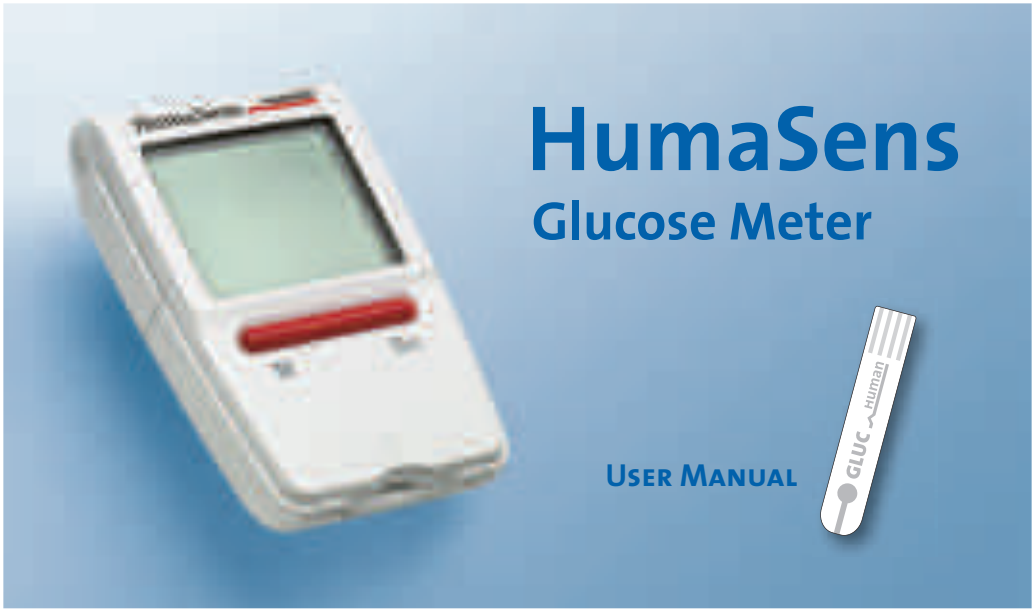


Human

Diagnostics Worldwide

Table of Contents

Chapter 1 HumaSens Glucose Meter

1.1 Introduction

The HumaSens Glucose Meter by HUMAN provides you with accurate, plasma-calibrated results based on electrochemical sensor technology. This system measures blood glucose levels precisely and displays results within 10 seconds.

Intended Use:

The HumaSens Glucose Meter is designed to measure the blood glucose levels in whole blood and must only be used with HumaSens Glucose test strips. The test strips are for self-testing outside the body (in vitro diagnostic use). The system is also suitable for use by healthcare professionals. It should be used only for testing glucose with fresh capillary blood samples taken from a fingertip.

The HumaSens Glucose test strips are calibrated against the Kodak EKTACHEM DT60 analyzer using venous plasma. Calibration can be referenced to the NIST SRM 917b standard.

Please read the entire user manual carefully before using the HumaSens Glucose Meter to test your blood glucose level. This user manual guides you through the operating procedures with illustrated directions and helps you find the required information.

1.2 Contents of the Kit

Please check the HumaSens Glucose Meter package for the following items:

Description	Qty.
HumaSens Glucose Meter	1
HumaSens Glucose test strips	(10 pcs/vial)
Code Strip (glucose)	1

HumaSens Glucose control solution	(4 ml)
HumaSens user manual	1
HumaSens quick guide	1
Lithium battery 3V (CR2032)	1
Pouch	1
Lancets	(10 pcs/bag)
Lancing device	1
Lancing device user instructions	1
Glucose test strip user instructions	1
Glucose control solution user instructions	1
Patient diary	1

Optional: (not included in the standard kit package, please contact your authorized distributor for ordering.)

	REF
HumaSens Glucose test strips (2x25 strips/box)	17542/25
Lancets (100 pcs)	17543
HumaSens Glucose control solution (2x4 ml)	17545
PC connector cable	17549
PC software	17550
Battery pack	17548

1.3 Symbols


Do not re-use


Keep dry


Storage temperature


Product conforms to directive 98/79/EC

Manufacturer


Expiry date


Consult manual


Attention


Recap immediately after use


Use within 3 months after initial opening

EC REP EC representative

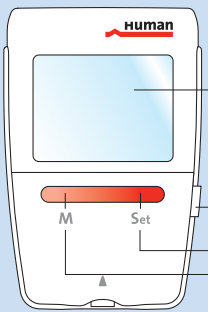
REF Catalogue number

IVD In vitro diagnostic device

LOT Lot number

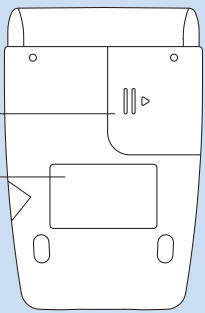
1.4 System Components

Glucose Meter (Front View)



Screen

Glucose Meter (Back View)



Battery cover

Type plate

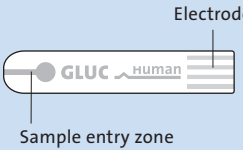
PC connection port

Set button

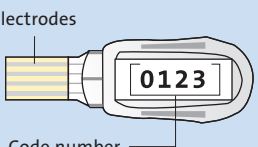
M button

Strip port

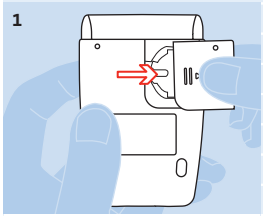
Glucose test strip



Code strip



1



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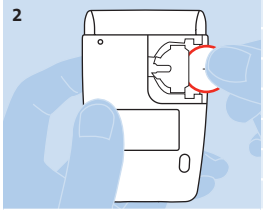

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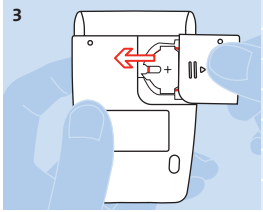


Before first use, remove the transparent protective foil from the battery.

2.1 Replacing the Battery

The battery is located inside the meter. Use only 3V lithium batteries (CR2032). Do not use with different types of batteries, as this may damage the electronics of the meter.

Instructions

1. Remove the back cover by pulling it to the side.

2. Insert a new battery into the battery socket with the "+" side facing up.

3. Replace the battery cover.

2.2 Set Date, Time and Units

The setup has to be completed before first use or after a battery change. Press and hold the "Set" button for at least two seconds. The meter will beep once and enter the setup mode.

In setup mode, the LCD screen of the meter shows all setting options consecutively, starting with a flashing year number:

1. Set the Year

A. When the meter enters setup mode, the year will flash on the screen.

B. Click the "M" button to advance in one-year increments to set the correct year.

C. After setting the desired year, click the "Set" button again, and the meter advances to the month setting.

2. Set the Month

A. Click the "M" button until the correct month appears.

B. Click the “Set” button, and the day segment starts flashing.

3. Set the Day

A. Click “M” button until the correct day appears.

B. Click the “Set” button, and the hour segment will start flashing.

4. Set the Hour

A. Click “M” button until the correct hour appears.

B. Click the “Set” button, and the minute segment will start flashing.

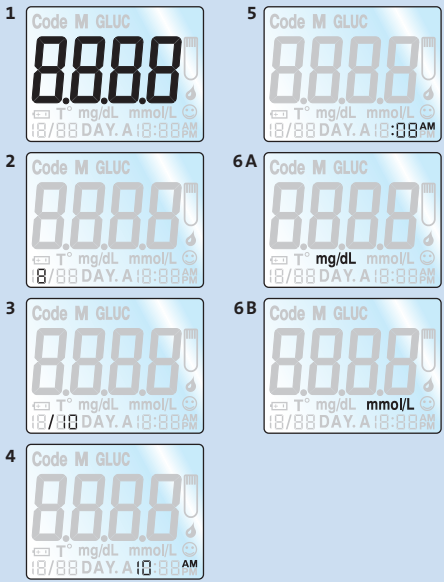
5. Set the Minute

A. Click the “M” button until the correct minute appears.

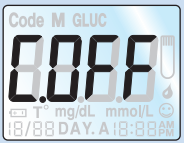
B. Click the “Set” button, and the measurement unit segment starts flashing.

6. Set the Measurements Units

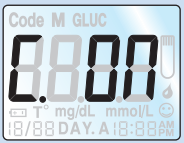
A. A flashing “mg/dl” will display on the screen.



7 A



7 B



B. Pressing the “M” button will switch the unit of measure between “mg/dl” and “mmol/l”. Click the “Set” button and the meter advances to patient condition index setting.

7. Enable/Disable the Patient Condition Index

A. A flashing “C.OFF” or “C. ON” will appear on the screen. This indicates whether entering the patient condition index during measurement mode is disabled or enabled.

B. Click the “M” button to switch between disabled and enabled. After the meter settings are complete, press the “Set” button. “OFF” will be displayed on the screen and the instrument will shut down.

Note:

Before each test, please make sure the preferred unit of measurement is set. Make sure that the sequence of setup is completed, or the settings will not be stored.

2.3 Coding the Meter

The HumaSens Glucose Meter must be coded before testing with HumaSens test strips for the first time, or every time a new lot of glucose test strips is used. Each vial of glucose test strips has an assigned code number. The code strip is packaged with the test strips and used to code the meter.

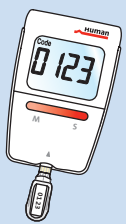
1

Procedure:

1. Make sure that the code number on the code strip is the same as on the glucose test strip vial.

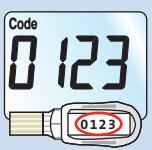
2. Insert a code strip into the test port of the meter. A code number will appear on the screen.

2



3. Make sure the code number on the screen is the same as the code number on the code strip and on the test strip vial. Remove the code strip. "☺" should appear on the screen, indicating that the meter has been successfully coded to the respective test strip lot.

3



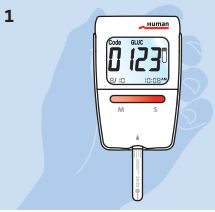
Caution:

If "E-E" appears on the screen during the coding procedure, there may be a problem with the code strip or a wrong category code strip is being used. Check that the correct strip type is being used. Perform the coding procedure again, using a different code strip if necessary. If "E-E" continues to appear, please contact your authorized distributor for service.

2.4 Control Test

The purpose of HumaSens Glucose control solution is to check the performance of the HumaSens Glucose Meter. The system is performing correctly if the control test result falls within the indicated control range listed on the test strip vial. Only use HumaSens Glucose control solution (REF 17545).

1

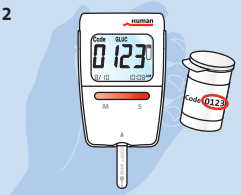


A control should be performed:

› If the meter is being used for the first time or a new lot of test strips is being used (indicated by a different code number).

› If you suspect that the meter or test strips are not working properly.

2

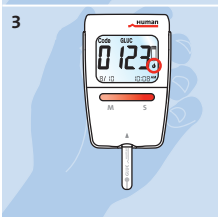


› Any time you see repeated unexpected blood glucose test results.

› Any time you drop or bump the meter.

› You should check system performance with the HumaSens Glucose control solution regularly or anytime you suspect that test results are inaccurate.

3



1. Insert a test strip into test port. The meter will switch on automatically.

2. The code number will appear on the screen. Make sure the code number is the same as the one on the test strip vial.

3. A blood drop symbol flashing on the screen means the system is ready for sample loading.

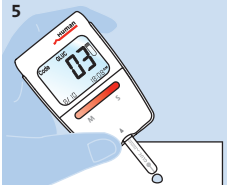
4. Shake the control solution vial well, then open the cap and discard the first three drops. After cleaning the dispensing tip with a tissue, drop some control solution onto a clean, non-absorbent surface.

5. Bring the sample inlet of the test strip in contact with the drop of control solution until the meter beeps. The screen will display a countdown from 10 seconds.

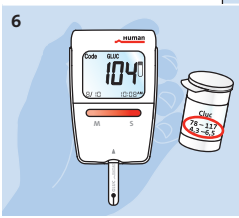
6. After counting down, the screen will display the control solution test result. Compare the test results to the control range shown on the test strip vial.

4

5



6



Note:

> Please read this user manual and the package insert for HumaSens control solution before use.

> The vial should be shaken well before use.

> Mark the freshly opened vials of control solution and test strips with the opening date.

> If the test results are outside the control range, repeat the test. If the result is still out of range, please contact your authorized distributor for service. Do not continue to use the meter for blood glucose measurement.

> Do not reuse the test strips and always close the cap of the test strip vial tightly after use.

3.1 Before Testing

Please follow these step-by-step instructions to ensure accurate test results. Materials required to perform a blood glucose test include:

> HumaSens Glucose Meter

> HumaSens Glucose test strip

> Lancing device

> Lancet

> Soap and water for thorough skin cleaning.

Procedure:

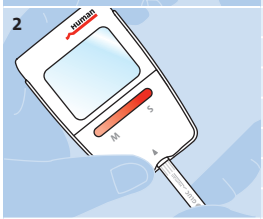
Load the lancing device with a lancet and adjust the desired penetration depth according to the lancing device manual. Clean your hands as described.

1

1. Take a test strip from the vial. Immediately recap the vial to keep the strips dry.

2. Fully insert the electrode end of the test strip (label side facing upwards) into the strip port of the meter. The meter will switch on automatically and the code number appears on the screen.

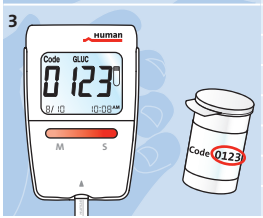
2



3. Make sure the code number on the screen is the same as the one on the test strip vial. If it is not, remove the test strip. Recoding the meter is necessary (described in section 2.3.)

4. If the patient condition index has been enabled during setup, one of the following indices will appear on the screen: “BEF” (before meal), “AFT” (after meal), or “ACT” (after activity). Pressing the “M” button will alternate between these indices (see illustrations on the following page).

3



Note:

> A measurement must be performed within 3 minutes, otherwise the meter switches off automatically. Remove and reinsert the test strip for measurement.

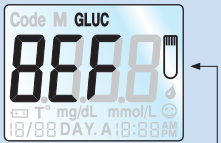
> Do not reuse test strips. Error message “E-U” will be displayed on the screen if a used test strip is inserted.

> If the wrong end of the test strip is inserted, or if the test strip is inserted upside down, the meter will not be activated.

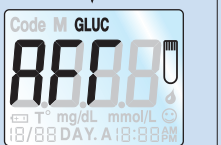
> Lancets must not be reused.

> Always use a lancet supplied by HUMAN to ensure safety.

⚠ **The lancing device must not be shared by multiple users.**



"M" button



"M" button

"M" button

3.2 Test Procedure for Blood Glucose

1. After choosing the appropriate index, press the "Set" button to enable loading the blood sample. Take a blood sample according to the instructions for the lancing device.

2. Touch the drop of blood on your fingertip with the sample entry zone of the strip until the meter beeps, indicating the sample has been drawn into the strip successfully.

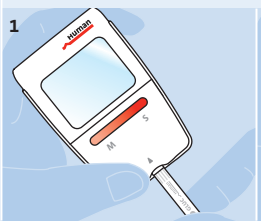
3. The meter will count down from 10 seconds. After 10 seconds the blood glucose concentration will be displayed on the screen.

Note:

> After lancing, make sure to wipe off the first drop of blood to avoid contamination with other body fluids.

> Use the strips before the expiry date and within 3 months after the first opening of the vial.

> Apply the blood sample to the correct position on the test strip.



Special Messages:

Messages	Glucose result
Lo	< 20 mg/dl (1.11 mmol/l)
Hi	> 600 mg/dl (33.3 mmol/l)

> Low or high blood glucose readings may indicate a potentially serious health condition. If your blood glucose reading is unusually low or high, or you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms, please contact a healthcare professional.

3.3 Safety Instructions

1. Improper handling of the meter, such as dropping, bumping or other violent impact may damage the meter.

2. Please keep the meter away from interference from magnetic fields, electromagnetic and radioactive radiation.

Warning:

> Do not disassemble the meter. This will nullify the warranty.

> Please follow local regulations when discarding used test strips, batteries and lancets.

> Used test strips, lancets and any other materials that have come in contact with blood should be treated as potential biohazards.

Chapter 4 Meter Memory Function

The HumaSens Glucose Meter automatically stores up to 360 blood glucose results or control test results. It also provides you with 7-, 14-, 21- and 28-day averages of the blood glucose test results. The memory counts up from M01 through M360 for glucose tests. Stored results are unaffected by low battery power or a battery change.

Memory Recall Procedure:

1. Make sure that no test strip is inserted in the meter.

Chapter 4 Meter Memory Function

2. Press the “M” button once to switch on the meter. After a short “beep” a full display will appear on screen, and the meter enters standby mode.

3. Press the “M” button once again and the meter will switch to memory mode. The 7-day average (7 DAY.A) will be displayed on the screen.

4. Repeated pressing of the “M” button will switch to the 14, 21 and 28-day averages.

5. After the 28-day average, the stored results appear on the screen, starting with M01. The memory number increases by one each time the button is pressed until M360 is reached.

6. Press the “Set” button for over 3 seconds and the meter will switch off after a long “beep”. The meter will also automatically shut down after max. 3 minutes without any input.

Note:

› If 360 test results are already stored and a new one is added, the oldest test result is automatically overwritten. The latest result will be recorded as M01.

Chapter 5 Storage & Handling

The performance of test strips may be affected by improper storage and handling. Please store the test strips and meter carefully according to the specifications listed in Chapter 8.

Note:

1. Store the meter, code strip, test strips and control solution at 10…30°C.

2. Do not store test strips in a high humidity environment or expose them to direct sunlight.

3. Do not freeze or refrigerate the meter or strips.

4. Keep the meter clean by wiping the exterior with a tissue or a lint-free cloth.

5. Handle the strip with clean, dry hands; the skin penetration site for the blood sample should be cleaned and dried thoroughly.

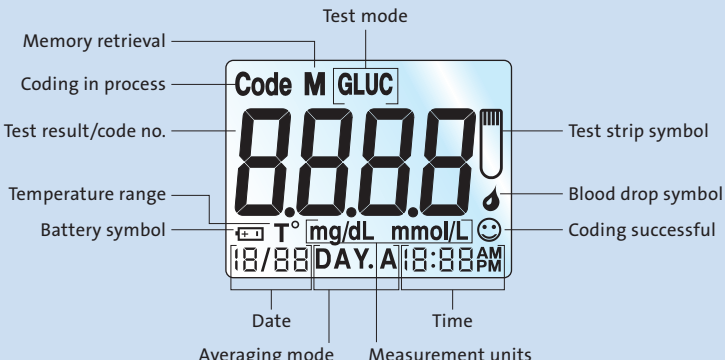
Chapter 6 Icons and Alert Tones

6.1 Screen Icons

Information is displayed on the screen by means of easy-to-understand icons.

6.2 Alert Tones

- Normal Alert Sound: short “beep”
- Warning Alert Sound: 5 short “beeps”
- Switching On/Off Alert Sound: long “beep”



Chapter 7 Error Messages and Troubleshooting

Message	Cause	Solution
E-0	Possible problem with the test strip or code strip.	Repeat the test with a new test strip. If the problem persists, please contact your authorized distributor for service.
E-b	Low battery power.	Replace the battery at once.
Err. 3	Reference voltage or circuit error.	Call your authorized distributor for assistance.
E-E	1. Possible problem with meter self-check. 2. Use of wrong or damaged code strip or the code strip was inserted improperly.	Switch off then retry. If the error appears again, contact your authorized distributor for service. Check that the code number on the meter display matches the code number on the test strip vial. Code the meter and retest, using a new code strip and test strip lot, if necessary. If the error message appears again, please contact your authorized distributor for service.
E-t & Temperature Icon	The temperature is outside the system operating range.	Repeat the test after the meter and the test strip have reached a temperature within the operating range.
E-U	Indicates a used test strip or a temporary or permanent electronic problem.	Repeat the test with a new test strip. If the error message appears again, please contact your authorized distributor for service.
E-9	The test strip was removed prematurely.	Do not remove the test strip until the measurement is completed.
E-A	Meter software problem.	Please contact your authorized distributor for assistance.
E-I	Non-authorized code strip.	Only use HUMAN code strips.
*	No display.	Remove the transparent protective foil from the battery.

Chapter 8 Specifications

System Accuracy:	± 20% at glucose level ≥75 mg/dl (4.17 mmol/l)
	± 15 mg/dl (0.83 mmol/l) at glucose level < 75 mg/dl (4.17 mmol/l)
Principle:	Electrochemical biosensor
Calibration:	Plasma-equivalent
Test Sample:	Fresh capillary whole blood
Measuring Time:	10 seconds
Measuring Range:	20 – 600 mg/dl
	(1.1 – 33.3 mmol/l)
Sample Volume:	Min. 1 µl
Hematocrit Range:	30 – 55%
Strip Storage Temperature:	10...30°C (50...86°F)
Operation Temperature:	10...40°C (50...104°F)
Relative Humidity:	Less than 95%
Memory:	360 test results
Battery Type:	One 3V (CR2032) lithium battery
Battery Life:	Approximately 1000 tests
Dimensions:	86x57x17 mm (LxWxH)
Weight:	Approx. 48 g (incl. battery)
Altitude Range:	Up to 10000 feet/3250 m

Latest information on test limitations can be found in the package insert of the Glucose test strips.

Additional Information for Healthcare Professionals:

› 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.

Since the glucose test strips are plasma calibrated to be used for whole blood, testing with serum or plasma will give falsely high results.

› Samples from patients undergoing oxygen therapy may yield falsely low results.

› In conditions of decreased peripheral blood flow (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.

› Lipemic samples: Cholesterol levels up to 500 mg/dl (12.94 mmol/l) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with HumaSens Glucose test strips.

Product no. 1754000 / Revision date 04/2011-12

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IVD

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