# **ONETOUCH** Verio Reflect®

Blood Glucose Monitoring System



Owner's Booklet Instructions for Use

# **ONETOUCH** Verio Reflect<sup>®</sup>

Blood Glucose Monitoring System

# **Owner's Booklet**

# Thanks for choosing OneTouch®!

The OneTouch Verio Reflect® Blood Glucose Monitoring System is one of the latest product innovations from OneTouch®.

Your OneTouch Verio Reflect® Meter is designed to connect (sync) with a variety of compatible wireless devices running software applications. By connecting your meter with the OneTouch Reveal® App you can review and graph your results, set Daily Test Goals, see Blood Sugar Mentor® Messages and help identify patterns. Meter results and other tracked data are sent to the compatible devices either through BLUETOOTH® (wireless) or USB cable connection. Visit www.myOneTouch.co.uk for more information about the OneTouch Reveal® App.

Every OneTouch<sup>®</sup> Meter is designed to help you test your blood glucose and manage your diabetes.

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 level. Please keep your Owner's Booklet in a safe place; you may want to refer to it in the future.

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

### Meter symbols and icons

#### Range Indicator icons and Colour Bar



Result below target range

Result at low end of target range

Result near middle of target range

Result in middle of target range

Result near middle of target range

Result at high end of target range

Result above target range

Result in range (text)

#### Meal and Event tags

<b>Ì</b>	Before Meal tag
ÎX 🛛	After Meal tag
	Event tag
B	Carbs Event tag
•••~	Stress Event tag
χv	Illness Event tag
0	Medication Event tag
3	Exercise Event tag

#### Patterns, Test Tracker, and Awards



Low Pattern Message (blue icon)

High Pattern Message (red icon)

Daily Test Goal met

Daily Test Goal not met

Gold award



Silver award

Bronze award

#### Main Menu and Settings Menu icons

Q	Summary
مم	Results Log
ŧ	Trend 90
\$	Settings Menu
0	Range Indicator icons as emoji
<b>F</b>	Range Indicator icons as text

#### Other meter icons



BLUETOOTH® feature on

Syncing

Control solution result

Low battery

•••••• Screen navigation progress dots

### Other symbols and icons

Â	Cautions and Warnings: Refer to the Owner's Booklet and inserts that came with your system for safety-related information.
	Direct current
i	Consult Instructions for Use
<b>A</b> AA	Manufacturer
LOT	Lot Number
SN	Serial Number
	Storage Temperature Limits
IVD	In Vitro Diagnostic Device
(2)	Do Not Re-use
STERILE R	Sterilised by irradiation
X	Not for general waste
$\leq$	Use By Date
Σ <n></n>	Contains sufficient for n tests



MD Medical Device



Underwriters Laboratories certification



Authorised representative in the European Community

# 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, OneTouch Verio® Control Solution and the OneTouch® Delica® Plus Lancing Device.

# ACAUTION:

Healthcare professionals must also read "Multi-patient use testing". See page 105.

#### IMPORTANT SAFETY INSTRUCTIONS:

• After use and exposure to blood, all parts of this kit are considered biohazardous. A used kit may potentially transmit infectious diseases even after you have performed cleaning and disinfection.

# Intended use

The OneTouch Verio Reflect<sup>®</sup> Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes mellitus for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips as an aid in the management of diabetes. The OneTouch Verio Reflect<sup>®</sup> Meter analyses patterns, tracks trends and provides guidance (educational, behavioral and motivational messages) to help aid in the understanding and management of glucose levels and the detection of excursions above or below a desired range. The meter is also designed to wirelessly communicate with compatible diabetes applications for the capture, transfer and analysis of blood glucose data and information, to help support diabetes self-management.

The OneTouch Verio Reflect<sup>®</sup> Blood Glucose Monitoring System should not be used as a substitute for healthcare professional advice. It also should not be used for the diagnosis or screening of diabetes or for neonatal use.

When the OneTouch Verio Reflect<sup>®</sup> Meter is set to "Basic mode", it can be used for multi-patient testing only by healthcare professionals as an aid to monitor the effectiveness of diabetes control programmes. The system is not intended for use in critical care environments.

### Test principle

Glucose in the blood sample mixes with the enzyme FAD-GDH (see page 118) in the test strip and a small electric current is produced. The strength of this current calculates your blood glucose level. It then displays the blood glucose result and stores it in the meter memory. Use only OneTouch Verio<sup>®</sup> Control Solution and Test Strips with the OneTouch Verio Reflect<sup>®</sup> Meter. Use of OneTouch Verio<sup>®</sup> Test Strips with meters for which they are not intended may yield inaccurate results.

## BLUETOOTH® wireless technology

BLUETOOTH<sup>®</sup> wireless technology is used by some smartphones and many other devices. Your OneTouch Verio Reflect<sup>®</sup> Meter uses BLUETOOTH<sup>®</sup> wireless technology to pair and to send your glucose results to compatible wireless devices.

The OneTouch Verio Reflect<sup>®</sup> Meter is designed to work with the OneTouch Reveal<sup>®</sup> Mobile App and other diabetes applications.

**NOTE:** Some diabetes management apps, including the OneTouch Reveal<sup>®</sup> Mobile App, may not be available in your country. Visit www.myOneTouch.co.uk to learn if the OneTouch Reveal<sup>®</sup> Mobile App is available in your country.

Visit www.myOneTouch.co.uk for information on which wireless devices are compatible with your OneTouch Verio Reflect<sup>®</sup> Meter, and where/how to download the software application.

When using the OneTouch Verio Reflect<sup>®</sup> System, we suggest you pair your OneTouch Verio Reflect<sup>®</sup> Meter with a compatible wireless device and track your results. See page 83 for pairing instructions.

Your meter is subject to and complies with applicable Worldwide Radio regulations and guidelines. Generally, these rules state two conditions specific to the operation of the device:

- 1. This device may not cause harmful interference.
- 2. 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.

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. ▲ WARNING: In locations where cell phone use is not permitted, such as hospitals, some healthcare professional offices and airplanes, you should turn the BLUETOOTH® feature off. See page 80 for more information.

**Do Not** leave your meter unattended or in a public place so that others may change your personal parameters or make physical connections to it.

The meter has been designed defensively to ward off malicious intent and has been tested accordingly.

# BLUETOOTH® trademark

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

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### Getting to know your system 1

# Your OneTouch Verio Reflect® Blood Glucose Monitoring System

Included with your kit:





OneTouch Verio Reflect<sup>®</sup> Meter (2 CR2032 lithium coin cell batteries included)



Lancets

**NOTE:** If any item is missing or defective in your kit, contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.

**NOTE:** If another type of lancing device was included, see the separate instructions for that lancing device.

#### Available separately:

# Items pictured below are required, but may not be included in your kit:

They are sold separately. Refer to your meter carton for a list of included items.





OneTouch Verio<sup>®</sup> Mid Control Solution\*

OneTouch Verio® Test Strips\*

\*OneTouch Verio<sup>®</sup> Control Solution and Test Strips are available separately. For availability of test strips and control solution, contact Customer Care or ask your pharmacist or healthcare professional. ▲ WARNING: Keep the meter and testing supplies away from young children. Small items such as the battery door, batteries, test strips, lancets, protective covers on the lancets, and control solution vial cap are choking hazards. Do Not ingest or swallow any items.

#### Getting to know your OneTouch Verio Reflect<sup>®</sup> Blood Glucose Monitoring System



1	Test strip port
	Insert test strip here to turn meter on
2	Battery icon Appears only when batteries are low
3	<pre>mmol/L is the pre-set unit of measure and cannot be changed*</pre>
4	Micro USB data port Connect to download to a computer
5	<ul> <li>OK button</li> <li>Turns meter on/off (press and hold)</li> <li>Confirms menu selections (press and release)</li> </ul>
6	<ul><li>Back button</li><li>Go back to the previous screen (press and release)</li><li>May be used to change a Meal tag or add an Event tag</li></ul>
7	<ul> <li>Up and down buttons</li> <li>Highlight selection (press and release)</li> <li>Increase scrolling speed (press and hold)</li> </ul>
8	Colour Bar
9	Range Indicator icon
10	Test Tracker icons

**WARNING:** \*Confirm that the unit of measure mmol/L is displayed. If your display shows mg/dL rather than mmol/L, stop using the meter and contact Customer Care.

### Getting to know your OneTouch Verio® Test Strip



11 Channel to apply sample

#### 12 Silver prongs

Insert into test strip port (1)

#### **Features overview**

The OneTouch Verio Reflect<sup>®</sup> Meter is equipped with features designed to help you manage your blood glucose in a variety of ways. We hope you will take advantage of these features and make them part of your diabetes management routine.

