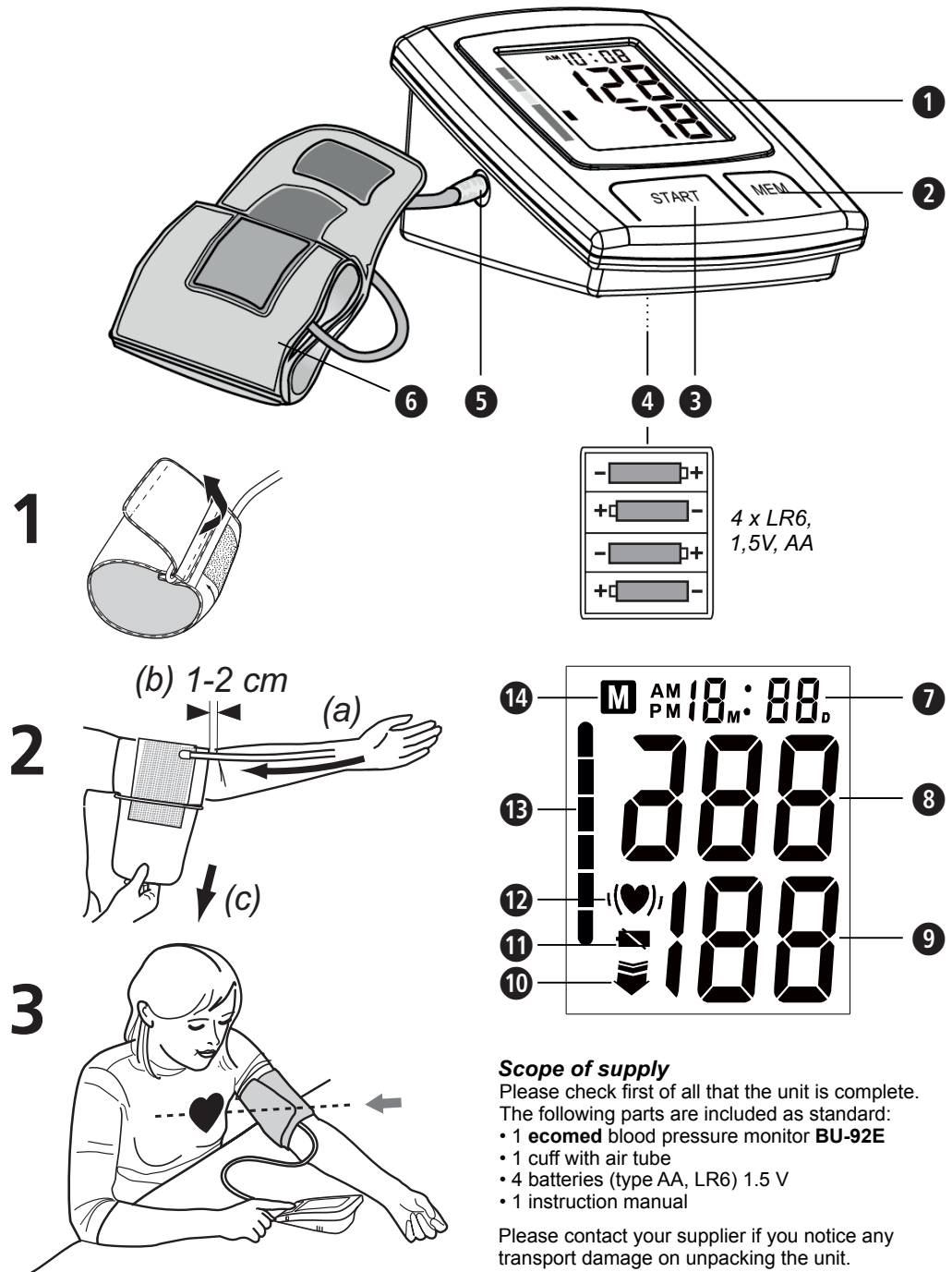


Upper arm blood pressure monitor BU-92E

Instruction Manual - Please read carefully!

GB Unit and LC-Display



Scope of supply
Please check first of all that the unit is complete. The following parts are included as standard:

- 1 ecomed blood pressure monitor BU-92E
- 1 cuff with air tube
- 4 batteries (type AA, LR6) 1.5 V
- 1 instruction manual

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

Proper use

- This fully automatic electronic blood pressure monitor is intended for measuring the blood pressure at home. It is a non-invasive blood pressure measurement system to measure the diastolic and systolic blood pressure and pulse of an adult using a non-invasive technique by means of a cuff, which needs to be fitted on the upper arm.

Contraindications

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

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



Keep dry



LOT number



Manufacturer



Date of manufacture

Common factors of wrong measurements

- Please keep quiet for 5-10 minutes and avoid eating, drinking alcohol, smoking, exercising and bathing before taking a measurement. All these factors will influence the measurement result.
- Remove any garment that fits closely to your upper arm.
- Always measure on the same arm (normally left).
- Measurements should be taken regularly at the same time of each day, as the blood pressure varies even during the day.
- Any effort to support the arm during measurement may increase the measured blood pressure.
- Make sure you are in a comfortable, relaxed position and do not move or constrict your muscles during measurement. Use a cushion to support your arm if necessary.
- If the arm artery lies lower or higher than the heart, a false reading will be obtained.
- A loose or open cuff causes false readings.
- 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.

GB Safety Instructions



Read the instruction manual carefully before using this device, especially the safety instructions, and keep the instruction manual for future use. Should you give this device to another person, it is vital that you also pass on these instructions for use.



- The unit is intended only for use in the home. Consult your doctor prior to using the blood pressure monitor if you are concerned about health matters.
- Only use the unit for its intended purpose in accordance with the instructions for use. Warranty claims become void if the unit is misused.
- 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 over 20 of the most commonly occurring types of arrhythmia and movement artifacts and indicates this with a symbol (♥) in the display.
- 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 ➊ to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
- The unit is not suitable 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 swallowing of small parts like packaging bag, battery, battery cover and so on may cause suffocation.
- If the device has been stored in cold places, allow it to acclimate to room temperature before use.
- 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 (see "electromagnetic compatibility").
- Do not use the equipment where flammable gas (such as anaesthetic gas, oxygen or hydrogen) or flammable liquids (such as alcohol) are present.
- No modification of this unit/device is allowed. Do not disassemble the device.
- The error-free and safe operation is only ensured, if the device is stored and used within the surrounding parameters as described under "Technical details".
- 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 high temperatures, direct sunlight and moisture. If liquid does manage to penetrate into the unit, remove the batteries immediately and do not continue to use the unit. In this case contact your specialist dealer or notify us directly.
- The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open-close cycles of the closure.
- Please do not hit the device heavily or let it fall down from a high place.
- 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.
- The device is not suitable for use on patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy.
- Never apply the cuff over hurt skin.
- If the unit is used by more than one person, each user should use his own cuff for hygienical reasons. The cuffs can be purchased separately in the commerce.
- Avoid compression or restriction of the connection tubing during measurement, as this may cause inflation errors or harmful injuries.
- Do not use this unit in a moving vehicle. This may result in erroneous measurement.
- If the unit is not going to be used for a long period, please remove the batteries.

SAFETY NOTES FOR BATTERIES

- Do not disassemble batteries!
- Replace all batteries if the unit display shows the low battery symbol.
- Never leave any low battery in the battery compartment since it may leak and cause damage to the unit.
- Increased risk of leakage! Avoid contact with skin, eyes and mucous membranes! If battery acid comes in contact with any of these parts, rinse the affected area with copious amounts of fresh water and seek medical attention immediately!
- If a battery has been swallowed, seek medical attention immediately!
- Replace all of the batteries simultaneously!
- Only replace with batteries of the same type, never use different types of batteries together or used batteries with new ones!
- Insert the batteries correctly, observing the polarity!
- Remove the batteries from the device if it is not going to be used for an extended period of 3 months or more!
- Keep batteries out of children's reach!
- Do not attempt to recharge batteries! **There is a danger of explosion!**
- Do not short circuit! **There is a danger of explosion!**
- Do not throw into a fire! **There is a danger of explosion!**
- Do not throw used batteries into the household refuse; put them in a hazardous waste container or take them to a battery collection point, at the shop where they were purchased!

Unit and LCD display

- ➊ LCD screen (display)
- ➋ MEM-button
- ➌ START-button
- ➍ Battery Compartment (on underside)
- ➎ Push-in Connector for air tube
- ➏ Cuff with air tube
- ➐ Display of Date/Time
- ➑ Display of Systolic Pressure
- ➒ Display of Diastolic Pressure
- ➓ Pulse Rate
- ♥ Symbol, "ready to inflate"
- ➔ Change Battery symbol
- ➗ Pulse symbol / Arrhythmia display (arrhythmia cords)
- ➕ Blood Pressure Indicator (green - yellow - orange - red)
- ➖ Memory-Symbol

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 ecomed BU-92E 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.

