GIMA
PROFESSIONAL MEDICAL PRODUCTS

GIMACARE

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located

GIMA 24128

REF TD-4216

TaiDoc Technology Corporation
B1-7F, No. 127, Wugong 2nd Rd., Wugu Dist.,
24888 New Taipei City, Taiwan
www.taidoc.com - Made in Taiwan

CE 0123

EC REP MedNet EC-REP GmbH
Borkstraße 10, 48163 Münster, Germania

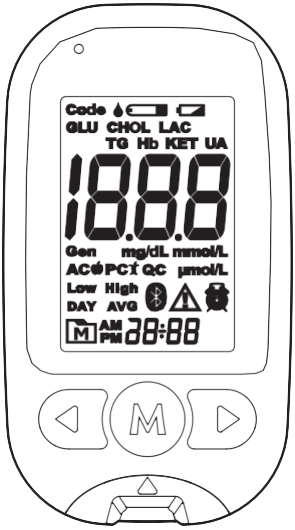



Imported by:
Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

M24128-EN-Rev.0- 10-24

Multi-Functional Monitoring System

Owner's Manual



Versión 2.0 2024/01 311-4216200-014

TABLE OF CONTENTS

Dear GIMACARE System Owner:

Thank you for choosing the GIMACARE Multi-Functional Monitoring System. This manual provides important information to help you to use the system properly. Before you begin, please read the following contents thoroughly and carefully. If you have other questions regarding this product, please contact the local customer service or place of purchase.

Intended Use

This system is intended for use outside the body (in vitro diagnostic use) to quantitatively measure the biochemical parameter - blood glucose, β-ketone, total cholesterol, triglycerides, uric acid, hemoglobin and lactate in fresh capillary whole blood. It is for home use or for healthcare professional use. It should NOT be used for diagnosis or screening of diseases.

Professionals may also use the test strips for blood glucose and hemoglobin measurement in venous, arterial, neonatal whole blood, and for β-ketone and lactate measurement in venous whole blood. Home use is limited to doing all biochemical parameter testing with fresh capillary whole blood.

Test Principle

Your system measures the amount of blood glucose / β-ketone / total cholesterol / triglycerides / uric acid / hemoglobin / lactate (biochemical parameters) in whole blood. The test is based on the measurement of electrical current generated by the reaction of the biochemical parameters with the reagent of the strip. The meter measures the current, calculates the biochemical parameters in the blood, and displays the result on the screen. The strength of the current produced by the reaction depends on the amount of biochemical parameters in the blood sample.

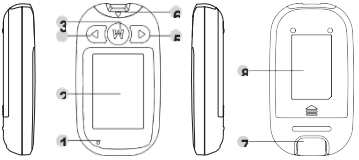
Important Safety Precautions

Please read the following carefully before use::

1. Use this device ONLY for the intended use described in this manual.
2. Do NOT use accessories that are not specified by the manufacturer.
3. Do NOT use the device if it is not working properly or is damaged.
4. This device does NOT serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
5. Keep the device and testing equipment away from children. Small parts such as the battery cover, batteries, test strips, lancets, and vial caps are choking hazards.
6. The presence of synthetic materials (synthetic clothing, carpet, etc.) may cause damaging static discharges that lead to erroneous results.
7. Do NOT use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
8. Proper maintenance and control solution tests are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact local customer service or place of purchase for assistance.
9. Severe dehydration and excessive water loss may cause readings that are inaccurate. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
10. We do not recommend using this product on severely hypotensive individuals or patients in shock. Please consult a healthcare professional before use.
11. Only use fresh whole blood sample. Using any body substances other than blood will lead to incorrect results.
12. If you are experiencing symptoms that are inconsistent with your test results and you have followed all the instructions in this owner's manual, contact your healthcare professional.
13. Before using this device to test blood glucose, β-ketone, total cholesterol, triglycerides, uric acid, hemoglobin or lactate, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
14. If your biochemical parameter results are lower or higher than usual, and you do not show any symptoms of illness, repeat the test first. If you develop any symptoms or continue to get results that are lower or higher than usual, consult your healthcare professional..
15. If any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established..

KEEP THESE INSTRUCTIONS AT A SAFE PLACE

Meter Overview



1) **Bluetooth Indication Light**
   Bluetooth is available for alternative data transmission.
2) **Display Screen**
3) **Left Scroll Button (◄)**
   Enter Day Average and adjust value decrement.
4) **Main Button (M)**
   Enter the meter memory.
5) **Right Scroll Button (►)**
   Enter Bluetooth function, adjust value increment and silence a reminder alarm..
6) **Test Strip Slot with Strip Indication Light**
   Insert test strip here to turn the meter on for testing. The indicator lights up when results appear.

