ONE DROP

Blood Glucose Monitoring System

OWNER'S GUIDE

Welcome to Your One Drop Blood Glucose Monitoring System

The One Drop Meter works with the One Drop for Diabetes App for iOS, or Android™ (the "One Drop App" or "App") installed on a supported device. Data is transmitted between the One Drop Meter and the One Drop App via *Bluetooth®* wireless technology.

Key Features in the One Drop Meter

Convenient Connection – The One Drop Meter uses *Bluetooth®* wireless technology for an easy to use wireless connection to supported devices.

Seamlessly Sync Results to App – Use the One Drop Meter with the One Drop App to sync glucose results directly to your iOS or Android™ device. The One Drop App can be used to conveniently store and manage your diabetes information, review trends, or share with your healthcare team. It can be downloaded from the App Store℠ or on Google Play™.

Small Size – The One Drop Meter is small and portable, for easy testing on the go.

System Requirements (One Drop Meter and One Drop App)

The One Drop Meter is compatible with devices running iOS 8.3 and above or Android™ 5.1 and above.

ONE DROP

Blood Glucose Monitoring System

Customer Service 1 (800) 437-1474
customerservice@onedrop.today

In case of emergency, contact your healthcare professional or emergency medical response.

By using the One Drop Blood Glucose Monitoring System (Meter) with the One Drop App (the App).
You agree that the use of this software together with an iPod, iPhone or iPad ("Apple Product") shall only be as a personal organization or supplemental data display tool and not as a source of medical advice. You agree that this software will never be used to replace the advice of a doctor, or your own common sense and independent judgment, and that you will not at any time rely on any information presented on your Apple Product as the basis for health care, medical or other decisions that may result in injury or other ill effects. You agree to take sole responsibility for your health care decisions, including contacting a physician or other health care professional regarding all medical conditions, tests, diagnoses and treatment options and agree that Apple shall have no liability for any action you or anyone using the software may take, regardless of the information received, displayed, calculated or transmitted by your Apple Product. Apple assumes no risk for your use of the software and makes no warranties whatsoever, express or implied, regarding the accuracy, completeness or usefulness of any information presented on your Apple Product as a result of using the software.

Designed by One Drop in USA

Manufactured exclusively for One Drop & Informed Data Systems, Inc. by AgaMatrix, Inc.
7C Raymond Avenue
Salem, NH 03079 USA

8100-10216 Rev B

The One Drop Meter is compatible with devices running iOS 8.3 and above or Android™ 5.1 and above.

Contents

CHAPTER 1 Important Information About Your One Drop System

One Drop Blood Glucose Monitoring System Intended Use:

The One Drop Blood Glucose Monitoring System is intended for quantitative measurement of blood glucose (sugar) levels in fresh capillary whole blood samples drawn from the fingertip. It is intended to be used by a single patient and should not be shared.

The One Drop Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

The One Drop Blood Glucose Monitoring System is not intended for use in diagnosis of, or screening for diabetes and not intended for use in neonates.

For use with One Drop Test Strips only. Do not use other brands of test strips with the One Drop Meter as this may produce inaccurate results.

IMPORTANT The One Drop Meter should be carried in the carrying case provided with the meter and not directly in a pocket. If the One Drop Meter is carried in a pocket, it could be damaged.

Limitations

- Not for diagnosis of or screening of diabetes mellitus
- Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill, or in a hyperosmolar state
- Not for persons undergoing Oxygen therapy
- Not for testing the glucose levels in neonates (children under 4 weeks)
- Not for testing glucose levels in arterial or venous blood samples
- Not for testing glucose from sites other than samples drawn from the fingertip

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Getting Started

This Owner's Guide is intended to instruct the user on how to use the One Drop Meter.

Your meter is ready to use right out of the box. Unpack your system. Check that all system contents are included–there is a list of contents in this Owner's Guide. Ensure that the retail carton has not been damaged.

See Chapter 5, Page 16, for more information.

CAUTION: Please read all the instructions provided in this

Owner's Guide and practice the testing procedures before using the One Drop Blood Glucose Monitoring System. Blood glucose monitoring should be done under the guidance of a healthcare professional (HCP).

Important Safety Instructions:

Only one person should use the One Drop Meter, One Drop Lancing Device, and lancets. Never share One Drop Meter, One Drop Lancing Device, or lancets. Used One Drop Meter, One Drop Lancing Device, One Drop Test Strips, and lancets may be considered biohazardous or medical waste in your city or town. Follow your healthcare professional's instructions for disposal.

In case of emergency, contact your healthcare professional or emergency medical response.

Keep the One Drop Meter and testing supplies away from young children. Small items such as One Drop Test Strips, lancets, protective covers on the lancets, and control solution vial cap are choking hazards. Do not ingest or swallow any items.

One Drop Blood Glucose Monitoring System Test Principle:

The One Drop Glucose Monitoring System measures a glucose concentration in a sample of fresh capillary whole blood drawn from the fingertip.

After insertion of a One Drop Test Strip into the One Drop Meter,

a sample of blood obtained by fingerstick is applied to the One Drop Test Strip. The blood sample size for the One Drop Meter is a minimum of 0.5 µL.

The blood reacts with a reagent on the One Drop Test Strip that contains glucose oxidase, an electron mediator, and other materials. The chemical reaction with glucose that takes place on the strip generates an electrical signal that is measured and processed by the One Drop Meter.

The meter computes a glucose concentration and displays the result. The measurement range of the system is 20 to 600 mg/dL glucose. Capillary whole blood samples with a hematocrit range of 20% to 60% can be measured.

The One Drop Meter is calibrated to provide a glucose concentration for a capillary whole blood sample that is equivalent to the plasma glucose concentration of that sample.

One Drop Test Strips

Use the One Drop Test Strips only with the One Drop Meter to quantitatively measure the glucose in fresh capillary whole blood drawn from your fingertip.

AgaMatrix Control Solutions

If you feel your meter is not working correctly, use AgaMatrix Control Solutions Levels 2 and 4, the One Drop Meter, and One Drop Test Strips to ensure that the One Drop Meter and One Drop Test Strips are working together properly and that the

test is performing correctly. To order either Level 2 or Level 4 Control Solution, please contact Customer Service at 1 (800) 437-1474.

Bluetooth® Wireless Technology

Bluetooth® wireless technology is a type of wireless RF (Radio Frequency) communication. Cell phones use *Bluetooth®* wireless technology as do many other devices. Your One Drop Meter uses *Bluetooth®* wireless technology to pair with compatible iOS and Android™ devices to send results to the One Drop App.

Minimum operating system requirements for compatible devices are iOS 8.3 and above or Android™ 5.1 and above.

