SEJOY®

BG-709 Blood Glucose Monitoring System

Owner's Booklet

Advanced Diabetes Management System

Contents

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

Thank you for choosing Sejoy BG-709 blood glucose monitoring system. Before you start testing, carefully read this Owner's Booklet.

Intended Use

The Sejoy BS-602 Test Strips are used with the Sejoy BG-709 Blood Glucose Meter to quantitative measure blood glucose with fresh capillary whole blood or venous blood or neonatal blood. The system is intended for in vitro diagnostic home-use and by healthcare professional in a clinical setting as an aid to monitor the effectiveness of diabetes control. This system is not for use in the diagnosis of diabetes mellitus.

Test Principle

The strip measures glucose by using amperometric technology employing a glucose dehydrogenase reaction. When whole blood or control solution is drawn into the tip of a test strip, glucose in the sample reacts with chemicals and produces an electrical current. The meter measures electrical current and calculates amount of glucose. The glucose result is displayed as a calculated plasma value.

- Venous whole samples collection and preparation should be obtained by healthcare professionals.

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 disinfection.
- 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 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.

  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 included. 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 glucose 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 use with fresh caillary whole blood and or venous blood and or neonatal blood.
- Inaccurate test results may be obtained at high altitude more than about 3048 meters above sea level.
- BS-602 blood glucose test strip: more than 70% of the hematocrit ratio will affect the measurement results. Please contact your doctor to determine your hematocrit ratio.
- 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.

Substance	Concentration	Substance	Concentration
Acetaminophen	1.11mmol/L(20mg/dL)	Ascorbic acid	0.17mmol/L(3mg/dL)
Bilirubin	2.22mmol/L(40Lmg/dL)	Cholesterol	27.78mmol/L(500mg/dL)
Creatinine	0.56mmol/L(10mg/dL)	Dopamine	1.1mmol/L(20mg/dL)
Gentisic acid	1.25mmol/L(22.5mg/dL)	Glutathione	2.17mmol/L(39mg/dL)
Haemoglobin	1111.11mol/L(20000mg/dL)	Heparin	500IU/dL
Ibuprofen	2.78mmol/L(50mg/dL)	Icodextrin	60.8mmol/L(1094.4mg/dL)
L-Dopa	0.03mmol/L(0.5mg/dL)	Maltose	555.56mmol/L(1,0000mg/dL)
Methyl-DOPA	0.22mmol/L(4mg/dL)	Salicylate	3.33mmol/L(60mg/dL)
Tolbutamide	5.55mmol/L(100mg/dL)	Tolazamide	0.56mmol/L(10mg/dL)
Triglycerides	83.33mmol/L(1500mg/dL)	Uric acid	1.33mmol/L(24mg/dL)
Xylose	2.78mmol/L(50mg/dL)	Pralidoxime Iodide	0.83mmol/L(15mg/dL)
EDTA	11.11mmol/L(200mg/dL)	Galactose	0.83mmol/L(15mg/dL)

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

INCLUDED IN YOUR KIT

a. Meter (battery included)

b. Test Strips

c. Lancing Device

d. Sterile Lancet

e. Control Solution

a

b

c

Manufacturer of Lancing Device and Sterile Lancet

Manufacturer of Lancing Device and Sterile LancetShandong Lianfa Medical Plastic Products Co.. Ltd.No.1
Shuangshan Sanjian Road, 250200, Zhangqiu City, Jinan, Shandong, PEOPLE'SREPUBLIC OF CHINA
EC REP ShanghaiInternational Holding Corp. GmbH (Europe)EC| REPEiffestrasse 80, 20537 Hamburg Germany

CE:for lancing device; CE:0123 for sterile lancet

Beijing Ruicheng Medical Suplies Co., Ltd.
No. 558 Zhangzikou, Yangsong Town, Huairou District, 10400 Bejing, China

EC REP Lotus NL B.V.
EC REPKoningin Julinaplein 10, Ie Verd,2595AA, The Hague, Netherlands.

