

SANITAS

SBM 21



- D** **Gebrauchsanleitung**
Blutdruckmessgerät..... (2–10)
- GB** **Instruction for Use**
Blood pressure monitor(11–18)
- F** **Mode d'emploi**
Tensiomètre(19–27)
- I** **Istruzioni per l'uso**
Misuratore di pressione..... (28–35)
- RUS** **Инструкция по применению**
*Прибор для измерения артериального
давления на предплечье*(36–44)



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Please read these instructions for use carefully and keep them for later use, be sure to make them accessible to other users and observe the information they contain.

1. Getting to know your instrument

The upper arm blood pressure monitor is used for non-invasive measurement and monitoring of adults' arterial blood pressure. You can use it to measure your blood pressure quickly and easily, storing the results and displaying the progression of readings together with the average.

A warning is issued for anyone suffering from cardiac arrhythmia. The values determined are classified and graphically evaluated according to WHO guidelines.

Keep these instructions carefully for further use and also let other users have access to them.

2. Important information



Advice on use

- Always measure your blood pressure at the same time of day, in order to ensure that values are comparable.
- Relax for approx. 5 minutes before each measurement.
- You should wait five minutes before measuring a second time.
- The readings that you take may only be used for information purposes – they are not a substitute for a medical examination! Discuss your results with the doctor. Never use them to make medical decisions independently (e.g. regarding medication and dosage thereof).

- There may be incorrect measurements where there is cardiovascular disease, as well as with very low blood pressure, circulatory disorders, dysrhythmia and other preexisting diseases.
- Only use the instrument on persons whose upper arm has the right circumference for the instrument.
- You can operate the blood pressure monitor with batteries. Note that it is only possible to save data when your blood pressure monitor is receiving power. As soon as the batteries are dead, the date and time on the blood pressure monitor are lost.
- The automatic switch-off function switches off the blood pressure monitor in order to preserve the batteries, if no button is pressed within 3 minutes.



Storage and Care

- The blood pressure monitor is made up of precision electronic components. Accuracy of readings and the instrument's service life depend on careful handling.
 - You should protect the device from impact, moisture, dirt, major temperature fluctuations and direct exposure to the sun's rays.
 - Never drop the device.
 - Do not use near strong electromagnetic fields, i.e. keep it away from any radio systems and mobile phones.
 - Only ever use the cuffs provided with the monitor or original replacement cuffs. Otherwise erroneous results will be recorded.

- Do not press any buttons until the cuff is in position.
- If the instrument is not used for any length of time, we recommend removing the batteries.



Advice on batteries

- Batteries can be fatal if swallowed. You should therefore store the batteries and products where they are inaccessible to small children. If a battery has been swallowed, call a doctor immediately.
- Batteries should not be charged or reactivated with any other means, nor should they be taken apart, thrown in the fire or short-circuited.
- Remove the batteries from the instrument if they are worn out or if you are not going to use the instrument for any length of time. This prevents any damage as a result of leakage. Always replace all the batteries at the same time.
- Never use different types of battery, battery brands or batteries with different capacities. You should preferably use alkaline batteries.



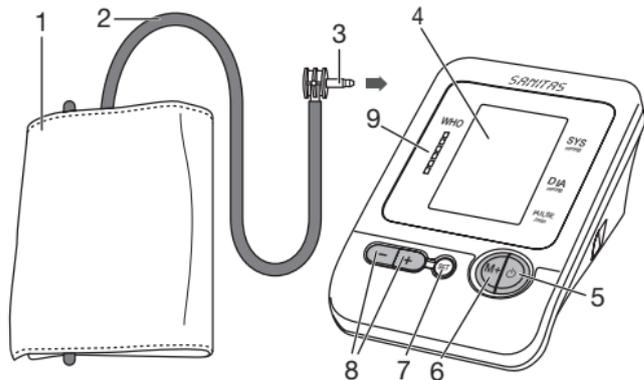
Repair and disposal

- Batteries do not belong in domestic refuse. Used batteries should be disposed of at the collection points provided.
- Never open the instrument. If these instructions are not heeded, the warranty will be null and void.
- Never attempt to repair the instrument or adjust it yourself. We can no longer guarantee perfect functioning if you do.

- Repairs may only be performed by Customer Service or authorized dealers. However, always check the batteries and replace them if necessary prior to making any complaint.
- The appliance should be disposed of according to Regulation 2002/96/EC-WEEE (Waste Electrical and Electronic Equipment). In case of queries, please contact the municipal authorities responsible for waste disposal in your area.



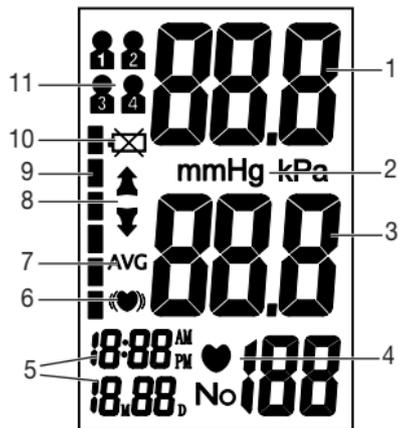
3. Unit description



1. Cuff
2. Cuff line
3. Cuff connector
4. Display
5. START/STOP button 
6. Memory button M+
7. SET button
8. Function buttons -/+
9. WHO scale

Icons in the display:

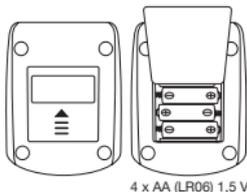
1. Systolic pressure
2. Unit in mmHg
3. Diastolic pressure
4. Pulse symbol  and calculated pulse value
5. Time and date
6. Cardiac arrhythmia symbol ()
7. Average values of the 3 most recent measurements – AVG
8. Pump up, release air (arrow)
9. WHO classification
10. Battery replacement symbol 
11. Symbol for users 1, 2, 3 and 4



4. Prepare measurement

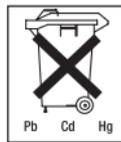
Inserting battery

- Remove the battery cover from the back of the monitor.
- Insert four AA 1.5 V alkaline batteries. Making absolutely sure that you insert them with the correct polarity as marked. Never use rechargeable batteries.
- Replace the battery cover carefully.



If 4 warning tones have been sounded and the symbol  appears simultaneously on the display, it is no longer possible to perform a measurement and all batteries must be replaced. Once the batteries have been removed from the device, the time must be set again. Used batteries should not be disposed of in normal household waste. Dispose of them via your electronics retailer or your local recycling point. You are legally obligated to do so.

Note: Batteries containing pollutant substances are marked as follows: Pb = Battery contains lead, Cd = Battery contains cadmium, Hg = Battery contains mercury.



Setting date and time

You should set the date and time without fail. Otherwise, you will not be able to save your measured values correctly with a date and time and to access them again later. The time is shown in 12-hour format i.e. the time from 13:00 is displayed as 01:00 PM.

Proceed as follows to set the date and time:

- Confirm twice using the SET button.
- Use the + or - buttons to first set the month 1–12, and then confirm using the SET button.
- Set the day/hour/minute and confirm each using the SET button.

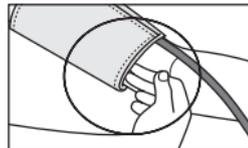
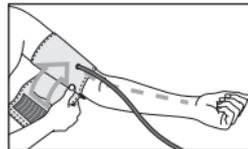
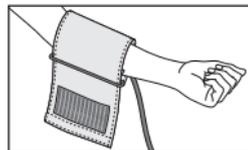
Press the button  to exit the settings mode.

5. Measuring blood pressure

Positioning cuff

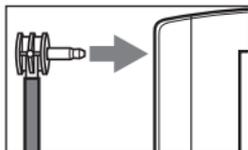
Fit the cuff round your bare left upper arm. Blood circulation in the arm should not be restricted by tight clothing or other objects.

The cuff should be placed on the upper arm so that the lower edge is 2 to 3 cm above the bend of the elbow and above the artery. The tube should be in line with the centre of the palm. Now place the free end of the cuff snugly, but not too tightly, around the arm, and fix it with the Velcro fas-



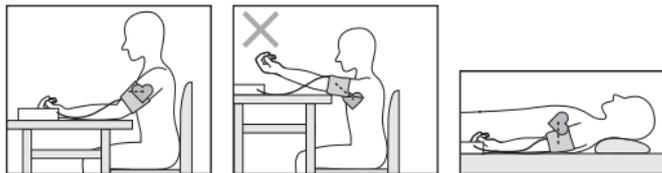
tener. The cuff should be fitted tight enough to allow just two fingers to fit beneath the cuff.

Insert the cuff tubing into the socket for the cuff attachment.



Important: The instrument should only be operated with the original cuff. The cuff is suitable for an arm circumference of 22 to 36 cm.

Correct posture



- Rest for approx. 5 minutes before each measurement. Otherwise there may be divergences.
- You can perform the measurement either sitting or lying down. Always make sure that the cuff is on a level with your heart.
- In order not to distort the result, it is important to keep still during the measurement and not talk.

Select memory

Press the SET button. Select the desired storage space by pressing the +/- function buttons. You have 4 memories with 30 spaces each to store the measurements of 4 different people separately or to separate measurements taken in the morning and at night.

Confirm your selection with the button .

Measuring blood pressure

- Put on the cuff as described previously and assume the position in which you want to carry out the measurement.
- Start the measurement by holding the button . After checking the display, during which all numbers light up, the cuff pumps up automatically. Whilst the cuff is pumping up, the device already calculates measurements for estimating the necessary pump pressure. If this pressure is insufficient, the device automatically pumps more pressure.
- Then the pressure in the cuff is slowly released and the pulse is measured.
- When the measurement has been completed, the remaining air pressure is released very quickly. The pulse, the systolic and the diastolic blood pressure are displayed.
- Measuring can be cancelled at any time by pressing the button .
- If a higher pump pressure is always required, you can bypass the additional pumping process by holding the M+ button shortly after the pumping process starts until the desired cuff pressure is reached. This should be approx. 30 mmHg above the systolic value.
- The Err icon appears if it has not been possible to perform the measurement properly. Observe the section in these instructions on error messages/troubleshooting and repeat the measurement.
- The device switches off automatically after 3 minutes.

Wait at least 5 minutes before taking another measurement!

Evaluating results

Cardiac arrhythmia:

This instrument can identify possible cardiac arrhythmia disorders during measurement and if necessary indicates the measurement with the flashing icon (❤️).

This may be an indicator for arrhythmia. Arrhythmia is a condition where the heart rhythm is abnormal as a result of defects in the bioelectrical system controlling the heart beat. The symptoms (omitted or premature heart beats, slow or excessively fast heart rate) may be caused, among other things, by heart disease, age, physical predisposition, excessive use of stimulants, stress or lack of sleep. Arrhythmia can only be ascertained through examination by your doctor.

Repeat the measurement if the flashing icon (❤️) is displayed after the measurement. Please note that you should rest for 5 minutes between measurements and not talk or move during the measurement. If the icon (❤️) appears often, please contact your doctor. Any self-diagnosis and treatment based on the test results may be dangerous. It is vital to follow your doctor's instructions.

WHO classification:

According to WHO Guidelines/Definitions and the latest findings, the test results can be classified and evaluated according to the following chart:

Range of blood pressure values	Systolic (in mmHg)	Diastolic (in mmHg)	Measure
Grade 3: Severe hypertension	≥ 180	≥ 110	Seek medical advice
Grade 2: Moderate hypertension	160–179	100–109	Seek medical advice
Grade 1: Mild hypertension	140–159	90–99	Have it checked regularly by doctor
High-normal	130–139	85–89	Have it checked regularly by doctor
Normal	120–129	80–84	Check it yourself
Optimal	< 120	< 80	Check it yourself

Source: WHO, 1999

The bar graph in the display and the scale on the unit indicate the range of the blood pressure which has been recorded. If the values for systolic and diastolic pressure are in two different WHO ranges (e.g. systolic in the high-normal range and diastolic pressure in the normal range) the graphic WHO classification on the unit indicates the higher range (high-normal in the example described).

