Blood Glucose Monitoring System

Owner's Booklet

Instructions for Use

GC 059874 Rev 2, Frazier 3, Owner's Booklet, Verio

Thanks for choosing {id_brandname_onetouch}! [c9073876]

The {id_productname_meter(Dev)} Blood Glucose Monitoring System is one of the latest product innovations from {id_brandname_onetouch}.

Your {id_productname_meter(Dev)} Meter is designed to connect (sync) with a variety of compatible wireless devices running software applications. By connecting your meter with the {id_productname_software(Reveal app)} App you can review and graph your results, set Daily Test Goals, see Blood Sugar Mentor Messages and help identify patterns. Meter results and other tracked data are sent to the compatible devices either through {id_productname_Bluetooth(caps)} (wireless) or USB cable connection. **[(Available: App_Reveal)**Visit {id_csweb} for more information about the {id_productname_software(Reveal app)} App.**]**

Every {id_brandname_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 {id_brandname_onetouch} products and services will continue to be a part of your life.

Meter symbols and icons [c8211659]

Table 1: Range Indicator icons and Color Bar

	Result below target range
	Result at low end of target range
	Result near middle of target range
	Result in middle of target range
	Result near middle of target range
	Result at high end of target range
	Result above target range
	Result in range (text)

Table 2: Meal and Event tags

	Before Meal tag
	After Meal tag
	Event tag
	Carbs Event tag
	Stress Event tag
	Illness Event tag
	Medication Event tag
	Exercise Event tag

Table 3: Patterns, Test Tracker, and Awards

	Low Pattern Message (blue icon)
	High Pattern Message (red icon)
	Daily Test Goal met
	Daily Test Goal not met
	Gold award
	Silver award
	Bronze award

Table 4: Main Menu and Settings Menu icons

	Summary
	Results Log
	Trend 90
	Settings Menu
	Range Indicator icons as emoji
	Range Indicator icons as text

Table 5: Other meter icons

	{id_productname_Bluetooth(caps)} feature on
	Syncing
	Control solution result
	Low battery

Table continued…

Screen navigation progress dots

Other symbols and icons [c4683873]

	Cautions and Warnings: Refer to the Owner's Booklet and inserts that came with your system for safety-related information.
	Direct current
	**[(EUSymbols_Yes)**Consult Instructions for Use **]**
	**[(EUSymbols_Yes)**Manufacturer **]**
	**[(EUSymbols_Yes)**Lot Number **]**
	**[(EUSymbols_Yes)**Serial Number **]**
	**[(EUSymbols_Yes)**Storage Temperature Limits **]**
	**[(EUSymbols_Yes)**In Vitro Diagnostic Device **]**
	**[(EUSymbols_Yes)**Do Not Re-use **]**
	**[(EUSymbols_Yes)**Sterilized by irradiation **]**
	**[(EUSymbols_Yes)**Not for general waste **]**
	**[(EUSymbols_Yes)**Use By Date **]**
	**[(EUSymbols_Yes)**Contains sufficient for n tests **]**
	**[(EUSymbols_Yes)**Underwriters Laboratories certification**]**

Before you begin [c9006354]

Before using this product to test your blood glucose, carefully read this Owner's Booklet, and the inserts that come with the {id_productname_ts} Test Strips, {id_productname_cs (Verio)}**[(CS_Multiple)** Control Solutions**][(CS_One)** Control Solution**][(Included: LancingDevice)** and the {id_productname_lancingdevice} Lancing Device**]**.

⚠ **CAUTION: [(Platform: HCP)**Healthcare professionals must also read "Multi-patient use testing". See page 109.**]**

[c8291661]

IMPORTANT SAFETY INSTRUCTIONS:

- **[(Platform: Consumer)**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.

[(FDA-US) For more information see: FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm.**]**

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

Intended use [c8211717]

The {id_productname_meter(Dev)} Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes mellitus for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips as an aid in the management of diabetes.

The {id_productname_meter(Dev)} Meter analyzes patterns, tracks trends and provides guidance (educational, behavioral and motivational messages) to help aid in the understanding and management of glucose levels and the detection of excursions above or below a desired range. The meter is also designed to wirelessly communicate with compatible diabetes applications for the capture, transfer and analysis of blood glucose data and information, to help support diabetes self-management.

[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR) The {id_productname_meter(Dev)} Blood Glucose Monitoring System should not be used as a substitute for healthcare professional advice. It also should not be used for the diagnosis or screening of diabetes or for neonatal use.**]**

[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)(Platform: Consumer) The system is intended to be used by a single patient and should not be shared.**]**

[(Platform: HCP) When the {id_productname_meter(Dev)} Meter is set to "Basic mode", it can be used for multi-patient testing only by healthcare professionals as an aid to monitor the effectiveness of diabetes control programs. The system is not intended for use in critical care environments.**]**

⚠ **WARNING: [(FDA-US)**This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by the FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.**]**

[(FDA-US)

Limitations

The {id_productname_meter(Dev)} Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. The {id_productname_meter(Dev)} System is not to be used for the diagnosis or screening of diabetes or for neonatal use. The {id_productname_meter(Dev)} System is not for use on critically ill patients, patients in shock, severely dehydrated patients or hyperosmolar patients (with or without ketosis). **Do Not** use serum or plasma. The {id_productname_meter(Dev)} System is not recommended for alternate site testing (AST).

{id_productname_ts} Test Strips should not be used at altitudes above 10,000 feet as there may be an adverse effect on test results. Hematocrit is the percentage of red blood cells in the blood. Extremes in hematocrit may affect test results. Hematocrit levels below 20% may cause false high readings. Hematocrit levels over 60% may cause false low readings. Talk to your healthcare professional if you don't know your hematocrit level. The {id_productname_meter(Dev)} Blood Glucose Monitoring System should not be used within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high results. **Do Not** use the {id_productname_meter(Dev)} Blood Glucose Monitoring System when PAM (Pralidoxime) is known or suspected to be in the whole blood sample.

If you have medical conditions that are associated with high uric acid level or hyperuricemia (e.g. Gout), then please check with your doctor before using the {id_productname_meter(Dev)} Blood Glucose Monitoring System. Uric acid at concentrations greater than 8 mg/dL can interfere with glucose measurements.

If you take drugs containing acetaminophen (e.g. Tylenol etc.) or Dopamine at doses higher than the recommended high therapeutic level, then you may obtain inaccurate readings from the {id_productname_meter(Dev)} Blood Glucose Monitoring System. Please check with your doctor if you are unsure.

]

Test principle [c8758294]

Glucose in the blood sample mixes with the enzyme FAD-GDH (see page 120) in the test strip and a small electric current is produced. The strength of this current calculates your blood glucose level. It then displays the blood glucose result and stores it in the meter memory.

Use only {id_productname_cs (Verio)}**[(CS_One)** Control Solution**][(CS_Multiple)** Control Solutions**]** and Test Strips with the {id_productname_meter(Dev)} Meter. Use of {id_productname_ts} Test Strips with meters for which they are not intended may yield inaccurate results.

{id_productname_Bluetooth(caps)} wireless technology [c8249601]

{id_productname_Bluetooth(caps)} wireless technology is used by some smartphones and many other devices. Your {id_productname_meter(Dev)} Meter uses {id_productname_Bluetooth(caps)} wireless technology to pair and to send your glucose results to compatible wireless devices.

The {id_productname_meter(Dev)} Meter is designed to work with the {id_productname_software(Reveal app)} Mobile App**[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)** and many other diabetes applications**]**.

***NOTE*: [(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**Some diabetes management apps, including the {id_productname_software(Reveal app)} Mobile App, may not be available in your country. Visit {id_csweb} to learn if the {id_productname_software(Reveal app)} Mobile App is available in your country.**]**

Visit {id_csweb} for information on which wireless devices are compatible with your {id_productname_meter(Dev)} Meter, and where/how to download the **[(FDA-US)** {id_productname_software(Reveal app)} Mobile App**][(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**software application**]**.

When using the {id_productname_meter(Dev)} System, we suggest you pair your {id_productname_meter(Dev)} Meter with a compatible wireless device and track your results. See page 85 for pairing instructions.

[(FDA-US) Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.**]**

[(FDA-US) This device complies with Part 15 of the FCC Rules. 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.**]**

***NOTE*: [(FDA-US)**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.]

[(HC-CA)This Class B digital apparatus complies with Canadian ICES-003.]

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

[(DEKRA-EU MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)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. [(DEKRA-EU MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)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:** [(Platform: Consumer)The {id_productname_Bluetooth(caps)} 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 {id_productname_Bluetooth(caps)} feature off. See page 83 for more information.

{id_productname_Bluetooth(caps)} trademark

The {id_productname_Bluetooth(caps)} word mark and logos are owned by Bluetooth SIG, Inc. and any use of such marks by LifeScan Scotland Ltd. is under license. Other trademarks and trade names are those of their respective owners.

Table of Contents

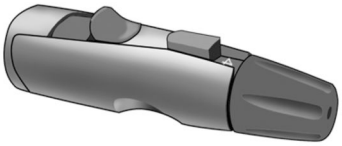
1 Getting to know your system

Your {id_productname_meter(Dev)} Blood Glucose Monitoring System [c8211755]

Included with your kit:

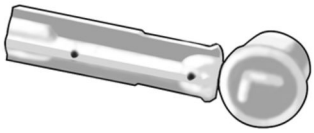
{id_productname_meter(Dev)} Meter (2 CR2032 lithium coin cell batteries included)

[(Included: LancingDevice)(Product: LancingDevice,Delica)Lancing device]



[(Included: LancingDevice)(Product: LancingDevice,MiniLancer)Lancing device]

[(Included: Lancets)(Product: Lancets,Delica)Lancets]



[(Included: Lancets)(Product: Lancets,UltraSoft)Lancets]

[(Included: CS_Mid){id_productname_cs_mid (Verio)}*]

[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)(Included: TS10){id_productname_ts} Test Strips*]

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

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

[GC Only: Available Separately] [c4829873]

Available separately:

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

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

[(Available: CS_Mid)(CS_Multiple)(vial with blue cap)]

[(Available: CS_Mid){id_productname_cs_mid (Verio)}*

[(Available: CS_High)(CS_Multiple)(vial with red cap)]

[(Available: CS_High){id_productname_cs_high (Verio)}*

[(Available: TS){id_productname_ts} Test Strips*]

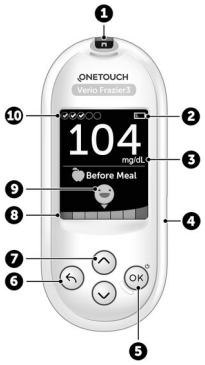
*{id_productname_cs (Verio)} Control Solution and Test Strips are available separately. For availability of test strips and control solution, contact Customer Service or ask your pharmacist or healthcare professional.

[(CS_Multiple)You can use either {id_productname_cs_mid (Verio)} or {id_productname_cs_high (Verio)} with your {id_productname_meter(Dev)} Meter.]

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

Getting to know your {id_productname_meter(Dev)} Blood Glucose Monitoring System [c8211792]

Meter



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

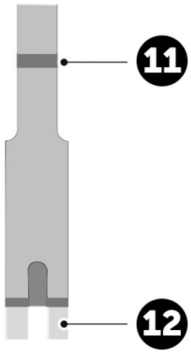
Table continued…

10	**Test Tracker icons**

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

Getting to know your {id_productname_ts} Test Strip [c8758420]

Test strip



11	**Channel to apply sample**
12	**Silver prongs** Insert into test strip port (1)

Features overview [c8211813]

The {id_productname_meter(Dev)} Meter is equipped with features designed to help you manage your blood glucose in a variety of ways. We hope you will take advantage of these features and make them part of your diabetes management routine.

Blood Sugar Mentor Messages

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

{id_productname_rangeindicator(ColorSure)} Dynamic Range Indicator

The {id_productname_rangeindicator(ColorSure)} Dynamic Range Indicator instantly lets you know if your current result is below (blue), within (green) or above (red) your range limits. It also shows when your result is near the low or high end of your target range.

Daily Test Tracker

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

Trend 90

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

2 Setting up your system

Setting up your meter

Turn your meter on [t8211857]

To turn your meter on, press and hold OK until the Welcome screen appears.

Once the Welcome screen is displayed, release OK. You can also turn the meter on by inserting a test strip.

Every time you turn your meter on, a Welcome screen will appear for a few seconds. If the meter does not power on, check the batteries. See page 105.

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

Example

[(Firsttime_Setup_No) If the meter was turned on by inserting a test strip, the **Apply Blood** screen will appear. To perform a blood glucose test, see page 39.**]**

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

Use the display backlight for better visibility [c8211879]

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

First time setup [t8211925]

This content is only displayed under special condition(s): (Firsttime_Setup_Yes)

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

***NOTE*:**

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

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

Pressing ↩ returns you to the previous screen.

1. **Press ^ or v to highlight the language you want, then press OK to select**

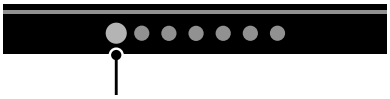
[(Available: App_Reveal) The meter will display a prompt giving the option to complete first time setup using the {id_productname_software(Reveal app)} App. Visit {id_csweb} for more information about the {id_productname_software(Reveal app)} App. If you do not want this option, highlight **No** and press OK to continue first time setup using only the meter.**]**

[(Available: App_Reveal)

]

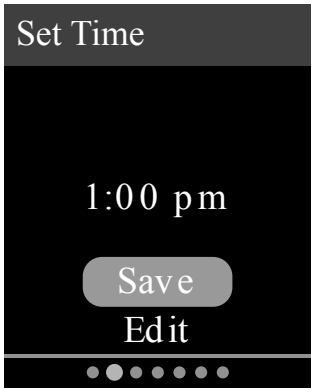
[**(Available: App_Reveal)**Selecting **Yes** will prompt you to pair the meter with your compatible wireless device. See page 84. After pairing, the {id_productname_software(Reveal app)} App will guide you through the process of first time setup. The remaining steps below will not be needed.]

