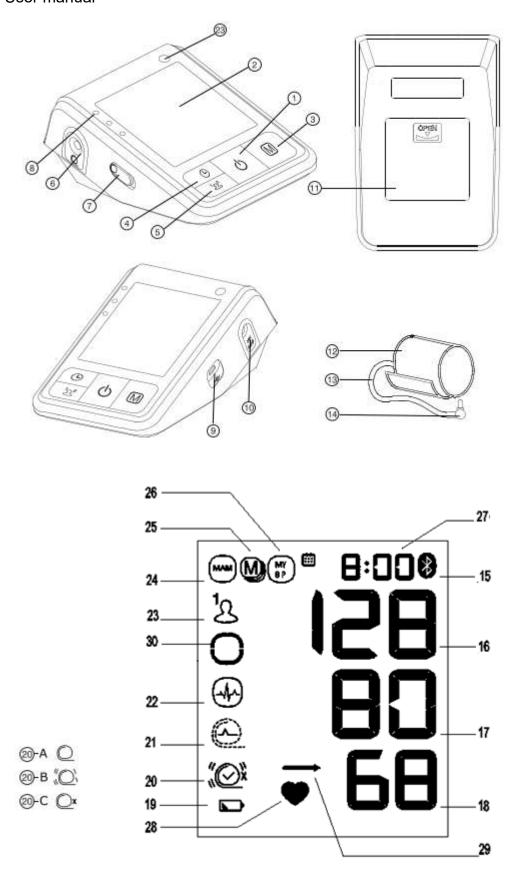
# B6 Advanced Connect User manual



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Read the instructions carefully before using this device.



Type BF applied part



# **Important Product and Safety Information**



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.

# **Indications for Use**

The Upper Arm Blood Pressure Monitor, Model BP3KV1-5W 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 upper arm for a circumference range from 22 to 42cm. 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.

# WARNING – Potentially hazardous situation that if not avoided may result in serious injury or death.

- Self-measuring means monitoring, not diagnosis or treatment. Unusual values
  must always be discussed with your doctor. Under no circumstances should you
  independently alter the dosages of any drugs prescribed by your physician
- Consult your physician before using this device if any of the following or similar conditions are present: arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, preeclampsia, renal diseases. Motion during measurement, including trembling or shivering may affect the measurement.
- Though not for use with children under 12, ensure that any children around this
  device are supervised; some parts are small enough to be swallowed.

#### DO NOT:

- Use this device if you think it is damaged or anything appears unusual (e.g. sporadic operation, open packaging upon purchase).
- Use the displayed pulse for checking the frequency of heart pacemakers as this
  device is not suitable for this action.
- Open/modify this device; inaccuracy and/or harmful injury may result.
- Conduct many frequent measurements as this may result in harmful injury due to blood flow interference.
- Place the Cuff over a wound as this may cause further injury.

- Place and pressurize the Cuff over/near any present intravascular access or therapy, or arteriovenous shunt, as this may cause blood flow interference and result in harmful injury.
- Place and pressurize the Cuff over a limb near the side of a mastectomy as this may cause harmful injury.
- Use the Blood Pressure Monitor on a limb simultaneously with other medical equipment on the same limb due to possible interference with such medical equipment.
- Maintain pressure in the Cuff applied to the limb for a prolonged amount of time.
   Ensure that circulation in the limb is not impaired by checking circulation if prolonged/repeated exposure to pressure occurs.
- Service the device when being used or when power is supplied. When the device
  is not in use and power is removed, batteries may be replaced by the user. No
  other parts/components are accessible.



# CAUTION – Potentially hazardous situation that if not avoided may result in minor/moderate injury, property damage, and/or damage to the device

- This device contains sensitive electronics components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g., mobile telephones, microwave ovens). These can lead to temporary impairment of the measuring accuracy. Move the device to another location if interference is determined.
- When not using the Blood Pressure Monitor for extended lengths of time, remove the batteries to avoid potential battery leakage and damage to the monitor.
- When replacing the batteries, ensure all the batteries are replaced simultaneously to avoid battery damage and potential damage to the monitor.
   Microlife USA does not recommend using rechargeable batteries.
- To avoid inaccurate measurements and to lessen any discomfort from Cuff pressure, ensure the Cuff is placed correctly on the limb and fits correctly when snug (not tight), as indicated by markings with the Cuff.
- Consult your physician in cases of frequent irregular heartbeat detections.
- This Risk Indicator feature is provided in order to help you understand your
  potential blood pressure risk. However, this feature is neither a diagnosis nor a
  substitute for a medical examination. It is important to consult with your physician
  to determine your risk.

#### DO NOT:

- Drop this device or expose it to strong vibrations; sensitive components may be affected resulting in inaccuracies and/or operational issues.
- Use the Blood Pressure Monitor outside of its specified operation temperature and humidity rating, or if stored outside of its specified storage temperature and humidity rating. Avoid storage in direct sunlight.
- Use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading
- Use this device in a moving vehicle; inaccurate measurements may result. Only
  use this device in a home healthcare environment.
- Use third party accessories. Only use Microlife authorized accessories, such as cuffs or AC adapters, as those not approved for use with the device may provide inaccurate measurements, injury, and/or damage the device.

# **STANDARDS**

This medical device is compliant with:

- Medical device and non-invasive blood pressure monitor standards IEC 60601-1,
   IEC 60601-1-2, IEC 60601-1-11, and AAMI/ANSI/IEC 80601-2-30, and
- Electromagnetic standards IEC 60601-1-2, along with FCC Part 15, and
- Clinical Testing per standard ISO 81060-2:2013 was conducted on blood pressure device using the same measurement technology.

Please note: According to international standards, your monitor should be checked for accuracy every 2 years.

# **TYPE**

IP20: Protected against solid foreign objects of 12.5 mm diameter and greater.



# **Expected Life**

**Monitor 5 Years** 

Cuff 2 Years

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

#### **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.

# **Trademark Usage:**

Apple, the Apple logo, iPad, and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

Android and Google Play are both trademarks of Google Inc.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks in this Blood Pressure Monitor is under license. Other trademarks and trade names are those of their respective owners.

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# 1. Using the Device for the First Time

# Inserting the batteries

After you have unpacked your device, first insert the batteries. The battery compartment 11 is on the bottom of the device. Insert the batteries (4 x 1.5 V, size AA), thereby observing the indicated polarity.

# Setting the date and time

- 1. After the new batteries are fitted, the year number flashes in the display. You can set the year by pressing Memory button 3. To confirm and then set the month, press the time button 4.
- 2. Press memory button 3 to set the month. Press the time button 4 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. 7 8 seconds until the year number starts to flash. Now you can enter the new values as described above

# Selecting the correct cuff

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

Cuff size	for circumference of upper arm
S	<del>17 – 22 cm</del>
M	<del>22 – 32 cm</del>
<del>M-L</del>	<del>22 - 42 cm</del>
F	<del>32 – 42 cm</del>
L-XL	<del>32 – 52 cm</del>

Only use Microlife cuffs.

- Contact your local Microlife Service if the enclosed cuff 12 does not fit.
- Connect the cuff to the device by inserting the cuff connector 14 into the cuff socket 3 as far as it will go.

# Selecting the user

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

- →Select the intended user (User 1 or User 2) 23 by pressing the user button 5.
- →Before each measurement, ensure that the correct user is selected.

# Select the measuring mode: standard or MAM mode

Before each measurement, select standard (single measurement) or MAM mode (automatic double measurement). In MAM mode, 2 measurements are automatically taken in succession and the result is then automatically analysed and displayed. Because blood pressure constantly fluctuates, a result determined in this way is more reliable than a single measurement is performed.

- •When you select MAM mode, the MAM-symbol 24 appears in the display.
- •To select standard mode, slide the MAM switch 7 on the side of the device downwards to position «1» and to select MAM mode, slide this switch upwards to position «3».
- •The bottom, right hand section of the display shows a 1 or 2 to indicated which of the 2 measurements is currently being taken.
- •There is a break of 15 seconds between the measurements. A count down indicates the remaining time. The circle icon 30 will go circle also during interval 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.

# 2. Checklist for taking a reliable measurement

- 1. Avoid activity, eating or smoking immediately before the measurement.
- 2. Sit down for at least 5 minutes before the measurement and relax.
- 3. Always measure on the same arm (normally left). It is recommended that doctors perform double arm measurements on a patient first visit in order to determine which arm to measure in the future. The arm with the higher blood pressure should be measured.
- 4. 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.
- 5. 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 located 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

- Select standard (single measurement) or MAM (Automatic double measurements);
   see details in chapter «1».
- 2. Press the ON/OFF button 1, the backlight will be turn on and to start the measurement.
- 3. The cuff will now pump up automatically. Relax, do not move and do not tense your arm muscles until the measurement result is displayed. Breathe normally and do not talk.
- 4. The cuff fit check 20 on the display indicates that the cuff is perfectly placed. If the icon 20-A appears, the cuff is fitted suboptimally, but it is still ok to measure.
- 5. When the correct pressure is reached, the pumping stops and the pressure falls gradually. If the required pressure was not reached, the device will automatically pump some more air into the cuff.
- 6. During the measurement, the pulse indicator 28 flashes in the display.
- 7. The result, comprising the systolic 16 and the diastolic 17 blood pressure and the pulse rate 18, Cuff Fit Check 20 (and MyCheck 29) 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).
  - \* The monitor is specially tested for use in pregnancy and pre-eclampsia. When you detect unusual high readings in pregnancy, you should measure after a short while again (eg. 1 hour). If the reading is still too high, consult your doctor or gynecologist.

# **Manual Inflation**

In case of high systolic blood pressure (e.g. above 135mmHg), it can be an advantage to set the pressure individually, Press the ON/OFF button 1 after the monitor has been pumped up to a level of approx. 30 mmHg (shown on the display). Keep the button pressed until the pressure is about 40 mmHg above the expected systolic value – then release the button.

# How not to store a reading

As soon as the reading is displayed, press and hold the ON/OFF button 1 until «M» 25 is flashing. Confirm to delete the reading by pressing the Bluetooth/Time button 4.

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

# How do I evaluate my blood pressure?

The LED traffic light indicator on the left-hand side of the display 8 indicates within which range the measured blood pressure lies. The value is either within the optimum (green), elevated (yellow) or high (red) range. The classification corresponds to the following range defined by ACC, AHA 2017 Guidelines. Data in mmHg.

	Range	Systoli		Diastolic	Recommendation
		С			
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».

# Average Indicator « MyCheck »

This symbol 29 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 high 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 downwards.
- \* If the measured Systole and Diastole do not differ by more than 5mmHg from the stored average, the arrow straight on.
- \* If the measured systole and diastole differ in different direction from the stored average, this is indicated first with the systole figure flashing, together with the up or down arrow for the seconds, Thereafter, the diastole figure flashes with the arrow pointing up or down for two seconds.

# Appearance of the Irregular heartbeat Indicator

This irregular heartbeat indicator 22 is displayed, when pulse irregularities occurred during the measurement. If the symbol appears, it is recommended to select MAM Mode and repeat measurement to double confirm the blood pressure reading: see details in chapter «1»

The irregular heartbeat symbol indicates that certain pulse irregularities were detected during the measurement. In this case, the result may deviate from your normal basal 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 symbol

This instrument is an oscillometric blood pressure monitor device that also analyzes pulse frequency during measurement. The instrument is clinically tested. If pulse irregularities occur during measurement, the irregular heartbeat symbol is displayed after the measurement. If the symbol appears more frequently (e.g., several times per week on measurements performed daily) or if it suddenly appears more often than usual, we recommend the patient to seek medical advice.

The instrument 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. Select either user1 or 2 by pressing the user button 5

# Viewing the average of the last 28 days

Press the Memory button 3 briefly, when the device is switched off. The display first shows «M» 25 and previous «28A», which stands for the average of measurement values of the last 28 days.

\* Blood pressure readings with suboptimal cuff fit 20-A are not considered in the average value.

# Viewing the clinical blood pressure average « MyBP »

Press the M-button again, allows you to see the clinically relevant blood pressure average with MyBP ». The display first shows with 25 and with MyBP 26. This clinical blood pressure average is only shown when 12 clinically relevant measurement values in the last 28 days have been performed.

