HumaSens2.0plus

Starter Pack

User Manual

3 in 1

GLU – CHOL – UA

Human

Diagnostics Worldwide

Table of Contents

Chapter 1 HumaSens2.0^{plus} Multi-Parameter System

1.1 Introduction

Thank you for choosing HumaSens2.0^{plus}. HumaSens2.0^{plus} Multi-Parameter System (meter) is based on electrochemical biosensor technology, which can check your blood glucose (GLU), total cholesterol (CHOL), and uric acid (UA) fast and convenient. Please read this user's manual carefully before using this product. If you need any further assistance, please contact your local customer service.

Intended Use

The HumaSens2.0^{plus} Starter Pack contains a hand-held multi-parameter instrument. In combination with the HumaSens^{plus} test strips it is used for the quantitative determination of blood glucose, total cholesterol and uric acid levels in human capillary whole blood from the finger prick. It is used to monitor the level of glucose, total cholesterol and uric acid. The HumaSens2.0^{plus} Starter Pack is designed as a semi-automated system. For near patient testing by healthcare professionals and laboratory testing by laboratory professionals.

The HumaSens2.0^{plus} System is plasma-calibrated by reference instruments which are traceable to the following standard reference materials and methods:

Test	Standard	Method
Glucose	NIST SRM 917	Glucose Oxidase
Total Cholesterol	NIST SRM 911	Abell/Kendall
Uric Acid	NIST SRM 913	Uricase/UV

Warning: Please carefully read the instructions and test procedures in this user's manual before using. Users should consult a healthcare professional before making any important medical decision.

1.2 Contents of the Starter Pack

The items included in the HumaSens2.0^{plus} Starter Pack:

(please check the meter outer box for exact detail)

Description	**Quantity**
HumaSens2.0^{plus} Multi-Parameter Meter *(with a CR2032 3V battery)*	1
User's Manual	1
Quick Guide	1
Pouch	1

Optional *(not included in the standard kit package, please contact your local distributor for ordering)*	**REF**
Glucose Test Strips Blue HumaSens2.0 / HumaSens2.0^{plus} / HumaSens / HumaSens^{Plus} (50) 2 x 25 pcs.	17562
Glucose Control HumaSens2.0 / HumaSens2.0^{plus} / HumaSens* / HumaSens^{Plus}* (*BLUE GLU strip) 2 x 2 ml	17562/10
Uric Acid Test Strips HumaSens2.0^{plus} 1 x 25 pcs.	17566
Uric Acid Control Solution HumaSens2.0^{plus} 2 x 2 ml	17566/10
Total Cholesterol Test Strips HumaSens2.0^{plus} 2 x 10 pcs.	17567
Total Cholesterol Control Solution HumaSens2.0^{plus} 2 x 1,5 ml	17567/10

1.3 Labelling and Information


Use by


Recap immidiately after use

Operation temperature limitation


Manufacturer

Use within 3 months after initial opening

Storage and transportation temperature limitation


Do not reuse


Attention

Storage and transportation relative humidity limitation


Keep dry

In-vitro diagnostic


Comply with WEEE Directive 2012/19/EU

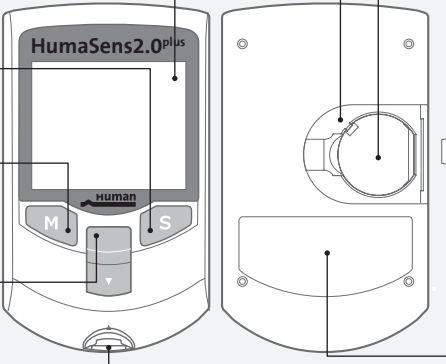

Keep away from sunlight

Lot number


Read instructions

Serial number

1.4 HumaSens2.0^{plus} Meter
Meter (Front Side & Back Side)



LCD Screen:
Display operating information and test results

Right "S" Button:
Confirm and set up

Left "M" Button:
Enter memory mode
Press long to turn off

Ejection Button:
Remove test strip

Test Port:
Insert test strip

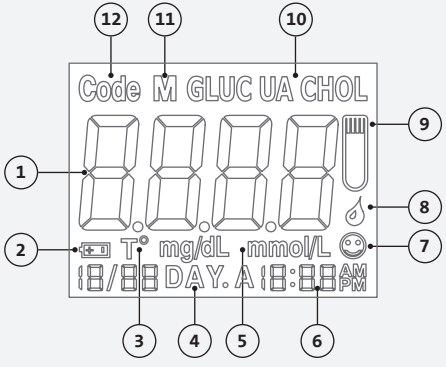
Serial Number Sticker

Battery:
3V lithium battery (CR2032)
Please remove the plastic tab before using

Battery Lid:
Slide to open.

Meter Label:
Information about meter

1.4 LCD Screen Display
Information and test result display



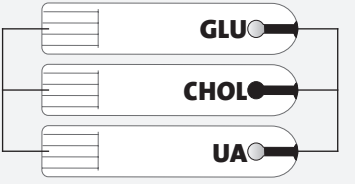
1. Result Area
2. Low Battery
3. Temperature Icon
4. Average (GLU)
5. Unit Icon
6. Time
7. System Check
8. Blood Loading Icon
9. Strip Loading Icon
10. Test Mode Icon
11. Memory Mode Icon
12. Code Number Icon

1.4 Alert Tones

- Normal Alert: a short “beep”
- Warning Alert: 3 short “beeps”
- Turning On/Off: a long “beep”

1.4 Test Strip
GLU – Glucose
CHOL – Cholesterin
UA – Uric Acid

Electronic Contact Bars:
Insert this end into meter test port.

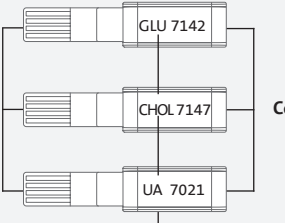


Sample Inlet:
The whole blood sample and control solution will be drawn from here.

Note:
Please fill up the round window with blood sample CHOL test and avoid disconnecting in the process.

1.4 Code Strip
The code strip is used to code the meter.
Please do the coding step when you use a new vial of strip.

Contact Bar:
Insert this end into the test port of the meter.



Code

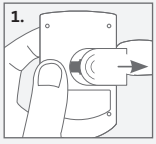
Test Mode

Chapter 2 Setting the Meter

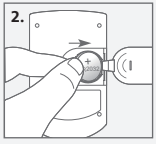
2.1 Installing/Replacing the Batteries

Please remove the plastic tab under the battery before using. This instrument uses a CR2032 3V lithium battery. Do not use or install different types of battery. It will damage the meter.

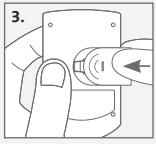
Installing Instructions:



Slide to remove the battery lid.



Insert the battery with the positive (+) side up.



Slide back the battery lid.

Note: Dispose the batteries according to your local environmental regulations.

2.2 Set Date, Time and Units

Press "S" button for over three seconds. You will hear one "beep" for entering the setting mode, then follow the instruction below to set up.

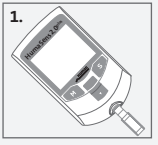
Setting order: **Year/Month/Date/Hour/Minute/Units**

- Click "M" button to advance one unit.
- Click "S" button to enter next setting and to end setting mode.
- The meter will turn off automatically after setting.

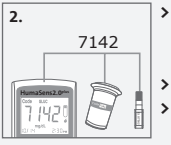
Note: Adjusting the correct time and date is important to help managing your health records.
Selectable units: "mg/dl" and "mmol/l"

2.3 Code the Meter

Each vial of strips has a code strip to code your meter. Code your meter when you first use it or open a new vial of strips. With the Auto Strip Identification function, once you code your meter, you do not have to switch the test mode every time you perform a test.



- Make sure the meter is off.
- Then insert the code strip into the test port.



- The Code number will show on the screen. Make sure the numbers on screen, code strip, and strip vial label are the same.
- Then remove the code strip.
- ☺ appears on the screen for a short moment, indicating that the meter has been successfully coded to the respective test mode and test strip lot.

Chapter 3 How to Perform a Test

Please follow the instruction carefully to ensure an accurate test result.

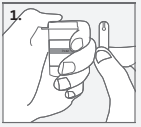
3.1 Before Testing

Materials you need to perform a test:

- HumaSens2.0^{plus} Meter
- HumaSens2.0^{plus} Test Strip
- Lancing Device/Lancets (not provided)
- Tissue or cotton ball with 75% ethanol or disinfection wipes for cleaning the sampling area before test.

Note: Wash your hands with water and soap thoroughly before and after testing, and make sure the sampling area is dry before testing.

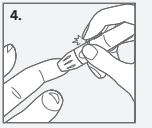
3.2 Perform the Test



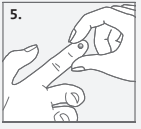
- Take out a test strip and close the vial immediately, or other strips will get damp.

- Insert the strip contact bar into meter test port.
- The meter will turn on automatically.

- Make sure the code numbers are the same on screen and strip vial label.
- You can start testing after 🩸 appears.
  Note: If 🩸 does not appear, remove the unused strip and repeat step 2.



- The patient's finger must be warm, dry at surface, clean, including being free from substances such as hand cream.
- Use a single use lancet (not provided) on the patient's finger to get a droplet of blood.

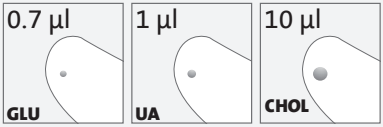


- Wipe off the first drop of blood.
- Massage your finger gently until a round drop of blood forms.

- Touch the blood sample with strip inlet.
- The sample will be drawn automatically.

Note: Make sure you have enough sample for the test.
If the blood smears, please wipe off and squeeze another drop of blood.

3.2 Perform the Test



Note: Insufficient fill up of blood sample could lead to inaccurate or failed test result.

- After count down of the respective tests time need (seconds), the result will display on the screen.
- Then eject the used strip into a biohazard waste container.
- The meter will turn off automatically.

Note:

- Please code your meter when you first use or open a new vial of strips. If you have any question, please read Chapter 2.3.
- Please follow the instruction while testing. Improper operation may result in inaccurate test result or damage the system.
- Please finish the test within 5 minutes or the meter will turn off automatically.
- The meter will not turn on if you insert the wrong end or wrong side of strip.
- Do not use expired strip.
- Apply the blood sample to the correct position on the test strip.

Warning :

- Lancets (not provided) cannot be reused.
- Please always use certified lancets (not provided) to ensure safety.
- Do not reuse test strips.
- Healthcare professionals using this system on multiple patients should follow the infection control procedures approved by their facility.

3.3 Care after Testing

1. Please follow the instruction to discard used lancets into an appropriate biohazard container.

› Discard the used lancet (not provided) into biohazard waste container.

2. Record your test result.

3. Store your instrument, strips and other items in a clean cool and dry environment. (Please check the specifications in Chapter 8.)

Test Mode	Special Messages	
	Lo	Hi
Glucose	< 20 mg/dl (1.10 mmol/l)	> 600 mg/dl (33.3 mmol/l)
Uric Acid	< 3 mg/dl (0.18 mmol/l)	> 20 mg/dl (1.19 mmol/l)
Total Cholesterol	< 100 mg/dl (2.59 mmol/l)	> 400 mg/dl (10.35 mmol/l)

Note:

- Please check your meter performance regularly.
- Dropping, bumping or other violent impact may damage the meter or cause malfunction.
- Do not use the meter in an environment with possible magnetic, electromagnetic, and radioactive interferences.

Warning :

- Do not disassemble the meter for any reason.
- Please follow local regulations to discard used test strips, lancets and batteries.
- Used test strips, lancets and any other materials which have been in contact with blood should be treated as potential biohazards.
- If a user has an infectious disease, the used test strips and other materials could be sources of infection.

Chapter 4 Meter Memory Function

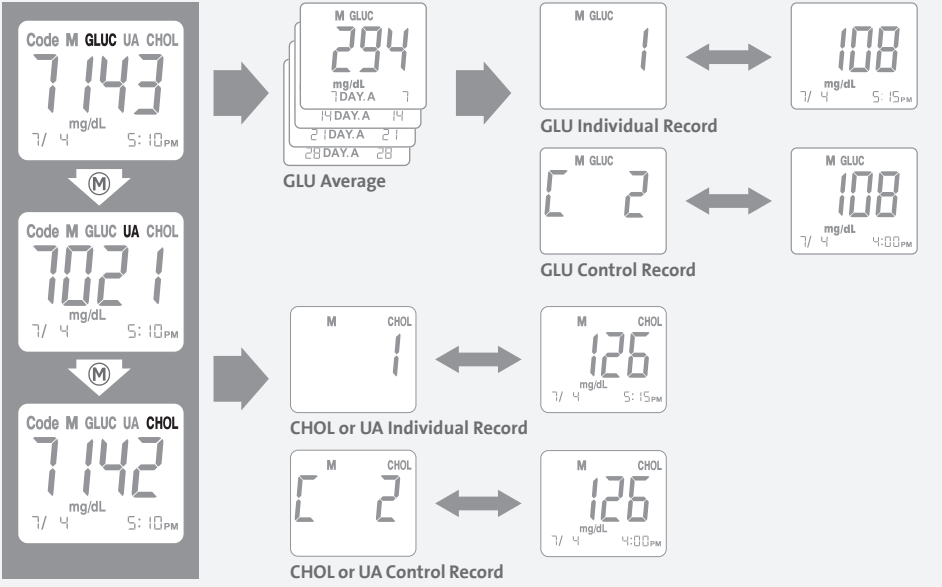
The meter can record 360 results of glucose, 50 results of total cholesterol, and 50 results of uric acid (includes test results and control solution test results). It can also count 7-, 14- 21- and 28-days average for glucose.

The latest test result will replace the oldest when the records exceed maximum memory capacity. The memories start record from M1 to M360 or M1 to M50.
Stored results are unaffected by low battery power or a battery change.

Directions for Checking Memories:

1. No test strip in the meter.
2. Press "M" button for 3 seconds till a short "beep" to enter the memory mode.
3. After a full display on screen, press "M" button to switch between GLU, CHOL, and UA mode.
   Press "S" button to select.
4. In GLU memory mode, it will display 7-, 14-, 21-, 28-days average first then individual record.
   CHOL and UA memory mode will show individual record directly.
   Press "S" button for next test record, and press "M" button for previous record.
5. Once you enter one memory mode, you cannot switch.
   Press "M" button for 3 seconds or wait for the meter to turn off. Then repeat step 1—3 to select another test mode.

Note: The control results are not included in the average.


Code M GLUC UA CHOL
7143
mg/dL
7/ 4 5:10PM
M
Code M GLUC UA CHOL
7021
mg/dL
7/ 4 5:10PM
M
Code M GLUC UA CHOL
7142
mg/dL
7/ 4 5:10PM
M GLUC
294
mg/dL
7DAY.A 7
14DAY.A 14
21DAY.A 21
28DAY.A 28
GLU Average
M GLUC
1
GLU Individual Record
M GLUC
108
mg/dL
7/ 4 5:15PM
M GLUC
C 2
GLU Control Record
M GLUC
108
mg/dL
7/ 4 4:00PM
M CHOL
1
CHOL or UA Individual Record
M CHOL
126
mg/dL
7/ 4 5:15PM
M CHOL
C 2
CHOL or UA Control Record
M CHOL
126
mg/dL
7/ 4 4:00PM

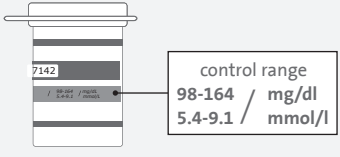
CHAPTER 5 Control Solution Test

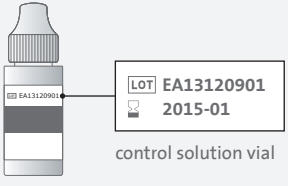
HumaSens2.0^{plus} control solution is used to check the performance of the HumaSens2.0^{plus} Multi-Parameter System. The system performs adequately when control test falls within the range listed on the respective test strip's vial label.

The system should be checked:

- If you suspect that the meter or test strips are not working properly.
- When the test result is or seems unusual, inaccurate or inconsistent.
- Any time you droped or bumped the meter.

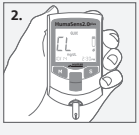
Control solution range is shown as follow: Please check your strip vial label for exact range.





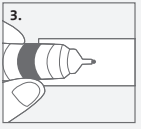
Directions:

- Insert an unused strip into the meter.



- Press "M" button for 3 seconds to enter the control solution mode.

3.

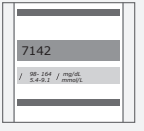


› Shake the vial well and discard the first three drops of control solution. And put one drop onto a clean, non-absorbant surface.

4.

› Touch the control solution with strip sample inlet.

5.



› The result will display after countdown.
› Compare the result with the range listed on test strip vial.

Note:

› Please read this user manual plus the package inserts for HumaSens2.0^{plus} strip and HumaSens2.0^{plus} control solution before use.
› Do not reuse the test strip.
› Newly opened vials of control solution and test strips must be marked with the opening date.
› Close the strip vial lid completely after use.
› Do not use the meter if the control range does not fall in the correct range.
› If the control test keeps displaying wrong results (outside the control range), please contact an authorized distributor for help and service. Do not continue to use the meter for patient sample measurement.
› Control solutions are not included. Please contact an authorized distributor to order.

Chapter 6 Care and Maintenance

6.1 Storing your Meter

The meter will be affected by improper storage and handling. Please follow the instructions and check Chapter 8 for specifications.

- Please avoid bumps or other strong forces, it may cause damage to the meter.
- Do not use this meter in a very dry environment, especially if synthetic materials are present. It may cause damaging static discharges in a dry environment.
- Do not use the meter near the source of electromagnetic radiation, e.g. electrical or electronic equipment. It may interfere with meter operation.
- Do not store the strips in high humidity environment, or expose them directly to the sunlight.
- Do not freeze or refrigerate the meter and strips.
- Keep the meter clean by wiping the exterior surfaces with tissues or lint-free cloth.
- Keep your and the patient's hands dry and clean while handing the strips and performing the test.
- Do not disassemble the meter for any reason.

6.2 Cleaning and Caring for Your Meter

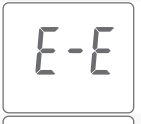
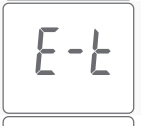
Gently wipe the meter surface with a soft lint-free cloth slightly damp with one of the following cleaning solutions:

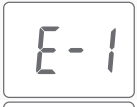
- 75% alcohol.
- Super Sani-Cloth disposable wipes.
- Mild dishwashing liquid with water.
- 10% household bleach solution made the same day. (1 part bleach with 9 parts water)

Note:

- Do not use any wet cloth or liquid to clean your meter.
- Do not allow any liquid run in or around the test port and battery cover.
- Make sure the meter is completely dry before use.

Chapter 7 Error Message and Trouble Shooting

Message	Cause	Solution
	› Problem with code strip. › Strip inserted in an improper way. › Problem with test strip.	Repeat the coding procedure and ensure the code number is the same in label, code strip and screen. Insert the strip again. If the problem persists, please contact the distributor for service.
	› The power of the battery is too low to run a test.	Replace with a new battery immediately.
	› Problem with code strip. › Code strip inserted in an improper way.	Repeat the coding procedure and ensure the code number is the same in label, code strip and screen. If the problem persists, please contact the distributor for service.
	› The temperature was below or above the meter operating range.	Repeat the test after the meter has reached to a temperature within the operating range. If the problem persists, please contact the distributor for service.
	› An used test strip or a damp strip.	Review the instructions and try again with a new test strip. If the problem persists, please contact the distributor for service.

	› Uncompleted test caused by removing the test strip during the measurement.	Review the instructions and try again with a new test strip. Please don't remove the strip before the test is completed.
	› Problem with strip.	Review the instructions and try again with the same test strip. If the problem persists, please contact the distributor for service.
	› Use of an improper code strip.	Repeat the coding procedure and ensure the code number is the same in label, code strip and screen. If the problem persists, please contact the distributor for service.
	› Not enough sample volume for the test.	Take a new strip and make sure you have enough sample volume for your test. Repeat the test again. If the problem persists, please contact the distributor for service.
	› Test result is higher than the range listed in Chapter 8.	**1.** Review the instructions and try again with a new test strip. **2.** If the problem persists, please call local authorized distributor for help.
	› Test result is lower than the range listed in Chapter 8.	**1.** Review the instructions and try again with a new test strip. **2.** If the problem persists, please call local authorized distributor for help.

Chapter 8 Specifications

System Accuracy	· ±15% at glucose level ≥100 mg/dl (5.55 mmol/l); · ±15 mg/dl (0.83 mmol/l) at glucose level < 100 mg/dl (5.55 mmol/l); · ±15% at uric acid level ≥ 5 mg/dl (0.30 mmol/l); · ± 0.75 mg/dl at uric acid level < 5 mg/dl; · ±20% at total cholesterol level ≥ 150 mg/dl; · ±30mg/dl at Total Cholesterol < 150 mg/dl
Principle	· Glucose & total cholesterol: electrochemical biosensor; · uric acid: electrochemical sensor
Calibration	Plasma-equivalent
Test Sample	Fresh Capillary Whole Blood
Measuring Time	· GLU: 5 seconds; · CHOL: 26 seconds; · UA: 15 seconds
Measuring Range	· GLU: 20 – 600 mg/dl (1.1 – 33.3 mmol/l); · CHOL: 100 – 400 mg/dl (2.59 – 10.35 mmol/l); · UA: 3 – 20 mg/dl (0.18 – 1.19 mmol/l);
Sample Volume	· GLU: 0.7 µl · CHOL: 10 µl · UA: 1 µl
Hematocrit Range	· 25%–60% (Glucose) · 30%–55% (Uric acid) · 35%–50% (Total cholesterol)
Storage Condition	4–30˚C (39–86˚F)
Operation Temperature	10–40˚C (50–104˚F)
Relative Humidity	10–90%
Memory	460 Test Results (GLU: 360; CHOL: 50; UA: 50)
Battery Type	One 3V (CR2032) lithium battery
Battery Life	Approximately 1,000 tests
Dimensions	88x52x16 mm
Weight	About 50 g (with battery)
Altitude Range	Up to 10000 feet/3048 m for glucose, uric acid and total cholesterol

Note: Please refer to the strip insert for accuracy, precision, limitation, and other important information.

Chapter 9 Limitations

9.1 All Tests

- Use only fresh capillary whole blood taken from a finger. Do not use serum or plasma.
- HumaSens2.0/HumaSens2.0^{plus} Glucose test strips and HumaSens2.0^{plus} Uric Acid and Total Cholesterol test strips are all plasma calibrated to be used with whole blood; testing with serum or plasma sample will give falsely high results.
- For in-vitro diagnostic use only (external use only).
- HumaSens2.0/HumaSens2.0^{plus} test strips are designed for single use only. Do not reuse.
- Do not perform a test while a mobile phone is used in the vicinity to prevent potential electronic signal interference.
- Hematocrit (Hct) levels outside the specifed range cause incorrect measurement results.
- Please consult a medical professional if you don't know the Hct level.
- In situations of decreased peripheral blood fow (examples would include but are not limited to severe dehydration, shock, or a hyperosmolar state [with or without ketosis] and hypertension), the test results may be falsely low.

9.2 Limitations of Blood Glucose Test

- Do not use the test strips for the testing of newborns.
- The test strips react with only D-glucose and do not react with other sugars which may be present in blood.
- HumaSens2.0/HumaSens2.0^{plus} Glucose test strips may be used at altitudes up to 10000 feet/3048 m without an effect on test results.
- In a clinical setting, when venous whole blood is used for the test, it can be collected into heparin-containing test tubes within 30 minutes after drawing. The results may be as much as 7% lower than a capillary sample.
- Samples from patients undergoing oxygen therapy may yield falsely low results.
- Lipemic samples: Cholesterol levels up to 326 mg/dl (8.43 mmol/l) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with the HumaSens2.0/ HumaSens2.0^{plus} Glucose test strips.

9.3 Limitations of Uric Acid Test

- HumaSens2.0^{plus} Uric Acid test strips may be used at altitudes up to 10000 feet/3048 m without an effect on test results.
- Lipemic samples: Cholesterol levels up to 322 mg/dl (8.34 mmol/l) do not affect the results. Triglycerides over 1500 mg/dl (16.34 mmol/l) and grossly lipemic samples have not been validated and are not recommended for testing with the HumaSens2.0^{plus} Uric Acid test strips.

9.4 Limitations of Total Cholesterol Test

- HumaSens2.0^{plus} Total Cholesterol test strips may be used at altitudes up to 10000 feet/3048 m without an effect on test results.

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