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



Progress dot

2. **Confirm the time, then press** OK **to save**



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

3. **Confirm the date, then press** OK **to save**

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

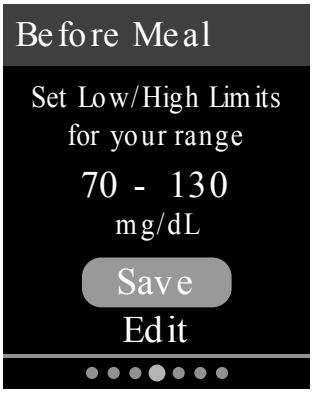
***NOTE*:**

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

Example

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

4. Confirm the Before Meal range limits, then press (OK) to save



Example

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

Your meter uses the Before Meal and After Meal range limits set in your meter to tell you when a test result is within, below or above your mealtime range limits. The mealtime range limits you set during first time setup will apply to all glucose results. They are used in the {id_productname_rangeindicator(ColorSure)} Dynamic Range Indicator feature, to detect Patterns and in the Summary. See page 52, page 71 and page 75 for more information.

Table 6: Before Meal range limits

pre-set low limit	[(DEKRA-EU FDA-US MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)70 mg/dL][(DEKRA-EU FDA-US MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)3.9 mmol/L][(HC-CA)4.0 mmol/L]
pre-set high limit	[(DEKRA-EU FDA-US MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)130 mg/dL][(DEKRA-EU FDA-US MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)7.2 mmol/L][(HC-CA)7.0 mmol/L]
low limit must be set within	[60 mg/dL][3.3 mmol/L] and [110 mg/dL] [6.1 mmol/L]
high limit must be set within	[90 mg/dL][5.0 mmol/L] and [300 mg/dL] [16.7 mmol/L]

5. **Confirm the After Meal range limits, then press** OK **to save**

Example

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

Table 7: After Meal range limits

pre-set low limit	[(DEKRA-EU FDA-US MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)70 mg/dL][(DEKRA-EU FDA-US MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)3.9 mmol/L][(HC-CA)5.0 mmol/L]
pre-set high limit	[180 mg/dL][10.0 mmol/L]
low limit must be within	[60 mg/dL][3.3 mmol/L] and [110 mg/dL] [6.1 mmol/L]
high limit must be within	[90 mg/dL][5.0 mmol/L] and [300 mg/dL] [16.7 mmol/L]

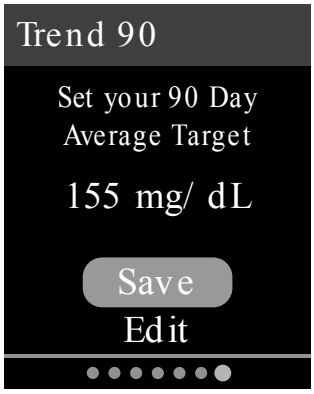
6. **Confirm the Test Tracker setting, then press OK to save**

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

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

The meter is pre-set with a Daily Test Goal of four tests per day. The maximum Daily Test Goal is eight. See page 93 for more information.

7. **Confirm the 90 Day Average Target, then press OK to save**



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

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

The meter is pre-set with a 90 Day Average Target of [155 mg/dL][8.6 mmol/L]. The minimum 90 Day Average Target is [99 mg/dL][5.5 mmol/L] and the maximum is [265 mg/dL][14.7 mmol/L]. See page 81 for more information.

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

If the meter was turned on by inserting a test strip, the **Apply Blood** screen will appear. To perform a blood glucose test, see page 39.

***NOTE*:** After first time setup, you can adjust your settings at any time. See page 89 for more information.

Understanding Basic Mode [c8215470]

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

When Basic Mode is selected, the Test Tracker, Meal and Event tagging, Before and After Meal averages, Trend 90, Pattern Messages, Mentor Tips and Awards will be turned off. In Basic Mode, range limits are general and are not defined by mealtime.

Range Indicator icons appear as text (for example, In Range) rather than as emoji (for example,).

For more information about turning Basic Mode on or off see page 92.

Turning the meter off [c8212518]

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.

3 Taking a test

Testing your blood glucose

Preparing for a blood glucose test [c8249708]

***NOTE*:** Many people find it helpful to practice testing with control solution before testing with blood for the first time. See page 60.

Have these things ready when you test:

{id_productname_meter(Dev)} Meter
{id_productname_ts} Test Strips
Lancing device
Sterile lancets

***NOTE*:**

- Use only {id_productname_ts} Test Strips.
- Unlike some blood glucose meters, no separate step to code your {id_productname_meter(Dev)} System is required.
- Testing must be done within operating temperature range ([(**DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**6-44°C]**[(FDA-US)**10-40°C]**[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**43-111°F]**[(FDA-US)**50-104°F])**[(FDA-US)** and 10-90% non-condensing relative humidity].
- Make sure your meter and test strips are about the same temperature before you test.
- Keep test strips in a cool, dry place between [41°F and 86°F][5°C and 30°C]**[(FDA-US)** and below 65% relative humidity].**[(FDA-US)**See page 97 for full storage instruction.]
- **Do Not** test if there is condensation (water build-up) on your meter. Move your meter and test strips to a cool, dry spot and wait for the meter surface to dry before testing.
- **Do Not** open the test strip vial until you are ready to remove a test strip and perform a test. Use the test strip **immediately** after removing it from the vial.
- Tightly close the cap on the vial immediately after use to avoid contamination and damage.
- Store unused test strips only in their original vial.
- **Do Not** return the used test strip to the vial after performing a test.
- **Do Not** re-use a test strip that had blood, control solution, or any contaminants applied to it. Test strips are for single use only.
- With clean, dry hands, you may touch the test strip anywhere on its surface. **Do Not** bend, cut or modify the test strip in any way.
- When you first open a vial of test strips, record the discard date on the label. Refer to the test strip insert or vial label for instructions on determining the discard date.

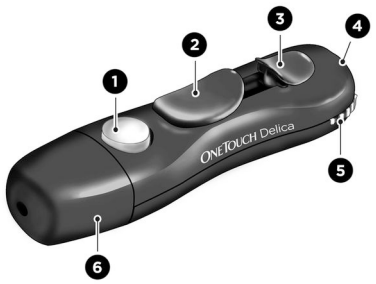
- Comparing your blood glucose test results taken with this meter to your results taken from a different meter is not recommended. Results may differ between meters and are not a useful measure of whether your meter is working properly. To check your meter accuracy, you should periodically compare your meter results to those obtained from a lab. See page 119 for more information.

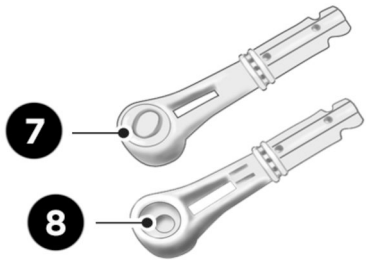
⚠ **IMPORTANT:** If another person assists you with testing, the meter should always be cleaned prior to use by that person. See page 97page 98.

⚠ **CAUTION:**

- **[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**The {id_productname_meter(Dev)} Blood Glucose Monitoring System should not be used for patients within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high results. **]**
- **[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)Do Not** use the {id_productname_family (Verio)} Family of Meters when PAM (Pralidoxime) is known or suspected to be in the patient's whole blood sample.**]**
- **Do Not** use your test strips if your vial is damaged or left open. This could lead to error messages or inaccurate results. Contact Customer Service immediately if the test strip vial is damaged. Contact information for Customer Service is listed at the end of this Owner's Booklet.
- If you cannot test due to a problem with your testing supplies, contact your healthcare professional. Failure to test could delay treatment decisions and lead to a serious medical condition.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.
- **Do Not** use test strips after the expiration date (printed on the vial) or the discard date, whichever comes first, or your results may be inaccurate.

Getting to know your {id_productname_lancingdevice} Lancing Device [c9085376]



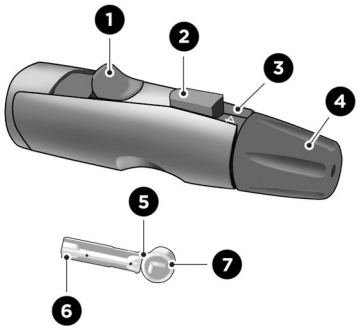


1	Release button
2	Cocking control
3	Ejection control
4	Depth indicator
5	Depth wheel
6	Lancing device cap (for fingertip sampling)
7	Lancet protective cover
8	Cupped side of protective cover

***NOTE*:**

- The {id_productname_lancingdevice} Lancing Device uses ONLY {id_productname_lancets} Lancets.
- If another type of lancing device was included, see the separate instructions for that lancing device.
- The {id_productname_meter(Dev)} Blood Glucose Monitoring System has not been evaluated for Alternate Site Testing (AST). Use only fingertips when testing with the system.
- The {id_productname_lancingdevice} Lancing System does not include the materials needed to perform Alternate Site Testing (AST). The {id_productname_lancingdevice} Lancing System should not be used on the forearm or palm with the {id_productname_meter(Dev)} Blood Glucose Monitoring System.]

Getting to know your {id_productname_lancingdevice} Lancing Device [c9085442]



1	Cocking control
2	Release button
3	Depth indicator
4	Lancing device cap
5	Lancet point
6	Sterile lancet
7	Protective cover

***NOTE*:**

- If another type of lancing device was included, see the separate instructions for that lancing device.
- The {id_productname_meter(Dev)} Blood Glucose Monitoring System has not been evaluated for Alternate Site Testing (AST). Use only fingertips when testing with the system.

Lancing precautions [t8261226]

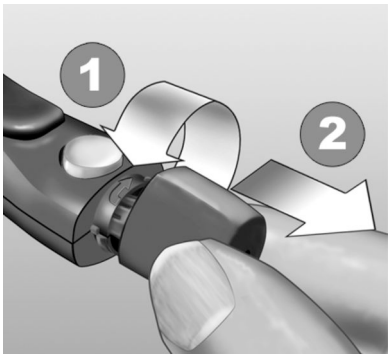
CAUTION: To reduce the chance of infection and disease spread by blood:

- **[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**Make sure to wash the sample site with soap and warm water, rinse and dry before sampling.**]**
- **[(FDA-US)**Make sure to wash the sample site with soap and warm water, rinse and dry before sampling. Contaminants on the skin may affect results.**]**
- 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 97page 98.)
- **[(Platform: Consumer)**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.

Preparing the lancing device [t4144351]

1. **Remove the lancing device cap**

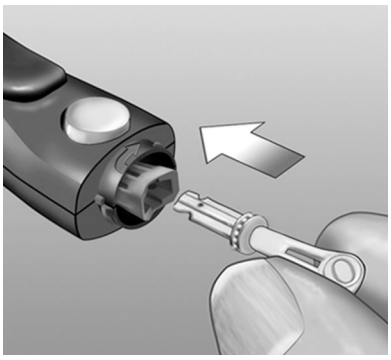
   Remove the cap by turning it counterclockwise and then pulling it straight off of the device.

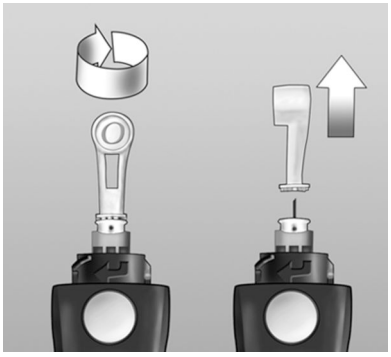


2. **Insert a sterile lancet into the lancing device**

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

Twist the protective cover one full turn until it separates from the lancet. **Save the protective cover for lancet removal and disposal.** See page 56.

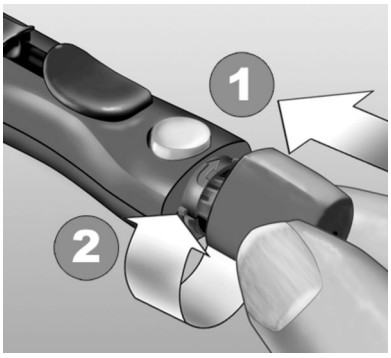


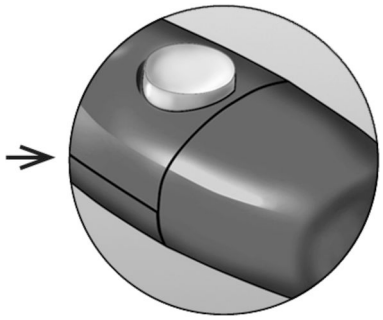


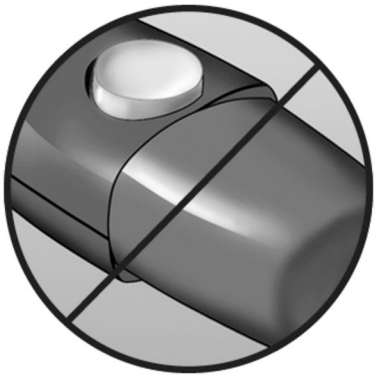
3. **Replace the lancing device cap**

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

   Do Not overtighten.

