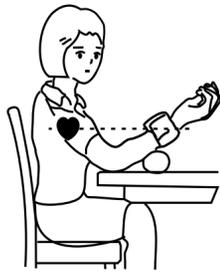
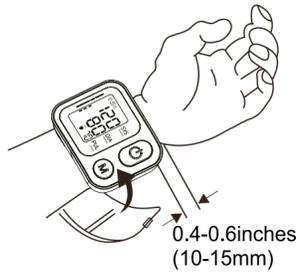
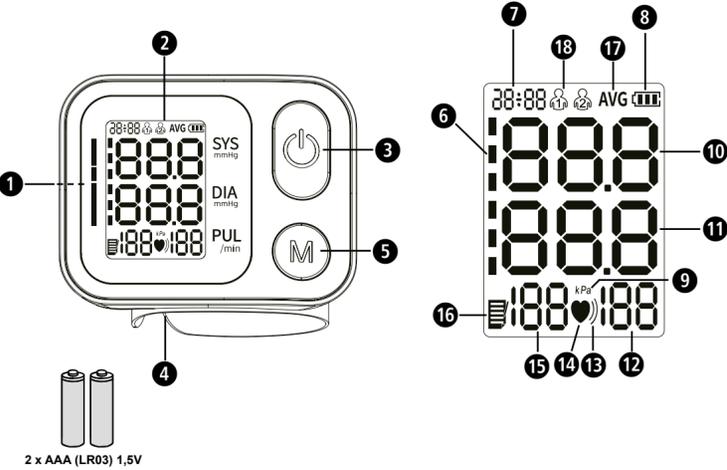


Unit and LC-display



Intended use

- The Wrist Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique by an inflatable cuff wrapped around the wrist. The unit can be used in medical facilities or at home.

Contraindications

- There are no known contraindications.

Explanation of symbols

IMPORTANT
Follow the instructions for use! Non-observance of these instructions can result in serious injury or damage to the device.

WARNING
These warning notes must be observed to prevent any injury to the user.

CAUTION
These notes must be observed to prevent any damage to the device.

NOTE
These notes give you useful additional information on the installation or operation.

Device classification: type BF applied part

General prohibition symbol

Keep dry

LOT
LOT number

Manufacturer

Date of manufacture

Observe local disposal guidelines!

MD Medical device

Temperature range

Ambient pressure limitation

Humidity range

Recycling symbols/codes: These are used to provide information about the material and its proper use and recycling.

Do not disassemble or dismantle!

CE 0123 CE sign

This side up

Keep away from sunlight

IP22
The device is protected against splashing water. Water splashed against the enclosure from any direction shall have no harmful effects.

SN
Serial number

EU authorized representative

GB Safety Instructions



Read the instruction manual carefully before using this device, especially the safety instructions and keep the instruction manual for future use. Should you give this device to another person, it is vital that you also pass on these instructions for use.



