

BG-208 Blood Glucose Monitoring System

Owner's Booklet



Advanced Diabetes Management System

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* Peel off the insulation film from battery compartment before first use.

Thank you for choosing BG-208 blood glucose monitoring system. Before you start testing, carefully read this Owner's Booklet.

Intended Use

It's intended to be used for the quantitative measurement of glucose(sugar) in fresh capillary whole blood. The system is intended for use outside the body (in vitro diagnostic use) by people with diabetes at home and by health care professional in a clinical setting as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of diabetes or for testing newborns.

Test Principle

Glucose in the blood sample mixes with special chemicals in the test strip and a small electric current is produced. The strength of this current changes with the amount of the glucose in the blood sample. The meter measures the current, calculates the blood glucose level, display the result , and stores it in its memory.

Important Safety information

 Warning

- During normal testing, any blood glucose meter or lancing device may come in contact with blood. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfecting.
- The meter and lancing device should never be used by more than one person. Do not share the meter and lancing device with anyone, including family members, due to the risk of infection from blood borne pathogens.
- Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, blood borne pathogens.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.
- Disinfect the meter and lancing device before allowing anyone else to handle them. Do not allow anyone else to test with the meter or lancing device.
- It is important to keep the meter and lancing device clean and disinfected. Clean and disinfect the lancing device once per week to remove visible dirt or other material for safe handling and/or prior to disinfecting.³ For instructions on how to clean and disinfect the meter and lancing device, see Chapter Maintenance.
- Wash hands thoroughly before and after handling the meter, lancing device, or test strips.
- Choking hazard. Small parts. Keep away from children.
- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use this meter close to sources of strong electromagnetic radiation.
- To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.

Important Health-Related information

- Patients undergoing oxygen therapy may receive inaccurate results.
- Some people with diabetes do not experience symptoms of low blood sugar (hypoglycemia). Others, such as children or people who are unconscious or have certain disabilities, may not be able to communicate their symptoms to caregivers. For these reasons, do not change any treatment without first talking to your doctor
- Run a control test when you open a new box of test strips or if you think that your test result is incorrect. Running a control test lets you know that the meter and test strips are working properly.
- **DO NOT CHANGE YOUR TREATMENT BASED ON A SINGLE RESULT THAT DOES NOT MATCH HOW YOU FEEL OR IF YOU BELIEVE THAT YOUR TEST RESULT COULD BE INCORRECT.** If your blood sugar result doesn't match how you feel and you have followed the instructions in this manual, follow your doctor's instructions, or call your doctor.
- Children should be taught how to use the meter and any other medical products appropriately
- Being severely dehydrated or losing a lot of water may give you false (low) test results. If you think you're suffering from dehydration, call your doctor right away.
- If you have followed all the instructions in this booklet and still have symptoms that don't seem to match your test results – or if you have questions – talk to your doctor.

- The system is designed for using with whole blood samples. Do not use serum or plasma samples.
- DO NOT test on neonatal samples (new born).
- Inaccurate test results may be obtained at high altitude more than about 3,048 meters above sea level.
- Hematocrit range: 30% to 55%. Hematocrit below 30% may cause higher results, and hematocrit above 55% may cause lower results.
- Some substances may cause false results with enzymatic tests.

Limitations

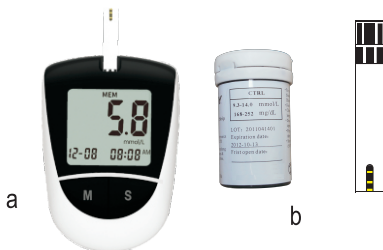
The interference listed below have been tested and shown no apparent influence on results at the normal or higher therapy levels.

Acetaminophen	2.0 mg/dL
Levodopa	No clear range of effective drug concentration
Ascorbic acid	2.0 mg/dL
Creatinine	1.5 mg/dL
Ibuprofen	4.2 mg/dL
Dopamine	0.04 mg/dL
Tetracycline	0.5 mg/dL
Urate	8.0 mg/dL

Other interfering substances in EN ISO 15197 : 2015 Annex A are not verified, it may also affect the test results.