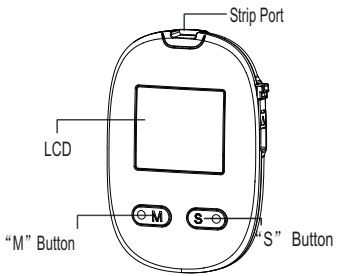
CE:for lancing device; CE:0197 for sterile lancet

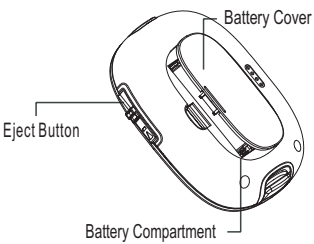
d

e

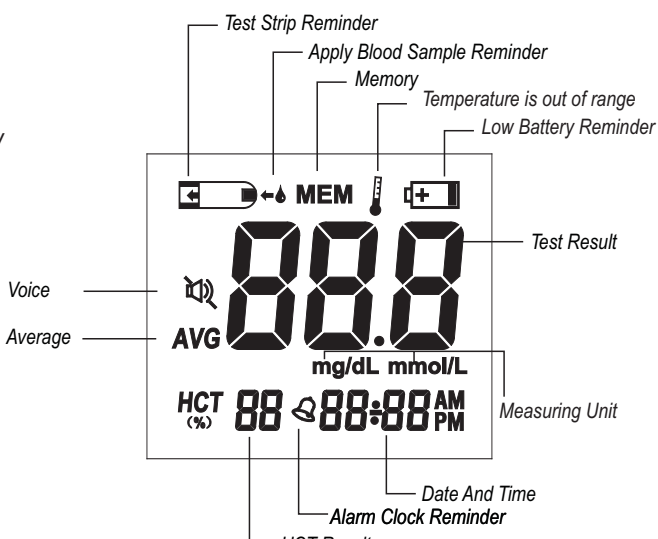
⚠ WARNING: Keep the meter and testing supplies away from children. Small items such as the battery cover, batteries, test strips, lancets, protective covers of the lancets, and control solution vial cap are choking hazards.
In-door glucose measurement is recommended.

a. Meter





Display



b. Test Strip

Contact Bar: Insert it into strip port. Push it all the way until it goes no further.
Top Edge: Apply blood sample here.
Confirmation Window: Sample checking area.

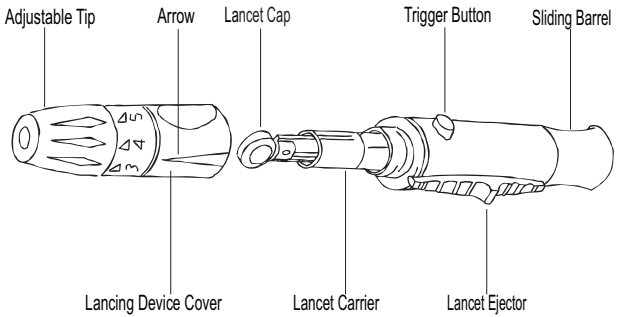
Important: the meter should only be used with BS-602 test strips.
Using other Test strips with this meter can produce inaccurate results.

Important Test Strip Information

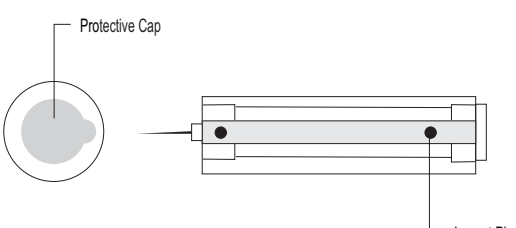
- The system has an operating range of 5℃~45℃ (41℉~113℉).
- Store the test strip package in a cool, dry place between 1℃~30℃ (33.8℉~ 86℉).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight or heat.
- Store your test strips in their original vial only; 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.

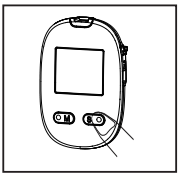
c. Lancing Device

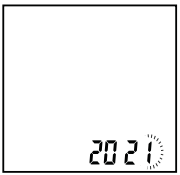


d. Lancet

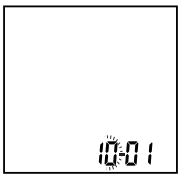


When using the meter for the first time, please set the parameters of the meter. With the meter off, long-press button “S” to enter setting mode.

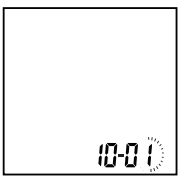




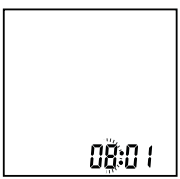
① Set the year
Press and release the button “M” to advance one year until the correct year appears.
After the year is set, press button “S”, the monthfigure is flashing automatically.



