

LD12

Little Doctor®

Wrist Digital Blood Pressure Monitor

Instruction Manual

ENG

**Ciśnieniomierz elektroniczny
automatyczny LD
do pomiaru ciśnienia tętniczego krwi i pulsu**

POL

Instrukcja Obsługi



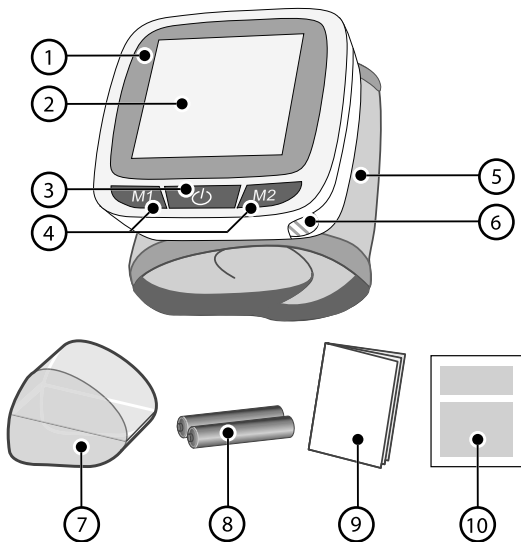
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PARTS AND COMPONENTS

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1. Electronic Unit.
2. LCD.
3. ⏻ (Power ON/OFF)
4. «M1» и «M2» (memory).
5. Arm cuff CUFF-LDA.
6. Cover of the battery compartment.
7. Case.
8. Power elements.
9. Instruction Manual.
10. Warranty card.

GENERAL INFORMATION


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This Instruction Manual is designed to assist the user with safe and effective operation of the automatic digital Device for measurement of blood pressure and heartbeat rate LD, (modification LD12) (hereinafter – the “Device”). Use this Device according to the rules described in this Manual. Operate the Device only as intended. Do not use the Device for any other purposes. Read and understand the whole Instruction Manual, in particular “Recommendations on Correct Measurement”.

INDICATIONS FOR USE

Use this Device to measure your systolic and diastolic blood pressure and heartbeat rate in patients aged from 15. This Device is recommended for use by persons with unstable blood pressure or known arterial hypertension at home as an addition to medical surveillance. The cuff is designed for the wrist with the circumference approximately from 12,5 to 20,5 cm.

OPERATION PRINCIPLE

This Device uses the oscillometric method of blood pressure with Fuzzy Algorithm and pulse rate measurement. Wrap the cuff with an electronic unit around your wrist. Press the  button on the live monitor to automatically start inflating the cuff and then while gradually deflating the cuff take its measurements. The sensitive element of the Device feels the weak pressure oscillations in the cuff generated by widening and contraction of the brachial artery in response to every heartbeat. Pumping in is ceased when cuff is adequately pumped in to determine diastolic and systolic pressure (the amplitude of the pressure waves is measured, converted into millimeters Hg and shown on the display as figures) after which air is released from cuff. The Device has Arrhythmia Indicator and 2 memories, by 90 cells, for storage of measurement results with Average value of the last three measurements function. Remember that the Device will not maintain the mentioned accuracy of a measurement if it is used or stored at a temperature or humidity other than those specified in Technical Specifications of this Manual. We are warning about possibility of mistakes in blood pressure measurement with this Device in persons with pronounced cardiac arrhythmia. Consult the doctor concerning blood pressure measurement of your child.

APPLIED NEW LD TECHNOLOGIES



Fuzzy Algorithm – algorithm for processing the measurement values with regard to peculiarities of the man's heartbeat, thus, ensuring high measurement accuracy.



Scale WHO – classification of measurement results according to recommendation of World Health Organization (WHO).



Indication of arrhythmia – special symbol « ♥ » on Device display informs about availability of irregular pulse; in this case.

