

MD4300



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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 device

Check that the packaging of the Sanitas MD4300 blood pressure monitor has not been tampered with and make sure that the required contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.


The wrist blood pressure monitor is used to carry out non-invasive measurement and monitoring of the arterial blood pressure values in adults.

This allows you to quickly and easily measure your blood pressure, save the measured values and display the development and average values of the measured values taken.




You are also warned of possible existing irregular heartbeat.










The recorded values are classified and evaluated graphically. Store these instructions for use for future reference and make them accessible to other users.

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
	Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive – WEEE
	Manufacturer
Storage  -25°C – 70°C RH ≤ 93%	Permissible storage temperature and humidity
Operating  5°C – 40°C RH 15-93 %	Permissible operating temperature and humidity
	Protect from moisture
	Serial number
 0123	The CE labelling certifies that the product complies with the essential requirements of Directive 93/42/EEC on medical products.

 Notes 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.
- Do not modify this equipment.

- 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 of eating, drinking, smoking or exercising.
- Repeat the measurement if you are unsure of the measured value.
- The measured values taken by you are for your information only – they are no substitute for a medical examination. Discuss the measured values 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 or patients with preeclampsia. We recommend consulting a doctor before using the blood pressure monitor during pregnancy.
- 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.
- 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, the 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.
- Make sure that the cuff is not placed on an arm in which the arteries or veins are undergoing medical treatment, e.g. intravascular access or intravascular 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.
- The blood pressure monitor can only be operated with batteries.
- If you do not press any buttons within 30 seconds, the blood pressure monitor switches off automatically to save the batteries.
- If you do not press any buttons within 3 minutes after a measurement, the blood pressure monitor switches off automatically to save the batteries.
- 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.
- The PATIENT is an intended OPERATOR, and comparable healthy to normal OPERATOR.
- While the EQUIPMENT is in use, no serving and maintenance can be operated.
- All function and basic maintenance like change battery or clean EQUIPMENT the PATIENT can perform.



Instructions for storage and maintenance

- The blood pressure monitor is made from precision and electronic components. The accuracy of the measured values 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.



Notes on handling batteries

- If your skin or eyes come into contact with battery fluid, rinse 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 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 relatively 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.

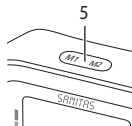
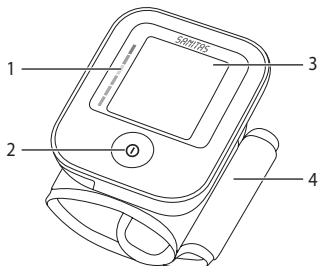
- Do not use rechargeable batteries.
- Do not disassemble, open or crush the batteries.

i 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 repair or adjust the device yourself. Proper operation can no longer be guaranteed in this case.
- Repairs must only be carried out by Customer Services or authorised suppliers.
- Do not open the device. Failure to comply will invalidate the warranty.
- 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.








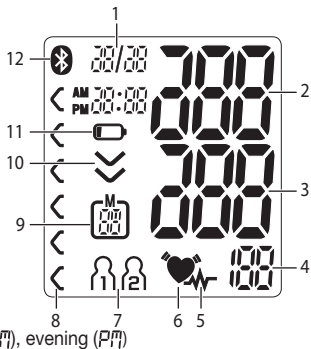
3. Device description



1. Scale for classifying the measurements
2. START/STOP button **i**
3. Display
4. Cuff
5. Memory buttons M1 /M2

Information on the display:

1. Time/date
2. Systolic pressure
3. Diastolic pressure
4. Calculated pulse value
5. Irregular heartbeat symbol 
6. Pulse symbol 
7. User memory 
8. Classification of measurements
9. Number of memory space/memory display for average value (A), morning (AM), evening (PM)
10. Release air (arrow)
11. Battery display symbol 
12. Symbol for Bluetooth® transfer 



System requirements for the HealthCoach app

Bluetooth® 4.0, iOS from Version 7.0, Android™ devices from Version 4.3 with Bluetooth® Smart Ready

List of compatible devices:




4. Preparing the measurement

Inserting the batteries

- Remove the battery compartment lid on the rear of the device.
- Insert 2x 1.5 V AAA (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.

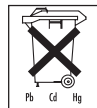


All display elements are briefly displayed, 24 h or 12 h flashes in the display. Now set the date and time as described below.

