

Handheld Electrochemical Meter
User Manual

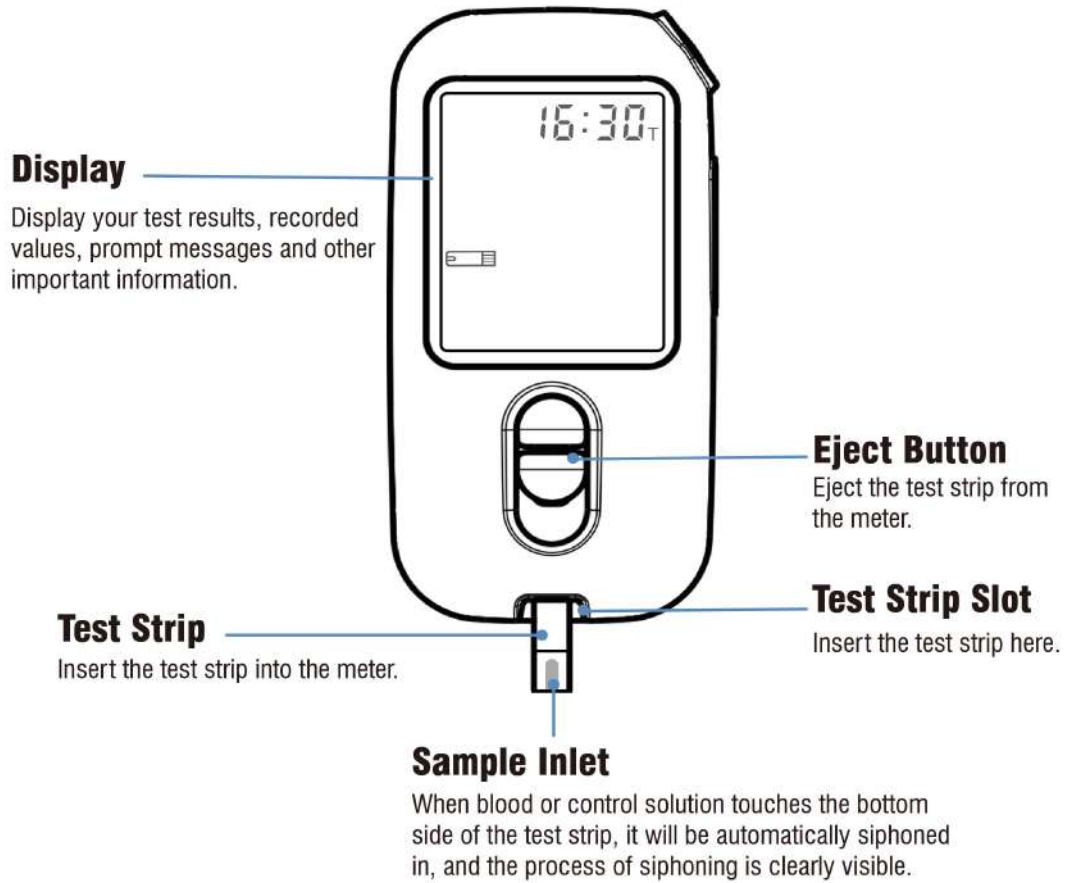
Important Notes:

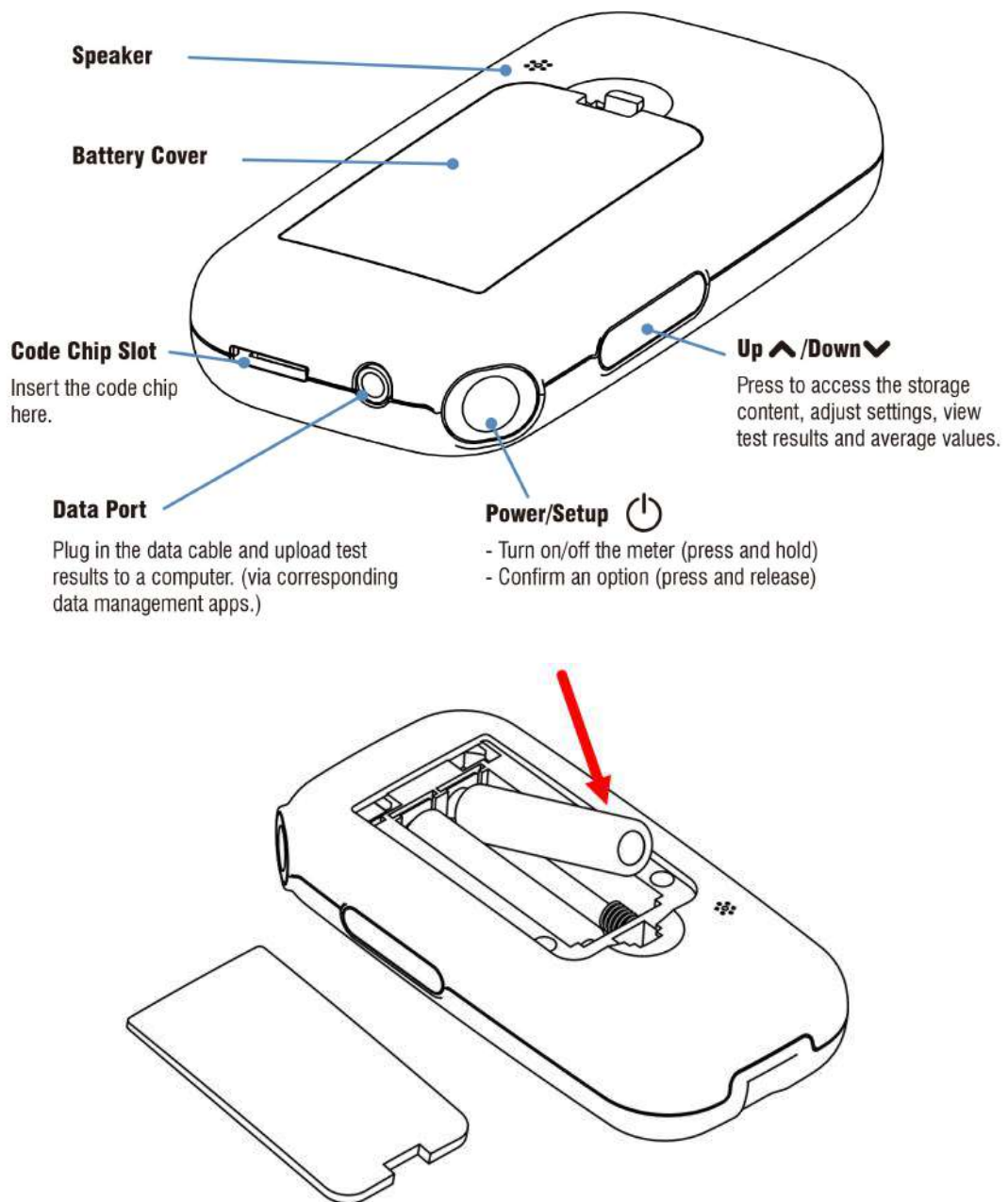
Refer to Eaglenos Creatinine Test Strips package insert for detailed information before testing. This product is an in vitro diagnostic device and is intended for prescription use only.

