FondCircle

Smart Devices. Connected Care.

Blood Glucose Monitoring System



User Manual

Model: VGM04 Version: 1.0.0_2507

FOREWORD

The FondCircle Blood Glucose Monitoring System 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 meter on multiple patients may lead to the transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
FondCircle assumes no liability and provides no warranty for any damage (including indirect damage) resulting from failure to comply with this user manual. Please read through this user manual carefully before using the product and strictly follow all safety precautions.

Video Tutorials

Scan the QR code to watch the tutorial videos, which demonstrate how to use the Blood Glucose Monitoring System safely.

Online Manual

Scan the QR code to get the manual as a PDF, which can be enlarged and viewed on your mobile device.

Quick Start Guide

Scan this QR code to download the Bluetooth Quick Start Guide as a PDF, which can be enlarged and viewed on your mobile device.

App Download

Scan the QR code with your phone or tablet to download the FondCircle App.

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WARNINGS AND PRECAUTIONS

IMPORTANT SAFETY INFORMATION

- The meter is for single-patient use only. Do not share it with anyone, including family members, or use it on multiple patients.
- Always keep the test strips in their original vial. Close the vial tightly immediately after removing a test strip.
- Do not use the meter if it has been dropped in water or splashed with water.
- Wash and dry your hands thoroughly before and after testing.
- Test strips and safety lancets are for single use only.
- Do not place blood directly onto the flat surface of the test strip.
- Check the expiration and discard dates on the test strip vial label (or foil pouch) and the control solution bottle label.
- Only use FondCircle Blood Glucose Test Strips with your FondCircle Blood Glucose Meter.
- Only use the FondCircle Control Solution with your FondCircle Blood Glucose Meter and FondCircle Blood Glucose Test Strips.
- Contact your physician or diabetes healthcare professional if you plan to make changes to your current medical therapy or diet based on test results.

⚠Potential Biohazard

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

Note:

1. The meter and safety lancet are for single-patient use only. Do not share them with anyone, including family members, and do not use them on multiple patients.

2. All parts of the kit are considered biohazardous and may potentially transmit infectious diseases from bloodborne pathogens, even after cleaning and disinfection. Please follow proper precautions when handling your meter and lancet and lancing device.

3. For more information, refer to the FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm.
You may also refer to the CDC Clinical Reminder: “Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) at http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.

LIMITATIONS

- For single-patient use only.
- Very high (above 70%) or very low (below 20%) hematocrit levels can cause inaccurate results. Consult your healthcare professional to determine your hematocrit level.
- If you are taking vitamin C (ascorbic acid in your blood > 3 mg/dL) then your glucose results using this meter may not be reliable.
- Oxygen therapy may cause inaccurate results.
- Not for use on patients with critical illness.
- Not for use on patients in shock, with severe dehydration, or in a hyperos molar state (with or without ketosis).
- The FondCircle Blood Glucose Monitoring System should not be used following xylose absorption procedures.
- Not for newborn use.
- Not for screening or diagnosing diabetes mellitus.
- Not for use in hypotensive individuals.
- Do not use at altitudes above 13,123 ft (4,000 meters) above sea level.
- This meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities, as it has not been cleared by the FDA for use in these environments. This includes routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to the transmission of Human Immunodeficiency

Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Note: The system is tested to accurately measure glucose in whole blood within the range of 20 to 600 mg/dL.

METER USE AND PRECAUTIONS

- The meter is preset to display blood glucose concentration in milligrams per deciliter (mg/dL) by default.
- The meter will automatically shut off after 2 minutes of inactivity.
- Avoid getting water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry. Avoid exposing it to extreme temperatures or humidity, and do not leave it in your car.
- Do not drop the meter or get it wet. If this occurs, check the meter by running a quality control test. Refer to the “Testing with Control Solution” section for instructions.
- Do not disassemble the meter, as this will void the warranty.
- Refer to the “Caring for Your Glucose Monitoring System” section for cleaning instructions.
- Keep the meter and all associated parts out of the reach of children.

Note: Follow proper precautions and local regulations when disposing of the meter and used batteries.