#### **Blood Sugar Mentor® Messages**

The Blood Sugar Mentor<sup>®</sup> provides insight on how you're doing and diabetes management guidance, including educational and motivational messages based on your current and previous glucose results and other tracked data. When you receive your blood glucose result, the meter may display Mentor Tips (guidance), Pattern Messages (insight) or Awards (encouragement).

#### Examples of Blood Sugar Mentor<sup>®</sup> Messages



Insight

Guidance

Encouragement

#### ColourSure® Dynamic Range Indicator

The ColourSure<sup>®</sup> Dynamic Range Indicator instantly lets you know if your current result is below (blue), within (green) or above (red) your range limits. It also shows when your result is near the low or high end of your target range.

#### **Test Tracker**

The Test Tracker lets you set the number of glucose tests you plan to take each day and automatically tracks progress towards achieving that goal.

#### Trend 90

Trend 90 lets you set your blood glucose 90 Day Average Target and tracks progress towards that goal. The graph of averages is automatically updated every two weeks and provides a view of how your overall glucose control is trending over time.

## Setting up your meter

#### Turn your meter on

To turn your meter on, press and hold or until the Welcome screen appears. Once the Welcome screen is displayed, release or. You can also turn the meter on by inserting a test strip.

Every time you turn your meter on, a Welcome screen will appear for a few seconds. If the meter does not power on, check the batteries. See page 102.

#### ACAUTION:

If you see any missing pixels within the Welcome screen, there may be a problem with the meter. Contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.



Example

**NOTE:** Whether you turn the meter on for the first time using (a) or a test strip, you will need to perform first time setup.

# 2 Setting up your system

#### Use the display backlight for better visibility

The backlight comes on automatically whenever the meter is turned on. After a few seconds of no activity, the backlight will dim. Pressing any button or inserting a test strip will turn the backlight back on.

#### First time setup

Before using your meter for the first time, you will be prompted to set the language, time, date, range limits, Daily Test Goal, and 90 Day Average Target.

#### NOTE:

- You will not be able to perform a blood glucose test until you complete first time setup.
- Be sure to talk to your healthcare professional about setting the right range limits, Daily Test Goal, and 90 Day Average Target for you. When selecting or changing these settings, you should consider factors such as your lifestyle and diabetes therapy. Never make significant changes to your diabetes care plan without consulting your healthcare professional.
- It is important to select the settings with care to ensure the correct information is stored with your test results.

The meter comes pre-set to help you with first time setup. But if you need to edit a setting, press  $\bigcirc$  or  $\bigcirc$  to highlight **Edit** and press  $\bigcirc$ . You can then press  $\bigcirc$  or  $\bigcirc$  to change values. After making your selection, highlight **Save** and press  $\bigcirc$  to confirm your selection and proceed to the next screen.

Pressing  $\bigcirc$  returns you to the previous screen.

# 1. Press 🔿 or 😒 to highlight the language you want, then press 🕅 to select

The meter will display a prompt giving the option to complete first time setup using the OneTouch Reveal® App. Visit www.myOneTouch.co.uk for more information about the OneTouch Reveal® App. If you do not want this option, highlight **No** and press (in continue first time setup using only the meter.



# 2 Setting up your system

Selecting **Yes** will prompt you to pair the meter with your compatible wireless device. See page 81. After pairing, the OneTouch Reveal<sup>®</sup> App will guide you through the process of first time setup. The remaining steps below will not be needed.

**NOTE:** The green progress dot will move from left to right as you navigate through the first time setup screens.

# 2. Confirm the time, then press 👀 to save

Selecting **Edit** will allow you to change the pre-set time.

# 3. Confirm the date, then press 座 to save

Selecting **Edit** will allow you to change the pre-set date.



#### NOTE:

- The time and date format cannot be changed.
- Once every 6 months, and every time you change the batteries, a screen will prompt you to confirm the time and date set in the meter.



Example

Selecting **Edit** will allow you to change the time and date. Once correct, select **Done**.



Before Meal Set Low/High Limits for your range **3.9 – 7.2** mmol/L Save Edit

Example

Selecting **Edit** will allow you to change the pre-set Before Meal range limits.

# 2 Setting up your system

Your meter uses the Before Meal and After Meal range limits set in your meter to tell you when a test result is within, below or above your mealtime range limits. The mealtime range limits you set during first time setup will apply to all glucose results. They are used in the ColourSure<sup>®</sup> Dynamic Range Indicator feature, to detect Patterns and in the Summary. See page 44, page 64 and page 71 for more information.

#### **Before Meal range limits**

pre-set low limit	3.9 mmol/L
pre-set high limit	7.2 mmol/L
low limit must be set within	3.3 mmol/L and 6.1 mmol/L
high limit must be set within	5.0 mmol/L and 16.7 mmol/L

# 5. Confirm the After Meal range limits, then press ( ) to save



#### Example

Selecting **Edit** will allow you to change the pre-set After Meal range limits.

#### After Meal range limits

pre-set low limit	3.9 mmol/L
pre-set high limit	10.0 mmol/L
low limit must be within	3.3 mmol/L and 6.1 mmol/L
high limit must be within	5.0 mmol/L and 16.7 mmol/L

# 6. Confirm the Test Tracker setting, then press or to save

Selecting **Edit** will allow you to change the pre-set Daily Test Goal for the Test Tracker.

The Test Tracker lets you set the number of glucose tests you plan to take each day and automatically tracks progress towards achieving that goal.

The meter is pre-set with a Daily Test Goal of four tests per day. The maximum Daily Test Goal is eight. See page 94 for more information.



# 7. Confirm the 90 Day Average Target, then press 🐨 to save

Selecting **Edit** will allow you to change the pre-set 90 Day Average Target.

Trend 90 lets you set your blood glucose 90 Day Average Target and tracks progress towards that goal. The graph of averages is automatically

updated every two weeks and provides a view of how your overall glucose control is trending over time.

The meter is pre-set with a 90 Day Average Target of 8.6 mmol/L. The minimum 90 Day Average Target is 5.5 mmol/L and the maximum is 14.7 mmol/L. See page 78 for more information.

Setup complete appears on the screen. Your meter is ready for use.





If the meter was turned on by inserting a test strip, the **Apply Blood** screen will appear. To perform a blood glucose test, see page 31.

**NOTE:** After first time setup, you can adjust your settings at any time. See page 88 for more information.

#### **Understanding Basic Mode**

The meter comes with many features to help track diabetes management progress. Basic Mode will turn off these features if you prefer not to use the meter in this way. Healthcare professionals should select Basic Mode to disable features that are inappropriate for a clinical multi-patient setting.

When Basic Mode is selected, the Test Tracker, Meal and Event tagging, Before and After Meal averages, Trend 90, Pattern Messages, Mentor Tips and Awards will be turned off. In Basic Mode, range limits are general and are not defined by mealtime. Range Indicator icons appear as text (for example, Image) rather than as emoji (for example, ).

For more information about turning Basic Mode on or off see page 93.

# 2 Setting up your system

# Turning the meter off

There are three ways to turn your meter off:

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

# Taking a test 3

### Testing your blood glucose

#### Preparing for a blood glucose test

**NOTE:** Many people find it helpful to practise testing with control solution before testing with blood for the first time. See page 53.

#### Have these things ready when you test:

OneTouch Verio Reflect<sup>®</sup> Meter OneTouch Verio<sup>®</sup> Test Strips Lancing device Sterile lancets

#### NOTE:

- Use only OneTouch Verio® Test Strips.
- Unlike some blood glucose meters, no separate step to code your OneTouch Verio Reflect<sup>®</sup> System is required.
- Testing must be done within operating temperature range (6-44°C).
- Make sure your meter and test strips are about the same temperature before you test.
- Keep test strips in a cool, dry place between 5°C and 30°C.

# **3** Taking a test

- Do Not test if there is condensation (water build-up) on your meter. Move your meter and test strips to a cool, dry spot and wait for the meter surface to dry before testing.
- **Do Not** open the test strip vial until you are ready to remove a test strip and perform a test. Use the test strip **immediately** after removing it from the vial.
- Tightly close the cap on the vial immediately after use to avoid contamination and damage.
- Store unused test strips only in their original vial.
- **Do Not** return the used test strip to the vial after performing a test.
- **Do Not** re-use a test strip that had blood, control solution, or any contaminants applied to it. Test strips are for single use only.
- With clean, dry hands, you may touch the test strip anywhere on its surface. **Do Not** bend, cut or modify the test strip in any way.
- When you first open a vial of test strips, record the discard date on the label. Refer to the test strip insert or vial label for instructions on determining the discard date.
- Comparing your blood glucose test results taken with this meter to your results taken from a different meter is not recommended. Results may differ between meters and are not a useful measure of whether your meter is working properly. To check your meter accuracy, you should periodically compare your meter results to those obtained from a lab. See page 116 for more information.

