

# ONETOUCH

## Select Plus Flex<sup>TM</sup>

Blood Glucose Monitoring System



## Owner's Booklet

Instructions for Use



**ONETOUCH**  
Select *Plus* Flex™  
Blood Glucose Monitoring System  
**Owner's Booklet**

## Thanks for choosing OneTouch®!

The OneTouch Select Plus Flex™ Blood Glucose Monitoring System is one of the latest product innovations from OneTouch®.

Your OneTouch Select Plus Flex™ Meter is designed to connect (sync) with a variety of compatible wireless devices running software applications that let you review and graph your results, and help identify patterns. Meter results are sent to the compatible devices either through BLUETOOTH® (wireless) or USB cable connection.

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

This Owner's 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® products and services will continue to be a part of your life.

## Compatible wireless devices

Visit [www.OneTouchMEA.com](http://www.OneTouchMEA.com) for information on which wireless devices are compatible with your OneTouch Select Plus Flex™ Meter, and where/how to download the software application on your compatible wireless device.

## Meter symbols and icons

	Meter Power
	Low Battery
	Battery Empty
	Control Solution
	Syncing
	BLUETOOTH® Feature On
	History Mode (Past results)
	Apply Sample
	Range Indicator Arrow
	Setting Mode

## Other symbols and icons



Cautions and Warnings: Refer to the Owner's Booklet and inserts that came with your system for safety-related information.



Direct current



Consult Instructions for Use



Manufacturer



Lot Number



Serial Number



Storage Temperature Limits



In Vitro Diagnostic Device



Do Not Re-use



Sterilised by irradiation



Not for general waste



Use By Date



Contains sufficient for n tests



Underwriters Laboratories certification

## 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 Select® Plus Test Strips, OneTouch Select® Plus Control Solution and the OneTouch® Delica™ Plus Lancing Device.

### IMPORTANT SAFETY INSTRUCTIONS:

- This meter and lancing device are for single patient use only. **Do Not** share them with anyone else, including family members! **Do Not** use on multiple patients!
- After use and exposure to blood, all parts of this kit are considered biohazardous. A used kit may potentially transmit infectious diseases even after you have performed cleaning and disinfection.

## Intended use

The OneTouch Select Plus Flex™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The system is intended to be used by a single patient and should not be shared.

The OneTouch Select Plus Flex™ Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and with their healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch Select Plus Flex™ Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes or for neonatal use.

The OneTouch Select Plus Flex™ Blood Glucose Monitoring System is not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients.

## **Test principle**

Glucose in the blood sample mixes with the enzyme Glucose Oxidase (see page 112) 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 result, and stores it in its memory.

Use only OneTouch Select® Plus Control Solution and Test Strips with the OneTouch Select Plus Flex™ Meter. Use of OneTouch Select® Plus Test Strips with meters for which they are not intended may yield inaccurate results.

## **BLUETOOTH® wireless technology**

BLUETOOTH® wireless technology is used by some smartphones and many other devices. Your OneTouch Select Plus Flex™ Meter uses BLUETOOTH® wireless technology to pair and to send your glucose results to compatible wireless devices.

The OneTouch Select Plus Flex™ Meter is designed to work with the OneTouch Reveal® Mobile App and many other diabetes applications on compatible wireless devices.

**NOTE:** Some diabetes management apps, including the OneTouch Reveal® Mobile App, may not be available in your country. Visit [www.OneTouchMEA.com](http://www.OneTouchMEA.com) to learn if the OneTouch Reveal® Mobile App is available in your country.

Visit [www.OneTouchMEA.com](http://www.OneTouchMEA.com) for information on which wireless devices are compatible with your OneTouch Select Plus Flex™ Meter, and where/how to download the software application on your compatible wireless device.

When using the OneTouch Select Plus Flex™ System, we suggest you pair your OneTouch Select Plus Flex™ Meter with a compatible wireless device and track your results. See page 31 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:** The BLUETOOTH® feature on your meter sends test results to your compatible wireless device. To prevent other people's results from being sent to your compatible wireless device, **Do Not** let anyone else use your meter to test their blood glucose. This meter is for single patient use only.

**⚠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 29 for more information.

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

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

## **BLUETOOTH® trademark**

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

# Table of Contents

<b>1</b>	<b>Getting to know your system</b>	<b>14</b>
<b>2</b>	<b>Setting up your system</b>	<b>24</b>
	Setting up your meter	24
	Connecting to a compatible wireless device	29
	Turning the meter off	35
<b>3</b>	<b>Taking a test</b>	<b>36</b>
	Testing your blood glucose	36
	Testing with control solution	68
<b>4</b>	<b>Reviewing past results</b>	<b>78</b>

<b>5</b>	<b>Editing Your Settings</b>	<b>82</b>
	Editing time and date	82
	Editing your range limits	83
<b>6</b>	<b>Caring for your system</b>	<b>86</b>
<b>7</b>	<b>Battery</b>	<b>90</b>
<b>8</b>	<b>Troubleshooting your system</b>	<b>94</b>
<b>9</b>	<b>Detailed information about your system</b>	<b>108</b>
<b>10</b>	<b>Index</b>	<b>122</b>

# 1 Getting to know your system

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

### Included with your kit:



OneTouch Select Plus Flex™  
Meter (CR2032 lithium coin  
cell battery included)



Lancing device



Lancets

**NOTE:** If any item is missing or defective in your kit, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

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

## 1 Getting to know your system

### Available separately:

**Items listed 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 Select® Plus  
Mid Control Solution\*



OneTouch Select® Plus  
Test Strips\*



Lancets\*

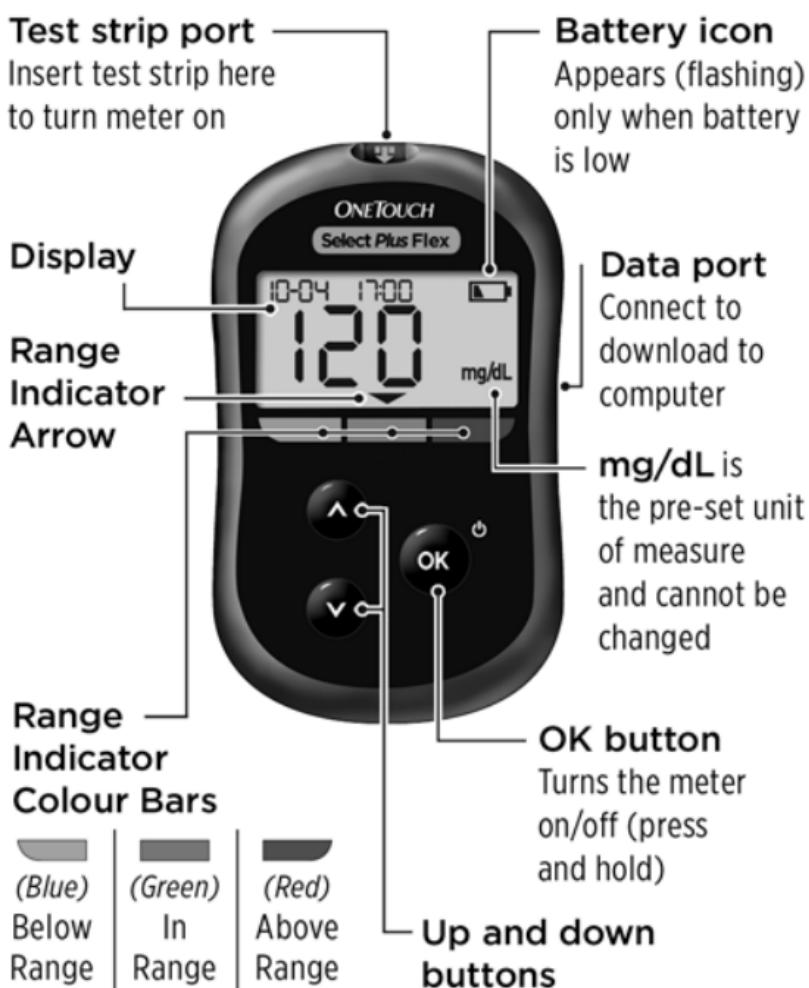
\*Lancets, OneTouch Select® Plus Control Solution and Test Strips are available separately. For availability of lancets, test strips and control solution, contact Customer Service or your healthcare professional.

