port light will turn off when you press and release the meter button once, or after about 30 seconds of no activity. Pressing the meter button or inserting a test strip will turn them both back on. The test strip port light provides additional light that may help you complete a test. Five seconds after applying blood (or control solution), the test strip port light will turn off.

# Turning your meter off

There are three ways to turn your meter off:

- Press and hold meter button for several seconds until the meter turns off. *Or,*
- Your meter will turn off by itself within 10 seconds after sending results to the Apple device. **Or**,
- In all other instances, the meter will turn off by itself if left alone for 2 minutes.

Using the meter button to turn the meter off will save battery power.

# Pairing your meter with the Apple device

Pairing prepares your OneTouch® Verio®Sync Meter and Apple device to communicate with each other. The devices must be within 10 feet of each other to pair and sync. Download the OneTouch® Reveal™ app from the App Store before pairing your meter and Apple device.

Multiple OneTouch® Verio®Sync Meters can be paired with your Apple device. For example, your Apple device can be paired with a meter at home and another at work (see Figure 1). To pair multiple meters, simply repeat the pairing instructions on pages 20-23 for each meter.



However, your OneTouch® Verio®Sync Meter can only be paired with **one Apple device at a time**. For example, you can pair your meter with an iPod touch, iPhone or iPad, but not more than one at the same time (see Figure 2).



Figure 2

# **▲ WARNING**

**Do Not** pair another person's meter with your Apple device.

# 1 Setting up your system

**NOTE:** Test result data sent to the app from multiple meters will be combined, just as though the data came from a single meter. If you do not want test data from multiple meters displayed together, **Do Not** pair any additional OneTouch® Verio®Sync Meters with the Apple device. See pages 18-19 and 28-29 for important information on pairing and syncing multiple meters.

# To pair the Apple device with your meter, start with your meter on and follow these steps:

# 1. To turn on Bluetooth®, press the meter button twice

The (\$) symbol will appear to indicate Bluetooth<sup>®</sup> is on. The ( $\nrightarrow$ ) symbol indicates that Bluetooth<sup>®</sup> is turned off. To switch between (\$) and ( $\bigstar$ ) modes, press the meter button twice quickly.



2. To turn on Bluetooth® on your Apple device tap the Settings icon on the home screen

3. Then select General



Settings icon

# Setting up your system

## 4. Next select Bluetooth and set Bluetooth to ON

Your devices are now searching for each other.

Bluetooth	ON
Devices	
Searching	B. C.
blace Discourse	
Now Discovera	ble
Now Discovera	ible

5. Look for a device named OneTouch, followed by the beginning of the Serial Number on the back of your meter

This is your meter.

6. Tap on the entry that represents your OneTouch meter



# 7. Enter your meter PIN number using the keypad

The PIN number can be found on the back of your meter in the box.



#### 8. Tap Pair

# 9. Wait for the device status to say "Connected"

Congratulations! Your meter and Apple device are now paired. Before testing, you must now initially sync the meter with the app.

**NOTE:** The Sync symbol (**C**) on the meter will continue to blink after successful pairing.



# Initial syncing of the meter and app

You must initially sync the meter and app before you start testing your blood glucose. The first time you sync, the Apple device will set the clock in the meter. However, you will not see the date and time on the meter display until after your first test.

The Apple device checks and updates the date and time in your meter each time you sync. Check the date and time on your Apple device often to be sure they are correct. For instructions on setting the date and time on your iPhone, iPad or iPod touch, see the user manual for your Apple device.

# 1 Setting up your system

**NOTE:** It is important to sync the meter and app before testing for the first time. This will ensure that the correct date and time are attached to your test results. Any glucose results from tests taken before your initial Sync will not be assigned a date or time, and will **never** be sent to the app.

# 1. Open the OneTouch® app on the Apple device

2. Turn your meter on

3. The Sync symbol ( $\mathcal{Q}$ ) blinks on the meter display

4. "Syncing Data" will appear on the app to notify you that the meter is communicating with the app



Syncing Data

**NOTE:** The first time you sync, the app will display a Meter Time Difference message.

Tap **Yes** to set the clock in your meter. The date and time will appear on your meter after your first test.



**NOTE:** If you tap **No** or do not act on the message, the clock in the meter will **not** be set. Any glucose results from tests taken before the meter clock is set will not be assigned a date or time, and will **never** be sent to the app. With your meter off, repeat steps 2-4 on page 24 to initially sync and set the meter clock.

