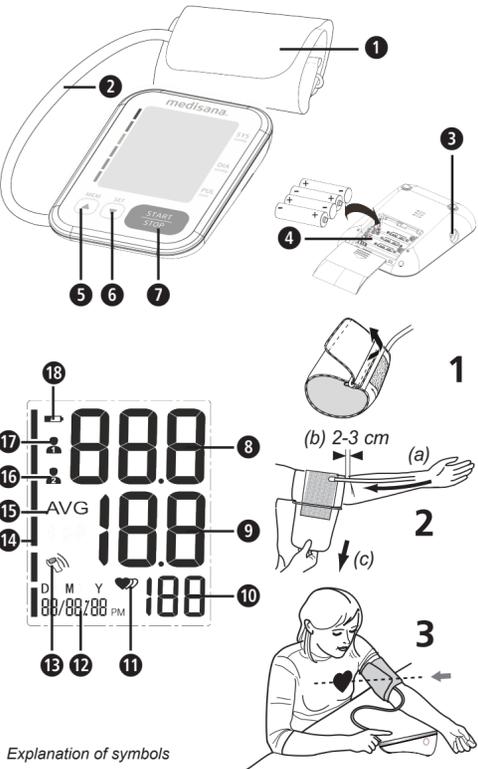


GB Instruction manual Blood Pressure Monitor BU 565

Unit and LC-Display



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



LOT number



Serial number



Direct current



Manufacturer



Date of manufacture

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 an oscillometric technique by means of a cuff, which needs to be fitted on the upper arm. The useable cuff circumference is 22 to 42 cm.
- The device is intended for adult indoor use only.

Contraindications

- The device is not suitable for use on pregnant women and patients with implanted, electronic devices (e.g. pacemaker or defibrillator).

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 private use in the home.
- 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 patient is an intended operator. The patient can measure data and change batteries under normal circumstances and maintain the device and its accessories according to the user manual.
- This blood pressure monitor is intended for adult use. The device is not suitable for measuring the blood pressure of children or infants. Ask your doctor before using it on older children.
- Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts.
- The device has sensitive components. Be careful and ensure that the operating and storage conditions are met.
- The device is not suitable for use on pregnant women, patients with implanted, electronic devices (e.g. pacemaker or defibrillator), patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
- The device is not intended for patient transport outside a healthcare facility.
- This device is intended for non-invasive measuring and monitoring of arterial blood pressure on the upper arm. It is not intended for use on extremities other than the upper arm or for functions other than obtaining a blood pressure measurement.
- Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Contact your doctor if you have any further questions about blood pressure measurement with this device.
- 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.
- 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.
- Pay attention during use and storage, that cable and air hose will not cause strangulation.
- Never bend the air hose during use as this may lead to injuries. Also never squeeze or block the air hose in any way.
- Do not take measurements, if any other equipment is applied to the same limb for monitoring. This could lead to disturbances or failures.
- Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
- This device cannot be used with surgical equipment at the same time.
- Do not apply the cuff over a wound, otherwise it can cause further injury.
- On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure >300 mmHg or constant pressure >15 mmHg for more than 3 minutes) applied to the arm may lead to an echymosis.
- To verify the calibration of the device, contact the customer service.
- This device is not suitable for continuous monitoring during medical emergencies or operations - risk of injuries!
- Do not use the equipment where flammable gas (such as anaesthetic gas, oxygen or hydrogen) are present.
- Before use, make sure the device functions safely and is in proper working condition. Do not service or maintain while the device is in use.
- Check the device for damage. The use of a damaged device can result in injury, incorrect readings or serious hazards.
- The unit may not be operated in the vicinity of appliances that emit strong electric radiation such as radio transmitters or mobile phones. This may affect the proper functioning (see "electromagnetic compatibility").
- The device and its components are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
- If you experience discomfort during a measurement, such as pain in the upper arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
- If the cuff pressure reaches 300 mmHg, the unit will automatically deflate. Should the cuff not deflate when pressure reaches 300 mmHg, detach the cuff from the arm and press the START/STOP button to stop inflation.
- Do not wash the cuff in a washing machine or dishwasher!
- The service life of the cuff may vary by the frequency of cleaning, skin condition, and storage state. The typical service life is 10,000 times.
- It is recommended that the performance should be checked every 2 years and after maintenance and repair. Contact the customer service to learn more.
- Do not touch output of batteries and the patient simultaneously.
- Please do not attempt to repair the unit yourself in the event of malfunctions. Only have repairs carried out by authorised service centres.
- Please ensure that the unit is kept away from the reach of children and pets. The swallowing of small part like packaging bag, battery, battery cover and so on may cause suffocation.
- Only use original additional or spare parts from the manufacturer. Other parts could damage the device or could lead to personal injury.
- Please report to **medisana** if any unexpected operation or events occur.
- The construction of the device possibly allows an inadvertently connection to intravascular fluid systems, allowing air to be pumped into a blood vessel - risk of injury!
- Only use the device under the conditions mentioned in the technical details. Otherwise, the lifespan and performance of the device could suffer.
- At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for the intended use.
- At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for the intended use.
- If the unit is not going to be used for a long period, please remove the batteries.

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BATTERY SAFETY INFORMATION

- Do not disassemble batteries!
- Renew the batteries when the battery icon appears on the display.
- Remove discharged batteries from the device immediately, because they can leak and damage the device!
- 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!
- Keep batteries out of children's reach!
- Do not attempt to recharge batteries, do not short-circuit and 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

- | | | |
|-----------------------------------|--|------------------------|
| Cuff | Air hose | Connector for the hose |
| Battery compartment (on backside) | MEM-button | SET-button |
| START/STOP-button | Systolic pressure | Diastolic pressure |
| Pulse rate | Pulse / Arrhythmia display | Time/Date |
| Movement detected | Blood Pressure Indicator (green - yellow - orange - red) | User memory 1 |
| Average value display ("AVG") | User memory 2 | |
| Battery symbol | | |

Scope of supply

Please check first of all that the device is complete and is not damaged in any way. In case of doubt, do not use it and contact your dealer or your service centre.

The following parts are included:

- 1 **medisana** blood pressure monitor **BU 565**
- 1 cuff with air tube
- 1 storage pouch
- 4 batteries (type AAA, LR03) 1.5V
- 1 instruction manual and EMV leaflet

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



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

How is blood pressure measured?

This **medisana** blood pressure monitor is a device, which is used to measure blood pressure at the upper arm. The measurement is carried out by a microprocessor - already during the inflating process of the cuff. The device detects the systole and the measurement is completed earlier than using conventional measurement methods. As a result, an unnecessarily excessive inflation pressure in the cuff is prevented. Additionally, your device is able to recognize irregular heartbeat (so-called arrhythmia), which may affect the measurements. In case an arrhythmia has been detected, the respective symbol will appear in the display of the unit.

Blood pressure classification

systolic mmHg	diastolic mmHg		Bloodpressure 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 five 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.

Getting started

Inserting/changing batteries

You must insert the batteries provided before you can use your unit. The lid of the battery compartment is located on the underside of the unit. Open it, remove it and insert the 4 x 1,5 V batteries, type AAA / LR03 supplied. Ensure correct polarity when inserting the batteries (as marked inside the battery compartment). Close the battery compartment. Replace the batteries if the change battery symbol and "Lo" appears on the display or if nothing appears on the display after the unit has been switched on.

Settings

Setting date and time

When unit is switched off, press SET . The time will be displayed. Now press and hold the SET button , until the year figure starts to flash for setting. Keep pressing the MEM button until the actual year figure appears. Press SET to confirm the year. Afterwards, you can proceed with the month/date setting, followed by the time format setting (12 or 24 hours), as well as hours and minutes. Adjust the corresponding figures accordingly. When finished, "dOnE" appears on the display along with the adjusted values. Afterwards, the device will switch off.

User memory setting

The **MEDISANA** blood pressure monitor features 2 separate memories, each with a capacity of 120 memory slots. By pressing and holding the MEM button when the device is switched off, you may choose between user 1 and user 2 . The display shows the current selection. Confirm your selection with the SET button .

Fitting the cuff

- Connect the air hose to the connector on the left side of the device.
- Slide the open end of the cuff through the metal bracket so that the Velcro fastener is on the outside and it becomes a cylindrical form (Fig.1). Slide the cuff over your left upper arm.
- Position the air hose in the middle of your arm in line with your middle finger (Fig.2) (a). The lower edge of the cuff should be 2 - 3 cm above the crease of the elbow. (b). Pull the cuff tight and close the Velcro fastener (c).
- Measure the blood pressure on your bare arm.
- Only position the cuff on the right arm if it cannot be used on the left arm. Always carry out measurements on the same arm.
- Correct measuring position for sitting (Fig.3).

Taking a blood pressure measurement

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

- Switch the unit on by pressing the START/STOP button .
- All display characters are shown (display test). This test can be used to check that the display is indicating properly and in full. The unit is ready for measurement and „0“ appears.
- The device then automatically inflates the cuff slowly in order to measure your blood pressure. The rising pressure in the cuff is shown on the display.
- When the device detects the signal, the heart symbol on the display starts to flash. If a result is determined, the device slowly will release the air from the cuff. The systolic and diastolic blood pressure and the pulse value with the time value appear on the display.
- The blood pressure indicator flashes next to the relevant coloured bar depending on the blood pressure classification.
- If the unit has detected an irregular heartbeat, the arrhythmia display appears additionally
- The readings are automatically saved in the selected memory or .
- Switch off the device using the START/STOP button .

