

Handheld Electrochemical Meter

User's Manual

User's manual information

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Notes Before Use

Thank you for purchasing the Handheld Electrochemical Meter from EAGLENOS SCIENCES, INC. The handheld electrochemical meter (hereinafter referred to as "meter") is a handheld rapid detection in vitro diagnostic equipment.

This user's manual is a reference for operating, maintaining and repairing the product. It describes in details the characteristics of the product and related information. Prior to usage, operators are strongly advised to thoroughly review the user's manual. This manual should be kept in a safe place. The user should strictly adhere to the recommendations provided in the user's manual, otherwise the protection provided by the equipment may be damaged. EAGLENOS SCIENCES, INC. does not assume any legal responsibility for any malfunction or accident arising from violations of the warnings and caution in this manual.

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Possession of this manual does not constitute a license to the intellectual property rights contained in the products.

The right to amend or update this manual and the final interpretation of this manual belongs to EAGLENOS SCIENCES, INC.

Registration Information

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Production Information

Product Name: Handheld Electrochemical Meter

Model No.: MG14, MG15, MC12, MC13, M422, M425, M426

Description: M stands for the series of the product, the first digit represents the product code, the second digit represents the number of targets, and the last digit represents the running number.

The specific differences between the models are as follows:

Model	Parameters	Bluetooth Transmission	Storage Capacity	Differences
MG14	Glucose	YES	500 tests	Both have Bluetooth transmission, with only the difference of varying storage capacity.
MG15	Glucose	YES	800 tests	
MC12	creatinine	YES	500 tests	Both have Bluetooth transmission, with only the difference of varying storage capacity.
MC13	creatinine	YES	800 tests	
M422	Glucose, creatinine	YES	800 tests	Both have Bluetooth transmission, with only the difference of varying storage capacity.
M425	Glucose, creatinine	YES	500 tests	
M426	Glucose, creatinine	YES	600 tests	

Product production date: see Handheld Electrochemical Meter for details

Usage lifetime: 5 years

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1 Safety Guidelines

Thank you for choosing EAGLENOS SCIENCES, INC.'s handheld electrochemical meter. To use the meter safely and effectively and avoid possible injuries, please read the user's manual in detail before use. The correct operation methods and precautions must be fully understood before use. Please keep this manual in a safe place.

Please read the following precautions and EMC instructions carefully to ensure proper use of the meter. EAGLENOS SCIENCES, INC. (hereinafter referred to as "Eaglenos") is not liable for any issues resulting from non-compliance with the warnings and cautions outlined in this manual.

Important Safety Instructions

- This product is a medical device and is intended for use only in the scope of application and operating environment described in this product's user's manual. Improper use and operation may result in erroneous test results. Before use, operators should read in detail the user's manual and that of the accompanying test strips, quality control solutions and accessories. Special attention should be drawn to the contents of the "Warnings" and "Caution" sections, and users should strictly comply with the use and operation specifications.
- Environmental requirements when performing blood glucose, uric acid and creatinine tests: see test strip instructions.
- Do not use accessories not supplied or recommended by the manufacturer.
- In case the meter sustains damage from a fall, water immersion, or persistently triggers malfunction alarms, refrain from further use. Contact your product distributor.
- Do not expose the meter or its accessories to excessive heat.
- Do not spill liquids on the meter or use the meter near liquids.
- Do not allow any debris to enter the various sockets of the meter.
- Do not use the meter in places with aerosol droplets, regulated oxygen, acidic volatile gases, or next to strong sources of radiation, as this may interfere with the normal operations of the equipment.

- Do not place any objects on top of the meter.
- Please avoid direct exposure to strong light.
- Do not perform a blood glucose test during or immediately after xylose absorption as xylose in blood can interfere with blood glucose test results.
- Users should perform periodic laboratory checks and compare handheld electrochemical meter test results with laboratory results.

Safety Instructions

- During blood glucose/uric acid/creatinine testing, the meter itself may come into contact with blood. Therefore, there is a risk of pathogens being carried by meters.
- When using the meter in a healthcare setting, healthcare workers should follow the infection control requirements for medical device in healthcare settings and disinfect the meter regularly.
- If a health or life-threatening accident occurs during usage of the product, you should immediately call the emergency hotline and seek the help of a healthcare professional.
- Contraindications: None.

Electromagnetic Compatibility (EMC)

- This IVD equipment complies with the emission and immunity requirements specified in IEC 61326-1 and IEC 61326-2-6.
- It is recommended to evaluate the electromagnetic environment of the meter before use. The meter should not be used in close proximity or stacked with other equipments. If such placement is unavoidable, monitor the meter closely to ensure proper functioning.
- It is the manufacturer's responsibility to provide the customers or users with the EMC information of the meter.
- It is the user's responsibility to ensure the proper EMC environment is maintained.



Warnings

- ✓ It is prohibited to use this equipment next to strong radiation sources (e.g., non-shielded RF sources), as this may interfere with the normal operation of the equipment.
- ✓ Use of this equipment in dry environments may cause damaging electrostatic

discharges, leading to erroneous results.

2 Understanding the Meter

Products

The handheld electrochemical meter is intended to be used in combination with the matching test strips produced by EAGLENOS SCIENCES, INC., and any blood collection pen, disposable blood collection needle or disposable blood collector with a valid medical device registration certificate. The handheld electrochemical meter is used to measure the concentration of blood glucose, uric acid and creatinine in a short period of time.

The handheld electrochemical meter also calculates the hemoglobin value during the test.

Intended Use

The handheld electrochemical meter is intended for use with Eaglenos blood glucose test strips and blood creatinine test strips for the in vitro automatic and quantitative measurement of glucose and creatinine concentrations in fingertip fresh capillary whole blood and venous whole blood.

This meter is intended to be used in the point of care or clinical laboratory settings by healthcare professionals or for self-testing by laypersons at home to monitor the effectiveness of a diabetes control program and creatinine levels in patients with kidney disease or renal dialysis. The meter is neither used for diagnosis and screening of diseases nor as a basis for adjustment of therapeutic drugs.

Product Kit

- ◆ Handheld Electrochemical Meter
- ◆ Two AAA Batteries
- ◆ Warranty Card
- ◆ User's Manual
- ◆ Certificate of Conformity
- ◆ Packing List

- ◆ Quick Start Guide
- ◆ Software applications (electronic only)

Notes:

- If items in the kit are missing or damaged, please contact Eaglenos customer service.
- If there is a complimentary item other than those listed, please refer to its accompanying descriptions.

