INSTRUCTION FOR USE

DIAGNOSTIC®

DM-200 IHB Plus

AUTOMATIC UPPER-ARM BLOOD PRESSURE
AND PULSE MONITOR

CE 0197

MD REF 5152

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ENGLISH

Table of contents

Thank you for buying the blood pressure and pulse monitor Diagnostic DM-200 IHB Plus. This model can be used with irregular pulse. If the device detects irregular pulse, the symbol appears on the display. In such a case, it is advisable to consult the physician. If you have any questions about how to use the device or report unforeseen events, please contact the Helpdesk at the telephone number indicated in the manual.

Please carefully read this users manual before the first use of the device. Please keep the instruction for use. Use the product only in accordance with its intended use described in this manual. The information contained herein may be needed in the future. Do not take any action of a medical nature medical without first consulting your doctor.

1. INTRODUCTION

1.1 Device features

Blood Pressure Monitor Diagnostic DM-200 IHB Plus is a fully automatic digital device to measure the blood pressure on the upper arm. It enables quick and reliable measurement of systolic and diastolic blood pressure, as well as pulse, using the oscillometric method. This device provides a very high accuracy of measurements and has been designed in such a way that its operation is as user-friendly as possible. The device is intended for self measurement of blood pressure at home. For more information on blood pressure and blood pressure measurement, please contact your doctor.

1.2 ⚠ Important information on self-measurement

- Using a cuff other than the recommended one may result in measuring error.
- Do not use the device for measuring blood pressure in infants.
- Do not use the device in pregnant patients with pre-eclamptic.
- Pay attention not to entangle the tubes because this may result in a serious injury of the patient or disturbances in blood pressure measurement.
- Too frequent measurements may cause trauma to the patient due to impaired
- blood flow.
- Wrapping the cuff on a wound may lead to a deterioration of its condition.
- Application of the cuff on the treated arm may lead to injury as a result of temporary obstruction of blood flow during pressure increase.
- Do not put on and inflate the cuff, on the side where the mastectomy procedure has been performed.
- Inflation of the cuff may cause temporary stoppage of equipment monitoring vital functions used on the same arm.
- Pressure measurement using the automatic device for measuring blood pressure does not cause long-term impairment of the patient's circulation.
- The device is not suitable for simultaneous monitoring with high-frequency electrosurgical apparatus (HF).

Self-measurement means control and not diagnosis and treatment. Unusual values should always be consulted with your doctor. The patient should not change the doses of medications prescribed by a doctor.

- Blood pressure may vary depending on the site of measurement, the patient's position, exercise or the patient's mental condition.
- Cuff pressure may temporarily cause loss of function of an electrical device used at the same time on the same arm.
- Observe the limb to ensure that the device being used does not cause chronic circulatory failure.
- The displayed pulse rate is not suitable for controlling the operating frequency of a pacemaker!
- In the case of arrhythmias, the measurement carried out by the device should be consulted with a doctor.
- The air tube or power cord may cause strangulation.

- Keep out of the reach of children. The small pieces of the set cause a risk of choking if swallowed.
- Do not use the device on infants or incapacitated persons communication.

Electromagnetic interference

The device contains sensitive electronic components, therefore, one should avoid strong electrical or electromagnetic fields (e.g., nearby cellular phones, microwave ovens). Otherwise, there may be a temporary deterioration in the accuracy measurements. Do not use the device when it is adjacent to another electrical device or lying on top of it, as this may cause improper operation. If such use is necessary, check that these devices operate normally. Portable communication equipment that emits radio waves (including peripheral devices, such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the equipment, including cables specified by the manufacturer. Otherwise, the performance of this device may be impaired.

Reporting of serious incidents

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2. IMPORTANT INFORMATION ON BLOOD PRESSURE AND ITS MEASUREMENT

2.1 How does hypertension / hypotension develop?

The level of blood pressure is regulated in the brain, in the circulatory center and adapted to the current conditions based on feedback involving the nervous system. It adjusts the blood pressure, the frequency and the strength of heart contractions and the diameter of blood vessels (the degree of contraction of smooth muscle of blood vessel walls). The level of blood pressure changes periodically in the cardiac cycle: during the contraction the value is the highest (systolic) and at the end of the diastole the value is the lowest (diastolic pressure). In order to prevent the development of dangerous diseases, the blood pressure values should be correct.

