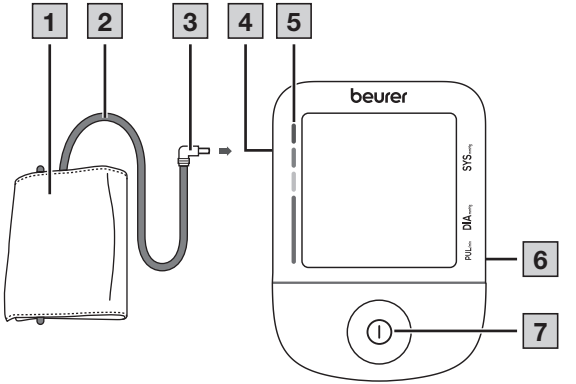
beurer

BM 48

EN Upper arm blood pressure monitor
Instructions for use

CE 0483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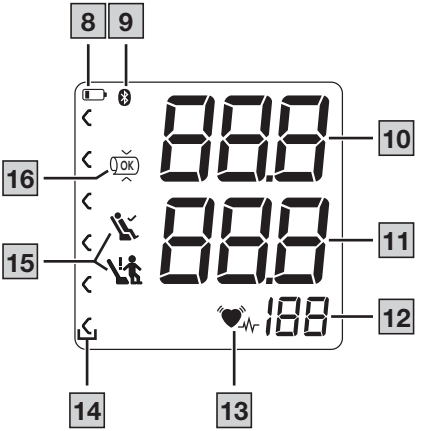
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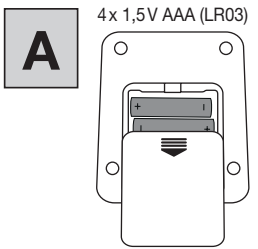
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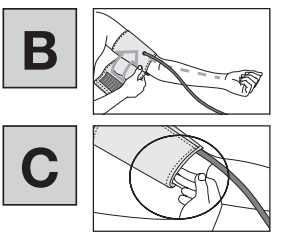
4 x 1,5 V AAA (LR03)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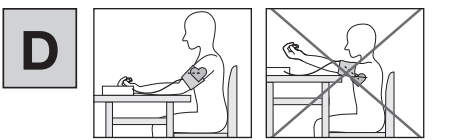
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ENGLISH

Read these instructions for use carefully. Observe the warnings and safety notes. Keep these instructions for use for future reference. Make the instructions for use accessible to other users. If the device is passed on, provide the next user with these instructions for use.

1. INCLUDED IN DELIVERY

Check that the exterior of the cardboard delivery packaging is intact and make sure that all contents are included in the delivery. Before use, ensure that there is no visible damage to the device and the supplied components 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.

- Upper arm blood pressure monitor
- Upper arm cuff (22 – 42 cm)
- Batteries, see chapter “Technical specifications”

2. SIGNS AND SYMBOLS

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

⚠ DANGER

Indicates an imminent danger. If it is not avoided, death or serious injury will occur.

⚠ WARNING

Indicates a potentially impending danger. If it is not avoided, death or serious injury will occur.

⚠ CAUTION

Indicates a potentially impending danger. If it is not avoided, slight or minor injuries may occur.

NOTICE

Indicates a potentially harmful situation. If it is not avoided, the system or something in its vicinity may be damaged.

	**Product information** Note on important information
	**Observe the instructions** Read the instructions before starting work and/or operating devices or machines
	The electronic device must not be disposed of with household waste
	Do not dispose of batteries containing harmful substances with household waste
	Manufacturer
	Date of manufacture

CE	**CE labelling** This product satisfies the requirements of the applicable European and national directives.
B A	Marking to identify the packaging material. A = material abbreviation, B = material number: 1–7 = plastics, 20–22 = paper and cardboard
RECYCLE	Separate the product and packaging elements and dispose of them in accordance with local regulations.
IP20	Protected against solid foreign objects 12.5 mm in diameter and larger
⎓	Direct current
UDI	Unique device identifier (UDI) Identifier for unique product identification
LOT	Batch designation
REF	Item number
SN	Serial number
CH REP	Swiss authorised representative
MD	Medical device
#	Type number
	Type BF applied part
	Temperature range
%	Humidity range
	Atmospheric pressure limitation
	Importer

3. INTENDED PURPOSE

Intended Use

The blood pressure monitor (hereinafter, device) is intended for the fully automatic, non-invasive measurement of arterial blood pressure and pulse values on the upper arm.
It is designed for self-measurement by adults in a domestic environment.

Intended Users

The blood pressure measurement is suitable for adult users whose upper arm circumference is within the range printed on the cuff.

Clinical benefits

The user can record their blood pressure and pulse values quickly and easily using the device. The recorded values are classified according to internationally applicable guidelines and evaluated graphically. Furthermore, the device can detect any irregular heart beats that occur during measurement and inform the user via a symbol in the display.

Indications

In the event of hypertension or hypotension, the user can independently monitor their blood pressure and pulse values at home.

However, the user does not need to be suffering from hypertension or arrhythmia in order to use the device.

Contraindications

⚠WARNING

- Do not use the device on newborns, children or pets.
- Persons with reduced physical, sensory or mental capabilities should be supervised by a person responsible for their safety and receive instructions from that person on how to use the device.
- Do not use the cuff on people who have undergone a mastectomy or who have had their lymph nodes removed.
- Do not place the cuff over wounds as this may cause further injury.
- Make sure that the cuff is not placed on an arm whose arteries or veins are undergoing medical treatment, e.g. intravascular access or intravascular therapy, or an arteriovenous (AV) shunt.
- Do not use the device on people with allergies or sensitive skin.

Undesirable side effects

- Skin irritation
- Negative influence on blood circulation

4. WARNINGS AND SAFETY NOTES

General warnings

⚠WARNING

- The measurements you take are for your information only – they are not a substitute for a medical examination! Discuss your measured values with your doctor and never make your own medical decisions based on them.
- Consult your doctor at regular intervals. Only they are able to give you personal target values for controlled blood pressure, particularly if you are receiving medical therapy.
- Always perform the measurement on the arm with the higher blood pressure values.
- 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.
- Using the blood pressure monitor outside your home environment or while on the move can influence the measurement accuracy and cause incorrect measurements.
- Cardiovascular diseases may lead to incorrect measurements or have a detrimental effect on measurement accuracy.
- If you have any of the following conditions, it is essential you consult your doctor before using the device: Cardiac arrhythmia, circulatory disorders, diabetes, pregnancy, pre-eclampsia, hypotension, chills, shivering.
- Consult your doctor if  is displayed frequently. Only they can determine, through an examination, whether there is an abnormality.
- Do not use the device at the same time as other medical electrical devices (ME equipment).
- Do not use the device outside of the specified storage and operating conditions. This could lead to incorrect measurements.
- Only use the cuffs included in delivery or described in these instructions for use with the device , based on your upper arm circumference. Using a different cuff may lead to inaccurate measurements.

- Note that when inflating the cuff, the functions of the limb affected may be impaired.
- Do not perform measurements more frequently than necessary. Due to the restriction of blood flow, some bruising may occur.
- Blood circulation must not be stopped for an unnecessarily long time during the blood pressure measurement. If the device malfunctions, remove the cuff from the arm.
- The circulation of the arm must not be hindered by tight clothing or similar.
- Place the cuff on the upper arm only. Do not place the cuff on other parts of the body.
- The air line poses a risk of strangulation for small children.
- Small parts may present a choking hazard for small children if swallowed. They should therefore always be supervised
- Keep packaging material away from children. There is a risk of suffocation.
- Keep away from children, pets and pests.
- Do not drop, step on or shake the device.
- Do not disassemble the device as this may cause damage, faults and malfunctions.
- Do not open the device except for the battery compartment. Failure to comply will invalidate the warranty.
- Do not repair or modify the device.
- Repairs must only be carried out by Customer Services or authorised retailers.
- Never operate the device during maintenance work. Maintenance work includes maintenance, inspection and repair.
- Use a mains connection that is easily accessible so that the mains plug can be removed quickly if necessary.
- Do not use any cleaning solutions or solvents.
- Under no circumstances hold the device or cuff under water.
- The user must not touch the patient and the output connector of the AC mains adapter at the same time.

General precautions

⚠ CAUTION

- The accuracy of the measurements and service life of the device depend on its careful handling.
- Protect the device and its mains adapter from impacts, humidity, dirt, drastic changes in temperature and direct sunlight.
- Ensure the device is at room temperature before taking a measurement. If the measuring device has been stored close to the maximum or minimum storage and transport temperatures and is placed in an environment with a temperature of 20 °C, it is recommended that you wait approx. 2 hours before using the measuring device.
- If you store the device and cuff, do not place heavy objects on the device and cuff.
- Avoid any mechanical restriction, compression or bending of the cuff line.
- During mains operation, there must not be any batteries in the battery compartment, as this could damage the device.
- To avoid any potential damage, the device may only be operated with a mains part that meets the specifications described in the chapter “Technical specifications”.
- Furthermore, the mains part must only be connected to the mains voltage that is specified on the type plate.

Notes on handling batteries

⚠ DANGER

- **Choking hazard!** Keep batteries out of the reach of children. Seek medical attention immediately if swallowed. Swallowing them may cause burns, severe internal injuries, and death.
- Never allow children to replace batteries without adult supervision.

⚠ WARNING

- **Risk of explosion! Risk of fire!** Failure to comply with the following points can result in personal injury or cause overheating, leakage, venting, breakage, explosion, or fire on the battery.
- This device contains non-rechargeable batteries which must not be charged.
- Do not throw batteries into a fire.
- Never charge, forcibly discharge, heat, disassemble, open, crush, deform, encapsulate, or modify batteries.
- Never short-circuit batteries or battery compartment contacts.
- Protect the batteries from direct sunlight, rain, heat, and water.
- Exposure of batteries to an environment with extremely high temperatures or an extremely low air pressure may result in explosion or leakage of flammable liquids and gases.
- Dispose of defective and discharged batteries immediately and properly (see chapter on disposal).
- Do not use modified or damaged batteries.
- Always select the correct battery type.
- Always insert the batteries correctly, taking into account the polarity (+ / -).
- Never mix batteries of different manufacturers, capacities (new and used), size, or type within a device.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- If fluid from a battery comes into contact with your skin or eyes, wash the affected areas with water and seek medical assistance.

⚠ CAUTION

- Store batteries in a well-ventilated, dry, and cool place in a non-conductive container in which the batteries cannot be short-circuited to each other or by other metal objects.
- Keep batteries clean and dry.
- Keep batteries away from water.
- If the device is not going to be used for a long period of time, remove the batteries from the battery compartment.

NOTICE

- Do not use rechargeable batteries.

Notes on electromagnetic compatibility

⚠ CAUTION

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The device may not be fully usable 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 and/or replacement parts other than those specified or provided by the manufacturer of this device could lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity; this can result in faulty operation.
- Keep portable RF communication devices (including peripheral equipment, such as antenna cables or external antennas) at least 30 cm away from all device parts, including all cables included in delivery.
- Failure to comply with the above can impair the performance of the device.
- Please note that portable and mobile HF communication systems may interfere with this device.
- Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.

5. DEVICE DESCRIPTION

The associated drawings are shown on page 3.

1	Cuff	2	Cuff line
3	Cuff connector	4	Connection for cuff connector (left-hand side)
5	Risk indicator	6	Connection for mains adapter
7	START/STOP button		

Information on the display

8	Low battery indicator	9	Symbol for *Bluetooth*® connection
10	Systolic pressure	11	Diastolic pressure
12	Calculated pulse value	13	Cardiac arrhythmia symbol / Pulse symbol
14	Risk indicator	15	Resting indicator display
16	Cuff position control		

6. USAGE

6.1 Initial use

Inserting the batteries

- Remove the battery compartment cover A.
- Insert the batteries, polarity according to the label A.
- Close the battery compartment cover.

After removing the batteries, reset the date and time. Saved measurements are retained.

Operation with the mains part

You can also operate this device with a mains part (not included in delivery). Ensure that you have removed the batteries from the device.

- Insert the mains adapter into the connection provided for this purpose on the device.
- Then insert the mains plug of the mains part into the mains socket.

- After using the device, unplug the mains part from the mains socket first and then disconnect it from the device. After unplugging the mains part, reset the date and time. Saved measurements are retained.

6.2 Transfer of measured values

Transfer via *Bluetooth*®

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

Click here for the app:

- Activate *Bluetooth*® in your smartphone’s settings.
- Start the app.
- Select BM 48 in the app and follow the instructions.

System requirements and compatible devices:

Please check whether *Bluetooth*® has been switched on by consulting the instructions provided for your device. When switched off, press ⏻ 5 seconds. Press and hold ⏻ to select whether automatic *Bluetooth*® data transfer is activated (bt on) or deactivated (bt oFF). Confirm by pressing and holding down ⏻.

6.3 Before the blood pressure measurement

General rules when measuring your own blood pressure

- To rule out a difference between sides, the measurement should initially be taken on both arms.
- Always perform the measurement when you are sufficiently physically rested.
- 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.
- Repeat the measurement if you have doubts about the measured value.

Attaching the cuff

You can measure your blood pressure on either arm.

- Always measure your blood pressure on the same arm.
- Before taking the measurement, check the fit using the index mark described below.
- Expose your upper arm.
- The cuff must be placed on the upper arm so that the bottom edge is positioned 2-3 cm above the elbow and over the artery. The line should point to the centre of the palm here B. The cuff should be fastened so that two fingers fit under the cuff when it is closed C.
- Now insert the cuff line into the connection for the cuff connector.
- The cuff is suitable for you if the index mark ▼ is within the OK range after fitting the cuff.

Adopting the correct posture

- Sit in a comfortable upright position. Lean back so that your back is supported.
- Place your arm on a surface D.
- Place your feet flat on the ground next to one another.
- The cuff must be level with your heart.
- Ensure that you do not speak or move during the measurement.

6.4 Taking a blood pressure measurement

Measurement

1. Press ⏻. All display elements are briefly displayed. The cuff inflates itself automatically. The measurement process starts. ♥ is displayed as soon as a pulse is detected.

   To cancel the measurement, press ⏻.
2. The systolic pressure, diastolic pressure and pulse measurements are displayed.

   "Er" is displayed if the measurement could not be performed properly. In this case, please refer to the "Troubleshooting" section.

   The device switches off automatically after approx. 1 minute. The value is saved to the selected or most recently used user.

6.5 Evaluating the results

Cardiac arrhythmia

The device can identify heart rhythm abnormalities during the blood pressure measurement. If ♥ is displayed after the measurement, this indicates that an irregularity has been detected in your pulse.
Repeat the measurement if ♥ is displayed.

When assessing your blood pressure, only use the results that have been recorded without any irregularities in your pulse.

Risk indicator (for general guidance only)

Measured blood pressure value range		Classification	Risk indicator colour
Systolic (in mmHg)	**Diastolic** (in mmHg)		
≥ 180	≥ 110	Stage 3 high blood pressure (severe)$_1$	Red
160 – 179	100 – 109	Stage 2 high blood pressure (moderate)$_1$	Orange
140 – 159	90 – 99	Stage 1 high blood pressure (mild)$_1$	Yellow
130 – 139	85 – 89	High normal$_1$	Green
120 – 129	80 – 84	Normal$_1$	Green
< 120	< 80	Optimal$_1$	Green
< 90	< 60	Low blood pressure$_2$	Orange

$_1$Source: WHO, 1999 (World Health Organization)
$_2$Source: National Health Service, 2023

The risk indicator 5 / 14 indicates which category the recorded blood pressure values fall into. If the measured values are in two different categories, the risk indicator always indicates the higher range.

Low blood pressure

⚠ WARNING

Low blood pressure (hypotension) can be a health hazard and cause dizziness or fainting. Blood pressure is considered low if

systolic and diastolic pressure are below 90/60 mmHg (source: National Health Service, 2023).
Seek medical attention if you suddenly suffer from low blood pressure.

Resting indicator (using HSD diagnostics)

	The measured blood pressure value was obtained when the user's circulatory system was sufficiently at rest and reliably represents the blood pressure at rest.
	Indicates that the value was obtained when the user's circulatory system was not sufficiently at rest. The measurement should therefore be repeated after a period of physical and mental rest lasting at least 5 minutes.
No resting indicator symbol is displayed	During the measurement it was not possible to determine whether the user's circulatory system was sufficiently at rest. In this case too, the measurement should be repeated after a period of rest lasting at least 5 minutes.

7. CLEANING AND MAINTENANCE

Clean the device and cuff using only a slightly damp cloth.

8. ACCESSORIES AND/OR REPLACEMENT PARTS

Accessories and/or replacement parts are available at www.beurer.com, under "Service".

Designation	Item number
Universal cuff (22-42 cm)	110.031
Mains part (EU)	072.78
Mains part (UK)	072.79

9. TROUBLESHOOTING

Error	Possible cause	Solution
Er 1	Unable to record a pulse.	Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement.
Er2	The measured blood pressure is outside the measurement range.	
Er3 	There is a pneumatic system error.	Repeat the measurement. Ensure that the cuff line is correctly connected and that you do not move or speak.
Er4	An error occurred during the measurement.	Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement.
Er5	The inflation pressure is higher than 300 mmHg.	Please take another measurement to check whether the cuff can be correctly inflated. Make sure that neither your arm nor other heavy objects are pressing on the line, and that the line is not bent.

Error	Possible cause	Solution
Er6	There is a system error.	If this error message appears, please contact Customer Services.
Er7	There are problems with the connection between the smartphone/tablet and the app.	Switch off the main unit, close the app and first deactivate *Bluetooth*® on your smartphone/ tablet before reactivating the function. Try to establish the connection again.
LO	The batteries are nearly flat.	Insert new batteries into the device.

10. DISPOSAL

Before making a complaint, first check the batteries and replace them if necessary.
For environmental reasons, do not dispose of the device in household waste at the end of its service life. Dispose of the device at a suitable local collection or recycling point. Observe the local regulations for material disposal. 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. You can obtain the location of collection points for old devices from the local authorities.

Disposal of the batteries

Used, completely discharged batteries must not be disposed of with household waste. Dispose of the batteries in specially designated collection boxes, at recycling points or at electronics retailers. You are legally required to dispose of the batteries correctly.

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

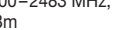
Type	BM 48/1
Model	BM 48
Measurement method	Oscillometric, non-invasive blood pressure measurement on the upper arm
Measurement range	Cuff pressure 300 mmHg, systolic pressure 50–280 mmHg, diastolic pressure 30–200 mmHg, pulse 40–199 beats/minute
Display accuracy	Systolic pressure ±3 mmHg, diastolic pressure ±3 mmHg, pulse ±5% of the displayed value
Measurement uncertainty	Max. permissible standard deviation according to clinical testing: systolic pressure 8 mmHg, diastolic pressure 8 mmHg
Dimensions	L 128 mm x W 91 mm x H 46 mm
Weight	Approx. 357 g (without batteries, with cuff)
Cuff size	22 to 42 cm upper arm circumference
Operating conditions	+10 °C to +40 °C, 10% – 85% relative humidity, 700–1060 hPa ambient pressure
Storage and transport conditions	-20 °C to +55 °C, ≤90% relative humidity (non-condensing)
Power supply	4 x 1.5V ⎓ LR03 AAA batteries

Battery life	For approx. 300 measurements depending on blood pressure and inflation pressure levels as well as the number of *Bluetooth*® connections
Product life cycle to be expected	Information on the life cycle of the product can be found at beurer.com
Classification	Internal power supply, IP20, no AP or APG, continuous operation Application part, type BF
Data transfer via *Bluetooth*® wireless technology	The device uses *Bluetooth*®, Frequency band 2400 – 2483 MHz, max. transmission power 5 dBm

The serial number is located on the device or in the battery compartment.
We reserve the right to make technical changes to improve and develop the product.

- The device conforms with the respective national regulations and European standard EN 60601-1-2 (Group 1, Class B, in accordance with CISPR-11, IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-7, IEC 61000-4-8, IEC 61000-4-11) and is subject to particular precautions with regard to electromagnetic compatibility.
- The device has been clinically tested in accordance with the requirements of ISO 81060-2.
- We hereby confirm that this product complies with the European RED Directive 2014/53/EU. The CE Declaration of Conformity for this product can be found at: https://www.beurer.com/conformity
- The accuracy of this device has been carefully checked and it has been developed with a long service life in mind. If the device is used for commercial medical purposes, the applicable national regulations determine whether it must be tested for accuracy by appropriate means.

Mains adapter

Model no.	LXCP12X-050100BG
Input	100 – 240 V, 50 – 60 Hz, 0.5 A max
Output	5 V DC, 1 A
Manufacturer	Shenzhen Longxc Power Supply Co., Ltd
	Polarity
	Insulated/protection class 2

12. GUARANTEE/SERVICE

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

Notification of incidents
For users/patients in the European Union and identical regulation systems, the following applies: If a major incident occurs during or through use of the product, 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.

Subject to errors and changes

UK-Importer: Beurer UK Ltd.
Suite 16, Stonecross Place, Stonecross Lane North, WA3 2SH Lowton, United Kingdom

Beurer GmbH, Söflinger Str. 218, 89077 Ulm, Germany, www.beurer.com

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