FEATURES

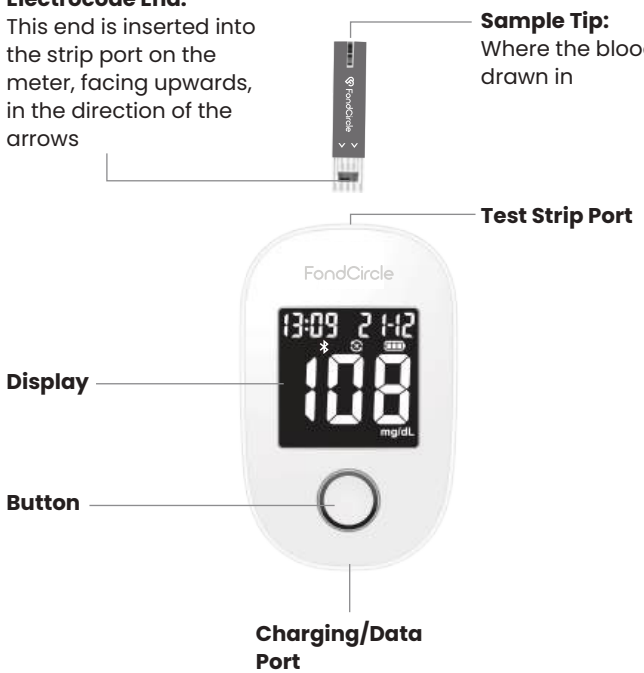
- Fast Results: Get accurate results in just 5 seconds.
- Internal Memory: Stores up to 500 test results with date and time.
- Rechargeable Battery: Convenient and eco-friendly, with long-lasting performance.
- Easy & Accurate: Simple to use with reliable, precise results.
- Auto Sync: Automatically syncs data to compatible devices for easy tracking.
- 0.8 uL Blood Sample: Requires a small blood sample for quick and minimal discomfort.
- Backlight & Strip Light: Equipped with a backlight and strip light for easy testing in low-light conditions.

PRODUCT DESCRIPTION

STRUCTURE

1. Meter System Overview

The FondCircle Blood Glucose Meter and FondCircle Blood Glucose Test Strip



2. Display

The picture below shows all the symbols that appear on your meter display.

Make sure the display is working properly before testing. When the meter is off, press and hold ◯ to view the complete display. All display segments should appear. If you need more time to check the display, repeat the above action.

If not, contact FondCircle Customer Support at (877) 899-7770 for assistance. Please contact your healthcare professional if you need further help.



Symbol	Description
88-18	Date
88:88	Time
	Battery Life
88.8	Test Results or Error Codes
	Ready to Test
	Control Test Result
mg/dL	Unit of Measurement
	Unable to Sync
M	Memory
	Bluetooth

Notes:
Your FondCircle Meter is pre-set with a beep sound function. The meter will beep when:
• Turning on the meter.
• Inserting the test strip and when it's ready to apply blood or control solution.
• Sufficient blood or control solution is drawn into the test strip.
• The test is complete.
• It’s time to perform a test, if you’ve set test alarms.
• An error occurs during operation.

INTENDED USE

The FondCircle Blood Glucose Monitoring System is comprised of the FondCircle Blood Glucose Meter (VGM04) and the FondCircle Blood Glucose Test Strips. The FondCircle Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. This system is intended for in vitro diagnostic use (outside the body) by people with diabetes, at home, as an aid in monitoring the effectiveness of diabetes management. It is not intended for neonatal use, or for diagnosing or screening diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use) and should only be used by a single person and should not be shared.

This meter 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 FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

HOW TO USE

PREPARATION BEFORE USE

App

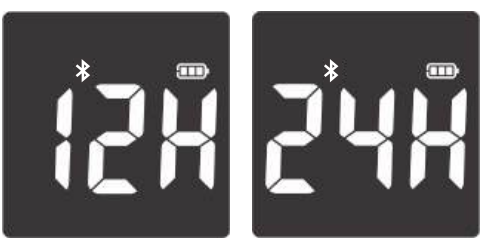
Before using the Blood Glucose Meter, download and install the FondCircle® app. Always use the latest version of the app. You can download it from Google Play or the App Store.

SETTING UP YOUR SYSTEM

Before using your meter for the first time, ensure that it is set up properly.