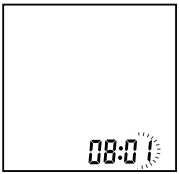
② Set the month
Press and release the button “M” to advance one month until the correct month appears.
After the month is set, press button “S”, the date figure is flashing automatically.



③ 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.



④ 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.



⑤ Set the minute

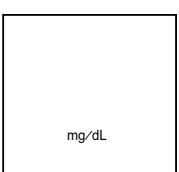
Press and release the button “M” to advance one minute until the correct minute appears. After the minute is set, press button “S”, the time format figure will appear.

OR

⑥ 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.



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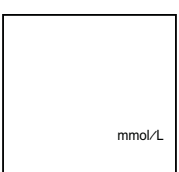
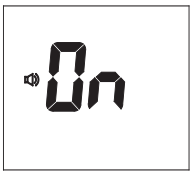


⑦ Set the measuring unit

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 voice mode setting.



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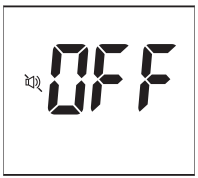
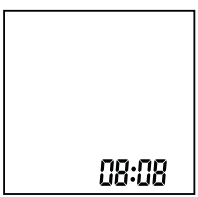


⑧ Set voice mode

Press and release button “M” to select the voice mode press. button “S” to enter the alarm clock setting.



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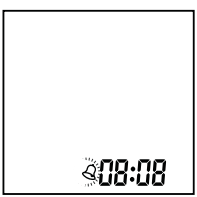


⑨ Set the alarm clock

The meter can set an alarm clock to remind you of the testing time.

Press button “M” to check the alarm function.

If the alarm is on, press button “S”, the time figure is flashing. For time setting, refer to step 3 and 4.

After setting, press button “S” to exit the setting mode.

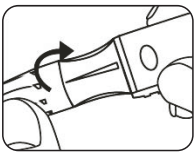
If there is no alarm function requirement, press the “S” key to exit the setting mode.

Preparing the lancing device

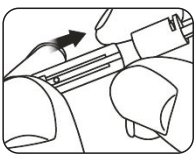
⚠ Warning

- 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 blood-borne pathogens, even after you have performed cleaning and disinfection.
- 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. 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 on the table. This could release the lancet and inadvertently cause injury.

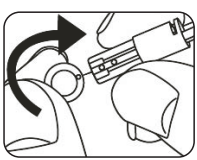
Preparing the lancing device



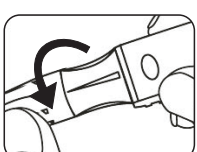
① Screw off the lancing device cover.



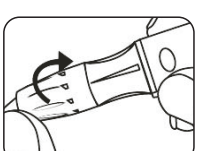
② Insert a new lancet into the lancet carrier firmly.



③ Hold the lancet needle cover and gently twist it off the lancet.



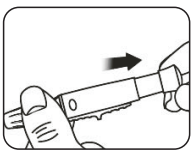
④ Put on the lancing device cap.
Avoid touching the trigger button.



⑤ Adjust the depth setting
The indication marks 5 levels of skin penetration. Switch the lancing device cap to the desired setting.

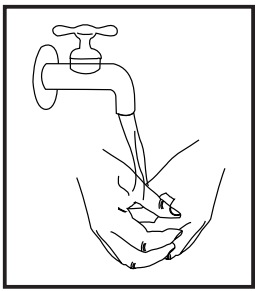
Note: To select the best depth:
1-2 for soft or thin skin, 3 for average skin.
4-5 for thick or calloused skin.

Preparing the lancing device

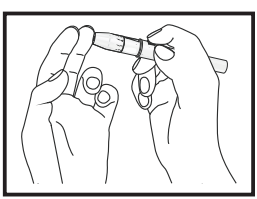


⑥ Hold the lancing device cover in one hand. Using the other hand, slowly pull the sliding barrel away from the lancing device cover. You will hear a click, indicating that the lancet carrier is locked into position. Release sliding barrel to return it to its original position.

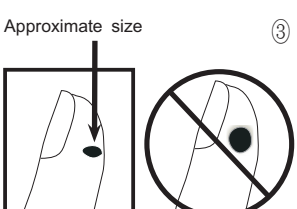
Blood Sampling



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 tip against the side 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.