**IMPORTANT:** If another person assists you with testing, the meter should always be cleaned prior to use by that person. See page 98.

# ACAUTION:

- The OneTouch Verio Reflect<sup>®</sup> 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.
- **Do Not** use the OneTouch Verio<sup>®</sup> Family of Meters when PAM (Pralidoxime) is known or suspected to be in the patient's whole blood sample.
- **Do Not** use your test strips if your vial is damaged or left open. This could lead to error messages or inaccurate results. Contact Customer Care immediately if the test strip vial is damaged. Contact information for Customer Care is listed at the end of this Owner's Booklet.
- If you cannot test due to a problem with your testing supplies, contact your healthcare professional. Failure to test could delay treatment decisions and lead to a serious medical condition.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.
- **Do Not** use test strips after the expiry date (printed on the vial) or the discard date, whichever comes first, or your results may be inaccurate.

#### Getting to know your OneTouch<sup>®</sup> Delica<sup>®</sup> Plus Lancing Device



1	Release button
2	Slider control
3	Depth indicator
4	Depth wheel
5	Lancing device cap
6	Protective cover

#### NOTE:

- The OneTouch<sup>®</sup> Delica<sup>®</sup> Plus Lancing Device uses OneTouch<sup>®</sup> Delica<sup>®</sup> or OneTouch<sup>®</sup> Delica<sup>®</sup> Plus Lancets.
- If another type of lancing device was included, see the separate instructions for that lancing device.
- The OneTouch Verio Reflect<sup>®</sup> Blood Glucose Monitoring System has not been evaluated for Alternate Site Testing (AST). Use only fingertips when testing with the system.
- The OneTouch<sup>®</sup> Delica<sup>®</sup> Plus Lancing System does not include the materials needed to perform Alternate Site Testing (AST). The OneTouch<sup>®</sup> Delica<sup>®</sup> Plus Lancing System should not be used on the forearm or palm with the OneTouch Verio Reflect<sup>®</sup> Blood Glucose Monitoring System.

#### Lancing precautions

The OneTouch<sup>®</sup> Delica<sup>®</sup> Plus Lancing Device is mainly used for blood micro sampling for self-monitoring of blood glucose with OneTouch<sup>®</sup> Delica<sup>®</sup> Lancets and OneTouch<sup>®</sup> Delica<sup>®</sup> Plus Lancets.

## **ACAUTION**:

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 lancing device with anyone.
- Always use a new, sterile lancet each time you test.
- Always keep your meter and lancing device clean. (See page 98.)

# **3** Taking a test

- 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.
- **Do Not** use lancets after the expiry date printed on the lancet packaging.

If a serious incident occurs while using the OneTouch<sup>®</sup> Delica<sup>®</sup> Plus Lancing Device, please contact Customer Care immediately. Call OneTouch<sup>®</sup> Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland). Lines open 9am-5pm Monday - Friday. www.myOneTouch.co.uk. You should also contact your local competent authority. Contact information for your country can be found at: https://ec.europa.eu/growth/sectors/medical-devices/ contacts

A serious incident is one that did or could have led to the following:

- The death of a patient, user, or other person;
- The temporary or permanent serious deterioration of a patient's, user's, or other person's state of health; or
- A serious public health threat.

# Preparing your lancing device

### 1. Remove the lancing device cap

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





# 2. Insert a sterile lancet into the lancing device

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



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



# **3** Taking a test

#### 3. Replace the lancing device cap

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

Ensure the cap is aligned as shown in the image.



#### 4. Adjust the depth setting

The device has 13 puncture depth settings (each dot shown between numbers 1 to 7 on the Depth Wheel indicates an additional available depth setting). Adjust the depth by turning the depth wheel. Smaller numbers are



for a shallower puncture and larger numbers for a deeper puncture.

**NOTE:** Try a shallower setting first and increase the depth until you find the one deep enough to get a blood sample of the proper size.

#### 5. Cock the lancing device

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

#### Preparing the meter

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

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

Silver prongs

Test strip port

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







The **Apply Blood** screen appears on the display. You can now apply your blood sample to the test strip.



#### Sampling blood from the fingertip

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

#### Before testing, wash your hands and the sample site with warm, soapy water. Rinse and dry completely. Contaminants on the skin may affect results.

#### 1. Puncture your finger

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



#### 2. Get a round drop of blood

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

**NOTE:** If the blood smears or runs, **Do Not** use that sample. Dry the area and gently squeeze another drop of blood or puncture a new site.

# Applying blood and reading results

#### Applying the sample

**NOTE:** Healthcare professionals must also read additional instructions in Multi-patient use testing. See page 105.





#### 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.



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

Channel



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



#### 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 a result will be displayed after approximately 5 seconds.

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



#### NOTE:

- Do Not smear or scrape the sample with the test strip.
- **Do Not** press the test strip too firmly against the puncture 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.

#### Viewing your result

#### ColourSure® Dynamic Range Indicator

The OneTouch Verio Reflect<sup>®</sup> Meter comes with a ColourSure<sup>®</sup> Dynamic Range Indicator feature that instantly lets you know if your current result is below (blue), within (green) or above (red) your range limits. It also shows when your result is near the low or high end of your target range. It does this by displaying your result with a Range Indicator icon pointing to a segment on the Colour Bar based on the ranges you have set in the meter. The Range Indicator icon may be either an emoji (for example, ) or text (for example Indicator icon and the segmented Colour Bar together to see where your result falls within your range limits.



If the Test Tracker is turned on, progress toward the Daily Test Goal will be indicated above the result. If the Test Tracker is turned off, the date and time will be shown above the result. The date and time are always recorded with each result and can be viewed in the Results Log. See page 75.

**WARNING:** Confirm that the unit of measure mmol/L is displayed. If your display shows mg/dL rather than mmol/L, stop using the meter and contact Customer Care.

# ACAUTION:

**Do Not** make immediate treatment decisions based on the ColourSure<sup>®</sup> Dynamic Range Indicator feature. Treatment decisions should be based on the numerical result and healthcare professional's recommendation and not solely on where your result falls within your range limits.

After the result screen appears, a Pattern Message, Mentor Tip or Award may be displayed. The Message can be dismissed by pressing (.). If you would like to bring the Message back, press (.) again. See page 63 for more information about Messages.



#### Example

A Before Meal tag will automatically be applied to your result. When you change a Before Meal tag to an After Meal tag, the Range Indicator icon may point to a different segment on the Colour Bar. A new Message may appear. See page 60 for information on tagging results.

### Interpreting unexpected results

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

# ACAUTION:

#### Low blood glucose results

If your blood glucose result is below 3.9 mmol/L or is shown as **EXTREME LOW GLUCOSE**, (meaning the result is less than 1.1 mmol/L), it may mean hypoglycaemia (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.

# **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 healthcare professional immediately.

# **CAUTION**:

#### High blood glucose results

If your blood glucose result is above 10.0 mmol/L, it may mean hyperglycaemia (high blood glucose) and you should consider re-testing. Talk to your healthcare professional if you are concerned about hyperglycaemia.



**EXTREME HIGH GLUCOSE** is displayed when your blood glucose result is over 33.3 mmol/L. You may have severe hyperglycaemia (very high blood glucose). Re-test your blood glucose level. If the result is **EXTREME HIGH GLUCOSE** again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional immediately.

# **CAUTION**:

#### Repeated unexpected blood glucose results

- If you continue to get unexpected results, check your system with control solution. See page 53.
- 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 programme without speaking to your healthcare professional.

#### Unusual red blood cell count

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

#### Removing the used lancet

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

# **3** Taking a test

#### 1. Remove the lancing device cap

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



#### 2. Cover the exposed lancet tip

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



#### 3. Eject the lancet

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



#### 4. Replace the lancing device cap

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

Ensure the cap is aligned as shown in the image.



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

#### 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.

# Testing with control solution

#### **Control solution testing precautions**

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

#### NOTE:

- Use only OneTouch Verio® Control Solution with your OneTouch Verio Reflect® Meter.
- 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.

# **CAUTION**:

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

#### When to do a control solution test

- When you open a new vial of test strips.
- If you suspect that the meter or test strips are not working properly.
- If you have had repeated unexpected blood glucose readings.
- If you drop or damage the meter.

# Preparing your meter for a control solution test

#### 1. Press and hold or to turn the meter on

Wait for the Main Menu to appear.

#### 2. Press 🔿 or 😒 to highlight Settings, then press 👀





# 3. Highlight Control Test, then press 👓

Wait for the **Insert Strip** screen to appear on the display.

#### 4. Insert a test strip into the test strip port

#### 5. Wait for the Apply Control Solution screen to appear on the display







#### Preparing the control solution

1. Before removing the cap, shake the vial gently

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

3. Squeeze the vial to discard the first drop



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







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



#### Applying the control solution

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



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

3. Wait for the channel to fill completely



#### Viewing your control solution result

After the control solution is applied, your meter will display a progress screen for approximately 5 seconds. Your result is displayed along with the date, time, unit of measure, and (for control solution).



Example

Control solution results are stored in the meter and can be seen when reviewing past results on the meter.

### **CAUTION**:

Make sure you select **Control Test** from the Settings Menu before you begin a control solution test. Follow the steps beginning on page page 53. If **O** does not appear on the screen, this result will be included in your averages and your averages will change too. Repeat the test with a new test strip. If the problem persists, Contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.

#### Checking if the result is in range

Compare the result displayed on the meter to the range printed **on your OneTouch Verio® Control Solution vial.** If your control solution result falls outside the expected range, repeat the test with a new test strip.



Example range OneTouch Verio® Mid Control Solution Control Range 5.7-7.7 mmol/L

# **CAUTION**:

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

#### Causes of out-of-range results

Out-of-range results may be due to:

- Not following the instructions for performing a control solution test.
- Control solution is contaminated, expired, or past its discard date.
- Test strip or test strip vial is damaged, expired, or past its discard date.
- Meter, test strips and/or control solution were not all at the same temperature when the control solution test was performed.
- A problem with the meter.
- Dirt or contamination in the small well on the top of the control solution cap.

# **CAUTION**:

If you continue to get control solution results that fall outside the range printed on the control solution vial, **Do Not** use the meter, test strips, or control solution. Contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.

#### Cleaning the control solution cap

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

# 4 Tagging results

#### Adding Meal and Event tags

Your OneTouch Verio Reflect® Meter allows you to attach a Before Meal ()) or After Meal ()) tag to your current blood glucose result. It is important to understand the link between blood glucose levels and food. When you tag your test results with Meal tags, you add information about food to your results. Your meter uses this information in a variety of ways and displays Pattern Messages, Mentor Tips and Awards. Talk to your healthcare professional to see how Meal tags may help you manage your diabetes. Consider the following guidelines when Meal tagging.

- A Before Meal blood glucose test is taken just before the start of your meal.
- An After Meal blood glucose test is typically taken one to two hours after the start of your meal.
- A blood glucose test taken while fasting should be tagged as Before Meal.

In addition to Meal tagging, your OneTouch Verio Reflect<sup>®</sup> Meter includes an Event tagging feature. Event tagging adds information about your health and lifestyle events to your blood glucose results. Your meter will review your past results and display Messages associated with tagged results when certain conditions are met. See page 3 for Event tag icons and their meanings.

# 1. View the current blood glucose result on the display

The result will automatically receive a Before Meal tag and no Event tag.

# 2. If a Message appears, press $\widehat{o\kappa}$ to clear the Message

3. To change to an After Meal tag, press (5) then highlight After Meal and press (3)

**NOTE:** The Range Indicator icon displayed with the result uses Before and After Meal ranges. When you change a Before Meal tag to an After Meal tag, the Range Indicator icon may point to a different segment on the Colour Bar. A new Message may appear.



4. To add an Event tag to your result, press 🕤

5. Press 🔿 or 😔 to highlight 🎙 Event Tag, then press 👀





# 6. Press 🔿 or 😔 to highlight an Event tag, then press 📧

You may add more than one Event tag to a result.

A 🖌 notes that an Event tag has been added.

# 7. When you have finished selecting Event tags, highlight Done and press 👀





Example

The result will be displayed with the tags. Pressing and holding () will allow you to edit the tags.

**NOTE:** Use care when adding tags to blood glucose results. When you leave the result screen, the tags and result are stored in the Results Log and **cannot** be changed. Incorrect Meal tagging can cause the meter to identify inaccurate Before and After Meal averages and Patterns. Incorrect Event tagging can cause the meter to display incorrect Messages.

### Blood Sugar Mentor® Messages overview

The OneTouch Verio Reflect<sup>®</sup> Meter reviews your past test results and may display Mentor Tips (guidance), Pattern Messages (insight) or Awards (encouragement). The meter will show you the most appropriate Message if more than one is applicable to your result.

- 1. Mentor Tips appear when your results are consistently in range or are currently trending low or high.
- 2. **Pattern Messages** appear when the meter identifies a pattern of glucose results that fall outside the high and low range limits you set in the meter.
- 3. Awards are earned when certain Award criteria are met, such as meeting the Daily Test Goal or tagging results.

Pressing  $\odot \kappa$  will dismiss Messages.

#### **Understanding Pattern Messages**

Low and High Pattern Messages appear when the meter identifies a Pattern of glucose results that fall outside the low and high mealtime range limits set in your meter.

Every time you test your blood glucose, your OneTouch Verio Reflect<sup>®</sup> Meter searches for any new Patterns that have developed over the past 5 days. Patterns are identified by finding results below or above the low and high mealtime range limits set in your meter, and cross referencing with the time of day the tests were taken. For a set of results to form a Pattern, the results must be within the same 3-hour time period over the past 5 days.

When a Pattern is identified, a Pattern message icon () appears below your result. A Pattern Message will be displayed after the result screen. Inaccurate results may cause Pattern Messages to appear.

Once a result is used in a Pattern, it will not be used again in future Pattern Messages.

### **Reviewing results that create Patterns**

There are two ways you can review the individual results that combine to create a Low or High Pattern.

To view a Low or High Pattern message after a test, press (or).



Example - Results screen with Pattern icon

To view the details about the individual blood glucose results that resulted in the Pattern, press (or) again.

Or you can access the Patterns using the Results Log screen. See page 75.



Example - Pattern Message



Example - Results that created Low Pattern

# 5 Understanding Messages

Low (or Hypo\*) Pattern Messages appear when any 2 results over the past 5 days are:

- within the same 3-hour period
- below your low mealtime range limits

**NOTE:** Follow your healthcare professional's advice for treating a low blood glucose result.

High Pattern Messages appear when any 3 results over the past 5 days are:

- within the same 3-hour period
- above your high mealtime range limits
- share the same Meal tag

Event tag Pattern Messages appear when any 3 results over the past 30 days are:

- within the same 3-hour period
- · above or below your mealtime range limits
- share the same Event tag

\*Lee-Davey, J., Alexander, S., & Raja, P. (2011, February 16). Clinical Patterns of Low Blood Glucose Identified by a Pattern Algorithm May Predict Increased Risk of Severe Hypoglycemia in the Following 24-Hour Period [PDF]. Inverness, Scotland: LifeScan. **NOTE:** To be sure that Low and High Pattern Messages appear:

- Basic Mode must be turned off and Pattern Messages must be turned on. See page 93 and page 95.
- Update the date and time if you change time zones, or if the time changes due to Daylight saving time.
- Test your blood glucose using only one OneTouch Verio Reflect<sup>®</sup> Meter. Using multiple meters may cause you to miss Patterns.
- Tag your blood glucose results carefully.
- Test when you feel your blood glucose may be high or low.

# ACAUTION:

- Always use your current result for immediate treatment decisions.
- **Do Not** use Pattern Messages to make immediate or significant changes to your diabetes care plan without first consulting your healthcare professional. Always consult your healthcare professional before making significant changes to your diabetes care plan.
- **Do Not** wait for Pattern Messages to treat low or high results.

# **Understanding Mentor Tips**

Mentor Tips let you know when your results are consistently in range, and display diabetes management information when results are trending low and high.

**NOTE:** Mentor Tips appear with current results and cannot be viewed later.

- **Unusually Low** Current result is below the low range limit, and is at least 0.3 mmol/L below your lowest result over the past 14 days.
- Morning Low Current result occurred in the morning and is below the low range limit.<sup>1</sup>
- Treat Low Current result is below the low range limit.<sup>1, 2</sup>
- **Unusually High** Current result is above the high range limit, and is more than 10% higher than the highest blood glucose result in the last 14 days.
- Morning High Current result occurred in the morning and is above the high range limit.<sup>1</sup>
- **Bedtime High** Current result occurred at night and is above the high range limit.<sup>1</sup>
- Congratulations Your 90-day average is improving.
- Trend 90 Rise Your 90-day average has increased.
- Trend 90 Update New 90-day average is available.
- Near Low Result is in range but close to low range limit.
- Near High Result is in range but close to high range limit.

