

beurer

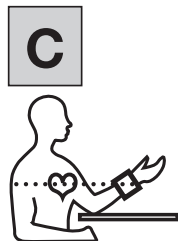
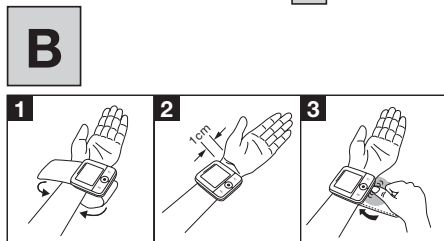
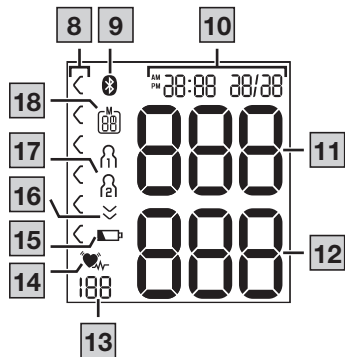
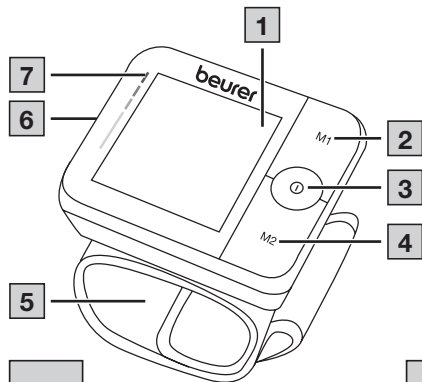
BC 54

EN Wrist blood pressure monitor
Instructions for use



CE 0483





ENGLISH



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

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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 and the supplied components and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Service address.

- Wrist blood pressure monitor
- Batteries, see chapter “Technical specifications”
- Storage box
- Quick guide
- Blood pressure pass

2. SIGNS AND SYMBOLS

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

⚠ DANGER

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

⚠ WARNING

Indicates a potentially impending danger. If it is not avoided, there is a risk of death or serious injury.

⚠ CAUTION

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

NOTICE

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



Product information

Note on important information



Observe the instructions

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



The electronic device must not be disposed of with household waste



Do not dispose of batteries containing harmful substances with household waste



Manufacturer



Date of manufacture



CE labelling

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



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.



IP22

Device protected against foreign objects ≥ 12.5 mm and against water dripping at an angle



Direct current



Battery

UDI

Unique device identifier (UDI)
Identifier for unique product identification

REF

Item number

	Serial number
	Swiss authorised representative
	Medical device
	Type number
	Type BF applied part
	Temperature range
	Humidity range
	Atmospheric pressure limitation
	Importer
	Manufacturer in accordance with the Packaging Regulation (PPWR)

3. INTENDED PURPOSE

Intended Use

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

It is designed for self-measurement by adults in a domestic environment.

Intended Users

The blood pressure measurement is suitable for adult users whose wrist 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 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

WARNING

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

Undesirable side effects

- Skin irritation
- Negative influence on blood circulation

4. WARNINGS AND SAFETY NOTES

General warnings

WARNING

- The measurements you take are for your information only – they are not a substitute for a medical examination! Discuss your measured values with your doctor and never make your own medical decisions based on them.
- Consult your doctor at regular intervals. Only they are able to give you personal target values for controlled blood pressure, particularly if you are receiving medical therapy.
- Always perform the measurement on the arm with the higher blood pressure values.
- The device is only intended for the purpose described in these instructions for use. The manufacturer is not liable for damage resulting from improper or incorrect use.
- Using the blood pressure monitor outside your home environment or while on the move can influence the measurement accuracy and cause incorrect measurements.
- Cardiovascular diseases may lead to incorrect measurements or have a detrimental effect on measurement accuracy.
- If you have any of the following conditions, it is essential you consult your doctor before using the device: Cardiac arrhythmia, circulatory disorders, diabetes, pregnancy, pre-eclampsia, hypotension, chills, shivering.

