INSTRUCTION MANUAL

DIAGNOSTIC®

EN

DM-400 IHB

AUTOMATIC UPPER-ARM BLOOD PRESSURE AND PULSE MONITOR

CE 0197

REF 5126

Thank you for buying the blood pressure and pulse monitor DM-400 IHB. The model can be used with irregular pulse. If the device detects irregular pulse, the symbol the display. In such a case, it is advisable to consult your physician.

Please carefully read this user manual before the first use of the device. Please keep the user manual. The information contained herein may be needed in the future.

CONTENTS

1. SAFETY INFORMATION

⚠ 1.1 WARNINGS

- Self-diagnosis and treatment on the basis of obtained results may pose risk to the health. You should follow the advice of a doctor.
- If the machine does not stop inflating the cuff, remove it or disconnect the unit from the power supply, otherwise it may result in injury.
- Measurements should be taken only with the cuff and power adapter supplied by the manufacturer. Otherwise, measurement results may be incorrect.
- Do not use the pressure monitor near strong electrical or electromagnetic fields. During the measurement, do not use your cellular phone.
- Do not use the device simultaneously with hyperbaric oxygen therapy unit or in its surroundings.
- Do not use the device in the following locations:
  - Dplaces exposed to vibration, such as ambulances and rescue helicopters
  - places where gas or flames are present
  - places where large volumes of water or steam are present
  - places where chemicals are stored
  - places where the device may accidentally fall on the ground
- When taking the measurement, the surrounding conditions must be taken into account, otherwise the results may be inaccurate.
- When using the power adapter or replacing batteries, the person taking the measurement should not touch those elements and the patient simultaneously.
- The battery has positive and negative terminals. If it is impossible to easily insert the battery in the device, do not push it forcibly.
- Do not use the Luer-type lock. If Luer-type lock connectors are used in the construction of the tubes, there is a risk of accidentally connecting to an intravascular flow system, allowing the pumping of air into the blood vessels.
- This product is intended for self-monitoring of blood pressure at home and for measurements performed by a doctor in hospital environment.

- Blood pressure measurements taken using the DM-400 IHB pressure monitor are equivalent to measurements taken by trained personnel using ausculatory method (in accordance with the American National Standard for manual, electronic and automatic sphygmomanometers)..
- The device should be kept out of reach of infants, small children and dependent people. Child's playing with the air tube can lead to suffocation of the child. Children may also swallow small parts of the device.
- Make sure that children do not play with the device.
- Use only parts and accessories supplied by the manufacturer. Parts and accessories which are not approved for use with this device may result in its damage.
- Do not rest your arm on the air tube, because it may restrict the flow of air to the cuff.
- Do not take measurements too often, because bruising may occur in the place where the cuff is wrapped.
- Do not put the cuff over a wound or an area affected by inflammation.
- Wrapping and inflating the cuff may cause temporary disturbance of blood flow, but this does not lead to patient injury.
- The use of the the device does not result in long-term deterioration of blood flow in the patient.
- The device should be placed in such a manner as to enable immediate disconnection of the power plug.
- Do not attempt to disassemble, repair or modify the pressure monitor or the.
- The patient may only replace batteries.

1.2 CONTRAINDICATIONS

- Persons suffering from arrhythmia, diabetes, after a stroke and with blood pressure problems should use the device physician's supervision.
- No clinical trials have been conducted on neonates and pregnant women. Do not use the measuring device on neonates and pregnant women.
- Do not use the pressure monitor for purposes other than measurement of blood pressure in humans.
- Premature atrial contractions, premature ventricular contractions and atrial fibrillation may cause inaccurate or erroneous measurement results.