INCLUDED WITH YOUR KIT

- Meter (battery included)
- Test Strips
- Lancing Device
- Sterile Lancet
- Control Solution
- Carrying case



a

b



c



d



e

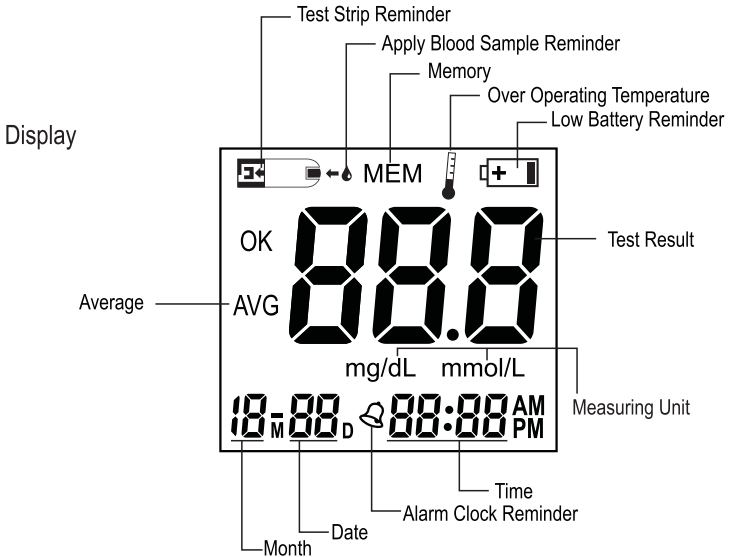
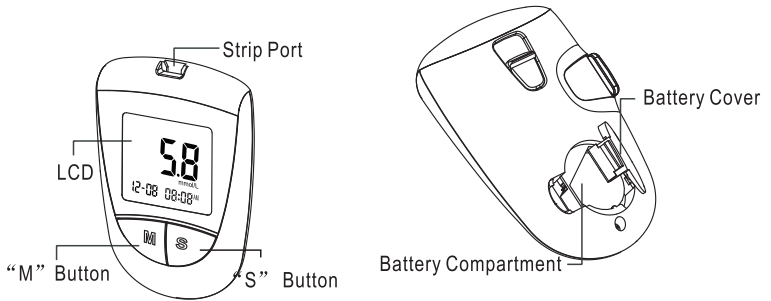


f

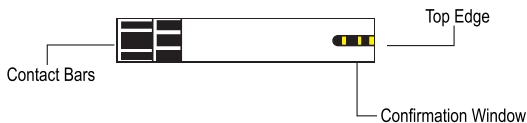


WARNING: Keep the meter and testing supplies away from young children. Small items such as the battery cover, batteries, test strips, lancets, protective covers on the lancets, and control solution vial cap are choking hazards.

a. Meter



b. Test Strip



Contact Bar: Insert it into strip port. Push it all the way until it will go no further.

Top Edge: Apply blood sample here

Confirmation Window: Sample checking area

Important: the meter should only be used with BS-102 test strips. Using other Test strips with this meter can produce inaccurate results.

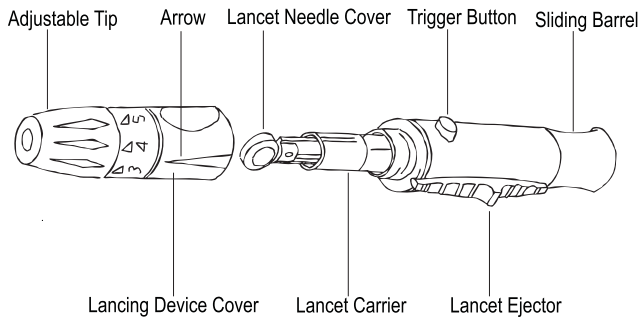
Important Test Strip Information

- The system has an operating range of $10^{\circ}\text{C} \sim 40^{\circ}\text{C}$ ($50^{\circ}\text{F} \sim 104^{\circ}\text{F}$).
- Store the test strip package in a cool, dry place between $1^{\circ}\text{C} \sim 30^{\circ}\text{C}$ ($33.8^{\circ}\text{F} \sim 86^{\circ}\text{F}$).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight or heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.
- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter test strips.

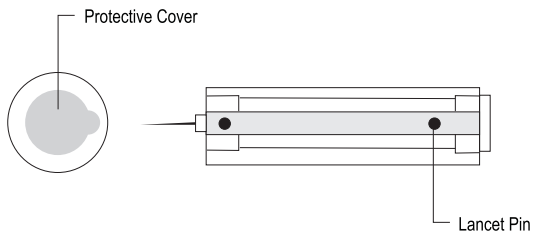


Warning: The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

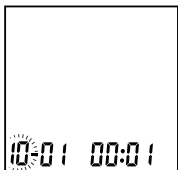
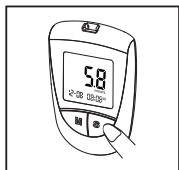
c. Lancing Device



d. Lancet

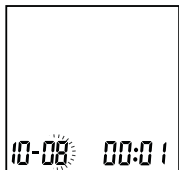


When use the meter for the first time, please set the parameters of the meter. With the meter off, long press button “S” to enter into setting mode.