- Well Done Result is back in range after a series of either 2 low or 3 high results.
- Keep It Up More than 70% of results over the past 7 days were in range.
- Weekly Average New 7-day average is shown.
- **Device Not Paired** Reminds you to pair the meter with a compatible wireless device.
- **Connect Device** Reminds you to sync the meter with the App.
- **Exercise Low** Current result is below the low range limit and received an Exercise Event tag.<sup>3,4</sup>
- Take a Break Current result is above the high range limit and received a Stress Event tag.<sup>4</sup>

<sup>1</sup>Riddle, M. C., MD (Ed.). (2018). 6. Glycemic Targets: Standards of Medical Care in Diabetes 2018 [Abstract]. *Diabetes Care, 41* (Suppl. 1), S60-61.

<sup>2</sup>American Association of Diabetes Educators. (2018). *HYPOGLYCEMIA What are the symptoms? And how should I treat it?* [Brochure]. Chicago, IL: Author.

<sup>3</sup>American Association of Diabetes Educators. (2017). *AADE7 Self-Care Behaviors, Problem Solving* [Brochure]. Chicago, IL: Author.

<sup>4</sup>Riddle, M. C., MD (Ed.). (2018). 6. Glycemic Targets, S44-45.

## **Understanding Awards**

The OneTouch Verio Reflect<sup>®</sup> Meter tracks the goals outlined below. Each time you earn bronze (a), silver (a) or gold (a) medal status, an Award will appear along with your in-range result. You can review your Awards later in the Summary. (See page 71.)

- **Test Goal Award** Meet your Daily Test Goal a set number of times in total or in a row.
- In-Range Award Achieve an in-range result a set number of times in a row.
- Event Tag Award Event tag your result a set number of times in total.
- Syncing Award Sync your meter to the OneTouch Reveal<sup>®</sup> App a set number of times in total.
#### Viewing the Summary

Depending on settings selected the Summary may display results by range, time of day, averages, mealtime averages, Test Tracker progress and Awards. You and your healthcare professional can reference the Summary to identify overall trends in your diabetes management.

#### NOTE:

- **Do Not** use result averages to make immediate treatment decisions. Result averages provide information from past results. Always consult your healthcare professional before making significant changes to your diabetes care plan.
- **Do Not** allow other people to use your meter as it may affect your averages.
- The meter calculates averages based on the 7-, 14- and 30-day periods ending on the current date setting. If you change the date setting, the averages may change too.
- The Summary screens displayed will reflect the features currently selected. See page 88 for information on turning meter features on or off.
- If Basic Mode is selected, your Summary will be limited to the 30-day Summary and Average views. See page 29 for more information about Basic Mode.

#### 6 Summary, Results Log and Trend 90

- In Averages, Pattern Messages and Awards, an EXTREME HIGH GLUCOSE result is always counted as 33.3 mmol/L, and an EXTREME LOW GLUCOSE result is always counted as 1.1 mmol/L.
- The green progress dot will move from left to right as you navigate through the summary screens.



• Pressing 🔿 will display the previous screen.

1. From the Main Menu, press or to highlight Summary and press or

The number of results that are low (blue), in-range (green) and high (red) are displayed and appear as bar graphs.





Example

### 2. Press 🕞 to display the Summary by time of day

The number of test results that are low, in-range and high, by time of day are displayed. The four time slots are Morning, Afternoon, Evening and Bedtime. The time frames for the four time slots cannot be changed.



#### Example

Morning 🖾	06:00 to 11:59
Afternoon 🝥	12:00 to 17:59
Evening	18:00 to 23:59
Bedtime	00:00 to 05:59

**NOTE:** If there were no results in the past 30 days in a target range and time period, that section of the chart is left blank.

# 3. Press 😔 to display your overall averages for the past 7, 14 and 30 days

## 4. If Basic Mode is off, press $\bigcirc$ to display your Before Meal averages for the past 7, 14 and 30 days

# 5. If Basic Mode is off, press $\bigcirc$ to display your After Meal averages for the past 7, 14 and 30 days

**NOTE:** If you do not have results in the past 7-, 14- and 30-day periods, dashes will appear in the mmol/L column.

Averages	
	mmol/L
7 Days	8.9
14 Days	10.0
30 Days	11.1
••••	

Example



Example



#### Example

6. If Test Tracker is on, press ⊗ to display the Daily Test Goal screens



7. If Awards is on, press 😔 to display the Award screens



#### Example

#### Viewing the Results Log

Using the Results Log, you can review the most recent 750 results.

See page 3 for definitions of meter icons that may appear with your result.

Pressing and releasing will allow you to view the previous screen.

1. From the Main Menu, press  $\bigcirc$  or  $\bigcirc$  to highlight Results Log and press  $\bigotimes$ 

Up to four results are displayed on the screen, starting with the most recent.

### 2. Press $\bigcirc$ or $\bigcirc$ to move through the list of results

**NOTE:** If a result is part of a Pattern, the Pattern icon will be displayed for that result instead of any tags that result may have.





Example



#### Example

### 3. Highlight a result with an icon and press or

The result screen will be displayed along with the date and time the result was taken and any tag, Pattern or Range Indicator icons. If you are uncertain whether the result you are viewing is your most current result, view the date and time on the screen.

If the result is part of a Pattern, indicated by , pressing ()) again will display the results that led to the Pattern. See page 64 for more information about Patterns.



Example



Example

#### Viewing the Trend 90

The OneTouch Verio Reflect<sup>®</sup> Meter averages results over the past 90 days to provide a view of the overall trend of blood glucose results. There must be at least 90 days of results stored in the meter for the first 90-day average to appear. A point will be graphed on the screen to represent the first 90-day average. After the first 90-day average a new point is displayed every 14 days.

#### NOTE:

- Basic Mode must be turned off to use the Trend 90 feature. (See page 93.)
- The Trend 90 is an average of blood glucose results. Always use your current result for immediate treatment decisions.

#### 1. From the Main Menu, press or → to highlight Trend 90 and press →



The current 90-day average will be displayed as a blood glucose value with the unit of measure. Each point on the graph represents a 90-day average automatically generated every 14 days. You can track your Trend 90 visually by following the path of points along the graph.



#### 2. Press (5) to return to the Main Menu

#### 7 Syncing your meter

### Connecting to a compatible wireless device

#### Turning the BLUETOOTH® feature on or off

In order to connect your meter with your compatible wireless device, the BLUETOOTH® feature will need to be turned on. The symbol will appear on the meter screen when the BLUETOOTH® feature is on. When the symbol is not present on the screen the BLUETOOTH® feature is off.

#### 1. Start by turning your meter on using the OK button

Wait for the Main Menu to appear, then press  $\bigcirc$  or  $\bigcirc$  to highlight **Settings** and press  $\bigcirc$ 

### 2. On the Settings Menu, highlight Bluetooth and press (OK)

#### Settings

Time/Date Language Range/90d

Features

Messages

Bluetooth

### A $\checkmark$ notes if BLUETOOTH<sup>®</sup> is currently set to On or Off.

# Bluetooth On Off Turn On to connect with the OneTouch Reveal mobile app. OneTouch 4444.

#### 3. Press 🔿 or 😔 to highlight On or Off and press 🕞

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

#### **Pairing overview**

Pairing allows your OneTouch Verio Reflect® Meter to communicate with compatible wireless devices. The devices must be within 8 metres of each other to pair and sync. Download the OneTouch Reveal® Mobile App from the App Store or on Google Play before pairing your meter and compatible wireless device.





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#### 7 Syncing your meter

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

Google Play and the Google Play logo are trademarks of Google LLC.

**NOTE:** Some diabetes management apps, including the OneTouch Reveal<sup>®</sup> Mobile App, may not be available in your country. Visit www.myOneTouch.co.uk to learn if the OneTouch Reveal<sup>®</sup> Mobile App is available in your country.

Multiple OneTouch Verio Reflect<sup>®</sup> Meters can be paired with your compatible wireless device. For example, your compatible wireless device can be paired with a meter at home and another at work. To pair multiple meters, repeat the pairing instructions for each meter. See page 83 for pairing instructions. Your OneTouch Verio Reflect<sup>®</sup> Meter can be paired with multiple compatible wireless devices. To pair multiple compatible wireless devices, repeat the pairing instructions for each compatible wireless device.