- Only use the unit for its intended purpose in accordance with the instructions for use. Warranty claims become void if the unit is misused.
- The unit is intended only for use in the home.
- Please consult your doctor prior to using the unit if you suffer from illnesses such as arterial occlusive disease.
- The unit may not be used to check the heart rate of a pacemaker.
- The result of a blood pressure measurement with this device is not suitable for self-diagnosis or self-treatment. To avoid health risks, always follow your doctor's instructions and contact him/her for an assessment of the measurement result.
- Never change the intake of medication prescribed by a doctor as a result of a measurement with this device and consult your doctor for advice on the best time to take the measurement before measuring.
- The device is not suitable for continuous monitoring of a patient, assessment of an existing disease or first aid.
- The device is not suitable for use on patients undergoing surgical treatment and should only be used in specified locations or in private homes.
- Pregnant women should take the necessary precautions and pay attention to their individual circumstances. Please consult your doctor if necessary.
- The patient is an intended operator and all the functions can be safely used.
- If you experience discomfort during a measurement, such as pain in the wrist or other complaints, press the Start/Stop - button ➊ to release the air immediately from the cuff. Loosen the cuff and remove it from your wrist.
- This device is not designed to be used by persons with limited physical, sensory or mental abilities, or by persons with insufficient experience and/or knowledge, unless under observation by a person responsible for their safety, or unless they have been instructed in the use of the device.
- This device is intended to be used by adults. The unit is unsuitable for children or flammable liquid (e.g. alcohol).
- Do not let a child below 12 years old or the people who can't express intention to use the device.
- Keep the appliance out of the reach of children.
- The device must not be operated in rooms with high radiation levels or in the vicinity of devices with high radiation levels, such as radio transmitters, mobile phones or microwaves, or together with high-frequency surgical devices (magnetic resonance [MR] devices). This may cause malfunctions or incorrect readings.
- Do not operate near active RF surgical equipment and the RF-shielded room of an ME system for magnetic resonance imaging where the intensity of EM interference is high.
- Do not move during the measurement.
- Protect the unit from moisture. Should liquid nevertheless penetrate the device, the batteries must be removed immediately and further applications avoided. In this case, contact your specialist dealer or inform us directly.
- Never use the unit outdoors or in damp rooms.
- Do not operate the unit near flammable gas (e.g. narcotic gas, oxygen or hydrogen) or flammable liquid (e.g. alcohol).
- 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.
- 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.
- 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Do not make any modifications to the unit, do not disassemble it and never repair the unit yourself. Have repairs carried out only by authorised service centres.
- Before using the device, it is the user's responsibility to determine that the device is safe and working properly.
- Repeated blood pressure measurements in high numbers can lead to undesirable side effects, e.g. nerve crushing or blood clots.
- Do not measure more than 3 times in a row and leave at least 5 minutes between two measurements. Do not measure more than 6 times a day in total.
- Never place the cuff over injured skin, with an existing catheter connection or after a mastectomy.
- Always keep an eye on the pressure reading on the display. If it exceeds 295 mmHg (39.3 kPa), press the Start/Stop - button ➊ immediately to deflate the cuff. The cuff is delicate and must be handled with care. Only inflate the cuff when it is correctly applied to the wrist.
- Protect the unit from heavy blows and do not drop it. Never use force, e.g. when putting on the cuff.
- Use only original accessories and spare parts from the manufacturer, otherwise damage to the unit or personal injury may result.
- Observe the local disposal guidelines if you wish to dispose of the unit.
- If you have any doubts about the proper functioning of the unit, stop using it and contact the service centre immediately.
- Swallowing small parts such as packaging material, battery, battery compartment cover, etc. can lead to suffocation. Therefore, never leave children alone with the unit.
- No maintenance or cleaning may be carried out during operation. Follow the maintenance and cleaning instructions in this manual.
- People with irregular or unstable peripheral blood circulation due to diabetes, liver disease, arteriosclerosis, etc. may experience fluctuations in the measured blood pressure values.
- Wash your hands before using the device.
- Do not measure blood pressure when other measurements are being taken on the same part of the body at the same time, as these may be disturbed or fail.
- If the ambient temperature is less than 5 °C or more than 40 °C, the waiting time from minimum storage temperature to use is at least 1 hour; the time from maximum storage temperature is at least 2 hours.
- Blood pressure values measured with this device are usually slightly lower than clinically determined values due to the quieter conditions.
- Remove the batteries if you are not using the device for a long time.
- Too frequent measurements can cause injury to the patient due to blood flow interference.
- The cuff has been tested for biocompatibility, but it varies from person to person, and some people may still be allergic to the contact material.
- Maintenance should be done by the operator as suggested.
- When the performance changes (such as: inaccurate measurement or abnormal display), please stop using it immediately and contact the after-sales service personnel in time.

SAFETY NOTES FOR BATTERIES

- Do not disassemble batteries!
- Replace all batteries if the unit display shows the low battery symbol.
- Never leave any low battery in the battery compartment since it may leak and cause damage to the unit.
- Increased risk of leakage! Avoid contact with skin, eyes and mucous membranes! If battery acid comes in contact with any of these parts, rinse the affected area with copious amounts of fresh water and seek medical attention immediately!
- If a battery has been swallowed, seek medical attention immediately!
- Replace all of the batteries simultaneously!
- Only replace with batteries of the same type, never use different types of batteries together or used batteries with new ones!
- Insert the batteries correctly, observing the polarity!
- Remove the batteries from the device if it is not going to be used for an extended period of 3 months or more!
- Keep batteries out of children's reach!
- Do not attempt to recharge batteries! There is a danger of explosion!
- Do not short circuit! There is a danger of explosion!
- Do not throw into a fire! There is a danger of explosion!
- Do not throw used batteries into the household refuse; put them in a hazardous waste container or take them to a battery collection point, at the shop where they were purchased!

Unit and LC-Display

- Battery compartment
- Start/Stop
- User selection / Memory / Settings
- Time/Date
- Blood pressure measuring unit
- Display of Diastolic Pressure
- Symbol irregular heartbeat
- Memory number
- Average value

- LC-Display
- Wrist cuff
- Blood pressure indicator
- Battery change icon
- Display of Systolic Pressure
- Display of Pulse Rate
- Pulse icon
- Memory icon
- User icon 1/2

Scope of delivery

First check that the unit is complete. The scope of delivery includes:

- 1 medisana Blood pressure monitor BW 345
- 2 Batteries (type AAA, LR03) 1.5V
- 1 Storage box
- 1 Instruction manual

If you notice any transport damage when unpacking, please contact your dealer immediately.



WARNING
Please ensure that the polythene packing is kept away from the reach of children! Risk of suffocation!

What is blood pressure?

Blood pressure is the pressure created in the blood vessels by each heart beat. When the heart contracts (= systole) and pumps blood into the arteries, it brings about a rise in pressure.

The highest value is known as the systolic pressure and is the first value to be measured. When the cardiac muscle relaxes to take in fresh blood, the pressure in the arteries also falls. Once the arteries are relaxed, a second reading is taken – the diastolic pressure.

Blood pressure classification

systolic mmHg	diastolic mmHg	Classification
≥ 160	≥ 100	High blood pressure
140 - 159	90 - 99	Mild hypertension
90 - 139	60 - 89	Normal blood pressure
< 90	< 60	too low blood pressure



WARNING
Blood pressure that is too low represents just as great a health risk as blood pressure that is too high! Fits of dizziness may lead to dangerous situations arising (e.g. on stairs or in traffic)!

Influencing and evaluating readings

- Measure your blood pressure several times, then record and compare the results. Do not draw any conclusions from a single reading.
- Your blood pressure readings should always be evaluated by a doctor who is also familiar with your personal medical history. When using the unit regularly and recording the values for your doctor, you should visit the doctor from time to time to keep him updated.
- When taking readings, remember that the daily values are influenced by several factors. Smoking, consumption of alcohol, drugs and physical exertion influence the measured values in various ways.
- Measure your blood pressure before meals.
- Before taking readings, allow yourself at least 5-10 minutes rest.
- If the systolic and diastolic readings seem unusual (too high or too low) on several occasions, despite correct use of the unit, please inform your doctor. This also applies to the rare occasions when an irregular or very weak pulse prevents you from taking readings.

Starting up: Insert / replace batteries

Before you can use your device, you must insert the enclosed batteries. The cover of the battery compartment ➊ is located on the back of the unit. Open it and insert 2 1.5V batteries, type AAA LR03. Pay attention to the polarity (as marked in the battery compartment). Close the battery compartment again. Replace the batteries immediately if the battery change symbol ➋ appears in the display or if nothing appears in the display after the unit has been switched on.

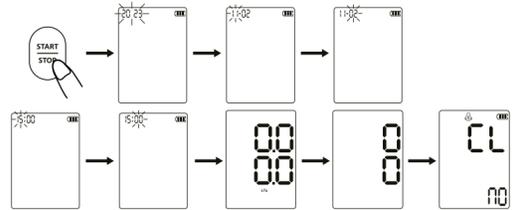
User setting

In standby mode, briefly press the START/STOP button ➊ and the User icon ➋ flashes. Then press the "M" button ➌ to switch between users 1 or 2 ➍. Press the START/STOP button ➊ to confirm the user.

Setting the date, time, measuring unit, Delete stored value

The wrist blood pressure monitor automatically stores up to 199 readings for each user (1 or 2). The memory function stores the readings with the date and time. Set the device to the current date and time before taking a measurement for the first time. The date and time cannot be changed during a measurement.

- Press "M" button ➌ until the year flashes.
- Press the "M" button ➌ to set the year and then press START/STOP button ➊ again to move to the month setting.
- Press the "M" button ➌ again to set the month and proceed analogously for the day, hour and minute settings. Then press START/STOP button ➊ to move to the measuring unit setting.
- There are two kinds of units of blood pressure display, mmHg and kPa. mmHg is set as default measuring unit. Press the "M" button ➌ to switch between mmHg/kPa. Then press the START/STOP button ➌ to move to memory setting.
- Press the "M" button ➌ to select which user's memories need to be deleted. Then keep pressing the "M" button ➌ for 3 seconds to delete the memories of the selected user and the "NO" icon will appear on the screen. Press the START/STOP button ➊ to end the settings.
- During these processes, if you want to stop the settings, press the START/STOP button ➊ for 3 seconds to exit the current settings and turn off the device.



Fitting the cuff

- Attach the clean cuff to the left wrist which is free from clothing with the palm of the hand facing upwards (see illustrations on the left).
- There should be a gap of approx. 10-15 mm (0.4"-0.6") between the cuff and the palm of the hand.
- Press the Velcro tape firmly around the wrist ensuring that it is not so tight that it could falsify the measured result.

How to measure correctly

- Perform the measurement while sitting down.
- Relax for 5 to 10 minutes before the measurement.
- Relax your arm and rest it loosely, e.g. on a table.
- Raise your wrist so that the pressure cuff is at heart level (see illustrations on the left).
- Keep calm during the measurement: do not move and do not talk, otherwise the measurement results may change.
- Never take a measurement after physical exertion or a bath.
- Keep your legs still during the measurement and do not cross your legs.
- Take the measurement at the same time every day.
- Always use only the original cuff and no spare parts that have not been approved by the manufacturer.
- Keep your feet flat on the floor.

Measure the blood pressure

After you have properly inflated the cuff, the measurement can be started:

- Press the START/STOP button ➊ to start the measurement. Automatically, the device slowly inflates the cuff to measure your blood pressure and the display shows "00".
- The device will continue to inflate the cuff until it reaches a sufficient pressure for the measurement. The device then slowly deflates the cuff and takes the measurement. As soon as the device detects a signal, the pulse icon ➋ starts flashing in the display.
- When the measurement is finished, the cuff is deflated. The systolic ➌ and diastolic ➍ blood pressure and the pulse value ➎ appear in the display. If the device has detected an irregular pulse, the symbol for irregular heartbeat ➏ also appears.
- The measured values are automatically stored in the selected user memory (1 or 2). Up to 199 readings can be stored in each user memory. If 199 values are already stored, the oldest value is overwritten.

Discontinuing a measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell) the START/STOP button ➊ can be pressed at any time. The device immediately decrease the cuff pressure automatically.

Display stored values

In standby mode, press the "M" button ➌ button once and the unit displays the average blood pressure reading for the last three times ("AVG" Average Value Icon ➏ lights up). You can then use the "M" button ➌ to display other readings. If you want to delete stored values, please refer to "Setting" section.

Automatic switch-off

If no operation is performed for approx. 20 seconds, the unit switches off automatically.

Error displays

In the event of unusual measurements, the following indications appear on the display:

Display	Cause / Solution
Er U	The inflation phase takes too long. The inflation pressure does not reach 30 mmHg within 12 seconds - please check the correct fit of the cuff.
Er H	Inflation pressure reaches 295 mmHg - automatic deflation after 20 ms.
Er 1	No pulse detected.
Er 2	Movement, talking or magnetic interference during the measurement process.
Er 3	Abnormal measurement result.
Er 23	Systolic value below 45 mmHg
Er 24	Systolic value above 230 mmHg
Er 25	Diastolic value below 25 mmHg
Er 26	Diastolic value above 160 mmHg

Troubleshooting

Problem	Cause and solution
No display although the unit is switched on and batteries are inserted	The batteries may be empty. Insert new batteries, observing the polarity. Check whether the unit is defective. If necessary, contact the customer service.
Measurement cannot be carried out or air escapes / no pressure build-up	Put the cuff on correctly. Repeat the measurement after a 30-minute rest period. Do not talk or move during the measurement.
Each measurement achieves widely differing results	Repeat the measurement in the correct manner after a 30-minute rest period. Follow all the instructions given in this manual for correct measurement and common causes of incorrect measurements. Slightly deviating results are normal as blood pressure is subject to constant fluctuations.
The measured results differ greatly from the values measured by the doctor	Save the measured values and discuss them with your doctor. It is not uncommon that values not measured at home can deviate greatly.