TABLE OF CONTENTS

1. OPERATION OVERVIEW	1
2. METER SYMBOLS	3
3. QUICK START - TESTING YOUR BLOOD CREATININE	4
4 INTENDED USE	5
5 GETTING TO KNOW THE METER.....	6
6 SETTING UP THE METER	7
7 CODE CHIP CALIBRATION	12
8. PERFORMING A BLOOD CREATININE TEST	14
9. UNDERSTANDING THE TEST RESULT	18
10 VIEWING TEST RECORDS	24
11 TAKING CARE OF YOUR METER.....	26
12 QUALITY CONTROL (QC) TESTING	28
13 CLEANING AND DISINFECTING YOUR METER	32
14 ERROR MESSAGES	33
15 TRANSFERRING METER DATA TO APPLICATIONS	34
16 TROUBLESHOOTING	36
17 METER SPECIFICATION	37
18 SYMBOLS	38
19 APPENDIX	39

1. Operation Overview

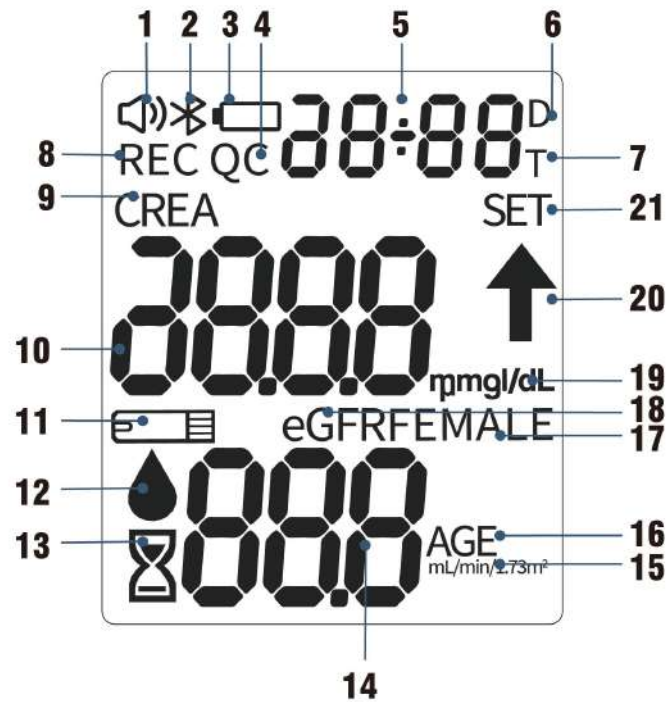




This product uses two AAA alkaline batteries.

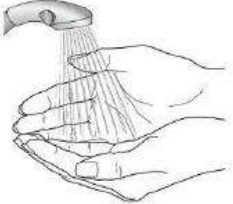
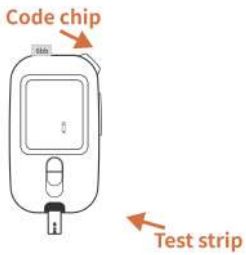
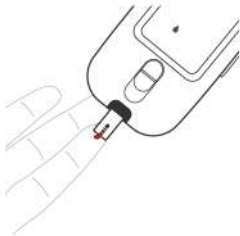
2. Meter Symbols

Full Screen Display:



Number	Symbol	What It Means	Number	Symbol	What It Means
1		Beep: audible alert	12		Ready to load blood sample when flashing
2		Bluetooth	13		Testing in progress when flashing
3		Flashing battery indicating low battery	14		Display eGFR values / age
4	QC	Quality control	15	mL/min/1.73m^2	eGFR unit: mL/min/1.73m^2
5	28:88	Display Time and Date	16	AGE	Age
6	D	DATE-appears when the value is months and dates	17	FEMALE	Gender: MAIL or FEMAIL
7	T	TIME-appears when the value is hours and minutes	18	eGFR	eGFR
8	REC	Stored results	19	$\mu\text{mol/L}$ or mg/dL	Unit: $\mu\text{mol/L}$ or mg/dL
9	CREA	Blood creatinine	20		High threshold reminder for blood creatinine test values
10	2888	Display blood creatinine test values / year / calibration code	21	SET	Setting
11		Ready to insert the test strip when flashing			

3. Quick Start – Testing Your Blood Creatinine

	1. Wash and dry hands before testing. Note: Check test strip expiry date.
	2. Insert the code chip and the test strip. Note: The code chip is only required when using a new box of test strips.
	3. Puncture the test site and load the blood sample.
	4. View result

4 Intended Use

The proposed creatinine monitoring system contains the creatinine meter and creatinine test strips. The system is used by laypersons with kidney disease for in vitro quantitative measurement of creatinine concentrations in the finger capillary fresh whole blood at home. Creatinine and estimated GFR are intended to be used in patients with non-dialysis-dependent kidney disease to monitor kidney function while receiving kidney disease therapy and to assess for the need of dialysis initiation or other renal replacement therapy.

Caution

- Follow the instructions in this manual for how and where to properly use this device.
Improper use may lead to incorrect test results.
- Read the user manuals carefully.
- The meter is for single patient use only and should not be shared.
- During blood creatinine testing, the meter itself may come into contact with blood.
Therefore, there is a risk of pathogens being carried by the meter.
- If a health- or life-threatening accident occurs while using the product, immediately call the emergency services and seek help from a healthcare professional.
- There are no contraindications.
- Not for neonatal use.
- Do not use accessories that are not supplied or recommended by the manufacturer.
- If the meter is damaged or constantly triggers malfunction alarms, do not use it. Contact customer service.
- 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 let any debris enter the various sockets of the meter.
- Do not place any objects on top of the meter.

5 Getting to Know the Meter

Turning the Meter On and Off

To turn the meter on:

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

Method 2: Insert the test strip to power on the meter directly.

To turn the meter off:

Method 1: Short press the  power button to enter the view history page. Then press and hold the  power button to turn off the meter.

Method 2: Leave the meter idle for 2 minutes.

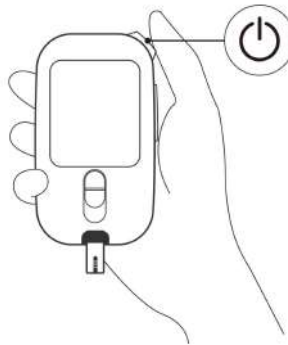
Note:

Pressing and holding the  power button during startup to enter the setup mode. To turn off the meter, press and hold the  power button again until it turns off.

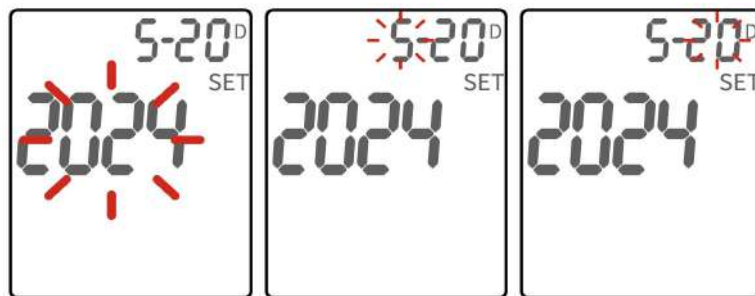
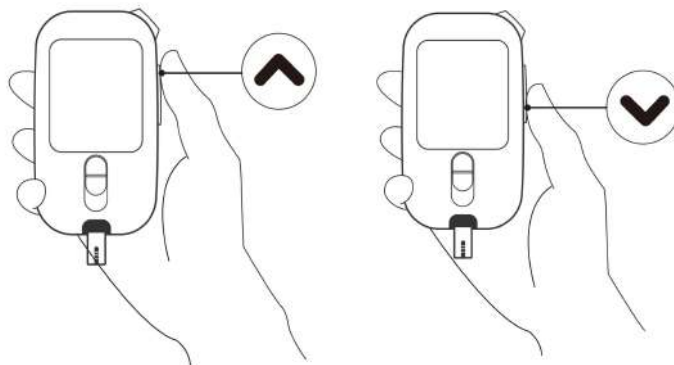
6 Setting Up the Meter

Set Date

- 1) Press and hold the  power button for about 3 seconds on the Home screen until the **SET** symbol appears on the screen.



- 2) Short press the  or  button to set the year, month and day. Press the  power button briefly to confirm.

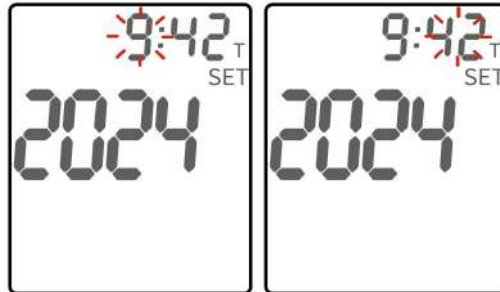


Year (first from left), month (second from left), day (third from left)

Set Time

- 3) Short press the  or  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)

Set Prompt Tone

- 4) Short press the  or  button to toggle On/Off. Press the  power button briefly to confirm.

Note:

- Skip this step if you accept the default setting as “On”, and press the  power button briefly to confirm.
- To exit setup, press and hold the  power button until the meter turns off.



Set Bluetooth On/Off

- 5) Short press the  or  button to toggle On/Off. Short press the  power button to confirm.

Note:

- Skip this step if you accept the default setting as “On”, and press the  power button briefly to confirm.
- To exit setup, press and hold the  power button until the meter turns off.

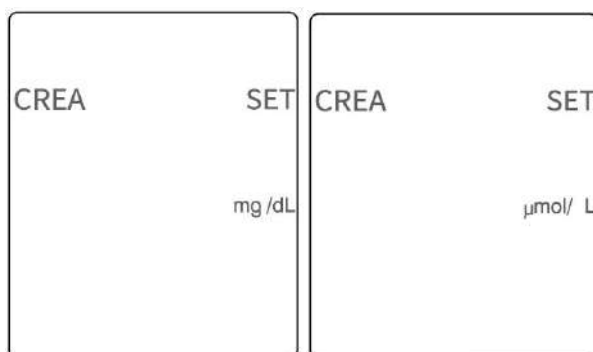


Change Result Units

- 6) Press the  or  button to switch the unit between $\mu\text{mol/L}$ and mg/dL .

Note:

- Skip this step if you accept the default setting as “mg/dL”, and press the  power button briefly to confirm.
- To exit setup, press and hold the  power button until the meter turns off.



Set the High Threshold Reminder

- 7) Short press the  or  button to toggle On/Off. Short press the  power button to confirm.



Note:

- Skip this step if you accept the default setting as “OFF”, and press the  power button briefly to confirm.
- To select “On”, consult the Understanding the Test Result section in this User Manual.
- To exit setup, press and hold the  power button until the meter turns off.

Set eGFR

- 8) Short press the  or  button to toggle “On/Off”. Short press the  power button to confirm.



Note:

- Skip this step if you accept the default setting as “OFF”, and press the  power button briefly to confirm.
- To select “On”, consult the Understanding the Test Result section in this User Manual.
- To exit setup, press and hold the  power button until the meter turns off.

Exit the setup

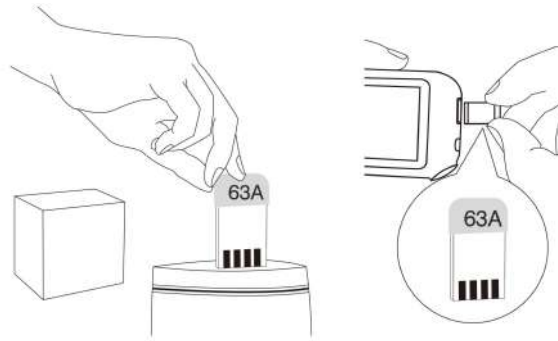
9) Exit the setup

- Finish all previous steps, and the meter will return to the Home screen automatically.
- Press and hold the  power button until the meter turns off at any setup step.

7 Code Chip Calibration

Each box of creatinine test strips contains a code chip. Replace the old code chip and insert the new one when opening a new box of test strips.

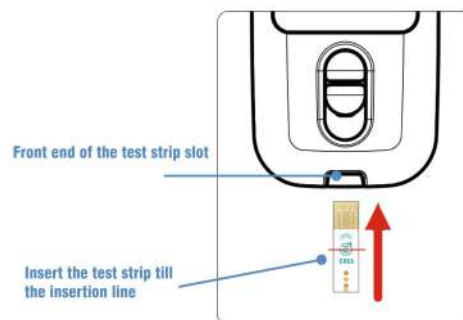
- 1) Take out the new code chip from the test strip box and insert it into the meter.



Caution

- Using a code chip from a different box of test strips will result in incorrect test results.
- If a new code chip is not inserted before testing, the meter will display the previous code.
- An E04 error message will appear when you use the meter for the first time without inserting the code chip.
- An E04 error message will appear when the inserted code chip does not match the test strip.

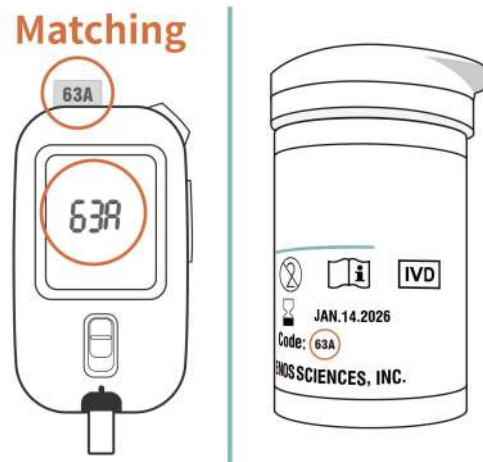
- 2) Insert the test strip and push it in fully until it stops.



- 3) The meter will automatically power on and display the calibration code.



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



8. Performing a Blood Creatinine Test



- Before testing, carefully read the user instructions of the corresponding test strips.
- Do not use non-matching, damaged or contaminated test strips.
- Do not reuse test strips.
- Make sure the meter, test strips, and QC solution are at room temperature before testing.

Preparing for a test

- 1) Prepare an appropriate blood collection device.
- 2) Select the site for blood sampling.
- 3) Wash your hands with soap, or use alcohol pads for cleaning. Then dry thoroughly



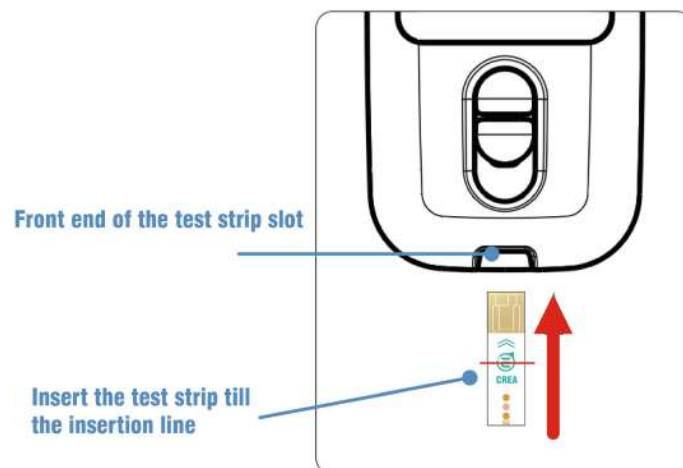
- Follow the user manual of the blood collection device for proper use and disposal.
- Do not use lotions or creams on the sampled area.

Performing a Test

- 1) **To turn on the meter**, press the  power button, or insert the test strip in the power off state.



- 2) **Insert the test strip** logo side up into the test strip slot and push the test strip in fully until it stops. A blinking blood drop icon on the screen indicates that the meter is ready for testing.

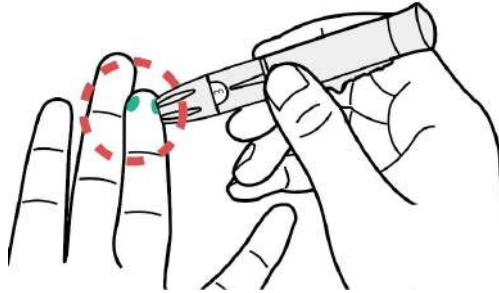


Caution

- Make sure the test strips are within the use-by date. Using expired test strips may lead to inaccurate results.

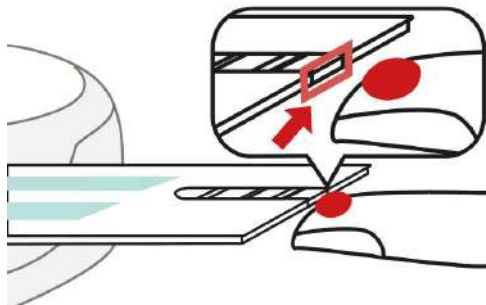
- Close the container of the test strip immediately after taking out a test strip.

3) **Obtain a blood sample** using the blood collection device. Please follow its instructions carefully.



4) **Load blood to the test strip**

Gently rub your fingertip to form a small drop of blood. Touch the droplet to the sample inlet (at the lower edge of the test strip) to draw the sample in. Make sure the blood sample fills the test strip completely.



 Caution

- Ensure the blood sample is drawn into the sampling area in a single attempt, not multiple times.
- Do not add samples other than blood (e.g., urine) to the test strip.
- Wipe away the first drop of blood and use the second drop for testing when using the blood from the fingertip.
- Perform the test immediately after blood collection.
- Do not touch or pull out the test strip until the results are displayed.

5) **View the result**

After the countdown, the meter will display the test result. The result is automatically stored in the meter's memory.



 Caution

- Do not remove test strips from the meter during testing.
- Repeat a new test when the meter does not start the test after loading blood sample.
- The meter does not store error data when an error message appears.

6) Eject the test strip

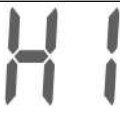
Toggle the eject button to eject the test strip. Dispose of the used test strip properly according to local regulations.



9. Understanding the Test Result

The meter displays blood creatinine results in mg/dL. This is a preset unit. You can change it into $\mu\text{mol/L}$.

The meter only displays results between 0.28 to 13.00 mg/dL (25 to 1150 $\mu\text{mol/L}$)

Alerts	What It Means	What To Do
 Appears when result is lower than 0.28 mg/dL (25 $\mu\text{mol/L}$)	Severe low creatinine or problems with the test system.	Repeat the test with a new test strip. If the result is LO, contact your healthcare professional immediately
 Appears when result is higher than 13.00 mg/dL (1150 $\mu\text{mol/L}$)	Severe high creatinine or problems with the test system.	Repeat the test with a new test strip. If the result is HI, contact your healthcare professional immediately



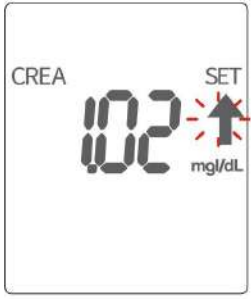
Warnings

- Contact your healthcare professional if your symptoms do not match the test result.
- If the test result does not match your estimation or is outside the normal range, retest with a new test strip. If the results are still abnormal, consult healthcare professionals.
- Do not change your medication based on the test results. You should always consult healthcare professionals.
- If the blood sample is too little to fill in the reaction zone, the results may be inaccurate. Repeat the test with a new test strip.

High Blood Creatinine Results

" " appears when the result exceeds the set threshold. To use this feature, the threshold reminder should be set to "On" (refer to the *Setup* section of this manual).

Alerts	What It Means	What To Do
--------	---------------	------------

	Appears when the result is higher than the set threshold.	Follow your healthcare professional's advice to treat high blood creatinine.
---	--	---

Adjust the Threshold Reminder

To adjust the threshold reminder, please follow the steps below.



Warnings

- The threshold level of creatinine may vary from person to person. Consult a healthcare professional before setting the value. The threshold reminder function is not a substitute for a healthcare professional's diagnosis.

- In the setup mode, press the  power button briefly until the " " icon appears and blinks.

Note:

- To enter the setup mode, refer to the Setting up the Meter section in this User Manual.



- Short press the  or  button to toggle "On/Off". Short press the  power button to confirm.
- Short press the  or  button to set the High Blood Creatinine Threshold Reminder. You can set range between 0.3 to 13.00 mg/dL (25 to 1150 μ mol/L)



Understanding eGFR

Estimated glomerular filtration rate (eGFR) is converted based on the creatinine test result.

The eGFR result can be displayed together with the creatinine test result. To use this feature, the eGFR option should be set “On” (refer to the *Setup* section of this manual).



Warnings

- You should **not** assume you have chronic kidney disease (CKD) unless it is confirmed by a physician.

Set up eGFR

- 1) In the setup mode, short press the  power button briefly until entering the eGFR setup screen.



Note:

- To enter the setup mode, refer to the Setting up the Meter section in this User Manual.
- 2) Short press the  or  button to toggle “On/Off.” Short press the  power button to confirm.



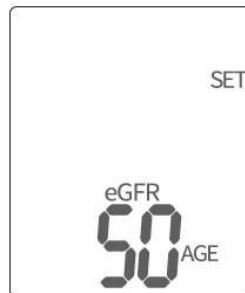
- 3) Short press the  power button to confirm the 2021 CKD-EPI Equation.



- 4) Short press the  or  button to set gender. You can choose MALE or FEMALE. Short press the  power button to confirm.



- 5) Short press the  or  button to set age with the selectable range from 1 to 99. Short press the  power button to confirm.



Warnings

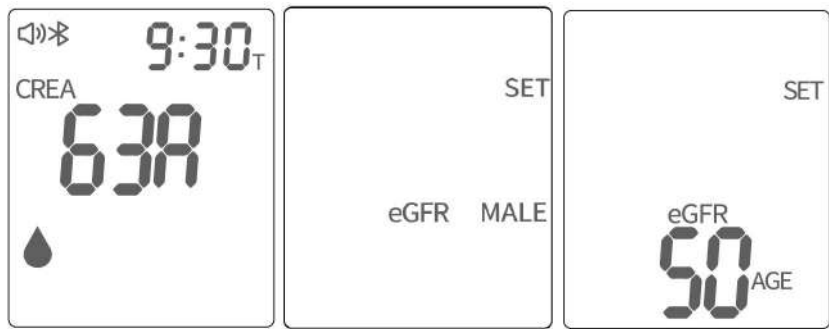
- Make sure the correct gender and age are entered during setup, as they are essential for accurate test results.

Alternative way to enter eGFR setup screen.

Before loading the blood sample, press the  power button to enter eGFR setup screen, provided the eGFR is set to “On” in the setup menu. From there, you can revise Gender and Age. Then the meter returns to Loading the blood sample screen automatically.

Note:

If the eGFR is set to “Off” in the setup menu, this option will not be available.



10 Viewing Test Records

The meter stores the last 800 or 500 test results and the last 20 quality control (QC) results.

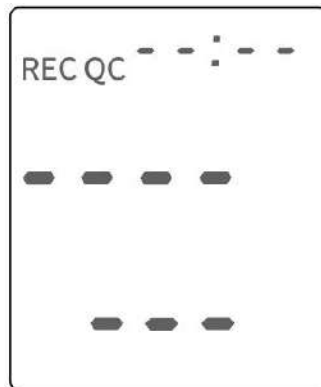
- 1) Short press the  power button to enter the view history page from the Home screen.
- 2) Press the  or  button to scroll through the records. "----" will appear when scrolling to the end.



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



- 4) Press the  or  button to scroll through the QC records. "----" will appear when scrolling to the end.

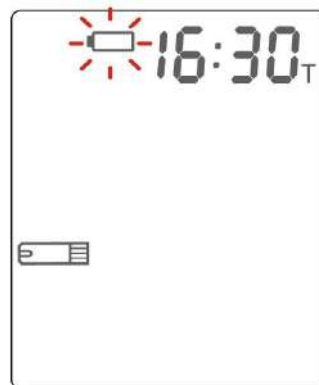


- 5) To exit, press and hold the  power button for 3 seconds to turn off the meter.

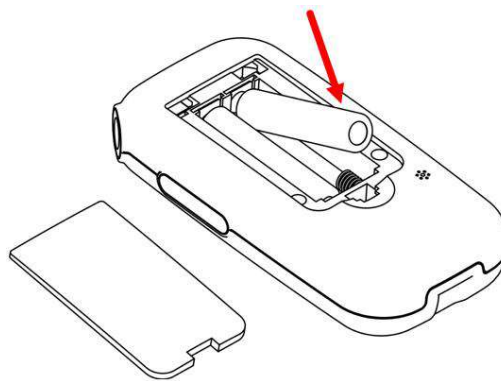
11 Taking Care of Your Meter

Battery Replacement

A blinking  indicates that the batteries are low, and should be replaced as soon as possible. An **E06** error message appears when the batteries are extremely low, and need to be replaced immediately.



- 1) Open the battery cover and replace the batteries. Install the battery correctly according to the positive (+) and negative (-) markings.



- 2) Close the battery cover until the clasp snaps securely into place. The "Set" message will appear on the screen.



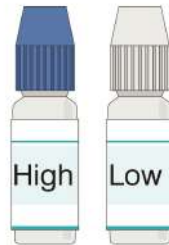
- 3) Reset the meter. See “Setting up the Meter” section in this user manual.
- 4) Dispose of the old batteries in accordance with local environmental regulations.

 Caution

- Do not remove the battery while the meter is connected to other devices, as this will affect data storage.
- If the meter will not be used for a long time, remove the batteries to prevent damage from potential leakage.

12 Quality Control (QC) Testing

A quality control (QC) test should be performed to confirm that the meter and test strips are working properly.



Note:

- Contact customer service for information on how to obtain control solutions.
- It is recommend to perform the QC test with 2 levels of QC solutions.



Warnings

- Only use the

s produced by EAGLENOS.
- Do not use expired QC solutions.
- Do not add water or other liquids to the QC solutions.
- Refer to the product instructions for the proper storage conditions of the QC solutions.
- QC results should be within the range indicated on the QC solution packaging.
- QC results do not reflect your blood creatinine levels.
- Be sure to insert the correct code chip before performing the test.
- In case of spillage, wipe and rinse off promptly.
- Make sure the meter, test strips, and QC solution are at room temperature before testing.

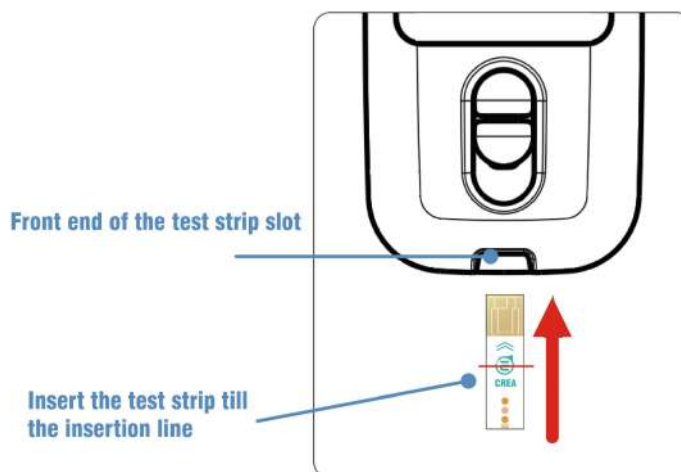
Performing a Quality Control Test

- 1) To enter QC mode, press and hold the  or  button from the Home screen.

"QC" is displayed at the top of the screen.



- 2) **Insert the test strip** into the test strip slot and push it in fully until it stops. The blinking blood drop icon on the screen indicates that the meter is ready for testing.



- 3) **Load Control solution to the test strip.**

Shake the bottle to mix the QC solution well. Gently squeeze the vial to release a drop. Discard the first drop. Squeeze another drop and touch it to the test strip sample inlet.

The meter will automatically start testing and display a countdown timer.



 Caution

- Be sure to fill the test strip sample loading area completely in one attempt with the QC solution.

4) **View the result.**

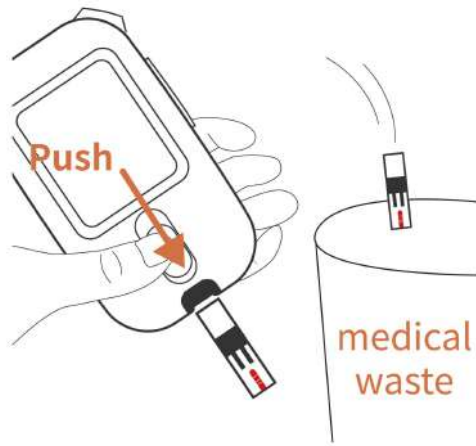
When the countdown is complete, the meter will display the QC results. Compare the QC results with the reference ranges on the QC solution packaging. The results should be within the range.



Out of Range QC Test Results:

- Repeat the test if QC test results are out of range.
- Stop using the meter if QC test results are consistently outside the range.
Contact customer service.

5) **Toggle the eject button to eject the test strip.** Dispose of the used test strip properly according to local regulations.



- 6) **Exit QC mode.** Press and hold the  or  button to exit QC mode.

13 Cleaning and Disinfecting Your Meter

Caution

- Do not clean or disinfect the meter while performing a blood or QC test.
- Do not spray liquid directly onto the meter.
- Do not immerse the meter in liquid.

Step	Action
1	Please read the instructions of Clorox® Germicidal Wipes (EPA Reg. No. 67619-12) before using it. Open the cap of the wipes container and pull out one towelette and close the cap.
2	Wipe the entire surface of the meter three times horizontally and three times vertically and carefully wipe around the test strip slot and other openings using one towelette to pre-clean blood and other body fluids. Dispose of the used towelette in a trash bin.
3	Pull out a new towelette. Wipe the meter's entire surface three times horizontally and vertically, then carefully clean around the test strip slot and other openings for disinfection.
4	Dispose of the used towelette in a trash bin.
5	Allow exteriors to remain wet for at least one minute to allow effective disinfection. For the meter, the cleaning and disinfection procedure should be performed once per week.
6	Allow the meter to air dry completely before performing a test.
7	When finished, thoroughly wash your hands with soap and water. For further assistance, contact customer service.

14 Error Messages

Error Message	What It Means	What To Do
E01	A damaged test strip OR sample aspiration before the system is ready	• Make sure meter's ambient temperature is within the specified operating range. • Retest with new test strips. • Confirm the test strips are supported by the meter.
E02	Abnormal ambient temperature	• Make sure that the ambient temperature around the meter is within the specified operating range. • Make sure that the test strip slot of the meter is not blocked by foreign objects. • Wait for meter and test strips to return to specified operating temperature. • Repeat the test with new test strips.
E03	Insufficient blood aspiration OR insufficient quality control solution aspiration	• Retest with new test strips.
E04	Wrong Code Chip	• Please insert the correct code chip.
E05	Electronic error	• Make sure meter's ambient temperature is within the specified operating range. • Restart the meter. • Retest with new test strips.
E06	Low battery	• Battery replacement.
E07	Poor contact or pulling out the test strip during testing	• Restart the meter and retest with new test strips.

Note:

If you cannot solve the above problems, please contact customer service.

15 Transferring Meter Data to Applications

Application Installation and Adding Devices

- 1) Download and install the “Eaglenos Health” App on a mobile device with internet access.
- 2) Open the App, and select the option to connect Handheld Electrochemical Meter via Bluetooth.
- 3) Follow the operating prompts to complete the connection.

Application Setting

In the mobile App, you can

- Calculate eGFR by entering the required parameters.
- View or record test results.
- Generate electronic test records.

Operating Environment

➤ Hardware Minimum Requirements:

iOS: A9 processor with 2GB RAM

Android: 6-core processor with 4GB RAM

➤ Software Environment:

Android 10 and later compatible versions

iOS 14 and later compatible versions

➤ Network environment: None.

Network Security Statement

➤ Data Interface - Bluetooth

Adopts standard Bluetooth protocol

Purpose: data transfer

➤ User Access Control

Transfer data via Bluetooth using an authorized device.

➤ Updating the software environment

Update implementation will be determined by Eaglenos following impact evaluation.

16 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 "Installing the Battery" section for proper battery installation instructions.
	Battery completely drained	Battery replacement.
	Extreme ambient temperature	Move the meter to a suitable temperature environment.
The test strip is inserted, but the correct interface is not displayed.	Test strip is not inserted correctly 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 "Installing the Battery" section for proper battery installation instructions.
	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 did not initiate after blood sample/QC aspiration	Blood sample volume or QC solution volume too low	- Check the section on "Conducting Tests" 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 Tests" 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.

Note:

If you cannot solve the above problems, please contact customer service.

17 Meter Specification

Assay method	Amperometry
Unit of measurement	mg/dL or $\mu\text{mol/L}$
Sample type	Fresh capillary whole blood from fingertips
Measurement range	0.28 to 13.00 mg/dL (25 to 1150 $\mu\text{mol/L}$)
Detection time	30 seconds
Memory capacity	MC12: 500 tests and 20 QC tests. MC13: 800 tests and 20 QC tests.
Data Transmission	Bluetooth
Automatic shutoff	More than two minutes of inactivity
Power supply	 3 V, 10 mA; two AAA alkaline batteries
Dimension	107 mm $\times$ 54 mm $\times$ 23 mm (± 5 mm)
Weight	100 $\pm$ 15 g (including batteries)
Usage lifetime	5 years
Operating condition	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 - 55°C Storage relative humidity: 10 - 93% (non-condensing)

Note: Refer to the control solutions and test strips package insert.

Electromagnetic Compatibility (EMC): The electrostatic discharge immunity testing was conducted in accordance with the basic standard IEC 60601-4-2. Additionally, the meter meets the electromagnetic emissions requirements as per IEC 60601-1-2. The meter's electromagnetic emission is thus deemed low, and it is not expected to cause interference with other electrically driven equipment.

18 Symbols

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
	Unique device identifier
	Importer
	Distributor

19 Appendix

Estimated Glomerular Filtration Rate (eGFR) Using the CKD-EPI Equation

Using the 2021 CKD-EPI Equation for Adults to calculate an estimated Glomerular Filtration Rate (eGFR)

$$\begin{aligned} \text{eGFR (ml/min/1.73 m}^2\text{)} &= 142 \times \min(\text{standardized } S_{Cr}/K, 1)^{\alpha} \times \\ &\max(\text{standardized } S_{Cr}/K, 1)^{-1.200} \times \\ &0.9938^{\text{Age}} \times \\ &1.012 \text{ [if female]} \end{aligned}$$

Where:

- S_{Cr} is serum creatinine in mg/dL
- K is 0.7 for females and 0.9 for males
- α is -0.241 for females and -0.302 for males
- min indicates the minimum of standardized S_{Cr}/K or 1
- max indicates the maximum of standardized S_{Cr}/K or 1

Date of issue: Apr 27th, 2025

Manufacturer: EAGLENOS SCIENCES, INC.

Address: B2-2, Treehouse Headquarters Cluster, No.73 Tanmi Road, Nanjing Jiangbei New Area, Nanjing, Jiangsu 210044, China

Website: <http://www.eaglenos.com/en>

FCC Statement

Any Changes or modifications 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.

RF warning

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

Note : This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates,uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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