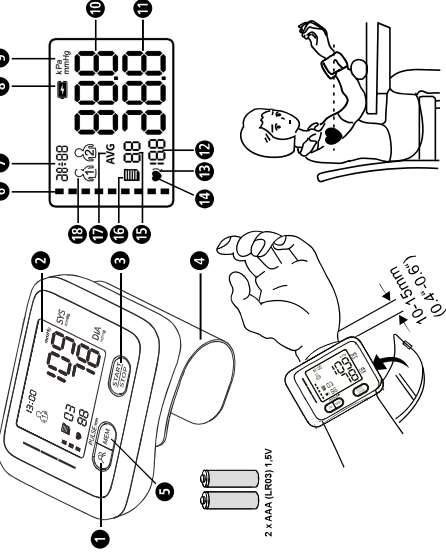


Blood pressure monitor BW-83E

Instruction manual - Please read carefully!

GB 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 carefully. Improper use can result in serious injury or damage to the device.
- WARNING**
The following 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 re-wrapping.
- Device classification: Type BF applied part**
- General prohibition symbol**
- Keep dry**
- LOT** LOT number
- Manufacturer**
- Date of manufacture**
- Observe local disposal guidelines!**
- Importer**
- Distributor**
- Serial number**
- EU authorized representative**
- Recycling symbols/codes:**
These are used to provide information about the material and its proper use and recycling.
- Do not disassemble or dismantle!**
- CE sign**

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GB Safety Instructions

Read the instruction manual carefully before using this device, especially the safety instructions. Keep the instruction manual for future use. It should be read by all persons who 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.
- Do not use 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 unit may not be used to check the heart rate of a patient who is always followed by your doctor's self-diagnosis of cardiac rhythm, to avoid health risks.
- Do not change the make of medication prescribed by a doctor as the best time 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 illness or for the treatment of an illness.
- 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 health.
- The patient is an inactive person, the device should be used as follows:
 - If you experience discomfort during the function, such as pain in the wrist or other complaints, press the Start/Stop - button to release the air immediately from the cuff. Loosen the cuff and remove it from your wrist.
 - Do not use the device if you experience dizziness, vertigo, or other symptoms 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 under 16 years of age.
 - If you want to use this device on young persons, medical devices may be used.
 - Do not let a child below 12 years old or the people who can't express intention to use the device.
 - Do not use the device on people with high radionuclide levels in the vicinity.
 - Do not use the device on people with radio transmitters, mobile phones or microwaves, or together with high-frequency surgical devices (magnetic resonance [MRI] devices). This may cause malfunctions or incorrect readings.
 - Do not operate near active RF surgical equipment and the RF-shielded room of an MRI system for magnetic resonance imaging where the intensity of EMF 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, the device should be replaced.
 - Never use the unit outdoors or in damp rooms.
 - Do not operate the unit near flammable gas (e.g. nitric oxide, oxygen or hydrogen) or flammable liquid (e.g. alcohol).
 - Use of the equipment adjacent to or stacked with other equipment should be avoided.
 - Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic interference of this equipment and result in incorrect operation.
 - Portable RF communications equipment (including peripherals such as antenna 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.
 - 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 suitable for use on the patient.
- 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.
- Do not use 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 235 mmHg (33.3 kPa), press the Start/Stop - button immediately to deflate the cuff when it is inflated.
- The cuff is delicate and must be handled with care. Only inflate the cuff when it is fully inflated.
- 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.
- 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 compartment cover, etc. can lead to suffocation. Therefore, never leave children alone with the device.
- 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, anemias, etc. may experience fluctuations in the measured blood pressure.
- 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.
- The ambient temperature is less than 5°C more than 40°C; the waiting time from 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.
- Incorrect 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.
- Measurements should be done by the operator as suggested.
- Warranty claims become void if the device is used for purposes other than intended or abnormal use.
- Always use the unit immediately and contact the after-sales service personnel in time.

SAFETY INSTRUCTIONS

- 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!
- 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.
- Remove the batteries with new ones.
- Keep batteries out of children's reach.
- Do not throw away or dispose of batteries in the trash.
- 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 a household refuse; put them in a hazardous waste bin.
- Do not throw used batteries into a battery collection bin; at the shop where they were purchased!

- Unit and LC-Display**
 - User selection settings
 - Memory icon
 - Battery change icon
 - Battery pressure measuring unit
 - Display of Diastolic Pressure
 - Display of Pulse Rate
 - Memory icon
 - Average value
 - User icon 1/2
- Scope of delivery**
First check that the unit is complete. The scope of delivery includes:
 - 1. ecomed Blood pressure monitor BW83E
 - 2. Wrist cuff (with AAA (LR03), 1.5V)
 - 1. Straps box

WARNING
If you notice any transport damage when unpacking, please contact your dealer immediately. Please ensure that the polystyrene packing is kept away from the reach of children! The polystyrene packing is kept away from the reach of children!

What is blood pressure?
Blood pressure is the pressure created in the blood vessels by each heart beat. When the heart contracts it exerts a force 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 heart relaxes, the pressure falls. The lowest value is known as the diastolic pressure. 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 dangerous situations arising (e.g. on stairs or in traffic)!

Influencing and evaluating readings
Your blood pressure readings should always be evaluated by a doctor who is also familiar with your condition. Do not record and compare the results. Do not draw any conclusions from a single reading.

Starting up / Insert / replace batteries
Before you can use your device, you must first insert the enclosed batteries. The cover of the battery compartment 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 cover. The batteries immediately if the battery change symbol appears in the display or if nothing appears in the display after the unit has been switched on.

User setting
Briefly press the button to change the user setting. Pressing the button again switches between users 1 or 2.

Setting the date and time
The wrist blood pressure monitor automatically stores up to 99 readings for each user (1 or 2). The memory function stores the readings with the date and time. The date and time cannot be changed during a measurement.

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, acetone, thinner or other solvents. Do not use the unit 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 device in a clean and dry place according to the environmental conditions for storage and transport.

Disinfection
Disinfect the housing with a soft cloth slightly moistened in the solution and wipe dry immediately. Do not disinfect with hypochlorite solution or ultraviolet radiation, as this could damage the unit and its components to a significant extent.

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 are still in use, to a collection point for the recycling of electrical and electronic equipment. The disposal of the device must be carried out in an environmentally appropriate manner. Remove the batteries before disposing of the device. 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 a recycling site.

Guidelines and standards

The EU standard for mechanical safety pressure measurement devices is specified according to EC directives and standards for mechanical safety pressure measurement devices. The device 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 mark but at a battery collection station at a recycling site or in a shop. Consult your local authority or your supplier for information about a recycling site.

Technical specifications

- Diastolic display
- 3.0mm x 2.15V batteries AAA/LR03
- 2 x 99 for measurement data
- Oscillometric
- Diastolic pressure measuring range: 30mmHg (4.0 kPa)
- 300 readings (480 Hz)
- 300 protection limit
- Diastolic pressure measuring range: Systolic: 45-230 mmHg (6.0-30.7 kPa); Diastolic: 25-160 mmHg (3.3-21.3 kPa)
- 46-199 beats/min.
- Maximum error tolerance for static pressure: ± 3 mmHg (± 0.4 kPa)
- Maximum error tolerance for pulse pressure: ± 3 mmHg (± 0.4 kPa)
- Maximum error tolerance for pulse rate: ± 3 mmHg (± 0.4 kPa)
- Continuous operation
- 5 years
- Operating conditions:
 - Temperature: +5 °C to +40 °C, 15 to 90 % max. relative humidity, atmospheric pressure: 70-106 kPa
 - Storage and transport conditions: -20 °C to +55 °C, 10 to 90 % max. relative humidity, atmospheric pressure: 70-106 kPa
- During transportation or storage, avoid shocks, direct light, corrosive gas, exposure to sunlight or rain. Ensure good ventilation.
- Dimensions (L x W x H): approx. 90 x 26.5 x 66 mm
- Weight: approx. 126 g without batteries
- Cuff: approx. 13.5 - 19.5 cm for adults
- Article number: 23105
- ENI number: 40 15589 23105 6

In the case of continuous product improvements, we reserve the right to make technical and design changes.

The current version of these instructions for use can be found at www.ecomed.com

Warranty and repair conditions

The unit is covered by a 2-year warranty. 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 date when the defect is. The following warranty terms apply:

- The warranty period for ecomed products is 2 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 when the warranty period.
- Repairs under warranty do not extend the warranty period after 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. misobservance of the instructions for use.
 - All damage which is due to repairs or tampering by the customer or unauthorised third parties.
 - Damage which has arisen due to transport from the manufacturer to the customer.
 - Accessories which are subject to normal wear and tear as batteries, etc.

Liability for direct or indirect consequential losses caused by the unit as excluded even if the damage to the unit is accepted as a warranty claim.

The service centre address is shown on the attached leaflet.

Automatic switch-off

If no operation is performed for approx. 20 seconds, the unit switches off automatically. If it is necessary to interrupt a measurement for any reason (e.g. the patient has to get up), the START/STOP button can be pressed at any time. The device immediately switches off.

Error display

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

Display Cause Solution

EU U The inflation pump takes too long. The inflation pressure does not reach 30 mmHg. The cuff is not wrapped around the wrist correctly.

EU H Inflation pressure reaches 235 mmHg - automatic deflation after 20 sec.

EU I No pulse detected.

EU 2 Movement, talking or magnetic interference during the measurement process.

EU 3 Abnormal measurement result.

EU 23 Systolic value below 45 mmHg

EU 24 Systolic value above 230 mmHg

EU 25 Diastolic value below 25 mmHg

EU 26 Diastolic value above 180 mmHg

Troubleshooting

Problem
No display although the unit is switched on and batteries are inserted in the unit correctly.

Cause and solution
The batteries may be empty. Insert new batteries, observing the correct polarity. Check the contact surfaces of the batteries and the battery compartment for dirt. Clean them with a cotton swab. Pull the lid on correctly. Repeat the measurement after a 30-minute rest period. Do not talk or move during the measurement.

The measured results differ greatly from the values measured by the doctor. It is not uncommon that values not measured at home can deviate greatly.

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, acetone, thinner or other solvents. Do not use the unit 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 device in a clean and dry place according to the environmental conditions for storage and transport.

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