



BG-710b 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 Sejoy BG-710b 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-710b Blood Glucose Meters to quantitative measuring blood glucose with fresh capillary whole blood from the finger or venous 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.

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 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.
- 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	1.11 mmol/L (20 mg/dL)
Bilirubin	2.22 mmol/L (40 mg/dL)
Creatinine	0.56 mmol/L (10 mg/dL)
Gentisic acid	1.25 mmol/L (22.5 mg/dL)
Haemoglobin	1111.11 mol/L (20000 mg/dL)
Ibuprofen	2.78 mmol/L (50 mg/dL)
L-Dopa	0.03 mmol/L (0.5 mg/dL)
Methyl-DOPA	0.22 mmol/L (4 mg/dL)
Tolbutamide	5.55 mmol/L (100 mg/dL)
Triglycerides	83.33 mmol/L (1500 mg/dL)
Xylose	2.78 mmol/L (50 mg/dL)
EDTA	11.11 mmol/L (200 mg/dL)
Substance	Concentration
Ascorbic acid	0.17 mmol/L (3 mg/dL)
Cholesterol	27.78 mmol/L (500 mg/dL)
Dopamine	1.1 mmol/L (20 mg/dL)
Glutathione	2.17 mmol/L (39 mg/dL)
Heparin	500 IU/dL
Icodextrin	60.8 mmol/L (1094.4 mg/dL)
Maltose	555.56 mmol/L (10000 mg/dL)
Salicylate	3.33 mmol/L (60 mg/dL)
Tolazamide	0.56 mmol/L (10 mg/dL)
Uric acid	1.33 mmol/L (24 mg/dL)
Pralidoxime Iodide	0.83 mmol/L (15 mg/dL)
Galactose	0.83 mmol/L (15 mg/dL)

Other interfering substances in ISO 15197 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



Manufacturer of Lancing Device and Sterile Lancet


 Manufacturer of Lancing Device and Sterile Lancet Shandong Lianfa Medical Plastic Products Co., Ltd. No.1 Shuangshan Sanjian Road, 250200, Zhangqiu City, Jinan, Shandong, PEOPLE'S REPUBLIC OF CHINA

 Shanghai International Holding Corp. GmbH (Europe) EC REPEIFFstrasse 80, 20537 Hamburg Germany

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


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

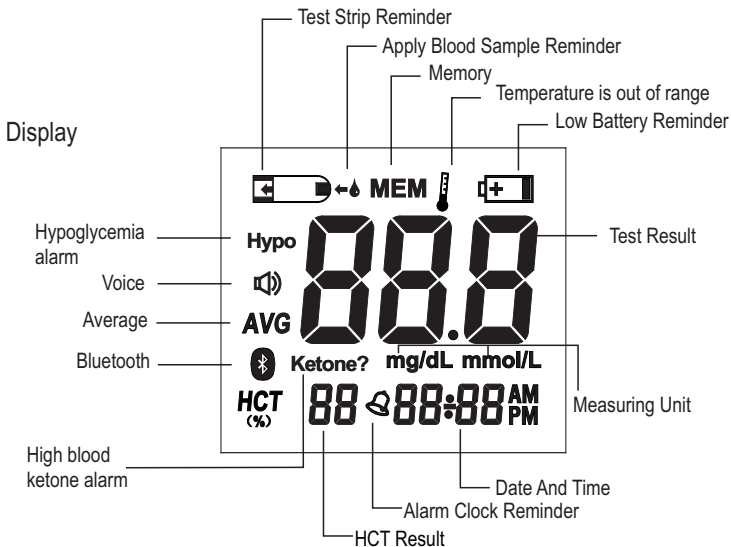
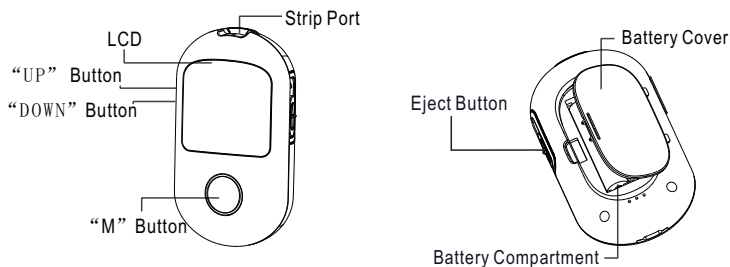

 Lotus NL B.V. EC REPKoningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands.

