INSTRUCTION FOR USE

DIAGNOSTIC®

PRO SENSE

AUTOMATIC UPPER-ARM BLOOD PRESSURE
AND PULSE MONITOR

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

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Thank you for buying the blood pressure and pulse monitor Diagnostic PRO SENSE. The blood pressure monitor has an MDI function - measuring pressure and pulse while the cuff is being inflated. The MDI technology ensures fast and accurate results. With less pressure on the arm, measurement is more comfortable. This device provides very high, clinically tested measurement accuracy and has been designed to be as user-friendly as possible.

Please carefully read this users manual 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

Blood Pressure Monitor Diagnostic PRO SENSE is a fully automatic digital device to measure the 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. The device is intended for self measurement of blood pressure at home.
For more information on blood pressure and blood pressure measurement, please contact the 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.
- 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 electro-surgical 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.

- 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 for babies. 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.

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 ypertension / 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

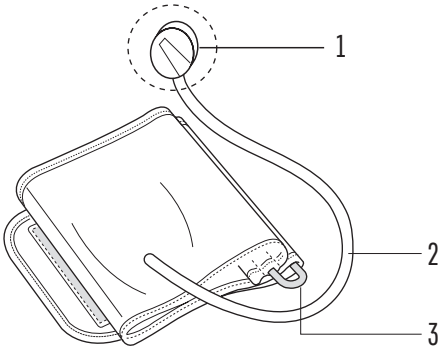
- **If the values of your blood pressure at rest are usually normal, but elevate during stress, you may suffer from labile (latent) hypertension, consult the doctor.**
- **Correctly measured diastolic pressure is above 120 mmHg, it requires immediate medical treatment.**

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

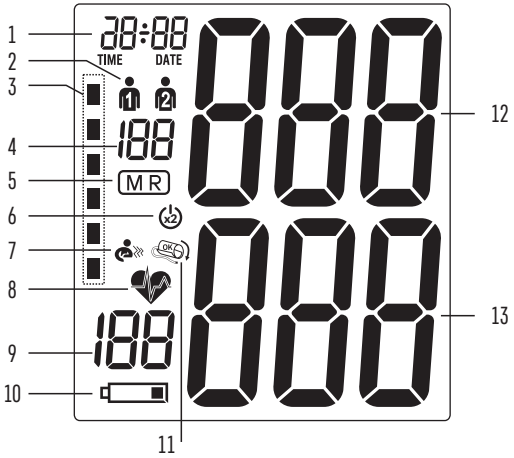
3.2 Cuff



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

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

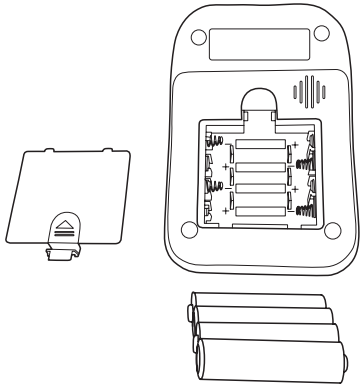
3.3 Display elements



1. Date/Time
2. Users/Groups
3. Blood pressure classification indicator according to the World Health Organization (WHO)
4. Number of the stored measurement
5. Symbol of the average measured value
6. 2 subsequent measurements mode (MAC)
7. Symbol of arm movement during measurement
8. Irregular cardiac detection symbol is displayed when the measurement is finished. Pulse symbol is displayed during the measurement
9. Pulse value
10. Low battery symbol
11. Cuff Fit Symbol
12. Unit of measurement
13. Systolic pressure
14. 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.

⚠ Important safety information

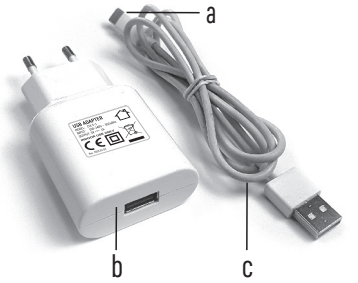
1. Replace batteries when Low Battery Indicator appears on the screen. Replace all batteries at the same time.
2. Do not use expired batteries.
3. After replacement of batteries set the time and date.
4. Insert batteries being careful to observe their correct polarity indicated in the battery compartment for batteries.
5. Do not mix battery types. Long-life alkaline batteries are recommended. It is not recommended to use 1,2 V batteries.
6. Remove the batteries from device when it is not used for more than 3 months.
7. Dispose batteries properly; observe local laws and regulations.
8. Do not mix new and expired batteries simultaneously.
9. The battery has a positive pole and a negative pole. If you cannot easily insert the the battery into the device, do not force it in.
10. During the use of the power supply or replacing batteries, the person taking the measurement, should not touch the elements and the patient simultaneously.
11. Periodically, make sure that the batteries have not passed their expiry date. If this is the case, replace them with new ones.

