SANITAS

SBC 21

CE 0483

ENGLISH

Contents

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.

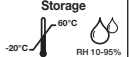
1. Getting to know your device

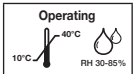
The wrist blood pressure monitor is used to carry out non-invasive measurement and monitoring of arterial blood pressure values in human adults. This allows you to quickly and easily measure your blood pressure and to display the last recorded measurement.
A warning is issued for anyone suffering from cardiac arrhythmia.
The recorded values are classified and evaluated graphically.

2. Important notes

⚠ Signs and symbols

The following symbols are used in these instructions for use, on the packaging and on the type plate for the device and the accessories:

	Attention
	Note Note on important information
	Observe the instructions for use
	Application part, type BF
	Direct current
	Dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment).
	Manufacturer
	Permissible storage temperature and humidity

	Permissible operating temperature and humidity
	Protect from moisture
SN	Serial number
CE 0483	The CE labelling certifies that the product complies with the essential requirements of Directive 93/42/EEC on medical products.

⚠ Advice on use

- In order to ensure comparable values, always measure your blood pressure at the same time of day.
- Before every measurement, relax for about five minutes.
- If you want to perform several measurements on the same person, wait five minutes between each measurement.
- Do not take a measurement within 30 minutes after eating, drinking, smoking or exercising.
- Repeat the measurement if you are unsure of the measured value.
- The measurements taken by you are for your information only – they are not a substitute for a medical examination! Discuss the measurements with your doctor, and never base any medical decisions on them (e.g. medicines and their administration)!
- Do not use the blood pressure monitor on newborns, pregnant women or patients with preeclampsia.
- In the case of restricted circulation on the arm as a result of chronic or acute vascular diseases (including vascular constriction), the accuracy of the wrist measurement is limited. In this case you should avoid using an upper arm blood pressure monitor.
- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Supervise children around the device to ensure they do not play with it.
- Cardiovascular diseases may lead to incorrect measurements or have a detrimental effect on measurement accuracy. The same also applies to very low blood pressure, diabetes, circulatory disorders and arrhythmias as well as chills or shaking.
- The blood pressure monitor must not be used in connection with a high-frequency surgical unit.
- Only use the unit on people who have the specified wrist measurement for the device.
- Please note that when inflating, the functions of the limb in question may be impaired.
- During the blood pressure measurement, blood circulation must not be stopped for an unnecessarily long time. If the device malfunctions, remove the cuff from the arm.
- Do not allow sustained pressure in the cuff or frequent measurements. The resulting restriction of the blood flow may cause injury.
- Ensure that the cuff is not placed on an arm in which the arteries or veins are undergoing medical treatment, e.g. intravascular access or therapy, or an arteriovenous (AV) shunt.

- Do not use the cuff on people who have undergone a mastectomy.
- Do not place the cuff over wounds as this may cause further injury.
- Place the cuff on your wrist only. Do not place the cuff on other parts of the body.
- The blood pressure monitor can only be operated with batteries.
- To conserve the batteries, the monitor switches off automatically if no buttons are pressed for two minutes.
- The device is only intended for the purpose described in these instructions for use. The manufacturer is not liable for damage resulting from improper or careless use.

⚠ Instructions for storage and maintenance

- The blood pressure monitor is made from precision and electronic components. The accuracy of the measurements and service life of the device depend on its careful handling:
  – Protect the device from impacts, humidity, dirt, marked temperature fluctuations and direct sunlight.
  – Do not drop the device.
  – Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.
- Do not press the buttons before the cuff is placed on the arm.
- We recommend that the batteries be removed if the device will not be used for a prolonged period of time.

