

Owner's Booklet

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Owner's Booklet

Thanks for choosing OneTouch®!

The OneTouch® Verio™ Sync™ Blood Glucose Monitoring System is one of the latest product innovations from LifeScan. The Bluetooth® (wireless RF) communication feature lets the meter send blood glucose test results to the OneTouch® Verio™ Reveal™ Application* on your compatible** Apple® device. The App will let you review and graph your results, and help identify patterns.

This Owner's Booklet offers a complete explanation of how to use your new meter and testing supplies, and reviews the do's and don'ts of testing your blood glucose. Clear instructions and visuals will help you get comfortable using the OneTouch® Verio™ Sync™ Meter, so you can expect to get reliable results every time you test. 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.

*Throughout this booklet, OneTouch® Verio™ Reveal™ Application 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.

**Apple® devices include the iPhone®, iPad®, and iPod® touch devices using iOS4+. Throughout this booklet, the iPhone®, iPad®, and iPod® touch will be referred to as "Apple® devices."

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Symbols

A 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® (wireless RF activated)

→ Airplane mode (wireless RF not activated)

S Synchronization with the OneTouch® Verio™ Sync™ App

C Control solution test result

Yellow = 5mm margin, Red = 7mm margin Table of Contents

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Before you begin

Before using this product to test your blood glucose, carefully read this Owner's Booklet, and 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® Verio™ Sync™ Meter. See pages 68-75 for instructions.

Apple® Legal Notice

"Made for iPod®," "Made for iPhone®," and "Made for iPad®" mean that an electronic accessory has been designed to connect specifically to iPod®, 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®, iPhone®, or iPad® may affect wireless performance.

Yellow = 5mm margin, Red = 7mm margin

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Important safety instructions

- This meter and lancing device are intended to be used by a single person and should not be shared, even with a family member.
- After use and exposure to blood, all parts of this kit are considered biohazardous. A used kit can 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://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.

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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. Not for critically ill patients, patients in shock, dehydrated patients or hyperosmolar 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 both the OneTouch® application on commercially available mobile devices and via USB cable with LifeScan diabetes PC-based applications.

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Test principle

Glucose in the blood sample mixes with the enzyme FAD-GDH (refer to page 94) in the test strip and a small electric current is produced. The strength of this current changes with the amount of glucose in the blood sample. Your meter measures the current, calculates your blood glucose level, displays the blood glucose result, and stores it in its memory.

About Bluetooth®

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

You must first pair the Apple® device with your meter for test results to be received. This will help ensure that only results from your OneTouch® Verio™ Sync™ Meter will be received by your Apple® device. Pairing is initiated from your Apple® device. See pages 18-23.

You will also need to download the OneTouch® Verio™ Reveal™ Application from the iTunes® App store to your Apple® device, for results to be received.

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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.

Other electronic wireless devices that are in use nearby, such as a cell or mobile phone, or a wireless network, may prevent or delay the transmission of data from your meter to your Apple® device. 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 the Bluetooth® feature is activated and in use; so, if not used correctly, your meter may interfere with your TV, radio, or other electronic devices that receive or transmit RF signals.

Yellow = 5mm margin, Red = 7mm margin

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If you experience meter interference problems, you should try moving your meter away from the source of the interference, or relocate the electronic device or its antenna to another location to resolve the problem.

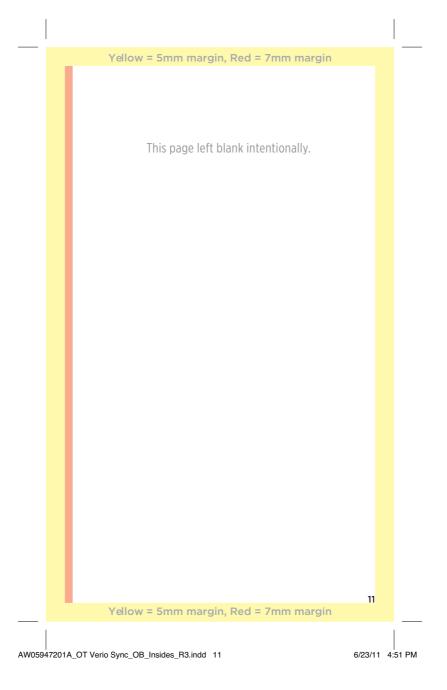
If you continue to experience interference problems, contact [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation], or contact support service for the manufacturer of the electronic device causing the interference.

