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Microlife VSA

CE0044 IB Microlife VSA EN 2519



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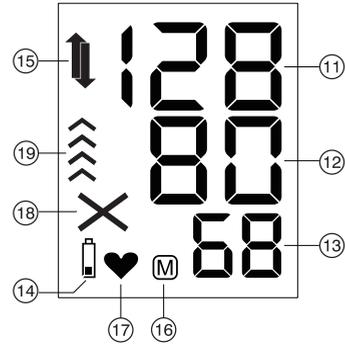
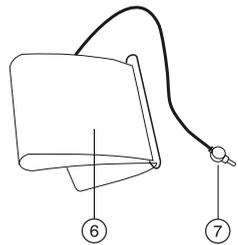
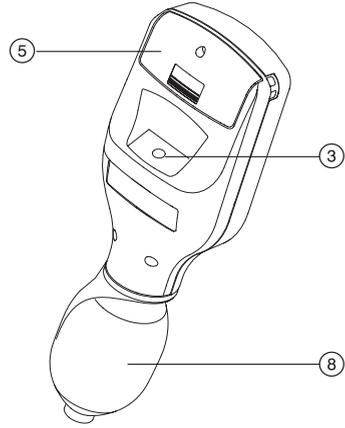
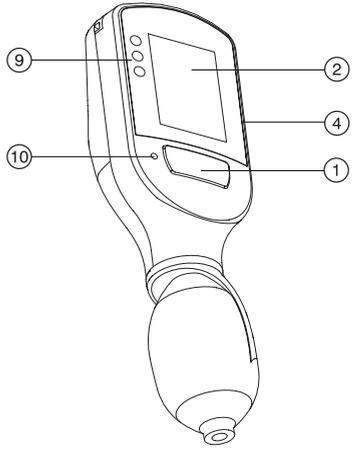
Microlife Vital Signs Alert

Instruction Manual



Microlife VSA

microlife®



Guarantee Card

Name of Purchaser _____

Serial Number _____

Date of Purchase _____

Specialist Dealer _____

- ① ON/OFF Button
- ② Display
- ③ Cuff socket
- ④ Micro USB Port (for charging only)
- ⑤ Battery Compartment
- ⑥ Cuff
- ⑦ Cuff Connector
- ⑧ Pump Ball
- ⑨ Traffic Light
- ⑩ Charging Indicator

Display

- ⑪ Systolic Value
- ⑫ Diastolic Value
- ⑬ Pulse Rate
- ⑭ Battery Indicator
- ⑮ Hypertension and Shock Indicator
- ⑯ Stored Value
- ⑰ Pulse Indicator
- ⑱ Error Indicator
- ⑲ Pumping-Up Indicator

Introduction:

This user manual is designed to help you understand the capabilities and operation of the Microlife VSA. Read this manual thoroughly before attempting to use the device.

Intended use of the Microlife VSA is a non-invasive digital blood pressure monitor using oscillometric technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures according to Korotkoff Phase I (for SBP) and V (for DBP). The device also incorporates an algorithm for the detection of hypovolemic shock.

This oscillometric blood pressure monitor is intended for measuring non-invasive blood pressure in people aged 12 years or older.

The VSA can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia. It combines the advantages of an automatic blood pressure monitor and auscultatory sphygmomanometer designed to provide convenient, accurate and reliable blood pressure measurements according to guidelines of the British Hypertension Society (BHS) and World Health Organization (WHO).

** The Microlife VSA in terms of measurement technology and algorithm is identical with the previous model Microlife BP 3AS1-2.*



Read the instructions carefully before using this device.



Keep dry



Type BF applied part

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Guarantee Card (see Back Cover)

1. Before Using the Instrument

Selecting the correct cuff

Microlife offers different cuff sizes. Select the cuff size to match the circumference of your upper arms (use marking on the cuff).

| Cuff size | for circumference of upper arm |
|-----------|--------------------------------|
| M | 22 - 32 cm |
| L | 32 - 42 cm |

- ☞ Use only Microlife cuffs.
Properly connect the cuff to the device by inserting the cuff connector (7) into the cuff socket (3) as far as it can go.
- ☞ If you buy a spare Microlife cuff, please remove the cuff connector(7) from the cuff tube(6) from the cuff supplied with the original device and insert this cuff connector into the tube of the spare cuff (valid for all cuff sizes).

2. Taking a Blood Pressure Measurement

Checklist for taking a reliable measurement

1. Always ensure that the correct cuff size is used.
 - Fit the cuff closely, but not too tight.
 - Make sure that the cuff is 2 cm above patient's 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 patient's arm so it is relaxed.
 - Ensure that the cuff is at the same height as patient's heart.
2. Switch on the device and wait until <<0>> appears in the display and the arrows (19) start to flash.
3. Pump up the cuff. Watch the pressure indication on the display and pump approx. 40 mmHg higher than the expected systolic blood pressure value (the upper value). A beep will sound and the flashing arrows will disappear when you have reached the appropriate pressure. If you have not pumped enough, the flashing arrows (19) will not disappear to indicate that you should pump higher.
4. After pumping, the measurement is taken automatically. Ask the patient to relax, not to move and not to tense the arm muscles until the measurement result is displayed. The patient should breathe normally and not talk.

- During the measurement, the pulse indicator ⑰ flashes on the display and a beep sounds every time a heartbeat is detected.
- The result, comprising the systolic ⑪, the diastolic ⑫ blood pressure value and the pulse rate ⑬ is displayed and a longer beep sound is heard. Also look at the explanations in this booklet.
- When the measurement is completed, remove the cuff from the patient's arm.
- Switch off the instrument. (The monitor does switch off automatically after approx. 30 sec.).

3. Hypertension and Shock Indicator

Shock, due to bleeding or sepsis, can cause a change in blood pressure and heart rate. Shock index is defined as heart rate divided by systolic blood pressure.

When measurement is completed, the symbol ⑱ and traffic light ⑨ may indicate that your blood pressure or shock index is higher than the recommended range.

| Range | Systolic | Diastolic | Traffic light |
|------------------------------------|----------------|---------------|--|
| severe shock | | | Red LED will flash and show the arrow down ↓ flashing |
| blood pressure dangerously high | ≥ 160 | ≥ 110 | Red LED will flash and show the arrow up ↑ constantly |
| shock | < 160 | | Yellow LED will flash and show arrow down ↓ flashing |
| blood pressure high | ≥ 140 and <160 | ≥ 90 and <110 | Yellow LED will flash and show arrow up ↑ constantly |
| blood pressure normal and no shock | < 140 | < 90 | Green LED will light constantly and don't show any arrow |

Note: the arrow downwards indicates the patient is in shock!

The higher value determines the evaluation.

Example: If no shock, a blood pressure of 150/85 or 120/98 will show as «blood pressure high».

4. Data Memory

This instrument automatically stores the last measured blood pressure values.

Viewing the stored value

Hold down the ON/OFF button (the instrument must have been switched off beforehand) until memory appears and then release the button.

5. Battery Indicator and Battery charging

Low battery - When the battery is almost empty the battery symbol ⑭ will flash as soon as the instrument is switched on (partly filled battery displayed). The instrument will continue to measure reliably, you should charge the battery after flat battery symbol appear.

Flat battery – charge the battery

When the battery is flat, the battery symbol ⑭ will flash as soon as the instrument is switched on (flat battery displayed).

You cannot take any further measurements and must charge the battery.

- Connect the instrument to the 5 V USB power adapter or computer using the USB cable.



The connected power adapter and computer need to meet IEC60950-1 or IEC60601-1 standard.



The USB connection can't be used to transfer any data between PC and device. It is used for charging the battery only.

- During the charging process, the charging indicator ⑩ will light up in orange.
- When the battery is completely charged, the charging indicator will light up in green.

 Before first use, charge the battery until the charging indicator turns to green.

 Do not let the battery run down completely, as this shortens the battery's service life.

 The screen will show << **ch--** >>, when pressing the ON/OFF button during the charging process. This device cannot be operated when being charged.

6. Error Messages

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

| Error | Description | Potential cause and remedy |
|----------------|---------------------------------|--|
| « X 1 » | Signal too weak | The pulse signals on the cuff are too weak. Re-position the cuff (see 2.1) and repeat the measurement.* |
| « X 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. |
| « X 3 » | No pressure in the cuff | No adequate pressure can be generated in the cuff. A leak may have occurred. Check that the cuff is correctly connected and is not too loose. Repeat the measurement. |
| « X 5 » | Invalid result | The measuring signals are invalid and therefore no result can be displayed. 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 299 mmHg) OR the pulse is too high (over 200 beats per minute). Relax and repeat the measurement.* |
| « LO » | Pulse too low | The pulse is too low (less than 40 beats per minute). Repeat the measurement.* |

* Please contact your dealer if the error persists.

7. Safety, Care, Accuracy Test and Disposal

Safety and protection

- This device may be used only for the purpose described in this instruction manual. The manufacturer cannot be held liable for damage caused by incorrect application.
- 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 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 the device if you think it is damaged or notice anything unusual.
- Never open the device.
- Read the additional safety instructions in the individual sections of this instruction.
- The measurement result 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 the 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

Take out the bladder. Fold and place the cuff cover inside a washing bag. Wash the cuff cover with warm water and a mild detergent in a washing machine. Air dry the cuff. DO NOT iron the cuff cover.

Accuracy test

The law recommends to verify the static calibration of a blood pressure monitor every two years or after mechanical shock.

How to check device calibration:

- Switch this device into the calibration mode (CA mode) by re-pressing the Start button while the device memory is displayed.
- Connect a reference pressure source by use of the device calibration connector (available as a special accessory)
- Compare the displayed pressure with the external reference pressure
- For further information please contact your local dealer.

Disposal



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

8. Guarantee

This device is covered by a **2 year guarantee** from the date of purchase.

- Battery, and wearing parts are not included.
- The cuff is included for the functional guarantee only (tightness) for 1 year.
- 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 dealer (see foreword).

9. Technical Specifications

Operating condition: 10 - 40 °C / 50 - 104 °F
15 - 90 % relative maximum humidity

Storage condition: -20 - +55 °C / -4 - +131 °F
15 - 90 % relative maximum humidity

Weight: 157.7 g (including battery)

Dimensions: 167 x 60 x 41 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: specify battery type (3.7 V , 350 mAh)

rechargeable via standard MicroUSB

Approximately 200 measurements per recharge cycle

Battery life:
Reference to standards:

ANSI/AAMI/ISO 81060-2;

EN 1060-1/-3/-4;

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

IEC 60601-1-11

Expected service life: 5 years or 10,000 measurements (battery and cuff are not included)

IP Class:

IP20

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