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



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

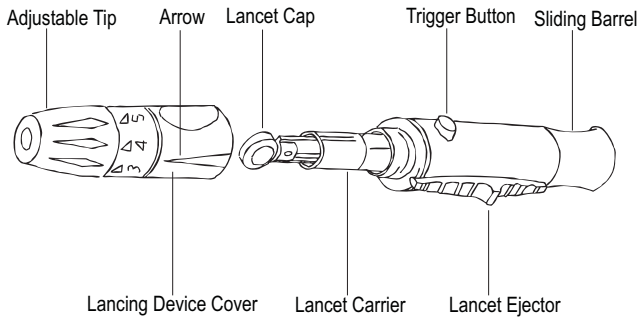
Important Test Strip Information

- The system has an operating range of $5^{\circ}\text{C} \sim 45^{\circ}\text{C}$ ($41^{\circ}\text{F} \sim 113^{\circ}\text{F}$).
- 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.

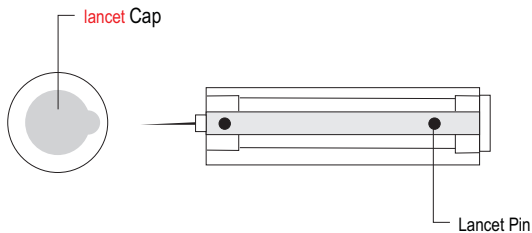


Warning: The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

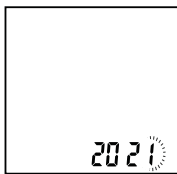
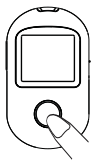
c. Lancing Device



d. Lancet



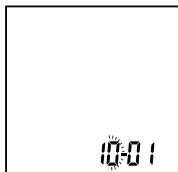
When use the meter for the first time, please set the parameters of the meter. With the meter off, Power on again to enter setting mode.



① Set the year

Press and release the Side up button or side down button to Forward or backward one year until the correct year appears.

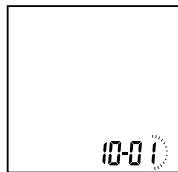
After the year is set, press button "M", the month figure is flashing automatically.



② Set the month

Press and release the Side up button or side down button to Forward or backward one month until the correct month appears.

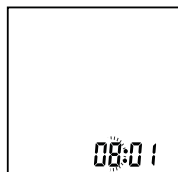
After the month is set, press button "M", the date figure is flashing automatically.



② Set the date

Press and release the Side up button or side down button to Forward or backward one day until the correct date appears.

After the date is set, press button "M", the Hour figure is flashing automatically.



③ Set the hour

Press and release the Side up button or side down button to Forward or backward one hour until the correct hour appears.

After the hour is set, press button "M", the Minute figure is flashing automatically.

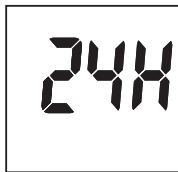


⑤ Set the minute

Press and release the Side up button or side down button to Forward or backward one minute until the correct minute appears. After the minute is set, press button "M", the Time format figure will appear.



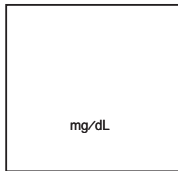
OR



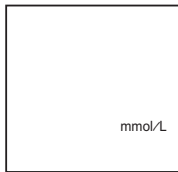
⑥ Set the time format

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

With the preferred time format on the display, press button "M", the measuring unit figure will appear.



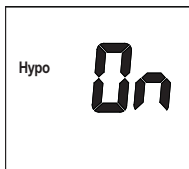
OR



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 Side up button or side down button for 5 seconds to select the preferred format.

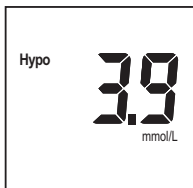
With the preferred measuring unit format on the display, press button "M" to enter the Set low blood sugar alarm function.



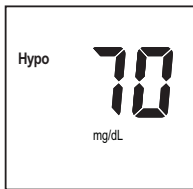
OR



- ⑧ Set low blood sugar alarm function
 Set low blood sugar alarm function
 Press and release the side up button or side down button To select the hypoglycemia alarm function, if Select "On", please press "M" key to enter low Blood glucose alarm concentration value setting. in case Select "OFF", please press "M" key to enter High blood sugar alarm function setting.