INDICATOR	MEANING
Green	Result in range
Red	Result below / above the range or ketone warning
Green	Result in range

7) **Test Strip Ejector**
   Eject the used strip by pressing this button
8) **Battery Compartment**
9)

Display Screen

1 **Code**

2 **Blood Glucose Symbol**

3 **Test Result**

4 **Measuring Mode**
Gen – any time of day
AC – before meal
PC – after meal

5 **QC Mode**
QC – control solution test

11 **Error Message / Ketone Warning**

12 **Bluetooth Symbol**

13 **Measurement Unit**

14 **Triglycerides Symbol**

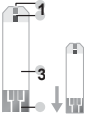
15 **Hemoglobin Symbol**

16 **Uric Acid Symbol**

17 **β-Ketone Symbol**

6	High / Low Indicator	18	Low Battery Symbol
7	Day Average	19	Lactate Symbol
8	Memory Mode	20	Test Strip Symbol
9	Date / Time	21	Total Cholesterol Symbol
10	Alarm Symbol	22	Blood Drop Symbol

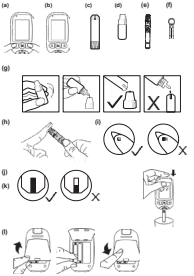
Test Strip



1	Absorbent Hole	3	Test Strip Handle
2	Confirmation Window	4	Contact Bars

NOTE
• The front side of the test strip should face up when inserting into the test strip slot. Test results might be inaccurate if the contact bar is not fully inserted into the test strip slot.
• The GIMACARE Multi-Functional Monitoring System should only be used with GIMACARE test strips. Using other test strips with this meter can produce inaccurate results.

Letter Indicator Guide



Refer to this letter indicator guide when necessary.

Setting The Meter

Setting your meter to the correct date and time will ensure the accuracy of the test results. Follow the steps below when you first start using the meter. When you change the meter battery or start using the meter again after taking the batteries out for a period of time (i.e. 3 months), you should check and update the following settings:

Entering the Setting Mode (a)

Start with the meter off (no test strip inserted). Press and hold ◄ and ► at the same time for 3 seconds.

1. Setting the date

The sequence of the date setting is: YEAR → MONTH → DAY. With the YEAR / MONTH / DAY flashing in sequence, press ◄ or ► to select the correct number. Press M.

2. Setting the time format and time

Press ◄ or ► to select the desired time format (12h or 24h). Press M.
With the HOUR / MINUTE flashing in sequence, press ◄ or ► to select the correct number. Press M.

3. Setting the blood glucose measuring unit

With the measuring unit flashing, press ◄ or ► to switch between mg/dL and mmol/L. Press M.

4. Setting the total cholesterol measuring unit

With the measuring unit flashing, press ◄ or ► to switch between mg/dL and mmol/L. Press M..

5. Setting the uric acid measuring unit

With the measuring unit flashing, press ◄ or ► to switch between mg/dL and µmol/L. Press M.

6. Setting the triglycerides measuring unit

With the measuring unit flashing, press ◄ or ► to switch between mg/dL and mmol/L. Press M.

7. Setting the hemoglobin measuring unit

With the measuring unit flashing, press ◄ or ► to switch between g/dL and mmol/L. Press M..

8. Setting the blood glucose's measuring mode target range

The sequence of the low and high target range setting is: Gen low → Gen high → AC low → AC high → PC low → PC high. With the target range settings flashing in sequence, press ◄ or ► until the desired target number appears. Press M.

You may refer to the table below to set your target range:

	Gen:	~CA	PC
LOW	60 – 100 mg/dL 3,3 – 5,5 mmol/L	60 – 100 mg/dL 3,3 – 5,5 mmol/L	60 – 100 mg/dL 3,3 – 5,5 mmol/L
HIGH	101 – 220 mg/dL 5,6 – 12,2 mmol/L	101 – 220 mg/dL 5,6 – 12,2 mmol/L	101 – 220 mg/dL 5,6 – 12,2 mmol/L

NOTE

- The meter comes with a set of default target range. Please consult your doctor to determine a target range that works best for you, and customize the target range according to the instructions.
- This function is applicable to blood glucose test ONLY.
- The target range setting is fixed between the numbers that showed in the table above..

9. Setting the buzzer

With the buzzer displays, press ◄ or ► to switch between “On” and “OFF”. Press M.

10. Deleting the memory

With “dEL” and “M” on the display, to select “no” and keep the results in memory, press M. To delete all the results, press ► to select “yes”, and press M to delete all the records.

11. Setting the reminder alarm

Your meter has 4 reminder alarms. The meter will display “On” or “OFF” and “ AL1 ”. If you don’t want to set an alarm, press M to skip this step. Or press ◄ or ► to select “On”, then press M. With the HOUR/ MINUTE flashing, press ◄ or ► to select the correct HOUR/ MINUTE..
Press M and go to the next alarm setting..

