



C4

Yellow = 5mm margin, Red = 10mm margin

Contents covered by one or more of the following U.S. patents: 5,708,247, 5,951,836, 6,241,862, 6,284,125, 7,112,265, 7,462,265, 7,807,031, and 8,398,664. Use of the monitoring device included herein is protected under one or more of the following U.S. patents: 6,413,410, 6,733,655, 7,250,105, 7,468,125, 8,066,866 and 8,093,903. Purchase of this device does not act to grant a use license under these patents. Such a license is granted only when the device is used with OneTouch® Select® *Plus* Test Strip. No test strip supplier other than LifeScan is authorized to grant such a license. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.

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
0344

MDD (93/42/EEC):

Lancing System
0120

Distributed by:

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Care on 0800 121 200 (UK)
or 1800 535 676 (Ireland)
during the hours of
8:30am-6pm Monday-Friday,
9am-1pm Saturday. Or visit
www.LifeScan.co.uk.



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**FPO**

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Statement of Use: Verify status before each use



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ONETOUCH[®] Select Plus Flex

Blood Glucose Monitoring System



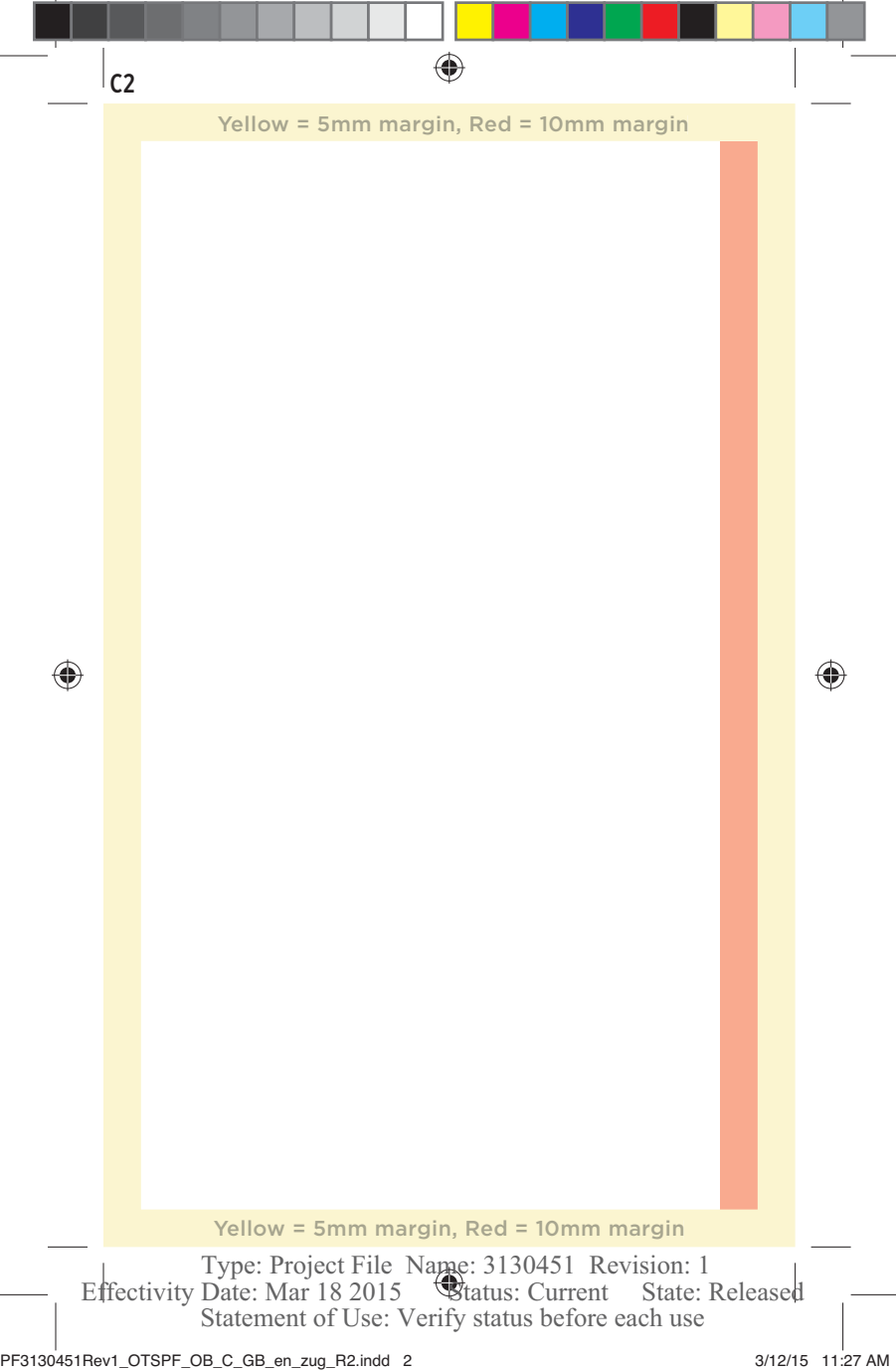
**Owner's
Booklet**
Instructions
for Use