1. Setting the Clock

When the meter is off, press and hold ◎ until the meter beeps to enter the set up mode. Then, set the clock to either 12 or 24 hour mode. Press ◎ to adjust it, then press and hold ◎ to save your choice. Start setting the year, month, and date.



2. Setting the Date

The year will now flash. Press ◎ to adjust it, then press and hold ◎ until the meter beeps to set. The meter will then shift to the next digit for setting. Repeat this action until the year setting is complete.



The month will now flash. Press ◎ to adjust the month, then press ◎ and hold until the meter beeps to set.



The date will now flash. Press ◎ to adjust the date, then press and hold ◎ until the meter beeps to set. The meter will then shift to the next digit for setting. Repeat this action until the date setting is complete.



Note:
Before using your meter for the first time, adjust the settings to set the date and time. This ensures that the results stored in the memory are shown with the correct date and time.

3. Setting the Time

If you select 12-hour mode, you can choose "AM" or "PM" before setting the hour. The hour will then flash. Press ◎ to adjust the current hour, then press and hold ◎ until the meter beeps to set. The meter will shift to the next digit for setting. Repeat this action until the hour setting is complete.



The minute will now flash. Press ◯ to adjust the minute, then press and hold to set.



4. Setting the Audio Feature

After setting the time, press ◯ to select "On" or "Off." Press and hold ◯ to set.





Your meter setup is now complete. A test strip symbol will appear, indicating that the meter is ready for testing.

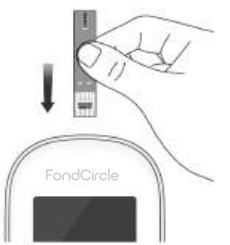


TAKING A TEST

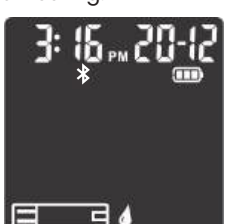
Set up your meter correctly and have all the necessary materials ready before you begin testing. This includes your FondCircle Blood Glucose Meter, FondCircle Blood Glucose Test Strips, and FondCircle lancets and lancing device.

PREPARING THE TEST STRIP

1. Wash and dry your hands thoroughly before testing.
2. Remove a test strip from the vial (or foil pouch). Immediately close the vial cap tightly after removing the test strip.
3. Insert the test strip into the meter in the direction of the arrows. The meter will turn on after a beep.



4. A symbol of a test strip with flashing blood will appear, indicating that the meter is ready for testing.



Note:

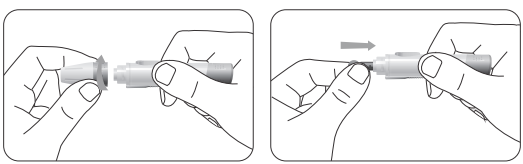
- Check the expiration and discard dates on the test strip vial. All expiration dates are printed in the Year-Month-Day format (e.g., 2025-01-01 indicates January 1st, 2025).
- Your FondCircle Test Strips have a 4-month shelf life after the vial is first opened. Write the discard date on the vial label when you first open it.

- Make sure the test strip is not damaged. Before testing, wipe the test site with an alcohol swab or clean with soapy water. If necessary, use warm water to wash your hands to increase blood flow. Then dry your hands and the test site thoroughly. Ensure there is no soap or lotion on the test site.

PREPARING THE LANCING DEVICE

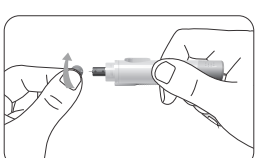
For fingertip sampling, adjust the depth of penetration to minimize discomfort. The clear cap is not needed for fingertip sampling.

1. Unscrew the lancing device cover from the body of the device. Insert a sterile lancet into the lancing device and push it until the lancet stops completely.

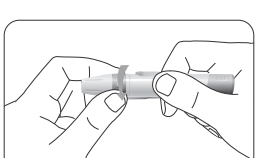


Note: Only use the FondCircle Lancing Device with FondCircle Lancets.

