




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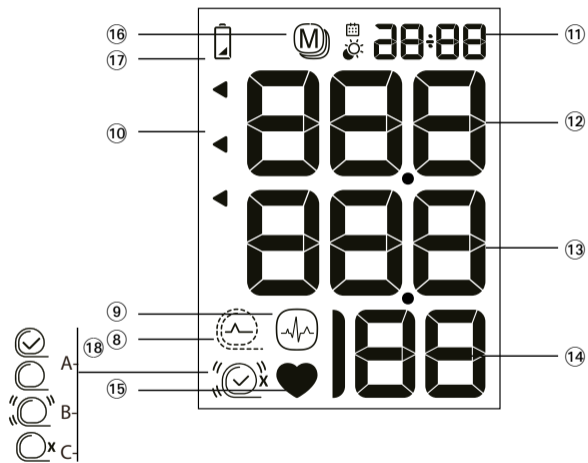


BP W10

Wrist Blood Pressure Monitor

EN → 1

microlife[®]



Name of Purchaser

Serial Number

Date of Purchase

Specialist Dealer

- ① ON/OFF button
- ② Display
- ③ M-button (memory)
- ④ Time button
- ⑩ Traffic light display
- ⑥ Battery compartment
- ⑦ Cuff

Display

- ⑧ Cuff signal indicator «ERR 1»
- ⑨ Irregular heartbeat (IHB) symbol
- ⑩ Traffic light indicator
- ⑪ Date/Time
- ⑫ Systolic value
- ⑬ Diastolic value
- ⑭ Pulse rate
- ⑮ Pulse indicator

- ⑯ Stored value
- ⑰ Battery display
- ⑱ Cuff fit check
 - A: Suboptimal cuff fit
 - B: Arm movement indicator «ERR 2»
 - C: Cuff pressure check «ERR 3»



Read the important information in this instructions for use before using this device. Follow the instructions for use for your safety and keep it for future reference.



Type BF applied part



Manufacturer



Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.



Authorized representative
in the European Community



Catalogue number



Serial number
(YYYY-MM-DD-SSSSS; year-month-day-
serial number)



Caution



Humidity limitation



Temperature limitation



Medical device

IP22

Protected against solid foreign objects of 12.5 mm Ø and greater. Protected against vertically falling water drops when enclosure tilted up to 15°.



Keep away from children of age 0 - 3

C € 0044

CE Marking of Conformity

Intended use, user and environment:

This device is an oscillometric blood pressure monitor intended for radial (wrist) blood pressure non invasively. It's suitable for use by adults (age 12 and above) for self measurement and measurement of others, in a domestic environment (e.g. home-use).

Dear Customer,

Your new Microlife blood pressure monitor is a reliable medical device for taking measurements on the wrist. This device was developed in collaboration with physicians and clinical tests prove its measurement accuracy to be very high.*

If you have any questions, problems or want to order spare parts please contact your local Microlife-Customer Service. Your dealer or pharmacy will be able to give you the address of the Microlife dealer in your country. Alternatively, visit the internet at www.microlife.com where you will find a wealth of invaluable information on our products. Stay healthy – Microlife AG!

** This device is tested according to the ESH protocol.*

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1. Important facts about blood pressure

- **Blood pressure** is the pressure of the blood flowing in the arteries generated by the pumping of the heart. Two values, the **systolic** (upper) value and the **diastolic** (lower) value, are always measured.
- The device indicates the **pulse rate** (the number of times the heart beats in a minute).
- **Permanently high blood pressure values can damage your health and must be treated by your doctor!**
- Always discuss your values with your doctor and tell him/her if you have noticed anything unusual or feel unsure. **Never rely on single blood pressure readings.**
- There are several causes of excessively **high blood pressure values**. Your doctor will explain them in more detail and offer treatment where appropriate.
- **Under no circumstances should you alter the dosages of drugs or initiate a treatment without consulting your doctor.**
- Depending on physical exertion and condition, blood pressure is subject to wide fluctuations as the day progresses. **You should therefore take your measurements in the same quiet conditions and when you feel relaxed!** Take at least two readings every time (in the morning: before taking medications and eating /

in the evening: before going to bed, bathing or taking medication) and average the measurements.