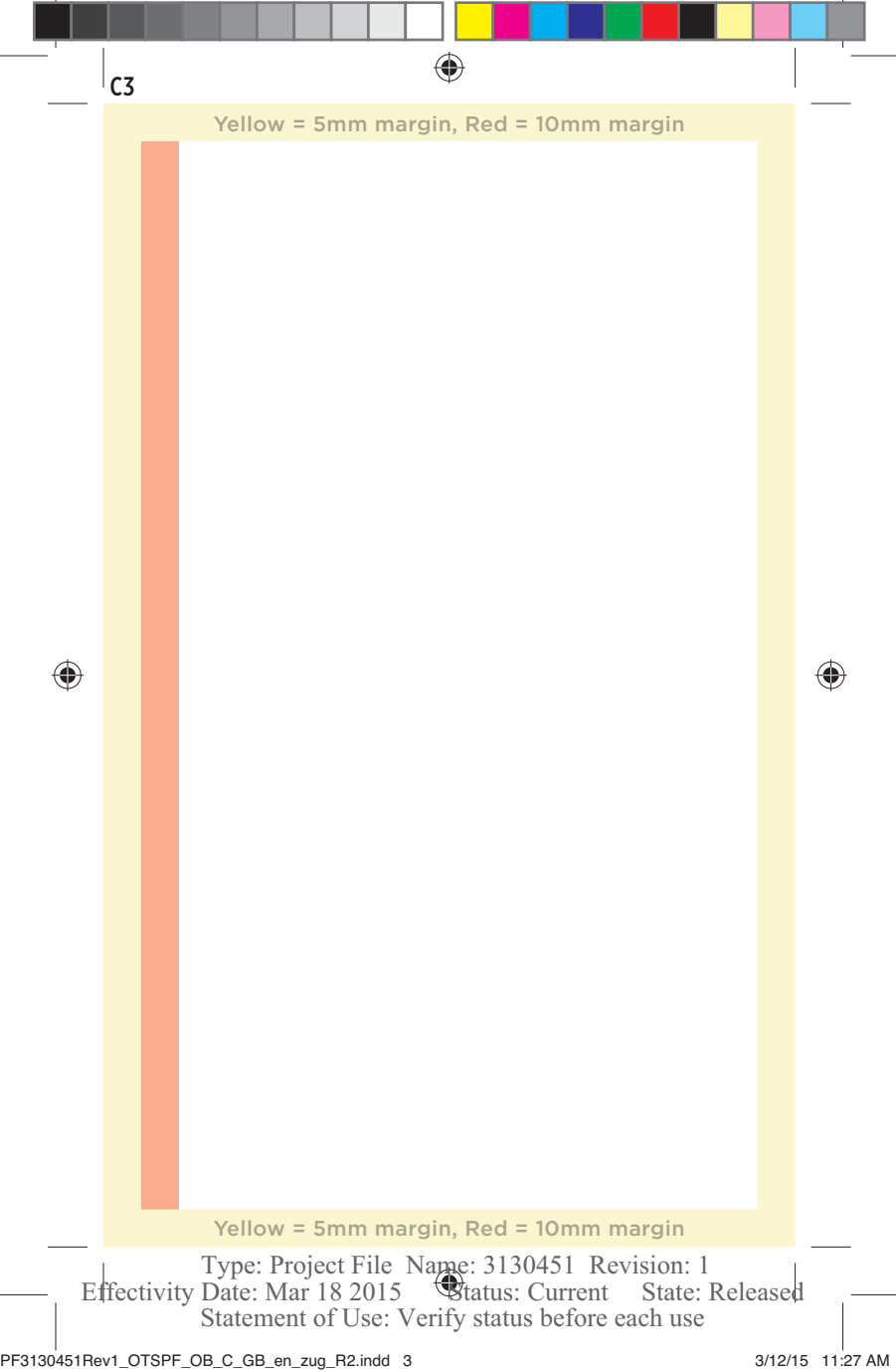
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Leg1

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PMS	N/A ☒	☒ CMYK ☐ Black	☐ Uncoated Area ☒ N/A	☐ N/A ☒	☐ Dieline ☒ N/A
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ONETOUCH[®] **Select *Plus Flex*[™]**

Blood Glucose Monitoring System

Owner's Booklet

1

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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 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® SMART (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.LifeScan.co.uk 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® SMART Feature On
	History Mode (Past results)
	Apply Sample
	Range Indicator Arrow
SET	Setting Mode

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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



Sterilized 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 Solutions and the OneTouch® Delica® 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.



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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 103) 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 Solutions and Test Strips with the OneTouch Select Plus Flex™ Meter.

BLUETOOTH® SMART wireless technology

BLUETOOTH® SMART wireless technology is used by some smartphones and many other devices. Your OneTouch Select Plus Flex™ Meter uses BLUETOOTH® SMART 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.LifeScan.co.uk to learn if the OneTouch Reveal® Mobile App is available in your country.

Visit www.LifeScan.co.uk 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 29 for pairing instructions.

Your meter is subject to and complies with applicable Worldwide Radio regulation 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.

LifeScan Europe declares that this equipment is in compliance with the applicable essential requirements and other relevant provisions of Directive 1999/5/EC.

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.

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.

⚠WARNING: The BLUETOOTH® SMART 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® SMART feature off. See page 27 for more information.

BLUETOOTH® SMART trademark

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



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Table of Contents

1	Getting to know your system	12
2	Setting up your system.....	22
	Setting up your meter.....	22
	Connecting to a compatible wireless device	27
	Turning the meter off.....	33
3	Taking a test	34
	Testing your blood glucose	34
	Testing with control solution.....	62
4	Reviewing past results	72



Yellow= 5mm Red=7mm margin

5 Editing Your Settings76

Editing time and date76

Editing your range limits77

6 Caring for your system80

7 Battery84

8 Troubleshooting your system.....88

9 Detailed information about your system100

10 Index114

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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

12

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

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Getting to know your system 1

NOTE: If any item is missing or defective in your kit, contact Customer Service. Call OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) during the hours of 8:30am-6pm Monday-Friday, 9am-1pm Saturday. Or visit www.LifeScan.co.uk.

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***

(vial with blue cap)



**OneTouch Select®
Plus High Control
Solution***

(vial with red cap)



**OneTouch Select®
Plus Test Strips***

*OneTouch Select® Plus Control Solution and Test Strips are available separately. For availability of test strips and control solution, contact customer service or your healthcare professional.

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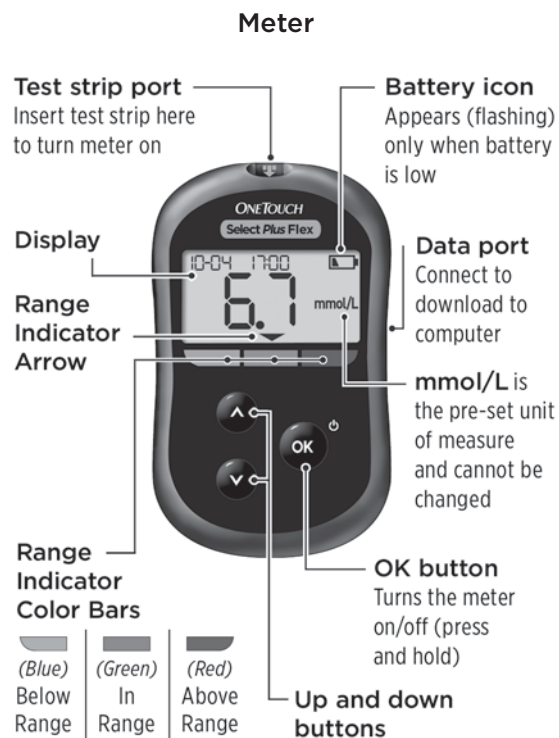
Getting to know your system **1**

OneTouch Select® Plus High Control Solution (vial with red cap) can be used in addition to OneTouch Select® Plus Mid Control Solution (vial with blue cap). If you test with OneTouch Select® Plus High Control Solution, you should always test with OneTouch Select® Plus Mid Control Solution first.

⚠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



16



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Getting to know your system **1**



17

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use



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1 Getting to know your system

Getting to know your OneTouch Select[®] Plus Test Strip

Test strip

Edge to apply sample



Confirmation window

Contact bars

Insert into test strip port

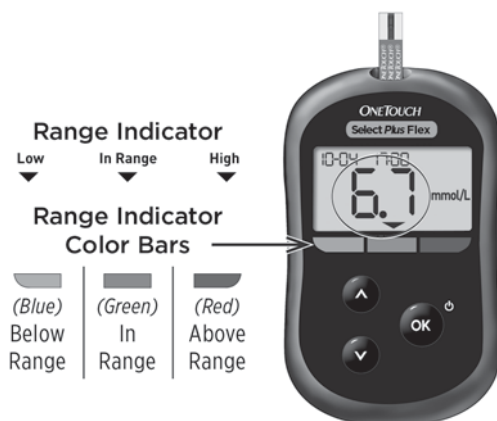
18

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

Getting to know your system **1**

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 Color Bar below the meter display. Use the Range Indicator Arrow and Color 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 3.9 mmol/L and the pre-set high range limit is 10.0 mmol/L. You can change these limits as needed to meet your needs. See page 77 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



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Getting to know your system **1**

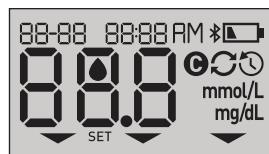
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2 Setting up your system

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 OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

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.

Setting up your system 2

First time setup

To turn your meter on, press and hold  until the start-up screen appears. Once the device is on, release . 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  to confirm.
- If the hour displayed is not correct, press  or  to change the hour and press  to confirm.



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.



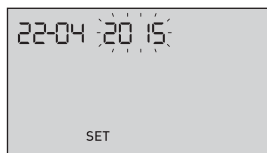
2 Setting up your system

Setting the date

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

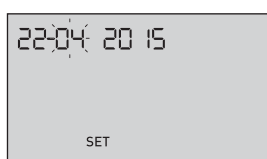
Year will flash

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

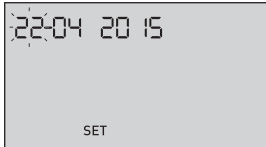


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Setting up your system 2

Day will flash

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



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.



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2 Setting up your system

Adjusting the time and date settings after first time setup

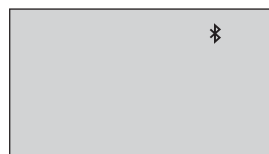
You can adjust the meter's time and date settings after first time setup. Press and hold **OK** to turn the meter on, then press and hold **OK** and **▼** at the same time. The SET screen will appear. See page 76.

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

Setting up your system **2****Connecting to a compatible wireless device****Turning the BLUETOOTH® SMART feature on or off**

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

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



The  symbol indicates the BLUETOOTH® SMART feature is on

NOTE: The BLUETOOTH® SMART 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 meters 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.LifeScan.co.uk 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 29 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.

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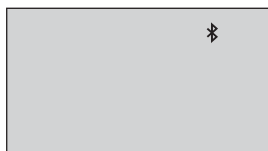
Setting up your system **2**

Pairing Instructions

1. Start by turning your meter on using the  button

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

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



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



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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



Serial
number

30

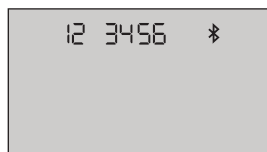
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Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

Setting up your system **2****5. When prompted by the OneTouch Reveal® Mobile App, the meter will display a six digit PIN number**

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

⚠CAUTION:

Make sure the PIN you enter on your compatible 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 **OK** 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 to turn the meter on and make sure the BLUETOOTH® SMART feature is ON as indicated by (⌵)

If needed, press  and  at the same time to turn the BLUETOOTH® SMART 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.

Setting up your system 2

Turning the meter off

There are three ways to turn your meter off:

- Press and hold **OK** 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® SMART connection for up to 4 hours. See page 57 for more details.

3 Taking a test

Testing your blood glucose

Test your blood glucose

NOTE: Many people find it helpful to practice testing with control solution before testing with blood for the first time. See page 62.

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.

Taking a test 3

- **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 80.

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 100 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 OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).
- 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.

Yellow= 5mm Red=7mm margin

Taking a test **3**

- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.
- **Do Not** use test strips after the expiration date printed on the vial.



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3 Taking a test

Getting to know your OneTouch® Delica® Lancing Device



38

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

Taking a test 3

NOTE:

- The OneTouch® Delica® Lancing Device uses ONLY OneTouch® Delica® 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® Lancing System does not include the materials needed to perform Alternate Site Testing (AST). The OneTouch® Delica® 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:

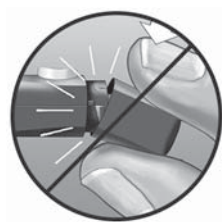
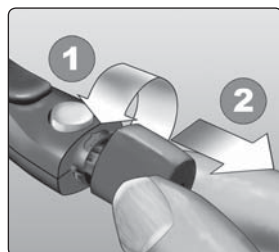
- Make sure to wash the sample site with soap and warm water, rinse and dry before sampling.
- The lancing device is intended for a single user. Never share a lancet or lancing device with anyone.
- Always use a new, sterile lancet each time you test.
- Always keep your meter and lancing device clean (See page 80).
- 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.

Taking a test **3**

Preparing the lancing device

1. Remove the lancing device cap

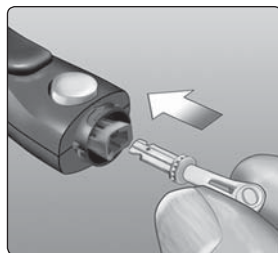
Remove the cap by turning it counterclockwise and then pulling it straight off of the device.



3 Taking a test

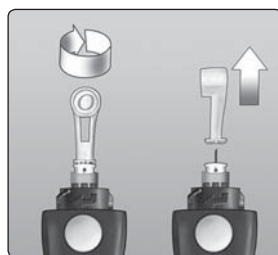
2. Insert a sterile lancet into the lancing device

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.

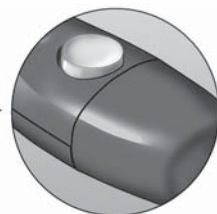
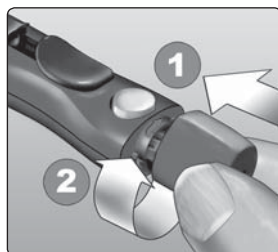
Save the protective cover for lancet removal and disposal. See page 59.



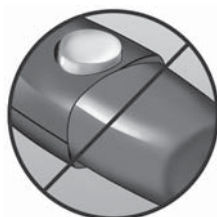
Taking a test **3**

3. Replace the lancing device cap

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



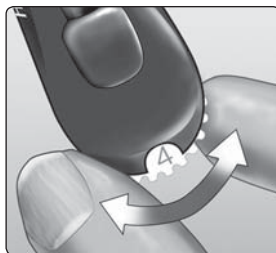
Do Not overtighten.



3 Taking a test

4. Adjust the depth setting

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



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

5. Cock the lancing device

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



Taking a test **3**

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.

Contact bars



Test strip port

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.



3 Taking a test

Getting a blood sample from the fingertip

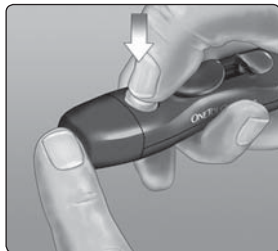
Choose a different puncture site each time you test.

Repeated punctures in the same spot may cause soreness and calluses.

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

1. Puncture your finger

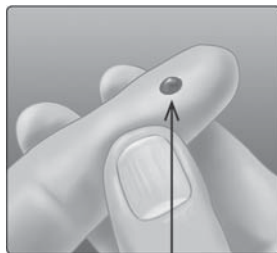
Hold the lancing device firmly against the side of your finger. Press the release button. Remove the lancing device from your finger.



Taking a test **3**

2. Get a round drop of blood

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



Approximate size

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.



3 Taking a test

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.

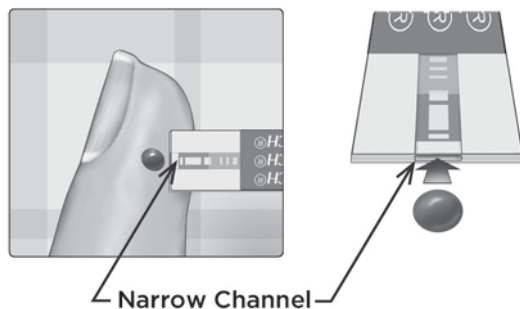


Do Not allow blood to enter the Data Port.

Taking a test **3**

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.



3 Taking a test

- **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.

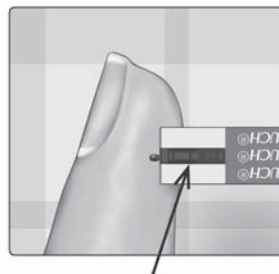


Yellow= 5mm Red=7mm margin

Taking a test 3

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



Yellow= 5mm Red=7mm margin

3 Taking a test

⚠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

52

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

Taking a test **3****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 19). The arrow will point to the appropriate Range Indicator Color Bar on the meter as a visual reminder.

⚠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 mmol/L is displayed. If your display shows mg/dL rather than mmol/L, stop using the meter and contact Customer Service.

**Example**

Below Range Result

**Example**

In Range Result

**Example**

Above Range Result

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 3.9 mmol/L or is shown as **LO** (meaning the result is less than 1.1 mmol/L), it may mean hypoglycemia (low blood



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

NOTE: When your glucose result is below 1.1 mmol/L, 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.

Taking a test **3****⚠CAUTION:****High results**

- If your result is above 10.0 mmol/L, it may mean hyperglycemia (high blood glucose) and you should consider re-testing. Talk to your healthcare professional if you are concerned about hyperglycemia.
- **HI** is displayed when your result is over 33.3 mmol/L. You may have severe hyperglycemia (very high blood glucose). Re-test your blood glucose level. If the result is **HI** again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional immediately.



NOTE: When your glucose result is above 33.3 mmol/L, both the **HI** and the Range Indicator Arrow will flash on the meter screen.



Yellow= 5mm Red=7mm margin

3 Taking a test

⚠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 program without speaking to your healthcare professional.

Unusual red blood cell count

A hematocrit (percentage of your blood that is red blood cells) that is either very high (above 55%) or very low (below 30%) can cause false results.

56

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

Sending your results to the app

If the BLUETOOTH® SMART feature on the meter is turned on, indicated by the BLUETOOTH® SMART symbol (⌘), the meter will automatically send the latest result to any paired wireless compatible 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 28.

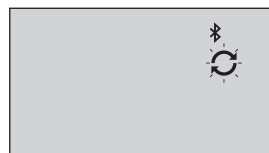
NOTE: If the BLUETOOTH® SMART feature on the meter is **turned off**, or the meter is out of range, the result is not sent to the compatible wireless device. The result is saved in the meter memory with the current date and time, and will be sent to the app the next time you sync. The sent results are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

3 Taking a test

- The Bluetooth feature on both devices is running (indicated by ) and the devices are within 8 meters 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® SMART symbol () remaining on the meter screen.



Example

If you are still unable to send results to the compatible wireless device, please call Customer Service. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

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.

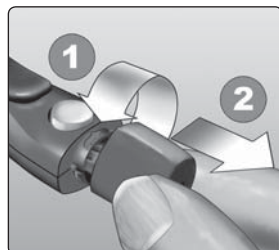
Taking a test **3**

Removing the used lancet

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

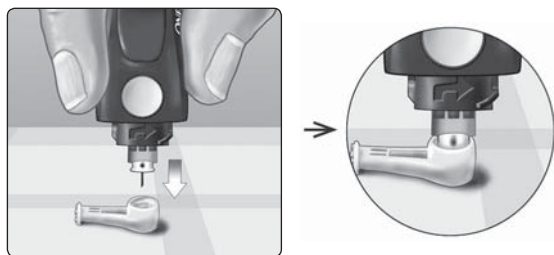
1. Remove the lancing device cap

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



2. Cover the exposed lancet tip

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



3 Taking a test

3. Eject the lancet

Slide the ejection control forward until the lancet comes out of the lancing device. Return the ejection control to its back position.

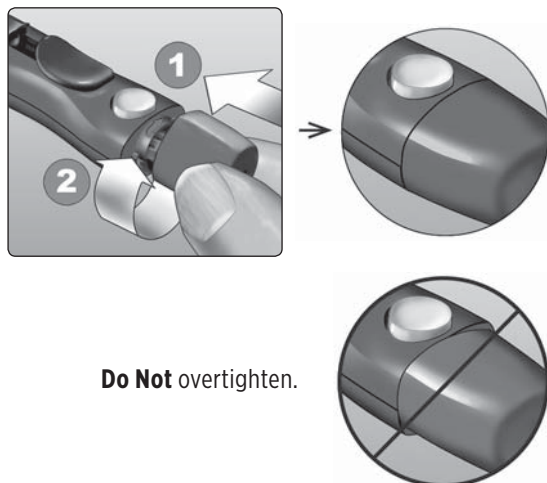
If the lancet fails to eject properly, cock the device again and then slide the ejection control forward until the lancet comes out.



Taking a test **3**

4. Replace the lancing device cap

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



Do Not overtighten.

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.



Yellow= 5mm Red=7mm margin

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:

- OneTouch Select® Plus High Control Solution (vial with red cap) can be used in addition to OneTouch Select® Plus Mid Control Solution (vial with blue cap). If you test with OneTouch Select® Plus High Control Solution, you should always test with OneTouch Select® Plus Mid Control Solution first.

Taking a test **3**

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

3 Taking a test

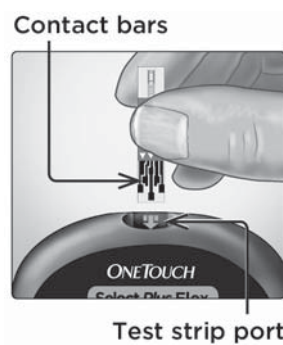
Do a control solution test

- 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.



Taking a test **3**

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



3. Press  or  until the control solution icon (Ⓢ) appears on the display

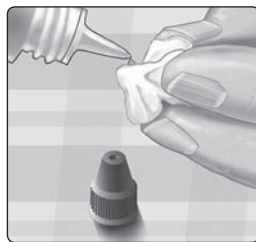


Preparing the control solution

1. Before removing the cap, shake the vial gently

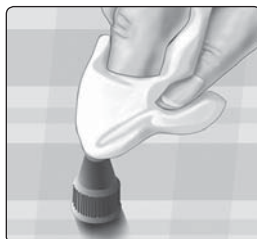
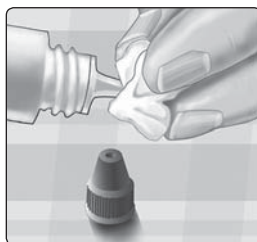
2. Remove the vial cap and place it on a flat surface with the top of the cap pointing up

3. Squeeze the vial to discard the first drop

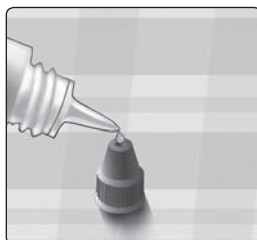


3 Taking a test

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



Taking a test **3**

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  (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  or  until the control solution icon  appears before you begin a control solution test. An  screen may appear if you applied control solution to the test strip without following the steps beginning on page 64. See page 97 for more information.

Taking a test 3

Checking if the result is in range

Compare the result displayed on the meter to the range printed **on your OneTouch Select® Plus Control Solution 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 5.7-7.7 mmol/L
OneTouch Select® Plus High
Control Solution Control
Range 16.5-22.4 mmol/L

⚠CAUTION:

The control solution ranges printed on the control solution vial are for control solution tests only **and are not recommended ranges for your blood glucose level.**

3 Taking a test

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 Service. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).



Yellow= 5mm Red=7mm margin

Taking a test **3**

Cleaning the control solution cap

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

71



Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

4 Reviewing past results

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 **OK** to turn History Mode on

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

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

2. Scroll through your results by pressing **▼** to move backwards and **▲** to move forward through your results



Reviewing past results 4**Downloading results to a computer**

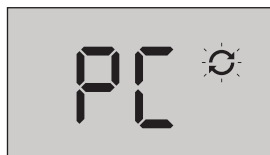
Your meter can work with diabetes management software, which provides a visual way to track key factors that affect your blood sugar. To learn more about diabetes management tools available to you, contact Customer Service. Call OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) during the hours of 8:30am-6pm Monday-Friday, 9am-1pm Saturday. Or visit www.LifeScan.co.uk.

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).

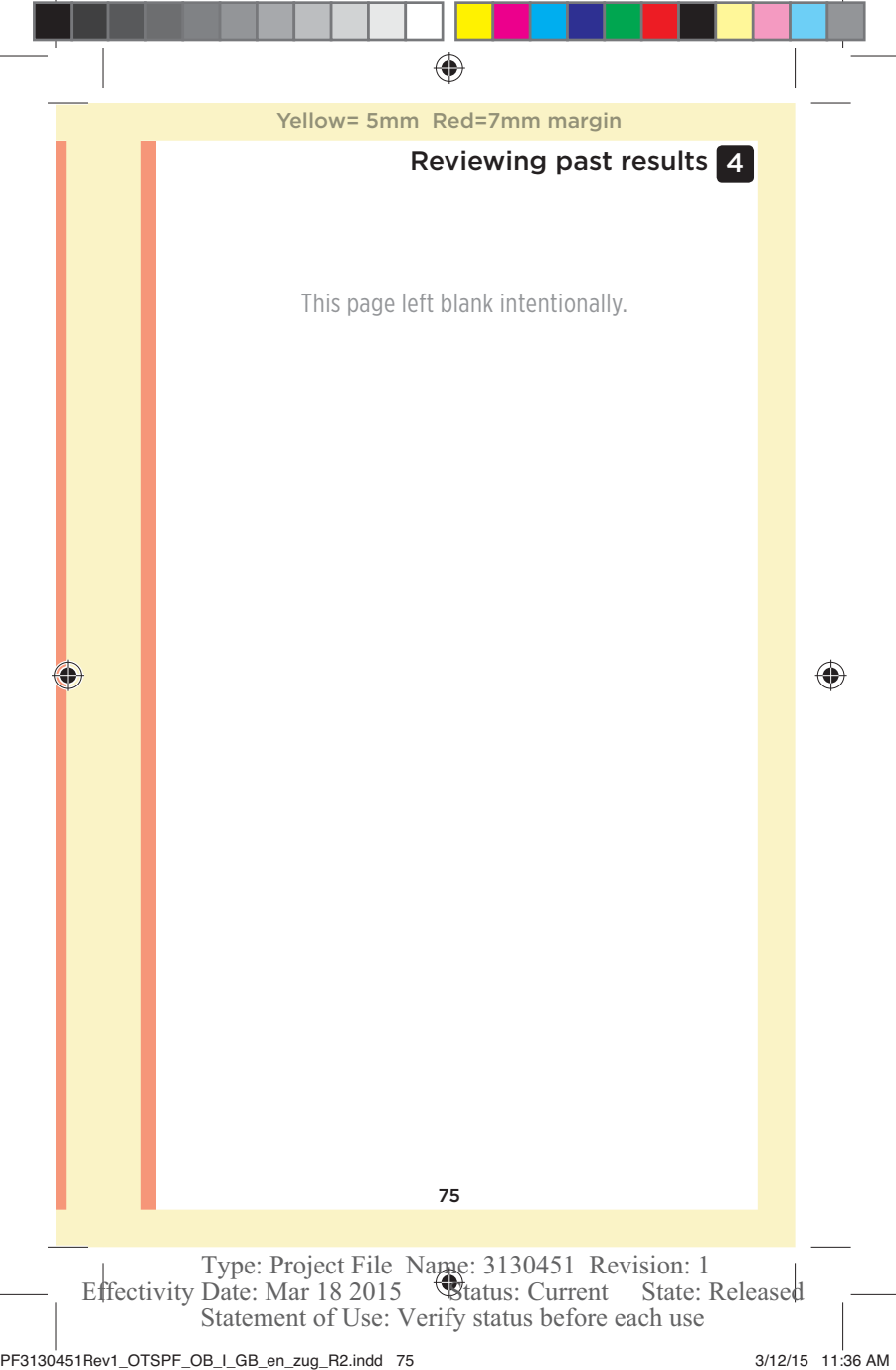
4 Reviewing past results

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 OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).



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 **OK** to turn the meter on, then press and hold **OK** 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 23.

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 Settings **5****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 3.9 mmol/L and the pre-set high range limit is 10.0 mmol/L. 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

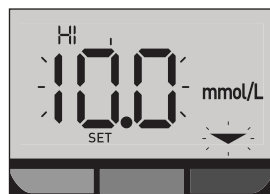
1. Review the pre-set low range limit displayed

- 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 3.3 mmol/L-6.1 mmol/L, 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 5.0 mmol/L-16.7 mmol/L, and then press **OK**.



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



Yellow= 5mm Red=7mm margin

Editing Your Settings 5

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.





Yellow= 5mm Red=7mm margin

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 80 and for disinfecting information, see page 82.

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.

80

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

Caring for your system **6**

- **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.



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.

Caring for your system **6**

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 OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

7 Battery

Replacing the battery

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

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 sliding it downward.



Battery cover

Battery 7

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.



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 OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

7 Battery

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



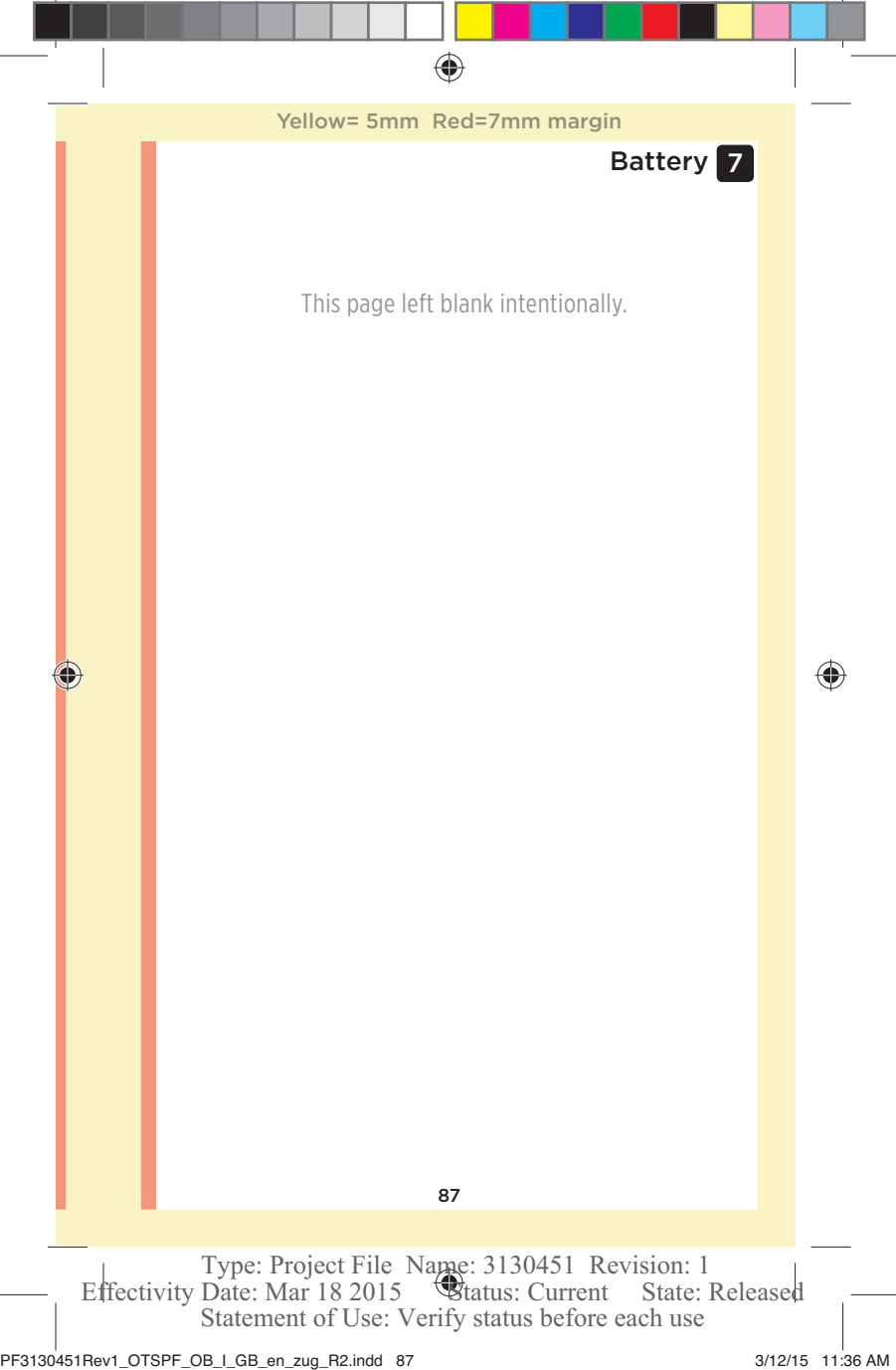
Battery cover

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.



8 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 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 Service. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

What it means

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



NOTE: When your glucose result is below 1.1 mmol/L, 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.

Yellow= 5mm Red=7mm margin

Troubleshooting your system 8

What it means

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



NOTE: When your glucose result is above 33.3 mmol/L, 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.

8 Troubleshooting your system

What it means

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

A digital display showing the text 'HI .t' in a black, segmented font on a light gray background.

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 OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

Yellow= 5mm Red=7mm margin

Troubleshooting your system 8

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 OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).



Yellow= 5mm Red=7mm margin

8 Troubleshooting your system

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 OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland). They will refer to the error number and code to help troubleshoot the problem.



Example Error
Screen Code

92

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Statement of Use: Verify status before each use

Troubleshooting your system 8

What it means

There is a problem with the meter.

What to do

Do Not use the meter. Contact Customer Service. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

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 49 or page 67. If this message continues to appear, contact Customer Service. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).



Yellow= 5mm Red=7mm margin

8 Troubleshooting your system

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 flashing  symbol appears on the display. If this message continues to appear, contact Customer Service. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

94

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
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Troubleshooting your system 8

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 34 for taking a blood glucose test, or page 64 for taking a control solution test. If the error message appears again, contact Customer Service. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

8 Troubleshooting your system

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 34 for taking a blood glucose test, or page 64 for taking a control solution test. If the error message appears again, contact Customer Service. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

Troubleshooting your system 8**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 34 for taking a blood glucose test, or page 64 for taking a control solution test. If the error message appears again, contact Customer Service. Contact OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).



Yellow= 5mm Red=7mm margin

8 Troubleshooting your system

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.

Troubleshooting your system 8

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 OneTouch® Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

9 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 0.83 mmol/L of a laboratory method when the glucose concentration is lower than 5.55 mmol/L and within 15% of 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.¹
- Your hematocrit is above 55% or below 30%.
- You are severely dehydrated.

For additional information, refer to the OneTouch Select® Plus Test Strip Insert.

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

100

Detailed information about your system 9

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.



Yellow= 5mm Red=7mm margin

9 Detailed information about your system

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.

102

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
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Detailed information about your system 9**Technical Specifications**

Assay method	Glucose Oxidase biosensor
Automatic shutoff	Two minutes after last action
Battery ratings	3.0 V d.c. (CR2032 lithium coin cell battery) 
Battery type	One replaceable 3.0 Volt CR2032 lithium coin cell battery (or equivalent)
Biological source	Aspergillus Niger
BLUETOOTH® SMART Technology:	Frequency Range: 2.4-2.4835 GHz 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	Micro USB Compatible with USB 2.0
Memory	500 test results



9 Detailed information about your system

Operating ranges	Temperature: 10–44°C Relative humidity: non-condensing 10–90% Altitude: up to 3048 meters Hematocrit: 30–55%
Reported result range	1.1–33.3 mmol/L
Sample	Fresh capillary whole blood
Sample volume	1.0 µL
Size	52(W) x 86(L) x 16(T) millimeters
Test time	Average test time is 5 seconds
Unit of measure	mmol/L
Weight	Approximately 50 grams

104

Effectivity Date: Mar 18 2015 Type: Project File Name: 3130451 Revision: 1
Status: Current State: Released
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Detailed information about your system 9**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 Select Plus Flex™ System and the YSI 2300 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 ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
67.2% (121/180)	93.3% (168/180)	96.7% (174/180)

105

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

9 Detailed information about your system**System Accuracy Results for Glucose Concentrations ≥ 5.55 mmol/L**

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 1.5 mmol/L and 26.8 mmol/L

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

Within ± 0.83 mmol/L or $\pm 15\%$
98.8% (593/600)

NOTE: Where 1.5 mmol/L represents the lowest glucose reference value and 26.8 mmol/L represents the highest glucose reference value (YSI value).

Detailed information about your system 9

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 ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L, and 95.9% within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

96.6% of the total number of samples were within ± 0.83 mmol/L or $\pm 15\%$ of the medical laboratory values.



Yellow= 5mm Red=7mm margin

9 Detailed information about your system

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 (mmol/L)
100	600	0.98	-0.01

95% CI Slope	95% CI Intercept (mmol/L)	Std. Error (S _{y,x}) (mmol/L)	R ²
0.97 to 0.98	-0.08 to 0.07	0.50	0.99

108

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

Detailed information about your system 9**Precision**

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

Data generated using the OneTouch Select Plus Flex™ Meter.

Target Glucose (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (%)
2.22	2.57	0.09	3.58
3.61	3.91	0.11	2.69
6.67	6.86	0.15	2.15
11.10	10.73	0.20	1.83
19.43	19.43	0.41	2.12

Results show that the greatest variability observed between test strips when tested with blood is 0.25 mmol/L SD or less at glucose levels less than 5.55 mmol/L, or 4.5% CV or less at glucose levels at 5.55 mmol/L or above.



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Detailed information about your system 9

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.LifeScan.co.uk 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.



Yellow= 5mm Red=7mm margin

9 Detailed information about your system

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.

112

Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use



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Detailed information about your system **9**

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113



Type: Project File Name: 3130451 Revision: 1
Effectivity Date: Mar 18 2015 Status: Current State: Released
Statement of Use: Verify status before each use

10 Index

AST.....	39
Batteries.....	84
Batteries, replacing.....	84
Battery empty icon.....	3
Battery empty warning.....	98
Battery low icon.....	3, 98
Blood glucose, testing.....	34
BLUETOOTH® SMART feature.....	7, 9, 27, 57
Buttons on meter.....	16
Cleaning your meter, lancing device and cap.....	80
Comparing meter results to laboratory results.....	100
Compatible wireless devices.....	3
Control solution.....	64
Control solution, discard and expiration dates.....	63
Control solution, testing.....	62, 68, 70
Data port.....	16
Date setting.....	24, 26
Dehydration.....	54, 100
Disinfecting your meter, lancing device and cap.....	82
Display check.....	22
Disposal, lancets and test strips.....	62
Downloading results to a computer.....	73
Edit date.....	76
Edit range limits.....	77

Edit time.....	76
Error messages.....	88
EXTREME HIGH GLUCOSE message.....	55, 89
EXTREME LOW GLUCOSE message.....	54, 88
Fingertip testing procedure	34
First time setup.....	23, 28
Guarantee.....	111
Hyperglycemia.....	55, 89
Hypoglycemia.....	54, 88
Icons.....	3, 4
Infection, reduce the chance.....	40
Intended use.....	6
Kit components.....	12
Lancing device.....	12, 39, 41, 80
mmol/L.....	16, 104
Pairing.....	28, 29
PIN.....	31
Plasma calibration.....	100, 103
Range Indicator feature.....	19
Range limits setting.....	77
Results, reviewing past.....	72
Serial number.....	31
Settings.....	23, 26, 76
Software, diabetes management.....	73

10 Index

Start-up screen.....	22
Storing your system.....	80
Symbols.....	3, 4
Syncing.....	32, 57
Technical specifications.....	103
Temperature.....	34, 63, 70, 80, 90, 91, 104
Test strip.....	18, 45, 64
Test strip, applying drop of blood.....	48, 49
Test strip, contact bars.....	18
Time setting.....	23, 26
Turning meter off.....	33
Turning meter on.....	22, 45, 64
Unexpected results.....	54, 56
Unit of measure.....	16, 104
Unusual red blood cell count (hematocrit).....	100, 104



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Element Delta User Manual - FCC Wording
Memorandum

Document ID: 3130961

Rev: 1

The purpose of this memo is to confirm the exact wording which will be added to the US manual for the One Touch Select Plus Flex (Element Delta) Blood Glucose Meter.

Item	Text
User Manual Statements to be added before product launch	Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: —Reorient or relocate the receiving antenna. —Increase the separation between the equipment and receiver. —Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. —Consult the dealer or an experienced radio/ TV technician for help.

Sign:

 DAVID LATHAM

Date:

16 FEB 2015

Title:

GPL

This device complies with Part 15 of the FCC Rules and with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Sign:



Date:

16 Feb 2015

Title:

Regulatory Affairs Specialist

	Element Delta User Manual - FCC Wording Memorandum	
	Document ID: 3130961	Rev: 1

Revision History

Revision	CR #	Originator	Description of Change
1	N/A	Ray Amphlett	New Document for Project Element Delta