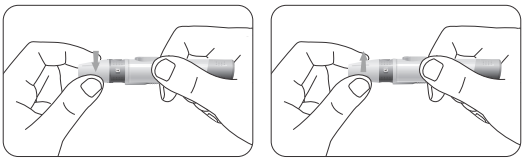
2. Hold the lancet firmly in the lancing device and twist the safety tab until it loosens. Then pull the safety tab off the lancet. Keep the safety tab for disposing of the used lancet.



3. Carefully screw the cover back onto the lancing device, avoiding contact with the exposed lancet. Ensure the cover is fully sealed.



4. Adjust the puncture depth by rotating the lancing device cover. There are 5 puncture depth settings. To reduce discomfort, use the lowest setting that still provides an adequate drop of blood.

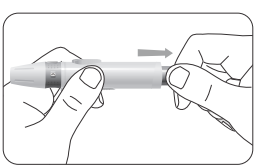


Adjustment Guidelines:
- 1: For delicate skin
- 2 and 3: For normal skin
- 4 and 5: For calloused or thick skin

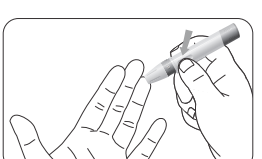
Note: Applying greater pressure with the lancing device against the puncture site will also increase the puncture depth.

GETTING A BLOOD DROP FOR TESTING

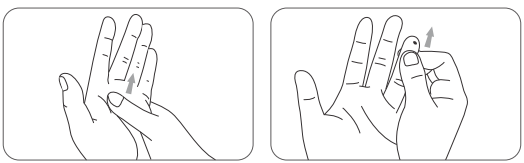
1. Pull the cocking barrel back to set the lancing device. You will hear a click when the device is ready for use.



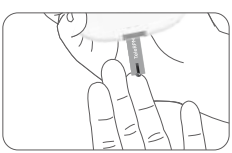
2. Press the lancing device against the side of the finger with the cover resting on the finger. Push the release button to prick the fingertip. You should hear a click as the device activates.



3. Discard the first drop of blood with a clean paper towel to ensure more accurate results. Gently massage the finger from base to tip to obtain the required blood volume (about half the size of a match head). Avoid smearing the drop of blood. For reduced pain, lance the side of the fingertip.
Test immediately after a good blood drop forms.



4. Immediately touch the tip of the test strip to the blood drop. The blood will be pulled into the test strip through the tip. Ensure the blood sample fills the check window at the tip of the strip. Hold the tip of the test strip in the blood drop until the meter beeps.



Note: If the blood sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new one.

5. The meter will count down for 5 seconds, and your result will appear on the display after a beep. The test result will automatically be stored in the meter's memory.



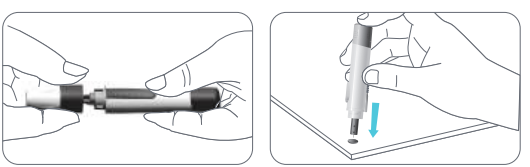
Important: Do not touch the test strip during the countdown, as this may cause an error.

⚠ Caution Statement

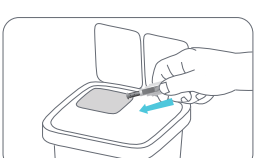
- Do not use the sterile lancet if the cap is missing or loose.
- Always use a new, sterile lancet. Do not reuse the sterile lancet.
- Avoid getting the sterile lancet dirty with hand lotion, oil, dirt or debris.
- Dispose of sterile lancets in the appropriate biohazard sharps container. If a biohazard sharps container is not available, use a heavy duty plastic container such as a laundry detergent bottle. Ensure the container is leak-resistant and has a hard puncture proof lid. Do not place loose sharps into the trash and do not flush down the toilet. Do not place strips into the recycle bin, as they are not recyclable.

REMOVING THE USED LANCET

1. Remove the lancing device cap and connecting collar. Place the lancet cap of the lancet on a hard surface and carefully insert the lancet needle into the lancet cap.



2. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to release the used lancet in an appropriate container. Do not use your fingers to pull the used lancet out to prevent injury from the lancet. Dispose of used lancets and follow local regulations for proper disposal to prevent injury from the lancets.



⚠ Potential Biohazard

Always dispose of the used lancet properly to prevent injury or contamination to others.