RECOMMENDATIONS ON CORRECT MEASUREMENTS

1. For correct measurement you should know that THE BLOOD PRESSURE IS SUBJECT TO SHARP VARIATIONS EVEN WITHIN THE SHORT TIME INTERVALS. The blood pressure depends on many factors. It is usually lower in summer and higher in winter. The blood pressure varies together with the atmospheric pressure, depends on physical loads, emotional excitement, stresses and dietary regime. Drugs, drinking alcohol and smoking produce significant effect. Even the very procedure of blood pressure measurement in a polyclinic sends the blood pressure high in many people, thus, the blood pressure measured at home often differs from the values received in a polyclinic. As the blood pressure tends to rise at low temperatures, make measurements at an indoor temperature (approximately 20° C). If this Device stayed under a low temperature, keep it for at least 1 hour at an indoor temperature before use, otherwise the measurement result may be incorrect. During a day the difference in readings for healthy people may be 30-50 mmHg of systolic pressure and to 10 mmHg of diastolic pressure. The dependence of the blood pressure on various factors is individual for each person. Accordingly, it is recommended to keep a special book with blood pressure records. ONLY A CERTIFIED DOCTOR USING YOUR RECORDS IS CAPABLE TO ANALYZE THE TENDENCY OF YOUR BLOOD PRESSURE VARIATIONS.

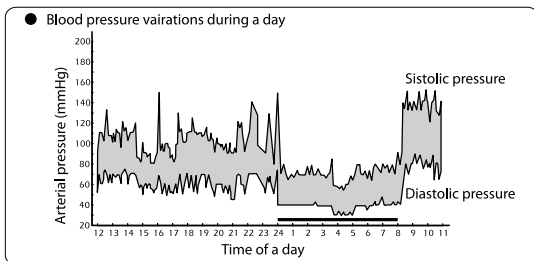


FIG.1

2. At cardiovascular and some other diseases requiring blood pressure monitoring make measurements in the hours fixed by your attending doctor. REMEMBER THAT THE DIAGNOSTIC AND ANY TREATMENT OF HYPERTENSION MAY BE CONDUCTED ONLY BY A CERTIFIED DOCTOR ON THE BASIS OF BLOOD PRESSURE VALUES OBTAINED BY THIS DOCTOR. TAKING OF DRUGS AND THEIR DOSES SHOULD BE PRESCRIBED ONLY BY YOUR ATTENDING DOCTOR.

3. At such disorders as deep vascular sclerosis, weak pulse wave and also in patients with the prominent distortions of cardiac rhythm it may be difficult to measure the blood pressure accurately.

IN SUCH CASES CONSULT A CERTIFIED DOCTOR ABOUT APPLICATION OF THE ELECTRONIC DEVICE.

4. KEEP QUIET DURING A MEASUREMENT TO OBTAIN THE ACCURATE VALUES OF YOUR BLOOD PRESSURE WITH THE ELECTRONIC DEVICE. MEASURE YOUR BLOOD PRESSURE IN THE CALM AND

COMFORTABLE CONDITIONS AT THE INDOOR TEMPERATURE. NO EATING AN HOUR BEFORE MEASUREMENT; NO SMOKING, TAKING TONIC AGENTS, ALCOHOL 1.5-2 HOURS BEFORE MEASUREMENT.

5. The accuracy of blood pressure measurement depends on whether the cuff matches the size of your arm. THE CUFF SHOULD NOT BE TOO SMALL OR TOO LARGE.

6. Wait 3 minutes between measurements for the blood to restore its circulation. However, the persons with prominent atherosclerosis due to considerable loss of vascular elasticity may need to increase the wait time between measurements (10-15 minutes). This also refers to the patients suffering for long from diabetes.

For more accurate determination of blood pressure it is recommended to make a series of 3 consecutive measurements and to use the average value.