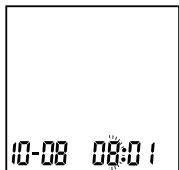
① Set the month

Press and release the button “M” to advance one month until the correct month appears.
After the month is set, press button “S”, the Date figure is flashing automatically.



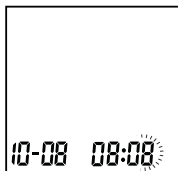
② Set the date

Press and release the button “M” to advance one day until the correct date appears.
After the date is set, press button “S”, the Hour figure is flashing automatically.



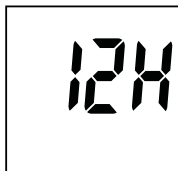
③ Set the hour

Press and release the button “M” to advance one hour until the correct hour appears.
After the hour is set, press button “S”, the Minute figure is flashing automatically.



④ Set the minute

Press and release the button “M” to advance one minute until the correct minute appears. After the minute is set, press button “S”, the Time format figure will appear.



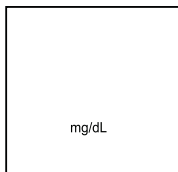
OR



⑤ Set the time format

The meter can display the time in either an AM/PM (12-hour) or a 24:00 (24-hour) format. Press and release button “M” to select the format.

With the preferred time format on the display, press button “S”, the measuring unit figure will appear.



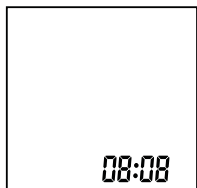
OR



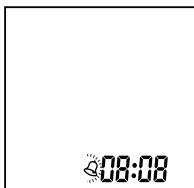
⑥ Set the measuring unit

The meter can display test results in either milligrams per decilitre (mg/dL) or millimoles per litre (mmol/L). Press and hold button “S” and “M” for 5 seconds to select the preferred format.

With the preferred measuring unit format on the display, press button “S” to enter the Alarm Clock setting.



OR



- ⑦ Set the alarm clock
The meter can set an alarm clock to remind you the time for testing.
Press button “M” to check the alarm function.
If the alarm is on, press button “S”, the time figure is flashing. Please refer to step 3 and 4 for the time setting. After the time is set, press button “S” button to exit the setting mode.
If there is no alarm function requirement, press button “S” to exit the setting mode.

Preparing the lancing device



Warning

- During normal testing, any blood glucose meter or lancing device may come in contact with blood. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from bloodborne pathogens, even after you have performed cleaning and disinfecting.
- The meter and lancing device should never be used by more than one person. Do not share the meter and lancing device with anyone, including family members, due to the risk of infection from bloodborne pathogens.
- Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, bloodborne pathogens.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.
- Disinfect the meter and lancing device before allowing anyone else to handle them. Do not allow anyone else to test with the meter or lancing device.
- It is important to keep the meter and lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see Chapter Maintenance.
- Wash hands thoroughly before and after handling the meter, lancing device, or test strips.
- You must not insert the lancet cap into the lancing device and simultaneously press the release button or hold the lancing device with the release button resting on a surface such as a table top. This could release a lancet and inadvertently cause injury.

Preparing the lancing device



- ① Twist off the lancing device cover.



- ② Insert a new lancet into the lancet carrier firmly.



- ③ Hold the lancet needle cover and gently twist it until it separates from the lancet.



- ④ Replace the lancing device cap. Avoid touching the lancet pin.



- ⑤ Adjust the depth setting
The adjustable tip offers 5 levels of skin penetration. Twist the lancing device cap until the desired setting appears.

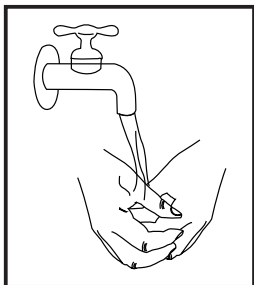
Note: To select the best depth:
1-2 for soft or thin skin 3 for average skin.
4-5 for thick or calloused skin.

Preparing the lancing device

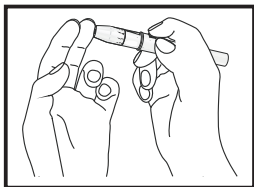


- ⑥ Hold the lancing device cover in one hand. Using the other hand, slowly pull the sliding Barrel away from the lancing device cover. You will hear a click, indicating that the lancet carrier is locked into position. Release sliding barrel to return it to its original position.

Blood Sampling

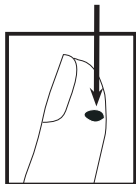


- ① Wash your hands and the puncture site with an alcohol swab or soapy water. Rinse and dry thoroughly.



- ② Position the end of the adjustable comfort tip against the side-tip of the finger. Press the trigger button, and then lift the lancing device away from the finger after the puncture is complete. Place the lancing device aside and wait a few seconds for a blood drop to form.