If you cannot solve a problem, contact customer service. Do not disassemble the unit yourself.

Cleaning and care

Remove the batteries before cleaning the device. Clean the unit and the cuff with a soft cloth lightly moistened with a mild soap solution. Never use harsh detergents, alcohol, naphtha, thinner or petrol etc.. Do not immerse the unit or any accessories in water. Make sure that no moisture enters the unit. Do not use the unit again until it is completely dry. Do not expose the unit to direct sunlight, protect it from dirt and moisture. Do not expose the unit to extreme heat or cold. Clean the unit once a week. Store the unit in a clean and dry place according to the environmental conditions for storage and transport.

Disinfection

We recommend disinfecting the unit with a 70% isopropanol solution for approx. 1 minute before and after each use. To do this, proceed as follows: Disinfect the housing with a soft cloth slightly moistened in the solution and wipe dry immediately.

Do not disinfect with high-temperature steam or ultraviolet irradiation, as this could damage the unit or accelerate its ageing!

For any cleaning and disinfection, ensure that the specified ambient conditions for operation are observed.

Disposal

This product must not be disposed of together with domestic waste. All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substances, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner. Remove the batteries before disposing of the device/unit. Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop. Consult your local authority or your supplier for information about disposal.

Guidelines and standards

This blood pressure monitor complies with the EU standard for non-invasive blood pressure monitors. It is certified according to EC directives and bears the CE mark (mark of conformity). The blood pressure monitor complies with the European regulations EN 60601-1 and EN 60601-1-2. This device is certified in accordance with EC Guidelines and carries the CE symbol (conformity symbol). The specifications of MDR (EU) 2017/745 are met.

Technical specifications

Name and model	: medisana Blood pressure monitor BW 345
Display system	: Digital display
Memory slots	: 2 x 199 for measurement data
Measuring method	: Oscillometric
Power supply	: 3V ⁻⁻⁻ , 2 x 1.5V batteries AAA LR03
Pneumatic pressure measuring range	: 0-295 mmHg (0-39 kPa)
Overpressure protection limit	: 300 mmHg (40 kPa)
Blood pressure measuring range	: Systolic: 45-230 mmHg (6-30.7 kPa); Diastolic: 25-160 mmHg (3.3-21.3 kPa)
Pulse measuring range	: 40-199 beats/min.
Maximum error tolerance for static pressure	: ± 3 mmHg (± 0.4 kPa)
Maximum error tolerance for pulse rate	: ± 5 beats/min.
Operation mode	: Continuous operation
Service life	: 5 years
Operating conditions	: +5 °C to +40 °C, 15 to 90 % max. relative humidity, atmospheric pressure: 70-106 kPa : -20 °C to +55 °C, 10 to 93 % max. relative humidity, atmospheric pressure: 70-106 kPa. During transportation or storage, avoid shocks, direct blows, corrosive gas, exposure to sunlight or rain. Ensure good ventilation.
Storage and transport conditions	: approx. 83.9 x 65.9 x 25.5 mm
Dimensions (L x W x H)	: approx. 40 x 28.5 mm
Screen size	: approx. 13.5 - 19.5 cm for adults
Cuff	: approx. 115 g without batteries
Weight	: 48153
Article number	: 40 15588 48153 6
EAN number	

In accordance with our policy of continual product improvement, we reserve the right to make technical and visual changes without notice.

Warranty and repair terms

Please contact your supplier or the service centre in case of a claim under the warranty. If you have to return the unit, please enclose a copy of your receipt and state what the defect is. The following warranty terms apply:

- The warranty period for medisana products is 3 years from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
- Defects in material or workmanship will be removed free of charge within the warranty period.
- Repairs under warranty do not extend the warranty period either for the unit or for the replacement parts.
- The following is excluded under the warranty:
 - All damage which has arisen due to improper treatment, e.g. nonobservance of the user instructions.
 - All damage which is due to repairs or tampering by the customer or unauthorised third parties.
 - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
 - Accessories which are subject to normal wear and tear.
- Liability for direct or indirect consequential losses caused by the unit are excluded even if the damage to the unit is accepted as a warranty claim.

Shenzhen AOJ Medical Technology Co., Ltd.

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EC REP

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