

heartscare C1

Monitoring System

Owner's Manual



Dear heartscare C1 System Owner:

Thank you for purchasing the heartscare C1 monitoring system.

This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

If you have other questions regarding this product, please contact the local customer service.

Intended Use

This system is intended for use in the quantitative measurement of β -ketone, total cholesterol, uric acid or lactate level in fresh capillary whole blood from the fingertips. This system is intended for self-testing outside the body (*in vitro* diagnostic use) by lay user as an aid in measuring the β -ketone, total cholesterol, uric acid or lactate level. It is not intended for the diagnosis of or screening for diseases, and is not intended for use on neonates.

The β -ketone, total cholesterol, uric acid and lactate test strips are all measured using fresh capillary whole blood samples from fingertips.

Test Principle

Your system measures the amount of β -ketone / total cholesterol / uric acid / lactate in fresh capillary whole blood samples from fingertips.

β -Ketone / total cholesterol / uric acid / lactate testing is based on the measurement of electrical current generated by the reaction of β -ketone / total cholesterol / uric acid / lactate with the reagent of the strip. The meter measures the current, calculates β -ketone / total cholesterol / uric acid / lactate level, and displays the result. The strength of the current produced by the reaction depends on the amount of β -ketone / total cholesterol / uric acid / lactate in the blood sample.

IMPORTANT SAFETY PRECAUTIONS

READ BEFORE USE

- For over-the-counter use.
- The meter and lancing device are for single patient use only. Do not share them with anyone including your family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For more information, please visit

- “FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)

<http://wayback.archive-it.org/7993/20170111013014/>

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

- “CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010) <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or if it is damaged.
4. Do **NOT** under any circumstances use the device on the neonates.
5. 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.
6. Before using this device to test β -ketone, total cholesterol, uric acid or lactate, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.

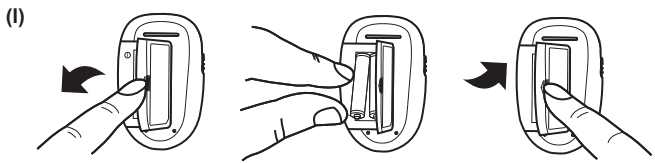
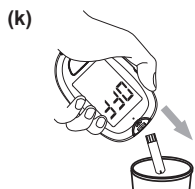
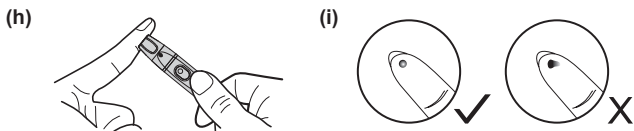
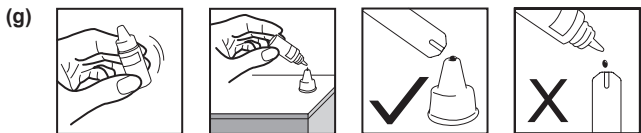
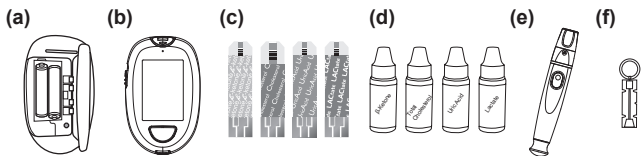
7. Keep the device and testing equipment away from children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
8. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, and carpets etc.) may cause damaging static discharges that may cause erroneous results.
9. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
10. Proper maintenance and periodically control solution test are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact customer service or place of purchase for help.
11. This device is **NOT** intended for use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism.
12. This device is **NOT** intended for assessing the risk of cardiovascular diseases.
13. This device is **NOT** intended for near patient testing (point of care).
14. This device is **NOT** intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

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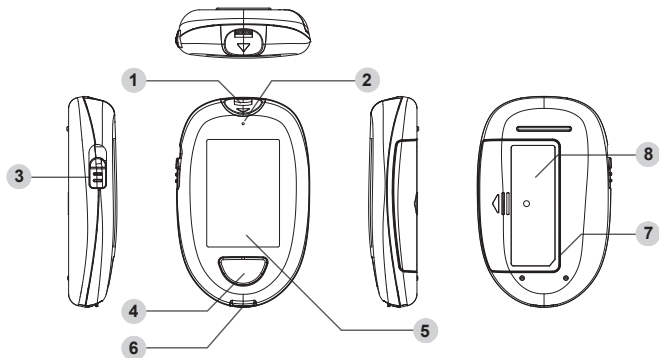


BEFORE YOU BEGIN

Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your β -ketone, total cholesterol, uric acid or lactate results are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh capillary whole blood samples from fingertips to perform a blood test. Using other substances will lead to incorrect results.
- If you are experiencing symptoms that are inconsistent with your test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- We do not recommend using this product on severely hypotensive individuals or patients in shock. Please consult your healthcare professional before use.

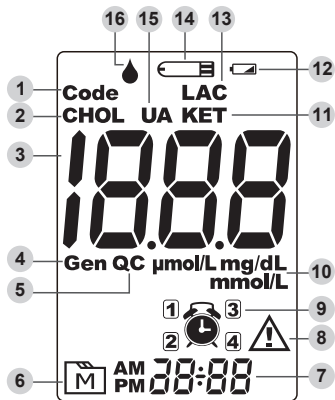
Meter Overview



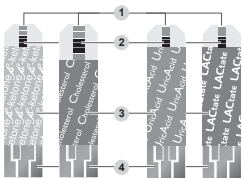
- 1 Test Strip Slot with Strip Indication Light**
Insert test strip here to turn the meter on for testing.
- 2 Bluetooth Indication Light**
(Bluetooth is available for test result data transmission)
- 3 Test Strip Ejector**
Eject the used strip by sliding up the button.
- 4 M Button (M)**
Enter the meter memory or silence a reminder alarm.
- 5 Display Screen**
- 6 Data Port (not available)**
- 7 SET Button (S)**
Enter and confirm the meter settings.
- 8 Battery Compartment**

Display Screen

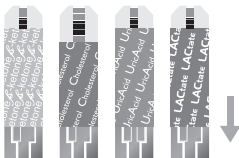
- 1 Code
- 2 Total Cholesterol Symbol
- 3 Test Result
- 4 Measuring Mode
Gen – any time of day
- 5 Auto QC Mode / QC Mode
QC – control solution test
- 6 Memory Mode
- 7 Date / Time
- 8 Error Message
- 9 Alarm Symbol
- 10 Measurement Unit
- 11 β -Ketone Symbol
- 12 Low Battery Symbol
- 13 Lactate Symbol
- 14 Test Strip Symbol
- 15 Uric Acid Symbol
- 16 Blood Drop Symbol



Test Strip



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



ATTENTION:

The front side of test strip should face up when inserting. Test results might be inaccurate if the contact bar is not fully inserted into the test slot.

NOTE:

The heartscore C1 monitoring system should only be used with heartscore C1 Test Strips. Using other test strips with this meter can produce inaccurate results.

SETTING THE METER

Before using your meter for the first time or if you change the meter battery, you should check and update these settings.

Entering the Setting Mode (a)

Start with the meter off (no test strip inserted). **Press SET Button (S)** under battery cover.

1. Setting the date

The sequence of the date setting is: YEAR → MONTH → DAY. With the YEAR / MONTH / DAY flashing in sequence, press **M** button to select the correct number. **Press SET Button (S)**.

2. Setting the time format

Press **M** button to select the desired time format (12h or 24h). **Press SET Button (S)**.

3. Setting the time

With the HOUR / MINUTE flashing in sequence, press **M** button to select the correct number. **Press SET Button (S)**.

4. Setting the total cholesterol measuring unit

With the measuring unit flashing, press **M** button to switch between mg/dL and mmol/L. **Press SET Button (S)**.


5. Setting the uric acid measuring unit

With the measuring unit flashing, press **M** button to switch between mg/dL and $\mu\text{mol/L}$. **Press SET Button (S)**.

6. Setting the buzzer


With the buzzer displays, press **M** button to switch between “On” and “Off”. **Press SET Button (S)**.

7. Deleting the memory

With “dEL” and “” on the display, press **M** button to select “no” to keep the results in memory then press **M** button to skip.

To delete all the results, press **M** button and select “yes” to delete all the memory records.

8. Setting the reminder alarm

Your meter has four reminder alarms. The meter will display “On” or “Off” and “”. If you don’t want to set an alarm, **press SET Button (S)** to skip this step. Or press **M** button to select “On”, then **press SET Button (S)**.

With the HOUR / MINUTE flashing in sequence, press **M** button to select the correct HOUR / MINUTE. **Press SET Button (S)** and go to the next alarm setting.

NOTICE:

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



Congratulations! You have completed all settings!

NOTE:



- These parameters can **ONLY** be changed in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

THE MEASURING MODES



For β -Ketone Testing

The meter provides you with one mode for measuring, General (GEN). Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display “”, a flashing “” and “KET”.



For Total Cholesterol Testing

The meter provides you with one mode for measuring, General (GEN). Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display “”, a flashing “” and “CHOL”.

For Uric Acid Testing

The meter provides you with one mode for measuring, General (GEN). Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display “”, a flashing “” and “UA”.

For Lactate Testing

The meter provides you with one mode for measuring, General (GEN). Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display “”, a flashing “” and “LAC”.

BEFORE TESTING

Calibration

Calibrate the meter at the beginning of each new box of test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the meter does not match the number printed on your test strip packet.

Operation

1. Insert the code chip when the meter is off. Wait until the number and KET / CHOL / UA / LAC appears on the display.
2. Remove the code chip. The display will show “Off ” then the meter will switch off.

Checking the Code Number

Make sure that the number and KET / CHOL / UA / LAC displayed on the meter matches the number on your test strip packet before you proceed. If it matches, you can proceed with your test. If the numbers do not match, please stop testing and insert the correct code chip. If the problem persists, contact Customer Service for help.

QUALITY CONTROL TESTING

When Should the Control Solution Test be Performed?



- 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,
- 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 **(f)** 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 blood test beforehand.

Performing a Control Solution Test

To perform a control solution test, you will need the meter **(b)**, test strips **(c)**, control solution **(d)**.

1. Insert the test strip to turn on the meter

Insert the test strip into the meter. Wait for the meter to display “” and a flashing “”.

2. Apply 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 absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down.

NOTE:

- For the control solution test, your device will tag this measurement as QC test automatically.
- To avoid contaminating the control solution, do not directly apply control solution onto a strip.

3. 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 package and it should fall within this 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 package is for control solution use only. It is not a recommended range for your blood test level.
- See the **MAINTENANCE** section for important information about your control solutions.

TESTING WITH BLOOD SAMPLE

WARNING:

To reduce the chance of infection:

- Never share a lancet or the 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.

Preparing the Lancing Device for Blood Testing

Please follow the instructions in the lancing device insert for collecting a blood sample.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the test value obtained. Blood from a site that has not been rubbed exhibits a measurably different β -ketone / total cholesterol / uric acid / lactate concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

Please follow the suggestions below before obtaining a drop of blood:

- **Wash and dry your hands before starting.**
- Select the puncture site.
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry.**
- **Fingertip testing (h)**

Press the 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.

NOTE:

Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.

Performing a Blood Test

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

1. Insert the test strip to turn on the meter

Wait for the meter to display the “” / “”, and “KET” / “CHOL” / “UA” / “LAC”.

2. Obtaining a blood sample (i)

Use the pre-set lancing device to puncture the desired site. The size of the drop should be at least 3 microliter (μL) of volume for total cholesterol test; 0.5 microliter (μL) of volume for uric acid test; 0.8 microliter (μL) of volume for both β -ketone and lactate test. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

3. 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 sample has been applied. Do **NOT** remove your finger until you hear a beep sound.

NOTE:

- Make sure to perform the test immediately after drawing the sample.
- Do not press the punctured site against the test strip or try to smear the blood.
- 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 after the drop of blood has moved away. Discard the used test strip and retest with a new one.
- If you have trouble filling the confirmation window, please contact your health care professional or the local customer service for assistance.

4. Read Your Result

The result of your blood test will appear after the meter counts down to 0. The blood test result will be stored in the memory automatically.

5. Eject the used test strip (k)

Eject the test strip by sliding up the eject button on the side. Use a sharp bin to dispose of used test strips. The meter will switch itself off automatically.

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

WARNING:

The used lancet and test strip may be biohazardous. Please discard them carefully according to your local regulations.

METER MEMORY

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

Reviewing Test Results

1. Press and release **M**.

“**M**” will appear on the display and the first reading you see is the last blood test result along with date, time and the measuring mode.

2. Press **M** to recall the test results stored in the meter each time you press. Press and hold **M** to switch off the meter.

NOTE:

Any time you wish to exit the memory, keep pressing **M** for 3 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.

BLUETOOTH PAIRING

Data Transmission via Bluetooth

You can transmit your data from the meter to your device via Bluetooth. The HeartsBio app is designed to assist you in easily monitoring your β -ketone, total cholesterol, uric acid and lactate levels.

How to Install and Update the HeartsBio App

You must connect to the internet to download the app. The App Store or Google Play can be accessed by tapping the App Store or Play Store icon on your iOS or Android devices.

The app can help to monitor your current condition and achieve your results.

System Requirement

For the requirement of OS version, please find on App Store or Google Play when you download the app. Please contact your local customer service or place of purchase for assistance. Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data.

Pairing with your mobile device

1. Turn on the Bluetooth function on your mobile device.
2. After the end of measuring mode or memory mode, "Off" is shown on the display of the meter. The Bluetooth indicator will turn to flash which means that the Bluetooth of meter is turned on automatically.
3. Follow the instructions of the HeartsBio app to pair the device. (Ex. Search to find the meter then add it into the app.)
4. After successfully pairing the app with the device, the Bluetooth function on the meter should be on before transmitting data to the HeartsBio app.

Bluetooth Indicator on the Meter:

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

WARNING:

- While the meter is in transmission mode, it will be unable to perform tests.
- Make sure your device supports Bluetooth Smart Technology. Also make sure the Bluetooth setting on your device is turned on and the meter is within the receiving range before transmitting the data. Please find OS version requirement on App Store or Google Play when you download the app.
- The Bluetooth functionality is implemented in different ways by the various mobile device manufacturers; compatibility issues between your mobile device and the meter may occur.
- The Bluetooth data transmission is only intended for archiving historical patient data, and not for active patient monitoring.




MAINTENANCE

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. The “” **symbol along with display messages:** The meter is functional and the result remains accurate, but it is time to change the batteries.
2. The “” **symbol appears with E-b,  and Low:** The power is not enough to do a test. Please change the batteries immediately.

Replacing the Battery

To replace the batteries (I), 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 battery does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the batteries according to your local environmental regulations.

Caring for Your Meter

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash and dry your hands thoroughly before and after the measurement.

What is Cleaning and Disinfection?

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), disinfection is the process of killing germs (e.g. bacteria and viruses). Routine cleaning/disinfecting should be undertaken once a week.

When to clean and Disinfect the Meter?

Clean the meter when you see any dirt on it. You should clean and disinfect the meter once a week to help prevent infection.

How to clean and Disinfect the Meter?

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt or blood or any other body fluid with the wipe. Use a second wipe to disinfect the meter. **Do NOT use organic solvents to clean the meter.**

For meter cleaning and disinfection We recommend the disinfecting wipes / towelettes from below. The following product with isopropyl alcohol as the active ingredient has been shown to be safe for use with the heartscore C1 monitoring system:

Micro-Kill+™ (Micro-Kill Plus™) by Medline (EPA Reg. No. 59894-10-37549)

To obtain disinfecting wipes and other information, please contact Medline at 1-800-MEDLINE (1-800-633-5463) or visit <https://athome.medline.com/>

You can also purchase it at Amazon (www.amazon.com) or Walmart (www.walmart.com).

Cleaning and Disinfecting Procedures

1. Wipe all meter's exterior surface display and buttons by three passes vertically and three passes horizontally with a disinfecting wipe. Be sure to clean the areas around slots and openings, while being careful not to get any excess liquid in them.
2. Disinfect the meter in the same way as cleaning with another disinfecting wipe.
3. Keep the meter surface wet with disinfection solution for a minimum of 2 minutes for Micro-Kill+™ wipes.



4. Dispose the used wipes. Allow the meter surface to dry completely.
5. Discard the used wipes and never reuse them. Wash your hands thoroughly with soap and water after handling the meter, lancing device and test strips to avoid contamination.

Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact local customer service 1-855-955-1177 (hours of operation: Mon - Fri, 10am to 4:30 pm PST). For assistance outside these hours, please contact your healthcare provider.

This device has been validated to withstand up to 260 cleaning and disinfection cycles using the recommended disinfecting wipe/towelette. The tested number of cycles is estimated by 1 cleaning and disinfection cycles per meter per week for 5 years, the expected life of the meter. The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, whichever comes first.

Stop using the meter if you see any signs of deterioration. For example:

- Meter cannot be turned on
- LCD display cracks or becomes cloudy
- Buttons no longer function
- Meter outer casing cracks
- Scratches or abrasions on meter are higher than acceptable
- Color or paint/printing on housing is abnormal
- Scratches or abrasions on meter are higher than acceptable

Please contact the customer service for a replacement meter if any of the signs of deterioration are noticed.

NOTE:

- Do **NOT** clean and disinfect the meter while performing tests.
- If the meter is being operated by a second person, the meter and lancing device should be decontaminated prior to use by the second person.
- Do **NOT** allow cleaning and disinfecting solution to get in the test slot.
- If you do get moisture in the test strip slot, wipe it away with a corner of tissue.
- Always dry the meter thoroughly before using.
- Do not spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry.

Meter Storage

- Storage conditions: -20°C to 60°C (-4°F to 140°F), between 10% and 93% relative humidity (non-condensing).
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Meter Disposal

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

The meter falls outside the scope of the European Directive 2002/96/EC-Directive on waste electrical and electronic equipment (WEEE).

Caring for Your Test Strips

- Storage conditions: 35.6°F to 86°F (2°C to 30°C) and between 10% to 85% relative humidity. Do **NOT** freeze.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- Touch the test strip with clean and dry hands.
- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Do not reuse test strips.

For further information, please refer to the test strip package insert.

Cleaning and Disinfection of Your Lancing Device

Please refer to your lancing device insert for more information. **The lancing device should be cleaned after each use.**

Important Control Solution Information

- Use only heartscore C1 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 solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 68°F to 77°F (20°C to 25°C). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.

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

MEASUREMENT RESULT READINGS

For β -Ketone Testing

MESSAGE	WHAT IT MEANS
Lo	< 0.1 mmol/L
^{KET} 3.2 mmol/L	0.1 to 8 mmol/L
Hi	> 8 mmol/L

Sample Size: 0.8 μ L

Reaction Time: 10 seconds

System Measurement Range: 0.1 to 8 mmol/L

Hematocrit Range: 10% to 70%

For Total Cholesterol Testing

MESSAGE	WHAT IT MEANS
Lo	< 100 mg/dL
^{CHOL} 150 mg/dL	100 to 400 mg/dL
Hi	> 400 mg/dL

Sample Size: 3 μ L

Reaction Time: 60 seconds

System Measurement Range: 100 to 400 mg/dL (2.5 to 10.3 mmol/L)

Hematocrit Range: 20% to 60%

For Uric Acid Testing

MESSAGE	WHAT IT MEANS
Lo	< 3 mg/dL
^{UA} 50 mg/dL	3 to 20 mg/dL
Hi	> 20 mg/dL

Sample Size: 0.5 μ L

Reaction Time: 15 seconds

System Measurement Range: 3 to 20 mg/dL

Hematocrit Range: 20% to 60%

For Lactate Testing

MESSAGE	WHAT IT MEANS
Lo	< 0.3 mmol/L
LAC 1.2 mmol/L	0.3 to 22 mmol/L
Hi	> 22 mmol/L

Sample Size: 0.8 μ L

Reaction Time: 5 seconds

System Measurement Range: 0.3 to 22 mmol/L

Hematocrit Range: 10% to 65%

Reference Values

For β -Ketone Testing

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/L¹.