Approximate size



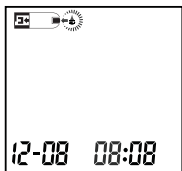
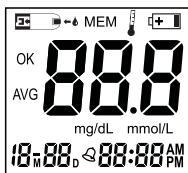
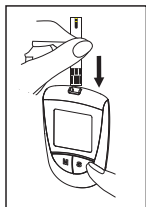
- ③ Gently squeeze your finger until you get a round drop of blood. Discard the first drop. If the blood smears or runs, Do Not use that sample. Wipe the area and gently squeeze another drop of blood or puncture a new site.

Blood Sampling

IMPORTANT:

- Use only Test Strips BS-102.
- Make sure your meter and test strips are about the same temperature before you test.
- Testing must be done within the operating temperature range $10^{\circ}\text{C} \sim 40^{\circ}\text{C}$ ($50^{\circ}\text{F} \sim 104^{\circ}\text{F}$).
For the most accurate results, try to test as close to room temperature $20^{\circ}\text{C} \sim 25^{\circ}\text{C}$ ($68^{\circ}\text{F} \sim 77^{\circ}\text{F}$) as you can.
- Tightly close the cap on the vial immediately after use to avoid contamination and damage.
- Store unused test strips only in their original vial.
- Do Not open the test strip vial until you are ready to remove a test strip and perform a test. Use the test strip immediately after removing it from the vial.
- Do Not return the used test strip to the vial after performing a test.
- Do Not re-use a test strip that had blood or control solution applied to it. Test strips are for single use only.
- Write the first open date on the vial label when you first open it. Discard the vial 3 months after first open date.

Testing



- ① With meter off or in setting mode and memory mode, insert a test strip to enter into testing mode.



Note: If you do not start the test within three minutes, the meter will turn off. To restart your meter, take out the unused test strip and reinsert it into the meter.

Important: The meter should only be used with BS-102 test strips. Using other test strips with this meter can produce inaccurate results.

- ② System check screen

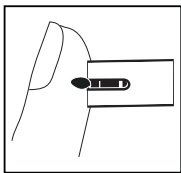
Each time the meter powers on, this screen briefly appears so that you can make sure the display is working properly.

Note:

- If  appears, it indicates the operating temperature is over range. Place the system in operating temperature room for half hour. Then test again.
- If  appears, it indicates the battery is almost out of power. Replace the battery now.

- ③ The blood drop symbol flashes on the display screen. Your meter is now ready to apply blood sample.

Testing

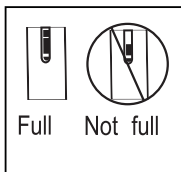


④ Apply the sample

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

Note:

- Discard the first drop of blood. Do Not smear or scrape the drop of blood with the test strip.
- Do Not apply more blood to the test strip after you have moved the drop of blood away.
- Do Not move the test strip in the meter during a test.



⑤ Wait for the confirmation window to fill completely

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

When the confirmation window is full, this means you have applied enough blood. Now you can move the test strip away from the blood drop and wait for the meter to count down from 5 to 1 with 1 beep sounds indicating the end of test.



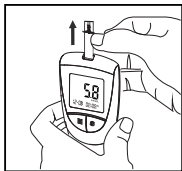
⑥ Read your result on the meter

Your blood glucose level appears on the display, along with the unit of measure, the date and time of the test. Blood glucose results are automatically stored in the meter's memory.



⑧ Delete the memory

If you don't want to keep the test result, press the "S" button and "M" button to delete it at the same time. After memory cleared, the meter will display "dEL" and then turn off automatically.



⑨ Turn your meter off.

Simply remove the test strip. Carefully dispose the used test strip.

Interpreting unexpected test results

The meter can accurately measure blood glucose concentrations between 2.2 to 33.3 mmol/L (40 to 600 mg/dL).

Expected Blood Glucose Level:

Time	Normal Blood Glucose Range
Before breakfast	3.9-5.8 mmol/L (70-105 mg/dL)
Before lunch or supper	3.9-6.1 mmol/L (70-110 mg/dL)
1 hour after meal	≤8.9 mmol/L (less than 160 mg/dL)
2 hour after meal	≤ 6.7 mmol/L (less than 120 mg/dL)
Between 2 am and 4 am	≤3.9 mmol/L (Greater than 70 mg/dL)

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



① Low glucose results

If your test result is lower than 2.2 mmol/L (40 mg/dL), LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).

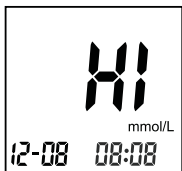
• LO Reading with Symptoms

If you have a LO reading and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.

• LO Reading without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, follow your doctor's recommendation to treat hypoglycemia.