OR



- ⑨ Set low blood glucose alarm concentration value
 Press and release the side up button or side down Key to move forward or backward one concentration
 Press until the correct concentration appears "M" key to enter high blood ketone alarm function Can be set



OR

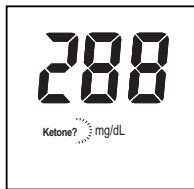
- ⑩ Set high blood ketone alarm function
 Press and release the side up button or side down button
 To select the high blood ketone alarm function, if Select "On", please press "M" to enter high Blood ketone alarm concentration value setting. in case, Select "OFF", Please press "M" key to enter Voice mode setting.

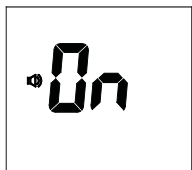


OR

- ⑪ Set high blood ketone alarm concentration value

Press and release the side up button or side down Key to move forward or backward one concentration
 Press until the correct concentration appears "M" key to enter the voice mode setting





OR



⑫ Set voice mode

Press and release Side up button or side down button to select the voice mode press. button "M" to enter the Alarm Clock setting.

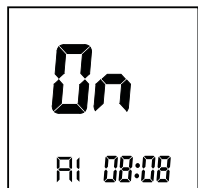


OR



⑬ Set the alarm clock

The meter can set 6 Alarm to remind you the time for testing. Press the side up button or the side down button to select which alarm to set, press the "M" button to confirm the alarm you selected, press the side up button or the side down button to choose whether to turn on the alarm clock, if it is on, press the M button to switch to the alarm clock For time setting, please refer to steps 3 and 4 for time setting. After setting, press M to enter the next alarm setting until all alarm settings are completed. If the alarm is off, skip the current alarm setting. Finally press the "M" key to exit the setting mode.



OR



In any setting stage of the setting mode, press and hold the "M" key for three seconds to directly shut down

Bluetooth requirements

The Glucose Meter requires a bluetooth device with:

- . Bluetooth 5.0 or later
- . Android 6.0 or later
- . IOS 10.0 or later

And works with:

- . iphone , iPod, iPad
- . Android Phones and Tablets

Using for the first time

1. Download the "JoyHeath" App from Website or APP Store (Such as Apple Store).
2. Open the App on your phone or tablet. If requested, you should enable Bluetooth on your device. You can enable Bluetooth under the Settings menu on your smart phone or tablet.
3. Create a new user login, or login with your existing user name and password.
4. Selection device "Glucose Meter system".

Match your with a Smart Device

1. If this is your first time using it, bind first. Open "SETTING" menu , choose "Bind and unbind device" and select the appropriate model.
The date and time on your Glucose Meter will automatically be updated when it's connected with your phone.
2. Confirm that your Glucose Meter is connected successfully.
When your Glucose Meter is connected successfully to your smart phone, the "📶" symbol stop flashing and keep showing.

Transfer your readings

1. As soon as your measurement is finished, open the app on your smart phone to transfer the readings.

Note: On the matched smart phone, Bluetooth must be enabled.

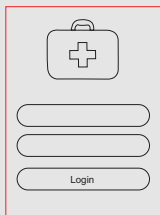


Figure 1

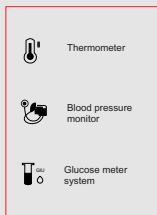


Figure 2

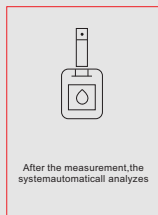


Figure 3

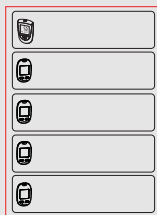


Figure 4

2. You can view your blood glucose level readings in the app.

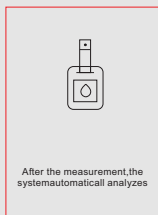


Figure 5

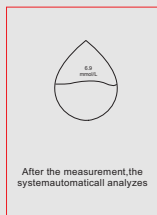


Figure 6

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.^{1,2}
- 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.

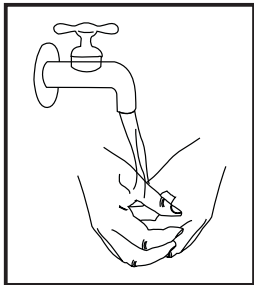
Note: To select the best depth:
1-2 for soft or thin skin 3 for average skin.
4-5 for thick or calloused skin.

Preparing the lancing device

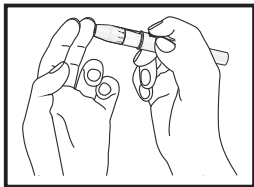


- ⑥ Hold the lancing device cover in one hand. Using the other hand, slowly pull the sliding Barrel away from the lancing device cover. You will hear a click, indicating that the lancet carrier is locked into position. Release sliding barrel to return it to its original position.