NOTE

When the alarm beeps, press ► to switch it off. Otherwise, it will beep for 2 minutes then switch off..

12. Setting the Bluetooth function

With “BLE” on display, press ◄ or ► to select “On” or “OFF”. Press M.

NOTE

This function is referring to the Bluetooth data transmission. If “On” is selected, your result will be transmitted automatically right after the test..

Congratulations! You have completed all settings!

NOTE

- These parameters can ONLY be changed in the setting mode.
- If the meter is idle for 1 minute during the setting mode, it will switch off automatically.

Calibration

Each time you start testing with a new package of β-ketone / total cholesterol / triglycerides / uric acid / hemoglobin / lactate test strips, you must calibrate the meter with correct code. Make sure that the code number displayed on the meter matches the code number on the test strips vial or individual foil packet before the test. If the code numbers do not match, the test results may be inaccurate. Do not proceed with the testand contact customer service for assistance.

Always follow the calibration instructions in the test strip insert.

Quality Control Tests

When to Perform a Control Solution Test?

- if it is mandatory following the local regulations in your country;
- if you suspect the meter or test strips are not working properly;
- if your test results are not consistent with how you feel, or if you think the results are not accurate;
- to practice the testing process; or
- if you have dropped or think you may have damaged the meter.

Test strips **(c)**, control solutions **(d)**, lancing device **(e)** or sterile lancets **(a)** may not be included in the kit (please check the contents on your product box). They can be purchased separately. Please make sure you have those items needed for the test beforehand.

Performing a Control Solution Test

To perform a control solution test, you will need: **(b)**, **(c)** and **(d)**.

1. Insert the test strip to turn on the meter

Insert the test strip into the meter. Wait for the meter to display " ", a flashing " ", and "GLU" / "KET" / "CHOL" / "TG" / "UA" / "Hb" / "LAC".

2. Press ► to mark this test as a control solution test (for Triglycerides and Hemoglobin test)

With "QC" displayed, the meter will store your test result in memory under "QC". If you press ► again, the "QC" will disappear and this test is no longer a control solution testl.

WARNING
When doing the control solution test, you have to mark it so that the test result will NOT mix with the blood test results stored in the memory. Failure to do so will mix up the blood test results with the control solution test results in memory.

3. Apply the control solution (g)

Shake the control solution vial thoroughly before use. Squeeze out the first drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the test strip absorbent hole to the droplet. Once the confirmation window fills completely, the meter will begin counting down.

4. Read and compare the result

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial or foil packet and it should fall within range. If not, please read the instructions again and repeat the control solution test. With "QC" displayed, the meter will store your test result in memory under "QC".

NOTE
• The control solution range printed on the test strip vial or foil packet is for control solution use only. It is not a recommended range for your blood test levels. • For the blood glucose, β-ketone, total cholesterol, uric acid and lactate control solution test, your device will tag this measurement as QC test automatically. • To avoid contaminating the control solution, do NOT directly apply the control solution onto a strip..

Important Control Solution Information

- ONLY use TAIDOC's control solutions with your meter.
- Do not use the control solution beyond the expiration date or 3 months after first opening. Write the opening date on the control.
- It is recommended that the control solution test to be done at room temperatures between 20°C to 25°C

(68°F to 77°F). Please make sure your control solution, meter, and test strips are at the specified temperature range before testing.

- Shake the vial before use, discard the first drop of control solution, and wipe it off the tip to ensure a pure sample and an accurate result.
- Store the control solution with the cap tightly closed at temperatures between 2°C to 30°C (35.6°F to 86°F). Do NOT freeze.

Prepare For Blood Tests

Prepare the Lancing Device for Blood Tests

Please follow the instructions in the lancing device insert on how to prepare the lancing device and collecting a blood sample.

WARNING
To reduce the chance of infection: ● Never share the lancet or lancing device; ● Always use a new, sterile lancet. Lancets are for single use only; ● Avoid getting hand lotion, oils, dirt or debris in or on the lancets and the lancing device. ● The used lancet may potentially be biohazardous. Discard it according to your local regulations. ● Do not reuse lancets. Always use a new, sterile lancet for testing.

Prepare the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the test value. Blood from a site that has not been rubbed exhibits a measurably different substance concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

Follow the steps listed below before obtaining a blood sample:

- Wash and dry your hands before you begin;
- Select a puncture site;
- Rub the selected site for about 20 seconds before penetration; and
- Clean the puncture site using cotton moistened with 70% alcohol and let it air dry.

Perform Blood Tests

To perform a blood test, you need: **(b)**, **(c)**, **(e)** and **(f)**.