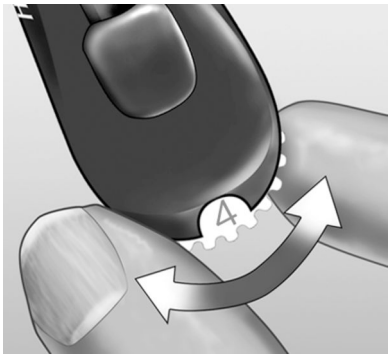






4. **Adjust the depth setting**

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



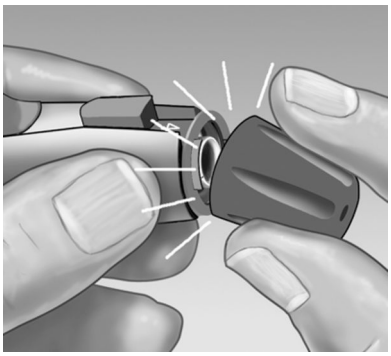
   ***NOTE*:** A shallower fingertip puncture may be less painful. Try a shallower setting first and increase the depth until you find the one deep enough to get a blood sample of the proper size.

5. **Cock the lancing device**

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

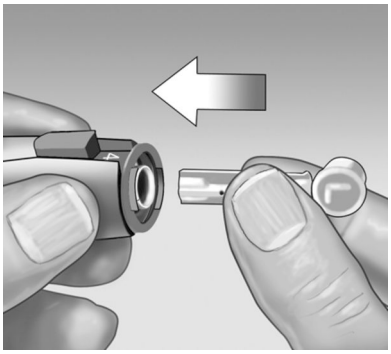
Preparing the lancing device [t7307171]

1. **Snap off the lancing device cap**

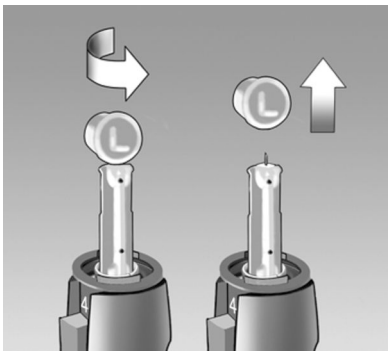


2. **Insert a sterile lancet**

   Firmly push the lancet into the holder.



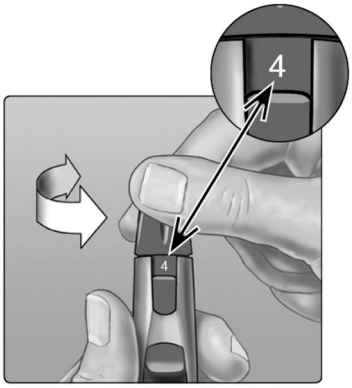
3. **Twist off the protective cover and save it for later use**



4. **Replace the lancing device cap**
5. **Adjust the depth setting**

   Twist the lancing device cap until the desired setting appears. Smaller numbers are for a shallower punctures, which may be less painful.

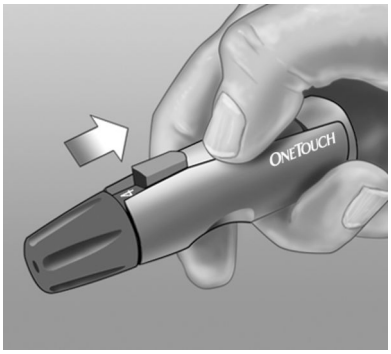
   Shallower punctures work for children and most adults. Deeper punctures work well for people with thick or callused skin.



6. **Cock the lancing device**

   Slide the cocking control back until it clicks.

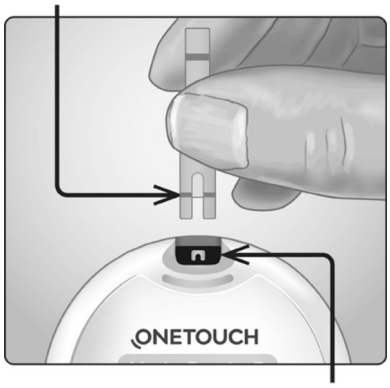
   If it does not click, that's okay. It may have been cocked when you inserted the lancet.



Preparing the meter [t8212968]

Insert a test strip to turn the meter on

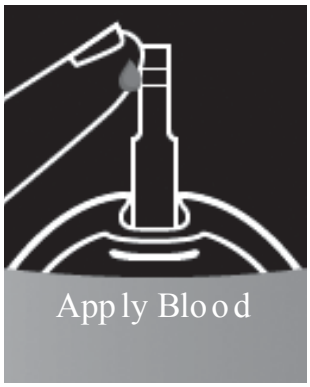
Insert a test strip into the test strip port with the gold side of the test strip and the two silver prongs facing you.



Silver prongs

Test strip port

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



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

Getting a blood sample from the fingertip [t9454392]

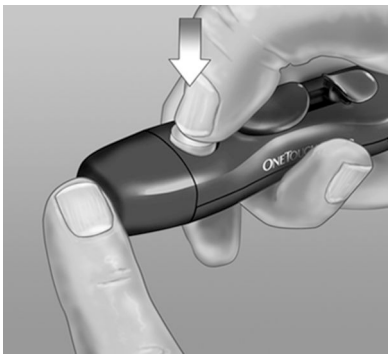
Choose a different puncture site each time you test.

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.[(FDA-US) Contaminants on the skin may affect results.]

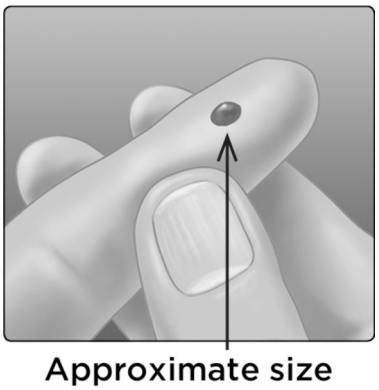
1. **Puncture your finger**

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



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

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



***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.

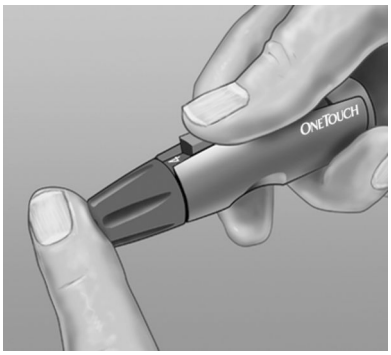
Getting a blood sample from the fingertip [t9454412]

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.[(FDA-US) Contaminants on the skin may affect results.]

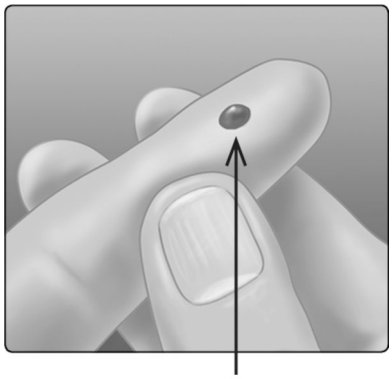
1. **Lance your finger**

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



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.

Applying blood and reading results

Applying the sample [t8758447]

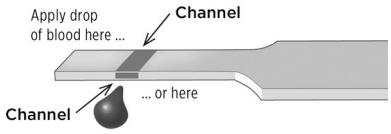
***NOTE*: [(Platform: HCP)Healthcare professionals must also read additional instructions in Multi-patient use testing. See page 109.]**

1. **Apply the sample to the test strip**

   You can apply blood to either side of the test strip.

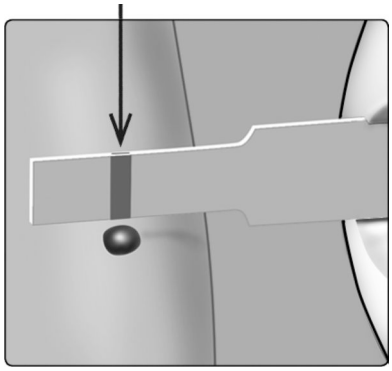
   Apply your sample to the opening of the channel.

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

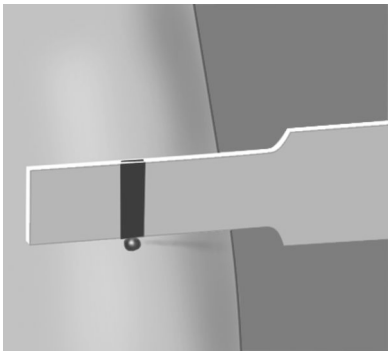


   Holding the meter at a slight angle, guide the channel to the blood drop.

Channel



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

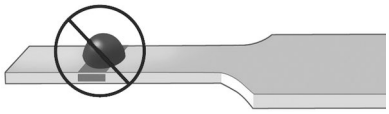


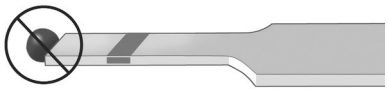
2. **Wait for the channel to fill completely**

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

   The channel turns red and a result will be displayed after approximately 5 seconds.

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





***NOTE*:**

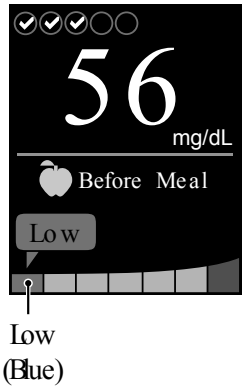
- **Do Not** smear or scrape the sample with the test strip.
- **Do Not** press the test strip too firmly against the puncture site or the channel may be blocked from filling properly.
- **Do Not** apply more blood to the test strip after you have moved the drop of blood away.
- **Do Not** move the test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

Viewing your result [c8213032]

{id_productname_rangeindicator(ColorSure)} Dynamic Range Indicator

The {id_productname_meter(Dev)} Meter comes with a {id_productname_rangeindicator(ColorSure)} Dynamic Range Indicator feature that instantly lets you know if your current result is below (blue), within (green) or above (red) your range limits. It also shows when your result is near the low or high end of your target range. It does this by displaying your result with a Range Indicator icon pointing to a

segment on the Color Bar based on the ranges you have set in the meter. The Range Indicator icon may be either an emoji (for example,) or text (for example). Use the Range Indicator icon and the segmented Color Bar together to see where your result falls within your range limits.



Low
(Blue)

Example - below range result

In Range
(Green)

Example - middle of range result

High
(Red)

Example - above range result

If the Test Tracker is turned on, progress toward the Daily Test Goal will be indicated above the result. If the Test Tracker is turned off, the date and time will be shown above the result. The date and time are always recorded with each result and can be viewed in the Results Log. See page 79.

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

CAUTION: Do Not make immediate treatment decisions based on the {id_productname_rangeindicator(ColorSure)} Dynamic Range Indicator feature. Treatment decisions should be based on the numerical result and healthcare professional's recommendation and not solely on where your result falls within your range limits.

After the result screen appears, a Pattern Message, Mentor Tip or Award may be displayed. The Message can be dismissed by pressing OK. If you would like to bring the Message back, press OK again. See page 71 for more information about Messages.

Example

A Before Meal tag will automatically be applied to your result. When you change a Before Meal tag to an After Meal tag, the Range Indicator icon may point to a different segment on the Color Bar. A new Message may appear. See page 67 for information on tagging results.

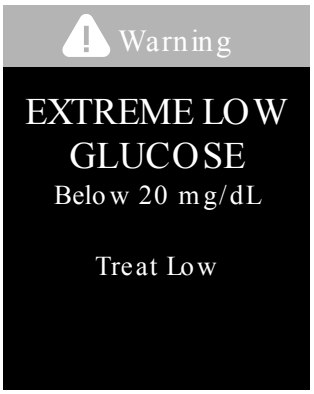
Interpreting unexpected results [c8213057]

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

CAUTION:

Low blood glucose results

If your blood glucose result is below [70 mg/dL][(DEKRA-EU MHLW-JP MOH-SA SFDA-CN TGA-AU)3.9 mmol/L][(HC-CA)4.0 mmol/L] or is shown as **EXTREME LOW GLUCOSE**, (meaning the result is less than [20 mg/dL][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.



CAUTION:

Dehydration and low blood glucose results

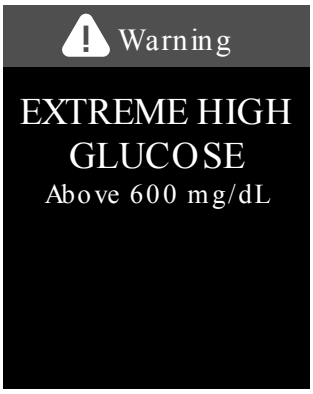
You may get false low blood glucose results if you are severely dehydrated. If you think you are severely dehydrated, contact your healthcare professional immediately.

CAUTION:

High blood glucose results

If your blood glucose result is above [180 mg/dL][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.

EXTREME HIGH GLUCOSE is displayed when your blood glucose result is over [600 mg/dL][33.3 mmol/L]. You may have severe hyperglycemia (very high blood glucose). Re-test your blood glucose level. If the result is **EXTREME HIGH GLUCOSE** again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional immediately.



CAUTION:

Repeated unexpected blood glucose results

- If you continue to get unexpected results, check your system with control solution. See page 60.
- If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this Owner's Booklet, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes management program without speaking to your healthcare professional.