Note: You should sync your One Drop Meter to the One Drop App to set your One Drop Meter's time and date before testing. This will ensure that results from One Drop Meter are sent wirelessly to the One Drop App. See Chapter 5, Page 16, for more information.

Supported Devices

The One Drop App, is an application that allows users to add, modify, and view health data, including glucose, insulin, carbs, and weight. The One Drop App works on a variety of iOS and Android™ devices. Minimum operating system requirements for compatible devices are iOS 8.3 and above or Android™ 5.1 and above.

When the One Drop App is paired with your One Drop Meter, the data from your One Drop Meter will automatically sync with the One Drop App whenever the two devices are in range and the One Drop Meter is turned on.

CHAPTER 2 Important Safety Instructions

The One Drop Meter and One Drop Lancing Device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For important instructions for disinfecting your meter and lancing device, please read Chapter 9, Page 34.

The Food and Drug Administration (FDA) and the Center for Disease Control (CDC) have issued warnings and notifications regarding the risk of bloodborne pathogen transmission when blood glucose monitoring systems have been used by more than one individual. Please read the following references for more information:

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1. http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm
2. http://www.cdc.gov/injectionsafety/fingerstickdevicesbgm.html
3. http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

- *"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)* [1]

- *"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)* [2]

- *"Infection Prevention during Blood Glucose Monitoring and Insulin Administration" (2012)* [3]

CHAPTER 3 The One Drop Blood Glucose Monitoring System

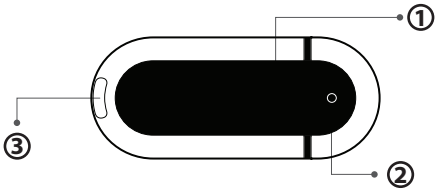
The One Drop Blood Glucose Monitoring System Contains:

- One Drop Blood Glucose Meter
- One Drop Lancing Device with Cap
- One Drop Test Strips — 2 Vials (100 Strips)
- One Drop Compact Carrying Case
- One Drop Owner's Guide
- Lancets — 10 Sterile
- Two Pre-installed CR2032, 3-Volt, Lithium Batteries

CHAPTER 4 About the One Drop Meter, One Drop Test Strips, and One Drop Lancing Device

About the One Drop Meter

Please note the correct orientation of the device in the sample image below.



(1) Display Area: Glucose test results, symbols, and messages appear here.

Inspect the display for damage by viewing the Intro Animation. You will see the Intro Animation every time you insert a One Drop Test Strip or press the meter button. If you see a significant portion of the display not lighting up appropriately, do not use the One Drop Meter and call Customer Service.

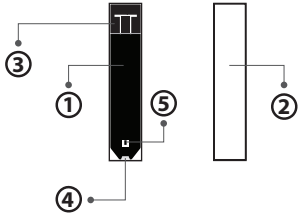
(2) Meter Button: The button is the circle on the front of the One Drop Meter. It is on the opposite side of the One Drop Meter's strip port. It is used to turn on the One Drop Meter and view past glucose test results.

(3) Test Strip Port: Insert the One Drop Test Strip, with the contact bars facing up, into the One Drop Test Strip port.

Note: The batteries are pre-installed in the One Drop Meter.

About the One Drop Test Strips

Use your system and your fingertip to test your blood glucose. Testing with the system requires a small sample size, 0.5µL of blood, about the size of a pinhead.



(1) Front of the One Drop Test Strip The front of the One Drop Test Strip is black in color. Ensure that the front (black-colored) side of the One Drop Test Strip is facing towards you, when inserting a One Drop Test Strip into the One Drop Meter's test strip port.

(2) Back of the One Drop Test Strip The back of the One Drop Test Strip is white in color. Ensure that the back (white-colored) side of the One Drop Test Strip is facing away from you, when inserting a One Drop Test Strip into the One Drop Meter's test strip port.

(3) Contact Bars This end is inserted, front of the One Drop Test Strip facing towards you, into the One Drop Meter's test strip port.

(4) Sample Area Blood should be applied to the tip of the One Drop Test Strip here.

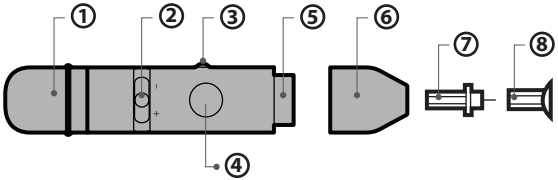
(5) Visual Fill Window This window will turn red when enough blood has been applied.

Important Test Strip Information:

- Store the One Drop Test Strip vial in a cool, dry place at 46°F to 86°F (8°C to 30°C) and at a relative humidity of 10% to 90%.
- Keep away from direct sunlight and heat.
- Store your One Drop Test Strips in their original vial only; never store them in another vial, any other container, or outside the vial.
- With clean, dry hands you may gently handle the One Drop Test Strip when removing it from the vial or inserting it into the One Drop Meter.
- After removing a One Drop Test Strip from the vial, immediately close the vial cap tightly.
- Do not use One Drop Test Strips beyond the expiration date or 180 days after first opening the vial. This may cause inaccurate results. Write the discard date (180 days from the first opening) on the One Drop Test Strip vial.
- Do not bend, cut, or alter One Drop Test Strips.

- Apply only fresh capillary blood to the sample area of the One Drop Test Strip.
- Use One Drop Test Strips only once.
- Only use One Drop Test Strips with the One Drop Meter.
- Dispose of used One Drop Test Strips properly.

About the One Drop Lancing Device



(1) Cocking Handle Cocks the device so it is ready to lance.

(2) Depth Adjustment Slider Adjusts how deep the lancet will lance the skin.

(3) Lancet Ejector Ejects the lancet.

(4) Release Button Fires the lancet.

(5) Lancet Holder Cup Holds the lancet into place inside the lancing device.

(6) Lancing Device Cap Covers the lancet when in lancing device.

(7) Lancet Lances the skin to produce a drop of blood.

(8) Lancet Cover Covers the lancet for safety. Remove after inserting into the lancet holder (cup).

CHAPTER 5 Pairing and Syncing Your One Drop Meter with the One Drop App

The One Drop App is an application that allows users to add, modify, and view health data, including glucose, insulin, carbs, and weight.

If you want to sync readings from your One Drop Meter to the One Drop App and set your One Drop Meter's time and date, you must pair your One Drop Meter with the One Drop App.

When the One Drop App is paired with your One Drop Meter, the data from your One Drop Meter will automatically sync with your One Drop App every time it is within close proximity (10 feet) of your paired device, and the One Drop Meter screen and App are activated.

Compatibility

Minimum operating system requirements for compatible devices are iOS 8.3 and above or Android™ 5.1 and above.

