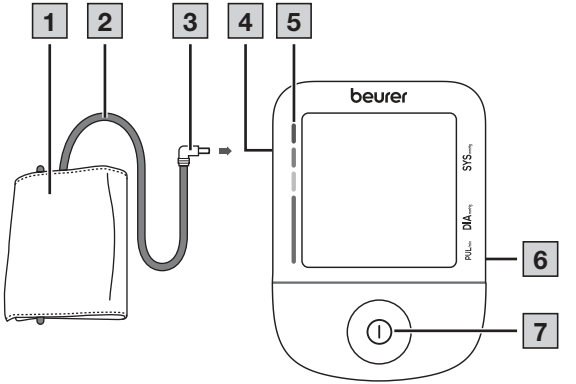
beurer

# BM 38


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

CE 0483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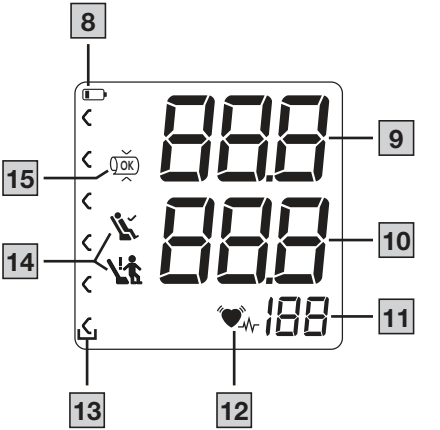
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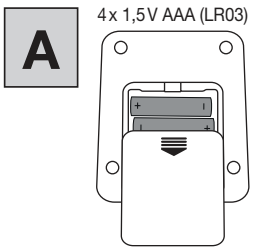
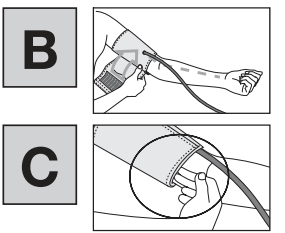

A
4 x 1,5 V AAA (LR03)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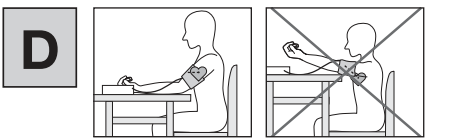
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# ENGLISH

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

## CONTENTS



## 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.

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

## 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:

**⚠ 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.

**Product information**
Note on important information

**Observe the instructions**
Read the instructions before starting work and/or operating devices or machines

Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive – WEEE

Pb Cd Hg

Do not dispose of batteries containing harmful substances with household waste

Manufacturer

Date of manufacture

**CE labelling**
This product satisfies the requirements of the applicable European and national directives.

Dispose of packaging in an environmentally friendly manner

B
A

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.

IP20

Protected against solid foreign objects 12.5 mm in diameter and larger

**Direct current**
The device is suitable for use with direct current only

UDI

Unique device identifier (UDI)
Identifier for unique product identification

LOT

Batch designation

REF

Item number

SN

Serial number

MD

Medical device

#

Type number

**Type BF applied part**

Temperature range

| | |
|---|---|
|  | Humidity range |
|  | Atmospheric pressure limitation |
|  | Importer symbol |

# 3. INTENDED USE

## Intended 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.

## 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 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.
- Do not use the device if you are using electrical implants (e.g. pacemakers).
- Do not use the device if you have metal implants.
- Do not use the cuff on people who have undergone a mastectomy or lymph node clearance.
- 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 (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.
- 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 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.
- Keep children away from the packaging material. 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 modify the device.
- To rule out a difference between sides, the measurement should initially be taken on both arms.
- 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.

## 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, major 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.

## 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 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.

# 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 | Systolic pressure |
| 10 | Diastolic pressure | 11 | Calculated pulse value |
| 12 | Cardiac arrhythmia symbol / Pulse symbol | 13 | Risk indicator |
| | | 14 | Resting indicator display |
| 15 | Cuff position control | | |

# 6. USAGE

## 6.1 Initial use

### Inserting the batteries

- Remove the battery compartment cover on the back of the device A.
- Insert the batteries (see chapter “Technical specifications”). Insert the batteries, making sure the polarity is correct according to the label A.
- Close the battery compartment cover.

If the symbol is displayed and does not disappear, measurement is no longer possible. Replace all the batteries.

### Operation with the mains part

You can 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.
- Insert the mains adapter into the connection provided for this purpose on the blood pressure monitor.
- 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.

## 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 5 minutes 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.
- Only use the device with the cuff supplied, based on your upper arm circumference.
- Before taking the measurement, check the fit using the index mark described below.
- Expose your 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**.

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 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.

## 6.3 Taking a blood pressure measurement

Requirement: cuff attached.

## 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.

   The cuff position control symbol is displayed throughout the entire measurement. If the cuff is too loose, and Er3 will be displayed. In such cases, the measurement is cancelled after approx. 15 seconds and the device switches itself off.

"Er" 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. 1 minute.

## 6.4 Evaluating the results

### General information about blood pressure

- Blood pressure is the force with which the bloodstream presses against the arterial walls. Arterial blood pressure constantly changes in the course of a cardiac cycle.
- 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)$_1$ | 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** / **13** 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.

## 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)

One of the most common errors made when taking a blood pressure measurement is not ensuring that the user's circulatory system is sufficiently at rest when taking the measurement. In this case, the measured systolic and diastolic blood pressure values do not represent the blood pressure at rest. However, it is this blood pressure at rest that should be used to assess the measured values.
This blood pressure monitor uses integrated haemodynamic stability diagnostics (HSD) to measure the user's haemodynamic stability when taking the blood pressure measurement. This enables it to indicate whether the blood pressure was taken when the user's circulatory system was sufficiently at rest.

| | |
|---|---|
|  | 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 blood pressure values measured in this case generally do not represent the blood pressure 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. |

The user's circulatory system not being sufficiently at rest can be the result of various factors, such as physical stress, mental strain/distraction, speaking or experiencing cardiac arrhythmia during the measurement.
In an overwhelming number of cases, HSD will give a very good guide as to whether the user's circulatory system is rested when a blood pressure measurement is taken.
However, certain patients suffering from cardiac arrhythmia or chronic mental conditions may remain haemodynamically unstable even in the long-term, something which persists even after repeated periods of rest. The accuracy of the results for the blood pressure at rest is reduced in these users.
Like any medical measurement method, the precision of HSD is limited and it can lead to incorrect results in some cases. Nevertheless, the blood pressure measurements taken when the user's

circulatory system is sufficiently at rest represent particularly reliable results.

## 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/OR REPLACEMENT PARTS

Accessories and/or replacement parts are available at www.beurer.de, under “Service”. Please state the corresponding order number.

| Designation | Item number and/or order number |
|---|---|
| Universal cuff (22-42 cm) | 110.031 |
| Mains part (EU) | 072.78 |
| Mains part (UK) | 072.79 |

## 9. TROUBLESHOOTING

| Error message | 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. |
| Er6 | There is a system error. | If this error message appears, please contact Customer Services. |
| LO | The batteries are nearly flat. | 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

| | |
|---|---|
| Type | BM 48/1 |
| Model | BM 38 |
| Measurement method | Oscillometric, non-invasive blood pressure measurement on the upper arm |
| Measurement range | Cuff pressure 300 mmHg,<br>systolic pressure 50–280 mmHg,<br>diastolic pressure 30–200 mmHg,<br>pulse 40–199 beats/minute |
| Display accuracy | Systolic pressure ±3 mmHg,<br>diastolic pressure ±3 mmHg,<br>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 (non-condensing), 700–1060 hPa ambient pressure |
| Storage and transport conditions | -20 °C to +55 °C, ≤ 90% relative humidity |
| Power supply | 4 x 1.5V ⎓ LR03 AAA batteries |
| Battery life | For approx. 300 measurements, depending on blood pressure and inflation pressure levels |

| | |
|---|---|
| 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<br>Blood pressure: Application part, type BF |

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.

- This device conforms with the 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. Please note that portable and mobile HF communication systems may interfere with this device.
- 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, the applicable national regulations determine whether it must be tested for accuracy by appropriate means.

## Mains adapter

| Model no. | LXCP12X-050100BG |
|---|---|
| Input | 100–240V, 50–60 Hz, 0.5A max |
| Output | 5 V DC, 1 A, in conjunction with Beurer blood pressure monitors only |
| Manufacturer | Shenzhen Longxc Power Supply Co., Ltd |
| Protection | This device is double-insulated and has a primary-side cutout switch which disconnects the device from the mains in case of malfunction. Make sure that you have removed the batteries from the battery compartment before you use the mains adapter. |
|  | Polarity |
|  | Insulated/protection class 2 |
| Housing and protective covers | The housing of the mains adapter protects users from touching parts that are or could be live (for example with their fingers, or with a needle or checking hook).<br>The user must not touch the patient and the output connector of the AC/DC mains adapter at the same time. |

# 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.

Subject to errors and changes

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CE 0483

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