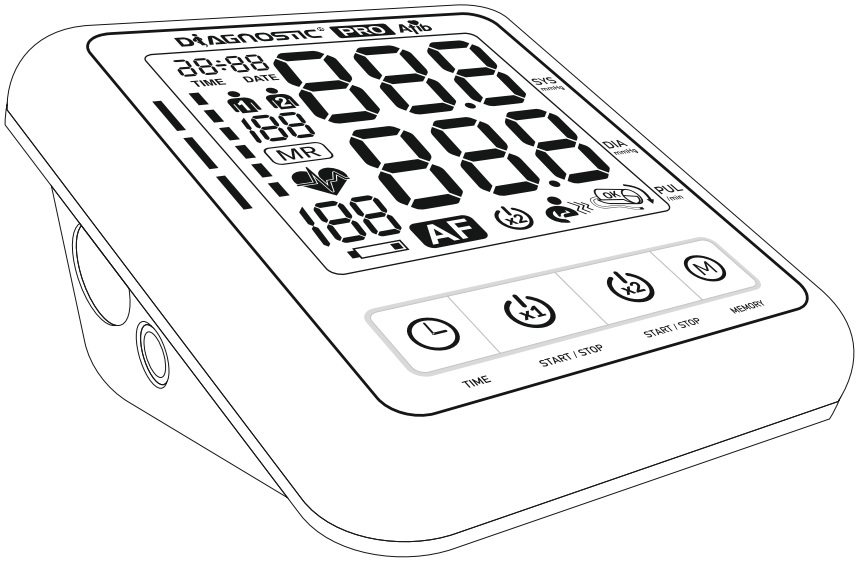
INSTRUCTION MANUAL

DIAGNOSTIC® PRO Afib

AUTOMATIC UPPER-ARM BLOOD PRESSURE AND PULSE MONITOR WITH ATRIAL FIBRILLATION DETECTION



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REF 5128

CE 0197

CONTENTS

Thank you for buying the blood pressure and pulse monitor Diagnostic PRO Afib. The model can be used with irregular pulse and atrial fibrillation. If the device detects irregular pulse, the symbol appears on the display. If the device detects atrial fibrillation, the symbol AF appears on 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.

1. INTRODUCTION

1.1. Device features

The Diagnostic PRO Afib 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 in pre-eclampsia.
- Pay attention not to entangle the tubing 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.

⚠ Self-measurement means control and not diagnosis and treatment .Unusual values should always be consulted with your doctor. You should under no circumstances 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.

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 self-measurements. 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 individually change 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
Hypotension below	100 below	60 Consult	your doctor
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 your doctor
Too high blood pressure	from 140 to 160	from 90 to 100	Imperative contact your doctor
Significantly elevated blood pressure	from 160 to 180	from 100 to 110	Imperative contact your doctor
Dangerously high blood pressure	Above 180	Above 110	Immediately contact your 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.

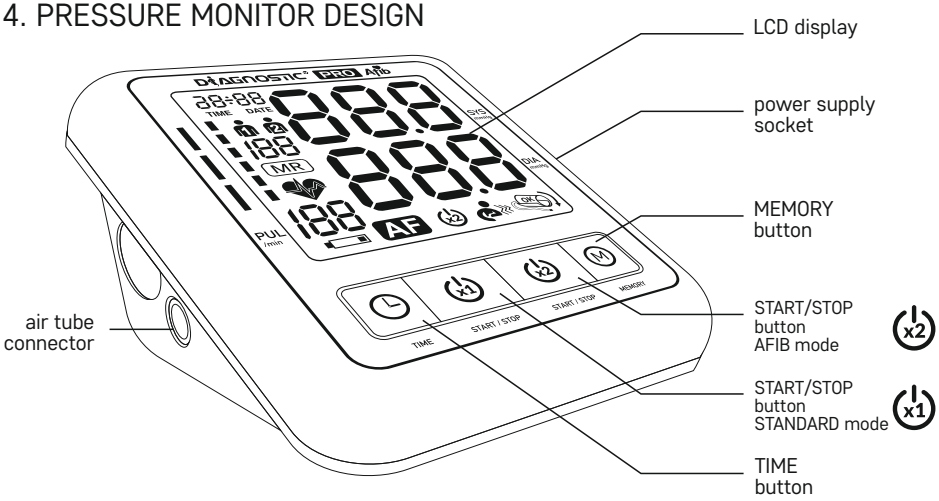
3.1 Harmful impact of atrial fibrillation for me and my family.