⚠ Caution

- Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.
- Do not use the lancet if the needle is bent.
- Be cautious whenever the lancet needle is exposed.
- Never share lancets or the lancing device with other people to prevent possible infections.
- In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.
- Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt, or debris.

DISCARDING THE USED TEST STRIP

You can discard the used test strip by hand. The meter turns off automatically after a beep.

⚠ Potential Biohazard

Dispose of the used test strips as medical waste.

Note:

- The meter and sterile lancet are for single-patient use only. Do not share them with anyone, including family members. Do not use on multiple patients.
- All parts of the kit are considered biohazardous. They can potentially transmit infectious diseases from bloodborne pathogens, even after cleaning and disinfection. Please follow proper precautions when handling your meter and sterile lancet.

Warning:

- If your blood glucose reading is below 50 mg/dL or you see LO (less than 20 mg/dL) on the meter display, contact your healthcare professional immediately.
- If your test result is above 250 mg/dL or you see HI (greater than 600 mg/dL) on the meter display, contact your healthcare professional immediately.
- Please consult your physician before making any changes to your current medical therapy based on the FondCircle test result.

GLUCOSE REFERENCE RANGES

Expected glucose values for people without diabetes:

Time of Day	Glucose Range
Fasting and before meals	< 100 mg/dL
2 hours after meals	< 140 mg/dL

Source: American Diabetes Association (Standards of Medical Care in Diabetes-2018.
Diabetes Care, January 2018, vol. 41, Supplement 1, S13-S27).

QUESTIONABLE OR INCONSISTENT RESULTS

If your blood glucose result does not match how you feel, follow these steps:

- Check the expiration and discard dates on the test strip vial. Ensure the vial has not been opened for more than 4 months.
- Confirm that the temperature during testing is between 41-113°F (5-45°C).
- Ensure that the test strip vial is tightly capped.
- Verify that the test strips have been stored at 36-86°F (2-30°C) and in 10-90% humidity.
- Make sure the test strip was used immediately after removing it from the vial (or foil pouch).
- Ensure that the test procedure was followed correctly.
- Perform a control solution test (see “Testing with Control Solution” for instructions).
- After checking all of the conditions listed above, repeat the test with a new test strip. If you are still uncertain about the results, please contact FondCircle Customer Support at (877) 899-7770 for assistance. If necessary, contact your healthcare professional for further guidance.

RECHARGING THE BATTERY

When the battery needs recharging, the empty battery symbol ( ) will appear. If the empty battery symbol ( ) appears by itself on the screen, the meter cannot be used. You must recharge the battery before using your meter.

The meter battery can be charged using one of the following options:
- **Micro-USB cable** (computer charging)
- **Micro-USB cable with AC adapter** (wall charging)

If you need a Micro-USB cable or AC adapter (not included in your kit), please contact your local distributor.

⚠ **Caution:**
- Do not charge the meter outdoors or in a wet area.
- Do not use the Micro-USB cable, AC adapter, or meter if it is damaged, discolored, abnormally hot, or has an unusual odor. Contact your local
- distributor.
- Do not plug the AC adapter into a wall socket and leave it unattended.
- Verify that the wall socket voltage matches the AC adapter voltage.
- Do not allow unsupervised children to charge the meter battery.
- Important:
- Do not insert a test strip when the meter is connected to a computer or wall outlet.

Note:
- Using the Micro-USB cable or AC adapter charges the battery in about 2 hours.
- When using the USB port on your computer to charge the battery, make sure the computer is turned on and not in standby mode. If the meter does not charge, try using another USB port on your computer.
- To optimize battery life, it is best to recharge the battery when the low battery symbol ( ) appears.

⚠ **Additional Caution:**
- If using an AC adapter not provided by FondCircle, ensure it meets the EN 60950-1 standard.
- If using a USB port on your computer to charge, ensure it meets the IEC 60950 standard.