**⚠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.

## 1 Getting to know your system

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

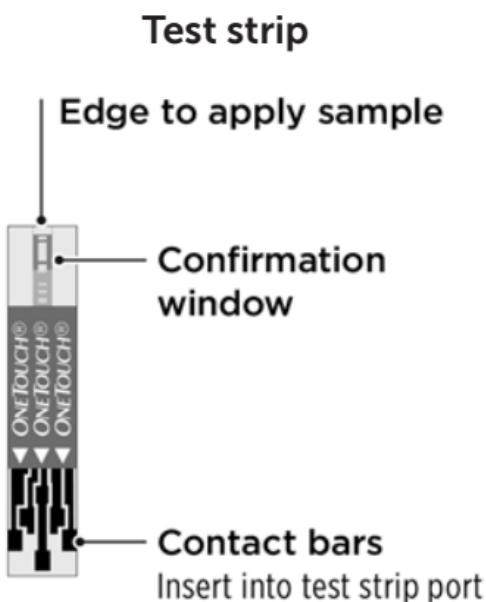
### Meter





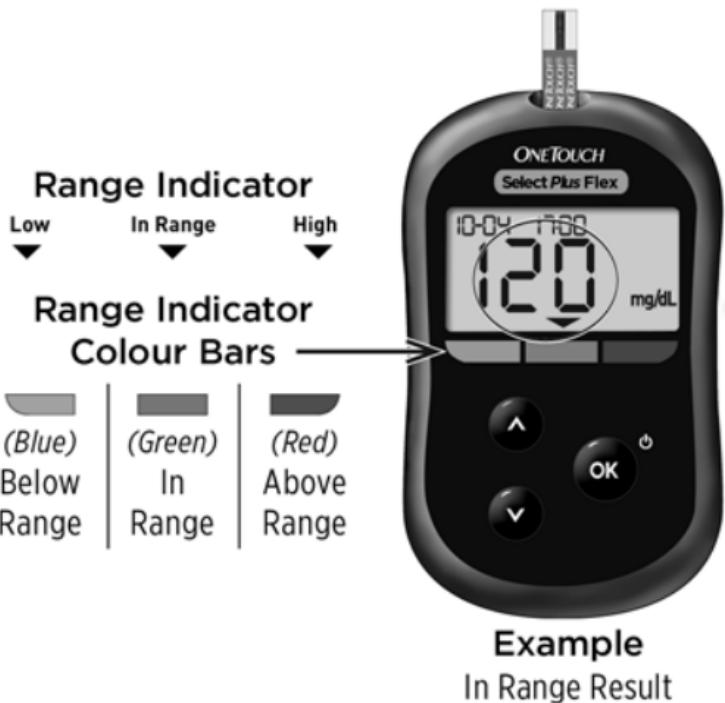
## 1 Getting to know your system

### Getting to know your OneTouch Select® Plus Test Strip



## The Range Indicator feature

The OneTouch Select Plus Flex™ Meter automatically lets you know if your current result is below, above or within your range limits. It does this by displaying your current result with a Range Indicator Arrow, pointing to a corresponding Range Indicator Colour Bar below the meter display. Use the Range Indicator Arrow and Colour Bar together to interpret your results.



## 1 Getting to know your system

### 3 Possible Range Indicator Displays

A Range Indicator Arrow will appear just below your result after each test depending upon how you set your low and high range limits in the meter.

Things you should know before using the Range Indicator feature:

- The meter comes with pre-set range limits. The pre-set low range limit is 70 mg/dL and the pre-set high range limit is 180 mg/dL. You can change these limits as needed to meet your needs. See page 83 for details on the pre-set range limits and on editing your range limits.
- If you decide to change your range limits, the Range Indicator Arrows stored with previous results in meter memory will not change. However, any new tests will display Range Indicator Arrows which reflect your changes.



Example  
Below Range Result



Example  
In Range Result



Example  
Above Range Result

This page left blank intentionally.

## 2 Setting up your system

### Setting up your meter

#### Turn your meter on

To turn your meter on, press and hold **OK** until the start-up test screen appears. Once the device is on, release **OK**. You can also turn the meter on by inserting a test strip.



Every time you turn your meter on, a start-up screen will appear for a few seconds. All segments of the display should appear briefly, indicating your meter is working properly. If the meter does not power on, check the battery.

#### **⚠ CAUTION:**

If you see any missing segments within the start-up screen, there may be a problem with the meter. Contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

**NOTE:** If you turned the meter on for the first time by inserting a test strip instead of pressing **OK**, you will not be able to perform a glucose test until you complete the first time setup.

## First time setup

To turn your meter on, press and hold **OK** until the start-up screen appears. Once the device is on, release **OK**. The meter will now automatically prompt you to set the time and date. The SET icon will appear on the screen to indicate that the meter has entered setup mode.

## Setting the time

### Hour will flash

- If the hour displayed is correct, press **OK** to confirm.
- If the hour displayed is not correct, press **▲** or **▼** to change the hour and press **OK** to confirm.



## 2 Setting up your system

### Minutes will flash

- If the minutes displayed is correct, press  to confirm.
- If the minutes displayed is not correct, press  or  to change the minutes and press  to confirm.



### Setting the date

After completing the time setup, the meter will automatically move to date setup.

### Year will flash

- If the year displayed is correct, press  to confirm.
- If the year displayed is not correct, press  or  to change the year and press  to confirm.



**Month will flash**

- If the month displayed is correct, press **OK** to confirm.
- If the month displayed is not correct, press **▲** or **▼** to change the month and press **OK** to confirm.

22-04 20 15

SET

**Day will flash**

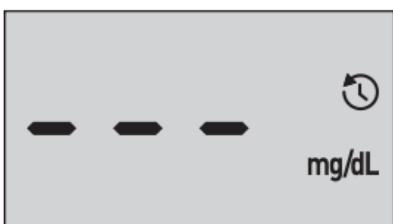
- If the day displayed is correct, press **OK** to confirm.
- If the day displayed is not correct, press **▲** or **▼** to change the day and press **OK** to confirm.

22-04 20 15

SET

## 2 Setting up your system

You are now ready to take a test. See the section *Testing your blood glucose* in Chapter 3.



**NOTE:** After completing first time setup, a screen with three dashes will appear. Once you begin testing, your last result will appear in place of the three dashes, along with the date and time the test was taken.

### Adjusting the time and date settings after first time setup

You can adjust the meter's time and date settings after first time setup. Press and hold **OK** to turn the meter on, then press and hold **OK** and **▼** at the same time. The SET screen will appear. See page 82.