When complete, the date and time of the initial Sync will appear under Last Sync on the app Summary screen. When you begin testing, the date and time of your test will appear on the meter.

**NOTE:** We recommend personalizing the app in your Apple device after initial syncing and before you begin testing your blood glucose. Refer to the OneTouch<sup>®</sup> Reveal<sup>™</sup> App Owner's Booklet or the Help file in the app.

# Syncing to send results wirelessly to the app

After pairing the meter with your Apple device and initially syncing with the app, you are ready to begin testing (see pages 30-54). Sync often to send test results wirelessly to the app.

## 1. Open the app on your Apple device

# 2. Turn your meter on and make sure the Bluetooth® symbol (\$) is displayed

If needed, press the meter button twice quickly to turn  $\mathsf{Bluetooth}^{\$}$  on.

# 3. The Sync symbol ( $\mathcal{Q}$ ) blinks on the meter display

4. "Syncing Data" will appear on the Apple device to let you know the meter is sending results to the app



Syncing Data

5. After the Sync, the app will display a list of any new blood glucose results sent from the meter



Example

1

### Using your meter without the app

The meter can be used without an Apple device or the app. You can still test your blood glucose and review your last result on the meter screen. To review additional results in the meter memory, you can download to a computer (see page 64). **However, no date and time will appear with results unless you have downloaded the app, paired your meter with your Apple device and initially synced your meter with the app (see pages 18-25).** 

## **IMPORTANT NOTE**

#### If you plan to sync more than one meter with the app

When sending test results to the app from more than one meter, it is recommended that the meters are synced one at a time. Each meter has a unique serial number that will appear on your Apple device when pairing. (The serial number will be shortened when you view it on your Apple device.)

1

### To sync multiple meters, follow these steps:

- 1. Be sure all meters are turned off.
- 2. Open the app on the Apple device.
- 3. Turn the first meter on and be sure Bluetooth<sup>®</sup> is on.
- 4. Wait for the meter to transmit its results.
- 5. Turn the meter off.

Repeat steps 1 through 5 to sync additional meters.



# Testing your blood glucose

**NOTE:** Many people find it helpful to practice testing with control solution before testing with blood for the first time. See Testing with control solution, pages 55-62.

## Preparing for a test

### Have these things ready when you test:

OneTouch® Verio®Sync Meter OneTouch® Verio® Test Strips Lancing device Sterile lancets

- Use only OneTouch® Verio® Test Strips.
- Unlike some blood glucose meters, no separate step to code your OneTouch® Verio®Sync System is required.
- 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.
- 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.
- 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** 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.
- **Do Not** return the used test strip to the vial after performing a test.
- **Do Not** re-use a test strip that had blood or control solution applied to it. Test strips are for single use only.
- 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.

**IMPORTANT:** If another person assists you with testing, the meter, lancing device and cap should always be cleaned and disinfected prior to use by that person. See Care and maintenance, pages 66-71.

# **▲** CAUTION

- The OneTouch® Verio®Sync Blood Glucose Monitoring System should not be used for patients within 24 hours of receiving a D-xylose absorption test as it may cause inaccurate high results.
- Do Not use your test strips if your vial is damaged or left open to air. This could lead to error messages or inaccurate results. Contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time) immediately if the test strip vial is damaged.
- 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.
- This meter meets the requirements for immunity to electrical interference at the frequency range and test levels specified in international standard ISO 15197:2003(E). **Do Not** use this meter near other sources of electromagnetic radiation.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.
- **Do Not** use test strips after the expiration date (printed on the vial) or the discard date, whichever comes first, or your results may be inaccurate.

# OneTouch® Delica® Lancing Device



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

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

# NOTE:

- The OneTouch<sup>®</sup> Verio<sup>®</sup>Sync Blood Glucose Monitoring System has not been evaluated for alternate site testing (AST). Use only fingertips when testing with the system.
- Your OneTouch® Delica® Lancing System does not include the materials needed to perform Alternate Site Testing (AST). The OneTouch® Delica® Lancing System should not be used to test on the forearm or palm with the OneTouch® Verio®Sync Blood Glucose 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 sampling.
- The lancing device is intended for a single user. Never share a lancet or a lancing device with anyone.
- Always use a new, sterile lancet each time you test.
- Always keep your meter and lancing device clean (see pages 66-68).
#### Getting a blood sample from the fingertip

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

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

#### 1. Remove the lancing device cap

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





## 2. Insert a sterile lancet into the lancing device

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

Twist the protective cover one full turn until it separates from the lancet. **Save the protective cover** for lancet removal and disposal. See pages 49-52.