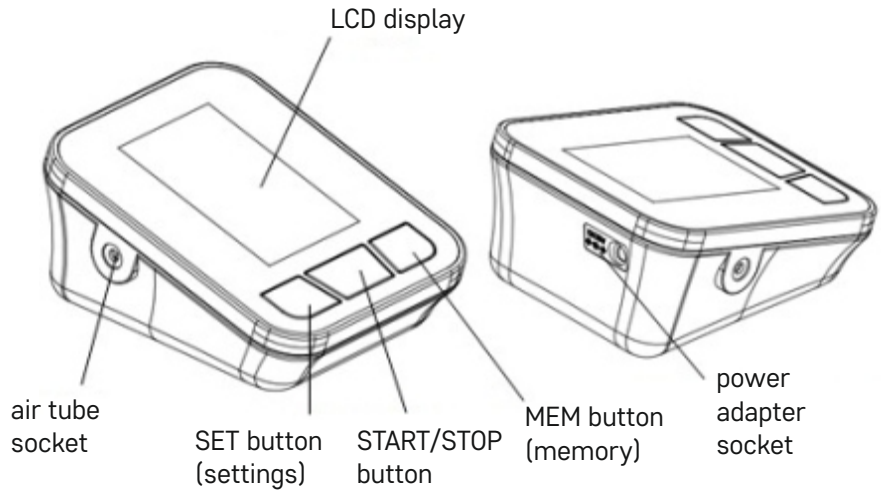
1.3 OPERATION AND MAINTENANCE

- Protect the device from high temperatures, humidity, dust and direct sunlight.
- The cover should be cleaned using a soft cloth, moistened with 75% solution of disinfecting alcohol.
- Do not soak or clean the cuff with water.
- After the measurement clean the cuff with a soft and dry cloth..
- Do not use the device at very high temperatures, high humidity and high altitude. Use the device only in acceptable ambient conditions
- Do not place heavy objects or the pressure monitor on the power cord.
- Do not connect and disconnect the power adapter with wet hands.
- Be careful not to drop the unit and not to expose it to strong shock.
- Do not use the device near large equipment that uses a switching relay for turning on and off.
- If the device is not going to be used for an extended period of time, remove the batteries.
- The blood pressure monitor has been subjected to inspections to ensure measurement accuracy. The user should perform annual calibration recommended by the manufacturer.
- In the case where servicing is necessary, contact the manufacturing.

2. DEVICE APPLICATIONS

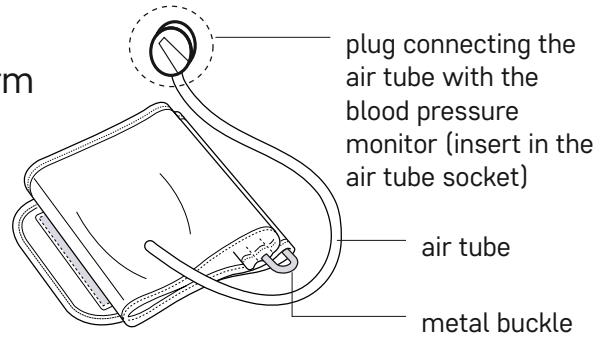
The DM-400 IHB blood pressure monitor is designed for self-measurement of blood pressure and pulse rate in adults at home and by healthcare professionals in a hospital environment.