2.2 What is the correct pressure value?

The value of blood pressure is too high if the diastolic pressure at rest is above 90 mmHg or the systolic pressure is over 160 mmHg. In such a case, you should immediately consult your doctor. Long-term persistence of pressure on such a level endangers human health due to the increased damage to bloodvessels. If systolic pressure is within the range of 140 to 160 mmHg or the diastolic pressure is between 90 to 100 mmHg, consult your doctor. Regular self-measurement of blood pressure will be necessary. In the case of values that are too low (the systolic pressure is below 100 mmHg or the diastolic pressure falls below 60 mmHg) consult the doctor. Even in the case of pressure values in the normal range, it is recommended to perform regular blood pressure selfmeasurements. That will detect any changes in the value of blood pressure at early stage and respond accordingly. If the patient is undergoing treatment for hypertension/hypotension, regular measurements should be taken at a specific time of day and the results recorded, and then presented to the doctor.

Do not change the dosage of medications prescribed by the doctor basing on measurement results.

Table of blood pressure value classification (unit: mmHg) according to the World Health Organization (WHO):

Range	Systolic Pressure	Diastolic Pressure	Remedial measures
Optimal blood pressure	up to 120	up to 80	Self-measurement
Normal blood pressure	from 120 to 130	from 80 to 85	Self-measurement
Slightly elevated blood pressure	from 130 to 140	from 85 to 90	Consult the doctor
Too high blood pressure	from 140 to 160	from 90 to 100	Consult the doctor
Significantly elevated blood pressure	from 160 to 180	from 100 to 110	Consult the doctor
Dangerously high blood pressure	Above 180	Above 110	Immediately contact the doctor

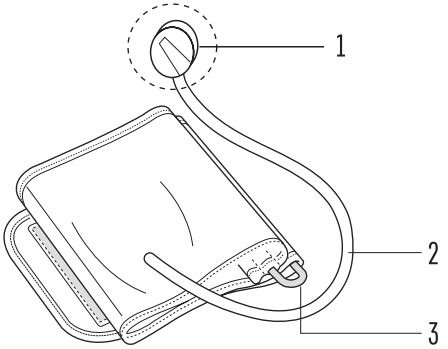
- If the values of your blood pressure at rest are usually normal, but elevate during stress, you may suffer from labile (latent) hypertension, consult the doctor.
- Correctly measured diastolic pressure is above 120 mmHg, it requires immediate medical treatment.
- The following factors may affect the performance of the device or the reading: arrhythmia, pregnancy, age, diabetes, kidney disease, motion, shocks, seizures, etc.

3. PRODUCT FEATURES

3.1 Blood pressure monitor

1. Air tube socket
2. DATE/TIME Button
3. START/STOP Button
4. MEMORY Button
5. Power supply socket
6. LCD Display

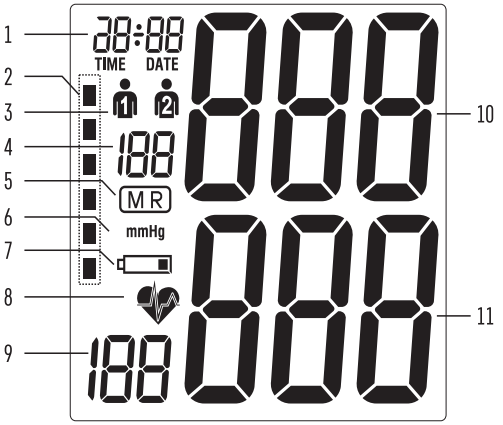
3.2 Cuff



1. plug connecting the air tube with the blood pressure monitor (insert into the air tube connector)
2. Air tube
3. Metal buckle

(Applied part type BF) Arm circumference range: 22–42 cm

3.3 Display



1. Date/Time
2. Blood Pressure Classification Indicator according to the World Health Organization (WHO)
3. Users/group
4. Number of the stored measurement
5. Symbol of the average measured value
6. Unit of measurement
7. Low battery symbol
8. Irregular heartbeat detection symbol is displayed when the measurement is finished / Pulse symbol is displayed during the measurement
9. Pulse value
10. Systolic pressure
11. Diastolic pressure

