BP3KY1-3B

Symbols & Definitions


Medical Device


Manufacturer


Caution


Type BF Applied part

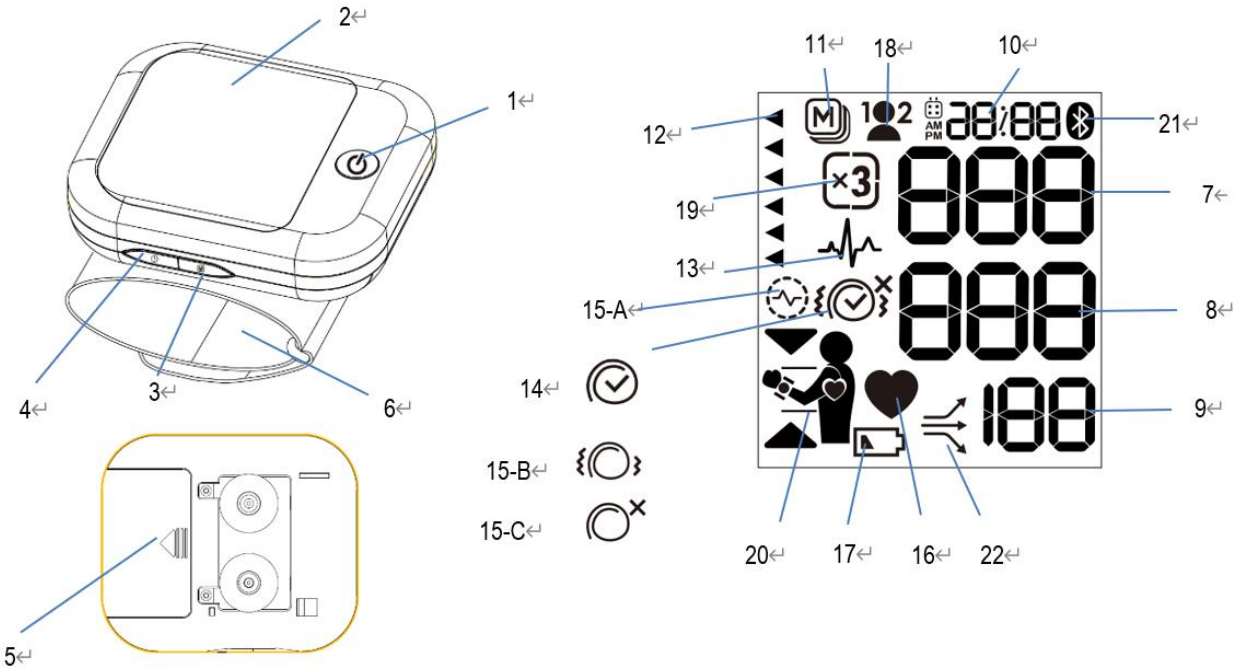
IP22 Protected against solid objects with a diameter of ≧12.5mm. ; Protected against vertically falling water drops when enclosure tilted up to 15°


Temperature limit


Humidity limitation


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.

Device Illustration



Device Illustration Legend

Device

1. ON/OFF button
2. Display
3. M-button (memory)
4. Time Button
5. Battery Compartment
6. Cuff

Display

7. Systolic Value
8. Diastolic Value
9. Pulse Rate
10. 10 Date/Time
11. 11 Stored Value
12. Traffic Light Indicator
13. Irregular Heartbeat (IHB) Symbol
14. 14 Cuff Fit OK

15-A: Cuff Signal Indicator «**ERR 1**»
15-B: Arm Movement Indicator «Err 2»
15-C: Cuff Pressure Check «Err 3»
15-D: Suboptimal Cuff Fit
16. Pulse Indicator
17. Battery Display
18. User Indicator
19. MAM Mode
20 Wrist Position Indicator
21 Active Bluetooth®
22 Average Indicator «MyCheck»

Important Information

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

Intended Purpose

A device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist for a circumference range from 13.5 to 21.5cm.
The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.
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).

Intended User, Patient, and Use Environment

This device is only intended to be used by user on patients in environments described in this section.

