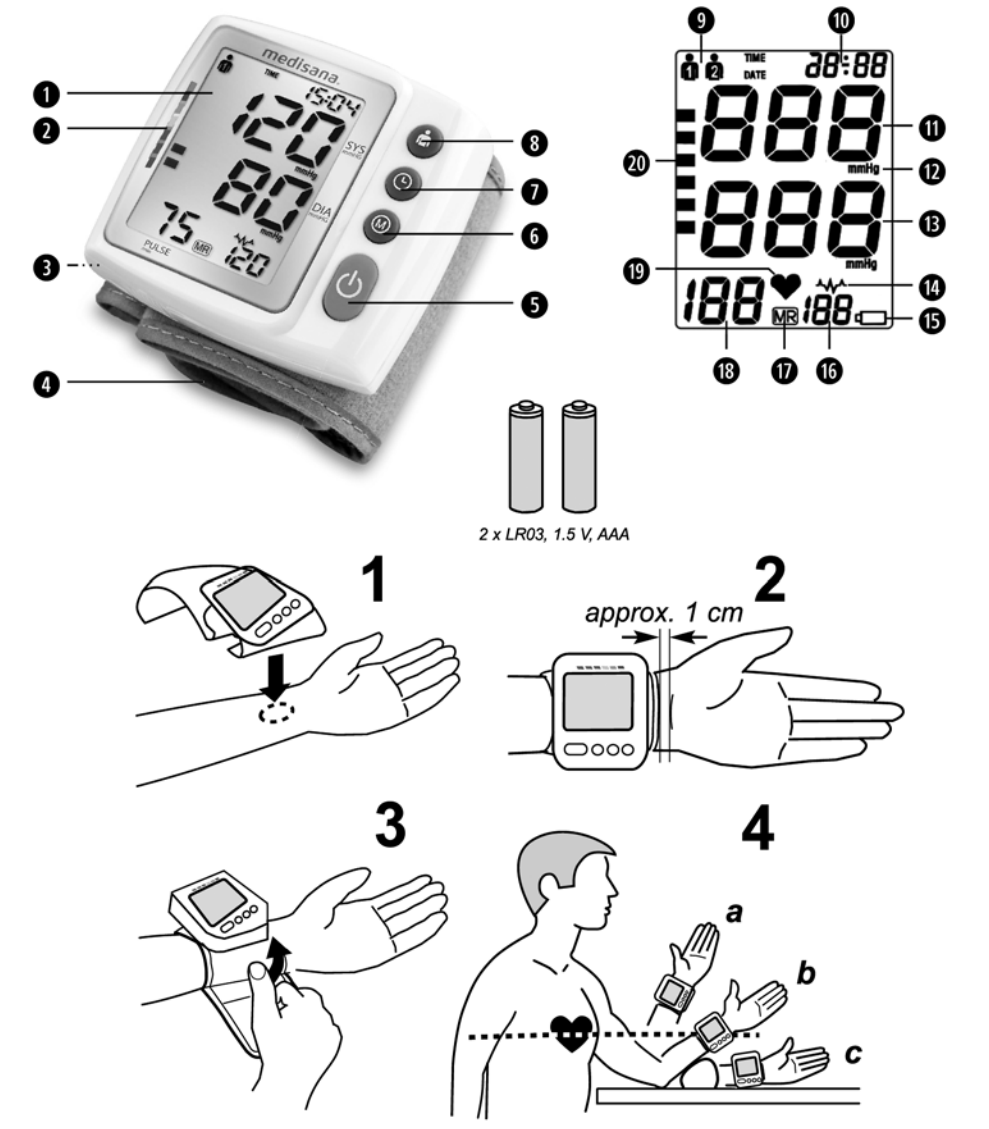


medisana®

Blood Pressure Monitor BW 315

Instruction manual - *Please read carefully!*

GB Unit and LC-Display



Proper 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.

Contraindications

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

Explanation of symbols

IMPORTANT
Follow the instructions for use!
Non-observation 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

Not to be used by very young children (0-3 years)!

Keep dry

LOT number

Manufacturer

Date of manufacture

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 315**
- 2 batteries (type AAA, LR03) 1.5 V
- 1 storage box
- 1 instruction manual

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

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.
- Extreme temperatures, humidity or altitudes may impair the performance of the device.
- 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 3-minute pause or after the arm has been held up in order to allow the accumulated blood to flow normally.

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.
- 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.
- Pregnant women should take the necessary precautions and pay attention to their individual circumstances. Please consult your doctor if necessary.
- If you experience discomfort during a measurement, such as pain in the wrist or other complaints, press the - button 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 and / or to blood circulation disorders. 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!
- Please ensure that the unit is kept away from the reach of children.
- 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 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 or together with HF surgical equipment, 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.
- Do not take measurements, if any other equipment is applied to the same limb for monitoring. This could lead to disturbances or failures.
- Never apply the cuff over hurt skin, in case of an inserted catheter or after a mastectomy.
- In cases of cardiac irregularity (arrhythmia) only use this device after consultation of your doctor.
- No modification of this unit/device is allowed.
- Please do not attempt to repair the unit yourself in the event of malfunctions, since this will void all warranty claims. Only have repairs carried out by authorised service centres.
- Only use original additional or spare parts from the manufacturer. Other parts could damage the device or could lead to personal injury.
- 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.
- The cuff is very sensitive and needs to be handled with care. Only inflate the cuff when it is properly positioned on the wrist.
- Protect the device from dirt, direct sunlight and extreme temperatures.
- Please do not use a dilution agent, alcohol or petrol to clean the unit.
- Please do not hit the device heavily or let it fall down from a high place.
- If the unit is not going to be used for a long period, please remove the batteries.

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

LC-display	Blood Pressure Indicator (green - yellow - orange - red)
Lid of the Battery Compartment	Wrist cuff
- button (ON/OFF)	- button (Memory recall)
- Taste (Clock/Date)	- button (User Setting)
User memory 1/2	Display of Clock / Date
Display of Systolic Pressure	Unit of measure
Display of Diastolic Pressure	Irregular heartbeat display
Change Battery symbol	Memory location number
Memory symbol	Display of Pulse Rate
Pulse symbol	Blood Pressure Indicator

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		Blood pressure indicator
≥ 180	≥ 110	serious hypertension	red
160 - 179	100 - 109	medium 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 is located on the left hand side of the unit. Open it and insert the 2 AAA LR03 type 1.5 V batteries supplied. Ensure correct polarity when inserting the batteries (as marked inside the battery compartment). Close the battery compartment. Replace the batteries immediately, if the change battery symbol appears on the display or if nothing appears on the display after the unit has been switched on.

Setting (date, clock, mmHg/kPa)

After insertion of the batteries you need to set the date and clock. To enter the setting mode, press and hold the - button for approx. 3 seconds. Firstly, the user memory 1 or 2 is flashing. Now press the - button again to adjust the correct year figure. Adjust to correct year by pressing - button and press - button to confirm the setting. The device now switches to the month setting mode. Proceed accordingly in the same way as with the year adjustment) to adjust the correct figures for month, day, hour and minute. Afterwards, the unit (mmHg/kPa) will be changed when press button each time. Press button to confirm the unit. Shortly, the current date appears and then the clock appears. If you want to look at the date later on, press the - button shortly. If the batteries are changed, the set information is lost and needs to be entered again.

Setting up the user memory

The **medisana** wrist blood pressure monitor **BW 315** gives you the opportunity to assign readings to one of two user memories, each of which provides 120 memory slots. Press - button to select the user memory or . Your selection will be saved by the device and will be considered in next blood pressure measurement respectively when the measurement result is saved. Your selection is valid until you make another selection.

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. Press the - button to start the measurement.
2. The device automatically inflates the cuff slowly in order to measure your blood pressure. The rising pressure in the cuff is shown on the display.
3. 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.
4. When the measurement is finished, the cuff is deflated completely. The systolic and diastolic blood pressure and the pulse value appear on the display . The blood pressure indicator is shown next to the relevant coloured bar depending on the blood pressure classification. If the unit has detected an irregular heartbeat, the irregular heartbeat display 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 (or). Up to 120 measured values with date and time can be stored in each memory.
6. The measurement readings remain on the display. The unit switches off automatically after approx. 3 minutes if no buttons are pressed. The unit may also be switched off using the - button .

Discontinuing a measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell) the - button 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. Press the - button to select the user (or). Now press the - button and the average values of the last 3 measurements appear on the display. Press the - button again and the latest stored measurement value will be shown, together with the memory symbol "MR" and the memory location place "1" . Repeatedly pressing the - button displays the respective values measured previously (MR2, MR3 and so on). If you have reached the final entry and do not press a button, the unit automatically switches itself off after approximately 3 min. Memory recall mode can be exited at any time by pressing the - button . The oldest value is deleted, if 120 measured values have been stored in the memory and a new value is saved - at the same time, "FUL" shortly appears on the display.

