

DIGITAL AUTOMATIC BLOOD PRESSURE MONITOR



MD4200

Instructions for use

Blood pressure monitor

ENGLISH

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 MD4200 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 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.


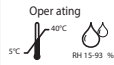


You are also warned of possible existing cardiac arrhythmia. The recorded values are classified and evaluated graphically. Store these instructions for use for future reference and make them accessible to other users.

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

 <p>Storage -25°C 70°C RH ≤ 93%</p>	Permissible storage temperature and humidity
 <p>Operating 5°C 40°C RH 15-93%</p>	Permissible operating temperature and humidity
	Protect from moisture
SN	Serial number
	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 preeclampsia. 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.
- Please note that data transfer and data storage is only possible when your blood pressure monitor is supplied with power. As soon as the batteries are empty, the blood pressure monitor loses the date and time.
- To conserve the batteries, the blood pressure monitor switches off automatically if no buttons are pressed for 30 seconds.
- 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

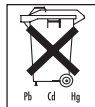
- The blood pressure monitor is made from precision and electronic components. The accuracy of the measured values and service life of the device depend on its careful handling:
 - Protect the device from impacts, humidity, dirt, marked temperature fluctuations and direct sunlight.
 - Do not drop the 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.

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.

Battery disposal

- 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

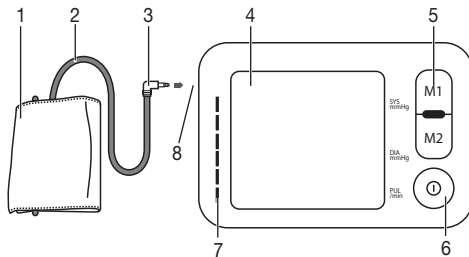



Instructions for repairs and disposal

- 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.

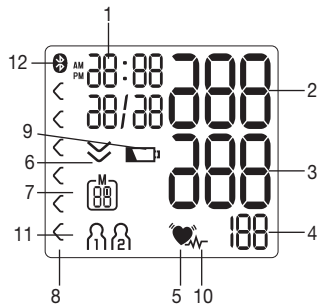


3. Device description



1. Cuff
2. Cuff line
3. Cuff connector
4. Display
5. Memory buttons M1 /M2
6. START/STOP button 
7. Scale for classifying the measurements
8. Connection for cuff connector (left-hand side)

Information on the display:



1. Time/date
2. Systolic pressure
3. Diastolic pressure
4. Calculated pulse value
5. Pulse symbol
6. Release air (arrow)
7. Number of memory space/memory display for average value (M), morning (M), evening (PM)
8. Classification of measurements
9. Battery display symbol
10. Cardiac arrhythmia symbol
11. User memory
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

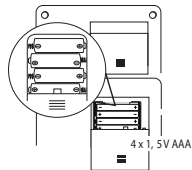
List of compatible devices:



4. Preparing the measurement

Inserting the batteries

- Remove the battery compartment lid on the rear of the device.
- Insert four 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.

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  for 5 seconds.

Hour format


The hour format now °ashes on the display.

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




Date

The year °ashes on the display.

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




The month °ashes on the display.


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



The day °ashes on the display.


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



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


Time

The hours °ash on the display.

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



The minutes °ash on the display.

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



The *Bluetooth*® symbol flashes on the display

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

i *Bluetooth*® transfers will reduce the battery life.

5. Measuring blood pressure

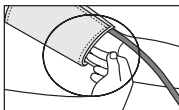
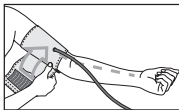
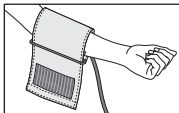
Ensure the device is at room temperature before measuring. The measurement can be performed on the left or right arm.

Attaching the cuff

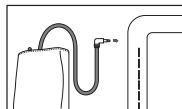
Place the *cu*₁ on to the bare left upper arm. The circulation of the arm must not be hindered by tight clothing or similar.

The *cu*₁ 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 should point to the centre of the palm.

Now tighten the free end of the *cu*₁, but make sure that it is not too tight around the arm and close the hook-and-loop fastener. The *cu*₁ should be fastened so that two fingers fit under the *cu*₁.



Now insert the *cu*₂ line into the connection for the *cu*₂ connector.



i If the measurement is performed on the right upper arm, the line should be located on the inside of your elbow. Ensure that your arm is not pressing on the line.

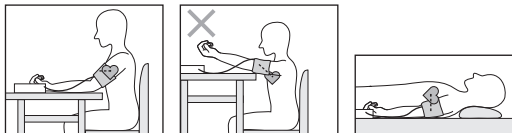
Blood pressure may vary between the right and left arm, which may mean that the measured blood pressure values are different. Always perform the measurement on the same arm.

If the values between the two arms are significantly different, please consult your doctor to determine which arm should be used for the measurement.

Important: The unit may only be operated with the original *cu*₁. The *cu*₁ is suitable for an arm circumference of 22 to 36 cm.

A larger *cu*₁ for upper-arm circumferences of 35 to 44 cm can be obtained from specialist retailers or from the service addressing order number 163.387.

Adopting the correct posture



- Before every measurement, relax for about five minutes. Otherwise deviations can occur
- You can take the measurement while sitting or lying down. 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.

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 **1** to start the blood pressure monitor. All display elements are briefly displayed.

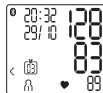


The blood pressure monitor will begin the measurement automatically after 3 seconds.

- You can cancel the measurement at any time by pressing the **START/STOP** button **1**.


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 M_1 or M_2 symbol appear on the display.
- Press the START/STOP button  to switch on the blood pressure monitor. The measurement is then stored in the selected user memory.
- If the device is not switched on manually, it will switch on automatically after 3 minutes.

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

- The *Bluetooth*® symbol on the display flashes and the blue LED lights up. 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 on. If the data transfer was unsuccessful, the blue LED goes out and "Er 7" appear 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 on automatically after 3 minutes.

- ⓘ Please note that you must add the blood pressure monitor in "My devices" in the "Health Coach" app to enable data transfers. The "Health Coach" 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 7.


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

- 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 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.

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.

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
Setting3: severe hypertension	~ 180	~ 110	seek medical attention
Setting2: moderate hypertension	160–179	100–109	seek medical attention
Setting1: 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)

7. Display and delete measured values

The result 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 (M1 or M2) with the M1 or M2 memory buttons if the device is switched on.

– To view the measurement data for user memory M1, press the M1 memory button.

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

If Bluetooth® is activated (the Bluetooth 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 are displayed. If you press the M2 button, the transfer is cancelled and the measurement data of user memory M2 is displayed. The Bluetooth 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).

P 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 on again, press the START/STOP button **I**.

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 flash 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.



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 on the device at any time by pressing the START/STOP button **I**.

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 **i** symbol appears in the top left of the display (see chapter 4 „Preparing the measurement“).



Step 1: MD4200

Activate *Bluetooth*® on your device (see chapter 4 "Preparing the measurement"; *Bluetooth*®).



Step 2: "HealthCoach" app

In the HealthCoach app, add the MD4200 under "Settings/My devices".



Step 3: MD4200

take a measurement.



Step 4: MD4200

data transfer immediately following measurements.

- 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 ①.

Step 4: MD4200

Data transfer at a later point:

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

① 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 cu_l 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 cu_l line should not be bent sharply.

In such cases repeat the measurement and/or data transfer. Ensure that the cu_l 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 Er_n appears on the display.

Error messages may appear if:

- it was not possible to record the pulse: Er₁;
- you move or speak during the measurement: Er₂;
- the cu_l is fastened too tightly or loosely: Er₃;
- errors occur during the measurement: Er₄;
- the pump pressure is higher than 300 mmHg: Er₅;
- the batteries are almost empty : Er₆;
- Er₇ the data could not be sent via *Bluetooth*®.

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10. Technical specifications

ModelNo.	MD4200
Measurement method	Oscillometric, non-invasive blood pressure measurement on the upper arm
Measurement range	Cuff pressure 0-250 mmHg, systolic 50-250 mmHg, diastolic 30-200 mmHg, pulse 40-180 beats/minute
Display accuracy	Systolic ± 3 mmHg, diastolic ± 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 139 mm x W 94 mm x H 48 mm
Weight	236 (without batteries and cuff)
Cuff size	22 to 44 cm
Permissible operating conditions	+5 °C to +40 °C, 15%- 93% relative air humidity (non-condensing)

Permissible storage conditions	-25°C to + 70°C, $\leq 93\%$ relative humidity, 700-1060 hPa ambient pressure
Power supply	4x 1.5 V \equiv AAA batteries
Battery life	Lasts for approx. 200 measurements depending on the blood pressure and inflation pressure as well as the number of Bluetooth® connections.
Accessories	Cuff, instructions for use, storage pouch
Classification	Internal supply, no AP or APG, continuous operation, application part type BF
Bluetooth (BLE) Module operation frequency:	2402-2480MHz
Maximum Transmit Power:	0.1dBm
Data transfer via Bluetooth® wireless technology	The blood pressure monitor uses <i>Bluetooth®</i> Smart (low energy), 2.4 GHz frequency band, compatible with <i>Bluetooth</i> 4.0 smartphones/tablets
	List of supported smartphones/tablets
	Service Life 1 Year



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

This device complies with European Standard EN60601-2 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 ISO EN81060-1 (non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automatic measurement type), 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.

- Instructions for use
- The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.
- Warning : Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Warning : Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.”
- Warning : Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Digital Automatic Blood Pressure Monitor (model name: MD4200), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- If any : a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).
- If any : the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term “ESSENTIAL PERFORMANCE” need not be used).

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.

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.

Appendix I

Guidance and manufacturer's declaration - electromagnetic emissions

The Sphygmomanometer (MD4200) is intended for use in the electromagnetic environment specified below. The customer or the user of the Sphygmomanometer (MD4200) should assure that it is used in such an environment.

Emissions test	Compliance
RF emissions CISPR11	Group 1
RF emissions CISPR11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance

Appendix II

Guidance and manufacturer's declaration - electromagnetic Immunity

The Sphygmomanometer (MD4200) is intended for use in the electromagnetic environment specified below. The customer or the user of the Sphygmomanometer(MD4200) should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV	Power supply lines: ±2 kV
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV 100 kHz repetition frequency	line(s) to line(s): ±1 kV 100 kHz repetition frequency
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC 61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz
Proximity Magnetic Fields IEC 61000-4-39	30KHz, CW,8A/m 134.2KHz - PM 2.1KHz, 65A/m 13.56MHz - PM 50KHz, 7.5A/m	N/A

N/A: UT is the a.c. mains voltage prior to application of the test level.

Remark *. The EUT do not contain magnetically sensitive components or circuitry. So this test do not need to evaluated.

Appendix III

Guidance and manufacturer's declaration - electromagnetic Immunity

The Sphygmomanometer (MD4200) is intended for use in the electromagnetic environment specified below. The customer or the user of the Sphygmomanometer (MD4200) should assure that it is used in such an environment.

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL(V/m)
	385	380-390	TETRA 400	Pulse modulation 18Hz	27
	450	430-470	GMRS 460, FRS 460	FM \pm 5 kHz deviation 1 kHz sine	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	9
	745				
	780				
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
	870				
	930				
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
	1845				
	1970				
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
	5500				
	5785				

Guidance and manufacturer's declaration - electromagnetic Immunity

The Sphygmomanometer (MD4200) is intended for use in the electromagnetic environment specified below. The customer or the user of the Sphygmomanometer (MD4200) should assure that it is used in such an environment.

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation ^a 2,1 kHz	65 ^b
13,56 MHz	Pulse modulation ^a 50 kHz	7,5 ^b

- a) The carrier shall be modulated using a 50% duty cycle square wave signal.
b) r.m.s., before modulation is applied.

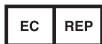


Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.

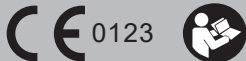
The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.



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P/N: 83-M4200-SEN00A-R #0503A

MADE IN CHINA

version number: 1.0
software version: 1.0