1. **Turn on the meter by inserting a test strip:** Wait for the meter to display the "  ", "  ", and "GLU" / "KET" / "CHOL" / "TG" / "UA" / "Hb" / "LAC".
2. **Select the appropriate measuring mode by pressing ► (For Blood Glucose: Gen / AC / PC)**
3. **Fingertip testing (h):** Hold the pre-set lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger. A click indicates that the puncture is complete.
4. **Obtaining a blood sample (i):** Gently squeeze the punctured site to obtain a drop of blood and use it as the sample for the test. Be careful NOT to smear the blood sample.

The amount of blood and time required for the blood test:

Hemoglobin	1.0 microliter (μL)	10-12 seconds
Blood Glucose	0.5 microliter (μL)	5 seconds
β-ketone	0.8 microliter (μL)	10 seconds
Total Cholesterol	3.0 microliter (μL)	60 seconds
Triglycerides	3.0 microliter (μL)	60 seconds
Uric Acid	0.5 microliter (μL)	15 seconds
Hemoglobin	1.0 microliter (μL)	10-12 seconds
Lactate	0.8 microliter (μL)	5 seconds

5. **Apply the sample (j):** Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Confirmation window should be completely filled if enough blood has been applied. Do NOT remove your finger until you hear a "beep" sound".

NOTE

- Do NOT press the punctured site against the test strip or try to smear the blood.
- Always apply a blood sample after the test strip is inserted into the meter.
- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to start a new test.
- The confirmation window should be filled with blood before the meter begins to count down. NEVER try to add more blood to the test strip. **Discard the used test strip and retest with a new one**.
- If you have trouble filling the confirmation window, please contact
- your healthcare professional or customer service for assistance**.**

1. **Read Your Result:** The result of your test will appear after the meter counts down to 0. The result will be stored in the memory automatically.
2. **Eject the used test strip (k):** Eject the test strip by pushing the eject button on the side. Use a sharps bin to dispose of used test strips. The meter will switch off automatically.

Always follow the instructions in the lancing device insert when removing the lancet.

WARNING
● The used lancet and test strip are considered biohazardous. Please discard them carefully according to local regulations. ● Clean and disinfect the meter and lancing device after each test.

Blood Glucose Tests

The meter provides you with three measuring modes: Gen, AC and PC. You can switch between each mode by:

- Insert a test strip to turn on the meter. The screen will display "", a flashing "" and "GLU". Press ► to select the appropriate measuring mode (Gen, AC or PC).
- The measurement unit used for indicating the concentration of blood or plasma glucose can either have a weight dimension (mg/dL) or a molarity (mmol/L). The approximate calculation rule for conversion of mg/dL into mmol/L is:

mg/dL	Divided by 18	= mmol/L	E.g. 120 mg/dL ÷ 18 ≈ 6.6 mmol/L
mmol/L	Times 18	= mg/dL	E.g. 7.2 mmol/L x 18 ≈ 129 mg/dL

Reference Values

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%*1.
The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes. The blood glucose readings deliver plasma equivalent results and are displayed either in milligrams of glucose per deciliter of blood (mg/dL) or in millimoles of glucose per liter of blood (mmol/L).

Time of day	Normal plasma glucose range for people **without** diabetes (mg/dL or mmol/L)
Fasting*2 and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 mmol/L)

*1 American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2022 Jan; 45(Supplement 1): S17-S38. https://doi.org/10.2337/dc22-S002

*2 Fasting is defined as no caloric intake for at least 8 hours.

Result Readings

INDICATION LIGHT	MENSSAGE	WHAT IT MEANS
NOT APPLICABLE		Result is < 10 mg/dL (0.56 mmol/L) Out of measurement range.

SOLID RED		Result is between 10 to 69 mg/dL (0.56 to 3.7 mmol/L)		
SOLID GREEN		**Gen:**	**∼CA**	**PC**
		Result is between 70 and 119 mg/dL (3,8 to 6,5 mmol/L)	Result is between 70 and 129 mg/dL (3,8 to 7,1 mmol/L)	Result is between 70 and 179 mg/dL (3,8 to 9,9 mmol/L)
SOLID RED		**Gen:**	**∼CA**	**PC**
		Result is between 120 and 239 mg/dL (6,6 to 13,2 mmol/L)	Result is between 130 and 239 mg/dL (7,2 to 13,2 mmol/L)	Result is between 180 and 239 mg/dL (10 to 13,2 mmol/L)
SOLID RED		Result is ≥ 240 mg/dL (13.3 mmol/L) **Ketone Warning:** This is shown when your blood glucose result is equal to or higher than 240 mg/dL (13.3 mmol/L). **What to Do:** Check blood ketone if checking ketones is part of your diabetes management program.		
NOT APPLICABLE		Result is > 800 mg/dL (44.4 mmol/L) Out of measurement range.		

Always consult your doctor to determine a target range that works best for you.

β-Ketone Tests

The meter provides you with one measuring mode: General.

- Insert a test strip to turn on the meter. The screen will display "", a flashing "" and "KET".

