beurer

BC 44

EN Blood pressure monitor

CE 0483

ENGLISH

Content

Included in delivery:

Blood pressure monitor with cuff
2 x 1.5 V LR03 AAA batteries
Storage box
Instructions for use

1. Getting to know your instrument

Check that the device 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 Services address.

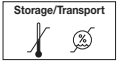
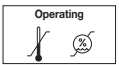
The wrist blood pressure monitor is used for non-invasive measurement and monitoring of adults' arterial blood pressure.
This allows you to quickly and easily measure your blood pressure and to display the last recorded measurement.
A warning is issued for anyone suffering from cardiac arrhythmia.
The recorded values are classified and evaluated graphically.

2. Important information

⚠ 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 accessories:

	Attention
	Note Note on important information
	Observe the instructions for use
	Application part, type BF
	Direct current
	Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive – WEEE
	Separate the packaging elements and dispose of them in accordance with local regulations.
	Separate the product and packaging elements and dispose of them in accordance with local regulations.
	Marking to identify the packaging material. A = material abbreviation, B = material number: 1-7 = plastics, 20-22 = paper and cardboard

	Manufacturer
	Permissible storage and transport temperature and humidity
	Permissible operating temperature and humidity
	Device protected against foreign objects ≥ 12.5 mm and against water dripping at an angle
	Serial number
	Item number
	Medical device
	**CE labelling** This product satisfies the requirements of the applicable European and national directives.

Advice 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 after 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 measurements taken by you are for your information only – they are not a substitute for a medical examination! Discuss the measurements with your doctor, and never base any medical decisions on them (e.g. medicines and their administration)!
- 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 preeclampsia. We recommend consulting a doctor before using the blood pressure monitor during pregnancy.
- 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 is responsible for their safety or are instructed by such a person in how to use the device. Supervise children around the device to ensure they do not play with it.
- 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 avoid using an upper arm blood pressure monitor.
- 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 unit 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, 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.
- Ensure that the cuff is not placed on an arm in which the arteries or veins are undergoing medical treatment, e.g. intravascular access or 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.
- The blood pressure monitor can only be operated with batteries.
- To conserve the batteries, the monitor switches off automatically if no buttons are pressed 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 careless use.

⚠ Storage and Care

- The blood pressure monitor is made up of precision electronic components. Accuracy of readings and the instrument's service life depend on careful handling.
  – You should protect the device from impact, moisture, dirt, major temperature fluctuations and direct exposure to the sun's rays.
  – Never drop the device.
  – Do not use near strong electromagnetic fields, i.e. keep it away from any radio systems and mobile phones.
- Do not press the start/stop button ⓘ before the cuff is placed on.
- We advise you to remove the batteries if the device is not going to be used for a longer period of time.

⚠ Notes on handling batteries

- If your skin or eyes come into contact with battery fluid, flush out the affected areas with water and seek medical assistance.
- ⚠ **Choking hazard!** Small children may swallow and choke on batteries. Store the 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 the batteries from excessive heat.
- ⚠ **Risk of explosion!** Never throw batteries into a fire.
- Do not charge or short-circuit batteries.
- If the device is not to be used for a 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.

ⓘ Repair and disposal

- Batteries do not belong in domestic refuse. Used batteries should be disposed of at the collection points provided.

- Never open the instrument. If these instructions are not heeded, the warranty will be null and void.
- Never attempt to repair the instrument or adjust it yourself. We can no longer guarantee perfect functioning if you do.
- Repairs may only be performed by Customer Service or authorized dealers. However, always check the batteries and replace them if necessary prior to making any complaint.
- 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 a suitable local collection or recycling point. 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.

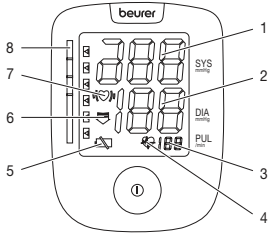
⚠ Notes on electromagnetic compatibility

- 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.

3. Unit description

1. Display
2. Risk indicator
3. Wrist cuff
4. START/STOP button ⓘ
5. Battery compartment lid

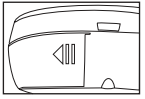
4. Icons in the display



1. Systolic pressure
2. Diastolic pressure
3. Pulse
4. Pulse symbol
5. Battery replacement symbol
6. Pump up, release air (arrow)
7. Cardiac arrhythmia symbol
8. Risk indicator

5. Prepare measurement

Inserting battery



- Remove the battery compartment lid on the lower left side of the device.
- Insert two 1.5V micro batteries (alkaline, type LR03).
- Make sure that the batteries are inserted with the correct polarity, according to the label on the battery compartment lid. Do not use rechargeable batteries.
- Replace the battery cover carefully.

If the battery change is continuously illuminated, measurement is no longer possible and you must replace all the batteries.

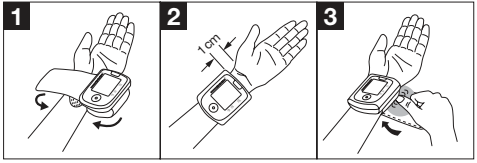
⚠ Battery disposal

- The 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

6. Measuring blood pressure

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

Positioning 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 edge of the monitor is positioned approx. 1 cm below the ball of your thumb.
- The cuff has to be fitted tightly around the wristbut should not constrict it.

Important: The instrument should only be operated with the original cuff.

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

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

Correct posture

- Before the initial blood pressure measurement, make sure always to rest for about 5 minutes. Otherwise there may be divergences.
- Furthermore, if you want to take several measurements in succession, make sure always to wait for at least 1 minute between the individual measurements.
- You can perform the measurement either sitting or lying down. To carry out a blood pressure measurement, 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. It is essential to support your arm and have it at an angle. Always make sure that the cuff is level with your heart. Otherwise there may be serious divergences. Relax your arm and the palms of your hands.

- In order not to distort the result, it is important to keep still during the measurement and not talk.

Measuring blood pressure

- Start the blood pressure monitor with the start/stop button ⓘ. A beep and a brief display of all the symbols confirm that the device is switched on.
- Before the measurement, the last saved test result is briefly displayed. If there is no measurement in the memory, the instrument always displays the value 0.
- The cuff automatically inflates. Cuff air pressure is released slowly.
- If a tendency towards high blood pressure is already detectable, the cuff is pumped up again and cuff pressure increased further. The pulse symbol flashes as soon as a pulse is found.
- After the pressure has been completely reduced, the systolic pressure, diastolic pressure and pulse readings are displayed.
- Measuring can be cancelled at any time by pressing the start/stop button ⓘ.
- Er_ appears if it has not been possible to perform the measurement properly. Observe the section in these instructions on error messages/troubleshooting and repeat the measurement.
- The test result is saved automatically.

Wait for at least 1 minute before taking another measurement.

7. Evaluating results

Cardiac arrhythmia:

This instrument can identify possible cardiac arrhythmia disorders during measurement and if necessary indicates the measurement with the flashing icon ((♥)).
This may be an indicator for arrhythmia. Arrhythmia is a condition where the heart rhythm is abnormal as a result of defects in the bioelectrical system controlling the heart beat. The symptoms (omitted or premature heart beats, slow or excessively fast heart rate) may be caused, among other things, by heart disease, age, physical predisposition, excessive use of stimulants, stress or lack of sleep. Arrhythmia can only be ascertained through examination by your doctor.
Repeat the measurement if the flashing icon ((♥)) is displayed after the measurement. Please note that you should rest for 5 minutes between measurements and not talk or move during the measurement. If the icon ((♥)) appears often, please contact your doctor. Any self-diagnosis and treatment based on the test results may be dangerous. It is vital to 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 unit 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**
Setting 3: severe hypertension	≥180	≥110	seek medical attention
Setting 2: moderate hypertension	160–179	100–109	seek medical attention
Setting 1: mild hypertension	140–159	90–99	regular monitoring by doctor

Blood pressure value category	Systole (in mmHg)	Diastole (in mmHg)	Action
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)

8. Error messages/troubleshooting

In case of faults, the Er_ message appears in the display.

- Error messages may appear if:
- systolic or diastolic pressure could not be measured (Er 1 or Er2 appears on the display)
- systolic or diastolic pressure was outside the measurement range (“Hı” or “Lo” appears on the display)
- the cuff is fastened too tightly or loosely (Er3 or Er4 appears on the display)
- the pump pressure is higher than 300 mmHg (Er5 appears on the display)
- pumping up takes longer than 160 seconds (Er6 appears on the display)
- there is a system or device error (ErA, Er0, Er7 or Er8 appears on the display)
- the batteries are almost empty .

In such cases, repeat the measurement. Ensure that you do not move or speak during the measurement. If necessary, reinsert or replace the batteries.

Technical alarm – description

Should the recorded blood pressure (systolic or diastolic) lie outside the limits specified in the section “Technical specifications”, the technical alarm will appear on the display indicating either “Hı” or “Lo”. In such cases, you should seek medical assistance and check the accuracy of your procedure.

The limit values for the technical alarm are factory set and cannot be adjusted or deactivated. These alarm limit values are accorded second priority under the standard IEC 60601-1-8.

The technical alarm is a non-locking alarm and must not be reset. The signal shown on the display will disappear automatically after about 8 seconds.

9. Cleaning and storing the device and cuff

- 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. The cuff line should not be bent sharply.

10. Technical details

Model no.	BC 44
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 inaccuracy	Max. permissible standard deviation according to clinical testing: systolic 8 mmHg/diastolic 8 mmHg
Dimensions	L 8,8 cm x W 6,5 cm x H 6,8 cm
Weight	Approx. 98 g (without batteries, with cuff)
Cuff size	140 to 195 mm
Permissible operating conditions	+10 °C to +40 °C, ≤90 % relative air humidity (non-condensing)
Permissible storage conditions	-20 °C to +55 °C, ≤90 % relative air humidity, 800–1050 hPa ambient pressure
Power supply	2 x 1,5 V ⎓ AAA batteries
Battery life	For approx. 300 measurements, depending on the blood pressure level and/or pump pressure
Classification	Internal supply, continuous operation, type BF applied part, IPX0, no AP or APG

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 unit is in line with European Standard EN 60601-1-2 (In accordance with CISPR 11, IEC 61000-4-2, IEC 61000-4-3 and IEC 61000-4-8) and is subject to particular precautions with regard to electromagnetic compatibility (EMC). Please note that portable and mobile HF communication systems may interfere with this unit.
- This device is in line with the EU Medical Devices Directive 93/42/EEC, the “Medizinproduktegesetz” (German Medical Devices Act) 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 safety and essential performance of automated non-invasive blood pressure monitors).

- The accuracy of this blood pressure monitor has been carefully checked and developed with regard to a long useful life. If using the device 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.

11. Warranty / service

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

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