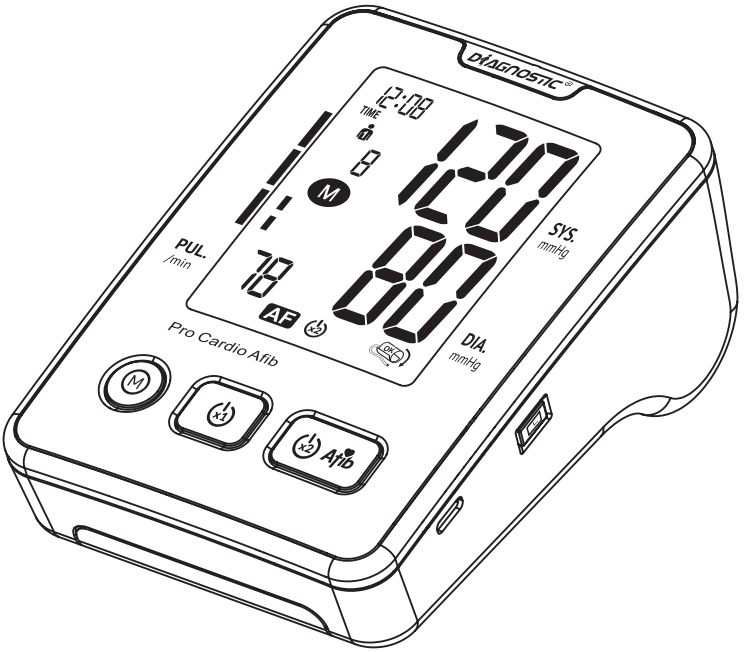
INSTRUCTION FOR USE

DIAGNOSTIC® Pro Cardio Afib

AUTOMATIC UPPER-ARM BLOOD PRESSURE AND PULSE MONITOR WITH THE FUNCTION TO DETECT SIGNS OF ATRIAL FIBRILLATION



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English

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Thank you for buying the blood pressure and pulse monitor Diagnostic Pro Cardio Afib. This modelcan be used with irregular pulse and atrial fibrillation. If the device detects irregular pulse, the symbol appears on the display. If the device detect signs of atrial fibrillation, the symbol AF appears on the display. In such a case, it is advisable to consult the physician.
The blood pressure monitor Diagnostic Pro Cardio Afib has an MDI function - measuring pressure and pulse while the cuff is being inflated. The MDI technology ensures fast and accurate results. Measurement is more comfortable due to less pressure on the arm.

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

1. INTRODUCTION

1.1. Device features

The Diagnostic Pro Cardio Afib blood pressure monitor is a fully automatic digital device for measuring blood pressure on the upper arm, which allows to take quick and reliable readings of systolic and diastolic pressure and pulse rate, using the oscillometric method. The device provides a very high accuracy of measurement and was designed to be as user-friendly as possible. The device is intended for taking blood pressure measurements at home. For more information on blood pressure and its 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 or in pre-eclamptic patients.
- 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.
- For this reason, every subsequent blood measurement should be carried out after a 5-minute break.
- 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 on the same arm where the monitoring virtal functions equipment is used may cause temporary stoppage of this equipment.
- 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 pacient should not change the doses of medications prescribed by a doctor.

- The displayed pulse rate is not suitable for controlling the operating frequency of a pacemaker!
- In the case of arrhythmias, the measurement made using the device should be consulted with a doctor.

The device should be stored out of the reach of inflants, small children and dependent persons. A child playing with air tube may result in suffocation. Children can also swallow small parts of the device. Make sure that children do not play with the device.

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.

2. IMPORTANT INFORMATION ON BLOOD PRESSURE AND ITS MEASUREMENT

2.1. How is hypertension / hypotension developed?

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. To adjust 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. Subsequently, regular self-measurement will be necessary. In the case of values that are too low, that is the systolic pressure is below 100 mmHg or the diastolic pressure falls below 60 mmHg, you should also consult your doctor. Even in the case of pressure values in the normal range, it is recommended to perform regular blood pressure selfmeasurements. This allows for detecting any changes in the value of blood pressure at an 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. Never use the obtained results to change by yourself the dosage of medications prescribed by your doctor.