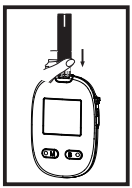
③ Gently squeeze your finger until you get a round drop of blood. Discard the first drop. Do not use, If the blood is smeared or running. Wipe the area and gently squeeze another drop of blood or puncture a new site.

Blood Sampling

IMPORTANT:

- Use only Test Strips BS-602.
- Make sure your meter and test strips are about the same temperature before you test.
- Testing must be done within the operating temperature range 5℃~45℃ (41℉~113℉).
  For the most accurate results, test at room temperature 20℃~25℃ (68℉~77℉).
- 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 6 months after first-open date.

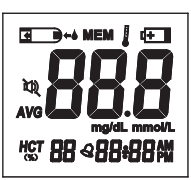
Testing



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-602 test strips. Using other test strips with this meter can produce inaccurate results.



② System check screen

The screen will briefly display all content to confirm that the display is working properly.

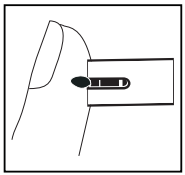
Note:

•If appears, it indicates that the operating temperature is out of range. Place the system in room temperature for half hour. Then test again.

•If appears, it indicates that the battery is almost empty. Replace the battery now.

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

Testing

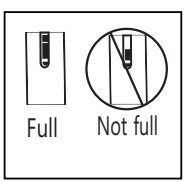


④ Apply the sample

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-sound indicating the end of test.

⑥ Read your result on the meter

After the measurement is over, the meter will display the blood glucose level along with the unit of measure, the date and time of the test. Blood glucose results are automatically stored in the meter's memory.

⑦ Delete the memory

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

⑧ Turn your meter off.

Push the eject button gently to automatically eject the test strip from the meter, or remove the test strip by hand, the meter will automatically shut down. Please handle the used test strip carefully.

Interpreting unexpected test results

The meter can accurately measure blood glucose concentrations between 0.5 to 33.3mmol/L (9 to 600mg/dL)

Expected Blood Glucose Level [1, 2, 3] :

Time	Normal Blood Glucose Range
Before breakfast	3.9-5.8 mmol/L（70-105mg/dL）
Before lunch or supper	3.9-6.1 mmol/L（70-110mg/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）

Source: 1. Clin Chem 51,2005:1573-1576;
2. Stedmans Medical Dictionary,27th Edition,2000:2802;
3. American Diabetes Association: Standard of Medical Care in Diabetes 2019, Vol.39.

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 0.5mmol/L(9mg/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 70%) hematocrit can cause inaccurate results.
  Please contact your doctor to determine your hematocrit ratio.

Comparing your meter's results with laboratory results periodically.
The results of the Sejoy BG-709 meter are plasma equivalent. This method will help you and your healthcare professional compare your meter results with laboratory test results. The Sejoy BG-709 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 ±0.83mmol/L (±15 mg/dL) of the laboratory result.
- If your blood glucose is equal to or over 5.55mmol/L (100 mg/dL), your results generally should fall within ±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.

While at the lab

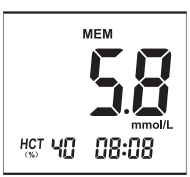
- Perform your meter test within 15 minutes from the lab test.
- Use fresh capillary blood obtained from the fingertip, venous blood, neonatal blood.
- Follow all instructions in this Owner's Booklet to perform a blood glucose test by your meter.

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. Setting the correct time and date helps ensure appropriate interpretation of stored blood glucose results.

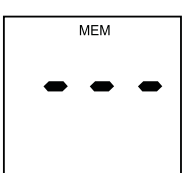
① Enter Memory Mode

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

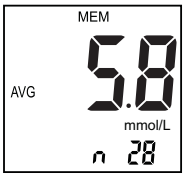


② View previous memory in order

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 **View 7-, 14-, 28-day average**

Press and release “S” button to enter the average value display.

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 **Delete all memory**

Long-press the “S” button approximately 3 seconds.

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

⑤ **Exit**

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 specific amount of glucose and is used to check that the meter and the test strips are working properly.