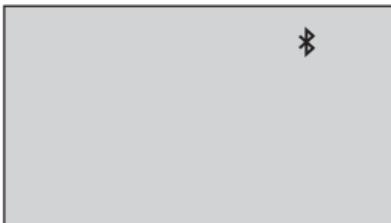
After adjusting the settings, your meter will exit settings mode and your last result screen will appear.

## Connecting to a compatible wireless device

### Turning the BLUETOOTH® feature on or off

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

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



The  symbol indicates the BLUETOOTH® feature is on

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

## 2 Setting up your system

### Pairing Overview

Pairing allows your OneTouch Select Plus Flex™ 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 appropriate app store before pairing your meter and compatible wireless device.

**NOTE:** Some diabetes management apps, including the OneTouch Reveal® Mobile App, may not be available in your country. Visit [www.OneTouchMEA.com](http://www.OneTouchMEA.com) to learn if the OneTouch Reveal® Mobile App is available in your country.

Multiple OneTouch Select Plus Flex™ Meters can be paired with your compatible wireless device. For example, your compatible wireless device can be paired with a meter at home and another at work. To pair multiple meters, repeat the pairing instructions for each meter. See page 31 for pairing instructions.

Your OneTouch Select Plus Flex™ Meter can be paired with multiple compatible wireless devices. To pair multiple compatible wireless devices, repeat the pairing instructions for each compatible wireless device.

### Pairing Instructions

1. Start by turning your meter on using the  button
2. The BLUETOOTH® feature is turned on by pressing  and  together

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



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

## 2 Setting up your system

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

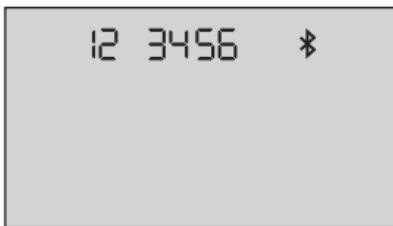


**5. When prompted by the OneTouch Reveal® Mobile App, the meter will display a six digit PIN number**

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

**⚠ CAUTION:**

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



Example of PIN number display on meter

**6. Wait for your compatible wireless device to indicate that your meter and compatible wireless device are paired**

## 2 Setting up your system

### Syncing to send results wirelessly to the OneTouch Reveal® Mobile App

After pairing the meter with your compatible wireless device, you are ready to send results to the OneTouch Reveal® Mobile App.

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

If needed, press **OK** and **▲** at the same time to turn the BLUETOOTH® feature on.

The Sync symbol (⌚) flashes on the meter display. "Syncing Data" will appear on the app to notify you that the meter is communicating with the app.



Syncing Data

After syncing, the Sync symbol will disappear, the "Syncing Data" message will disappear on the app, and the app will display a list of any new results sent from the meter.

**NOTE:** Inserting a test strip during the transmission will cancel the transfer of all results. The flashing  symbol appears on the screen and you can proceed with testing.

## Turning the meter off

There are three ways to turn your meter off:

- Press and hold  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.

**NOTE:** Following a glucose test, the meter will still be available for BLUETOOTH® connection for up to 4 hours. See page 62 for more details.

## 3 Taking a test

### Testing your blood glucose

#### Test your blood glucose

**NOTE:** Many people find it helpful to practise testing with control solution before testing with blood for the first time. See page 68.

#### Preparing for a test

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

OneTouch Select Plus Flex™ Meter

OneTouch Select® Plus Test Strips

Lancing device

Sterile lancets

#### **NOTE:**

- Use only OneTouch Select® Plus Test Strips.
- Make sure your meter and test strips are about the same temperature before you 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.

- Keep test strips in a cool, dry place between 5°C and 30°C.
- **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, especially in high humidity environments.
- 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 or control solution applied to it. Test strips are for single use only.
- **Do Not** test with a test strip that is bent or damaged.
- 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.

**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 page 86.

### 3 Taking a test

**NOTE:** 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 108 for more information.

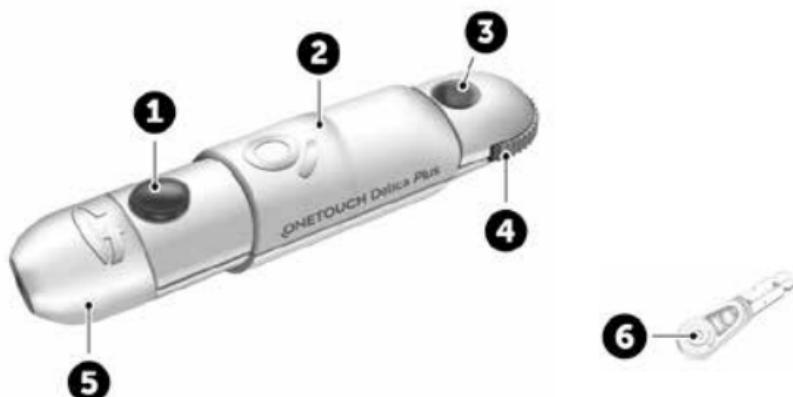
#### CAUTION:

- **Do Not** use the OneTouch Select Plus Flex™ System when PAM (Pralidoxime) is known or suspected to be in the patient's whole blood sample, as it may cause inaccurate results.
- **Do Not** use your test strips if your vial is damaged or left open to air. This could lead to error messages or inaccurate results. Contact Customer Service immediately if the test strip vial is damaged.  
Contact LifeScan Customer Service at:  
[service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

- 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.

### 3 Taking a test

## Getting to know your OneTouch® Delica™ Plus Lancing Device



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

**NOTE:**

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

### 3 Taking a test

#### Lancing precautions

##### CAUTION:

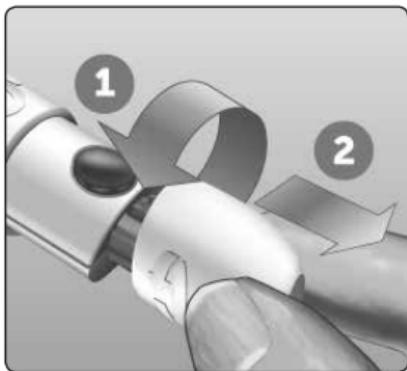
To reduce the chance of infection and disease spread by blood:

- 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 lancing device with anyone.
- Always use a new, sterile lancet each time you test.
- Always keep your meter and lancing device clean (See page 86).
- The meter and lancing device are for single patient use only. **Do Not** share them with anyone, including family members! **Do Not** use on multiple patients!
- 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.

## Preparing your lancing device

### 1. Remove the lancing device cap

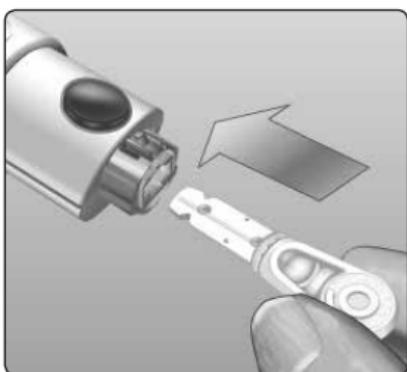
Remove the cap by rotating it and then pulling it straight off the device.