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 .

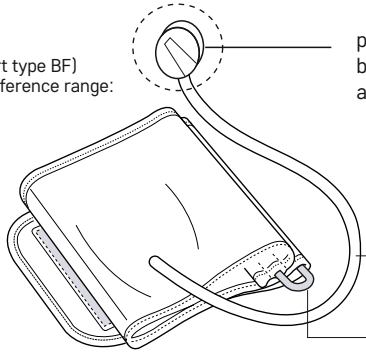
Pro Afib detection provides a convenient way to screen for AFIB. Knowing your blood pressure and knowing whether you or your family members have atrial fibrillation can help reduce the risk of stroke. Pro Afib detection provides a convenient way to screen for atrial fibrillation whilst taking your blood pressure. Risk factors you can control high blood pressure and atrial fibrillation are both considered controllable risk factors for strokes. Knowing your blood pressure and knowing whether you have atrial fibrillation is the first step in proactive stroke prevention.

4. PRESSURE MONITOR DESIGN

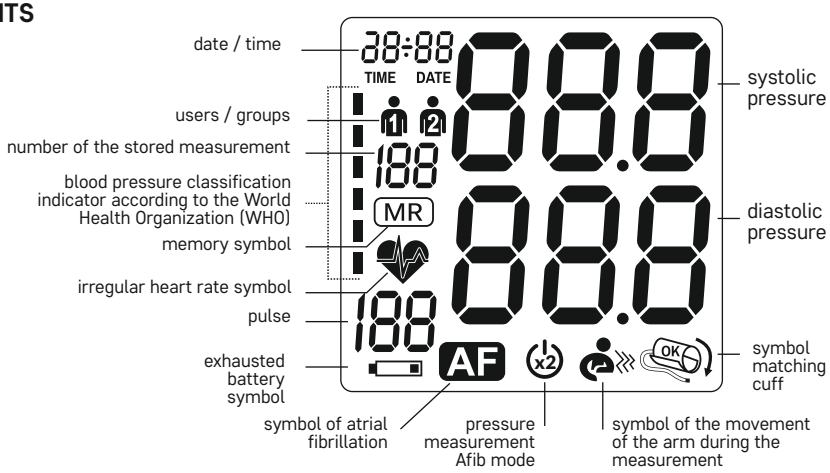


CUFF

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



DISPLAY ELEMENTS



5.STARTING THE DEVICE

5.1 Installing battery

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. Reinstall 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 must be replaced, otherwise the device may fail to operate properly.
   - After replacing batteries, you must reset the time and date..
   - After the battery warning icon is displayed, the device will not turn on until the battery is replaced.
   - Use batteries of AA Long-Life type or alkaline 1.5 V. It is not recommended to use 1.2 V rechargeable batteries.
   - DIf the 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 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.

If the low battery symbol is displayed, they should be replaced with new ones.

5.3 Power adapter

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.
   - Power adapter specification: 100~240 V, 50/60Hz; output: 6V, min. 600mA
   - 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 adaptor is added to the set.**


power supply

5.4 User selection and setting date and time

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. Change the user by pressing the memory button (M). To confirm user selection, press the START/STOP button.

c) We recommend that the first person who takes measurement is 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 reading. After inserting the new batteries, the CLOCK will be set to 12:00 and the DATE to 1-01. You must then 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 hours character will flash.
8. Set the hour using the MEMORY button.
9. Press the TIME button again. Now the last two characters will flash (minutes).
10. Set the exact time, i.e. minutes, using the MEMORY button.
11. Press the TIME button: the measurement unit will start flashing.
12. Press the MEMORY button to set the unit of measurement (mmHg or kPa).
13. After completing the settings, press TIME. Now the settings are confirmed and the timer starts running.
14. After completing all the settings, press the TIME button once again.

The device will briefly display the date and time. Now the entered settings are 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 Prior to 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,
- sitting on a chair in a quiet environment 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.