### 3. Replace the lancing device cap

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





Do Not overtighten.



#### 4. Adjust the depth setting

The lancing device has seven puncture depth settings, numbered 1 through 7. Smaller numbers are for a shallower puncture and the larger numbers are for a deeper puncture. Shallower punctures work for children and most adults. Deeper punctures work well for people with thick or callused skin. Turn the depth wheel to choose the setting.



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

## 5. Cock the lancing device

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



#### 6. Insert a test strip to turn the meter on

Insert a test strip into the test strip port with the gold side of the test strip and the two silver prongs facing you.

No separate step to code the meter is required.

#### Silver prongs



Test strip port

**NOTE:** When testing **in low light conditions or in the dark**, the test strip port light provides additional light that may help you complete the test. If the test strip port light has turned off, press and release the meter button to turn it back on.

When the Apply Blood symbol () blinks on the display, you can apply your blood sample to either side of the test strip.



#### 7. Puncture your finger

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



## 8. Get a round drop of blood

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

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





Approximate size



## 2 Taking a test

#### Applying blood and reading results

#### 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.





**NOTE:** When you apply your blood sample, the test strip port light turns off to indicate that blood has been applied to the test strip.

#### 2. Wait for the channel to fill completely

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

The channel turns red and the meter will count down from 5 to 1.

Blood should **not** be applied on the top of the test strip or to the top edge of the test strip.



- Do Not smear or scrape the sample with the test strip.
- **Do Not** press the test strip too firmly against the sample site or the channel may be blocked from filling properly.
- **Do Not** apply more blood to the test strip after you have moved the drop of blood away.
- Do Not move the test strip in the meter during a test or you may get an error message or the meter may turn off.
- **Do Not** remove the test strip until the result is displayed or the meter will turn off.
- Do Not test while the battery is charging.

2

#### 3. Read your result on the meter

Your blood glucose result appears on the meter display along with the unit of measure. The date and time for this result will then appear after about 3 seconds.

**NOTE:** If the date and time do not appear above your result, the clock on the meter has not been set. Sync with the app again. Any glucose results from tests taken before your initial Sync will not be assigned a date and time, and will never be sent to the app.

If mg/dL does not appear with the blood glucose result, contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).

## 

If the letter  $\mathbf{C}$  (for a control solution result) appears on the screen when testing your blood glucose, repeat the test with a new test strip. If the problem persists, contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).



Example

If Bluetooth<sup>®</sup> on the meter is turned on, the Sync symbol (♥) will blink next to the Bluetooth<sup>®</sup> symbol (\$) on the meter result screen. This means that the meter is trying to sync with the app. When syncing is complete, the Sync symbol (♥) will disappear. See Step 4.

**NOTE:** If Bluetooth<sup>®</sup> on the meter is **turned off** at the time of the test, the airplane symbol (→) appears instead of the Sync symbol (〇), and the test result is not sent to the Apple device. The test 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.

## 4. Confirm that the result was received by the Apple device

For the meter to sync with the app immediately after testing, the app must be opened either before or within 90 seconds of completing the test. When complete, the date and time of the Sync will appear under Last Sync on the app Summary screen. The date and time of your most recent test result will be displayed on the meter screen. The Sync is now confirmed. A list of your synced results will be displayed.



Example Apple Device Display

**NOTE:** The app can detect High and Low Patterns in your glucose results. Be sure test results are sent to the Apple device frequently, so that pattern messages are triggered on a timely basis. Results cannot trigger a pattern message until they are sent to the app. See your app instructions for more information.

## To ensure that glucose test results are successfully sent to the app, check the following:

- The meter is correctly paired with your Apple device and initially synced with the app.
- Bluetooth<sup>®</sup> on both devices is turned on (indicated by \$).
- The Apple device and meter are both turned on.
- The app is opened either before or within 90 seconds of turning your meter on.
- There is no interruption during the Sync.

#### NOTE:

- Any interruption in transmission will cancel the transfer of all results. Results will remain in the meter and will be sent to the app the next time a Sync is successfully completed.
- Inserting a test strip during transmission will cancel the transfer of all results. The Apply Blood screen appears and you can proceed with testing.

## 2 Taking a test

#### NOTE:

- Glucose results can only be sent to the Apple device if the meter and Apple device are paired and the meter is initially synced with the app (see pages 18-25).
   Bluetooth<sup>®</sup> on the meter and Apple device must also be turned on (see page 20) and the app must be open on the Apple device.
- When you sync, the app checks the date and time stored in the meter. If the time difference between the Apple device and the meter is 15 minutes or less, the time in the meter is always automatically updated to match the current time in the Apple device.