Do a control solution test:

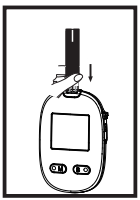
- Whenever you open a new vial of test strips.
- Whenever you want to check if you are testing correctly.
- If you suspect the meter and test strips are not working properly.
- If you have had repeated unexpected blood glucose results.
- If you drop or damage the meter.
- If you left the test strip container 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:

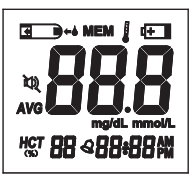
- Only use the Sejoy CS-201 control solution.
- Close the control solution bottle tightly after use.
- Write the date you open the control solution bottle on the bottle label. The control solution must be discarded 3 months after the first open date or the expire date on the vial label, whichever comes first.
- Do not use control solution that exceeds 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.

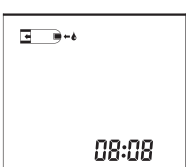
Performing a control test



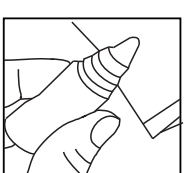
① Insert a test strip to turn the meter on



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.

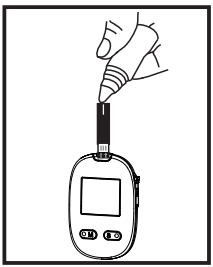


③ The blood drop symbol flashes on the display screen. Your meter is now ready to apply blood sample.

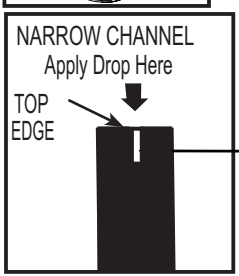


④ Shake the control solution vial before each test. Remove the cap and squeeze the vial to discard the first drop. Then wipe the tip with a clean tissue or cloth. Hold the vial upside down and gently squeeze a hanging drop.

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. After the measurement is over, the meter will display the blood glucose level along with the unit of measurement, the date and time of the test.

Results are automatically stored in the meter's memory.

Understanding out-of-range control test results

Compare the result displayed on the meter to the control solution range printed on the test strip vial. Each control solution have a different control solution range.

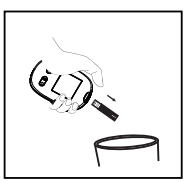
Out-of-range results may be due to:
- not following the instructions detailed in steps 1–6
- expired or contaminated control solution
- expired or damaged test strip
- use of a test strip or control solution that passed its discard date
- a problem with the meter.

⚠ CAUTION: The control solution range printed on the test strip vial is for Sejoy 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 at the same time to delete it After memory cleared, the meter will display "dEL" and then turn off automatically.



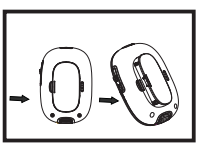
⑧ Turn your meter off

Push the eject button gently to automatically eject the test strip from the meter, or remove the test strip by hand, the meter will automatically shut down. Please handle the used test strip carefully.

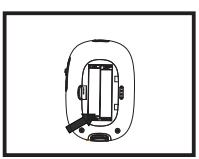
Replacing the battery

Your meter comes with two AAA batteries, alkaline battery.
The battery provides enough power for the meter to perform about 1000 tests. If your battery runs low, the battery symbol "  " appears on display screen until you change the battery.

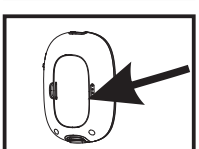
Important: When this symbol appears, you should replace the battery immediately.



① With the meter off, open the battery cover.



② Remove the old batteries and place the new batteries.



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.

Please dispose of the waste batteries according to the local regulations

Meter maintenance

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℃~30℃ (33.8℉~86℉). Meter and other items should be stored between -20℃~ 55℃ (-4℉~131℉).

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 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 using it,

We recommend to disinfect periodically. When you assist others to make blood glucose testing with 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 damped 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 down. Use a soft cloth damped with this solution to wipe the outside of the meter and lancing device. Be sure to squeeze out any excess liquid first.

After wiping, cover the surface you are disinfecting with the soft cloth damped with the bleach solution for 1 minute. Then wipe with a clean soft cloth and wait until it dries.
Wash hands thoroughly with soap and water after handling the meter and lancing device.

