SEJOY®

Multi-function Monitoring System

CDS-101b

Owner's Booklet

4 in 1

- Blood β-Ketone
- Blood Glucose
- Uric Acid
- Total Cholesterol

Contents

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

Thank you for choosing CDS-101b Multi-function monitoring system. Before you start testing, carefully read this Owner's Booklet.

Product number: CDS-101b-0001, CDS-101b-0002, CDS-101b-0003, CDS-101b-0004, CDS-101b-0005, CDS-101b-0006, CDS-101b-0007, CDS-101b-0008, CDS-101b-0009, CDS-101b-0010, CDS-101b-0011, CDS-101b-0012

Intended Use

The BS-602a Test Strips are intended to be used with the CDS-101b Multi-function Meter to quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips, palm, forearm, upperarm and thigh for self-testing by lay person. Capillary, venous, arterial blood and neonatal blood collected for near-patient testing and professional laboratory use by Healthcare professionals. The system is intended for in-vitro diagnostic use by individuals at home or by healthcare professional in a clinical setting as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of, or screening for diabetes.

The KS-101 Blood β-ketone Test Strips are used with the CDS-101b Multi-function Meter to quantitative measurement of β-hydroxybutyrate in fresh capillary whole blood drawn from the fingertips for self-testing by lay person.Capillary, venous, and neonatal blood collected for near-patient testing and professional laboratory use by Healthcare professionals.The system is intended for in-vitro diagnostic use at home or by healthcare professional in a clinical setting as an aid to monitor the effectiveness of blood β-hydroxybutyrate. It is intended to be used by a single person and should not be shared. It should not be used for the diagnosis of, or screening for diabetes or ketosis.

The US-201 Uric Acid Test Strips are used with the CDS-101b Multi-function Meter to quantitative measurement of uric acid in fresh capillary whole blood drawn from the fingertips for self-testing by lay person. Capillary and venous blood measured for near-patient testing and professional laboratory use by healthcare professionals. The system is intended for in vitro diagnostic home-use or by healthcare professional in a clinical setting as an aid to monitor the effectiveness of hyperuricemia control. This system is not used for the diagnosis and screening of hyperuricemia.

The TS-101 Total Cholesterol Test Strips are used with the CDS-101b Multi-function Meter to quantitative measurement of total cholesterol in fresh capillary whole blood drawn from the fingertips for self-testing by lay person. Capillary and venous blood measured for near-patient testing and professional laboratory use by healthcare professionals.The system is intended for in vitro diagnostic home-use or by healthcare professional in a clinical setting as an aid to monitor the effectiveness of cholesterol control. This system is not used for the diagnosis and screening of hyperlipidemia.

It is not automated.

Test Principle

The BS-602a Blood Glucose Test Strips is a plastic strip containing chemistries and electrodes.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.
The KS-101 Blood β-ketone Test Strip is a plastic strip containing chemistries and electrodes.The strip measures β-hydroxybutyrate by using amperometric technology employing a hydroxybutyrate dehydrogenase reaction. When whole blood or control solution s drawn into the tip of a test strip, β-hydroxybutyrate in the sample reacts with chemicals and produces an electrical current. The meter measures electrical current and calculates amount of β-hydroxybutyrate. The β-hydroxybutyrate result is displayed as a calculated plasma value.
The US-201 Uric Acid Test Strip is a plastic strip containing chemistries and electrodes.The strip measures uric acid by using amperometric technology employing an uric acid electrochemical reaction. When whole blood or control solution is drawn into the tip of a test strip, uric acid in the sample reacts with chemicals and produces an electrical current. The meter measures electrical current and calculates amount of uric acid. The uric acid result is displayed as a calculated plasma value.
The TS-101 Total Cholesterol Test Strip is a plastic strip containing chemistries and electrodes.The strip measures total cholesterol by using amperometric technology employing an total cholesterol electrochemical reaction. When whole blood or control solution is drawn Into the tip of a test strip, cholesterol in the sample reacts with chemicals and produces an electrical current. The meter measures electrical current and calculates amount of total Cholesterol. The total Cholesterol result is displayed as a calculated plasma value.
Remark: Analytical performance characteristics, traceability, and clinical performance characteristicsare detailed in the BS-602a Blood Glucose Test Strips Instruction Manual, US-201 Uric Acid Test Strips Instruction Manual, KS-101 Blood β-ketone Test Strips Instruction Manual, TS-101 Total Cholesterol Test Strips Instruction Manual.

The environment of near patient testing

Pharmacy, Physical examination, Free clinic/Home treatment, Endocrinology/Diabetes Specialist, Inpatient Department/Outpatient Department, Laboratory and Neonatology(blood glucose, blood β-ketone).

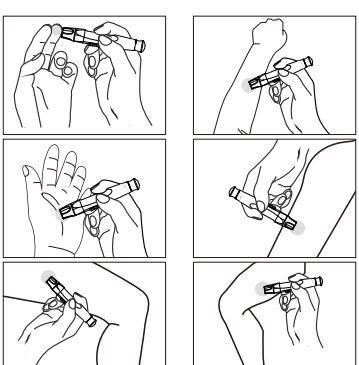
Capillary, venous, arterial blood and neonatal blood samples collection and preparation should be obtained by healthcare professionals.

Alternative Site Testing (AST) for blood glucose

AST

You have the option to obtain blood sample from other sites on your body besides the fingertip. Alternative sites include the palm, forearm,upperarm and thigh.

Blood samples obtained from the palm are equivalent to blood samples from fingertip. Both can be used at any time to perform a blood glucose test. Test with blood from other sites may not have the same result as testing with fingertip and palm. This might lead to misinterpretation of your actual blood glucose level, because the blood glucose level in your forearm, upper arm etc. changes slower than in your palm and fingertip. In general, you may do a forearm, upperarm, thigh test when you are fasting or before meal. You better test with you fingertip or palm when you have meal within 2 hours, use insulin, do exercise, experience illness or have hypoglycemia.
Consult with your diabetes team or healthcare professionals for more detailed instruction on AST.



WARNING

- Ask your health care professional if Alternative Site Testing (AST) is right for you.
- Do not calibrate a continuous glucose monitoring device from an AST result.
- Do not calculate an insulin dose based on an AST result.

Your meter can be used for fingertip or AST testing.
Do not use AST under the following conditions:

- If you think your blood sugar is low.
- When blood sugar is changing rapidly, such as after a meal, after aninsulin dose,or during or after exercise.
- If you are unable to feel symptoms of low blood sugar(hypoglycemic unawareness).
- If you get alternative site blood sugar results that do not agree with how you feel.
- During illness or times of stress.
- If you will be driving a car or operating machinery.

Important safety information

Warning

- During normal testing, any 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.
- 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 handles 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.
- 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.
- The user should not take any decision of medical relevance without first consulting the appropriate healthcare professional.
- For some minors who are not able to test by themselves should completed the test with the help of guardians.
- Blood samples from heel are only used for testing neonatal blood glucose and blood β-ketone.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- other cables and accessories may negatively affect EMC performance.