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

⚠ WARNING

The Bluetooth® 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.

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- OneTouch® Verio™ Sync™ Meter (rechargeable battery included)
- B Carrying Case
- AC Adapter
- OneTouch® Delica® Sterile Lancets
- Mini USB Cable
- OneTouch® Delica® Lancing Device
- **©** OneTouch® Verio[™] Level 3 (Mid) Control Solution*
- OneTouch® Verio™ Test Strips*
- OneTouch® Verio™ Level 4 (High) Control Solution*

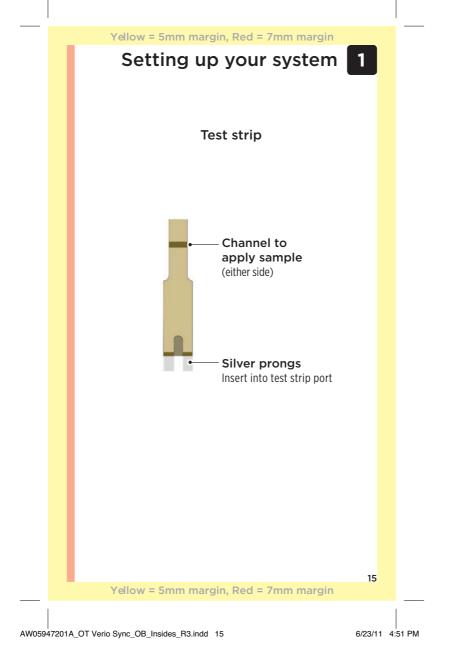
*For availability of test strips and control solutions, ask your pharmacist or health care professional.

△ 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.

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1 Setting up your system

Turning your meter on

 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 [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].

Next, the Last Result screen appears. The arrow (→) indicates that this is the Last Result screen and the three dashes (- - -) mean that no results are currently stored in the meter. The airplane symbol (→) indicates that Bluetooth® is not activated. When Bluetooth® is activated, your meter will automatically attempt to sync (②) any unsent blood glucose readings.



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Using the display backlight and test strip port light

The backlight and test strip port light come on automatically whenever 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 120 seconds.

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

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1 Setting up your system

Pairing your meter with the Apple® device

Pairing prepares your OneTouch® Verio™ Sync™ Meter and Apple® device to communicate (sync) with each other. The devices must be within 10 feet of each other to pair and

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.

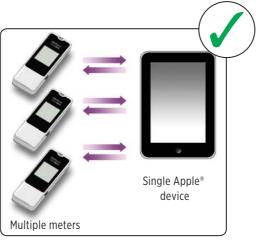


Figure 1

Yellow = 5mm margin, Red = 7mm margin

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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 Apple® iPhone® or iPod® touch, but not both at the same time (see Figure 2).

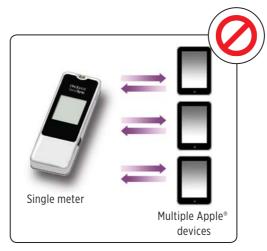


Figure 2

⚠ WARNING

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

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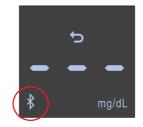
1 Setting up your system

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 26 for important information on pairing and syncing multiple meters.

To pair the Apple® device with your meter, follow these steps:

1. To activate the Bluetooth® feature on your meter, press the meter button twice

The (*) symbol will appear to indicate Bluetooth® is active.
The (→) symbol indicates that Bluetooth® is turned off. To switch between (*) and (→) modes, press the meter button twice quickly.