Blood Sampling

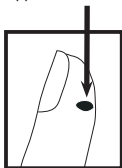


- ① Wash your hands and the puncture site with an alcohol swab or soapy water. Rinse and dry thoroughly.



- 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



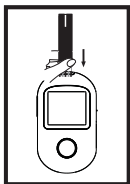
- ③ Gently squeeze your finger until you get a round drop of blood. Discard the first drop. If the blood smears or runs, Do Not use that sample. Wipe the area and gently squeeze another drop of blood or puncture a new site.

Blood Sampling

IMPORTANT:

- Use only Test Strips BS-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 $5^{\circ}\text{C} \sim 45^{\circ}\text{C}$ ($41^{\circ}\text{F} \sim 113^{\circ}\text{F}$).
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 6 months after first open date.

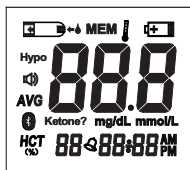
Testing



- 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.

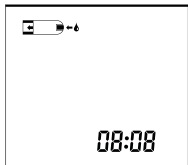


- ② System check screen

The backlight will be lit every time the meter is turned on. The screen will briefly display all content to confirm that the display is working properly.

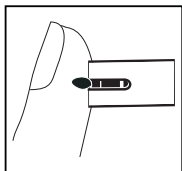
Note:

- 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

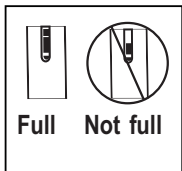


④ Apply the sample

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.



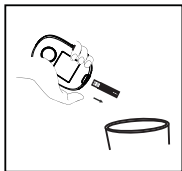
⑥ Read your result on the meter

After the measurement is over, the meter will voice broadcast the measurement result and 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 "S" button and "M" button to delete it at the same time. After memory cleared, the meter will display "dEL" for approx. 3 seconds, and the meter will automatically turn off.



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:

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)

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 red blood cell count

- 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.

Comparing your meter's results with laboratory results periodically.

The results of the Sejoy BG-710b meter are plasma equivalent. This method will help you and your healthcare professional compare your meter results with laboratory test results. The Sejoy BG-710b 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 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.
- Take the meter to the lab

While at the lab

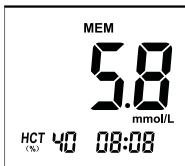
- Conduct your meter test of the lab test within 15 minutes.
- Use only fresh, capillary blood obtained from the fingertip.
- Follow all instructions in this Owner's Booklet to performing a blood glucose test by your meter.

Storing Blood glucose and Control Test results

The meter automatically stores up to 1000 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.

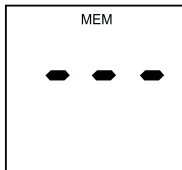
① Entering Memory Mode

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

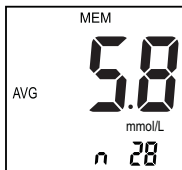


② Viewing previous memory in order

Short press the side up button or side down button to scroll forward or backward 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

Long press the side “up” button for 3 second to, enter the average value query.

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

Long Press the side “down” button approximately 3 seconds. After memory cleared, the meter will display “dEL” for approx. 3 seconds, and then automatically turns off.

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

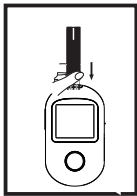
NOTE:

- Only use the 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 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 Exp. 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.

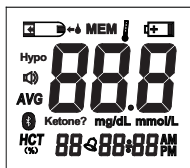


CAUTION: Do Not swallow control solution. It is not for human consumption. Do Not apply control solution to the skin or eyes as it may cause irritation.

Performing a control test



- ① Insert a test strip to turn the meter on

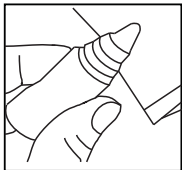


- ② System check screen

The backlight will be lit every time the meter is turned on. The screen will briefly display all content to confirm that the display is working properly.



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

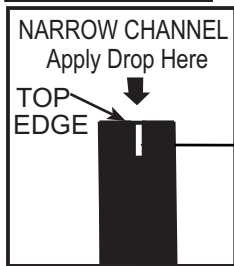


- ④ Shake the control solution vial before each test. Remove the cap and squeeze the vial to discard the first drop. Then wipe the tip with a clean tissue or cloth. Hold the vial upside down and gently squeeze a hanging drop.

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.