⚠ Notes on handling batteries

- If your skin or eyes come into contact with battery fluid, flush out the affected areas with water and seek medical assistance.
- ⚠ **Choking hazard!** Small children may swallow and choke on batteries. Store the batteries out of the reach of small children.
- Observe the plus (+) and minus (-) polarity signs.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- Protect the batteries from excessive heat.
- ⚠ **Risk of explosion!** Never throw batteries into a fire.
- Do not charge or short-circuit batteries.
- If the device is not to be used for a long period, take the batteries out of the battery compartment.
- Use identical or equivalent battery types only.
- Always replace all batteries at the same time.
- Do not use rechargeable batteries.
- Do not disassemble, split or crush the batteries.

ⓘ Instructions for repairs and disposal

- Batteries do not belong in household waste. Please dispose of empty batteries at the collection points intended for this purpose.
- Do not open the device. Failure to comply will result in voiding of the warranty.
- Do not repair or adjust the device. Proper operation can no longer be guaranteed in this case.
- Repairs must only be carried out by Customer Services or authorised suppliers. Before making a claim, please check the batteries first and replace them if necessary.
- For environmental reasons, do not dispose of the device in the household waste at the end of its useful life. Dispose of

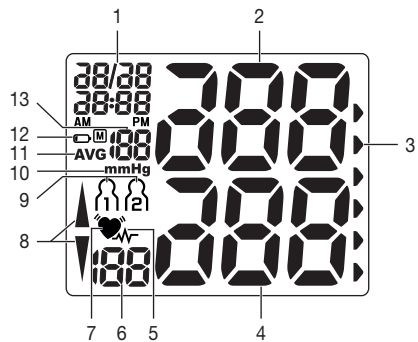
the device at a suitable local collection or recycling point. Dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.

3. Unit description

1. Display
2. Scale for classifying the measurements
3. Wrist cuff
4. START/STOP button
5. User selection button
6. Memory button **+/M**
7. Date/time setting button
8. Battery compartment lid

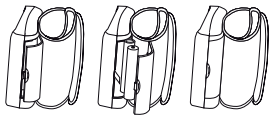
Information on the display:

1. Time and date
2. Systolic pressure
3. Classification of measurements
4. Diastolic pressure
5. Cardiac arrhythmia symbol
6. Calculated pulse value
7. Pulse symbol
8. Pump up, release air (arrow)
9. User memory /
10. Unit in mmHg
11. Average value of the last three measurements **AVG**
12. Battery level indicator
13. Memory space number



4. Preparing the measurement

Insert the batteries



- Remove the battery compartment lid on the left side of the device.
- Insert two 1.5V micro (alkaline type LR03) batteries.
  Make sure that the batteries are inserted the correct way round. Do not use rechargeable batteries.
- Close the battery compartment lid again carefully.

If the battery change symbol is flashing and E6 appears, no more measurements are possible and you must replace all batteries.
After inserting the batteries, the year appears on the display and you can then set the date and time.

Battery disposal

- The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.
- The codes below are printed on batteries containing harmful substances:
  Pb = Battery contains lead,
  Cd = Battery contains cadmium,
  Hg = Battery contains mercury.

Setting the date and time

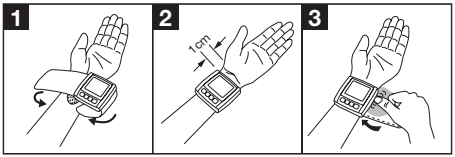
You should set the date and time without fail. Otherwise, you will not be able to save your measured values correctly with a date and time and access them again later. The time is displayed in the 24-hour format.

To set the date and time, proceed as follows:
1. After inserting the batteries:
- Following the display check, during which all segments appear, the year flashes on the display.
- Using the **+/M** button, you can increase the basic values to be set. Set the year and confirm the entry using the button.
- Now set the month using the **+/M** button. Confirm using the button.
- Set the day/hour/minute and confirm each using the button.
- To switch off, press the START/STOP button .

2. At any time:
- Press the button to display the date/time and current user memory.
- Press and hold the button again for about 3 seconds to reach Date and time mode.
- Set as described above.

5. Measuring blood pressure

Attach the cuff



- Expose your left wrist. Ensure that the circulation of the arm is not hindered by tight clothing or similar.
  Place the cuff on the inside of your wrist.
- Fasten the cuff with the hook and loop fastener so that the upper edge of the monitor is positioned approx. 1 cm below the ball of your thumb.
- The cuff must be fitted tightly around the wrist, but must not constrict.

Adopt the correct posture

- Before every measurement, relax for about five minutes. Otherwise deviations can occur.
- You can perform the measurement while sitting or lying. To carry out a blood pressure measurement, make sure you are sitting comfortably with your arms and back leaning on something. Do not cross your legs. Place your feet flat on the ground. Make sure to rest your arm and move it. Always make sure that the cuff is at heart level.

  Otherwise significant deviations can occur. Relax your arm and the palm of your hand.
- To avoid falsifying the measurement, it is important to remain still during the measurement and not to speak!

Selecting memory

Press the ◔ button to display the date/time and current user memory. Select the desired user memory by pressing the user selection button 🧍. Confirm your selection with the ⏻ button. You have 2 memories with 60 memory spaces each to store the measurements of 2 different people separately or to separate measurements taken in the morning and at night.

Performing the blood pressure measurement

- As described above, attach the cuff and adopt the posture in which you want to perform the measurement.
- Select the user memory 🧍 or 🧍2. Start the measurement by holding the ⏻ button. Following the display check, during which all numbers appear, the cuff inflates 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 detected.
- When the measurement has been taken, the remaining air pressure dissipates very quickly. The pulse, the systolic and diastolic blood pressure are displayed.
- Measuring can be cancelled at any time by pressing ⏻.
- The symbol E_ appears if the measurement could not be performed properly. Take note of the chapter on error messages/

trouble-shooting in these instructions for use and repeat the measurement.

- The device switches off automatically after 2 minutes.

Wait at least 5 minutes before taking another measurement!

Evaluating results

Cardiac arrhythmias:

This unit can identify potential disruption of the heart rhythm when measuring and if necessary, indicates this after the measurement with the symbol .

This can be an indicator for arrhythmia. Arrhythmia is an illness in which the heart rhythm is abnormal because of flaws in the bioelectrical system that regulates the heartbeat. The symptoms (skipped or premature heart beats, pulse being slow or too fast) can be caused by factors such as heart disease, age, physical make-up, excess stimulants, stress or lack of sleep. Arrhythmia can only be determined through an examination by your doctor. If the symbol is shown on the display after the measurement has been taken, it should be repeated. Please ensure that you rest for 5 minutes beforehand and do not speak or move during the measurement. If the symbol appears frequently, please consult your doctor. Self-diagnosis and treatment based on the measurements can be dangerous. Always follow your GP's instructions.

Classification of measurements:

The measurements can be classified and evaluated in accordance with the following table.

However, these standard values serve only as a general guideline, as the individual blood pressure varies in different people and different age groups etc.

It is important to consult your doctor regularly for advice. Your doctor will tell you your individual values for normal blood pressure as well as the value above which your blood pressure is classified as dangerous.

The classification on the display and the scale on the unit show which category the recorded blood pressure values fall into. If the values of systole and diastole fall into two different categories (e.g. systole in the ‚High normal' category and diastole in the ‚Normal' category), the graphical classification on the device always shows the higher category; for the example given this would be ‚High normal'.

Blood pressure value category	**Systole** (in mmHg)	**Diastole** (in mmHg)	**Action**
Setting 3: severe hypertension	≥180	≥110	seek medical attention
Setting 2: moderate hypertension	160–179	100–109	seek medical attention
Setting 1: mild hypertension	140–159	90–99	regular monitoring by doctor
High normal	130–139	85–89	regular monitoring by doctor
Normal	120–129	80–84	self-monitoring
Optimal	<120	<80	self-monitoring

Source: WHO, 1999 (World Health Organization)

6. Saving and displaying measurements

- The results of every successful measurement are stored together with the date and time. If there are more than 60 measurements, the oldest measurements are lost.
- Use the button and then the button to select the desired user memory. Pressing the **+/M** button displays the average value of the 3 most recent measurements stored in the user memory. If you continue to press the memory button **+/M**, the most recent individual measured values are displayed in turn with the date and time.