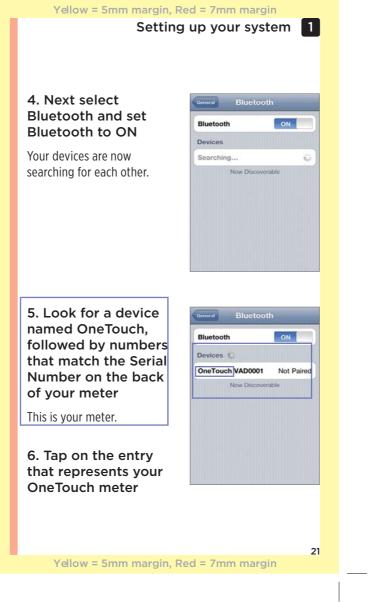
2. To activate the Bluetooth® feature on your Apple® device, tap on the Settings icon on the home screen

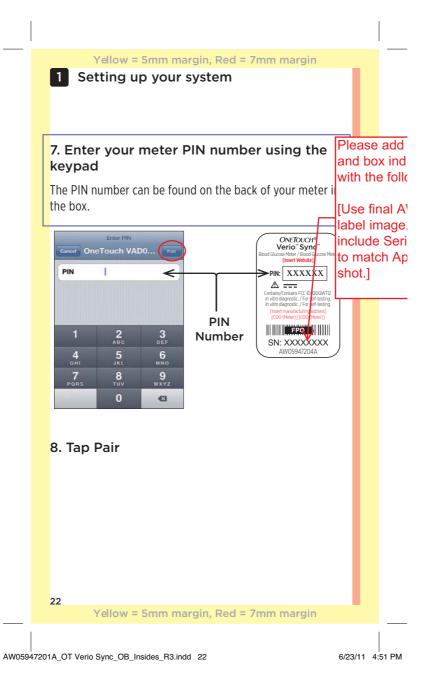


Settings icon

3. Then select General

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Yellow = 5mm margin, Red = 7mm margin Setting up your system 1 9. Wait for the device status to say "Connected" Congratulations! Your meter OneTouch VADO... Connected ② Now Discoverable and Apple® device are now paired. Syncing your meter with the App 1. Open the Apple® device 2. Turn your meter on 3. The Sync symbol (3) blinks on the meter display 23 Yellow = 5mm margin, Red = 7mm margin

1 Setting up your system

4. "Connecting to Meter" followed by "Syncing Data" will appear on the App to notify you that the meter is sending results to the App

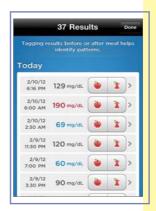
When the Sync is complete, the date and time under Last Sync will be updated to the current date and time in the Apple® device. The Sync is now complete.





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



Setting the date and time in the meter

The first time you sync the devices, the date and time set in the Apple[®] device will be sent to the meter to start the clock in the meter. Once the clock starts in the meter, the date and time will be stored with each test result. Afterward, whenever you sync the meter with the App (see page 23), the time and date in the meter will be updated to the current time and date set in the Apple® device.

NOTE: It is important to sync the meter and Apple® device before testing for the first time to ensure that the correct date and time are attached to your test result. Any glucose results from tests taken before syncing will not be assigned a date or time, and will **never** be displayed in the App.

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1 Setting up your system

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 60). No time and date will appear with results unless the meter has been initially synced with the App.