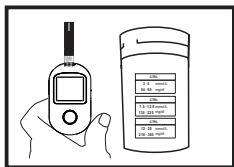
CONFIRMATION WINDOW



- 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 voice broadcast the measurement result and 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.

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.

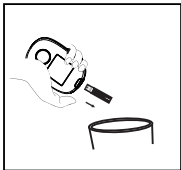


CAUTION: If you continue to get control solution test results that fall outside the range printed on the test strip vial, Do Not use the meter, the test strips, or the control solution. **Contact Customer Service. Contact us at (+86)571-81957767.**



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" about 3 seconds, and then automatically turns off.



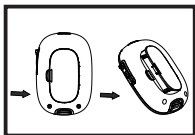
⑧ Turn your meter off

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.

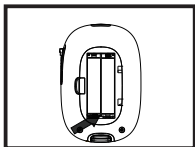
Replacing the battery

Your meter comes with 2xAAA batteries, 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.

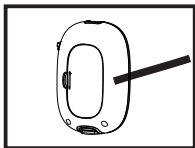
Important: When this symbol appears, you should replace the battery immediately.



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



- 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 according to the local regulations

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, lancing device should be disinfected before and after each use. Be sure to clean the meter, lancing device before disinfecting


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.

The CaviWipes® Disinfecting Towelettes have been shown to be safe for use with our blood glucose monitoring system and can be obtained from retail websites offering disinfection products, e.g., www.officedepot.com or www.staples.com. For more information on purchase options contact Customer Service. Contact us at (+86)571-81957767.

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.	Make sure that the Strip model is correct and 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	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.	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-710b Blood Glucose Monitoring System
Assay method	Glucose dehydrogenase biosensor
Measurement range	0.5-33.3 mmol/L (9~600 mg/dL)
Sample	Fresh capillary whole blood
Sample size	Approximate 0.6 microlitre
Response time	5 seconds
Calibration	Plasma equivalent glucose values
Battery	2xAAA batteries
Battery life	Approximately 1,000 tests
Unit of measure	mmol/L or mg/dL; switchable
Memory	1000 blood glucose results with date and time
Size	94.9*56.5*22.8 mm (L*W*H)

Specifications

LCD size	35.4*30.9 mm (L*H)
Weight	Approximate 73 g, battery not included
Operating environment	5°C ~ 45°C (41°F ~ 113°F)
	10 ~ 90% RH (non-condensing)
Meter storage environment	-20°C ~ 55°C (-4°F ~ 131°F)
	10 ~ 95% RH (non-condensing)
Strip storage environment	1°C ~ 30°C (33.8°F ~ 86°F)
Altitude	Up to 10,000 feet (3,048 meters) above sea level
Hematocrit	0%~70%
Expected service life	Three years

Electromagnetic Compatibility

This meter meets the electromagnetic immunity requirements as standard IEC 60601-1-2. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 60601-1-2. In addition, it meets the electromagnetic emissions requirements as standard IEC 60601-1-2. 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 Sejoy Blood Glucose Monitoring System BG-710b is control solution. The traceability of the control solution is referenced to the YSI glucose analyzer.

The YSI 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: 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

Bias	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)
Percentage	129/174 (74.1%)	173/174 (99.4%)	174/174 (100.0%)

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

Table2. System accuracy results for glucose concentration ≥ 5.55 mmol/L

Bias	Within ± 5 %	Within ± 10 %	Within ± 15 %
Percentage	67.4% (287/426)	99.8% (4254/426)	100.0% (426/426)

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

This study shows that the system compares well with a laboratory method and meets the minimum acceptable performance criteria defined in **IEC 60601-1-2**.

Precision:

Intermediate Precision	Control Solution av 2.42mmol/L CV=5.2% Control Solution av 7.52 mmol/L CV=3.1% Control Solution av 20.78mmol/L CV=2.5
Repeatability	Blood av 2.43mmol/L CV=5.4% Blood av 5.02 mmol/L CV=3.7% Blood av 7.48 mmol/L CV=3.3% Blood av 12.20 mmol/L CV=2.4% Blood av 20.80 mmol/L CV=2.4%













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 irradiation
	Do not reuse
	Use by
	Storage humidity limitation

	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
	Biological risks
	Keep dry
	Please dispose of the waste according to the local regulations
	Direct Current

Caution: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user authority to operate the equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

*Note:

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

1. "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)
<http://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
2. CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010)
<https://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>for Disinfection and Sterilization in Healthcare Facilities,Atlanta."

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