- The device is intended to be used by patients (self-measurement) or on a third person in a home healthcare environment (such as general household use).
- The device is intended to be operated by adult users with the vision and motor functions as well as the literacy and basic educations capable of understanding the content of this instructions for use and operating general household electrical appliances.
- The intended patients are normotensive and hypertensive adults and adolescents (aged 12 years or older) of the general population.

Indication & Clinical Benefits

This device is suitable for use for the following conditions and clinical benefits described in this section.

- The device is intended to measure human brachial blood pressure non-invasively for monitoring of the systolic and diastolic pressures, to support the diagnosis medical conditions or diseases related to blood pressure, including:
  - Diagnosis 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

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

- The device is not intended for measuring blood pressure in pediatric patients of age younger than 12 years old (children, infant, or neonates).
- Presence of significant cardiac arrhythmia during measurement may interfere with blood pressure measurement and affect the reliability of blood pressure readings. Consult with your doctor about whether the device is suitable for use in this case.
- The device is not intended for measuring blood pressure in adults with conditions of diabetes, pregnancy, or pre-eclampsia.
- The device measures blood pressure using pressured cuff over wrist. If the measuring wrist suffers from injuries (for example open wounds) or under conditions or treatments (for example intravenous drip) making it unsuitable for surface contact or pressurization of the arm, DO NOT use the device, to avoid worsening of the injuries or conditions.
- Patient motions during measurement may interfere with the measurement process and influence results. Avoid taking measurements of patients with conditions, diseases, and susceptible to environment conditions that lead to incontrollable motions (e.g. trembling or shivering) and inability to communicate clearly (for example children and unconscious patients).
- The device uses oscillometric method to determine blood pressure, and requires the measured arm with normal perfusion. The device is not intended to be used on a wrist with restricted or impaired blood circulation. Consult with your doctor if you severer perfusion or blood disorders before using the device.
- Avoid taking measurement on the arm on the side of a mastectomy or lymph node clearance.
- The device is not intended to measure pulse rate to check the frequency of pacemaker.
- DO NOT use this device in a moving vehicle (for example in a car or on an aircraft).

Side Effects

Use of the device may be accompanied by minor side effects.

- In some cases, slight bruising may result after measurement due to pressurization of the wrist.

Warning

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

- 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.
- DO NOT change the patient medication and treatment based the result of one or multiple measurements. Treatment and medication changes should be prescribed only by a medical professional.
- Inspect the device, cuff, and other parts for damage. DO NOT use the device, cuff or parts if they appear damaged or operating abnormally.
- Blood flow of the arm is temporarily interrupted during measurement. Extended interruption of blood flow reduces peripheral circulation and may cause tissue injury. Beware of signs (for example tissue discoloration) of impeded peripheral circulation if taking measurements continuously or for an extended period of time.
- Prolonged exposure of the wrist to cuff pressure will reduce peripheral perfusion and may lead to injury. Avoid situations of extended cuff pressurization beyond normal measurements. In the case of abnormally long pressurization, abort the measurement or loose the cuff to depressurize the cuff.
- DO NOT use this device in oxygen rich environment or near flammable gas.
- The device is not water resistant or waterproof. Do not spill or immerse the device in water or other liquids.
- 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.
- Keep the device away from children and people incapable of operating the device. Beware of the risks of accidental ingestion of small parts of this device. DO NOT let children operate the device alone.
- DO NOT use this device with other medical electrical (ME) equipment simultaneously. This may cause device malfunction or measurement inaccuracies.
- DO NOT use this device in proximity of equipment that may cause electromagnetic disturbance (EMD), such as high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, and computerized tomography (CT) scanners. This may cause device malfunction and measurement inaccuracies.
- 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 results in device malfunction and the safety of usage.
- In case of repeated or extended measurements, loosen the cuff and rest the arm for at least 1 minute to restore perfusion before taking another measurement.