Unusual red blood cell count

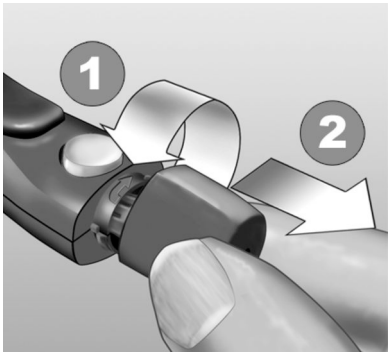
A hematocrit (percentage of your blood that is red blood cells) that is either very high (above 60%) or very low (below 20%) can cause false results.

Removing the used lancet [t4144504]

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

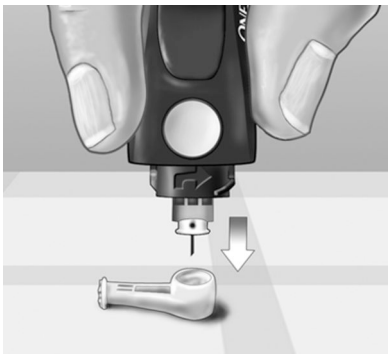
1. **Remove the lancing device cap**

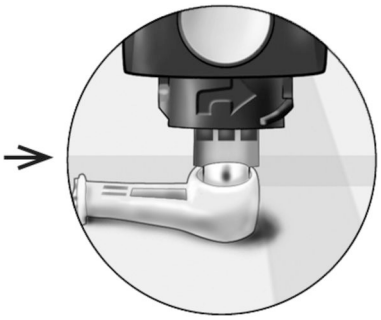
   Remove the cap by turning it counterclockwise and then pulling it straight off of the device.



2. **Cover the exposed lancet tip**

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





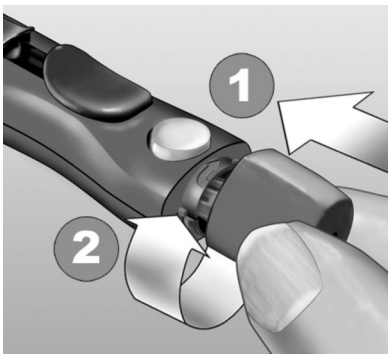
3. **Eject the lancet**

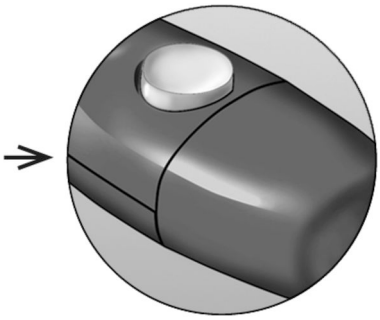
   Slide the ejection control forward until the lancet comes out of the lancing device. Return the ejection control to its back position.

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

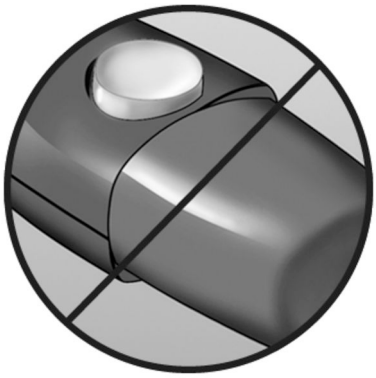
4. **Replace the lancing device cap**

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





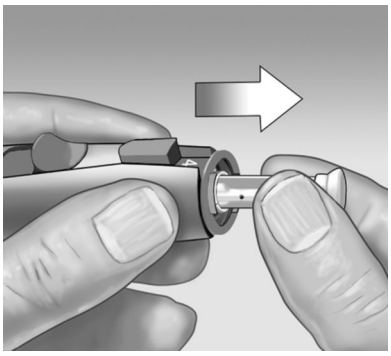
Do Not overtighten.



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.

Removing the used lancet [t7307413]

1. **Remove the lancing device cap**
2. **Place the lancet protective cover on a hard surface and push the lancet tip into the cover**
3. **Remove the lancet and place it in a container for sharp objects**



4. **Replace the lancing device cap**

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

Disposing of the used lancet and test strip [c1617770]

This content is only displayed in countries regulated by: FDA-US DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU

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.

Disposing of the used lancet and test strip [c7341103]

This content is only displayed in countries regulated by: ANVISA-BR

Used test strips and lancets are considered biohazardous waste. It is important to discard the used lancet carefully after each use to avoid unintended sharps injuries. Dispose of lancets in a sharps disposal container. Test strips must be disposed of properly. Be sure to follow your local regulations or health care professional's recommendations 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 [c3551910]

{id_productname_cs (Verio)} 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*:**

- [(CS_One)Use only {id_productname_cs (Verio)} Control Solution with your {id_productname_meter(Dev)} Meter.][(CS_Multiple)Use only {id_productname_cs_mid (Verio)} or {id_productname_cs_high (Verio)} with your {id_productname_meter(Dev)} Meter. Either level can be used to check your system.]
- When you first open a new vial of control solution, record the discard date on the vial label. Refer to the control solution insert or vial label for instructions on determining the discard date.
- Tightly close the cap on the control solution vial immediately after use to avoid contamination or damage.

CAUTION:

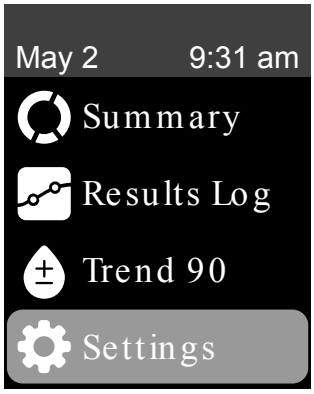
- **Do Not** swallow or ingest control solution.
- **Do Not** apply control solution to the skin, eyes, ears or nose as it may cause irritation.
- **Do Not** use control solution after the expiration date (printed on the vial label) or the discard date, whichever comes first, or your results may be inaccurate.

When to do a control solution test

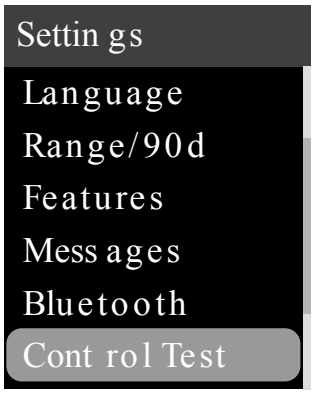
- When you open a new vial of test strips.
- If you suspect that the meter or test strips are not working properly.
- If you have had repeated unexpected blood glucose readings.
- If you drop or damage the meter.

Preparing your meter for a control solution test [t8213083]

1. **Press and hold OK to turn the meter on**
   Wait for the Main Menu to appear.
2. **Press ^ or v to highlight Settings, then press OK**



3. **Highlight Control Test, then press OK**

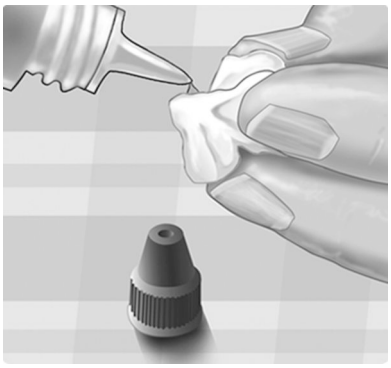


Wait for the **Insert Strip** screen to appear on the display.

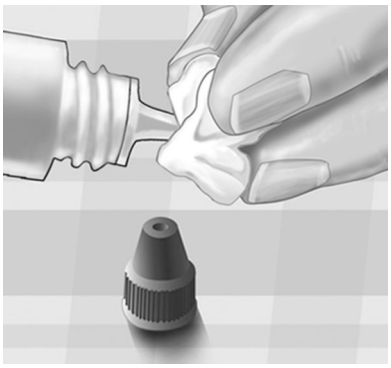
4. **Insert a test strip into the test strip port**
5. **Wait for the Apply Control Solution screen to appear on the display**

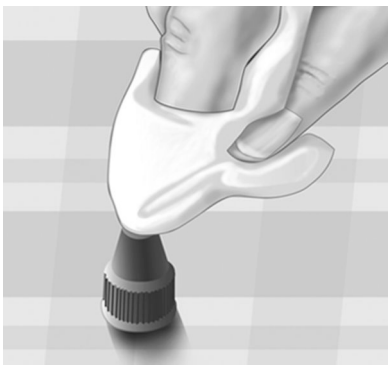
Preparing the control solution [t4160820]

1. **Before removing the cap, shake the vial gently**
2. **Remove the vial cap and place it on a flat surface with the top of the cap pointing up**
3. **Squeeze the vial to discard the first drop**

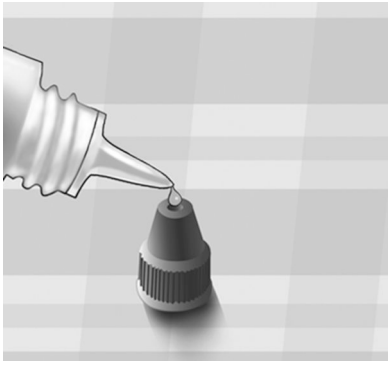


4. **Wipe both the tip of the control solution vial and the top of the cap with a clean, damp tissue or cloth**





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



Applying the control solution [t8758502]

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

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

Viewing your control solution result [c8213128]

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

Example

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

⚠ **CAUTION:** Make sure you select **Control Test** from the Settings Menu before you begin a control solution test. Follow the steps beginning on page page 60. If C does not appear on the screen, this result will be included in your averages and your averages will change too. Repeat the test with a new test strip. If the problem persists, contact Customer Service. Contact information for Customer Service is listed at the end of this Owner's Booklet.

Checking if the result is in range [c8213141]

[(FDA-US)(CS_Multiple)Each vial of test strips has both {id_productname_cs_mid (Verio)} and {id_productname_cs_high (Verio)} ranges printed on its label. Compare the result displayed on the meter to either the {id_productname_cs_mid (Verio)} or {id_productname_cs_high (Verio)} range printed **on the test strip vial**, depending on the type of control solution you used.]

[(FDA-US)(CS_One)Each vial of test strips has the {id_productname_cs_mid (Verio)} range printed on its label. Compare the result displayed on the meter to the {id_productname_cs_mid (Verio)} range printed **on the test strip vial**.]

[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)Compare the result displayed on the meter to the range printed **on your {id_productname_cs (Verio)} Control Solution vial**. If your control solution result falls outside the expected range, repeat the test with a new test strip.]

{id_productname_cs_mid (Verio)} Control Range [102-138 mg/dL][5.7-7.7 mmol/L]

[(CS_Multiple){id_productname_cs_high (Verio)} Control Range [298-403 mg/dL] [16.5-22.4 mmol/L]

⚠ **CAUTION:** [(FDA-US)The range printed on the test strip vial is for control solution tests only **and is not a recommended range for your blood glucose level.]**

Example range

CAUTION: **[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**The range printed on the control solution vial is for control solution tests only **and is not a recommended range for your blood glucose level.]**

Causes of out-of-range results [c8261253]

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 **[(FDA-US)**test strip**][(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**control solution**]** vial, **Do Not** use the meter, test strips, or control solution. Contact Customer Service. Contact information for Customer Service is listed at the end of this Owner's Booklet.

Cleaning the control solution cap [t3604343]

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

4 Tagging results

Adding Meal and Event tags [t8213207]

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

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

In addition to Meal tagging, your {id_productname_meter(Dev)} Meter includes an Event tagging feature. Event tagging adds information about your health and lifestyle events to your blood glucose results. Your meter will review your past results and display Messages associated with tagged results when certain conditions are met. See page 5 for Event tag icons and their meanings.

1. **View the current blood glucose result on the display**
   The result will automatically receive a Before Meal tag and no Event tag.
2. **If a Message appears, press OK to clear the Message**
3. **To change to an After Meal tag, press then highlight After Meal and press OK**

***NOTE*:** The Range Indicator icon displayed with the result uses Before and After Meal ranges. When you change a Before Meal tag to an After Meal tag, the Range

Indicator icon may point to a different segment on the Color Bar. A new Message may appear.

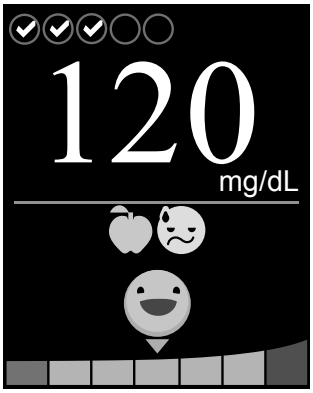
4. **To add an Event tag to your result, press** ↩

5. **Press ^ or v to highlight Event Tag, then press OK**

6. **Press ^ or v to highlight an Event tag, then press OK**
You may add more than one Event tag to a result.

A ✓ notes that an Event tag has been added.

7. **When you have finished selecting Event tags, highlight Done and press OK**



Example

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

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

5 Understanding Messages

Blood Sugar Mentor Messages overview [c8213295]

The {id_productname_meter(Dev)} Meter reviews your past test results and may display Mentor Tips (guidance), Pattern Messages (insight) or Awards (encouragement). The meter will show you the most appropriate Message if more than one is applicable to your result.

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

Pressing OK will dismiss Messages.