PRESSURE MONITOR DESIGN

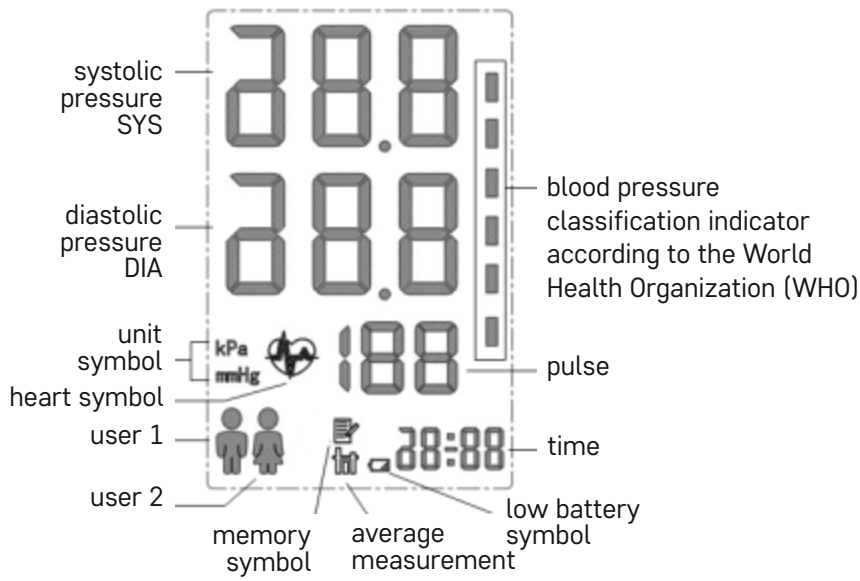


CUFF

(Applied part type BF) Arm circumference range: 22-36 cm

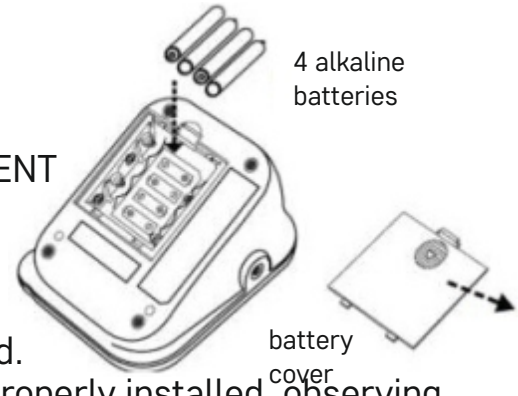


LCD DISPLAY



3. BEFORE TAKING READINGS

3.1 BATTERIES



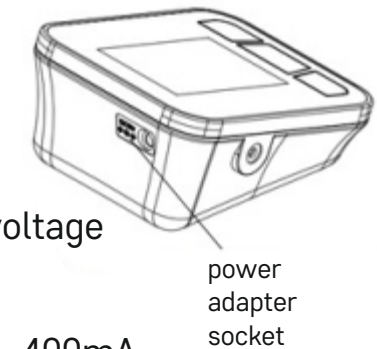
3.1.1 INSTALLATION AND REPLACEMENT

1. Remove the battery cover.
2. Insert 4 standard AA alkaline batteries as indicated in the picture.
   - Use batteries of the same brand.
   - Note that all the batteries are properly installed, observing polarity.
3. Reinstall the battery cover.
4. Batteries must be replaced when the icon indicating low batteries appears ▭, otherwise the device may fail to operate properly.
   - Do not mix old and new batteries.
   - If the device is not going to be used for an extended period of time, remove the batteries.
   - After replacing batteries, you must reset the time and date..

3.1.2 BATTERY LIFE

- Four new LR6 (AA) batteries last for approximately 200 measurements (1 per day, at room temperature 23°C), battery life varies depending on the temperature in which they are used, and may be shorter at lower temperatures.
- You can check the battery status in the lower right corner of the screen. If the low battery symbol ▭ is displayed, they should be replaced with new ones.

3.2 POWER ADAPTER (OPTIONAL)



1. Connect the plug of the power cord into the power supply connector
2. Plug the power adapter unit into electrical outlet.
   - Use power adapter suitable for local mains voltage (mains current 100~240 V)
   - Specification of power adapter: input: mains current 100~240 V, 50/60Hz; output: 6V, min. 400mA
   - We recommend using only the power adapter supplied by the manufacturer, model Diagnostic ZID 6-1 (100~240 V, 50/60Hz, 6 V, 1000 mA (1 A))
   - If the device is defective, unplug the power supply or the power cord.

- Do not touch the power adapter with a wet hand.
- Do not tangle the wires during usage.
- The power adapter is added to the set optionally (charged additionally)

power supply connector

3.3 SETTINGS

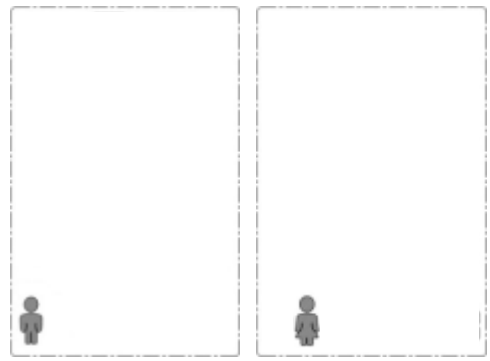
3.3 Settings

WITH THE DEVICE POWERED OFF:

1. Press the SET button, the appliance enters the date setting mode.
   a) Changing values
      - press the MEM button to go one digit up
      - jif you press and hold the MEM button, the value will change quickly
   b) Set the two digits indicating year.
   c) Press the SET button and continue to set the values for month.
   d) Repeat steps a) to (c) to set the month, day, hour and minutes.
2. Changing units (mmHg to kPa)
   a) Press the SET button until the unit (mmHg or kPa) starts flashing. By pressing the MEM button you will be able to change the unit
   b) Complete the settings, press the START/STOP button to finish.

3.4 USER/GROUP SELECTION

With the device powered on, hold the START/STOP button to go into settings. The memory group icon starts blinking. Press START/STOP to select the memory group. In the device settings mode, you can store measurement results in 2 different groups. This allows 2 users to record individual measurement results (up to 60 per group). Measurement results are automatically stored in each selected group.



