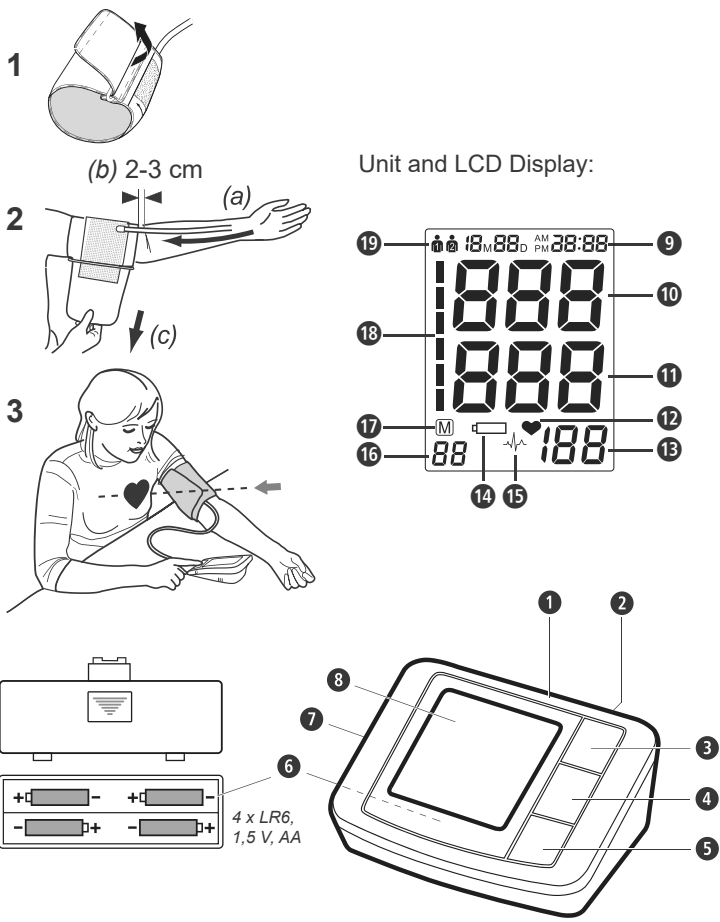


medisana®

GB Instruction Manual - Upper Arm Electronic Blood Pressure Monitor BU 516



Intended purposes
This automatic blood pressure device is intended to measure systolic pressure, diastolic pressure and pulse rate through upper arm. The device is expected to be used in private homes and is intended for people over 12 years old.

Intended users
Adults or children over 12 years, who can read and understand the user manual.

Intended patient population
The device is intended to be used by people over 12 years of age, people who need pulse or blood pressure measurement, including normal people or patients with hypertension, hypotension, abnormal pulse.

Contraindication
1. This device cannot be used by patients with severe heart insufficiency to avoid suffocation and death.
2. Do not use this product if you have coronary atherosclerotic heart disease to avoid narrowing or blockage of the blood vessel lumen, which may cause ischemia and lack of oxygen to the heart.
3. Do not use this product if you have diabetes, as it may cause damage to the heart and blood vessels.
4. Pregnant women, patients with implanted, electronic devices, 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.
5. Those who have arrhythmia, blood circulation or apoplexy problem, please use under the physician's instruction, lest cause disease exacerbation.

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
This symbol identifies hazards that may cause serious personal injury or death.

CAUTION
This symbol identifies hazards that may cause minor personal injury, product damage or property damage.

IP21 Ingress of water or particular matter into ME Equipment

CE Mark: Conforms to essential requirements of EU MDR 2017/745

Specifies serial number

Batch code

Device classification: type BF applied part

Manufacturer

Date of manufacture

Direct current

Medical Device

Unique device identification

Ambient pressure limitation

Temperature range

Humidity range

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

Importer

GB Safety instructions

Read the instructions for use carefully, especially the safety instructions, before using the appliance and keep the instructions for use or hand them on when passing the appliance on.

- 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 upper arm or other complaints, press the START button **➡** to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
- Use the right cuff, otherwise it can not work.
- The unit is unsuitable for children.
- 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 cuff hose around the neck may cause suffocation.
- The swallowing of small part like packaging bag, battery, battery cover and so on may cause the suffocation.
- The user must check that the equipment functions safely and see that it is in proper working condition before being used.
- Only the cuff provided can be used, and cannot be changed to any other branded cuff. It can only be replaced with a cuff of exactly the same type.
- 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 liquid (such as alcohol) are present.
- 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.
- 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 don't use a dilution agent, alcohol or petrol to clean the unit.
- Please don't hit heavily or fall down the product 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 the new batteries if the unit display a low battery symbol.
- Never leave any low battery in the battery compartment since they 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!
- Please take off the battery if you won't use in 3 months.
- Remove the batteries from the device if it is not going to be used for an extended period!
- Keep batteries out of children's reach!
- Do not attempt to recharge these batteries! Do not short circuit! 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 LCD Display

- ➡** Blood Pressure Monitor
- ➡** Cover for Battery Compartment
- ➡** MEM-button (Memory Recall)
- ➡** START/STOP-button
- ➡** SET-button
- ➡** Battery compartment (on underside)
- ➡** Push-in Connector for air tube
- ➡** LCD screen (display)
- ➡** Display of Date/Time
- ➡** Display of Systolic Pressure
- ➡** Display of Diastolic Pressure
- ➡** Pulse symbol
- ➡** Display of Pulse rate
- ➡** Change Battery symbol
- ➡** Irregular heartbeat
- ➡** Memory Location number
- ➡** Memory-Symbol
- ➡** Blood Pressure Indicator (green - yellow - orange - red)
- ➡** User memory 1 / 2

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 **U83CH**
 - 1 cuff with air tube
 - 4 batteries (type AA, LR6) 1.5 V
 - 1 storage pouch
 - 1 instruction manual

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

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 U83CH** is a blood pressure unit which is used to measure blood pressure at the upper arm. 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.

About irregular heartbeat

An irregular heartbeat is a heartbeat rhythm that varies by more than 25% from the average heartbeat rhythm detected while the device is measuring the systolic and diastolic blood pressure. Irregular heartbeat (IHB) indicator

1. When P1 or P2>0.12s,
2. When P1/Pa*100%>25% or P2/Pa*100%>25%
Any of the above two conditions occurs, it is determined that irregular heartbeat may occur.

Remarks:
Pa is the mean value of the measured inter-beat intervals throughout the measurement.
P1 is the difference between the maximum and mean values of the inter-beat interval.
P2 is the difference between the mean and minimum values of the inter-beat interval.

The benefits of using an Upper Arm Electronic Blood Pressure Monitor

The Upper Arm Electronic Blood Pressure Monitor accurately measures the blood pressure and heart rate of people aged 12 years and above, providing a convenient and low-cost means for doctors or patients to track and assess blood pressure and pulse changes in hospital or home settings. Regular monitoring enables early detection of fluctuations in blood pressure and pulse, improves blood pressure control and provides monitoring data for the management and treatment of patients with hypertension or other conditions caused by hypertension, allowing for appropriate responses to the diseases to guide medication.

Common factors of wrong measurement

- Please keep quiet for 5-10 minutes and avoid eating, drinking alcohol, smoking, exercising and bathing before taking measurement. All these factors will influence the measurement result.
- Remove any garment that fits closely to your upper arm.
- Always measure on the same arm (normally left).
- Take measurement regularly at the same time of every day, as blood pressure changes even during the day.
- All efforts by the patient to support their arm can increase blood pressure.
- Make sure you are in a comfortable, relax position and do not activate any of the muscles in the measurement arm during measurement. Use a cushion for support if necessary.
- If the arm artery lies lower or higher than the heart, a false reading will be obtained.

Blood pressure classification

Low blood pressure	systolic <100 diastolic <60
Normal blood pressure	(green display area ➡) systolic 100 - 139 diastolic 60 - 89
<i>Forms of hypertension</i>	
Mild hypertension	(yellow display area ➡) systolic 140 – 159 diastolic 90 – 99
Moderate hypertension	(orange display area ➡) systolic 160 – 179 diastolic 100 – 109
Severe hypertension	(red display area ➡) systolic ≥ 180 diastolic ≥ 110

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 underside of the unit. Open it, remove it and insert the 4 AA LR6 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 if the change battery symbol **➡** appears on the display **➡** or if nothing appears on the display after the unit has been switched on.

Settings

1. User setting:
Press SET button **➡** when power off.
The screen will display **➡** or **➡**, press **MEM**-button to switch between **➡** and **➡**, press SET button **➡** to confirm the user. Afterwards the computer will enter into year setting mode.

2. Year setting:
The input for setting the year then starts flashing. Keep pressing the **MEM**-button **➡** until the required year appears. Press SET button **➡** when you confirm the year, then it will switch to the month and date setting mode.

3. Month and date setting:
The month starts flashing. Keep pressing the **MEM**-button **➡** until the required month appears. Press SET button **➡** to confirm the month, then computer will proceed to set the date. As with the month setting, keep pressing the **MEM**-button **➡** until the required day appears. Press SET button **➡** to confirm the date, then computer will switch to time setting mode.

4. Time setting:
The hour starts flashing. Keep pressing the **MEM**-button **➡** until the required hour appears. Press SET button **➡** to confirm the hour and proceed in the same way for minute setting. Afterwards **CL** appears in the display. You can quit set-up mode by pressing SET button **➡**. If the batteries are changed the information is lost and the date and time need to be set again.

Fitting the cuff

- Push the end piece of the air tube **➡** into the hole on the left side of the unit prior to use.
- 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 pulse 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).

- Notes:
- Only use the cuff provided by the manufacturer. Replacing cuff with other manufacturers parts will cause inaccurate measurement results.
 - A loose or open cuff causes false reading.
 - With repeated measurements, blood accumulates in the arm which can lead to false reading. Consecutive blood pressure measurements should be repeated after 1 minute pause or after the arm has been held up in order to allow the accumulated blood to flow away.

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 **➡**.
 - If the START/STOP button **➡** is pressed, two short beeps are heard and 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 the number **0** flashes for 2 seconds. It automatically inflates the cuff slowly in order to measure your blood pressure. The rising pressure in the cuff is shown on the display.
 - 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 **➡** on the display starts to flash, you can hear the beep for every heartbeat once the heartbeat signal is detected.
 - When the measurement is finished, you can hear a long beep and the cuff is deflated completely. The systolic and diastolic blood pressure and the pulse value with the pulse symbol 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 symbol **➡** also flashes.

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.

- The readings are automatically saved in the selected memory (**➡** or **➡**). Up to 90 measured values with date and time can be stored in each memory.
- 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 START/STOP button **➡**.

Discontinuing a measurement

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

Displaying stored values

This unit features 2 separate memories, each with a capacity of 90 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. All values average appear on the display. Pressing the MEM button **➡** again, the last measurement value will be shown. Repeatedly pressing the MEM button **➡** displays the respective values measured previously. If you have reached the final entry and do not press a button, the unit automatically switches itself off after approximately 120 seconds in memory recall mode. 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 90 measured values have been stored in the memory and a new value is saved.

Deleting stored values

If you are sure that you want to permanently remove all stored memories, press the SET button **➡** for 7 times until **CL** appears when power off. Press the START/STOP button **➡**, **CL** will flash for 3 times to clear all the memories. After this press MEM button **➡**, **M** and "no" will be shown on the display which mean that no memory in store.

Error messages and error remedying

Error indicators: The following symbol will appear on the display when measuring abnormal.

Symbol	Cause	Remedying
E-1	Weak signal or pressure change suddenly	Wrap the cuff properly. Remeasure with correct way.
E-2	External strong disturbance	When near cell phone or other high radiant device, the measurement will be failed. Keep quiet and no chatting when mesure.
E-3	Inflation error	Wrap the cuff properly. Make sure that he plug is properly inserted in the unit. Remeasure.
E-5	Abnormal blood pressure	Repeat the measurement after relax for 30 mins. If get unusual readings for 3 times, please contact your doctor.
	Weak batteries	The batteries are too low or empty. Replace all four batteries with new 1.5V type AA LR6 batteries.

Troubleshooting

Problem	Check	Cause and solutions
No power	Check the battery power. Check the polarity position.	Replace batteries. Check for correct installation of the batteries (polarity).
No inflation	Check whether the plug is inserted correctly. Check whether the plug is broken or leak.	Insert into the air socket tightly. Change cuff.
Err appears & measurement is interrupted	Movement or speaking during measurement.	Do not move or speak during the measurement.
Cuff leaks	Check whether the cuff is damaged or too loose.	Wrap the cuff tightly. Change cuff.

Please contact the customer service 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 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 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 case when no use. Store the unit in a clean and dry location.

Cuff cleaning and disinfecting

Use a dust-free cloth dipped in water to wipe the cuff surface, until there is no visible stain and then use a dry dust-free cloth to wipe the water off the cuff surface. After cleaning, check the internal and external surfaces of the cuff to ensure that these are clean. If dirt is found, clean repeatedly until there is no visible stain and then place it in a cool, ventilated and dry place (high temperature treatment such as ironing and drying is not allowed).

Disinfecting the cleaned and dried cuff: Wipe the cuff surface back and forth with a dust-free cloth dipped with 75% rubbing alcohol by volume to remove the sebum and other micro-organisms from the surface for 1 minute each time, totally 10 times. After disinfection, dry it with a clean dust-free cloth to allow the residual alcohol to volatilize naturally. The cuff can be cycled and cleaned 10 times out of 1000 uses. When the cuff inflation time exceeds 20 seconds during normal measurement of the device and the device displays E-3, the cuff needs to be replaced. When the cuff bonding surface does not bind effectively, the cuff needs to be replaced. Please contact the manufacturer if you need to purchase a suitable cuff.

The cuff is consumable with a service life of 1,000 times (under company's test conditions). It is recommended to replace it in time to accurately measure blood pressure. If cuff is too small, please call the manufacturer or seller (retailer) for further information. In case of air leakage, contact the service centre for replacement. The cuff is treated as the applied part.

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 Upper Arm Electronic Blood Pressure Monitor cannot be used in an MRI environment. It 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 0123". The device meets the requirements of IEC 80601-2-30, Part 2 for non-invasive blood pressure monitors. Reporting adverse events for the users/patients/customers in EU countries: If users/patients/customers think that they or someone in the family has experienced a serious incident that has occurred in relation to the device, users/patients/customers are encouraged to report the incident to the manufacturer and the competent authority of the Member State in which the user/patient/customer is established.

Technical specifications

Name and model	: Blood pressure monitor Model: U83CH
Display system	: Digital display
Memory slots	: 2 x 90 for measurement values
Measuring method	: Oscillometric
Voltage supply	: 6V $\approx$, 4 x 1.5V batteries AA LR6
Measuring range blood pressure	: 0 – 299 mmHg
Measuring range pulse	: 40 – 199 beats/min.
Maximum measuring deviation of static pressure	: $\pm$ 3 mmHg
Maximum measuring deviation of pulse values	: $\pm$ 5 % of the values
Main unit lifetime	: 10,000 times under normal use
Battery life	: Could be used for 300 times at normal condition
Pressure generation	: Automatic with pump
Air release	: Automatic
Autom. switch-off	: after approx. 3 minutes
Operating environment	: +5 °C to +40 °C, min. 15 to 93 % max. relative humidity, air pressure 86kPa to 106kPa Note: The product cannot be operated at an altitude of 2,000 m or above.
Storage & transportation environment	: -20 °C to +55 °C, min. 10 to 93 % max. relative humidity, air pressure 86kPa to 106kPa avoid crash, sunlight or rain during transportation.
Dimensions (L x W x H)	: approx. 130 x 109 x 60 mm
Cuff	: 500 x 150 mm / 22 - 36 cm for adults
Weight (main unit)	: approx. 254 g without batteries
Item number	: 51166
EAN number	: 40 15588 51166 0
Replacement parts	: - Cuff M 22 – 36 cm for adults with average upper arm circumference Art. No. 51193 / EAN 40 15588 51193 6 - Cuff, L 32 - 42 cm for adults with upper arm of large circumference (not included, can be purchased separately) Art. No. 51194 / EAN 40 15588 51194 3

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

Clinical Accuracy

The product was clinically investigated according to the requirements of ISO 81060-2 and complies with the accuracy requirements of +/-5mmHg at a standard deviation of max. 8mmHg.

Warranty and repair terms

Your statutory warranty rights are not restricted by our guarantee below. Please contact your dealer 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 three 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. non-observance 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.

The service centre address is shown on the attached leaflet.

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