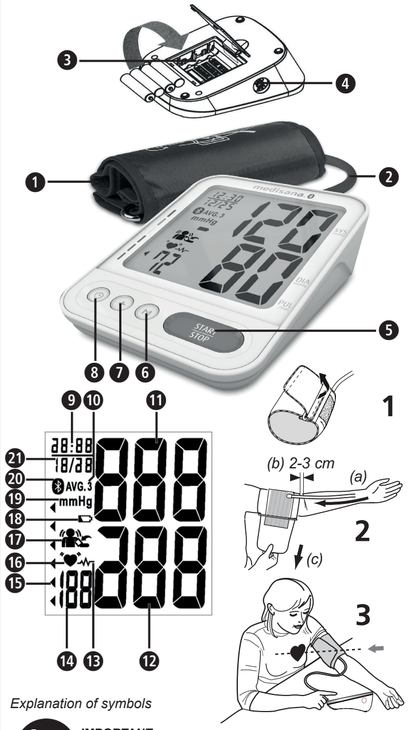
medisana®

Upper Arm Blood Pressure Monitor

BU 584 connect

Instruction manual

GB Unit and LC-display



Explanation of symbols

IMPORTANT
Non-observance of these instructions can result in serious injury or damage to the device.

WARNING
These warning notes must be observed to prevent any injury to the user.

CAUTION
These notes must be observed to prevent any damage to the device.

NOTE
These notes give you useful additional information on the installation or operation.

WARNING: To avoid inaccurate results due to electromagnetic interference, portable RF communication devices (including peripherals such as antenna cables and external antennas) should not be closer than 30 cm to any part of the instrument. The performance of this device may be affected.

Device classification:
type BF applied part

Temperature range

Humidity range

IP22 Ingress protection rating

Atmospheric pressure range

Non-ionizing electromagnetic radiation

LOT LOT number

SN Serial number

Manufacturer

Date of manufacture

Device information:
- Internally powered equipment
- Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide
- Continuous operation with short-time loading

Intended use
- This fully automatic over-the-counter electronic blood pressure monitor is intended for measuring human's systolic and diastolic blood pressure and heart rate by using an oscillometrique technique by means of a cuff, which needs to be fitted on the upper arm. All values can be read out in one LCD panel. The useable cuff circumference is 23 to 43 cm. The device is intended for adult indoor use at home only.
- The device is able to detect irregular heartbeat and indicate this with a symbol.

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

CE 0297

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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. The applied part is the cuff.
- 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.
- 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.
- The device has sensitive components. Be careful and ensure that the operating and storage conditions are met.
- Wait at least 30 minutes after consuming caffeine or tobacco before taking a measurement.
- Before taking a measurement, rest for 5-10 minutes and do not eat, drink alcohol, smoke, do not do any physical work, do not exercise or bathe. All these factors can influence the measurement result.
- Repeated measurements cause the blood to congestion, which can lead to a false result and/or unpleasant sensations (e.g. numbness in the arm). Successive blood pressure measurements should be taken with 3-minute breaks. If the symptoms do not subside within a few minutes, contact your doctor.
- Always measure on the same upper arm (usually left). For those who have had a mastectomy or lymph node clearance, it is recommended to take a measurement on the unaffected side.
- Measure your blood pressure regularly, at the same time every day, because blood pressure changes throughout the day.
- Ensure a comfortable and relaxed position and do not tense any muscle of the arm being measured during the measurement. If necessary, use a support cushion.
- Keep calm during the measurement: do not move or speak, otherwise the measurement results may change.
- Extreme temperatures, humidity or altitude can affect the performance of the unit.
- A loose or open cuff causes an incorrect measurement.
- Do not take measurements, if any other equipment is applied to the same limb for monitoring. This could lead to disturbances or failures. This device is not suitable during intravenous injection to limbs or during dialysis treatment.
- The device is not suitable for use on pregnant women, patients with implanted, electronical 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.
- If you suffer from circulation problems, arteriosclerosis, diabetes, liver disease, kidney disease, severe hypertension or peripheral circulation problems, consult your doctor before using the device.
- 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 irregular heartbeat, which it indicates with the icon ⓭. In this case, contact your physician.
- Pay attention during use and storage, that cable and air hose will not cause strangulation. To reduce the risk of strangulation, keep this product away from children and do not place the hose around the neck.
- Never bend the air hose during use as this may lead to injuries. Also never squeeze or block the air hose in any way.
- 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.
- If you experience discomfort during a measurement, such as pain in the upper arm or other complaints, press the START/STOP button ❺ to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
- 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 ecchymosis.
- 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.
- 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.
- 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.
- Only use the device under the conditions mentioned in the technical details. Otherwise, the lifespan and performance of the device could suffer.
- If you have any infectious skin disease or the device is used by users with infectious skin disease, please do not continue using the device. Before using the device, user should check the appearance of cuff. If you notice blood or other soil on cuff, please do not use this device. If there is one of above situations, please dispose of the device without reuse.
- Protect the appliance from heavy blows and do not drop it.
- If the unit is not going to be used for a long period, please remove the batteries.
- Accuracy: In case it is needed to have the device checked for calibration, please consult the service center.

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

❶ Cuff
❷ Air hose
❸ Battery compartment (on backside)
❹ Connector for the hose
❺ START/STOP button
❻ M-button
❼ "+" button
❽ ◷ button (Time / Date)
❾ Timet (Hours : Minutes)
❿ Average of the last 3 measurements
⓫ Systolic pressure
⓬ Diastolic pressure
⓭ Irregular heartbeat
⓮ Pulse frequency
⓯ Blood Pressure Indicator (green - yellow - orange - red)
⓰ Pulse symbol
⓱ Movement detected / cuff incorrectly applied
⓲ Battery symbol
⓳ Measurement unit
⓴ Bluetooth® symbol
㉑ Date (Month : Day)

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 584 connect**
- 4 batteries (type AAA, LR03) 1.5V
- 1 instruction manual and EMC leaflet
- 1 cuff with air tube
- 1 storage pouch

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.

Blood pressure classification

systolic mmHg	diastolic mmHg		Bloodpressure indicator ⓯
≥ 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 ❸ 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 ⓲ appears on the display or if nothing appears on the display after the unit has been switched on.

Settings - Setting date, clock and Bluetooth® function
Press the ◷ - button ❽ to set the date and time. First the year flashes, which you can adjust with the "+" button ❼. Then press the -◷ - button ❽ again to confirm the entry and to move to the next setting option. Proceed in the same way for month, day, hour and minute. Finally, you can set whether the **Bluetooth**® function should be active ("On") or inactive ("Off"). The device then switches back to the initial standby mode.

Fitting the cuff
1. Connect the air hose to the connector ❹ on the left side of the device.
2. 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.
3. 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).
4. Tighten the end of the cuff so that it wraps evenly around your arm, leaving room for 2 fingers between the cuff and your arm.
5. Measure the blood pressure on your bare arm.
6. 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.
7. Correct measuring position for sitting (Fig.3). Make sure that the cuff does not slip during measurement and that the printed arrow points to the crook of the arm.

User memory setting
The **medisana** blood pressure monitor features 2 separate memories, each with a capacity of 120 memory slots. Press the "+" button ❼ to select user memory 1 (display: **no 1**) or 2 (**no 2**).

Taking a blood pressure measurement
1. After applying the cuff and setting the user memory, press the START/STOP button ❺.
2. 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 „**00**" appears.
3. 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.
4. When the device detects the signal, the heart symbol ⓰ 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 appear on the display.
5. The blood pressure indicator ⓯ appears next to the relevant coloured bar depending on the blood pressure classification.
6. If the unit has detected an irregular heartbeat, the irregular heartbeat display ⓭ appears additionally. To stop the measurement, press START/STOP button ❺. The cuff will deflate immediately after the button is pressed.
7. The readings are automatically saved in the selected memory (1 or 2).
8. The measurement results will automatically be transferred via **Bluetooth**® to receive-ready devices, if the function is activated. During this process, the **Bluetooth**®-symbol ⓴ will appear. If **Bluetooth**® is not active, you may manually activate it by pressing and holding START/STOP button ❺ when unit is switched off for approx. 5 seconds, until the **Bluetooth**®-symbol ⓴ appears.
9. After about 1 minute without further operation, the machine switches off automatically.

Transfer via Bluetooth®
This device offers the possibility to transfer your measured values via Bluetooth® to the VitaDock® app. The VitaDock® app allows the evaluation, storage and synchronisation of your data between multiple iOS- and Android-devices to have access to it anytime and anywhere. You may share your results with your friends or your doctor. Therefore you need a free user account, which you can create on the website www.vitadock.com. For Android or iOS mobile devices, you may download the respective apps. You will find a detailed instruction for how to install and use the software on the mentioned website. After each measurement an automatic transfer of the values will take place (provided that Bluetooth® is activated and configurated on the receiving device).

WARNING
- **Keep the device at least 20 centimeters away from the human body (especially the head) when the Bluetooth® data transmission is proceeding after measurement.**
- **The distance between the device and the receiver should be between 1 meter to 10 meters to avoid possible disturbances.**

Bluetooth® type: 4.2 BLE; System requirements: Android 6.0 or newer; iOS 7.0 or newer
RF Frequency range: 2402 MHz - 2480 MHz; Equivalent isotropic radiant power: 3,99 dBm;
Maximum permitted power: 0,47 mW; Transmitting distance: 10 m (Class 2); Data throughput: 1 Mbps

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. To call up the stored measured values, press the "+" button ❼ to select user memory 1 (display: **no 1**) or 2 (**no 2**). Then press the M-button ❻. The average values of the last 3 measurements ❿ appear on the display. If you now press the M-button ❻ again, the last measurement taken appears on the display. Press the M-button ❻ again to scroll through the measured values. By pressing the START/STOP button ❺ you can leave the memory recall mode at any time and at the same time the device switches to standby mode. If 120 measured values are stored in the memory and a new value is saved, the oldest value is deleted.

Deleting stored values
Enter the memory recall mode as described above and press and hold the ◷ - button ❽ and the "+" button ❼ at the same time. The memory of the relevant user memory is cleared ("**CLA**" appears).

Troubleshooting

Display	Cause	Solution
No display	Batteries do not have enough voltage or are inserted incorrectly.	Insert new batteries. Insert the batteries according to the instructions.
EE	Blood pressure too high or too low or effective pulse too low.	Switch the device off and on again. Then repeat the measurement in correct way.
E1	Airflow anomaly. The air hose may not be connected correctly.	Check the connection of the air hose. Repeat the measurement.
E2	Inflation pressure over 300 mmHg.	Switch the device off and on again. Then repeat the measurement.
E3	Measurement unsuccessful. Cuff not correctly applied or movement or speech during measurement.	Wrap the cuff properly. Remeasure in correct way. Do not speak or move during the measurement.
E4	**Bluetooth**® error. Could not connect to a connected device for more than 45 seconds. The **Bluetooth**® function will be disabled.	If you want to reactivate the **Bluetooth**® function, press and hold the M-button ❻ for about 3 seconds.
	Motion or speech detected during measurement. Cuff may not be correctly applied. Measurement values may be incorrect.	Wrap the cuff properly. Remeasure in correct way. Do not speak or move during the measurement.
	Cuff not correctly applied (e.g. too tight or too loose).	Wrap the cuff properly. Remeasure in correct way.
No **Bluetooth**®-connection possible	Pairing not successful / **Bluetooth**® not activated / Distance between transmitter and receiver too great / An incompatible device is used / Electrical or mechanical defect	Follow the instructions to establish the **Bluetooth**® function. The distance between devices should be less than 10m. Switch all devices off and after a short waiting period switch them on again and try to connect again.
EP	Contact the customer service.	

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.

Disinfection
1. If used by yourself in a home environment, wipe the cuff once a month with a commercially available cotton cloth with 75% alcohol for more than 30 seconds at a time for disinfection in addition to the normal cleaning routine.
2. If used for more than one person (home use), wipe the cuff once a week with a commercially available cotton cloth with 75% alcohol for more than 30 seconds at a time for disinfection in addition to the normal cleaning routine.
3. After cleaning/disinfection and before use, make sure that there are no blood stains or dirt on the display, the device or the cuff. If there are blood spots or dirt that cannot be removed, please dispose of the device without reusing it.
4. If used in a complex environment (e.g. in a hospital) or by persons outside your own family, replace the cuff with a new one after use.

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 1060-3, EN 1060-4, EN 81060-1, EN 81060-2 and EN 80601-2-30. The specifications of EU Guideline "93/42/EEC of the Council Directive dated 14 June 1993 concerning medical devices" are met and likewise those of the RED 2014/53/EC. You can request the complete Conformity Declaration from **medisana** GmbH, Carl-Schurz-Str. 2, 41460 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** Upper arm blood pressure monitor **BU 584 connect**
Display system / Memory slots:	Digital display / 2 x 120
Measuring method / Mode of operation:	Oscillometric / Continuous operation
Power supply:	4 x 1.5V ⎓ AAA "LR03" alkaline battery
Rated cuff pressure:	0 - 300 mmHg
Measurement pressure:	40 - 280 mmHg
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 / Deflation:	Automatic with pump / Automatic
Shelf life (batteries):	3 years (Temperature 20 ± 2°C; rel. humidity 65 ± 20 %)
Battery life:	Approx. 250 measurements
Product life span:	Approx. 5 years with 4 times daily use
Operating conditions:	+5°C to +40°C, 15 to 93 % relative humidity, non-condensing, 700-1060 hPa atmospheric pressure
Storage / Transportation conditions:	-25°C to +70°C, relative humidity ≤ 93 %
Dimensions / Cuff:	Approx. 137 x 98.5 x 52 mm / 23 - 43 cm (9" - 17")
Weight (main unit):	Approx. 276 g ± 5 g without batteries
Item number:	48943
EAN number:	40155 88 48943 3

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.
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