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	from 100 to 120	from 60 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 elevated during stress, you may suffer from labile (latent) hypertension. If you suspect that this might be possible, contact your doctor.
- Correctly measured diastolic pressure above 120 mmHg requires immediate medical treatment.

3. IMPORTANT FACTS ABOUT ATRIAL FIBRILLATION (AFIB)

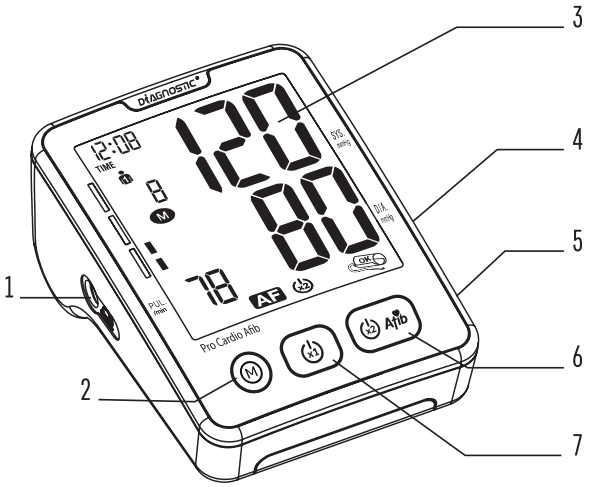
Normally, your heart contracts and relaxes to a regular beat. Certain cells located in a specially dedicated areas of the heart tissue form system which produce electrical signals responsible for heart contracting and pumping blood. Atrial fibrillation occurs when rapid and uncoordinated electrical signals are present in the heart's two upper chambers, (called the atria). These signals cause the heart muscle to contract irregularly (this is called fibrillation). Atrial fibrillation is the most common form of heart arrhythmia or irregular heart beat which often causes no symptoms, yet it significantly increases your risk of stroke. In such case, medical attention is required.

3.1. Harmful impact of atrial fibrillation for me and my family.

People with atrial fibrillation have a five-fold higher risk of getting stroke. Since the chance of having a stroke increases with age, atrial fibrillation screening is recommended for people over 65 years and older. However, for people from the age of 50 years with high blood pressure (hypertension), diabetes, coronary heart failure or have had a previous stroke atrial fibrillation screening is also recommended. Early diagnosis of atrial fibrillation followed by adequate treatment can significantly reduce the risk of getting stroke. In young people AFIB screening is not recommended as it could generate false positive results and unnecessary anxiety. In addition, young individuals with atrial fibrillation have a relatively low risk of getting stroke as compared to elder people. For more information please visit our website: www.diagnosis.pl

The Atrial Fibrillation detection function provides a convenient method of monitoring this arrhythmia while measuring blood pressure. High blood pressure and atrial fibrillation are recognised as risk factors for stroke, which can be controlled with appropriate medication. Knowing your blood pressure and knowing whether you have atrial fibrillation is the first step in proactive stroke prevention.

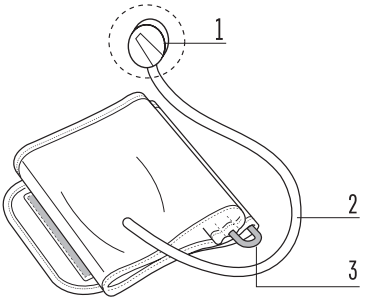
4. PRODUCT FEATURES



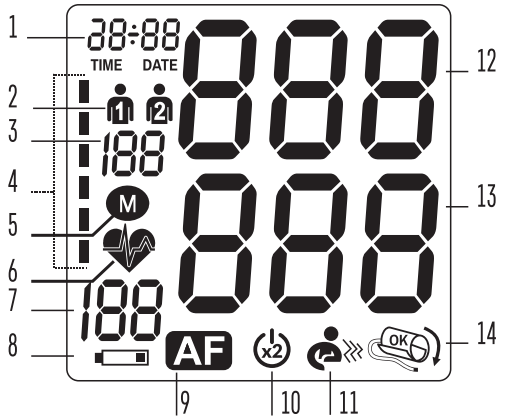
1. Air tube socket
2. MEMORY button
3. LCD display
4. Power supply socket
5. TIME / TIME button
6. START/STOP button AFIB mode
7. START/STOP button STANDARD mode