Blood pressure classification WHO

These values have been specified by the World Health Organisation (WHO) without making any allowance for age.

Low blood pressure	systolic <100	diastolic <60
Normal blood pressure	(green display area ➊)	
	systolic 100 - 139	diastolic 60 - 89

Forms of high blood pressure / hypertension

Mild hypertension	(yellow display area ➋)
	systolic 140 - 159 diastolic 90 - 99
Moderate hypertension	(orange display area ➌)
	systolic 160 - 179 diastolic 100 - 109
Severe hypertension	(red display area ➍)
	systolic ≥ 180 diastolic ≥ 110



WARNING

Blood pressure that is too low represents just as great a health risk as too high! Fits of dizziness may lead to dangerous situations arising (e.g. on stairs or in traffic)!

Inflencing 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 ➍ is located on the underside of the unit. Open 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 ➑ or if nothing appears on the display after the batteries have been inserted correctly.

Setting date and time

After inserting the batteries, time and date are shown in turns on the display ➊. Press and hold START-button ➋ and MEM-button ➌ at the same time, until a short beep can be heard and the month figure (M) starts to flash. Adjust the correct month by pressing the MEM-button ➌ and press the START-button ➋ to confirm and proceed to the day figure. Repeat these steps for day, hours and minutes, until these are correctly adjusted. Press the START-button ➋ after adjustment of the minute figure to return to the normal display of time and date. After approx. 1 minute without any button pressed, the device will automatically return to the display of time and date. If the batteries are changed, the set information is lost and needs to be input again.

Fitting the cuff

1. Push the end piece of the air tube into the hole on the left side of the unit ➎ prior to use.
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 distance between the edge of the cuff should be 1-2 cm above the crease of the elbow. (b). Pull the cuff tight and close the Velcro fastener (c).
4. Measure the pulse on your bare arm.
5. 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.
6. Correct measuring position for sitting (Fig.3).

Taking a blood pressure measurement

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

1. Press the START-button ➋. A long beep can be heard and all display characters are shown (display test). This test can be used to check that the display is indicating properly and completely.
2. Now "U1" (User memory 1) or "U2" (User memory 2) are flashing in the display ➑. By pressing MEM-button ➌ you may switch between U1 and U2. Press START-button ➋ or do not press any button for approx. 5 seconds to start the cuff inflation.
3. The device is ready for measurement and the number 0 and the symbol "ready to inflate" ➗ flashes for approx. 2 seconds. The unit automatically inflates the cuff slowly in order to measure your blood pressure.
4. 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.
5. When the measurement is finished, the cuff is deflated completely. The systolic and diastolic blood pressure and the pulse value appear on the display ➑. The blood pressure indicator ➕ flashes next to the relevant coloured bar depending on the WHO blood pressure classification. If the unit has detected an irregular heartbeat, the arrhythmia display (♥) ➗ 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.

6. The readings are automatically saved in the selected memory (U1 or U2). Up to 60 measured values with date and time can be stored in each memory.
7. The measurement readings remain on the display. The unit switches off automatically (however, date and time will still be displayed) after approx. 1 minute if no buttons are pressed. The unit may also be switched off using the START-button ➋.

Discontinuing a measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell) the START-button ➋ can be pressed at any time. The device immediately decreases the cuff pressure automatically.

Display stored values

This unit features 2 separate memories, each with a capacity of 60 memory slots. Results are automatically stored in the memory selected by the user. Press the MEM button ➌ when power off (but still time and date are displayed), to call up the measured values stored. "U1" or "U2" will be flashing in the display ➑ along with the memory symbol ➔ and the number of total results stored in this memory slot. Press START-button ➋ to switch between U1 and U2. Press MEM-button ➌ (or do not press any button for approx. 5 seconds) and the average values of the 3 last results stored will be displayed (along with the memory symbol ➔ and "A"). If no results are stored, "-.-" will appear. Press the MEM-button ➌ again to display the most recently stored measurement result. Repeatedly pressing the MEM-button ➌ 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 (however, date and time will still be displayed) after approximately 1 minute. Memory recall mode can be exited at any time by pressing the START-button ➋, which will also switch the unit off. The oldest value is deleted if 60 measured values have been stored in the memory and a new value is saved.

Memory - clear of measurements

If you are sure that you want to permanently remove all stored memories, press and hold the MEM-button ➌ for approx. 3 seconds during the display of a freely chosen memory value (except during the display of the average value). The device will beep 3 times and will then delete all stored results in the respective memory slot. The display will show "-.-".

Troubleshooting

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

- The battery change symbol "➔" ➔ appears in the display: The batteries are too low or empty. Replace all four batteries with new batteries of type 1.5V, AA/LR6.

- Unusual measurement results or "HI" or "Lo" are displayed:
Fit the cuff correctly and assume the correct position. Keep still during the measurement. This blood pressure monitor is not suitable for persons with a strong arrhythmia.
- This unit is able to detect different errors and emits an according error code. A running measurement will be aborted:
"Er 0" to "Er 4": Failure in pressure system or failed to detect systolic resp. diastolic pressure. The connection to the air hose could be interrupted. Check the connections between the cuff and the main unit, fit the cuff correctly and repeat the measurement. Keep still during the measurement.
The pressure in the cuff is too high (over 300 mmHg).
Relax for 5 minutes and repeat the measurement.
"Er 5":
The pressure in the cuff is over 15 mmHg since more than 3 minutes.
Relax for 5 minutes and repeat the measurement.
"Er 6":
The pressure in the cuff is over 15 mmHg since more than 3 minutes.
Relax for 5 minutes and repeat the measurement.

"Er 7" / "Er 8" /

"Er A": Electronic-, parameter- or sensor error. Relax for 5 minutes and repeat the measurement.

Important: Please contact your doctor if the error messages appear repeatedly. Keep still and do not move during the measurement.

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, naphtha, thinner or gasoline etc.. Never immerse the unit or any component in water. Be cautious not to get any moisture in the main unit.
Do not 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 original packing 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 non-invasive blood pressure monitors. It is certified in accordance with EC Guidelines and carries the CE symbol (conformity symbol) "CE 0297". The blood pressure monitor corresponds to European standards EN 60601-1, EN 60601-1-2, EN 80601-2, EN 1060-1 and EN 1060-3. The specifications of EU Guideline "93/42/EEC of the Council Directive dated 14 June 1993 concerning medical devices" are met.

Electromagnetic compatibility: Guidance and manufacturer's declaration
(as per 25th March 2014)

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

Electromagnetic immunity			
The blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the blood pressure monitor should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic immunity			
The blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the blood pressure monitor should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the "blood pressure monitor" including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the concomitant level in each frequency in each frequency range. Interference may occur in the vicinity of equipment marked with the following Symbol: ((())) NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the "blood pressure monitor" is used exceeds the applicable RF compliance level above, the blood pressure monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the "blood pressure monitor". b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] 3 V/m.

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

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

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Technical specifications

Name and model	: ecomed Upper arm blood pressure monitor BU-92E
Display system	: Digital display
Memory slots	: 2 x 60 measurement values with time & date
Measuring method	: Oscillometric
Power supply	: 6 V=, 4 x 1.5V batteries AA LR6
Blood pressure measuring range	: 40 – 260 mmHg
Pulse measuring range	: 40 – 180 beats/min.
Maximum error tolerance for static pressure	: ± 3 mmHg
Maximum error tolerance for pulse rate	: ± 5 % of the value
Pressure generation	: Automatic with pump
Deflation	: Automatic
Operating conditions	: +5 °C to +40 °C, 90 % max. relative humidity
Storage conditions	: -20 °C to +55 °C, 90 % max. relative humidity
Dimensions (L x W x H)	: Approx. 136 x 100 x 65 mm
Cuff	: 22 - 30 cm for adults
Weight (main unit)	: Approx. 236 g without batteries and cuff
Item number	: 23205
EAN number	: 40 15588 23205 3
Accessories	: • Cuff, large 30 - 42 cm for adults with upper arm of large circumference Art.-Nr. 51126 • Cuff, normal 22 - 30 cm for adults with upper arm of normal circumference Art.-Nr. 51135

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:

1. The warranty period for ecomed products is two years from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Defects in material or workmanship will be removed free of charge within the warranty period.
3. Repairs under warranty do not extend the warranty period either for the unit or for the replacement parts.
4. The following is excluded under the warranty:
 - a. All damage which has arisen due to improper treatment, e.g. nonobservance of the user instructions.
 - b. All damage which is due to repairs or tampering by the customer or unauthorised third parties.
 - c. Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
 - d. Accessories which are subject to normal wear and tear as batteries, cuff etc..