- \* Only measurement that were performed in the morning between (05:00-10:59) or in the evening (17:00-22:59)
- \* A maximum of 4 readings per day are considered (2 from the morning and 2 from the evening)
- \* Measurements performed in standard mode and in MAM-mode are considered in the average, when they have been performed during the right time of the day.
- \* Measurements performed in MAM-modes or single standard mode are both classed as single measurement for working out the «MyBP average».
- \* Blood pressure reading with suboptimal cuff fit 20-A are not considered in the average value.

# Viewing the stored single values

Pressing the M-button again, allows you to see the last performed measurement. The display first shows « M » 25 and a value, e.g. « M17 ».single values in memory. Pressing the M-button again displays the previous value. Pressing the M-button repeatedly enables you to move from on stored value to another.

\* Pay attention that the maximum memory capacity of 99 memories is not exceeded. When the 99 memory is full, the oldest value is automatically overwritten with the 100<sup>th</sup> 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 Memory button (the device must have been switched off beforehand) until «CL» appears and then release the button. To permanently clear the memory, press the Memory button while «CL» is flashing. Individual values cannot be cleared.

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

# 5. Battery Indicator and Battery change Low battery

When the batteries are approximately  $\frac{3}{4}$  empty the battery symbol 19 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 19 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 11 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 memory retains all values although date and time must be reset the year number therefore flashes automatically after the batteries are replaced.

# Which batteries and which procedure?

- \* Use 4 new, long-life 1.5 V, size AA alkaline batteries.
- \* Do not use batteries beyond their date of expiry.
- \* Remove batteries if the device is not going to be used for a prolonged period.

# Using rechargeable batteries

You can also operate this device using rechargeable batteries.

- \* Only use «NiMH» type reusable batteries.
- \* Batteries must be removed and recharged when the flat battery symbol appears.

  They should not remain inside the device as they may become damaged (total discharge as a result of low use of the device, even when switched off).
- \* Always remove the rechargeable batteries if you do not intend to use the device for a week or more.
- \* Batteries cannot be charged in the blood pressure monitor. Recharge batteries in an external charger and observe the information regarding charging, care and durability.

# 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 4 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: https://www.microlife.com/technologies/connect

#### **Bluetooth operations:**

The Bluetooth® icon indicator on your blood pressure monitor, located in the upper right portion of the screen, is designed to provide information about the connection between your device and the monitor. Please note the following:

- 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®.
- The Bluetooth® icon on your blood pressure monitor will flash initially when ready to connect with a device, and continue flashing for 2 minutes until a connection occurs.

The blood pressure monitor will also display "Id" and a 6-digit number to indicate the unique, monitor-specific MAC ID for the recognition of the monitor unit.

- Manually turn on Bluetooth: Press Bluetooth/Time button 4 to activate Bluetooth, Bluetooth symbol 15 on display will blink.
- Automatically turn on Bluetooth: Bluetooth will activate automatically after a measurement. Bluetoooth symbol 15 on display will blink.
- Manually turn off Bluetooth: Press ON/OFF button 1 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 on the foreground, not in the background.)
- 2. Turn on Bluetooth manually to connect device to smartphone.
- 3. Find the name and the unique MAC ID of blood pressure monitor in the pairing list displayed on your phone, check if MAC ID displayed on the monitor and on the phone are matching; if the name and MAC ID information are correct, select to proceed with the pairing, then Bluetooth® icon showed without blinking. If the name and MAC ID shown on the phone is not the same as displayed on the monitor, please abort the connection and make sure the correct monitor and phone are used.
- 4. For 1st pairing, both phone and monitor will show 6 digits "Passkey" before pairing. Make sure the numbers are the same between phone & monitor to avoid misconnection to wrong BT device. It will be paired automatically without Passkey from next connection. If the "Passkey" on the monitor and on the phone are not the same, the monitor maybe connected to an incorrect phone, and the pairing should be aborted.
- 5. After pairing, the App will show message to setup 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).
- 6. 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 15 blinking slowly: Bluetooth is activated and waiting for connection.
- Bluetooth symbol 15 not blinking: Bluetooth connection established.
- Bluetooth symbol 15 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 7 for details.

#### 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.

# 8. PC-Link Functions

This device can be used in conjunction with a personal computer (PC) running the Microlife Blood Pressure Analyser (BPA+) software. The memory data can be transferred to the PC by connecting the monitor via a cable.

If no download-voucher and cable is included download the BPA software from <a href="https://www.microlife.com/technologies/connect/bpaplus">www.microlife.com/technologies/connect/bpaplus</a> and use a Micro-USB cable.

# 9. 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	The pulse signals on the cuff are too weak.		
21	weak	Re-position the cuff and repeat the measurement.*		
«ERR 2»	BP Error signal	During the measurement, error signals were		
20-B		detected by the cuff, caused for instance by		
		movement or muscle tension. Repeat the		
		measurement, keeping your arm still.		
«ERR 3»	BM No	An adequate pressure cannot be generated in the		
20-C	pressure	cuff. A leak may have occurred. Check that the cuff		
	in the cuff	is correctly connected and is not too loose. Replace		
		the batteries if necessary. Repeat the measurement.		
«ERR 5» Abnormal		The measuring signals are inaccurate and no result		
	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.*		

Bluetooth symbol	Bluetooth connection error. Turn off the device Bluetooth and	
blinks rapidly.	close the App on the smartphone. Wait for 1 minute, open the	
	App on the smartphone and manually activate Bluetooth on	
	device, to re-try Bluetooth connection & data transfer.	
Bluetooth	Bluetooth is malfunctioning. Contact your local Microlife	
self-check error.	distributor.	
Pulse or cuff	The pressure in the cuff is too high (over 300	
Pressure too	mmHg) OR the pulse is too high (over 200 beats per	
high	minute). Relax for 5 minutes and repeat the	
	measurement.*	
Pulse too low	The pulse is too low (less than 40 beats per minute).	
	Repeat the measurement.*	
	blinks rapidly.  Bluetooth self-check error. Pulse or cuff Pressure too high	

<sup>\*</sup> Please 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 2» carefully.

# 10. Safety, Care, Accuracy Test and Disposal Safety and protection

- This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.
- This device comprises sensitive components and must be treated with caution.
   Observe the storage and operating conditions described in the «Technical Specifications» section.
- Protect it from:
- water and moisture
- extreme temperatures
- impact and dropping
- contamination and dust
- direct sunlight
- heat and cold
- The cuffs are sensitive and must be handled with care.
- Do not exchange or use any other kind of cuff or cuff connector for measuring with this device.
- Only pump up the cuff once fitted.
- Do not use this device close to strong electromagnetic fields such as mobile telephones or radio installation. Keep a minimum distance of 3.3m from such devices when using this device.
- No 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 spots on the cuff with a damp cloth and soapsuds. To avoid cross-infection, rub 70% Isopropyl alcohol on the surface of cuff for disinfection before using after another user.

**WARNING:** Do not wash the cuff in a washing machine or dishwasher!

# 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.

#### 11. Guarantee

This device is covered by a 5 year guarantee from the date of purchase. The guarantee is valid only on presentation of the guarantee card completed by the dealer (see back) confirming date of purchase or the receipt.

- Batteries and parts that become worn with use are not included.
- Opening or altering the device invalidates the guarantee.
- The guarantee does not cover damage caused by improper handling, discharged batteries, accidents or non-compliance with the operating instructions.

• The cuff has a functional guarantee (bladder tightness) for 2 years.

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

# 12. Technical Specifications

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

15 - 95 % relative maximum humidity

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

15 - 95 % relative maximum humidity

Weight: 415 g (including batteries)

Dimensions: 157.5 x 105 x 61.5 mm

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

Atmospheric pressure range: 70KPa -106KPa Transmission method: Bluetooth® Low Energy

Wireless communication: Frequency range: 2.4 GHz (2400 - 2483.5 MHz)

Modulation: GFSK

Effective radiated power: < 20 dBm

Compatibility: iOS: iOS 8.0 or newer Android: Android 4.4.2 or newer

Voltage source: 4 x 1.5 V alkaline batteries; size AA

Mains adapter DC 6V, 600 mA (optional)

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

IP Class: IP20

Reference to Standards: EN 1060-1 /-3 /-4; IEC 60601-1; IEC 60601-1-2 (EMC); IEC

60601-1-11

**Expected service life:** Device: 5 years or 10000 measurements

Accessories: 2 years

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

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# 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