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IB BP B4 AFIB BT EN 2026-04-06

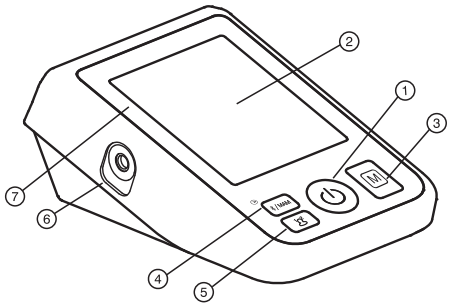
microlife®

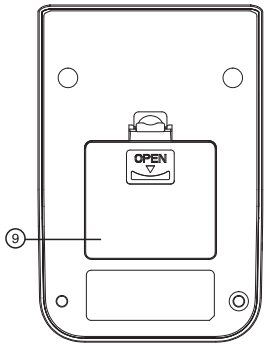
BP B4 AFIB BT

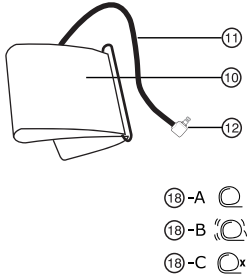
Bluetooth® Blood Pressure Monitor

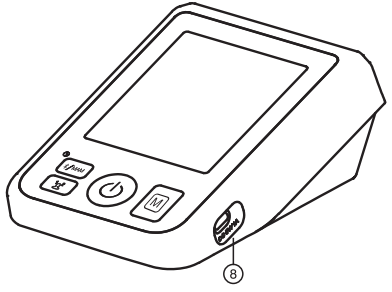
Connected Health+
microlife

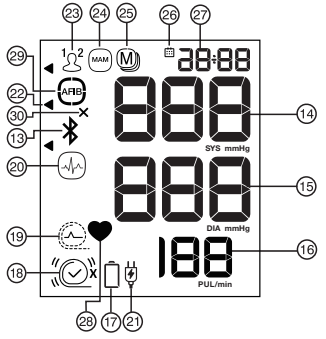
Bluetooth®











Name of Purchaser _____

Serial Number _____

Date of Purchase _____

Specialist Dealer _____

microlife®

① ON/OFF button
② Display
③ M-button (memory)
④ Bluetooth/MAM button
⑤ User Button
⑥ Cuff socket
⑦ Traffic light indicator
⑧ USB Type-C Adapter Socket
⑨ Battery compartment
⑩ Cuff
⑪ Cuff tube
⑫ Cuff connector

Display

⑬ Active Bluetooth®
⑭ Systolic value
⑮ Diastolic value
⑯ Pulse rate
⑰ Battery display
⑱ Cuff fit check
-A: Suboptimal cuff fit
-B: Arm movement indicator **«Err 2»**
-C: Cuff pressure check **«Err 3»**
⑲ Cuff signal indicator **«Err 1»**
⑳ Irregular heartbeat (IHB) symbol
㉑ External power source indicator
㉒ Traffic light display
㉓ User indicator
㉔ MAM Mode
㉕ Stored value
㉖ Date
㉗ Date/Time
㉘ Pulse indicator
㉙ Atrial Fibrillation Indicator (AFIB)
㉚ Function OFF

Dear Customer,
Atrial fibrillation (AF) is a major risk factor for stroke, affecting approximately 40 million people worldwide [1,2]. Many AF cases go undiagnosed because they are asymptomatic, increasing the risk of severe complications. However, early detection followed by proper treatment can prevent up to 68% of AF-related strokes [3,4].
Microlife AFIBsens® technology is at the forefront of AF screening, providing individuals with a reliable and clinically validated tool to monitor their heart rhythm. Developed in collaboration with leading medical experts, this patented technology integrates an advanced algorithm into blood pressure monitors, allowing users to screen for AF and hypertension simultaneously.
It is important to note that an AF diagnosis can only be confirmed by a physician using an electrocardiogram (ECG). If AF is detected with a Microlife AFIBsens®-integrated blood pressure monitor, users should consult a doctor for further evaluation.
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 Corporation!

[1] Giuseppe Lippi, Global epidemiology of atrial fibrillation: An increasing epidemic and public health challenge, International Journal of Stroke, 2021 Feb;16(2):217-221.

[2] Kornej J, Börschel C, Benjamin E, Schnabel R. Epidemiology of atrial fibrillation in the 21st century: novel methods and new insights. Circ Res. 2020;27:4–20.

[3] Van Gelder, Isabelle C., et al. «2024 ESC Guidelines for management of Atrial Fibrillation Developed in Collaboration with the European Association for Cardio-Thoracic Surgery (EACTS).» Eur Heart J, 45, 36, 2024: 3314–414.

[4] Hart RG, Benavente O, McBride R, Pearce LA: Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a meta-analysis. Ann Intern Med 1999; 131:492-501.

Table of contents

1. Introduction

Document scope

Read the instructions carefully before using this device.

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.

Disclaimers

2. Important information

Device description
A digital home-use blood pressure monitor is a medical device that utilizes the principles of cuff-based oscillometric method and digital signal process to compute and provide a blood pressure measurement.

Intended purpose
This device is intended to measure systolic and diastolic blood pressure and pulse rate.
This device is also intended to detect irregular pulses suggestive of Atrial Fibrillation (AF), a type of cardiac arrhythmia, during a measurement.

Intended user
The device is intended to be operated by adults with adequate vision, motor functions, and education, capable of understanding the instructions for use and operating general household electrical appliances.

Intended patient population
Adult patient population (aged 12 years and older).

Intended use environment and conditions
The device is intended for use in a home healthcare environment (e.g. general household without medically trained personnel) and a professional healthcare environment by patients (e.g. for self-measurement) or by a care giver.

Indications
This device provides blood pressure measurement data to support general health monitoring and clinical decisions related to hypertension, including:

- Screening and diagnosis of white-coat hypertension and masked hypertension and identifying white-coat effect and masked uncontrolled hypertension.
- Evaluating blood pressure in response to treatment.
- Confirming the diagnosis of resistant hypertension.
- Detecting morning hypertension.

The device also screens for possible Atrial Fibrillation (AF) episodes based on pulse irregularities that occur during the measurement.

Contraindications

- Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.
- The device is not intended for measuring blood pressure in pediatric patients younger than 12 years of age (children, infant, or neonates).
- The device measures blood pressure using a pressured cuff. If the measuring limb suffers from injuries (for example open wounds) or under conditions (for example skin inflammation or ulcer) or treatments (for example intravenous drip) making it unsuitable for surface contact or pressurization, do not use the device, to avoid causing or worsening injuries or conditions.
- Avoid taking measurements of patients with conditions, diseases, and susceptible to environment conditions that lead to incontrollable 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 and requires the measured limb with normal perfusion. The device is not intended to be used on a limb with restricted or impaired blood circulation. Consult with your doctor if you have severe perfusion or blood disorders before using the device.

Side effects
In rare cases, slight bruising or skin tears may occur after the measurement due to pressurization of the arm.

Warning

NOTE: Warning items indicate potentially hazardous situations, if not avoided, may result in death, critical or serious injury to the user or patient.

- Avoid taking measurement on the arm on the side of a mastectomy or lymph node clearance.
- Avoid taking measurements on the arm with intravascular access or therapy or an arterio-venous (A-V) shunt. Cuff and pressurization may temporarily interfere with blood flow and could result in injury.
- 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.
- Consult your physician before using this device if the patient suffers from conditions or diseases that could affect oscillometric blood pressure readings: pregnancy, pre-eclampsia, diabetes, atherosclerosis, renal disease.
- DO NOT use this device in a moving vehicle (for example in a car or on an aircraft).
- DO NOT use this device for purposes beyond described in these instructions for use. The manufacturer cannot be held liable for damage caused by incorrect application.
- The measurement result of this device is not a medical diagnosis and not intended to substitute consultation and diagnosis by a qualified professional healthcare provider (e.g., physician, pharmacist, or other licensed health-care professionals).
- DO NOT use this device for self-diagnosis or for self-treatment of a medical condition. Seek advice from a health-care professional immediately if the patient is clearly unwell and/or having physiological or medical symptoms.
- 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 from cuff pressurization. Extended periods of cuff pressurization reduces peripheral circulation. Beware of signs (e.g tissue discoloration) of impeded peripheral circulation when taking prolonged or multiple measurements. It is recommended to rest between measurements. Abort measurement, loosen the cuff (or disconnect the cuff and device) and rest to restore perfusion.
- DO NOT use this device in oxygen rich environment or near flammable gas.
- DO NOT use this device with other medical electrical (ME) equipment simultaneously. This may cause device malfunction or 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 results in device malfunction and the safety of usage.
- 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.
  DO NOT let children operate the device alone.
- This device might not detect possible atrial fibrillation in patients with pacemakers or defibrillators correctly. Consultation with physician is recommended before using this device in patients with pacemakers or defibrillators.
- The atrial fibrillation (AF) screening function of this device is not meant to diagnose atrial fibrillation. Diagnosis of atrial fibrillation must be made by a cardiologist based on interpretation of electrocardiograms (ECG). DO NOT make medical decisions based solely on the results.

Caution

NOTE: Caution items indicate potentially hazardous situations, if not avoided, may result in minor or negligible injury to the user or patient, or damage to the property or environment.
- The device is not intended to measure pulse rate to check the frequency of a pacemaker.
- 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.
- This device is intended solely for measuring blood pressure on the upper arm. Measurements at other body sites may not be accurate.
- When measuring patients of arm circumference of 50 cm or above, please ensure the cuff is fitted and secured tightly on the patient's arm. Measurement errors may occur more frequently if the cuff is fitted loosely; it's recommended to re-fit and tighten the cuff, then re-attempt measurement in such case.
- After a measurement session is completed, loosen the cuff and rest the arm for at least 1 minute to restore limb perfusion, before taking another measurement.
- Avoid kinking, pressing, and moving of the cuff tube during device operation, as this affects reading reliability and may cause injury if the cuff pressurization is prolonged, and deflation interrupted.

- Use this device only with compatible accessories and parts from Microlife, including cuffs, connectors, and AC adapters. Using non-compatible accessories may compromise the safety and performance of the device.
- 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 is reusable. It is recommended to clean the device and the accessory before and after use if the device is dirty from use or after storage.
- Always use the arm cuff of range appropriate for the mid arm circumference of the patient (upper arm only).
- Stop using this device and cuff and consult with your physician if you experience skin irritation, discomfort, or signs of skin injury (for example blistering, skin tearing, or persistent redness).
- DO NOT use this device, cuff, or parts after the expiration of its stated service life.
- If this device is stored at the maximum or minimum storage and transport temperature and is moved to an environment with a temperature of 20 °C, we recommend waiting for approximately 4 hours before using the device.
- When using this device for the purpose of opportunistic screening of atrial fibrillation in a community setting, it is recommended to perform additional measurements or supplement with other tools such as electrocardiography to confirm a positive result to reduce false positive rate.

Electromagnetic compatibility

- This device is compliant with electromagnetic disturbances standard.

Further documentation in compliance with EN 60601-1-2 EMC standard is available from Microlife on www.microlife.com/electro-magnetic-compatibility.

- DO NOT use this device in proximity of equipment that may cause electromagnetic disturbance (EMD), such as high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, and computerized tomography (CT) scanners. This may cause device malfunction and measurement inaccuracies.
- This device is not certified to be used in the vicinity of medical equipment including high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) and computerized tomography (CT) instruments.
- 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 0.3 m from such devices when using this device.
- This device features Bluetooth® that emits radio frequency (RF) in the 2.4GHz band. Do not use this device in locations where RF is restricted (for example, on an aircraft). Turn off the device and remove the power source if necessary when in RF restricted locations.
- This device operates in an unlicensed ISM band at 2.4GHz. In case this device is used near other wireless devices (for example wireless LAN) which operates on the same frequency band as this device, there is a possibility that interference may occur. If interference occurs, stop the operation of other devices or relocate this product away from other wireless devices before using it.

Caution: The use of non-Microlife or non-compatible accessories may result in increased emissions or decreased immunity of the equipment or system.

Adverse events and reporting

Please report any serious incident, injury or adverse event that has occurred in relation to the device to the manufacturer/ European authorized representative (EU REP), and to the competent authority.

3. Device information

Package Contents

1 x Microlife BP B4 AFIB BT
1 x Microlife Soft Cuff M-L
1 x Instruction manual
1 x Storage bag
4 x 1.5 V alkaline batteries; type LR3 (AAA)

CAUTION: Inspect the device, cuff, and other parts for damage. DO NOT USE the device, cuff or parts if they appear damaged or operating abnormally.

Device accessories

Blood pressure cuffs

Microlife offers cuffs, covering a wide range of arm sizes.

Microlife Soft Cuff S	Range 17-22 cm
Microlife Soft Cuff M	Range 22-32 cm
Microlife Soft Cuff M-L	Range 22-42 cm
Microlife Soft Cuff L	Range 32-42 cm
Microlife Soft Cuff L-XL	Range 32-52 cm

Contact your local authorized Microlife distributor if the standard cuff of the device is not the correct size for your arm.

AC adapter

You can operate this device using the Microlife AC adapter model DSA-5PF21-05 (DC 5V, 1.0 A).

Warning: Do not use the AC adapter if the adapter or the cable is damaged. If the device, adapter, or cable is damaged, turn off the power and unplug the AC adapter immediately.

Warning: Only use the AC adapter with outlets of compatible voltage rating.

Warning: Do not plug or unplug the AC adapter from the outlet with wet hands.

Warning: Do not damage the AC Adapter. Handle the AC adapter with care. Avoid pulling, bending, and tempering of the adapter cable.

Warning: Unplug the AC adapter before cleaning this device.

Warning: The mains adapter is not waterproof. DO NOT pour or spray liquid on the mains adapter.

Note: When using the AC adapter, it is recommended to remove the batteries to prevent draining.

Note: When the AC adapter is detected by the device, the external power source indicator ㉑ will be displayed on the display.

1. Plug the adapter jack into a suitable adapter socket ⑧. Check to ensure the adapter or cable are not damaged.
2. Plug the adapter plug into the mains socket.

Batteries

Use 4 new 1.5 V, size LR3 (AAA) alkaline batteries.

Caution: Do not use expired batteries or mix new and used batteries together.

Caution: Remove batteries if the device is not going to be used for a prolonged period.

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).

Batteries cannot be charged in the blood pressure monitor. Recharge batteries in an external charger and observe the information regarding charging, care and durability.

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 ⑨ 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 «Setting the date and time».

4. Device installation and setup

Inserting the batteries

After you have unpacked your device, first insert the batteries. The battery compartment ⑨ is on the bottom of the device. Insert the batteries (4 x 1.5 V, size LR3 (AAA)), thereby observing the indicated polarity.

Caution: Inserting the batteries in incorrect polarity orientations may lead to short circuiting and damage the device!

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 Bluetooth/MAM button ④.
2. Press the M-button to set the month. Press the Bluetooth/MAM 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 Bluetooth/ MAM 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 Bluetooth/MAM button for approx. 7 – 8 seconds until the year number starts to flash. Now you can enter the new values as described above.

⚠ **Caution:** Make sure date and time settings are correct on the device. Incorrect settings results in misleading data and time records of the measurements.

Setting the AFIBsens® ON or OFF

AFIBsens® can be manually turned off if required.

1. Press and hold the Bluetooth/MAM button ④for approximately 3 seconds until «SET» appears on the display, then release the button.
2. Press the Bluetooth/MAM button ④ repeatedly until the AFIB icon is shown on the display.
3. Press the M-button ③ to change the AFIB mode On or Off
4. Press Bluetooth/MAM button ④ to confirm.

☞ **Note:** The AFIBsens® mode setting can be set individually for each user.

Selecting the correct cuff

Check if the cuff size is suitable for the circumference of your upper arms. The upper arm circumference can be measured using a tape measure around the mid-point of the upper arm.
Please see cuff range in chapter «Device accessories».

⚠ **Caution:** Only use compatible Microlife cuffs and connectors with this device.

⚠ **Caution:** Using an undersized or oversized cuff for measurement can result in inaccurate blood pressure values. Use the correct sized cuff for measurement to ensure the readings are reliable.

Contact your local Microlife Service if the enclosed cuff ⑩ does not fit.

☞ If you buy a spare Microlife cuff, please remove the cuff connector ⑫ from the cuff tube ⑪ from the cuff supplied with the original device and insert this cuff connector into the tube of the spare cuff (valid for all cuff sizes).

Connecting the cuff to the device

Connect the cuff to the device by inserting the cuff connector ⑫ into the cuff socket ⑥ as far as it will go.

⚠ Make sure the cuff connector is securely inserted into the cuff socket of your blood pressure monitor. **A distinct «CLICK» must be heard when fully inserted.**

☞ **Note:** A loose connection will result in inaccurate readings, and an error message (**«Err 3»**).

User Selection

This device allows you to store the results for 2 individual users.

- Select the intended user (user 1 or user 2 ㉓) by pressing the user button ⑤.

☞ Before each measurement, ensure that the correct user is selected.

Selecting standard or MAM mode

Before each measurement, select standard (single measurement) or MAM mode (automatic triple measurement). In MAM mode, 3 measurements are automatically taken in succession and the result is then automatically analysed and displayed. Because the blood pressure constantly fluctuates, a result obtained in this way is more reliable than when a single measurement is performed.

- Press and hold the Bluetooth/MAM button ④for approximately 3 seconds until «SET» appears on the display, then release the button.
- Press the M-button to switch between ON and OFF, then press the Bluetooth/MAM button to save the setting.
- When MAM is turned ON, the interval of 15, 30, or 60 seconds between each measurement can be selected by pressing the M-button.
- The bottom, right hand section of the display shows a 1, 2 or 3 to indicate which of the 3 measurements is currently being taken.
- There is a break between the measurements. A count down indicates the remaining time.
- The individual results are not displayed. Your blood pressure will only be displayed after all measurements are taken.

- Do not remove the cuff between measurements.
- If one of the individual measurements was questionable, an additional measurement is automatically taken.

☞ In MAM mode, if one of the individual measurements was questionable, the device automatically takes an additional measurement.

☞ AFIBsens® is only activated in MAM mode.

5. Measurement preparation

Before taking a measurement

- Avoid heavy activity, eating or smoking immediately before the measurement.
- Empty your bladder prior to measurement.
- Sit down on a back-supported chair and relax for 5 minutes. Keep your feet flat on the floor and do not cross your legs.
- **Always measure on the same arm** (normally left). It is recommended that doctors perform double arm measurements on a patients first visit in order to determine which arm to measure in the future. The arm with the higher blood pressure should be measured.

Correct cuff fitting and posture for taking a measurement

- Always ensure that the correct cuff size is used (marking on the cuff).
- Remove close-fitting garments from the upper arm. To avoid constriction, shirt sleeves should not be rolled up - they do not interfere with the cuff if they are laid flat.
- Fit the cuff closely, but not too tight.
- Make sure that the cuff is positioned 1-2 cm above the elbow.
- The **artery mark** on the cuff (ca.3 cm long bar) must lie over the artery which runs down the inner side of the arm.
- Support your arm so it is relaxed.
- Ensure that the cuff is at the same height as your heart.

6. Measurement operation

Starting measurement

1. Select standard (single measurement) or MAM mode (automatic triple measurement): see details in chapter «Device installation and setup»
2. Press the ON/OFF button ① to start the measurement.

☞ **Note:** If AFIBsens® is turned off in the device settings, the symbols «AFIB» and «OFF» will be displayed.

☞ **Note:** If Bluetooth® automatic activation is turned off in the device settings, the symbols «BT» and «OFF» will be displayed.

3. The cuff will now pump up automatically. Relax, do not move and do not tense your arm muscles until the measurement result is displayed. Breathe normally and do not talk.
4. 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.
5. 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.
6. During the measurement, the pulse indicator ㉘ flashes in the display.
7. The result, comprising the systolic ⑭ and the diastolic ⑮ blood pressure and the pulse rate ⑯ are displayed. Note also the explanations on further display symbols in this booklet.
8. When the device has finished measuring, remove the cuff.
9. Switch off the device. (The monitor does switch off automatically after approx. 1 min.).

⚠ **Caution:** Remain still and do not move or talk during measurement. Motions caused by talking, moving, trembling and other vibrations may interfere with the measurement and affect the measurement accuracy!

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

Manual inflation

In case of high systolic blood pressure, it can be an advantage to set the pressure individually. Press the ON/OFF button after the monitor has been pumped up to a level of approx. 30 mmHg (shown on the display). Keep the button pressed until the pressure is about 40 mmHg above the expected systolic value – then release the button.

7. Measurement interpretation

How do I evaluate my blood pressure

The triangle on the left-hand edge of the display ㉒ points at the range within which the measured blood pressure value lies. The value is either within the optimum (green), elevated (yellow) or high (red) range.

The classification of blood pressure ranges is defined by the European Society of Cardiology (ESH) guideline for home blood pressure monitoring*.

** European Society of Hypertension practice guidelines for home blood pressure monitoring. J Hum Hypertens. 2010 Dec;24(12):779-85.*

☞ **NOTE:** The blood pressure classification is a general guideline of blood pressure level at home, but diagnosis of hypertension should be made by a healthcare professional based on specific conditions of the patient. Consult with your doctor for questions about the interpretation and classification of your blood pressure values.

Range		Systolic	Diastolic	Classifications
1.	High	**≥135**	**≥85**	Hypertensive
2.	Elevated	**130 - 134**	**80 - 84**	Elevated
3.	Optimum	**<130**	**< 80**	Normal

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».

Appearance of the irregular heartbeat (IHB) symbol

This symbol ⑳ indicates that an irregular heartbeat was detected during the measurement.

⚠ **Caution:** When IHB is detected, the result may deviate from your normal blood pressure. It is recommended to repeat the measurement, with MAM mode if possible. (See chapter «Selecting standard or MAM mode» about MAM mode)

Appearance of the atrial fibrillation (AFIB) symbol

- This device can detect atrial fibrillation (AF).
- This symbol indicates that atrial fibrillation (AF) was detected by AFIBsens®screening technology during the measurement. It is recommended to consult with a healthcare professional about screening-detected AF.

⚠ **Caution:** In the presence of atrial fibrillation detection indicated by AFIB symbol ㉙, re-taking additional measurements is recommended to obtain more reliable blood pressure values based on measurement average. Keep the arm still while measuring to avoid false readings.

8. Data memory function

This device automatically stores up to 99 measurement values for each of the 2 users.
Select either user 1 or 2 by pressing the user button ⑤.

Viewing the average of all stored values

Press the M-button ③ briefly, when the device is switched off. The display first shows **«M»** ㉕, and **«A»**which stands for the average of all stored values.

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

Viewing the stored single values

Pressing the M-button again, allows you to see the last performed measurement. The display first shows **«M»** ㉕ and a value, e.g. «M17». This means that there are 17 single values in the memory. Pressing the M-button again displays the previous value. Pressing the M-button repeatedly enables you to move from one stored value to another.

☞ Pay attention that the maximum memory capacity of 99 memories is not exceeded. **When the 99 memory is full, the oldest value is automatically overwritten with the 100 th value.** Values should be evaluated by a doctor before the memory capacity is reached – otherwise data will be lost.

Clearing all values

Make sure the correct user is activated.
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 ALL»** appears and then release the button. To permanently clear the memory, press the Bluetooth/MAM button while **«CL ALL»** is flashing. **Individual values cannot be cleared.**

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

How not to store a reading
As soon as the reading is displayed press and hold the ON/OFF button ① until **«M»** ㉕ is flashing. Confirm to delete the reading by pressing the Bluetooth/MAM button ④.

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

9. Bluetooth® function operation

Setting the Bluetooth® function ON or OFF
1. Press and hold the Bluetooth/MAM button ④for approximately 3 seconds until «SET» appears on the display, then release the button.
2. Press the Bluetooth/MAM button ④ repeatedly until the Bluetooth® icon is shown on the display.
3. Press the M-button ③ to change the Bluetooth® function «On» or «Off».
4. Press Bluetooth/MAM button ④ to confirm.

☞ **Note:** the Bluetooth® function setting can be configured individually for each user.

Use the Bluetooth® function to transfer data to «Microlife Connected Health+» App on a smartphone (Android OS or iOS).

Information available on: www.microlife.com/technologies/connect

Bluetooth® operations
- Manually turn on Bluetooth®: Press Bluetooth/MAM button ④ to activate Bluetooth®, Bluetooth® symbol ⑬ on display will blink.
- Automatically turn on Bluetooth®: Bluetooth® will activate automatically after a measurement. Bluetooth® symbol ⑬ on display will blink.
- Manually turn off Bluetooth®: Press ON/OFF button ① to turn off Bluetooth®.
- Automatically turn off Bluetooth®: Bluetooth® will turn off automatically after 2 minutes if a smartphone does not connect to the device.

Bluetooth® pairing and app setup
1. Open «Microlife Connected Health+» App on the smartphone (Make sure the app is running in the foreground, not in the background.)
2. Press Bluetooth/MAM button ④ to connect device to smartphone.
3. When smartphone finds the device, the smartphone will show a message to pair with the device. Confirm on smartphone to complete pairing. Cancel to abort pairing.
4. After pairing, the app will show a message to setup the device user selection (1 or 2) to the app user profile. Confirm to proceed with setup. Cancel to abort setup (if user selection is incorrect).
5. After setup, the device will automatically exchange measurement data and date/time settings with the app. Bluetooth® turns off automatically after data exchange.

Bluetooth® status
- Bluetooth® symbol ⑬ blinking slowly: Bluetooth® is activated and waiting for connection.
- Bluetooth® symbol ⑬ not blinking: Bluetooth® connection established.
- Bluetooth® symbol ⑬ blinking rapidly: Bluetooth® connection error.

☞ In case of Bluetooth® connection error, turn off device Bluetooth®, wait for a minute, then re-try Bluetooth® connection. Refer to chapter «10. Device error and troubleshooting» for details.

Caution: Make sure date and time settings are correct on the device. Incorrect settings results in misleading data and time records of the measurements.

10. Device error and troubleshooting

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» ⑲	Signal too weak	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.*

Error	Description	Potential cause and remedy
«Err 2» ⑱-B	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» ⑱-C	Abnormal cuff pressure 	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. Make sure the cuff connector is securely inserted into the cuff socket of your blood pressure monitor. **A distinct «CLICK» must be heard when fully inserted.**
«Err 5»	Abnormal result	The measuring signals are inaccurate and no result can therefore be displayed. Read through the checklist for taking a reliable measurement and then repeat the measurement.*
«HI»	Pulse or cuff pressure too high	The pressure in the cuff is too high (over 299 mmHg) 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.*
	Bluetooth® symbol ⑬ blinks rapidly	Bluetooth® connection error. Turn off the device Bluetooth® and close the app on the smartphone. Wait for 1 minute, open the app on the smartphone and manually activate Bluetooth® on the device, to re-try Bluetooth® connection and data transfer.
«Err bt»	Bluetooth® self check error	Bluetooth® is malfunctioning. Contact your local Microlife distributor.

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

11. Device maintenance and disposal

Cleaning the device
The device can be cleaned when necessary (e.g., between uses by different patients).
Use a soft cloth, dry or wet with detergent, to gently wipe the exterior of the device to remove dust or stains.

Cleaning the cuff
Use a soft cloth, dry or wet with mild detergent, to carefully wipe the cuff to remove dust or stains.

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

Cleaning the AC adapter
Clean the AC adapter with a dry cloth.

Storage
When not in use:
- Disconnect the cuff and parts from the device.
- Keep the device and accessories in a dry, cool place away from sunlight, with ambient conditions within the temperature and humidity ranges described in the «Technical specifications» section.
- Remove the batteries from the device if the device will not be used for an extended period.

Warning: Storing the device **unused** for an extended period without removing batteries increases the chance of battery fluid leakage, which may lead to device damage and skin irritation when in contact. If your eye or skin is exposed to battery fluid, wash the exposed part immediately with ample clean water. Consult a doctor if irritation or discomfort persists.

Calibration and support
The device is calibrated during manufacturing. In general, it is recommended to have the device verified by your local designated

Microlife device distributor every two years, or after mechanical impact, liquid ingress, and/or device malfunctions. For questions related to device measurement accuracy, please contact your local designated Microlife device distributor.

Caution: Do not attempt to service or calibrate the device and accessories yourself.

Disposal

This device is medical electrical equipment. Dispose this device and batteries in accordance with the Waste Electrical and Electronic Equipment (WEEE) directive and applicable local regulations. Do not dispose of the device and batteries with domestic or commercial waste.

12. Specifications and compliance

Technical specifications

NOTE: Technical specifications subjected to change without notice.

Device Type:	Digital non-invasive blood pressure monitor
Model number:	BPHJB6-D
Reference number	BP B4 AFIB BT
Operating conditions:	10 – 40 °C / 50 – 104 °F 15 – 90 % relative maximum humidity 700 hPa – 1060 hPa
Storage and transport conditions:	-20 – +55 °C / -4 – +131 °F 15 – 90 % relative maximum humidity
Weight:	260 g (including batteries)
Dimensions:	141 x 94.5 x 56 mm
Measuring procedure:	Oscillometric, corresponding to Korotkoff method: Phase I systolic, Phase V diastolic
Pressure resolution:	1 mmHg
Cuff pressure display range:	0 – 299 mmHg
Measurement range:	SYS: 60 – 255 mmHg DIA: 40 – 200 mmHg Pulse: 40 – 199 beats per minute
Static accuracy:	± 3 mmHg
Pulse accuracy:	± 5 % of the readout value
Wireless Communication:	Bluetooth® low energy
Power source – internal:	4 x 1.5 V LR3 (AAA) batteries
Power source – external (optional):	AC Adapter model: Microlife DSA-5PF21-05 Input: 100-240 V Output: 5.0 V, 1.0 A, 5 W
Ingress protection (IP) rating:	IP21: Protected against solid objects with a diameter of 12.5 mm. Dripping water (vertically falling drops) shall have no harmful effect.
Applied part type reference:	Type BF
Service life – device:	5 years or 10000 measurements, whichever comes first
Service life – cuff:	2 years or 5000 measurements, whichever comes first
Battery lifetime:	approx. 400 measurements (1.5 V alkaline batteries; size LR3 (AAA))

Compliance information

This device complies with the requirements of the Medical Device Regulation (EU)2017/745.

Compliant standards:

EN 60601-1
EN 60601-1-2
EN 60601-1-11
EN IEC 80601-2-30
EN ISO 81060-2

Clinical validation:

1. This device has been clinically validated for blood pressure measurement in adult general population in accordance with ISO 81060-2.
2. This device has been clinically validated for blood pressure measurement in diabetic patients.
3. This device has been clinically validated for blood pressure measurement in pregnant and pre-eclampsia patients.

13. Supplement information for users and patients

Information about blood pressure

Factors influencing blood pressure

Blood pressure is a dynamic vital sign influenced by both patient-related and environmental factors. Individual blood pressure readings can be affected by the measurement site, body position, posture and other physiological conditions and health status (e.g. cardiovascular or renal diseases, tremors, and pregnancy). Generally, it is recommended to take measurements at the same measurement site with the same body position, under similar physiological conditions at the same time of the day and follow instructions for measurement preparation, to ensure the reliability of the blood pressure values. For individual instructions please consult your physician.

For more information visit our website: www.microlife.com/magazine/blood-pressure/faq-blood-pressure-management.

Information about irregular heartbeat

What is irregular heartbeat (IHB)?

An Irregular Heartbeat (IHB) occurs when an irregular interval between heart beats is detected during measurement. Presence of IHB may affect blood pressure measurement; it's recommended to retake measurement if IHB is detected, to ensure reliability of blood pressure reading. Occasional IHB detection is no cause for concern. Consult with your doctor if IHB is detected frequently (e.g. in majority of measurements).

What is Atrial Fibrillation (AF)?

Normally, your heart contracts and relaxes to a regular beat. Certain cells in your heart produce electrical signals that cause the heart to contract and pump blood. Atrial fibrillation occurs when rapid, disorganized electrical signals are present in the heart's two upper chambers, called the atria; causing them to contract irregularly (fibrillation) and result in blood clot formation.

Who should be screened for Atrial Fibrillation?

AF screening is recommended for people over 65 years of age, since the chance of having a stroke increases with age. AF screening is also recommended for people from the age of 50 years who have high blood pressure (e.g. SYS higher than 159 or DIA higher than 99) as well as those with diabetes, coronary heart failure or for those who have previously had a stroke.

In young people or in pregnancy AF screening is not recommended as it could generate false results and unnecessary anxiety. In addition, young individuals with AF have a low risk of getting stroke as compared to elder people.

Why screen for Atrial Fibrillation?

Atrial fibrillation is the most common form of heart arrhythmia. It often causes no symptoms yet significantly increases the risk of stroke and other thromboembolic events. Atrial fibrillation (AF) is a major risk factor for stroke, affecting approximately 40 million people worldwide[1,2]. Many AF cases go undiagnosed because they are asymptomatic, increasing the risk of severe complications. However, early detection followed by proper treatment can prevent up to 68% of AF-related strokes[3,4]. Early diagnosis of AF followed by adequate treatment can significantly reduce the risk of stroke. Managing risk factors including blood pressure level and presence of possible AF is the first step in proactive stroke prevention.

Microlife AFIBsens® technology

This is a clinically validated device able to detect atrial fibrillation (AF) with Microlife AFIBsens® technology for screening purpose, with sensitivity of 80.6% (95% CI 69.5 to 88.9) and specificity of 98.7% (95% CI 98.3 to 98.9)[5]. Device indicates AFIB symbol when possible atrial fibrillation is detected during a measurement. Because paroxysmal AF may occur intermittently, the device cannot detect possible AF if AF episodes occur outside measurements. In some rare cases, the symbol may appear due to other types of arrhythmias. Please consult with a cardiologist when AF detection indication appears. It is important to note that an AF diagnosis can only be confirmed by a physician using an electrocardiogram (ECG). If AF is detected with a Microlife AFIBsens®-integrated blood pressure monitor, users should consult a physician for further evaluation. More information available on: www.microlife.com/afib

Sources:

[1] Giuseppe Lippi, Global epidemiology of atrial fibrillation: An increasing epidemic and public health challenge, International Journal of Stroke, 2021 Feb;16(2):217-221.

[2] Kornej J, Börschel C, Benjamin E, Schnabel R. Epidemiology of atrial fibrillation in the 21st century: novel methods and new insights. Circ Res. 2020;27:4–20.

[3] *Van Gelder, Isabelle C., et al. «2024 ESC Guidelines for management of Atrial Fibrillation Developed in Collaboration with the European Association for Cardio-Thoracic Surgery (EACTS).» Eur Heart J, 45, 36, 2024: 3314–414.*

[4] *Hart RG, Benavente O, McBride R, Pearce LA: Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a meta-analysis. Ann Intern Med 1999; 131:492-501.*

[5] *P.-H. Chan, C.-K. Wong, L. Pun, Y.-F. Wong, M. M.-Y. Wong, D. W.-S. Chu, C.-W. Siu Diagnostic performance of an automatic blood pressure measurement device, Microlife WatchBP Home A, for atrial fibrillation screening in a real-world primary care setting. BMJ open. 7, e013685 (2017).*

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 using non-Microlife specified accessories or parts, incorrect application or non-compliance with the instruction 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, power adapter (optional).

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.

Symbols and definitions

MD	Medical device
CE	CE Marking of Conformity
	Importer
EU REP	Authorized representative in the European Union
CH REP	Authorized representative in Switzerland
	Manufacturer
CC	Country of manufacture (Date of manufacture if date printed next to symbol)
#	Model number
REF	Reference number
SN	Serial number (YYYY-MM-DDXXXXX; YYYY-MM-DD = date of manufacture, XXXXX = sequence number)
LOT	Lot number (YYYY-MM-DD; YYYY-MM-DD = Date of manufacture)
UDI	Unique Device Identifier
	Caution
	General warning sign
	Type BF applied part
	Direct current
IP21	IP21: Protected against solid objects with a diameter of 12.5 mm. Dripping water (vertically falling drops) shall have no harmful effect.
	Keep dry
	Temperature limitation for operating **or** storage
%	Humidity limitation for operating **and** storage

Atmospheric pressure limitation

Read instructions for use before operating the device.

Dispose in accordance with waste electrical
and electronic equipment (WEEE) directive.

Patient information website

Reminder/Note

Not made with natural rubber latex