

MD3600



Blood pressure monitor
Instructions for use

ENGLISH

Content

1. Getting to know your device
2. Important notes
3. Unit description
4. Preparing the measurement
5. Measuring blood pressure
6. Evaluating results
7. Saving, displaying and deleting measured values
8. Transferring measured values
9. Error messages/troubleshooting
10. Cleaning and storing the unit
11. Technical specifications
12. Warranty / service
13. FCC statement

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 upper arm 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 cardiac arrhythmia. The recorded values are classified according to the WHO guidelines 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
SN	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.
- 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 pre-eclampsia. We recommend consulting a doctor before using the blood pressure monitor during pregnancy.
- 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 device on people who have the specified upper arm 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.
- Avoid any mechanical restriction, compression or bending of the cuff line.
- 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.

- To conserve the batteries, the blood pressure monitor switches off automatically if no buttons are pressed for one minute.
- 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 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.
 - Only use the cuff included with the delivery or original replacement parts. Otherwise incorrect measured values will be recorded.
- 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 batteries

- Swallowing batteries can be extremely dangerous. Keep the batteries and products out of the reach of small children. If a battery is swallowed, seek medical attention immediately.
- Batteries must not be recharged, taken apart, thrown into an open fire or short circuited.
- If the batteries are empty or you do not intend to use the device for longer periods, remove the batteries from the device. This prevents damage which could occur due to leakage. Always replace all batteries at the same time.
- Do not use different types of batteries, different brands or batteries with different capacities.
For preference, use alkaline batteries.



Instructions for repairs and disposal

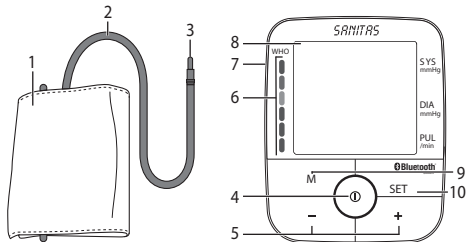
- Batteries do not belong in household waste. Please dispose of empty batteries at the collection points intended for this purpose.
- Do not open the device. Failure to comply will result in voiding of the warranty.
- Do not repair or adjust the device yourself. Proper operation can no longer be guaranteed 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.
- Please dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment).



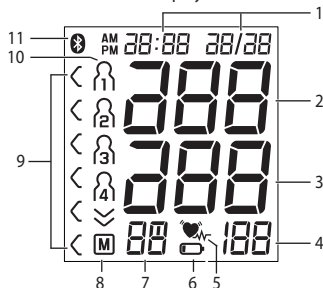
If you have any questions, please contact the local authorities responsible for waste disposal.

3. Unit description



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

Information on the display:



1. Time and date
2. Systolic pressure
3. Diastolic pressure
4. Calculated pulse value
5. Cardiac arrhythmia symbol
6. Battery replacement symbol
7. Memory display: average value (R), morning (R_M), evening (P_M), memory space number
8. Release air
9. WHO classification
10. User memory
11. Symbol for Bluetooth® transfer

System requirements for the “Sanitas HealthCoach” app
Bluetooth®4.0, iOS from Version 7.0, Android™ devices from Version 4.3 with Bluetooth® Smart Ready

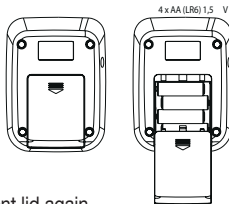
List of compatible devices:



4. Preparing the measurement

Inserting the batteries

- Open the battery compartment lid.
- Insert four 1.5V AA (alkaline type LR6) 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 flashes in the display. Now set the date, time and Bluetooth® as described below.



If the low battery indicator  is permanently displayed, you can no longer perform any measurements and must replace the batteries. 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: The codes below are printed on batteries containing harmful substances: Pb: battery contains lead, Cd: battery contains cadmium, Hg: battery contains mercury.

Setting the hour format, date, Bluetooth® and time

It is essential to set the 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.

To set the date, Bluetooth® and time, proceed as follows:

- Insert the batteries, or press and hold the setting button SET for at least 5 seconds if the batteries have already been inserted.
- Select 12h or 24h mode using the + button. Confirm with SET The year starts flashing. Set the year with the + button and confirm with SET .
- Set the month, day, hour and minute and confirm each with the setting button SET .