4. STARTING THE DEVICE

4.1 Batteries installation

1. Remove the battery cover.
2. Insert 4 standard AAA alkaline batteries.
   - Use batteries of the same brand.
   - Note that all the batteries are properly installed, observing polarity.
3. Install the battery cover.
4. If the battery icon is displayed on the screen, it means that there is 20% power left until the battery is drained completely.
5. If the battery icon is displayed on the screen, it indicates low batteries. Batteries should be replaced, otherwise the device will not operate properly.
   - Do not mix old and new batteries
   - After replacing the batteries, you should set the time and date again.
   - After the battery warning icon is displayed, the device will not turn on until the battery is not replaced.
   - Use batteries of Long-Life AAA type or alkaline 1.5 V. It is not recommended to use 1.2 V rechargeable batteries.
   - If the blood pressure monitor is left without use for an extended period of time, the batteries should be removed.

4.2 Battery life

- Four new LR6 (AAA) batteries last for approximately 1000 measurements (1 measurement per day, at room temperature 23°C). Batteries life depend on the temperature in which they are used, and may be shorter at lower temperatures.
- The battery status can be checked in the lower left corner of the screen. If low battery symbol is displayed, replace the batteries with new ones.

4.3 Power supply (optional)

1. Connect the plug of the power cord into the power supply connector.
2. Plug the power supply into electrical outlet.
   - Use power adapter suitable for local mains voltage.
   - Power adapter specification: 100~240 V, 50/60Hz; output: Micro USB DC 5V, 1A
   - We recommend using only the power supply provided by the manufacturer.
   - If the device is defective, unplug the power supply or the power cord.
   - Do not touch the power supply with a wet hand.
   - When the device is operating, do not tangle, twist and break cables.
   - Disconnect before cleaning the AC supply plug
   - Do not tangle the wires during usage.
   - The power supply is added to the set optionally.

4.4 User selection, date and time settings

4.4.1 User selection

The blood pressure monitor allows you to track blood pressure readings of 2 users.

a. Before starting the measurement, make sure that the appropriate user is set. The device can track the results of up to 2 users (user 1, user 2).
b. Hold down the TIME button for at least 3 seconds. The screen will display a blinking user icon.
c. Change the user by pressing the memory button M. To confirm user selection, press ⏻.
d. It is recommended to set the first person who takes measurement as user 1.

4.4.2 Time and date settings

The device has an integrated clock and displays the date. This permits saving not only the result of blood pressure measurement, but also the exact date and time of taking the readings. After inserting the new batteries, the CLOCK will be set to 12:00 and the DATE to 1-01. Set the correct time and date. For this purpose, do the following:

1. Hold down the TIME button for at least 3 seconds. The user icon starts blinking. Next, press the TIME button again to display the year (4 characters flashing).
2. Enter the year by pressing the MEMORY M button.
3. Press the TIME button again. Now the date with the flashing month icon appears on the screen.
4. Set the month using the MEMORY M button.
5. Press the TIME button again. Now the last two characters will flash (day).
6. Set the day using the MEMORY M button.
7. Press the TIME button again. Now the system switches to time settings; the hour symbol will flash.
8. Set the hour using the MEMORY M button.
9. Press the TIME button again. Now the last two symbols will flash (minutes).
10. Set the exact time, i.e. minutes, using the MEMORY M button.
11. Press the TIME button: the measurement unit will start flashing.
12. After completing all the settings, press the TIME button once again. Briefly the date will be displayed followed by the time. The settings are now confirmed and the clock starts running.

4.4.3 Other information

With each press, the TIME ⏲ button moves to the next setting. The MEMORY Ⓜ button changes the value by 1 (e.g. switching from hours to minutes or changing the value by +1). Holding the button for 3–4 seconds makes the switching much faster.

5. TAKING MEASUREMENTS

5.1 Before the measurement

- Directly prior to measurement one should not: eat, smoke and avoid physical effort because all these activities have an impact on measurement results. Prior to measurement you should relax, sit on a chair in comfortable position for approximately 10 minutes.
- Measurements should always be taken on the same arm (normally left).
- Take measurements on a regular basis, every day at the same time, because blood pressure varies throughout the day.

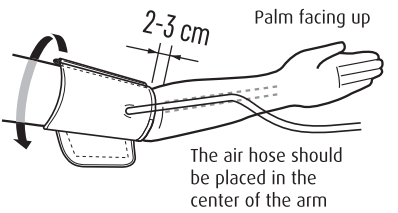
5.2 Most frequent errors

For blood pressure measurements to be comparable, the same measurement conditions are necessary! These conditions always include peaceful surroundings.