Interpreting unexpected test results



② High glucose results

If your test is above 33.3 mmol/L (600 mg/dL), HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).

• HI Reading with Symptoms

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.

• HI Reading without Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip. If you still get a HI reading, follow your doctor's recommendation to treat hyperglycemia.

③ Unusual hematocrit

Too high (above 55%) or too low (below 30%) hematocrit can cause inaccurate results.

Comparing your meter's results with laboratory results periodically. The results of the BG-208 meter are plasma equivalent. This method will help you and your healthcare professional compare your meter results with laboratory test results. The BG-208 meter's test result and laboratory test results both are expressed in plasma-equivalent units. However, your blood glucose meter result may differ from your laboratory result due to normal variation. Your blood glucose meter results can be affected by factors and conditions that do not affect laboratory results in the same way.

- If your blood glucose is below 5.55mmol/L (100 mg/dL), your results generally should fall within ± 0.83 mmol/L (± 15 mg/dL) of the laboratory result.
- If your blood glucose is equal to or above 5.55 mmol/L (100 mg/dL), your results generally should fall within $\pm 15\%$ of the laboratory result.

To maximize your chances of an accurate comparison between meter and laboratory results, please follow a few basic guidelines:

Before going to the lab

- Perform a control solution test to make sure the meter is working properly.
- Do Not eat for at least eight hours before you test your blood glucose.
- Take the meter to the lab.

While at the lab

- Conduct your meter test of the lab test within 15 minutes.
- Use only fresh, capillary blood obtained from the fingertip.
- Follow all instructions in this Owner's Booklet to performing a blood glucose test by your meter.

Storing Blood glucose and Control Test results

The meter automatically stores up to 360 blood glucose test results with the time and date of the test and any test markers. Results can be reviewed at any time. Test results are stored from the newest to the oldest, so set the time and date correctly in the meter. Having the correct time and date setting helps ensure appropriate interpretation of stored blood glucose results by you and your healthcare professional.

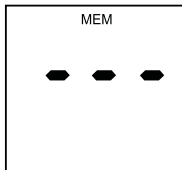
① Entering Memory Mode

Start with the meter off (no test strip inserted). Press and release the “M” button to enter memory mode.

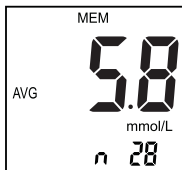


② Viewing previous memory in order

Press and release “M” button to scroll forward to all results. Your most recent result will display first.



Note: If there is no test result stored, the meter will display “- - -” for a few seconds then automatically turn off.



③ Viewing 7-, 14-, 28-day average

Press and release “S” button to scroll forward to averages.

The first memory display screen you see is your 7-day average.

This average includes all the readings from the last period days.

n = indicates the number of results included in your average



④ Deleting all memory

Press and hold “S” button approximately 3 seconds.

After memory cleared, the meter will display “dEL” and then turn off automatically.

⑤ Exiting

In memory mode, press and hold the “M” button for few seconds until the meter turns off.

When to perform a control test

Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly.

Do a control solution test:

- Whenever you open a new vial of test strips.
- Whenever you want to check if you are testing correctly
- If you suspect the meter and test strips are not working properly.
- If you have had repeated unexpected blood glucose results.
- If you drop or damage the meter.
- If you left the test strip container open or you think the test strips have been damaged
- If the test strips were stored in extreme temperatures and/or humidity
- Your test result does not match how you feel

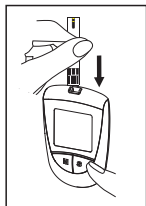
NOTE:

- Only use the CS-101 control solution.
- Close the control solution bottle tightly after use
- Write the date you open the control solution bottle on the bottle label. The control solution must be discarded 3 months from the first open date or the expire date on the vial label, whichever comes first.
- Do not use control solution that is past the expired date or discard date.
- Refer to the control solution label for control solution storage conditions.
- The control solution can stain fabric. Remove stains by washing with soap and water.

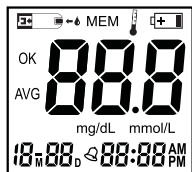


CAUTION: Do Not swallow control solution. It is not for human consumption. Do Not apply control solution to the skin or eyes as it may cause irritation.

Performing a control test

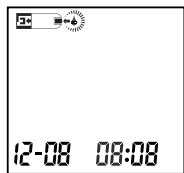


- ① Insert a test strip to turn the meter on

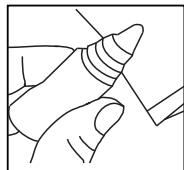


- ② System check screen

Each time the meter powers on, this screen briefly appears so that you can make sure the display is working properly.

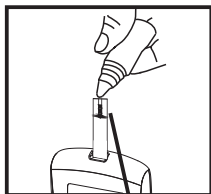


- ③ The blood drop symbol flashes on the display screen. Your meter is now ready to apply blood sample.