Understanding Pattern Messages [c8213325]

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

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

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

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

Reviewing results that create Patterns [t8213397]

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

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

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

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

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

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

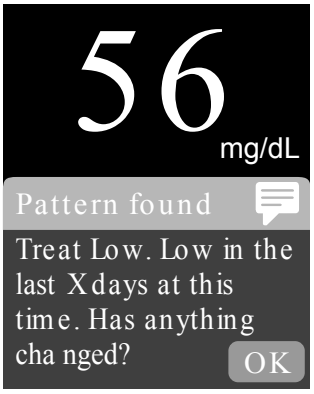
Event tag Pattern Messages appear when any 3 results over the past 30 days are:

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

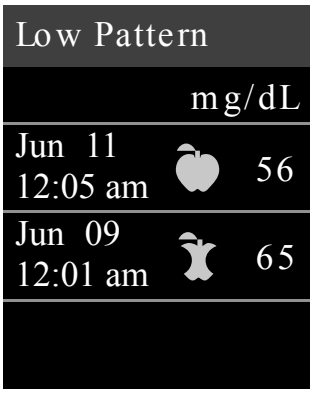
There are two ways you can review the individual results that combine to create a Low or High Pattern.

You can press OK twice on any test result screen that indicates a Pattern was found to cycle between result screen, Pattern Message and Pattern results.

Example - Results screen with Pattern icon



Example - Pattern Message



Example - Results that created Low Pattern

Or you can access the Patterns using the Results Log screen. See page 79.

***NOTE*:** To be sure that Low and High Pattern Messages appear:

- Basic Mode must be turned off and Pattern Messages must be turned on. See page 92 and page 94.
- Update the date and time if you change time zones, or if the time changes due to Daylight saving time.
- Test your blood glucose using only one {id_productname_meter(Dev)} Meter. Using multiple meters may cause you to miss Patterns.
- Tag your blood glucose results carefully.
- Test when you feel your blood glucose may be high or low.

⚠ **CAUTION:**

- Always use your current result for immediate treatment decisions.
- **Do Not** use Pattern Messages to make immediate or significant changes to your diabetes care plan without first consulting your healthcare professional. Always consult your healthcare professional before making significant changes to your diabetes care plan.
- **Do Not** wait for Pattern Messages to treat low or high results.
- **[(Platform: Consumer)Do Not** allow other people to use your meter or your Patterns may be affected.**]**

Understanding Mentor Tips [c8213467]

Mentor Tips let you know when your results are consistently in range, and display diabetes management information when results are trending low and high. Mentor Tips appear with current results and cannot be viewed later.

- **Unusually Low** - Current result is below the low range limit, and is at least **[**5 mg/dL**]** **[**0.3 mmol/L**]** below your lowest result over the past 14 days.
- **Morning Low** - Current result occurred in the morning and is below the low range limit.*
- **Treat Low** - Current result is below the low range limit.*

- **Unusually High** - Current result is above the high range limit, and is more than 10% higher than the highest blood glucose result in the last 14 days.
- **Morning High** - Current result occurred in the morning and is above the high range limit.*
- **Bedtime High** - Current result occurred at night and is above the high range limit.*
- **Congratulations** - Your 90-day average is improving.
- **Trend 90 Rise** - Your 90-day average has increased.
- **Trend 90 Update** - New 90-day average is available.
- **Near Low** - Result is in range but close to low range limit.
- **Near High** - Result is in range but close to high range limit.
- **Well Done** - Result is back in range after a series of either 2 low or 3 high results.
- **Keep It Up** - More than 70% of results over the past 7 days were in range.
- **Weekly Average** - New 7-day average is shown.
- **Device Not Paired** - Reminds you to pair the meter with a compatible wireless device.
- **Connect Device** - Reminds you to sync the meter with the App.
- **Exercise Low** - Current result is below the low range limit and received an Exercise Event tag.*
- **Take a Break** - Current result is above the high range limit and received a Stress Event tag.*

*Belton AB. Personal Communication, April 15, 2011.

Understanding Awards [c8213420]

The {id_productname_meter(Dev)} Meter tracks the goals outlined below. Each time you earn bronze (), silver () or gold () medal status, an Award will appear along with your in-range result. You can review your Awards later in the Summary. (See page 75.)

- **Test Goal Award** - Meet your Daily Test Goal a set number of times in total or in a row.
- **In-Range Award** - Achieve an in-range result a set number of times in a row.
- **Event Tag Award** - Event tag your result a set number of times in total.
- **[(Available: App_Reveal)Syncing Award** - Sync your meter to the {id_productname_software(Reveal app)} App a set number of times in total.**]**

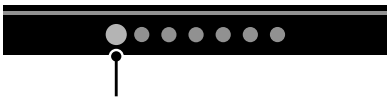
6 Summary, Results Log and Trend 90

Viewing the Summary [t8216983]

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

***NOTE*:**

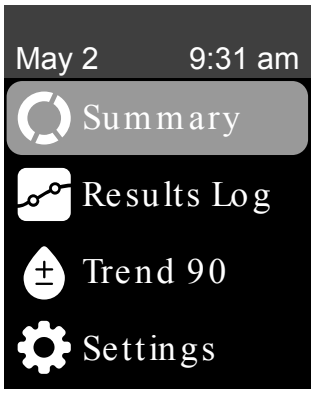
- **Do Not** use result averages to make immediate treatment decisions. Result averages provide information from past results. Always consult your healthcare professional before making significant changes to your diabetes care plan.
- **Do Not** allow other people to use your meter as it may affect your averages.
- The meter calculates averages based on the 7-, 14- and 30-day periods ending on the current date setting. If you change the date setting, the averages may change too.
- The Summary screens displayed will reflect the features currently selected. See page 89 for information on turning meter features on or off.
- If Basic Mode is selected, your Summary will be limited to the 30-day Summary and Average views. See page 37 for more information about Basic Mode.
- In Averages, Pattern Messages and Awards, an **EXTREME HIGH GLUCOSE** result is always counted as [600 mg/dL][33.3 mmol/L], and an **EXTREME LOW GLUCOSE** result is always counted as [20 mg/dL][1.1 mmol/L].
- The green progress dot will move from left to right as you navigate through the summary screens.



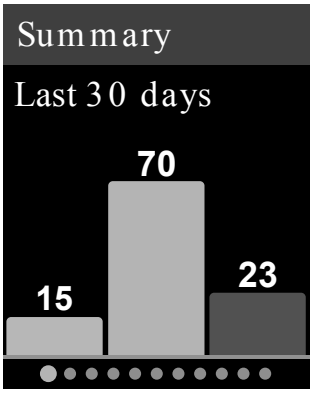
Progress dot

- Pressing ^ will display the previous screen.

1. **From the Main Menu, press ^ or v to highlight Summary and press OK**



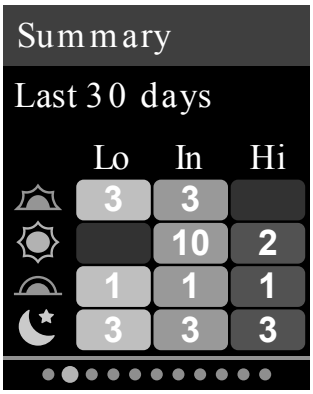
The number of results that are low (blue), in-range (green) and high (red) are displayed and appear as bar graphs.



Example

2. **Press to display the Summary by time of day**

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



Example

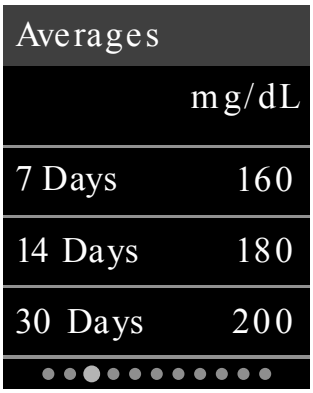
Morning	[6:00 am to 11:59 am][06:00 to 11:59]

Table continued…

Afternoon	[12:00 pm to 5:59 pm][12:00 to 17:59]
Evening	[6:00 pm to 11:59 pm][18:00 to 23:59]
Bedtime	[12:00 am to 5:59 am][00:00 to 05:59]

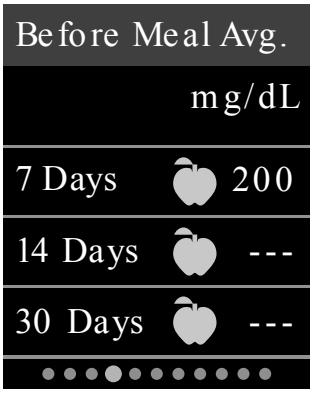
***NOTE*:** If there were no results in the past 30 days in a target range and time period, that section of the chart is left blank.

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



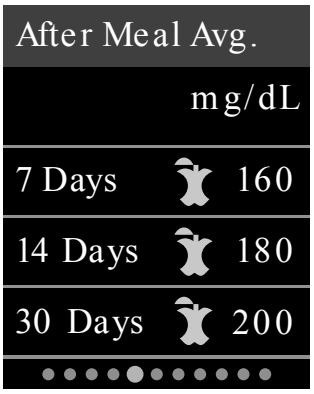
Example

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



Example

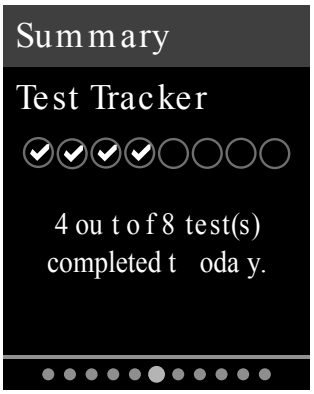
5. **If Basic Mode is off, press to display your After Meal averages for the past 7, 14 and 30 days**



Example

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

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



Example

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

Example

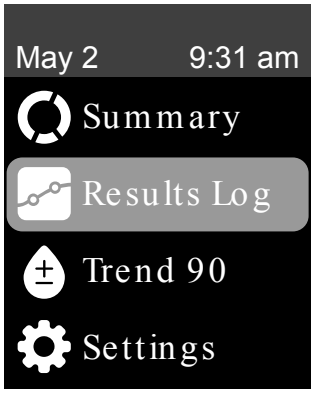
Viewing the Results Log [t8224861]

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

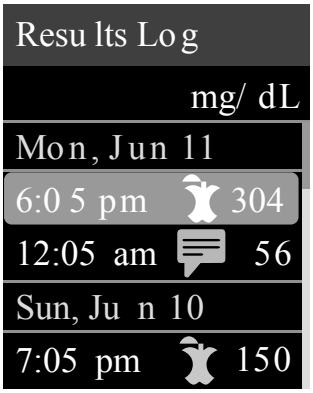
See page 5 for definitions of meter icons that may appear with your result.

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

1. **From the Main Menu, press ^ or v to highlight Results Log and press OK**



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



Example

2. **Press v or ^ to move through the list of results**

Example

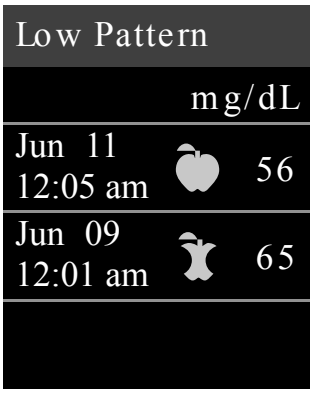
***NOTE*:** If a result is part of a Pattern, the Pattern icon will be displayed for that result instead of any tags that result may have.

3. **Highlight a result with an icon and press** OK

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

Example

If the result is part of a Pattern, indicated by , pressing OK again will display the results that led to the Pattern. See page 71 for more information about Patterns.



Example

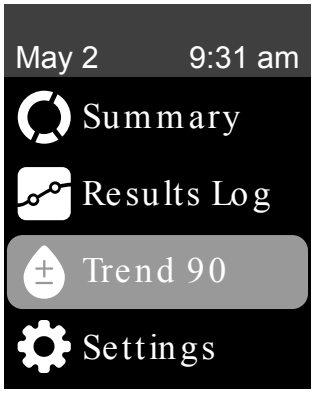
Viewing the Trend 90 [t8225174]

The {id_productname_meter(Dev)} Meter averages results over the past 90 days to provide a view of the overall trend of blood glucose results. There must be at least 90 days of results stored in the meter for the first 90-day average to appear. A point will be graphed on the screen to represent the first 90-day average. After the first 90-day average a new point is displayed every 14 days.

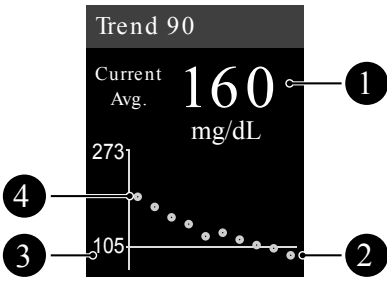
***NOTE*:**

- Basic Mode must be turned off to use the Trend 90 feature. (See page 92.)
- The Trend 90 is an average of blood glucose results. Always use your current result for immediate treatment decisions.

1. **From the Main Menu, press ^ or v to highlight Trend 90 and press OK**



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



Example

1	Current 90-day average
2	Newest average point
3	90 Day Average Target set in the meter
4	Oldest average point

2. Press ↶ to return to the Main Menu

7 Syncing your meter

Connecting to a compatible wireless device

Turning the {id_productname_Bluetooth(caps)} feature on or off [t8225367]

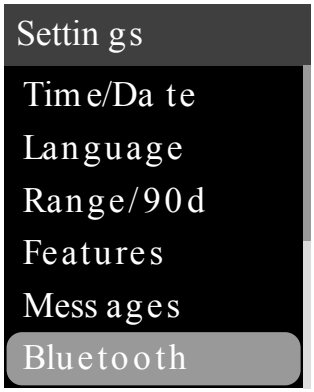
In order to connect your meter with your compatible wireless device, the {id_productname_Bluetooth(caps)} feature will need to be turned on. The symbol will appear on the meter screen when the {id_productname_Bluetooth(caps)} feature is on.

When the symbol is not present on the screen the {id_productname_Bluetooth(caps)} feature is off.

