

# beurer

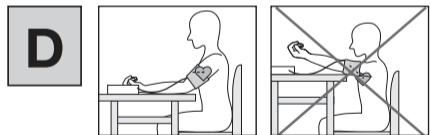
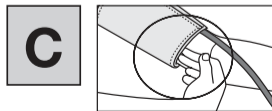
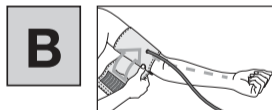
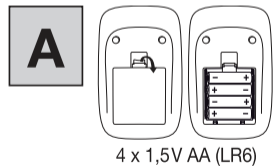
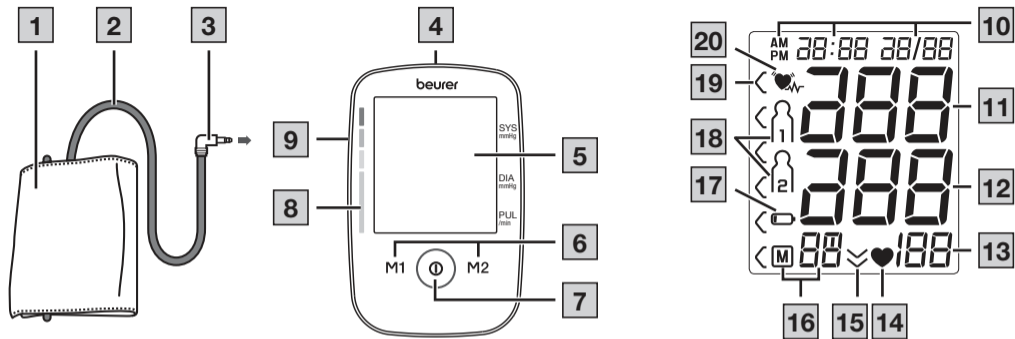
# BM 45



**EN** Upper arm blood pressure  
monitor  
Instructions for use

CE 0483

M



# 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 instructions for use to the next user as well.**

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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 Services address.






- 1x blood pressure monitor
- 1x upper arm cuff (22-36 cm)




- 1x instructions for use
- 4x 1.5V AA LR6 batteries
- 1x storage bag




## 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:

 <p><b>WARNING</b></p>	<p>Indicates a potentially impending danger. If it is not avoided, death or serious injury will occur.</p>
 <p><b>CAUTION</b></p>	<p>Indicates a potentially impending danger. If it is not avoided, slight or minor injuries may occur.</p>
	<p><b>Product information</b> Note on important information</p>
	<p><b>Observe the instructions</b> Read the instructions before starting work and/or operating devices or machines</p>

	<p>Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive – WEEE</p>
	<p>Do not dispose of batteries containing harmful substances with household waste</p>
	<p>Manufacturer</p>
	<p><b>CE labelling</b> This product satisfies the requirements of the applicable European and national directives.</p>
	<p>Dispose of packaging in an environmentally friendly manner</p>

	Marking to identify the packaging material. A = material abbreviation, B = material number: 1–7 = plastics, 20–22 = paper and cardboard
	Separate the product and packaging elements and dispose of them in accordance with local regulations.
<b>IP20</b>	Protected against solid foreign objects 12.5 mm in diameter and larger
	<b>Direct current</b> The device is suitable for use with direct current only
<b>UDI</b>	Unique device identifier (UDI) Identifier for unique product identification
<b>LOT</b>	Batch designation
<b>REF</b>	Item number

<b>SN</b>	Serial number
<b>MD</b>	Medical device
<b>#</b>	Type
	<b>Type BF applied part</b> Galvanically isolated applied part (F stands for “floating”); meets the requirements for leakage currents for type B
	Temperature range
	Humidity range

	Atmospheric pressure limitation
	Date of manufacture

### 3. INTENDED USE

#### Purpose

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.

#### Target group

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. The device saves the recorded measurements and can also output average values of previous measurements. The recorded data can provide health-care service providers with support during the diagnosis and treatment of blood pressure problems, and therefore it plays a part in the long-term monitoring of the user's health.

### 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 blood pressure monitor 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.
- If you have any of the following conditions, it is essential you consult your doctor before using the device: Cardiac arrhythmia, circulatory problems, diabetes, pregnancy, pre-eclampsia, hypotension, chills, shaking
- Do not use the device if you are using electrical implants (e.g. pacemakers).
- 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.
- 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.

## 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 (e.g. regarding medicine doses).
- 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 (e.g. while travelling in a car, ambulance or helicopter, or while undertaking physical activity such as playing sport) can influence the measurement accuracy and cause incorrect measurements.
- Cardiovascular diseases may lead to incorrect measurements or have a detrimental effect on measurement accuracy.
- Do not use the device at the same time as other medical electrical devices (ME equipment). This could cause the measuring device to malfunction and/or an inaccurate measurement.