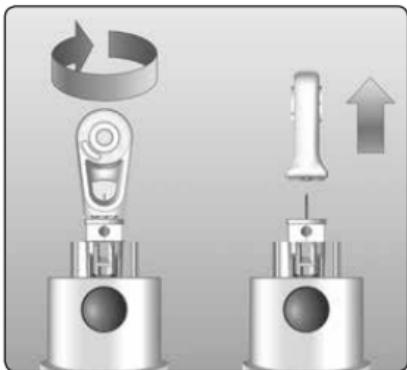
### 3 Taking a test

#### 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.



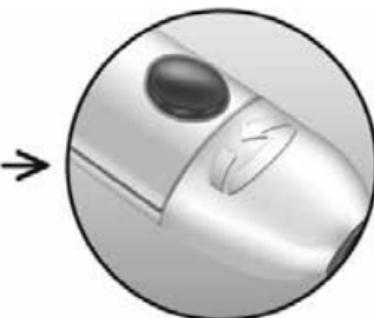
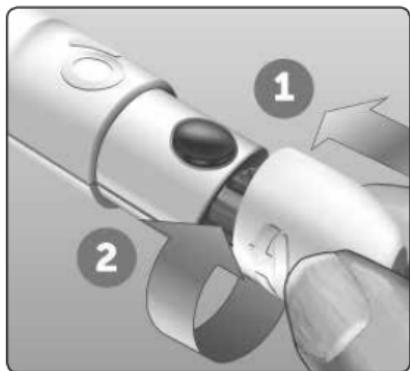
Twist the protective cover one full turn until it separates from the lancet. **Save the protective cover for lancet removal and disposal.** See page 65.



### 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.

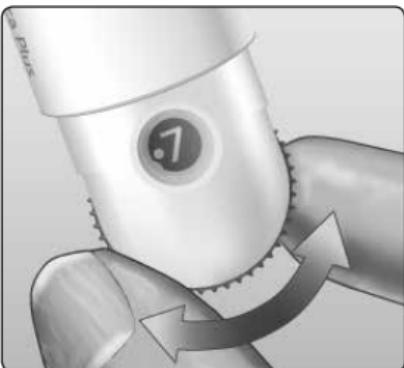


### 3 Taking a test

#### 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).

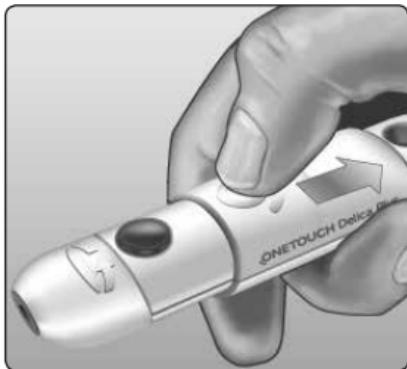
Adjust the depth by turning the depth wheel. Smaller numbers are for a shallower puncture and larger numbers for a deeper puncture.



**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.



### 3 Taking a test

#### Preparing the meter

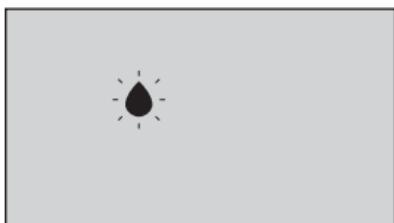
##### 1. Insert a test strip to turn the meter on

Insert a test strip into the test strip port with the contact bars facing you.



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

The flashing blood drop icon (💧) appears on the display. You can now apply your blood sample to the test strip.



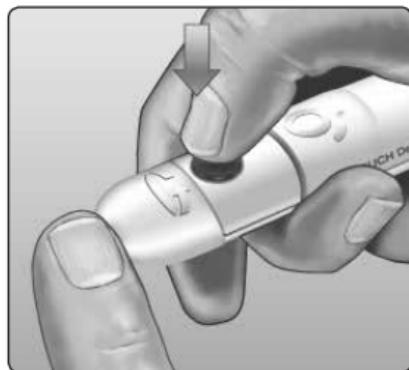
## Sampling blood from the fingertip

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

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

### 1. Puncture your finger

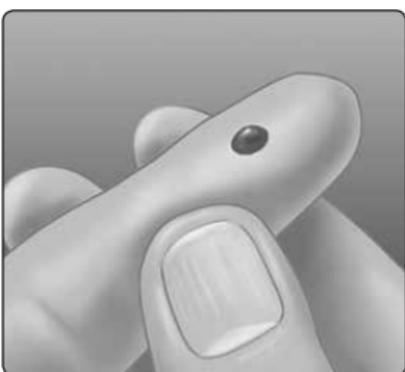
Hold the lancing device firmly against the side of your finger. Press the release button. Remove the lancing device from your finger.



### 3 Taking a test

#### 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.



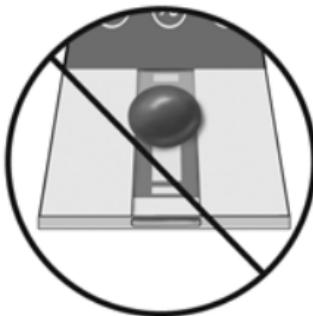
## Applying blood and reading results

### Prepare to apply the sample

Keeping your finger extended and steady, move the meter and test strip toward the blood drop.



**Do Not** apply blood on the top of the test strip.



**Do Not** hold the meter and test strip underneath the blood drop. This may cause blood to run into the test strip port and damage the meter.

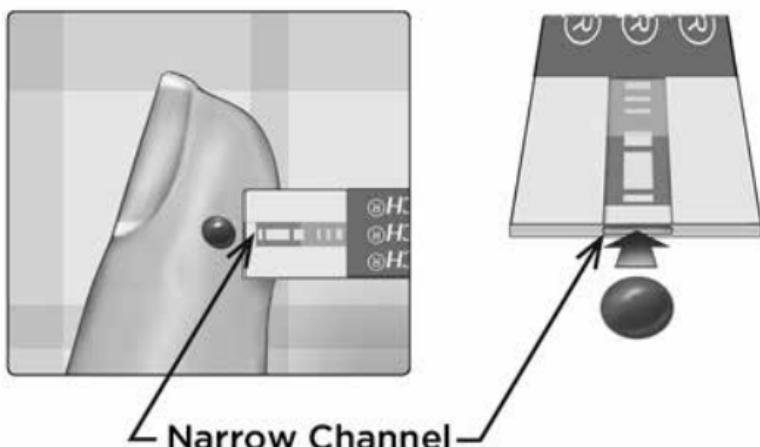
**Do Not** allow blood to enter the Data Port.



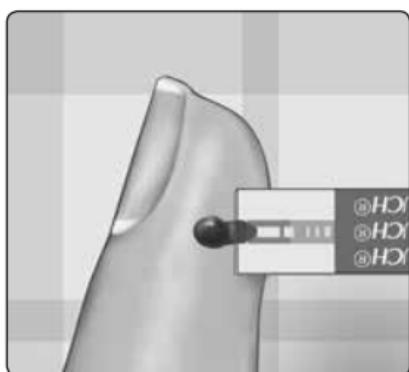
### 3 Taking a test

#### Applying the sample

Line up the test strip with the blood drop so that the narrow channel on the edge of the test strip is almost touching the edge of the blood drop.



Gently touch the channel to the edge of the blood drop.