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

   Wait for the Main Menu to appear, then press ^ or v to highlight **Settings** and press OK

2. **On the Settings Menu, highlight Bluetooth and press OK**



A ✓ notes if {id_productname_Bluetooth(caps)} is currently set to On or Off.

3. **Press ^ or v to highlight On or Off and press OK**

   ***NOTE*:** The {id_productname_Bluetooth(caps)} feature will turn OFF during a blood glucose test.

Pairing overview [c8225448]

Pairing allows your {id_productname_meter(Dev)} Meter to communicate with compatible wireless devices. The devices must be within [26 feet][8 meters] of each other to pair and sync. Download the {id_productname_software(Reveal app)} Mobile App on Google Play or from the App Store before pairing your meter and compatible wireless device.

***NOTE*: [(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)]Some diabetes management apps, including the {id_productname_software(Reveal app)} Mobile App, may not be available in your country. Visit {id_csweb} to learn if the {id_productname_software(Reveal app)} Mobile App is available in your country.[]**

Multiple {id_productname_meter(Dev)} 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 85 for pairing instructions.

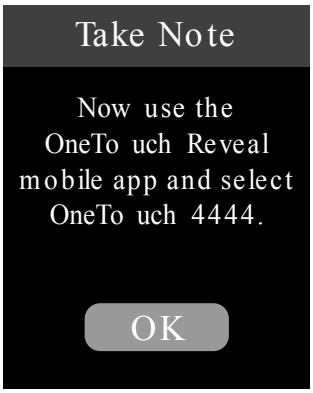
Your {id_productname_meter(Dev)} Meter can be paired with multiple compatible wireless devices. To pair multiple compatible wireless devices, repeat the pairing instructions for each compatible wireless device.

Pairing instructions [t8212415]

The {id_productname_Bluetooth(caps)} feature must be turned on in order to pair the meter with the app. See page 83.

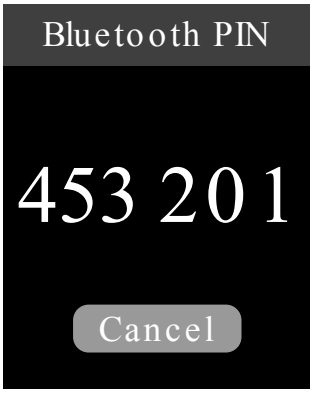
1. **Open the {id_productname_software(Reveal app)} Mobile App and follow instructions to pair the meter with your compatible wireless device**
2. **Look for "OneTouch" and the last 4 characters of the meter serial number on the compatible wireless device display to correctly identify your meter**

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



Example

3. **When prompted by the {id_productname_software(Reveal app)} Mobile App, the meter will display a six digit PIN number**



Example PIN

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

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

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

Sending your results to the app [c8225493]

If the {id_productname_Bluetooth(caps)} feature on the meter is turned on, indicated by the {id_productname_Bluetooth(caps)} symbol ( ), the meter will automatically send your results to any paired compatible wireless device.

The Sync symbol ( ) flashes on the meter display. After syncing, the Sync symbol will disappear and the app will display a list of any new results sent from the meter. You can then share your results with your caregiver or healthcare professional.

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

***NOTE*:** The compatible wireless device must have the app open and have already been paired to the meter before sending a result. See page 84.

***NOTE*:** If the {id_productname_Bluetooth(caps)} 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 {id_productname_Bluetooth(caps)} 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 {id_productname_Bluetooth(caps)} feature on both devices is running (indicated by) and the devices are within [26 feet][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.

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

***NOTE*:**

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

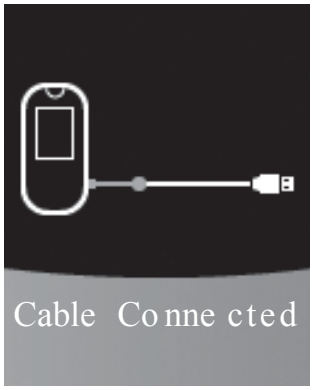
Downloading results to a computer [c8213632]

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

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 {id_productname_meter(Dev)} Meter to a computer to download results (not included).

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



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

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

8 Adjusting meter settings

Settings Menu overview [c8212043]

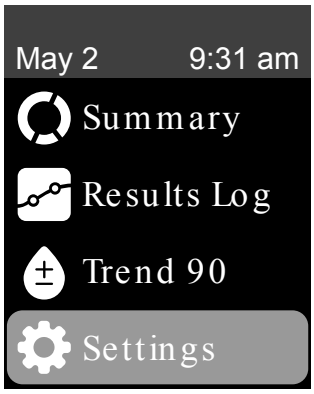
After first time setup, you can use the Settings Menu to adjust the meter settings and access additional features.

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

***NOTE*:** For information on **Bluetooth**, see page 19. For information on **Control Test**, see page 60.

Navigating to the Settings Menu [t8261327]

From the Main Menu, press ^ or v to highlight Settings and press OK



The Settings Menu is displayed.

Adjusting the time and date [t8212085]

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

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

1. **From the Settings Menu, press ^ or v to highlight Time/Date and press OK**
2. **Highlight the time or date and press OK**
3. **Adjust the desired setting and press OK**
   Repeat this step as necessary.

Adjusting the language [t8212138]

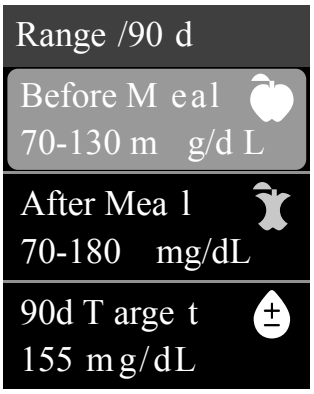
1. **From the Settings Menu, press ^ or v to highlight Language and press OK**
   A ✓ appears next to the current language set in the meter.
2. **Highlight the desired language, then press OK**
   The Settings Menu will be displayed in the new language you have selected.

Adjusting range limits and 90 Day Average Target [t8212162]

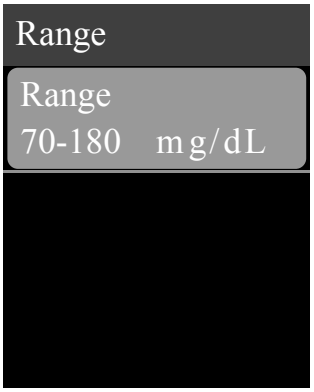
***NOTE*:**

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

1. **From the Settings Menu, press ^ or v to highlight Range/90d (or Range for Basic Mode) and press OK**
   Your current meter settings are displayed.

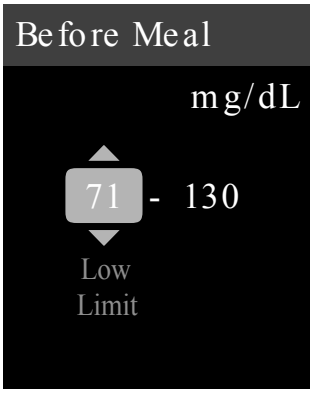


Example - Basic Mode Off



Example - Basic Mode On

2. **Highlight the range setting to be adjusted and press OK**
3. **Adjust the Low Limit and press OK**



Example - Before Meal

Repeat this step to change the High Limit. See page 31 for information about Before and After Meal low and high limits.

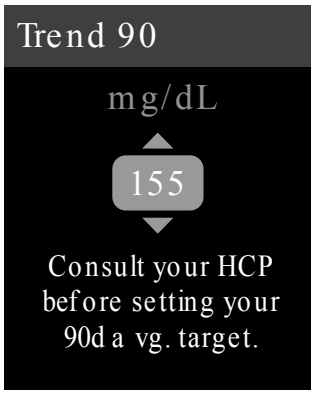
***NOTE*:** In Basic Mode, range limits are general and are not defined by mealtime. General range limits are pre-set.

Table 8: General range limits

pre-set low limit	[(DEKRA-EU FDA-US MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)70 mg/dL][(DEKRA-EU FDA-US MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)3.9 mmol/L][(HC-CA)4.0 mmol/L]
pre-set high limit	[180 mg/dL][10.0 mmol/L]
low limit must be set within	[60 mg/dL][3.3 mmol/L] and [110 mg/dL][6.1 mmol/L]
high limit must be set within	[90 mg/dL][5.0 mmol/L] and [300 mg/dL][16.7 mmol/L]

4. **To adjust the 90 Day Average Target, highlight the 90d Target setting and press** OK

5. **Adjust the 90 Day Average Target and press** OK



The meter is pre-set with a 90 Day Average Target of [155 mg/dL][8.6 mmol/L]. The minimum 90 Day Average Target is [99 mg/dL][5.5 mmol/L] and the maximum is [265 mg/dL][14.7 mmol/L].

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

Turning Basic Mode on or off [t8212230]

***NOTE*:** Selecting Basic Mode affects the information the meter displays. See page 37 for more information.

1. **From the Settings Menu, press ^ or v to highlight Features and press OK**
   The Features Menu indicates whether Basic Mode is currently on or off.
2. **Highlight Basic Mode and press OK**
   A ✓ appears next to the current mode set in the meter.
3. **Highlight On or Off and press OK**
   In Basic Mode, Test Tracker and Range Indicator are removed from the Features Menu.
   Basic Mode uses pre-set general range limits which are different from the ones set during first time setup. See page 90 for information on adjusting range limits.

Turning the Test Tracker on or off and setting a Daily Test Goal [t8212304]

1. **From the Settings Menu, press ^ or v to highlight Features and press OK**
   The Features Menu indicates the current Test Tracker setting.

   ***NOTE*:** If Basic Mode is selected the Test Tracker will not appear in the Features Menu.
2. **Highlight Test Tracker and press OK**
3. **Adjust the Daily Test Goal, then press OK**
   The meter is pre-set with a Daily Test Goal of four tests per day. The maximum Daily Test Goal is eight.

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

   To turn off the Test Tracker, press ^ or v until **Off** is highlighted, and press OK.

Set the Range Indicator icon to emoji or text [t8942044]

1. **From the Settings Menu, press ^ or v to highlight Features and press OK**
   Your current meter settings are displayed.
2. **Highlight Range Indicator and press OK**
   A ✓ appears next to the current setting in the meter.
3. **Highlight Emoji or Text, then press OK**

Turning Pattern Messages, Mentor Tips and Awards on or off [t8212378]

***NOTE*:**

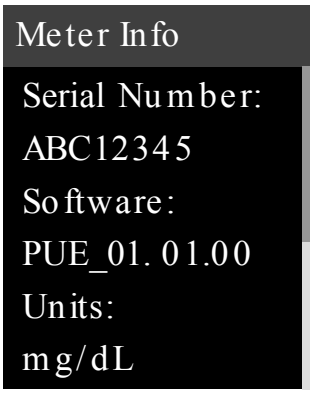
- Basic Mode must be turned off for the Messages Menu to appear in Settings. See page 92.
- If Pattern Messages are turned off, you will no longer see Patterns with results, Summary or Results Log screens. The meter will continue to track Pattern information. If you turn Pattern Messages back on again, Pattern icons will be displayed in the Summary and Results Log. See page 71 for more information about Pattern Messages.
- If Mentor Tips are turned off, you will no longer see Mentor Tips with results. See page 73 for more information about Mentor Tips.
- If Awards are turned off, you will no longer see Awards with results or in the Summary view. See page 74 for more information about Awards.

1. **From the Settings Menu, press ^ or v to highlight Messages and press OK**
   Your current meter settings are displayed.
2. **Highlight Pattern, Mentor Tips or Awards and press OK**
   A ✓ appears next to the current setting in the meter.
3. **Highlight On or Off and press OK**

View meter info and last sub-error code [t8212463]

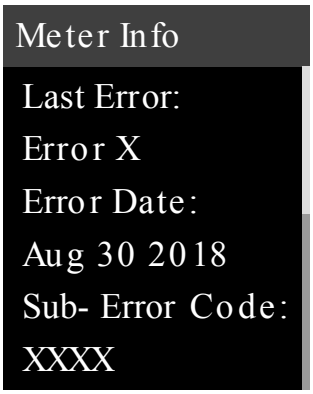
The meter serial number, software version, and information about the last meter sub-error are stored in your meter. You can check this information at any time and use it for troubleshooting.

1. **From the Settings Menu, press ^ or v to highlight Meter Info and press OK**
   The meter serial number, software version, and unit of measure are displayed.



Example

2. Press to view information about the last meter error



Example

Pressing returns you to the Settings Menu.

9 Caring for your system

Storing your system [c8213651]

[(FDA-US)Once opened, store your meter, test strips, control solution and other items in your carrying case. Keep in a cool, dry place between [(FDA-US)41°F and 86°F] [(FDA-US)5°C and 30°C] and below 65% relative humidity. Keep away from direct sunlight and heat. **Do Not** store the test strip vial in rooms where the air is humid such as the kitchen, laundry room or bathroom. Exposure to temperatures outside the storage limits, as well as moisture and humidity, may cause inaccurate readings.]

[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)Store your meter, test strips, control solution and other items in your carrying case. Keep in a cool, dry place between [(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)41°F and 86°F][(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)5°C and 30°C]. **Do Not** refrigerate. Keep all items away from direct sunlight and heat. Exposure to temperatures outside the storage limits, as well as moisture and humidity, may cause inaccurate readings.]