- Consult your doctor if  is displayed frequently. Only they can determine, through an examination, whether there is an abnormality.
- Do not use the device at the same time as other medical electrical devices (ME equipment).
- Do not use the device outside of the specified storage and operating conditions. This could lead to incorrect measurements.
- Only use the cuffs included in delivery or described in these instructions for use with the device. Using a different cuff may lead to inaccurate measurements.
- Note that when inflating the cuff, the functions of the limb affected may be impaired.
- Do not perform measurements more frequently than necessary. Due to the restriction of blood flow, some bruising may occur.
- Blood circulation must not be stopped for an unnecessarily long time during the blood pressure measurement. If the device malfunctions, remove the cuff from the arm.
- The circulation of the arm must not be hindered by tight clothing or similar.
- Place the cuff on the wrist only. Do not place the cuff on other parts of the body.
- Small parts may present a choking hazard for small children if swallowed. They should therefore always be supervised
- Keep packaging material away from children. There is a risk of suffocation.

- Keep away from children, pets and pests.
- Do not drop, step on or shake the device.
- Do not disassemble the device as this may cause damage, faults and malfunctions.
- Do not open the device except for the battery compartment. Failure to comply will invalidate the warranty.
- Do not repair or modify the device.
- Repairs must only be carried out by Customer Services or authorised retailers.
- Never operate the device during maintenance work. Maintenance work includes maintenance, inspection and repair.
- Do not use any cleaning solutions or solvents.
- Under no circumstances hold the device or cuff under water.

General precautions

CAUTION

- The accuracy of the measurements and service life of the device depend on its careful handling.
- Protect the device from impacts, humidity, dirt, drastic changes in temperature and direct sunlight.
- Ensure the device is at room temperature before taking a measurement. If the measuring device has been stored close to the maximum or minimum storage and transport temperatures and is placed in an environment with a temperature of 20 °C, it is recommended that you wait approx. 2 hours before using the measuring device.

- If you store the device and cuff, do not place heavy objects on the device and cuff.

Notes on handling batteries

DANGER

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

WARNING

- **Risk of explosion! Risk of fire!** Failure to comply with the following points can result in personal injury or cause overheating, leakage, venting, breakage, explosion, or fire on the battery.
- This device contains non-rechargeable batteries which must not be charged.
- Do not throw batteries into a fire.
- Never charge, forcibly discharge, heat, disassemble, open, crush, deform, encapsulate, or modify batteries.
- Never short-circuit batteries or battery compartment contacts.
- Protect the batteries from direct sunlight, rain, heat, and water.
- Exposure of batteries to an environment with extremely high temperatures or an extremely low air pressure may result in explosion or leakage of flammable liquids and gases.

- Dispose of defective and discharged batteries immediately and properly (see chapter on disposal).
- Do not use modified or damaged batteries.
- Always select the correct battery type.
- Always insert the batteries correctly, taking into account the polarity (+ / -).
- Never mix batteries of different manufacturers, capacities (new and used), size, or type within a device.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- If fluid from a battery comes into contact with your skin or eyes, wash the affected areas with water and seek medical assistance.

CAUTION

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

NOTICE

- Do not use rechargeable batteries.

Notes on electromagnetic compatibility

⚠ CAUTION

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The device may not be fully usable in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this could lead to faulty operation. If, however, it is necessary to use the device in the manner stated, this device as well as the other devices must be monitored to ensure they are working properly.
- The use of accessories and/or replacement parts other than those specified or provided by the manufacturer of this device could lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity; this can result in faulty operation.
- Keep portable RF communication devices (including peripheral equipment, such as antenna cables or external antennas) at least 30 cm away from all device parts, including all cables included in delivery.
- Failure to comply with the above can impair the performance of the device.
- Please note that portable and mobile HF communication systems may interfere with this device.

- Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.

5. DEVICE DESCRIPTION

The associated drawings are shown on page 2.

- | | |
|-------------------------------------|----------------------------------|
| 1 Display | 2 Memory button M1 |
| 3 START/STOP button ① | 4 Memory button M2 |
| 5 Wrist cuff | 6 Battery compartment lid |
| 7 Risk indicator | |

Information on the display

- | | |
|---|--|
| 8 Risk indicator | 9 Symbol for <i>Bluetooth®</i> transfer  |
| 10 Time and date | 11 Systolic pressure |
| 12 Diastolic pressure | 13 Calculated pulse value |
| 14 Cardiac arrhythmia symbol 
Pulse symbol  | 15 Battery status indicator  |
| 17 User memory  /  | 16 Release air  |
| 18 Memory space number/memory display average value (R), morning (R ^M), evening (R ^N) | |

6. USAGE

6.1 Initial use

Inserting the batteries

- Remove the battery compartment cover **6**.
- Insert the batteries, polarity according to the label **A**.
- Close the battery compartment cover.

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

Adjusting the settings

Ensure the device settings are correct to use all functions. Otherwise, measured values cannot be saved with date and time.

You can access the settings menu in two ways:

- When inserting new batteries (initial use or after replacement), the menu appears 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.

Set these settings in the order shown below:



Use **M1/M2** to set the hour format / date (year, month, day) / time.

Confirm each setting by pressing **1**.

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

- Press **M1/M2** to select the user.
- The device switches off automatically.

Bluetooth®

The *Bluetooth®* symbol flashes on the display.

- Press **M1/M2** to select whether automatic *Bluetooth®* data transfer is activated or deactivated and confirm this by pressing **1**.

Bluetooth® data transfers will shorten the battery life.

6.2 Before the blood pressure measurement

General rules when measuring your own blood pressure

- To rule out a difference between sides, the measurement should initially be taken on both arms.
- Always perform the measurement when you are sufficiently physically rested.
- Do not take a measurement within 30 minutes of eating, drinking, smoking or exercising.
- Before the initial blood pressure measurement, make sure always to rest for about 5 minutes.
- Repeat the measurement if you have doubts about the measured value.

Attaching the cuff

You can measure your blood pressure on either arm.

- Always measure your blood pressure on the same arm.
- Before using the device, the user should check the fit of the cuff and make sure that their wrist circumference is within the range printed on the cuff.
- Uncover your wrist.
- Now place the cuff on your wrist so that the palm of your hand and the device's display are facing upwards **B1**.
- Position the cuff so that there is a distance of 1.0–1.5 cm between it and the heel of your hand **B2**.
- Now fasten the cuff firmly around your wrist using the hook-and-loop fastener. Make sure that it fits tightly, but does not cut into your wrist **B3**.

Adopting the correct posture

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

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 **M1/M2** each measurement:

- Use **M1/M2** to select the desired user. Confirm your selection by pressing **1**. The device switches off automatically.

6.3 Taking a blood pressure measurement

Measurement

1. Press **1**. 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 **1**.

2. The systolic pressure, diastolic pressure and pulse measurements are displayed.

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

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

6.4 Evaluating the results

Cardiac arrhythmia

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

Repeat the measurement if  is displayed.

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

Risk indicator (for general guidance only)

Measured blood pressure value range		Classification	Risk indicator colour
Systolic (in mmHg)	Diastolic (in mmHg)		
≥ 180	≥ 110	Stage 3 high blood pressure (severe)	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 **7** / **8** indicates which category the recorded blood pressure values fall into. If the measured values are in two different categories, the risk indicator always indicates the higher range.

Low blood pressure

⚠ WARNING

Low blood pressure (hypotension) can be a health hazard and cause dizziness or fainting. Blood pressure is considered low if systolic and diastolic pressure are below 90/60 mmHg (source: National Health Service, 2023).

Seek medical attention if you suddenly suffer from low blood pressure.

6.5 Displaying and deleting measured values

User

If there are more than 60 saved measurements, the oldest measurement records are deleted.

1. To select the corresponding user memory, press the **M1** memory button (for user ) or **M2** (for user ) on the switched-off device. Confirm your selection by pressing the START/STOP button **1**.
 2. If *Bluetooth®* is activated (the  symbol flashes on the display), the blood pressure monitor attempts to connect to the app. The buttons are deactivated and the  symbol ceases to flash as soon as a connection is established and the data is transferred.
- i** If you press the memory button **M1** or **M2** in the meantime, the transfer is cancelled. The  symbol is no longer shown.

Average value

Bluetooth® activated  in the display: Measurement data is transferred automatically.

A Average of all stored measurements.

AM Morning average of the last 7 days (5:00–9:00).

PM Evening average of the last 7 days (18:00–20:00).

Press **M1** to scroll through.

Individual measured values

1. Press **M1** again, the last individual measurement is displayed.
2. Press **M1** again, to view the individual measured values.
3. Press  to exit the menu.

Press  to switch the device off again.

Deleting measured values

1. Select the corresponding user.
 -  flashes on the display, the average value of all this user's saved measured values is displayed.
2. Press and hold **M1 / M2** for approx. 5 seconds.

CL 00 appears on the display. All this user's values are deleted.

The device switches off automatically.

6.6 Transfer of measured values

Transfer via **Bluetooth®**

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

Click here for the
“beurer HealthManager Pro” app
*



- Activate **Bluetooth®** in your smartphone's settings.
- Start the app.
- Select BC 54 in the app and follow the instructions.
- When connecting for the first time, a six-digit PIN code will be displayed on the device. Enter the PIN code on the smartphone. After successfully entering the code, the device will be connected to the smartphone.

List of system requirements and compatible devices



* This product satisfies the requirements of the applicable European directives.

7. CLEANING AND MAINTENANCE

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

8. TROUBLESHOOTING

Error	Possible cause	Solution
Er1	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	You have moved or spoken during the measurement.	
Er3	The cuff was not attached correctly.	Please observe the notes in chapter „6. Usage“ under the section „Attaching the cuff“. During a new measurement, check whether the cuff can now be inflated properly.
Er4	An error occurred during 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 or the measured blood pressure is outside the measuring range.	
Er6	The batteries are almost empty.	Insert new batteries into the device.

Error	Possible cause	Solution
Er7	The data could not be sent via <i>Bluetooth®</i> .	Proceed as described in chapter „6. Usage“ under the section „Transfer via <i>Bluetooth®</i> “ into the manual memory mode and try to restart the data transfer.
Er8	A device error has occurred.	Please repeat the measurement after a pause of one minute.

9. REPAIR AND DISPOSING

Before making a complaint, first check the batteries and replace them if necessary.

For environmental reasons, do not dispose of the device in household waste at the end of its service life. Dispose of the device at a suitable local collection or recycling point. Observe the local regulations for material disposal. Dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal. You can obtain the location of collection points for old devices from the



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



10. TECHNICAL SPECIFICATIONS

Type	BC 54
Measurement method	Oscillometric, non-invasive blood pressure measurement on the wrist
Measurement range	Cuff pressure 0–299 mmHg, systolic pressure 60–230 mmHg, diastolic pressure 40–130 mmHg, pulse 40–199 beats/minute
Display accuracy	Systolic pressure ± 3 mmHg, diastolic pressure ± 3 mmHg, pulse $\pm 5\%$ of the displayed value
Measurement uncertainty	Max. permissible standard deviation according to clinical testing: systolic pressure 8 mmHg, diastolic pressure 8 mmHg
Memory	2 x 60 memory spaces

Dimensions	L 80,5 mm x W 69,5 mm x H 76 mm
Weight	Approx. 116 g (without batteries, with cuff)
Cuff size	13,5 to 21,5 cm wrist circumference
Operating conditions	+5 °C to +40 °C, 15% – 90% relative humidity, 700–1060 hPa ambient pressure
Storage and transport conditions	-20 °C to +60 °C, $\leq 93\%$ relative humidity (non-condensing)
Power supply	2 x 1.5V  LR03 AAA batteries
Battery life	For approx. 150 measurements depending on blood pressure and inflation pressure levels as well as the number of <i>Bluetooth</i> ® connections
Product life cycle to be expected	Information on the life cycle of the product can be found at beurer.com
Classification	Internal power supply, IP22, no AP or APG, continuous operation Blood pressure: Application part, type BF
Data transfer via <i>Bluetooth</i> ® wireless technology	The device uses <i>Bluetooth</i> ®, Frequency band 2402–2460 MHz, max. transmission power 7 dBm

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

We reserve the right to make technical changes to improve and develop the product.

- The device conforms with the respective national regulations and European standard EN 60601-1-2 (Group 1, Class B, in accordance with CISPR-11, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-8, IEC 61000-4-39) and is subject to particular precautions with regard to electromagnetic compatibility.
- The device has been clinically tested in accordance with the requirements of ISO 81060-2.
- We hereby confirm that this product complies with the European RED Directive 2014/53/EU. The CE Declaration of Conformity for this product can be found at: <https://www.beurer.com/conformity>
- The accuracy of this device has been carefully checked and it has been developed with a long service life in mind. If the device is used for commercial medical purposes, the applicable

national regulations determine whether it must be tested for accuracy by appropriate means.

11. GUARANTEE/SERVICE

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

Notification of incidents

For users/patients in the European Union and identical regulation systems, the following applies: If a major incident occurs during or through use of the product, notify the manufacturer and/or their representative of this as well as the respective national authority of the member state in which the user/patient is located.

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