The One Drop App can be downloaded for free from the App Store℠ on your iPhone® or iPod touch® or on Google Play™ on your Android™ device.

IMPORTANT: Please note that the One Drop App stores sensitive health-related information on your supported device. We recommend keeping your supported device up-to-date with the latest security software. For more information on keeping your supported device and information safe, please contact the manufacturer of your supported device.

Pair Versus Sync

All devices that communicate via *Bluetooth*® wireless technology need to first "pair" with each other so they can establish a connection and get authorized to communicate with each other. You will only have to pair your One Drop Meter to another device one time.

After your One Drop Meter is paired with your device, it will "sync", or transfer data, every time it is within close proximity (10 feet) of your paired device, and the One Drop Meter screen and App are activated.

Pairing for the First Time

Before pairing your One Drop Meter with the One Drop App for the first time, the One Drop App must be installed on your supported device. Ensure that the date and time on your supported device is correct.

Note: Test results without a set time and date will be saved to the One Drop Meter in chronological order, but will not sync to the One Drop App when paired. Test results without a set time

and date will be displayed on your One Drop Meter with "--:--" and "--/--" in place of the time and date.

Go to: http://onedrop.today/setup
This website includes up-to-date instructions on how to get set up and pair your meter.

The One Drop Meter and the One Drop App must be within 10 feet of each other in order to pair and transfer data.

Note: Test results taken prior to the time and date being set will not have a time and date associated with them on the One Drop Meter. You can manually add these readings to the One Drop App to include them in your statistics. Test results without a set time and date will be displayed on your One Drop meter with "--:--" and "--/--" in place of the time and date.

Important Pairing Information

The *Bluetooth*® wireless technology feature on your One Drop Meter sends test results to your supported device.

To prevent other people's test results from being sent to your supported device:

[1] Do not let another person test their blood glucose with your One Drop Meter. This meter is for single patient use only.

[2] Do not pair or sync a One Drop Meter used by another person with your supported device. If you pair with another person's One Drop Meter, the data from each One Drop Meter will be combined in the One Drop App and will cause your

logbook history and statistics to be incorrect.

How to Pair an Additional One Drop Meter

Follow the same steps above to pair additional One Drop Meters.

Automatic Data Transfer (Sync)

The first time your One Drop Meter pairs with your supported device it will set the date and time on your One Drop Meter.

Every time your One Drop Meter and supported device are within 10 feet of each other, and the One Drop Meter and One Drop App are activated, any recent data will be transferred to the One Drop App and the date and time will be set to match the date and time on your supported device.

Time and Date

The time and date settings on the One Drop Meter are configured to match the supported device's time and date settings.

For example: if your supported device is set to 12 hour time, the One Drop Meter's time will be set to 12 hour time. If your device is set to 12 hour time, you will see an "a" or "p" next to the time.

Example of 12 hour time:

Example of 24 hour time:

For example: a date of "10/12" will mean Oct 12 if your supported device set to MM/DD, and it will mean Dec 10 if your supported device is set to DD/MM.

Note: Test results taken prior to the time and date being set will not have a time and date associated with them on the One Drop Meter, and will not sync to the One Drop App. You can manually add these readings to the One Drop App to include them in your statistics. Test results without a set time and date will be displayed on your One Drop Meter with "--:--" and "--/--" in place of the time and date.

Airplane Mode

You can keep your One Drop Meter paired with your supported device while flying — just turn Bluetooth on while the device is in Airplane mode.

Force Data Transfer (Sync)

If you suspect that data is not being transferred from the One Drop Meter to the One Drop App, you can force the two to sync.

[1] Open the One Drop App.

[2] On your One Drop Meter, press and hold the Meter Button until the Bluetooth® wireless technology symbol displays with a checkmark.

All new data will transfer to the One Drop App and the One Drop Meter will be set with the time and date of your supported device.

CHAPTER 6 Before You Test Your Blood – Important Health-Related Information

[1] Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. This device should not be used to test critically ill patients.

[2] Severe dehydration and excessive water loss may yield inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.

[3] Patients undergoing oxygen therapy may receive inaccurate results.

[4] Results below 70 mg/dL may mean low blood glucose levels (hypoglycemia).

[5] Results over 240 mg/dL may mean high blood glucose levels (hyperglycemia). Checking ketones may be advisable.

[6] If you get results below 70 mg/dL or above 240 mg/dL and do not have symptoms of hypoglycemia or hyperglycemia, repeat the test. If you have symptoms, or continue to get results that fall below 70 mg/dL or rise above 240 mg/dL, follow the treatment plan recommended by your healthcare provider or contact your healthcare professional immediately.

[7] If you are experiencing symptoms that are not consistent with your blood glucose test and you have followed all instructions described in this Guide, follow your healthcare professional's recommendations.

[8] If you get repeated error messages and are experiencing symptoms of hypo or hyperglycemia, contact your healthcare professional immediately as this may indicate low or high glucose. If this error code persists on retesting, consult your healthcare professional (see Chapter 11: Error Messages).

[9] Do not use One Drop Test Strips that are expired or appear to be damaged, as they may return inaccurate results.

[10] Always follow your healthcare professional's recommendations.

[11] Treatment goals are individualized for each patient. Speak with your healthcare professional about the target

blood glucose ranges that are right for you.

[12] Prior to performing a blood glucose measurement be sure the testing environment is between the operating temperature and relative humidity range of your system (found at the back of this Guide).

Expected Values/Reference Range

Expected blood glucose levels for people without diabetes: Fasting <100 mg/dL, two hours after meals <140 mg/dL.[4]

Test Site

The One Drop Meter only requires a small droplet of blood (0.5 µL), about the size of a pinhead, to perform a glucose test. Test using blood from the tip of any finger.

CAUTION: To ensure accurate results and reduce chance of infection and disease spread by blood, wash your hands and the test site with warm, soapy water, rinse and dry thoroughly before every test. Unwashed hands and test sites may lead to inaccurate results. Make sure there is no grease, oil, or lotion on the test site. Use lancets only once. Do not use any lancing device or lancet that has been used by another person. Always keep your One Drop Meter and One Drop Lancing Device clean.

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4. *American Diabetes Association. Classification and diagnosis of diabetes. Sec. 2. In* Standards of Medical Care in Diabetes—2016. *Diabetes Care 2016;39 (Suppl. 1): S13–S22*

CHAPTER 7 How to Test Your Blood Glucose Level

IMPORTANT: You must pair your One Drop Meter to the One Drop App to be able to sync readings and to set your One Drop Meter's time and date. For instructions on how to pair refer to Chapter 5.

Test results without a set time and date will be saved to the One Drop Meter in chronological order, but will not sync to the One Drop App. Test results without a set time and date will be displayed on your One Drop Meter with "--:--" and "--/--" in place of the time and date.

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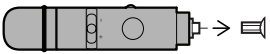
[1] Prepare the One Drop Lancing Device

Remove Lancing Device Cap: Pull off the cap from the lancing device.

Insert New Lancet: Insert a new lancet firmly into the lancet holder cup as shown in the picture below. Pushing the lancet into the lancet holder cup may cock device; this is OK.

Pull the Lancet Cover Off: Hold the lancet firmly in place with one hand and use your other hand to pull off the lancet cover. Keep the lancet cover. It should be used when discarding your used lancet.

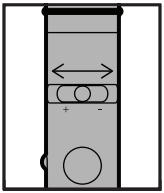


Replace Lancing Device Cap: Replace the lancing device cap until it snaps into place. Be careful not to touch the exposed needle on the lancet.

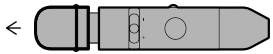
Set the Lancing Level: The One Drop Lancing Device offers five depth settings.

Slide the depth adjustment slider to the desired setting.

If you have never lanced before, it is recommended that you start with slider in the middle position. Slide toward the minus "-" symbol to decrease depth setting.
Slide toward the plus "+" symbol to increase the depth setting.

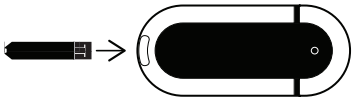


Cock the Handle: Pull the cocking handle out until it clicks. You may have already cocked the handle while inserting the lancet, this is OK.



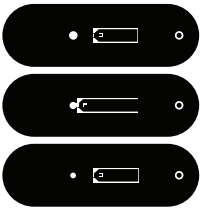
The lancing device is now ready for use.

[2] Insert a Test Strip: Insert a new One Drop Test Strip into the One Drop Meter's test strip port. Make sure you insert the One Drop Test Strip, with the contact bars facing towards you, into the test strip port. The One Drop Meter will turn on.



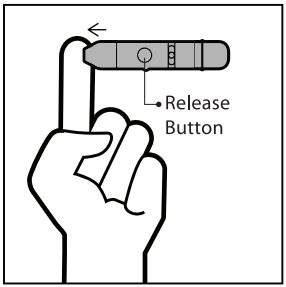
[3] One Drop Meter Ready For Test: The One Drop Meter now displays the *Apply Sample to Test Strip* animation indicating it is now ready for you to apply blood. You do not need to set a calibration code for this meter.

Apply Sample to Test Strip animation:



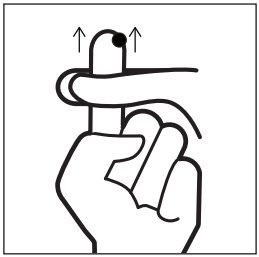
[4] Lance the Test Site: Keep your hand warm or gently massage the site you are lancing to stimulate blood flow.

Press the lancing device against the site to be lanced. Press the release button.



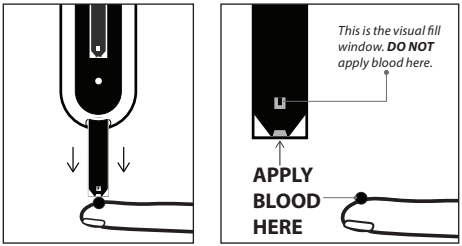
[5] Obtain a Drop of Blood: Squeeze from the base of your finger up towards the tip, milking your finger, until a small blood drop forms.

Do not squeeze directly around the lanced area!



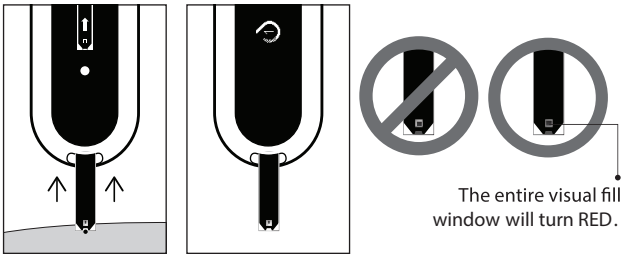
[6] Bring One Drop Test Strip to Blood Sample Immediately bring the One Drop Meter with the inserted One Drop Test Strip to the blood sample at a 90 degree angle. The test strip fills from the tip. Do not try to smear blood on the top surface.

The One Drop Test Strip acts like a sponge and draws the blood into itself through the sample area.



The visual fill window of the test strip will turn red indicating blood has been absorbed in the test strip.

[7] Remove Your Finger From the One Drop Test Strip When the Visual Fill Window Completely Turns Red and the One Drop Meter Beeps During testing, the *sample applied* symbol will appear on the One Drop Meter's screen and the One Drop Meter will beep when you should remove the One Drop Test Strip from the blood sample.



CAUTION: If the visual fill window does not completely fill, you may get an inaccurate result. Retest and ensure that the visual fill window is completely full.

The calculating animation will begin on the One Drop Meter display. This animation indicates that a sample has been applied to the One Drop Test Strip and the One Drop Meter is calculating the test result.

Calculating Animation:

PRECAUTIONS:

- Remove the One Drop Test Strip from the blood sample as soon as the One Drop Test Strip's visual fill window completely turns red (you will also hear a beep).
- Do not press the One Drop Test Strip against the test site.
- Do not scrape blood onto the One Drop Test Strip.
- Do not apply blood to the top side of the One Drop Test Strip.
- Do not apply blood to the One Drop Test Strip when the One Drop Test Strip is out of the One Drop Meter.
- Do not put blood or foreign objects into the One Drop Test Strip port.
- Do not apply more blood after the One Drop Test Strip's visual fill window completely turns red and the calculating animation begins on the One Drop Meter's display.

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[8] Viewing Blood Glucose Test Result The blood glucose test result will appear on the One Drop Meter display. The date, time, and unit of measure (mg/dL) will scroll to the right of the blood glucose test result.

Example Result:

The test result is stored in the One Drop Meter's memory.

Carefully read the test results on the One Drop Meter screen before making any treatment decisions.

Glucose Display Messages

CAUTION: Low or high blood glucose test results can indicate a potentially serious medical condition. Follow your healthcare professional's recommendations.

LOW MESSAGE:

Glucose test result is lower than 20 mg/dL. This low result may indicate hypoglycemia (low blood glucose). It also indicates that the result is below our measuring range. The low result is stored in the meter. On the One Drop App it will be saved as a test result of <20 mg/dL with time and date. The value will be represented as 20 mg/dL in the statistics in the One Drop App.