Reference Values

The β-Ketone readings deliver plasma equivalent results and are displayed in millimoles of β-Ketone per liter of blood (mmol/L).

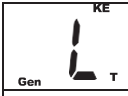
The β-Ketone test measures Beta-Hydroxybutyrate (β-OHB), the most important of the three β-Ketone bodies in the blood. Normally, levels of β-OHB are expected to be **less than 0.6 mmol/L**[1].

β-OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your β-Ketone result is "Lo", repeat the β-Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional. Follow your healthcare professional's advice before you make any changes to your diabetes medication program. If your β-Ketone result is between 0.6 and 1.5 mmol/L, this indicate a development of problem that may require medical assistance. Follow your healthcare professional's instructions. If your β-Ketone result is higher than 1.5 mmol/L, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).

[1]: Wiggam MI, O'Kane MJ, Harper R, et al. Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management. Diabetes Care. 1997; 20(9): 1347-52

Result Readings

MESSAGE	WHAT IT MEANS
	Result is < 0.1 mmol/L Out of measurement range.

	
	Result is between 0.1 to 8.0 mmol/L
	Result is > 8.0 mmol/L Out of measurement range.

Please consult your doctor to determine a target range that works best for you.

Total Cholesterol Tests

The meter provides you with one measuring mode: General.

- Insert a test strip to turn on the meter. The screen will display "  ", a flashing "" and "CHOL".
- After obtaining the first drop of blood, wipe it off. Squeeze again to obtain another drop of whole blood as the sample for the test.
- The measurement unit used for indicating the concentration of blood or plasma cholesterol can either have a weight dimension (mg/dL) or a molarity (mmol/L). The approximate calculation rule for conversion of mg/dL into mmol/L is:

mg/dL	Divided by 38.665	= mmol/L	E.g. 100 mg/dL ÷ 38.665 ≈ 2.5 mmol/L
mmol/L	Times 38.665	= mg/dL	E.g. 4.2 mmol/L x 38.665 ≈ 162 mg/dL

Reference Values

The total cholesterol readings deliver plasma equivalent results and are displayed in milligrams of total cholesterol per deciliter of blood (mg/dL) or in millimoles of total cholesterol per liter of blood (mmol/L).

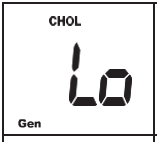
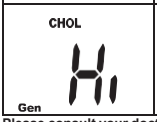
Total Cholesterol (mg/dL or mmol/L)	
Desirable	< 200 mg/dL (5.1 mmol/L)
Borderline High	200 - 239 mg/dL (5.1 - 6.1 mmol/L)
High	≥ 240 mg/dL (6.2 mmol/L)

A healthcare professional will discuss values that are specifically appropriate for each patient. At least two measurements of cholesterol in separate occasions should be made before a medical decision is made, since a single reading may not be representative of a patient's usual cholesterol concentration. An elevated cholesterol level is only one risk factor for heart disease. There are many others. A cholesterol less than 200 mg/dL is desirable.

Source: National Institutes of Health, National Heart, Lung, and Blood Institute. ATP III Guidelines At-A-Glance Quick Desk Reference. https://www.nhlbi.nih.gov/files/docs/guidelines/ atglance.pdf. Published May, 2001.

Result Readings

MESSAGE	WHAT IT MEANS

	Result is < 100 mg/dL (2.5 mmol/L) Out of measurement range.
	Result is between 100 to 400 mg/dL (2.5 to 10.3 mmol/L)
	Result is > 400 mg/dL (10.3 mmol/L) Out of measurement range.

Please consult your doctor to determine a target range that works best for you.

Triglycerides Tests

The meter provides you with one measuring mode: General.

- Insert a test strip to turn on the meter. The screen will display "  ", a flashing "" and "TG".
- After obtaining the first drop of blood, wipe it off. Squeeze again to obtain another drop of whole blood as the sample for the test.
- The measurement unit used for indicating the concentration of blood or plasma triglycerides can either have a weight dimension (mg/dL) or a molarity (mmol/L). The approximate calculation rule for conversion of mg/dL into mmol/L is:

mg/dL	Divided by 88.574	= mmol/L	E.g. 120 mg/dL ÷ 88.574 ≈1.35 mmol/L
mmol/L	Times 88.574	= mg/dL	E.g. 2.5 mmol/L x 88.574 ≈221 mg/dL

Reference Values

The triglycerides readings deliver plasma equivalent results and are displayed in milligrams of triglycerides per deciliter of blood (mg/dL) or in millimoles of triglycerides per liter of blood (mmol/L).