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

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



DISPLAY ELEMENTS



1. Date / time
2. Users / Groups
3. Number of the memorized measurement
4. Blood pressure classification index according to WHO (World Health Organization)
5. Symbol of memory
6. Irregular heartbeat symbol
7. Pulse
8. Battery discharge symbol
9. Signs of atrial fibrillation symbol
10. Pressure measurement in AFIB mode
11. Arm movement symbol during the measurement
12. Systolic pressure
13. Diastolic pressure
14. Cuff fit symbol

5. STARTING THE DEVICE

5.1. Batteries installation

1. Remove the battery cover.
2. Insert 4 standard AA 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 reset the time and date.
- After the battery warning icon is displayed, the device will not turn on until the battery is not replaced.
- Use batteries of AA Long-Life 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, you should remove the batteries.

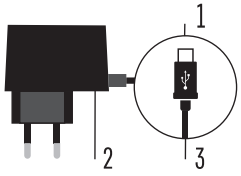
5.2. Battery life

Four new LR6 (AA) batteries last for approximately 200 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.

5.3. Power supply

1. Connect the plug USB-C of the power cord into the power adapter connector.
2. Plug the power supply into electrical outlet.

- Use power adapter suitable for local mains voltage.
- Power adapter specification: 100-240 V, 50/60 Hz; Output: USB-C DC 5 V, 1 A
- Use a power supply suitable for the local power supply.
- We recommend to use only the power supply unit supplied by manufacturer.



1. USB-C Plug
2. Power supply USB
3. USB cable

- 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 broke cables.

5.4. User selection, date and time settings

User selection: The blood pressure monitor allows you to follow 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. Change the user by pressing the memory button (M). To confirm user selection, press the START/STOP button.
c) We recommend to set the first person who takes measurement as user 1.

5.5. 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. You should set the correct time and date. For this purpose, please 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 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 button.
5. Press the TIME button again. Now the last two characters will flash (day).
6. Set the day using the MEMORY 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 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 button.
11. After completing the settings, press TIME. Now the settings are confirmed and the clock starts running.
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.

After pressing the TIME and MEMORY buttons, data is entered (e.g. switching from hours to minutes or changing the value by +1). After pressing and holding the button, the switching is much quicker.

6. TAKING MEASUREMENTS

6.1. 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.
- Take measurements on a regular basis, every day at the same time, because blood pressure varies throughout the day.

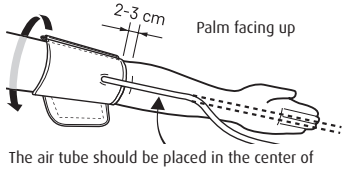
6.2. Most frequent errors

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. Select 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.

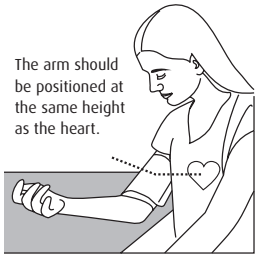
6.3. Fitting the cuff

1. Firmly insert air tube plug in the air tube socket that is on the left side of the device (air tube socket) - page 4.
2. Insert the end of the cuff under the metal buckle, with the velcrofacing 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 go easily fitted on the arm and the
6. Velcro should be closed easily.
7. After wrapping 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.
9. Your feet should not be crossed and rest flat on the floor; shoulders and arms should be supported.



The air tube should be placed in the center of the arm

- 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.



6.4. 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.

7. MEASUREMENT PROCEDURE

7.1. Standard measuring mode (one measurement mode)

In standard measuring mode it is possible to detect arrhythmia, but it is impossible to detect signs of atrial fibrillation (AFIB).

After wrapping the cuff properly, you can start taking the measurement:

a) Press the button, the cuff will start inflating. The increasing cuff pressure is displayed continuously on the LCD.

b) Cuff indicator: if the cuff does not fit correctly, the symbol will be displayed and flash during taking the measurement. The symbol indicates well-fitted cuff. (Fig.1)

c) Movement Error Indicator: the symbol appears if the arm movement is detected. This, in fact may compromise the accuracy of the measurement. In the case of the slighest arm movement the measurement can be continued. In the case of the significant arm movement, the measurement will not be continued, the symbol „Err2" will be dispalyed (Fig.2)