Cleaning and disinfection [c8249145]

This content is only displayed in countries regulated by: FDA-US

Cleaning and disinfection are different. Both should be performed at least once per week. Cleaning is part of your normal care and maintenance, but does not kill germs. You should clean your meter, lancing device and cap before disinfecting. After use and exposure to blood, all parts of this kit may transmit infectious diseases. Disinfection is the only way to reduce your exposure to disease.

For cleaning information, see page 98 and for disinfecting information, see page 100.

For cleaning and disinfecting, Clorox® Germicidal Wipes* containing 0.55% sodium hypochlorite as the active ingredient have been shown to be safe for use with the {id_productname_meter(Dev)} System and can be obtained from retail websites offering disinfection products, e.g., www.officedepot.com or www.staples.com. For more information on purchase options, visit www.onetouch.com/disinfection, or contact Customer Service. Contact information for Customer Service is listed at the end of this Owner's Booklet.

*Other products, such as Clorox® Disinfecting Wipes, have not been tested and should not be used. Only Clorox® Germicidal Wipes should be used. Follow manufacturer's instruction for handling and storage of wipes. Clorox® is a registered trademark of the Clorox Company.

⚠ **IMPORTANT:** If another person assists you with testing, the meter, lancing device and cap should always be cleaned and then disinfected prior to use by that person.

Cleaning and disinfection [c8249167]

This content is only displayed in countries regulated by: DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR

Cleaning and disinfection are different and both should be performed. Cleaning is part of your normal care and maintenance and should be performed prior to disinfection, but cleaning does not kill germs. Disinfection is the only way to reduce your exposure to disease. For cleaning information, see page 99, and for disinfection, see page 102.

Cleaning your meter, lancing device and cap [t8213664]

This content is only displayed in countries regulated by: FDA-US

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

1. **Use a Clorox® Germicidal Wipe to wipe the outside of the meter and lancing device**

   To clean your meter, hold it with the test strip port pointed down. Be sure to squeeze out any excess liquid before you wipe the meter.

   Wipe the outside of the lancing device cap.

2. **Wipe dry with a clean, sterile gauze**

Cleaning your meter, lancing device and cap [t8213690]

This content is only displayed in countries regulated by: DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR

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][a ½ teaspoon] of regular strength liquid dish soap into [250 mL][a cup] 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 27.)
- **Do Not** spray cleaning solution on the meter or immerse it in any liquid.

1. **Holding the meter with the test strip port pointed down, use a soft cloth dampened with water and mild detergent to wipe the outside of the meter and lancing device**

   Be sure to squeeze out any excess liquid before you wipe the meter. Wipe the outside of the cap.

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

Disinfecting your meter, lancing device and cap [t8213728]

This content is only displayed in countries regulated by: FDA-US

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

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

   Follow step 1 of page 98.

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

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

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

3. **Wipe dry with a clean, sterile gauze**

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

- **Do Not** use alcohol or any other solvent.
- **Do Not** allow liquids, dirt, dust, blood or control solution to enter the test strip port or the data port.
- **Do Not** squeeze the germicidal wipe into test strip port.
- **Do Not** spray cleaning solution on the meter and lancing device.
- **Do Not** immerse the meter and lancing device in any liquid.

The {id_productname_meter(Dev)} System withstood cleaning and disinfection cycles well in excess of LifeScan's recommendation. See page 101 for more details.

Examples of damage to the meter may include fogged display, cracked housing or lens, illegible labels, button not working or meter malfunction (such as repeated error messages). Examples of damage to the lancing device and cap may include cracking, illegible depth setting numbers and lancing device malfunction (such as failure to load, cock or release).

Do Not use your meter or lancing device if you see evidence of such damage. If you have questions about cleaning or disinfecting, or if you see evidence of physical damage, contact Customer Service. Contact information for Customer Service is listed at the end of this Owner's Booklet.

Cleaning and disinfecting cycles [c8213820]

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The meter can be cleaned daily for 4 years and has been tested up to 3316 cleaning cycles.

The meter can be disinfected weekly for 4 years, and has been tested up to 475 cleaning and disinfection cycles.

The lancing device and cap can be cleaned daily for 3 years and have been tested up to 2829 cleaning cycles.

The lancing device and cap can be disinfected weekly for 3 years, and have been tested up to 412 cleaning and disinfection cycles.

Disinfecting your meter, lancing device and cap [t8213785]

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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)*. **[(DEKRA-EU MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**Prepare a solution of 1 part household bleach and 9 parts water.**][(HC-CA)**Prepare a solution of 1 part household bleach and 9 parts water or obtain equivalent (0.55% sodium hypochlorite*) wipes.**]**

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

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

   [(DEKRA-EU MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR) 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.**]**

   [(HC-CA) Use a soft cloth dampened with this solution or a 0.55% equivalent sodium hypochlorite wipe 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. **[(DEKRA-EU MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)After wiping, cover the surface you are disinfecting with the soft cloth dampened with the bleach solution for 1 minute][(HC-CA)After wiping, cover the surface you are**

disinfecting with the soft cloth dampened with the bleach solution or 0.55% equivalent sodium hypochlorite wipe 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 information for Customer Service is listed at the end of this Owner's Booklet.

10 Batteries

Replacing the batteries [t8213843]

Your {id_productname_meter(Dev)} Meter uses 2x CR2032 lithium batteries. One battery powers the meter only and the other powers the backlight. See page 116 for information on when to change the meter batteries.

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

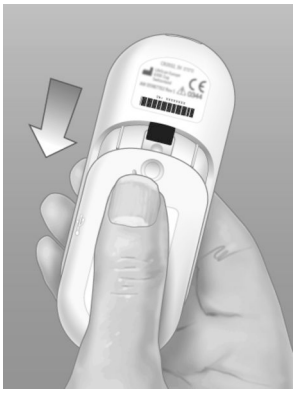
Do Not change the batteries when connected to a PC.

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

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

1. **Remove the old batteries**

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

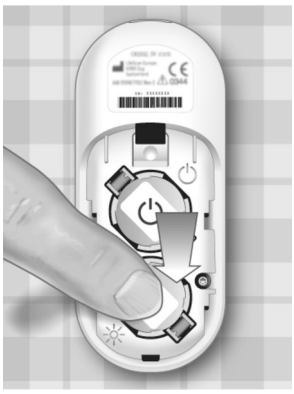


   Pull up firmly on the plastic ribbons. The plastic ribbon with the ⏻ symbol is for the meter battery, and the plastic ribbon with the ☼ symbol is for the backlight battery. Always change both batteries at the same time.

2. **Insert the new batteries**

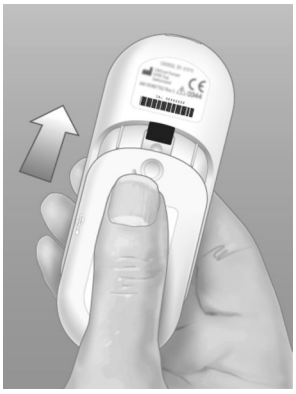
   With the "+" side facing up toward you, place each battery in the compartment within the fold of the plastic ribbon.

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



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

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



3. **Check your meter settings**

   You will be prompted to set the time and date whenever you change the batteries. See page 90.

4. **Dispose of batteries**

[(DEKRA-EU FDA-US HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU) Dispose of batteries according to your local environmental regulations.**]**

[(ANVISA-BR) It is important to dispose of used batteries correctly to avoid harm to the environment. The batteries are considered hazardous waste. After use, remove the batteries from the meter and dispose of them in appropriate locations.**]**

11 Multi-patient use testing

Healthcare professional information [c9006368]

Only healthcare professionals working in a professional capacity in healthcare settings may perform blood glucose tests on more than one patient using the {id_productname_meter(Dev)} Meter. Always follow recognized procedures for handling objects that are potentially contaminated with human material when using the meter.

⚠ **CAUTION:**

- **Any patient with an infection or suffering from an infectious disease, or is suspected to be, and any patient who is a carrier of a multi-resistant microorganism must be assigned his/her own meter. During this time the meter must not be used to test any other patient.**
- Patients and medical staff are potentially at risk of becoming infected if the same {id_productname_meter(Dev)} Meter is used to test blood glucose in more than one patient. All objects that come into contact with human blood are potential sources of infection.
- When testing multiple patients, it is important to follow your institution's policies and local standards and guidelines that apply to your region.
- Follow your institution's policy and procedure guidelines for when to perform a control solution test.
- Follow your institution's policy for treating hypoglycemia and hyperglycemia.
- The patient's hands should be washed with warm water and soap or cleaned with an alcohol wipe and then dried well prior to testing.
- Results may be falsely low if the patient is severely dehydrated.
- If uncertain about which patient a blood glucose test result belongs to, **retest prior to treatment.**
- **Do Not** use results stored in the Results Log to make immediate treatment decisions. The meter stores up to 750 past results and these may be from multiple patients. Always use the current result for immediate treatment decisions.
- If a single meter is used to test more than one patient, the meter must be **disinfected after each patient**, (see page 102) whether or not blood- or body fluid-contamination is suspected.
- Follow your institution's policy/guidelines for proper disposal of meter and test strips.
- If used for a single patient and a risk of contamination exists, the meter should be disinfected after each use.
- If used for a single patient clean the meter at least once per week.

Personal protective equipment

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

Lancing devices

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

***NOTE*:**

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

Meter

- It is recommended that the meter is set to Basic Mode for multi-patient use.
- It is important to follow your institution's policies and guidelines before changing any meter settings.
- If possible, a separate {id_productname_meter(Dev)} Meter should be assigned to each patient, and used only to test that patient.
- If the meter is being used with multiple patients, the previous result may belong to a different patient.

Lifespan of meter:

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

Applying blood samples [t9028437]

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

Follow all instructions for performing a blood glucose test. See page 39.

12 Troubleshooting

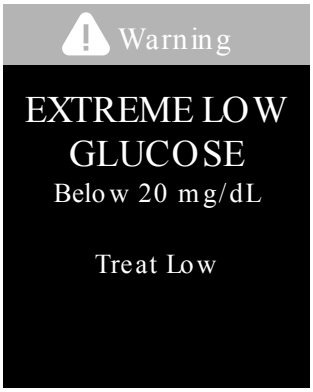
Error and other messages [c7391893]

The {id_productname_meter(Dev)} Meter displays messages when there are problems with the test strip, with the meter or when your glucose levels are above [600 mg/dL] [33.3 mmol/L] or below [20 mg/dL][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 information for Customer Service is listed at the end of this Owner's Booklet.

***NOTE*: [(MHLW-JP)]If you follow the instructions on the display but the same messages continue to appear, follow the instructions in this Owner's Booklet or contact Customer Service.]**

(GC only:) Extreme low glucose [c8213880]



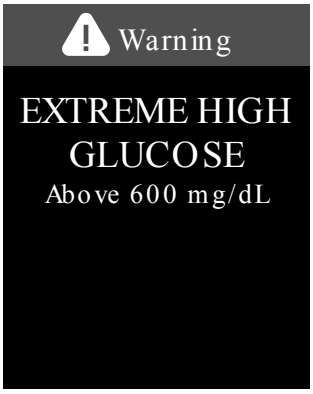
What it means

You may have a very low blood glucose level (severe hypoglycemia), below [20 mg/dL] [1.1 mmol/L].

What to do

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

(GC only:) Extreme high glucose [c8213930]



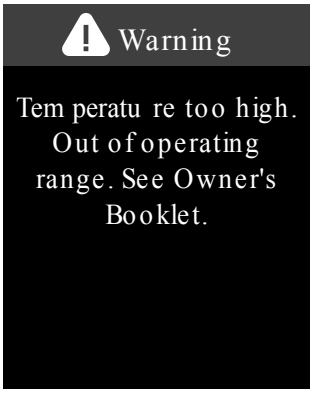
What it means

You may have a very high blood glucose level (severe hyperglycemia), over [600 mg/dL] [33.3 mmol/L].

What to do

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

(GC only:) Temperature too high [c8213904]



What it means

Meter is too hot (above **[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**44°C**][(FDA-US)**40°C**][(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**111°F**][(FDA-US)**104°F**]**) to perform a test.

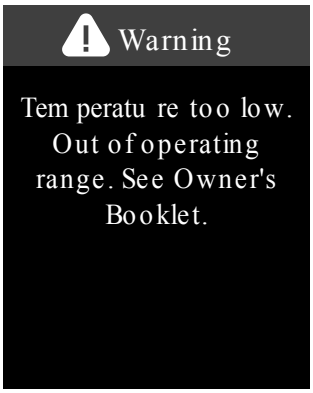
What to do

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 (**[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)**6-44°C**][(FDA-US)**10-40°C**][(DEKRA-EU HC-CA**

MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)43-111°F][(FDA-US)50-104°F]). If you do not get another **Temperature too high** message, you can proceed with testing.

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

(GC only:) Temperature too low [c8213954]



What it means

Meter is too cold (below [(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)6°C][(FDA-US)10°C][(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)43°F][(FDA-US)50°F]) to perform a test.

What to do

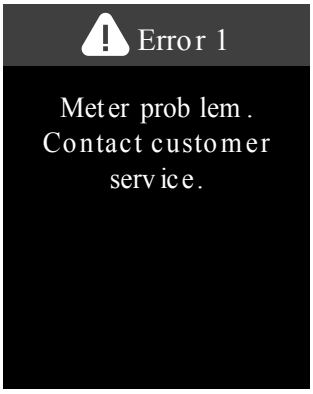
Move the meter and test strips to a warmer area. Insert a new test strip when the meter and test strips are within the operating range ([(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)6-44°C][(FDA-US)10-40°C][(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)43-111°F][(FDA-US)50-104°F]). If you do not get another **Temperature too low** message, you can proceed with testing.