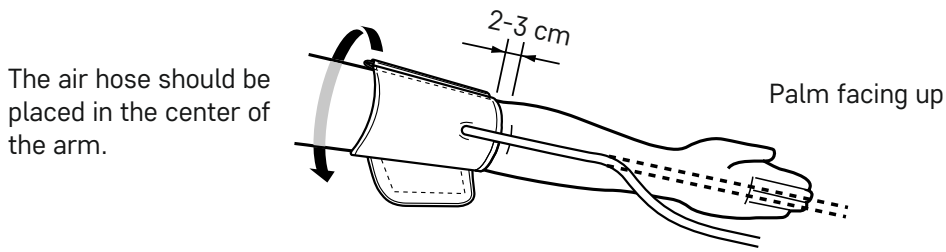
4. TAKING MEASUREMENT

4.1 IMPORTANT NOTES

- Do not eat, drink alcohol, smoke, take a shower or exercise at least 30 minutes prior to measuring blood pressure. Do not take any medication that may increase it
- Try not to take readings when you are upset or worried, because blood pressure will be higher.
- Relax for 5-10 minutes before measurement. Sit in a comfortable and relaxed body position. During the measurement, do not move excessively. Keep your legs still and breathe freely and calmly.
- If possible, take each reading on the same arm.
- The measurement of blood pressure at the same time on different days should essentially provide the same result (excluding external factors, such as physical effort).
- Changing medication and dietary supplements may also affect the measurement results. Before introducing any changes in the medication and dietary supplements, consult your doctors.

4.2 WRAPPING THE CUFF

1. Insert the air tube in the socket on the left side of the device.
2. Insert the end of the cuff under the metal buckle, with the velcro facing out.
3. Wrap the cuff approximately 2-3 cm above the elbow. For best results, wrap the cuff on bare skin, at heart level.
4. The compression of arm caused by tucked up sleeve may prevent accurate reading.

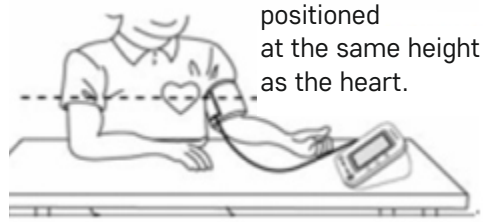


5. The cuff should be wrapped easily on the shoulder and the Velcro should fasten easily.
6. After wrapping the cuff, make sure that there is sufficient space under the cuff to fit a finger.
7. If the cuff does not fit on the arm, the accuracy of measurements may be incorrect.

- Do not fold the cuff or the air tube
- To disconnect the cuff, remove the air tube plug from the device.
- Measurement can be started only after wrapping the cuff properly.
- The cuff must be replaced if there is a leak or when the cuff is not operating properly.
- In order to ensure the accuracy of readings, you should only use the cuff supplied by the manufacturer.

4.3 BODY POSTURE DURING MEASUREMENT

Relax, rest the elbow on the table with palm facing up; the cuff should be at heart level. Accuracy of readings may be reduced if the cuff is not wrapped properly. The arm should be at the same height as the heart. If the arm is too low, the reading results will be too high. If the arm is too high, the reading results will be too low.



The arm should be positioned at the same height as the heart.

4.4 MEASUREMENT

After installing the batteries and wrapping the cuff, the device is ready to take measurement:.

1. To ensure that the results are most accurate, during taking the reading, relax, do not smoke, do not take deep breaths, do not talk loudly and try not to move.
2. Press the [START/STOP] button; it will light up for 1 second, as shown in Figure 1.
3. Then the display will switch as shown in Figure 2.
4. When the device detects pulse, the heart symbol starts blinking, as shown in Figure 3. The cuff is filled with air and the measurement of pulse rate and blood pressure is performed.
5. After the measurement, the air will automatically be released from the cuff and the results of the measurement will be displayed on the screen as shown in Figure 4. The bar on the right side of the display will indicate the level of blood pressure. The classification of blood pressure level is presented on page 10.
6. You can turn off the device or compare the reading with previous results.
7. The device automatically turns off after 3 minutes.

8. If a problem occurs during the measurement, the screen displays the "Err" (error) message.
9. At the end of the measurement, if irregular pulse is detected, the symbol will appear on the screen together with the measurement result..

Fig. 1

Fig. 2

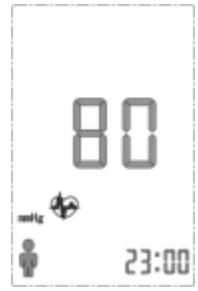


Fig. 3

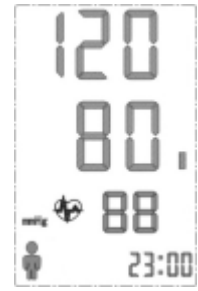
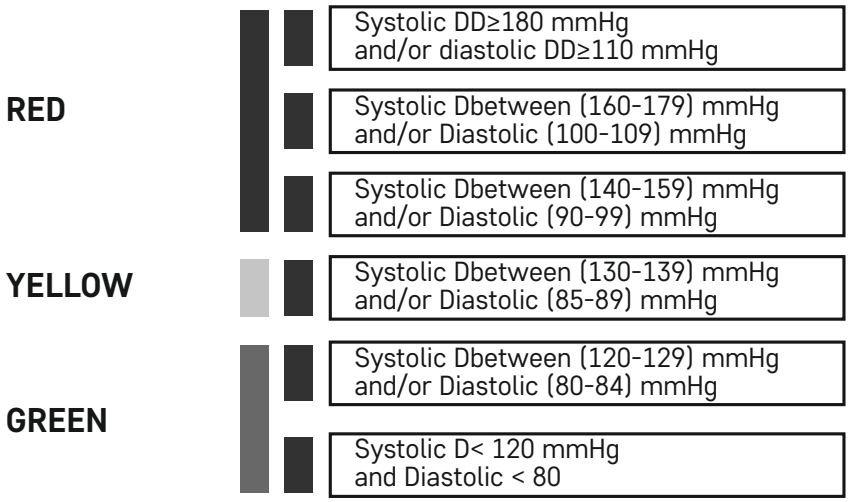


Fig. 4

BLOOD PRESSURE CLASSIFICATION



NOTES:

- Do not perform self-diagnosis based on the obtained results. Follow the advice of your doctor or qualified healthcare professional.
- The bar on the right side of the display and the color of the element indicate the level of blood pressure, blood pressure classification and definition, as shown in the figure above.
- If the device causes any discomfort during the measurement or fails to work properly, it should be turned off and its use discontinued.
- .Pressure reduction time with 260 mmHg (34.67 kPa) to 15mmHg (2kPa) does not exceed 10 sec.
- If the cuff is inflated to the level of 300 mmHg (40 kPa) and inflation continues, disconnect the cuff from the unit or turn off the power.

4.5 MEMORY

Internal memory stores up to 2x60 measurement results.

1) Recalling results from memory
    a) To access memory, press the MEM button.
    b) The device displays the average result of 3 most recent measurements.
    c) After pressing the MEM button, the user can view data from the newest to the oldest. Pressing the SET button allows to view the results in reverse order.
    d) If the heart symbol stored in the memory, it indicates that irregular pulse rate was detected during the measurement.

NOTE: Holding the MEM button longer will erase all data from the memory.

2) Deleting data from memory:
    a) You must go into memory mode.
    b) Press and hold down the MEM button until "---"is displayed.
    c) All data will be deleted, it is not possible to delete a single record.
    d) Press the START/STOP button to exit the memory mode and turn off the device.

NOTE: The results of previous measurements will be displayed only from the last used memory group. To see the results of measurements in other groups, first select the desired group, and then turn off the pressure monitor. (See "Group/user selection" on page 7)

5. BLOOD PRESSURE INFORMATION

5.1 WHAT IS BLOOD PRESSURE?

Blood pressure (BP) is the pressure exerted by the circulating blood on blood vessel walls and is one of the essential vital parameters.

During blood pressure measurements two values are read:

- Systolic blood pressure is a measure of the pressure during contraction of the heart
- Diastolic blood pressure is a measure of the pressure during relaxation of the heart

5.2 WHAT IS HIGH BLOOD PRESSURE?

High blood pressure also known as HBP or hypertension is a commonly misunderstood medical condition. It is believed that people with hypertension are tense, nervous or hyperactive, but pressure has nothing to do with personality.

A person can in fact be peaceful, relaxed and at the same time suffer from hypertension. Let's look at the facts regarding blood pressure, so that we gain a better understanding on how the body works and why it is prudent to start taking care of yourself right now, regardless of what the results of our blood pressure are.

By maintaining blood pressure in the "healthy" range we achieve the following:

- The risk of overloading and damaging the walls of blood vessels is reduced
- The risk that the heart will have to pump blood with greater force to overcome obstacles is reduced
- We protect our body through regular supply of oxygen-rich blood to the tissues

In accordance with the World Health Organization (WHO) standard, the classification of blood pressure is as follows:

CATEGORY	Systolic BP (mmHg)		Diastolic Bp (mmHg)
OPTIMUM	<120	and	<80
NORMAL	120-129	and/or	80-84
PREHYPER TENSION	130-139	and/or	85-89
HYPERTENSION	≥140	and/or	≥90
STAGE 1 HTN	140-159	and/or	90-99
STAGE 2 HTN	160-179	and/or	100-109
BLOOD PRESSURE DANGEROUSLY HIGH	≥180	and/or	≥110

These categories have been defined by the American Heart Association. This table applies to adults aged 20 and older..

5.3 WHAT IS MORNING SURGE IN BLOOD PRESSURE?

A morning surge in blood pressure is defined as the pressure within 1 to 2 hours after you wake up in the morning (more than 135/85 mmHg; averaged within a week). Studies have shown that increased pressure in the morning constitutes a risk factor for cardiovascular events, including ischemic and haemorrhagic strokes. It has been shown that cardiovascular events intensify in the morning, which coincides with the morning blood pressure surge. It has also been shown that heart attacks, strokes and circulatory failures occur mainly on Mondays. With the morning rise in blood pressure also organ damage and diabetes complications are associated, similarly to microangiopathy and heart attack in older people.

It has been shown that the morning surge in blood pressure correlates to early phases and the development of atherosclerosis. Patients who properly control blood pressure may continue to experience a morning surge in blood pressure and it is so in 50% of the cases. Patients with hypertension have about 78% greater risk of stroke, compared to 48% in other patients with hypertension, who do not experience the morning blood pressure surge. Morning surge in blood pressure is also associated with changes in the heart volume and rhythm. These changes may lead to myocardial infarction and circulatory failure. Increased pressure in the morning can be detected only within 1 to 2 hours after waking up. We recommend that the users of the blood monitor control their blood pressure at home.

STANDARDS

- IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests
- IEC 80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
- ANSI/AAMI/ISO 81060-2-2009 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type

6. ERROR MESSAGES

ERROR CODE	CAUSE	HOW TO REPAIR
Er30	The power is turned on, the cuff is filled too slowly or the device does not connect the cuff.	1. Reconnect the air tube plug into the device. 2. Leakage of the cuff or tubing. Purchase a new cuff. 3. Make sure that the cuff is properly wrapped. Take new measurement.
Er 2	Weak signal or cuff is too loose	The cuff is too loose, make sure that the cuff is properly wrapped. Take new measurement
Er 3	Calculation error, strong impact, error during	Remain motionless. Take new measurement.
Er 5	Bad signal, movement or talking during measurement	Pozostać nieruchomo. Dokonać ponownego pomiaru.
Er 7	Incorrect measurement.	Please take new measurement.
Lo	Battery level too low, not able to inflate	Replace the batteries with new ones.

7. PROBLEM SOLVING

In the event of irregularities during operation, please refer to the following:

PROBLEM	HOW TO REPAIR
After replacing batteries and turning on the device, nothing displays	1. Check battery polarity 2. If you still cannot turn on the device, reinstall or replace the batteries.
Mesured results are too high or too low	1. Make sure that the cuff is correctly wrapped. 2. If the user's clothing restricts normal blood flow, it should be removed and take another measurement. 3. Relax, rest the elbow on the table with palm facing up; the cuff should be at heart level. Take new measurement.
The pumping is too slow or in correct	1. Reconnect the air tube plug with the device. 2. Leakage of the cuff or air tubing. Replace with a new one.
The air from the cuff is released too quickly	1. The cuff is too loose, make sure that the cuff is properly wrapped.
Mesured result is different from the one mesured by doctor	1. The value of blood pressure varies during the day, which is also caused by the emotional state and physical condition. 2. Take notes of the differences and consult them with your doctor.

*if the above guidelines are not helpful in solving the problem, please contact Diagnosis. Free hotline: 800 70 30 11

8. SPECIFICATION

Description	Automatic upper arm blood pressure monitor	Model	Diagnostic DM-400 IHB
Display	Digital display LCD	Measurement princip	Oscillometric method
Measurement range	Pressure: 0~280 mmHg Pulse: 40~180 bpm	Accuracy	Pressure: ±3mmHg (±0.4 kPa) Pulse: ±5%
Memory	2x60 measurement results	Automatic power off	Idle for 3 minutes
Power source	4 AA alkaline batteriesor power adapter DC 6V, min. 400mA (optional)	Battery life	Approximately 200 measurements
Protection against electric shock	Type BF	IP Classification	Ip21
Operating environment	Temperature: +5°C ~ 40°C Humidity: D15-93% Pressure: 70.0kPa~106.0kPa Altitude: D ≤3000 m	Storage and transportation conditions	Temperature: -25°C ~ 70°C Humidity: 10 ~95% Pressure:50 kPa~106 kPa
Weight	294g (without batteries)	Dimensions	140 mm × 110 mm × 67 mm
Useful life of parts	Casing 5 years or 10000 times Cuff 10000 times	Contents	Cuff (arm circumference: 22-36 cm) power adapter (optional)4 x AA alkaline batteries User manual

Specifications may change without prior notice. Batteries must be disposed of in accordance with local regulations.

9. STANDARDS

GUIDELINES AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

The devices are intended for use in the electromagnetic environment as described below. The customer or the user of the device should assure that the device is used in such an environment.		
Emission test	Fulfillment of requir	Guidelines regarding electromagnetic environment
The emission of radio frequency waves; CISPR standard	Group 1	The device uses radio-frequency energy only for its internal functions. Therefore, these emissions are very low and should not cause interference in nearby electronic equipment.
The emission of radio frequency waves; CISPR	Class B	The device can be used in all buildings, including residential buildings, and those that are directly connected to the public low-voltage network, supplying power to buildings intended for residential purposes.
Harmonic emissions IEC 61000-3-2	non applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3		

Guidelines and manufacturer's declaration regarding electromagnetic immunity
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the DEVICE should assure that it is used in such an environment.

Immunity test	Poziom testowy, norma IEC 60601	Compatibility	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wooden, concrete or made of ceramic tiles. If floors are covered with synthetic materials, the relative humidity should be at least 30%. If ESD interferes with the device, you should consider the use of compensatory elements i.e. wrist strap, grounding.
Fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Non applicable	The quality of power supply should be adequate for typical commercial installation or hospital environment..
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Non applicable	The quality of power supply should be adequate for typical commercial installation or hospital environment
Spadki napięcia, krótkie przerwy i zmiany napięcia na wejściach linii zasilania IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip de UT) for 5 s	Non applicable	The quality of power supply should be adequate for typical commercial installation or hospital environment. If the user [of the device or system] requires continuous use even during power interruptions, it is recommended to connect the device or system to emergency power supply.
Voltage dips, short interruptions and voltage changes on power supply inlets IEC 61000-4-11	3 A/m	3 A/m	The level of magnetic fields of power sources should be within the limits applicable for typical commercial installations or hospital environment.

Guidelines and manufacturer's declaration regarding electromagnetic immunity

With respect to the EQUIPMENT or SYSTEMS, which do not serve as LIFE SUPPORTING SYSTEMS

GUIDELINES AND MANUFACTURER'S DECLARATION REGARDING ELECTROMAGNETIC IMMUNITY

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the DEVICE should assure that it is used in such an environment.

Immunity test	**Test level, IEC 60601 standard**	**Compatibility level**	**Electromagnetic environment - guidelines**
Conducted radio-frequency signal IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile radio communication measures should be used at a distance from any of the elements [of the DEVICE or SYSTEM], including cables, which is not lower than the recommended distance calculated from the transmitter frequency equation. Recommended distance d = 1.2 d = 1.2 80 MHz to 800 MHz d = 2.3 800 MHz to 2.5 GHz where P is the maximum power rating of the transmitter in watts (W) as specified by the manufacturer, and (d) is the recommended distance in meters (m). Field strengths from fixed RF transmitters, as determined in field measurements of electromagnetic fields, should be lower than the compatibility level for each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: Recommended distance d = 1.2 
Emitted radio-frequency signal IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	

Recommended spacing between portable and mobile radio communication equipment and a DEVICE in relation to devices that do not serve as LIFE SUPPORTING SYSTEMS

Recommended spacing between portable and mobile radio communication equipment and the [DEVICE

The [DEVICE or SYSTEM] is intended for use in the electromagnetic environment in which the interference caused by the emission of radio waves is controlled. The buyer or the user of the [DEVICE or SYSTEM] can help prevent electromagnetic interference by keeping a minimum distance between portable and mobile radio communication equipment (transmitters) and the [DEVICE or SYSTEM], as recommended below, according to the maximum output power of the communication equipment.

Maximum rated power of the transmitter W	Distance according to frequency of the transmitter m		
	150 kHz to 80 MHz d = 1,16	80 MHz to 800 MHz d = 1,16	800 MHz to 2.5 GHz d = 2,33
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 assessed at the maximum output power not listed below, the recommended distance d in meters (m) can be estimated using the equation corresponding to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

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

NOTE 2: these guidelines do not apply in all situations. The propagation of electromagnetic waves is affected by the absorption and reflection from the buildings, objects and people.

IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

Along with a growing number of electronic devices, such as PCs and mobile phones, medical equipment becomes more prone to electromagnetic interference that can interfere with its operation and potentially threaten its security.

To adjust the requirements for EMC (electromagnetic compatibility) and prevent dangerous situations, the IEC60601-1-2 standard has been introduced. The standard specifies the levels of immunity to electromagnetic interference and maximum levels of electromagnetic emissions for medical devices.

This medical device meets the requirements of the IEC60601-1-2:2007 standard for immunity emissions.

Regardless, certain precautionary measures should be applied:

- Do not use cellular phone or other devices that generate strong electrical or magnetic fields near medical devices. This can result in abnormal operation of the device and create a potentially dangerous situation.

It is recommended to keep a distance of at least 7m. If the distance is shorter, the correct operation of the device must be verified.

For further information, in the form of documentation according to the IEC60601-1-2:2007 standard, contact the manufacturer at the address provided in this user manual.

10. EXPLANATION OF SYMBOLS

START/STOP	Pause and turn on	CE 0197	The product complies with the requirements of the European Union
SYS	Systolic pressure in mmHg	Rev.	Date of the last revision
DIA	Diastolic pressure in mmHg		Manufacturer
PUL./min.	Pulse rate		Manufacturing date
⊕ CR6 (LR6, AA) ⊖	Note on installing battery	SN	Serial number
⎓	Direct current		Read the user manual
IP21	Degree of protection	LOT	Batch number
	Important warnings	REF	Catalog number
	Type BF: device, cuff and tubing are designed to provide special protection against electrical shocks.		

The worn out product should be taken to a waste collection facility. Contains components that are dangerous for the environment. The correct disposal of the device allows to preserve valuable resources and avoid negative effects on health and the environment, which may be threatened by inappropriate handling of waste.

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Diagnosis®

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store stamp and signature of salesperson

WARRANTY CARD

DEVICE NAME . . . . . .

MODEL . . . . . .

SERIAL NUMBER . . . . . .

DATE OF SALE . . . . . .

WARRANTY TERMS

1. Diagnosis S.A. grants a warranty:
   - 24 months for DIAGNOSTIC blood pressure monitors and cuffs (excluding pump assembly)

Hardware defects revealed during the warranty period will be rectified free of charge within 21 days. The term runs from the date of delivery of the equipment to the service center.

2. The purchaser shall be entitled to replace the equipment for a new one, free of defects, when:
   - the repair has not been made within the time limit set in item 1
   - an authorized service center found an irreparable manufacturing defect
   - during the warranty period, 4 repairs were effected, and the equipment still shows defects that prevent its use in accordance with its intended purpose.
   - The concept of repair shall not include operations related to equipment check and cleaning.
3. The warranty shall not cover: batteries, products with illegible or damaged serial number, damage due to the operation and storage inconsistent with the user manual, ingress of liquids or foreign bodies, overvoltage of mains, repairs by unauthorized persons and random events.
4. Faulty equipment should be delivered by the buyer to the address of the main service center or one of the Authorized Service Centers (listed in the appendix).
5. The warranty for the sold consumer goods shall not exclude, restrict, or suspend the powers of the buyer resulting from non-conformity of the goods with the contract.
6. The only basis for the warranty rights shall be the warranty card with the date of sale, stamp and signature of the salesperson. If the card is not completed, filled in wrongly, with traces of corrections and entries made by unauthorized persons, illegible as a result of damage - it shall be invalid.