

GB Instruction Manual Blood Pressure Monitor BW 335

Unit and LC-Display



Scope of supply

Please check first of all that the unit is complete.

The following parts are included as standard:

- 1 **medisana** Blood Pressure Monitor **BW 335**
- 2 batteries (type AAA, LR03) 1.5V
- 1 storage box
- 1 instruction manual

Please contact your supplier if you notice any transport damage on unpacking the unit.

Explanation of symbols



IMPORTANT

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



LOT number



Protection rating agains foreign objects and water



Serial number



Manufacturer



Date of manufacture

Common factors of wrong measurements

- Please keep quiet for 5-10 minutes and avoid eating, drinking alcohol, smoking, exercising and bathing before taking a measurement. All these factors will influence the measurement result.
- Remove watches or other spruce from your wrist before measurement.
- Always measure on the same wrist (normally left).
- Measurements should be taken regularly at the same time of each day, as the blood pressure varies even during the day.
- Any effort to support the arm during measurement may increase the measured blood pressure.
- Make sure, you are in a comfortable, relaxed position and do not move or constrict your muscles during measurement. Use a cushion to support your arm if necessary.
- If the wrist is not at heart level, a false reading may be obtained.
- A loose or open cuff causes false readings.
- With repeated measurements, blood accumulates in the wrist, what may lead to false readings. Consecutive blood pressure measurements should be carried out after a 1.5-minute pause or after the arm has been held up in order to allow the accumulated blood to flow normally.

Intended use

- This fully automatic electronic blood pressure monitor is intended for measuring the blood pressure at home. It is a non-invasive blood pressure measurement system to measure the diastolic and systolic blood pressure and pulse of an adult using a non-invasive technique by means of a cuff, which needs to be fitted on the wrist. The cuff circumference is limited to 14 – 19.5 cm.

Contraindications

- The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
- This device is not suitable for persons who suffer from strong arrhythmia.

CE 0297

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.



- The unit is intended only for use in the home. Consult your doctor prior to using the blood pressure monitor if you are concerned about health matters.
- The patient is the intended operator.
- Only use the unit for its intended purpose in accordance with the instructions for use. Warranty claims become void if the unit is misused.
- 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.
- Like on any other oscillometric blood pressure measurement devices, certain medical conditions can affect the measurement accuracy, among others: cardiac arrhythmias, low blood pressure, circulatory disorders, states of shock, diabetes, pregnancy, pre-eclampsia etc. Always consult a physician before you use the device.
- This device is not suitable to provide a medical diagnosis. The measurement results are for reference only. Contact your physician to get information about treatment and medicine, which are necessary for you.
- The arrhythmia function does not replace a professional cardiac examination. Check with your doctor if any treatment or medical action is necessary for you.
- Irregularity of pulse or arrhythmia can lead to difficulties in recording a correct reading when measurements are taken using oscillometric blood pressure devices. This device is electronically equipped to detect arrhythmia which it indicates with the icon (♥). In this case, contact your physician.
- Please contact your physician about the specific risks of cuff pressure in your individual case.
- If you experience discomfort during a measurement, such as pain in the wrist or other complaints or in case the device does not stop to inflate the cuff, press the (⏏) - button ② to release the air immediately from the cuff. Loosen the cuff and remove it from your wrist.
- Blood pressure measurements in high repetition rates may lead to unwanted side effects, e.g. nerval compression or blood clots.
- Blood pressure measurements - especially if executed frequently - may lead to temporary marks on the skin. These marks may be visible for several days in individual cases. If necessary, contact your physician to get more information.
- 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 babies. Contact your doctor, if you want to use this device on young persons.

- Do not allow children to use the unit. Medical products are not toys!
- The swallowing of small parts like packaging bag, battery, battery cover and so on may cause suffocation.
- The user needs to check that the equipment functions properly and that it is in proper working condition before being used.
- The device needs to be used in accordance to the specified ambient conditions (see "Technical specifications") only. Otherwise the accuracy of readings might be affected.
- Do not use the device in moving vehicles.
- Do not use this device if you are allergic to plastic or rubber.
- The device may not be operated in rooms with high levels of radiation or in the vicinity of high-radiation devices, such as radio transmitters, mobile telephones or microwaves, as this could cause functional defects or incorrect measurements.
- Do not use the equipment where flammable gas (such as anaesthetic gas, oxygen or hydrogen) or flammable liquids (such as alcohol) are present.
- Contact your physician before using the device, if:
 - the cuff should be applied over hurt or burned skin
 - the cuff should be applied on limbs with an inserted catheter or shunt
 - the cuff should be applied on the same side of the body where a mastectomy or lymph node clearance has been realized
 - a blood pressure measurement should be executed together with other measurements on the same part of the body
 - a control of the blood circulation of the user is necessary
- Never use any other cuff than the one supplied and do not use the cuff together with other persons to avoid infections.
- Do not apply the cuff on any other part of the body than the left wrist.
- The cuff must not be applied over clothes as this may lead to injuries or inaccurate readings.
- Do not kink or fold the cuff and do not pull it over sharp edges.
- No modification of this unit/device is allowed.
- Do not disassemble the device.
- Avoid high temperatures and direct sunlight.
- Protect the unit against moisture. If liquid does manage to penetrate into the unit, remove the batteries immediately and do not continue to use the unit. In this case contact your specialist dealer or notify us directly.

- Please do not attempt to repair the unit yourself in the event of malfunctions. Only have repairs carried out by authorised service centres.
- If the device has been stored at cool temperatures, you should allow some time to acclimatise at room temperature before using.
- Please do not use a dilution agent, alcohol or petrol to clean the unit.
- Do not hit the device heavily or let it fall down from a high place.
- Do not insert any objects into the device openings and never push the buttons with heavy force or with the help of peak objects. This may lead to damages of the device.
- The monitor requires 6 hours to warm from the minimum storage temperature between uses until the monitor is ready for its intended use when the ambient temperature is 20 °C.
- The monitor requires 6 hours to cool from the maximum storage temperature between uses until the the monitor is ready for its intended use when the ambient temperature is 20 °C .
- If the unit is not going to be used for a long period, please remove the batteries.

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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!
- Make sure the battery cover is intact and not damaged before installing the batteries.
- 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

- ① Blood Pressure Indicator (green - yellow - orange - red)
- ② LC-display
- ③ (⏏) - button (START/STOP)
- ④ M - button (Memory Recall)
- ⑤ Wrist cuff
- ⑥ Battery compartment
- ⑦ Display of time
- ⑧ Display of date
- ⑨ Change Battery symbol
- ⑩ Display of Systolic Pressure
- ⑪ Display of Diastolic Pressure
- ⑫ Display of Pulse Rate
- ⑬ Pulse symbol
- ⑭ User memory
- ⑮ Memory Location number
- ⑯ Arrhythmia display (arrhythmia cordi)
- ⑰ M - symbol (memory)
- ⑱ Blood Pressure Indicator
- ⑲ Deflation symbol

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.

How is blood pressure measured?

The **medisana BW 335** is a blood pressure unit which is used to measure blood pressure from the wrist. The measurement is carried out by a microprocessor, which, via a pressure sensor, measures the vibrations resulting from the inflation and deflation of the cuff over the artery.

Blood pressure classification

systolic mmHg	diastolic mmHg		Blood Pressure Indicator ① / ⑱
≥ 180	≥ 110	severe hypertension	red
160 - 179	100 - 109	moderate hypertension	orange
140 - 159	90 - 99	mild hypertension	yellow
130 - 139	85 - 89	high-normal blood pressure	green
120 - 129	80 - 84	normal blood pressure	green
< 120	< 80	optimal blood pressure	green

! 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

You must insert the batteries provided before you can use your unit. The lid of the battery compartment ⑥ is located on the underside of the unit. Open it by pushing the cover outward and remove it. Insert the 2 AAA LR03 type 1.5 V batteries supplied. Ensure correct polarity when inserting the batteries (as marked on the battery compartment cover). Close the battery compartment. Replace the batteries immediately, if the change battery symbol ⑨ appears on the display or if nothing appears on the display after the unit has been switched on.

Settings

Set date and time

After inserting the batteries, time and date need to be adjusted correctly. The device automatically switches to settings mode after insertion of the batteries. If you want to enter settings mode manually, press and hold the (⏏) - button ③ and the M - button ④ for approx. 3 seconds after switching on the unit.

1. Adjustment of the display format:

Firstly, the display format (24 or 12 hour format of the clock) needs to be set. Adjust the desired value with the M - button ④. Press the (⏏) - button ③ afterwards to enter the date and time setting mode.

2. Adjustment of date and clock:

Adjust the year, month, day, hour and minute figure in sequence. You may adjust the flashing value by pressing M - button ④ and confirm the value and go to next step by pressing the (⏏) - button ③. After the minutes have been set and (⏏) - button ③ is pressed, all adjustments have been done and the device will switch off. If no button is pressed during 30 seconds during the setting process, the device will automatically switch to standby-mode. If the batteries are changed, the set information is lost and needs to be entered again.

Attach / exchange the cuff

The **medisana** blood pressure device **BW 335** features an exchangeable cuff.

The cuff is already attached in delivery condition.

You may remove the cuff if needed. To re-attach the cuff, align the 4 plugs

with the 4 notches and press the cuff onto the device until it firmly fits.

Fitting the cuff

1. Attach the clean cuff to the left wrist which is free from clothing with the palm of the hand facing upwards (fig.1).
2. There should be a gap of approx. 1 cm between the cuff and the palm of the hand (fig.2).
3. Press the Velcro tape firmly around the wrist ensuring that it is not so tight that it could falsify the measured result (fig.3).

Correct position for taking readings

- Carry out the measurement whilst seated.
- Relax your arm and place it comfortably, on a table for instance.
- Raise the wrist so that the cuff of the monitor is at heart level (fig. 4, position a = too high, b = correct, c = too low).
- Keep still during the measurement. Do not move and do not talk as this may alter the measurements.

Taking a blood pressure measurement

After the cuff has been appropriately positioned, the measurement can begin.

1. Switch the unit on by pressing the (⏏) - button ③. The display will shortly show all available symbols.
2. The **medisana** blood pressure monitor **BW 335** gives you the opportunity to assign readings to one of two user memories, each of which provides 120 memory slots. After switching on the device, press the M - button ④ to choose between user 1 and user 2. If no selection is made within 5 seconds, the following measurement will be assigned to the current shown user.
3. The unit is ready for measurement and it automatically inflates the cuff slowly in order to measure your blood pressure. The rising pressure in the cuff is shown on the display.
4. The unit inflates the cuff until sufficient pressure has built up for a measurement. Then the unit slowly releases air from the cuff and carries out the measurement. When the device detects the signal, the heart symbol ♥ starts to flash on the display. When the measurement is finished, the cuff is deflated completely. The systolic and diastolic blood pressure and the pulse value appear on the display ②. The blood pressure indicator ⑱ is shown next to the relevant coloured bar depending on the blood pressure classification.

If the unit has detected an irregular heartbeat, the arrhythmia display (♥) ⑱ will also be shown.

! WARNING - Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor.

5. The readings are automatically saved in the selected memory (M1 or M2). Up to 120 measured values with date and time can be stored in each memory along with time and date.
6. The measurement readings remain on the display. The unit switches off automatically after approx. 1 minute if no buttons are pressed. The unit may also be switched off using the (⏏) - button ③.

Discontinuing a measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), the (⏏) - button ③ can be pressed at any time. The device immediately decreases the cuff pressure automatically.

Display stored values

This unit features 2 separate memories, each with a capacity of 120 memory slots. Results are automatically stored in the memory selected by the user. To call up the measured values stored, press the M - button ④ when the device is switched on to activate the memory recall mode. A user memory (M1 or M2) is shown. Use the M - button ④ to change memory slots. Use the (⏏) - button ③ to confirm the user memory. The number of measurements stored in this memory is now displayed and afterwards the average of all measurements stored in this user memory (if no measurements are stored, a "0" appears). Now press the M - button ④ to show the average value of all measurements of this user in the last 7 days between 5 and 9 o'clock (again, a "0" appears here, if no corresponding measurements are stored). Press the M - button ④ again to see the average of all measurements of this user over the last 7 days between 6 p.m. and 8 p.m. If you press the M - button ④ again to display the last measurement value of the user. Repeatedly pressing the M - button ④ displays the respective values measured previously. If no further values are saved, the display will show a „0“. If no button is pressed, the unit automatically switches itself off after approximately 1 minute. Memory recall mode may also be exited at any time by pressing the (⏏) - button ③, which will also switch the unit off. The oldest value is deleted if 120 measured values have been stored in the memory and a new value is saved.

Delete saved values

If you want to delete saved values, view any value of that user (see "Display stored values"). Then press and hold the M - button ④ for about 3 seconds - all values of the corresponding user memory slot will be deleted.

Error messages and error remedying

The following notifications in the display indicate problems or errors:

Display	Cause and correction
Hi or Lo	The measurement result is out of the measurable range. Repeat the measurement and contact your physician if necessary.
Unusual measurement results	Cuff not fitted properly; Movement or speaking during measurement; Incorrect body posture; Heart arrhythmia. Repeat the measurement and contact your physician if necessary.
	Replace both batteries.
Er 0 / Er 1 / Er 2	Pressure system instable at start of the measurement / Error in measuring the systolic pressure / Error in measuring the diastolic pressure. Do not move!
Er 3 / Er 4	Pressure system is blocked or sleeve is too tight during inflation / Pressure system has a leak or sleeve is too loose during inflation. Put the sleeve on correctly!
Er 5 / Er 6 / Er 7 / Er 8 / Er A	Sleeve pressure above 300 mmHg / Longer than 3 min. with sleeve pressure over 15 mmHg / EEPROM access error / Error when testing the functions on the device / Failure of pressure sensor. Perform measurement again after 5 minutes!
No reaction after pressing a button or insertion of batteries	Remove the batteries, wait for 5 minutes and reinsert the batteries.

Please contact the manufacturer resp. the service centre if you can't solve the problem. Do not disassemble the unit by yourself.

Cleaning and care

Remove the batteries before cleaning the unit. Clean the unit and the cuff using a soft cloth lightly moistened with a mild soapy solution. Never use abrasive cleaning agents, alcohol, naptha, thinner or gasoline etc.. Never immerse the unit or any component in water. Be cautious not to get any moisture in the main unit. Do not use the unit again until it is completely dry. Only inflate the cuff when it is in position around the wrist.

Do not expose the unit to direct sunlight; protect it against dirt and moisture. Do not subject the unit to extreme hot or cold temperature. Keep the unit in the original packing when not in use. Store the unit in a clean and dry location. Servicing and calibration: The unit has been calibrated by the manufacturer for a period of two years' use. In the case of commercial use, the unit must be serviced and recalibrated at least once every two years. This calibration will be charged for and can be carried out by an appropriate authority or an authorised service centre - in accordance with the regulations for users of medical equipment. The device is designed for maintaining the safety and performance characteristics for a minimum of 10,000 measurements resp. 3 years. The cuff integrity is maintained after 1,000 open/close cycles of the closure.

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 / Standards

This blood pressure monitor meets the requirements of the EU standard for non-invasive blood pressure monitors. It is certified in accordance with EC Guidelines and carries the CE symbol (conformity symbol) "CE 0297". The specifications of EU Guideline "93/42/EEC of the Council Directive dated 14 June 1993 concerning medical devices" are met. The blood pressure monitor corresponds to European standards: IEC 60601-1 Edition 3.1 2012-08/EN 60601-1:2006/A11:2013, IEC60601-1-2:2014/EN 60601-1-2:2015, IEC60601-2-30:2009+AMD1:2013/EN 80601-2-30:2010/A1:2015, EN 1060-1:1995 + A2: 2009, EN 1060-3: 1997 + A2: 2009, ISO81060-2:2013. *Electromagnetic compatibility:* The device complies with the standards for electromagnetic compatibility. You can find details on this measurement data on the separate enclosure.

Technical specifications

Name and model:	medisana Blood pressure monitor BW 335
Display system:	Digital display
Memory slots:	2 x 120 measurement values
Measuring method:	Oscillometric
Power supply:	3 V=, 2 x 1.5V batteries AAA LR03
Blood pressure measuring range:	40 - 260 mmHg
Pulse measuring range:	40 – 180 beats/min.
Maximum error tolerance for static pressure:	± 3 mmHg
Maximum error tolerance for pulse rate:	± 5 % of the value (≥ 60); ± 3 beats/min. (<60)
Precision of the displayed values:	1 mmHg
Pressure generation:	Automatic with pump
Deflation:	Automatic
Automatic switch-off:	After approx. 1 minute
Battery life:	approx. 200 measurements
Operating conditions:	+10 °C to +40 °C, ≤ 85 % relative humidity; Air pressure 80 kPa - 105 kPa -20 °C to +50 °C, ≤ 85 % relative humidity; Air pressure 80 kPa - 105 kPa
Storage conditions:	Approx. 89 x 60 x 31 mm (L x W x H) 14 - 19.5 cm for adults Approx. 69.5 g without batteries 51077 EAN number: 40 15588 51077 9

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

The current version of this instruction manual can be found under www.medisana.com

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:

1. 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.
2. Defects in material or workmanship will be removed free of charge within the warranty period.
3. Repairs under warranty do not extend the warranty period either for the unit or for the replacement parts.
4. The following is excluded under the warranty:
 - a. All damage which has arisen due to improper treatment, e.g. nonobservance of the user instructions.
 - b. All damage which is due to repairs or tampering by the customer or unauthorised third parties.
 - c. Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
 - d. Accessories which are subject to normal wear and tear.
5. 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.



medisana GmbH
Jagenbergstr. 19, 41468 NEUSS
GERMANY

The service centre address is shown on the attached leaflet.