If the time difference is greater than 15 minutes, you can set the app to prompt you to match the meter time with the time in the Apple device. See Chapter 2, Using the app to set/update the date and time in the meter in the OneTouch® Reveal™ App Owner's Booklet or the Help file in the app for more details.

- Check the date and time on your Apple device often to be sure they are correct. For instructions on setting the date and time on your iPhone, iPad or iPod touch, see the user manual for your Apple device.
- If you do not sync the meter with the app after each glucose test, test results are stored in the meter. They will be sent to the app the next time the meter and app are synced.

### After getting a blood glucose result

If left alone, the meter will turn off automatically after 2 minutes, or within 10 seconds of sending results to the Apple device. You can also turn the meter off by pressing and holding the meter button.

#### Removing the used lancet

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

### 1. Remove the lancing device cap

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



#### 2. Cover the exposed lancet tip

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



#### 3. Eject the lancet

Slide the ejection control forward until the lancet comes out of the lancing device. Return the ejection control to its back position. If the lancet fails to eject properly, cock the device again and then slide the ejection control forward until the lancet comes out.



### 4. Replace the lancing device cap

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



It is important to use a new lancet each time you obtain a blood sample. This will help prevent infection and sore fingertips.

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

Discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used lancets and test strips may be considered biohazardous waste in your area. Be sure to follow your healthcare professional's recommendations or local regulations for proper disposal.

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

# Interpreting unexpected test results

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

### 

#### Low blood glucose results

If your blood glucose 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.

2

### 

#### Dehydration and low blood glucose results

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

#### High blood glucose results

If your blood glucose 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 blood glucose results

HI is displayed when your blood glucose 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.

## 

#### Repeated unexpected blood glucose results

If you continue to get unexpected results, check your system with control solution. See Control solution testing, pages 55-62.

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

#### Unusual 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.

## Testing with control solution

OneTouch<sup>®</sup> Verio<sup>®</sup> Control Solution is used to check that the meter and test strips are working together properly and that you are performing the test correctly. (Control solution is available separately.)

#### NOTE:

- Use only OneTouch<sup>®</sup> Verio<sup>®</sup> Control Solution, OneTouch<sup>®</sup> Verio<sup>®</sup> Level 3 or OneTouch<sup>®</sup> Verio<sup>®</sup> Level 4, with your OneTouch<sup>®</sup> Verio<sup>®</sup>Sync 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.
- Control solution test results will not be sent to the app.

## 

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

#### 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 results.
- If you drop or damage the meter.

#### Performing a control solution test

1. Insert a test strip to turn the meter on

I Silver prongs



Test strip port

Wait for the Apply Blood symbol (**(**) to blink on the display.

**NOTE:** The same Apply Blood symbol (**()**) that blinks during a blood glucose test also appears during a control solution test.



#### 2. Prepare the control solution

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

Squeeze the vial to discard the first drop.



Example OneTouch® Verio® Level 3 Control Solution

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





Taking a test 2

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



#### 3. Apply the control solution

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



Touch the channel on the side of the test strip to the control solution. Wait for the channel to fill completely.



#### 4. Read your result on the meter

The meter will count down from 5 to 1. Your result is displayed along with the unit of measure and the letter **C** (control solution). The meter automatically marks the result as a control solution test. The date and time for this result will then appear on the display after about 3 seconds.

Control solution test results are stored in the meter, but are **not sent to the Apple device**.



Example

**NOTE:** If Bluetooth<sup>®</sup> on the meter is turned on, the meter will try to send any **blood glucose** test results to the app that have not yet been sent.

#### **▲** CAUTION

If the letter  $\mathbf{C}$  does not appear on the screen, repeat the test with a new test strip. If the problem persists, contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).

### 5. Check if the result is in range

Each vial of test strips has both OneTouch® Verio<sup>®</sup> Level 3 and OneTouch® Verio® Level 4 Control Solution ranges printed on its label. Compare the result displayed on the meter to either the OneTouch<sup>®</sup> Verio<sup>®</sup> Level 3 or OneTouch® Verio<sup>®</sup> Level 4 Control Solution range printed on the test strip vial. depending on the type of control solution you used.



Level 3 Control Range 102-138 mg/dL Level 4 Control Range 298-403 mg/dL

#### Example ranges

#### Out-of-range results may be due to:

- Not following the instructions on pages 57-61.
- Control solution is contaminated, expired, or past its discard date.
- Test strip or test strip vial is damaged, expired, or past its discard date.