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 programme. If your β -Ketone result is between 0.6 and 1.5 mmol/L, this may indicate development of a problem that could 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.

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

For Total Cholesterol Test

Your 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). The measurement unit is based on the actual meter you used.

Total Cholesterol (mg/dL or mmol/L)	
Desirable	< 200 mg/dL (5.1 mmol/L)
Borderline High	200 to 300 mg/dL (5.6 - 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 Cholesterol Education Program. ATP III Guidelines At-A-Glance Quick Desk Reference. National Institutes of Health. National Heart, Lung and Blood Institute. NIH Publication No. 01-3305, May 2001.

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

For Uric Acid Test

Your uric acid readings deliver plasma equivalent results and are displayed in milligrams of uric acid per deciliter of blood (mg/dL) or micromolar of uric acid of blood ($\mu\text{mol/L}$). The measurement unit is based on the actual meter you used.

Reference Values	
Male	3.5 to 7.2 mg/dL (208 to 428 $\mu\text{mol/L}$)
Female	2.6 to 6 mg/dL (155 to 357 $\mu\text{mol/L}$)

Source: National Kidney Foundation (2014).

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

For Lactate Test

The meter provides you with plasma equivalent results and are displayed in millimoles of lactate per liter of blood (mmol/L).

Desirable Range	
Lactate	0.3 to 2.4 mmol/L

Source: Mary A. Williamson, L. Michael Snyder, 10th ed, 2015. Wallach's interpretation of diagnostic test: pathways to arriving at a clinical diagnosis. Philadelphia: Wolters Kluwer.

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

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	Appears when the batteries are too low.	Replace the batteries immediately.
E-U	Appears when a used test strip is inserted.	Repeat with a new test strip.
E-2	Appears when the strip/code chip 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.
E-t	Appears when ambient temperature is above or below system operation range.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above 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 the customer service for assistance.
E-F	Appears when 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 the local customer service for assistance.


E-8	Appears when the code chip is not inserted before testing or the meter does not support certain parameters.	Check that the code chip is inserted for coding correctly. Make sure the code chip you used supports the parameter. If the problem persists, please contact the local customer service for assistance.
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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 services.

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

POSSIBLE CAUSE	WHAT TO DO
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (3 minutes 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 services.

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 vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature 68°F to 77°F (20°C to 25°C) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer services.
Improper working of meter and test strip.	Please contact customer services.

SPECIFICATIONS

Model No.: C1

Dimension & Weight: 90.3 (L) x 52.3 (W) x 18 (H) mm, 58 g

Power Source: Two 1.5V AAA alkaline batteries

Display: LCD with backlight

Memory: 1000 measurement results with respective date and time

External Output: Bluetooth

Auto electrode insertion detection

Auto reaction time count-down

Auto switch-off after 3 minutes without action

Temperature Warning

Operating Condition:

50°F to 104°F (10°C to 40°C), 10% to 85% R.H. (non-condensing)

Meter Storage / Transportation Conditions:

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

Strip Storage / Transportation Conditions:

β -ketone / total cholesterol / uric acid / lactate: 35.6°F to 86°F (2°C to 30°C), between 10% and 85% R.H. (non-condensing)

Measurement Units:

β -ketone test: mmol/L

Total cholesterol test: either mg/dL or mmol/L

Uric acid test: either mg/dL or μ mol/L

Lactate test: mmol/L

Sample Volume:

β-ketone: 0.8μL

Total cholesterol test: 3 μL

Uric acid test: 0.5 μL

Lactate test: 0.8 μL

Measurement Range:

β-ketone test: 0.1 to 8 mmol/L

Total cholesterol test: 100 to 400 mg/dL (2.5 to 10.3 mmol/L)

Uric acid test: 3 to 20 mg/dL (179 to 1190 μmol/L)

Lactate test: 0.3 to 22 mmol/L

Reaction Time:

β-ketone test: 10 seconds

Total cholesterol test: 60 seconds

Uric acid test: 15 seconds

Lactate test: 5 seconds

Expected Service Life: 5 years

Operating Altitude: Up to 3500m, for indoor use

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.

heartscare C1

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For self-testing.
Read instructions before use.
For *in vitro* diagnostic use.