



BP 3MS1-4K (BP A200 AFIB)



Stroke Prevention
3 out of 4 Atrial Fibrillation related to
STROKE can be prevented if you are
already diagnosed.

 Microlife AG
Esenstrasse 139
9443 Widnau - Switzerland
www.microlife.com
www.microlife.it

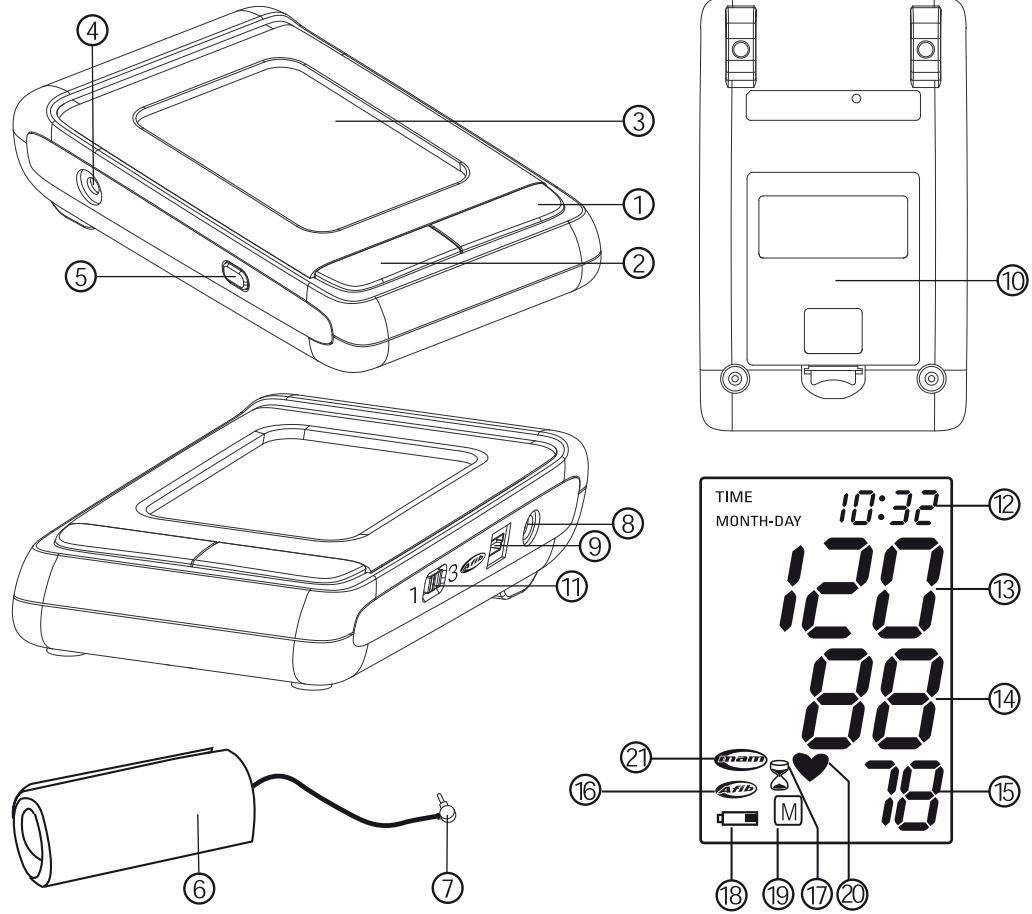
CE0044

IB BP 3MS1-4K (BP A200 AFIB)5117





BP 3MS1-4K (BP A200 AFIB)



microlife

- ① ON/OFF Button
- ② M-Button (Memory)
- ③ Display
- ④ Cuff Socket
- ⑤ Time Button
- ⑥ Cuff
- ⑦ Cuff Connector
- ⑧ Mains Adapter Socket
- ⑨ USB Port
- ⑩ Battery Compartment
- ⑪ MAM Switch

Display

- ⑫ Date/Time
- ⑬ Systolic Value
- ⑭ Diastolic Value
- ⑮ Pulse
- ⑯ Atrial Fibrillation Indicator
- ⑰ MAM Interval Time
- ⑱ Battery Display
- ⑲ Stored Value
- ⑳ Pulse Rate
- ㉑ MAM Mode



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.



Type BF applied part

Dear Customer,

Your new Microlife blood pressure monitor is a reliable medical instrument 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 instrument was developed in collaboration with physicians and clinical tests proving its measurement accuracy to be very high.*

Microlife AFIB detection is the world's leading digital blood pressure measurement technology for the early detection of atrial fibrillation (AFIB) and hypertension. These are the two top risk factors of heart disease and stroke which increase the risk 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 can 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 97-100% certainty.**^{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 Corporation!

** This instrument 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.*

Table of Contents

1. Important Facts about Blood Pressure and Self-Measurement

- How do I evaluate my blood pressure?

2. Important facts about atrial fibrillation (AFIB)

- What is Atrial Fibrillation (AFIB)?
- How does AFIB impact my family or me?
- Microlife AFIB detection provides a convenient way to screen for AFIB (only in MAM mode)
- Risk factors you can control

3. Using the Instrument for the First Time

- Activating the fitted batteries
- Setting the date and time
- Selecting the correct cuff
- Select the measuring mode: standard or MAM mode
- MAM Mode

4. Taking a Blood Pressure Measurement using this Instrument

- How not to store a reading

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

6. PC-Link Functions

- Installation and data transmission

7. Data Memory

- Viewing the stored values
- Memory full
- Clearing all values

8. Battery Indicator and Battery change

- Low battery
- Flat battery – replacement
- Which batteries and which procedure?
- Using rechargeable batteries

9. Using a Mains Adapter

10. Error Messages

11. Safety, Care, Accuracy Test and Disposal

- Safety and protection
- Instrument care
- Cleaning the cuff
- Accuracy test
- Disposal

12. Guarantee

13. Technical Specifications Guarantee Card

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 instrument also 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.**
- Enter your readings in the enclosed **blood pressure diary**. This will give your doctor a quick overview.
- There are many causes of excessively **high blood pressure values**. Your doctor will explain them in more detail and offer treatment where appropriate. Besides medication, relaxation techniques, 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 measurements per day, one in the morning and one in the evening.
- It is quite normal for two measurements taken in quick succession to produce significantly **different results**.
- **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 a much clearer picture than just one single measurement.

- **Leave a small break** of at least 15 seconds between two measurements.
- If you are **pregnant**, you should monitor your blood pressure very closely as it can change drastically during this time!
- If you suffer from an **irregular heartbeat**, measurements taken with this instrument should only be evaluated after consultation with your doctor.
- **The pulse display is not suitable for checking the frequency of heart pacemakers!**

How do I evaluate my blood pressure?

Table for classifying blood pressure values in adults in accordance with the World Health Organisation (WHO) in 2003. Data in mmHg.

Range	Systolic	Diastolic	Recommendation
blood pressure too low	↓ 100	↓ 60	Consult your doctor
1. blood pressure optimum	100 - 120	60 - 80	Self-check
2. blood pressure normal	120 - 130	80 - 85	Self-check
3. blood pressure slightly high	130 - 140	85 - 90	Consult your doctor
4. blood pressure too high	140 - 160	90 - 100	Seek medical advice
5. blood pressure far too high	160 - 180	100 - 110	Seek medical advice
6. blood pressure dangerously high	180 ↑	110 ↑	Urgently seek medical advice!

The higher value is the one that determines the evaluation.

Example: a readout value between **150/85** or **120/98** 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 quickly fast and irregularly (this is called fibrillation). Atrial fibrillation is

the most common form of heart arrhythmia or irregular heart beat. You can live with atrial fibrillation, but it can lead to other rhythm problems, chronic fatigue, heart failure and - worst of all - a stroke. You'll need a doctor to help you control the problem.

How does AFIB impact my family or me?

One in every six strokes is AFIB-related. Whilst individuals above the age of 65 are more likely to have AFIB, individuals as young as 40 can exhibit AFIB. Early diagnosis can help reduce the risk of a stroke.

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

Knowing your blood pressure and knowing whether or not 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 or not you have AFIB is the first step in proactive stroke prevention.

3. Using the Instrument for the First Time

Activating the fitted batteries

Pull out the protective strip projecting from the battery compartment ⑩.

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-button ②. To confirm and then set the month, press the time button ⑤.
2. You can now set the month using the M-button. Press the time button to confirm and then set the day.
3. Please 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 size	for circumference of upper arm
S	17 - 22 cm (6.75 - 8.75 inches)
M	22 - 32 cm (8.75 - 12.5 inches)
L	32 - 42 cm (12.5 - 16.5 inches)
M - L	22 - 42 cm (8.75 - 16.5 inches)

 Optional preformed cuffs «Easy» are available.

 Only use Microlife cuffs.

- ▶ Contact Microlife Service if the enclosed cuff ⑥ does not fit.
- ▶ Connect the cuff to the instrument by inserting the cuff connector ⑦ into the cuff socket ④ as far as it will go.

Select the measuring mode: standard or MAM mode

This instrument enables you to select either standard (standard single measurement) or MAM mode (automatic triple measurement). To select standard mode, slide the MAM switch ⑪ on the side of the instrument downwards to position «1» and to select MAM mode, slide this switch upwards to position «3».

MAM Mode

In MAM mode, 3 measurements are automatically taken in succession and the result is then automatically analysed and displayed. Because the blood pressure constantly fluctuates, a result determined in this way is more reliable than one produced by a single measurement. AFIB detection is activated in MAM mode.

- After pressing the ON/OFF button ①, the selected MAM mode appears in the display as the MAM-symbol ⑫.
- 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 and a beep will sound 5 seconds before the 2nd and 3rd readings will begin.
- 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 Instrument

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).
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 cuff is positioned correctly, as shown in the pictures illustrated on the short instruction card.
 - Fit the cuff closely, but not too tight.
 - Make sure that the cuff is 2 cm (0.75 inch) above your elbow with the tube on the inside of your arm.
 - Support your arm so it is relaxed.
 - Ensure that the cuff is at the same height as your heart.
6. Press the ON/OFF button ① to start the measurement.
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 instrument will automatically pump some more air into the cuff.
9. During the measurement, the heart symbol ⑳ flashes in the display every time a heartbeat is detected.
10. The result, comprising the systolic ⑬ and the diastolic ⑭ blood pressure and the pulse ⑮ is displayed. Note also the explanations on further displays in this booklet.
11. When the measurement has finished, remove the cuff.
12. Enter the result in the enclosed blood pressure pass and switch off the instrument. (The monitor does switch off automatically after approx. 1 min.).

How not to store a reading

Press the ON/OFF button (1) while the reading is being displayed. Keep the button pressed until «M» (19) is flashing and then release it. Confirm by pressing the M-button.

☞ 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).

☞ **If the systolic blood pressure is known to be very high,** it can be an advantage to set the pressure individually. Press the ON/OFF 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 MAM mode)

This symbol (16) indicates that an atrial fibrillation was detected during the measurement. This device is able to detect atrial fibrillation (AFIB). If AFIB is present during blood pressure measurement, the AFIB Indicator is displayed. In this case, the result may deviate from your normal blood pressure. It is highly recommended to take an additional measurement an hour later to increase the specificity of the detection. 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 visit your doctor. Please, provide the following explanation:

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

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

The arrhythmia symbol is displayed after the measurement, if atrial fibrillations 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.

The instrument does not replace a cardiac examination, but serves to detect atrial fibrillations at an early stage.

☞ Sometimes the device will detect atrial fibrillation even when it is not there. This can happen if the arm moves during the reading or another rhythm problem is present. Keep the arm still during the reading. Visiting your doctor with this device may be necessary to check out any rhythm problems.

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

6. PC-Link Functions

This device can be used in connection 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 cable with the PC.

If no CD and cable is included download the BPA software from www.microlife.com and use a standard USB cable.

Installation and data transmission

1. Insert CD into CD ROM drive of your PC. The installation will start automatically. If not, please click on «SETUP.EXE».
2. Connect the monitor via cable with the PC; 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 successfully made. As long as the cable is plugged, the bars will keep flashing and buttons are disabled.

☞ During the connection, the device is completely controlled by the computer. Please refer to the «help» file for software instructions.

7. Data Memory

At the end of a measurement, this instrument automatically stores each result, including date and time.

Viewing the stored values

Press the M-button (2) briefly, when the instrument is switched off. The display first shows «M» (19) and then a value, e.g. «M 17». This means that there are 17 values in the memory. The instrument then switches to the last stored result.

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 200 is not exceeded. **When the memory is full, the old values are automatically overwritten with new ones.** Values should be evaluated by a doctor before the memory capacity is reached – otherwise data will be lost.

Clearing all values


If you are sure that you want to permanently remove all stored values, hold down the M-button (the instrument must have been switched off beforehand) until «**CL**» appears and then release the button. To permanently clear the memory, press the M-button while «**CL**» is flashing. Individual values cannot be cleared.


8. Battery Indicator and Battery change


Low battery

When the batteries are approximately $\frac{3}{4}$ empty the battery symbol  will flash as soon as the instrument is switched on (partly filled battery displayed). Although the instrument will continue to measure reliably, you should obtain replacement batteries.




Flat battery – replacement

When the batteries are flat, the battery symbol  will flash as soon as the instrument 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 instrument.
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 3.».





 The memory retains all values although date and time (and possibly also set alarm times) 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 AA batteries.
-  Do not use batteries beyond their date of expiry.
-  Remove batteries if the instrument is not going to be used for a prolonged period.



Using rechargeable batteries


You can also operate this instrument 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 instrument as they may become damaged (total discharge as a result of low use of the instrument, even when switched off).
-  Always remove the rechargeable batteries if you do not intend to use the instrument 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.

9. Using a Mains Adapter

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

-  Only use the Microlife mains adapter available as an original accessory appropriate for your supply voltage, e.g. the «Microlife 230V adapter».
-  Ensure that neither the mains adapter nor the cable are damaged.

1. Plug the adapter cable into the mains adapter socket  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.


10. 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»	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.

Error	Description	Potential cause and remedy
«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	There were too many errors during the measurement in MAM mode, making it impossible to obtain a final result. Read through the checklist for performing reliable measurements and then repeat the measurement.*
«HI»	Pulse or cuff pressure too high	The pressure in the cuff is too high (over 300 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 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.

11. Safety, Care, Accuracy Test and Disposal

Safety and protection

- This instrument may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
- This instrument 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 the instrument close to strong electromagnetic fields such as mobile telephones or radio installations.
- Do not use the instrument if you think it is damaged or notice anything unusual.
- Never open the instrument.
- If the instrument is not going to be used for a prolonged period the batteries should be removed.
- Read the additional safety instructions in the individual sections of this booklet.

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.

Instrument care

Clean the instrument 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 instrument 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 instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

12. Guarantee

This instrument 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 wearing parts are not included.
- Opening or altering the instrument 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 is included for the functional guarantee only (tightness) for 2 years.

Please contact Microlife-Service (see foreword).

13. Technical Specifications

Operating temperature:	10 - 40 °C / 50 - 104 °F
Relative humidity:	15 - 95 % relative maximum humidity
Storage temperature:	-20 - +55 °C / -4 - +131 °F
Relative humidity:	15 - 90 % relative maximum humidity
Weight:	560 g (including batteries)
Dimensions:	152 x 92 x 42 mm
Measuring procedure:	oscillometric, corresponding to Korotkoff method: Phase I systolic, Phase V diastolic
Measurement range:	30 - 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:	<ul style="list-style-type: none">• 4 x 1.5 V Batteries; size AA• Mains adapter DC 6V, 600 mA (optional)
Reference to standards:	EN 1060-1 /-3 /-4; IEC 60601-1; IEC 60601-1-11 IEC 60601-1-2 (EMC)
Expected service life:	5 years
Cuff life :	2 years
Battery life :	Approximately 920 measurements
IP20:	Protected against solid foreign particles with a diameter of more than 12.5 mm, no protection against water. Keep dry



CE 0044

The stipulations of the EU Directive 93/42/EEC for Medical Devices Class IIa have been fulfilled.

Technical alterations reserved.