IMPORTANT NOTE

If you plan to sync more than one meter with the App

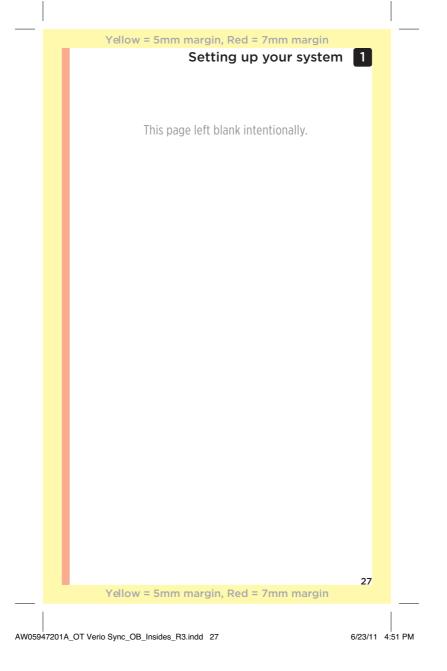
When sending test results to the App from more than one meter, it is recommended that the meters are synced one at a time.

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 the Bluetooth® feature is activated.
- 4. Wait for the meter to transmit its results.
- 5. Turn the meter off.

Repeat steps 1 through 5 to sync additional meters.

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Taking a test

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 51-58.

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.

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- 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 62-67.

△ CAUTION

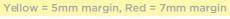
• The OneTouch® Verio™ Sync™ Blood Glucose Monitoring System should not be used for patients within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high results.

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△ CAUTION

- **Do Not** use your test strips if your vial is damaged or left open to air. This could lead to error messages or inaccurate results. Contact [CS Lead-in(Abbr.)] [CS Contact][CS Hours of Operation] immediately if the test strip vial is damaged.
- If you cannot test due to a problem with your testing supplies, contact your health care 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.

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OneTouch® Delica® Lancing Device



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

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NOTE:

- The OneTouch® Verio™ Sync™ Blood Glucose Monitoring System has not been evaluated for alternate site testing (AST). Use fingertips when testing with the system.
- The lancing device shown here is for fingertip testing only, and is not intended for sampling "alternate" sites, like the forearm or palm.

△ CAUTION

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

- Make sure to wash the sample site with soap and warm water, rinse and dry before sampling.
- The lancing device is intended for a single user. Never share a lancet or a lancing device with anyone.
- Always use a new, sterile lancet each time you test.
- Always keep your meter and lancing device clean (see page 63).

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Getting a blood sample from the fingertip

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

1. Remove the lancing device cap

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



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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 46-48.



3. Replace the lancing device cap

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

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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.

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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.

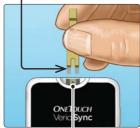


6. Insert a test strip to turn the meter on

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.





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.

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Yellow = 5mm margin, Red = 7mm margin

Taking a test 2

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



7. Lance your finger

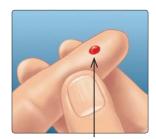
Hold the lancing device firmly against the side of your finger. Press the release button. Remove the lancing device from your finger.



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8. Get a round drop of blood

Gently squeeze your finger until you get a round drop of blood.



Approximate size

If the blood smears or runs, **Do Not** use that sample.

Wipe the area and gently
squeeze another drop of blood
or lance a new site.



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Yellow = 5mm margin, Red = 7mm margin

Taking a test 2

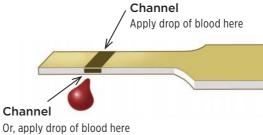
Applying blood and reading results

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.

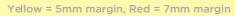
Be sure to apply your sample immediately after you get a drop of blood.



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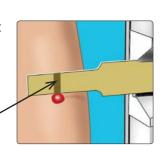
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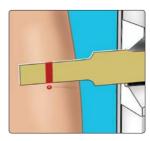


Holding the meter at a slight angle, guide the channel to the blood drop.





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



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.

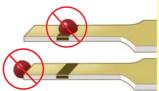
40

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 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.

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.

If mg/dL does not appear with the blood glucose result, contact [CS Lead-in (Abbr.)][CS Contact] [CS Hours of Operation].



Example

△ CAUTION

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 [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].

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If the Bluetooth® feature on the meter is activated, the Sync symbol (2) will blink next to the Bluetooth® symbol (₹) on the meter result screen. This indicates that the meter is trying to sync with the App. When syncing is complete, the Sync symbol (3) will disappear. See Step 4.

NOTE: If the Bluetooth® feature on the meter is **not activated** at the time of the test, the airplane symbol (+) appears instead of the Sync symbol (2), 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 the meter and Apple® device are synced.

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

For the meter to sync with the Apple® device, the App must be opened either before or within 90 seconds of completing the test. When the Sync is complete, the date and time under Last Sync on the App Summary screen will be updated to the current date and time. 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 the Apple® device.
- The Bluetooth® feature on both devices is activated (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.

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NOTE:

- Glucose results can only be sent to the Apple® device and synced with the App if the meter and Apple® device are paired (see pages 18-23), the meter and Apple® device Bluetooth® features are activated (see page 20) and the App is open on the Apple® device.
- Whenever the meter is synced with the App, the App checks the date and time stored in the meter. If the time difference between the Apple® device and meter is less than or equal to 15 minutes, the time of day in the meter is automatically updated to match the current time in the Apple® device. If the difference is greater than 15 minutes (e.g., Daylight Saving Time), the App will prompt you to match the meter time with the App time.
- If you do not sync the meter with the App after each glucose test, these test results are stored in the meter and will be sent to the App the next time the meter and the App are synced.

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After getting a blood glucose result

If left alone, the meter will turn off automatically after 120 seconds, 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.



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3. Eject the lancet

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



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 health care 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 whenever your blood glucose results are higher or lower than what you expect.

△ CAUTION

Low blood glucose results

If your blood glucose result is below 70 mg/dL or is shown as LO, it may mean hypoglycemia (low blood glucose). This may require immediate treatment according to your health care professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do another test.

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△ CAUTION

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 health care 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 health care 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 health care professional immediately.

49

△ CAUTION

Repeated unexpected blood glucose results

If you continue to get unexpected results, check your system with control solution. See Control solution testing, pages 51-58.

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 health care professional. Never ignore symptoms or make significant changes to your diabetes management program without speaking to your health care 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.

50

Testing with control solution

OneTouch® Verio™ 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.)

- Use only OneTouch® Verio™ Control Solution, Level 3 (Mid) or Level 4 (High), with your OneTouch® Verio™ Sync™ Meter. Either level can be used to check your system.
- When you first open a new vial of control olution, 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.

51

△ CAUTION

- 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

- Whenever 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.

52

Performing a control solution test

1. Insert a test strip to turn the meter on 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.



53

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.



ExampleLevel 3 (Mid)
Control Solution

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





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.



55

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 the Bluetooth® feature on the meter is activated, the meter will attempt to send any "blood glucose" test results to the App that have not yet been sent.

⚠ CAUTION

If the letter **C** does not appear on the screen, repeat the test with a new test strip. If the problem persists, contact [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].

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5. Check if the result is in range

Each vial of test strips has both OneTouch® Verio[™] Level 3 (Mid) and OneTouch® Verio™ Level 4 (High) Control Solution ranges printed on its label. Compare the result displayed on the meter to either the OneTouch® Verio[™] Level 3 (Mid) or OneTouch® Verio™ Level 4 (High) Control Solution range printed on the test strip vial, depending on the type of control solution you used.



Example range

Out-of-range results may be due to:

- Not following the instructions detailed on pages 53-57.
- Control solution is contaminated, expired, or past its discard date.
- Test strip or test strip vial is damaged, expired, or past its discard date.