7. Deleting stored values

To delete individual measurements, you must first select them. Press and hold the memory button **+/M** until CL appears in the display. Then confirm the deletion with the user selection button (CL and 00 appear on the display).

To delete measurements from a user memory, you must first select them. Press the memory button **+/M** and the average value of the last 3 saved measurements is displayed. Then press and hold the memory button **+/M** again until CL appears in the display. Confirm the deletion with the user selection button (CL and 00 appear on the display).

8. Error message/troubleshooting

In the event of errors, the error message E_ appears on the display.

Error messages may appear if:

- it was not possible to record the pulse: E 1;
- you move or speak during the measurement: E2;
- the cuff is fastened too tightly or loosely: E3;
- errors occur during the measurement: E4;
- the pump pressure is higher than 300 mmHg: E5;
- the batteries are almost empty E6.

In such cases, repeat the measurement. Ensure that you do not move or speak. If necessary, reinsert or replace the batteries.

9. Cleaning and storing the device and cuff

- Clean the device and cuff carefully using a slightly damp cloth only.
- Do not use any cleaning agents or solvents.
- Under no circumstances hold the device and cuff under water, as this can cause liquid to enter and damage the device and cuff.
- If you store the device and cuff, do not place heavy objects on the device and cuff. Remove the batteries.

10. Technical specifications

Model no.	SBC 21
Measurement method	Oscillometric, non-invasive blood pressure measurement on the wrist
Measurement range	Cuff pressure 0-300 mmHg, systolic 50-250 mmHg, diastolic 30-200 mmHg, pulse 40-180 beats/minute
Display accuracy	Systolic ± 3 mmHg, diastolic ± 3 mmHg, pulse ± 5 % of the value shown
Measurement inaccuracy	Max. permissible standard deviation according to clinical testing: systolic 8 mmHg / diastolic 8 mmHg

Memory	2 x 60 memory spaces
Dimensions	L 70 mm x W 72 mm x H 27.5 mm
Weight	Approximately 105 g (without batteries)
Cuff size	135 to 195 mm
Permissible operating conditions	+10 °C to +40 °C, 30-85 % relative humidity (non-condensing)
Permissible storage conditions	-20 °C to +60 °C, 10-95 % relative humidity, 700-1050 hPa ambient pressure
Power supply	2 x 1.5V ⎓ AAA batteries
Battery life	For approx. 300 measurements, depending on levels of blood pressure and pump pressure
Accessories	Instructions for use, 2 x 1.5V AAA batteries, storage box
Classification	Internal supply, IPX0, no AP or APG, continuous operation, application part type BF

- This unit is in line with European Standard EN 60601-1-2 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 unit. More details can be requested from the stated Customer Services address or found at the end of the instructions for use.
- This device is in line with the EU Medical Devices Directive 93/42/EEC, the “Medizinproduktegesetz” (German Medical Devices Act) and the standards EN 1060-1 (non-invasive sphygmomanometers, Part 1: General requirements), EN 1060-3 (non-invasive sphygmomanometers, Part3: Supplementary requirements for electro-mechanical blood pressure measuring systems) and IEC 80601-2-30 (Medical electrical equipment – Part 2-30: Particular requirements for the safety and essential performance of automated non-invasive blood pressure monitors).
- The accuracy of this blood pressure monitor has been carefully checked and developed with regard to a long useful life. If using the device for commercial medical purposes, it must be regularly tested for accuracy by appropriate means. Precise instructions for checking accuracy may be requested from the service address.