- Meter, test strips and/or control solution were not all at the same temperature when the control solution test was performed.
- A problem with the meter.
- Dirt or contamination in the small well on the top of the control solution cap (see Step 2).

#### 6. Cleaning

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

Control solution results can be seen immediately after a test or if it is your last result in the meter.

### 

- 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 at 1 888 567-3003 (available 7 days a week, 8 a.m. 10 p.m. Eastern Time).
- The control solution ranges printed on the test strip vial are for control solution tests only **and are not recommended ranges for your blood glucose level**.

## Taking a test 2

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## **3** Viewing your results

When you turn your meter on, your last test result is shown, as indicated by the arrow ().

**NOTE:** The meter displays the date and time of your last result only. It does not display the current date and time.



**NOTE:** Your meter stores up to 500 test results but only your last result can be displayed. When the memory is full, the oldest result is removed as the newest is added. To view results for the past 14 days, sync the meter with the app (see pages 26-27). Download to a computer to review all results stored in the meter.

### Downloading results to a computer

OneTouch® Diabetes Management Software (DMS) can store all of your records and help you spot patterns for planning meals, exercise, insulin dosing, and medication. To learn more about OneTouch® DMS and to order the software, visit http://www.onetouch.com/software\_kit or contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time) or visit www.OneTouch.com.

Use only the mini USB interface cable provided by LifeScan, Inc. Connect only to a computer certified to UL 60950-1.

Follow the OneTouch® DMS instructions to download results from the meter.

**NOTE:** The mini USB cable used to download data to a computer is included with your kit. This cable is also used to recharge the meter battery. See pages 72-79 for more information.

Once the command to download is sent from the computer to the meter, the meter displays **PC.** This means the meter is in communication mode.

**NOTE:** When the meter is connected to a computer, the meter battery will recharge. See pages 75-79 for more information.

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



## 4 Care and maintenance

#### Storing your system

Store your meter, test strips, control solution and other items in your carrying case. Keep in a cool, dry place between 41°F and 86°F. Keep all items away from direct sunlight and heat.

#### **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 and disinfection information, see pages 67-71.

## Care and maintenance 4

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® Verio®Sync System and can be obtained from retail websites offering disinfection products, e.g. www.officedepot.com or www.officemax.com. For more information on purchase options, visit www.onetouch.com/disinfection, or contact Customer Service at 1 888 567-3003.

\*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 when they are visibly dirty and before disinfection. Clean your meter at least once per week.

## 1. Use a Clorox<sup>®</sup> 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



## Disinfecting your meter, lancing device, and cap

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

## 1. First, clean your meter, lancing device and cap prior to disinfecting

Follow step 1 on the previous page.

#### 2. Use a new Clorox® Germicidal Wipe to wipe the outside of the meter, lancing device, and cap until the surface is damp

Be sure to squeeze out any excess liquid before you wipe the meter. Hold the meter with the test strip port pointed down.



Allow the surface of the meter, lancing device, and cap to remain damp for 1 minute.

## 4 Care and maintenance

## 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 OneTouch® Verio®Sync System withstood cleaning and disinfection cycles well in excess of LifeScan's recommendation\*. See table below 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 at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time) or visit www.OneTouch.com.

	Recommended Usage*	Tested
Daily cleaning	1096 cleaning cycles (365 days x 3 years)	2160 cleaning cycles
Weekly Disinfecting	157 disinfecting cycles (52 weeks x 3 years)	310 disinfecting cycles

\*Based on a use life of three years.

## 5 Battery (recharging)

## Battery

Your OneTouch® Verio®Sync Meter uses a rechargeable battery. When fully charged, the meter will perform blood glucose or control solution tests for about 1 to 2 weeks before recharging is needed, depending on use. Using the meter button to turn the meter off will preserve battery power.

**NOTE:** When the battery can no longer hold a charge, the meter needs to be replaced. Contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time) for more information.

## **▲ CAUTION**

The meter battery is permanent and is not replaceable. **Do Not** try to open the meter and remove or replace the battery.

## Battery (recharging) 5

## Low/Empty battery power indicator

When the meter needs to be recharged, the Low Battery (( ) or Empty Battery ( ) start-up screen will appear. The symbol will blink when you turn the meter on.

The Low Battery symbol () means there is still enough power to perform a test. The symbol will appear by itself on the start-up screen and blink for several seconds. Then, the symbol will continue to blink on all screens until the battery is recharged.