- The Bluetooth® symbol is shown in the display, “On” or “Off” flashes at the same time. With the function buttons “-/+”, choose whether automatic Bluetooth® data transfer should be activated (“On” flashes) or deactivated (“Off” flashes) and confirm with the setting button SET .
- If Bluetooth® is activated (“ON”), the data transfer will start automatically after the measurement.

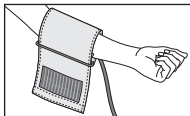
 Bluetooth® transfers will reduce the service life of the battery.

5. Measuring blood pressure

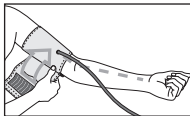
Ensure the device is at room temperature before measuring.

Attaching the cuff

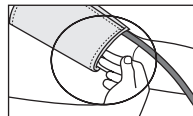
Place the cuff on to the bare left upper arm. The circulation of the arm must not be hindered by tight clothing or similar.



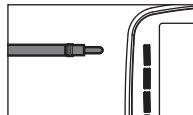
The cuff must be placed on the upper arm so that the bottom edge is positioned 2 – 3 cm above the elbow and over the artery. The line points to the centre of the palm.



Now tighten the free end of the cuff, but make sure that it is not too tight around the arm and close the hook-and-loop fastener. The cuff should be fastened so that two fingers fit under the cuff.



Now insert the cuff line into the connection for the cuff connector.

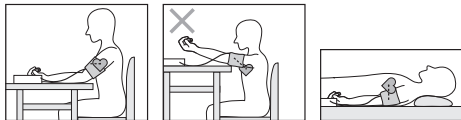


Important: The unit may only be operated with the original cuff. The cuff is suitable for an arm circumference of 22 to 36 cm.



Please ensure that the cuff is not bent at any point and that the reinforced end lies flat against your arm.

Adopt the correct posture



- Before every measurement, relax for about five minutes. Otherwise deviations can occur.
- You can take the measurement while sitting or lying. Always make sure that the cuff is at heart level.
- 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.
- To avoid falsifying the measurement, it is important to remain still during the measurement and not to speak.

Selecting memory

Press the setting button **SET**. Select the desired user memory (1 ... 4) by pressing the **-/+** function buttons. You have 4 memories, each with 30 memory spaces to store the measurements of 4 different people separately. Confirm your selection with the **START/STOP** button ① or wait for 3 seconds. Your selection is then automatically stored.

Performing the blood pressure measurement

- As described above, attach the cuff and adopt the posture in which you want to perform the measurement.
- Start the blood pressure monitor with the **START/STOP** button ①. After the full-screen display, the most recently stored measurement appears. If there is no measurement in the memory, the unit displays the value "0".
- The cuff automatically inflates. The cuff's air pressure is slowly released. If you already recognise a tendency for high blood pressure, you should reinflate the cuff and increase the cuff's pressure again. As soon as a pulse is found, the pulse symbol ♥ will be displayed.
- The systolic pressure, diastolic pressure and pulse rate measurements are displayed.
- You can cancel the measurement at any time by pressing the **START/STOP** button ①.
- E_u appears if the measurement has not been performed properly. Observe the chapter on error messages/troubleshooting in these instructions for use and repeat the measurement.
- The measurement is automatically stored.
- To switch off, press the **START/STOP** button ①. If you forget to switch off the device, the device switches itself off automatically after approx. 1 minute.

If Bluetooth® data transfer has been activated, the data is transferred. The blood pressure monitor shows the Bluetooth® symbol during data transfer. Switch off the blood pressure monitor by pressing the **START/STOP** button again. Please note that to transfer data to the “Sanitas HealthCoach” app, you must add the blood pressure monitor under “My devices”. The “Sanitas HealthCoach” app must be active to allow data transfer. If the latest data is not displayed on your smartphone, repeat the data transfer as described in chapter 8.

If you forget to turn off the blood pressure monitor, it will switch off automatically. In this case too, the value is stored in the selected user memory and the data is transferred if Bluetooth® data transfer has been activated. The Bluetooth® symbol appears on the blood pressure monitor display during data transfer.

During the data transfer, no button function can be performed.

Wait at least 5 minutes before taking another measurement.

6. Evaluating results

Cardiac arrhythmia:

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 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, 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.

WHO classification:

In accordance with the guidelines/definitions of the World Health Organization and the latest findings, the measurements can be classified and assessed according to 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.

Blood pressure value category	Systole (in mmHg)	Diastole (in mmHg)	Action
Level 3: severe hypertension	≥ 180	≥ 110	seek medical attention
Level 2: moderate hypertension	160 – 179	100 – 109	seek medical attention
Level 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

The bar chart 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 WHO categories (e.g. systole in the ‘High normal’ category and diastole in the ‘Normal’ category), the graphical WHO classification on the unit always shows the higher category; for the example given this would be ‘High normal’.

7. Saving, displaying and deleting measured values

The results of every successful measurement are stored together with the date and time. If there are more than 30 measurements, the oldest measurements are lost.

- Press the setting button **SET**. Select the desired user memory ( ... ) by pressing the **-/+** function buttons. Confirm your selection with the **START/STOP** button .

- If you press the memory button **M**, the average value $\bar{P}$ of all the stored measured values in the user memory will be displayed. If you press the memory button **M** again, the average value of the morning measurement for the last 7 days will be displayed. (morning: 5 a.m. – 9 a.m., display $\bar{P}_M$). If you continue to press the memory button **M**, the average value of the evening measurements for the last 7 days will be displayed. (evening: 6 p.m. – 8 p.m., display $\bar{P}_N$). If you continue to press the memory button **M**, the most recent individual measured values will be displayed with the date and time.
- To switch off, press the **START/STOP** button .
- If you forget to switch off the device, it will switch itself off automatically after 1 minute.
- If you want to delete the whole memory for a specific user, press the memory button **M**. Press and hold down both function buttons **-/+** simultaneously for 5 seconds.

8. Transferring measured values

Bluetooth® Smart transfer

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

Proceed as follows to manually transfer values:

Select the memory mode (chapter 7 “Saving, displaying and deleting measured values”). As soon as the average value of all the measured values is displayed, a Bluetooth® connection is established. The Bluetooth® symbol is displayed during transfer.

More information:

www.sanitas-online.de

9. Error messages/troubleshooting

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

Error messages may appear if:

- It was not possible to correctly record the pulse: E 1;
- You speak or move during the measurement: E 2;
- The cuff is fastened too tightly or loosely: E 3;
- Errors occur during the measurement: E 4;
- The pump pressure is higher than 300 mmHg: E 5;
- The batteries are almost empty: E 6.
- The data could not be sent via Bluetooth: E 7.

In such cases, repeat the measurement. Ensure that you do not move or speak.

If necessary, reinsert or replace the batteries.

10. Cleaning and storing the unit

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

11. Technical specifications

Model No.	MD3600
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 inaccuracy	Max. permissible standard deviation according to clinical testing: Systolic 8 mmHg / Diastolic 8 mmHg
Memory	4 x 30 memory spaces
Dimensions	L 139 mm x W 103 mm x H 54 mm
Weight	Approximately 267 g (without batteries and cuff)
Cuff size	22 to 36 cm
Permissible operating conditions	+5 °C to +40 °C, 15 to 93% relative humidity (non-condensing)
Permissible storage conditions	-25°C to +70°C, < 93% relative humidity, 700-1060 hPa ambient pressure
Power supply	4 x 1.5 V — AA batteries
Battery life	For approx. 200 measurements, depending on levels of blood pressure and pump pressure / Bluetooth® transfer

Accessories	Instructions for use, 4 x 1.5V AA batteries, storage pouch
Classification	Internal supply, IPX0, no AP or APG, continuous operation, application part type BF
Data transfer via Bluetooth® wire - less technology	The blood pressure monitor uses Bluetooth® Smart (low energy), 2.4 GHz frequency band

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/EC, 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.

12. Warranty / service

We provide a 3-year warranty covering faults in materials or manufacture of the product from the purchase date.

The warranty does not cover:

- Damage resulting from improper use.
- Wear parts.
- Defects that were known to the customer at the time of purchase.
- Damage for which the customer was responsible.

This warranty does not affect the customer's legal rights.

The customer must provide proof of purchase in order for any warranty claims within the warranty period to be honoured.

Claims under the warranty within a period of 3 years from the date of purchase are honoured by

13. 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.

MODIFICATION: Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the device.

14. Industry Canada RSS standard

This device complies with Industry Canada RSS standard(s). Operation is subject to the following two conditions:

- (1) this device may not cause interference, and
- (2) this device must accept any interference, including interference that may cause undesired operation of the device.



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.



Grandway Technology (Shenzhen) Limited,
Block 7, Zhu Keng Industrial Zone,
Ping Shan District, 518118 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA



Shanghai International Trading Corp. GmbH (Hamburg)
Eiffestrasse 80, 20537 Hamburg, Germany.



P/N: 83-M3600-SEN00A-R #0723B

MADE IN CHINA