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, blood β-ketone, uric acid or Total Cholesterol 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.
- 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.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the established competent authority of the Member State.
- If not used in accordance with the manufacturer's specified method, it may lead to other risks.

• The system is designed for use with fresh caillary whole blood or venous blood. Neonatal blood is only used for the Blood β-ketone and Blood Glucose test. Arterial blood is only used for the Blood Glucose test.
• Inaccurate test results may be obtained at high altitude more than about 3048 meters above sea level.
• BS-602a blood glucose test strip more than 70% of the hematocrit ratio will affect the measurement results.
• KS-101 blood β-ketone test strip :more than 70% or less than 10% of the hematocrit ratio will affect the measurement results.
• US-201 uric acid test strip: more than 60% or less than 20% of the hematocrit ratio will affect the measurement results.
• TS-101 total cholesterol test strip: more than 60% or less than 20% of the hematocrit ratio will affect the measurement results.
• Some substances may cause false results with enzymatic tests. Consult with your doctor or professional healthcare team.
• Use of this instrument in a dry environment ,especially if synthetic materials are present(synthetic clothing ,carpets etc.)may cause damaging electrostatic discharges that may cause erroneous results.
• The user responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended .Do not use this instrument in proximity to sources of strong electromagnetic radiation ,as these may interfere with the proper operation. Such as induction cooker, microwave oven and so on.
This equipment is designed for use in a HOME HEALTHCARE ENVIRONMENT.
• If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
• PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas)should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.
• The description about The Summary of safety and Performance (SSP) is available in the European database on medical devices (see Eudamed public website: https://ec. europa.eu/tools/eudamed). If not available, please email us using email address (poct@sejoy.com).

Limitations for blood glucose

• Using with capillary, venous, arterial and neonatal blood samples.

• Hematocrit range: 0% to 70%. Hematocrit above 70% may cause deviated results. Severe dehydration and excessive water loss may cause false low results. If you think you may be dehydrated, consult your healthcare professional immediately.

• The interferent listed below were tested. Blood samples tested at the following substance concentration levels will not interfere.

Substance	Concentration	Substance	Concentration
Acetaminophen	20 mg/dL	Ascorbic acid	3 mg/dL
Bilirubin	40 mg/dL	Cholesterol	500 mg/dL
Creatinine	10 mg/dL	Dopamine	20 mg/dL
Gentisic acid	1.8mg/dL	Glutathione	92mg/dL
Haemoglobin	1000 mg/dL	Heparin	500 IU/dL
Ibuprofen	50 mg/dL	Icodextrin	1094.4 mg/dL
L-Dopa	0.5 mg/dL	Maltose	1000 mg/dL
Methyl-DOPA	1000 mg/dL	Salicylate	60 mg/dL
Tolbutamide	100 mg/dL	Tolazamide	40 mg/dL
Triglycerides	1500 mg/dL	Uric acid	20 mg/dL
Xylose	50 mg/dL	Pralidoxime Iodide	15 mg/dL
EDTA	200 mg/dL	Galactose	15 mg/dL

Limitations for blood β-ketone

- Using with capillary, venous blood and and neonatal blood samples.
- Hematocrit range: 10% to 70%. Hematocrit above 70% may cause deviated results.
- Severe dehydration and excessive water loss may cause false low results. If you think you may be dehydrated, consult your healthcare professional immediately.
- The interferent listed below were tested. Blood samples tested at the following substance concentration levels will not interfere.

Substance	Concentration
Dopamine	10mg/dL
Acetaminophen	25mg/dL
Ascorbic acid	3mg/dL
Cholesterol	500mg/dL
L-DOPA	0.6 mg/dL
Gentisic acid	1.8 mg/dL
Uric acid	20mg/dL
Bilirubin	520 mg/dL
Triglyceride	1500mg/dL

Limitations for uric acid

• Using with the capillary whole blood from the finger or venous whole blood.

• The venous whole blood is tested for professional use only.

• Hematocrit range: 20% to 60%. Hematocrit below 20% or above 60% may cause deviated results.

• Severe dehydration and excessive water loss may cause false low results.
If you think you may be dehydrated, consult your healthcare professional immediately.

• Ascorbic acid, Glucose and Creatinine will not affect the test results at normal physiological concentration.

• The concentration of Acetaminophen above 0.8mg/dL and that of L-DOPA above 0.4 mg/dL may affect the test results.

• High concentration of Cholesterol up to 400 mg/dL and that of Triglycerides up to 240 mg/dL will not affect the test results.

• The user is suggested to test uric acid in the morning after fasting for 12 hours.

Limitations for total cholesterol

• Using with the capillary whole blood from the finger or venous whole blood.

• The venous whole blood is tested for professional use only.

• Hematocrit range: 20% to 60%. Hematocrit below 20% or above 60% may cause deviated results.

• Severe dehydration and excessive water loss may cause false low results.

• Ascorbic acid, Glucose and Creatinine will not affect the test results at normal physiological concentration.

• The concentration of Acetaminophen above 6 mg/dL and that of L-DOPA above 1.0 mg/dL may affect the test results.

• The user is suggested to test Total Cholesterol in the morning after fasting for 12 hours.

INCLUDED IN METER KIT

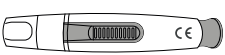
a. Meter (battery included)

b. BS-602a Test Strip

c. KS-101 Test Strip

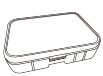
d. US-201 Test Strip

e. TS-101 Test Strip



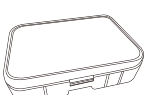
f. Lancing Device

g. Sterile Lancet



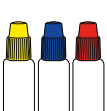
h. storage bag

I. USB cable



J. Printer(include Printer cable, carrying case, paper roller)

K.Owner's booklet



L.CS-201a
Control Solution

M.CS-401
Control Solution

M.CS-501
Control Solution

M.CS-601
Control Solution

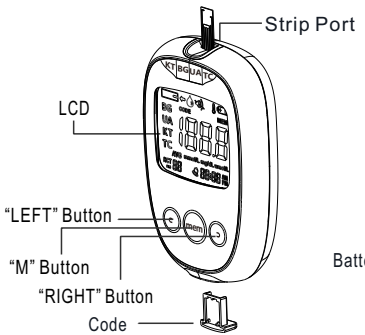
Note: Test strips,strile lancets, USB data cable, Printer, or control solutions may not be included in the kit (please check the contents on your product package). They can be purchased separately.

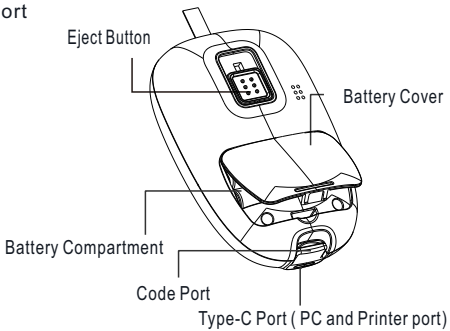
Materials need but not provide:

1. Isopropyl alcohol swabs 2.GLUCOJOY PC software

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 measurement is recommended.