When the Empty Battery symbol () appears by itself and blinks on the start-up screen, the meter cannot be used. The display backlight and test strip port light do not come on when the battery is empty. You must recharge the battery before using your meter.



## Recharging the meter battery

The meter battery may be charged using one of the following options:

- Mini USB cable (computer charging)
- Mini USB cable with the AC adapter (wall charging)

Both the mini USB cable and AC adapter are included in your kit.

## 

- Only use the LifeScan mini USB cable and AC adapter with the OneTouch<sup>®</sup> Verio<sup>®</sup>Sync Meter. If you misplace the mini USB cable or AC adapter, contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).
- **Do Not** charge meter outdoors or in a wet area.
- Do Not use the mini USB cable, AC adapter or meter if it is damaged, discolored, abnormally hot, or has an unusual odor. Contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).
- **Do Not** plug the AC adapter into wall outlet and leave it unattended.
- Only plug the mini USB cable included with your kit into the AC adapter.

- Verify that the wall outlet voltage matches the AC adapter voltage.
- **Do Not** allow unsupervised children to charge the meter battery.

## 1. Connect the end of the mini USB cable to the meter

Start with the meter turned off. Insert the mini USB cable into the data/battery charging port located on the right side of your meter.



## 5 Battery (recharging)

## 2. Plug the cable into the power source

Plug the other end of the cable into the AC adapter. Then, plug the AC adapter into the wall outlet.

When traveling outside of the United States, you may need an adapter to plug the AC charger into a local power outlet. A voltage converter is not needed when traveling outside the United States.



## Or,

Plug the other end of the cable into the USB port on your computer.

**NOTE:** Use only the mini USB interface cable provided by LifeScan, Inc. Connect only to a computer certified to UL 60950-1.



## A WARNING

**Do Not** insert a test strip while the meter is connected to a computer or wall outlet.

## NOTE:

- Using the mini USB cable or AC adapter charges the battery in about 2 hours.
- When using the USB port on your computer to charge the battery, be sure the computer is turned on and not in standby mode. If the meter does not charge, try using another USB port on your computer.
- To optimize battery life, it is best to recharge the battery when the Low Battery symbol ( ) appears (see page 90).

## 3. Charge the battery

When the meter is connected to a computer or when using the AC adapter, the Low Battery Charging symbol (IFF) or the Empty Battery Charging symbol (IFF) appears on the display. The symbol that appears depends on the available battery power when you began charging.

The charging symbol  $(\mathbf{1})$  will blink to indicate that the battery is charging.

## 5 Battery (recharging)

The Do Not Apply Blood symbol (S) also appears on the display to remind you not to insert a test strip while the meter is connected to a computer or wall outlet.



If the battery power is too low to take a test, let the battery charge until the Low Battery Charging symbol () appears on the display. Be sure to disconnect the meter from the wall outlet or computer **before testing your blood glucose**. After testing, reconnect your meter and complete the charge.

**NOTE:** When the meter is connected to a computer or wall outlet, the test strip port light will turn off. This indicates that you should not insert a test strip.

## 4. Complete the charge

When the charge is completed (about 2 hours when charging an empty battery) the Battery Charging symbol (IED) will disappear from the display. Remove the mini USB cable from the meter before turning the meter on or taking a test.

## NOTE:

- If the meter is not fully charged after 2 hours, check that the cable is plugged in correctly. If this does not solve the problem, contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).
- Even when battery power is extremely low, it will not affect results stored in the meter. However, if the date and time were lost, you may need to sync your meter with the app to reset the date and time in the meter. See pages 26-27.

## Meter disposal

Dispose of the meter and internal lithium ion battery according to your local/country laws and regulations.

## Troubleshooting

## Meter and Apple device communication problems

If a glucose test result on your meter was not received by your Apple device, be sure to check the following:

- Your OneTouch<sup>®</sup> Verio<sup>®</sup>Sync Meter(s) are properly paired with your Apple device and initially synced with the app (see pages 18-25).
- The Apple device and meter are both turned on.
- Bluetooth<sup>®</sup> on the meter and Apple device is on (see pages 20-21).
- The meter and Apple device are within 10 feet of each other.
- The app is open on the Apple device.

**NOTE:** Any interruption in transmission will cancel the transfer of all results. Results remain in the meter and will be sent to the app the next time a Sync is successfully completed.