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- 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

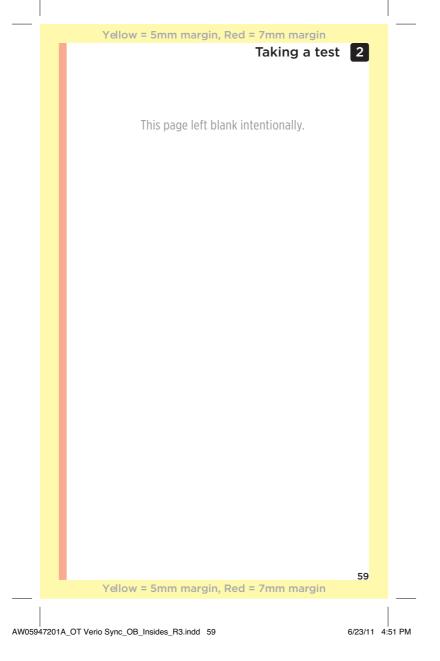
Clean the top of the control solution cap with a clean, damp tissue or cloth.

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

⚠ CAUTION

- If you continue to get control solution results that fall outside the range printed on the test strip vial,
 Do Not use the meter, test strips, or control solution.
 Contact [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].
- 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.

58



3

Viewing your results

Whenever you press and hold the meter button to turn the meter on your last test result, indicated by the arrow (ᠫ), appears on the display.



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 all results, sync the meter with the App (see pages 23-25) or download the results to a computer.

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 www.OneTouchDiabetes.com or contact [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].

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

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Viewing your results 3

To transfer meter data, follow the instructions provided with the OneTouch® DMS to download the 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 62-72 for more information.

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

NOTE: When the meter is connected to a computer, the meter battery will recharge. See pages 68-72 for more information.



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

61



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 and both should be performed. Cleaning is part of your normal care and maintenance and should be performed prior to disinfection, but cleaning does not kill germs. After use and exposure to blood, all parts of this kit can potentially transmit infectious diseases. Disinfection is the only way to reduce your exposure to disease. For cleaning information, see page 63 and for disinfecting information, see pages 64-67.

62

4

Cleaning your meter, lancing device, and cap

The meter, lancing device, and cap should be cleaned whenever they are visibly dirty. For cleaning, obtain regular strength liquid dish soap and sterile gauze where you purchase household cleaning products. Prepare a mild detergent solution by stirring a ½ teaspoon of regular strength liquid dish soap into one cup of water.

Holding the meter with the test strip port pointed down, use a sterile gauze dampened with water and mild detergent to wipe the outside of the meter and lancing device. Be sure to squeeze out any excess liquid before you wipe the meter. Wipe the inside and the outside of the cap.



Wipe dry with a clean sterile gauze.



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Disinfecting your meter, lancing device, and cap

The following disinfection schedule should be followed:

Device	If blood is visible	lf blood is not visible
Meter	Disinfect immediately	Disinfect periodically (weekly)
Lancing device and cap	Disinfect immediately	Disinfect after each use

Clean your meter, lancing device and cap prior to disinfecting. For disinfecting, obtain regular household bleach (6% sodium hypochlorite)* where you purchase household cleaning products and prepare a solution of 1 part household bleach and 9 parts water.

*Follow manufacturer's instruction for handling and storage of bleach.

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1. Use a sterile gauze dampened with this solution to wipe the meter

Squeeze out any excess liquid and then wipe the outside of the meter, lancing device, and cap until the surface is damp. Hold the meter with the test strip port pointed down.



2. After wiping, cover the surface you are disinfecting with the dampened gauze for 1 minute



3. Wipe the meter, lancing device, and cap with a new gauze dampened with water, and allow to air dry



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 gauze 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 on page 67 for more details.

If you have questions about cleaning or disinfecting, or if you see evidence of physical damage, contact [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].

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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).

	Example Usage	Tested
Weekly Cleaning	156 cleaning cycles (52 weeks x 3 years)	XX cleaning cycles
Weekly Disinfecting	156 disinfecting cycles (52 weeks x 3 years)	XX disinfecting cycles

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Yellow = 5mm margin, Red = 7mm margin

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 [CS Lead-in (Abbr.)] [CS Contact][CS Hours of Operation] 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.

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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 and 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.



69

5 Battery (recharging)

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.

⚠ CAUTION

- Only use the LifeScan mini USB cable and AC adapter with the OneTouch® Verio™ Sync™ Meter. If you misplace the mini USB cable or AC adapter, call [CS Lead-in (Abbr.)] [CS Contact][CS Hours of Operation].
- 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. Call [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].
- 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.

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- 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.



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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 Unites 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.



△ WARNING

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

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NOTE:

- Using the mini USB cable or AC adapter charges the batteries 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 86).

3. Charge the battery

When the meter is connected to a computer or when using the AC adaptor, the Low Battery Charging symbol (151) or the Empty Battery Charging symbol () appears on the display. The symbol that appears depends on the available battery power when you began charging.

The charging symbol (*) will blink to indicate that the battery is charging.

73

5 Battery (recharging)

The Do Not Apply Blood symbol (②) 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.



Low Battery Charging

Empty Battery Charging

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.

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4. Complete the charge

When the charge is completed (about 2 hours when charging an empty battery) the Battery Charging symbol (**)** will disappear from the display. Remove the mini USB cable from the meter before turning the meter on or before you take 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, call [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].
- 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 23-25.

Meter disposal

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

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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® Verio™ Sync™ Meter(s) and Apple® device are properly paired
- The Apple® device and meter are both turned on
- The Bluetooth® feature on the meter and Apple® device are activated
- The meter and Apple® device are within 10 feet of each
 ather.
- 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.

76

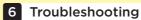
Troubleshooting 6

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 [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].

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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 health care professional's recommendations.

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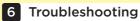


You may have a very high blood glucose level (severe hyperglycemia), above 600 mg/dL.

What to do

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

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There is a problem with the meter.

What to do

Do Not use the meter. Contact [CS Lead-in (Abbr.)] [CS Contact][CS Hours of Operation].



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 39-42) or control solution testing (pages 51-58). If this message continues to appear, contact [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].

Yellow = 5mm margin, Red = 7mm margin

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What it means

The sample was applied before the meter was ready.

What to do

Repeat the test with a new test strip. Apply a blood or control solution sample only after Apply Blood symbol (♠) appears on the display. If this message continues to appear, contact [CS Lead-in (Abbr.)][CS Contact] [CS Hours of Operation].



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 39-42) or control solution testing (pages 51-58). If the error message appears again, contact [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].

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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 39-42) or control solution testing (pages 51-58). If the error message appears again, contact [CS Lead-in (Abbr.)][CS Contact][CS Hours of Operation].

NOTE: There is no **Er6** message.

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6 Troubleshooting



What it means

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 (43-111°F). If you do not get another Temperature too high (Er7) message, you can proceed with testing.

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What it means

Meter is too cold (below 43°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 (43-111°F). If you do not get another Temperature too low (Er8) message, you can proceed with testing.

Yellow = 5mm margin, Red = 7mm margin

6/23/11 4:51 PM

85



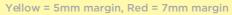
What it means

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

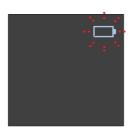
What to do

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.

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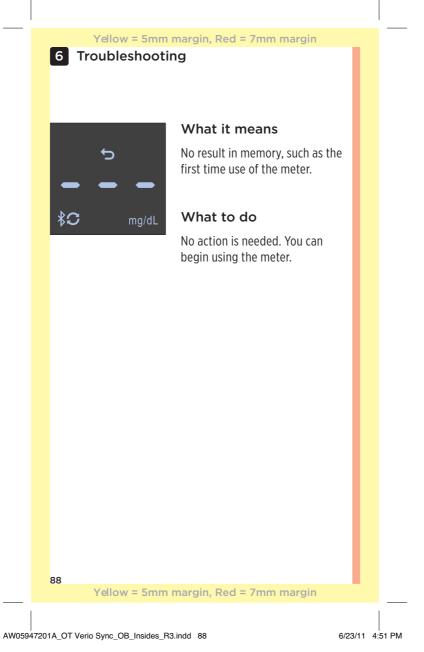
What it means

Blinking Empty Battery symbol (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 () appears on the display (see pages 68-75 for more information).