Fig. 1

Fig. 2

d) When the appropriate pressure in the cuff is reached, the pump stops and pressure starts to decrease slowly. During the measurement, pressure of the cuff is displayed (capital digits). When the pulse is detected, the heart icon will start blinking on the screen.
e) After completing the measurement, the values of systolic and diastolic pressure and the pulse rate appear on the screen (Fig. 3)

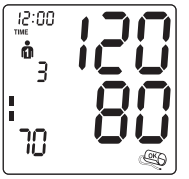
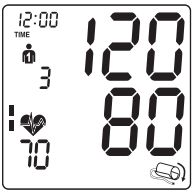
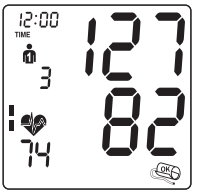


Fig. 3

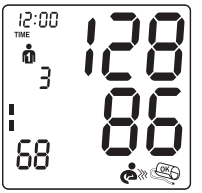
EXAMPLE 1
Systolic pressure 120, diastolic pressure 80, pulse 70. Arrhythmia is detected, too loosely fitting cuff.



EXAMPLE 2
Systolic pressure 127, diastolic pressure 82, pulse 74. Arrhythmia is detected, cuff is wrapped correctly.



EXAMPLE 3
Systolic pressure 128, diastolic pressure 86, pulse 68. Arm movement is detected, cuff is wrapped correctly.



The results of the measurement will be displayed until the device is turned off. If no button is pressed within 3 minutes, the unit will automatically turn off to save the battery power.

7.2. AFIB measuring mode (two measurements mode)

In AFIB measuring mode, the device takes two subsequent measurements and the result is automatically analysed and displayed. Blood pressure varies constantly, due to that the result based on two measurements is more reliable than in case of one measurement.

- Press the button Afib, the symbol will appear on the screen.
- On the bottom left side of the screen, digits "1" or "2" are displayed. They indicate the first or the second measurement.
- There is 15-seconds interval between measurements. In accordance with "Blood Pressure Monitoring, 2001, 6:145-147", a 15-second interval between the readings is enough to perform the next measurement. A timer counts down showing how much time remains to a new measurement.
- The device does not display separate results. The values of blood pressure appear on the screen only after two measurements were performed.

NOTICE: Do not remove the cuff between measurements.
If one of the measurement results is doubtful , the device will automatically take the third one.

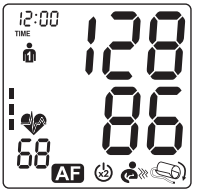
Measuring procedure:

The pressure of the cuff is displayed when the measurement is performed. When pulse rate is detected, the heart symbol will start flashing on the screen.

Measurement results:

The values of systolic and diastolic pressure and the pulse rate will appear on the screen.

EXAMPLE 4
Systolic pressure 128, diastolic pressure 86, pulse 68, arrhythmia is detected. Arrhythmia and signs of atrial fibrillation AF are displayed on the screen. The arm movement is detected, too loosely fitted cuff.



EXAMPLE 4

EXAMPLE 5

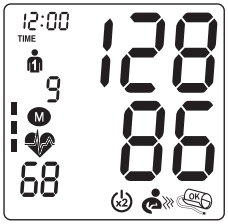
Systolic pressure 128, diastolic pressure 86, pulse 68, arrhythmia is detected, but signs of atrial fibrillation is not detected. The arm movement is detected; the cuff is wrapped correctly.

EXAMPLE 5

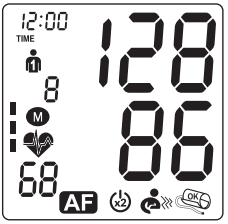
The results of the measurement will be displayed until the device is turned off. If no button is pressed within 3 minutes, the unit will automatically turn off to save battery power.

8. MEMORY

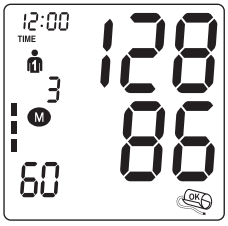
Internal memory stores 120 of measurement results.
After pressing the MEMORY button, the device will display the average score of 3 most recent measurements, also the last measurement and further 120 measurements (Mr119, Mr118,...,MR1) one by one.



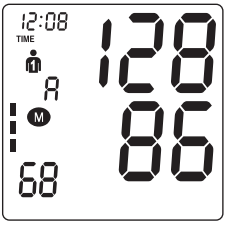
AFIB measuring mode
the measurement result no. 9



AFIB measuring mode
the measurement result no. 8



STANDARD measuring mode
the measurement result no. 3

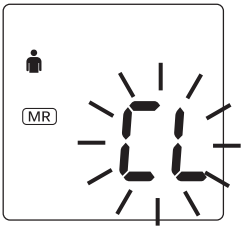


Symbol "A" indicates the average score
of 3 most recent measurements

8.1. Deleting all measurements

NOTICE

Before you delete all the results stored in memory, make sure you will not need them in the future. It is sensible to have a written register of measurement results, due to that more information can be provided to a doctor during a visit at doctor's office. To remove all saved results, hold down the "MEMORY" button for at least 5 seconds. Release the button, when "CL" appears on the screen. Press the button "MEMORY" while blinking "CL" to permanently delete the memory of saved measurements.



9. SYMBOL INDICATING ARRHYTHMIA

Diagnostic Pro Cardio Afib blood pressure monitor is a fully automatic digital device that also analyses pulse rate during blood pressure measurement. If an irregular pulse (arrhythmia) is detected during measurement, the symbol is displayed after completion of the measurement (when the measurement results are displayed). In most cases, this does not give cause for concern. However, if this symbol appears frequently (e.g. several times per week on measurements performed daily), we recommend you to inform your doctor. This device does not replace heart diseases diagnostics, but serves as a device to detect arrhythmia at an early stage.

10. SYMBOL INDICATING DETECTION OF SIGNS OF ATRIAL FIBRILLATION

The device detects signs of atrial fibrillation. If signs of atrial fibrillation is detected during the measurement, the symbol AF is displayed after completion of the measurement (when the measurement results are displayed). If this symbol is displayed after having performed a full measurement (two-fold measurement), we advise you to wait one hour and retake your measurement. If the signs of atrial fibrillation symbol is displayed again, we recommend you to inform your doctor. If after repeated measurement, the symbol does not appear there is no cause for concern. In that case, it is advisable to take another measurement again the next day. The device may not detect signs of atrial fibrillation for patients with pacemakers and defibrillators.

11. ERROR MESSAGES

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

Error code	Possible cause ERR
ERR 1	No pulse detected.
ERR 2	Measurement results affected by interference. Cause: there was an arm movement during measurement.
ERR 3	Inflation of the cuff has taken 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 carefully following the instructions. If unusual results still occuers, contact the doctor.
ERR 8	The pressure 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 AT OPENING THE DEVICE WILL VOID THE WARRANTY!
If, during the use of the device, a problem occurs, please check the following items and undertake the listed remedial measures.

NOTICE: Use only the accessories provided by the manufacturer. Parts and accessories that have not been approved for use with this device may cause damage.

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.
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).

12. MAINTENANCE

- Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
- When fitting the cuff, be careful and avoid deformation by twisting or bending.
- 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!
- Be careful not to drop the device and handle it with care. Avoid strong vibrations.
- Do not open the device.

Periodic services:

- The measuring device requires regular services.
- For that reason, we recommend to carry out periodic services of the pressure monitor every 2 years. More information will be provided by Diagnosis or local distributor.

13. WARRANTY

The Diagnostic Pro Cardio Afib blood pressure monitor is covered by a 5-years warranty starting from the purchase date. The warranty does not cover damage due to improper handling, accidents, noncompliance with the user manual, or changes made in the device by third parties. The warranty is only valid on presentation of the warranty card.

14. ⚠ SAFETY AND DISPOSAL

- This appliance may only be used for its intended purpose as described 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.
- Ensure that children do not use the device unsupervised, as some parts of this appliance are small and can be swallowed.
- Use only original elements supplied by the manufacturer. The use of other elements may reduce the level of safety.

