

**BM 27** Upper arm blood pressure monitor

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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.

# 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 accessories and/or replacement parts. 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

- Upper arm blood pressure monitor
- Upper arm cuff (22-42 cm)
- Batteries, see chapter "Technical specifications"
- Storage bag
- Instructions for use

#### 2. SIGNS AND SYMBOLS

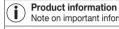
The following symbols are used on the device, in these instructions for use, on the packaging and on the type plate for the device:

#### **A** WARNING

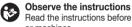
Indicates a potentially impending danger. If it is not avoided, death or serious injury will occur.

### **A**CAUTION

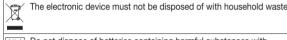
Indicates a potentially impending danger. If it is not avoided, slight or minor injuries may occur



Note on important information



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



Do not dispose of batteries containing harmful substances with household waste



Manufacture



Date of manufacture



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



Separate the 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



Separate the product and packaging elements and dispose of them in accordance with local regulations.



Protected against solid foreign objects 12.5 mm in diameter and larger, and against vertically falling drops of water

-- Direct current

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

## 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

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 international ly 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 healthcare 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

### **A**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 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

- Negative influence on blood circulation

### 4. WARNINGS AND SAFETY NOTES

#### **General warnings**

#### **A 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 disorders, diabetes, pregnancy, pre-eclampsia, hypotension, chills, shivering.
- 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 dur-
- ing 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 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 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

## **General precautions**

## **A** 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 from impacts, moisture, 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.
- 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

- 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.

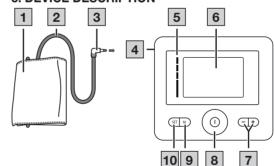
## **A** CAUTION

- · 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

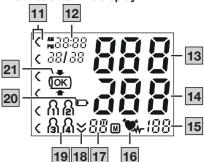
- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The device may not be fully usable in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.
- 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



- 1 Cuff
- 2 Cuff line
- 3 Cuff connector
- 4 Connection for cuff connector
- 5 Risk indicator
- 6 Display
- 7 Function buttons -/+
- 8 START/STOPbutton (1)
- 9 Memory button M 10 Setting button SET

## Information on the display



- 11 Risk indicator
- 13 Systolic pressure
- 15 Calculated pulse value
- average value (R), morning (RR), evening (RR), memory space number
- 19 User memory A
- 20 Battery replacement symbol
- 21 Cuff position control

on the back of the device • Insert the batteries (see chapter "Technical specifications"). Insert the batteries, making sure the polarity is correct ac-

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

# Adjusting the settings

ured values with the date and time and access them later.

• Press -/+ to select the year

The day flashes:

Time The hour flashes:

Press -/+ to select the hour.

The minutes flash:

• Press -/+ to select the user.

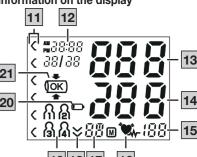
# 6.2 Before the blood pressure measurement

## General rules when measuring your own blood pressure

sure that can be used for comparisons, you should measure your blood pressure regularly and always at the same time of day.

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

- or exercising.
- · Before the initial blood pressure measurement, make sure always to rest
- for about 5 minutes



12 Time and date

14 Diastolic pressure

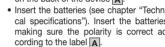
16 Cardiac arrhythmia symbol

17 Memory display M:

## 6.1 Initial use

6. USAGE





Close the battery compartment cover.

set again. Any saved measured values are retained.

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 meas-

There are two different ways to access the settings menu: Before initial use and after each time you replace the battery:

If the batteries have already been inserted:

Set these settings in the order shown below

# Press SET to confirm your selection each time.

Time format Time format flashes: • Press -/+ to select the time format.

Date The year flashes:

The month flashes: • Press -/+ to select the month.

• Press -/+ to select the dav. if the time format is set to the 12-hour format, the order in which the day and month are displayed is reversed.

## • Press -/+ to select the minutes

The user symbol flashes:

• The device switches off automatically.

• In order to generate an informative profile of changes in your blood pres-

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

• Do not take a measurement within 30 minutes of eating, drinking, smoking

When inserting batteries into the device, you will be taken to the relevant menu automatically Press and hold **SET** on the switched off device for approx. 5 seconds. Hour format → Date Time

4 x 1.5 V AA (I R6)

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 cir-
- 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 posi-В tioned 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  $\bigvee$  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 meas-
- urement and do not talk

## Selecting the user

This device can have up to 4 users with 30

memory spaces each, allowing you to separately save measurements from 4 different people.

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

Use M to select the desired user.

## 6.3 Taking a blood pressure measurement

Requirement: cuff attached, user selected

#### Measurement

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

To cancel the measurement, press (1).

- 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. 1 minute. 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 the force with which the bloodstream presses against the arterial walls. Arterial blood pressure constantly changes in the course
- 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

### 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 re corded without any irregularities in your pulse.

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

### Risk indicator

Hisk indicator				
Measured blood pressure value range		Oleanification	Risk	
Systolic (in mmHg)	Diastolic (in mmHg)	Classification	indicator colour	
≥ 180	≥ 110	Stage 3 high blood pressure (severe) <sub>1</sub>	Red	
160 – 179	100 – 109	Stage 2 high blood pressure (moderate) <sub>1</sub>	Orange	
140 – 159	90 – 99	Stage 1 high blood pressure (mild) <sub>1</sub>	Yellow	
130 – 139	85 – 89	High normal₁	Green	
120 – 129	80 – 84	Normal <sub>1</sub>	Green	
< 120	< 80	Optimal <sub>1</sub>	Green	
< 90	< 60	Low blood pressure <sub>2</sub>	Orange	

Source: WHO, 1999 (World Health Organization) «Source: National Health Service, 2023

The risk indicator 5 / 11 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

## **A** 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

### 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 30 saved measurements, the oldest measurement records are deleted.

Press the memory button **M**. Select the desired user memory  $(\{\}\}$  ...  $\{\}\}$  by pressing the memory button M again

#### Average value

#### R flashes

The average value of all this user's saved measured values is displayed. 1. Press +.

#### Rn flashes:

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

#### Pf flashes:

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

#### Individual measured values

- 1. If you press + again, the last individual measurement is displayed.
- 2. If you press + again, you can view the individual measured values.
- 3. Press ① to switch the device off again

#### Deleting measured values

- 1. If you want to delete the whole memory for a specific user, press the memory button M.
- 2. Press and hold down the memory button **M** and the setting button **SET** simultaneously for 5 seconds.

## 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

## 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)	110.127

## 9. TROUBLESHOOTING

In the event of errors, the error message E appears on the screen. Error messages may appear if

- It was not possible to correctly record the pulse: E ;
- The measured blood pressure is outside the measurement range: E2;
- The cuff is fastened too tightly or loosely: E3;
- Errors occur during the measurement: E'4: • The pump pressure is higher than 300 mmHg: E5;
- There is a system error. If this error message appears, please contact Customer Services: E.E.
- The batteries are almost empty:

In such cases, repeat the measurement. Ensure that the cuff line is correctly attached and that you do not move or speak during the measurement. If necessary, reinsert or replace the batteries.<

## 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 collec-

- tion 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 27
Measurement method	Oscillometric, non-invasive blood pressure measurement on the upper arm
Measurement range	Cuff pressure 0–300 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
Memory	4 x 30 memory spaces
Dimensions	L 112 mm x W 110 mm x H 53 mm
Weight	Approx. 341 g (without batteries, with cuff)
Cuff size	22 to 42 cm upper arm circumference
Operating con- ditions	+10 °C to +40 °C, <90% relative humidity, 800–1050 hPa ambient pressure
Storage and trans- port conditions	-20 °C to +55 °C, <90% relative humidity (non-condensing)
Power supply	4 x 1.5 V LR6 AA batteries
Battery life	For approx. 700 measurements, depending on blood pressure and inflation pressure levels
Expected service life	Information on the service life of the product can be found on the homepage
Classification	Internal power supply, IP21, no AP or APG, continuous operation, type BF applied part

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 61000-4-2, IEC 61000-4-3. IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-8) 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

## 12. GUARANTEE/SERVICE

Contact your pharmacy if you are not satisfied with the product. Take the product with you when making a complaint.

If you have questions, tips or comments, visit your nearest Apotek Hiärtat or call Customer Service 0771-405 405.

www.apotekhjartat.se Apotek Hiärtat, Box 4075, 169 04 Solna, Sweden,

### 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.