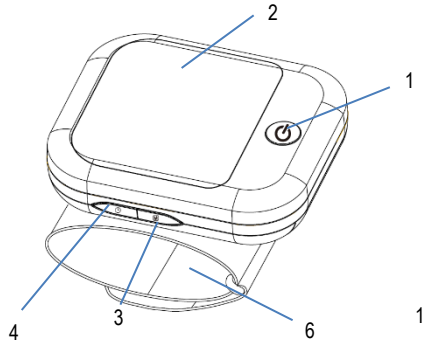
BP3KY1-3B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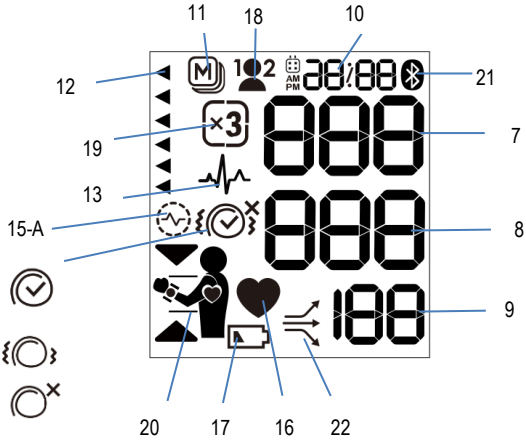
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15-A
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15-B
15-C
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22

BP3KY1-3B

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 Date/Time
11 Stored Value
12 Traffic Light Indicator
13 Irregular Heartbeat (IHB) Symbol
14 Cuff Fit OK
15
-A: Cuff Signal Indicator«**ERR 1**»
-B: Arm Movement Indicator «**ERR 2**»
-C: Cuff Pressure Check «**ERR 3**»
16 Pulse Indicator
17 Battery Display
18 User Indicator
19 MAM Mode
20 Wrist Position Indicator
21 Active Bluetooth®
22 Average Indicator «MyCheck»

Type BF applied part

Keep dry

Read the instructions carefully before using this device.

Intended use:
The module is 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 running the APP. The memory data can be transferred to the smart phone via Bluetooth.

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.micro- life.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.

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.

FCC ID: U7I-BP3KY1-3B

Table of Contents

1 Using the Device for the First Time

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.

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.

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.

Detection
Start

Postion
Too High

Postion
Too Low

- 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.

Postion
Correct

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.

2. Checklist for Taking a Reliable Measurement

1. Avoid activity, eating or smoking immediately before the measurement.
2. 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. Adjust your seat height to make sure the distance between your seat and the top of the table is within 30 ± 5 cm (12 ± 2 inches).
3. Always measure in a sitting position and on the same wrist. Use the wrist which usually shows higher blood pressure values.
4. Remove any items of clothing and your watch, for example, so that your wrist is free.
5. Always ensure that the cuff is positioned correctly, as shown in the pictures illustrated on the short instruction card.
6. Fit the cuff comfortably but not too tight. The cuff will cover a wrist circumference of 13.5 – 21.5 cm (5.25 – 8.5 inches).

Support your arm in a relaxed position and ensure that the **device is at the same height as your heart.**

3. Taking a Blood Pressure Measurement

1. Select standard (single measurement) or MAM mode (automatic triple measurement): see details in chapter«1».
2. Press the ON/OFF button 1 to start the measurement.
3. 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 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**» 12 is flashing. Confirm to delete the reading by pressing the time button 4.

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

How do I evaluate my blood pressure?

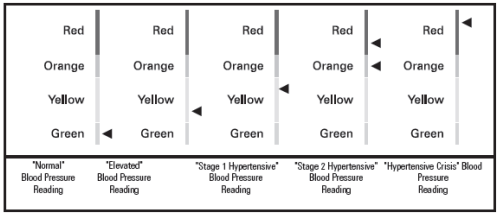
The triangle on the left-hand edge of the display 12 points at the range within which the measured blood pressure value lies. The colored indicator on the left-hand edge of the display has been designed to provide a quick visual representation of your blood pressure. Once a measurement has been completed, 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



Average Indicator «MyCheck»

This symbol 22 indicates after each measurement, if the most recent measured value lies below, above or on the same level as your stored average value (see also chapter «4. Data memory»).

- If the measured Systole or Diastole is more than 5mmHg higher than the stored average, the arrow shows upwards.
- If the measured Systole or Diastole is more than 5mmHg lower than the stored average, the arrow shows down- wards.
- If the measured Systole and Diastole do not differ by more than 5mmHg from the stored average, the arrow shows straight on.
- If the measured systole and diastole differ in different direc- tions from the stored average, this is indicated first with the systole figure flashing, together with the up or down arrow for two seconds. Thereafter, the diastole figure flashes with the arrow pointing up or down for two seconds.

Appearance of the Irregular Heartbeat (IHB) Symbol

This symbol 13 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 measure- ments 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 IHB symbol

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

The IHB 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 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.

5. Battery Indicator and Battery change

Low battery

When the batteries are approximately ¾ empty the battery symbol 17 will flash as soon as the device is switched on (partly filled battery displayed). Although the device will continue to measure reliably, you should obtain replacement batteries.

Flat battery – replacement

When the batteries are flat, the battery symbol 17 will flash as soon as the device is switched on (flat battery displayed). You cannot take any further measurements and must replace the batteries.

1. Open the battery compartment 5 by pulling off the cap.
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 memory retains all values although date and time must be reset – the year number therefore flashes automatically after the batteries are replaced.

(after MAM mode and Wrist Position Indicator setting).

Which batteries and which procedure?

☞ Use 2 new, long-life 1.5 V, size AAA 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. Bluetooth® Function

Please download the Microlife Connected Health App

(referred to as App in this document) from Apple's App Store® or Google Play® before pairing your devices.

Bluetooth® operations

- Manually turn on Bluetooth®: press ON/OFF for 4 seconds until the Bluetooth symbol starts flashing.
- Automatically turn on Bluetooth®: Bluetooth® will activate automatically after a measurement. Bluetooth® symbol on display will blink.
- Manually turn off Bluetooth®: press ON/OFF button to turn off Bluetooth®.
- Automatically turn off Bluetooth®: Bluetooth® will turn off automatically after 2 minutes if a smartphone does not connect to the device.

Bluetooth® pairing & 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. Turn on Bluetooth® manually to connect device to smartphone.
3. When smartphone finds the device, the smartphone will show a message to pair with the device. Confirm on smartphone to complete pairing. Cancel to abort pairing.
4. After pairing, the app will show a message to setup the device user selection (1 or 2) to the app user profile. Confirm to proceed with setup. Cancel to abort setup (if user selection is incorrect).
5. After setup, the device will automatically exchange measurement data and date/time settings with the app. Bluetooth® turns off automatically after data exchange.

Bluetooth® status

- Bluetooth® symbol 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 section 7. *Error messages* for details.

7. 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. Reposition 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. Read through the checklist for performing reliable measurements and then repeat the measurement.*
«**ERR 6**»	MAM Mode error	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.*
«**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.*
	Problem with Bluetooth® connection	If any problem occurs with the Bluetooth® connection, the Bluetooth® icon blinks rapidly for approximately 10 seconds. To solve the problem, please visit www.microlife.com/connect.

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

☞ If you think the results are unusual, please read through the information in «Section 1.» carefully.

8. Safety, Care, Accuracy Test and Disposal

Safety and protection

Follow instructions for use. This document provides important product operation and safety information regarding this device. Please read this document thoroughly before using the device and keep for future reference.

This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.

This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in the «Technical Specifications» section.

Protect it from:

- water and moisture
- extreme temperatures
- impact and dropping
- contamination and dust
- direct sunlight
- heat and cold

The cuffs are sensitive and must be handled with care.

Only pump up the cuff once fitted.

Do not use this device close to strong electromagnetic fields such as mobile telephones or radio installations. Keep a minimum distance of 3.3 m from such devices when using this device.

Do not use this device if you think it is damaged or notice anything unusual.

Never open this device.

If the device is not going to be used for a prolonged period the batteries should be removed.

Read the additional safety information provided within the individual sections of this instruction manual.

The measurement results given by this device is not a diagnosis. It is not replacing the need for the consultation of a physician, especially if not matching the patient's symptoms. Do not rely on the measurement result only, always consider other potentially occurring symptoms and the patient's feedback. Calling a doctor or an ambulance is advised if needed.

Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed. Be aware of the risk of strangulation in case this device is supplied with cables or tubes.

Device care

Clean the device only with a soft, dry cloth.

Cleaning the cuff

Carefully remove any marks on the cuff with a damp cloth and mild detergent.

Accuracy test

We recommend this device is tested for accuracy every 2 years or

after mechanical impact (e.g. being dropped). Please contact your local Microlife-Service to arrange the test (see foreword).

Disposal

Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

9. 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, cuff 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.

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

10. Technical Specifications

Operating conditions:	10 - 40 °C / 50 - 104 °F 15 - 90 % relative maximum humidity
Storage conditions:	-20 - +55 °C / -4 - +131 °F 15 - 90 % relative maximum 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)
Measuring procedure:	oscillometric, corresponding to Korotkoff method: Phase I systolic, Phase V diastolic
Measurement range:	SYS: 60-255 mmHg, DIA: 40-200 mmHg, 40 - 199 beats per minute – pulse
Cuff pressure display range:	0 - 299 mmHg
Resolution:	1 mmHg
Static accuracy:	pressure within ± 3 mmHg
Pulse accuracy:	± 5 % of the readout value
Communication:	Bluetooth® 4.2
Compatibility:	iOS: iOS 10.0 or newer Android: Android 5 or newer
Voltage source:	2 x 1.5 V alkaline batteries; size AAA
IP Class:	IP22
Reference to standards:	IEC 60601-1; IEC 60601-1-2 (EMC); IEC 60601-1-11
Expected service life:	Device: 5 years or 10000 measurements Cuff: 2 years or 5000 measurements

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