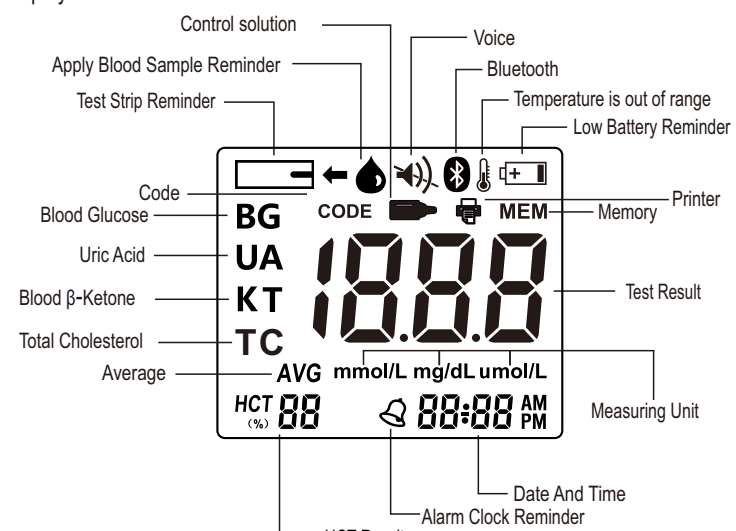
a. Meter





Meters with product numbers CDS-101b-0005, CDS-101b-0007, CDS-101b-0008 do not haveType-C port

Display



MARK " " 0nly applicable to CDS-101b-0009, CDS-101b-0010, CDS-101b-0011, CDS-101b-0012

b. Test strip

Contact Bars: 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 the macthing test strips.
Using other Test strips with this meter can produce inaccurate results.

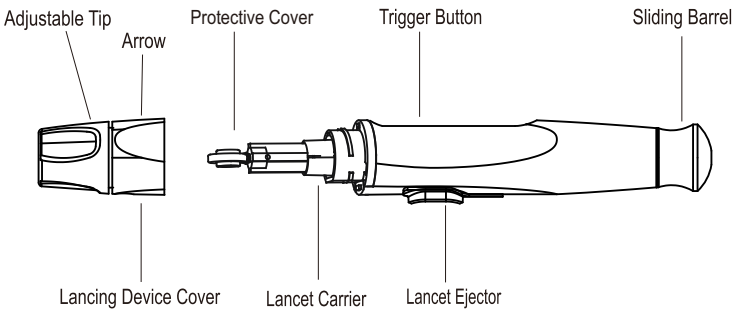
Important Test Strip Information

- indoor use.
- 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 Uric Acid Test Strips and total cholesterol test strips at temperatures between 10℃~40℃ (50℉~104℉). Use other 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.

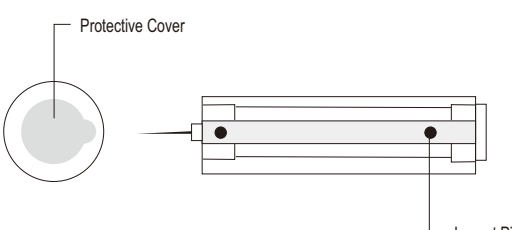
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.
- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter test strips.

⚠ 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

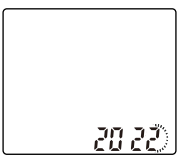


d. Lancet



When using the meter for the first time, please set the parameters of the meter. With the meter off, power on again or press and hold button “M” 1 second to enter setting mode.

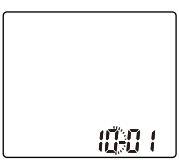
Setting the date and time



① Set the year

Press and release the LEFT button or RIGHT button to backward or forward 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 LEFT button or RIGHT button to backward or forward one month until the correct month appears.

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

③ Set the date

Press and release the LEFT button or RIGHT button to backward or forward one day until the correct date appears.

After the date is set, press button “M”, the hour figure is flashing automatically.

④ Set the hour

Press and release the LEFT button or RIGHT button to backward or forward one hour until the correct hour appears.

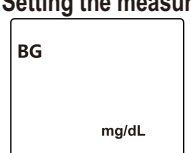
After the hour is set, press button “M”, the minute figure is flashing automatically.

⑤ Set the minute
Press and release the LEFT button or RIGHT button to backward or forward one minute until the correct minute appears. After the minute is set, press button “M”, the time format figure will appear.

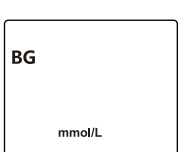
OR

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 LEFT button or RIGHT button to select the format.
With the preferred time format on the display, press button “M”, the measuring unit figure will appear.

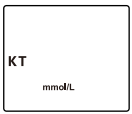
Setting the measuring unit



OR



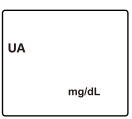
⑦ Set the measuring unit of BG
The meter can display test results in either milligrams per decilitre (mg/dL) or millimoles per litre (mmol/L). Press and hold both LEFT button and RIGHT button for 5 seconds to select the preferred format.
With the preferred measuring unit format on the display, press button “M” to set the measuring unit of KET.



OR

⑧ Set the measuring unit of KET

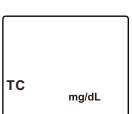
The meter can display test results in either milligrams per decilitre (mg/dL) or millimoles per litre (mmol/L). Press and hold both LEFT button and RIGHT button for 5 seconds to select the preferred format. With the preferred measuring unit format on the display, press button "M" to set the measuring unit of UA.



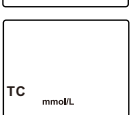
OR

⑨ Set the measuring unit of UA

The meter can display test results in either milligrams per decilitre (mg/dL) or micromoles per litre (umol/L). Press and hold both LEFT button and RIGHT button for 5 seconds to select the preferred format. With the preferred measuring unit format on the display, press button "M" to set the measuring unit of TC.



OR



⑩ Set the measuring unit of TC

The meter can display test results in either milligrams per decilitre (mg/dL) or millimoles per litre (mmol/L). Press and hold both LEFT button and RIGHT button for 5 seconds to select the preferred format. With the preferred measuring unit format on the display, press button "M" to set the print mode.

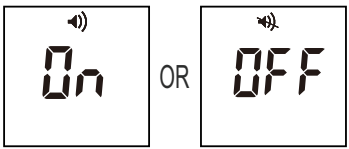
OR

⑪Set Print mode

Press and release LEFT button or RIGHT button to select the print mode. Press button "M" to save and enter the voice mode setting.

Note: Only applicable to CDS-101b-0009, CDS-101b-0010, CDS-101b-0011, CDS-101b-0012

Setting the test reminder

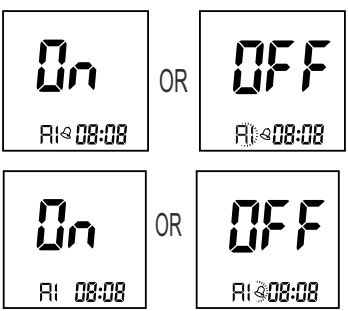


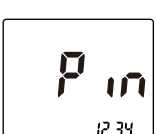
⑫ Set voice mode

Press and release LEFT button or RIGHT button to select the voice mode. Press button “M” to save and enter the alarm clock setting.