#### **Pairing instructions**

The BLUETOOTH<sup>®</sup> feature must be turned on in order to pair the meter with the app. See page 80.

1. Open the OneTouch Reveal<sup>®</sup> Mobile App and follow instructions to pair the meter with your compatible wireless device

2. Look for "OneTouch" and the last 4 characters of the meter serial number on the compatible wireless device display to correctly identify your meter

The meter screen will display the pairing info to look for on your compatible wireless device.



Example

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



Example PIN

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

#### **CAUTION**:

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

### 4. Wait for your compatible wireless device to indicate that it is paired with your meter

#### Sending your results to the app

If the BLUETOOTH<sup>®</sup> feature on the meter is turned on, indicated by the BLUETOOTH<sup>®</sup> symbol (), the meter will automatically send your results to any paired compatible wireless device. The Sync symbol  $(\overline{\mathbb{Q}})$  flashes on the meter display. After syncing, the Sync symbol will disappear and the app will display a list of any new results sent from the meter. You can then share your results with your caregiver or healthcare professional.

#### **CAUTION**:

Always use the current result on your meter for immediate treatment decisions.

**NOTE:** The compatible wireless device must have the app open and have already been paired to the meter before sending a result. See page 81.

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

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

• The compatible wireless device and meter are both turned on, and the app is running.

#### 7 Syncing your meter

- The meter is correctly paired with your compatible wireless device.
- The BLUETOOTH<sup>®</sup> feature on both devices is running (indicated by ) and the devices are within 8 metres of each other.
- The meter will attempt to transmit results up to 4 hours after a test, even if the meter appears to be off.

If you are still unable to send results to the compatible wireless device, try un-pairing and re-pairing with the device, moving the meter and compatible wireless device closer together, or relocating them from possible sources of interference. If you continue to have difficulties, please call Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet. Please address any app issues to the app customer care department.

#### NOTE:

- Inserting a test strip during the transmission will cancel the transfer of all results. The **Apply Blood** screen appears and you can proceed with testing.
- Keep your meter in your care to avoid inaccurate results from being sent to your compatible wireless device.

#### Downloading results to a computer

Your meter can work with diabetes management software, which provides a visual way to track key factors that affect your blood sugar. To learn more about diabetes management tools available to you, contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.

Connect only to a computer certified to UL 60950-1 (()).

To transfer meter data, follow the instructions provided with the diabetes management software product to download the results from the meter. You will need a standard micro USB interface cable to connect your OneTouch Verio Reflect<sup>®</sup> Meter to a computer to download results (not included).

Once the command to start the download is sent from the computer to the meter, the **Cable Connected** screen will appear, indicating that the meter is in communication mode.

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

If you are unable to download your results to a computer, please call Customer Care.



#### 8 Adjusting meter settings

#### Settings Menu overview

After first time setup, you can use the Settings Menu to adjust the meter settings and access additional features.

Time/Date	Set the time and date	
Language	Set the language displayed on screens	
Range/90d	<ul><li>Set Before Meal limits</li><li>Set After Meal limits</li><li>Set the 90 Day Average Target</li></ul>	
Features	<ul> <li>Turn Basic Mode on or off</li> <li>Turn Test Tracker on or off</li> <li>Set Daily Test Goal</li> <li>Set Range Indicator icon to emoji or text</li> </ul>	
Messages	<ul> <li>Turn Pattern Messages on or off</li> <li>Turn Mentor Tips on or off</li> <li>Turn Awards on or off</li> </ul>	
Bluetooth	Turn the BLUETOOTH <sup>®</sup> feature on or off	
Control Test	Initiate a control solution test	
Meter Info	View meter serial number, software version and last sub-error code	

*NOTE:* For information on **Bluetooth**, see page 9. For information on **Control Test**, see page 53.

#### Navigating to the Settings Menu

From the Main Menu, press  $\bigcirc$  or  $\bigcirc$  to highlight Settings and press  $\bigcirc$ 

The Settings Menu is displayed.



#### Adjusting the time and date

You can change the time and date setting whenever needed, such as during travel.

**NOTE:** Adjusting this setting to a time and date prior to your last blood glucose or control solution test will cause the Results Log to appear out of sequence. The Results Log will display results in the order in which they were taken.

1. From the Settings Menu, press  $\frown$  or  $\bigodot$  to highlight Time/Date and press  $\bigcirc$ 

2. Highlight the time or date and press 碗

3. Adjust the desired setting and press or

Repeat this step as necessary.

#### Adjusting the language

1. From the Settings Menu, press  $\bigcirc$  or  $\bigcirc$  to highlight Language and press  $\boxdot$ 

A  $\checkmark$  appears next to the current language set in the meter.

#### 2. Highlight the desired language, then press 👀

The Settings Menu will be displayed in the new language you have selected.

### Adjusting range limits and 90 Day Average Target

#### NOTE:

- If you adjust your range limits, your previous Range Indicator icons in the Results Log will not change. Only new results will be affected by your range limit changes.
- Consult with your healthcare professional about the range limits and 90 Day Average Target that are right for you.

### 1. From the Settings Menu, press 🔿 or 🕞 to highlight Range/90d (or Range for Basic Mode) and press 👀

Your current meter settings are displayed.



Example - Basic Mode Off



Example - Basic Mode On

- 3. Adjust the Low Limit and press (OK)



Example - Before Meal

#### 8 Adjusting meter settings

Repeat this step to change the High Limit. See page 22 for information about Before and After Meal low and high limits.

**NOTE:** In Basic Mode, range limits are general and are not defined by mealtime. General range limits are pre-set.

#### General range limits

pre-set low limit	3.9 mmol/L
pre-set high limit	10.0 mmol/L
low limit must be set within	3.3 mmol/L and 6.1 mmol/L
high limit must be set within	5.0 mmol/L and 16.7 mmol/L

### 4. To adjust the 90 Day Average Target, highlight the 90d Target setting and press or

#### 5. Adjust the 90 Day Average Target and press 👀



The meter is pre-set with a 90 Day Average Target of 8.6 mmol/L. The minimum 90 Day Average Target is 5.5 mmol/L and the maximum is 14.7 mmol/L.

**NOTE:** Be sure to talk to your healthcare professional about the 90 Day Average Target that is right for you.

#### Turning Basic Mode on or off

**NOTE:** Selecting Basic Mode affects the information the meter displays. See page 29 for more information.

### 1. From the Settings Menu, press $\bigcirc$ or $\bigcirc$ to highlight Features and press $\bigotimes$

The Features Menu indicates whether Basic Mode is currently on or off.

2. Highlight Basic Mode and press ()

A  $\checkmark$  appears next to the current mode set in the meter.

#### 3. Highlight On or Off and press 🕞

In Basic Mode, Test Tracker and Range Indicator are removed from the Features Menu.

#### 8 Adjusting meter settings

Basic Mode uses pre-set general range limits which are different from the ones set during first time setup. See page 90 for information on adjusting range limits.

### Turning the Test Tracker on or off and setting a Daily Test Goal

### 1. From the Settings Menu, press $\bigcirc$ or $\bigcirc$ to highlight Features and press $\bigcirc$

The Features Menu indicates the current Test Tracker setting.

**NOTE:** If Basic Mode is selected the Test Tracker will not appear in the Features Menu.

#### 2. Highlight Test Tracker and press 🕞

#### 3. Adjust the Daily Test Goal, then press 🔿

The meter is pre-set with a Daily Test Goal of four tests per day. The maximum Daily Test Goal is eight.

**NOTE:** Be sure to talk to your healthcare professional about the Daily Test Goal that is right for you.

To turn off the Test Tracker, press  $\bigcirc$  or  $\bigcirc$  until **Off** is highlighted, and press  $\bigcirc$ .

### Set the Range Indicator icon to emoji or text

### 1. From the Settings Menu, press $\bigcirc$ or $\bigcirc$ to highlight Features and press $\bigcirc$

Your current meter settings are displayed.

2. Highlight Range Indicator and press 👀

A  $\checkmark$  appears next to the current setting in the meter.

3. Highlight Emoji or Text, then press 👀

### Turning Pattern Messages, Mentor Tips and Awards on or off

#### NOTE:

- Basic Mode must be turned off for the Messages Menu to appear in Settings. See page 93.
- If Pattern Messages are turned off, you will no longer see Patterns with results, Summary or Results Log screens. The meter will continue to track Pattern information. If you turn Pattern Messages back on again, Pattern icons will be displayed in the Summary and Results Log. See page 64 for more information about Pattern Messages.

