

beurer



EN Wrist blood pressure monitor Instructions for use



ENGLISH



Read these instructions for use carefully and keep them for later use. Make them accessible to other users and note the information they contain.

Dear customer.

thank you for choosing a product from our range. Our name stands for high-quality, thoroughly tested products for applications in the areas of heat, weight, blood pressure, body temperature, pulse, gentle therapy, massage, beauty and air. Please read these instructions for use carefully and keep them for later use, be sure to make them accessible to other users and observe the information they contain.

With kind regards, Your Beurer team

Table of contents

Table of Contents		
1. Included in delivery3	7. Usage	13
2. Signs and symbols 3	8. Cleaning and maintenance	20
3. Proper use 5	9. What if there are problems?	21
4. Warnings and safety notes6	10. Disposal	22
5. Device description10	11. Technical specifications	23
6. Initial use11	12. Warranty/service	24

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 Service address.

- 1 x wrist blood pressure monitor with cuff
- 1 x instructions for use
- 1 x blood pressure pass
- 1 x storage box
- 2 x 1.5 V LR03 AAA batteries

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 Warning notice indicating a risk of injury or damage to health
À	Important Safety note indicating possible damage to the device/accessory
i	Product information Note on important information
(3)	Observe the instructions Read the instructions before starting work and/or operating devices or machines

⅓	Isolation of applied parts Type BF Galvanically isolated application part (F stands for "floating"); meets the requirements for leakage currents for type B
===	Direct current The device is suitable for use with direct current only
Z	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
0	Separate the packaging elements and dispose of them in accordance with local regulations.
ŽB A	Marking to identify the packaging material. A = Material code, B = Material number: 1-7 = Plastics, 20-22 = Paper and cardboard
(F	Separate the product and packaging elements and dispose of them in accordance with local regulations.
	Manufacturer
EC REP	Authorised representative in the European Community

Storage/Transport	Permissible storage and transport temperature and humidity
Operating 3	Permissible operating temperature and humidity
IP22	IP class Device protected against foreign objects ≥ 12.5 mm and against water dripping at an angle
SN	Serial number
C € ₀₅₉₈	CE labelling This product satisfies the requirements of the applicable European and national directives.
MD	Medical device
REF	Item number

3. Proper use

Intended use

The blood pressure monitor is intended for the fully automatic, non-invasive measurement of arterial blood pressure and pulse values on the wrist.

Target group

It is designed for self-measurement by adults in the home environment and is suitable for users whose wrist circumference is within the range printed on the cuff.

Indication/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 healthcare service providers with support during the diagnosis and treatment of blood pressure problems, and therefore plays a part in the long-term monitoring of the user's health.

4. Warnings and safety notes



Contraindications

- Do not use the blood pressure monitor on newborns, children or pets.
- People with restricted physical, sensory or mental skills should be supervised by a person responsible for their safety and receive instructions from this 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.
- People with pacemakers or other electrical implants should consult their doctor before using the device.
- The blood pressure monitor must not be used in connection with a high-frequency surgical unit.
- 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 in which the arteries or veins are undergoing medical treatment, e.g. intravascular access or intravascular therapy, or an arteriovenous (AV) shunt.



General warnings

- The measurements taken by you are for your information only they are no substitute for a medical examination! Discuss the measured values with your doctor and never make your own medical decisions based on them (e.g. regarding dosages of medicines).
- 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 whilst on the move (e.g. whilst travelling in a car, ambulance or helicopter, or whilst undertaking physical activity such as playing sport) can influence the measurement accuracy and cause incorrect measurements.
- 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 lead to a malfunction of the measuring device 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 cuffs described in these instructions for use for the device. Using another cuff may lead to measurement inaccuracies.
- Note that when inflating the cuff, the functions of the limb in question may be impaired.
- · Do not perform measurements more frequently than necessary. Due to the restriction of blood flow, some bruising may occur.
- During the blood pressure measurement, the blood circulation must not be stopped for an unnecessarily long time. If the device malfunctions remove the cuff from the arm.
- Place the cuff on your wrist only. Do not place the cuff on other parts of the body.



