beurer



EN Blood pressure monitor Instructions for use



ENGLISH



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.

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, body temperature, pulse, gentle therapy, massage, beauty, baby and air.

With kind regards, Your Beurer team

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1. Included in delivery

Check that the exterior of the cardboard delivery packaging is intact 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.

1x Blood pressure monitor with cuff

2x 1.5 V LR03 AAA batteries

1x Storage box

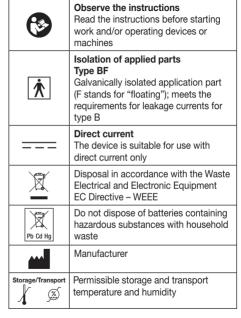
1x Instructions for use

2. Signs and symbols

The following symbols are used in these instructions for use, on the packaging and on the type plate for the device and the accessories:

....

| \triangle | WARNING Warning notice indicating a risk of injury or damage to health |
|-------------|--|
| \triangle | IMPORTANT Safety note indicating possible damage to the device/accessory |
| i | Product information Important information to note |



| Operating (%) | Permissible operating temperature and humidity |
|----------------------------|---|
| IP22 | IP class Device protected against foreign objects ≥ 12.5 mm and against water dripping at an angle |
| SN | Serial number |
| C € ₀₄₈₃ | CE labelling This product satisfies the requirements of the applicable European and national directives. |
| 0 | Separate the packaging elements and dispose of them in accordance with local regulations. |
| ZB A | Marking to identify the packaging material. A = Material code, B = Material number: 1-7 = Plastics, 20-22 = Paper and cardboard |
| (F | Separate the product and packaging elements and dispose of them in accordance with local regulations. |
| MD | Medical device |

REF

Item number

3. Intended use

The wrist blood pressure monitor serves as a non-invasive way of measuring and monitoring arterial blood pressure and pulse values in adults with wrist circumferences of 14 – 19.5 cm. This allows you to quickly and easily measure your blood pressure and pulse, save the measurements and display the development of the measurements. The recorded values are classified and evaluated graphically. You are also warned of possible existing cardiac arrhythmia.

4. Warning and safety notes

Notes on use

- In order to ensure comparable values, always measure your blood pressure at the same time of day.
- Do not take a measurement within 30 minutes of eating, drinking, smoking or exercising.
- Before the initial blood pressure measurement, make sure always to rest for about 5 minutes.
- Furthermore, if you want to take several measurements in succession, make sure always to wait for at least 1 minute between the individual measurements.

- Repeat the measurement if you are unsure of the measured value.
- The measured values taken by you are for your information only they are no substitute for a medical examination. Discuss the measured values with your doctor and never base any medical decisions on them (e.g. medicines and their dosages).
- Using the blood pressure monitor outside your home environment or whilst on the move (e.g. whilst travelling in a car, ambulance or helicopter, or whilst undertaking physical activity such as playing sport) can influence the measurement accuracy and cause incorrect measurements
- Do not use the blood pressure monitor on newborns or patients with pre-eclampsia. We recommend consulting a doctor before using the blood pressure monitor during pregnancy.
- In the case of restricted circulation on the arm as a result of chronic or acute vascular diseases (including vascular constriction), the accuracy of the wrist measurement is limited. In this case you should use an upper arm blood pressure monitor instead.

- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Supervise children around the device to ensure they do not play with it.
- Cardiovascular diseases may lead to incorrect measurements or have a detrimental effect on measurement accuracy. The same also applies to very low blood pressure, diabetes, circulatory disorders and arrhythmias as well as chills or shaking.
- The blood pressure monitor must not be used in connection with a high-frequency surgical unit.
- Only use the device on people who have the specified wrist measurement for the device.
- Please note that when inflating, the functions of the limb in question may be impaired.
- During the blood pressure measurement, the blood circulation must not be stopped for an unnecessarily long time. If the device malfunctions, remove the cuff from the arm.
- Do not allow sustained pressure in the cuff or frequent measurements. The resulting restriction of the blood flow may cause injury.

- Make sure that the cuff is not placed on an arm in which the arteries or veins are undergoing medical treatment, e.g. intravascular access or intravascular therapy, or an arteriovenous (AV) shunt.
- Do not use the cuff on people who have undergone a mastectomy.
- Do not place the cuff over wounds as this may cause further injury.
- Place the cuff on your wrist only. Do not place the cuff on other parts of the body.
- The blood pressure monitor can only be operated with batteries.
- To conserve the batteries, the blood pressure monitor switches off automatically if you do not press any buttons for one minute.
- The device is only intended for the purpose described in these instructions for use. The manufacturer is not liable for damage resulting from improper or incorrect use.