Triglycerides Levels (mg/dL or mmol/L)	
Desirable	< 150 mg/dL (1.70 mmol/L)
Borderline High	≥ 150 – 199 mg/dL (1.70 – 2.25 mmol/L)
High	≥ 200 – 499 mg/dL (2.26 – 5.64 mmol/L)
Very High	≥ 500 mg/dL (5.65 mmol/L)

A healthcare professional will recommend an appropriate value that are specific for individual patient. At least two measurements in separate occasions should be performed before a medical decision is made, since a single reading may not represent a patient's usual triglycerides concentration. An elevated triglycerides level is only one of the risk factors for heart disease. There are many others. A triglycerides level less than 150 mg/dL (1.70 mmol/L) is desirable. Source: National Cholesterol Education Program. Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report. National Institutes of Health. National Heart, Lung and Blood Institute. NIH Publication No. 02-5215, September 2002.

Result Readings

MESSAGE	WHAT IT MEANS

	Result is < 70 mg/dL (0.79 mmol/L) Out of measurement range.
	Result is between 70 to 600 mg/dL (0.79 to 6.77 mmol/L)
	El resultado es > 600 mg/dL (6,77 mmol/L) Fuera del rango de medición.

Please consult your doctor to determine a target range that works best for you.

Uric Acid Tests

The meter provides you with one measuring mode: General.

- Insert a test strip to turn on the meter. The screen will display "  ", a flashing "  " and "UA".
- After obtaining the first drop of blood, wipe it off. Squeeze again to obtain another drop of whole blood as the sample for the test.
- The measurement unit used for indicating the concentration of blood or plasma uric acid can either have a weight dimension (mg/dL) or a molarity (µmol/L). The approximate calculation rule for conversion of mg/dL in µmol/L is:

mg/dL	Times 59.48	= µmol/L	E.g. 10 mg/dL x 59.48 ≈ 594.8 µmol/L
µmol/L	Divided by 59.48	= mg/dL	E.g. 594.8 µmol/L ÷ 59.48 ≈ 10 mg/dL

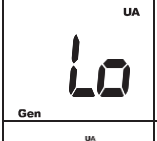
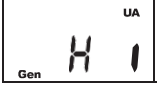
Reference Values

The uric acid readings deliver plasma equivalent results and are displayed in milligrams of uric acid per deciliter of blood (mg/dL) or micromoles of uric acid of blood (µmol/L).

Male	3.5 to 7.2 mg/dL (208 to 428 µmol/L)
Female	2.6 to 6 mg/dL (155 to 357 µmol/L)

Source: National Kidney Foundation. 2014..

Result Readings

MESSAGE	WHAT IT MEANS
	Result is < 3 mg/dL (178 µmol/L) Out of measurement range..
	Result is between 3 to 20 mg/dL (178 to 1189 µmol/L)
	Result is > 20 mg/dL (1189 µmol/L) Out of measurement range.

Please consult your doctor to determine a target range that works best for you.

Hemoglobin Tests

The meter provides you with one measuring mode: General.

- Insert a test strip to turn on the meter. The screen will display "  ", a flashing "  " and "Hb".
- The measurement unit used for indicating the concentration of blood or plasma hemoglobin can either have a weight dimension (g/dL) or a molarity (mmol/L). The approximate calculation rule for conversion of g/dL into mmol/L is:

g/dL	Times 0.6206	= mmol/L	E.g. 15 g/dL x 0.6206 ≈ 9.3 mmol/L
mmol/L	Divided by 0.6206	= g/dL	E.g. 10 mmol/L ÷ 0.6206 ≈16.1 g/dL

Reference Values

Hemoglobin (Hb)	
Males	14.0 to 18.0 g/dL
Females	12.0 to 16.0 g/dL

Source: Laboratory Reference Range Values

Result Readings

MESSAGE	WHAT IT MEANS
	Result is < 6.8 g/dL (4.22 mmol/L) Out of measurement range.
	Result is between 6.8 to 24 g/dL (4.22 to 14.89 mmol/ L)
	Result is > 24 g/dL (14.89 mmol/L) Out of measurement range.

Always consult your doctor to determine a target range that works best for you.

Lactate Tests

The meter provides you with one measuring mode: General.

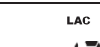
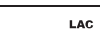
- Insert a test strip to turn on the meter. The screen will display "", a flashing "" and "LAC".
- After obtaining the first drop of blood, wipe it off. Squeeze again to obtain another drop of whole blood as the sample for the test. It is important that you perform the test IMMEDIATELY after drawing the blood sample.

Reference Values The meter provides you with plasma equivalent results and are displayed in millimoles of lactate per liter of blood (mmol/L). The desirable range is **0.3 to 2.4 mmol/L**[1].

[1]:Williamson MA, Snyder LM. Wallach's Interpretation of Diagnostic Tests: Pathways to Arriving at a Clinical Diagnosis. 10th ed. Philadelphia: Wolters Kluwer Health.2015.

Result Readings

MESSAGE	WHAT IT MEANS

LAC  Gen	Result is < 0.3 mmol/L Out of measurement range.
LAC  Gen	Result is between 0.3 to 22 mmol/L
LAC  Gen	Result is > 22 mmol/L Out of measurement range.