- It is quite normal for two measurements taken in quick succession to produce significantly **different results**.
- **Deviations** between measurements taken by your doctor or in the pharmacy and those taken at home are quite normal, as these situations are completely different.
- **Several measurements** provide much more reliable information about your blood pressure than just one single measurement.
- **Leave a small break** of 5 minutes between two measurements.
- If you suffer from an **irregular heartbeat** (arrhythmia, see «Section 5.»), measurements taken with this device should be evaluated with your doctor.
- **The pulse display is not suitable for checking the frequency of heart pacemakers!**
- If you are **pregnant**, you should monitor your blood pressure regularly as it can change drastically during this time.



A number of factors can affect the accuracy of measurements taken on the wrist. In some cases, the result may differ from the measurement taken on the upper arm. We therefore advise you to compare these values with those produced by the upper arm measurement and discuss them with your doctor.

2. Using the device for the first time

Inserting the batteries

After you have unpacked your device, first insert the batteries. The battery compartment ⑥ is on the bottom of the device. Insert the batteries (2 x 1.5 V, size AAA), thereby observing the indicated polarity.

Setting the date and time


1. After the new batteries are fitted, the year number flashes in the display. You can set the year by pressing the M-button ③. To confirm and then set the month, press the time button ④.
2. Press the M-button to set the month. Press the time button to confirm and then set the day.
3. Follow the instructions above to set the day, hour and minutes.
4. Once you have set the minutes and pressed the time button, the date and time are set and the time is displayed.
5. If you want to change the date and time, press and hold the time button for approx. 3 seconds in the setting mode. Press time button again and then the year number starts to flash. Now you can enter the new values as described above.

3. Checklist for taking a reliable measurement

- ▶ Avoid activity, eating or smoking immediately before the measurement.
- ▶ Sit down on a back-supported chair and relax for 5 minutes. Keep the feet flat on the floor and do not cross your legs.
- ▶ **Always measure on the same wrist** (normally left). It is recommended that doctors perform double arm measurements on a patient's first visit in order to determine which wrist to measure in the future. The wrist with the higher blood pressure should be measured.
- ▶ Remove any items of clothing and your watch, for example, so that your wrist is free.
- ▶ Always ensure that the cuff is positioned correctly, as shown in the pictures illustrated on the short instruction card.
- ▶ Wrap the cuff on your wrist about 0.5 - 1 cm above your hand. Fit the cuff comfortably but not too tight. The cuff will cover a wrist circumference of 13.5 - 21.5 cm (5.25 - 8.5 inches).


4. Taking a blood pressure measurement

1. Press the ON/OFF button ① to start the measurement.
2. The cuff will now pump up automatically. Support your arm in a relaxed position with the device at the same height as your heart. Relax, do not move and do not tense your arm muscles until the measurement result is displayed. Breathe normally and do not talk.
Support your arm in a relaxed position and ensure that the **device is at the same height as your heart.**
3. The cuff fit check ⑱ on the display indicates that the cuff is perfectly placed. If the icon ⑱-A appears, the cuff is fitted suboptimally, but it is still ok to measure.
4. When the correct pressure is reached, the pumping stops and the pressure falls gradually. If the required pressure was not reached, the device will automatically pump some more air into the cuff.
5. During the measurement, the pulse indicator ⑮ flashes in the display.
6. The result, comprising the systolic ⑫ and the diastolic ⑬ blood pressure and the pulse rate ⑭ are displayed. Note also the explanations on further display symbols in this booklet.
7. When the device has finished measuring, remove the cuff.
8. Switch off the device. (The monitor does switch off automatically after approx. 1 min.).

 You can stop the measurement at any time by pressing the ON/OFF button (e.g. if you feel uneasy or an unpleasant pressure sensation).

How not to store a reading

As soon as the reading is displayed press and hold the ON/OFF button ① until «M» ⑯ is flashing. Confirm to delete the reading by pressing the time button ④.

 «CL» is displayed when the reading is deleted from the memory successfully.

How do I evaluate my blood pressure

The triangle on the left-hand edge of the display ⑩ points at the range within which the measured blood pressure value lies. The value is either within the optimum (white), elevated (hatched gray) or high (black) range. The classification corresponds to the following ranges defined by international guidelines (ESH, AHA, JSH). Data in mmHg.

Table for classifying blood pressure values in adults in accordance with the World Health Organisation (WHO) in 2003. Data in mmHg.

Range	Systolic	Diastolic	Recommendation
1 blood pressure too high	≥135	≥85	Seek medical advice

Range		Systolic	Diastolic	Recommendation
2	blood pressure elevated	130 - 135	80 - 85	Self-check
3	blood pressure optimum	<130	<80	Self-check

The higher value is the one that determines the evaluation. Example: a blood pressure value of **140/80** mmHg or a value of **130/90** mmHg indicates «blood pressure too high».

5. Appearance of the irregular heartbeat (IHB) symbol

This symbol ⑨ indicates that an irregular heartbeat was detected. In this case, the measured blood pressure may deviate from your actual blood pressure values. It is recommended to repeat the measurement.

Information for the doctor in case of repeated appearance of the IHB symbol:

This device is an oscillometric blood pressure monitor that also measures the pulse during blood pressure measurement and indicates when the heart rate is irregular.

6. Data memory

This device automatically stores the last 30 measurement values.

Viewing the stored values

Press the M-button ③ briefly, when the device is switched off. The display first shows «M» ⑯, and «A» which stands for the average of all stored values.

Pressing the M-button again displays the previous value. Pressing the M-button repeatedly enables you to move from one stored value to another.




Blood pressure readings with suboptimal cuff fit ⑱-A are not considered in the average value.



Pay attention that the maximum memory capacity of 30 memories is not exceeded. **When the 30 memory is full, the oldest value is automatically overwritten with the 31 value.** Values should be evaluated by a doctor before the memory capacity is reached – otherwise data will be lost.

Clearing all values

If you are sure that you want to permanently remove all stored values, hold down the M-button (the device must have been switched off beforehand) until «CL» appears and then release the button. To permanently clear the memory, press the M-button while «CL» is flashing. **Individual values cannot be cleared.**

 **Cancel deletion:** press ON/OFF button ① while «CL» is flashing.

7. Battery indicator and battery change


Low battery

When the batteries are approximately $\frac{3}{4}$ empty the battery symbol ⑰ will flash as soon as the device is switched on (partly filled battery displayed). Although the device will continue to measure reliably, you should obtain replacement batteries.




Flat battery - replacement

When the batteries are flat, the battery symbol ⑰ will flash as soon as the device is switched on (flat battery displayed). You cannot take any further measurements and must replace the batteries.

1. Open the battery compartment ⑥ at the back of the device.
2. Replace the batteries – ensure correct polarity as shown by the symbols in the compartment.
3. To set date and time, follow the procedure described in Section «2. Using the device for the first time».





 The measurements stored in the memory are deleted when the batteries are removed from the battery compartment (e.g. when replacing batteries).

Which batteries and which procedure?

-  Use 2 new, long-life 1.5 V, size AAA alkaline batteries.
-  Do not use batteries beyond their date of expiry.
-  Remove batteries if the device is not going to be used for a prolonged period.

Using rechargeable batteries

You can also operate this device using rechargeable batteries.

-  Only use «NiMH» type reusable batteries.
-  Batteries must be removed and recharged when the flat battery symbol appears. They should not remain inside the device as they may become damaged (total discharge as a result of low use of the device, even when switched off).
-  Always remove the rechargeable batteries if you do not intend to use the device for a week or more.
-  Batteries cannot be charged in the blood pressure monitor. Recharge batteries in an external charger and observe the information regarding charging, care and durability.

8. Error messages

If an error occurs during the measurement, the measurement is interrupted and an error message, e.g. «ERR 3», is displayed.

Error	Description	Potential cause and remedy
«ERR 1»	Signal too weak	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.*
«ERR 2»	Error signal	During the measurement, error signals were detected by the cuff, caused for instance by movement or muscle tension. Repeat the measurement, keeping your arm still.
«ERR 3»	No pressure in the cuff	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Check that the cuff is correctly connected and is not too loose. Replace the batteries if necessary. Repeat the measurement.
«ERR 5»	Abnormal result	The measuring signals are inaccurate and no result can therefore be displayed. Read through the checklist for performing reliable measurements and then repeat the measurement.*

Error	Description	Potential cause and remedy
«HI»	Pulse or cuff pressure too high	The pressure in the cuff is too high (over 299mmHg) OR the pulse is too high (over 200 beats per minute). Relax for 5 minutes and repeat the measurement.*
«LO»	Pulse too low	The pulse is too low (less than 40 beats per minute). Repeat the measurement.*

** Please immediately consult your doctor, if this or any other problem occurs repeatedly.*

9. Safety, care, accuracy test and disposal



Safety and protection

- Follow instructions for use. This document provides important product operation and safety information regarding this device. Please read this document thoroughly before using the device and keep for future reference.
- This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.
- This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in the «Technical specifications» section.

- The cuffs are sensitive and must be handled with care.
- Only pump up the cuff once fitted.
- Do not use this device if you think it is damaged or notice anything unusual.
- Never open this device.
- Read the additional safety information provided within the individual sections of this instruction manual.
- The measurement results given by this device is not a diagnosis. It is not replacing the need for the consultation of a physician, especially if not matching the patient's symptoms. Do not rely on the measurement result only, always consider other potentially occurring symptoms and the patient's feedback. Calling a doctor or an ambulance is advised if needed.



Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed. Be aware of the risk of strangulation in case this device is supplied with cables or tubes.



Contra-indications

Do not use this device if the patient's condition meets the following contra-indications, to avoid inaccurate measurements or injuries.

- The device is not intended for measuring blood pressure in pediatric patients of age younger than 12 years old (children, infant, or neonates).

- Presence of significant cardiac arrhythmia during measurement may interfere with blood pressure measurement and affect the reliability of blood pressure readings. Consult with your doctor about whether the device is suitable for use in this case.
- The device measures blood pressure using a pressured cuff. If the measuring limb suffers from injuries (for example open wounds) or under conditions or treatments (for example intravenous drip) making it unsuitable for surface contact or pressurization, do not use the device, to avoid worsening of the injuries or conditions.
- Patient motions during measurement may interfere with the measurement process and influence results.
- Avoid taking measurements of patients with conditions, diseases, and susceptible to environment conditions that lead to uncontrollable motions (e.g. trembling or shivering) and inability to communicate clearly (for example children and unconscious patients).
- The device uses oscillometric method to determine blood pressure. The arm being measure should have normal perfusion. The device is not intended to be used on a limb with restricted or impaired blood circulation. If you suffer with perfusion or blood disorders, consult your doctor before using the device.
- Avoid taking measurement on the arm on the side of a mastectomy or lymph node clearance.

- Do not use this device in a moving vehicle (for example in a car or on an aircraft).


 **WARNING**

Indicates a potentially hazardous situation, which if not avoided, could result in death or serious injury.

- This device may only be used for the intended uses described in this Instructions for Use. The manufacturer cannot be held liable for damage caused by incorrect application.
- Do not change the patient medication and treatment based the result of one or multiple measurements. Treatment and medication changes should be prescribed only by a medical professional.
- Inspect the device, cuff, and other parts for damage. DO NOT USE the device, cuff or parts if they appear damaged or operating abnormally.
- Blood flow of the arm is temporarily interrupted during measurement. Extended interruption of blood flow reduces peripheral circulation and may cause tissue injury. Beware of signs (for example tissue discoloration) of impeded peripheral circulation if taking measurements continuously or for an extended period of time.
- Prolonged exposure to cuff pressure will reduce peripheral perfusion and may lead to injury. Avoid situations of extended cuff pres-

surization beyond normal measurements. In the case of abnormally long pressurization, abort the measurement or loose the cuff to depressurize the cuff.

- Do not use this device in oxygen rich environment or near flammable gas.
- The device is not water resistant or water proof. Do not spill or immerse the device in water or other liquids.
- Do not disassemble or attempt to service the device, accessory and parts, during use or in storage. Access to the device internal hardware and software is prohibited. Unauthorized access and servicing of the device, during use or in storage, may compromise the safety and performance of the device.
- Keep the device away from children and people incapable of operating the device. Beware of the risks of accidental ingestion of small parts and of strangulation with the cables and tubes of this device and accessories.

 **CAUTION**

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the device or other property.

- The device is intended only for measuring blood pressure at wrist. Do not measure other sites because the reading does not reflect your blood pressure accurately.
- After a measurement is completed, loosen the cuff and rest for > 5 minutes to restore limb perfusion, before taking another measurement.
- Do not use this device with other medical electrical (ME) equipment simultaneously. This may cause device malfunction or measurement inaccuracies.
- Do not use this device in proximity of high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, and computerized tomography (CT) scanners. This may cause device malfunction and measurement inaccuracies.
- Use and store the device, cuff and parts in temperature and humidity conditions specified in the «Technical specifications». Usage and storage of the device, cuff and parts in conditions outside ranges given in the «Technical specifications» may result in device malfunction and the safety of usage.
- Protect the device and accessories from the following to avoid damaging the device:
 - water, other liquids, and moisture
 - extreme temperatures
 - impacts and vibrations

- direct sunlight
- contamination and dust
- This device has 2 user settings. Please ensure it is cleaned and disinfected between users to prevent any cross contamination.
- Stop using this device and cuff and consult with your doctor if you experience skin irritation or discomfort.
- The device warranty is 5 years. Please check for accuracy every 2 years.

Electromagnetic Compatibility Information

This device is compliant with EN60601-1-2: 2015 Electromagnetic Disturbances standard.

This device is not certified to be used in vicinity of High Frequency (HF) medical equipment.

Do not use this device close to strong electromagnetic fields and portable radio frequency communication devices (for example microwave oven and mobile devices). Keep a minimum distance of 3.3 m from such devices when using this device.

Device care

Clean the device only with a soft, dry cloth.

Cleaning the cuff

Carefully remove spots on the cuff with a damp cloth and soapsuds.



WARNING: Do not wash the cuff in a washing machine or dishwasher!



WARNING: Do not dry the cuff cover in a tumble dryer!



WARNING: Under no circumstances may you wash the inner bladder!

Accuracy test

We recommend this device is tested for accuracy every 2 years or after mechanical impact (e.g. being dropped). Please contact your local Microlife-Service to arrange the test (see foreword).

Disposal



Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

10. Guarantee

This device is covered by a **5 year guarantee** from the date of purchase. During this guarantee period, at our discretion, Microlife will repair or replace the defective product free of charge.

Opening or altering the device invalidates the guarantee.

The following items are excluded from the guarantee:

- Transport costs and risks of transport.
- Damage caused by incorrect application or non-compliance with the instructions for use.
- Damage caused by leaking batteries.
- Damage caused by accident or misuse.
- Packaging/storage material and instructions for use.
- Regular checks and maintenance (calibration).
- Accessories and wearing parts: Batteries.

The cuff is covered by a functional guarantee (bladder tightness) for 2 years.

Should guarantee service be required, please contact the dealer from where the product was purchased, or your local Microlife service. You may contact your local Microlife service through our website:

www.microlife.com/support

Compensation is limited to the value of the product. The guarantee will be granted if the complete product is returned with the original invoice. Repair or replacement within guarantee does not prolong or renew the guarantee period. The legal claims and rights of consumers are not limited by this guarantee.

11. Technical specifications

Operating conditions:	10 - 40 °C / 50 - 104 °F 15-90 % relative maximum humidity
Storage conditions:	-20 - +55 °C / -4 - +131 °F 15-90 % relative maximum humidity
Weight:	127 g (including batteries)
Dimensions:	131 x 90 x 60.5 mm
Measuring procedure:	oscillometric, corresponding to Korotkoff method: Phase I systolic, Phase V diastolic
Measurement range:	SYS: 60 ~ 200 mmHg, DIA: 40 ~ 200 mmHG 40 - 199 beats per minute – pulse
Cuff pressure display range:	0 - 299 mmHg
Resolution:	1 mmHg
Static accuracy:	within ± 3 mmHg
Pulse accuracy:	± 5 % of the readout value
Voltage source:	2 x 1.5 V alkaline batteries; size AAA
Battery lifetime:	approx. 700 measurements (using new batteries)
IP Class:	IP 22

Reference to standards:	EN 1060-1 /-3 /-4; IEC 60601-1; IEC 60601-1-2 (EMC); IEC 60601-1-11
Expected service life:	Device: 2 years or 10000 measurements, whichever comes first Accessories: 2 years or 10000 measurements, whichever comes first

This device complies with the requirements of the Medical Device Directive 93/42/EEC.
Technical alterations reserved.