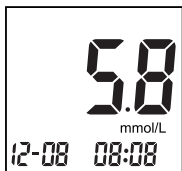
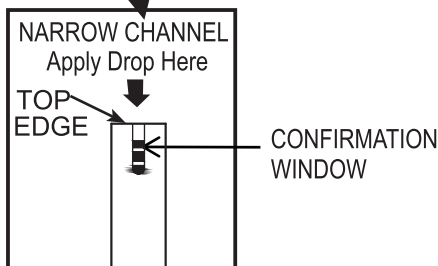


- ④ Shake the control solution vial before each test. Remove the cap and squeeze the vial to discard the first drop. Then wipe the tip with a clean tissue or cloth. Hold the vial upside down and gently squeeze a hanging drop.

Performing a control test

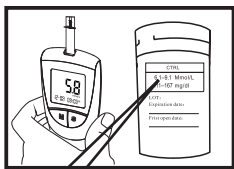


- ⑤ Touch and hold the hanging drop of control solution where the narrow channel meets the TOP EDGE of the test strip. Make sure the confirmation window fills completely. Control solution should not be applied to the flat face of the test strip.



- ⑥ Read the result on the meter
When the confirmation window is full, the meter will count down from 5 to 1. blood glucose level appears on the display, along with the unit of measure, the date and time of the test.
The results are automatically stored in the meter's memory.

Understanding out-of-range control test results



6.1–9.1 mmol/L
(Example)

Compare the result displayed on the meter to the control solution range printed on the test strip vial. Each vial of test strips may have a different control solution range. If the results you get are not within this range, the meter and test strips may not be working properly. Repeat the control solution test.

Out-of-range results may be due to:

- not following the instructions detailed in steps 1–6
- expired or contaminated control solution
- expired or damaged test strip
- use of a test strip or control solution passed its discard date
- a problem with the meter.



CAUTION: The control solution range printed on the test strip vial is for Control Solution only. It is not a recommended range for your blood glucose level.

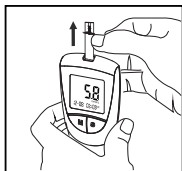


CAUTION: If you continue to get control solution test results that fall outside the range printed on the test strip vial, Do Not use the meter, the test strips, or the control solution. Contact the vendor.




⑦ Delete the memory

If you don't want to keep the test result, press the "S" and "M" button to delete it at the same time. After memory cleared, the meter will display "dEL" and then turn off automatically.

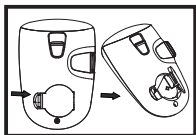


⑧ To turn your meter off, simply remove the test strip. Carefully dispose of the used test strip.

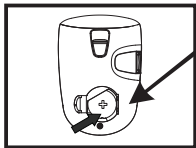
Replacing the battery

Your meter comes with one preinstalled, 3 volt, type 2032, lithium battery. The battery provides enough power for the meter to perform about 1000 tests. If your battery runs low, the battery symbol “” appears on every display screen until you change the battery.

Important: When this symbol appears, you should replace the battery immediately.

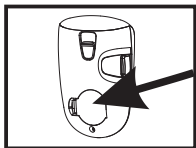


- ① With the meter off, open the battery cover.



(+) side facing up

- ② Remove the old batteries and place the new ones in the battery compartment with the (+) side facing up.



- ③ Put the battery cover back into position until it locks into place.

- ④ Check your meter settings

Replacing the battery does not affect your stored results. However, you may need to re-set your meter settings. See Setting Up Your Meter section.



Note: Batteries need to be properly disposed of. Contact your local government for disposal or recycling practices in your area.

Caring for your system

Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip port.

Important: Never immerse the meter in water or any other liquid. This may cause inaccurate reading or meter malfunction.

Storing your system

Store your meter, test strips, control solution and other items in your carrying case after each use. Store each item in a cool, dry place.

Test strips and control solution should be stored between $1^{\circ}\text{C} \sim 30^{\circ}\text{C}$ ($33.8^{\circ}\text{F} \sim 86^{\circ}\text{F}$). Meter and other items should be stored between $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$ ($-4^{\circ}\text{F} \sim 131^{\circ}\text{F}$).

Do Not refrigerate. Keep all items away from direct sunlight and heat. Tightly close the cap on the test strip vial and/or control solution vial immediately after use to avoid contamination or damage. Store test strips only in their original vial.

Checking for expiration or damages to test strips and control solution

Expiration dates for test strips and control solutions are printed on their vial labels. When you first open a new vial of test strips or control solution, record the discard date on the label. Refer to the test strip or control solution vial for instructions on determining the discard date.