TESTING WITH CONTROL SOLUTION

WHY PERFORM CONTROL TESTS

Performing a control test lets you know that your meter and test strips are working properly to give reliable test results. You should perform a control test once a week and when:

- You open a new box of test strips
- You want to check the meter and test strips
- Your test strips were stored in extreme temperatures or humidity
- After cleaning your meter
- After dropping the meter
- Your test result does not match with how you feel

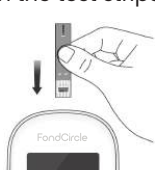
ABOUT THE CONTROL SOLUTIONS

- Only use FondCircle Control Solutions (1, 2, or 3) to practice on the system.
- Your meter automatically recognizes the control solution.
- The control solution results are not included in the average value calculation.
- Store the control solution at 36-86°F, 10-90% humidity.
- All expiration dates are printed in Year-Month-Day format. 2025-01-01 indicates January 1st, 2025.
- Do not use a control solution that is out of the expiration date or discard date (the control solution will expire 4 months after the bottle is opened for the first time).
- Shake the bottle well before use.
- Close the bottle tightly after use.

PERFORMING A CONTROL TEST

1. Remove a test strip from the test strip vial (or foil pouch). Immediately close the vial cap tightly after removing the test strip.
Note: Check the expiration and discard dates on the test strips. Do not use expired test strips.

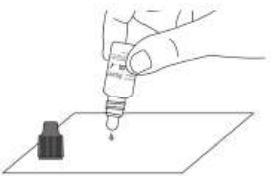
2. Insert the test strip into the meter in the direction of the arrows.



3. The meter will turn on with a beep. An image of a test strip with a flashing blood drop will appear, indicating that the meter is ready for testing.



4. Shake the control solution bottle thoroughly. Gently squeeze the bottle and discard the first drop. Squeeze out a second small drop onto a clean,



Note: Do not apply the control solution directly to the test strip from the bottle.

5. Immediately touch the tip of the test strip to the drop of control solution. The control solution will be drawn into the test strip through the tip.



Note: If the control solution sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new one.

6. Hold the tip of the test strip in the drop until the meter beeps. The meter will then count down, followed by the display of your control test result after another beep.



Note: The meter will automatically recognize and mark the control result. Control results are not included in the 7, 14, or 30-day average calculations.

UNDERSTANDING YOUR CONTROL TEST RESULT

Compare your control test result with the ranges printed on the test strip vial label.



Notes:

If your control test result is out of range:

- Check the expiration and discard dates of the test strips and
- control solution. Ensure neither has been opened for more than 4
- months. Discard any expired test strips or control solution.
- Confirm that the temperature during testing is between 50-104°F
- (10-40°C).
- Ensure the test strips and control solution were stored at 36-86°F
- (2-30°C) and 10-90% humidity.

• Make sure the test strip vial and the control solution bottle are
• tightly capped.
• Ensure the test strip was used immediately after removal from the
• vial (or foil pouch).
• Confirm that the control solution was mixed well.
• Verify that you are using the FondCircle brand control solution.
• Ensure that you followed the test procedure correctly.

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall outside the range indicated on the test strip vial label, your meter or test strips may not be working properly. Do not use the system to test blood. Contact FondCircle Customer Support at (877) 899-7770. Please contact your healthcare professional if you need assistance.

To turn off your meter, simply remove the test strip. Dispose of the used test strips as medical waste. The result will be automatically marked and stored in the meter memory. Control results will not be included in your blood glucose averages.

USING THE METER MEMORY

Your meter automatically stores up to 500 results, including the time and date of each test. Test results are stored from the most recent to the oldest.

Note: If there are already 500 records in memory, the oldest record will be erased to make room for a new one.

VIEWING YOUR TEST RESULTS

When your meter is off, press ◎ to turn it on. After a beep, a test strip symbol will flash on the display, indicating the meter is ready. Continue pressing ◎ to review previous results in order, starting with the most recent. Each result will display the date and time the test was taken.

When END appears on the display, you have viewed all the results stored in the meter's memory.

SYMPTOMS OF HIGH OR LOW BLOOD GLUCOSE

Understanding your blood glucose test results is easier when you are aware of the symptoms of high or low blood glucose. According to the American Diabetes Association, here are some of the most common symptoms:

Low Blood Glucose (Hypoglycemia):
- Shakiness
- Sweating
- Fast heartbeat
- Blurred vision
- Confusion
- Passing out
- Irritability
- Seizures
- Extreme hunger
- Dizziness

High Blood Glucose (Hyperglycemia):
- Frequent urination
- Excessive thirst
- Blurred vision
- Increased fatigue
- Hunger

Ketones (Ketoacidosis):
- Shortness of breath
- Nausea or vomiting
- Very dry mouth

Warning:
- If you experience any of these symptoms, test your blood glucose immediately.
- If your blood glucose is under 50 mg/dL or above 250 mg/dL, contact your healthcare professional immediately.

CLEANING AND DISINFECTION

Your FondCircle Blood Glucose Meter should be cleaned and disinfected at least once per week. Use only Clorox™ Healthcare Bleach Germicidal Wipes, which have been proven safe for use with the FondCircle Blood Glucose Meter.

Cleaning is part of your normal care and maintenance and should be performed before disinfection. However, cleaning alone does not kill germs. After exposure to blood, all parts of the kit may potentially transmit infectious diseases. Disinfection reduces the risk of transmitting such diseases.

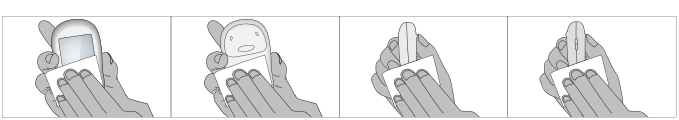
Note: If the meter is being operated by a second person who is assisting with testing, the meter should be cleaned and disinfected before it is used by them.

CARING FOR YOUR GLUCOSE MONITORING SYSTEM

- Store the meter in the carrying case provided whenever possible.
- Wash and dry your hands thoroughly before handling the meter to prevent water and other contaminants from affecting the meter and test strips.
- The FondCircle Blood Glucose Meter is a precision electronic instrument; handle it with care.
- Avoid exposing the meter and test strips to excessive humidity, heat, cold, dust, or dirt.

CLEANING YOUR METER

Step 1: Take one piece of Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12) from the container.
Step 2: Wipe down the entire surface of the meter, including the front, back, and sides.



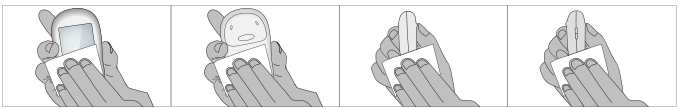
Front side | Back side | Right side | Left side

Note: The meter should be cleaned whenever it is visibly dirty or at least once per week. This cleaning prepares the meter for disinfection.

DISINFECTING YOUR METER

Step 1: After cleaning the meter, take another new piece of Clorox™ Healthcare Bleach Germicidal Wipes.

Step 2: Wipe the entire surface of the meter, including the front, back, and sides, using a back-and-forth motion.



Front side | Back side | Right side | Left side

Step 3: Keep the meter surface wet with the wipe for at least one minute.

IMPORTANT NOTES AND POTENTIAL ALTERATIONS

Clorox™ Healthcare Bleach Germicidal Wipes contain Sodium hypochlorite (0.55%), which has been proven safe for use with the FondCircle system. These wipes are available by contacting Krasity Medical Supply at 800-537-1394, or you can purchase them online at Walmart and Staples.
The meter should be disinfected at least once per week. This disinfection process has been validated for 608 disinfection cycles, which equates to cleaning and disinfecting your meter every 3 days for 5 years to ensure it operates properly throughout the meter's 5-year life.

Important Notes:
- 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 data port.
- Do not squeeze the wipe or gauze into the test strip port.
- Do not spray cleaning solutions on the meter.
- Do not immerse the meter in any liquid.

Potential Alterations:
Although not commonly observed, some alterations may appear on your meter as a result of the cleaning and disinfection process.

These may include:
- Cloudy display window
- Cracked plastic housing
- Non-functioning meter buttons
- Partial display on a full screen
- Difficulty executing the initial setup

If you notice any of these external changes or any changes in the meter's performance, stop using the meter and contact Customer Support for assistance.

For any questions about cleaning or disinfection, or if you notice any physical damage, contact FondCircle Customer Support at (877) 899-7770. If you need medical assistance, please contact your healthcare professional.