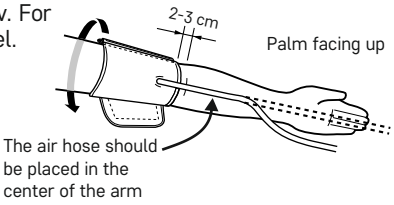
6.2 Most frequent errors

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 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 fitting 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 Wrapping the cuff

1. Insert the tip of the air duct firmly in the opening on the left side of the unit (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 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.
8. Your feet should not be crossed and rest flat on the floor; shoulders and arms should be supported.
   - 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 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.

7. MEASUREMENT PROCEDURE

7.1. Measurement STANDARD mode (one measurement mode)

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

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

a) Press the (x1) button, the cuff will start inflating. The increasing cuff pressure is displayed continuously.

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

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. 2

d) When the appropriate pressure of the cuff is reached, the pump stops and pressure starts to slowly decrease. 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 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, which is why the result based on two measurements is more reliable than in case of one measurement.

- Press the button (x2), the symbol (x2) will appear on the screen.
- On the bottom left-hand side of the screen, digits "1" or "2" of the measurement performed are displayed (first or second measurement).
- There is 15-seconds interval between measurements. (In order to perform next measurement, a 15-second interval between blood pressure readings is accurate, in accordance with "Blood Pressure Monitoring, 2001, 6:145-147"). A timer counts down showing how much time remains for starting 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 during the measurement is performed. When pulse rate is detected, the heart symbol will start blinking on the screen.

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

EXAMPLE 4

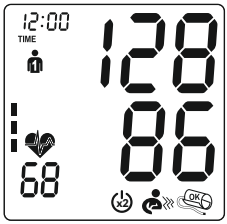
EXAMPLE 4 Systolic pressure 128, diastolic pressure 86, pulse 68, arrhythmia is detected. Arrhythmia and atrial fibrillation symbols are displayed on the screen AF. The arm movement is detected, too loosely fitting cuff.

EXAMPLE 5:

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

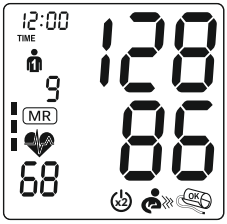
The results of the measurement will be displayed until the device is turned off. If no button is pressed within 3 minutes, the unit will automatically turn off to save battery power.

EXAMPLE 5

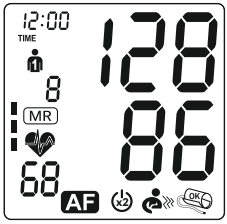


8. MEMORY

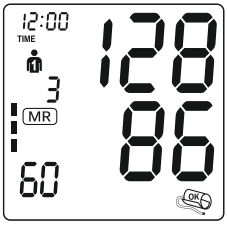
Internal memory stores 120 of measurement results.
After pressing the MEMORY button, the device will display the average score of 3 most recent measurements, also the last measurement and further 120 measurements (Mr119, Mr118,...,MR1) one by one.



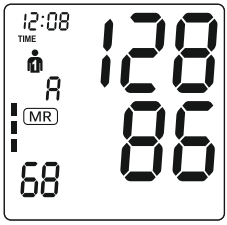
AFIB measuring mode
the measurement result no. 9



AFIB measuring mode
the measurement result no. 8



STANDARD measuring mode
the measurement result no. 3

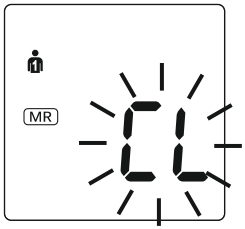


Symbol "A" indicates the average score of 3 most recent measurements

8.1 Deleting all measurements

NOTICE

Before deleting all the results stored in the memory, make sure that they will not be needed in the future. It is prudent to conduct a measurement log, which allows to provide more information during a visit to the doctor's office. To remove all stored results, press and hold the MEMORY button for at least 5 seconds. Release the button when the screen displays "CL". To permanently delete the entire memory, press the MEMORY button while the "CL" is flashing.



9. SYMBOL INDICATING ARRHYTHMIA

Pro Afib 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 ATRIAL FIBRILLATION

The device detects atrial fibrillation. If 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 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 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 wrapped 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 persist, contact your doctor.

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). If, 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 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.

FAULT	REMEDIAL MEASURES
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.	1. 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.	1. 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 wrapping 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 inspections

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

13. WARRANTY

The **Diagnostic PRO Afib** blood pressure monitor is covered by a 2-year warranty starting from the purchase date. The warranty does not cover damage due to improper handling, accidents, non-compliance 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

⚠
- The device may be used only for its intended purpose as described in the user manual. 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 wrapped
- The device is not intedud for usa in the electromagnetic enviranment generated by all 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.
- Take care to prevent children from using the device without supervision; some parts of the device are small and may be swallowed.
- Use only original elements supplied by the manufacturer. The use of other elements may reduce the level of safety.

15. SYMBOLE

SYMBOL	FUNCTION/MEANING	SYMBOL	FUNKCJA/ZNACZENIE
⊕ AA ⊖	Indication of battery polarity	⚠	Warnings
CE 0197	Symbol attesting compliance with the European Union Directive 93/42/ECC for medical devices	⎓	Direct curret
		SN	Serial number
	Application part type BF		Manufacturing date
REF	Product catalog number		Manufacturer
	Irregular pulse symbol	Rev.	Date of the last revision
AF	Atrial Fibrillation Indicator Symbol	SYS	Systolic blood pressure in mmHg
	Protect against moisture	DIA	Diastolic blood pressure in mmHg
	Keep away from sunlight	PUL./min	Pulse. Number of beats per minute.
	Read the user manual before use	IPX0	Protection against ingress of water

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. If you are in doubt where to return the used appliance, contact Diagnosis. Free infoline 800 70 30 11

12. TECHNICAL DATA

Measurement	Oscillometric Digital
Display method	LCD display
Measurement range	Pressure 30 to 280 mmHg (± 1 mmHg) Pulse: 40 do 200 beats per minute
Measurement accuracy	Pressure: ±3mmHg Pulse: ±5% reading
Inflating	Automatic pumping device
Deflating	Automatically through air valve
Memory function	2 x 120 measurements with date and time
Power supply	4 x AA alkaline batteries or power adapter DC 6.0 V, min. 600 mA (optional)
Conditions of use	5~40°C, 15%~85% relative humidity
Transportation and storage	-10~55°C, 10%~95% relative humidity
Dimensions	135×115×72±1.0 mm
Weight	540 g±5g
Protection against electric shock	Internally powered equipment
Safety classification	Type BF
Operation	Continuous mode
Protection against ingress of water	IPX0
Accessories	Cuff sized M/L (22-42 cm), 4x batteries AA, adaptor Diagnostic ZID 6-1 (100-240 V, 50/60 Hz, 6 V, 1000 mA (1 A)), user manual, carrying case

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 requirements	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 standard	Group 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		

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

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	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	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.
Voltage dips, short interruptions and voltage changes on power supply inlets IEC 61000-4-11	<5 % UT (>95 % clip in UT) for 0,5 cycle 40 % UT (60 % clip in UT) for 5 cycle 70 % UT (30 % clip in UT) for 25 cycle <5 % UT (>95 % dip de UT) dla 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.
Magnetic field of the power supply frequency (50/60 Hz) IEC 61000-4-8	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.

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

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 do 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.
Emitted radio-frequency signal IEC 61000-4-3	3 V/m 80 MHz do 2,5 GHz	3V/m	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 

Note 1: For 80 MHz and 800 MHz, the higher frequency range is assumed.

Note 2: The provided information does not apply in every situation. The propagation of electromagnetic waves is affected by the absorption and reflection from the surfaces, 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 DEVICE operates exceeds the appropriate level of compliance, normal operation of the DEVICE should be checked. If improper operation is observed, it may be necessary to take appropriate preventive steps such as moving or relocating the DEVICE.

(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 distance 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 do 80 MHz d = 1,16	80 MHz do 800 MHz d = 1,16	800 MHz do2.5 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.

Diagnosis S.A.
ul. Gen. W. Andersa 38A, 15-113 Białystok, Poland
Free infoline 800 70 30 11
tel./fax 85 732 46 22, 732 40 99
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ul. Przemysłowa 8,
16-010 Wasilków, Polska
tel. 85 874 60 45
serwis@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:
   - 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.

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