Cleaning and disinfection

Cleaning and disinfection are different, both of them should be performed.

Cleaning is a part of normal care and maintenance that should be performed prior to disinfection, but cleaning does not kill germs.

Disinfection is a important way to reduce your exposure to disease. Even though you are the only person who use it,

we recommend to disinfect periodically. When you assist others to make blood glucose testing, if you take the meter, please disinfect it or wear gloves to protect yourself.

Cleaning your meter and lancing device

To clean your meter and lancing device, wipe the outside with a soft cloth dampened with water and mild detergent. Do not use alcohol or another solvent. Do not get any liquids, dirt, dust, blood, or control solution inside the meter through the strip port. Never spray cleaning solution on the meter or immerse it in any liquid. Do not immerse the lancing device in any liquid.

Disinfecting your meter and lancing device


The meter and lancing device should be disinfected periodically.

Clean your meter and lancing device prior to disinfecting.

To disinfect, prepare a solution of 1 part household bleach and 9 parts water. Hold the meter with the strip port and pointed down. Use a soft cloth dampened with this solution to wipe the outside of the meter and lancing device until the surface is damp. Be sure to squeeze out any excess liquid before you wipe the meter.

After wiping, cover the surface you are disinfecting with the soft cloth dampened with the bleach solution for 1 minute. Then wipe with a clean damp soft cloth and allow to air dry.

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

Message	Possible Cause	What to do
E-1	The system check may be failed	Remove the battery and reinsert it after 30 seconds. If it still doesn't work, please contact the vendor.
E-2	The test strip may be used or damaged.	Retest with a new strip.
E-3	The sample was applied before the meter was ready.	Repeat with a new strip. Applying blood after the  symbol flashes on the screen.
E-4	The test strip may be moved during testing or sampling data is unstable.	Retest with a new strip. Make sure that the method of applying sample is correct, and test strip can not be moved during testing.
E-5	The strip check has problem.	Retest with a new strip.



Battery power is low.

Replace the battery soon



The meter is out of operating temperature range.

Place the system in appropriate operating environment for 30 minutes before retesting.

Meter does not enter the test mode after inserting a test strip.	
Probable Cause	What to Do
The battery is dead.	Replace the battery (and reset the date and time, if necessary.)
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
Test strip inserted upside down, or incompletely inserted into the meter.	Insert the test strip with the printed side up and the top of the strip in the meter.
Defective meter or test strips.	Contact the vendor.
Blood or foreign objects put into the test strip port.	Contact the vendor.
Test does not start after applying the blood sample.	
Probable Cause	What to Do
Defective test strip.	Repeat the test with a new test strip.
Sample applied after meter times out and turns off.	Remove the test strip, and repeat the test using a new test strip. Wait until you see the blood and test strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Contact the vendor.

Specifications

Product description	BG-208 Blood Glucose Monitoring System
Assay method	Glucose oxidase biosensor
Measurement range	2.2-33.3 mmol/L (40~600 mg/dL)
Sample	Fresh capillary whole blood
Sample size	Approximate 1 microlitre
Response time	5 seconds
Coding	No coding
Battery	One 3.0V CR2032 lithium battery, replaceable
Battery life	Approximately 1,000 tests
Calibration	Plasma equivalent glucose values
Unit of measure	mmol/L or mg/dL; switchable
Memory	360 blood glucose results with date and time
Size	83.7*58*16.7 mm (L*W*H)

Specifications

LCD size	34.6*31.1 mm (L*H)
Weight	Approximate 38.0 g, battery not included
Operating environment	10°C ~ 40°C (50°F ~ 104°F)
	10 ~ 70% RH (non-condensing)
Meter storage temperature	-20°C ~ 55°C (-4°F ~ 131°F)
	10 ~ 70% RH (non-condensing)
Altitude	Up to 10,000 feet (3,048 meters) above sea level
Hematocrit	30%~55 %
Automatic power off	Approx. 3 minutes after last user action

Electromagnetic Compatibility

This meter meets the electromagnetic immunity requirements as standard EN ISO 15197 : 2015. The chosen basis for electrostatic discharge immunity testing was basic standard EN 61326 : 2013. Its electromagnetic emission is thus low. Interference from the meter to other electrically-driven equipment is not anticipated.

Warning

- Any product coming in contact with blood is considered contaminated (potentially infectious).
- During normal testing, any blood glucose meter may come in contact with blood.
- Lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions.

Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used meters, used test strips, used lancets, and used batteries.

Please consider the following points when disposing of used testing materials:

- Consider recycling of the meters and batteries at an appropriate facility. Be aware the meter is potentially hazardous electronics scrap (e-scrap) and should be disposed of accordingly. The batteries are potentially hazardous also and should be disposed of accordingly.
- Disinfect the meter before recycling or disposing.