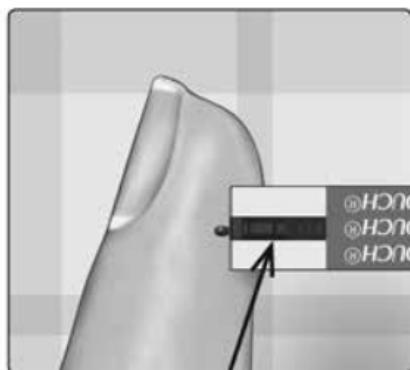
- **Do Not** press the test strip too firmly against the puncture site or the channel may be blocked from filling properly.
- **Do Not** smear or scrape the drop of blood with the test strip.
- **Do Not** apply more blood to the test strip after you have moved the drop of blood away.
- **Do Not** move 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.



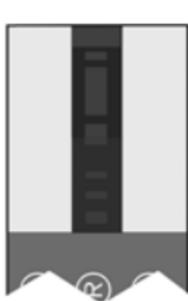
### 3 Taking a test

**Wait for the confirmation window to fill completely.**

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



**Confirmation window full**



**Full**

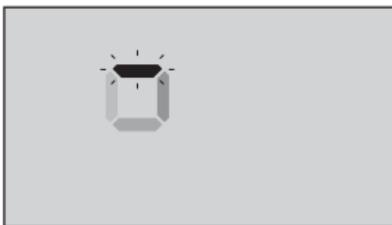


**Not full**

**⚠ CAUTION:**

You may get an error message or an inaccurate result if the blood sample does not fill the confirmation window completely. Discard the used strip and re-start the test process with a new test strip.

When the confirmation window is full, this means you have applied enough blood. The Countdown screen will appear. Now you can move the test strip away from the drop of blood and wait for the meter to count down (about 5 seconds).



Countdown Screen

### 3 Taking a test

#### Viewing your result

Your result appears on the display, along with the unit of measure, and the date and time of the test. After your glucose result appears, the meter will also display a Range Indicator Arrow below your glucose result to indicate if your result is below, above or within your range limits (see page 21). The arrow will point to the appropriate Range Indicator Colour Bar on the meter as a visual reminder.



#### Example

Below Range Result



#### Example

In Range Result



#### Example

Above Range Result

**⚠ CAUTION:**

**Do Not** make immediate treatment decisions based on the Range Indicator feature. Treatment decisions should be based on the numerical result and healthcare professional recommendation and not solely on where your result falls within your range limits.

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

### 3 Taking a test

#### Interpreting unexpected results

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

##### **⚠ CAUTION:**

##### **Low results**

If your result is below 70 mg/dL or is shown as **LO** (meaning the result is less than 20 mg/dL), it may mean 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.



**NOTE:** When your glucose result is below 20 mg/dL, both the **LO** and the Range Indicator Arrow will flash on the meter screen.

**⚠ CAUTION:****Dehydration and low results**

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

### 3 Taking a test

#### ⚠ CAUTION:

#### High results

- If your result is above 180 mg/dL, it may mean hyperglycaemia (high blood glucose) and you should consider re-testing. Talk to your healthcare professional if you are concerned about hyperglycaemia.
- **HI** is displayed when your result is over 600 mg/dL. You may have severe hyperglycaemia (very high blood glucose). Re-test your blood glucose level. If the result is **HI** again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional immediately.



**NOTE:** When your glucose result is above 600 mg/dL, both the **HI** and the Range Indicator Arrow will flash on the meter screen.

**⚠ CAUTION:****Repeated unexpected results**

- If you continue to get unexpected results, check your system with control solution.
- If you are experiencing symptoms that are not consistent with your results and you have followed all instructions in this Owner's 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 55%) or very low (below 30%) can cause false results.

### 3 Taking a test

#### Sending your results to the app

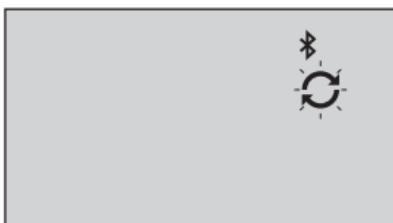
If the BLUETOOTH® feature on the meter is turned on, indicated by the BLUETOOTH® symbol (✿), the meter will automatically send the latest result to any paired compatible wireless device. The compatible wireless device must have the app running and have already been paired to the meter before sending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

**NOTE:** The compatible wireless device must have the app open and have already been paired to the meter before sending a result. See page 30.

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

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

- The compatible wireless device and meter are both turned on, and the app is running.
- The meter is correctly paired with your compatible wireless device.
- The BLUETOOTH® feature on both devices is running (indicated by \*) and the devices are within 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. This is indicated by the BLUETOOTH® symbol (\*) remaining on the meter screen.



Example

### 3 Taking a test

If you are still unable to send results to the compatible wireless device, please call Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

**NOTE:** Inserting a test strip during the transmission will cancel the transfer of all results. The  symbol appears on the screen and you can proceed with testing.

### Using the meter without syncing to an app

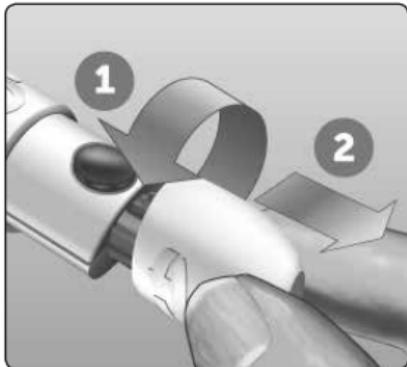
The meter can be used without a compatible wireless device or the app. You can still test your blood glucose and review up to 500 results on the meter.

## Removing the used lancet

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

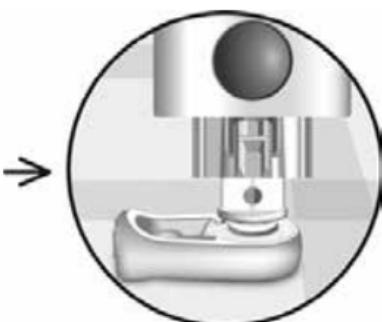
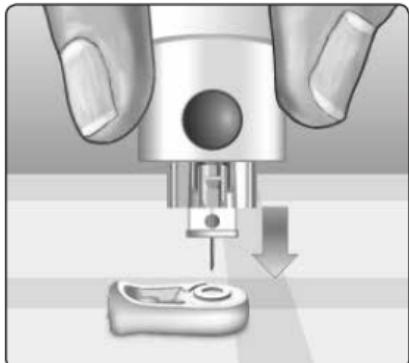
### 1. Remove the lancing device cap

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



### 2. Cover the exposed lancet tip

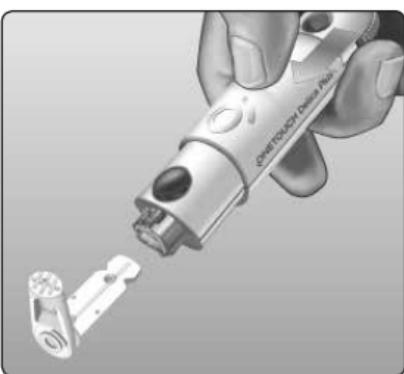
Before removing the lancet, place the lancet protective cover on a hard surface then push the lancet tip into the flat side of the disk.



### 3 Taking a test

#### 3. Eject the lancet

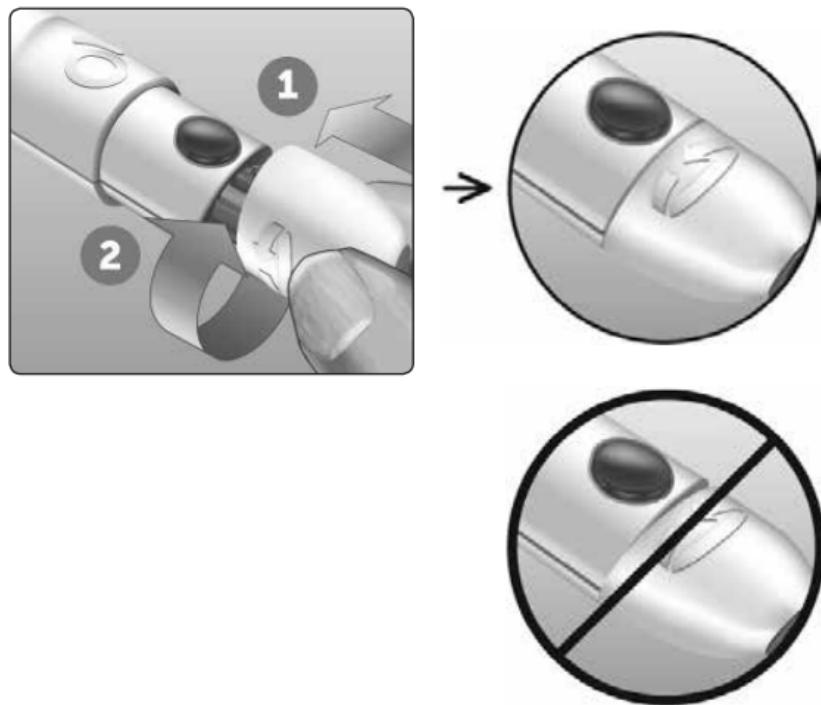
Holding the lancing device directed downwards, push the slider forward until the lancet comes out of the lancing device. If the lancet fails to eject properly, cock the device then push the slider control forward until the lancet comes out.



#### 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.

### **3 Taking a test**

#### **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 Select® Plus Control Solution is used to check that the meter and test strips are working together properly and that the test is performing correctly. (Control solution is available separately.)

**NOTE:**

- 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.
- **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, especially in high humidity environments.
- Control solution tests must be done at room temperature (20-25°C). Make sure your meter, test strips and control solutions are at room temperature before testing.

**⚠ 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 expiry date (printed on the vial label) or the discard date, whichever comes first, or your results may be inaccurate.

### 3 Taking a test

#### 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.

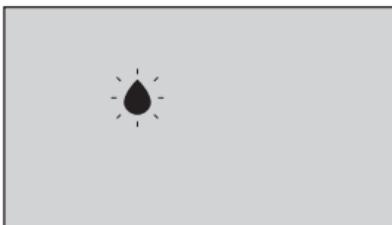
#### Preparing your meter for a control solution test

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

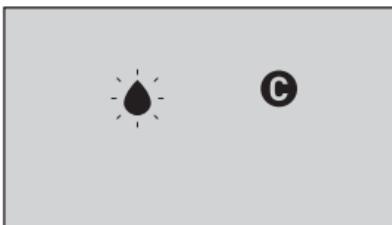
Insert the test strip with the test strip port and contact bars facing you.



2. Wait for the flashing blood drop icon (●) to appear on the display



3. Press and hold **▲** or **▼** until the control solution icon (C) appears 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



### 3 Taking a test

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 narrow channel at the top edge of the test strip is at a slight angle to the drop of control solution



2. Touch the channel on the top edge of the test strip to the control solution
3. Wait for the channel to fill completely



### 3 Taking a test

#### Viewing your control solution result

After the control solution is applied, the meter will count down until the test is complete. Your result is displayed along with the date, time, unit of measure, and **C** (for control solution) and stored in the meter.



Control solution results can be seen when reviewing past results on the meter.

**⚠ CAUTION:** Make sure you press and hold **▲** or **▼** until the control solution icon **C** appears before you begin a control solution test. An **E-6** screen may appear if you applied control solution to the test strip without following the steps beginning on page 70. See page 104 for more information.

## Checking if the result is in range

Each vial of test strips has the OneTouch Select® Plus Mid Control Solution range printed on its label. Compare the result displayed on the meter to the OneTouch Select® Plus Mid Control Solution range printed **on the test strip vial**.

If your control solution result falls outside the expected range, repeat the test with a new test strip.



### Example Range

OneTouch Select® Plus Mid Control Solution Control Range 102-138 mg/dL

### 3 Taking a test

#### ⚠ CAUTION:

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

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

Out-of-range results may be due to:

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

**⚠ CAUTION:**

If you continue to get control solution results that fall outside the range printed on the test strip vial, **Do Not** use the meter, test strips, or control solution. Contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

**Cleaning the control solution cap**

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

## Reviewing past results on your meter

Your meter stores your most recent 500 blood glucose and control solution test results and displays them in the order the tests were taken. The (⌚) symbol will appear on your screen when in History Mode.

### 1. When the meter is off, press and hold to turn History Mode on

The (⌚) symbol indicates you are viewing your past results.

The (◀) symbol indicates if the result was below, above or within range at the time of the test, by pointing to the appropriate colour bar.

### 2. Scroll through your results by pressing to move backwards and to move forward through your results



## Downloading results to a computer

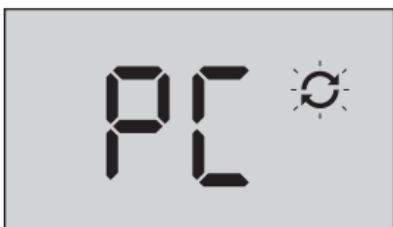
Your meter can work with diabetes management software, which provides a visual way to track key factors that affect your blood sugar. To learn more about diabetes management tools available to you, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

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

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 Select Plus Flex™ Meter to a computer to download results (not included).

## 4 Reviewing past results

Once the command to start the download is sent from the computer to the meter, the meter display will show the flashing Sync symbol (⌚) indicating that the meter is in communication mode.



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

If you are unable to download your results to a computer, please call Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

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## 5 Editing Your Settings

### Editing time and date

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

For instructions on adjusting the time and date, see page 25.

After adjusting the settings, you will exit settings mode and your last glucose result screen will appear. The adjusted time and date will be displayed once a new glucose test has been completed and the result appears on the screen.

**NOTE:** You will not be able to perform a blood glucose test until you finish editing the time and date.

**NOTE:** The OneTouch Reveal® Mobile App on your compatible wireless device checks and updates the time and date in your meter each time you sync. Check the time and date often on your compatible wireless device to be sure they are correct. See the App instructions for more information.

## Editing your range limits

Your meter uses low and high range limits to tell you when your result is below, above or within your set range. The meter comes with pre-set range limits that can be changed. The pre-set low range limit is 70 mg/dL and the pre-set high range limit is 180 mg/dL. To edit the pre-set range limits press and hold  and  at the same time. The SET screen will appear with the current low range limit displayed, and the number and range indicator arrow will flash.

**NOTE:** The low and high range limits you set apply to all glucose test results. This includes tests taken before or after mealtimes, medications and around any other activities that may affect your blood glucose.

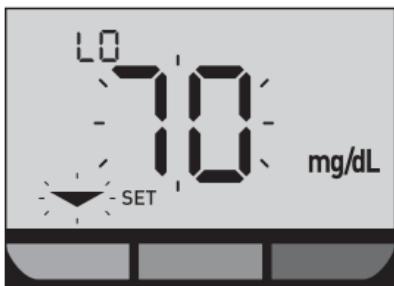
### **CAUTION:**

Be sure to talk to your healthcare professional about the low and high range limits that are right for you. When selecting or changing your limits, you should consider factors such as your lifestyle and diabetes therapy. Never make significant changes to your diabetes care plan without consulting your healthcare professional.

