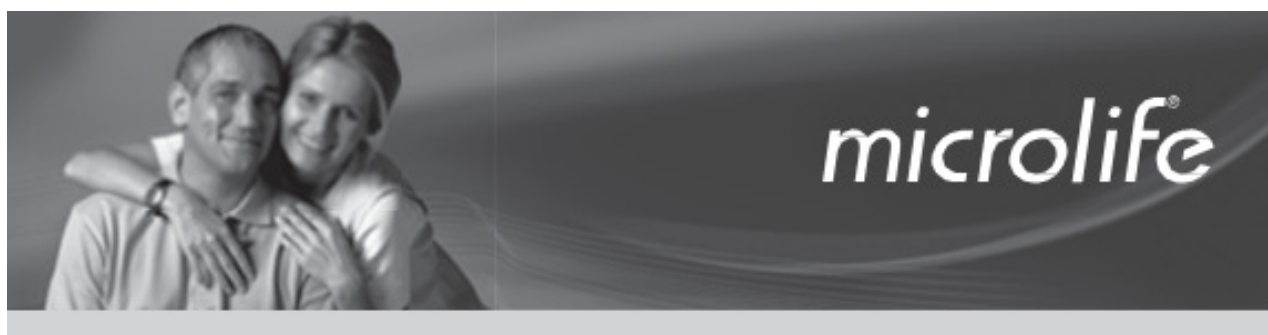




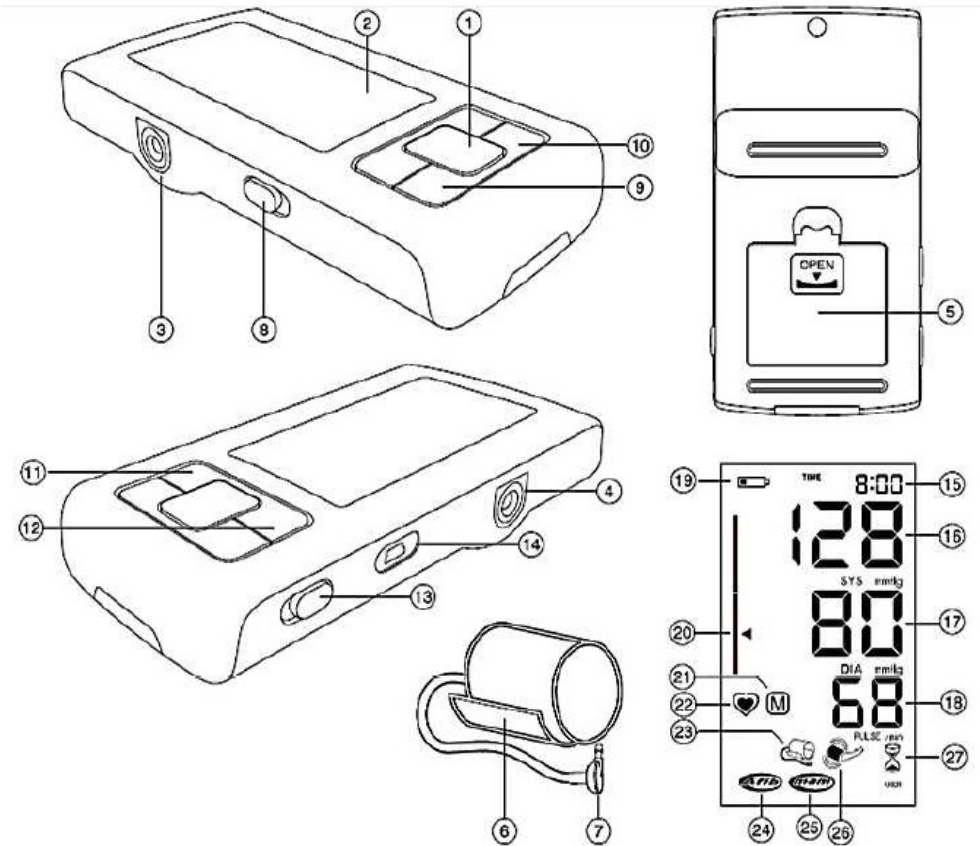
AFIB BT



microlife



Microlife AFIB BT – BP A6 BT



Microlife AFIB BT – BP A6 BT

Name of Purchaser⁺
⁺

_____+

Serial Number⁺

_____+

Date of Purchase ⁺
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Specialist Dealer⁺
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microlife[®]

Microlife AFIB BT – BP A6 BT

- (1) START/STOP Button
- (2) Display
- (3) Cuff Socket
- (4) Mains Adapter Socket
- (5) Battery Compartment
- (6) Cuff
- (7) Cuff Connector
- (8) AFIB/MAM Switch
- (9) Time Button
- (10) M-button (memory)
- (11) - «Backward» Button
- (12) + «Forward» Button
- (13) Lock Switch
- (14) USB Port

Display

- (15) Date/Time
- (16) Systolic Value
- (17) Diastolic Value
- (18) Pulse Rate
- (19) Battery Display
- (20) Traffic Light Display
- (21) Stored Value
- (22) Pulse Indicator
- (23) Cuff Check Indicator
- (24) Atrial Fibrillation Indicator (AFIB)
- (25) AFIB/MAM Mode
- (26) Arm Movement Indicator
- (27) MAM Interval Time



Read the instructions carefully before using this device



Type BF applied part

Microlife AFIB BT – BP A6 BT

Dear Customer,

Your new Microlife blood pressure monitor is a reliable medical device for taking measurements on the upper arm. It is simple to use, accurate and comes highly recommended for blood pressure monitoring in your home. This device was developed in collaboration with physicians and clinical tests carried out prove its measurement accuracy to be of a very high standard.*

Microlife AFIB detection is the world's leading digital blood pressure measurement technology for the detection of atrial fibrillation (AFIB) and hypertension. These are the two top risk factors of getting a stroke or heart disease in the future. It is important to detect AFIB and hypertension at an early stage, even though you may not experience any symptoms. Appropriate treatment will reduce your risk of suffering a stroke. For this reason, it is recommended that you visit your doctor when the device gives an AFIB signal during your blood pressure measurement. The AFIB algorithm of Microlife has been clinically investigated by several prominent clinical investigators and showed that the device detects patients with AFIB at a certainty of 97-100%. ^{1,2}

Please read through these instructions carefully so that you understand all functions and safety information. We want you to be happy with your Microlife product. If you have any questions, problems or want to order spare parts please contact Microlife Customer Service. Your dealer or pharmacy will be able to give you the address of the Microlife dealer in your country. Alternatively, visit the internet at www.microlife.com where you will find a wealth of invaluable information on our products.

Stay healthy – Microlife AG

**This device uses the same measuring technology as the award winning «BP 3BTO-A» model tested according to the British Hypertension Society (BHS) protocol.*

1. Stergiou GS, Karpettas N, Protogerou A, Nasothimiou EG, & Kyriakidis M. Diagnostic accuracy of a home blood pressure monitor to detect atrial fibrillation. J Hum Hyperten 2009; 1-5.

2. Wiesel J, Fitzig L, Herschman Y, & Messineo FC Detection of Atrial Fibrillation Using a Modified Microlife Blood Pressure Monitor. Am J Hypertens 2009; 848-852.

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1. Important Facts about Blood Pressure and Self- Measurement

- **Blood pressure** is the pressure of the blood flowing in the arteries generated by the pumping of the heart. Two values, the **systolic** (upper) value and the **diastolic** (lower) value, are always measured.
- The device indicates the **pulse rate** (the number of times the heart beats in a minute).
- **Permanently high blood pressure values can damage your health and must be treated by your doctor!**
- Always discuss your values with your doctor and tell him/her if you have noticed anything unusual or feel unsure. **Never rely** on single blood pressure readings.
- There are several causes of excessively **high blood pressure values**. Your doctor will explain them in more detail and offer treatment where appropriate. Besides medication, weight loss and exercise can also lower your blood pressure.
- **Under no circumstances should you alter the dosages of any drugs prescribed by your doctor!**
- Depending on physical exertion and condition, blood pressure is subject to wide fluctuations as the day progresses. **You should therefore take your measurements in the same quiet conditions and when you feel relaxed!** Take at least two readings every time (in the morning and in the evening) and average the measurements.
- It is quite normal for two measurements taken in quick succession to produce significantly **different results**. Therefore we recommend to use the MAM technology.
- **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.
- **Several measurements** provide much more reliable information about your blood pressure than just one single measurement. Therefore we recommend to use the MAM technology.
- **Leave a small break** of at least 15 seconds between two measurements.
- If you suffer from an **irregular heartbeat**, measurements taken with this device should be evaluated with your doctor.
- **The pulse display is not suitable for checking the frequency of heart pacemakers!**
- If you are **pregnant**, you should monitor your blood pressure very closely as it can change drastically during this time!



This monitor is specially tested for use in pregnancy and preeclampsia. When you detect unusual high readings in pregnancy, you should measure again after 4 hours. If the reading is still too high, consult your doctor or gynaecologist.

How do I evaluate my blood pressure?

Table for classifying home blood pressure values in adults in accordance with the international Guidelines (ESH, AHA, JSH). Data in mmHg.

	Range	Systolic	Diastolic	Recommendation
	blood pressure too low	100	60	Consult your doctor
1	blood pressure optimum	100 - 130	60 - 80	Self-check
2	blood pressure elevated	130 - 135	80 - 85	Self-check
3	blood pressure too high	135 - 160	85 - 100	Seek medical advice
4	blood pressure	160	100	Urgently seek medical advice!

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»

2. Important Facts about Atrial Fibrillation (AFIB)

What is Atrial Fibrillation (AFIB)?

Normally, your heart contracts and relaxes to a regular beat. Certain cells in your heart produce electrical signals that cause the heart to contract and pump blood. Atrial fibrillation occurs when rapid, disorganized electrical signals are present in the heart's two upper chambers, called the atria; causing them to contract irregularly (this is called fibrillation). Atrial fibrillation is the most common form of heart arrhythmia or irregular heart beat. It often causes no symptoms, yet it significantly increases your risk of stroke. You'll need a doctor to help you control the problem.

How does AFIB impact my family or me?

People with AFIB have a five-fold higher risk of getting stroke. Since the chance of having a stroke increases with age, individuals above the age of 55 years benefit most from screening for AFIB. However, for younger individuals with risk factors such as diabetes or hypertension screening for AFIB is also recommended. Early diagnosis of AFIB followed by adequate treatment can significantly reduce the risk of getting stroke.

Younger individuals with AFIB have a relatively low risk of getting stroke as compared to elder people.

For more information please visit our website: www.microlife.com.

Microlife AFIB detection provides a convenient way to screen for AFIB (only in AFIB/MAM mode)

Knowing your blood pressure and knowing whether you or your family members have AFIB can help reduce the risk of stroke. Microlife AFIB detection provides a convenient way to screen for AFIB whilst taking your blood pressure.

Risk factors you can control

High blood pressure and AFIB are both considered «controllable» risk factors for strokes. Knowing your blood pressure and knowing whether you have AFIB is the first step in proactive stroke prevention.

3. 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 (4 x size AAA 1.5 V), thereby observing the indicated polarity. Switch the Lock Switch (13) to «unlock» position.

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 either the «+» (12) or the «-» (11) button. To confirm and then set the month, press the time button (9).
2. Press the «+» (12) or the «-» (11) button to set the month. Press the time button (9) 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 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	for circumference of upper
S	17 - 22 cm
M	22 - 32 cm
M - L	22 - 42 cm
L - XL	32 - 52 cm



Optional preformed cuffs «Easy» are available for better fitting and comfort.



Only use Microlife cuffs.

- › Contact Microlife Service if the enclosed cuff (6) does not fit.
- › Connect the cuff to the device by inserting the cuff connector (7) into the cuff socket (3) as far as it will go.

Select the measuring mode: standard or AFIB/MAM mode

This device enables you to select either standard (standard single measurement) or AFIB/MAM mode (automatic triple measurement). To select standard mode, slide the AFIB/MAM switch (8) on the side of the device downwards to position «1» and to select AFIB/MAM mode, slide this switch upwards to position «3».

AFIB/MAM mode (highly recommended)

In AFIB/MAM mode, 3 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 one produced by a single measurement. AFIB detection is only activated in AFIB/ MAM mode.

- After pressing the START/STOP button (1), the selected AFIB/ MAM mode appears in the display as the MAM-symbol (25).
- The bottom, right hand section of the display shows a 1, 2 or 3 to indicate which of the 3 measurements is currently being taken.
- There is a break of 15 seconds between the measurements (15 seconds are adequate according to «Blood Pressure Monitoring, 2001, 6:145-147» for oscillometric instruments). A count down indicates the remaining time.
- The individual results are not displayed. Your blood pressure will only be displayed after all 3 measurements are taken.
- Do not remove the cuff between measurements.
- If one of the individual measurements was questionable, a fourth one is automatically taken.

4. Taking a Blood Pressure Measurement using this device

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 patients 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.
6. Slide the lock switch (13) down to the «unlock» position. Press the START/STOP button (1) to start measuring.
7. 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.
8. 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.
9. During the measurement, the pulse indicator (22) flashes in the display.
- 10 The result, comprising the systolic (16) and the diastolic (17) blood pressure and the pulse rate (18) is displayed. Note also the explanations on further display symbols in this booklet.
11. When the device has finished measuring, remove the cuff.

12. Switch off the device. (The monitor does switch off automatically after approx. 1 min.).

How not to store a reading

Press the START/STOP button (1) while the reading is being displayed. Keep the button pressed until «M» (21) is flashing and then release it. Confirm by pressing the M-button (20) again.



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



If the systolic blood pressure is known to be very high, it can be an advantage to set the pressure individually. Press the START/STOP button after the monitor has been pumped up to a level of approx. 30 mmHg (shown on the display). Keep the button pressed until the pressure is about 40 mmHg above the expected systolic value – then release the button.

5. Appearance of the Atrial Fibrillation Indicator for early Detection (only in AFIB/MAM mode)

This device is able to detect atrial fibrillation (AFIB). This symbol (24) indicates that atrial fibrillation was detected during the measurement. If AFIB is present during blood pressure measurement, the AFIB indicator is displayed flashing at the end of the triple measurements. It is highly recommended to take an additional AFIB/MAM measurement an hour later to confirm the result. If after repeated measurement the AFIB symbol is no longer displayed there is no cause for concern. In such case it is recommended to measure again the next day.

However, if the symbol appears on a regular basis (e.g. several times a week with measurements taken daily) we advise you to visit your doctor. Please provide the following explanation:

Information for the doctor on frequent appearance of the atrial fibrillation indicator

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

The AFIB symbol is displayed after the measurement, if atrial fibrillation occurred during measuring. If the symbol appears more frequently (e.g. several times per week on measurements performed daily) we recommend the patient to seek medical advice. The device does not replace a cardiac examination, but serves to detect atrial fibrillation that often remains undiagnosed until stroke occurs.



Keep the arm still during measuring to avoid false readings.



This device may not detect atrial fibrillation in people with pacemakers or defibrillators.

6. Traffic Light Indicator in the Display

The bars on the left-hand edge of the traffic light display (20) show you the range within which the indicated blood pressure value lies. Depending on the height of the bar, the readout value is either within the optimum (green), elevated (yellow), too high (orange) or dangerously high (red) range. The classification corresponds to the 4 ranges in the table as defined by the international guidelines (ESH, AHA, JSH), as described in «Section 1.».

7. PC-Link Functions

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

If no CD and cable is included download the BPA software from www.microlife.com and use a USB cable with a Mini-B 5 pin connector.