⑬ Set the alarm clock

The meter can set 5 alarms to remind you of the testing time. Press the LEFT button or the RIGHT button to select which alarm to set, press the "M" button to confirm the alarm you selected, press the LEFT button or the RIGHT button to turn on/off the alarm clock. If it is on, press the M button to switch to the alarm clock. For time setting, refer to steps 3 and 4. After setting, press “M” button 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 enter the PIN code display



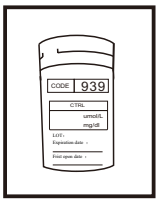


⑭ PIN code display

On this interface, you can see the PIN code of the instrument, which is used for Bluetooth connection. Finally, press the “M” key to exit the setting mode.

⑮ In any setting stage of the setting mode, press and hold the "M" key for three seconds to directly shut down.

Coding the meter



① Check the code on the test strip vial first

BS-602a blood glucose test strip and KS-101 blood glucose test strip is code free, but the codes for US-201 uric acid test strip and TS-101 total cholesterol test strip are needed to be checked.

Code numbers are used to calibrate the meter with the test strips are using.

② Put the code chip from strip package into the chip port of meter.

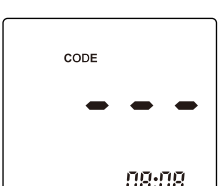
Each strip package contains one chip code.

Replaced the old code chip when start to use a new vial of strips.

③ Insert a test strip to turn on the meter and check the matching codes.

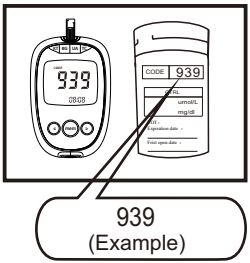
Insert the test strip by pointing the end of the contact bars into the test port.

Push the test strip in as far as it can go.



Note: If there's no chip on the meter, the LCD will display

Follow step 2 to install the code chip.



④ Match the code on the meter with the code on the test strip vial

- If the code on the meter match the code on the test strip vial, the meter is now ready for testing
- If the code on the meter does not match the code on the test strip vial, please discard this vial test strips and contact the vendor.

CAUTION: Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results.

Computer Connection

0nly applicable to CDS-101b-0001, CDS-101b-0002, CDS-101b-0003, CDS-101b-0004, CDS-101b-0006, CDS-101b-0011, CDS-101b-0012

Using for the first time

1. Install the GLUCOJOY PC software on the computer.
2. Connect the CDS-101b meter with the computer via USB cable.
3. Create a new user login, or login with your existing user name and password.

When your CDS-101b Meter is connected successfully to your computer, Press the "M" key on the meter until the instrument shows "PC". Then press the "M" key again and it will display "YES". For detailed instructions, please refer to the user manual of GLUCOJOY PC software.

Software operating environment

This software supports running on the following operating systems:

Operating System	32 bit	64 bit
Windows 10	×	v
Windows 11	×	v

Using for the first time

① Download the HealthJoy App from Google Play or Apple Store.

② Open the App on your mobile device. If requested, you should enable Bluetooth on your mobile device. You can enable Bluetooth under the Setting menu on your mobile device.

③ Create a new user login, or login with your existing user name and password.

When your Glucose Meter is connected successfully to your mobile device the " " symbol keep showing. Refer to the quick guide for the HealthJoy App for more information.

For cybersecurity,please follow these guidelines:

• Keep the login information secure and change the login password regularly.

• The meter can only pair with 1 device at a time.

• If Bluetooth cannot connect to the App, please check whether the mobile device's Bluetooth is on. If yes, please restart the meter to reconnect Bluetooth. If it remains unconnected are 3 attempts, please call the local supplier.

•The meter cannot be updated or patched by user, so DO NOT accept any change or update to the Meter.

•The meter has not been tested or certified for use with any software other than the HealthJoy App. The manufacturer is not responsible for any erroneous results from the use of other software.

•If any other suspected cybersecurity event occurs, please do not allow the Meter automatically connect the Bluetooth, but the meter can test blood glucose still, and call the local supplier.

Using Your Meter without the App

The meter can be used without a Smart Phone or the App. You can still test your blood glucose, blood β-ketone, uric acid, Total Cholesterol and review your test results on the meter screen.

Printer Connection

0nly applicable to CDS-101b-0009，CDS-101b-0010, CDS-101b-0011, CDS-101b-0012

1. Connect the mete and the printer using the printer cable.
2. Press and hold the printer power button to turn it on.
3. On the reading interface（measurement end interface and memory interface), long-pressing the right button allows the measurement results to be output through the printer.

NOTE:

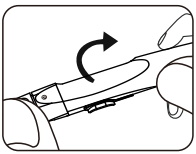
1. Use the matching printer and data cable; otherwise, abnormal phenomena may occur.

Preparing the lancing device

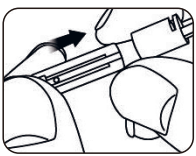
⚠ Warning

- The multi-function system requires a tiny of blood sample from your fingertip to test the blood glucose, blood β-ketone, uric acid, Total Cholesterol. Before sampling your blood, wash your hands and the puncture site with an isopropyl alcohol swab or soapy water. Rinse and dry thoroughly. Venous, arterial blood or neonatal blood may be used, but must be collected by healthcare professional.
- During normal testing, any multi-function 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.
- 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.

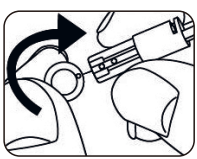
Preparing the lancing device



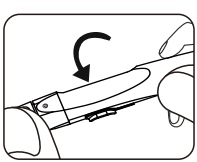
① Screw off the lancing device cover.



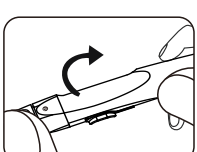
② Insert a new lancet into the lancet carrier firmly.



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



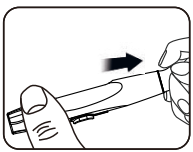
④ Put on the lancing device cap.
Avoid touching the trigger button.



⑤ Adjust the depth setting
The indication marks 9 levels of skin penetration. Switch the lancing device cap to the desired setting.

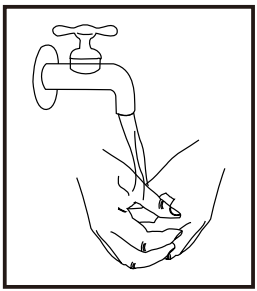
Note: To select the best depth:
1-3 for soft or thin skin, 4-6 for average skin.
7-9 for thick or calloused skin.