ACTIONS: If you feel symptoms such as weakness, sweating, nervousness, headache or confusion, follow your healthcare professional's recommendations. If you get a low glucose test result but have no symptoms of low blood glucose, then retest with a new test strip. If you still get a low test result, follow the treatment plan recommended by your healthcare team or contact your healthcare professional immediately.

HIGH MESSAGE:

Glucose test result is above 600 mg/dL. This high result

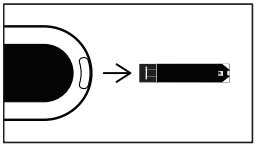
may indicate hyperglycemia (high blood glucose). It also indicates that the result is above our measuring range. The high result is stored in the One Drop Meter. On the One Drop App it will be saved as a test result of >600 mg/dL with time and date. The value will be represented as 600 mg/dL in the statistics in the One Drop App.

ACTIONS: If you feel symptoms such as fatigue, thirst, excessive urination, or blurry vision, follow your healthcare professional's recommendations. If you get a high glucose test result but have no symptoms of high blood glucose, then retest with a new One Drop Test Strip. If you still get a high glucose test result, follow your healthcare professional's recommendations. Checking ketones may be advisable.

If you feel that your results do not match how you are feeling, contact your doctor or nurse.

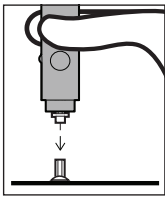
[9] Remove the Used One Drop Test Strip From the One Drop Meter Test Strip Port: Avoid touching the One Drop Test Strip's sample area (where blood was applied).

Removing the used One Drop Test Strip will turn off your One Drop Meter. If you leave the One Drop Test Strip in your One Drop Meter, it will time out after 90 seconds.

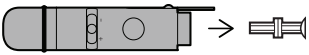


[10] Removing the Lancet
When you have finished testing, pull off the cap from the lancing device. Be

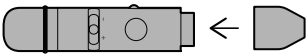
careful not to touch
the lancet tip. Place the lancet cover onto a hard, even surface (such as a tabletop) with the open end facing up. While the lancet is still in the lancing device, bring the lancet tip to the lancet cover to recover the used lancet. You can then safely handle the used lancet.



Extract the Lancet from the Lancet Holder Cup by holding the body of the lancing device and sliding the Lancet Ejector forwards to push the Lancet out of the Lancet Holder Cup.



Slide the Lancet Ejector backwards to its home position. Replace the lancing device cap onto the lancing device until it snaps or clicks into place.



Discard the used lancet properly. Follow your healthcare professional's instructions for disposal.

WARNING: The information from the One Drop App should only be used as a reference. Do not make treatment decisions based solely on the information provided by the One Drop App. All health-related decisions should be made in conjunction with the advice of a qualified healthcare professional (HCP). It is important that you and your HCP understand how the statistics are calculated before making any adjustments to treatment. This information can be found in the One Drop App User's Guide (accessible from the One Drop App).

CHAPTER 8 Viewing Past Test Results on Your One Drop Meter

The One Drop Meter will store up to 300 of the most recent blood glucose and control solution test results. When the One Drop Meter reaches the 300 result capacity, the oldest test results will be deleted so that new test results can be saved.

Note: If the One Drop Meter is synced with the One Drop App, glucose test results can be reviewed in the One Drop App even after they have been deleted from the One Drop Meter.

[1] Viewing the Most Recent Test Result Press the One Drop Meter Button to display the most recent test result. The date, time, and unit of measure will scroll to the right of the test result.

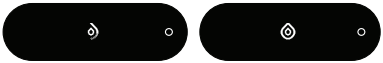
Example Result:

If it was a control solution test result, the control solution icon will appear to the right of the test result.

Example Result:

Test results without a set time and date will be displayed on your One Drop Meter with "--:--" and "--/--" in place of the time and date. These readings will not sync to the One Drop App.

[2] Viewing All Stored Test Results Continue pressing the One Drop Meter button to view every test result, starting from the most recent and ending with the oldest. When you reach the oldest reading stored on the device, you will see a brief animation before the most recent reading is displayed again.



[3] Turning Off Your One Drop Meter The One Drop Meter will turn off automatically (time out) 30 seconds after the last button press.

CHAPTER 9 Important Cleaning and Disinfection Procedures

When using your One Drop Meter, avoid getting dirt, dust, blood, control solution, water, or any other foreign substance into the test strip port. You should wash your hands thoroughly after handling the One Drop Meter, lancet, One Drop Lancing Device, or One Drop Test Strips. Your meter and lancing device should be cleaned and disinfected at least once per week. Cleaning and disinfecting your One Drop Meter and One Drop Lancing Device is important to prevent the spread

of infectious diseases thereby killing the bacteria and viruses that you cannot see.

Cleaning

Cleaning is the physical removal of organic soil from the One Drop Meter and lancing device surfaces. Cleaning allows for successful disinfection when using the recommended wipes and process for cleaning and disinfecting outlined below.

Disinfection

Disinfection is a process that destroys pathogens, such as viruses and other microorganisms, on the One Drop Meter and One Drop Lancing Device surfaces. Disinfecting the One Drop Meter and One Drop Lancing Device helps ensure that no infection is passed on when you or others come in contact with the One Drop Meter and One Drop Lancing Device. The One Drop Meter and One Drop Lancing Device should be cleaned with a separate wipe prior to each disinfection.

Cleaning and disinfecting your One Drop Meter and One Drop Lancing Device

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CAUTION: Never immerse the One Drop Meter or the body of the One Drop Lancing Device in water or any other liquid solution. Be careful when cleaning and disinfecting your One Drop Meter to avoid getting liquid into the One Drop Test Strip port.

When should you clean and disinfect your One Drop Meter and One Drop Lancing Device?

- We recommend that you clean and disinfect once a week, since you are the only person operating them.

- If the One Drop Meter is being operated by a second person who is providing testing assistance to the user, the One Drop Meter and One Drop Lancing Device should be cleaned and disinfected prior to being handled by the second person.

The disinfection instructions listed below were validated for 260 cleaning and 260 disinfection cycles, for a total of 520 wipes (260 cleaning wipes plus 260 disinfecting wipes) on the One Drop Lancing Device and One Drop Meter.

The life of the One Drop Meter, defined as 5,000 test strip insertions, is between 3 to 5 years, depending on use. The number of cleaning and disinfecting wipes used simulates cleaning and disinfecting your meter once a week for 5 years.

What can you use to clean and disinfect your One Drop Meter and One Drop Lancing Device?

See Table 1 for the suggested disinfecting wipe. You should use wipes that are pre-saturated with disinfectant. Do not immerse your meter or body of the lancing device in any liquid solution.