Instructions for storage and maintenance

- The blood pressure monitor is made from precision and electronic components. The accuracy of the measured values and service life of the device depend on careful handling:
 - Protect the device from impacts, humidity, dirt, marked temperature fluctuations and direct sunlight.

- Do not drop the device.
- Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.
- We recommend that the batteries be removed if the device will not be used for a prolonged period of time.

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.
- Aisk 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, split or crush the batteries.

Notes on electromagnetic compatibility

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The use of the device may be limited in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this could lead to faulty operation. If, however, it is necessary to use the device in the manner stated, this device as well as the other devices must be monitored to ensure they are working properly.
- The use of accessories other than those specified or provided by the manufacturer of this device can lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity; this can result in faulty operation.
- Failure to comply with the above can impair the performance of the device.

5. Device description

- 1. Display
- 2. Wrist cuff
- 3. Risk indicator
- 4. Start/stop button ()
- 5. Memory button ${\bf M}$
- 6. Battery compartment lid



Information on the display:

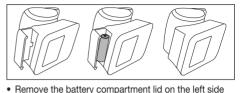
- 1. Systolic pressure
- 2. Risk indicator (
- 3. Diastolic pressure
- 4. Calculated pulse rate
- 5. Cardiac arrhythmia symbol 🍑 ӎ-
- 6. Pulse symbol ♥
- 7. User memory \mathbb{A}/\mathbb{A}
- 8. Memory space number/ memory display for average value (A), morning (ATI), evening (PTI)

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- 9. Battery replacement symbol
- 10. Time and date
- 11. Release air (arrow)

6. Initial use

Inserting the battery



- of the device.
- Insert two 1.5V micro (alkaline type LR03) batteries.
- Make sure that the batteries are inserted the correct way round in accordance with the markings. Do not use rechargeable batteries.
- Carefully close the battery compartment lid again. If the battery replacement symbol is displayed, you can no longer perform any measurements and must replace all batteries.

Setting the hour format, date and time

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.

There are two different ways to access the menu from which you can adjust the settings:

 Before initial use and after each time you replace the battery:

When inserting the batteries into the device you will be taken to the relevant menu automatically.

• If the batteries have already been inserted:
With the device switched off press and hold the
START/STOP button ① for approx. 5 seconds.

In this menu you can adjust the following settings in succession:



Hour format

- Press and hold the START/STOP button ①
 for 5 seconds or insert the batteries. The full
 display appears.
- Select the desired hour format using the memory button M and confirm with the START/STOP button (D.



Date

The year flashes on the display.

 Select the desired year using the memory button M and confirm with the START/STOP button (I).

The month flashes on the display.

 Select the desired month with the memory button M and confirm with the START/ STOP button O.



-20 15-

The day flashes on the display.

- Select the desired day using the memory button M and confirm with the START/STOP button ①.
- -)((
- If the hour format is set as 12h, the day/month display sequence is reversed.

Time

The hours flash on the display.

 Select the desired hour using the memory button M and confirm with the START/ STOP button (I).



The minutes flash on the display.

 Select the desired minute using the memory button M and confirm with the START/ STOP button (I).



Once all the data has been set, the device switches off automatically.

7. Usage

Ensure the device is at room temperature before measuring. The measurement can be performed on the left or right wrist.

Attaching the cuff



- Expose your wrist. Ensure that the circulation of the arm is not hindered by tight clothing or similar.
- · Place the cuff on the inside of your wrist.
- Fasten the cuff with the hook-and-loop fastener so that the upper end of the display is approx. 1 cm below the heel of your hand.
- The cuff must be fitted tightly around the wrist, but must not constrict.

Blood pressure may vary between the right and left arm, which may mean that the measured blood pressure values are different. Always perform the measurement on the same arm.

If the values between the two arms are significantly different, please consult your doctor to determine which arm should be used for the measurement.

Adopting the correct posture

- Before the initial blood pressure measurement, make sure always to rest for about 5 minutes. Otherwise deviations can occur.
- You can take the measurement while sitting or lying down. To take your blood pressure, make sure you are sitting comfortably with your arms and back leaning on something. Do not cross your



- legs. Place your feet flat on the ground. Make sure to support your arm and bend it. Always make sure that the cuff is at heart level. Otherwise significant deviations can occur. Relax your arm and the palm of your hand.
- To avoid falsifying the measurement, it is important to remain still during the measurement and not to speak.
- Wait for at least 1 minute before taking another measurement.

Performing the blood pressure measurement

As described above, attach the cuff and adopt the posture in which you want to perform the measurement.

- Press the START/STOP button to start the blood pressure monitor
 ①. All displays will illuminate briefly.
- The last measured value is displayed and the blood pressure monitor automatically begins the measurement after 3 seconds.



You can cancel the measurement at any time by pressing the **START/STOP** button ①.

As soon as a pulse is found, the pulse symbol • will be displayed.

 Systolic pressure, diastolic pressure and pulse measurements are displayed.



• Er_ appears if the measurement has not been performed properly. Observe the chapter on error messages/troubleshooting in these instructions for use and repeat the measurement.

- Now select the desired user memory by pressing the memory button M. If you do not select a user memory, the measurement is stored in the most recently used user memory. The relevant not not symbol appears on the display.
- Press the START/STOP button ① to switch off the blood pressure monitor. The measurement is then stored in the selected user memory.

If you forget to turn off the device, it will switch off automatically after approx. 1 minute.

In this case too, the value is stored in the selected or most recently used user memory.

Wait for at least 1 minute before taking another measurement.

Evaluating results Cardiac arrhythmia

This device can identify potential disruptions of the heart rhythm when measuring and, if necessary, indicates this after the measurement with the symbol .

This can be an indicator for arrhythmia. Arrhythmia is an illness in which the heart rhythm is abnormal because of flaws in the bioelectrical system that regulates the heart-beat. The symptoms (skipped or premature heart beats, pulse being slow or too fast) can be caused by factors such as heart disease, age, physical make-up, excess

stimulants, stress or lack of sleep. Arrhythmia can only be determined through an examination by your doctor. If the symbol his shown on the display after the measurement has been taken, repeat the measurement. Please ensure that you rest for 5 minutes beforehand and do not speak or move during the measurement. If the symbol has appears frequently, please consult your doctor. Self-diagnosis and treatment based on the measurements can be dangerous. Always follow your doctor's instructions.

Risk indicator

The measurements can be classified and evaluated in accordance with the following table.

However, these standard values serve only as a general guideline, as the individual blood pressure varies in different people and different age groups etc.

It is important to consult your doctor regularly for advice. Your doctor will tell you your individual values for normal blood pressure as well as the value above which your blood pressure is classified as dangerous.

The classification on the display and the scale on the device show which category the recorded blood pressure values fall into. If the values of systole and diastole fall into two different categories (e.g. systole in the "High normal" category and diastole in the "Normal" category), the graphical classification on the device always shows

the higher category; for the example given this would be "High normal".

| Blood pressure value category | Systole (in mmHg) | Diastole (in mmHg) | Action |
|--------------------------------------|----------------------|-----------------------|------------------------------------|
| Level 3: severe hypertension | ≥180 | ≥110 | Seek medical attention |
| Level 2: moderate hypertension | 160-179 | 100-109 | Seek medical attention |
| Level 1: mild hypertension | 140-159 | 90-99 | Regular monitoring by doctor |
| High normal | 130-139 | 85-89 | Regular monitoring by doctor |
| Normal | 120-129 | 80-84 | Self-monitoring |
| Optimal | < 120 | < 80 | Self-monitoring |

Source: WHO, 1999 (World Health Organization)

Saving, accessing and deleting measured values

The results of every successful measurement are stored together with the date and time. The oldest measurement is overwritten in the event of more than 60 measurements.

• To retrieve the measurement, press the memory button M.

ser memory **A** flashes on the display. The average value of all saved measured values in this user memory is displayed.



To change the user memory, press and hold the memory button **M** for approx. 2 seconds.

• Press the memory button M.

A flashes on the display. The average value of the morning measurements for the last 7 days is displayed (morning: 5 a.m. - 9 a.m.).



· Press the memory button M.

PM flashes on the display. The average value of the evening measurements for the last 7 days is displayed (evening: 6 p.m. - 8 p.m.).



• When you press the memory button M again, the last individual measurement is displayed (in this example, measurement 03).



- When you press the memory button **M** again, you can view vour individual measured values.
- To switch the device off again, press the START/ STOP button (1).
- i) You can exit the menu at any time by pressing the START/STOP button (1).

- To clear the relevant user memory, you must first select a user memory.
- Start the retrieval of the average measured values.
 R flashes on the display and the average value of all saved measured values in this user memory is displayed.
- Press and hold the memory button M and the START/STOP button ① for 5 seconds, depending on the user memory you are in.

All values of the current user memory are deleted and the device switches off



8. Cleaning and maintenance

- Clean the device and cuff carefully using a slightly damp cloth only.
- . Do not use any cleaning agents or solvents.
- Under no circumstances hold the device and cuff under water, as this can cause liquid to enter and damage the device and cuff.
- If you store the device and cuff, do not place heavy objects on the device and cuff. Remove the batteries.

9. What if there are problems?

| · | | |
|------------------|---|---|
| Error message | Possible cause | Solution |
| Er for Er2 | The systolic or diastolic pressure could not be measured. | Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement. |
| Hi or LO | The systolic or diastolic pressure is outside of the measurement range. | Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement. If the message is displayed again, you should seek medical assistance and check the accuracy of your procedure. |
| Er∃or Er4 | The cuff was not attached correctly. | Please observe the information in the chapter on "Attaching the cuff". |

| Error message | Possible cause | Solution |
|----------------------------|---|---|
| ErS | The blood pressure is higher than 300 mmHg for more than 1.5 seconds. | Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement. If the message is displayed again, you should seek medical assistance and check the accuracy of your procedure. |
| Er6 | Pumping up takes longer than 180 seconds. | Please take another measurement to check whether the cuff can be correctly inflated. Please observe the information in the chapter on "Attaching the cuff". |
| ErR, ErO, Er Tor Er8 | There is a system or device error. | Please contact customer service. |
| | The batteries are almost empty. | Insert new batteries into the device. |

10. Disposal

Repairing and disposing of the device

- Batteries do not belong in household waste. Please dispose of empty batteries at the collection points intended for this purpose.
- Do not open the device. Failure to comply will invalidate the warranty.
- Do not repair or adjust the device yourself. Proper operation can no longer be guaranteed in this case.
- Repairs must only be carried out by Customer Services or authorised retailers.
- Before making a claim, please check the batteries first and replace them if necessary.
- For environmental reasons, do not dispose of the device in the household waste at the end of its useful life. Dispose of the device at corresponding collection points 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.



∆ Battery disposal

- 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.



11. Technical specifications

| Model no. | BC 28 |
|--------------------|---|
| Measurement method | Oscillometric, non-invasive blood pressure measurement on the wrist |
| Measurement range | Cuff pressure 0-300 mmHg, systolic 60-260 mmHg, diastolic 40-199 mmHg, pulse 40-180 beats/minute |
| Display accuracy | Systolic ±3 mmHg, diastolic ±3 mmHg, pulse ±5% of the value shown |

| Measurement uncertainty | Max. permissible standard deviation according to clinical testing: systolic 8 mmHg / diastolic 8 mmHg |
|----------------------------------|---|
| Memory | 2 x 60 memory spaces |
| Dimensions | L 84 mm x W 60 mm x H 29 mm |
| Weight | Approx. 92 g (without batteries, with cuff) |
| Cuff size | 140 to 195 mm |
| Permissible operating conditions | +10°C to +40°C, ≤85% relative humidity (non-condensing) |
| Permissible storage conditions | -20°C to +50°C, ≤85% relative humidity, 800–1050 hPa ambient pressure |
| Power supply | 2 x 1.5-V = AAA batteries |
| Battery life | For approx. 170 measurements, depending on levels of blood pressure and inflation pressure |
| Classification | Internal supply, IP22, no AP or APG, continuous operation, application part type BF |
| | |

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

Technical information is subject to change without notification to allow for updates.

- This device complies with the European standard EN 60601-1-2 (compliance with CISPR 11, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-8) and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this device.
- The device complies with the EU Medical Devices Directive 93/42/EEC, the German Medical Devices Act (Medizinproduktgesetz) and the standards EN 1060-1 (Non-invasive sphygmomanometers Part 1: General requirements), EN 1060-3 (Non-invasive sphygmomanometers Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems) and IEC 80601-2-30 (Medical electrical equipment Part 2 30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers).
- The accuracy of this blood pressure monitor has been carefully checked and developed with regard to a long useful life. If the device is used for commercial medical purposes, it must be regularly tested for accuracy by appropriate means. Precise instructions for checking accuracy may be requested from the service address.

12. Warranty/service

Further information on the guarantee and guarantee conditions can be found in the guarantee leaflet supplied.