The following items are not included in the kit and must be purchased separately:

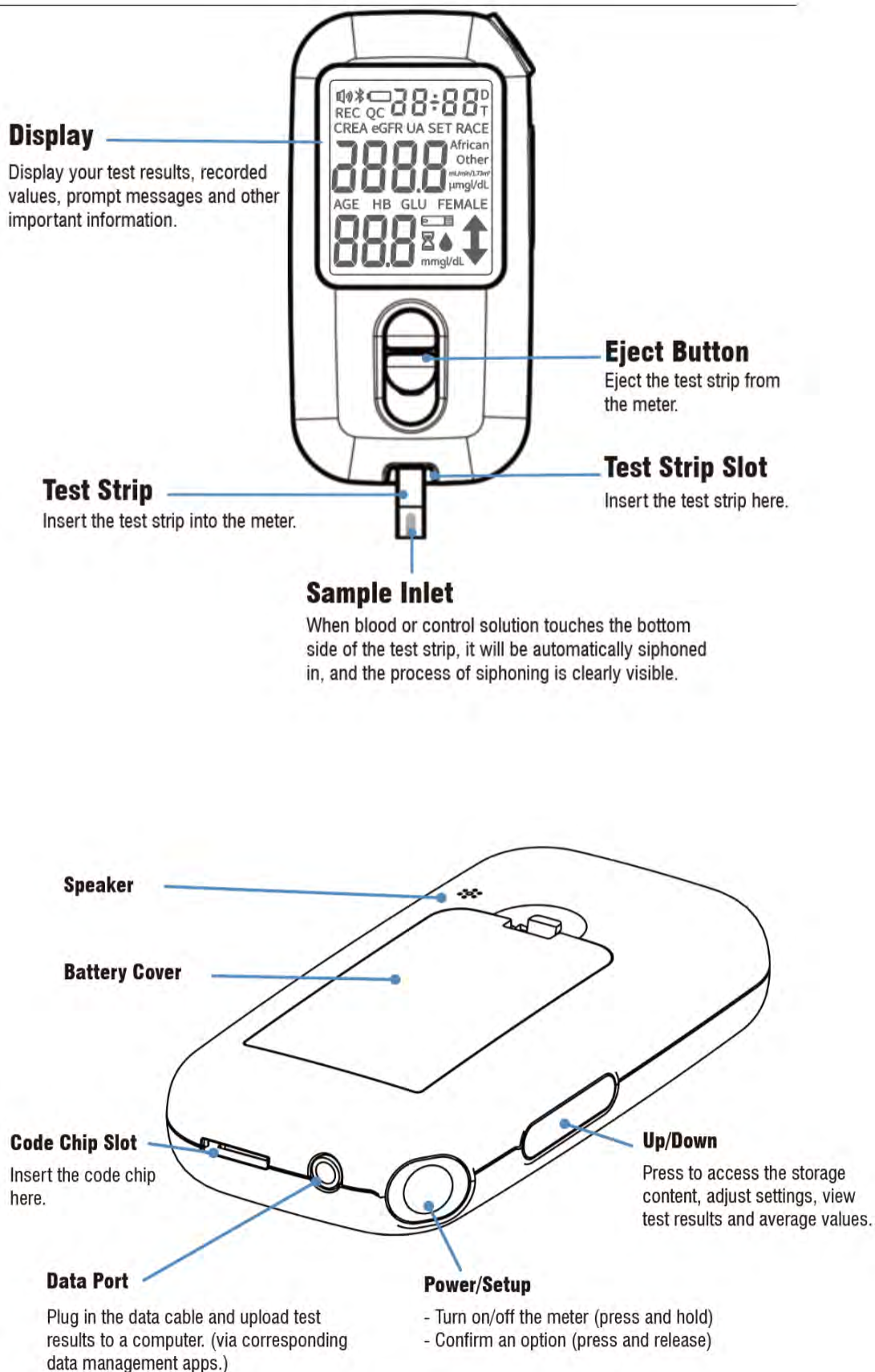
- ◆ Blood Glucose Test Strips
- ◆ Blood Uric Acid Test Strips
- ◆ Blood Creatinine Test Strips
- ◆ Blood Glucose Control Solutions
- ◆ Uric Acid Control Solutions
- ◆ Creatinine Control Solutions



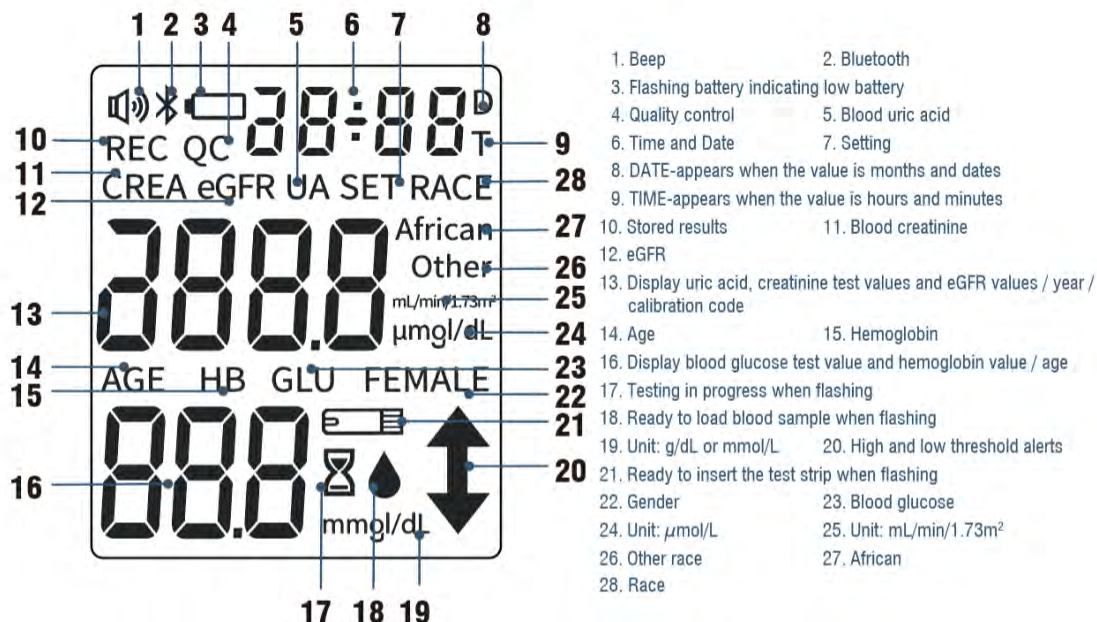
Warnings

- ✓ Keep the meter and supplies away from children. Swallowing meter parts and meter companion accessories (e.g., battery caps, batteries, test strips, blood collection needles, blood collection needle protective caps, quality control fluid caps, etc.) may result in choking.
- ✓ Do not store the test strips in a hot, humid place. High temperatures and humidity will damage the test strips.

Appearance & Composition



Full Screen Display: The meter will display the following after being powered on:

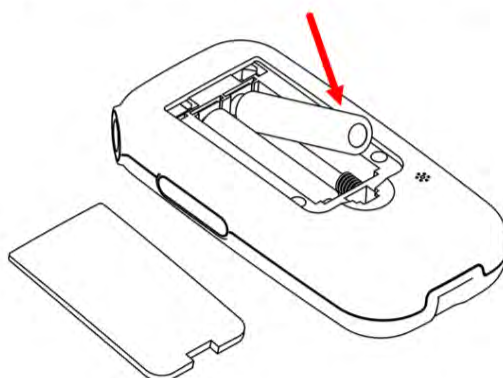


3 Installation and Setup

Installing the Battery

This product uses two AAA alkaline batteries.

- 1) Open the battery cover and insert the batteries. Please install the battery correctly according to the positive (+) and negative (-) markings.



- 2) Put the battery cover back until the clasp snaps securely into place. The message "Set" appears on the screen. Refer to the "Set" section to complete the setup.



Note: The red radial lines indicate that the icon here will be blinking.

Battery Replacement

A flashing battery icon in the upper right corner of the display indicates that the battery is low and needs to be replaced as soon as possible.



The date and time need to be reset after changing the batteries. See section "Setting the Time and Date".



Caution

- Do not remove the battery while the meter is connected to other devices as this will affect data storage.
- Please dispose of the old batteries in accordance with local environmental regulations.

Power ON/OFF

Power on

Method 1: Short press on the power button to enter the boot screen.



Method 2: Insert the test strip directly while the meter is off and the meter will automatically turn on and enter the test mode.



Power off

- Press and hold the power button to turn off the meter.



Caution

- A long press on the power button during the process of powering on will prompt the setup mode. To turn off the meter, press and hold the power button again until the meter is turned off.

Set Up

Before using the meter for the first time or after replacing the meter's batteries, make sure the meter's time and date are set correctly.

Functionality	Action	Factory Setting
Time and date	• Setting the time or date	Default date
Prompt tone	• Select On or Off	On
Bluetooth	• Select On or Off	On

High and low threshold alerts	- Select On or Off; - Threshold reminder adjustable range: Hyperglycemia: 4.0 to 33.3 mmol/L; Hypoglycemia: unalterable. Hyperuric acid: 181 to 1188 $\mu\text{mol/L}$; High creatinine: 25 to 1150 $\mu\text{mol/L}$; Low hemoglobin: 10.0 to 20.0 g/dL.	OFF Threshold preset value: Hyperglycemia: 6.1 mmol/L Hypoglycemia: 3.9 mmol/L High uric acid: 420 $\mu\text{mol/L}$ High creatinine: 110 $\mu\text{mol/L}$ Low hemoglobin: 13.0 g/dL
eGFR	- Set formula version - Set race (select "African" or "Other") - Set gender (select Male or Female) - Set age	OFF

Go to Settings

- 1) Press and hold the power button while the meter is turned on until the message "Set" appears on the screen.

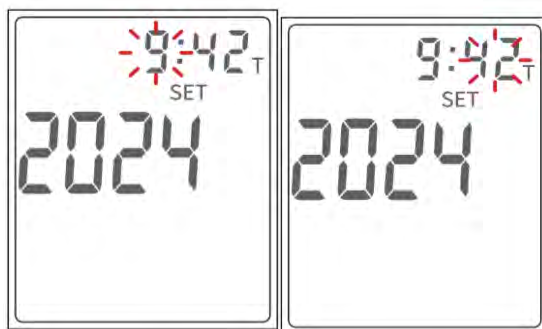
Setting the Time and Date

- 1) After entering the setup mode, short press the Up/Down button to set the year, month and day. Short press the Power button to confirm.



Year (first from left), month (second from left), day (third from left)

- 2) Short press the up/down button to set the hours (24 hours system) and minutes. Press the power button briefly to confirm.



Hours (first from left), minutes (second from left)

Prompt Tone Setting

- 1) After entering the setup mode, press the power button repeatedly and briefly until you enter the prompt tone setting.
- 2) Short press the Up/Down key to toggle On/Off. Press the power button briefly to confirm. To exit, press and hold the power button until it is turned off.



Bluetooth Setting

- 1) After entering the setup mode, press the power button repeatedly and briefly until you enter the Bluetooth setup interface.
- 2) Short press the Up/Down button to toggle On/Off. Short press the power button to confirm. To exit, press and hold the power button to turn off.

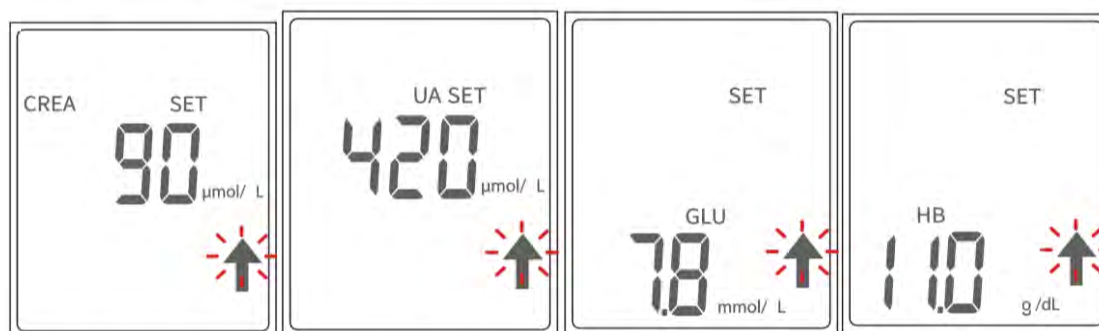


Setting High and Low Threshold Alerts

- 1) After entering the setup mode, press the power button repeatedly and briefly until the blinking "↑" icon appears on the screen.



- 2) Short press the Up/Down button to toggle On/Off. Press the power button slightly to confirm. If On is selected, a reminder of the high "↑" and low "↓" thresholds for each indicator will appear on the screen.
- 3) Short press the Up/Down button to set the threshold.



- 4) Repeat step 3 to complete the threshold settings for all analytes.



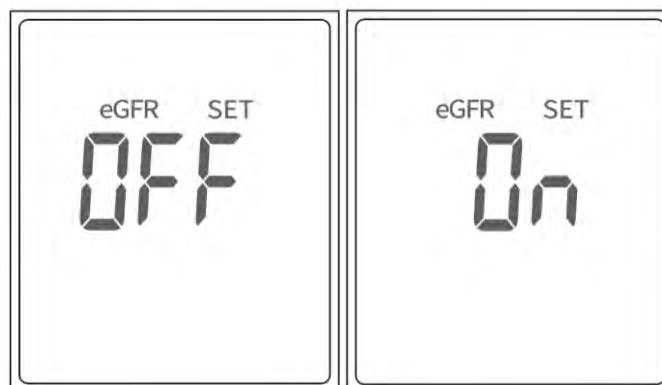
Warnings

- ✓ The threshold level of each indicator may vary from person to person, please consult a healthcare professional before setting this range. The threshold reminder function is not a substitute for a healthcare professional's diagnosis on the clinical significance of the indicator.

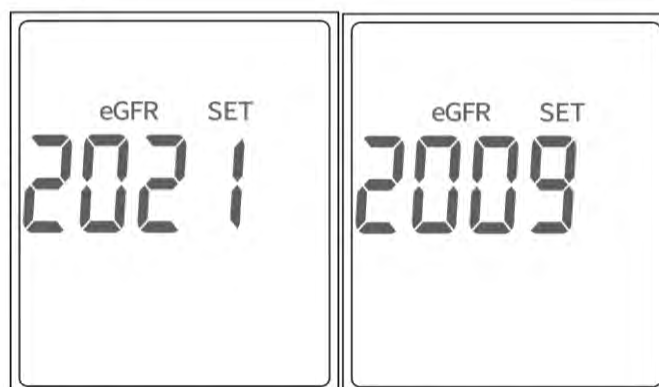
eGFR Setup

- 1) After entering the setup mode, press the power button repeatedly and briefly until entering the eGFR setup interface.

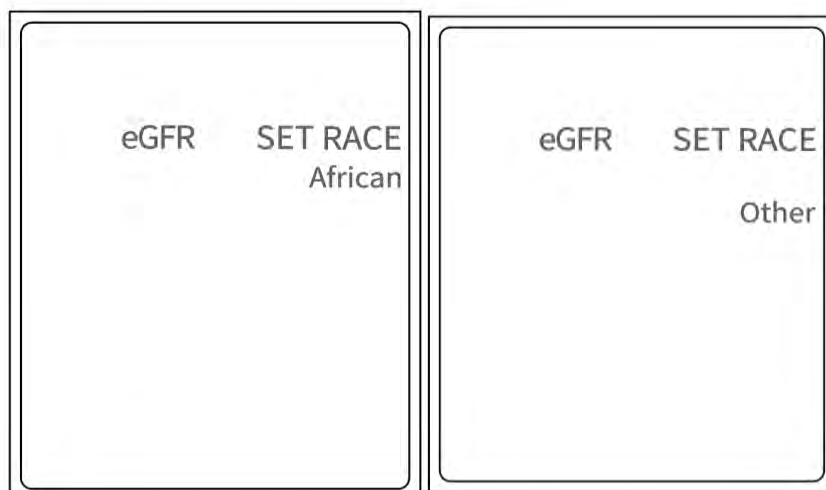
- 2) Short press the Up/Down button to toggle “On/Off”, while pressing the power button to select. If “On” is selected, the screen will display the settings for formula version, race, gender and age. To exit, press and hold the power button to turn off.



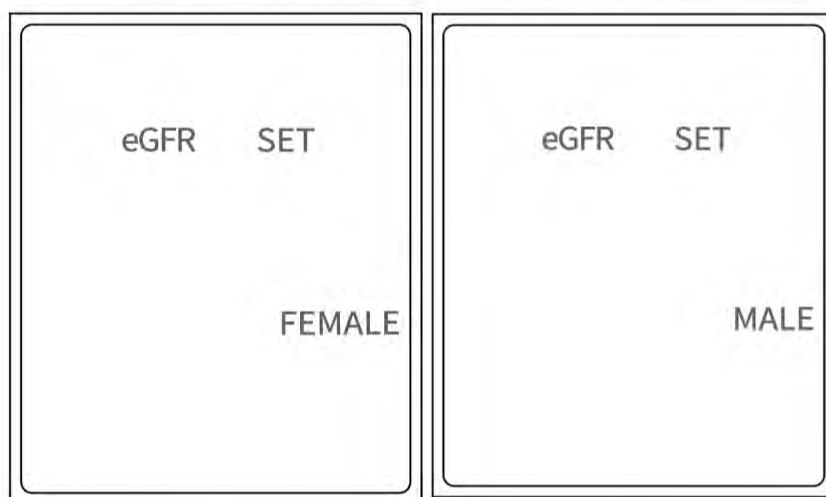
- 3) Short press the Up/Down button to set the formula versions. Two formula versions, 2009 version and 2021 version, are displayed on the screen. Press the power button repeatedly and briefly to select. When 2009 version is selected, it will proceed to race setting. When 2021 version is selected, it will skip race setting and proceed directly to gender setting.



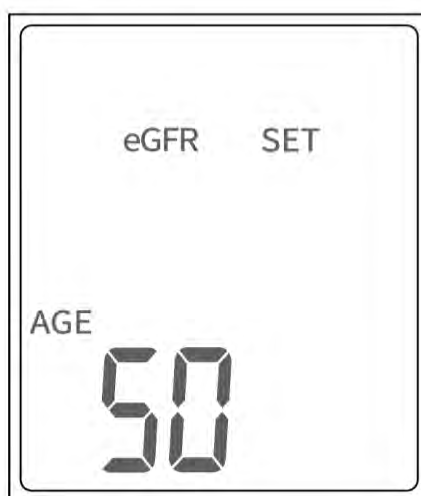
- 4) Short press the Up/Down button to set race. Press the power button to confirm.



- 5) Short press the Up/Down button to set gender. Press the power button to confirm.



- 6) Short press the Up/Down button to set age with the selectable range from 1 to 99.
Press the power button to confirm.



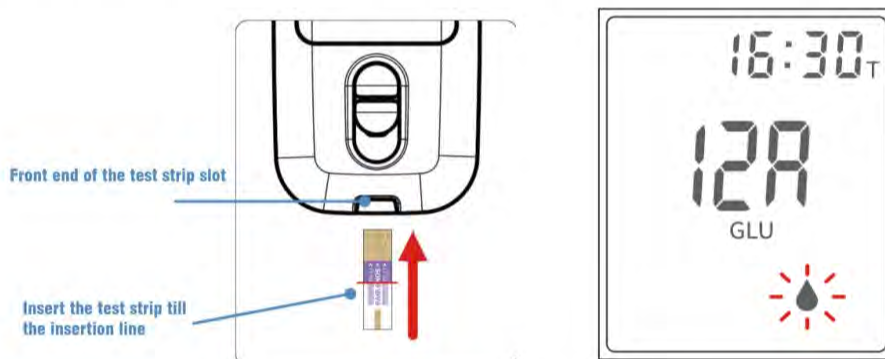
Code Chip Calibration

Each box of test strips contains a meter code chip. Each time you open a new box of test strips, you need to replace the old code chip and insert the new code chip.

- 1) Remove the new code chip from the test strip box and insert it into the meter.



- 2) Insert the test strip with the logo side up into the test strip slot and push it all the way in. The meter will automatically power on and display the calibration code.



- 3) Confirm that the code displayed on the screen matches with that on the code chip, and then remove the code chip.



Caution

- Use of code chips from a different box of test strips will result in erroneous test results.
- If a new code chip is not inserted before the test begins, the meter will by default use the stored code of the last inserted code chip.
- If there is no calibration code information available in the meter or if the inserted code chip does not match the inserted test strip, the meter will report an error.

4 Conducting Tests



Caution

Collecting Blood Samples

- Read carefully the user's instructions of the selected blood collection pen and disposable blood collection needle/tube before blood collection.
- Blood collection needles and devices are single-use, non-reusable and cannot be shared with others.
- If a blood collection pen is used to collect blood, be careful of needlestick injuries when attaching the blood collection needle.
- If a blood collection pen is used, it should be cleaned and sterilized promptly after testing according to its instructions.

Test strip

- Please read the user's instructions of the corresponding test strips carefully before testing.
- Do not use non-matching, damaged or contaminated test strips.
- Make sure the test strips are within the expiration date. Using expired test strips may result in inaccurate results.
- Test strips are disposable, not to be inserted or removed twice and not to be reused.
- During the test, the blood sample should be aspirated in the sampling area in one attempt, not twice or more.
- After collecting the blood sample, the test strip should not be touched or pulled out before the test results are displayed, otherwise the accuracy of the test results may be affected.
- Users should not add drops of samples other than blood (e.g., urine, etc.) to the test strip.

Preparing the test strips

- 1) Prepare blood pens and disposable blood collection needles or prepare disposable blood collection devices.
- 2) Select the site for blood sampling.
- 3) Please wash your hands with soap and warm water and dry them, or use alcohol pads for cleaning.



Caution

- Make sure the meter, test strips, and QC solution return to room temperature before testing.
- Venous whole blood samples must be collected by a healthcare professional. Anticoagulant tubes of sodium heparin (90 USP units/4mL), lithium heparin (75 USP units/4mL), and EDTA (3.6mg/2mL) may be used to collect the blood sample. Do not use tubes with other anticoagulants.
- Do not use lotions or creams on the sampled area.

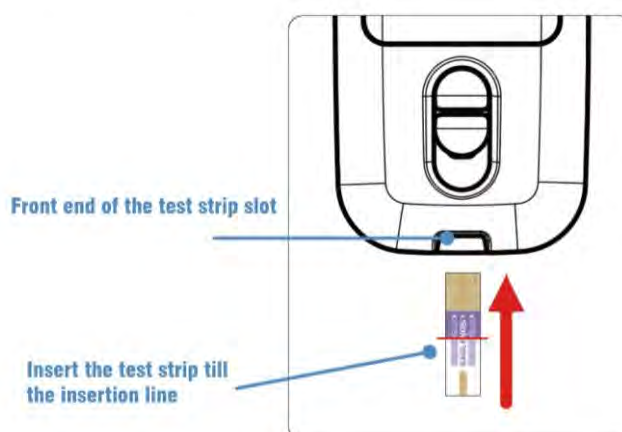
Performing a Test

Insertion of the test strip

- 1) After pressing the power button to turn on the meter, the test strip icon on the display flashes. (This step can also be skipped by inserting the test strip in the power off state)



- 2) After taking a test strip out, please close the test strip container immediately to avoid moisture exposure.
- 3) Insert the test strip logo side up into the test strip slot and push the test strip all the way in.



Caution

- When inserting the test strip, keep your hands away from the bottom edge of the test strip (sample inlet) to avoid contamination.
- 4) When the test strip is inserted into place, the screen will display the pre-stored calibration code. The blood drop icon on the screen flashes to indicate that the meter is ready for testing.



eGFR setting

Before the loading the blood sample onto the creatinine test strip, and when the eGFR setting is “On”, there are two methods to set the eGFR.

- a) Automatic eGFR setup: Insert the creatinine test strip while keeping the creatinine code chip inserted, and it will automatically enter the eGFR setup interface. After eGFR setup, the blood drop icon on the screen flashes to indicate that the meter is ready for sample loading.



b) Manual eGFR setup: Insert the creatinine test strip while code chip is removed from the meter, and press the power button to setup eGFR manually. If the eGFR has been set and no updating is required, please skip this step. After setup, the blood drop icon on the screen flashes to indicate that the meter is ready for sample loading.

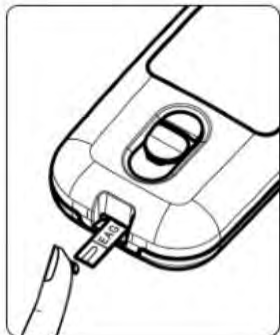


Collection of blood samples

- 1) Blood samples are obtained using a blood pen or blood collection device.



- 2) Rub your fingertip gently to obtain a small drop of blood. Bring in contact the droplet and the sample inlet (located on the lower edge of the test strip) to draw the sample in. Make sure the blood sample fills the test strip fully.



Caution

- When fresh capillary whole blood from the fingertip is used, the first drop of blood should be wiped away and a second whole blood sample should be used for testing.
- The test should be performed immediately after blood collection. If too much blood is squeezed out and contaminates the test strip or too little blood is collected and does not fill the sample zone, take a new test strip and perform the test again.

Reading the results

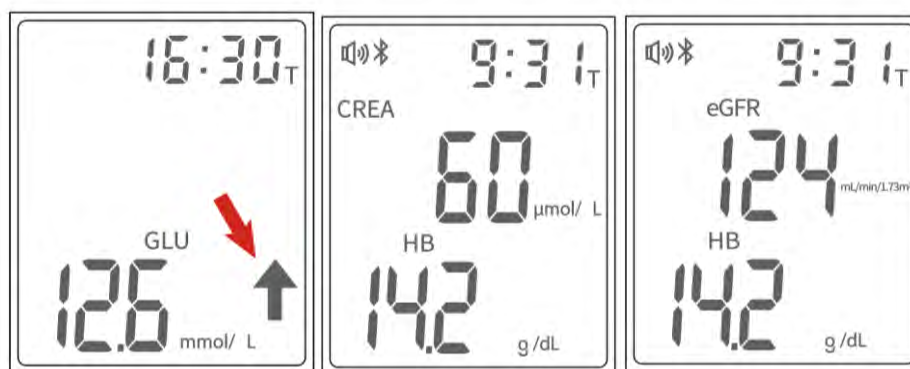
- 1) Once the blood sample fills the sample zone, the meter will automatically begin testing and display a countdown timer.



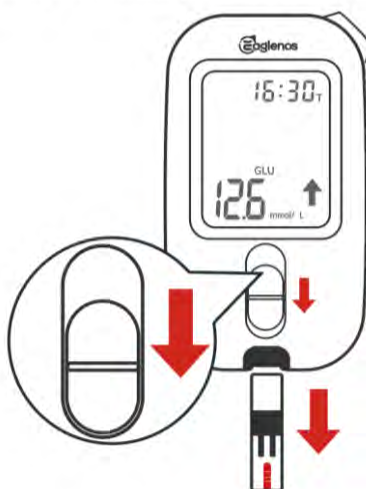
Caution

- Test strips must not be removed from the meter during testing.
- If the meter does not start the test after completing the sample aspiration, restart the test with a new test strip.

- 2) After the countdown is complete, the meter will display the test results. If the user has set a high/low threshold alert, an arrow will appear when the test result exceeds the threshold. If the eGFR is set “On”, the creatinine test results are displayed alternately with the eGFR calculation results after the creatinine test. Glucose test results are shown in mmol/L. Creatinine test results are shown in $\mu\text{mol/L}$. Hemoglobin results are shown in g/dL. eGFR results are shown in mL/min/1.73m^2 .



- 3) Toggle the eject button and the test strip will be automatically ejected.



Blood Glucose, Uric Acid or Creatinine Test Results



Caution

- If the blood sample used for the test is not sufficient and does not fill the feed zone, the results may be affected. It is recommended that a new piece of test strip should be used for testing.

- When poor peripheral circulation and insufficient bleeding affect the test results, the test should be performed by a professional at a medical facility.
 - Possible reasons for erroneous test results are: expired test strip, improper storage of test strips (such as moisture) or failure to test at specified temperature and humidity.
 - When the test results do not match your self-estimated concentration or the results are outside the normal range, it is recommended to retest with a new test strip. If the results are still abnormal, it is recommended to seek professional support from a healthcare provider. Do not adjust your medication based on the results of the Eaglenos test strips until you have consulted your doctor or healthcare professional.
- ◆ Glucose Reference Ranges
- Due to regional variations in population distribution and climate, the reference intervals for blood glucose test strips differ. To ensure the accuracy of clinical test reports, it is recommended that clinical laboratories establish their own reference intervals for blood glucose test strips. This should be done based on relevant literature and combined with clinical data.

Interpretation of Blood Glucose Test Results

- The meter displays results between 0.6 and 33.3 mmol/L. The meter screen displays "LO" when the results are below 0.6 mmol/L (10 mg/dL) and "HI" when above 33.3 mmol/L (600 mg/dL). In this case, re-test with a new test strip. If the problem persists, it is advisable to seek professional support from a healthcare provider.
 - Some known interfering substances may affect blood glucose measurements. Refer to the blood glucose test strips instructions for details.
- ◆ Uric Acid Reference Range
- Uric acid levels may be elevated during fasting, strenuous exercise, having gout, or sickness.
 - Each laboratory should experimentally determine the applicability of reference intervals and, if necessary, establish specific reference intervals for their own use.

Interpretation of Uric Acid Test Results

- When the results are above 1188 $\mu\text{mol/L}$, the meter screen displays "HI" and when below 181 $\mu\text{mol/L}$, the meter screen displays "LO". In this case, re-test with a new test strip. If the problem persists, it is advisable to seek professional support from a healthcare provider.
 - It is known that some interfering substances may affect uric acid measurements when limits are exceeded. Refer to the uric acid test strips instructions for details.
- ◆ Creatinine Reference Range
- Each laboratory should experimentally determine the applicability of reference intervals and, if necessary, establish specific reference intervals for their own use.

Interpretation of Creatinine Test Results

- When the results are above 1150 $\mu\text{mol/L}$, the meter screen displays "HI" and when below 25 $\mu\text{mol/L}$, the meter screen displays "LO". In this case, re-test with a new test strip. If the problem persists, it is advisable to seek professional support from a healthcare provider.
- Some known interfering substances may affect creatinine measurements. Refer to the creatinine test strips instructions for details.

5 Viewing Records

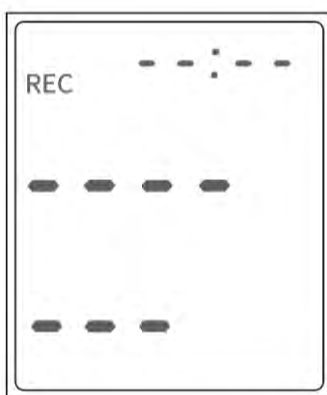
View Previous Test Results

The meter stores the last 800 test results and the last 20 QC results. Assays are stored in the order from the most recent to oldest, therefore the meter's time and date should be set correctly.

- 1) Short press the power button to enter the history view page when the device is powered on. The screen will display the most recent test records. The upper right corner alternately displays the date and time of that test.



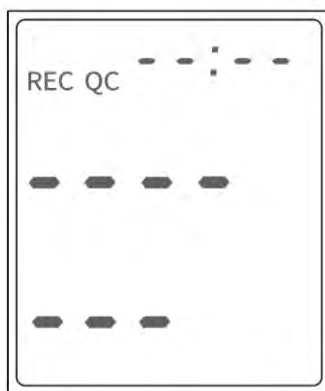
- 2) Press the up/down button to scroll through the records, and "----" is displayed when scrolling to the bottom.



- 3) Short press the power button again to switch to QC records.



- 4) Press the up/down key to scroll through the QC records, and "----" is displayed when scrolling to the bottom.



Caution

- The meter does not store error data when an error occurs.

6 Quality Control Testing (QC)

A QC test using Eaglenos control solution can help determine if the meter and test strips are working adequately.

Situations Requiring Quality Control Testing

Typically, QC testing is recommended in the following situations:

- 1) Test strips with new lot number
- 2) Replacement of meter's batteries
- 3) The meter and test strips may not be in optimal conditions (impact, drop, high temperature, low temperature, humidity, etc.).



Warnings

- ✓ The meter can only be used with the matching blood glucose/uric acid/creatinine control solutions provided by EAGLENOS SCIENCES, INC.
- ✓ Do not use expired QC solutions.
- ✓ Do not add water or other liquids to the QC solutions.
- ✓ For storage conditions of the QC solutions, please refer to the instructions inside the QC solutions package.
- ✓ QC results should be within the range of QC solutions indicated on the instructions.
- ✓ QC results do not reflect your blood glucose/uric acid/creatinine levels.

- ✓ If spillage of QC fluid occurs, wipe and rinse off promptly.
- ✓ Make sure the meter, test strips, and QC solutions return to room temperature before testing.

Quality Control (QC)

- 1) After powering on the device, press and hold the down button to enter QC mode.
"QC" is displayed at the top of the screen.



Caution

- You need to make sure that the meter has been inserted with the corresponding code chip before performing the QC test.
- 2) After taking a test strip out, please close the test strip container immediately to avoid moisture exposure.
 - 3) Once the test strip is inserted into place, the screen will display the pre-stored calibration code in the meter. The blood drop icon on the screen blinks to indicate that a drop of QC fluid can now be aspirated.



- 4) Shake the bottle to mix the QC solution. After discarding the first drop of the QC solution, wipe the dropper tip. Bring the QC solution and the inlet port on the lower edge of the test strip in contact and the QC solution will be automatically drawn in. Be sure to fill the test strip collection area with the QC solution.



Caution

- Please perform at least 2 levels of QC solution testing.
- 5) When the QC solution fill the sampling zone, the meter will automatically start detection and display a countdown timer.



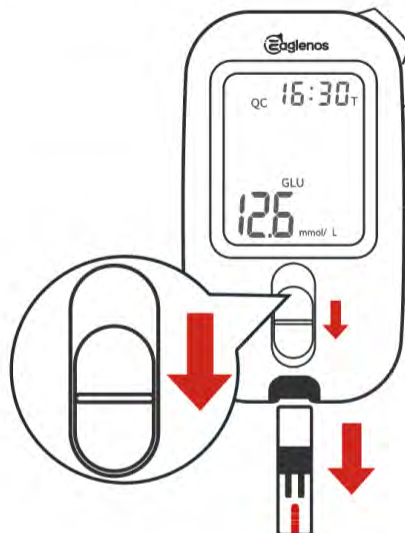
Caution

- Test strips must not be removed from the meter during testing.
- If the meter does not start the test after completing the sampling, restart the test with a new test strip.

- 6) When the countdown is complete, the meter will display the QC results.



- 7) Compare the QC results with the reference ranges on the QC solution instructions.
The results should be within the range.
- 8) Toggle the eject button and the test strip will be automatically ejected.



Caution

- If the QC results are not within the reference range, it indicates that the meter system is unstable. Please redo the QC again with a new test strip immediately.
- If the results are consistently out of the target value range, stop the test and contact your distributor or Eaglenos after-sales service.

7 Connection to Applications

Operating Environment

- 1) Hardware minimum configuration: IOS A9 processor with 2G RAM or Android 6 core with 4G RAM.
- 2) Software environment: Android 10 and its compatible versions, IOS 14 and its compatible versions.
- 3) Network environment: None.

Application Installation and Adding Devices

- 4) Download and install the software application from the mobile device with internet connection.

- 5) Open the application, click the option to connect Handheld Electrochemical Meter.
- 6) Follow the operating prompts to complete the wireless connection.

Application Setting

In the app running on the mobile device, users can set alerts on/off and calculate eGFR by inputting or selecting the parameters in the equation.

8 Storage Conditions

- 1) When the meter is not used for a long time, please remove the batteries to prevent the meter from being damaged by battery leakage.
- 2) The product should be stored in a dry, cool, non-corrosive gas and well-ventilated place.
- 3) Transportation and Storage:
Storage temperature: -20°C - 55°C
Storage relative humidity: 10% to 93% (non-condensing)
- 4) Do not drop or disassemble the meter.

9 Cleaning, Maintenance and Repair

Cleaning

Make sure the meter is not dusty. If you need to clean or sanitize the meter, follow these guidelines:

- 1) Make sure the meter is turned off.
- 2) Gently wipe the surface of the meter with a soft cloth moistened with 75% alcohol.
Do not use bleach or strong detergents.

Maintenance

- When the meter is not used for a long time, please remove the batteries to prevent the meter from being damaged by battery leakage.
- Do not allow liquids to enter the sockets of the meter.

- Do not spray cleaning solutions directly onto the meter.
- Keep your hands and the blood collection site clean and dry for handling.
- Only Eaglenos or Eaglenos authorized agents may inspect or supply any parts (excluding batteries).

10 Troubleshooting

Error Messages

This chapter describes common problems with the meter, and the user can refer to the following solutions when a problem occurs:

Error Number	Issue	Solution
E01	Damaged test strip or sample aspiration before starting the test	• Verify that the ambient temperature around the meter is within the meter's nominal ambient operating range • Retest with new test strips
E02	Abnormal ambient temperature	• Make sure that the ambient temperature of the meter is within the nominal detection range of the test strips, and make sure that the test strip slots of the meter are not blocked by foreign objects • Wait for meter and test strips to return to normal operating temperature • Repeat the test with new test strips
E03	Insufficient blood or quality control solution for test strip aspiration	• Retest with new test strips
E04	Wrong Code Chip	• Please insert the correct code chip
E05	Electronic error.	• Verify that the ambient temperature around the meter is within the meter's nominal ambient operating range • Turn off the meter • Retest with new test strips
E06	Low battery	• Battery replacement
E07	Poor contact or pulling out the test strip during testing	• Turn off the meter and retest with new test strips

If you are unable to solve the above problems by yourself, we recommend you to consult Eaglenos customer service for technical support.