Preparing the lancing device



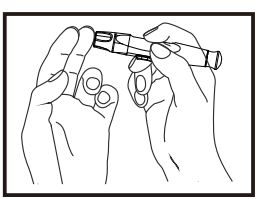
⑥ Hold the lancing device cover in one hand. Using the other hand, slowly pull the sliding barrel away from the lancing device cover. You will hear a click, indicating that the lancet carrier is locked into position. Release sliding barrel to return it to its original position.

Blood sampling

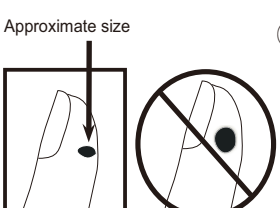


① Wash hands and the puncture site with an isopropyl alcohol swab or soapy water. Rinse and dry thoroughly.

Note: Never use iodine solution to disinfect puncture site.



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 the finger until get a round drop of blood.Do not test with the blood drop if it is smeared or running. Wipe the area and gently squeeze out another drop of blood or do the lancing at another spot.

Blood sampling

IMPORTANT:

- Use only Test Strip BS-602a to test the blood glucose.
- Use only Test Strip KS-101 to test the blood β-ketone.
- Use only Test Strip US-201 to test the uric acid.
- Use only Test Strip TS-101 to test the total cholesterol.
- Testing must be done within the operating temperature range 5℃~45℃ (41℉~113℉). And testing Uric Acid and total cholesterol must be done at temperatures between 10℃～40℃ (50℉～104℉).
- 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 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 first open it. Discard the vial of BS-602a or KS-101 6 months after first-open date.Discard the vial of US-201 or TS-101 3 months after first-open date.

Remark: Blood sample requirement detailed in the BS-602a Blood Glucose Test Strips Instruction Manual, US-201 Uric Acid Test Strips Instruction Manual, KS-101 Blood β-ketone Test Strips Instruction Manual, TS-101 Total Cholesterol Test Strips Instruction Manual.

Testing

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

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

Important:

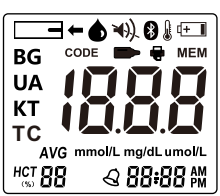
When test blood glucose, the meter should only be used with BS-602a test strips.

When test blood β-ketone, the meter should only be used with KS-101 test strips.

When test uric acid, the meter should only be used with US-201 test strips.

When test total cholesterol, the meter should only be used with TS-101 test strips.

Using other test strips with this meter can result in errors or inaccurate readings.



② System check screen

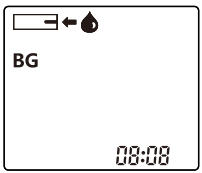
The screen will briefly display all content to confirm that the display is working properly.

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.

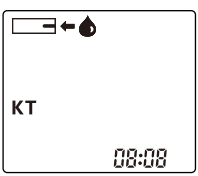
•If appears, it indicates that the battery is almost empty. Replace the battery now.

Insert BS-602a



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

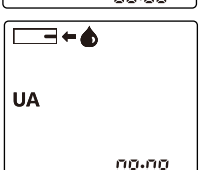
Insert KS-101



④The blood drop symbol flashes on the display screen.
The meter is now ready to apply blood sample.

Insert US-201

⑤ System code of UA
The code with time will briefly appear after the system check screen so that can make sure the meter is set to the correct code.



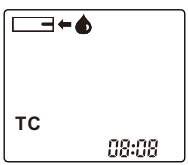
⑥ The blood drop symbol flashes on the display screen.
the meter is now ready to apply blood sample.

Testing

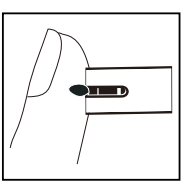
Insert TS-101

⑦System code of TC

The code with time will briefly appear after the system check screen so that can make sure the meter is set to the correct code.



⑧ The blood drop symbol flashes on the display screen. the meter is now ready to apply blood sample.

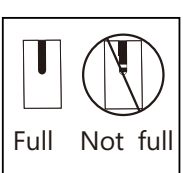


⑨ Apply the sample

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 the drop of blood has been moved away.
- Do Not move the test strip in the meter during a test.

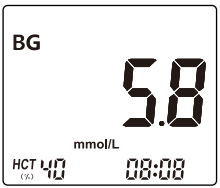


⑩ Wait for the confirmation window to fill completely

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

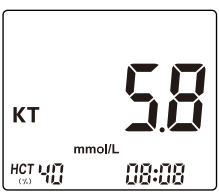
When the confirmation window is full, this means enough blood have been applied. Now the test strip can be moved away from the blood drop and wait for the meter to count down from 5 to 1 with 1 beep-sound indicating the end of test.

When test blood glucose



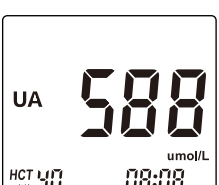
⑪ Read blood glucose result on the meter
After the measurement is over, the meter will display the blood glucose level along with the unit of measure, the date and time of the test. Blood glucose results are automatically stored in the meter's memory.

When test blood β-ketone



⑫ Read blood β-ketone result on the meter
After the measurement is over, the meter will display the blood β-ketone level along with the unit of measure, the date and time of the test. Blood β-ketone results are automatically stored in the meter's memory.

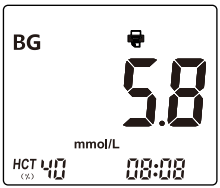
When test uric acid



⑬ Read uric acid result on the meter
After the measurement is over, the meter will display the uric acid level along with the unit of measure, the date and time of the test. Uric acid results are automatically stored in the meter's memory.

When test Total Cholesterol

⑭ Read total cholesterol result on the meter
After the measurement is over, the meter will display the total cholesterol level along with the unit of measure, the date and time of the test. total cholesterol results are automatically stored in the meter's memory.



⑮ print test results

If the meter is connected to a printer and the print mode is enabled, long press the RIGHT button to print the test results.

⑯ Delete the memory

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

⑰ Turn the 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 for blood glucose

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
Fasting blood-glucose	⩽5.6 mmol/L (⩽100mg/dL)
2 hours after meal	Less than 7.8mmol/L (⩽140mg/dL)

Time	Pregnant adults Blood Glucose Range
Fasting blood-glucose	Less than 5.3 mmol/L (≤95mg/dL)
2 hours after meal	Less than6.7mmol/L (⩽120mg/dL)

Time	Neonatal Blood Glucose Range
NA	⩽7.1 mmol/L (⩽128mg/dL)

Source:

1. American Diabetes Association; Standards of Care in Diabetes—2024..
2. Organization, World Health . "Definition and diagnosis of diabetes mellitus and intermediate hyperglycaemia: report of a WHO/IDF consultation." Geneva World Health Organization (2006).
3. Diabetes Care 2019;42(Suppl. 1):S13–S28
4. Standards of care for type 2 diabetes in China, 2013

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

① **Low glucose results**

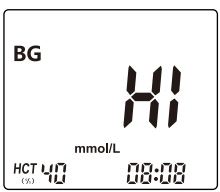
If the test result is lower than 0.5mmol/L(9mg/dL), Lo will appear on the meter display screen.