ERRORS AND TROUBLESHOOTING

Symbol	Problem	Solution
	Blood or control solution was applied to the test strip before the flashing blood drop appeared on the display	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	The meter is sensing a used or contaminated test strip	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	Incorrect test strip	Discard the test strip and repeat the test with a new test strip. Make sure that you are using a FondCircle test strip.
	Incorrect sample	Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and FondCircle control solution are used for the test.
	Temperature out of range	Move to an area that is within the operating range for the meter. Let the meter adjust to this temperature for 20 minutes before performing a test.
	Potential hardware issue	Restart the meter. If the problem continues, contact FondCircle Customer Support at (877) 899-7770. Please contact your health care professional if you need help.
	A test strip was inserted while the meter was connected to a computer or wall outlet	When the charge is completed (about 2 hours when charging an empty battery), remove the Micro-USB cable from the meter, and then take a test.

	Insufficient sample	Repeat the test and apply enough sample to fill the test strip check window.
	The test result is above 600 mg/dL	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes HI, contact your health care professional as soon as possible.
⚠ Caution: Glucose levels above 250 mg/dL may indicate a potential serious medical condition.		
	The test result is below 20 mg/dL	Repeat the test using a new test strip. If your result still flashes LO, contact your health care professional as soon as possible.
⚠ Caution: Glucose levels below 50 mg/dL may indicate a potential serious medical condition.		

SPECIFICATIONS

Measurement Method	Measures glucose in fingertip
Measurement Range	20-600 mg/dL
Hematocrit Range	20-70%
Sample	Fresh capillary whole blood
Sample Volume	0.8 µL
Glucose Units of Measurement	mg/dL
Test Time	5 seconds
Memory	Up to 500 records with date and time
Power Source	Rechargeable 3.7 lithium battery
Charging Current	100mA ⎓ Direct current
Battery Type	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
Operating Conditions	Temperature: 5-45°C (41-113°F) Humidity: 10-90% RH, non-condensing
Auto Power-off	2 minutes
Device Dimensions	83 × 52 × 18.7 mm
LCD Size	32 × 32 mm
Charging/Data Port	Micro-USB
Weight	Approx. 53 g
Bluetooth	Bluetooth Low Energy (BLE)

PERFORMANCE TESTING OF THE FONDCIRCLE BLOOD GLUCOSE MONITORING SYSTEM

The FondCircle Blood Glucose Monitoring System was evaluated through testing with 352 lay users using capillary blood samples across three different FondCircle test strip lots. The results from the FondCircle system were compared with the readings obtained from the YSI Model 2300 STAT PLUS Glucose Analyzer, a widely recognized laboratory instrument used for glucose testing.
Below are the comparison results between the two methods:

Table 1-Linear Regression Results

Slope	1.0137
Intercept	-2.3501 mg/dL
Correlation coefficient (R)	0.9977
Number of sample	352
Range tested	52.3 ~ 516.0 mg/dL

Table 2-Consumers Accuracy Results

The numbers and percentages represented in this table are the number of meter results compared to a laboratory result.

Difference range between the true blood glucose level and the FondCircle Blood Glucose Meter result	Within 5%	Within 10%	Within 15%	Within 20%
The percent (and number) of meter results that match true blood glucose level within x%	71.9% (253/352)	96.6% (340/352)	100% (352/352)	100% (352/352)

Accurate Results (Meter result is ±15% of laboratory result)	352 out of 352 (100% of results)
More Accurate Results (Meter result is ±10% of laboratory result)	340 out of 352 (96.6% of results)
Most Accurate Results (Meter result is ±5% of laboratory result)	253 out of 352 (71.9% of results)

FCC REGULATIONS

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.

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.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

WARRANTY AND CUSTOMER SUPPORT

Warranty

The device is covered by a 12-month warranty from the date of purchase, subject to the following terms and conditions.

The warranty does not cover:

- The batteries, packaging, or any other consumables.
- Damage resulting from improper use, including but not limited to:
  - Unauthorized disassembly or modification of the device.
  - Accidental dropping or impact during use or transportation.
  - Failure to follow the instructions provided in the user manual.

To claim warranty service, users must provide proof of purchase and comply with the terms outlined in the user manual.

Customer Support:

Email: support@fondcircle.com

Tel: 1-877-899-7770 (US) (Mon-Fri, 8:00 AM-5:00 PM PST)

Web: www.fondcircle.com

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PN:
Date: