

FUZZY - LUGLIO 2004



...for your health

FUZZY

**MISURATORE DI
PRESSIONE AUTOMATICO
ONE TOUCH**

**AUTOMATIC
BLOOD PRESSURE
MONITOR ONE TOUCH**



Questo dispositivo è conforme alle disposizioni della Direttiva Comunitaria Europea 93/42/CEE.
This device fulfils the provisions of the EC Directive 93/42/EEC.

Vietata la duplicazione. Riproduzioni, anche parziali, in qualsiasi forma, sono vietate se non preventivamente autorizzate per iscritto dal Fabbricante.
Le specifiche tecniche, la descrizione, la dotazione di accessori e l'aspetto esteriore dei prodotti possono variare senza preavviso.



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Automatic Blood Pressure Monitor One Touch Instruction manual

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1. INTRODUCTION

1.1. MEDEL FUZZY features

MEDEL FUZZY blood-pressure monitor is a automatic, digital blood-pressure measuring device for use on the upper arm, which enables very fast and reliable measurement of the systolic and diastolic blood-pressure as well as the pulse frequency by way of the oscillometric method of measuring.

The device offers a very high and clinical tested measurement accuracy and has been designed to provide the maximum user-friendliness.

Thanks to the large MEDEL FUZZY LCD display, both operational status and cuff pressure are visible during measurement.

Before using, please read through this instruction manual carefully and then keep it in a safe place. For further questions on the subject of blood-pressure and its measurement, please contact your doctor.

⚠ Attention!

1.2. Important information about fuzzy-measurement

- Do not forget: self-measurement means control, not diagnosis or treatment. Unusual values must always be discussed with your doctor.
Under no circumstances should you alter the dosages of any drugs prescribed by your doctor.
- The pulse display is not suitable for checking the frequency of heart pace-makers!
- In cases of cardiac irregularity (Arrhythmia), measurements made with this instrument should only be evaluated after consultation with the doctor.

Electromagnetic interference:

The device contains sensitive electronic components (Microcomputer). Therefore, avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens). These can lead to temporary impairment of the measuring accuracy.

2. IMPORTANT INFORMATION ON THE SUBJECT OF BLOOD-PRESSURE AND ITS MEASUREMENT

2.1. How does high/low blood-pressure arise?

The level of blood-pressure is determined in a part of the brain, the so-called circulatory centre, and adapted to the respective situation by way of feedback via the nervous system.

To adjust the blood-pressure, the strength and frequency of the heart (Pulse), as well as the width of circulatory blood vessels is altered. The latter is effected by way of fine muscles in the blood-vessel walls.

The level of arterial blood-pressure changes periodically during the heart activity: during the 'blood ejection' (Systole) the value is maximal (systolic blood-pressure value), at the end of the heart's 'rest period' (Diastole) it is minimal (diastolic blood-pressure value).

The blood-pressure values must lie within certain normal ranges in order to prevent particular diseases.

2.2 Which values are normal?

Blood pressure is too high if at rest, the diastolic pressure is above 90mmHg and/or the systolic blood-pressure is over 160mmHg. In this case, please consult your doctor immediately. Long-term values at this level endanger your health due to the associated advancing damage to the blood vessels in your body.

Should the systolic blood-pressure values lie between 140mmHg and 160mmHg and/or the diastolic blood-pressure values lie between 90mmHg and 100mmHg, likewise, please consult your doctor. Furthermore, regular self-checks will be necessary.

With blood-pressure values that are too low, i.e. systolic values under 105mmHg and/or diastolic values under 60mmHg, likewise, please consult your doctor.

Even with normal blood-pressure values, a regular self-check with your blood-pressure monitor is recommended. In this way you can detect possible changes in your values early and react appropriately.