• Lo Reading with Symptoms

If have a Lo reading and have symptoms such as weakness, sweating, nervousness, headache or confusion It is recommended to use the hospital's professional

equipment to measure again. Our equipment is only for in vitro diagnosis and blood sugar monitoring. It cannot be used for the diagnosis and screening of diabetes, nor can it be used as a basis for drug adjustment.

• Lo Reading without Symptoms
If get a Lo reading, but have no symptoms of low blood glucose, then retest with a new test strip on fingers.



② High glucose results

If the test result is above 33.3 mmol/L(600 mg/dL), HI will appear on the display screen.

• HI Reading with Symptoms
If the patient feels symptoms such as fatigue, thirst, excess urination, or blurry vision, It is recommended to use the hospital's professional equipment to measure again. Our equipment is only for in vitro diagnosis and blood sugar monitoring. It cannot be used for the diagnosis and screening of diabetes, nor can it be used as a basis for drug adjustment.

• HI Reading without Symptoms
If get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip.

③Unusual hematocrit

• Too high (above 70%)hematocrit can cause inaccurate results.

Interpreting unexpected test results for blood β-ketone

The meter can accurately measure blood β-ketone concentrations between 0.1 to 8 mmol/L (1 to 83.3mg/dL)

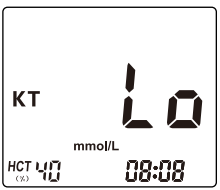
Expected Blood β-Ketone Level:

Time	Normal Blood β-Ketone Range
Before breakfast	≤ 0.5mmol/L (≤ 5.2mg/dL)

Time	Neonatal Blood β-ketone Range
N/A	≤1 mmol/L (≤10.4mg/dL)

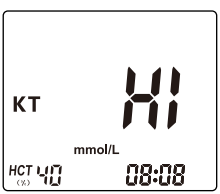
Source:
1. Society of Endocrinology, Chinese Medical Association. Expert consensus on the monitoring for diabetic blood ketone bodies in China [J]. Chinese Journal of Endocrinology and Metabolism, 2014, 30 (3): 177-183.
2. P B O'Donohoe, Kessler R , Beattie T F .Exploring the clinical utility of blood ketone levels in the emergency department assessment of paediatric patients[J].Emergency medicine journal : EMJ, 2006.
3. Melichar, V. , Z. Drahota , and P. Hahn . "Ketone bodies in the blood of full term newborns, premature and dysmature infants and infants of diabetic mothers. " Biol Neonat 11.1-2(1967):23-28.

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



① Low ketone results

If the test result is lower than 0.1mmol/L(1 mg/dL), Lo will appear on the meter display screen.



② High ketone results

If the test result is above 8 mmol/L(83.3 mg/dL), HI will appear on the display screen.

③ Unusual hematocrit

- Too high (above 70%) or too low(below 10%)hematocrit can cause inaccurate results.

Interpreting unexpected test results for uric acid

The meter can accurately measure uric acid concentrations between 180 to 1190 umol/L (3 to 20 mg/dL)

Expected Uric Acid Level:

Time	Reference values
Male	202 - 416 umol/L(3.4 - 7.0 mg/dL)
Female	142 - 360 umol/L(2.4 - 6.0 mg/dL)

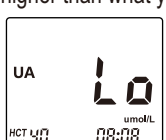
Source:

1.Guidelines for the diagnosis and treatment of hyperuricemia and gout in China (2019). The Chinese Society of Endocrinology, Chinese Medical Association.

2.2018 Updated European League Against Rheumatism evidence-based recommendations for the diagnosis of Gout;

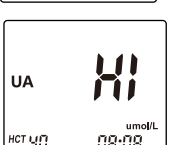
3.2019 American College of Rheumatology Guideline for the Management of Gout;

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



① **Low uric acid results**

If the test result is lower than 180 umol/L(3 mg/dL), Lo will appear on the meter display screen.



② **High uric acid results**

If the test is above 1190 umol/L(20 mg/dL), HI will appear on the display screen.

③ **Unusual hematocrit**

- Too high (above 60%) or too low(below 20%)hematocrit can cause inaccurate results.

Interpreting unexpected test results for total cholesterol

The meter can accurately measure total cholesterol concentrations between 2.6 to 10.4 mmol/L (100 to 400 mg/dL)

Expected total cholesterol Level:

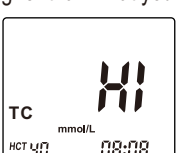
Recommend reference values
<5.2mmol/L (200 mg/dL)

Source:

l.Chinese lipid management guidelines(2023). Chin J Cardiol, March 2023, Vol. 51, No. 3.

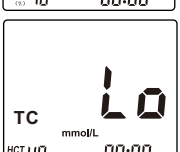
2.Watson, Joan E. . "National Cholesterol Education Program: Guidelines for Treating High Blood Cholesterol in Adults. " Journal of the American Academy of Nurse Practitioners 1.1(2010):14-19.;

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



① Low total cholesterol results

If the test result is lower than 2.6 mmol/L (100 mg/dL), Lo will appear on the meter display screen.



② High total cholesterol results

If the test is above 10.4 mmol/L (400 mg/dL), HI will appear on the display screen.

③ Unusual hematocrit

- Too high (above 60%) or too low(below 20%)hematocrit can cause inaccurate results.

Comparing meter's results with laboratory results periodically.
The results of the CDS-101b meter are plasma equivalent. This method will help healthcare professional compare the meter results with laboratory test results. The CDS-101b meter's test result and laboratory test results both are expressed in plasma-equivalent units. The results can be affected by factors and conditions that do not affect laboratory results in the same way.
To maximize the 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

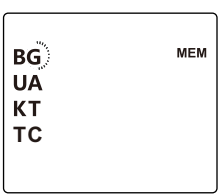
- Wash your hands before obtaining a blood sample.
- Obtain blood samples for a laboratory test and for your meter within 10 minutes of each other. This will ensure an accurate comparison of result.

Storing Test results and Control Test results

The meter automatically stores up to 200 blood glucose test results,200 blood β-ketone test results, 200 uric acid test result and 200 total cholesterol test result 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 test results.

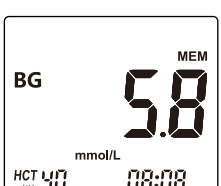
① Enter Memory Mode

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



② Select Memory Group

Press LEFT button or RIGHT button to select which memory group. Press button “M” to view memory.

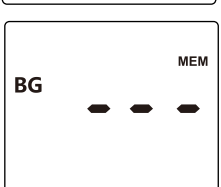


③ View previous memory in order

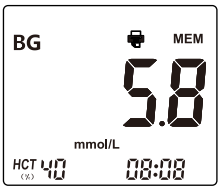
Short press the LEFT button or RIGHT button to scroll backward or forward.

The most recent result will be displayed first.

Press button “M” to exit and select memory group again.

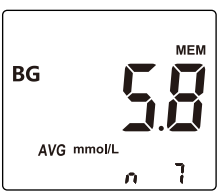


Note: If there is no test result stored, the meter will display “ - - - ” for a few seconds then automatically turn off.



④ **Print memory results**

If the meter is connected to a printer and the print mode is enabled, long press the RIGHT button to print the memory results .



⑤ **View 7-, 14-, 28-day average**

Long-press the RIGHT button for 3 seconds to enter the average value display.

The first memory display screen shown is the 7-day average. This average does not include the control test results.

Press LEFT button or RIGHT button to change average days.

Press button “M” to return to the preview screen.

n = indicates the number of results included in the average

⑥ **Delete all memory of current memory group**

Long-press the RIGHT button and LEFT button approximately 3 seconds. After memory cleared, the meter will display “dEL” and then turn off automatically.

Notice: Delete memory only for the current memory group, the other three memory groups are not affected.

⑦ **Exit**

Press and hold the “M” button for few seconds until the meter turns off.

When to perform a control test

Control solutions are used to check that the meter and the test strips are matched and they are working properly in that:

CS-201a control Solution is used for blood glucose control solution test.

CS-401 Control Solution is used for blood β-ketone control solution test.

CS-501 Control Solution is used for uric acid control solution test.

CS-601 Control Solution is used for total cholesterol control solution test.

Do a control solution test:

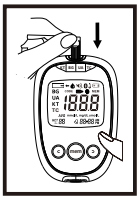
- Whenever open a new vial of test strips.
- Whenever want to check if the testing is correct.
- If suspect the meter and test strips are not working properly.
- If have had repeated unexpected test results.
- If drop or damage the meter.
- If left the test strip container open or it is probable the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

NOTE:

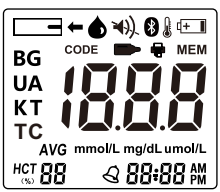
- Only use the CS-201a Control Solution to test BS-602a.
- Only use the CS-401 Control Solution to test KS-101.
- Only use the CS-501 Control Solution to test US-201.
- Only use the CS-601 Control Solution to test TS-101.
- Close the control solution bottle tightly after use.
- Write the date open the 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.
- The control solution is not included in the kit (Only applicable to CDS-101b-0006). If need, the customers can buy it from the local supplier

⚠ 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.

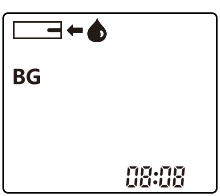
Performing a control test



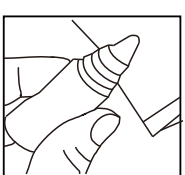
① Insert a test strip to turn the meter on



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.

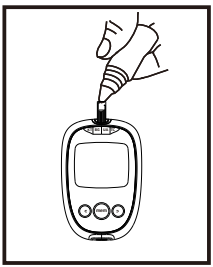


③ The blood drop symbol flashes on the display screen. The meter is now ready to apply blood sample.

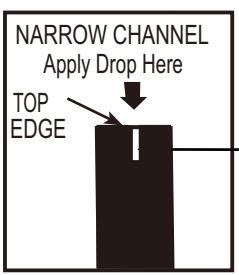


④ Shake the control solution vial before each test. Remove the cap and squeeze the vial to discard the first drop. Then wipe the tip with a clean tissue or cloth. Hold the vial upside down and gently squeeze a hanging drop.

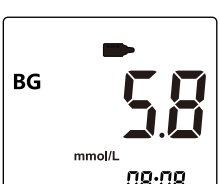
Performing a control test



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.

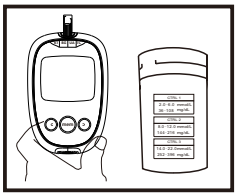


⑥ Read the result on the meter



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, the control solution symbol. 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 Control Solution only. It is not a recommended range for the test results level.

⚠ CAUTION: If 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 don't want to keep the test result, press LEFT and RIGHT button at the same time to delete it.

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

⑧ Turn the 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.

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 the system

Store the meter, test strips, control solution in the 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 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 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.

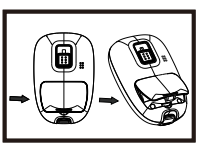
Cleaning and disinfection

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 the exposure to disease. Even though there is only one user.

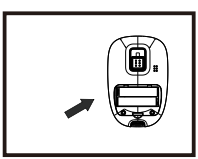
Replacing the battery

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

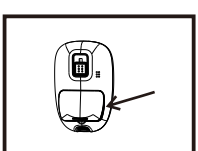
Important: When this symbol appears, the battery should be replaced immediately.



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 the meter settings
Replacing the battery does not affect the stored results. However, the meter need to be reset.
See Setting up the meter section.

Note: Batteries need to be properly disposed of. Contactyour local government for disposal or recycling practicesin your area.

We recommend to disinfect periodically. When the user assists others to make blood glucose, blood β-ketone,uric acid, total cholesterol testing with the meter, please disinfect it or wear gloves to protect himself/herself.

Cleaning the meter and lancing device

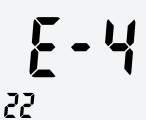
To clean the meter and lancing device, wipe the outside with a soft cloth damped with water and mild detergent. Do not use alcohol or another solvent. Do not get any liquids, dirt, dust, blood, or control solution inside the meter through the strip port. Never spray cleaning solution on the meter or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

Disinfecting the 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.

Or prepare Isopropyl Alcohol Prep Pads .Hold the meter with the strip port down. Use the Isopropyl Alcohol Prep Pads to wipe the outside of the meter and lancing device.

After wiping,allow it to dry naturally.
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. "22" is the Internal error code.
	The strip check has problem.	Make sure that the strip model is correct and retest with a new strip.
	Failed to synchronize historical data.	Synchronize historical data again.

	Battery power is low.	Replace the battery soon
	No code chip or the chip is not well installed.	Insert the code chip to the meter correctly.
	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 see the blood and test strip symbols on the display screen before apply the blood sample.
Defective meter or test strips.	Contact the vendor.