Please consult your doctor to determine a target range that works best for you.

Review Test Results

The meter stores the most recent 1000 test results along with respective dates and times in its memory. To enter memory mode, **start with the meter switched off**.

1. Press and release **M**, "M" will appear on the display and the first reading you see is the latest test result with the date, time and measuring mode.
2. Press ◄ **or** ► to scroll through all the test results stored in the meter. Press ► to view the old test result and press ◄ to see the new one. "toP" will be on display when you reach the latest test result. "End" will be on display when you reach the oldest result.

Reviewing Blood Glucose Average Results

1. Start with the meter switched off. Press and release ◄ to enter memory mode for average results with "M" and "DAY AVG" display on the screen. Your 7-day average result measured in general mode will appear on the display.
2. Press ◄ **or** ► to review 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC and PC.

NOTE
● Any time you wish to exit the memory mode, keep pressing **M** for 3 seconds or leave it without any action for 1 minute. The meter will switch off automatically.
● Control solution results are NOT included in the day average.

Data Transfer via Bluetooth

Data Transfer to a Computer

You can use the Health Care Management System to view test results on a **Windows 10 (or above)** computer. To learn more about the Health Care Management System, please contact TAIDOC or place of purchase for assistance. Please note that you must complete the pairing between the meter and your computer before transferring data.

Pairing with your computer

1. Obtaining and installing the software

To download the Health Care Management System, please visit TAIDOC's website: www.taidoc.com.

2. Connecting to a computer

Turn on the Bluetooth function on the meter and your computer, then pair the meter with your computer.

3. Data transfer

To transfer data, follow the instructions provided with the software. Results will be transferred with date and time.

Data Transfer to a Mobile Device

You can transfer testing results from the meter to **ProCheck app** on your mobile device via Bluetooth. The **ProCheck app** is designed for self-monitoring and analysis to your health. Please download and install the **ProCheck app** first. For the requirement of OS version, please find on App Store or Google Play when you download the app.

Please note that you must complete the pairing between the meter and your mobile device before transferring data.

Pairing with your mobile device

1. Turn on the Bluetooth function on your mobile device.
2. Follow the Quick Start Guide (For Bluetooth Pairing) to pair the device. (E.g. Search to find the meter and then add it into the app).
3. After successfully pairing the app with the device, the Bluetooth function of meter shall be on before transferring data to the **ProCheck app**.

Bluetooth Indicator on the Meter

BLUETOOTH INDICATOR ON THE METER	STATUS
Flashing Blue	The Bluetooth function is on and waiting for connection.
Solid Blue	The Bluetooth connection is established.

NOTE
● The meter will be unable to perform a test while it is in transfer mode. ● Please make sure your device supports Bluetooth Smart Technology, the Bluetooth setting on your device is turned on, and the meter is within the receiving range before transferring the data. ● The Bluetooth functionality is implemented in different ways by various mobile device manufacturers; compatibility issue between your mobile device and the meter may occur.

Maintenance

Meter Cleaning and Disinfecting

- Wipe the meter exterior with soft damp cloth or mild cleaning agent, then dry the device with soft dry cloth. Do NOT use organic solvents to clean the meter.
- Do NOT rinse or immerse in water or other liquids.
- Always disinfect the surfaces of the meter with cotton moistened with 70% alcohol after taking a test.
- Avoid getting any moisture into any openings (e.g. test strip port, battery compartment).

Meter Storage

- Always store or transport the meter in its original storage case.
- Avoid dropping the meter or heavy impact.
- Avoid direct sunlight or high humidity.

Meter Disposal

The used meter should be treated as a contaminated item that may carry a risk of infection during measurement. The batteries in the used meter should be removed and the meter should be disposed in accordance with local regulations.

Caring for Your Test Strips

- Store the test strips in their original vial ONLY. Do NOT transfer them to a new vial or any other containers. (For strip vial only)

- Use each test strip immediately after taking it out of the vial or individual foil packet. Close the vial immediately after taking out a strip. (For strip vial only)
- Keep the vial closed at all times. (For strip vial only)
- Keep the test strips away from direct sunlight. Do NOT store the test strips in high humidity.
- Do NOT touch the test strips with wet hands.
- Do NOT bend, cut, or alter the test strips.

For more information, please refer to the test strip insert.

Battery

Your meter comes with two 1.5V AAA size alkaline batteries.

Low Battery Signal

The meter will display one of the messages below to alert you when the meter power is getting low.

1. When the "  **" symbol appears along with display messages:** The meter is functioning properly and the result remains accurate, but it is time to change the batteries.

2. When the "  **" symbol appears with E-b:** The power is too low to perform a test. Please change the batteries immediately.

Replacing the Battery

To replace the batteries (l), make sure the meter is turned off.

