beurer medical

GL60
EN

german engineering

BLOOD GLUCOSE MONITOR

Step by step

IVD — Blood glucose measuring system, # GL60 (including GL60, test strips for GL60)

CE 0483

MD — # Soft

CE 0123

MD — # LD 04

CE

Contents

1. Getting to know your device

Dear customer,

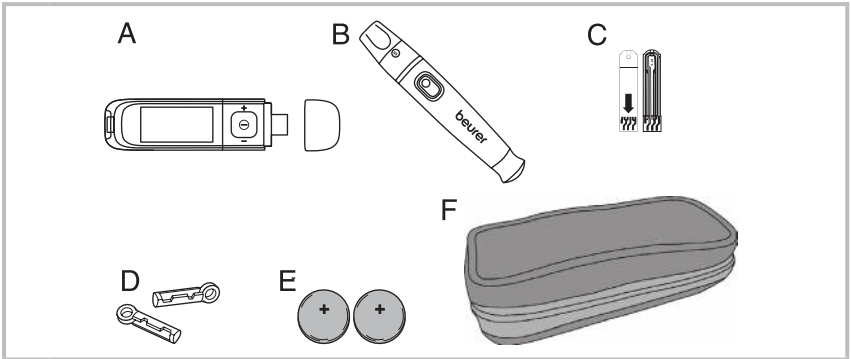
Thank you for choosing a product from our range. Our name stands for high-quality, thoroughly tested products for applications in the areas of heat, weight, blood pressure, blood glucose, body temperature, pulse, gentle therapy, massage and air.
Please read these instructions for use carefully and keep them for later use, make them accessible to other users, and observe the information they contain.
With kind regards,
Your Beurer team.

Getting to know your device

The GL60 blood glucose monitor is intended for fast and simple blood glucose measurement in 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, save 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 backlit display shows measurements clearly. The user-friendly design with handy test strips and simple operation by means of just a few buttons guarantee simple yet reliable measurements.
The measured values can be transferred via *Bluetooth*® or USB to the “beurer HealthManager Pro” app.

1.1 Scope of delivery and accessories and/or replacement parts

Check the set to ensure that packaging has not been tampered with and make sure that all contents are present. Before use, ensure that there is no visible damage to the device and accessories and/or replacement parts 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	10 sterile lancet needles (5 x 28G blue, 5 x 33G purple)
E	2 button cell batteries, 3 V CR2032 (already inserted)
F	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 monitor.

Note

- Use only original accessories and/or replacement parts from the manufacturer.

1.2 Follow-up purchases

You can obtain test strips, control solution and lancets without a prescription.

Article	Item no.	PZN (PIP) Germany
25 pcs GL60 test strips	463.56	–
50 pcs GL60 test strips	463.58	PZN 16382647
100 pcs GL60 test strips	463.63	PZN 16382653
GL60 control solution (LEVEL 9 & LEVEL 10)	463.75	PZN 16382682
100 pcs Lancet needles	457.01	PZN 3774707
100 pcs Soft-touch lancets	457.24	PZN 12734635
100 pcs Safety lancets	457.41	PZN 15996554
200 pcs Safety lancets	457.42	PZN 15996548

1.3 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 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 for the last 7, 14, 30 and 90 days,
- display the average labelled measured blood glucose values from the last 7, 14, 30 and 90 days,
- set the time and date,
- transfer the saved measurements to the “beurer HealthManager Pro” app and evaluate them there.

The monitor also includes the following monitoring functions:

- Warning in the event of unsuitable temperatures
- Ketone warning in the event of high blood glucose levels and glucose warning in the event of low blood glucose levels.

- Battery replacement indicator when batteries are low.
- Warning that test strip is insufficiently filled.

⚠ Warning

- **This device should not be used to diagnose diabetes; it is exclusively intended for regular monitoring.**
- **Insulin dosages must be determined in conjunction with your physician.**

1.4 Signs and symbols

The symbols on the packaging and type plate of the monitor, accessories and/or spare parts represent the following:

IVD	In vitro diagnostics
MD	Medical device
CE	**CE marking** This product satisfies the requirements of the applicable European and national directives.
REF	Order number
#	Type number
SN	Serial number
LOT	Batch designation
	Use by
	Manufacturer
EC REP	Authorised representative in the European Community
	Importer symbol

	Temperature range
	Humidity range
	Observe the instructions for use
mg/dL mmol/L	Unit of measurement for blood glucose value
	Biohazard, risk of infection
Σ <n>	Contents sufficient for <n> tests
1	Reuse on a single patient
6 M	Maximum usage life after opening, in months (in this example, 6 months)
2	Not for reuse / for single use only
STERILE R	Sterilised by radiation (lancets)
2 STERILIZE	Indicates that the device should not be re-sterilised after it has been sterilised once.

	Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive (WEEE)
	Separate the product and packaging elements and dispose of them in accordance with local regulations.
	Separate the packaging elements and dispose of them in accordance with local regulations.
	Marking to identify the packaging material. A = material abbreviation, B = material number: 1-7 = plastics, 20-22 = paper and cardboard

	Do not use if packaging is damaged.
	Single sterile barrier system with protective packaging on the outside.
	Protect from sunlight
	Keep dry

The instructions for use include symbols that represent the following:

⚠ Warning

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

⚠ Important

Safety note indicating possible damage to the device, accessories and/or replacement parts.

ⓘ Note

Note on important information.

2. Warnings and safety notes

Risk of infection

All components of the monitor, its accessories and/or its replacement parts may come into contact with human blood and are therefore a possible source of infection.

⚠ Warning

- **Blood glucose values are displayed using mg/dL or mmol/L as units.**
  You risk damaging your health if you measure your blood glucose value in an unfamiliar unit of measurement, then misinterpret the values and incorrectly take action on that basis. As such, please ensure that this monitor is set to display a unit of measurement that you are familiar with. The unit of measurement accompanies each blood glucose value.
  Please contact Customer Services if the device is displaying the incorrect unit of measurement.
- When using the monitor for multiple people, observe the generally applicable regulations regarding disinfection, safety and contamination.
- Medical carers and others who use this system on multiple patients must be aware that all products or objects that come into contact with human blood must be handled as though they could transfer pathogens, even after cleaning.

- The lancing device is suitable for self-testing. Do not share the lancing device and lancet needles with others, or use them with multiple 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 and mobile telephones.

Measuring blood glucose

Warning

- Measurements you take yourself are for your information only – they are no substitute for a medical examination! Consult your physician regularly to discuss your measured values. Never independently deviate from your physician's instructions.
- **Though the Beurer GL60 monitor for self-monitoring of blood glucose levels is simple to use, you may need to seek instruction in using the system from a healthcare professional (for example, your physician, chemist or diabetes consultant). Only with correct usage can precise measurements be guaranteed.**
- **This device may be used by people with reduced mental capabilities, provided that they are supervised or have been instructed in how to use the device safely and are fully aware of the consequent risks of use.**
- Dehydration, high fluid loss, for example through perspiration, frequent urination, severe hypotension (low blood pressure), shock or hyperosmolar hyperglycaemic non-ketotic coma (HHNC) may result in incorrect measurements.
- A haematocrit value between 0% and 70% has no significant influence on the measurements.
- A very high haematocrit value (proportion of red blood cells) may lead to incorrect measurements. If the haematocrit value is very high (above 70%), the displayed blood glucose value may be too low. Consult your physician if you do not know your haematocrit value.
- Do not use the test strips to measure blood glucose values of newborn babies.
- Do not test any severely ill patients using this device.
- Use fresh whole blood only. Do not use serum or plasma.
- Use capillary blood obtained without squeezing the puncture area. Squeezing the area causes the blood to be diluted with tissue fluid and this may lead to an incorrect measurement.
- Do not use the test strips above an altitude of 3275 m.
- **Very high levels of humidity may influence the test results. Relative humidity of more than 90% may lead to inaccurate results.**

Note

- The Beurer GL60 monitoring system is intended for measuring capillary whole blood.