If the battery replacement symbol  is permanently displayed, you can no longer perform any measurements and must replace all batteries. Once the batteries have been removed from the device, the date and time must be set again. Any saved measured values are retained.

The empty, completely discharged 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.



Set the hour format, date, time and Bluetooth® settings

The following section describes the functions and settings available on the blood pressure monitor.

Hour format



Date



Time

Bluetooth®

It is essential to set the correct date and time. Otherwise, you will not be able to save your measured values correctly with a date and time and access them again later.

- ❗ If you press and hold the M1 or M2 memory button, you can set the values more quickly.

Press and hold the START/STOP button ① for 5 seconds.

All display elements are briefly displayed.

Hour format

The hour format now flashes on the display.

- Select the desired hour format using the M1/M2 memory buttons and confirm with the START/STOP button ①.



Date

The year flashes on the display.

- Select the year using the M1/M2 memory buttons and confirm with the START/STOP button ①.



The month flashes on the display.

- Select the month using the M1/M2 memory buttons and confirm with the START/STOP button ①.



Date

The day flashes on the display.

- Select the current day using the M1/M2 memory buttons and confirm with the START/STOP button ①.



- ❗ If you have set the 12h hour format, the month is displayed before the day.

Time

The hours flash on the display.

- Select the current hours using the M1/M2 memory buttons and confirm with the START/STOP button ①.



The minutes flash on the display.

- Select the current minutes using the M1/M2 memory buttons and confirm with the START/STOP button ①.



Bluetooth®

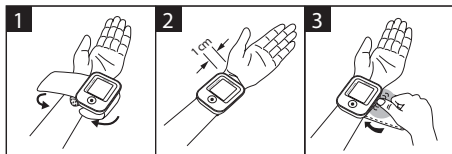
The Bluetooth® symbol ② flashes on the display.

- Use the M1/M2 memory buttons to select whether automatic Bluetooth® data transfer is activated (Bluetooth® symbol ② flashes) or deactivated (Bluetooth® symbol ② is not shown) and confirm with the START/STOP button ①.

- ❗ Bluetooth® transfers will reduce the battery life.

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.
- Close the cuff with the hook-and-loop fastener such that the upper edge of the device is positioned approx. 1 cm underneath the heel of the hand.
- 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.



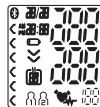
Otherwise significant deviations can occur. Relax your arm and the palm of your hand.

- To avoid falsifying the measurement, it is important to remain still during the measurement and not to speak!

Performing the blood pressure measurement

As described above, attach the cuff and adopt the posture in which you want to perform the measurement.

- Press the **START/STOP** button **ⓘ** to start the blood pressure monitor. All display elements are briefly displayed.

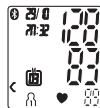


The blood pressure monitor will begin the measurement automatically after 3 seconds.

- **ⓘ** You can cancel the measurement at any time by pressing the **START/STOP** button **ⓘ**.


As soon as a pulse is found, the pulse symbol **♥** will be displayed.


- The systolic pressure, diastolic pressure and pulse rate measurements are displayed.







- **Er** appears if the measurement could not be performed properly (see chapter 9 "Error messages/troubleshooting"). Repeat the measurement.



- Now select the desired user memory by pressing the M1 or M2 memory buttons. If you do not select a user memory, the measurement is stored in the most recently used user memory. The relevant f_{11} or f_{21} symbol appears on the display.
- Press the START/STOP button  to switch off the blood pressure monitor. The measurement is then stored in the selected user memory.
- If the device is not switched off manually, it will switch off automatically after 3 minutes.

If Bluetooth[®] data transfer has been activated, data is by transferred after having confirmed the user memory by pressing the pressing the START/STOP button .

- The Bluetooth[®] symbol  flashes on the display. The blood pressure monitor now attempts to connect to the app for approx. 30 seconds.
- The Bluetooth[®] symbol  stops flashing as soon as a connection is established. All measurement data is automatically transferred to the app. Once the data has been successfully transferred, the device switches off. If the data transfer was unsuccessful, "Err" appears on the display.
- If a connection to the app cannot be established after 30 seconds, the Bluetooth[®] symbol  goes out and the blood pressure monitor switches off automatically after 30 seconds.

-  Please note that you must add the blood pressure monitor in "My devices" in the "HealthCoach" app to enable data transfers. The "HealthCoach" app must be active to allow data transfer. If the latest data is not displayed on your smart-phone, repeat the data transfer as described in chapter 7.


If you forget to turn off the blood pressure monitor, it will switch off automatically after approximately 3 minutes. In this case too, the value is stored in the selected or most recently used user memory and the data is transferred automatically after 3 minutes if Bluetooth[®] data transfer has been activated.

- Wait at least 5 minutes before taking another measurement.





6. Evaluating results

Irregular heartbeat:

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

This can be an indicator for irregular heartbeat. Irregular heartbeat is a condition 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. Irregular heartbeat can only be determined through an examination by your doctor. If the symbol  is shown on the display after the measurement has been taken, repeat the measurement. 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 hyper-tension	≥ 180	≥ 110	seek medical attention
Setting 2: moderate hyper-tension	160 – 179	100 – 109	seek medical attention
Setting 1: mild hyper-tension	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)

7. Display and delete measured values

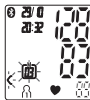
User memory

The results of every successful measurement are stored together with the date and time. The oldest measurement is overwritten in the event of more than 60 measurements.

- Select the desired user memory ( ) with the M1 or M2 memory buttons if the device is switched off.
- To view the measurement data for user memory , press the M1 memory button.

- To view the measurement data for user memory M_2 , press the M2 memory button. The average of all measurements appears on the display.

If Bluetooth® is activated (the B symbol flashes on the display), the blood pressure monitor attempts to connect to the app. If you press the M1 button in the meantime, the transfer is cancelled and the average values for morning measurements are displayed. If you press the M2 button, the transfer is cancelled and the measurement data of user memory M_2 is displayed. The B symbol is no longer shown. The buttons are deactivated as soon as a connection is established and the data is transferred.



- i** Press the M1 button if you have selected user memory 1.
Press the M2 memory button if you have selected user memory 2.

A flashes on the display.

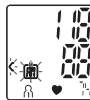
The average value of all saved measured values in this user memory is displayed.



- Press the relevant memory button (M1 or M2).

M flashes on the display.

The average value of the morning measurements for the last 7 days is displayed (morning: 5.00 a.m. – 9.00 a.m.).



Press the relevant memory button (M1 or M2).

M flashes on the display.

The average value of the evening measurements for the last 7 days is displayed (evening: 6.00 p.m. – 8.00 p.m.).



When the relevant memory button (M1 or M2) is pressed again, the last individual measurement is displayed (in this example, measurement 03).





When the relevant memory button (M1 or M2) is pressed again, you can view your individual measurements.

- To switch the device off again, press the START/STOP button I .
If you forget to turn off the blood pressure monitor, it will switch off automatically after 30 seconds.
- i** You can exit the menu at any time by pressing the START/STOP button I .

- To clear the memory of the relevant user memory, you must first select a user memory.
- Start the retrieval of the average measured values. A flashes on the display and the average value of all saved measured values in this user memory is displayed.
- Press and hold the memory button M1 or M2 for 5 seconds depending on the user memory you are in.

All the values in the current user memory are deleted.

If Bluetooth[®] is activated (the  symbol flashes on the display), the blood pressure monitor attempts to connect to the app. When the symbol  is flashing, it is not possible to delete all values from the selected user memory.



To clear individual measurements from the relevant user memory, you must first select a user memory.


- Start the retrieval of the individual measured values.
- Press and hold the memory button M1 or M2 for 5 seconds (depending on the user memory you are in).
- The selected value is deleted. The device briefly displays CL 00.
- If you would like to delete other values, repeat the process described above.

You can switch off the device at any time by pressing the START/STOP  button.

Transfer via Bluetooth[®] Smart

It is also possible to transfer the measured values saved on the device to your smartphone using Bluetooth[®] Smart. You will need the HealthCoach app for this. The app is available from the App Store.

Proceed as follows to transfer values:

If Bluetooth[®] is activated in the settings menu, the data is transferred automatically after the measurement. The  symbol appears in the top left of the display (see chapter 4 „Preparing the measurement“).



Step 1: MD4300

Activate Bluetooth[®] on your device (see chapter 4 "Preparing the measurement", Bluetooth[®]).



Step 2: "HealthCoach" app

In the HealthCoach app, add the MD4300 under "Settings/My devices".




Step 3: MD4300

take a measurement.



Step 4: MD4300

data transfer immediately following measurements.

- If Bluetooth® data transfer has been activated, data is transferred after having confirmed the user memory by pressing the button .

Step 4: MD4300

Data transfer at a later point:

- Go to memory mode (chapter 7). Select the desired user memory. The Bluetooth® transfer starts automatically.

 The HealthCoach app must be active to allow data transfer.

If your smartphone has a protective cover, remove this to ensure that there is no interference during the transfer. Begin the data transfer in the HealthCoach app.

8. Cleaning and storing the unit


- Clean the device and cuff carefully using a slightly damp cloth only.
- Do not use any cleaning agents or solvents.
- Under no circumstances should you hold the unit under water, as this can cause liquid to enter and damage the unit.
- If you store the device, no heavy objects should be placed on top of it. The cuff line should not be bent sharply.

In such cases, repeat the measurement and/or data transfer. Ensure that the cuff line is correctly attached and that you do not move or speak during the measurement.

9. Error messages/troubleshooting

In the event of errors, the error message $E_{r_}$ appears on the display.

Error messages may appear if:

- it was not possible to record the pulse: E_{r1} ;
- you move or speak during the measurement: E_{r2} ;
- the cuff is fastened too tightly or loosely: E_{r3} ;
- errors occur during the measurement: E_{r4} ;
- the pump pressure is higher than 300 mmHg: E_{r5} ;
- the batteries are almost empty : E_{r6} ;
- E_{r7} the data could not be sent via Bluetooth®.

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10. Technical specifications

Model No.	MD4300
Measurement method	Oscillometric, non-invasive blood pressure measurement on the upper arm
Measurement range	Cuff pressure 0 – 300 mmHg, Systolic 50 – 250 mmHg, Diastolic 30 – 200 mmHg, Pulse 40 – 180 beats/minute
Display accuracy	Systolic \pm 3 mmHg, Diastolic \pm 3 mmHg, Pulse \pm 5 % of the value shown

Measurement accuracy	Max. permissible standard deviation according to clinical testing: Systolic 8 mmHg / Diastolic 8 mmHg
Memory	2 x 60 memory spaces
Dimensions	L 78 mm x W 63 mm x H 23 mm
Weight	66.5 g (Without cuff and batteries)
Cuff size	14 to 19.5 cm
Permissible operating conditions	+5°C to + 40°C, 15-93% relative humidity (non-condensing)
Permissible storage conditions	-25°C to + 70°C, ≤ 93% relative humidity, 700 –1060 hPa ambient pressure
Power supply	2x 1.5 V — AAA batteries
Battery life	Lasts for approx. 200 measurements depending on the blood pressure and pump pressure as well as the number of Bluetooth® connections.
Accessories	Instructions for use, storage box
Classification	Internal supply, IP22, no AP or APG, continuous operation, application part type BF

Data transfer via Bluetooth® wireless technology

The blood pressure monitor uses Bluetooth® Smart (low energy), 2.4 GHz frequency band, compatible with Bluetooth 4.0 smartphones/tablets



List of supported smartphones/tablets

Technical information is subject to change without notification to allow for updates.

- This device complies with European Standard EN60601-1-2 and is subject to particular precautions with regard to electromagnetic compatibility. 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.
- The device complies with the EU Medical Devices Directive 93/42/EEC, the German Medical Devices Act (Medizinproduktegesetz) and the standards EN1060-1 (non-invasive sphygmomanometers – Part 1: General requirements), EN1060-3 (non-invasive sphygmomanometers – Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems) and IEC80601-2-30 (Medical electrical equipment – Part 2 – 30: Particular requirements

for the basic safety and essential performance of automated non-invasive sphygmomanometers).

- 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.
- We hereby guarantee that this product complies with the European R&TTE Directive 1999/5/EC.
Please contact the specified service address to obtain more detailed information such as the CE conformity declaration.

11. FCC statement

Changes or modifications to the product not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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

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

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.



Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.

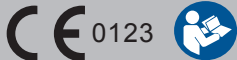
The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.



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P/N: 83-M4300-SEN00A-R #1201A
MADE IN CHINA

PEMS# E3F5-DC75