General precautions

- 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, marked temperature fluctuations and direct sunliaht.
- Ensure the device is at room temperature before measuring. 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 drop the 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 that the batteries be removed if the device will not be used for a prolonged period of time.

Measures for 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.
- 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.
- Protect batteries from excessive heat.
 - Do not charge or short-circuit batteries.
 - If the device is not 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 use of the device may be limited in the presence of electromagnetic disturbances. This could
 result in issues such as error messages or the failure of the display/device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this
 could lead to faulty operation. If, however, it is necessary to use the device in the manner stated,
 this device as well as the other devices must be monitored to ensure they are working properly.
- The use of accessories other than those specified or provided by the manufacturer of this device can lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity; this can result in faulty operation.

5. Device description

Blood pressure monitor and cuff:

- 1. Display
- 2. Memory button M1
- 3. Memory button M2
- 4. Battery compartment lid
- START/STOP button ① with integrated positioning indicator
- 6. Wrist cuff
- 7. Risk indicator

Display:

- 1. Time and date
- 2. Systolic pressure
- 3. Diastolic pressure
- 4. Calculated pulse rate
- 5. Pulse symbol 🛡
- 6. Battery indicator 🗗
- 7. Memory space number/memory display for average value (R), morning (RM), evening (PM)
- 8. Risk indicator
- 9. Cardiac arrhythmia symbol
- 10. Release air 🔀
- 11. User memory 分/分

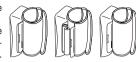




6. Initial use

Inserting the batteries

- Remove the battery compartment lid on the right side of the device.
- Insert two 1.5 V AAA micro (alkaline type LR03) batteries. Make sure that the batteries are inserted the correct way round in accordance with the markings. Do not use rechargeable batteries.



- · Close the battery compartment lid again carefully.
- All display elements are briefly displayed, 24h flashes on the display. Now make the settings as
 described below.

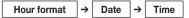
If the battery replacement symbol \square flashes, you can no longer perform any measurements and must replace all batteries. Once the batteries have been removed from the device, the date and time must be set again. Any saved measured values are retained.

Making settings

You must make sure that the device has the correct settings before use in order to be able to make full use of all functions. Only by doing so can your measurements with associated date and time be saved and accessed later by you.

- There are two different ways to access the menu from which you can adjust the settings:
 - 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 ① for approx. 5 seconds.

In this menu you can adjust the following settings in succession:



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The hour format flashes on the display.

• Select the desired hour format using the M1 or M2 memory button and confirm with the START/STOP button ①.



The year flashes on the display.

• Select the desired year using the memory button **M1** or **M2** and confirm with the **START/STOP** button ①.



The month flashes on the display.

 Select the desired month with the memory button M1 or M2 and confirm with the START/STOP button ①. 1 : 1;

The day flashes on the display.

- Select the desired day using the memory button **M1** or **M2** and confirm with the **START/STOP** button (1)
- (i) If the hour format is set as I2h, the day/month display sequence is reversed.

The hours flash on the display.

 Select the desired hour using the memory button M1 or M2 and confirm with the START/STOP button (1).



The minutes flash on the display.

 Select the desired minute using the memory button M1 or M2 and confirm with the START/STOP button O.



The device then switches itself off automatically.

7. Usage

General rules when measuring blood pressure yourself

- In order to generate as informative a profile of the progression of your blood pressure as possible
 and ensure that the measured values can be compared, you should measure your blood pressure
 regularly and always at the same times of day. It is recommended that you measure your blood
 pressure twice a day: once in the morning after getting up and once in the evening.
- You should always carry out the measurement when you are sufficiently physically rested. You should therefore avoid taking measurements during stressful periods.
- 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.
- Furthermore, if you want to take several measurements in succession, make sure always to wait
 for at least 1 minute between the individual measurements.
- Repeat the measurement if you are unsure of the measured value.

Attaching the cuff

- Fundamentally, blood pressure can be measured on both arms. Certain deviations between the
 measured blood pressure on the right arm and left arm are due to physiological causes and completely normal. You should always perform the measurement on the arm with the highest blood
 pressure values. Before starting self-measurement, consult your doctor in this regard. From this
 point on, always take measurements on the same arm.
- The device may only be operated with the cuff attached when supplied. Before using the device, the user should check the fit of the cuff and, in doing so, ensure that their wrist circumference is within the range printed on the cuff.

 Uncover your wrist. Ensure that the circulation of the arm is not hindered by tight clothing or similar.



- Now place the cuff on the wrist so that the palm of your hand and the device display are facing upwards.
- Position the cuff so that there is a distance of 1.0 1.5 cm between it and the heel of your hand.
- Now fasten the cuff tightly around your wrist using the hook-and-loop fastener. Make sure that it
 is tight but that it does not cut into your wrist.

Adopting the correct posture

- To carry out a blood pressure measurement, make sure you are sitting upright and comfortably.

 Lean back and place your arm on a surface. Do not cross your legs. Place your

 feet next to each other flat on the floor.
- Always make sure that the device is at heart level during the measurement.

 Otherwise significant measurement deviations can occur due to physiological causes. To do so, place your elbow on a table to support your arm. In order to make the measurement even more comfortable for you, you can place your lower arm on a suitable object (e.g. the storage box).
- Relax your arm and the palm of your hand.
- To avoid distorting the measurement, you should remain as still as possible during the measurement and not speak.

Positioning indicator

As an additional application aid, the device has a positioning indicator built into the **START/STOP** button ①. This is intended to help you determine the correct measuring position of the instrument at heart level and depends on the angle of observation.

at heart level and depends on the angle of observation.		
Display	Interpretation	
Positioning indicator is red in colour.	You have not yet reached the recommended position of the measuring device at heart level – your wrist is either positioned too high or too low.	
Positioning indicator is coloured green, the word "OK" appears.	You have reached the recommended position of the measuring device at heart level and can start the measurement by pressing the START/STOP button ①.	

In the vast majority of use cases, the positioning indicator provides very good orientation as to whether the measuring device is at heart level. Due to physical differences such as size and/or physique on the user side, this function may not be helpful in all cases. If you feel that the wrist position accor-

ding to the positioning indicator does not match the level of the heart, use your own judgement. You can also start the measurement in these cases at any time by pressing the **START/STOP** button ①.

Selecting the user

This device has 2 user memories with 120 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 relevant user is set before each measurement.

To select the relevant user memory, press the memory button **M1** (for user $\[mathbb{N}\]$) or **M2** (for user memory $\[mathbb{N}\]$) when the device is switched off. Then confirm your selection by pressing the **START/STOP** button $\[mathbb{O}\]$.

Performing the blood pressure measurement

- Press the START/STOP button ① to start the blood pressure monitor. All display elements are briefly displayed.
- The blood pressure monitor will begin the measurement automatically after approx. 3 seconds.
- The cuff inflates automatically while the actual measuring process starts. As soon as a pulse is found, the pulse symbol ♥ is displayed.
-) You can cancel the measurement at any time by pressing the **START/STOP** button Ω
- The remaining air is released guickly once the measurement is complete.
- Systolic pressure, diastolic pressure and pulse measurements are displayed.
 Err_ appears if the measurement could not be performed properly. In this case, please read the section"What if there are problems?".
- Press the START/STOP button ① to switch off the blood pressure monitor. The
 measurement is then stored in the selected user memory.





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 in the cycle is called systolic blood pressure. This arises when the heart muscle contracts and blood is pumped into the blood vessels.
 - The lowest is diastolic blood pressure, which is when the heart muscle has completely stretched back out and the heart fills with blood.
- Fluctuations in blood pressure are normal. Even during repeat measurements, considerable differences between the measured values may occur. 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.

Risk indicator

The World Health Organization (WHO) has defined the internationally recognised classification for the evaluation of measured blood pressure values listed in the table below:

Measured blood pressure value range		Classification	Colour of the risk indicator
Systole (in mmHg)	Diastole (in mmHg)	- Olassinoation	orion of the risk maister
≥180	≥110	High blood pressure stage 3 (severe)	Red
160-179	100-109	High blood pressure stage 2 (moderate)	Orange
140-159	90-99	High blood pressure stage 1 (mild)	Yellow
130-139	85-89	High normal	Green

Measured blood pressure value range		Classification	Colour of the risk indicator
Systole (in mmHg)	Diastole (in mmHg)	Ciassilication	Colour of the risk indicator
120-129	80-84	Normal	Green
<120	<80	Optimal	Green
Source: WHO,	1999 (World Heal	th Organization)	

category the recorded blood pressure values fall into. If the measured values are in two different classifications (e.g. systole in the high normal category and diastole in the normal category), the risk indicator then always shows you the higher category – "high normal" in the example described. Please be aware that these standard values can only serve as a general guideline, as the individual blood pressure varies in different people and different age groups, etc.

Furthermore, it must be noted that measurements taken yourself while at home are generally lower

The risk indicator (the arrow in the display and the associated scale on the device) shows which

Furthermore, it must be noted that measurements taken yourself while at home are generally lower than those that are taken by the doctor. For this reason, it is important that you regularly consult your doctor for advice. Only they are able to give you your personal target values for controlled blood pressure – in particular if you receive medicinal therapy.

Cardiac arrhythmia

This device can identify any cardiac rhythm disturbances as part of the analysis of your recorded pulse signal during blood pressure measurement. In this case, after the measurement, the device will indicate any irregularities in your pulse by displaying the spymbol in the display. This can be an indicator for arrhythmia. Arrhythmia is an illness in which the heart rhythm is abnormal because of flaws in the bioelectrical system that regulates the heartbeat. The symptoms (skipped or premature heart beats, pulse being slow or too fast) can be caused by factors such as heart disease, age, physical disposition, excess alcohol and tobacco, stress or lack of sleep. If the symphol appears on the display after the measurement, the measurement must be repeated as the measurement

accuracy may be impaired. To assess your blood pressure, only use the results that have been recorded without corresponding irregularities in your pulse. If the w symbol appears frequently, please consult your doctor. Only they can establish the existence of an arrhythmia during a checkup. using their means of diagnosis.

Saving, accessing and deleting measured values

The results of every successful measurement are stored together with the date and time. The Jser memory oldest measurement is overwritten in the event of more than 120 measurements.

• To select the relevant user memory, press the memory button M1 (for user Ω) or M2 (for user memory (2)) when the device is switched off. Then confirm your selection by pressing the START/STOP button (1).

R flashes on the display.

The average value of all saved measured values in this user memory is displayed.



Press the memory button M1.

HM flashes on the display.

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



• Press the memory button M1.

Pff flashes on the display.

The average value of the evening measurements for the last 7 days is displayed (evening: 6 p.m. - 8 p.m.).



 When you press the memory button M1 again, the last individual measurement is displayed (in this example, measurement 03).



- When you press the memory button M1 again, you can view your individual measurements.
- To switch the device off again, press the **START/STOP** button ①.
- (i) You can exit the menu at any time by pressing the **START/STOP** button 0.
- In order to delete an entire user memory, first select the user memory to be deleted
 by pressing the memory button M1 or M2 when the device is switched off and confirming your selection by pressing the START/STOP button ①.
- The average value of all measurements for the selected user memory appears on the display; at the same time fl flashes on the display.
- Now press and hold the memory buttons M1 and M2 at the same time for 5 seconds.
 **UD appears in the display. All the values in the selected user memory have now

8. Cleaning and maintenance

been deleted.

- Clean the device and cuff carefully using a slightly damp cloth only.
- Do not use any cleaning agents or solvents.

 Under no circumstances hold the device and cuff under water, as this can cause liquid to enter and damage the device and cuff.

9. What if there are problems?

Error message	Possible cause	Solution
Err00	Unable to record a pulse.	Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement.
Err01	An error occurred while inflat- ing the cuff or the inflation pressure is over 300 mmHg.	Please take another measurement to check whether the cuff can be correctly inflated. Please observe the information in chapter "Attaching the cuff" in particular.
Err02	The measured blood pressure is outside the measurement range.	Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the
Err03	An error occurred during the measurement.	measurement.
Err	System error	Please contact Customer Services.
	The batteries are almost empty.	Insert new batteries into the device.

If the problem still occurs despite the suggested corrective actions, please contact Customer Services.

10. Disposal



Repairing and disposing of the device

- Do not repair or adjust the device yourself. Proper operation can no longer be guaranteed in this case.
- Do not open the device. Failure to comply with this instruction will void the warranty.
- Repairs must only be carried out by Customer Services or authorised retailers. Before making a claim, please check the batteries first and replace them if necessary.
- For environmental reasons, do not dispose of the device in the household waste at the end of its useful life. Dispose of the device at a suitable local collection or recycling point in your country. 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.



Disposing of the batteries

- Batteries must not be disposed of in the household waste. They may contain poisonous heavy metals and are subject to special refuse treatment.
- 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

Model no.	BC 51
Measurement method	Oscillometric, non-invasive blood pressure measurement on the wrist
Measurement range	Cuff pressure 0-300 mmHg, systolic 60-255 mmHg, diastolic 40-200 mmHg, pulse 40-199 beats/minute
Display accuracy	Systolic ± 3 mmHg, diastolic ± 3 mmHg, pulse $\pm 5\%$ of the value shown
Measurement uncertainty	Max. permissible standard deviation according to clinical testing: systolic 8 mmHg / diastolic 8 mmHg
Memory	2 x 120 memory spaces
Dimensions	95 x 68 x 20 mm
Weight	Approximately 105 g (without batteries, with cuff)
Cuff size	125 to 210 mm
Permissible operating conditions	+10°C to +40°C, < 85% relative humidity (non-condensing), 700 –1060 hPa ambient pressure
Permissible storage and transport conditions	-20°C to +50°C, < 85% relative humidity
Power supply	2 x 1.5 V = = AAA batteries
Battery life	For approx. 300 measurements, depending on levels of blood pressure and inflation pressure

Classification Internal supply, IP22, no AP or APG, continuous operation, application part type BF	ation
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The serial number is located on the device or in the battery compartment.

Technical information is subject to change without notification to allow for updates.

- This device complies with the European standard EN 60601-1-2 (in compliance with CISPR 11, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-8) and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this device.
- This device complies with the EU Medical Devices Directive 93/42/EEC, the German Medical Devices Act (Medizinproduktgesetz) and the standards EN 1060-1 (Non-invasive sphygmomanometers Part 1: General requirements), EN 1060-3 (Non-invasive sphygmomanometers Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems) and IEC 80601-2-30 (Medical electrical equipment Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers).
- The accuracy of the blood pressure monitor has been carefully checked. No calibration is required.
- The device has been developed with regard to a long useful life. The expected operating life is 5 years.
- 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.

12. Warranty/service

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

	San Chung District,24158 New Taipei City, Taiwan
EC REP	Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany
Distributed by:	Beurer GmbH, Söflinger Straße 218, 89077 Ulm, Germany

AViTA Corporation 9F, No. 78, Sec.1, Kwang-Fu Rd.,



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