The app must be open while the meter is trying to sync. The meter will attempt to sync for 90 seconds. There are two times when a meter will attempt to sync: after the meter is turned on, or immediately after a test. We recommend opening the app prior to syncing. Troubleshooting 6

## Error and other messages

The OneTouch® Verio®Sync 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 at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).



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

## 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.

Troubleshooting

6



#### What it means

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

## What to do

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



There is a problem with the meter.

## What to do

**Do Not** use the meter. Contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).



## What it means

## One of the following may apply:

- Testing with used test strip.
- Testing with a moist test strip or wet hands.
- · Problem with the meter.

## What to do

Repeat the test with a new, dry test strip; see blood application (pages 42-44) or control solution testing (pages 55-62). If this message continues to appear, contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).



The sample was applied before the meter was ready.

## What to do

Repeat the test with a new test strip. Apply a blood or control solution sample only after Apply Blood symbol () appears on the display. If this message continues to appear, contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).

## 6 Troubleshooting



## 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 blood application (pages 42-44) or control solution testing (pages 55-62). If the error message appears again, contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).

6



#### 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 blood application (pages 42-44) or control solution testing (pages 55-62). If the error message appears again, contact Customer Service at 1 888 567-3003 (available 7 days a week, 8 a.m. – 10 p.m. Eastern Time).

NOTE: There is no Er6 message.



Meter is too hot (above 111°F) to work correctly.

## What to do

Move the meter and test strips to a cooler area. Insert a new test strip when the meter and test strips are within the operating range (50-111°F). If you do not get another Temperature too high (**Er7**) message, you can proceed with testing.



Meter is too cold (below 50°F) to work correctly.

## What to do

Move the meter and test strips to a warmer area. Insert a new test strip when the meter and test strips are within the operating range (50-111°F). If you do not get another Temperature too low (**Er8**) message, you can proceed with testing.



Blinking Low Battery symbol () means battery power is low, but there is still enough power to perform a test.

## What to do

Recharge the battery as soon as possible. Blinking Low Battery symbol (>>) will continue to be displayed on all screens until the battery is recharged or the battery reaches the empty battery state.



Blinking Empty Battery symbol (D) means there is not enough battery power to perform a test.

## What to do

Recharge the battery now. If you need to test your blood glucose right away, charge the meter battery until the Low Battery Charging symbol (IMDE) appears on the display (see pages 72-79 for more information).



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

## What to do

No action is needed. You can begin using the meter. Make sure to pair and initially sync your meter before beginning to test (see pages 18-25).



Glucose test taken before meter and app were initially synced, so no date and time appears with the result. This result will **never** be sent to the app.

## What to do

Sync the meter and app to be sure date and time are assigned to future results. See pages 23-25.

## 6 Troubleshooting



## What it means

The meter is connected to a computer <u>and</u> is attempting to download data.

## What to do

**Do Not** test until you have disconnected your meter from the computer.

## Troubleshooting 6

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# 7 Detailed information about your system

## Comparing meter results to laboratory results

Results obtained from the OneTouch® Verio®Sync 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® Verio®Sync Meter is considered accurate when it is within ±20% of the lab result.

Meter results can be affected by factors that do not affect lab results in the same way, which may cause a difference of more than  $\pm 20\%$ . Specific factors that may cause your meter result to vary from your lab result by more than  $\pm 20\%$  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® Verio® Test Strip insert.

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

## Detailed information 7 about your system

## Guidelines for obtaining accurate meter to lab comparisons:

## Before going to the lab:

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

## Testing with your OneTouch® Verio®Sync Meter at the lab:

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

## **Technical Specifications**

Reported result range	20-600 mg/dL
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample volume	0.4 μL
Test time	5 seconds
Assay method	FAD-GDH (flavin adenine dinucleotide dependent glucose dehydrogenase)
Power source	Rechargeable 3.7 Volt Lithium Ion battery
Expected meter battery life	At least one week between charges
Charging current	100mAh, $=$ = = Direct current
Charging temperature	32-122°F
Unit of measure	mg/dL
Memory	500 test results stored Last test result (only) displayed
Automatic shutoff	2 minutes after last action 10 seconds after syncing with app
Size	3.94 x 1.63 x 0.46 inches

## **Technical Specifications**

Weight	Approximately 1.7 ounces	
Operating ranges	Temperature: 50-111°F	
	Relative humidity: non-condensing 10-90%	
	Altitude: up to 10,000 feet	
	Hematocrit: 20-60%	
Battery type	Rechargeable, non-serviceable, 150mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)	
Wireless frequency	2.4 GHz Band	

## **Technical Specifications**

## **Device compatibility**

Device	Version	Connections	Sharing
iPod	4th generation	WiFi	Email
touch	3rd generation		
iPhone	iPhone 4S	4G, 3G, WiFi	SMS, Email
	iPhone 4		
	iPhone 3GS		
iPad	iPad 3rd generation	4G LTE, 3G, WiFi	iMessage, Email
	iPad 2		
	iPad		

Standard text messaging rates or other carrier charges may apply.