Installation and data transmission

1. Insert CD into the CD ROM drive of your PC. The installation will start automatically. If not, please click on «SETUP.EXE».
2. Connect the monitor via the cable to the PC; there is no need to switch the device on. 3 horizontal bars will appear on the display and last for 3 seconds.
3. The bars will then flash to indicate that the connection between PC and device is successful. As long as the cable is plugged in, the bars will keep flashing and the buttons are disabled. During the connection, the device is completely controlled by the computer. Please refer to the «help» file for software instructions.

8. BT-Link Functions

This device can be used in conjunction with an iPhone running the Microlife Blood Pressure APP (microlife–vitalis) software.

The memory data can be transferred to the iPhone by connecting the monitor via a Bluetooth. Installation and data transmission

1. Install the APP (microlife–vitalis) from APPLE store.
2. Connect the monitor via the Bluetooth; when the monitor stays in stand-by and press “+” Key, “bt” will appear on the display in right angel.
3. The APP carried out the device pair with monitor. If the device pair is successful, the end-user will proceed to download all data or download newest data or view data.



Storage capacity depends on the phone itself, the amount of storage space.



Effective transmission distance is 10 m for Bluebooth.

9. Data Memory

This device automatically stores up to 99 measurement value

Viewing the stored values

Press the M-button (10) briefly, when the device is switched off. The display first shows «**M**» (21) and then an average value. The device then switches to the last stored value.

Press the M-button again to exit the memory mode. Pressing the «+» (12) or the «-» (11) button repeatedly enables you to move from one stored value to another.

Memory full



Pay attention that the maximum memory capacity of 99 memories per user is not exceeded.

When the 99 memory is full, the oldest value is automatically overwritten with the

100th value. Values should be evaluated by a doctor before the memory capacity is reached – otherwise data will be lost.

Clearing all values

1. Hold down the M-button (11) until «CL» appears and then release the button. when the device is switched off.
2. Press the M-button while «CL» is flashing to permanently clear all values of the selected user.

Cancel deletion: press START/STOP button (1) while «CL» is flashing.



Individual values cannot be cleared.

10. 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. To set date and time, follow the procedure described in «Section 3»
2. Open the battery compartment (5) on the bottom of the device
3. Replace the batteries – ensure correct polarity as shown by the symbols in the compartment.



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 1.5V, size AAA 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.

11. Using a Mains Adapter

You can operate this device using the Microlife mains adapter (DC 6V, 600mA).



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.

12. Error Messages

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

Error	Description	Potential cause and remedy
«ERR 1»	Signal too weak	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.*
«ERR 2» (26)	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» (23)	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
«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»	AFIB/MAM Mode	There were too many errors during the measurement in AFIB/MAM mode, making it impossible to obtain a final result. Read through the checklist for performing reliable measurements and then repeat the
«HI»	Pulse or cuff pressure too	The pressure in the cuff is too high (over 300 mmHg) OR the pulse is too high (over 200 beats per minute). Relax for 5 minutes and
«LO»	Pulse too low	The pulse is too low (less than 40 beats per minute). Repeat the

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 1.» carefully.

13. 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 installations.
- 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 in the individual sections of this instructions.



Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed.

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.



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 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.

14. 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 wearing parts 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 Microlife-Service (see foreword).

14. Technical Specifications

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

15 - 95 % relative maximum humidity

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

15 - 95 % relative maximum humidity

Weight: 320 g (including batteries)

Dimensions: 160 x 80 x 32 mm

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

Measurement range: 20 - 280 mmHg – blood pressure

40 - 200 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

Voltage source: 4 x 1.5 V Batteries; size AAA

Mains adapter DC 6V, 600 mA (optional)

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

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

Technical alterations reserved.

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.

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 correct the interference by one or more of the following measures:

- Reorient the receiving antenna.
- Increase the separation between the equipment and receiver.

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

Changes or modifications not expressly approved by the party responsible for compliance could void your authority to operate the equipment.