UPPER ARM BLOOD PRESSURE MONITOR

BASIS CONTROL PLUS

aponorm®
die marke der apotheke

The specialist for triple measurements[1] with smartphone connection[2]

- Bluetooth connectivity[5]
- Triple measurement 15 sec.[1] (3 MAM)
- Pulse anomaly detection (IHB)
- Two users with 99 memory spaces[3] (x 99)
- Blood pressure scale (120 / 80)
- Display (XXL)
- Cuff check

Also suitable for:

- Diabetic patients
- Kidney disease
- Pregnant women
- For people 12+

PRÜFSIEGEL Hochdrucktage – Hypertoniegefahr ärztlich validiert 2025

Connected Health+
microlife

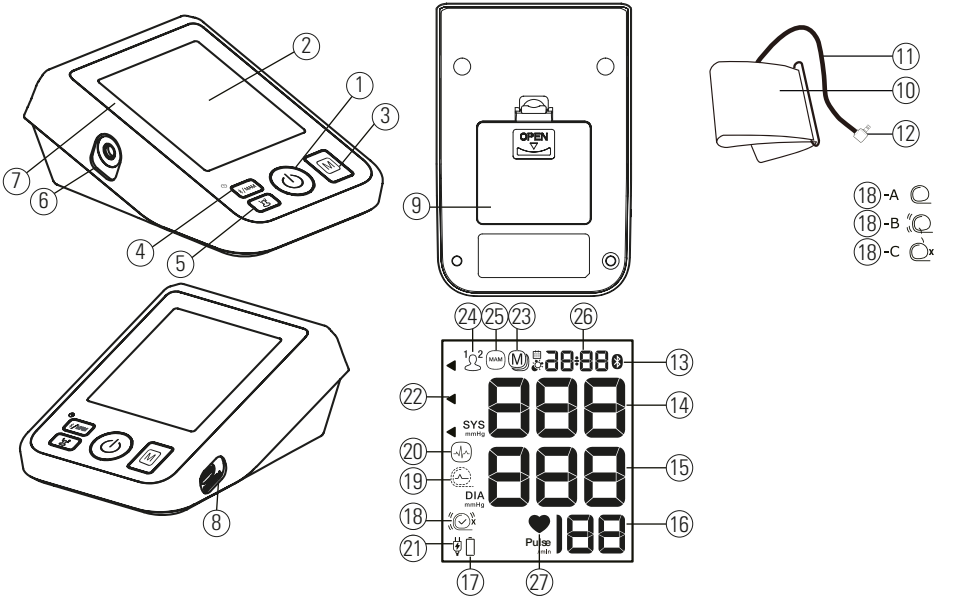
CLINICALLY PROVEN

5 year warranty[4]

S-XL cuffs available[6]

[1] Triple measurements based on the National Healthcare Guidelines for Hypertension 2023; single measurement mode optionally adjustable. [2] Use of the app free of charge; system requirements at www.aponorm.de/app provider of the app is Microlife Corporation [3] local device memory; storage space in the app unlimited [4] The warranty does not extend to wear parts, batteries and accessories (the cuff has a 2-year functional warranty). The warranty is granted for consumers residing in Germany and Austria. Additional warranty terms from page 31 [5] The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of these trademarks by Microlife Corporation is under licence. Other trademarks and trade names are those of their respective owners. [6] alternative sizes to the included standard cuff available separately (see page 14).

A quality brand of WEPA
DIE APOTHEKENMARKE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Schalter, Gehäuse & Zubehör

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-Anzeigen

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 Stored value
㉔ User indicator
㉕ MAM Mode
㉖ Date/Time
㉗ Pulse indicator

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.*

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] 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.

Available formats for the visually impaired:
The instructions for use available at www.aponorm.de/bmg-downloads in PDF format can be printed out in enlarged format (see also the QR code below).

www.aponorm.de/bmg-downloads

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
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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 use
This device is intended to measure brachial blood pressures (systole and diastole) and pulse rate.

Intended user
The device is intended to be operated by adults and adolescents with adequate vision, motor functions, and education, capable of understanding the instruc-

tions for use and operating general household electrical appliances.

Intended patient
The intended patients are normotensive and hypertensive adults and adolescents (aged 12 years or older) of the general population. The intended patients also include those with conditions of diabetes, pregnancy, preeclampsia, atherosclerosis.

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

Indications
This device measures blood pressures for indications of:

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

Contra-indications

- The device is not intended for measuring blood pressure in pediatric patients of age younger than 12 years old (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 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.
- 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 pres-sure 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 may result after 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 mastec-tomy or lymph node clearance.
- Avoid taking measurements on the arm with intravascular access or therapy or an arterio-venous (AV) 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.
- 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 this 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 diag-nosis 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 profes-sional 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 oper-ating abnormally.
- Blood flow of the arm is temporarily interrupted during measure-ment from cuff pressurization. Extended periods of cuff pressur-ization 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 «Specifications and compli-ance». Usage and storage of the device, cuff and parts in conditions outside ranges given in the «Specifications and compliance» 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.

Caution

NOTE: Caution items indicate potentially hazard-ous 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 dissemble 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.
- The device is intended only for measuring blood pressure on your upper arm. DO NOT measure other sites because the reading does not reflect your blood pressure accurately.
- 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 reattempt measurement in such case.
- After a measurement is completed, loosen the cuff, and rest the arm 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 doctor if you experience skin irritation or discomfort.
- DO NOT use this device, cuff, or parts after the expiration of its stated service life.
- Remove the arm cuff if it does not start deflating during the measurement.
- Do not use this monitor in high-use environments such as medical clinics or physician offices.
- If this monitor 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 approxi-mately 2 hours before using the monitor.

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 device is not certified for operation near these equipments, which may cause device malfunction and measurement inaccuracies.
- 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.

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 (EC REP), and to the competent authority.

3. Device information

Package Contents

- Upper arm blood pressure monitor
- Conical cuff
  Universal size M-L (22-42 cm, latex-free)
- Instructions for use + warranty card
- Quick start guide
- Storage bag
- Blood pressure passport with the "8 golden rules of blood pressure measurement"
- Cuff measuring tape
- 4 AAA alkaline batteries

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.

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

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

Only use aponorm® cuffs or cuffs from the manufacturer Microlife.

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

An overview of available aponorm® accessories such as upper arm cuffs and mains adapters can be found at www.aponorm.de/bmg-zubehoer.

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 deteced by the device, the external power source indicator (21) will be displayed on the display.

How to use the power adapter:

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.

Vorsicht: 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 attery 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.

Further helpful tips can be found online at www.aponorm.de/bmg-batterien.

www.aponorm.de/bmg-batterien

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.

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 midpoint of the upper arm.

Please see cuff range in chapter «Device accessories».

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

Vorsicht: Using an undersized or oversized cuff for measurement can result in inaccurate blood pressure values. Use the correctly 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»).

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

- Select the intended user (user 1 or user 2 BN) 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.

- UTo select MAM mode, press the Bluetooth/MAM button ④ for 3-4 seconds until the MAM symbol

㉕ appears on the display. Press the M-button to switch between ON and OFF, then press the Bluetooth/MAM button to save the setting.

- 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.

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

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.

☞ Further guidelines on performing a correct blood pressure can be found at www.aponorm.de/blutdruck-messregeln.

www.aponorm.de/blutdruckmessregeln

6. Measurement operation

Starting measurement

1. Select standard (single measurement) or MAM mode (auto-matic triple measurement): see details in chapter «Device installation and setup»
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.

☞ Blood pressure readings with suboptimal cuff fit (18)-A art NOT included in the average value.

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 (27) 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 (white), elevated (hatched gray) or high (black) range.

The classification of blood pressure ranges is defined by the European Society of Cardiology (ESH) guideline for home blood pressure monitoring[1].

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

[1]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. Always consult your doctor in the event of abnormal or unclear values.

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. 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.

8. Data memory function

This device automatically stores up to 30 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» (23), and «A» which stands for the average of all stored values.

☞ Blood pressure readings with subopt imal cuff fit (18) -A are

Viewing the stored single values
Pressing the M-button again, allows you to see the last performed measurement. The display first shows «M» (23) 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 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
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»** (23) 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. App and Bluetooth® function

Using the Bluetooth® function, transfer data to the "Microlife Connected Health+" app on a smartphone (with Android OS or iOS).

Detailed information on system requirements, installation and use of the app can be found at www.aponorm.de/app.

Bluetooth® activation on the device

Activate Bluetooth® manually: Press the Bluetooth/MAM/Clock button ④ to activate Bluetooth®. The Blutooth® symbol ⑬ flashes on the display.

Activate Bluetooth® automatically: Bluetooth® is automatically activated after each measurement. The Blutooth® symbol ⑬ flashes on the display.

To deactivate Bluetooth® manually: Press the On/Off button ① to deactivate Bluetooth®.

To deactivate Bluetooth® automatically: Bluetooth® switches off automatically after 2 minutes if the smartphone is no longer connected to the device.

Setting up Bluetooth® pairing and app

1. Open the "Microlife Connected Health+" app on your smartphone. (The app must be running in the foreground.)
2. Press the Bluetooth/MAM/Clock button ④ to connect the device to the smartphone.
3. As soon as the smartphone finds the device, it shows a message that it can be paired with the device. Confirm the pairing on the smartphone to connect the device. Tap » Cancel «to cancel the pairing.
4. After pairing, the app prompts you in a message to link the user selection of the device (1 or 2) to the user profile of the app. Confirm to continue with the setup. Tap » Cancel «to cancel the setup (if the user selection is incorrect).
5. After the setup, the device automatically exchanges measurement data and date/time settings with the app. Bluetooth® switches off automatically after data exchange.

Bluetooth® status display

- Bluetooth® symbol ⑬ flashes slowly: Bluetooth® is activated and waiting for a connection.

  Bluetooth® symbol does not ⑬ flash: Bluetooth® connection is established.

  Bluetooth® symbol ⑬ flashes quickly: Bluetooth® connection error.

☞ In the event of a Bluetooth® connection error, deactivate the Bluetooth® function of the device, wait one minute, and then try again to establish a Bluetooth® connection. Details can be found in the following chapter 10.

⚠ **Caution:** Make sure that the date and time are set correctly on the device. Incorrect settings cause misleading data and time recordings of 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.

☞ Note: Troubleshooting help for the device can also be found in the download area of the product website www.aponorm.de/bmg-downloads.

www.aponorm.de/bmg-downloads

Error	Description	Potential cause and remedy
«ERR 1» ⑲	Signal too weak	The pulse signals on the cuff are too weak. Reposition the cuff and repeat the measurement.[1]

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.

Error	Description	Potential cause and remedy
«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.**

Error	Description	Potential cause and remedy
«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.[1]
«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.[1]
«LO»	Pulse too low	The pulse is too low (less than 40 beats per minute). Repeat the measurement.[1]

Error	Description	Potential cause and remedy
⑬ blinks rapidly	Bluetooth®-connection error	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.

[1]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 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, metrological control and service

The device is calibrated during manufacture.

For devices used commercially (e.g. medical devices), a measurement control test must be conducted every two years and verified by 31 December.

A measurement control test is not required for privately purchased devices. We recommend carrying out a check in

any case after significant mechanical stress (e.g. if the device has been dropped, if there is liquid ingress, or if malfunctions occur frequently). A measurement control test is not a warranty service.

If you have any questions about the measurement accuracy of the device or about a measurement control test/verification of the device, please contact your local pharmacy or www.aponorm.de/kontakt.

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

Disposal

This device is a medical electrical device. Dispose of this device and the batteries in accordance with the Waste Electrical and Electronic Equipment Directive (WEEE, ElekroG and BattV) and the applicable local regulations. Do not dispose of the device and batteries with household 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:	BPHJB2-D
Reference number	aponorm® Basis Control PLUS^{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:	 Typ 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 ISO 81060-2
EN IEC 80601-2-30

13. Warranty conditions

We, WEPA Apothekenbedarf GmbH & Co. KG, voluntarily grant consumers residing in Germany and Austria a 5-year warranty on all aponorm® Basis Control PLUS Bluetooth® blood pressure monitors according to the following terms and conditions.

Object and scope of the warranty

The warranty applies to all aponorm® Basis Control PLUS Bluetooth® blood pressure monitors of consumers residing in Germany and Austria. WEPA Apothekenbedarf GmbH & Co. KG guarantees the purchaser that the product is free from material and manufacturing defects. If, despite proper use of the product, a defect occurs within the five-year warranty period, WEPA Apothekenbedarf GmbH & Co. KG will repair the product free of charge or, at its discretion, replace it entirely (excluding transport costs for sending the device).

Exclusions from the warranty

Claims under this warranty are not valid in the event of damage caused by the customer or third parties as a result of a fall, accident, or improper handling. The same applies to damage caused by leaking batteries or failure to follow the instructions for use.

A warranty coverage by WEPA Apothekenbedarf GmbH & Co. KG is also excluded if a defect/damage is attributable to improper repair or other interventions by third parties.

The warranty does not cover wear parts, accessories (e.g. cables, etc.), batteries and the cuff supplied with the product. We provide a 2-year functional warranty on the cuff (airtightness of the bladder).

Term of the warranty

The warranty is valid for a period of 5 years from the date of purchase (warranty period). The date of the purchase

receipt or the warranty card filled out by the dealer with the date of purchase is decisive.

The warranty period is not extended by any provision of services under this warranty, especially as it relates to repair or replacement of the device. The warranty period does not start over again in these cases either.

Assertion of warranty claims

The customer may exercise their warranty rights by presenting the defective product and proof of purchase, or a warranty card completed by the dealer, either to WEPA Apothekenbedarf GmbH & Co. KG or to the dealer from whom the product was purchased, within the warranty period.

In the event of a warranty claim, WEPA Apothekenbedarf GmbH & Co. KG will repair the product free of charge or replace it completely at its own discretion (except for the transport costs for sending the device).

If the check reveals that there is no valid warranty claim, the product can be repaired by WEPA Apothekenbedarf GmbH & Co. KG at the customer's expense. In this case, WEPA Apothekenbedarf GmbH & Co. KG will provide the customer with a cost estimate before carrying out the repair. The customer may then choose to have the product repaired at their own expense or request the return of the unrepaired product. WEPA will not bear any transport costs.

Further rights of the purchaser

WEPA Apothekenbedarf GmbH & Co. KG provides the warranty under the stated conditions.

In addition, the customer may be entitled to further legal rights.

The customer's contractual and statutory rights, especially statutory warranty rights against the seller of the product, remain unaffected by this warranty.

The warranty is subject to the laws of the Federal Republic of Germany.

14. Reporting serious incidents

If serious incidents occur during the use of the product, such as a deterioration in health or other significant events, please report them to WEPA Apothekenbedarf GmbH & Co. KG or to the manufacturer Microlife (contact details can be found on the back of the instructions for use).

You may also report the incident to the competent authority of the respective EU Member State. In the Federal Republic of Germany this is:

Federal Institute for Medicines and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany, www.bfarm.de
Incidents are considered serious if they have directly or indirectly caused, could cause, or might cause

a) the death of a person,
b) a temporary or permanent serious deterioration in a person's state of health, or

c) a serious risk to public health.

15. Product help

For any other questions about the product or for technical support, please use the contactform on the product website www.aponorm.de/kontakt.

www.aponorm.de/kontakt

16. Symbols and definitions

MD	Medical device
CE	CE Marking of Conformity
	Importer
EU REP	Authorized representative in the European Community
	Manufacturer
	Country of manufacture (Date of manufacture if date printed next to symbol)
#	Model number
SN	Serial number (YYYY-MM-DD-SSSSS; year-month-day-serial number)
REF	Reference number
LOT	Lot number (YYYY-MM-DD; year-month-day)
UDI	Unique Device Identifier
	Patient information website
	Reminder/Note
	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

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Temperature limitation for operating or storage

Humidity limitation for operating & storage

Atmospheric pressure limitation

Read instructions for use before operating the device.

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

Caution

General warning sign

Not made with natural rubber latex

Product features

PLUS Blood pressure analysis via your smartphone

Easy blood pressure assessment

Suitable for risk groups and children

PLUS Triple safety thanks to triple measurement

Extra comfortable reading

Detects irregular heartbeat

Supports correct handling

CLINICALLY PROVEN

Meets the highest quality standards

5-year warranty

PLUS Automatic blood pressure documentation for two

PLUS = extended functions compared to the aponorm® Basis Control model

www.aponorm.de

technology by microlife

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NeiHu, Taipei 114, Taiwan, China
www.microlife.com

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CE 1639

MD Medical device

Order No. 048214

Equipment item number:
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WEPA DIE APOTHEKENMARKE

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