beurer medical instructions for use

Codefree

BLOOD GLUCOSE MONITOR
Step by Step

29. 10. 20:32

95
mg/dL

EINFACHE BEDIENUNG
easy to use

germanlengineering

IVD

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www.beurer.com

CE 0483

Contents

Dear customer,

Thank you for choosing one of our products. Our name stands for high-quality, thoroughly tested products for applications in the areas of heat, weight, blood pressure, blood glucose, body temperature, pulse, gentle therapy, massage and air.

Please read these instructions for use carefully and keep them for later use, be sure to make them accessible to other users and observe the notes they contain.

With kind regards,

Your Beurer team.

Getting to know your instrument

The GL42 blood glucose monitor is intended for fast and simple blood glucose measurement of fresh capillary blood samples, either for self-testing or in a clinical environment by trained personnel. It enables you to measure your blood glucose quickly and easily, store the measured values and display the average of all measured values, thereby providing optimum assistance for monitoring your diabetes. The test is performed exclusively externally (IVD).

The large display shows the measured values clearly. The user-friendly design with handy test strips and the simple controls with just a small number of buttons guarantee simple, yet reliable measurements.

1.1 Delivery scope, replacements and accessories

Check that the set packaging has not been tampered with and make sure that all components are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.

A	1 Blood glucose monitor
B	1 lancing device
C	10 test strips
D	AST cap with groove for taking blood samples from alternative parts of the body
E	1 button cell battery, 3 V CR2032 (already inserted)
F	10 sterile lancet needles
G	1 practical case
	These instructions for use, additional information
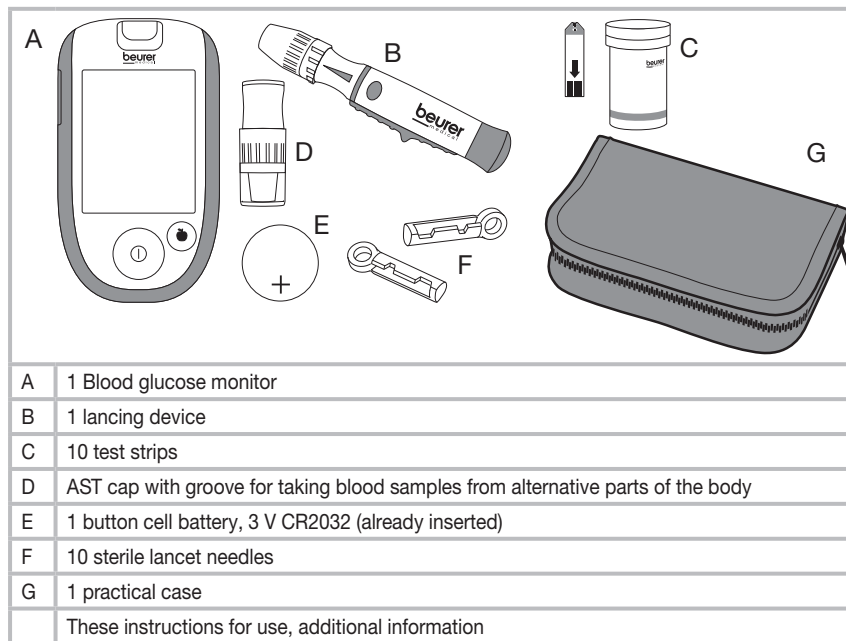
- If the packaging has sustained considerable damage or the contents are incomplete, please return the system to your retailer.
- The blood glucose monitor, test strips and additionally available control solutions have been specially designed to complement each other. For this reason, use only test strips and control solutions that have been approved for this blood glucose monitor.

(i) **Note**

- Use original manufacturer accessories only.

Follow-up purchases
You can also obtain test strips, control solution and lancet needles without a prescription.

Item	REF	PIP Germany
50 test strips	REF 461.15	PIP 10146271
Control solution LEVEL 5 and 6	REF 457.11	PIP 10146288
100 lancet needles	REF 457.01	PIP 03774707

1.2   Functions of the device
This device is intended for measuring the blood glucose content in human blood. It is also suitable for self-testing at home.
The blood glucose monitor enables you to quickly and simply:
• Measure your blood glucose level
• Display, label and save measured values
• Display the average measured blood glucose value from the last 7, 14, 30 and 90 days
• Display the average of the labelled measured blood glucose values from the last 7, 14, 30 and 90 days
• Set the time and date

The blood glucose monitor also includes the following monitoring functions:
• Warning in the event of unsuitable temperatures
• Low battery display
• Low test strips warning

⚠️ **Warning**

• **Do not use the device to diagnose diabetes; it is intended for regular monitoring only.**
• **Consult your GP with regard to insulin doses.**

1.3   Signs and symbols
The symbols on the packaging, type plate of the blood glucose monitor and accessories represent the following:

IVD	In vitro diagnostics	🏭	Manufacturer
SN	Serial number	📖i	Observe the instructions for use
2°C–30°C	Temperature limit +2 °C to +30 °C	РСТ	PCT: certification symbol for products that are exported to the Russian Federation and members of the CIS
②	Not for re-use/For single use only		
⧖	Use by	♻	Green dot (Der Grüne Punkt): German dual waste collection system

3 M	Maximum shelf life after initial opening in months	$\sum_{<n>}$	Contents sufficient for <n> tests
LOT	Batch designation	REF / Item no.	Order number
STERILE R	Sterilised by radiation (lancets)	mg/dL	Unit of measurement for blood glucose value
⚠	Warning, see accompanying documents	☣	Biohazard, risk of infection

In the Instructions for use, the symbols represent the following:

⚠ Warning

Warning instruction indicating a risk of injury or damage to your health / your patient's health.

⚠ Important

Safety note indicating possible damage to the unit/accessory.

ⓘ Note

Note on important information.

2. WARNINGS AND SAFETY NOTES

Risk of infection

All components of the blood glucose monitor and its accessories may come into contact with human blood and are therefore a possible source of infections. ☣

⚠ Warning

• This blood glucose monitor must display the blood glucose content in mg/dL. The unit of measure-ment mg/dL accompanies each blood glucose value. Please contact Customer Services if the device does not display mg/dL. You risk damaging your health if you measure your blood glucose value using a unit of measurement with which you are not familiar, misinterpret the values and therefore take incorrect measures.
• When using the blood glucose monitor for various persons, observe the generally applicable regula-tions regarding disinfection, safety and contamination.
• Medical carers and others who use this system on several patients must be aware that all products or objects that come into contact with human blood must be handled, even after cleaning, as though they could transfer pathogens.
• The lancing device is suitable for self-testing. Do not share the lancing device or lancet needles with others or amongst various patients **(risk of infection!)**.
• Use a new, sterile lancet needle for each blood sample (**for single use only**).

General notes

⚠️ **Warning**

Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.

Measuring the blood glucose content

⚠️ **Warning**

• The measurements taken by you are for your information only – they are no substitute for a medical examination! Consult your GP regularly regarding your measured values. Do not alter the procedures prescribed by your GP.
• Despite the simple usage of the Beurer GL42 monitor for self-monitoring of blood glucose levels, you may possibly need to obtain instructions for using the system from your healthcare professional (for example, your GP, chemist or diabetes consultant). Only proper use will guarantee exact measurements.
• A lack of water, high fluid loss, for example perspiration, frequent passing of water, severe hypotension (low blood pressure), shock or hyperosmolar hyperglycaemic non-ketotic coma may lead to incorrect measured results.
• An excessively high or low hematocrit value (proportion of red blood cells) may lead to incorrect measurements. In the event of a very high hematocrit value (above 60%), the displayed blood glucose value may be too low; in the event of a very low hematocrit value (below 20%), it may be too high. Consult your GP if you do not know your hematocrit value.
• Do not use the test strips to measure blood glucose values on newborns.
• Do not use NaF or potassium oxalate anticoagulants to prepare for venous blood samples.
• Do not test any severely ill patients using this device.
• The level of Acetaminophen (up to 10 mg/dL), Ascorbic acid (up to 4 mg/dL), Bilirubin (up to 20 mg/dL), Cholesterol (up to 500 mg/dL), Creatinine (up to 10 mg/dL), Dopamine (up to 5 mg/dL), EDTA (up to 400 mg/dL), Fructose (up to 200 mg/dL), Galactose (up to 200 mg/dL), Gentistic acid (up to 2 mg/dL), Glutathione (up to 3 mg/dL), Haemoglobin (up to 200 mg/dL), Heparin (up to 60 mg/dL), Ibuprofen (up to 40 mg/dL), Icodextrin (up to 200 mg/dL), Lactose (up to 200 mg/dL), L-DOPA (up to 3.0 mg/dL), Maltose (up to 200 mg/dL), Methyl-DOPA (up to 1.25 mg/dL), Pralidoxime Iodide (up to 1.25 mg/dL), salicylate (up to 20 mg/dL), Tetracycline (up to 4 mg/dL), Tolazamide (up to 55 ug/dL), Tolbutamide (up to 100 mg/dL), Triglyceride (up to 3000 mg/dL), Uric acid (up to 7 mg/dL), and Xylose (up to 5 mg/dL) in blood has no significant interference reaction (the average difference between the test sample and the control sample ≤ 0.55 mmol/L (10 mg/dL) at glucose concentration of 50~100 mg/dL and ≤ 10% at glucose concentration of 250-300 mg/dL) on GL42.
• The xylose level (up to 10 mg/dL) in the blood causes a significant deviation with the GL42 device (average deviation between test and control test >0.55 mmol/L (10 mg/dL) with a blood glucose concentration of 50-100 mg/dL and >10% with a blood glucose concentration of 250-300 mg/dL).
• Use fresh capillary whole blood only. Do not use serum or plasma.
• Use capillary blood without squeezing the penetration area. If the area is squeezed, the blood is diluted with tissue fluid and this may lead to an incorrect result.
• Do not use the test strips above an altitude of 6,000 m.

• Very high levels of humidity may influence the test results. Relative humidity of more than 90% may lead to inexact results.

ⓘ **Note**

• The Beurer GL42 mg/dL measuring system is intended for measuring capillary and venous whole blood.

Storage and maintenance

⚠ **Warning**

• Store the blood glucose monitor and its accessories out of reach of small children and pets. Small parts, such as lancet needles, parts of the lancing device, batteries or test strips may be life-threatening when swallowed. If swallowed, seek medical attention immediately.
• The test strip box contains desiccant, which may irritate the skin or eyes when inhaled or swallowed. Keep the box out of the reach of children.

The blood glucose monitor is made from precision and electronic components. The accuracy of the measurements and service life of the device depend on its careful handling:
• Protect the device and its accessories from impacts, humidity, dirt, marked temperature fluctuations and direct sunlight. Do not store the device, test strips and control solution in your vehicle, in the bathroom or in a cooling appliance!
• Do not drop the device.

Batteries/Saving measured values

⚠ **Warning**

• Keep batteries out of the reach of children. Children could put batteries in their mouth and swallow them. This may severely damage their health. In such cases, seek medical assistance immediately!
• Normal batteries must not be charged, heated or thrown into an open fire (**risk of explosion!**).

⚠ **Important**

• Batteries must not be taken apart or short circuited.
• Leaking batteries may damage the device. If you do not intend to use the device for longer periods, remove the batteries from the battery compartment.

Attention!

• Leaking or damaged batteries may burn the skin, therefore use suitable protective gloves if this is the case.

ⓘ **Note**

• The stored blood glucose values are retained when the batteries are replaced. If applicable, the date and time must be reset after replacing the batteries.
• Use lithium-ion batteries only.

Repairs

(i) **Note**

- Do not open the device. Failure to comply will result in voiding of the warranty.
- Do not repair the device. Proper operation can no longer be guaranteed in this case.
- Do not dismantle the lancing device into individual parts, except in the steps described in these instructions.
- Please contact Customer Services for repairs.

Disposal

⚠ **Warning**

- It is essential to comply with the generally applicable safety precautions for handling blood when disposing of materials of the blood glucose monitor. Dispose of all blood samples and materials with which you or your patients come into contact correctly in order to prevent injury and infection of other persons.
- After use, dispose of test strips and lancets in a puncture-proof container.

(i) **Note**

Batteries must not be disposed of with household waste. As a consumer, you are required by law to recycle used batteries. You can recycle your old batteries at public collection points in your community or wherever batteries of the relevant type are sold.

The codes below are printed on batteries containing harmful substances:
- Pb = Battery contains lead,
- Cd = Battery contains cadmium,
- Hg = Battery contains mercury.

For environmental reasons, do not dispose of the device in the household waste at the end of its useful life. Please dispose of the unit in accordance with EC Directive WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.
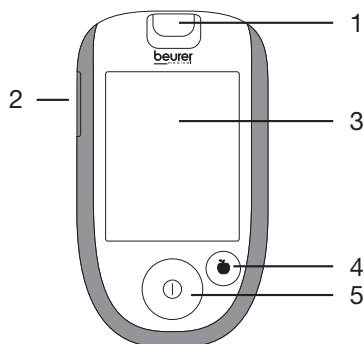
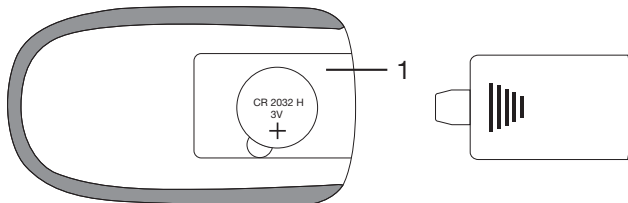## 3. DESCRIPTION OF UNITS AND ACCESSORIES

3.1 Blood glucose monitor

Front
1. Slot for test strips
2. Rocker switch "+", "-"
3. Display
4. Highlight button
5. On/Off button

Rear
1. Battery compartment (bottom side)

3.2 Display symbols

1. Date
2. Symbols for highlighting measured values
3. Measured value display, display Hi, Lo, Average blood glucose, Err
4. Temperature symbol
5. Memory symbol
6. Speaker symbol
7. Replace battery symbol
8. Blood glucose unit mmol/L – not functional
9. Blood glucose unit mg/dL
10. Hand symbol
11. Test strip symbol
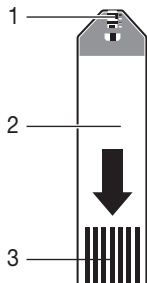12. Blood droplet symbol
13. Time
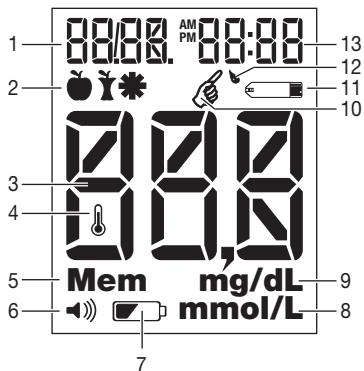
ⓘ Note

The blood glucose monitor is supplied with the following basic settings:

• Blood glucose unit: mg/dL
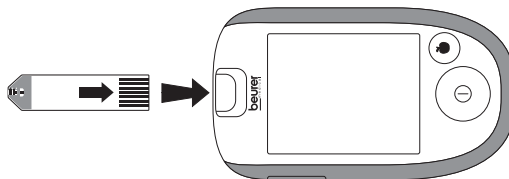• Acoustic signal on

3.3 Test strips

Front

1. Gap for blood input
2. Handle
3. Contacts

Back

You can identify the rear by the contact tracks.

Insert the test strip into the device so that the contacts are pointing inside the slot.
Make sure that the front of the test strip is facing you.

ⓘ Note

Read carefully the following information on handling and storing your test strips. The test strips will only provide accurate measurements if all notes are followed.

⚠ Warning

Use each test strip only **once** and for **one** patient only!

Handling test strips

ⓘ Note

- Securely close the test strip box immediately after taking out a test strip.
- Do not use the test strips if they have expired. The use of expired test strips may lead to incorrect measurements. The expiry date is printed on the box next to the hourglass symbol ⧗.
- Test strips expire three months after the box is opened. Make a note of the expiry date (opening date + 3 months ⧗) on the label. The shelf life is limited to the expiry date (see date next to the hourglass symbol ⧗).
- Do not use the test strips if one of the expiry dates has passed (⧗/⧗).
- You can touch any part of the test strip with clean, dry hands.
- Use the test strip for measurement immediately after removing it from the box.
- Do not bend, cut or otherwise modify the test strips.
- Do not use test strips that have come into contact with fluids.

Storing test strips

ⓘ Note

- Keep the test strips in a cool, dry place above +2°C and below +30°C. Do not expose the test strips to direct sunlight or heat. Do not store in your vehicle, in the bathroom or in a cooling appliance.
- Permitted relative air humidity below 90%.
- Keep the test strips in the original box only – never use other containers.

4. INITIAL USE AND BASIC SETTINGS

4.1 Removing the battery insulation strips, replacing the battery

ⓘ **Note**

• Remove the insulation strip before initial use.
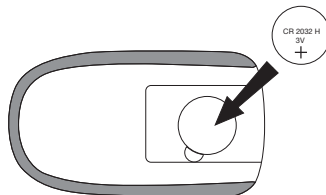
CR 2032 H
3V
+

1 Remove the battery compartment lid on the underside of the device.

2 If you are replacing the battery, reset the date and time as required ("Making and changing basic settings" on page 14).

3 Insert a new battery of type CR 2032 3 V. Make sure that the battery is inserted with the correct polarity, according to the label. See the graphic in the battery compartment.

4 Close the battery compartment lid again carefully.

ⓘ **Note**

• The batteries are almost empty if the replace battery symbol 🔋 appears. Replace the battery as soon as possible.
• If "LP" appears on the display, the battery power level is so low that no more measurements can be taken.

4.2 Making and changing basic settings

1 Remove the battery and then reinsert it. Alternatively, press the "+" button [2] and the On/Off button for a minimum of five seconds.
An acoustic signal sounds.
The year display flashes.

2 **Setting the date and time**

ⓘ **Note**

• You must set the date and time. Otherwise, you will not be able to save your measured values correctly with a date and time to retrieve them later.
• The time is displayed in the 24-hour format.

Set the year (calendar to 2099) by pressing the "+" or "–" [2] button. Confirm by pressing the On/Off button [5].
The day display flashes.
Proceed as described above for the month, day, hour and minute.

3 **Switching the acoustic signal on/off**
To switch the acoustic signal off, press the "+" or "–" button.
"bEEP" and "OFF" is displayed.
The speaker symbol is no longer shown in the display.
Confirm by pressing the On/Off button [5].
"Mem" and "OK" are displayed.

4 **Deleting stored values**
Proceed as follows to delete stored values:
• Press the "+" or "–" button. "Mem" and "dEL" are displayed.
• Confirm by pressing the On/Off button [5]. "Mem" and "dEL" flash in the display.
• To irreversibly delete your values, press the On/Off button again to confirm. "Mem", "dEL" and "OK" are displayed.

If you do not wish to delete your values, press the "+" or "–" [2] button. "Mem" and "OK" are displayed again. Confirm by pressing the On/Off button.

5 The blood glucose monitor is now ready for use.

5. BLOOD GLUCOSE MEASUREMENT

⚠ **Warning**

Before starting to take blood samples, make sure without fail that you have read the enclosed in-structions for use, "Taking blood samples". These instructions describe how to prepare and take a blood sample correctly.

ⓘ **Note**

• Do **not** add blood later if the device does not start measurement. Remove the test strip and end this test. Use a new test strip.
• The device switches itself off if the test strip has already been inserted into the device but no blood is added to the test strip within two minutes. Briefly remove the test strip and reinsert it so that the device automatically switches itself back on.
• Contact Customer Services if you are unable to cover the test strip in blood correctly.

5.1 Evaluating the result

As soon as the gap is sufficiently filled with blood, the device performs the blood glucose measure-ment. The blood glucose monitor counts down for approx. five seconds.
The measured result is then shown on the display.

Read the measured value. For explanations and measures for the measured values, see chapter "5.2 Evaluating measured blood glucose values". If an error message is displayed, read chapter "9. What if there are problems?"

Highlighting measured values

You have the following options to highlight measured values.

🍎	Before meals.
🍏	After meals.
✻	General highlight (e.g. after exercising).

Labelling measured values enables you, your GP or diabetes consultant to better monitor your blood glucose values. For example, you can display the average values of all measurements taken before meals.

The measured value can be highlighted as soon as it is displayed. You cannot highlight it later.
For this purpose, briefly press the highlight button [4].
a) Pressing once highlights the value with 🍎.
b) Pressing again highlights the value with 🍏.
c) Pressing yet again highlights the value with ✻.
d) Pressing once more removes the highlight.

The selected label is stored in the memory of the device when it is switched off.

5.2   Evaluating measured blood glucose values

Your blood glucose monitor can process values between 20 and 630 mg/dL. The "Lo" warning is displayed for measured results below 20 mg/dL. The "Hi" warning is displayed for measured results above 630 mg/dL.

⚠️ **Warning**

• If you suspect that the blood glucose results are incorrect, first repeat the test and, if applicable, perform a functional test using control solution. Seek medical advice if dubious results persist.
• Immediately seek medical attention if your symptoms are not in line with your measured blood glucose values and you have observed all instructions for the Beurer GL42 blood glucose monitor.
• Do not ignore symptoms of too high/low blood glucose levels. Seek medical attention.

Blood glucose
The following table provides a classification of blood glucose values according to the diabetes guidelines of the German Diabetes Association (Deutsche Diabetes Gesellschaft – DDG).

Time of blood glucose measurement	Normal blood glucose values	Suspicion	Diabetes
Plasma glucose **on an empty stomach**	Below 100 mg/dL	100-125 mg/dL	≥ 126 mg/dL
Two hours after a meal	Below 140 mg/dL	140-199 mg/dL	≥ 200 mg/dL

Source: German Diabetes Association (Deutsche Diabetes Gesellschaft – DDG) 2012

Evaluating critical measured values

Display	Blood glucose	Action
Lo	Very low blood glucose level Below 20 mg/dL	Seek medical attention immediately.
65 mg/dL	Low blood glucose level Below 70 mg/dL	Have a suitable snack. Follow your GP's instructions.
150 mg/dL	High blood glucose level On an empty stomach above 100 mg/dL Two hours after a meal Above 140 mg/dL	If this high value persists two hours after your last meal, this may indicate hyperglycaemia. Seek medical attention to coordinate any measures, if applicable.
300 mg/dL **KEt**	High blood glucose level, possibly ketones Above 240 mg/dL	Perform a ketone test. For this purpose, seek medical attention.
Hi	Very high blood glucose level Above 630 mg/dL	Take another measurement using a new test strip. If the result is identical: seek medical attention immediately.

6. FUNCTIONAL CHECK USING CONTROL SOLUTION

The control solution is used to test the entire blood glucose monitoring system. This helps to determine whether the monitor and the test strips are working optimally together and whether the test is being performed correctly.
Perform the control solution test if you suspect that the blood glucose monitor and/or the test strips could be faulty or if you have repeatedly measured unusual blood glucose values. Also test the blood glucose monitor if it has been dropped or is damaged. The control solution is available separately. Please observe the additional notes in the instructions for using the control solution for the test.

⚠ Important

- Do not use third-party control solution. Correct functioning of the measuring device can only be tested using the Beurer control solutions (LEVEL5 + LEVEL6).
- Control solution measurements: When using the device, specialist personnel must follow statutory guidelines.
- Do not apply any blood samples or control solutions to the test strip before inserting it in the monitor.

Performing a functional test using control solution

⚠ Warning

To obtain correct results, the measuring device, the test strip and the control solution must be the same temperature. For the "Functional test using the control solution", the temperature is to be between 20 °C and 26 °C.

1	Hold the blood glucose monitor so that the display is facing you.
2	Insert a test strip into the slot on the blood glucose monitor with the contacts first. Make sure that the front of the test strip is facing you (see "Test strips" on page 12).
3	The device automatically switches on and briefly shows the initial display. The device is ready for measurement as soon as the hand 🖐 and the ◉ symbol flash.

IMPORTANT: Control solutions and blood react to temperature influences in different ways. It is therefore of vital importance that control solution measurement is always performed in control solution mode. If this mode is not used, results may be obtained that are outside the target range.

ⓘ Note

Press the rocker switch "+" or "–" [2] to change to the control mode. "ᒐᒉᒪ" is shown on the display. This means that the result value is not stored in the memory, therefore not influencing your measured value statistics. Press "+" or "–" [2] again. "ᒐᒉᒪ" disappears from the display and the value is stored normally in the memory.

| 4 | A clean surface is required to correctly perform a functional test. Shake the control solution well before use. Undo the cap and press two drops next to each other on the clean surface without touching them. Use the second drop for the measurement. |
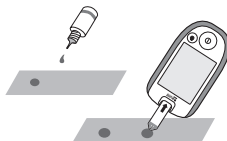
ⓘ Note

Do not apply the drop directly to the test strip to avoid contaminating the remaining control solution in the bottle by touching the test strip with the tip of the bottle.

5 Hold the input gap (at the tip of the test strip) to the drops of control solution until the gap is completely filled and the measuring device in the display starts counting backwards.
When the gap is sufficiently filled with solution, the device performs a measurement. The device counts down for approx. five seconds. The measured result is then shown on the display.

6 Check whether the result is within the specified range of results for the control solution. This range of results is printed on the test strip box.

Expected results

At room temperature, the measurements of the test using the control solution should be within the range printed on the test strip box in approx. 95% of all tests.

⚠ **Warning**

The result range printed on the test strip box applies only to the control solution. **This is not a recommended value for your blood glucose level.**

If measured values are outside the specified range, check the following possible causes:

Cause	Action
• The first drop of control solution was not disposed of. • The tip of the bottle was not cleaned correctly. • The bottle was not shaken well enough.	Rectify the cause and repeat the test.
Control solution and/or test strips have passed their expiry date or are contaminated.	Repeat the test using a new bottle of control solution and/or new test strip.
The control solution, test strips or blood glucose monitor are too warm or too cold.	Bring the control solution, test strips and blood glucose monitor to room temperature (+20 °C to +26 °C) and repeat the test.
The test strips and control solution were kept at a temperature and humidity outside the specified range.	Repeat the test using new/correctly stored test strips and control solution.
Damaged test strips. For example • Test strips that were exposed to fresh air for too long. • The test strip box was not closed completely.	Repeat the test using a new test strip and/or a new box of correctly stored test strips.
Old test strips.	Open a new box of test strips. Repeat the test.
There is a problem with the blood glucose monitor.	Contact Customer Services.
Functional test was incorrectly performed.	Repeat the test and follow the instructions.

⚠ Warning

Do not use the system to measure your blood glucose level if you are repeatedly provided with measurements outside the specified range when using control solution. Contact Customer Services.

7. MEASURED VALUE MEMORY SPACES

For each measurement, your blood glucose value is automatically saved with the date and time unless "CtL" was activated for a blood glucose measurement using control solution.
The memory can store a maximum of 480 measured values. If the memory is full, the oldest value is replaced by the most recent value. You can call up every individual measured blood glucose value. You can also calculate and display the average value for the last 7, 14, 30 and 90 days.

ⓘ Note

- If you have already saved measured values and you reset the date, the average values are calculated as from the new period.
- "---" indicates an empty memory for measured values. Press the On/Off button to switch off the device.

7.1 Displaying individual values

The individual values from the last 480 measurements are displayed. The most recent measured value is displayed first, and the oldest last. The date and time are also displayed on the monitor at the same time.

1 Switch the measuring device on using the On/Off button [5]. The initial display is shown briefly. Press the "+" or "–" rocker switch [2].

2 The most recent measured value and the number of saved blood glucose tests are displayed. The display then switches and, instead of the number of saved blood glucose tests, it then shows the date of the most recent measurement.
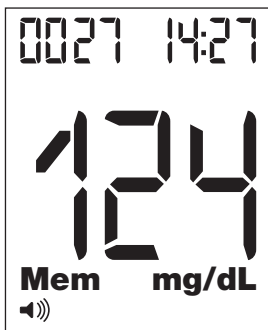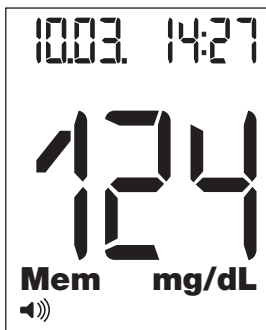

Image 1

Image 2

3	Pressing the rocker switch "–" [2] will display the previous measured value each time. You can display a maximum of 480 previous measurements.
4	You can cancel the process at any time. To do so, press the On/Off button or wait until the device switches itself off automatically after two minutes.

7.2 Displaying average blood glucose values

You can display the average measured blood glucose value from the last 7, 14, 30 and 90 days.

1	Switch the measuring device on using the On/Off button [5]. The initial display is shown briefly. Press the "+" rocker switch [2] twice. The measurement unit of the blood glucose value, "Ø7 d" and the average value are displayed.
2	Press "+" [2] repeatedly to display the average value for 7, 14, 30 and 90 days.
3	You can cancel the process at any time. To do so, press the On/Off button or wait until the device switches itself off automatically after two minutes.

Item explanation

1. Average value
2. Time period, e.g. 7
3. Number of saved values used to calculate the average
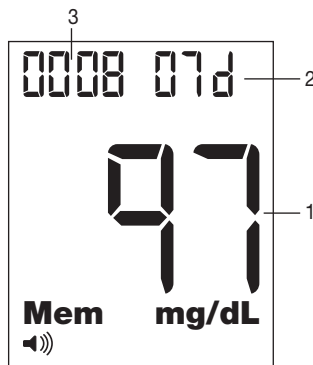
7.3 Displaying average blood glucose values for highlighted values

You can display the average measured blood glucose value for labelled values from the last 7, 14, 30 and 90 days.

1	Switch the monitor on using the On/Off button [5]. The initial display is shown briefly. Press the "+" rocker switch [2] twice. The measurement unit of the blood glucose value, "Ø7 d" and the average of all measured values are displayed.

2 Press "+" [2] repeatedly to display the average value of all measured values for 14, 30 and 90 days.

After the average of all measured values for 90 days is displayed,
- the seven-day average for values measured "before a meal"
- the 🍎 symbol
- the unit of measurement for blood glucose values and
- "07 d"

are shown on the display.
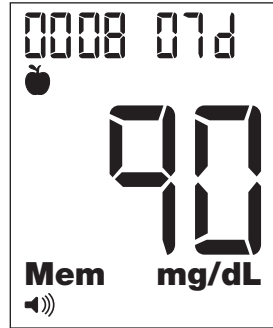
Press "+" [2] repeatedly to display the average value from the last 14, 30 and 90 days "before meals" 🍎.

After displaying the average value for 90 days "before meals" 🍎
- the seven-day average for values measured "after meals"
- the 🍎 symbol
- the unit of measurement for blood glucose values and
- "07 d"

are shown on the display.

Press "+" [2] repeatedly to display the average value from the last 14, 30 and 90 days "after meals" 🍎.

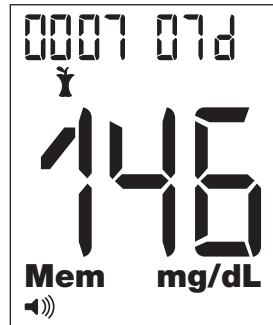| 2 | After displaying the average value for 90 days "after meals" ☙
• the average for the last seven days of values highlighted as "general"
• the ✱ symbol
• the unit of measurement for blood glucose values and
• "07 d"
are shown on the display. | <div align="right">0008 07d
✱
97
Mem   mg/dL
◀))</div> |
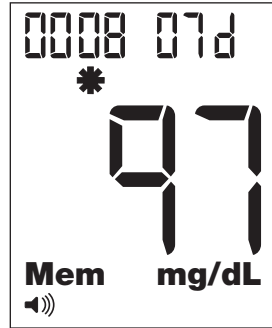
Press "+" [2] repeatedly to display the average value from the last 14, 30 and 90 days for values highlighted as "general" ✱.

| 3 | You can cancel the process at any time. To do so, press the On/Off button or wait until the device switches itself off automatically after two minutes. |

ⓘ **Note: Speed function**

You are in the measurements memory. By pressing the highlight button [4], you can switch to the different 7-day average values. In this way, you can get to the desired average value more quickly. For example:
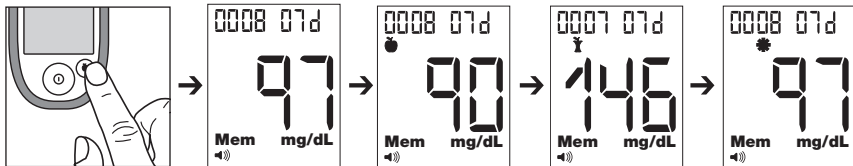
7.4   Deleting individual measured values from the memory

| 1 | Press the buttons as described in 7.1 until the value appears that you would like to delete. |

| 2 | Press the On/Off button, keep it pressed and also press down the "-" button for approx. 2 seconds.
"dEL", "Mem" and the number of the value to be deleted flash.
Press the On/Off button again. "dEL", the number of the value to be deleted, "Mem" and "OK" are displayed.
If you do not wish to delete the value, briefly press the "+" or "−" button. You are taken back to the memory area. |

| 3 | The device then indicates that the subsequent measured value has moved to the memory space of the deleted measured value. |

7.5 Deleting all stored values

Proceed as described in "4.2 Making and changing basic settings". After explaining how to set the acoustic signal, the section explains how to delete the measured value memory.

8. STORING, MAINTAINING AND DISINFECTING THE DEVICE

Storing

Keep the Beurer GL42 blood glucose monitor in the case supplied after each measurement and do not expose it to direct sunlight.

(i) **Note**

• Do not store the device, test strips and control solution in your vehicle, in the bathroom or in a cooling appliance!
• Retain these instructions for use.
• Remove the batteries if you do not intend to use the device for a prolonged period of time.

8.1 Cleaning

Device

Only clean the device when it is switched off.
Clean the surface of the device using a soft, slightly damp cloth (water or a mild cleaning solution). Dry the device using a lint-free cloth.
Make sure that moisture does not enter the test strip insertion slot. Do not spray cleaning agent directly on the device. Do not submerge the device in water or any other fluids and make sure that no fluids can get into the device.

Lancing device

Clean the surface of the lancing device using a soft, slightly damp cloth (water, a mild cleaning solution or rubbing alcohol). The lancing device must not be immersed in water or other liquids or be cleaned in the dishwasher. Dry the lancing device using a lint-free cloth.

8.2 Disinfection

Device

Please comply with the generally applicable guidelines on disinfection when using the device on different persons. Do not submerge the device in disinfection solutions or any other fluids and make sure that no fluids can enter the device.

(i) **Note**

The blood glucose monitor is made of precision components. The accuracy of the measurements and service life of the device depend on its careful handling:
• Protect the device from impacts and do not drop it.

- Protect the device from damaging factors such as moisture, dirt, dust, blood, control solution or water, marked temperature fluctuations, direct sunlight and extreme cold.
- Do not use the device in the vicinity of strong electromagnetic fields, radio systems or mobile telephones.

9. WHAT IF THERE ARE PROBLEMS?

Display messages on batteries and blood glucose measurement

no.	Cause	Solution
LP	Empty battery.	Replace battery.
Ht	Temperature of the measuring environment, blood glucose monitor or test strip above the permitted range.	Repeat the test using a new test strip as soon as the measuring environment, measuring device and test strips have reached room temperature (+20 °C to +26 °C).
Lt	Temperature of the measuring environment, blood glucose monitor or test strip below the permitted range.	Repeat the test using a new test strip as soon as the measuring environment, measuring device and test strips have reached room temperature (+20 °C to +26 °C).
Err ⊑▬	Used or contaminated test strip inserted.	• Insert an unused test strip that has not expired. • Repeat the blood glucose measurement.
Err001	System error.	Remove battery and reinsert battery. Contact Customer Services if the problem persists.
Err002	Insufficient blood on the test strip.	Repeat the measurement using a new test strip.
12 127 130	System error.	Contact Customer Services.
	Unknown error messages.	Remove battery and reinsert battery. Contact Customer Services if the problem persists.

Problem: device does not switch on

Cause	Solution
Empty battery.	Replace battery.
Incorrectly inserted or missing batteries.	Check whether the battery has been inserted correctly (see "Removing the battery insulation strips, replacing the battery" on page 14).
Test strip inserted incorrectly or not completely.	Firmly insert the test strip into the slot on the device with the contacts first. Make sure that the front of the test strip is facing you (see "Test strips" on page 12).
Device faulty.	Contact Customer Services.

Problem: the test does not start after inserting the test strip into the device and applying blood.

Cause	Solution
Insufficient blood or test strip not filled correctly.	Repeat test using a new test strip and a larger drop of blood. Please note the correct filling of the test strip.
Faulty test strip.	Repeat the test using a new test strip.
Blood was applied while the device was switched off.	Repeat the test using a new test strip and only apply blood after 🩸 and 💧 flash.
The basic settings of the device were changed and the changes were not completed (see "Making and changing basic settings" on page 14).	Remove the test strip and press the "On/Off" button until "OFF" is displayed. Repeat test.
Device faulty.	Contact Customer Services.

10. TECHNICAL SPECIFICATIONS

Dimensions (L x W x H)	88 x 51 x 15 mm
Weight	41 g incl. battery
Power supply	1 x 3 V CR 2032 button cell battery
Battery life	Over 1000 measurements
Measured value memory	480 measured values with date/time Data retained when batteries are changed
Average values	For 7, 14, 30, 90 days
Automatic switch-off	Two minutes after last actuation
Storage/transport temperature	Temperature: +2 °C – +30 °C Relative humidity: < 90%
Operating ranges	Temperature: +10 °C – +40 °C Relative humidity: < 90% non-condensing
Measuring range, glucose	Glucose: 20 – 630 mg/dL
Blood sample	Capillary whole blood, venous whole blood
Amount of blood	0.6 microlitres
Blood glucose measuring duration	Approx. 5 seconds
Calibration	Plasma
Test procedure	Amperometric bio sensor
Use	Suitable for self-testing
System function test	Each time device is switched on

EMC

This device complies with the European standard EN 61326 and is subject to specific precautions with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit. For more details, please contact customer services at the address provided.

Test strip functionality

Test strips enable a quantitative measurement of the glucose level in fresh whole blood. When the gap for taking blood comes into contact with a drop of blood, it is automatically filled by simple capillary action. The blood is sucked into the absorbing gap on the test strip and the blood glucose monitor measures the blood glucose level in the blood.

The test is based on the measurement of an electric current that is generated by the chemical reaction of the glucose with the enzyme glucose dehydrogenase (Aspergillus sp.) on the strip.

During the reaction, a mediator transports electrons through the electrode surface and so generates a current.

The blood glucose monitor analyses this current. The current flow is proportional to the glucose content in the blood sample. The results are shown on the blood glucose monitor display. Only a small

amount of blood is required (0.6 microlitres) and measurement duration is approx. five seconds. The test strip detects blood glucose values from 20 to 630 mg/dL.

Chemical components of the test strip sensor
• FAD glucose dehydrogenase   10%
• Potassium ferricyanide   46%
• Non-reactive components   44%

Control solution functionality
The control solution contains a fixed amount of glucose that reacts with the test strip. A test with control solution is similar to a blood test. However, control solution is used instead of blood. The measured result using control solution must be within the result range. This range is printed on each test strip box.

Chemical composition of the control solution
The control solution is a red solution with the following D-glucose level (in percentage shares):

Ingredients	Control solution LEVEL 5	Control solution LEVEL 6
D-glucose	0.12%	0.35%
Non-reactive components	99.88%	99.65%

Standards
The Beurer GL42 monitor corresponds to European guidelines IVD (98/79/EC) and MDD (93/42/EC).

11. COMPARISON OF MEASURED VALUES WITH LABORATORY VALUES

Precision
Three lots of the GL42 blood glucose test strips have been tested to assess the precision of the GL42 blood glucose measuring system. This includes a repeat assessment using venous blood and a laboratory precision assessment using the control material. The blood glucose content of the venous blood samples ranges from 44.9 to 362.3 mg/dL and control material from three concentrations is used.

Results of the repeat precision measurements

Sample	Venous blood (mg/dL)	Grand mean value (mg/dL)	Pooled standard deviation	Pooled coefficient of variation (%)
1	44.9	44.8	3.2	7.1
2	90.6	94.1	3.2	3.5
3	120.0	114.9	3.2	2.8
4	225.8	212.1	6.9	3.2
5	362.3	347.0	11.2	3.2

Results of the intermediate precision measurement

Sample	Control material (mg/dL)	Grand mean value (mg/dL)	Pooled standard deviation	Pooled coefficient of variation (%)
1	46.2	43.8	2.2	5.1
2	135.0	131.7	3.7	2.8
3	350.0	346.3	8.5	2.4

System accuracy

The GL42 blood glucose monitor in comparison with the YSI.

Three lots of GL42 blood glucose test strips have been tested to assess the system accuracy of the GL42 blood glucose measuring system and to compare it with the reference method in which capillary whole blood concentrations of 24.8 to 715 mg/dL have been used.

Result of the system accuracy for glucose concentrations <100 mg/dL (<5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28 mmol/L)	Within ±10 mg/dL (Within ±0.56 mmol/L)	Within ±15 mg/dL (Within ±0.83 mmol/L)
116/186 (62.4%)	172/186 (92.5%)	184/186 (98.9%)

Results of the system accuracy for glucose concentrations ≥100 mg/dL (≥5.55 mmol/L)

Within ±5%	Within ±10%	Within ±15%
250/414 (60.4%)	379/414 (91.5%)	413/414 (99.8%)

Results of the system accuracy for combined glucose concentrations between 24.8 mg/dL (1.4 mmol/L) and 715 mg/dL (39.7 mmol/L).

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
597/600 (99.5%)

In comparison to the YSI, the GL42 met the EN ISO 15197:2013 standard, whereby 95% of the blood glucose values measured have to fall within the following zones: either ±0.83 mmol/L (±15 mg/dL) of the measured average value when using the reference measuring procedure for blood glucose concentrations <100 mg/dL (<5.55 mmol/L) or ±15% for blood glucose concentrations of ≥100 mg/dL (≥5.55 mmol/L). 99% of the individual measured blood glucose values must fall within zones A and B of the Consensus Error Grid (CEG) for diabetes type 1.

Performance evaluation by the user

A study to assess the glucose values of blood samples of capillary blood from the fingertips, which were obtained from 150 individuals that had no special training, produced the following results: 100% within ±15 mg/dL (±0.83 mmol/L) and 98.9% within ±15% of the values obtained in the medical laboratory with glucose concentrations of at least 100 mg/dL (5.55 mmol/L).

You will find further details and information regarding blood glucose results and various technologies in generally relevant specialist medical literature.

12. WARRANTY AND CUSTOMER SERVICE

Warranty

We offer a 3-year product warranty against material and production faults.
The warranty does not cover:
• Damage due to improper operation
• Wearing parts
• Deficiencies already known to the customer upon purchase
• Cases of personal negligence on the part of the customer
• Outside interference
The warranty does not affect the customer's statutory liability rights. To assert a warranty claim within the warranty period, the customer must provide proof of purchase. The warranty claim must be submitted within a period of 3 years from the date of purchase to BEURER GmbH, Söflinger Straße 218, D-89077 Ulm (Germany). In the event of a warranty claim, the customer reserves the right to have the goods repaired at our own workshop or at a workshop authorised by us. No further rights are granted to the customer (on the basis of the warranty).

Customer service address

Please contact our customer service if you have any questions: Please refer to the address list enclosed for our customer service address.

OUR COMMITMENT TO YOU: We aim to satisfy you by providing high-quality medical products and the best customer service. Please contact our customer service if you are not entirely satisfied with the product.

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