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

Error Screens [c8213980]

If there is a problem with the meter, the following error screens may appear. If you cannot resolve the error with your meter, contact Customer Service. They will refer to the error number, and a sub-error code found in the Meter Info screen, to help troubleshoot the problem. See page 94 for more information on viewing the Meter Info screen.

(GC only:) Error 1 [c8213994]



What it means

There is a problem with the meter.

What to do

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

(GC only:) Error 2 [c8214010]

What it means

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

What to do

Repeat the test with a new test strip; see page 39 or page 60. If this message continues to appear, contact Customer Service. Contact information for Customer Service is listed at the end of this Owner's Booklet.

(GC only:) Error 3 [c8214039]

What it means

The sample was applied before the meter was ready.

What to do

Repeat the test with a new test strip. Apply a blood or control solution sample only after the **Apply Blood** or **Apply Control Solution** screen appears on the display. If this message continues to appear, contact Customer Service. Contact information for Customer Service is listed at the end of this Owner's Booklet.

(GC only:) Error 4 [c8214052]

What it means

One of the following may apply:

- Not enough blood or control solution was applied or more was added after the meter began to count down.
- The test strip may have been damaged or moved during testing.
- The sample was improperly applied.
- There may be a problem with the meter.

What to do

Repeat the test with a new test strip; see page 39 or page 60. If the error message appears again, contact Customer Service. Contact information for Customer Service is listed at the end of this Owner's Booklet.

(GC only:) Error 5 [c8214071]

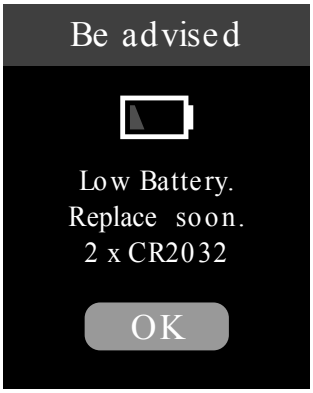
What it means

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 39 or page 60. If the error message appears again, contact Customer Service. Contact information for Customer Service is listed at the end of this Owner's Booklet.

(GC only:) Battery Power Low [c8214085]



What it means

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

What to do

Press OK to continue, but replace the batteries as soon as possible.

(GC only:) Battery Power Empty [c8214118]

What it means

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

What to do

Replace the batteries immediately.

13 System information

Comparing meter results to laboratory results [c8758524]

Results obtained from the {id_productname_meter(Dev)} 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 {id_productname_meter(Dev)} Meter is considered accurate when it is within [15 mg/dL][0.83 mmol/L] of a laboratory method when the glucose concentration is lower than [(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)100 mg/dL][(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)5.55 mmol/L][(FDA-US)75 mg/dL][(FDA-US)4.5 mmol/L] and within 15% of a laboratory method when the glucose concentration is [(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)100 mg/dL][(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)5.55 mmol/L][(FDA-US)75 mg/dL][(FDA-US)4.5 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 [70 mg/dL][3.9 mmol/L] higher than a lab test using blood drawn from a vein.[1]
- Your hematocrit is above 60% or below 20%.
- You are severely dehydrated.

For additional information, refer to the {id_productname_ts} Test Strip Insert.

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

[(DEKRA-EU FDA-US HC-CA MOH-SA SFDA-CN TGA-AU ANVISA-BR)Guidelines for obtaining an accurate meter to lab comparison] [(MHLW-JP)Important notes about obtaining an accurate meter to lab comparison] [c4564225]

[(DEKRA-EU FDA-US HC-CA MOH-SA SFDA-CN TGA-AU ANVISA-BR)Before going to the lab:][(MHLW-JP)Before performing a test for meter to lab comparison:]

- Perform a control solution test to make sure your meter is working properly.
- [(DEKRA-EU FDA-US HC-CA MOH-SA SFDA-CN TGA-AU ANVISA-BR)**Do Not** eat for at least 8 hours before you test your blood.]
- [(MHLW-JP)**Do Not** eat for at least 8 hours before you test your blood for meter to lab comparison.]

- [(DEKRA-EU FDA-US HC-CA MOH-SA SFDA-CN TGA-AU ANVISA-BR)Take your meter and testing supplies with you to the lab.]
- [(MHLW-JP)Take your meter and testing supplies with you to the medical institution.]

Testing with your {id_productname_meter(Dev)} 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 [r8214165]

Assay method	FAD-GDH (flavin adenine dinucleotide dependent glucose dehydrogenase)
Automatic shutoff	Two minutes after last action
Battery ratings	Two 3.0 V d.c., (2x CR2032 batteries), ⎓ 15 mA
Battery type	2 replaceable 3.0 Volt CR 2032 lithium batteries (or equivalent)
{id_productname_Bluetooth(caps)} technology	Frequency range: 2.4-2.4835 GHz Maximum power: 0.4 mW Operating Range Distance: minimum [26.25 feet] [8 meters] (unobstructed) Operating Channels: 40 Channels Security Encryption: 128-bit AES (Advanced Encryption Standard)
Calibration	Plasma-equivalent
Data port type	Compatible with micro USB 2.0
Memory	750 test results
Operating ranges	[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)43-111°F][(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)6-44°C][(FDA-US)50-104°F][(FDA-US)10-40°C]

Table continued…

	Relative humidity: Non-condensing 10-90% Altitude: up to [10,000 feet][3048 meters] Hematocrit: 20 - 60%
Reported result range	[20-600 mg/dL][1.1-33.3 mmol/L]
Sample	Fresh capillary whole blood
Sample volume	0.4 µL
Size	[1.69(W) x 3.97(L) x 0.61(T) inches][43.0(W) x 101.0(L) x 15.6(T) mm]
Test time	Approximately 5 seconds
Unit of measure	[mg/dL][mmol/L]
Weight	Approximately [<1.87 ounces][<53 grams]

System accuracy [c8758562]

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Diabetes experts have suggested that [(DEKRA-EU MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)glucose meters][(HC-CA)95% of glucose meter results] should agree within [15 mg/dL][0.83 mmol/L] of a laboratory method when the glucose concentration is lower than [100 mg/dL][5.55 mmol/L], and within 15% of a laboratory method when the glucose concentration is [100 mg/dL][5.55 mmol/L] or higher.

Samples from TBD patients were tested using both the {id_productname_meter(Dev)} System and the YSI 2900 Glucose Analyzer laboratory instrument.

System accuracy results for glucose concentrations <[100 mg/dL] [5.55 mmol/L] [r8758575]

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

Within ±[5 mg/dL] [0.28 mmol/L]	**Within ±[10 mg/dL] [0.56 mmol/L]**	**Within ±[15 mg/dL] [0.83 mmol/L]**
TBD% (TBD/TBD)	TBD% (TBD/TBD)	TBD% (TBD/TBD)

System accuracy results for glucose concentrations ≥[100 mg/dL] [5.55 mmol/L] [r8758604]

This content is only displayed in countries regulated by: DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR

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

Within ±5%	Within ±10%	Within ±15%
TBD% (TBD/TBD)	TBD% (TBD/TBD)	TBD% (TBD/TBD)

System accuracy results for glucose concentrations between [TBD mg/dL] [TBD mmol/L] and [TBD mg/dL][TBD mmol/L] [r8758627]

This content is only displayed in countries regulated by: DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR

Within ±[15 mg/dL][0.83 mmol/L] or ±15%
TBD% (TBD/TBD)

***NOTE*:** Where [TBD mg/dL][TBD mmol/L] represents the lowest glucose reference value and [TBD mg/dL][TBD mmol/L] represents the highest glucose reference value (YSI value).

Regression statistics [r8758652]

This content is only displayed in countries regulated by: DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR

Samples were tested in duplicate on each of three test strip lots.

# of Subjects	# of Tests	Slope	Intercept [(mg/dL)] [(mmol/L)]
TBD	TBD	TBD	[TBD][TBD]

95% CI Slope	95% CI Intercept [(mg/dL)][(mmol/L)]	Std. Error ($S_{y.x}$) [(mg/dL)][(mmol/L)]	R^2
TBD to TBD	[TBD to TBD][TBD to TBD]	[TBD][TBD]	TBD

User performance accuracy [c8758705]

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

TBD% within ±[15 mg/dL][0.83 mmol/L] of the medical laboratory values at glucose concentrations below [100 mg/dL][5.55 mmol/L], and TBD% within ±15% of the medical laboratory values at glucose concentrations at or above [100 mg/dL][5.55 mmol/L].

TBD% of the total number of samples were within ±[15 mg/dL][0.83 mmol/L] or ±15% of the medical laboratory values.

Precision [r8758720]

This content is only displayed in countries regulated by: DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR

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

Data generated using the {id_productname_meter(Dev)} Meter.

Target Glucose [(mg/dL)][(mmol/L)]	Mean Glucose [(mg/dL)][(mmol/L)]	Standard Deviation [(mg/dL)][(mmol/L)]	Coefficient of Variation (%)
[TBD][TBD]	[TBD][TBD]	[TBD][TBD]	TBD
[TBD][TBD]	[TBD][TBD]	[TBD][TBD]	TBD
[TBD][TBD]	[TBD][TBD]	[TBD][TBD]	TBD
[TBD][TBD]	[TBD][TBD]	[TBD][TBD]	TBD
[TBD][TBD]	[TBD][TBD]	[TBD][TBD]	TBD

Total Precision (TBD Control Solution Tests per Glucose Level)

Data generated using the {id_productname_meter(Dev)} Meter.

Glucose Level Ranges [(mg/dL)] [(mmol/L)]	Mean Glucose [(mg/dL)] [(mmol/L)]	Standard Deviation [(mg/dL)][(mmol/L)]	Coefficient of Variation (%)
[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)Low] [(25-49)][(1.39–2.72)]	[TBD][TBD]	[TBD][TBD]	TBD

Table continued…

Glucose Level Ranges [(mg/dL)] [(mmol/L)]	Mean Glucose [(mg/dL)] [(mmol/L)]	Standard Deviation [(mg/dL)][(mmol/L)]	Coefficient of Variation (%)
[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)Mid] [(102-138)] [(5.67-7.67)]	[TBD][TBD]	[TBD][TBD]	TBD
[(DEKRA-EU HC-CA MHLW-JP MOH-SA SFDA-CN TGA-AU ANVISA-BR)High] [(298-403)] [(16.56-22.39)]	[TBD][TBD]	[TBD][TBD]	TBD

Lay user accuracy [c8758867]

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User Accuracy of the system was assessed at TBD clinical sites. TBD patients tested their blood using the {id_productname_meter(Dev)} System where results were compared to the YSI 2900 Glucose Analyzer laboratory instrument.

Fingertip results for glucose concentrations <[75 mg/dL][4.2 mmol/L] [r8758873]

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

Within ±[5 mg/dL] [0.28 mmol/L]	Within ±[10 mg/dL] [0.56 mmol/L]	Within ±[15 mg/dL][0.83 mmol/L]
TBD% (TBD/TBD)	TBD% (TBD/TBD)	TBD% (TBD/TBD)

Fingertip results for glucose concentrations ≥[75 mg/dL][4.2 mmol/L] [r8758902]

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

Within ±5%	Within ±10%	Within ±15%	Within ±20%
TBD% (TBD/TBD)	TBD% (TBD/TBD)	TBD% (TBD/TBD)	TBD% (TBD/TBD)

Regression statistics [r8758928]

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Samples were tested on each of three test strip lots. Results indicate that the {id_productname_meter(Dev)} System compares well with a laboratory method.

# of Subjects	# of Tests	Slope	Intercept [(mg/dL)]
TBD	TBD	TBD	[TBD]

95% CI Slope	95% CI Intercept [(mg/dL)]	Std. Error ($S_{y.x}$) [(mg/dL)]	R^2
TBD to TBD	[TBD to TBD]	TBD	TBD

Precision [r8758975]

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

Data generated using the {id_productname_meter(Dev)} Meter.

Target Glucose [(mg/dL)]	Mean Glucose [(mg/dL)]	Standard Deviation [(mg/dL)]	Coefficient of Variation (%)
[TBD]	[TBD]	[TBD]	TBD
[TBD]	[TBD]	[TBD]	TBD
[TBD]	[TBD]	[TBD]	TBD
[TBD]	[TBD]	[TBD]	TBD
[TBD]	[TBD]	[TBD]	TBD

Results show that the greatest variability observed between test strips when tested with blood is [TBD mg/dL] SD or less at glucose levels less than [75 mg/dL] or TBD% CV or less at glucose levels at [75 mg/dL] or above.

Total Precision (TBD Control Solution Tests per Glucose Level)

Data generated using the {id_productname_meter(Dev)} Meter.

Glucose Level Ranges [(mg/dL)]	Mean Glucose [(mg/dL)]	Standard Deviation [(mg/dL)]	Coefficient of Variation (%)
[(FDA-US)Level 2] [(25-49)]	TBD	TBD	TBD
[(FDA-US)Level 3] [(102-138)]	TBD	TBD	TBD
[(FDA-US)Level 4] [(298-403)]	TBD	TBD	TBD

Guarantee [c9087573]

LifeScan guarantees that the {id_productname_meter(Dev)} Meter will be free of defects in material and workmanship for three years, valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable. If the meter stops working or a defect occurs on any part, contact Customer Service. Contact information for Customer Service is listed at the end of this Owner's Booklet.

Electrical and safety standards [c8214807]

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 TBD.

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

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

[r8759090]

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