If you suspect your One Drop Meter is not working properly after disinfecting, verify that your system is working properly by performing a control solution test. If your control solution

test result falls out of control range, call Customer Service at 1 (800) 437-1474. If you notice any signs of deterioration on the One Drop Meter or One Drop Lancing Device, such as clouding on the One Drop Meter, corrosion or erosion of One Drop Meter or One Drop Lancing Device plastic housing, cracking of plastic housing, display, or button) or if the One Drop Meter does not turn on, or if the lancing device or adapters do not work after cleaning and disinfection, discontinue use of the system and contact Customer Service.

Availability of disinfecting wipe may vary. For updated information, call Customer Service.

Table 1

EPA #	Brand Name	Manufacturer	Available at	Contact Time
9480-4*	Super Sani-Cloth Germicidal Disposable Wipe	Professional Disposables International, Inc. (PDI)	Online: Amazon.com Officedepot.com	2 Minutes

*Active ingredient: Quaternary ammonium chlorides and isopropanol

How do you clean and disinfect your One Drop Meter and One Drop Lancing Device?

[1] Before you disinfect your One Drop Meter and One Drop Lancing Device, clean the outside of the meter and lancing device with a disinfecting wipe listed in the table above.

Wipe each side of your One Drop Meter and One Drop Lancing Device with moderate pressure 3 times using the follow-

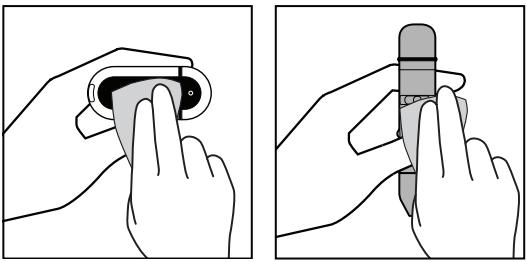
ing method:

a. Wipe up and down 3 times.
b. Wipe left and right 3 times.
c. Avoid getting disinfectant inside the One Drop Test Strip port.

[2] With a new disinfecting wipe, disinfect your One Drop Meter and One Drop Lancing Device using the disinfecting wipe listed in the table above and follow the instructions below.

In addition, follow the instructions on the disinfecting wipe container label for safe handling of the wipes.

[3] Wipe each side of your One Drop Meter and One Drop Lancing Device with moderate pressure 3 times using the following method:
a. Wipe up and down 3 times.
b. Wipe left and right 3 times.
c. Avoid getting disinfectant inside the One Drop Test Strip port.



[4] After 2 minutes of contact time, let air dry.

You should wash your hands thoroughly with soap and water after handling the One Drop Meter, One Drop Lancing Device, lancet, and One Drop Test Strip.

If you require technical assistance regarding cleaning and disinfecting your One Drop Meter or lancing device, call Customer Service at 1 (800) 437-1474.

CHAPTER 10 Batteries

Your One Drop Meter comes with two pre-installed CR2032, 3 volt, lithium batteries.

Batteries are harmful if swallowed. Keep away from small children.

LOW BATTERY MESSAGE
(This message appears for 2 seconds.)

You can still perform a test when you see a low battery message, but you should replace your batteries as soon as possible. Use only CR2032 or DL2032 batteries.

DEAD BATTERY MESSAGE

The batteries in your One Drop Meter do not have enough power to activate your One Drop Meter and perform a test;

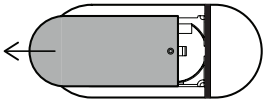
batteries must be replaced.

IMPORTANT: When the batteries are replaced, the time and date will be erased from your One Drop Meter. You must sync your One Drop Meter with your supported device to ensure your readings have time and date. To sync your One Drop Meter, see instructions in Chapter 5, Page 17. Removing the batteries does not affect the stored glucose records.

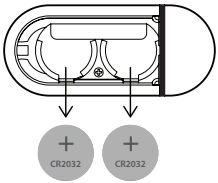
NOTE: Dispose of used batteries according to your local environmental regulations. Your One Drop Meter is also an electronic device. When disposing of your One Drop Meter, follow all local environmental regulations.

How to Replace the Batteries

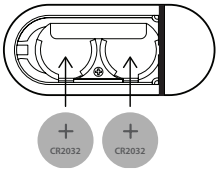
[1] Open Battery Door Make sure the One Drop Meter is off. Turn the One Drop Meter so you are looking at the battery door. Slide the battery door off the One Drop Meter.



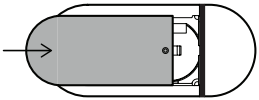
[2] Remove the Old Batteries To remove the old batteries, use a non metallic tool.



[3] Install the New Batteries Install the new batteries with the positive (+) sign facing up towards you.



[4] Close Battery Door Slide the battery door onto the One Drop Meter. Make sure that the battery door is completely closed before using One Drop Meter.



CHAPTER 11 Error Messages

The One Drop Meter is designed to work accurately under most usual conditions. On rare occasions, the One Drop Meter will display an error message instead of a glucose result.

The One Drop Meter is able to detect specific problems which may allow you to determine the cause of the error without wasting valuable One Drop Test Strips. When you are presented with an error message, check for possible problems related to each message listed in this chapter.

CAUTION: In certain cases, the One Drop Meter may return an error code or provide an inaccurate result if it is being used near electrical equipment, like a power generator.

CAUTION: If you get repeated error messages and are experiencing symptoms of hypo or hyperglycemia, contact your healthcare professional immediately as this may indicate low or high glucose. If this error code persists on retesting, consult your healthcare professional.

Error 1

Problems have occurred that are related to One Drop Test Strip use.

[1] If this message appears the moment the One Drop Test Strip is inserted, the One Drop Test Strip may be wet or damaged.
[2] If the message appears during a test, the One Drop Test Strip may have been removed too early. Retest using a new One Drop Test Strip.
[3] If this message appears after the 1-2-3 countdown instead of a result, it may indicate that you applied more blood after testing began.

Error 2

The One Drop Meter has detected an irregularity with the sample.

[1] The One Drop Test Strip may be partially filled. Retest us-

ing a new One Drop Test Strip. Ensure that enough blood is applied to the One Drop Test Strip when retesting.
[2] The sample may not be blood or control solution. Retest using a new One Drop Test Strip. Ensure that the test site is clean prior to performing a blood glucose test or that the control solution bottle tip is wiped clean prior to performing a control solution test.

Error 3

The meter has detected that the One Drop Test Strip is in poor condition.