Displaying stored results

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 MEM button when power off, to call up the measured values stored. The average values of the last 3 measurements appear on the display (if already 3 measurements have been stored for the respective user. Press the MEM button again to call up the last measurement value. Repeatedly pressing the MEM button or the SET button displays the respective values measured in other measurements. Memory recall mode can be exited at any time by pressing the START/STOP button , 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.

Deleting stored values

Enter the memory recall mode as described above and let the device show the value you want to delete. Now press and hold the SET button for approx. 3 seconds, until „dEL one“ is shown in the display (this is not working during average value display mode "AVG"). Now press and hold the START/STOP button to delete the value. If you want to delete ALL stored values of a user, press and hold the MEM button during the memory recall mode „dEL ALL“ will be displayed. Now press and hold the START/STOP button to delete all values. To exit the deletion mode, you may press the START/STOP button at any time.

Error messages and error remedying

Display	Cause	Solution
No display	Batteries may be exhausted or inserted incorrectly. Check if the power connection has been established properly.	Insert new batteries. Insert the batteries according to the instructions given.
+ Lo	Weak batteries	Batteries are weak or empty. Replace all 4 batteries by new ones (1.5V, type AAA / LR03).
E01	Cuff not properly fitted	Wrap the cuff properly. Remeasure in correct way.
E02	Movement or speaking during measurement	Rest 30 minutes and remeasure in correct way. Do not speak or move during the measurement.
E03	Pulse cannot be detected	Wrap the cuff properly. Loosen the clothing on the arm. Remeasure in correct way.
E04	Measurement failed	Wrap the cuff properly. Remeasure in correct way.
EExx	Calibration error ("xx" can be a figure, e.g. 01, 02 etc.)	Wrap the cuff properly. Remeasure in correct way.
out	Out of measurement range	Relax for a moment. Refasten the cuff and measure again. If the problem persists, contact your physician.

Cleaning and maintenance

Remove the batteries before cleaning the unit. Clean the unit using a soft cloth lightly moistened with a mild soapy solution. Never use abrasive cleaning agents, alcohol, naphta, 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 wet the cuff or attempt to clean the cuff with water. Using a dry cloth, gently wipe away any excess moisture that may remain on the cuff. Lay the cuff flat in an unrolled position and allow the cuff to air dry. Do not expose the unit to direct sunlight; protect it against dirt and moisture. Do not expose the unit to extreme hot or cold temperatures. Keep the device in the storage case 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 the EU standard for noninvasive 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 60601-1-6, EN 60601-1-11, EN 1060-3, EN 81060-1 and EN 81060-2. The specifications of EU Guideline "93/42/EEC of the Council Directive dated 14 June 1993 concerning medical devices" are met. You can request the complete Conformity Declaration from **medisana** GmbH, Jagenbergstr. 19, 41468 Neuss, Germany, or you can also download it from the **medisana** homepage (www.medisana.de). Electromagnetic compatibility: (see attached leaflet)

Technical specifications

Name and description:	medisana Blood pressure monitor BU 565
Software version:	A01
Display system:	Digital display
Memory slots:	2 x 120
Measuring method / Mode of operation:	Oscillometric / Continuous operation
Power supply:	6 V=, 4 x 1,5 V batteries AAA LR03, internally powered
Rated cuff pressure:	0 - 299 mmHg (0 - 39.9 kPa)
Measurement pressure:	SYS: 60-230mmHg (8-30.7kPa); DIA: 40-130mmHg (5.3-17.3kPa)
Pulse measuring range:	40 – 199 beats per minute
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
Protection marking against particles and water:	IP21
Operating conditions:	+5°C to +40°C, 15 to 90 % relative humidity, non-condensing, 700-1060 hPa atmospheric pressure
Storage conditions:	-20°C to +60°C, relative humidity ≤ 93 %
Dimensions (L x W x H):	approx.130 x 93 x 32,5 mm
Cuff:	22 - 42 cm for adults
Weight (main unit):	approx. 190 g without batteries
Item number:	51200 (BU 565 black); 51202 (BU 565 white)
EAN number:	40 15588 51200 1; 40 15588 51202 5
Accessories:	Spare cuff Art. No. 51299 / EAN 40 15588 51299 5

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:

- 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.

medisana GmbH
Jagenbergstr. 19
41468 NEUSS, GERMANY

The service centre address is shown on the attached leaflet.