#### 8 Adjusting meter settings

- If Mentor Tips are turned off, you will no longer see Mentor Tips with results. See page 68 for more information about Mentor Tips.
- If Awards are turned off, you will no longer see Awards with results or in the Summary view. See page 70 for more information about Awards.

### 1. From the Settings Menu, press $\bigcirc$ or $\bigcirc$ to highlight Messages and press $\odot$

Your current meter settings are displayed.

#### 2. Highlight Pattern, Mentor Tips or Awards and press or

A  $\checkmark$  appears next to the current setting in the meter.

3. Highlight On or Off and press 👀

#### View meter info and last sub-error code

The meter serial number, software version, and information about the last meter sub-error are stored in your meter. You can check this information at any time and use it for troubleshooting.

#### Adjusting meter settings 8

#### 1. From the Settings Menu, press ∧ or ∨ to highlight Meter Info and press ○ĸ

The meter serial number, software version, and unit of measure are displayed.

### 2. Press $\bigcirc$ to view information about the last meter error

Meter Info

Serial Number: ABC12345 Software: PUE\_01.01.00 Units: mmol/L

Example

Meter Info Last Error: Error X Error Date: 30 Aug 2018 Sub-Error Code: XXXX

Example

Pressing 🕤 returns you to the Settings Menu.

#### 9 Caring for your system

#### Storing your system

Store your meter, test strips, control solution and other items in your carrying case. Keep in a cool, dry place between 5°C and 30°C. **Do Not** refrigerate. Keep all items away from direct sunlight and heat. Exposure to temperatures outside the storage limits, as well as moisture and humidity, may cause inaccurate readings.

#### **Cleaning and disinfection**

Cleaning and disinfection are different 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. Disinfection is the only way to reduce your exposure to disease. For cleaning information, see page 99, and for disinfection, see page 100.

### Cleaning your meter, lancing device and cap

The meter, lancing device and cap should be cleaned whenever they are visibly dirty and before disinfection. Clean your meter at least once per week. For cleaning obtain regular strength liquid dish soap and a soft cloth. Prepare a mild detergent solution by stirring 2.5 mL of regular strength liquid dish soap into 250 mL of water.

- 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. (See page 16.)
- **Do Not** spray cleaning solution on the meter or immerse it in any liquid.



#### 1. Holding the meter with the test strip port pointed down, use a soft cloth 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 outside of the cap.



#### 2. Wipe dry with a clean, soft cloth



### Disinfecting your meter, lancing device and cap

The meter, lancing device and cap should be disinfected periodically. Clean your meter, lancing device and cap prior to disinfecting. For disinfecting, obtain regular household bleach (*containing a minimum* of 5.5% sodium hypochlorite as the active ingredient)\*. Prepare a solution of 1 part household bleach and 9 parts water.

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

### 1. Hold the meter with the test strip port pointed down

Use a soft cloth dampened with this solution to wipe the outside of the meter and lancing device until the surface is damp. Be sure to squeeze out any excess liquid before you wipe the meter.



# 2. After wiping, cover the surface you are disinfecting with the soft cloth dampened with the bleach solution for 1 minute

Then wipe with a clean, damp, soft cloth.



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

If you see signs of wear, please contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.



#### **Replacing the batteries**

Your OneTouch Verio Reflect<sup>®</sup> Meter uses 2x CR2032 lithium batteries. One battery powers the meter only and the other powers the backlight. See page 115 for information on when to change the meter batteries.

If the meter does not turn on, or remains dim after pressing a button, check the batteries.

**Do Not** change the batteries when connected to a PC.

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

**IMPORTANT:** Use only CR2032 lithium batteries with your meter. **Do Not** use rechargeable batteries. Use of an incorrect battery type or a used battery may result in your meter providing fewer tests than normal.

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

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

#### 2. Insert the new batteries

With the "+" side facing up toward you, place each battery in the compartment within the fold of the plastic ribbon.

Push each battery in until it snaps into the battery clasp.









#### 10 Batteries

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

If the meter does not power on after you have replaced the batteries, check that the batteries are correctly installed with the "+" side up. If the meter still does not power on, contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.



#### 3. Check your meter settings

You will be prompted to set the time and date whenever you change the batteries. See page 89.

#### 4. Dispose of batteries

Dispose of batteries according to your local environmental regulations.

#### Healthcare professional information

Only healthcare professionals working in a professional capacity in healthcare settings may perform blood glucose tests on more than one patient using the OneTouch Verio Reflect<sup>®</sup> Meter. Always follow recognised procedures for handling objects that are potentially contaminated with human material when using the meter.

#### **CAUTION**:

- Any patient with an infection or suffering from an infectious disease, or is suspected to be, and any patient who is a carrier of a multi-resistant microorganism must be assigned his/her own meter. During this time the meter must not be used to test any other patient.
- Patients and medical staff are potentially at risk of becoming infected if the same OneTouch Verio Reflect<sup>®</sup> Meter is used to test blood glucose in more than one patient. All objects that come into contact with human blood are potential sources of infection.
- When testing multiple patients, it is important to follow your institution's policies and local standards and guidelines that apply to your region.
- Follow your institution's policy and procedure guidelines for when to perform a control solution test.

#### 11 Multi-patient use testing

- Follow your institution's policy for treating hypoglycaemia and hyperglycaemia.
- The patient's hands should be washed with warm water and soap and then dried well prior to testing.
- Results may be falsely low if the patient is severely dehydrated.
- If uncertain about which patient a blood glucose test result belongs to, retest prior to treatment.
- **Do Not** use results stored in the Results Log to make immediate treatment decisions. The meter stores up to 750 past results and these may be from multiple patients. Always use the current result for immediate treatment decisions.
- If a single meter is used to test more than one patient, the meter must be **disinfected after each patient**, (see page 100) whether or not blood- or body fluidcontamination is suspected.
- Follow your institution's policy/guidelines for proper disposal of meter and test strips.
- If used for a single patient and a risk of contamination exists, the meter should be disinfected after each use.
- If used for a single patient clean the meter at least once per week.
## Personal protective equipment

Healthcare professionals should follow their institution's policy and procedure guidelines for PPE and hand hygiene.

## Lancing devices

A single-use, retractable-needle lancing device should be used for each patient skin puncture. Dispose of single-use lancing devices in an appropriate biohazard sharps container immediately after use.

## NOTE:

• The single-use lancing device is for getting a capillary whole blood sample only. Not supplied with this kit. If a lancing device and lancets were provided with this kit, dispose of them immediately following your institution's policy and procedure guidelines.

## Meter

- It is recommended that the meter is set to Basic Mode for multi-patient use.
- It is important to follow your institution's policies and guidelines before changing any meter settings.
- If possible, a separate OneTouch Verio Reflect<sup>®</sup> Meter should be assigned to each patient, and used only to test that patient.
- If the meter is being used with multiple patients, the previous result may belong to a different patient.

## 11 Multi-patient use testing

Lifespan of meter:

- 9 months in a multi-patient use setting
- During the use of the product, users should properly maintain according to this Owner's Booklet.
- The meter can be disinfected after each test for 9 months and has been tested to 3799 disinfection cycles.
- After 9 months in a multi-patient use setting, as long as you can ensure the basic safety and effectivity, the meter can continue to be used.
- If the meter stops working or a defect occurs on any part, contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.

## Applying blood samples

**NOTE:** When applying a whole blood sample from the finger, keep the meter pointed down to prevent blood from entering the test strip port.

Follow all instructions for performing a blood glucose test. See page 31.

## Troubleshooting 12

## Error and other messages

The OneTouch Verio Reflect<sup>®</sup> Meter displays messages when there are problems with the test strip, with the meter or when your glucose levels are above 33.3 mmol/L or below 1.1 mmol/L. 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 Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.

## What it means

You may have a very low blood glucose level (severe hypoglycaemia), below 1.1 mmol/L.

## What to do

### This may require immediate

treatment. Although this message

could be due to a test error, it is safer to

treat first and then do another test. Always treat according to your healthcare professional's recommendations.



## What it means

You may have a very high blood glucose level (severe hyperglycaemia), over 33.3 mmol/L.

## What to do

**Re-test your blood glucose level.** If the result is **EXTREME HIGH GLUCOSE** 

again, obtain and follow instructions from your healthcare professional right away.

## What it means

Meter is too hot (above 44°C) to perform a test.