## 5 Editing Your Settings

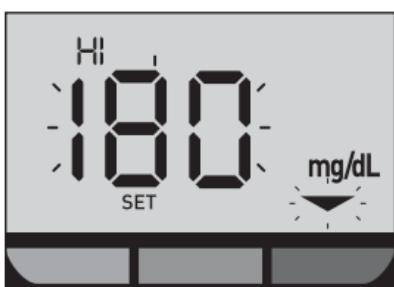
### 1. Review the pre-set low range limit displayed

- To accept the pre-set low range limit, press **OK**.
- To edit the pre-set low range limit, press **▲** or **▼** to change the value between 60 mg/dL-110 mg/dL, and then press **OK**.



### 2. Review the pre-set high range limit displayed

- To accept the pre-set high range limit, press **OK**.
- To edit the pre-set high range limit, press **▲** or **▼** to change the value between 90 mg/dL-300 mg/dL, and then press **OK**.



Your meter will exit settings mode and your last result screen will appear.

**NOTE:** If you change your range limits, this will only affect whether future test results are displayed as below, above or within your range limits. Changing your range limits does not affect how past results are displayed.

**NOTE:** You will not be able to perform a glucose test until you finish editing the range limits.

**NOTE:** You can use the OneTouch Reveal® Mobile App on your compatible wireless device to change the range limits stored in your meter. See the instructions that came with the app for more information.

## 6 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.

### 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 86 and for disinfecting information, see page 88.

### 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 18.)
- **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.



## 6 Caring for your system

### 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 Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

## Replacing the battery

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

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

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

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

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

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

## 1. Remove the old battery

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



Battery cover

Pull up on the battery ribbon to lift the battery out of the compartment.

**Do Not** remove the battery while the meter is connected to a computer.



## 7 Battery

### 2. Insert the new battery

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



If the meter does not power on after you have replaced the meter battery, check that the battery is correctly installed. If the meter still does not power on, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

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



**Battery cover**

#### **4. Check your meter settings**

Removing the meter battery will not affect your stored results. However, you will need to check your date and time settings.

#### **5. Dispose of battery**

Dispose of the battery according to your local environmental regulations.

## Troubleshooting your system

### Error and other messages

The OneTouch Select Plus Flex™ Meter displays messages when there are problems with the test strip, with the meter or when your glucose levels are above 600 mg/dL or below 20 mg/dL. Improper use may cause an inaccurate result without producing an error message.

**NOTE:** If the meter is on but does not operate (locks-up), contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

## What it means

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



**NOTE:** When your glucose result is below 20 mg/dL, both the **LO** and the Range Indicator Arrow will flash on the meter screen.

## What to do

**This may require immediate treatment.** Although this message could be due to a test error, it is safer to treat first and then do another test. Always treat according to your healthcare professional's recommendations.

## 8 Troubleshooting your system

### What it means

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



**NOTE:** When your glucose result is above 600 mg/dL, both the **HI** and the Range Indicator Arrow will flash on the meter screen.

### What to do

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

## 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 (10-44°C). If you do not get another **HI.t** message, you can proceed with testing.

If this message continues to appear, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

## 8 Troubleshooting your system

### What it means

Meter is too cold (below 10°C) to perform a test.

### What to do

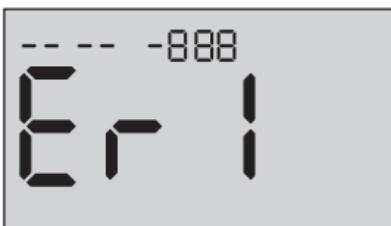
Move the meter and test strips to a warmer area. Insert a new test strip when the meter and test strips are within the operating range (10-44°C). If you do not get another **LO.t** message, you can proceed with testing.

If this message continues to appear, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).



## Error Screens

If there is a problem with your meter, there are six possible error screens that may appear. Along with an error number, there is also an error code in the upper left corner of your meter screen. If you cannot resolve the error with your meter, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com). They will refer to the error number and code to help troubleshoot the problem.



Example Error Screen  
Code

## 8 Troubleshooting your system

### What it means

There is a problem with the meter.



### What to do

**Do Not** use the meter. Contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

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### What it means

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



### What to do

Repeat the test with a new test strip; see page 52 or page 73. If this message continues to appear, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

## What it means

The sample was applied before the meter was ready.



Er 3

## What to do

Repeat the test with a new test strip. Apply a blood or control solution sample only after the flashing  symbol appears on the display. If this message continues to appear, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

## 8 Troubleshooting your system

### 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 36 for taking a blood glucose test, or page 70 for taking a control solution test. If the error message appears again, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

## What it means

*One of the following may apply:*

- Not enough blood or control solution was applied or 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 page 36 for taking a blood glucose test, or page 70 for taking a control solution test. If the error message appears again, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

## 8 Troubleshooting your system

### What it means

The meter has detected a problem with the test strip. Possible cause is that you did not apply the correct sample type to the test strip when prompted by the meter for a blood or control solution sample.



### What to do

Repeat the test with a new test strip. See page 36 for taking a blood glucose test, or page 70 for taking a control solution test. If the error message appears again, contact Customer Service. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

## What it means

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



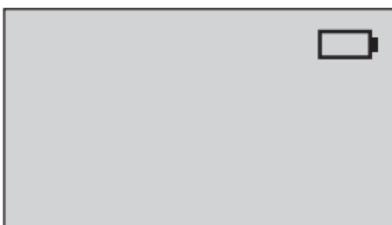
## What to do

Replace the meter battery soon.

---

## What it means

There is not enough battery power to perform a test.



## What to do

Replace the battery immediately.

## 8 Troubleshooting your system

### What it means

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



### What to do

Contact Customer Service to report this occurrence, **unless** this is your first use of the meter. You can still perform a blood glucose test or control solution test and get an accurate result. Contact LifeScan Customer Service at: [service@LifeScanMEA.com](mailto:service@LifeScanMEA.com).

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## Detailed information about your system

### Comparing meter results to laboratory results

Results obtained from the OneTouch Select Plus Flex™ Meter and laboratory tests are reported in plasma-equivalent units. However, your meter result may differ from your lab result due to normal variation. A result from your OneTouch Select Plus Flex™ Meter is considered accurate when it is within 15 mg/dL of a laboratory method when the glucose concentration is lower than 100 mg/dL and within 15% of a laboratory method when the glucose concentration is 100 mg/dL or higher.

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

- You have eaten recently. This can cause a result from fingertip testing to be up to 70 mg/dL higher than a lab test using blood drawn from a vein.<sup>1</sup>
- Your haematocrit is above 55% or below 30%.
- You are severely dehydrated.

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

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

## 9 Detailed information about your system

### 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.

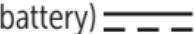
### **Testing with your OneTouch Select Plus Flex™ Meter at the lab:**

- 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

<b>Assay method</b>	Glucose Oxidase biosensor
<b>Automatic shutoff</b>	Two minutes after last action
<b>Battery ratings</b>	3.0 V d.c. (CR2032 lithium coin cell battery) 
<b>Battery type</b>	One replaceable 3.0 Volt CR2032 lithium coin cell battery (or equivalent)
<b>Biological source</b>	Aspergillus Niger
<b>BLUETOOTH® Technology:</b>	Frequency band: 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)
<b>Calibration</b>	Plasma-equivalent

<b>Data port type</b>	Micro USB Compatible with USB 2.0
<b>Memory</b>	500 test results
<b>Operating ranges</b>	Temperature: 10-44°C Relative humidity: non-condensing 10-90% Altitude: up to 3048 metres Haematocrit: 30-55%
<b>Reported result range</b>	20-600 mg/dL
<b>Sample</b>	Fresh capillary whole blood
<b>Sample volume</b>	1.0 µL
<b>Size</b>	52(W) x 86(L) x 16(T) millimetres
<b>Test time</b>	Average test time is 5 seconds
<b>Unit of measure</b>	mg/dL
<b>Weight</b>	Approximately 50 grams

## 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 100 mg/dL, and within 15% of a laboratory method when the glucose concentration is 100 mg/dL or higher. Samples from 100 patients were tested using both the OneTouch Select Plus Flex™ System and the YSI 2300 Glucose Analyzer laboratory instrument.

### System Accuracy Results for Glucose Concentrations <100 mg/dL

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

Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL
67.2% (121/180)	93.3% (168/180)	96.7% (174/180)

## System Accuracy Results for Glucose Concentrations $\geq 100$ mg/dL

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

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
63.3% (266/420)	95.5% (401/420)	99.8% (419/420)

## System Accuracy Results for Glucose Concentrations between 26.6 mg/dL and 482.0 mg/dL

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

Within $\pm 15$ mg/dL or $\pm 15\%$
98.8% (593/600)

**NOTE:** Where 26.6 mg/dL represents the lowest glucose reference value and 482.0 mg/dL represents the highest glucose reference value (YSI value).

## User Performance Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 174 lay persons showed the following results:

100.0% within  $\pm 15$  mg/dL of the medical laboratory values at glucose concentrations below 100 mg/dL, and 95.9% within  $\pm 15\%$  of the medical laboratory values at glucose concentrations at or above 100 mg/dL.

96.6% of the total number of samples were within  $\pm 15$  mg/dL or  $\pm 15\%$  of the medical laboratory values.

## Regression Statistics

Samples were tested in duplicate on each of three test strip lots. Results indicate that the OneTouch Select Plus Flex™ System compares well with a laboratory method.

# of Subjects	# of Tests	Slope	Intercept (mg/dL)
100	600	0.98	-0.13

95% CI Slope	95% CI Intercept (mg/dL)	Std. Error (S <sub>y,x</sub> ) (mg/dL)	R <sup>2</sup>
0.97 to 0.98	-1.48 to 1.21	9.02	0.99

## 9 Detailed information about your system

### Precision

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

Data generated using the OneTouch Select Plus Flex<sup>TM</sup> Meter.

Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
40	46.21	1.66	3.58
65	70.39	1.89	2.69
120	123.56	2.65	2.15
200	193.22	3.54	1.83
350	350.02	7.41	2.12

Results show that the greatest variability observed between test strips when tested with blood is 1.89 mg/dL SD or less at glucose levels less than 100 mg/dL, or 2.15% CV or less at glucose levels at 100 mg/dL or above.

## Total Precision (600 Control Solution Tests per Glucose Level)

Data generated using the OneTouch Select Plus Flex™ Meter.

Glucose Level Ranges (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Low (30-50)	45.45	1.23	2.71
Mid (96-144)	110.44	2.01	1.82
High (280-420)	365.84	6.04	1.65

## **Software Updates**

LifeScan will periodically notify you about software and feature upgrades to your meter. The OneTouch Select Plus Flex™ Meter software can be upgraded by connecting to a PC via USB cable connection and visiting [www.OneTouchMEA.com](http://www.OneTouchMEA.com) and following the step-by-step instructions. Software updates will not affect your settings and historical data in your meter.

## **Guarantee**

LifeScan guarantees that the OneTouch Select Plus Flex™ 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: 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 ISO 15197.

Use of this meter near electrical or electronic equipment that are sources of electromagnetic radiation, may interfere with proper operation of this meter. It is advisable to avoid testing in close proximity to sources of electromagnetic radiation.

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

AST	41
Batteries	90
Batteries, replacing	90
Battery empty icon	3
Battery empty warning	105
Battery low icon	3, 105
Blood glucose, testing	36
BLUETOOTH® feature	7, 10, 11, 29, 62
Buttons on meter	18
Cleaning your meter, lancing device and cap	86
Comparing meter results to laboratory results	108
Compatible wireless devices	3
Control solution	70
Control solution, discard and expiry dates	69
Control solution, testing	68, 74, 76
Data port	18
Date setting	26, 28
Dehydration	59, 109
Disinfecting your meter, lancing device and cap	88
Display check	24
Disposal, lancets and test strips	68
Downloading results to a computer	79
Edit date	82
Edit range limits	83

Edit time	82
Error messages	94, 95
EXTREME HIGH GLUCOSE message	60, 96
EXTREME LOW GLUCOSE message	58, 95
Fingertip testing procedure	36
First time setup	25, 30
Guarantee	120
Hyperglycaemia	60, 96
Hypoglycaemia	58, 95
Icons	3, 4
Infection, reduce the chance	42
Intended use	6
Kit components	14
Lancet	40, 43
Lancet, expiry date	42
Lancing device	14, 40, 43, 86
mg/dL	18, 113
Pairing	30, 31
PIN	33
Plasma calibration	108, 112
Range Indicator feature	21
Range limits setting	83
Results, reviewing past	78
Serial number	32

Settings.....	25, 28, 82
Software, diabetes management.....	79
Start-up screen.....	24
Storing your system.....	86
Symbols.....	3, 4
Syncing.....	34, 62
Technical specifications.....	112
Temperature.....	36, 37, 69, 76, 86, 97, 98, 113
Test strip.....	20, 48, 70
Test strip, applying drop of blood.....	51, 52
Test strip, contact bars.....	20
Time setting.....	25, 28
Turning meter off.....	35
Turning meter on.....	24, 48, 70
Unexpected results.....	58, 61
Unit of measure.....	18, 113
Unusual red blood cell count (haematocrit).....	61, 109, 113



Contents covered by one or more of the following U.S. patents: 6,733,655, 7,462,265, 7,468,125, 8,066,866, 8,093,903, 6,602,191, 6,976,958, and 7,156,809. Purchase of this device does not act to grant a use licence under these patents. Such a licence is granted only when the device is used with OneTouch Select® Plus Test Strip. No test strip supplier other than LifeScan is authorised to grant such a licence. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.

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

**IVDD (98/79/EC):**



Blood Glucose Meter,  
Test Strips, and Control  
Solution

**MDD (93/42/EEC):**



Lancets

Lancing Device

**RED (2014/53/EU):**



Blood Glucose  
Meter



Contact LifeScan  
Customer Service at:  
service@LifeScanMEA.com.



LifeScan Europe GmbH  
Gubelstrasse 34  
6300 Zug  
Switzerland

Meter Made in China

Jordan Telecommunications  
Approval  
TRC/LPD/2015/112

**TRA**  
**REGISTERED No:**  
**ER41149/15**  
**DEALER No:**  
**DA45564/15**

**Lifescan**™



AW 06985406A



AW 06985406A  
023-413  
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Rev. Date: 02/2020