Message	Possible Cause	What to do
	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.
	The test strip may be used or damaged.	Make sure that the strip model is correct and retest with a new strip.
	The sample was applied before the meter was ready.	Repeat with a new strip. Applying blood after the symbol flashes on the screen.
	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.
	The strip check has problem.	Make sure that the strip model is correct and 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**
Battery power is low.	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.
Test strip inserted upside down, or incompletely inserted into the meter.	Check that the test strip is inserted correctly.
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-709 Blood Glucose Monitoring System
Assay method	Glucose dehydrogenase biosensor
Measurement range	0.5-33.3mmol/L (9~600mg/dL)
Sample	Fresh capillary whole blood, venous blood, neonatal blood.
Sample size	Approximate 0.6 microlitre
Response time	5 seconds
Calibration	Plasma equivalent glucose values
Battery	2xAAA alkaline batteries
Battery life	Approximately 1,000 tests
Unit of measure	mmol/L or mg/dL; switchable
Memory	360 blood glucose results with date and time
Size	90*61*23.6mm (L*W*H)

Specifications

LCD size	35.4*30.9mm (L*H)
Weight	Approximate 51.6g, battery not included
Operating environment	5℃~45℃ (41℉~113℉)
	10 ~ 90% RH (non-condensing)
Meter storage environment	-20℃~55℃ (-4℉~131℉)
	10 ~ 95% RH (non-condensing)
Strip storage environment	1℃~ 30℃ (33.8℉~86℉)
Altitude	Up to 10,000 feet (3,048 meters) above sea level
Hematocrit	0%~70%
Shelf life	Three years

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. It meets the electromagnetic emissions requirements as standard EN 61326. 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. For disposal of sharps, refer to local regulation.

Refer to 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 that 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 – Blood-borne 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 is not included in the warranty.

Traceability

The traceability of the control solution is referenced to the YSI2500 Biochemistry Analyzer. The YSI2500 Biochemistry Analyzer is the reference method used to assess the accuracy with which glucose results are obtained using the system. The value of the glucose is traceable to the National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 917c (D-Glucose).
Concentration: 200 mg/dL

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

Range: The display range of the meter is 0.5mmol/L to 33.3 mmol/L (9mg/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 YSI Glucose Analyzer, a laboratory instrument.

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

Within ±0.28mmol/L (Within ±5mg/dL)	Within ±0.56mmol/L (Within ±10mg/dL)	Within ±0.83mmol/L (Within ±15mg/dL)
118/150 (78.7%)	150/150 (100%)	150/150 (100%)

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

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

Within ±5%	Within ±10%	Within ±15%	Within ±20%
277/450(61.6%)	400/450(88.9%)	446/450(99.1%)	450/450(100%)

When the blood glucose is equal to or above 5.55mmol/L(100mg/dL), 99.1% of measured glucose results should fall within ±15 % of the laboratory result.

Table3. System accuracy results for glucose between 0.5 mmol/L (9 mg/dL) and 33.3 mmol/L (600 mg/dL)

Within ±0.83mmol/L or ±15% (Within ±15mg/dL or ±15%)
596/600(99.3%)

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

Precision:

Intermediate Precision	Control Solution av 2.20mmol/L CV=3.69% Control Solution av 4.89mmol/L CV=2.82% Control Solution av 7.19mmol/L CV=1.97% Control Solution av 10.99mmol/L CV=1.77% Control Solution av 18.09mmol/L CV=1.36%
Repeatability	Blood av 2.55mmol/L CV=4.3% Blood av 4.79mmol/L CV=4.2% Blood av 7.34mmol/L CV=2.3% Blood av 11.42mmol/L CV=2.6% Blood av 20.5mmol/L CV=1.6%

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 fresh capillary blood obtained from the fingertip, venous blood, neonatal blood.
- 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 limitations
	Sterilized using ethylene oxide
	Do not reuse
	Use by

CE *XXXX*	The Product confoems to the requirements of the EC Directive IVDD(98/97/EC) on in vitro diagnostic medical devices“ *xxxx* ” is the identification number of notify body
	Keep dry
	Please dispose of waste according to the local regulations
	Direct Current
EC REP	European Authorized Representative

1. Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Blood-borne Pathogens: Initial Communication, (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. Accessed June 8, 2011
2. CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood-borne Pathogens, (2010) http://www.cdc.gov/injectionsafety/Fingerstick-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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Hangzhou Sejoy Electronics & Instruments Co., Ltd.
Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 ZheJiang P.R. China

EC REP

Shanghai International Holding Corp.Gmbh (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany