beurer medical

GL 44
EN

# Instructions for use

Blood glucose monitor
Step by step

german engineering


IVD GL 44 CE 0483

Lancet needles / Lanzetten / lancettes / lancetas / lancette CE 0197

MD LD 03 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. Be sure to make them accessible to other users and observe the information they contain.

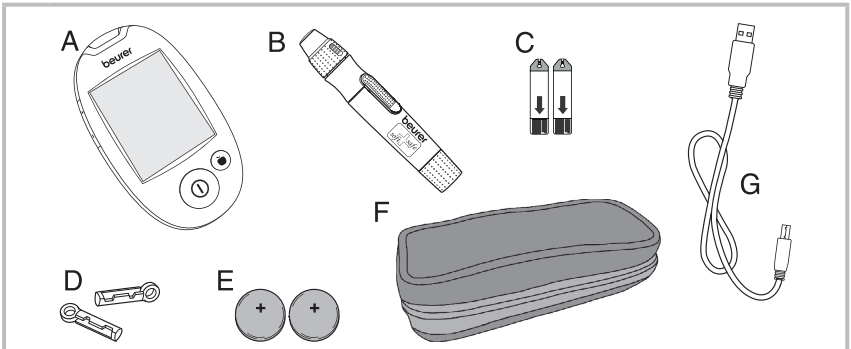
With kind regards,
Your Beurer team.

## Getting to know your device

The GL44 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 backlit display shows 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.
The device can be connected directly to a PC using the USB cable provided. You can evaluate the measured values on your PC using blood glucose diary software and use the results to monitor your blood glucose values.
Blood glucose diary software is available to download for free at www.beurer.com.

### 1.1 Scope of delivery and accessories

Check that the set 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 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 Service 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 |
| G | 1 USB cable |
| | 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 original manufacturer accessories only.

## 1.2 Replacements

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

| Item | REF |
|---|---|
| 50 test strips | REF 464.15 |
| 50 test strips, individually film packed | REF 464.17 |
| 100 test strips | REF 464.13 |
| Control solution LEVEL 3 and 4 | REF 464.16 |
| 100 soft touch lancets 33G | REF 457.24 |
| 100 lancet needles 28G | REF 457.01 |
| 100 safety lancets | REF 457.41 |
| 200 safety lancets | REF 457.42 |

## 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 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
- Transfer stored measured values to a PC for evaluation (additional accessories required)

The monitor also includes the following monitoring functions:

- Warning in the event of unsuitable temperatures
- Battery replacement display for low batteries
- Warning that test strip is insufficiently filled

**Warning**

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

## 1.4 Signs and symbols

The symbols on the packaging and type plate of the monitor and accessories represent the following:

| | | | |
|---|---|---|---|
| IVD | In vitro diagnostic device | | Manufacturer |
| SN | Serial number | | Observe the instructions for use |

| | |
|---|---|
|   | Temperature limit<br>+2 °C to +30 °C |
|  | Use by |
|   | Maximum shelf life after initial opening in months |
|   | Batch designation |
|   | Sterilised by radiation (lancets) |
|  | Warning, see accompanying documents |
|   | Medical device (MDR Symbol) |
|  | Read the instructions |

| | |
|---|---|
|  | Not for re-use/for single use only |
|  | Green dot (Der Grüne Punkt): German dual waste collection system |
|   | Contents sufficient for <n> tests |
|   / | Order number |
|   | Unit of measurement for blood glucose value |
|  | Biohazard, risk of infection |
|  | **CE labelling**<br>This product satisfies the requirements of the applicable European and national directives. |

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 device/accessory.

**Note**

Note on important information.

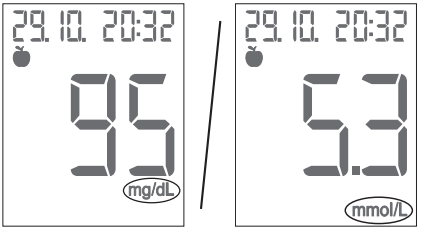
## 2 Warnings and safety notes

**Risk of infection**

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

**Warning**

- **Blood glucose values are displayed in mg/dL or mmol/L.**
  **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 subsequently take incorrect measures. Therefore, please ensure that this monitor displays a unit of measurement with which you are familiar.**
  **The unit of measurement accompanies each blood glucose value.**
  **Please contact Customer Services if the device displays the incorrect unit of measurement.**



Example

- When using the monitor for various persons, observe the generally applicable regulations 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. Never 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. Never independently alter the procedures prescribed by your GP.
- Despite the simple usage of the Beurer GL44 monitor for self-monitoring of blood glucose levels, you may possibly need to obtain instructions for using the system from your healthcare profes-

sional (for example, your GP, chemist or diabetes consultant). Only proper use will guarantee exact measurements.
- This device may be used by people with reduced mental capabilities provided that they are supervised or have been instructed on how to use the device safely and are fully aware of the consequent risks of use.
- 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 measurements.
- A haematocrit value between 20% and 60% has no significant influence on the measurements.
- A very high or low haematocrit value (proportion of red blood cells) may lead to incorrect measurements. In the event of a very high haematocrit value (above 60%), the displayed blood glucose value may be too low; in the event of a very low haematocrit value (below 20%), it may be too high. Consult your GP if you do not know your haematocrit 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.
- Use fresh whole blood only. Do not use serum or plasma.
- Use capillary blood without squeezing the penetration 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 7010 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 GL44 measuring system is intended for measuring capillary and venous whole blood.

**Storage and maintenance**

**Warning**

- Store the monitor and its accessories 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 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 monitor is made from precision and electronic components. The accuracy of the measured values 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**

⚠ **Notes on handling batteries**

- If your skin or eyes come into contact with battery fluid, rinse the affected area with water and seek medical assistance.
- ⚠ **Choking hazard!** Small children may swallow and choke on batteries. 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 batteries.
- If the device is not to be used for a relatively long period, take the batteries out of the battery compartment.
- Use identical or equivalent battery types only.
- Always replace all batteries at the same time.
- Do not use rechargeable batteries.
- Do not disassemble, open or crush the batteries.

**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**

**Note**

- Do not open the device. Failure to comply with this instruction will void the warranty.
- Do not repair the device yourself. 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 from the 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.

**Note**

Empty, completely flat batteries must be disposed of through 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.

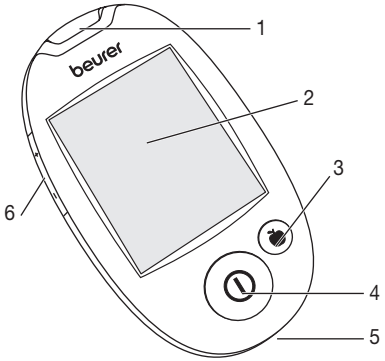

For environmental reasons, do not dispose of the device in the household waste at the end of its service life. Dispose of the device at a suitable local collection or recycling point in your country. Dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment).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

## 3 Description of device and accessories

### 3.1 Blood glucose monitor

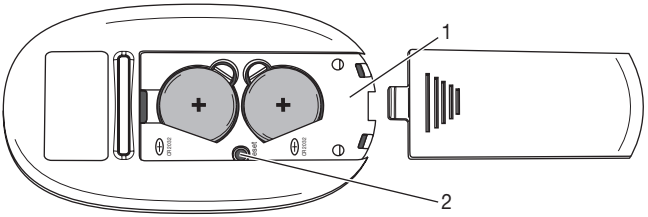
**Front**

1 Receptacle for test strips, illuminated
2 Display
3 Highlight button
4 On/Off button
5 PC connection
6 “+ –” rocker switch



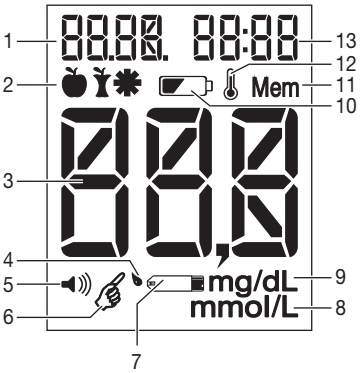

**Rear**

1 Battery compartment (bottom side)
2 Reset button



### 3.2 Display symbols

1 Date
2 Symbols for highlighting measurements
3 Measured value display, HI, LO display, average blood glucose value, Err
4 Blood droplet symbol
5 Speaker symbol
6 Hand symbol
7 Test strip symbol
8 Blood glucose unit mmol/L
9 Blood glucose unit mg/dL
10 Battery replacement symbol
11 Memory symbol
12 Temperature symbol
13 Time




**Note**

The monitor is supplied with the following basic settings:

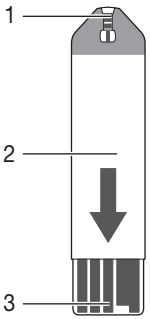
- Acoustic signal off
- Backlighting off

**Warning**

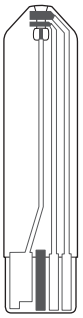
Ensure that you are using the device with the correct blood glucose unit (either mg/dL or mmol/L) setting for you.
If in doubt, consult your GP.

### 3.3 Test strips

**Front**



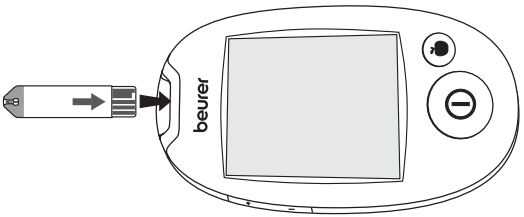

**Rear**



1 Gap for blood input
2 Grip area
3 Contacts

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 information is 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 located next to the hourglass symbol on the box or on the respective film packaging of the individual test strips.
- Test strips expire 18 months after the box is opened. Make a note of the expiry date (opening date + 18 months) on the label. The shelf life is limited to the expiry date (see date next to the hourglass symbol). This does not apply for individual test strips, which are to be used immediately after opening.
- Discontinue use of the test strips if one of the two 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/film packaging.
- 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**

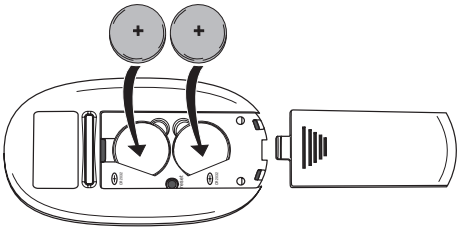
- Keep the test strips in a cool, dry place above +2°C and below +30°C. Do not expose the test strips to direct sunlight or heat. Do not store in your vehicle, in the bathroom or in a cooling appliance.
- Permitted relative humidity: below 90%.
- The test strips must be stored in the original box/unopened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

## 4 Initial use and basic settings

### 4.1 Removing the battery insulation strip, replacing the batteries

**Note**

- Two batteries are included in delivery of the blood glucose monitor. These have already been inserted into the battery compartment.
- Remove the insulation strip before initial use.



1. Remove the battery compartment lid on the underside of the device.
2. When replacing the batteries, remove all batteries. The device retains the date and time as long as one battery is still inserted. If necessary, reset the date and time (see “Making and changing basic settings”, page 14).
3. Insert two new **CR 2032 3 V** batteries. Make sure that the batteries are inserted the correct way round in accordance with the markings. Observe the graphic in the battery compartment.
4. Close the battery compartment lid again carefully.

**Note**

- The batteries are almost empty if the battery replacement symbol appears. Replace both batteries as soon as possible.
- If “LP” appears on the display, the battery power level is so low that no more measurements are possible.

### 4.2 Making and changing basic settings

1. Remove the batteries and reinsert them. Alternatively, press the “+” button and the On/Off button for a minimum of 5 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 and access them again later.
   - The time is displayed in the 24-hour format.

2 Set the year (calendar to 2099) by pressing the "+" or "–" button. Confirm by pressing the On/Off button [4].
The day display flashes.
Proceed as described above for the day, month, hour and minute.
"dISP LIt" and "OFF" are displayed.

3 **Switching backlighting on/off**
To switch the backlighting on/off, press the "+" or "–" button. "dISP LIt" and "On" are displayed for switched on and "dISP LIt" and "OFF" are displayed for switched off. The background of the display is simultaneously illuminated for a few seconds. Confirm by pressing the On/Off button [4]. "bEEP" and "OFF" are displayed.

4 **Switching the acoustic signal on/off**
To switch the acoustic signal on/off, press the "+" or "–" button. "bEEP", "On" and the speaker symbol are displayed for switched on, and "bEEP" and "OFF" are displayed for switched off. Confirm by pressing the On/Off button [4].

5 The monitor is now ready for use.

## 5 Taking the blood glucose measurement

**Warning**

- If the protective disc on a lancet needle has already been removed, do not use the lancet needle.
- If you drop the lancing device with an inserted lancet needle, 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 you are using a third-party lancing device, please read the respective instructions for use.

### 5.1 Preparing to take a blood sample

1 Using the lancing device, you can take a blood sample from the fingertip. To make the procedure as painless as possible, do not take samples directly from the centre of the fingertip, but slightly to either side.

**Warning**

- **In the event of suspected hypoglycaemia: take blood from the fingertip only.**
  Reason: changes to blood glucose levels can be detected quickly in blood samples taken from the fingertip.

2 Prepare the following items: monitor, test strip box or test strips in film packaging, lancing device, sterile lancet needles.

3 Wash your hands with soap and warm water before taking a blood sample. This not only ensures optimal hygiene but also encourages good blood circulation at the puncture area on the finger. Dry your hands carefully.

**Warning**

If you have used alcohol for cleaning, ensure that the area has fully dried prior to measuring.

## 5.2 Taking a blood sample

**Warning**

- Change the puncture area for each measurement, e.g. a different finger or the other hand. Repeatedly using the same area may cause inflammation, numbness or scarring.
- Without the cap, there is a danger of injury from the exposed lancet.
- Do not squeeze your finger to obtain a larger drop of blood. If squeezed, the blood is diluted with tissue fluid and this may lead to an incorrect measurement.
- Please note that insufficient blood circulation at the puncture area, e.g. caused by cold temperatures or illness, may lead to incorrect results.

**Important**

Do not apply any blood samples or control solutions to the test strip before inserting it in the monitor.

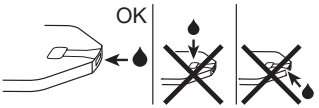
**Please also note the following:**

- 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 amount of blood, repeat steps 1 to 12 of 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 with the second drop of blood.

3 Hold the blood input gap (at the tip of the test strip) to the drop of blood until the gap is completely filled and the monitor in the display starts counting backwards. Do not press the penetration area to the test strip. The blood must not be spread. The blood is sucked into the gap.




**Note**

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

**Note**

- Do **not** apply blood to the sides of the test strips.
- Do **not** add blood later if the device does not start the 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 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. The test strip light switches on and makes it easier to insert the test strip. The backlight is also switched on in the results display.

## 5.3 Reading the result and highlighting measurements

### Reading the result

As soon as the gap 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.

Read the measured value. For explanations and actions for the measured values, see chapter “5.5 Evaluating measured blood glucose values”. If an error message is displayed, read chapter “8. What if there are problems?”

### Highlighting measured values

You have the following options to label measured values.

| | |
|---|---|
|  | Before meals. |
|  | After meals. |
|  | General highlighting (e.g. after exercising). |

Highlighting 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 labelled as soon as it is displayed. You cannot label it later.
For this purpose, briefly press the highlight button [3].
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 final time removes the label.

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

## 5.4. Post-processing and disposal

Remove the test strip from the device and carefully dispose of it according to the currently applicable regulations to avoid infecting others.

## 5.5 Evaluating measured blood glucose values

Your blood glucose monitor can process measured values between 20 and 630 mg/dL (1.1 and 35.0 mmol/L). The "Lo" warning is displayed for measured values below 20 mg/dL (1.1 mmol/L). The "Hi" warning is displayed for measured values above 630 mg/dL (35.0 mmol/L).

**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 GL44 blood glucose measuring system.
- Do not ignore symptoms of too high/low blood glucose levels. Consult your doctor.

**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 the blood glucose measurement | Normal blood glucose values | Increased risk of diabetes (prediabetes)* | Diabetes |
|---|---|---|---|
| On an empty stomach (fasting plasma glucose) | Below 100 mg/dL<br>Below 5.6 mmol/L | 100 – 125 mg/dL<br>5.6 – 6.9 mmol/L | ≥ 126 mg/dL<br>≥ 7.0 mmol/L |
| Two hours after an oral glucose tolerance test (consumption of 75 g) | Below 140 mg/dL<br>Below 7.8 mmol/L | 140 – 199 mg/dL<br>7.8 – 11.0 mmol/L | ≥ 200 mg/dL<br>≥ 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%*<br>< 53 mmol/mol* |
| Preprandial capillary plasma glucose | 80 – 130 mg/dL*<br>4.4 – 7.2 mmol/L* |
| Peak value of postprandial capillary plasma glucose** | < 180 mg/dL*<br>10.0 mmol/L* |

** For individual 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, hypoglycaemia unawareness, 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 at the highest.*

**Evaluating critical measured values**

| Display | | Blood glucose | Action |
|---|---|---|---|
|  |  | Very low blood glucose level<br><br>under 20 mg/dL (under 1.1 mmol/L) | Seek medical attention immediately. |
|  |  | Low blood glucose level<br><br>under 70 mg/dL (under 3.9 mmol/L) | Have a suitable snack.<br>Follow your GP's instructions. |
|  |  | High blood glucose level on an empty stomach, above 100 mg/dL (5.6 mmol/L)<br><br>2 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). Seek medical attention to coordinate any measures, if applicable. |
|  |  | High blood glucose level, possibly ketones<br><br>over 240 mg/dL (13.3 mmol/L) | Perform a ketone test. For this purpose, seek medical attention. |
|  |  | Very high blood glucose level<br><br>over 630 mg/dL (35.0 mmol/L) | Take another measurement using a new test strip. If the display is the same as before: seek medical assistance immediately. |

## 5.6 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 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 solutions by a different manufacturer. Correct functioning of your monitor can only be tested using Beurer control solutions (LEVEL3 + LEVEL4).

- 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 monitor, 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.
The check performed at room temperature is used as a general functional 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 with the contacts first. Ensure the front of the test strip is facing you (see “Test strip”, 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 “–”, to change to the control mode. “CtL” is shown on the display. This means that the result value is not stored in the memory, therefore not influencing your measured value statistics. Pressing “+” or “–” again causes “CtL” to disappear 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 squeeze 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 drop of control solution until the gap is completely filled and the display of the monitor 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 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 or the test strip packaging or on the information sheet included.

**Expected results**

At room temperature, the measurements from the test using the control solution should be within the range printed on the test strip box or on the information sheet included with the test strips in film packaging in approx. 95% of all tests.

**Warning**

The specified value range (see test strip box or information sheet with the test strips in film packaging) 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.<br>• The tip of the bottle was not cleaned correctly.<br>• 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 or new film packaging. |
| The control solution, test strips or monitor are too warm or too cold. | Bring the control solution, test strips and monitor to room temperature (+20°C to +26°C) and repeat the test.<br>The check performed at room temperature is used as a general functional 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.<br>For example:<br>• Test strips that were exposed to fresh air for too long.<br>• The test strip box was not closed completely.<br>• Film packaging was already opened or damaged. | Repeat the test using a new test strip and/or correctly stored test strips from a new box or new film packaging. |
| There is a problem with the 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.

## 6 Measurement memory

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 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 memory for measured values. Press the On/Off button to switch off the device.

### 6.1 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 monitor on using the On/Off button [4]. The initial display is shown briefly. Press the "+" or "–" rocker switch [6].
2. The recorded measured value with the measurement unit, time, "Mem" 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).

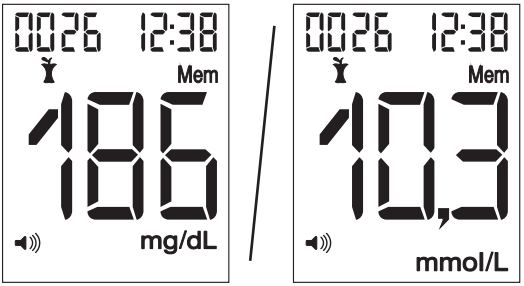



Image 1

2

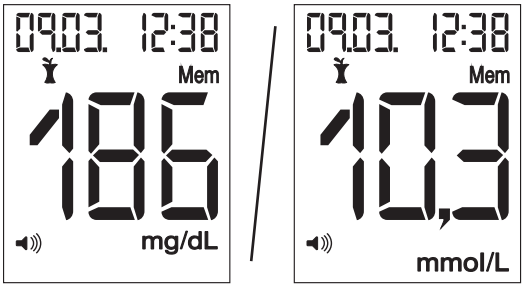



Image 2

3 Pressing the rocker switch "–" [6] 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 2 minutes.

### 6.2 Displaying average blood glucose values

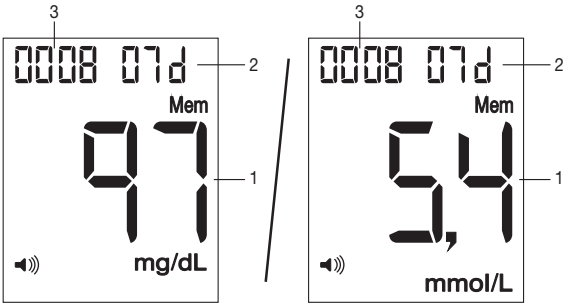
You can display the average measured blood glucose value from the last 7, 14, 30 and 90 days.

1 Switch the monitor on using the On/Off button [4]. The initial display is shown briefly. Press the "+" rocker switch [6] twice.
The measurement unit of the blood glucose value, "07 d" and the average value are displayed.

2 Press "+" [6] 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.

| No. | Explanation |
|---|---|
| 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

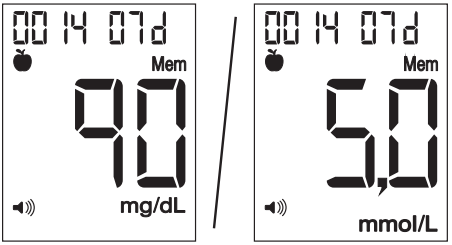
You can display the average measured blood glucose value for labelled values from the last 7, 14, 30 and 90 days.

**1** Switch the monitor on using the On/Off button [4]. The initial display is shown briefly. Press the "+" rocker switch [6] twice.
The measurement unit of the blood glucose value, "07d" and the average of all measured values are displayed.

**2** Press "+" [6] 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 for values measured "before meals"
- the symbol
- the unit of measurement for blood glucose values and
- "07d"

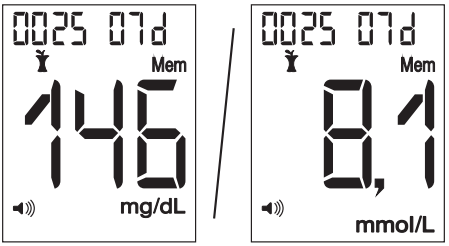
are shown on the display.




Press "+" [6] repeatedly to display the average blood glucose value from the last 14, 30 and 90 days for values measured "before meals" .

After displaying the average value for 90 days "before meals"
- the 7-day average for values measured "after meals"
- the symbol
- the unit of measurement for blood glucose values and
- "07d"

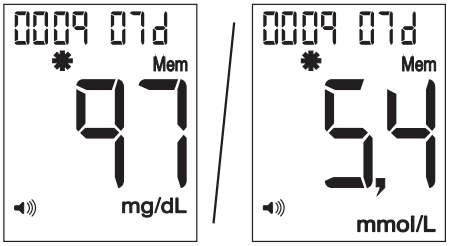
are shown on the display.




Press "+" [6] repeatedly to display the average value for 14, 30 and 90 days "after meals" .

2 After displaying the average value for 90 days “after meals”
- the average for the last 7 days of values labelled as “general”
- the ✱ symbol
- the unit of measurement for blood glucose values and
- “07d”

are shown on the display.

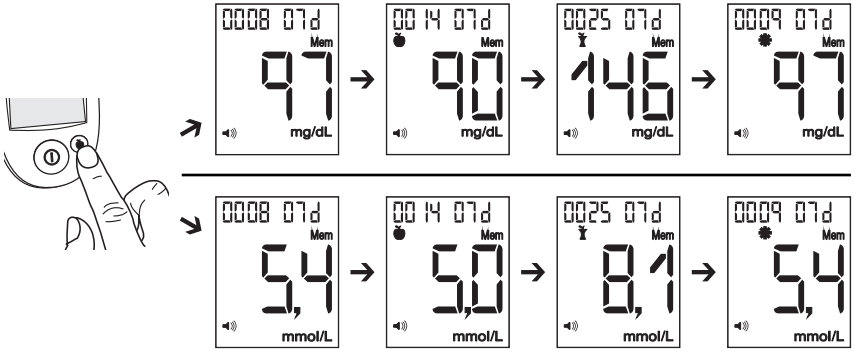



Press “+” [6] repeatedly to display the average blood glucose value from the last 14, 30 and 90 days for values labelled as “general” ✱.

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 2 minutes.

**Note: Speed function**

You are in the measurements memory. By pressing the label button [3], 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:




## 6.4 Reset to basic settings

1 The monitor must be switched off.
2 Remove the battery compartment lid.
3 Press the ‘RESET’ button for 1 second. All settings are then deleted.
4 Close the battery compartment lid again.
5 The monitor is now in the settings mode.

## 6.5 Transferring measurements to a PC

The GL44 blood glucose monitor includes a PC interface [5] that enables you to transfer measured values saved on the device to a PC (for the position of the connection port, see page 11).
Beurer blood glucose diary software is available to download for free at www.beurer.com. This software enables you to evaluate your measured values, add insulin doses and print results. The software helps you and your GP to better monitor your blood glucose level.
For more information, please read the instructions for use of the blood glucose diary software (also available to download). This includes all the information required for data transfer and a detailed description of the software (in English and German).

The GL44 monitor is also compatible with Diabass and SiDiary.

**Note**

- An effective evaluation is only possible if you have correctly set the date and time (see page 14).
- During data transfer, no measurements can be taken.
- The measurements remain saved on the monitor after they have been transferred to the PC.

**Important**

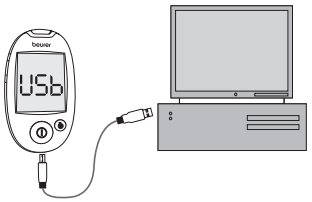
Use only the USB cable provided for data transfer. Otherwise you may damage your monitor or PC.

**Preparation**

- Position the blood glucose monitor near to your PC.
- Connect the GL44 monitor to your PC using the USB cable provided.
- Install the blood glucose diary software on your PC as described in the instructions for use of the software.

**Transferring measurements**

1. The monitor must be switched off. Insert the larger, flat USB connector of the connection cable into a USB port on your PC. Insert the mini USB connector into the integrated interface socket of the GL44 monitor.
2. "USb" is shown on the display of the monitor. The monitor is now ready for the data transfer.




3. Follow the information on data transfer and evaluation provided in the software and the instructions for use of the software.

# 7 Storing, maintaining and disinfecting the device

**Storing**

Keep the Beurer GL44 blood glucose monitor in the case supplied after each measurement and do not expose it to direct sunlight.

**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.

## 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 products 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.

## 7.2 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.

**Note**

The 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.
- 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 electro-magnetic radiation, as this may affect normal operation.
- It is a good idea to carry out an assessment of the electro-magnetic environment before using the device commercially.

## 8 What if there are problems?

**Display messages on batteries and blood glucose measurement**

| No. | Cause | Solution |
|---|---|---|
| LP | Batteries empty. | Replace all batteries. |
| Ht | Temperature of the measuring environment, 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 room temperature (+20°C to +26°C). The check performed at room temperature is used as a general functional check. The operating range specified in the technical specifications is valid without restriction. |
| Lt | Temperature of the measuring environment, monitor or test strip below the permitted range. | Repeat the test using a new test strip as soon as the measuring environment, monitor and test strip have reached room temperature (+20°C to +26°C). The check performed at room temperature is used as a general functional check. The operating range specified in the technical specifications is valid without restriction. |
| Err  | Used or contaminated test strip inserted. | • Insert an unused test strip that has not expired.<br>• Repeat the blood glucose measurement. |
| Err001 | System error. | Remove batteries, reinsert batteries. Should the problem persist, contact Customer Services. |
| Err002 | Insufficient blood on the test strip. | Repeat the measurement using a new test strip. |
| Err003 | The haematocrit value is outside the range 20–60%. | Repeat the measurement using a new test strip. Should the problem persist, contact Customer Services. |
| Err005 | System error. | Remove batteries, reinsert batteries. Should the problem persist, contact Customer Services. |
| | Unknown error messages. | Remove batteries, reinsert batteries. Should the problem persist, contact Customer Services. |

**Problem: device does not switch on**

| Cause | Solution |
|---|---|
| Batteries empty. | Replace batteries. |
| Incorrectly inserted or missing batteries. | Check whether the batteries have been inserted correctly (see “Inserting and replacing the batteries” 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 strip” 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 (see page 16). |
| 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 when 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.<br>Repeat test. |
| Device faulty. | Contact Customer Services. |

## 9 Technical specifications

| | |
|---|---|
| **Dimensions (W x H x D)** | 52 x 95 x 16 mm |
| **Weight** | 44 g incl. batteries |
| **Power supply** | 2 x 3 V CR 2032 button cell batteries |
| **Battery life** | 500 measurements with backlighting<br>1000 measurements without backlighting |
| **Measured value memory** | 480 measured values with date/time<br>Data retained when batteries are changed |
| **Average values** | for 7, 14, 30, 90 days |

| | |
|---|---|
| **Automatic switch-off** | 2 minutes after last actuation |
| **Storage/transport temperature** | Temperature: +2 °C – +30 °C<br>Relative humidity: < 90% |
| **Operating ranges** | Temperature: +10 °C – +40 °C<br>Relative humidity: < 90% non-condensing |
| **Measurement range, glucose** | Glucose: 20 – 630 mg/dL (1.1 - 35.0 mmol/L) |
| **Blood sample** | Capillary whole blood |
| **Amount of blood** | 0.6 microlitres |
| **Blood glucose measurement duration** | Approx. 5 seconds |
| **Calibration** | Plasma |
| **Testing method** | Amperometric bio sensor |
| **Use** | Suitable for self-testing |
| **System function test** | Each time device is switched on |

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 our 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 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 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 oryzae) on the strip.
During the reaction, a mediator transports electrons through the electrode surface and so 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 (0.6 microlitres) and the duration of measurement is approx. five seconds. The test strips detect blood glucose values from 20 to 630 mg/dL (1.1 to 35.0 mmol/L).

**Chemical components of the test strip sensor**

- FAD glucose dehydrogenase 6%
- Potassium ferricyanide 56%
- Non-reactive components 38%

**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 using control solution must be within the result range. This value range is printed on every test strip box and/or on the information sheet included with the test strips in film packaging.

**Chemical composition of the control solution**

The control solution is a red solution with the following D-glucose level (in percentage shares).

| Substances | LEVEL 3 control solution | LEVEL 4 control solution |
|---|---|---|
| D-glucose | 0.14% | 0.37% |
| Non-reactive components | 99.86% | 99.63% |

**Standards**

For the device (including test strips and control solution), the Beurer GL 44 measuring system complies with the European directive IVD (98/79/EC). The lancet needles comply with the European directive MDD (93/42/EC). The lancing device complies with the regulation (EU) MDR (2017/745) on medical devices.

## 10 Comparison of measured values with laboratory values

**Precision**

Three lots of the GL44 blood glucose test strips have been tested to assess the precision of the GL44 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 42.7 to 418.0 mg/dL (2.4 to 23.2 mmol/L) and control material from three concentrations is used.

**Results of the repeat precision measurements**

| Sample | Venous blood | | Grand mean value | | Pooled standard deviation | | Pooled coefficient of variation (%) |
|---|---|---|---|---|---|---|---|
| | mg/dL | mmol/L | mg/dL | mmol/L | mg/dL | mmol/L | |
| 1 | 42.7 | 2.4 | 36.0 | 2.0 | 2.0 | 0.1 | 5.6 |
| 2 | 62.0 | 3.4 | 59.2 | 3.3 | 3.5 | 0.2 | 5.9 |
| 3 | 120.5 | 6.7 | 127.1 | 7.1 | 4.1 | 0.2 | 3.2 |
| 4 | 201.0 | 11.2 | 213.8 | 11.9 | 6.7 | 0.4 | 3.1 |
| 5 | 316.5 | 17.6 | 329.9 | 18.3 | 10.1 | 0.6 | 3.1 |
| 6 | 418.0 | 23.2 | 433.5 | 24.1 | 14.5 | 0.8 | 3.3 |

**Results of the intermediate precision measurement**

| Sample | Control material | | Grand mean value | | Pooled standard deviation | | Pooled coefficient of variation (%) |
|---|---|---|---|---|---|---|---|
| | mg/dL | mmol/L | mg/dL | mmol/L | mg/dL | mmol/L | |
| 1 | 70.0 | 3.9 | 71.3 | 4.0 | 1.0 | 0.1 | 1.4 |
| 2 | 135.6 | 7.5 | 136.3 | 7.6 | 1.4 | 0.1 | 1.1 |
| 3 | 351.5 | 19.5 | 350.8 | 19.5 | 2.8 | 0.2 | 0.8 |

**System accuracy**

The GL44 blood glucose monitor in comparison to the YSI.
Three lots of GL44 blood glucose test strips have been tested to assess the system accuracy of the GL44 blood glucose measuring system and to compare it with the reference method in which capillary whole blood concentrations of 36.0 mg/dL (2.0 mmol/L) to 442.5 mg/dL (24.6 mmol/L) have been used.

**Results 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) |
|---|---|---|
| 101/168 (60.12%) | 161/168 (95.83%) | 166/168 (98.81%) |

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

| Within ±5% | Within ±10% | Within ±15% |
|---|---|---|
| 182/432 (42.13%) | 358/432 (82.87%) | 426/432 (98.61%) |

**Results of the system accuracy for combined glucose concentrations between 36.0 mg/dL (2.0 mmol/L) and 442.5 mg/dL (24.6 mmol/L).**

| Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%) |
|---|
| 592/600 (98.67%) |

In comparison to the YSI, the GL44 met the EN ISO 15197:2015 standard, whereby 95% of the blood glucose values measured have to fall within the following zones: either ±15 mg/dL (± 0.83 mmol/L) of the measured average values 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 103 individuals that had no special training, produced the following results:
96.7% within ±15 mg/dL (±0.83 mmol/L) and 95.9% 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.

## 11 Usage limits for specialist personnel from 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 500 mg/dL (13 mmol/L) and triglyceride levels up to 1,000 mg/dL (11.4 mmol/L) do not influence the results. Severely lipaemic blood samples were not tested with the Beurer GL44 blood glucose monitor; therefore, using the device with these samples is not recommended.
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 / Blood glucose value / Concentration of tested substances | | | 50-100 mg/dL (2.8-5.6 mmol/L) | 250-350 mg/dL (13.9-19.4 mmol/L) |
|---|---|---|---|---|
| Acetaminophen | 7 mg/dL | (0.46 mmol/L) | 6.6 mg/dL (0.37 mmol/L) | 4.5% |
| Ascorbic acid | 4 mg/dL | (0.23 mmol/L) | 3.3 mg/dL (0.18 mmol/L) | 5.1% |
| Bilirubin | 3.3 mg/dL | (0.06 mmol/L) | 0.1 mg/dL (0.01 mmol/L) | -1.4% |
| Cholesterol | 400 mg/dL | (10.34 mmol/L) | -6.8 mg/dL (-0.38 mmol/L) | -6.2% |
| Creatinine | 30 mg/dL | (2.65 mmol/L) | 0.0 mg/dL (0.00 mmol/L) | -0.1% |
| Dopamine | 2.2 mg/dL | (0.14 mmol/L) | 5.0 mg/dL (0.28 mmol/L) | 1.0% |
| EDTA | 5.0 mg/dL | (0.17 mmol/L) | -2.0 mg/dL (-0.11 mmol/L) | -2.4% |

| Influence / Concentration of tested substances | | | 50-100 mg/dL (2.8-5.6 mmol/L) | 250-350 mg/dL (13.9-19.4 mmol/L) |
|---|---|---|---|---|
| | | Blood glucose value | | |
| Ephedrine | 40 mg/dL | (2.42 mmol/L) | -3.9 mg/dL (-0.22 mmol/L) | 2.4% |
| Galactose | 20 mg/dL | (1.11 mmol/L) | -3.1 mg/dL (-0.17 mmol/L) | 0.5% |
| Gentisic acid | 7 mg/dL | (0.45 mmol/L) | 7.2 mg/dL (0.40 mmol/L) | 2.9% |
| Glutathione | 1 mg/dL | (0.03 mmol/L) | -2.6 mg/dL (-0.14 mmol/L) | -3.7% |
| Haemoglobin | 300 mg/dL | (0.05 mmol/L) | -3.1 mg/dL (-0.17 mmol/L) | -2.6% |
| Heparin | 2.1 mg/dL | (0.0018 mmol/L) | -3.0 mg/dL (-0.17 mmol/L) | -1.3% |
| Ibuprofen | 50 mg/dL | (2.43 mmol/L) | -2.6 mg/dL (-0.15 mmol/L) | -1.9% |
| Icodextrin | 1094 mg/dL | (0.64~0.78 mmol/L) | -4.17 mg/dL (-0.23 mmol/L) | -2.9% |
| L-Dopa | 2 mg/dL | (0.10 mmol/L) | 9.3 mg/dL (0.52 mmol/L) | 7.9% |
| Maltose | 278 mg/dL | (7.72 mmol/L) | -1.53 mg/dL (-0.09 mmol/L) | -2.6% |
| Methyldopa | 4 mg/dL | (0.19 mmol/L) | 7.3 mg/dL (0.41 mmol/L) | 0.9% |
| Pralidoxime iodide | 5 mg/dL | (0.14 mmol/L) | 1.7 mg/dL (0.09 mmol/L) | -0.1% |
| Sodium salicylate | 40 mg/dL | (2.50 mmol/L) | -3.1 mg/dL (-0.17 mmol/L) | -0.6% |
| Salicylic acid | 60 mg/dL | (4.34 mmol/L) | -0.1 mg/dL (-0.01 mmol/L) | 7.6% |
| Tolbutamide | 100 mg/dL | (3.70 mmol/L) | 0.5 mg/dL (0.03 mmol/L) | -0.8% |

| 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) |
|---|---|---|---|---|
| Tolazamide | 2.5 mg/dL | (0.08 mmol/L) | -2.3 mg/dL (-0.13 mmol/L) | 1.8% |
| Triglyceride | 800 mg/dL | (9.37 mmol/L) | -7.50 mg/dL (-0.42 mmol/L) | -4.0% |
| Uric acid | 16.5 mg/dL | (0.98 mmol/L) | 6.6 mg/dL (0.37 mmol/L) | 1.8% |
| Xylose | 9.5 mg/dL | (0.63 mmol/L) | 5.6 mg/dL (0.31 mmol/L) | 6.6% |

## 12 Instructions for use for the lancing device LD 03

### 12.1 Proper use

**Indication/clinical benefits**

The lancing device, in combination with a lancet needle, is intended for taking a blood sample for measuring glucose levels in human blood. Use the lancing device only on the skin areas intended for taking the glucose measurement (fingertips).


**Contraindications**

Use the lancing device only on the body parts listed in these instructions for use. Never use the lancing device on injured, inflamed or scarred skin. Never use the lancing device on areas already affected by a sensory disorder. If you drop the lancing device with an inserted lancet needle, 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.

**Target group**

The device is suitable for domestic use by humans.
This 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.

## 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 needle for each blood sample (for single use only).
- If you drop the lancing device with an inserted lancet needle, 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.

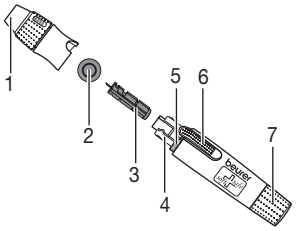
**⚠ Risks to the device**

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

## 12.3 Device description

**Lancing device and lancet needles**

1 Cap
2 Protective lancet disc
3 Sterile lancet needle
4 Lancet holder
5 Safety switch
6 Trigger
7 Tensioning device

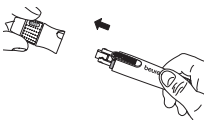



## 12.4 Initial use

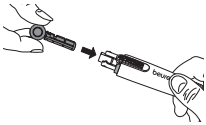
Unpack the lancing device and check that all the contents are present and intact. Before using the device for the first time, check that the lancing process works correctly. To do this, tension the lancing device once without an inserted lancet and press the trigger. When testing that the device functions 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 from the lancing device.



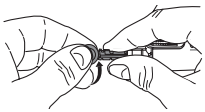
2 Place a sterile lancet needle into the lancing device and secure the lancet.



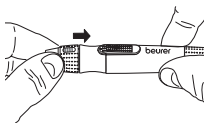
**Note**

Your starter set contains lancet needles in 2 different 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 disc of the lancet by rotating it while holding the shaft of the lancet. Retain the protective disc for the safe disposal of the used lancet needle after taking a blood sample.



4 Place the cap onto the lancing device.

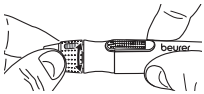



5 **Setting the penetration depth**

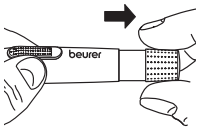
You can set seven different penetration depths on the lancing device. The penetration depth is displayed by the markings in the cap.

- soft or thin skin
- normal skin
- thick or callous skin

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




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

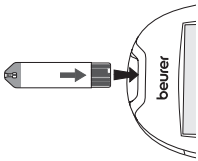



7 Put the already prepared lancing device to one side and prepare the device for measurement.

8 Take a test strip from the film packaging/box and immediately close it again.

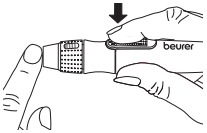
9 Hold the measuring device so that the display is facing you.

10 Firmly insert a test strip into the device with the contacts first. Please make sure that the front is facing you. You can touch any part of the test strip with clean, dry hands.
Use the test strip within three minutes of removal.



11 The device automatically switches on and shows the start display.
As soon as the hand and the droplet symbol start to flash, the device is ready for measurement.

12 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 blood droplet to take a measurement.




**Blood sample from the fingertip**
The best penetration areas 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. Remove the lancing device from the finger. A round drop of blood of at least 0.6 microlitres (corresponds to approx. 1.4 mm, original size: ●) must have formed.

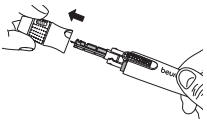
**Please also note the following:**

- 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.

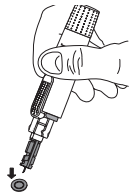
13 If there is an insufficient amount of blood, repeat steps 1 to 12 with a greater penetration depth.

## 12.6 Post-processing and disposal

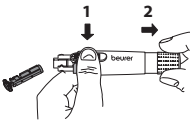
1 Carefully remove the cap from the lancing device.



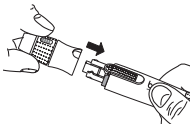
2 Place the retained protective disc flat on a hard surface. Stick the tip of the needle into the protective disc so the needle is covered. Take care not to touch the used lancet.



3 Press and hold the trigger and pull the tensioning device with your other hand. 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 back onto the lancing device.



### 12.7 Cleaning and maintenance

Clean the lancing device after each use. Remove and dispose of the lancet as described in points 7.15. to 7.16. in 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 measuring device and its accessories may come into contact with human blood and are therefore a possible source of infection.

### 12.8 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 Warranty/service

Beurer GmbH, Söflinger Straße 218, 89077 Ulm, Germany (hereinafter referred to as “Beurer”) provides a warranty for this product, subject to the requirements below and to the extent described as follows.

**The warranty conditions below shall not affect the seller’s statutory warranty obligations which ensue from the sales agreement with the buyer.**
**The warranty shall apply without prejudice to any mandatory statutory provisions on liability.**

Beurer guarantees the perfect functionality and completeness of this product.

The worldwide warranty period is 5 years, commencing from the purchase of the new, unused product from the seller.

The warranty 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 warranty 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 warranty conditions.

**If the buyer wishes to make a warranty claim, they should approach their local retailer in the first instance: see the attached “International Service” list of service addresses.**

The buyer will then receive further information about the processing of the warranty claim, e.g. where they can send the product and what documentation is required.

A warranty claim shall only be considered if the buyer can provide Beurer, or an authorised Beurer partner, with
– a copy of the invoice/purchase receipt, and
– the original product.

The following are explicitly excluded from this warranty:
– deterioration due to normal use or consumption of the product;
– accessories supplied with this product which are worn out or used up through proper use (e.g. batteries, rechargeable batteries, cuffs, seals, electrodes, light sources, attachments and 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 seconds or as 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 an exchange in full do not extend the warranty period under any circumstances.

The product complies with the EU Medical Device Directive (MDD) 93/42/EC and the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, as well as the respective national provisions.
For users/patients in the European Union and identical regulation systems (EU Medical Device Regulation (MDR) 2017/745), the following applies: If during or through use of the product a major incident occurs, notify the manufacturer and/or their representative of this as well as the respective national authority of the member state in which the user/patient is located.

**Where can I obtain this lancing device?**
Available without need for a prescription from your pharmacist or outlets selling the Beurer blood glucose measuring device. Please contact our Customer Service 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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Beurer GmbH • Söflinger Straße 218 • 89077 Ulm, Germany
www.beurer.com • www.beurer-healthguide.com

CE 0483

Lancet needles / Lanzetten / lancettes / lancetas / lancette:

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No. 168, PuTuoShan Road,
New District, Suzhou 215153, China

EC REP

Emergo Europe
Prinsessegracht 20,
2514 AP The Hague, The Netherlands

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