### What to do

Move the meter and test strips to a cooler area. Insert a new test strip when the meter and test strips are within the operating range (6-44°C). If you do



L Warning

EXTREME HIGH

GLUCOSE

Above 33.3 mmol/L

Temperature too high. Out of operating range. See Owner's Booklet.

not get another **Temperature too high** message, you can proceed with testing.

If this message continues to appear, contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.



## What it means

Meter is too cold (below 6°C) to perform a test.

## What to do

Move the meter and test strips to a warmer area. Insert a new test strip when the meter and test strips are within the operating range (6-44°C). If



Temperature too low. Out of operating range. See Owner's Booklet

you do not get another **Temperature too low** message, you can proceed with testing.

If this message continues to appear, contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet

## **Error Screens**

If there is a problem with the meter, the following error screens may appear. If you cannot resolve the error with your meter, contact Customer Care. They will refer to the error number, and a sub-error code found in the Meter Info screen, to help troubleshoot the problem. See page 96 for more information on viewing the Meter Info screen.

## 12 Troubleshooting

## What it means

There is a problem with the meter.

## What to do

**Do Not** use the meter. Contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.



### What it means

Error message could be caused by a used test strip, applying blood to the test strip before inserting it into the meter or a problem with the meter or test strip.

## What to do

Repeat the test with a new test strip;

see page 31 or page 53. If this message continues to appear, contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.



Meter or strip problem. Retest with a new strip.

## What it means

The sample was applied before the meter was ready.

## What to do

Repeat the test with a new test strip. Apply a blood or control solution sample only after the Apply Blood or Apply Control Solution screen appears



on the display. If this message continues to appear, contact Customer Care Contact information for Customer Care is listed at the end of this Owner's Booklet

## 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.



## 12 Troubleshooting

### What to do

Repeat the test with a new test strip; see page 31 or page 53. If the error message appears again, contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.

## 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 page 31 or page 53. If the error message appears again, contact

Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.



Be advised

Low Battery. Replace soon.

2 x CR2032

## What it means

Battery power is low but there is still enough battery power to perform a test. Test results will still be accurate. The flashing low battery ( continue to appear until the batteries are replaced.

## What to do

Press  $(\circ \kappa)$  to continue, but replace the batteries as soon as possible.

## What it means

There is not enough meter battery power to perform a test.

## What to do

Replace the batteries immediately.



## Comparing meter results to laboratory results

Results obtained from the OneTouch Verio Reflect<sup>®</sup> 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 Reflect<sup>®</sup> Meter is considered accurate when it is within 0.83 mmol/L of a laboratory method when the glucose concentration is lower than 5.55 mmol/L and within 15% of a laboratory method when the glucose concentration is 5.55 mmol/L or higher.

Meter results can be affected by factors that do not affect lab results in the same way. Specific factors that may cause your meter result to vary from your lab result may include:

- You have eaten recently. This can cause a result from fingertip testing to be up to 3.9 mmol/L higher than a lab test using blood drawn from a vein.<sup>1</sup>
- Your haematocrit is above 60% or below 20%.
- You are severely dehydrated.

For additional information, refer to the OneTouch Verio<sup>®</sup> Test Strip Insert.

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

## Guidelines for obtaining an accurate meter to lab comparison

### 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 Reflect® 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.

## Comparing your meter results to those taken from another meter

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

## **Technical specifications**

Assay method	FAD-GDH (flavin adenine dinucleotide dependent glucose dehydrogenase)
Automatic shutoff	Two minutes after last action
Battery ratings	Two 3.0 V d.c., (2x CR2032 batteries),
Battery type	2 replaceable 3.0 Volt CR 2032 lithium batteries (or equivalent)
BLUETOOTH® technology	Frequency range: 2.4-2.4835 GHz Maximum power: 0.4 mW Operating Range Distance: minimum 8 metres (unobstructed) Operating Channels: 40 Channels Security Encryption: 128-bit AES (Advanced Encryption Standard)
Calibration	Plasma-equivalent
Data port type	Compatible with micro USB 2.0
Memory	750 test results

Operating ranges	6-44°C Relative humidity: Non-condensing 10-90% Altitude: up to 3048 metres Haematocrit: 20-60%
Reported result range	1.1-33.3 mmol/L
Sample	Fresh capillary whole blood
Sample volume	0.4 µL
Size	43.0(W) x 101.0(L) x 15.6(T) mm
Test time	Approximately 5 seconds
Unit of measure	mmol/L
Weight	Approximately <53 grams

## System accuracy

Diabetes experts have suggested that glucose meters should agree within 0.83 mmol/L of a laboratory method when the glucose concentration is lower than 5.55 mmol/L, and within 15% of a laboratory method when the glucose concentration is 5.55 mmol/L or higher.

Samples from 100 patients were tested using both the OneTouch Verio Reflect<sup>®</sup> System and the YSI 2900 Glucose Analyzer laboratory instrument.

## System accuracy results for glucose concentrations <5.55 mmol/L

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

Within	Within	Within
<u>+</u> 0.28 mmol/L	<u>+</u> 0.56 mmol/L	<u>+</u> 0.83 mmol/L
73.7% (137/186)	96.8% (180/186)	100% (186/186)

## System accuracy results for glucose concentrations ≥5.55 mmol/L

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

Within <u>+</u> 5%	Within <u>+</u> 10%	Within <u>+</u> 15%
65.2% (270/414)	93.2% (386/414)	99.3% (411/414)

# System accuracy results for glucose concentrations between 1.9 mmol/L and 25.0 mmol/L

Within  $\pm 0.83$  mmol/L or  $\pm 15\%$ 

99.5% (597/600)

**NOTE:** Where 1.9 mmol/L represents the lowest glucose reference value and 25.0 mmol/L represents the highest glucose reference value (YSI value).

## **Regression statistics**

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

# of Subjects	# of Tests	Slope	Intercept (mmol/L)
100	600	1.02	0.04

95% CI Slope	95% CI Intercept (mmol/L)	Std. Error (S <sub>y.x</sub> ) (mmol/L)	R <sup>2</sup>
1.01 to 1.03	-0.03 to 0.11	0.49	0.99

## User performance accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 313 lay persons showed the following results:

97.1% within  $\pm 0.83$  mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L, and 96.4% within  $\pm 15\%$  of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

96.5% of the <u>total number of</u> samples were within  $\pm 0.83$  mmol/L or  $\pm 15\%$  of the medical laboratory values.

## Precision

Within Run Precision (300 Venous Blood Samples Tested per Glucose Level)

Data generated using the OneTouch Verio Reflect® Meter.

Target Glucose (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (%)
2.2	2.2	0.06	2.68
5.0	4.9	0.13	2.66
7.2	7.1	0.21	2.98
11.1	11.2	0.31	2.73
19.4	19.8	0.52	2.60

Results show that the greatest variability observed between test strips when tested with blood is 0.13 mmol/L SD or less at glucose levels less than 5.55 mmol/L, or 2.98% CV or less at glucose levels at 5.55 mmol/L or above.

Total Precision (600 Control Solution Tests per Glucose Level)

Data generated using the OneTouch Verio Reflect® Meter.

Glucose Level Ranges (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (%)
Low (1.39-2.72)	2.13	0.07	3.3
Mid (5.67-7.67)	6.70	0.15	2.2
High (16.56-22.39)	19.34	0.46	2.4

## Guarantee

LifeScan guarantees that the OneTouch Verio Reflect<sup>®</sup> 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. If the meter stops working or a defect occurs on any part, contact Customer Care. Contact information for Customer Care is listed at the end of this Owner's Booklet.

## **Electrical and safety standards**

This meter complies with CISPR 11:Class B (Radiated Only). Emissions of the energy used are low and not likely to cause interference in nearby electronic equipment. The meter has been tested for immunity to electrostatic discharge as specified in IEC 61326-2-6. This meter complies with immunity to radio frequency interference as specified in IEC 61326-1 and 61326-2-6.

The meter meets the requirements for immunity to electrical interference at the frequency range and test level specified in international standard EN 60601-1-2:2014.

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

Hereby, LifeScan Europe GmbH declares that the radio equipment type (blood glucose meter) is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.onetouch.com/doc.



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LifeScan self-test blood glucose monitoring devices conform to the following EU Directives:

IVDD (98/79/EC):

CF Blood Glucose Meter, Test Strips, 0344 and Control Solution

MDD (93/42/EEC):

 $\mathbf{C}\mathbf{E}$ 1639

Regulation EU 2017/745:



**C E** Lancing Device

RED (2014/53/EU):

Blood Glucose Meter

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





Call OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland), Lines open 9am-5pm Monday - Friday. www.myOneTouch.co.uk.



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## EC REP

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