microlife®

BP B3 AFIB

Automatyczny

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CE 0044

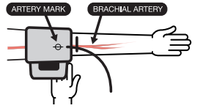
IB BP B3 AFIB EN 0619

Preparation

1. 

Sit on a back-supported chair and keep your legs uncrossed.

2. 
Avoid thick or close-fitting garments on the upper arm.

3. 

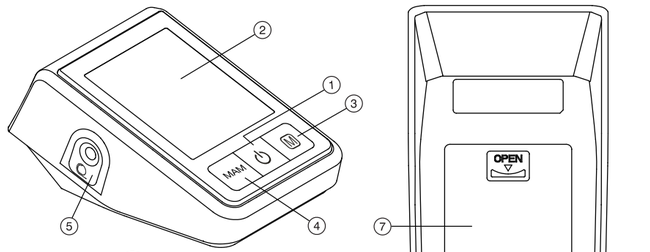
Place the artery-mark on the cuff over your artery.

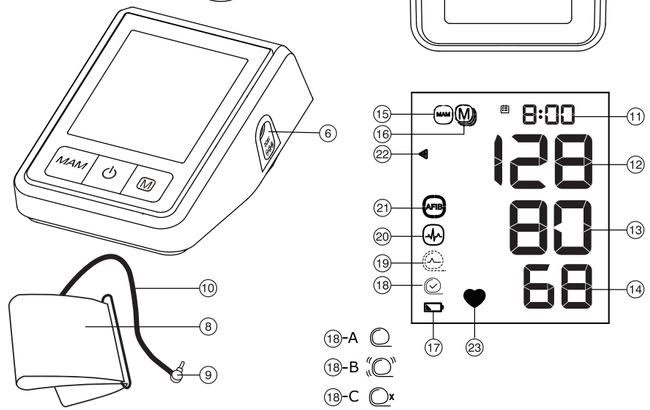
4. 
Fit the cuff closely, but not too tight.

5. 

Position the cuff 2-3 cm above your elbow.

6. 
Keep your arm still and do not speak during the measurement.





1.

Avoid eating, bathing, smoking or caffeine (approx. 30 min).

2.

Avoid activity and relax for 5-10 min.

3.

Measure before medication intake.

Name of Purchaser _____

Serial Number _____

Date of Purchase _____

Specialist Dealer _____

microlife®

① ON/OFF button
② Display
③ M-button (memory)
④ MAM button
⑤ Cuff Socket
⑥ Mains Adapter Socket
⑦ Battery Compartment
⑧ Cuff
⑨ Cuff Connector
⑩ Cuff Tube

Display

⑪ Date/Time
⑫ Systolic Value
⑬ Diastolic Value
⑭ Pulse Rate
⑮ MAM Mode
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**»
⑲ Cuff Signal Indicator «**Err 1**»
⑳ Pulse Arrhythmia Indicator (PAD)
㉑ Atrial Fibrillation Indicator (AFIB)
㉒ Traffic Light Indicator
㉓ Pulse Indicator

Follow Instructions for Use. This document provides important product operation and safety information regarding this Blood Pressure Monitor. Please read this document thoroughly before using the device and keep for future reference.

Type BF applied part

Keep dry

Intended use:
This oscillometric blood pressure monitor is intended for measuring non-invasive blood pressure in people aged 12 years or older.
It is clinically validated in patients with hypertension, hypotension, diabetes, pregnancy, pre-eclampsia, atherosclerosis, end-stage renal disease, obesity and the elderly.
The device can detect an irregular pulse suggestive of Atrial Fibrillation (AF). Please note that the device is not intended to diagnose AF. A diagnosis of AF can only be confirmed by ECG. The patient is advised to see a physician.

Dear Customer,
This device was developed in collaboration with physicians and clinical tests carried out prove its measurement accuracy to be of a very high standard.*
Microlife AFIBsens is the world's leading digital blood pressure measurement technology for the detection of atrial fibrillation (AF) and arterial hypertension. These are the two top risk factors of getting a stroke or heart disease. It is important to detect AF and hypertension at an early stage, even though you may not experience any symptoms. AF screening in general and thus also with the Microlife AFIB algorithm, is recommended for people of 65 years and older. The AFIB algorithm indicates that atrial fibrillation may be present. For this reason, it is recommended that you visit your doctor when the device gives an AFIB signal during your blood pressure measurement. The AFIB algorithm of Microlife has been clinically investigated by several prominent clinical investigators and showed that the device detects patients with AFIB at a certainty of 97-100%. [1,2]
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 uses the same measuring technology as the award winning «BP 3BTO-A» model tested according to the British and Irish Hypertension Society (BIHS) protocol.*

[1] *Kearley K, Selwood M, Van den Bruel A, Thompson M, Mant D, Hobbs FR et al.: Triage tests for identifying atrial fibrillation in primary care: a diagnostic accuracy study comparing single-lead ECG and modified BP monitors. BMJ Open 2014; 4:e004565.*

[2] *Wiesel J, Arbesfeld B, Schechter D: Comparison of the Microlife blood pressure monitor with the Omron blood pressure monitor for detecting atrial fibrillation. Am J Cardiol 2014; 114:1046-1048.*

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Guarantee Card (see Back Cover)

1. Appearance of the Atrial Fibrillation Indicator for early Detection (Active only in MAM mode)

This device is able to detect atrial fibrillation (AF). This symbol ㉑ indicates that atrial fibrillation was detected during the measurement. Please refer to the next paragraph for information regarding the consultation with your doctor.

Information for the doctor on frequent appearance of the atrial fibrillation indicator

This device is an oscillometric blood pressure monitor that also analyses pulse irregularity during measurement. The device is clinically tested.
The AFIB symbol is displayed after the measurement, if atrial fibrillation occurred during measuring. If the AFIB symbol appears after having performed a full blood pressure measurement episode (triplicate measurements), the patient is advised to perform another measurement episode (triplicate measurements). If the AFIB symbol appears again, we recommend the patient to seek medical advice.
If the AFIB-symbol appears on the screen of the blood pressure monitor, it indicates the possible presence of atrial fibrillation. The atrial fibrillation diagnosis however, **must** be made by a **cardiologist** based on ECG interpretation.

- ☞ Keep the arm still during measuring to avoid false readings.
- ☞ This device may not or wrongly detect atrial fibrillation in people with pacemakers or defibrillators.
- ☞ In the presence of atrial fibrillation the diastolic blood pressure value may not be accurate.
- ☞ In the presence of atrial fibrillation using MAM-mode is recommended for more reliable blood pressure measurement.

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 (this is called fibrillation). Atrial fibrillation is the most common form of heart arrhythmia. It often causes no symptoms, yet it significantly increases your risk of stroke. You'll need a doctor to help you control the problem.

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.

Risk factors you can control
Early diagnosis of AF followed by adequate treatment can significantly reduce the risk of getting stroke. Knowing your blood pressure and knowing whether you have AF is the first step in proactive stroke prevention.
For more information visit our website: www.microlife.com/afib.

2. Using the Device for the First Time

Inserting the batteries
After you have unpacked your device, first insert the batteries. The battery compartment (7) is on the bottom of the device. Insert the batteries (4 x 1.5 V, size AA), 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 MAM button (4).
2. Press the M-button to set the month. Press the 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 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 MAM button for approx. 3 seconds until the year number starts to flash. Now you can enter the new values as described above.

Selecting the correct cuff
Microlife offers different cuff sizes. Select the cuff size to match the circumference of your upper arms (measured by close fitting in the centre of the upper arm).

Cuff size	for circumference of upper arm
S	17 - 22 cm
M	22 - 32 cm
M - L	22 - 42 cm
L	32 - 42 cm
L - XL	32 - 52 cm

☞ Pre-shaped cuffs are optionally available.
☞ Only use Microlife cuffs.
- Contact your local Microlife Service if the enclosed cuff (8) does not fit.
- Connect the cuff to the device by inserting the cuff connector (9) into the cuff socket (5) as far as it will go.

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.
- To select MAM mode, press the MAM button (4) until the MAM-symbol (15) appears on the display. To change to standard mode (single measurement), press the MAM-button again, until the MAM-symbol disappears.
- 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 of 15 seconds 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 3 measurements are taken.
- Do not remove the cuff between measurements.
- If one of the individual measurements was questionable, a fourth one is automatically taken.

☞ AF detection is only activated in MAM mode.

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 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.

- 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.
- Always ensure that the correct cuff size is used (marking on the cuff).
  - Fit the cuff closely, but not too tight.
  - Make sure that the cuff is positioned 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.

4. Taking a Blood Pressure Measurement

1. Select standard (single measurement) or MAM mode (automatic triple measurement): see details in chapter «2.».
2. Press the ON/OFF button ① to start the measurement.
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 ㉓ flashes in the display.
7. The result, comprising the systolic ⑫ and the diastolic ⑬ blood pressure and the pulse rate ⑭ is 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.).

☞ AF detection is only activated in MAM mode.

☞ 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).

☞ This monitor is specially tested for use in pregnancy and pre-eclampsia. When you detect unusual high readings in pregnancy, you should measure after a short while again (eg. 1 hour). If the reading is still too high, consult your doctor or gynecologist.
In pregnancy the AFIB symbol can be ignored.

Manual inflation

In case of high systolic blood pressure (e.g. above 135 mmHg), 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.

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 MAM 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 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 corresponds to the following ranges defined by international guidelines (ESH, ESC, JSH). Data in mmHg.

Range		Systolic	Diastolic	Recommendation
1.	blood pressure too high	**≥135**	**≥85**	Seek medical advice
2.	blood pressure elevated	**130 - 134**	**80 - 84**	Self-check
3.	blood pressure normal	**<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».

Appearance of the Pulse Arrhythmia (PAD)

This symbol ⑳ indicates that certain pulse irregularities were detected during the measurement. In this case, the result may deviate from your normal blood pressure – repeat the measurement. In most cases, this is no cause for concern. However, if the symbol appears on a regular basis (e.g. several times a week with measurements taken daily) we advise you to tell your doctor. Please show your doctor the following explanation:

Information for the doctor on frequent appearance of the Arrhythmia indicator

This device is an oscillometric blood pressure monitor that also analyses pulse irregularity during measurement. The device is clinically tested.
The arrhythmia symbol is displayed after the measurement, if pulse irregularities occur during measurement. If the symbol appears more frequently (e.g. several times per week on measurements performed daily) we recommend the patient to seek medical advice.
This device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

☞ In MAM mode Atrial Fibrillation (AF) will also be checked: follow the directions in chapter «1.».

☞ If the symbol appears, select MAM mode and measure again: see details in chapter «2.».

5. Data Memory

This device automatically stores the last 99 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 99 memories is not exceeded. **When the 99 memory is full, the oldest value is automatically overwritten with the 100th 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 ALL**» appears and then release the button. To permanently clear the memory, press the MAM button while «**CL ALL**» is flashing. Individual values cannot be cleared.

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

6. Battery Indicator and Battery change

Low battery

When the batteries are approximately ¾ 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 ⑦ 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.».

☞ The memory retains all values although date and time must be reset – the year number therefore flashes automatically after the batteries are replaced.

Which batteries and which procedure?

☞ Use 4 new, long-life 1.5 V, size AA 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.

7. Using a Mains Adapter

You can operate this device using the Microlife mains adapter (DC 6V, 600 mA).

☞ Only use the Microlife mains adapter available as an original accessory appropriate for your supply voltage.

☞ Ensure that neither the mains adapter nor the cable are damaged.

1. Plug the adapter cable into the mains adapter socket ⑥ in the blood pressure monitor.
2. Plug the adapter plug into the wall socket.

When the mains adapter is connected, no battery current is consumed.

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**» ⑲	Signal too weak	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.*
«**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.
«**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.*
«**Err 6**»	MAM Mode	There were too many errors during the measurement in MAM mode, making it impossible to obtain a final result. Read through the checklist for performing reliable measurements 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.*

** 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.
- Protect it from:
  - water and moisture
  - extreme temperatures
  - impact and dropping
  - contamination and dust
  - direct sunlight
  - heat and cold
- The cuffs are sensitive and must be handled with care.
- Do not exchange or use any other kind of cuff or cuff connector for measuring with this device.
- Only pump up the cuff once fitted.
- Do not use this device close to strong electromagnetic fields such as mobile telephones or radio installations. Keep a minimum distance of 3.3 m from such devices when using this device.
- Do not use this device if you think it is damaged or notice anything unusual.
- Never open this device.
- If the device is not going to be used for a prolonged period the batteries should be removed.

- 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.
- **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.**
- **Under no circumstances should you alter the dosages of drugs or initiate a treatment without consulting your doctor.**
- **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.
- **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.

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.

Device care

Clean the device only with a soft, dry cloth.

Cleaning the cuff

The cuff delivered with this device is washable.

1. Remove the cuff connector ⑨ from the cuff tube ⑩ and carefully pull the bladder through the opening at the edge of the cuff cover.
2. Hand wash the cuff cover in soapsuds: not hotter than 30 °C.
3. Completely dry the cuff cover by linen drying.
4. Loop the cuff tube back through its opening and carefully place the bladder flat in the cuff cover.
5. Reattach the cuff connector on the cuff tube.

☞ The bladder must lay straight in the cuff cover, not folded.

☞ Do not use fabric softener.

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. The guarantee is valid only on presentation of the guarantee card completed by the dealer (see back) confirming date of purchase or the receipt.

- Batteries and parts that become worn with use are not included.
- Opening or altering the device invalidates the guarantee.
- The guarantee does not cover damage caused by improper handling, discharged batteries, accidents or non-compliance with the operating instructions.
- The cuff has a functional guarantee (bladder tightness) for 2 years.

Please contact your local Microlife-Service (see foreword).

11. Technical Specifications

Operating conditions:	10 - 40 °C / 50 - 104 °F 15 - 95 % relative maximum humidity
Storage conditions:	-20 - +55 °C / -4 - +131 °F 15 - 95 % relative maximum humidity
Weight:	402 g (including batteries)
Dimensions:	138 x 94.5 x 62.5 mm
Measuring procedure:	oscillometric, corresponding to Korotkoff method: Phase I systolic, Phase V diastolic
Measurement range:	20 - 280 mmHg – blood pressure 40 - 200 beats per minute – pulse
Cuff pressure display range:	0 - 299 mmHg
Resolution:	1 mmHg
Static accuracy:	pressure within ± 3 mmHg
Pulse accuracy:	± 5 % of the readout value
Voltage source:	4 x 1.5 V alkaline batteries; size AA Mains adapter DC 6V, 600 mA (optional)
Battery lifetime:	approx. 920 measurements (using new batteries)
IP Class:	IP20
Reference to standards:	EN 1060-1 /-3 /-4; IEC 60601-1; IEC 60601-1-2 (EMC); IEC 60601-1-11
Expected service life:	Device: 5 years or 10000 measurements Accessories: 2 years

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