Delete saved values

If you are sure that you want to permanently remove all stored memories of a user, press and hold the - button for approx. 5 seconds, until CL appears in the display. Release the button. Now press the - button again to confirm the deletion.

Error indicators

The following error codes will appear on the display when a measurement is abnormal.

Display	Cause
ERR1	No pulse was detected.
ERR2	Movement or talking during measurement.
ERR3	Inflation process lasts too long. The cuff probably has not been positioned properly.
ERR5	Systolic and diastolic pressure are too far apart from each other. Repeat the measurement. If you constantly receive unusual measurement results, please contact your doctor.

Troubleshooting

Problem	Cause and solutions
No display although the device is switched on and batteries are inserted	Maybe the batteries are weak. Insert new batteries and pay attention to correct polarity. Check, if the device is working well. In the case of doubt, contact the service centre.
Measurement can not be proceeded or measurement failed	Put on the cuff correctly. Repeat the measurement after relaxing 30 minutes. Do not speak or move during the measurement.
Each measurement result strongly deviates from the one before	Repeat the measurement in correct way after relaxing 30 minutes. Pay attention to all the instructions in this manual and to the common factors of wrong measurements. Slightly deviating measurement results are quite normal, as the blood pressure is constantly changing.
The measured values are remarkably different from values measured in a doctors surgery	Store the measured results and consult your doctor. It is not unusual to measure strongly deviating values outside of your home.

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, naphtha, 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 storage box when not in use. Store the unit in a clean and dry location.

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 in 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 blood pressure monitor corresponds to European standards EN 60601-1, EN 60601-1-2, EN 60601-1-11, EN 80601-2, EN 1060-1, EN 1060-3. The specifications of EU Guideline "93/42/EEC of the Council Directive dated 14 June 1993 concerning medical devices" are met.

Electromagnetic compatibility: Guidance and manufacturer's declaration (as per 17th April 2014)

Electromagnetic emissions		
The blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the blood pressure monitor should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The "blood pressure monitor" uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The "blood pressure monitor" is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity			
The blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the blood pressure monitor should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines; ± 1 kV for input/ output lines	not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U _n (> 95% dip in U _n) for 0.5 cycle; 40% U _n (60% dip in U _n) for 5 cycles; 70% U _n (30% dip in U _n) for 25 cycles; < 5% U _n (> 95% dip in U _n) for 5 sec	not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the blood pressure monitor requires continued operation during power mains dip & interruptions, it is recommended that the blood pressure monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	not applicable	not applicable
NOTE: U _n is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity			
The blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the blood pressure monitor should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the "blood pressure monitor" including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d=1.2 / √P d=1.2 / √P 80 MHz to 800 MHz d=2.3 / √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency in each frequency range. Interference may occur in the vicinity of equipment marked with the following Symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electro-magnetic site survey should be considered. If the measured field strength in the location in which the "blood pressure monitor" is used exceeds the applicable RF compliance level above, the blood pressure monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the "blood pressure monitor".			
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the blood pressure monitor

The "blood pressure monitor" is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the blood pressure monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the "blood pressure monitor" as recommended below according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d=1.2 / √P	80 MHz to 800 MHz d=1.2 / √P	800 MHz to 2.5 GHz d=2.3 / √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the re-commended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Technical specifications

Name and model : **medisana** Blood pressure monitor **BW 315**

Display system : Digital display

Memory slots : 2 x 120 measurement values

Measuring method : Oscillometric

Power supply : 3 V_{max} = 2 x 1.5V batteries AAA LR03

Blood pressure measuring range : 30 – 280 mmHg

Pulse measuring range : 40 – 200 beats/min

Maximum error tolerance for static pressure : ± 3 mmHg

Maximum error tolerance for pulse rate : ± 5 % of the value

Pressure generation : Automatic with pump

Deflation : Automatic

Automatic switch-off : After approx. 3 minutes

Operating conditions : +5 °C to +40 °C; 15 to 85 % max. relative humidity

Storage conditions : -10 °C to +55 °C, 10 to 95 % max. relative humidity

Cuff : 12.5 - 21.5 cm for adults

Dimensions (main unit) : approx. 63 x 63 x 29 mm (L x W x H)

Weight : approx. 110 g without batteries

Item number : 48628

EAN number : 40 15588 48628 9

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:
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 as batteries etc..
 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
Carl-Schurz-Str. 2, 41460 NEUSS, GERMANY