Specifications

Product description	CDS-101b Multi-function Monitoring System	
Assay method	Blood Glucose	Glucose dehydrogenase biosensor
	Blood β-Ketone	Ketone electrochemical biosensor
	Uric Acid	Uric acid electrochemical biosensor
	Total Cholesterol	Total Cholesterol electrochemical biosensor
Measurement range	Blood Glucose	0.5-33.3mmol/L (9~600mg/dL)
	Blood β-Ketone	0.1 - 8mmol/L (1~83.3mg/dL)
	Uric Acid	180-1190umol/L (3~20mg/dL)
	Total Cholesterol	2.6 to 10.4 mmol/L (100 to 400 mg/dL)
Sample	Blood Glucose	Fresh capillary whole blood, venous blood, arterial blood, neonatal blood.
	Blood β-Ketone	Fresh capillary whole blood, venous blood, neonatal blood.
	Uric Acid	Fresh capillary whole blood, venous whole blood.
	Total Cholesterol	
Sample size	Blood Glucose	Approximate 0.5 microlitre
	Blood β-Ketone	Approximate 0.8 microlitre
	Uric Acid	Approximate 1.0 microlitre
	Total Cholesterol	Approximate 1.5 microlitre

Specifications

Response time	Blood Glucose	5 seconds
	Blood β-Ketone	
	Uric Acid	
	Total Cholesterol	25 seconds
Calibration	Blood Glucose	Plasma equivalent glucose values
	Blood β-Ketone	Plasma equivalent ketone values
	Uric Acid	Plasma equivalent uric acid values
	Total Cholesterol	Plasma equivalent total cholesterol values
Unit of measure	Blood Glucose	mmol/L or mg/dL; switchable
	Blood β-Ketone	mmol/L or mg/dL; switchable
	Uric Acid	umol/L or mg/dL; switchable
	Total Cholesterol	mmol/L or mg/dL; switchable
Battery	3.0V DC(2xAAA alkaline batteries)	
Battery life	Approximately 1,000 tests	
Memory	1000 results with date and time,Including 250 blood glucose results,250 blood β-ketone results and 250 uric acid results and 250 total cholesterol results.	
Size	101.1*66.5*24.6mm (L*W*H)	
LCD size	46.0*38.7mm (L*H)	
Weight	Approximate 80g, battery not included	

Specifications

<table>
<tr><td rowspan="4">Operating environment</td><td>Blood Glucose</td><td rowspan="2">5℃~45℃(41℉~113℉)
5~95% RH (non-condensing)</td></tr>
<tr><td>Blood β-Ketone</td></tr>
<tr><td>Uric Acid</td><td rowspan="2">10℃~40℃(50℉~104℉)
5~95% RH (non-condensing)</td></tr>
<tr><td>Total Cholesterol</td></tr>
<tr><td rowspan="2">Meter storage environment</td><td colspan="2">-20℃~55℃ (-4℉~131℉)</td></tr>
<tr><td colspan="2">10~90% RH (non-condensing)</td></tr>
<tr><td>Strip storage environment</td><td colspan="2">1℃~30℃ (33.8℉~86℉)</td></tr>
<tr><td>Altitude</td><td colspan="2">Up to 10,000 feet (3,048 meters) above sea level</td></tr>
<tr><td rowspan="4">Hematocrit</td><td>Blood Glucose</td><td>0%~70%</td></tr>
<tr><td>Blood β-Ketone</td><td>10%~70%</td></tr>
<tr><td>Uric Acid</td><td>20%~60%</td></tr>
<tr><td>Total Cholesterol</td><td>20%~60%</td></tr>
<tr><td>Service life</td><td colspan="2">Three years</td></tr>
<tr><td>Pollution degree</td><td colspan="2">2</td></tr>
</table>

Electromagnetic Compatibility

The chosen basis for electrostatic discharge immunity testing was basic standard EN 61326 . 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. This Blood Glucose meets the electromagnetic immunity requirements as standard EN ISO 15197 : 2015.

Warning

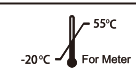
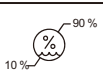
- Any product coming in contact with blood is considered contaminated (potentially infectious).
- During normal testing, any meter may come in contact with blood.
- Lancets may also be considered sharps. For disposal of lancets, refer to local regulations.

Refer to any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact the 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.

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.

	Consult instructions for use
	In vitro diagnostic medical device
	Serial number
	Caution
	Batch code
	Manufacturer
	Storage temperature limitation for meter
	Do not reuse
	Use by
	Storage humidity limitation
	General symbol for recovery/recyclable
	Unique device identifier

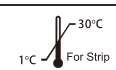
CE 0197	The product conforms to the requirements of the REGULATION (EU) 2017/746 IVDR in vitro diagnostic medical device, “0197” is the identification number of notify body
	Keep dry
	Please dispose of the waste according to the local regulations
EU REP	European Union Authorized Representative
	Manufacture Date
	Storage temperature limitation for strip
	Transportation and storage atmospheric pressure limit is 70kPa-106kPa
	importer
	Contain sufficient for < n > tests

Table 1 Electromagnetic compatibility declaration

Guidance and declaration of manufacturer-electromagnetic emissions	
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.	
Emissions test	**Compliance**
Radiated emission	Group 1 Class B
Conducted emission	Group 1 Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Table 2 Immunity test requirements for equipment intended to be used in a Home HEALHCARE ENVIRONMENT

PORT	Phenomenon	Basic standard	Test value	Performance criterion
ENCLOSURE	Electrostatic discharge	IEC 61000-4-2	± 6 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	B B
	Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 15 kV air	C C
	Electromagnetic field[a]	IEC 61000-4-3	10V/m(80 MHZ to 1 Ghz) 3V/m(1 GHz to 6 GHz)	A A
	Magnetic field	IEC 61000-4-8	30A/m(50 Hz,60Hz)	A
AC power	Voltage dip	IEC 61000-4 -11	0 % during 0,5 cycle 0 % during 1 cycle 70 % during25/30 cycles	B B C
	Short interruptions	IEC 61000-4 -11	0 % during 250/300 cycle	C
	Burst	IEC 61000-4-4	± 2 kV (5kHz or 100kHz)	B
	Surge	IEC 61000-4-5	±0.5kV, ±1kV line-to line ±0.5kV, ±1kV, ±2kV line-to ground	B B

Table 2 Immunity test requirements for equipment intended to be used in a Home HEALHCARE ENVIRONMENT(continued)

PORT	Phenomenon	Basic standard	Test value	Performance criterion
AC power	Conducted RF	IEC 61000-4-6	3 V (150 kHz- 80 MHZ)	A
			6 V in ISM and amateur radio bands in the frequency range 150 KHz and 80 MHz 80 % AM at 1kHz	A

Table 3 Immunity test requirements for equipment intended to be used in a Home HEALHCARE ENVIRONMENT

PORT	Phenomenon	Basic standard	Test value	Performance criterion
ENCLOSURE.1	Electromagnetic field[a]	IEC 61000-4-3	9V/m(710MHz,745MHz,780MHz) 28V/m(1720MHz,1845MHz,1970MHz) 28V/m(2450MHz) 9V/m(5240MHz,5500MHz,5785MHz) With a pulse modulation of 217 Hz .The carrier shall be modulated using a 50% duty cycle square wave signal.	B
ENCLOSURE.2	Electromagnetic field[a]	IEC 61000-4-3	27V/m(385MHz) 28V/m(810MHz,870MHz,930MHz) With a pulse modulation of 18 Hz .The carrier shall be modulated using a 50% duty cycle square wave signal.	B
ENCLOSURE.3	Electromagnetic field[a]	IEC 61000-4-3	28V/m(430MHz to 470MHz) FM[b] ±5kHz deviation, 1kHz sine	B

a If necessary to achieve the immunity test level, the distance between the transmitting antenna and the equipment may be reduced to 1 m .The 1m test distance is permitted by IEC 61000-4-3.

b AS an alternative to FM modulation , 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation ,it would be worst case sensitive equipment.

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