If you are undergoing medical treatment to control your blood pressure, please

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keep a record of the level of your blood pressure by carrying out regular self-measurements at specific times of the day. Show these values to your doctor. **Never use the results of your measurements to alter independently the drug doses prescribed by your doctor.**

Table for classifying blood-pressure values (units mmHg):

Range	Systolic Blood-pressure	Diastolic Blood-pressure	Measures
Hypotension	lower than 100	lower than 60	Check with your doctor
Normal range	between 100 and 140	between 60 and 90	Self-check
Mild hypertension	between 140 and 160	between 90 and 100	Consult your doctor
Moderately serious hypertension	between 160 and 180	between 100 and 110	Consult your doctor
Serious hypertension	higher than 140	higher than 110	Urgent! See your doctor
Specific systolic hypertension	higher than 140	lower than 90	Consult your doctor

Further information

- If your values are mostly standard under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you are suffering from so-called "labile hypertension". Please consult your doctor if you suspect that this might be the case.
- Correctly measured diastolic blood-pressure values above 120mmHg require immediate medical treatment.

2.3. What can be done, if regular increased/low values are obtained?

- Please consult your doctor.
- Increased blood-pressure values (various forms of hypertension) are associated long- and medium term with considerable risks to health. This concerns the arterial blood vessels of your body, which are endangered due to

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constriction caused by deposits in the vessel walls (Arteriosclerosis). A deficient supply of blood to important organs (heart, brain, muscles) can be the result. Furthermore, with long-term continuously increased blood-pressure values, the heart will become structurally damaged.

- There are many different causes of the appearance of high blood pressure. We differentiate between the common primary (essential) hypertension, and secondary hypertension. The latter group can be ascribed to specific organic malfunctions. Please consult your doctor for information about the possible origins of your own increased blood pressure values.
- There are measures which you can take, not only for reducing a medically established high blood pressure, but also for prevention. These measures are part of your general way of life:

A) Eating habits

- Strive for a normal weight corresponding to your age. Reduce overweight!
- Avoid excessive consumption of common salt.
- Avoid fatty foods.

B) Previous illnesses

- Follow consistently any medical instructions for treating previous illness such as:
 - Diabetes (Diabetes mellitus)
 - Fat metabolism disorder
 - Gout

C) Habits

- Give up smoking completely.
- Drink only moderate amounts of alcohol.
- Restrict your caffeine consumption (Coffee).

D) Physical constitution:

- After a preliminary medical examination, do regular sport.
- Choose sports which require stamina and avoid those which require strength.
- Avoid reaching the limit of your performance.
- With previous illnesses and/or an age of over 40 years, please consult your doctor before beginning your sporting activities. He will advise you regar-

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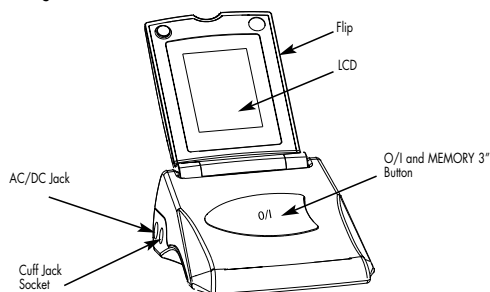
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ding the type and extent of types of sport that are possible for you.

3. THE VARIOUS COMPONENTS OF THE BLOOD-PRESSURE MONITOR

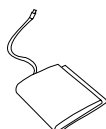
The illustration shows the blood-pressure monitor MEDEL FUZZY, consisting of:

a) Measuring unit



b) Cuff:

Standard: for arm circumference 22-32 cm
X-Large: for arm circumference 32-42 cm
 (available as optional accessory)



4. PUTTING THE BLOOD-PRESSURE MONITOR INTO OPERATION

4.1. Inserting the batteries

After you have unpacked your device, first insert the batteries. The battery compartment is located on the underside of the device (see illustration).

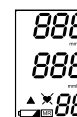
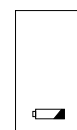
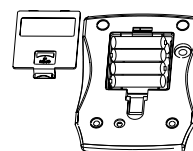
- Remove cover as illustrated.
- Insert the batteries (4 x size AA 1,5V), thereby observing the indicated polarity.
- Open the flip and press O/I button to turn on the device.
- If the battery warning appears in the display, the batteries are empty and must be replaced by new ones.

Functional check: press O/I button to test all the display elements. When functioning correctly, all segments must appear.

⚠ Attention!

- After the battery warning appears, the device is blocked until the batteries have been replaced.
- Please use 'AA' Long-Life or Alkaline 1.5V Batteries. The use of 1.2V Accumulators is not recommended.

If the blood-pressure monitor is left unused for long periods, please remove the batteries from the device.



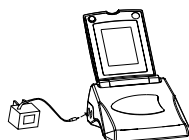
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4.2. Using a mains adapter (optional accessory)

It is possible to operate this blood-pressure device through a mains adapter (output 6 V DC / 600 mA with DIN plug). Use only original MEDEL mains adapter.

- Plug the DIN plug into the socket at the back of the device.
- Plug the mains adapter into a 230 V power socket.
- Test that power is available by opening the flip.

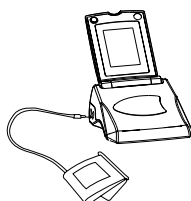


⚠ Attention!

- No power is taken from the batteries while the mains adapter is connected to the instrument.
- If the mains voltage is interrupted during the measurement (e.g. by removal of the mains adapter from the mains socket), the device must be reset by removing the DIN plug from its socket.
- Please consult a specialist dealer if you have questions relating to the mains adapter.

4.3. Tube connection

Insert the cuff tube into the opening provided on the left side of the device, as shown in the picture.



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5. CARRYING OUT A MEASUREMENT

5.1. Before the measurement:

- Avoid eating, smoking as well as all forms of exertion directly before the measurement. All these factors influence the measurement result. Try and find time to relax by sitting in an armchair in a quite atmosphere for about ten minutes before the measurement.
- Remove any garment that fits closely to your upper arm.
- Measure always on the same arm (normally left).
- Attempt to carry out the measurements regularly at the same time of day, since the blood-pressure changes during the course of the day.

5.2. Common sources of error:

Note: Comparable blood-pressure measurements always require the same conditions!

These are normally quiet conditions.

- All efforts by the patient to support the arm can increase the blood-pressure. Make sure you are in a comfortable, relaxed position and do not activate any of the muscles in the measurement arm during the measurement. Use a cushion for support if necessary.
- If the arm artery lies considerably lower (higher) than the heart, an erroneously higher (lower) blood-pressure will be measured (Each 15cm difference in height results in a measurement error of 10mmHg!).
- Cuffs that are too narrow or too short result in false measurement values. Selecting the correct cuff is of extraordinary importance. The cuff size is dependent upon the circumference of the arm (measured in the centre). The permissible range is printed on the cuff. If this is not suitable for your use, please contact your dealer.

Attention: Only use clinically approved MEDEL original cuffs!

- A loose cuff or a sideways protruding air-pocket causes false measurement values.

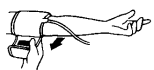
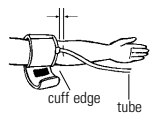
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- With repeated measurements, blood accumulates in the respective arm, which can lead to false results. Correctly executed blood-pressure measurements should therefore first be repeated after a 5 minute pause or after the arm has been held up in order to allow the accumulated blood to flow away (after at least 3 minutes).

5.3. Fitting the cuff

- Pass the end of the cuff (with sewn-in rubber stopper) through the metal stirrup so that a loop is formed. The Velcro closer must be facing outwards. (Ignore this step if the cuff has already been prepared.)
- Push the cuff over the left upper arm so that the tube points in the direction of the lower arm.
- Position the cuff on the arm as illustrated. Make certain that the lower edge of the cuff lies approximately 2 to 3 cm above the elbow and that the rubber tube leaves the cuff on the inner side of the arm. Important!! The mark (ca. 3 cm long bar) must lie exactly over the artery which runs down the inner side of the arm.
- Tighten the free end of the cuff and close the cuff with the closer.
- There must be no free space between the arm and the cuff as this would influence the result. Clothing must not restrict the arm. Any piece of clothing which does (e.g. a pullover) must be taken off.

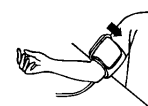
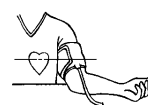


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- Secure the cuff with the Velcro closer in such a way that it lies comfortably and is not too tight. Lay the arm on the table (palm upwards) so that the cuff is at the same height as the heart. Make sure that the tube is not kinked.
- Remain seated quietly for two minutes before you begin the measurement.

Comment:

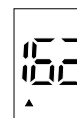
If it is not possible to fit the cuff to the left arm, it can also be placed on the right one. However all measurements should be made using the same arm.



5.4. Measuring procedure

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

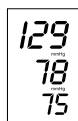
- Open the flip and press the O/I button. The device begins to inflate the cuff. The rising pressure in the cuff is shown in the display.
- After the suitable inflation pressure has been reached, the device stops and the pressure gradually falls. The cuff pressures are displayed.
- When the device detects a pulse, the heart symbol in the display starts to flash and a beep is heard for every heart beat.



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- d) A longer beep is sounded when the measurement has been completed. The systolic, diastolic blood pressures and pulse rate now appear in the display.
- e) The results of the measurement remain on the display until you switch off the device. If no button is pressed for a period of 3 minutes the device switches itself off in order to preserve the batteries.



5.5. Discontinuing a measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), the O/I button can simply be pressed at any time. You can also close the flip to turn off the device. The device then immediately reduces the cuff pressure.



5.6. Memory – displaying the last measurement

The measured results are stored in the device until a new measurement is carried out or the batteries are removed. You can call up the stored values at any time when the flip is open by pressing the O/I button for at least 3 sec.



Further information

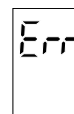
Measurements should not occur soon after each other, since otherwise, the results will be falsified. Wait therefore for several minutes in a relaxed position, sitting or lying, before you repeat a measurement.

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6. ERROR MESSAGES/MALFUNCTIONS

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If an error occurs during a measurement, the measurement is discontinued and a corresponding error code is displayed (example: error no. 1):



Error n°	Possible cause(s)
Err 1	The systolic pressure was determined but afterwards the cuff pressure fell below 20 mmHg. This situation can occur, for example, if the tube becomes unplugged after the systolic blood pressure has been measured. Further possible cause: No pulse has been detected.
Err 2	Unnatural pressure impulses impair the result of the measurement. Cause: the arm was moved during the measurement (artefact).
Err 3	Inflation of the cuff takes too long. Cause: 1) The cuff is not correctly seated or the hose connection is not sealed. 2) The cuff could be damaged, change it.
Err 5	The measured readings indicated an unacceptable difference between systolic and diastolic pressures. Take another reading following directions carefully. Contact your doctor if you continue to get unusual readings.

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Other possible malfunctions and their elimination

If problems occur when using the device, the following points should be checked and if necessary, the corresponding measures are to be taken:

Malfunction	Remedy
The display remains empty when the instrument is switched on although the batteries are in place.	1) Check whether the batteries are installed with the correct polarity and correct if necessary. 2) If the display is unusual, remove the batteries and then them, or exchange them for new.
The pressure does not rise although the pumping ball is pressed.	1) Check the connection of the cuff tube and connect properly if necessary. 2) The cuff could be damaged, change it.
The instrument frequently fails to measure the blood pressure values, or the values measured are too low (too high).	1) Fit the cuff correctly on the arm. 2) Before starting the measurement make sure that the cuff is not fitted too tightly and that there is no rolled-up sleeve exerting pressure on the arm above the measuring position. Take off articles of clothing if necessary. 3) Measure the blood pressure again in complete peace and quiet.
Every measurement produces a different value although the instrument functions normally and the values displayed are normal.	1) Please read the following information and the points listed under "Common sources of error". Repeat the measurement.
The blood pressure values measured differ from those measured by the doctor.	1) Record the daily development of the values and consult your doctor about them.

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Further information

The level of blood-pressure is subject to fluctuations even with healthy people. Important thereby is, that **comparable measurements always require the same conditions (Quiet conditions)!**

If, in spite of observing all these factors, the fluctuations are larger than 15mmHg, and/or you hear irregular pulse tones on several occasions, please consult your doctor.

For licensing, the device has been subjected to strict clinical tests, by which the computer programme used to measure the blood-pressure values was tested by experienced specialist doctors in Germany. The same computer programme is used in every individual device, and has thus also been clinically tested.

The manufacture of the devices takes place according to the terms of the European standard for blood-pressure measuring devices (see technical data) under the supervision of the Technical Monitoring Association Essen (RWTÜV-Essen).

Should the device not start working properly, address immediately to an authorized technical service centre or to MEDEL CUSTOMER SERVICE.

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7. MAINTENANCE AND REPAIRS

In case of failure, address to qualified personnel authorized by Medel.
Never open the device. There are no user-serviceable parts within. The device requires no lubrication or maintenance.

8. CARE AND MAINTENANCE, RECALIBRATION

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- a) Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight. 
- b) The cuff contains a sensitive air-tight bubble. Handle this carefully and avoid all types of straining through twisting or buckling.
- c) Handle the tube carefully. Do not pull on it. Likewise, this is not to be buckled or laid over sharp edges.
- d) Clean the device with a soft, dry cloth. Do not use petrol, thinners or similar solvent. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff must not be washed! 
- e) Do not drop the instrument or treat it roughly in any way. Avoid strong vibrations. 
- f) **Never open the device!** Otherwise the manufacturer calibration becomes invalid! 

Periodical recalibration

Sensitive measuring devices must from time to time be checked for accuracy. We therefore recommend a periodical inspection of the static pressure display every 2 years.

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9. REFERENCE TO STANDARDS

Device standard:	Device corresponds to the requirements of the European standard for non-invasive blood-pressure monitor EN1060-1 / 12:95 EN1060-3 / 09:97 DIN 58130, NIBP - clinical investigation ANSI / AAMI SP10, NIBP - requirements
Electromagnetic compatibility:	Device fulfils the stipulations of the European standard EN 60601-1-2
Clinical testing:	The clinical performance test was carried out in Germany according to the DIN 58130 / 1997 procedure N6 (sequential).
The stipulations of the EU-Guidelines 93/42/EWG for Medical Products Class IIa have been fulfilled.	



This device is validated by a protocol (Protocol for the evaluation of blood pressure measuring) created by the **British Hypertension Society**.
MEDEL FUZZY has obtained, thanks to its accuracy, the highest evaluation level:
Systolic pressure - **A Degree**
Diastolic pressure - **A Degree**

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10. TECHNICAL SPECIFICATIONS

Weight:	430 g (with batteries)
Size:	113(W) x 169(D) x 56(H) mm
Storage temperature:	-5 to +50°C
Humidity:	15 to 85% relative humidity maximum
Operation temperature:	10 to 40°C
Display:	LCD (Liquid Crystal Display)
Measuring method:	oscillometric
Pressure sensor:	capacitive
Measuring range:	SYS/DIA: 30 to 280 mmHg Pulse: 40 to 200 per minute
Memory:	Storing the last measurements automatically
Measuring resolution:	1 mmHg
Accuracy:	Pressure within ± 3 mmHg Pulse $\pm 5\%$ of the reading
Power source:	4 dry cells (batteries) UM-3, size AA, 1.5 V
Accessories:	cuff for arm circumference 22-32 cm
Optional accessories:	a) mains adapter output 6 V DC 600mA (optional) b) cuff for arm circumference 32-42 cm

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11. WARRANTY CERTIFICATE

Warranty conditions

- The device is covered by a 5 years warranty from date of purchase for any defects in the design or in the materials used.
- The warranty consists in the replacement and/or repair free of charge of originally defective components.
- The warranty does not cover the accessories supplied with the device and those parts subject to normal wear and tear.
- The device must be repaired by authorized technical service centres only.
- The device must be sent to the authorized service centre for repair within 8 days after the defect is noticed.
- Transport costs for the device are at user's charge.
- Any repair out of warranty conditions are at user's charge.
- The warranty does not cover failures resulting from misuse, abuse of the product or in case the damage is not due to manufacturer's liability (accidental fall, rough transportation, etc.).
- The warranty does not involve any compensation for any kind of damages to persons or things, either direct or indirect, occurred when the device is not operating.
- The warranty is valid from the date of purchase certified by the ticket or the invoice which have to be peremptorily attached to the warranty coupon.
- The lack of warranty coupon properly filled in and validated by a certification of purchase voids the warranty.

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COUPON TO BE RETURNED IN CASE OF REPAIRS

THE WARRANTY IS VALID ONLY IF ACCOMPANIED BY THE TICKET/INVOICE

Product type: _____

Model: _____

Serial No.: _____

Date of purchase: _____

BUYER DATA:

Name: _____

Address: _____

Phone number: _____

Defect description: _____

Signature for acceptance of the above mentioned warranty conditions

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