Caution

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

- 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 at wrist. Do not measure other sites because the reading does not reflect your blood pressure accurately.
- Overly frequent measurement within a short time (e.g. 5 – 10 minutes) may reduce peripheral perfusion and cause injury. After a measurement is completed, loosen the cuff and rest the wrist for a few minutes to restore limb perfusion, before taking another measurement.
- 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
- 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.
- 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.

Electromagnetic Compatibility Information

- This device is compliant with IEC 60601-1-2 Electromagnetic Disturbances standard.
- This device is not certified to be used in vicinity of medical equipment including high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) and computerized tomography (CT) instruments.
- DO NOT use this device close to strong electromagnetic fields and portable radio frequency communication devices (for example microwave oven and mobile devices). Keep a minimum distance of 0.3 m from such devices when using this device.
- This device features Bluetooth(R) that emits radio frequency (RF) in the 2.4GHz band. Do not use this device in locations where RF is restricted (for example, on a aircraft). Turn off the device

and remove the power source if necessary when in RF restricted locations.

- This device operates in an unlicensed ISM bad at 2.4GHz. In case this device is used near other wireless devices (for example wireless LAN) which operates on the same frequency band as this device, there is a possibility that interference may occur. If interference occurs, stop the operation of other devices or relocate this product away from other wireless devices before using it.

MR Unsafe

Data Transmission

- This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals. Turn off the Bluetooth® feature in this monitor, remove batteries when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.

FCC

- 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. Changes or modifications to the product are not approved by Microlife USA and could void the user's authority to operate the equipment under FCC jurisdiction.
- 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: 1) Reorient or relocate the receiving antenna. 2) Increase the separation between the equipment and receiver. 3) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. 4) Consult the dealer or an experienced radio/TV technician for help.

- This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance.

Important Information about Blood Pressure – for Patients

- This device is clinically validated for blood pressure measurement in adults and adolescents.
- Blood pressure is a dynamic vital sign and its level is influenced by the patient and the environment during the measurement. Individual blood pressure reading can be affected by measurement site, patient's body position, and patient's physiological conditions and health (e.g. cardiovascular or renal diseases, trembling, and pregnancy). It's recommended to always take measurements at the same measurement site with the same body position, under similar physiological conditions at the same time of the day, to ensure the reliability of the blood pressure values.
- The measurement result of the device is not a diagnosis, and a single measurement is not representative of the health condition. Consult with your doctor for any questions related to the diagnosis and treatment of your conditions or disease. 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 and the white coat effect may lead to different values.
- If you are entering pregnancy, you should monitor your blood pressure regularly as it can change drastically throughout the pregnancy.

Important Information about Irregular Heart Beat (IHB) - for Patients

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

Important Information about Irregular Heart Beat (IHB) – for Doctors

- Irregular Heartbeat (IHB) is defined a beat-to-beat interval that is 25% faster or 25% slower than the average pulse interval detected during the measurement.

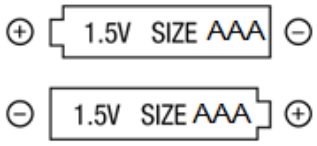
Adverse Events & Reporting

- In case of an adverse event, please contact your local Microlife distributor, the manufacturer, and the competent authority of the Member State.

Device Preparations before Using

Inserting the batteries

After you have unpacked your device, first insert the batteries. The battery compartment 5 is on the bottom of the device. Insert the batteries (2 x 1.5 V, size AAA), thereby observing the indicated polarity.



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

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

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-button3. to confirm and then set the month, press the time button4.
2. Press the M-button to set the month. Press the time button to confirm and then set the day.
3. Follow the instructions above to set the day, hour and minutes.
4. Once you have set the minutes and pressed the time button, the date and time are set and the time is displayed.

5. If you want to change the date and time, press and hold the time button down for approx. 3 seconds to enter setting menu. Press time button twice to skip MAM mode/ Wrist Position Indicator setting until the year number starts to flash. Now you can enter the new values as described above.

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

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 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, Press and Hold the TIME button till 3 to 4 second, the MAM mode-symbol & “OFF” appears in the display. Press the Memory button to select ON or OFF, then press TIME button to confirm. Then, to bypass setting Position Indicator and Time and date, press TIME button.
- The bottom, right hand section of the display shows a 1 or 2 or 3 to indicated 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 measurements are taken.
- Do not remove the cuff between measurements.
- If one of the individual measurements was questionable, an additional one is automatically taken.

Selecting Wrist Position Indicator

Keeping the wrist at the same height level as heart during measurement is one of the most important facts to use a wrist blood pressure monitor. The Incorrect wrist position might lead to an inaccurate result. Follow the instruction of the Wrist Position Indicator to make sure the wrist height is the same level as heart.

After the MAM mode is selected, the Wrist Position Indicator ON/OFF selection will appear on the display. Press the M-button to select ON or OFF the Wrist Position Indicator. Press the Time Button to confirm and then press Time button to bypass the date and time setting.

There are a height detection plus two small hearts to help the user determine if the monitor is at the correct height.

When the monitor is at higher position relative to your heart, a downward arrow appears to remind you to lower the wrist slowly until two heart symbols appear. Conversely, a upward arrow appears when your wrist height is lower to heart level and raise the wrist higher as indication.

Adjust your wrist to correct height level and keep about 2 sec, the monitor will start measurement automatically.

Please retain this wrist height during measurement, and do not move even in the

interval time of MAM mode until the result displayed on the LCD.
If the user doesn't adjust the wrist at correct heart level in time (about 2 sec), the monitor will still start measurement with upward/downward arrows as an indication. However, we recommend to repeat the measurement to make sure getting an accurate result.

⚠ **Caution:** The Wrist Position Check is only an approximate indication and may not be accurate for all users because of differences in individual physique and size. If you are unable to make your seat or table adjustments and find the height of wrist is not same as your heart level obviously, please turn off the Wrist Position Check feature and position your wrist at heart level by yourself.

Setting the user

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

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

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

Patient Preparations of Measurement

⚠Caution**:** Follow these steps to obtain reliable blood pressure reading. Lack of rest, incorrect body posture, arm position, and improper cuff fitting may lead to inaccurate blood pressure reading!

Prior to Taking a Measurement

- 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.
- Avoid exercising, bathing, eating, drinking, and smoking, 30 minutes prior to measurement.
- Empty your bladder prior to measurement.
- Sit down on a back-supported chair, keep the feet flat on the floor, and do not cross your legs.
- Sit down on a Relax for at least 5 minutes before taking measurement.

Taking a Blood Pressure Measurement

Starting measurement

Select standard (single measurement) or MAM mode (automatic triple measurement): see details in chapter«1».

Press the ON/OFF button 1 to start the measurement.

After Wrist Position Indicator checked (see details in chapter«1»), 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.

1. The cuff fit OK 14 on the display indicates that the cuff is perfectly placed.
2. The measurement is performed during the inflation. The inflation speed may vary, this is a normal occurrence.
3. During the measurement, the pulse indicator 16 flashes in the display.
4. The result, comprising the systolic 7 and the diastolic 8 blood pressure and the pulse rate 9 is displayed. Note also the explanations on further display symbols in this booklet.
5. Remove and switch off the monitor and enter the result in the enclosed blood pressure pass. (The monitor does switch off automatically after approx. 1 min.).

You can stop the measurement at any time by pressing the ON/OFF button (e.g. if you feel uneasy or an unpleasant pres- sure sensatio

⚠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!

Aborting measurement (Emergency Stop)

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

How not to store a reading

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

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

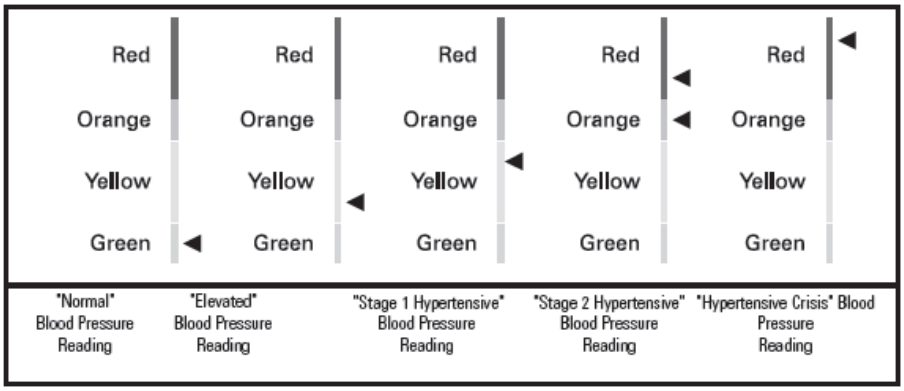
How do I evaluate my blood pressure?

The triangle on the left-hand edge of the display points at the range within which the measured blood pressure value lies. The colored indicator on the left-hand edge of the display has been designed to provide a quick visual representation of your blood pressure. Once a measurement has been completed, a black triangle will display onscreen next to the colored hypertension indicator. The height of the black triangle will show if the measurement is within the normal (green), borderline (yellow/orange) or danger (red) range.

This classification is based on standards established by the American Heart Association (AHA) and American College of Cardiology (ACC) in 2017.

If the black triangle is in the:

- green zone, your measurement is "Normal."
- lower yellow zone, it is "Elevated."
- upper yellow zone, it is "Stage 1 Hypertensive."
- orange zone, it is "Stage 2 Hypertensive."
- lower red zone, it is "Stage 2 Hypertensive."
- upper red zone, it is "Hypertensive Crisis."0



Caution: The blood pressure classification is a general guide of blood pressure levels, but diagnosis of hypertension should be made by a healthcare profession based on specific conditions of the patient. Consult with your doctor for questions about the interpretation and classification of your blood pressure values.

Average Indicator (My Check)

This symbol (21) indicates after each measurement, if the most recent measured value lies below, above or on the same level as your stored averages value

1. If the measured Systole or Diastole is more than 5mmHg higher than the stored average, the arrow shows upwards.
2. If the measured Systole or Diastole is more than 5mmHg lower than the stored average, the arrow shows downwards

3. If the measured Systole and Diastole's difference between the stored average are within 5mmHg, the arrow shows straight on.
4. If the measured Systole and Diastole values are trending in different directions from the stored average, the Systole value flashes first with the up or down arrow for two seconds. Then, the diastole value flashes with the up or down arrow for two seconds.

Appearance of the Irregular Heartbeat (IHB)

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

Caution: When IHB is detected, the result may deviate from your normal blood pressure. It is recommended to repeat the measurement.

Review Measurement in Memory

This model is designed for two users and can store up to 99 blood pressure readings for each user. Select either user 1 or 2 by pressing the time button.

Viewing the average of the last 28 days

Press the M-button 3 again. The display first shows «M» 11 and «28A», which stands for the average measurement values of the last 28 days.

Viewing the stored single values

Pressing the M-button 3 again, allows you to see the last performed measurement. The display first shows «M» 26 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.

Memory full

Pay attention that the maximum memory capacity of 99 memo- ries 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

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 time button while «**CL ALL**» is flashing. Individual values cannot be cleared.

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

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/technologies/connect

Bluetooth® pairing & app setup

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

Please set the date & time on your blood pressure monitor before pairing to your phone.

Note:

The App will not be able to receive readings unless the date & time have been properly set on your blood pressure monitor.

Bluetooth® operations

- Automatically turn on Bluetooth®: Bluetooth® will activate automatically after a measurement. Bluetooth® symbol on display will blink.
- Automatically turn off Bluetooth®: Bluetooth® will turn off automatically after 2 minutes if a smartphone does not connect to the device.
- Manually turn on Bluetooth®: To manually activate the Bluetooth® on your monitor, press POWER button for 4 seconds until the Bluetooth® icon starts blinking.
- Manually turn off Bluetooth®: Press POWER button to turn off Bluetooth®.

Bluetooth® status

- Bluetooth® symbol blinking slowly: Bluetooth® is activated and waiting for connection.
- Bluetooth® symbol not blinking: Bluetooth® connection established.
- Bluetooth® symbol blinking rapidly: Bluetooth® connection error.
- In case of Bluetooth® connection error, turn off device Bluetooth®, wait for a minute, then re-try Bluetooth® connection. Refer to chapter «10. Error messages» for details.