6. Saving, retrieving and deleting results

- The results of each successful measurement are stored together with date and time. With more than 30 items of measured data, the earliest items of data measured are lost.
- Use the SET button and then the -/+ buttons to select the desired user memory and confirm using the . Press-

ing the M+ button displays the average value AVG of the 3 most recent measurements stored in the user memory. By pressing the + button, the most recent measurements are displayed; by pressing the - button, the oldest are displayed.

- The average value AVG can only be displayed if there are 3 saved values in the respective user memory.
- To clear the memory, you must first select a user memory. Hold the SET button pressed for approx. 3 seconds. All the values in the current user memory are deleted after 3 brief beeps are output.
- If you wish to change the user memory, see “Select memory”.

7. Cleaning and storing the instrument

- Clean your device and cuff carefully only with a slightly moistened cloth.
- Do not use detergents or solvents.
- On no account must you immerse the computer in water, otherwise liquid can enter it and cause damage.
- When storing the device, make sure that no heavy objects are placed on top of it. Remove the batteries. The cuff tube should not have any sharp kinks.

8. Error messages/troubleshooting

In case of faults, the Err message appears in the display. Error messages can occur when

1. inflation pressure is higher than 300 mmHg,
2. blood pressure is unusually high or low,
3. you move or talk during the measurement.

In the above cases, you must repeat the measurement. Make sure that the cuff tube is properly inserted and that you do

not move or talk. Re-insert the batteries if necessary, or else replace them.

9. Specifications

Model No.	SBM 21
Method of Measurement	Oscillometric, non-invasive blood pressure measurement on the upper arm
Range of Measurement	systolic 0–300 mmHg, diastolic 0–300 mmHg, pulse 30–180 beats/minute
Accuracy of the pressure reading	systolic ± 3 mmHg/diastolic ± 3 mmHg/ pulse $\pm 5\%$ of the displayed value
Measuring uncertainty	max. permissible standard deviation according to clinical testing: systolic: 8 mmHg/diastolic: 8 mmHg
Sets of Memory	4 x 30 memory places
Unit Dimension	L155 x W110 x H70 mm
Unit Weight	Approx. 405 g
Cuff Size	Cuff for upper arm circumference of 22 to 36 cm
Operating Temperature	+5 °C to +40 °C, < 85 % RH
Storage- and transporttemperature	-10 °C to +55 °C, < 95 % RH
Power Supply	4 x 1,5 V AA batteries (alkaline type LR06)

Battery Life	For approx. 250 measurements, depending on blood pressure level or inflation pressure
Accessories	With storage pouch, instruction manual, 4 pcs AA battery LR 06
Classification	Application part Type B
Protection class	internal power supply, IPXO, no AP or APG, continuous operation
Key to symbols	Application part Type B  Important! Read the operating instruction! 

These specification are subject to change without notice for purpose of improvement.

- This unit is in line with European Standard EN60601-1-2 and is subject to particular precautions with regard to electromagnetic compatibility (EMC). Please note that portable and mobile HF communication systems may interfere with this instrument. For more details, please contact customer service at the address indicated.
- The instrument is in line with the EU Medical Products Directive 93/42/EC, the German medical products act and European standards EN1060-1 (non-invasive blood pressure monitors, Part 1: general requirements) and EN1060-3 (non-invasive blood pressure monitors, Part 3: Supplementary Requirements for Electromechanical Blood Pressure Measurement Systems).

- If you are using the instrument for commercial or economic purposes, you must check measurement precision regularly in accordance with the “Operators’ Ordinance on Medical Products”. Even in the case of private use, we recommend checking measurement precision every two years at the manufacturers.