Visit www.OneTouch.com for updates on compatible Apple devices.

## System Accuracy

Diabetes experts have suggested that glucose meters should agree within 15 mg/dL of a laboratory method when the glucose concentration is lower than 75 mg/dL, and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher. Samples from 100 patients were tested using both the OneTouch® Verio®Sync System and the YSI Model 2300 Glucose Analyzer laboratory instrument.

## System Accuracy Results for Glucose Concentrations <75 mg/dL

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

Within	Within	Within
±5 mg/dL	±10 mg/dL	±15 mg/dL
70.2%	96.5%	100.0%
(40/57)	(55/57)	(57/57)

## System Accuracy Results for Glucose Concentrations ≥ 75 mg/dL

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

Within	Within	Within	Within
±5%	±10%	±15%	±20%
71.6%	96.7%	99.6%	100.0%
(174/243)	(235/243)	(242/243)	(243/243)

## System Accuracy Results across the entire Glucose Range

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

## Within ±15 mg/dL or ±20%

100.0% (300/300)

Therefore, 100% of the total results obtained with the OneTouch® Verio®Sync System achieved the goal suggested by the diabetes experts.

#### **Regression Statistics**

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

# of	# of	Slope	Intercept
Subjects	Tests		(mg/dL)
100	300	0.99	2.61

95% Cl Slope	95% CI Intercept	Std. Error (S <sub>y.x</sub> ) (mg/dL)	R <sup>2</sup>
0.98 to 1.00	0.60 to 4.63	9.15	0.99

## Precision

Within Run Precision (300 Venous Blood Tests per Glucose Level)

Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
40	38.47	0.87	2.27
100	101.46	2.55	2.52
130	134.04	2.98	2.22
200	199.76	4.64	2.32
350	345.58	9.07	2.62

Results show that the greatest variability observed between test strips when tested with blood is 2.62% or less.

## **Total Precision**

(200 Control Solution Tests per Glucose Level)

Glucose Level Ranges (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 2 (25-49)	38.63	0.88	2.27
Level 3 (102–138)	117.39	2.00	1.70
Level 4 (298-403)	335.91	6.25	1.86

## Fingertip Results for Glucose Concentrations <75 mg/dL

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

Within	Within	Within
±5 mg/dL	±10 mg/dL	±15 mg/dL
21.7%	65.2%	95.7%
(5/23)	(15/23)	22/23

## Fingertip Results for Glucose Concentrations ≥75 mg/dL

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

Within	Within	Within	Within
±5%	±10%	±15%	±20%
56.4%	87.6%	96.8%	99.2%
(141/250)	(219/250)	(242/250)	(248/250)

#### Guarantee

LifeScan guarantees that the OneTouch® Verio®Sync Meter will be free of defects in material and workmanship for three years, valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable.

## Electrical and safety standards

This meter complies with CISPR 11: 2009, 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 Level 3 electrostatic discharge as specified in IEC 61000-4-2. This meter has been tested for immunity to radio frequency interference over the frequency range 80MHz to 2.5GHz at 3V/m as specified in IEC 61000-4-3.

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


## Notes

## Notes

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Contents covered by one or more of the following U.S. patents: 6,179,979, 6,193,873, 6,284,125, 6,716,577, 6,749,887, 6,797,150, 6,863,801, 6,872,298, 7,045,046, 7,498,132, and 7,846,312. Use of the monitoring device included herein is protected under one or more of the following U.S. patents: 6,413,410, 7,749,371, and 8,163,162. Purchase of LifeScan meter does not act to grant a use license under these patents. Such a license is granted only when the device is used with OneTouch® Verio™ Test Strip. No test strip supplier other than LifeScan is authorized to grant such a license. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.

Manufactured By:

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If you have questions about the use of the OneTouch® Verio®Sync Meter, contact Customer Service at 1888 567-3003 (available 7 days a week, 8 a.m. - 10 p.m. Eastern Time) or visit www.OneTouch.com. If you cannot reach Customer Service, contact your healthcare professional for advice.



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