Storage and maintenance

⚠ Warning

- Store the monitor, its accessories and/or replacement parts out of the reach of small children and pets. Small parts, such as lancet needles, parts of the lancing device, batteries or test strips may cause a risk to life if swallowed. If a part is swallowed, seek medical attention immediately.
- The test strip box contains desiccant, which may irritate the skin or eyes if inhaled or swallowed. Keep the box out of the reach of children.

The monitor is made with precision and electronic components. The accuracy of the measured values and service life of the device depend on careful handling:

- Protect the device, its accessories and/or replacement parts from impact, humidity, dirt, dramatic temperature fluctuations and direct sunlight. Do not store the device, test strips or control solution in a vehicle, in the bathroom or in a cooling appliance!
- Do not drop the device.

Batteries / saving measured values

⚠ Notes on handling batteries

- If your skin or eyes come into contact with battery fluid, rinse the affected areas with water and seek medical assistance.

⚠ Choking hazard!

Small children may swallow and choke on batteries. Therefore, store batteries out of the reach of small children!

- Observe the plus (+) and minus (-) polarity signs.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- Protect batteries from excessive heat.

⚠ Risk of explosion!

Do not throw batteries into a fire.

- Do not charge or short-circuit the batteries.
- If the device is not going to be used for a long period of time, remove the batteries from the battery compartment.
- Use identical or equivalent battery types only.
- Always replace all batteries at the same time.
- Never use rechargeable batteries!
- Do not disassemble, open or crush the batteries.

ⓘ Note

- The saved 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 of the correct type only.

Repairs

Note

- Do not open the device. Failure to comply with this instruction will void the guarantee.
- Do not repair the device yourself. Proper operation can no longer be guaranteed in this case.
- Do not dismantle the lancing device into its individual parts, apart from 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 from the monitor. Correctly dispose of all blood samples and materials with which you or your patients come into contact in order to prevent injury and infection of other persons.
- After use, dispose of test strips and lancets in a puncture-proof container.

Note

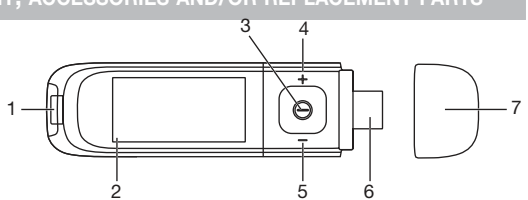
The empty, completely flat batteries must be disposed of at specially designated collection boxes, recycling points, or electronics retailers. You are legally required to dispose of the batteries.
The codes below are printed on batteries containing harmful substances:
Pb = battery contains lead,
Cd = battery contains cadmium
Hg = battery contains mercury

For environmental reasons, do not dispose of the device in household waste at the end of its service life. Dispose of the device at a suitable local collection or recycling point in your country. Dispose of the device in accordance with EC Directive Waste Electrical and Electronic Equipment (WEEE). If you have any questions, please contact the local authorities responsible for waste disposal.

3. Description of equipment, accessories and/or replacement parts

3.1 Blood glucose monitor

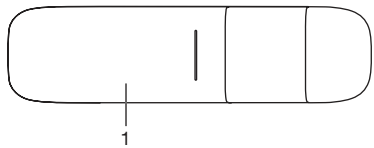
Front



1. Slot for test strips
2. Display
3. “ON/OFF” button
4. “+” button
5. “-” button
6. Plug-in USB
7. Cap

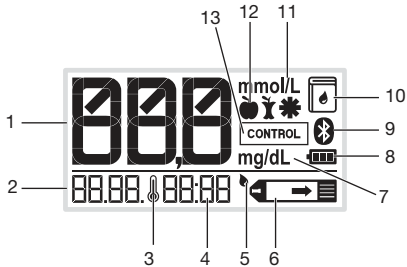
Rear

1. Battery compartment cover



3.2 Display symbols

1. Measurement display
2. Date
3. Temperature indicator
4. Time
5. Blood droplet symbol
6. Test strip symbol
7. Measurement unit mg/dL
8. Charging status
9. *Bluetooth*®
10. Measurement memory symbol
11. Measurement unit mmol/L
12. Measurement labelling
13. Control solution mode



Note

The monitor is supplied with the following default settings:

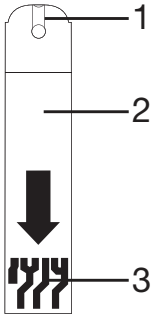
- Language English.
- Acoustic signal off.
- *Bluetooth*® on.

Warning

Ensure that you are using a device with the correct blood glucose unit (either mg/dL or mmol/L) option for you. The blood glucose unit on the device cannot be set or changed. If you are unsure, consult your physician.

3.3 Test strips

Front



1. Recess for blood collection
2. Handling surface
3. Contacts

Rear

You can identify the rear by the contact bars.

Insert the test strip into the device so that the contacts are pointing into the slot.
Make sure that the device display and the front of the test strip are facing you.
The arrow printed on the front must point towards the device.

Note

Carefully read the following information on handling and storing your test strips. The test strips will only provide accurate measurements if all points are followed.

Warning

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

Handling test strips

Note

- Securely close the test strip box immediately after taking out a test strip.
- Do not use test strips if they have expired. Using expired test strips may lead to incorrect measurements. The expiry date is printed on the box next to the hourglass symbol.
- Use the test strip to take a measurement immediately after removing it from the box.
- You can touch any part of the test strip with clean, dry hands.
- Do not bend, cut or otherwise modify the test strips.
- Do not use test strips that have come into contact with fluids.

Storage of test strips

Note

- Store test strips in a cool, dry place above 2°C (35.6°F) and below 32°C (89.6°F). Do not expose test strips to direct sunlight or heat. Do not store them in a vehicle, a bathroom or in a cooling appliance.
- Permissible relative humidity between 10% and 90%.
- Keep test strips in the original box only – never use other containers.

4. Initial use and basic settings

4.1 Removing the battery isolation strips, replacing the batteries

Note

- Two batteries are included in delivery with the blood glucose monitor. These are already inserted in the battery compartment.
- Remove the isolation strips before initial use.

1. Remove the battery compartment cover on the underside of the device.
2. When using the device for the first time, remove the isolation strips and make sure that the batteries are inserted correctly.
3. When replacing the batteries, remove all batteries. If necessary, adjust the date and time (see “Making and changing basic settings” on page 14).
4. Insert two new **CR2032** batteries. Make sure that the batteries are inserted the correct way round in accordance with the markings. Observe the graphic in the battery compartment.
5. Carefully close the battery compartment cover.

Note

- If the symbol appears on the display, the batteries are almost empty. Replace both batteries as soon as possible.
- If "LP" appears on the display, the battery power level is too low to take any more measurements.

4.2 Making and changing basic settings

Note

The abbreviations shown in the display vary depending on the selected language. Detailed explanations can be found in the following table:

Full German (DE)	Full English (EN)	DE	IT	EN	FR	ES	TR
Ja	Yes	Ja	Sì	Yes	Oui	Sí	Eet
Nein	no	No	No	No	Non	No	Hyr
Setzen	Set	Set	Set	Set	Rég	Aju	Ayr
Beep	Beep	Beep	Bep	Bep	Bip	Pit	Bip
An	On	An	On	ON	ON	ON	Açk
Aus	Off	Aus	OFF	OFF	OFF	OFF	OFF
Ketone	Ketone	Ket	Che	Ket	Cet	Cet	Ket
Bluetooth	Bluetooth	BT	BT	BT	BT	BT	BT
Zielwert	Target Value	BZ	Des	Tar	Cib	Obj	Hdf
Verbinden	Pairing	Con	Con	Con	Con	Con	Con
Nicht OK	not ok	nOK	nOK	nOK	pOK	nOK	Bşz
Löschen	delete	Del	El	Del	Eff	Eli	Sil
Unterzucker	Hypoglycaemia	Unt	Ipo	HyP	HyP	HiP	HiP
Niedrig	low	Lo	Lo	Lo	Lo	Lo	Lo
Hoch	high	Hi	Hi	Hi	Hi	Hi	Hi
USB	USB	uSb	uSb	uSb	uSb	uSb	uSb

1 Remove the batteries and then reinsert them. Alternatively, press the "+" button and the "ON/OFF" button simultaneously until the *Bluetooth*® indicator flashes.

2 **Switching *Bluetooth*® on/off**

Switch *Bluetooth*® on/off by pressing the "+" button or "-" button.
"BT" "On" is displayed when it is switched on and "BT" "OFF" is displayed when it is switched off.
Confirm by pressing the "ON/OFF" button.

3 **Setting the language**

Set the language by using the "+" and "-" buttons to switch between languages. The languages available are: DE, IT, EN, FR, ES and TR. Confirm your selection using the "ON/OFF" button.

4 **Switching the acoustic signal on/off**
Switch the acoustic signal on/off by pressing the "+" button or "-" button. "bEEP" and "On" are displayed when it is switched on and "bEEP" and "OFF" are displayed when switched off.
Confirm by pressing the "ON/OFF" button.

5 Setting the date and time

Note

- It is essential that you set the date and time. Otherwise, you will not be able to save your measured values correctly with a date and time and access them again later.
- The time is displayed in the 24-hour format.

Set the year (calendar to 2099) by pressing the "+" button or "-" button. Confirm by pressing the "ON/OFF" button.
The month display flashes.
Do the same for month, day, hour and minute.

6 **Setting the target range**
You can set a normal range for your blood glucose measurement results using the target scale. After a measurement is taken, the LED on the test strip insertion slot shows the corresponding colour.
Red light = measured value is below the set target range (Tar Lo)
Green light = measurement value is within the set target range
Yellow light = measured value is above the set target range (Tar Hi)

Set the lower limit of your target range (Tar Lo) by pressing the "+" button or "-" button. Confirm by pressing the "ON/OFF" button.
Set the upper limit of your target range (Tar Hi) by pressing the "+" button or "-" button. Confirm by pressing the "ON/OFF" button.

7 The monitor is now ready for use.

5. Taking the blood glucose measurement

Warning

- If the protective disc on a lancet has already been removed, do not use the lancet.
- If you drop the lancing device with a lancet needle inserted, carefully pick it up and dispose of the lancet.

Important

- Use the lancing device only with lancet needles from the same manufacturer. Using other lancet needles may prevent the lancing device from working properly.
- If using a lancing device from another manufacturer, please read the accompanying instructions for use.

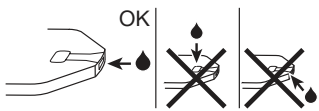
Please also note the following:

- If the blood glucose test results do not match how you feel, carry out another test using blood from your fingertip.
- DO NOT change your treatment purely on the basis of a measurement that was carried out using blood taken from an alternative area. Carry out another test with blood from your fingertip in order to confirm the test result.
- If you often fail to notice that you have a low blood glucose level, carry out a test using blood from your fingertip.

1 If there is an insufficient quantity of blood, repeat steps 1 to 12 from the lancing device instructions at the end of these instructions for use, with a greater penetration depth.

2 Discard the first drop of blood. Always only take measurements using the second drop of blood.

3 Hold the blood collection recess (at the end of the test strip) to the blood droplet until the recess is completely filled and the monitor in the display starts counting backwards. Do not press the puncture area onto the test strip. The blood must not be spread out. The blood will be sucked into the recess.



Note

Error message “002” appears on the display if the recess is not correctly and sufficiently filled with blood. Repeat the measurement using a new test strip and a greater puncture depth.

Note

- **Do not** apply blood to the sides of the test strips.
- **Do not** subsequently add extra blood if the device does not start the measurement. Remove the test strip and end this test process. Use a new test strip.
- If no further action is taken or no button is pressed within 30 seconds after activating the device, the display backlight switches off. The illuminated test strip slot will start to flash in white until the device switches off automatically, after a total of two minutes of inactivity.
- 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 fill the test strip with blood correctly.
- If you are measuring in a dark environment, press the On/Off button to switch the device on. This switches on the test strip slot light, making it easier to insert the test strip. It also switches on the backlight in the results display.

5.1 Reading the result and labelling the measurement values

Reading the result

As soon as the recess is sufficiently filled with blood, the device performs the blood glucose measurement. The monitor counts down for approx. five seconds.
The measurement is then shown on the display.

Reading the target scale

You can use the target scale to determine if your blood glucose measurement is within the set normal range. After a measurement is taken, the test strip insertion slot lights up in a colour. This colour indicates the measured value's position in relation to the target range.
Red light = measured value is below the set target range
Green light = measurement value is within the set target range
Yellow light = measured value is above the set target range

Labelling measured values

You have the following options for labelling measured values.

	Before a meal.
	After a meal.
	General labelling (e.g. after physical exertion).

Labelling measured values enables you, your physician or diabetes consultant to better monitor your blood glucose values. For example, it means you can display the average values of all measurements taken before meals.
The measured value can be labelled when it is first displayed. You cannot adds labels later.
To do this, briefly press the "+" button.
a) Pressing once labels the value with  .
b) Pressing again labels the value with  .
c) Pressing yet again labels the value with .
d) Pressing a further time removes the label.
Use the minus button to set the previous label.
Confirm the desired label with the "ON/OFF" button.
The selected label is saved in the device memory when it is switched off.

5.2 Final steps and disposal

Remove the test strip from the device. Carefully dispose of the test strip in accordance with the currently applicable regulations, to avoid infecting other people.

5.3 Evaluating measured blood glucose values

Your blood glucose monitor can process measured values between 10 and 630 mg/dL (0.56 and 35.0 mmol/L). The "Lo" warning message is displayed for measured values below 10 mg/dL (0.56 mmol/L). The "Hi" warning message is displayed for measured values above 630 mg/dL (35.0 mmol/L).

⚠ Warning

- If you suspect incorrect blood glucose results, first repeat the test and then, if applicable, perform a functionality test using control solution. Seek advice from your physician if questionable results persist.
- Please contact your physician if your symptoms are not in line with your measured blood glucose values and you have observed all instructions for the Beurer GL60 Blood Glucose Monitoring System.
- Do not ignore symptoms of too high/low blood glucose levels. Consult your physician.

Blood glucose values

The following tables list blood glucose values based on the STANDARDS OF MEDICAL CARE IN DIABETES 2016 from the ADA (American Diabetes Association).

Time of blood glucose measurement	Normal blood glucose values	Increased risk of diabetes (prediabetes)*	Diabetes
• On an empty stomach • (fasting plasma glucose)	Below 100 mg/dL Below 5.6 mmol/L	100-125 mg/dL 5.6-6.9 mmol/L	≥ 126 mg/dL ≥ 7.0 mmol/L
Two hours after an oral glucose tolerance test (consumption of 75 g)	Below 140 mg/dL Below 7.8 mmol/L	140-199 mg/dL 7.8-11.0 mmol/L	≥ 200 mg/dL ≥ 11.1 mmol/L

** The risk increases continually, beginning with values below the lower limit of the range and increasing disproportionately towards the upper limit of the range.*

Overview of glycaemic recommendations for non-pregnant adults with diabetes	
A1C	< 7.0%* < 53 mmol/mol*
Preprandial capillary plasma glucose	80-130 mg/dL* 4.4-7.2 mmol/L*
Peak value of postprandial capillary plasma glucose**	< 180 mg/dL* 10.0 mmol/L*

** For certain patients, more or less strict glycaemic targets may be appropriate. The target values should be adjusted depending on the length of time the person has had diabetes, age/life expectancy, accompanying diseases, known cardiovascular diseases or advanced microvascular complications, disrupted hypoglycaemia perception, as well as individual patient considerations.*

*** The postprandial glucose value can serve as a target value if the A1C values are not met despite the preprandial glucose targets having been reached. Postprandial blood glucose measurements should be taken one to two hours after the start of a meal, as this is when diabetics' values are generally highest.*

Evaluating critical measured values

Display		Blood glucose	Action
Lo	Lo	Measurement result is outside the detectable range below 10 mg/dL (below 0.56 mmol/L)	Immediate medical treatment is required.
65 mg/dL	3,6 mmol/L	Low blood glucose level below 70 mg/dL (below 3.9 mmol/L)	Have a suitable snack. Follow the instructions from your physician.

Display		Blood glucose	Action
		High blood glucose level on an empty stomach, above 100 mg/dL (5.6 mmol/L) Two hours after a meal, over 140 mg/dL (7.8 mmol/L)	If this high value persists 2 hours after your last meal, this may indicate hyperglycaemia (high blood glucose). Consult your physician about any measures you may need to take.
		High blood glucose level, possibly ketones above 250 mg/dL (13.9 mmol/L)	Conduct ketone test Consult your physician on how to do this.
		Very high blood glucose level above 630 mg/dL (35.0 mmol/L)	Take another measurement using a new test strip. If the result is the same as before, immediately seek medical assistance.

5.4 Functionality 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 that tests are being performed correctly. Perform the control solution test if you suspect that the monitor and/or the test strips could be faulty or if you have repeatedly measured unusual blood glucose values. Also test the monitor if it has been dropped or is damaged. The control solution is available separately. For the control solution test, please observe the additional notes in the instructions for use for the control solution.

⚠ Important

- Do not use control solution from a different manufacturer. Correct functioning of your monitor can only be tested using Beurer control solutions (463.75, LEVEL 9 + 10).
- Control solution measurements: When using the device, specialist personnel must follow federal, state and regional guidelines.
- Do not apply any blood samples or control solutions to the test strip before inserting it in the monitor.

Carrying out a functionality test using control solution

⚠ Warning

To obtain correct results, the monitor, the test strip and the control solution must be the same temperature. For the “functionality test with control solution” this should be room temperature, between 18°C and 28°C. Testing at room temperature serves as a general functionality check. The operating range specified in the technical specifications is valid without restriction.
Testing at room temperature serves as a general functionality check. The operating range specified in the technical specifications is valid without restriction.

1. Hold the monitor so that the display is facing you.
2. Insert a test strip into the slot on the monitor, contacts first. Make sure that the front of the test strip is facing you.
3. The device switches on automatically and briefly shows the initial display. The device is ready for measuring once the test strip droplet symbol  starts flashing.

   IMPORTANT: Control solutions and blood respond differently to temperature influences. 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 “+” button or “-” button to change to control mode. “CONTROL” is shown on the display. This means that the result value is not stored in the memory, and as such does not impact your measured value statistics. Press “+” or “-” again. “CONTROL” disappears from the display and the value is stored 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 squeeze two drops next to each other on the clean surface without touching them.
   You must use only the second drop for the measurement.

   Note

   Do not apply the drop directly to the test strip; this is to avoid contaminating the remaining control solution in the bottle by touching the test strip with the tip of the bottle.
5. Hold the collection recess (at the end of the test strip) to the drop of control solution until the recess is completely filled and the display of the monitor starts counting backwards.
   When the recess is filled with solution, the device performs the measurement. The device counts down for approx. five seconds. The measurement 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, the test strip packaging or on the information sheet included.

Expected results

At room temperature, the measured values from the test using the control solution should be at approx. 95% of all tests in the range of values.

Warning

The specified range of values only applies for the control solution. **This is not a recommended value for your blood glucose level.**
If measurements 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 from a new box.
The control solution, test strips or monitor are too warm or too cold.	Bring the control solution, test strip and monitor to room temperature (+18°C to +28°C) and repeat the test. Testing at room temperature serves as a general functionality check. The operating range specified in the technical specifications is valid without restriction.
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 air for too long. • The test strip box was not closed completely.	Repeat the test using a new test strip and/or correctly stored test strips from a new box.
There is a problem with the monitor.	Contact Customer Services.
Functionality test was performed incorrectly.	Repeat the test and follow the instructions.

Warning

If you repeatedly obtain measurements outside the specified range when using control solution, **do not use the system to measure your blood glucose level.** Contact Customer Services.

6. Measured-value memory

For each measurement, your blood glucose value is automatically saved with the date and time as well as the measured value label. This does not apply to values measured in control solution mode (“CONTROL”). These are not saved.
The memory can store a maximum of 900 measured values. If the memory is full, the oldest value is replaced with the most recent value. You can call up every individual measured blood glucose value. You can also calculate and display the average blood glucose 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 measured-value memory. Press the “ON/OFF” button to switch off the device.

6.1 Displaying individual values

The individual values from the last 900 measurements are displayed. The most recent measured value is displayed first, and the oldest last. At the same time, the monitor displays the date and time of the measurement as well as the memory position of the measured value. A label saved with the measurement can additionally be displayed.

1 Switch on the monitor using the “ON/OFF” button. The initial display is shown briefly. Access the measured-value memory by pressing and holding the “+” button or “-” button.

2 The recorded measurement value with the measurement unit, time, , and any measurement label is briefly displayed together with the memory space number (image 1). The memory space number is then replaced in the display by the date (image 2).

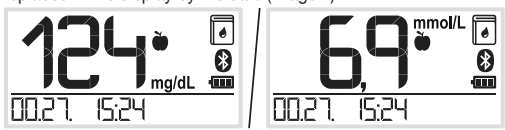


Image 1

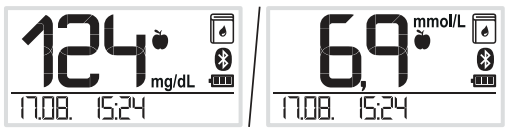


Image 2

3 Each time the “+” key or “-” key is pressed again, another measured value is displayed. You can display a maximum of 900 previous measurements.

4 You can cancel the process at any time. To do this, press the “ON/OFF” button or wait until the device switches off automatically after 2 minutes.

6.2 Displaying average blood glucose values

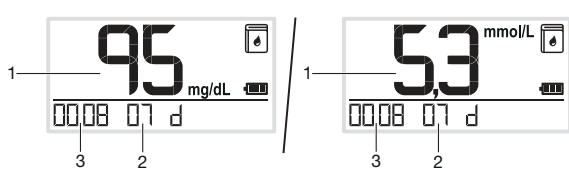
You can display the average measured blood glucose value for the last 7, 14, 30 and 90 days.

1 Switch on the monitor using the “ON/OFF” button. Access the measured-value memory by pressing and holding the “+” button or “-” button. The last measured value is displayed. Press the “ON/OFF” button to display the average value for 7 days.

2 Press “+” 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 2 minutes.

Pos.	Meaning
1	Average value
2	Number of days, e.g. 7
3	Number of saved values used to calculate the average



6.3 Displaying average blood glucose values for labelled values

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

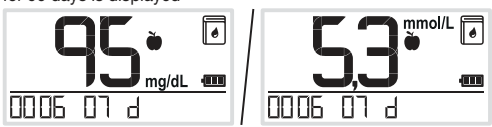
1 Switch on the monitor using the “ON/OFF” button. The initial display is shown briefly. Enter the measured-value memory by pressing and holding the “+” or “-” button. The last measured value is displayed. Briefly press the “ON/OFF” button to display the average value for 7 days.

2 Press “+” 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 7-day average of “before meal” measured values,
- the symbol,
- the unit of measurement for blood glucose values and
- “07 d”

are shown on the display.



Press “+” repeatedly to display the average of measured values from the last 14, 30 and 90 days.

After displaying the 90-day average of “before meal” measured values, the 7-day average of “after meal” measured values, the symbol, the blood glucose value unit and “07 d” are shown in the display.

Press “+” repeatedly to display the average of “after meal” measured values from the last 14, 30 and 90 days.

After displaying the 90-day average of “after meal” measured values the 7-day average of “general” labelled values, the symbol, the blood glucose value unit and “07 d” are shown in the display.

Press “+” repeatedly to display the average of “general” labelled values from the last 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 2 minutes.

6.4 Transferring of measured values

Transfer via *Bluetooth*®

- Download the free “beurer HealthManager Pro” from the Apple App Store or Google Play.

Click here for the “beurer HealthManager Pro” app*

- Activate *Bluetooth*® in your smartphone’s settings.
- Start the app.
- Select GL60 in the app and follow the instructions.
- When connecting for the first time, a six-digit PIN code will be displayed on the device. Enter the PIN code on the smartphone. After successfully entering the code, the device will be connected to the smartphone.

List of system requirements and compatible devices

* This product satisfies the requirements of the applicable European directives.

6.5 Transferring via USB

You can transfer your data using the “beurer HealthManager Pro USB-Uploader” PC software. This requires a USB cable (included in delivery).
You can download the software free of charge at the following link: connect.beurer.com/download/software
Once you have transferred the data using the PC software, you can view it in the “beurer HealthManager Pro” app and web view.

System requirements for the “beurer HealthManager Pro USB-Uploader” PC software

7. Storage, maintenance and disinfection of the device

Storage

Keep the Beurer GL60 measuring system in the case supplied after each measurement and do not expose it to direct sunlight.

Note

- Do not store the device, test strips or control solution in a 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.

7.1 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 liquids 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, nor be cleaned in the dishwasher. Dry the lancing device using a lint-free cloth.

7.2 Disinfection

Device

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

Note

The monitor is made with precision components. The accuracy of the measurements and service life of the device depend on its careful handling:

- Protect the device from impact and do not drop it.
- Protect the device from damaging influences such as moisture, dirt, dust, blood, control solution or water, marked temperature fluctuations, direct sunlight and extreme cold.
- If the device is used in a dry environment, in particular near synthetic materials (clothes containing synthetic fibres and carpets, for example), the damaging static discharges which occur may cause erroneous results.
- Do not use the device near sources of strong electromagnetic radiation, as this may affect normal operation.
- It is a good idea to carry out an assessment of the electromagnetic environment before using the device commercially.

8. What if there are problems?

Display messages about batteries and blood glucose measurement

No.	Cause	Solution
LP	Flat batteries.	Replace all batteries.
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, monitor and test strip have reached the permissible operating temperature.

No.	Cause	Solution
Lt	Temperature of the measuring environment, blood glucose monitor or test strip was below the permitted range.	Repeat the test using a new test strip as soon as the measuring environment, monitor and test strip have reached the permissible operating temperature.
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 and reinsert batteries. If the problem persists, contact Customer Services.
Err002	Insufficient blood on the test strip	Repeat the measurement using a new test strip.
Err004	System error	Remove and reinsert batteries. If the problem persists, contact Customer Services.
	Unknown error messages	Remove and reinsert batteries. If the problem persists, contact Customer Services.

Problem: Device does not switch on

Cause	Solution
Flat batteries.	Replace batteries.
Incorrectly inserted or missing batteries.	Check that the battery has been inserted correctly (see “Removing the battery isolation strips, replacing the batteries” on page 13)
Test strip incorrectly or incompletely inserted.	Firmly insert the test strip into the slot on the device, contacts first. Make sure that the front of the test strip is facing you (see “Test strips” on page 12).
Defective device.	Contact Customer Services.

Problem: The test does not begin 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 how to correctly fill the test strip (see page 16).
Defective 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. The device is only ready for measuring when the test strip symbol droplet  in the display starts flashing.
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.
Defective device.	Contact Customer Services.

9. Technical specifications

Dimensions (W x H x D)	113 mm x 29.5 mm x 14.7 mm
Weight	38.4 g
Power supply	2 x 3 V CR 2032 button cell batteries
Battery life	650 measurements
Measured-value memory	900 measured values with date/time/measured value labelling Data retained when batteries are changed
Average values	for 7, 14, 30, 90 days
Automatic switch-off	2 minutes after last activity
Storage/transport temperature	**The following applies to the device without accessories:** Temperature: -20°C (-4°F) to 60°C (122°F) Relative humidity: 10-90% **The following applies to the set:** Temperature: 2°C (35.6°F) to 32°C (89.6°F) Relative humidity: 10-90%
Operating range for the set	Temperature: 4°C (50°F) to 40°C (104°F) Relative humidity: 10-90%
Glucose measurement range	Glucose: 10-630 mg/dL (0.56-35.0 mmol/L)
Blood sample	Capillary whole blood
Amount of blood	0.5 microlitres
Blood glucose measurement duration	Approx. 5 seconds
Calibration	Plasma
Testing method	Amperometric bio sensor
Usage	Suitable for self-testing
System function test	Each time device is switched on
Data transfer via *Bluetooth*® low-energy technology	The blood glucose monitor uses *Bluetooth*® low-energy technology, frequency band 2.4-2.48 GHz, the maximum transmission power emitted in the frequency band 0 dBm (1 mW), compatible with *Bluetooth*® 4.0 smartphones/tablets. Technical specifications are subject to change without notification to allow for updates.

The serial number is located on the device or in the battery compartment.

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 device. For more details, please contact Customer Services at the address indicated.

Test strip functionality

Test strips enable a quantitative measurement of the glucose level in fresh whole blood. When the recess for collecting blood comes into contact with a droplet of blood, it is automatically filled by simple capillary action.

The blood is sucked into the absorbing recess on the test strip and the monitor measures the glucose level in the blood.
The test is based on the measurement of an electric current that is generated by means of the chemical reaction of the glucose with the enzyme glucose dehydrogenase (Aspergillus oryzae) on the strip.
During the reaction, a mediator transports electrons through the electrode surface and thereby generates a current.
The 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 (0.5 microlitres) and the duration of measurement is approx. five seconds. The test strips detect blood glucose values from 10 to 630 mg/dL (0.56 to 35.0 mmol/L).

Chemical components of the test strip sensor

- FAD glucose dehydrogenase 1.2%
- GDH 4.03 U/test strips
- Electron shuttle 2.2%
- Enzyme protector 5%
- Non-reactive components 91.6%

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 measurement obtained using control solution must be within the appropriate results range. This results 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 9	Control solution LEVEL 10
D-glucose	0.13%	0.35%
Non-reactive components	99.87%	99.65%

Standards

The Beurer GL60 measuring system complies with European guidelines IVD (98/79/EC) and MDR (EU) 2017/745).
We hereby confirm that this product complies with the European RED Directive 2014/53/EU.
The CE Declaration of Conformity for this product can be found under:
https://www.beurer.com/web/we-landingpages/de/cedeclarationofconformity.php

10. Comparison of measured values with laboratory values

Precision

Three batches of the GL60 blood glucose test strips were tested to assess the precision of the GL60 blood glucose measuring system. This included a repeatability assessment using venous blood and a laboratory precision assessment using the control material. The blood glucose content of the venous blood samples ranged from 39.5 to 330.0 mg/dL (2.2 to 18.3 mmol/L) and control material at three concentrations was used.

Results of the repeatable precision measurements

Sample	Venous blood		Overall average value		Pooled standard deviation		Pooled coefficient of variation (%)
	mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L	
1	39.5	2.2	36.9	2.1	2.2	0.12	5.9
2	80.9	4.5	83.5	4.6	2.8	0.16	3.4
3	123.5	6.9	122.9	6.8	3.0	0.17	2.4
4	234.0	13.0	231.9	12.9	5.7	0.32	2.4
5	330.0	18.3	331.3	18.4	7.6	0.42	2.3

Results of the intermediate precision measurement

Sample	Control material		Overall average value		Pooled standard deviation		Pooled coefficient of variation (%)
	mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L	
1	40	2.2	46.9	2.6	1.5	0.08	3.2
2	120	6.7	122.6	6.8	2.1	0.12	1.7
3	350	19.4	345.0	19.2	6.1	0.34	1.8

System accuracy

The GL60 blood glucose monitor in comparison to the YSI.
Three batches of GL60 blood glucose test strips were tested to assess the system accuracy of the GL60 blood glucose measuring system and to compare it with the reference method, for which capillary whole blood concentrations of 34.6 ± 0.9 mg/dL (1.9 ± 0.05 mmol/L) to 545.9 ± 14.1 mg/dL (30.6 ± 0.8 mmol/L) were used.

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

Within ±5mg/dL (Within ±0.28 mmol/L)	Within ±10mg/dL (Within ±0.56 mmol/L)	Within ±15mg/dL (Within ±0.83 mmol/L)
123/168 (73.2%)	158/168 (94.0%)	167/168 (99.4%)

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

Within ±5%	Within ±10%	Within ±15%
274/432 (63.4%)	386/432 (89.4%)	428/432 (99.1%)

Results of the system accuracy for combined glucose concentrations between 34.6 ± 0.9 mg/dL (1.9 ± 0.05 mmol/L) and 545.9 ± 14.1 mg/dL (30.6 ± 0.8 mmol/L).

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
595/600 (99.2%)

In comparison to the YSI, the GL60 met the EN ISO 15197:2015 standard, whereby 95% of the blood glucose values measured have to fall within the following ranges: either ±15 mg/dL (±0.83 mmol/L) of the measured average value when using the reference measuring procedure for blood glucose concentrations of <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 ranges 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 106 individuals that had no special training, produced the following results:
100% within ±15 mg/dL (±0.83 mmol/L) with glucose concentrations <100 mg/dL (<5.55 mmol/L) and 96.8% within ±15% of the values obtained in the medical laboratory with glucose concentrations of at least 100 mg/dL (5.55 mmol/L).

11. Usage limitations for specialist personnel in the healthcare sector

1. If the patient exhibits the following symptoms, it may be the case that no correct values can be obtained:
   - Acute dehydration
   - Acute hypotension (low blood pressure)
   - Shock
   - Hyperosmolar hypoglycaemic condition (with or without ketosis)
2. Lipaemic samples: Cholesterol levels up to 1200 mg/dL (31.036 mmol/L) and triglyceride levels up to 1525 mg/dL 15.256 g/L do not influence the results. Severely lipaemic blood samples were not tested with the Beurer GL60 blood glucose measuring system; we therefore do not recommend using the device with these samples.
3. In the case of severely ill patients, blood glucose monitors for home use should not be used.
4. The effect of interfering substances on the measurements depends on the concentration in the blood. The maximum concentrations of certain substances listed below do not significantly influence the measurements.

Influence / Concentration of tested substances			Blood glucose value 50-100 mg/dL (2.8-5.6 mmol/L)	Blood glucose value 250-350 mg/dL (13.9-19.4 mmol/L)
Acetaminophen	4.25 mg/dL	0.281 mmol/L	4.6 mg/dL (0.25 mmol/L)	3.97%
Ascorbic acid	3 mg/dL	0.17 mmol/L	2.2 mg/dL (0.12 mmol/L)	1.2%

Influence / Concentration of tested substances			Blood glucose value 50-100 mg/dL (2.8-5.6 mmol/L)	250-350 mg/dL (13.9-19.4 mmol/L)
Bilirubin	25 mg/dL	0.428 mmol/L	-0.2 mg/dL (-0.01 mmol/L)	-8.87%
Cholesterol	1200 mg/dL	31.036 mmol/L	-4.3 mg/dL (-0.24 mmol/L)	3.37%
Creatinine	10 mg/dL	0.884 mmol/L	0.1 mg/dL (0.0037 mmol/L)	2.97%
Dopamine	2 mg/dL	0.131 mmol/L	6.4 mg/dL (0.36 mmol/L)	1.23%
EDTA	200 mg/dL	6.844 mmol/L	1.4 mg/dL (0.08 mmol/L)	-4.0%
Ephedrine	40 mg/dL	2.42 mmol/L	-0.9 mg/dL (-0.05mmol/L)	3.43%
Galactose	500 mg/dL	27.75 mmol/L	-2.8 mg/dL (-0.15 mmol/L)	-0.5%
Gentisic acid	2.5 mg/dL	0.162 mmol/L	5.8 mg/dL (0.32 mmol/L)	3.73%
Glutathione	100 µmol/L	0.10 mmol/L	1.7 mg/dL (0.096 mmol/L)	-3.43%
Haemoglobin	3000 mg/dL	0.465 mmol/L	-0.7 mg/dL (-0.04 mmol/L)	-2.13%
Heparin	5 IU/ml	5000 IU/l	-0.5 mg/dL (-0.03 mmol/L)	-5.6%
Ibuprofen	500 µg/ml	2.424 mmol/L	1.1 mg/dL (0.06 mmol/L)	1.27%
Icodextrin	750 mg/dL	0.468 mmol/L	-2.7 mg/dL (-0.15 mmol/L)	0.63%
L-Dopa	5 µg/ml	0.025 mmol/L	0.4 mg/dL (0.02 mmol/L)	1.57%
Maltose	2575 mg/dL	75.226 mmol/L	-7.7 mg/dL (-0.43 mmol/L)	-4.1%
Methyldopa	3 mg/dL	0.142 mmol/L	8.3 mg/dL (0.46 mmol/L)	-1.20%
Pralidoxime iodide	5 mg/dL	0.189 mmol/L	6.6 mg/dL (0.37 mmol/L)	-3.93%
Salicylate	500 µg/ml	3.62 mmol/L	3.7 mg/dL (0.2 mmol/L)	-2.2%

Influence / Concentration of tested substances		Blood glucose value	50-100 mg/dL (2.8-5.6 mmol/L)	250-350 mg/dL (13.9-19.4 mmol/L)
Salicylic acid	5 mg/dL	0.362 mmol/L	3.2 mg/dL (0.18 mmol/L)	1.83%
Tolbutamide	100 mg/dL	3.699 mmol/L	5.5 mg/dL (0.31 mmol/L)	-0.87%
Triglyceride	1525 mg/dL	15.256 g/l	-4.1 mg/dL (-0.23 mmol/L)	-6.4%
Uric acid	8 mg/dL	0.476 mmol/L	1.7 mg/dL (0.1 mmol/L)	4.4%
Xylose	5 mg/dL	0.333 mmol/L	6.8 mg/dL (0.38 mmol/L)	5.97%
Hydrogenated starch hydrosolate (HSH)	0.09 mg/dL	0.002 mmol/L	-0.5 mg/dL (-0.03 mmol/L)	-1.87%
Isomalt	0.09 mg/dL	0.002 mmol/L	-1.1 mg/dL (-0.06 mmol/L)	0.87 %
Lactitol	0.09 mg/dL	0.003 mmol/L	-0.1 mg/dL (-0.01 mmol/L)	-3.57 %
Maltitol	0.09 mg/dL	0.003 mmol/L	-1.7 mg/dL (-0.09 mmol/L)	-3.67 %
Mannitol	0.09 mg/dL	0.005 mmol/L	0.5 mg/dL (0.03 mmol/L)	-1.07 %
Sodium carbonate	37.5 mEq/l	37.5 mmol/L	6.6 mg/dL (0.3645 mmol/L)	9.77 %
Sorbitol	0.09 mg/dL	0.005 mmol/L	-2.8 mg/dL (-0.15 mmol/L)	-2.1 %
Tetracycline	5 mg/dL	0.112 mmol/L	-7.8 mg/dL (-0.43 mmol/L)	-5.07 %
Tolazamide	6 mg/dL	0.193 mmol/L	4.6 mg/dL (0.26 mmol/L)	2.03 %
Xylitol	0.09 mg/dL	0.006 mmol/L	-0.2 mg/dL (-0.01 mmol/L)	-6.0 %

12. Instructions for use of the LD 04 lancing device and the Soft lancets

12.1 Purpose

The lancing device is intended to be used in conjunction with a separate lancet to take a blood sample for measuring the sugar content of human capillary blood.
Use the lancing device with lancets only on the skin areas intended for taking the glucose measurement (fingertips).

Target group

The lancing device with lancets is suitable for use by humans at home. The lancing device is not suitable for use by people (including children) with restricted physical, sensory or mental abilities, or lack of experience and/or lack of knowledge, unless they are supervised by someone who is responsible for their safety, or have received instructions from this person on how to use the device. Do not allow children to play with the device.
The lancets are suitable for use on adults and children from 2 years of age.

Clinical benefits

Taking a blood sample to determine the glucose value in human capillary blood and to inform any medical treatment that may be prescribed as a result.

Indication

Applicable for diabetes mellitus to determine the glucose value in human capillary blood.

Contraindications

Use the lancing device with lancets only on the body parts listed in these instructions for use. Do not use on injured, inflamed or scarred skin or in areas where there is already sensory dysfunction.
If you drop the lancing device with a lancet inserted, carefully pick it up and dispose of the lancet. Change the puncture area each time you take a measurement, e.g. use a different finger or the other hand. Repeatedly using the same area may cause inflammation, numbness or scarring. Make sure the puncture area is hygienically clean.

12.2 Warnings and safety notes

⚠ Risks to the user

- The lancing device is suitable for self-testing. Never share the lancing device or lancet with others (risk of infection).
- Supervise children when using the device to ensure they do not play with it.
- Use a new sterile lancet for each blood sample (for single use only).
- If you drop the lancing device with a lancet inserted, carefully pick it up and dispose of the lancet.
- Change the puncture area each time you take a measurement, e.g. use a different finger or the other hand. Repeatedly using the same area may cause inflammation, numbness or scarring.
- Make sure the puncture area is hygienically clean.

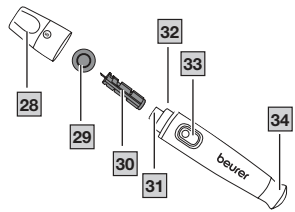
⚠ Risks to the device

- Use the lancing device only with lancets from the same manufacturer. Using other lancets may permanently prevent the lancing device from working properly.

12.3 Device description

Lancing device and lancets

28. Cap
29. Protective lancet disc
30. Sterile lancet
31. Lancet holder
32. Lancet ejection
33. Trigger button
34. Tensioning device

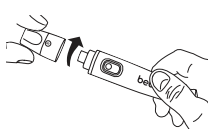


12.4 Initial use

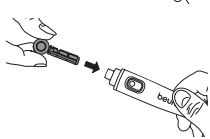
Unpack the lancing device and check that all the contents are present and intact. Before using the device for the first time, check that the lancing process works correctly. To do this, tension the lancing device once without a lancet inserted and press the trigger. When testing that the device functions correctly, make sure that there is NOT a lancet inserted in the lancing device.
If you have any doubts about whether the lancing device is working correctly, please contact our Customer Service team specified in these instructions for use.

12.5 Usage

1 Remove the cap **28** from the lancing device.



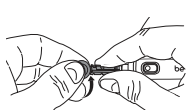
2 Insert a sterile lancet **30** into the lancing device and press it firmly into place.



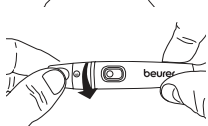
Note

Your starter set contains lancets in 2 different needle sizes. If you are unable to take an adequate blood sample using the smaller needles (purple, 33G), please use the slightly larger needles (blue, 28G).

3 Remove the protective lancet disc **29** by turning it while holding the shaft of the lancet. Retain the protective disc for the safe disposal of the used lancet after taking a blood sample.

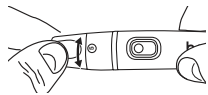


4 Place the cap **28** onto the lancing device.

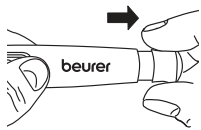


5 **Setting the penetration depth**
You can set seven different penetration depths on the lancing device. The penetration depth is displayed as a number.
- 1-3 = for soft or thin skin
- 4-6 = for normal skin
- 7-9 = for thick or callused skin

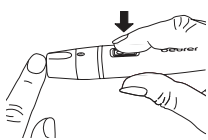
Turn the movable upper part of the cap until the desired penetration depth is displayed.



6 Pull the tensioning device 34 back until it audibly engages. Release the tensioning device. It automatically snaps back into the default position. The lancing device is now ready for use.



7 You may now use the lancing device to take a blood sample. Make sure that the blood remains as a droplet and is not spread. Immediately use the obtained blood droplet to take a measurement.



12.6 Blood sample from the fingertip

The best puncture points are the middle finger and the ring finger. Firmly position the lancing device slightly to the side of the centre of the fingertip. Press the trigger button. Remove the lancing device from the finger. A round drop of blood of at least 0.5 microlitres (corresponding to approx. 1.2 mm, actual size: ●) must have formed.

12.7 Please also note the following:

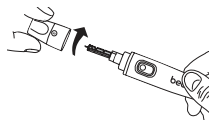
- If the blood glucose test results do not match how you feel, carry out another test using blood from your fingertip.
- DO NOT change your treatment purely on the basis of a measurement that was carried out using blood taken from an alternative area. Carry out another test with blood from your fingertip in order to confirm the test result.
- If you often fail to notice that you have a low blood glucose level, carry out a test using blood from your fingertip.

8 If there is an insufficient amount of blood, repeat steps 1 to 7 with a greater penetration depth.

9 Remove the test strip from the device using the test strip ejection slider. Carefully dispose of the test strip in accordance with the currently applicable regulations, to avoid infecting other people.

12.8 Final steps and disposal

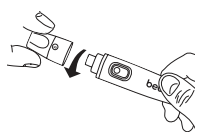
1 Carefully remove the cap **28** from the lancing device.



2 Place the retained protective disc flat on a hard surface. Stick the needle tip into the protective disc so the needle is no longer exposed. Take care not to touch the used lancet.

3 Use the sliding switch on the side.
This causes the lancet to drop out of the holder.
Carefully dispose of all blood samples and materials with which you or your patient have come into contact. Dispose of the lancet in a puncture-proof container. This prevents injuries and the infection of others.

4 Place the cap **28** back onto the lancing device.



12.9 Cleaning and maintenance

Clean the lancing device after each use. Remove and dispose of the lancet as described in points 7.9. to 7.12. of these instructions for use.
For cleaning, use a soft cloth or cotton bud that can be moistened with disinfectant or 70% alcohol. To clean the entire device, please use a soft cloth slightly moistened with a mild soapy solution. Under no circumstances may liquid enter the device. Do not use the device again until it is completely dry.

⚠ Risk of infection

All components of the monitor, its accessories and/or its replacement parts may come into contact with human blood and are therefore a possible source of infection.

12.10 Disposal

It is essential to comply with the generally applicable safety precautions for handling blood when disposing of the lancing device and lancets. Carefully dispose of all blood samples and materials with which you have come into contact in order to prevent injury and infection of others.

13. Guarantee and Customer Services

Beurer GmbH, Söflinger Strasse 218, 89077 Ulm, Germany (hereinafter referred to as “Beurer”) provides a guarantee for this product, subject to the requirements below and to the extent described as follows.
The guarantee conditions below shall not affect the seller’s statutory guarantee obligations which ensue from the sales agreement with the buyer.
The guarantee shall apply without prejudice to any mandatory statutory provisions on liability.
Beurer guarantees the perfect functionality and completeness of this product.
The worldwide guarantee period is 5 years, commencing from the purchase of the new, unused product by the buyer.
The guarantee only applies to products purchased by the buyer as a consumer and used exclusively for personal purposes in the context of domestic use.
German law shall apply.
During the guarantee period, should this product prove to be incomplete or defective in functionality in accordance with the following provisions, Beurer shall carry out a repair or a replacement delivery free of charge, in accordance with these guarantee conditions.
If a buyer wishes to file a guarantee claim, they should start by contacting the Beurer Customer Services team:
Beurer GmbH, Service Centre
Tel: +49 731 3989-144
For timely processing, please use the contact form on our homepage www.beurer.com under the “Service” section.
The buyer will then receive further information about the processing of the guarantee claim, e.g. the address to which they can send the product free of charge, and what documentation is required.
A guarantee claim shall only be considered if the buyer can provide:

- a copy of the invoice/purchase receipt, and
- the original product

to Beurer or an authorised Beurer partner.
The following are explicitly excluded from this guarantee:

- wear due to normal use or consumption of the product;
- accessories supplied with this product and/or replacement parts which are worn out or have been consumed through proper use (e.g. batteries, rechargeable batteries, cuffs, seals, electrodes, light sources, attachments, nebuliser accessories);
- products that are used, cleaned, stored or maintained improperly and/or contrary to the provisions of the instructions for use, as well as products that have been opened, repaired or modified by the buyer or by a service centre not authorised by Beurer;
- damage that arises during transport between manufacturer and customer, or between service centre and customer;
- products purchased as B-grade or used goods;
- consequential damage arising from a fault in this product (however, in this case, claims may exist arising from product liability or other compulsory statutory liability provisions).

Repairs or a full exchange do not extend the guarantee period under any circumstances.
OUR COMMITMENT TO YOU: We aim to satisfy customers by providing high-quality medical devices and the best customer service. Please contact Customer Services if you are not entirely satisfied with the product.

Where is the lancing device available?

Available without need for a prescription from your pharmacist or outlets selling Beurer blood glucose monitors. Please contact our Customer Services team if you have any further questions concerning the lancing device.

Current status of service addresses

www.beurer.com/service

Subject to errors and changes

beurer medical

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