[1] The One Drop Test Strip may have been improperly stored (e.g. hot, humid conditions) or may be expired. Check the One Drop Test Strip vial for the expiration date. Do not use One Drop Test Strips beyond the expiration date or 180 days after first opening the vial. You may need to retest using a new One Drop Test Strip from a new vial of One Drop Test Strips.
[2] The One Drop Test Strip may have been mishandled by vigorous bending or shaking. Retest using a new One Drop Test Strip.
[3] Parts of the One Drop Test Strip may have become covered in grease, oil, or lotion. Retest using a new One Drop Test Strip.
[4] The One Drop Test Strip port on your One Drop Meter may be dirty. Call Customer Service for assistance. The phone number is printed on the back of your One Drop Meter.

Error 4

The One Drop Meter was unable to produce a result or unusual One Drop Test Strip problems have occurred that may be related to extreme conditions.

[1] This error may be caused by extremely high glucose. If you are experiencing symptoms of hyperglycemia, contact your healthcare professional immediately. If this error code persists on retesting, call Customer Service or consult your healthcare professional.
[2] Confirm that you are testing within the system operating temperature range of 50°F to 104°F (10°C to 40°C) and operating relative humidity range of 10% to 90%.

Error 5

The One Drop Meter was unable to produce a reliable result.

[1] This may be caused by a non-blood sample, or a combination of high glucose and other medical conditions.
[2] If this error code persists on retesting, call Customer Service or consult your healthcare professional.

Error 6

The One Drop Test Strip has taken too long to generate a signal.

[1] This may be caused by a combination of cold operating temperature and high hematocrit levels. Retest in a warmer location.

[2] If this error code persists on retesting, call Customer Service. The phone number is printed on the back of your One Drop Meter.

Error 7 

One Drop Meter problems have occurred that are beyond your control.

Contact Customer Service for assistance. The phone number is printed on the back of your One Drop Meter.

Error 8 

A problem has occurred related to the One Drop Meter hardware.

Contact Customer Service for assistance. The phone number is printed on the back of your One Drop Meter.

If there is a temperature warning or error, the thermometer symbol is displayed for 5 seconds and then the One Drop Meter turns off.

LOW TEMPERATURE MESSAGE 

The One Drop Meter is below its system operating temperature range of 50°F to 104°F (10°C to 40°C).

ACTIONS: Move to an area with an ambient temperature range

of 50°F to 104°F (10°C to 40°C) and relative humidity range of 10% to 90%. Wait for the One Drop Meter and One Drop Test Strips to reach the new temperature (usually 10-20 minutes) before using the One Drop Meter or performing a test.

HIGH TEMPERATURE MESSAGE

The One Drop Meter is above its system operating temperature range of 50°F to 104°F (10°C to 40°C).

ACTIONS: Move to an area with an ambient temperature range of 50°F to 104°F (10°C to 40°C) and relative humidity range of 10% to 90%. Wait for the One Drop Meter and One Drop Test Strips to reach the new temperature (usually 10-20 minutes) before using the One Drop Meter or performing a test.

CHAPTER 12 Troubleshooting

Troubleshooting Situation #1 One Drop Meter does not display the Apply Sample to Test Strip Animation after inserting a One Drop Test Strip.

[1] CAUSE The One Drop Meter's batteries have insufficient power.
ACTION The One Drop Meter's batteries must be changed immediately. Sync the One Drop Meter with your supported device to set the date and time.

[2] CAUSE The One Drop Test Strip has been inserted upside

down, wrong end in, or incompletely inserted into the One Drop Meter.
ACTION Remove the One Drop Test Strip from the One Drop Meter's test strip port. Reinsert the One Drop Test Strip with the black side up and the end of the One Drop Test Strip with contact bars inserted up into the One Drop Meter's test strip port. Ensure that the One Drop Test Strip is fully inserted.

[3] CAUSE Defective One Drop Meter or defective One Drop Test Strips.
ACTION Call Customer Service. The phone number is printed on the back of your One Drop Meter.

[4] CAUSE Blood or foreign objects put into the One Drop Meter test strip port.
ACTION Call Customer Service. The phone number is printed on the back of your One Drop Meter.

Troubleshooting Situation #2 After applying the blood sample, the One Drop Meter doesn't begin the Calculating Animation and no test result is displayed.

[1] CAUSE Defective One Drop Test Strip.
ACTION Repeat the test with a new One Drop Test Strip. If this does not work, call Customer Service. The phone number is printed on the back of your One Drop Meter.

[2] CAUSE Sample was applied after 90 seconds of inserting a One Drop Test Strip.
ACTION Repeat the test using a new One Drop Test Strip. Wait until you see the *Apply Sample to Test Strip* Animation appear on the meter display screen before you apply the blood

sample.

[3] CAUSE Defective One Drop Meter.
ACTION Call Customer Service. The phone number is printed on the back of your One Drop Meter.

Troubleshooting Situation #3 Meter results are not syncing to the supported device.

[1] CAUSE The One Drop Meter and supported device are not properly paired or were not initially synced.
ACTION See Chapter 5 to pair your One Drop Meter with your supported device. If the One Drop Meter is already paired, but not syncing, follow the instructions in that chapter to force sync your devices.

[2] CAUSE *Bluetooth*® wireless technology on the supported device is turned off.
ACTION Go to the settings menu in your supported device and ensure that *Bluetooth*® wireless technology is turned on. If you continue to experience issues, check your supported device's instructions for more information.

[3] CAUSE The One Drop Meter and supported device are not within 10 feet of each other.
ACTION Bring your One Drop Meter and supported device next to each other and attempt to force sync the two devices.

[4] CAUSE The blood glucose test results do not have a time and date, and show "--:--" and "--/--" in place of the time and date.
ACTION Blood glucose test results without a time and date

will not sync to the One Drop App. See Chapter 5 to pair and sync your One Drop Meter with your supported device. The date and time on the One Drop Meter will be set to the date and time on your supported device. Future blood glucose test results will have a time and date and will sync to the One Drop App.

[5] CAUSE One Drop Meter is paired with more than one supported device and blood glucose test results are syncing to another supported device.
ACTION If you sign in to your account on both devices, results will sync between the devices through the cloud. Alternately, you can turn off the *Bluetooth*® wireless technology on one device. The results will then sync to your other supported device.

[6] CAUSE Pairing between the One Drop Meter and the supported device is not functioning properly and needs to be repaired.
ACTION In the One Drop App, find the page that lists your One Drop Meter and swipe to forget your One Drop Meter. Then, go to your supported device's *Bluetooth*® wireless technology settings, find the One Drop Meter, and select forget the device. Then, follow the steps in this Guide to pair the One Drop Meter and the supported device again.

[7] CAUSE The App has been forced to close and results are not transferring.
ACTION Open the App on your supported device. Press the Meter Button to activate your One Drop Meter. Results should now transfer. If you force close your App, results will not transfer.

Troubleshooting Situation #4 One Drop Meter is paired with more than one supported device but results are not syncing to all supported devices. (For example, your One Drop Meter is paired with an iPhone® and Android™ phone, but results are only syncing to the iPhone®).