Troubleshooting

Problem	Possible causes	Solution
Short press the power button, cannot power on or no display	Batteries not inserted or batteries not inserted correctly	See the "Battery Installation" section for instructions on how to properly install the battery
	Battery completely drained	Battery replacement
	Extreme ambient temperature	Move the meter to a suitable temperature environment
The test strip has been inserted into the test strip slot, but the meters screen does not show the status of the inserted test strip.	Test strip is not inserted correctly or completely into the meter	Replace the test strip with a new one, make sure the label is facing up, insert it in place and retest
	Batteries not inserted or batteries not inserted correctly	See the "Battery Installation" section for instructions on how to properly install the batteries
	Batteries completely drained	Battery replacement
	Meter may be connected to a computer	Disconnect the meter from the computer
	Problems with meter or test strips	Please take a new test strip for testing
Test not started after blood sample or QC solution aspiration	Blood sample volume or QC solution volume too low	- Check the section on "Conducting the Test" for information on how to test correctly - Please take a new test strip for testing
	Aspirating samples after the meter is turned off	- Check the section on "Conducting the Test" for information on how to test correctly - Please take a new test strip for testing
	Problems with meters or test strips	Please take a new test strip for testing
If you are unable to solve the above problems by yourself, we recommend you to consult Eaglenos's customer service for technical support.		

11 Technical Information

Specifications

Unit of measurement	Blood glucose mmol/L; uric acid $\mu\text{mol/L}$, creatinine $\mu\text{mol/L}$
Sample type	Fresh capillary whole blood from fingertips, venous whole blood
Detection time	Blood glucose: 5 seconds; uric acid: 10 seconds; creatinine: 30 seconds
Memory capacity	MG14, MC12 and M425 can store 500 tests and 20 QC tests. MG15, MC13, M422 can store up to 800 tests and 20 QC tests. M426 can store up to 600 tests and 20 QC tests.
Automatic shutdown	In 2 minutes
Power supply	--- 3V, 10mA
Dimension	107mm $\times$ 54mm $\times$ 23mm ($\pm 5\text{mm}$)
Weight	100 $\pm$ 15 g (including batteries)
Usage lifetime	5 years
Operating condition	Blood glucose: 10°C to 40°C Uric acid: 15°C to 35°C Creatinine: 15°C to 40°C Operating relative humidity: 10% to 85% (non-condensing) Atmospheric pressure: 68 kPa to 106.6 kPa
Storage/transportation conditions	Storage temperature: -20°C - 55°C Storage relative humidity: 10% to 93% (non-condensing)
Electromagnetic interference	No electromagnetic interference with other devices has been observed with this product and it complies with current domestic standards for electromagnetic emissions.
Storage conditions for test strips and quality control solutions	See instructions inside the package of test strips and QC solutions

Test Principle

The meter's test principle is electrochemical. During the test, fingertip blood (or venous whole blood) is collected by medical personnel with a matching blood collection device, and the blood sample is aspirated via the sample inlet located at the edge of the test strip. When the blood sample reaches the detection area through the siphon principle, the specific analyte in the blood reacts with the reagents on the electrodes, generating an electric current measured by the

electrodes. The meter determines the type of analyte according to the code of the test strip, and calculates the concentration of blood glucose, uric acid and creatinine in the blood sample by measuring the reaction current, ambient temperature, sample impedance and other parameters.

Limitations of use

Please read the instructions accompanying the test strips and QC solutions for information related to product specifications and limitations.

Network Security Statement

➤ Data Interface - Bluetooth

Adopts standard Bluetooth protocol

Purpose: data transfer

➤ User Access Control

Users are able to transfer data via Bluetooth using an authorized device.

➤ Requirements related to updating the software environment

In principle, no updates are necessary. However, if there's a need for a new version of the system software to address an existing issue, Eaglenos will assess the potential impact of these changes on the meter. Based on this evaluation, a decision will be made regarding whether to proceed with the update.

12 Symbols

The following graphics, symbols, and abbreviations may appear on product packaging, labels, displays, and instruction manuals, and their meanings are explained in the table below:

Symbol	Description
	Consult instructions for use
	Biohazard
	In Vitro Diagnostic Medical Device
	Serial number

	Manufacturer
	Date of manufacture
	Caution
	Warnings
	Keep dry
	This way up
	Stacking Layer Limit
	Fragile, handle with care

13 After-sales and Warranty

If you have a problem with your Handheld Electrochemical Meter, do not repair or adjust the meter yourself. EAGLENOS SCIENCES, INC. provides you with a warranty card when you purchase this product. Please read it carefully and fill it out completely.

14 EMC Information

The handheld electrochemical meter meets the requirement of electromagnetic compatibility in IEC 60601-1-2 and IEC 60601-4-2 and shall maintain basic safety and essential performance with respect to EMC.



Caution

- Use of the meter in dry environments, especially dry environments such as man-made materials (man-made fabrics, carpets), may cause damaging electrostatic discharges, leading to erroneous conclusions.
- It is prohibited to use the meter next to a source of strong radiation, as this may interfere with the normal operation of the equipment.

- It is the user's responsibility to ensure an EMC environment in which the meter can operate properly. It is recommended that the electromagnetic environment be evaluated before the equipment is used.

Guidance and manufacturer's declaration -Electromagnetic emissions		
Emissions test	Compliance	Electromagnetic Environment--Guideline
Radiated Emissions	Class B, Group 1	This meter uses RF energy only for its internal functions. Therefore, its RF radiation is very low and is unlikely to cause any interference with nearby electronic equipment.

Guidance and manufacturer's declaration-Electromagnetic immunity		
Immunity Test	Basic EMC standard or test method	Immunity Test Levels
Electrostatic discharges (ESD)	IEC 60601-4-2	±8 Kv Contact ±2, ±4, ±8, ±15 Kv Air
Radiated RF electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz-2,7 GHz; 80% AM at 1 kHz;
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Table 9 of 4th ed./61000-4-3
Rated power frequency magnetic field	IEC 61000-4-8	30 A/m 50Hz or 60Hz
Proximity magnetic fields	IEC61000-4-39	Frequencies 30 kHz, 8A/m, CW Modulation Frequencies 134, 2 kHz, 65A/m, Pulse modulation 2,1 kHz Frequencies 13, 56 MH, 7.5A/m, Pulse modulation 50 kHz

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's 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.