- 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. 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.
- 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.
- Do not drop, step on or shake the device.
- Do not disassemble the device as this may cause damage, faults and malfunctions.
- Do not use the device if you have metal implants.

## General precautions

### ⚠ CAUTION

- The blood pressure monitor is made from precision and electronic components. 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, marked temperature fluctuations 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.
- Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.
- We recommend removing the batteries if the device is not going to be used for a prolonged period of time.
- Avoid any mechanical restriction, compression or bending of the cuff line.
- Do not use the device on people with allergies or sensitive skin.

## Notes on handling batteries

### **⚠ WARNING**

- 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.
- Seek medical attention immediately if swallowed.
- Risk of explosion! Do not throw batteries into a fire.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- Do not disassemble, open or crush the batteries.
- Observe the plus (+) and minus (-) polarity signs.

### **⚠ CAUTION**

- Protect batteries from excessive heat.
- Do not charge or short-circuit the batteries.
- If the device is not going to be used for a long period of time, remove the batteries from the battery compartment.
- Use identical or equivalent battery types only.
- Always replace all batteries at the same time.
- 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 or replacement parts 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.
- 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.







## 5. DEVICE DESCRIPTION

The associated drawings are shown on page 2.

- |  |   |
|--|---|
| <b>1</b> Cuff  | <b>2</b> Cuff line                                      |
| <b>3</b> Cuff connector  | <b>4</b> Connection for mains part*<br>(rear of device) |
| <b>5</b> Display   | <b>6</b> Memory buttons <b>M1/M2</b>                    |
| <b>7</b> Start/stop button  | <b>8</b> Risk indicator                                 |
| <b>9</b> Connection for cuff connector (left-hand side)  |   |

\* not included in delivery



### Information on the display


- |   |   |
|---|---|
| <b>10</b> Date/time   | <b>11</b> Systolic pressure   |
| <b>12</b> Diastolic pressure  | <b>13</b> Calculated pulse value  |
| <b>14</b> Pulse symbol                 | <b>15</b> Release air    |
| <b>16</b> Number of memory space/memory display average value (P), morning (P <sub>M</sub> ), evening (P <sub>M</sub> ) |   |
| <b>17</b> Battery replacement symbol   | <b>18</b> User memory   |
| <b>19</b> Risk indicator  | <b>20</b> Cardiac arrhythmia symbol    |

## 6. USAGE

### 6.1 Initial use

#### Inserting the batteries

- Remove the battery compartment cover on the back of the device .
- Insert four 1.5 V AA (alkaline type LR6) batteries. Insert the batteries, making sure the polarity is correct according to the label .
- Close the battery compartment cover.

If the  symbol is displayed and does not disappear, measurement is no longer possible. Replace all the batteries. Once the batteries have been removed from the device, the date and time must be set again. Any saved measured values are retained.

#### Operation with the mains part

You can alternatively also operate this device with a mains part (not included in delivery). However, before connecting the device with the mains part, please ensure that you have removed the batteries from the device. 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.
- First, remove the protective cap of the mains part connector – located on the rear of the device – and insert the mains part into the connection intended for this purpose.
- Then insert the mains plug of the mains part into the mains socket.
- After using the blood pressure monitor, unplug the mains part from the mains socket first and then disconnect it from the blood pressure monitor. As soon as you unplug the mains part, the blood pressure monitor loses the date and time setting but the saved measured values are retained.

## Adjusting the settings

Make sure that the device’s settings have been set correctly so you can make full use of all its functions. Otherwise you will not be able to save your measured values with the date and time and access them later.

There are two different ways to access the settings menu:

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

When inserting 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 **ⓘ** for approx. 5 seconds.

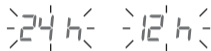
Set these settings in the order shown below:



Press **ⓘ** to confirm your selection each time.

### Time format

Time format flashes:

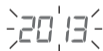


- Press **M1/M2** to select the time format

### Date

The year flashes:

- Press **M1/M2** to select the year



The month flashes:

- Press **M1/M2** to select the month



The day flashes:

- Press **M1/M2** to select the day



**ⓘ** If the time format is set to the 12-hour format, the order in which the day and month are displayed is reversed.

## Time

The hour flashes:

- Press **M1/M2** to select the hour

The minutes flash:

- Press **M1/M2** to select the minutes



## 6.2 Before the blood pressure measurement

### General rules when measuring your own blood pressure

- In order to generate an informative profile of changes in your blood pressure that can be used for comparisons, you should measure your blood pressure regularly and always at the same time of day.

Measure your blood pressure twice a day: once in the morning after getting up and once in the evening.

- Always perform the measurement when you are sufficiently physically rested. Avoid taking measurements at stressful times.
- 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.

- If you want to take several measurements in succession, always make sure that you leave at least 1 minute between each measurement.
- Repeat the measurement if you have doubts about the measured value.

### Attaching the cuff

You can measure your blood pressure on either arm. Some deviations between the values in the right and left arm are perfectly normal. Always perform the measurement on the arm with the higher blood pressure values. Consult your doctor about this before starting self-measurement.

- Always measure your blood pressure on the same arm.
- Place the cuff onto the bare upper arm. The circulation of the arm must not be hindered by tight clothing or similar.
- 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**.
- Guide the end of the cuff that is sticking out through the metal ring, fold it back over the arm and close the cuff using the hook-and-loop fastener. The cuff should be fastened tightly, but not too tightly, so that two fingers can still fit under the closed cuff **C**.

- The cuff is suitable for you if the index mark (▼) is within the OK range after fitting the cuff.
- Now insert the cuff line into the connection for the cuff connector.

## Adopting the correct posture

- Sit in a comfortable upright position when taking the blood pressure measurement. 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.
- Stay as still as possible during the measurement and do not talk.

## Selecting the user

This device has 2 users with 60 memory spaces each in order that you can save measurements from 2 different people separately from each other.

If multiple people are using the device, make sure that the correct user has been selected before each measurement:

- Use the **M1** or **M2** memory button to select the desired user. Confirm your selection by pressing **I**.


- If you do not select a user memory, the measurement is stored in the most recently used user memory. The relevant symbol **M1** or **M2** appears on the display.
- Using the Start/stop button **I**, 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. 3 minutes. In this case too, the value is stored in the selected or most recently used user memory.

## 6.3 Taking a blood pressure measurement

Requirement: cuff attached, user selected.

### Measurement

1. Press **I**. 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 **I**.
2. The systolic pressure, diastolic pressure and pulse measurements are displayed. E \_ is displayed if the measurement could not be performed properly. In this case, please refer to the “Troubleshooting” section. If necessary, re-attach the cuff after 1 minute.


The device switches off automatically after approx. 3 minutes. The value is saved to the selected or most recently used user.

## 6.4 Evaluating the results

### General information about blood pressure

- Blood pressure is always stated in the form of two values:
- The highest pressure is the **systolic blood pressure**. This occurs when the heart muscle contracts and blood is pumped into the blood vessels.
- The lowest pressure is the **diastolic blood pressure**. This occurs when the heart muscle has completely relaxed again and the heart is filling with blood.
- Fluctuations in blood pressure are normal. Even during repeat measurements, there may be considerable differences between the measured values. One-off or irregular measurements therefore do not provide reliable information about the actual blood pressure. Reliable assessment is only possible when you perform the measurement regularly under comparable conditions.


### 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.


Consult your doctor if  is displayed frequently. Only they can determine, through an examination, whether there is an abnormality.

### Risk indicator

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

Source: WHO, 1999 (World Health Organization)

The risk indicator **8** / **19** indicates which category the recorded blood pressure values fall into. If the measured values are in two different categories (e.g. systolic pressure in the “high normal” range and diastolic pressure in the “normal” range), the risk indicator always indicates the higher range – “high normal” in the example described.



 Note that these default values are for general guidance only, as individual blood pressures may vary.


Please note that self-measurement at home usually results in values lower than those recorded at a doctor’s surgery. 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.

## 6.5 Displaying and deleting measured values

### User

The results of every successful measurement are saved with the date and time. If there are more than 60 measurements, the oldest measurements are deleted.

1. To access memory recall mode, the blood pressure monitor must first be started. To do this press the Start/stop button **1**.
2. After the full-screen display, select the relevant user memory that you want to see the measurement data for within 3 seconds using the **M1** or **M2** memory button (**M1** for  or **M2** for .
3. Your last measurement will appear on the display.
4. Press the relevant memory button (**M1** or **M2**).

 If you have selected user memory1, the **M1** memory button must be pressed.  
If you have selected user memory2, the **M2** memory button must be pressed.

### Average value

 flashes:

The average value of all this user’s saved measured values is displayed.

1. Press the relevant memory button (**M1** or **M2**).

 flashes:

The average value of the morning measurements for the last 7 days is displayed (morning: 5:00–9:00).

2. Press the relevant memory button (**M1** or **M2**).



PM flashes:

The average value of the evening measurements for the last 7 days is displayed (evening: 18:00–20:00).



## Individual measured values

1. When the relevant memory button (**M1** or **M2**) is pressed again, the last individual measurement is displayed (in this example, measurement 03).
2. When the relevant memory button (**M1** or **M2**) is pressed again, you can view your individual measurements.
3. Press **1** to switch the device off again.  
Press **1** to exit the menu.



## Deleting measured values

1. To delete all of a user's measured values, select the corresponding user.  
Start individual measurement access.
2. Press and hold the **M1** & **M2** memory buttons for 5 seconds.  
[L] appears on the display. All this user's values are deleted.  
The device switches off automatically.

## 7. CLEANING AND MAINTENANCE

- Clean the device and cuff carefully using only a slightly damp cloth.
- Do not use any cleaning solutions or solvents.
- Under no circumstances hold the device or 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. The cuff line should not be bent sharply.
- Remove the batteries if the device is not going to be used for a long period of time.

## 8. ACCESSORIES AND REPLACEMENT PARTS


Accessories and replacement parts are available on the homepage [www.beurer.de](http://www.beurer.de), under "Service". Please state the corresponding order number.

Designation	Item number and/or order number
Standard cuff (22-36 cm)	163.388

Designation	Item number and/or order number
XL cuff (35-44 cm)	163.387
Mains part (EU)	071.95


## 9. TROUBLESHOOTING

Error message	Possible cause	Solution
E1	Unable to record a pulse.	Please wait one minute and repeat the measurement.
E2	You moved or spoke during the measurement.	Ensure that you do not speak or move during the measurement.
E3	The cuff was not attached correctly.	Please observe the information in chapter "Attaching the cuff".

Error message	Possible cause	Solution
E4	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.
E5	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.
E6 	The batteries are almost empty.	Insert new batteries into the device.

## 10. DISPOSAL

### Repairing and disposing of the device

- Do not repair or modify the device yourself. Proper operation can no longer be guaranteed in this case.
- Do not open the device except for the battery compartment. Failure to comply will invalidate the warranty.
- Repairs must only be carried out by Customer Services or authorised retailers. Before making a complaint, first check the batteries and replace them if necessary.
- The device must not be disposed of with household waste. 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).  Please contact the local authorities responsible for waste disposal if you have any questions regarding disposal.

### 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

### Device

Type	BM 45
Measurement method	Oscillometric, non-invasive blood pressure measurement on the upper arm
Measurement range	Cuff pressure 0–300 mmHg, systolic 60–250 mmHg, diastolic 30–199 mmHg, Pulse 40–180 beats/minute
Display accuracy	Systolic $\pm 3$ mmHg, diastolic $\pm 3$ mmHg, pulse $\pm 5\%$ of the value shown
Measurement inaccuracy	Max. permissible standard deviation according to clinical testing: systolic 8 mmHg/diastolic 8 mmHg
Memory	2 x 60 memory spaces



Dimensions	L 160 mm x W 107 mm x H 50 mm
Weight	Approx. 408 g (without batteries, with cuff)
Cuff size	Standard cuff (22-36 cm) XL cuff (35-44 cm)
Permissible operating conditions	+5 °C to +40 °C, 15–90 % relative air humidity (non-condensing)
Permissible storage and transport conditions	-25 °C to +70 °C, ≤90 % relative air humidity, 700hPa–1060hPa ambient pressure
Power supply	4x 1,5 V  AA batteries (LR6)
Battery life	For approx. 250 measurements, depending on the blood pressure level and/or pump pressure
Classification	Internal supply, IP20, no AP or APG, continuous operation, application part type BF (cuff), CLASS II (when using a mains part)

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

Technical specifications are subject to change without notification to allow for updates.

- This device conforms with the European standard EN 60601-1-2 (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. Please note that portable and mobile HF communication systems may interfere with this unit.
- The device complies with Regulation (EU) 2017/745 of the European Parliament and of the Council for medical devices as well as the respective national regulations and the standard IEC 80601-2-30 (Medical electrical equipment Part 2-30 – Particular requirements for 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.

## Mains part

Model no.	LXCP12-006060BEH
Input	100–240 V, 50–60 Hz, 0.5 A max
Output	6 V DC, 600 mA, in conjunction with Beurer blood pressure monitors only
Manufacturer	Shenzhen Longxc Power Supply Co., Ltd.
Protection	This device is double protected and has a primary-side cutout switch which disconnects the device from the mains in case of malfunction. Ensure that you have removed the batteries from the battery compartment before you use the mains part.
	Polarity of the DC voltage connection
	Insulated/protection class 2

Housing and protective covers	The housing of the mains part protects users from touching live parts or parts that could be live (for example with their fingers, or with a needle or checking hook). The user must not touch the patient and the output connector of the AC/DC mains part at the same time.
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## 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 (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.



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