CAUSE One Drop Meter only establishes a connection with one supported device at a time.
ACTION If you sign in to your account on both devices, results will sync between the devices through the cloud. Alternately, you can turn off the *Bluetooth*® wireless technology on one device. The results will then sync to your other supported device.

Troubleshooting Situation #5 One Drop Meter does not appear in the One Drop App when adding a new One Drop Meter.

[1] CAUSE The One Drop Meter cannot be detected.
ACTION On your One Drop Meter, press and hold the Meter Button until the *Bluetooth*® wireless technology symbol appears. Once the One Drop Meter has connected successfully, a confirmation screen will appear on your phone screen.

[2] CAUSE *Bluetooth*® wireless technology on the supported device is turned off.
ACTION Go to the settings menu in your supported device and ensure that *Bluetooth*® wireless technology is turned on. If you continue to experience issues, check your supported device's instructions for more information.

[3] CAUSE One Drop Meter is paired with another supported device.
ACTION Turn off *Bluetooth*® wireless technology on any devices already paired with your meter. This will ensure connection with your additional supported device.

Troubleshooting Situation #6 Passkey does not appear on the One Drop Meter when pairing with a supported device.

[1] CAUSE The One Drop Meter has previously been paired with the supported device.
ACTION If the One Drop Meter was paired with a supported device and then unpaired, a passkey may not be required when pairing again with the same supported device. If the meter appears in the Meters section in the One Drop App, then it has been successfully paired.

[2] CAUSE Another One Drop Meter selected.
ACTION If multiple One Drop Meters are listed in the One Drop App when adding a new One Drop Meter, each One Drop Meter is identified by the serial number found under the One Drop Meter battery door. Ensure that the correct One Drop Meter is selected.

Troubleshooting Situation #7 The time and date do not appear on blood glucose test results.

[1] CAUSE The One Drop Meter is not paired with a supported device.
ACTION See Chapter 5 to pair your One Drop Meter with your

supported device. The date and time will be set to the date and time on your supported device. Future blood glucose test results will appear with a date and time.

[2] CAUSE One Drop Meter has not synced after replacing the batteries.
ACTION See Chapter 5 to sync your One Drop Meter with your supported device.

[3] CAUSE Meter time and date has returned an error.
ACTION Remove batteries, wait 30 seconds, then re-install. Sync meter with your supported device before attempting another test. If this problem continues please call customer service.

Troubleshooting Situation #8 The time and date on the meter do not match the time and date on the supported device.
CAUSE: One Drop Meter has not recently synced with your supported device.
ACTION: See Chapter 5 to sync your One Drop Meter with your supported device.

CHAPTER 13 One Drop System Specifications

TECHNICAL SPECIFICATIONS

Assay Method: Dynamic Electrochemistry
Maximum Altitude: 10,000 feet
Calibration: Plasma equivalent
Coding: No Code
Control Solution Storage Temperature: 36°F to 86°F (2°C to 30°C)
Sample: Whole blood, capillary
Blood Sample Size: 0.5 microliters
Average Glucose Test Time: 5 seconds
Measurement Units: mg/dL
Result Range: 20 to 600 mg/dL
Hematocrit: 20% to 60%
Operating Relative Humidity Range: 10% to 90%
System Operating Temperature Range: 50°F to 104°F (10°C to 40°C)
Memory: 300 blood glucose and control solution test results with date, time
Power Source: Two CR2032 3-volt lithium batteries
Automatic Shutoff: 30 seconds after last user action
One Drop Meter Size: Width 1.18" x Length 2.76" x Height 0.47" (30 mm x 70 mm x 12 mm)
One Drop Test Strip Storage Temperature: 46°F to 86°F (8°C to 30°C)
One Drop Test Strip Storage Relative Humidity: 10%-90%
Weight: 19.8 g
Wireless Frequency: 2.4 GHz worldwide ISM band (Instrumentation, Scientific and Medical)

Equipment not suitable for use in the presence of flammable mixtures.

When disposing of your One Drop Meter follow all local environmental regulations.

CHAPTER 14 Electrical Safety and Standards

In locations where cell phone use is not permitted, such as some hospitals and some healthcare professional offices, the meter should be off.

The One Drop Meter has been tested and found to be appropriate for use at home. In most cases, it should not interfere with other home electronic devices if used as instructed. However, the One Drop Meter gives off radio frequency (RF) energy from the *Bluetooth*® wireless technology feature. If not used correctly, the One Drop Meter may interfere with your TV, radio, or other electronic devices that receive or transmit RF signals. With the exception of your iOS or Android™ device, other electronic wireless devices that are in use nearby, such as another cell phone or a wireless network, may prevent or delay the transmission of data from your One Drop Meter to the One Drop App. Moving away from or turning off these electronic devices may allow communication.

If you experience meter interference problems, try moving your One Drop 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. If you continue to experience interference, contact Customer Service.

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.

FCC guidelines help ensure that the One Drop Meter will not affect the operation of other nearby electronic devices. Additionally, other electronic devices should not affect the use of your meter.

One Drop Meter complies with CISPR 11: 2009, Class B (Radiated Only). Emissions of the energy used are low and not likely to cause interference in nearby electronic equipment.

One Drop Meter meets the requirements for immunity to electrical interference at the frequency range and test levels including:

Electromagnetic immunity requirements as per EN 61326-2-6 and IEC 60601-1-2. The meter has been tested for immunity to Level 3 electrostatic discharge as specified IEC 61000-4-2.

One Drop Meter has been tested for immunity to radio frequency interference over the frequency range 80MHz to 2.5GHz at 3V/m as specified in IEC 61000-4-3.

Electromagnetic emissions requirements as per EN 61326-2-6 and IEC 60601-1-2. Its electromagnetic emission is therefore low.

The recommended wireless security measures include AES encryption.

Contains Transmitter Module FCC ID: QOQBLE113

CHAPTER 15 Warranty

Warranty Terms

We offer customers who buy ("You") a new blood glucose meter (defined as "One Drop Meter") within the United States the following purchase protections. We extend a limited lifetime warranty to customers who buy a new One Drop Meter. Under this limited warranty, Your new One Drop Meter is covered for the period of ownership as long as it has not been modified, altered, or misused. Under this warranty we will replace, free of charge, Your One Drop Meter if it is defective in material or workmanship. In order to have Your One Drop Meter replaced under this warranty, please call customer service. No other warranties, express or implied, are made. We will not be liable for any incidental or consequential damages You may incur. This warranty gives You specific legal rights, and You may also have other rights that vary from state to state. We may discontinue this program at any time without notice.

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