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.
3. Close the battery cover. If the batteries are inserted correctly, you will hear a "beep" afterwards.

NOTE
• Replacing the batteries does not affect the test results stored in the meter.
• All batteries should be kept away from children. If swallowed, seek medical assistance immediately.
• Batteries might leak chemicals if left unused for a long time. Remove the batteries if you are not going to use the device for an extended period of time (i.e. 3 months or more).
• Properly dispose of the batteries according to your local environmental regulations.

System Troubleshooting

If you follow the recommended action but the problem persists, please call your local customer service

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	The batteries are too low.	Replace the batteries immediately.
E-U	A used test strip is inserted.	Repeat with a new test strip.
E-t	Ambient temperature is above or below system operation range.	Repeat the test after the meter and test strip are within the operation temperature range.

E-0 E-A E-E E-C	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact customer service for assistance.
E-F	Test strip is removed while counting down, or insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact customer service for help.
E-2	The code chip or test strip is expired.	Make sure the date you set on the meter is correct and check the expiry date shown on the packaging. If the problem persists, repeat with a new code chip or test strip.
E-8	The code chip is not inserted before testing or the meter does not support certain parameters.	Check the code chip is inserted for coding correctly. Make sure the code chip you used supports the parameter. If the problem persists, please contact customer service for help.

Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer service.

2. If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (1 minute after last user action).	Repeat the test with a new test strip. Apply sample only when flashing " " appears on the display.
Defective meter.	Please contact customer service.

3. If the control solution testing result is out of range:

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution thoroughly and repeat the test again.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature 20°C to 25°C (68°F to 77°F) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer service.
Improper working of meter and test strip.	Please contact customer service.

Symbol Information

SYMBOL	REFERENT	SYMBOL	REFERENT
IVD	*In vitro* diagnostic medical device	EC REP	Authorized representative in the European Community
	Consult instructions for use or consult electronic instructions for use		Manufacturer
	Temperature limit		Caution
SN	Serial number		RoHS compliance
#	Model number	UDI	Unique device identifier
	Humidity limitation	CE	In vitro diagnostic medical device compliant with Directive 98/79 / EC
	WEEE disposal		Date of manufacture
REF	Product code	STERILE R	Sterilized using irradiation
LOT	Lot number		Disposable device, do not re-use
	Expiration date		Imported by

Specifications

Model: GIMACARE

Dimension: 102.5 (L) x 59.6 (W) x 21.8 (H) mm

Weight: 64.4 g (without batteries)

Power Source: Two 1.5V AAA alkaline batteries

Display: LCD with backlight **Memory:** 1000 measurement results **External Output:** Bluetooth

Auto sample loading detection Auto electrode insertion detection Auto reaction time count-down
Auto switch-off after 1 minute without action

Temperature Warning

Operating Conditions:

Blood Glucose: 8°C to 45°C (46.4°F to 113°F) and 10% to 90% R.H. (non-condensing);

β-Ketone, Total Cholesterol, Triglycerides, Uric Acid and Lactate: 10°C to 40°C (50°F to 104°F) and 10% to 85% R.H. (non-condensing)

Hemoglobin: 10°C to 40°C (50°F to 104°F) and 10% to 90% R.H. (non-condensing)

Meter Storage / Transportation Conditions:

-20°C to 60°C (-4°F to 140°F) and 10% to 93% R.H. (non-condensing)

Strip Storage/Transportation Conditions:

Blood Glucose, Hemoglobin: 2°C to 30°C (35.6°F to 86°F) and 10% to 90% R.H. (non-condensing);

β-Ketone, Total Cholesterol, Triglycerides, Uric Acid and Lactate: 2°C to 30°C (35.6°F to 86°F) and 10% to 85% R.H. (non-condensing **Measurement Units:**

Blood Glucose / Total Cholesterol / Triglycerides: mg/dL or mmol/L

β-Ketone / Lactate: Fixed mmol/L Uric Acid: mg/dL or µmol/L Hemoglobin: g/dL or mmol/L

Measurement Range:

Blood Glucose Test: 10 to 800 mg/dL (0.56 to 44.4 mmol/L)

β-Ketone Test: 0.1 to 8.0 mmol/L

Total Cholesterol Test: 100 to 400 mg/dL (2.5 to10.3 mmol/L) Triglycerides Test: 70 to 600 mg/dL (0.79 to 6.77 mmol/L)

Uric Acid Test: 3 to 20 mg/dL (178 to 1189 µmol/L)

Hemoglobin: 6.8 to 24 g/dL (4.22 to 14.89 mmol/L)

Lactate Test: 0.3 to 22 mmol/L

Expected service life: 5 years

Operating Altitude: Up to 2000m, for indoor use

Degree of Pollution: Pollution degree 2

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1, IEC/EN 61326-2-6, EN 300 328.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty