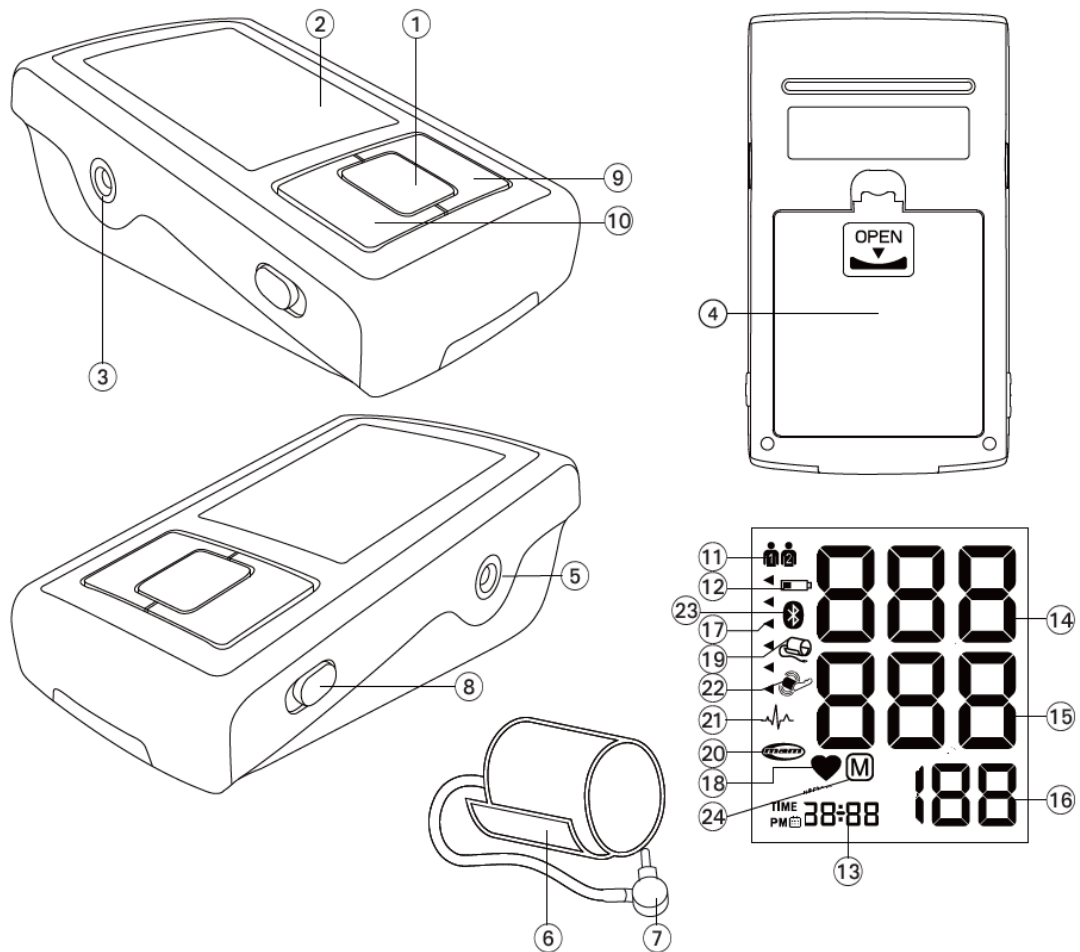


Microlife BP A3L PC (BP3GX1-3BPBX)



- ① ON/OFF button
- ② Display
- ③ Cuff Socket
- ④ Battery Compartment
- ⑤ Mains Adapter Socket
- ⑥ Cuff
- ⑦ Cuff Connector
- ⑧ MAM Switch
- ⑨ M-button (memory)
- ⑩ Time Button
- ⑪ User Indicator
- ⑫ Battery Display
- ⑬ Date/Time
- ⑭ Systolic Value
- ⑮ Diastolic Value
- ⑯ Pulse Rate
- ⑰ Traffic Light Indicator

- 18 Pulse Indicator
- 19 Cuff Pressure Check
- 20 MAM Mode
- 21 Irregular Heartbeat Detection (IHB)
- 22 Arm Movement Indicator
- 23 Bluetooth
- 24 Stored Value



Type BF applied part



Keep dry



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.

Intended use:

This oscillometric blood pressure monitor is intended for measuring non-invasive blood pressure in people aged 12 years or older.

The device can be used in connection with a smart phone via Bluetooth. The measurement data can be transferred to a smart phone running the Microlife Connected Health+ mobile software (App).

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 AG!

* This device is tested according to the ESH protocol and ISO81060-2:2013.

Warning



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

- This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.
- Protect the device & accessories from the following to avoid damaging the device:
 - Water, other liquids, and moisture
 - Extreme temperatures
 - Impacts and vibrations
 - Direct sunlight
 - Contamination and dust
- DO NOT change the patient medication and treatment based the result of one or multiple measurements. Treatment and medication changes should be prescribed only by a medical professional.
- Inspect the device, cuff, and other parts for damage. DO NOT use the device, cuff or parts if they appear damaged or operating abnormally.
- Observing the operation of the device and arm to make sure no prolonged impairment of the circulation of the blood.
- 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.
-  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.
- Blood flow of the arm is temporarily reduced during measurement. Extended interruption of blood flow reduces peripheral circulation and in extreme cases may result in injuries. Beware of signs (for example tissue discoloration) of impeded peripheral circulation if taking measurements continuously or for an extended period of time (for example more than 30 minutes).
- DO NOT use this device in oxygen rich environment or near flammable gas.
- The device is not water resistant or water proof. DO NOT spill or immerse the device in water or other liquids.
- 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
- This device is reusable. It is recommended to clean and disinfect the device and the

accessory prior to use if contamination or cross contamination are possible.

- Always use the arm cuff of range appropriate for the mid arm circumference of the patient.
- 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.

Precaution



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

- The device is intended only for measuring blood pressure at upper arm. DO NOT measure other sites because the reading does not reflect your blood pressure accurately.
- 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 with doctor before the application of the CUFF over a wound, as this can cause further injury.
- Consult with doctor before the application of the CUFF and its pressurization on an arm where intravascular access or therapy, or an arterio-venous (A-V) shunt is present because of temporary interference with blood flow and could result in injury.
- Consult with doctor before the application of the CUFF and its pressurization on the arm on the side of a mastectomy or lymph node clearance
- DO NOT use this device with other medical electrical (ME) equipment simultaneously. This may cause device malfunction or measurement inaccuracies.
- Do not use this device 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.
- This device is not intended for use in ambulatory environments.
- This device is not intended for use on aircraft.
- The cuffs are sensitive and must be handled with care.
- Avoid kinking, pressing, and moving of the cuff tube during device operation, as this affects reading reliability and may cause injury if the device deflation is interrupted.
- Use this device only with compatible accessories from Microlife, including cuffs, connectors, and adaptors. Using non-compatible accessories may compromise the safety and performance of the device.

- Only pump up the cuff once fitted
- Use and store the device, cuff and parts in temperature and humidity conditions specified in the Technical Description. Usage and storage of the device, cuff and parts in conditions outside ranges given in the Technical Description may result in device malfunction and the safety of usage.
- Read the additional safety information provided within the individual sections of this instruction manual.

FCC

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Important Information about Blood Pressure

- 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 patients 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.**
- **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!**
- Take blood pressure measurements more often than necessary frequency is not advised and may cause injury to the PATIENT due to blood flow interference
- If you are **pregnant**, you should monitor your blood pressure regularly as it can change drastically during this time.

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11. Technical Specifications

1. Using the Device for the First Time

Inserting the batteries

After you have unpacked your device, first insert the batteries. The battery compartment ④ 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 ⑬ flashes in the display. You can set year by pressing the M-button ⑨, press the Time button ⑩ to confirm. Then set the month, press the Time button ⑩.
2. Then, press the M-button ⑨ to set the month. Press the Time button ⑩ to confirm. Follow the instructions above to set the day, hour and minutes.
4. Once you have set the minutes and pressed the Time button ⑩, the date and time are set and the time is displayed.
5. If you want to change the date and time, press, and hold the Time button ⑩ until the User Indicator ⑪ and Diastolic Value ⑮ start to flash. Release the button when the User Indicator ⑪ stop flashing but only Diastolic Value ⑮ still flash, and then you can enter the new values of date and time as described above.

Selecting the correct cuff

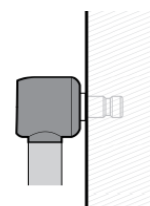
Only use Microlife cuffs.

Contact your local Microlife Service if the enclosed cuff ⑥ does not fit.

Tube connection

Push the cuff connector ⑦ into the cuff socket ③ as far as it will go.

Note: Please make sure the plug is totally inserted into cuff socket (see



picture). A loose connection will result in inaccurate readings and "Err 3".

Selecting the user

The device allows to store the results for individual users.

Select the intended user (user 1 or user 2 ①) by pressing and hold the Time button ⑩ for approx. 3 seconds until the User Indicator ① start to flash. Then, press the M-button ⑨ to set the intended user. Press the Time button ⑩ to confirm.

Before each measurement, ensure the correct user is selected.

Selecting standard or MAM mode

Before each measurement, select standard (single measurement) or MAM mode (automatic double measurement). In MAM mode, 3 measurements are automatically taken in succession and the result is then automatically analyzed 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 standard mode, slide the MAM switch ⑧ on the side of the device downwards to position «1» and to select MAM mode, slide this switch upwards to position «3».

MAM mode (highly recommended)

- In MAM mode, 3 measurements are automatically taken in succession and the result is then automatically analyzed and displayed. Because the blood pressure constantly fluctuates, a result determined in this way is more reliable than one produced by a single measurement.
- When you select the 3 measurements, the MAM-symbol ②① appears in the display.
- 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.

2. 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 patient's 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.

3. Taking a Blood Pressure Measurement

1. Select standard (single measurement) or MAM mode (automatic double measurement): see details in chapter «1.».
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 measurement is performed during the inflation. The inflation speed may vary, this is a normal occurrence.
5. During the measurement, the pulse indicator ⑧ flashes in the display.
7. The result, comprising the systolic ⑭ and the diastolic ⑮ blood pressure and the pulse rate ⑯ 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.).



You can stop the measurement at any time by pressing the ON/OFF button ① (e.g. if you feel uneasy or an unpleasant pressure sensation).

How not to store a reading

As soon as the reading is displayed press and hold the ON/OFF button ① until «M» Stored Value ②④ is flashing. Confirm to delete the reading by pressing the Time button ⑩. «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 ⑰ points at the range within which the measured blood pressure value lies. The value is either within the normal (green), borderline (yellow), danger (orange, red) range. The classification corresponds to the following ranges defined by ACC, AHA 2017 Guidelines. Data in mmHg.

Range	Systolic		Diastolic	Recommendation
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1	blood pressure too high	≥ 130	or	≥ 80	Seek medical advice
2	blood pressure elevated	120 -130	and	< 80	Self-check
3	blood pressure optimum	< 120	and	< 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 Irregular Heartbeat Detection (IHD)

This symbol  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 Irregular Heartbeat Detection (IHD)

This device is an oscillometric blood pressure monitor that also analyses pulse irregularity during measurement. The device is clinically tested.

The Irregular Heartbeat Detection (IHD) 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.

4. Data Memory

This device automatically stores up to 99 measurement values for each of the 2 users.

Viewing the stored values

Press the M-button  briefly, when the device is switched off. The display first shows «M»  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.



Pay attention that the maximum memory capacity of 99 memories per user 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 ⑨ (the device must have been switched off beforehand) until «CL ALL» appears and then release the button. To permanently clear the memory, press the time button ⑩ while «CL ALL» is flashing. Individual values cannot be cleared.

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

5. Battery Indicator and Battery change

Low battery

When the batteries are approximately $\frac{3}{4}$ empty the battery symbol ⑫ 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 ⑫ 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 ④ 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 1.».

 The 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.

6. 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 AT 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

7. Bluetooth® Function

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/connect

NOTE

1. Wireless communication interference

This product operates in an unlicensed ISM band at 2.4 GHz. In the event this product is used near other wireless devices such as microwave and wireless LAN, which operate on the same frequency band as this product, there is a possibility that interference may occur. If interference occurs, stop the operation of the other devices or relocate this product away from other wireless devices before attempting to use it.

2. Medical Device Data System

The Bluetooth® of this monitor is a medical device data system (MDDS) as its only function is for transfer of records and no additional functions. The Bluetooth® is not active when the monitor is recording data or during blood pressure measurement. The monitor will not sound any alarm with or without Bluetooth®. The Bluetooth® is used only to transfer data from point A to point B. The App on your smart devices cannot be used to start or stop the monitor, nor update the firmware of monitor via Bluetooth®.

Bluetooth® Operations:

- Manually turn on Bluetooth®: Press Bluetooth/Time button ⑩ to activate Bluetooth®, Bluetooth® symbol 23 on display will blink.
- Automatically turn on Bluetooth®: Bluetooth® will activate automatically after a measurement. Bluetooth® symbol 23 on display will blink.
- Manually turn off Bluetooth®: Press ON/OFF button ① to turn off Bluetooth®.

Bluetooth® pairing & app setup

1. Turn on Bluetooth® manually to connect device to smartphone.
2. 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 23 blinking slowly: Bluetooth® is activated and waiting for connection.
- Bluetooth® symbol 23 not blinking: Bluetooth® connection established.
- Bluetooth® symbol 23 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 «8. Error Messages» for details

8. Error Messages

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

Error	Description	Potential cause and remedy
«Err 1»	Signal too weak	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.*
«Err 2» 22	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» 19	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. Please follow the procedure described in “Tube connection” to ensure the cuff is properly connected.
«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.*
	Bluetooth® symbol 23 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 retry 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.

9. Maintenance, Service, and Disposal

Maintenance

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

Description.

- Remove the batteries from the device if the device will not be used for an extended period.



Precaution: Storing the device disuse 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.

Cleaning

The device can be cleaned prior to disinfection, or when necessary (for example between uses by different patients).

Device

Use a soft cloth, dry or wet with a mild detergent, to gently wipe the exterior of the device remove dusts or stains.

Cuff

Spots on the cuff can be removed carefully with a damp cloth and soapsuds.



Precaution:

- The cuff must not be washed in a dishwasher, clothes washer or submerged in water.

Service & Calibration

We recommend this device is tested by trained personnel of Microlife distributor for accuracy every 2 years. Please contact your local Microlife Service to arrange the test.



Precaution: The device and accessories can only be serviced (tested & calibrated) by a trained personnel qualified for servicing Microlife products. DO NOT attempt to service or calibrate the device and accessories yourself.

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 .

How to contact us

Distributed by

Microlife USA, Inc.

1617 Gulf to Bay Blvd.

Clearwater, FL 33755

Toll Free Help Line: 1-800-568-4147

Email: custserv@microlifeusa.com

www.microlifeusa.com

11. Technical Specifications

Operating conditions: 10 - 40 °C / 50 - 104 °F

15 - 90 % relative maximum humidity 70KPa -106KPa

Storage conditions: -20 - +55 °C / -4 - +131 °F

15 - 90 % relative maximum humidity

Weight: 385 g (including batteries)

Dimensions: 143 x 85 x 58 mm

Measuring procedure: oscillometric, corresponding to Korotkoff method: Phase I systolic, Phase V diastolic

Measurement range:

Sys: 60 - 225 mmHg

Dia: 40 - 200 mmHg

Pulse 40-199 beats per minute

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

Battery lifetime: approx. 920 measurements (using new batteries)

IP20: Protected against solid foreign particles with a diameter of more than 12.5 mm,
no protection against water

Reference to standards: ISO 81060-2 ; IEC 60601-1; IEC 80601-2-30

IEC 60601-1-2 (EMC); IEC 60601-1-11;

Expected service life: Device: 5 years or 10000 measurements

Cuff: 2 years (when used 6 times a day)

*Years or measurements of use, whichever comes first

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

Technical alterations reserved.