7. The rate of wrist blood pressure may be different from that of the arm. If to regard a healthy person, this variation may be specified within the range of ± 10 mm Hg for both the systolic and diastolic pressure. The persons to have such health problems, as hypertension, diabetes, liver function abnormality, peripheral blood flow etc. must be very careful. In this case, wrist and arm measurements may substantially vary.

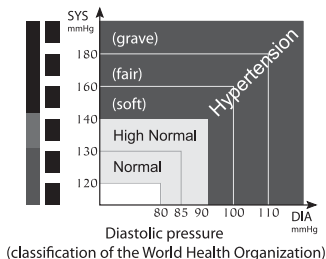


FIG.2

BATTERY INSTALLATION

- 1) Open the cover of the battery compartment and install 2 AAA size batteries according to polarity marked inside the compartment. Do not use much force to remove the cover of the battery compartment.
- 2) Close the cover of the battery compartment.

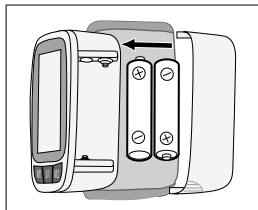





FIG.3

Replace all batteries when the Low Battery Indicator “” appears on the screen or when there is no any indication on the screen. The Low Battery Indicator does not show the discharge level.


SETTING OF DATE AND TIME

To shift to mode of date and time setting, it is necessary, holding button M1, depress button . Selected parameter will blink. Change of selected parameter toward increasing is taking place when depressing button M2, towards decreasing – when depressing button M1.

To shift to setting of the next parameter, year/month/hours/min, it is necessary to depress .

If no actions are done in mode of date and time setting for more than 1 minute, the Device is independently changed over to mode of date and time indication.

If battery cells are replaced, date and time values will be reset. It is permitted to measure pressure and take pulse readings without setting date and time values.

To switch off mode of date and time setting, it is necessary to press and hold  for over 5 seconds or to do no actions more than 3 minutes.

CORRECT POSITION DURING MEASUREMENT

Correct position during measurement

1. Sit on the chair.
2. Raise a hand so that your palm is up and place your elbow on a table.
3. Put a case or folded towel under your forearm and make sure that the cuff is at the same level as your heart.

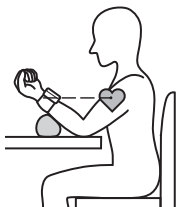


FIG.4

When no table is available

1. Sit on the chair.
2. Bring the cuff to the level of your heart slightly pressing your left hand to a breast.
3. While measuring slightly rest your left hand on the right one.



FIG.5

Measurement the blood pressure lying on the back

1. Lie on your back.
2. Put a case or folded towel under your forearm and make sure that the cuff is at the same level as your heart.



FIG.6

- Make 5-6 deep inhales and exhales before taking a measurement and relax.
- Measured results may slightly vary depending on your posture under measurement. While measuring do not cross your legs.
- Take measurements on the same wrist and at the same posture.
- If the cuff brought up to the level below/above your heart, measurement results will be overrated/underrated respectively.

CUFF PREPARATION

- 1 While holding your left hand palm up, move the cuff to your wrist so that the monitor display faces your palm. Should you fail to put the cuff on your left-hand wrist, wrap it around the right one and, thereafter, the measurement results may slightly vary.
- 2 Place the cuff on your hand so that its edge is 5-10 mm off your palm end. Align the monitor on your wrist.
- 3 Fasten the cuff on your wrist so that no free space is left between the cuff and wrist. The cuff must comfortably fit. While wrapping the cuff around your wrist make sure that no cloth occurs under the cuff.

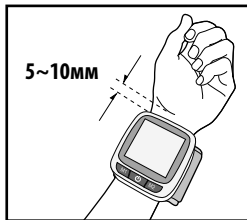





FIG.7

MEASUREMENT PROCEDURE

1. Make 5-6 deep inhales and exhales before taking a measurement and relax. Do not move, do not speak and do not toughen your arm. Switch on the Device by press  – date and time will display on the screen.
2. Press .
3. All symbols will appear on the display screen for a short time (fig. 7) and the Unit will inflate automatically the air into the cuff. At first the inflation will stop at the level of 190 mmHg. (fig. 8).
4. After reaching the level of 190 mmHg the cuff will gradually deflate. The figures on the screen will count back. The pulse symbol «» will start flickering. AS THE BLOOD PRESSURE AND PULSE ARE MEASURED DURING AIR DEFLATION FROM THE ARM CUFF KEEP QUIET AND DO NOT MOVE YOUR ARM AND DO NOT TOUGHEN YOUR ARM MUSCLES.
5. When the measurement is complete the arm cuff completely deflates and your measurement results flash on the screen and Indicator «M1/M2» will blink, reminding that to retain results, it is necessary to choose memory 1 or 2, having depressed M1 or M2, respectively. If memory is not chosen for more than 3 minutes the Device is independently changed over to mode of date and time indication.

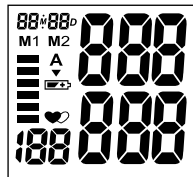


FIG.8



FIG.9

If irregular pulse rhythm is detected during measurement, symbol of arrhythmia "♥", will appear upon measurement end. Appearance of arrhythmia indicator may also be caused by body movement during measurement. During periodical appearance of this indication apply to You attending doctor.

Apart from numerical value of pressure, result is also displayed on scale WHO (fig. 10). Scale WHO – three-color scale of classification of received value of arterial pressure, according to recommendation of World Health Organization. Using the scale on the left display field, estimate your findings against the following classification: blood pressure is normal; blood pressure is exceeded or specific degree of arterial hypertension is detected.

6. Press \odot to change to mode of date and time indication. For taking a new measurement repeat all steps described in this paragraph.

TO OBTAIN THE ACCURATE RESULT MAKE INTERVAL BETWEEN MEASUREMENTS TO RESTORE THE BLOOD CIRCULATION. WAIT FOR AT LEAST 3 MINUTES BEFORE MAKING A NEW MEASUREMENT. Result of each measurement (pressure, pulse) will kept in the device memory automatically.

THE DATA WILL BE KEPT IN THE MEMORY EVEN IF THE DEVICE IS STORED WITHOUT BATTERIES. TO DELETE ALL VALUES STORED IN THE MEMORY YOU SHOULD MAKE ACTIONS DESCRIBED IN "MEMORY FUNCTION".

If no actions are done in mode of date and time setting for more than 3 minute, the Device is independently changed over to mode of date and time indication.

AUTOMATIC RE-INFLATION

When during the first blood pressure measurement the cuff inflation to a level of 190 mmHg is not sufficient or you move your arm the Unit stops measurement and re-inflates the cuff to the higher level. The Unit has 4 fixed levels of the arm cuff inflation: 190, 230, 270 and 300 mmHg.

The automatic re-inflation is repeated until the measurement is completed successfully. This is not a defect.

FORCED DEFLATION FROM A CUFF

For rapid air release from of the arm cuff during arm cuff inflation or during a measurement (slow deflation) press the \odot . Button. The device will quickly release all air from cuff and will switch off.

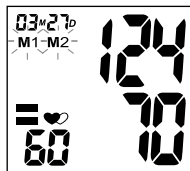


FIG.9

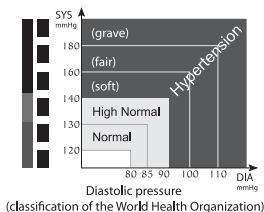


FIG.10

MEMORY FUNCTION

1. Result of each measurement (pressure, pulse, time and date of measurement) may be kept in the device memory. For this purpose, after measurement, within not more than 3 minutes, memory M1 or M2 shall be selected for memory storage. IF THE NOTICE ON ERROR APPEARS THE MEASUREMENT RESULT WILL NOT BE STORED.

2. Up to 90 measurement results and mean value of last 3 measurements may be kept in each device memory. When the number of measurements exceeds 90, the oldest record is deleted to save the most recent values.

3. Press the M1 (or M2) Button to see the figures stored in the memory. At the first depression of button M1 (or M2), will appear on the screen, marked by symbol «A» (fig. 11). At repeated depression of button M1 (or M2) indicator of selected memory M1 (or M2) and number of memory cell will appear on the screen, and in 1 second its content is displayed (fig. 12). When content of memory cell is displayed, date and time of measurement are displayed alternately in the display lower line. Each depression of button M1 (or M2) causes shifting to the next memory cell.

If no measurement results are stored in the memory and M1 (or M2) buttons are pressed for the first time, current date and time will be displayed.

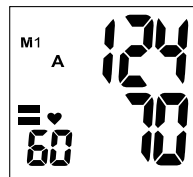


FIG.11

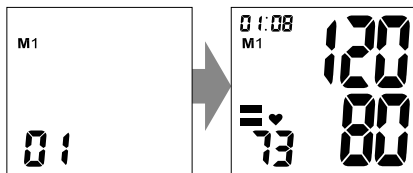


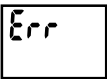
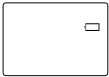
FIG.12

MEMORY CLEARING

To delete all values stored in the memory, press the M1 (or M2) Button and hold it down for more than 3 seconds. Symbols "Clr" will appear on the screen and all values will be deleted from the memory.

INFORMATION ABOUT ERRORS

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<i>Indication</i>	<i>Likely cause</i>	<i>Methods of correction</i>
	<p>The arm cuff is applied incorrectly or the air tube plus is inserted not tightly enough.</p> <p>Measurements cannot be made due to hand movement or talking during measurements.</p> <p>At such disorders as deep vascular sclerosis, weak pulse wave and also in patients with the prominent distortions of cardiac rhythm it may be difficult to measure the blood pressure accurately.</p>	<p>Be sure that the arm cuff is applied correctly and the plug is inserted tightly. Repeat the whole measurement procedure.</p> <p>Repeat the measurement following strictly the recommendations of this Manual.</p> <p>In such cases consult a certified doctor about application of the electronic Unit.</p>
	<p>Batteries are discharged.</p>	<p>Replace the batteries for new ones.</p>

CARE, STORAGE, REPAIR AND DISPOSAL

1. Keep this Device from exposure to higher humidity, direct sunlight, shocks, vibration. THIS DEVICE IS NOT WATERTIGHT!!
2. Do not keep and use this Device near heating installations and open fire.
3. Remove the batteries if the Unit will be unused for a long time. Battery leaking may damage the Unit. KEEP BATTERIES OUT OF REACH OF CHILDREN!
4. Keep the Unit clean and protect it from dust. Use the dry soft cloth to clean the Unit.
5. Keep the Unit and its components away from water, solvents, spirit and petrol.
6. Protect the arm cuff from contacting on sharp things; do not stretch or fold tightly the arm cuff.
7. Do not subject the Unit to strong shocks, such as dropping on the floor.
8. This Unit does not contain special controls to adjust the measurement accuracy. It is prohibited to open individually the electronic block. Repair the Unit only in authorized organizations.
9. On expiration of the warranted service life apply from time to time to authorized repair organizations to check the technical condition of the Unit.

10. Dispose of the Unit and its components according to the application local regulations. No special requirements to disposal of this Unit are defined by the manufacturer.
11. The arm cuff may withstand multiple sanitary treatments. The internal tissue surface of the arm cuff (contacting on arm) may be cleaned with cotton ball soaked in 3%-solution of hydrogen peroxide. At long use the partial color fading of the tissue coating of the arm cuff is possible. Washing and ironing of the arm cuff are not allowed.

TROUBLESHOOTING TIPS

PROBLEM	LIKELY CAUSE	METHOD OF CORRECTION
After pressing the  no indication on the display.	Discharge of batteries. Polarity of batteries is not observed. Battery terminals are contaminated.	Replace all batteries for new ones. Install batteries correctly. Clean the terminals with dry cloth.
Inflation is stopped and resumed.	Automatic re-inflation to obtain correct measurements. Perhaps you talk or move your arm during the measurement?	See MEASUREMENT PROCEDURE. Calm down and repeat the measurement.
Every time the blood pressure is different. Measurements are too low/high.	Check that the arm cuff is level with your heart? Check that the arm cuff is applied correctly? Perhaps your arm muscles are tough? Perhaps you talk or move your arm during the measurement?	Take the correct position for measurement. Take the correct position for measurement. Apply the arm cuff correctly. Keep silence and quiet during measurement.
Measurements of the pulse rate are too low/high.	Perhaps your arm muscles are tough? Perhaps you talk or move your arm during the measurement?	Keep silence and quiet during measurement. Repeat the measurement at least in 5 min.
Impossibility to make a large of number of measurements.	Application of poor batteries.	Use only alkali batteries of well-known manufacturers.

Spontaneous failure of power supply.	Actuation of automatic de-energizing system	This is not a defect. The Unit is disconnected automatically in 3 minutes after the last operation of the Unit.
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If regardless of the above recommendation you are unable to get correct measurement results, stop the use of this Device and apply to a maintenance organization (addresses and telephones of authorized organizations may be found in the warranty card). Do not try to adjust the internal mechanism by yourself.

WARRANTY

1. The following LD product is covered by warranty for the period specified in the warranty card.
2. The warranty liabilities are contained in the warranty card given at the sale of this unit to a purchaser.
3. The addresses of organizations for warranty maintenance are given in the warranty card.

TECHNICAL SPECIFICATIONS

Measurement method	oscillometric with Fuzzy Algorithm
Display	LCD
Pressure indication range in an arm cuff, mmHg	from 0 to 300
Measurement range: pressure in an arm cuff, mmHg pulse rate, 1/min	from 40 to 260 from 40 to 160
Range of admissible absolute error at measurement of air pressure in an arm cuff, mmHg	± 3
Range of admissible absolute error at measurement of pulse rate measurement, %	± 5
Date and time	yes
Memory	2x90 recent measurements + average value of the last three measurements
Power source, V	3
Type of power supply	2 AAA size batteries
Max power intake, W	1,5

Operation conditions: temperature, °C relative humidity, % Rh	from 10 to 40 85 and lower
Storage and transportation conditions temperature, °C relative humidity, % Rh	from -20 to 50 85 and lower
Cuff: Type Size	CUFF-LD12 a preformed type cuff adult (circumference 12,5 –20,5 cm)
Dimensions: Size (electronic block), mm Weight (without package, case, batteries and adapter), g	66 x 70 x 32 118
Completeness	electronic Unit, cuff (connect to electronic Unit), 2 power elements, case, instruction manual, warranty card, package
Year of manufacture	year the manufacture is given in the bottom of the Device body in a serial number after symbols "AA"

Symbols:

 ⁰¹²³ Compliance with the Directive 93/42/EEC



Important: Please read the Manual



European Authorized Representative



Manufacturer



Keep dry



Type II



Type BF



Sign of conformity to the Technical regulations of Ukraine

Revision date of the present Manual is indicated on the last page as EXXX/YYMM/NN, where YY is the year, MM is the month and NN is the number of revision. Specifications may change without prior notice in order to improve the performance and quality of the product.

CERTIFICATION AND STATE REGISTRATION

This Device manufacturing is certified according to international standard ISO 13485.

Devices LD12 comply with the requirements of European Directive MDD 93/42/EEC, international standards EN980, EN1041, EN1060-1, EN1060-3, EN10601-1-2, ISO 14971.

✉ Complaints and requests should be addressed to:

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