* 29 CFR 1910.1030 – Bloodborne pathogens

* Directive 2002/96/EC – Directive on waste electrical and electronic equipment (WEEE)

Limited 2-Year Warranty

The meter is guaranteed for 2-year from the date of purchase. If the meter does not function properly due to defective components or poor workmanship, we will repair or replace it freely. This warranty does not cover damage due to improper handling in any way. Battery does not included in the warranty.

The calibrator of the Blood Glucose Monitoring System BG-208 is control solution. The traceability of the control solution is referenced to the EKF BIOSEN C line-Clinic glucose analyzer. The EKF is the reference method used to assess the accuracy with which glucose results are obtained using the system. The value of the calibrator for glucose is traceable to the National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 917b (D-Glucose). Concentration: 12 mmol/L se.

The performance of the system has been evaluated both in laboratory and in clinical tests.

- **Range:** The display range of the meter is 2.2mmol/L to 33.3 mmol/L (40mg/dL to 600 mg/dL). "HI" and "Lo" messages indicate results outside of this range.
- **Accuracy:** The accuracy of the system was assessed by comparing blood glucose results obtained using EKF Glucose Analyzer, a laboratory instrument.

Table1. System accuracy results for glucose concentration < 5.55 mmol/L (100 mg/dL)

Within $\pm 0,28$ mmol/L (Within ± 5 mg/dL)	Within $\pm 0,56$ mmol/L (Within ± 10 mg/dL)	Within $\pm 0,83$ mmol/L (Within ± 15 mg/dL)
110/156 (70.5%)	156/156 (100%)	156/156 (100%)

When the blood glucose is below 5.55mmol/L (100 mg/dL), 100% of measured glucose results should fall within ± 0.83 mmol/L (± 15 mg/dL) of the laboratory result.

Table2. System accuracy results for glucose concentration ≥ 5.55 mmol/L (100 mg/dL)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
435/444 (98.0%)	444/444(100%)	444/444(100%)	444/444(100%)

When the blood glucose is equal to or above 5.55mmol/L (100 mg/dL), 100% of measured glucose results should fall within ± 15 % of the laboratory result.

Table 3. System accuracy results for glucose between 2.2 mmol/L (40 mg/dL) and 33.3 mmol/L (600 mg/dL)

Within $\pm 0,83$ mmol/L or $\pm 15\%$ (Within ± 15 mg/dL or $\pm 15\%$)
600/600 (100%)

This study shows that the system compares well with a laboratory method and meets the minimum acceptable performance criteria defined in ENISO 15197 : 2015.

Precision:

Intermediate Precision	Control Solution av 2.5 mmol/L	SD=0.12mmol/L
	Control Solution av 7.0 mmol/L	CV=2.4%
	Control Solution av 23.0 mmol/L	CV=3.7%
Repeatability	Blood av 2.5 mmol/L	SD=0.12mmol/L
	Blood av 4.1 mmol/L	CV=2.9%
	Blood av 7.0 mmol/L	CV=1.9%
	Blood av 10.6 mmol/L	CV=1.9%
	Blood av 19.9 mmol/L	CV=3.8%












To maximize your chances of an accurate comparison between meter and laboratory results, follow a few basic guidelines:







Before going to the lab

- Perform a control solution test to make sure the meter is working properly.
- Do Not eat for at least eight hours before you test your blood.
- Take your meter with you to the lab.

While at the lab

- Conduct your meter test within 15 minutes of the lab test.
- Use only fresh, capillary blood obtained from the fingertip.
- Follow all instructions in this Owners Booklet for performing a blood glucose test with your meter.

	Consult instructions for use
	In vitro diagnostic medical device
	Serial number
	Caution
	Batch code
	Manufacturer
	Contain sufficient for < n > tests
	Storage temperature limitation
	Sterilized using ethylene oxide
	Do not reuse
	Use by

	The Product conforms to the requirements of the EC Directive IVDD(98/97/EC) on in vitro diagnostic medical devices“0197” is the identification number of notify body
	Biological risks
	Keep dry
	This symbol indicates that you should not discard waste electrical or electronic equipment (WEEE) in the trash. For proper disposal, contact your local
	Direct Current
	European Authorized Representative

1. Use of Fingertick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication , (2010)
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.
Accessed June 8, 2011
2. CDC Clinical Reminder:"Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens , (2010)
<http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>.
Accessed June 8,2011
3. Healthcare Infection Control Pratices Advisory Committee (HICPAC), William A. Rutala, Ph.D.,M.P.H., and David J. Weber,M.D.,M.P.H. Centers for Disease Control and Prevention, 2008."Guideline for Disinfection and Sterilization in Healthcare Facilities,Atlanta."

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