- All the patient's efforts to support the arm may result in increased blood pressure. Set in a comfortable and relaxed position. During the measurement, do not stretch any muscles of the arm on which the cuff is wrapped. If necessary, use a pillow as a support.
- The operation of the blood pressure monitor may be disturbed by extreme temperatures, humidity and taking measurements at high altitudes.
- Pay attention not to pinch or bend the tubes.
- A loosely fitted cuff will cause incorrect measurement results.
- In the case of repeated measurements there is a build-up of blood in the arm, leading to incorrect results. For this reason, the correct blood pressure measurement should be carried out after a 5 minute break, or by raising the arm to let the accumulated blood to float away (at least after 3 minutes).

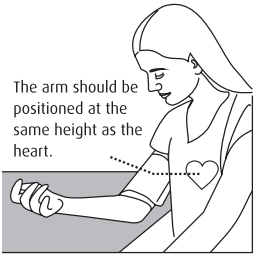
5.3 Fitting the cuff

1. Firmly insert air tube plug in the air tube socket that is on the left side of the device.
2. Insert the end of the cuff under the metal buckle, with the velcrofacing out.
3. Remove the tight-fitting clothing from the arm on which the measurement is being made. You shouldn't put the cuff on thick clothing.
4. Wrap the cuff approximately 2–3 cm above the elbow. For best results, wrap the cuff on bare skin, at heart level. The cuff should be wrapped easily on the shoulder so that the air tube is pointing towards the hand.
5. The compression of arm caused by tucked up sleeve may prevent accurate reading.



6. The cuff should go easily fitted on the arm and the Velcro should be closed easily.
7. After fitting the cuff, make sure that there is sufficient space under the cuff to fit a finger.
8. If the cuff does not fit on the arm, the accuracy of measurements may be incorrect.

5.4 Body posture during the measurement



Relax and rest your elbow on the table so that the inside of your palm faces upwards. 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. Sit on a chair, the legs should not be crossed and feet should not rest on the floor. Sit with straight backs and have back and arm support. The patient should not talk during the measurement.

5.5 MEASUREMENT PROCEDURE

After fitting the cuff properly, you can start taking the measurement.

a. Press the button START/STOP, all elements will be displayed and the cuff will start inflating. The increasing cuff pressure is displayed continuously on the LCD (Fig. 1).
b. Once the correct pressure is reached, it will start to decrease slowly. When the heart rate is detected the heart icon will flash on the screen (Fig. 2).
c. When the measurement is completed, the systolic pressure measurement, diastolic and heart rate values are displayed (Fig. 3).

For example (Fig. 3): Systolic blood pressure is 136, diastolic blood pressure is 88, heart rate is 78. The measurement results will be displayed until the device is turned off. If none of the button is pressed for 3 minutes, the device will automatically turn on to save batteries.

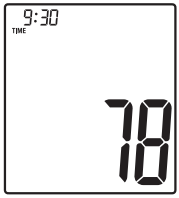


Fig. 1

Fig. 2

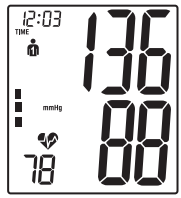


Fig. 3

5.6 Stopping the measurement

To stop the blood pressure measurement (for example, when the patient does not feel well), you can press the START / STOP button immedietly at any time. The device will automatically low the cuff pressure.

6. MEMORY

The internal memory stores up to 120 measurement results for each user.

1. Memory viewing MR

- To access the memory resources, press the MEMORY Ⓜ button.
- The device will display the average result of the last 3 measurements (Fig. 4).
- After pressing the MEMORY Ⓜ button, the last measurement will be displayed (Fig. 5).
- Pressing the MEMORY Ⓜ button again allows the user can view the measurement results from the newest to the oldest (Figures 6 and 7).

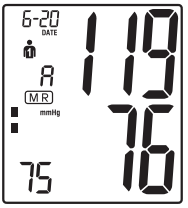


Fig. 4

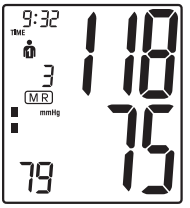


Fig. 5

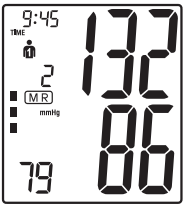


Fig. 6

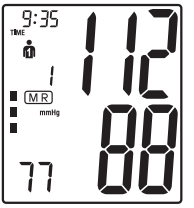


Fig. 7

6.1 Memory – deleting all measurement results

Before you delete all the results stored in the memory, make sure that you will not need them in the future. It is wise to keep a written record so that more information can be provided when you visit your doctor's surgery. To delete all stored results, hold down the MEMORY Ⓜ button for at least 5 seconds. Release the button when 'CL' is displayed on the screen. To erase the entire memory, press the MEMORY Ⓜ button while 'CL' is flashing.

6.2 Early arrhythmia detection

If this symbol 💔 is displayed after the measurement, it means that during the measurement irregular heart rate has been detected. In this case, the result may be different from yours normal blood pressure – repeat the measurement. In most cases, there is no reason to worry, but if this symbol appears regularly (e.g. several times a week with daily measurements), it is recommended to consult the doctor.

PROVIDE THE DOCTOR THE FOLLOWING EXPLANATION

Information for the physician regarding the frequent occurrence of the arrhythmia icon. This device is an oscillometric sphygmomanometer, which analysis the heart rate during the measurement. The device has been tested in clinical conditions. If the device detects an irregular heartbeat, the arrhythmia symbol will be displayed after the measurement. If this symbol appears regularly (e.g. several times a week with daily measurements), it is recommended to contact the doctor. The device is not a substitute for a cardiological examination, but helps to detect arrhythmia at early stage.

7. ERROR MESSAGES

If an error occurs during the measurement, the reading will be interrupted and an error code will be displayed.

Error code	Possible cause
ERR 1	Pulse does not detected.
ERR 2	Measurement results affected by interference. Cause: there was an arm movement during the measurement.
ERR 3	The cuff has been inflacted too long. The cuff has not been fitted properly
ERR 5	Measurement has indicated unacceptable difference between the systolic and diastolic pressure values. Perform another measurement according to the instructions. If unusual results still occuers, contact the doctor.
ERR 8	The pressure in the cuff is higher then 290 mmHg

Further information. Blood pressure varies even in healthy people, that is why it is important to always take measurements under the same conditions (peaceful environment). Despite following these principles, the fluctuations will be higher than 15 mmHg and irregular pulse rate occurs repeatedly, consult your doctor. In the event of problems, you should consult with Diagnosis S.A.

⚠ **YOU SHOULD NEVER ATTEMPT TO REPAIR THE DEVICE BY YOURSELF!**
ALL UNAUTHORIZED ATTEMPTS TO OPEN THE DEVICE WILL VOID THE WARRANTY!
If a problem arises when using the unit, check the following points and apply the listed remedies. NOTE: Use only parts and accessories supplied by the manufacturer. Parts and accessories that have not been approved for use with this appliance may cause damage to the appliance.

8. TROUBLESHOOTING

If problem occurs while using the device, please check the following points and take the specified measures.

Problem	Solution
The screen remains dark despite turning off the device and inserting new batteries	1. Check if batteries are arranged correctly (polarity) and, if necessary, correct their positioning. 2. If the display is incorrect, reinstall the batteries or replace them.
The device is frequently unable to measure the pressure or measurement results are too low (or too high).	1. Check positioning of the cuff. 2. Take another blood pressure measurement in a quiet and peaceful environment, following the instructions for use.
The results of each measurement are different, despite the fact that the device is working correctly, and the values are also displayed correctly.	Read the following information and the information included in "Most frequent errors". Repeat the measurement. Please remember: Blood pressure varies constantly, which is why subsequent measurements will be characterized by some variability.

Problem	Solution
The result of blood pressure measurement is different from the one that has been taken by the doctor	Take daily notes of measurement results and consult them with your doctor. Please remember: during a visit to the doctor some people feel nervous, which can raise blood pressure (relative to the readings taken at home).

9. MAINTENANCE AND CALIBRATION

a. Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
b. The cuff has a sensitive, impermeable reservoir (bladder).When fitting the cuff, be careful and avoid its deformation by twisting or bending.
c. Clean the device with a soft and dry cloth. Do not use gasoline, thinners or similar solvents. Stains on the cuff should be removed with care using a damp cloth and suds. Do not wash the cuff!
d. Be careful not to drop the device and handle it with care. Avoid strong vibrations.
e. Do not open the device. Otherwise, calibration performed by manufacturer will be invalid!

Periodic services

- The measuring device requires regular services.
- For that reason, it is recommended to carry out periodic services of the pressure monitor every 2 years. More information will be provided by Diagnosis or local distributor.
- The life of the product is set at 5 years.

10. SAFETY AND DISPOSAL

- This device may only be used for its intended use as described in the in the instructions for use. The manufacturer is not liable for damage caused by incorrect use of the device.
- The device has sensitive elements and must be handled with care. It is necessary to follow the conditions of storage and use (technical data).
- Protect the device from water and moisture, extreme temperatures, impact, dropping, dust, direct sunlight, heat and cold.
- Inflate the cuff only after it has been properly fitted.
- The device is not intended for use in the electromagnetic environment generated by mobile phones or radio.
- Do not use the device if it is damaged.
- If the device is not used for an extended period of time, remove the batteries.
- Use only original elements supplied by the manufacturer. The use of other elements may reduce the level of safety.

Keep out of reach of children, pets and pests. Some parts of the device are small and can be swallowed.

11. SYMBOLS

Symbols	Function/Meaning	Symbols	Function/Meaning
⊕ AAA ⊖	Indication of battery polarity		Keep dry
	Isolation Class II		Keep away from sunlight
	Type BF Applied Part		Follow Instructions for Use
Rev.	Date of the last revision		Caution
REF	Catalogue Number		Direct current
SN	Serial number	LOT	Batch code
MD	Medical device		Manufacturing date
	Atmospheric pressure limitation		Manufacturer
	Temperature limit		Indoor use only
	Storage humidity	UDI	Unique Device Identifier
IP	IP classification – means degree of protection provided by the enclosure in accordance according to the requirements of IEC 60529		The worn out product and batteries 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. If you are in doubt where to return the used appliance, contact Diagnosis S.A. or your local distributor.

12. TECHNICAL SPECIFICATION

Product description	Automatic blood pressure monitor for measuring blood pressure and pulse on the arm	
Model	Diagnostic DM-200 IHB Plus	
Measurement method	Oscillometric Digital	
Display	LCD display	
Measurement range	Pressure SYS DIA	 60–255 mmHg 30–199 mmHg
	Pressure measurement accuracy	±3 mmHg
	Pulse	40–199 beats per minute
	Pulse measurement accuracy	±5% reading
Cuff pressure range	0–290 mmHg	
Air inflating	Automatic pumping device	
Air deflating	Automatically through air valve	
Memory function	2×120 measurements with date and time	
Power supply	4×1,5 V alkaline batteries or power adapter Micro USB DC 5,0 V / 1,0 A (optionally)	
Operating Conditions	Temperature: 5–40°C Humidity: 15–85% R.H. Atmospheric pressure: 700–1060 hPa	
Storage and Transportation Conditions	Temperature: –10–55°C Humidity: 10–95% R.H. Atmospheric pressure: 500–1060 hPa	
Dimensions	135×90×41 mm ±1,0 mm (length×width×height)	
Weight	372 g ±5 g with batteries and cuff	
Cuff	Size M/L 22–42 cm	
Protection against electric shock	Internally powered medical equipment (if powered only by batteries) Class II, electric medical equipment (power supply is added optionally)	
Safety classification	Type BF	
IP classification	IP20 – Protection against finger touch and against penetration of foreign bodies. Protection against foreign solids with a diameter of 12.5 mm and larger.	
Product lifetime	Blood pressure monitor: 5 years Cuff: 1 year	
Contents	Blood pressure monitor, cuff size M/L (22–42cm), 4×AAA batteries, instruction for use, carrying case, power adapter (optional)	

The manufacturer reserves the right to change the technical parameters of the device without notice.

13. ELECTROMAGNETIC SAFETY

13.1 Guidelines and manufacturer's declaration – electromagnetic emissions.

Diagnostic DM-200 IHB Plus is intended for use in the electromagnetic environment specified below. The customer or the user of Diagnostic DM-200 IHB Plus should assure that it is used in such an environment.

Emission test	Fulfillment of requirements	Guidelines regarding electromagnetic environment
The emission of radio frequency waves; CISPR 11 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 11 standard	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	Compliance	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliance	

RF – frequency of the electromagnetic spectrum section, which is between the low range of long-wave radio frequencies and the infrared range; frequency useful for radio transmission. 9 kHz and 3 000 GHz are generally accepted as limits.

13.2 Guidelines and manufacturer's declaration regarding electromagnetic immunity

Diagnostic DM-200 IHB Plus is intended for use in the electromagnetic environment specified below. The customer or the user of Diagnostic DM-200 IHB Plus should assure 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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%.
Fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	±0,5 kV, ±1 kV line to line ±0,5 kV, ±1 kV, ±2 kV line to ground	±0,5 kV, ±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage changes on power supply inlets IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle; <5% U_T (95% dip in U_T) for 1 cycle; 70% U_T (30% dip in U_T) for 25/30 cycles; <5% U_T (>95% dip in U_T) for 5/6 s	<5% U_T (>95% dip in U_T) for 0,5 cycle; <5% U_T (95% dip in U_T) for 1 cycle; 70% U_T (30% dip in U_T) for 25/30 cycles; <5% U_T (>95% dip in U_T) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the all models require continued operation during power mains interruptions, it is recommended that the all models be powered from an uninterruptible power supply or a battery.
Magnetic field of the power supply frequency (50/60 Hz) IEC 61000-4-8	30 A/m	Not applicable	Not applicable

Note: U_T is the alternating voltage (AC) of the power grid prior to the application of the test level.

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	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of all models, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted radiofrequency signal IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	$d=[3,5/V_1]\times P^{1/2}$
	6 Vrms in ISM and amateur radio bands	N/A	
Radiated radiofrequency signal IEC 61000-4-3	10 V/m, 80 MHz to 2,7 GHz	10 V/m, 80 MHz to 2,7 GHz	$d=1,2\times P^{1/2}$ 80 MHz to 800 MHz $d=2,3\times P^{1/2}$ 800 MHz to 2,7 GHz 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 meters [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b). Interference may occur In the vicinity of equipment marked with the following symbol: 
	385–5785 MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment	385–5785 MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment	

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 power from certain transmitters, such as mobile communication base stations, radio transmitters, amateur radio, AM and FM radio transmission and TV transmission cannot be predicted theoretically with accuracy. To assess the electromagnetic environment, tests of local conditions should be considered. If the measured field strength in the location where the Diagnostic DM-200 IHB Plus operates exceeds the appropriate level of compliance, normal operation of Diagnostic DM-200 IHB Plus should be checked. If improper operation is observed, it may be necessary to take appropriate preventive steps such as moving or relocating the Diagnostic DM-200 IHB Plus.
(b) For frequencies outside the range of 150 kHz to 80 MHz, the field strength should not be higher than 3 V/m.
RF – frequency of the electromagnetic spectrum section, which is between the low range of long-wave radio frequencies and the infrared range; frequency useful for radio transmission. 9 kHz and 3 000 GHz are generally accepted as limits

13.3 Recommended separation distance between portable and mobile radio communication equipment and Diagnostic DM-200 IHB Plus

Diagnostic DM-200 IHB Plus 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 Diagnostic DM-200 IHB Plus can help prevent electromagnetic interference by keeping a minimum distance between portable and mobile radio communication equipment (transmitters) and Diagnostic DM-200 IHB Plus, as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d=1,2\times P^{1/2}$	80 MHz to 800 MHz $d=1,2\times P^{1/2}$	800 MHz to 2,7 GHz $d=2,3\times P^{1/2}$
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.

Diagnosis S.A.
Gen. W. Andersa 38A
15-113 Białystok, Poland
www.diagnosis.pl; info@diagnosis.pl

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:
- 2 years for Diagnostic DM-200 IHB PLUS blood pressure monitor
- 1 year for cuff (excluding pump assembly)
- 1 year for power supply Diagnostic

   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 or your local distributor.

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 distributor address in your country.
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.

WARNING! Before sending the device for repair, please clean it from all kinds of dirt.

ANNOTATIONS OF THE SERVICE POINT

Nr	Date of application	Date of repair	Warranty extended to	Description of actions	Stamp and signature of the contractor

MANUFACTURER

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Helpdesk (Polish language only)

+48 800 70 30 11
for landline phones

+48 85 874 69 28
for cell phones (the cost of the call is borne by the caller according to the operator's tariff)

MAIN SERVICE

(Concerns only customers from Poland. If you are outside Poland please contact distributor in your country.)

Diagnosis S.A.
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