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Glucose test taken before meter and Apple® device were synced, so no date and time appears with the result. This result will never appear in the App.

What to do

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

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6 Troubleshooting



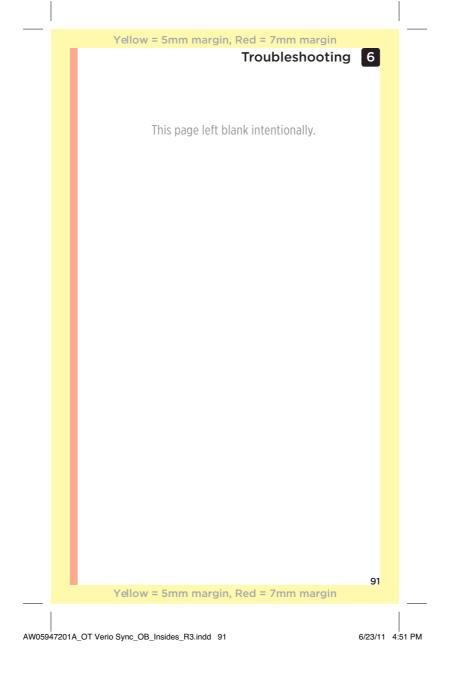
What it means

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.

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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 ±20%. Specific factors that may cause your meter result to vary from your lab result by more than ±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.¹
- 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.

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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.

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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 3.6 Volt Lithium lon battery
Expected meter battery life	At least one week between charges
Unit of measure	mg/dL
Memory	500 test results stored Last test result (only) displayed
Device Compatibility	Apple® iPhone®, iPad®, and iPod® touch devices using iOS4+

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Technical Specifications

Automatic shutoff	120 seconds after last action 10 seconds after syncing with Apple® device
Size	3.94 x 1.63 x 0.46 inches
Weight	Approximately 1.62 ounces
Operating ranges	Temperature: 43-111°F
	Relative humidity: non-condensing 10-90%
	Altitude: up to 10,000 feet
	Hematocrit: 20-60%
Battery type	Rechargeable, Non-serviceable, 150mAh, 3.6 Volt DC nominal, lithium battery (5V input charge voltage)
Charging current	100mAh, === Direct current
Charging temperature	32-122°F
Wireless Frequency	2.4 GHz Band

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 00 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
00%	00%	00%
(00/00)	(00/00)	(00/00)

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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 %
00%	00%	00%	00%
(00/00)	(00/00)	(00/00)	(00/00)

System Accuracy Results across the entire Glucose Range

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

Within ± 15 mg/dL or $\pm 20\%$ 00% (00/00)

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

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Regression Statistics

Samples were tested in duplicate on 00 test strip lots. Results indicate that the OneTouch® Verio™ Sync™ System compares well with a laboratory method.

# of Subjects	# of Tests	Slope	Intercept (mg/dL)
000	000	0.000	0.000

95% CI	95% CI	Std. Error	R ²
Slope	Intercept	(S _{y.x})	
0.000 to 0.000	0.000 to 0.000	00.000	0.000

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Precision

Within Run Precision (00 Venous Blood Tests)

Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
00	00.00	0.00	0.00
000	00.00	0.00	0.00
000	00.00	0.00	0.00
000	000.00	0.00	0.00
000	00.00	0.00	0.00

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

Total Precision (00 Control Solution Tests)

Glucose Level Ranges (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Low (00-00)	00.00	0.00	0.00
Mid (000-000)	000.00	0.00	0.00
High (000-000)	00.00	0.0	0.0

99

7 Detailed information about your system

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
00%	00%	00%
(00/00)	(00/00)	(00/00)

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 %
00%	00%	00%	00%
(00/00)	(00/00)	(00/00)	(00/00)

100

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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Yellow = 5mm margin, Red = 7mm margin

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