Battery Indicator and Battery Replacement

Low battery

When the batteries are approximately 25% left, the battery symbol will flash as soon as the device is switched on (partly filled battery displayed). Although the device will continue to measure reliably, it's recommended to replace the batteries as soon as possible.

Flat battery and replacement

When the batteries are flat, the battery symbol 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 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.

Spare Parts

Batteries

- Use 2 new 1.5 V, size AAA alkaline batteries. Do not use expired batteries or mix new and used batteries together.
- Inserting the batteries in incorrect polarity orientations may lead to short circuiting and damage the device!
- Remove batteries if the device is not going to be used for a prolonged period.
- The device can be used with rechargeable batteries. Rechargeable batteries cannot be charged in the device. Batteries must be removed and recharged when the flat battery symbol appears.

Error Messages & Troubleshooting

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

Error	Description	Potential cause and remedy
«ERR 1» 	Signal too weak	The pulse signals on the cuff are too weak. Re- position the cuff and repeat the measurement.*
«ERR 2» 	Error signal	During the measurement, error signals were detected by the cuff, caused for instance by movement or muscle tension. Repeat the measurement, keeping your arm still.
«ERR 3» 	No pressure in the cuff	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Check that the cuff is correctly connected and is not too loose. Replace the batteries if necessary. Repeat the measurement.
«ERR 5»	Abnormal result	The measuring signals are inaccurate and no result can therefore be displayed. Or This is low priority technical alarm. The measurement value is out of measuring range . Read through the checklist for taking reliable measurements and then repeat the measurement. *
«ERR 21»	Wrist Position Indicator error	Possibly some problem occurs on the sensor for Wrist Position Indicator. Turn off and remove the battery then repeat measurement. If still displayed, please contact your local Microlife-Service.
«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.

Maintenance, Service, and Disposal

Maintenance

When not in use:

- 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.

⚠**Caution:** 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 when necessary (e.g. between uses by different patents).
Use a soft cloth, dry or wet with detergent, to gently wipe the exterior of the device remove dusts or stains.

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 (see foreword).

⚠Caution**:** 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 (Waste Electrical and Electronic Equipment)

This device is an electronic device. The device and batteries must be disposed of in accordance with the locally applicable regulations, not with domestic or commercial waste.

Guarantee

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

- This device is covered by a guarantee of 10,000 measurements or 5 years, whichever occurs earlier, from the date of purchase.
- 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.

Technical Specification

Product Name: Digital Non-invasive Blood Pressure Monitors for Home Use Series

Product Description: Wrist automatic blood pressure monitor

Model Number: BP3KY1-3B

Operation Conditions: 10 – 40℃, 15 – 90% relative humidity, 700hPa – 1060hPa

Storage & Transport Conditions: -20 - +55℃,15 – 90% relative humidity

Weight: 149 ± 5 g (including batteries)

Dimensions: 87 x 74 x 23.8 mm

Cuff size: 13.5 - 21.5 cm (5.25 - 8.5 inches)

Measurement Method: Oscillometric method, corresponds to Korotkoff method:

Phase I systolic / Phase V diastolic

Pressure Resolution: 1mmHg

Cuff Pressure Display Range: 0 – 299 mmHg

Measurement Ranges:

Systole: 60 – 255 mmHg

Diastole: 40 – 200 mmHg

Pulse: 40 – 199 beats / minute

Accuracy – Static Pressure: ±3 mmHg

Accuracy - Pulse: ±5% of readout value

Power Source: 2 x 1.5V LR3(AAA) batteries

IP Rating: IP22: Protected against solid objects up to 12.5 mm; Protected against vertically falling water drops when enclosure tilted up to 15°

Applied Part Type Reference: Type BF 

Service Life - Device: 10,000 measurements or 5 years, whichever occurs earlier

Battery Life: Approx. 320 measurements (new Alkaline LR3 batteries)

Compliant Standards:

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

Back Cover

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Made in China

IFU BP3KY1-3B- EN V1-2508