15. SYMBOLS

Symbol	FUNCTION/MEANING	Symbol	FUNCTION/MEANING
⊕ AA ⊖	Indication of battery polarity	⚠	Caution
MD	Medical Device	IP20	Protection against ingress of water and foreign objects.
☐	Isolation Class II	⎓	Direct current
	Type BF Applied Part	SN	Serial number
REF	Catalogue number		Date of manufacture
	Irregular pulse symbol		Manufacturer
AF	Signs of Atrial Fibrillation Indicator Symbol	Rev.	Date of the last revision
	Keep dry	SYS	Systolic blood pressure in mmHg
	Keep away from sunlight	DIA	Diastolic blood pressure in mmHg
	Follow Instructions for Use	Pul./min	Pulse. Number of beats per minute.
CE 0197	Symbol attesting compliance with the European Union Directive 93/42/ECC for medical devices		
	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 or your local distributor.		

16. TECHNICAL SPECIFICATION

Measurement method	Oscillometric Digital
Display	LCD display
Measurement range	Pressure: 30–280 mmHg (±1 mmHg) Pulse: 40–199 beats per minute
Measurement accuracy	Pressure: ±3mmHg Pulse: ±5% reading
Air inflating	Automatic pumping device
Air deflating	Automatically through air valve
Memory function	2 x 120 measurements with date and time
Power supply	6V (4 x AA alkaline batteries) or power adapter USB-C. Input: AC 100-240 V - 50/60 Hz 0.15A; Output: DC 5.0 V / 1,0 A
Operating Conditions	Temperature: 5–40°C (41–104°F); Humidity: 15–85% RH Atmospheric pressure: 860–1060 hPa
Storage and Transportation Conditions	Temperature: -10–55°C (14-131°F); Humidity: 10–95% RH Atmospheric pressure: 860–1060 hPa
Dimensions	128 × 92 × 61 ±1.0 mm
Weight	505 g ±5 g
Protection against electric shock	Internally powered equipment
Safety classification	Type BF
Operating mode	Continuous operation
Protection against ingress of water	IP20
Contents	Blood pressure monitor, cuff size M/L (22-42cm), 4x AA batteries, instruction for use, carrying case, power adapter USB-C

Manufacturer reserves the right to make changes to specification

Standard for the device: This device is subject to the requirements of the European standard for non-invasive blood pressure monitors.
Standards
IEC 60601-1-6:2010+A1:2013+A2:2020 / EN 60601-1-6:2010+A1:2015+A2:2021
IEC 60601-1:2005+A1:2012+A2:2020 / EN 60601-1:2006+A11:2011+A1:2013+A12:2014+A2:2021
IEC 60601-1-2:2014+A1:2020 / EN 60601-1-2:2015+A1:2021
IEC/EN 60601-1-11:2015+A1:2020
IEC 80601-2-30:2018 / EN 80601-2-30:2019
The provisions of the EU guideline 93/42/EEC for class IIa medical devices are fulfilled.

Guidelines and manufacturer's declaration - electromagnetic emissions

Diagnostic Pro Cardio Afib is intended for use in the electromagnetic environment specified below. The customer or the user of Diagnostic Pro Cardio Afib 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.

Guidelines and manufacturer's declaration regarding electromagnetic immunity

Diagnostic Pro Cardio Afib is intended for use in the electromagnetic environment specified below. The customer or the user of Diagnostic Pro Cardio Afib 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.

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	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 Pro Cardio Afib operates exceeds the appropriate level of compliance, normal operation of Diagnostic Pro Cardio Afib should be checked. If improper operation is observed, it may be necessary to take appropriate preventive steps such as moving or relocating the Diagnostic Pro Cardio Afib.
(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

Recommended separation distance between portable and mobile radio communication equipment and Diagnostic Pro Cardio Afib

Diagnostic Pro Cardio Afib 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 Pro Cardio Afib can help prevent electromagnetic interference by keeping a minimum distance between portable and mobile radio communication equipment (transmitters) and Diagnostic Pro Cardio Afib, 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 2,5 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.

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pieczątka sklepu i podpis sprzedawcy

WARRANTY CARD

Diagnostic Pro Cardio Afib

MODEL ..... SERIAL NUMBER ..... DATE OF SALE .....

WARRANTY TERMS

1. Diagnosis S.A. grants a warranty :
- 5 years for blood pressure monitor Diagnostic Pro Cardio Afib
- 2 years for cuffs Diagnostic
- 1 year for power adapter 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.

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! Do not send items or accessories which are not the subject of the complaint e.g. air tube, power supply, etc. Before sending the device for repair, please clean it from all kinds of dirt. Concerns only customers from Poland. If you are outside Poland please contact distributor in your country.

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