4.2 Battery life

- Four new LR6 (AAA) batteries last for approximately 700 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.

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, model Diagnostic ZUI 5-1
   - Do not use the power adapter if the device or power cord is damaged. Immediately turn off the power and unplug the cable from the outlet.
   - Do not touch the power supply with a wet hand.
   - When the device is operating, do not tangle, twist and broke cables.
   - Disconnect before cleaning the AC supply plug.
   - The power supply is added to the set optionally. (additionally paid)



a. Micro USB, b. Power supply USB c. USB cable

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.

- 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**).
- Hold down the TIME button ⏲ with the device OFF for at least 3 seconds. The screen will display a blinking user icon.
- Change the user by pressing the memory button Ⓜ. To confirm user selection, press ⏻.
- It is recommended to set the first person who takes measurement as **user 1**.
- After pressing the TIME button ⏲, the set date will be displayed.

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 ⏲ with the device OFF 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 or TIME/DATE button ⏲. 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.

Each time the TIME button ⏲ is pressed, it moves to the next settings. The MEMORY button Ⓜ changes the value by 1 (In case of date/time settings it causes +1 change, while in the measurement history it causes going to an older measurement). When you hold the button down for 3–4 seconds the switching goes quicker.

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.

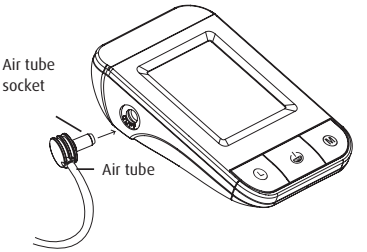
5.2 Most frequent errors

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

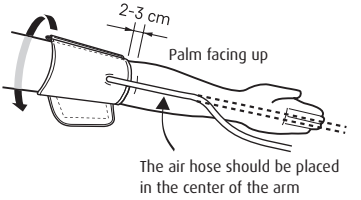
- All the patient's efforts to support the arm may result in increased blood pressure. Select a comfortable and relaxed position. During the measurement, do not stretch any muscles of the arm on which the cuff is wrapped. If necessary, use a pillow as a support.
- The operation of the pressure monitor may be disturbed by extreme temperatures, humidity and atmospheric pressure.
- Pay attention not to press, pinch or bend the cuff and 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).

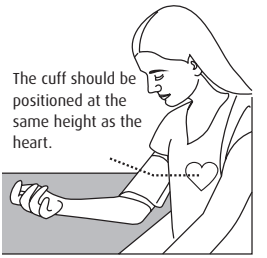
5.3 Fitting the cuff



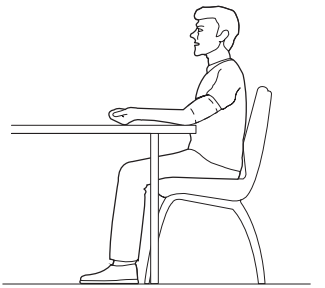
1. Insert the tip of the air duct firmly in the opening on the left side of the device (air tube socket signed CUFF).
2. Insert the end of the cuff under the metal buckle, with the velcro facing out.
3. Remove the tight-fitting clothing from the arm on which the measurement is being made. You shouldn't 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. The compression of arm caused by tucked up sleeve may prevent accurate reading.



5. The cuff should be easily fitted on the arm and the Velcro should be closed easily.
6. After fitting the cuff, make sure that there is sufficient space under the cuff to fit a finger.
7. If the cuff does not fit on the arm, the accuracy of measurements may be incorrect.
   - Do not fold the cuff or the air tube.
   - To disconnect the cuff, remove the air tube plug from the device.
   - Measurement can be started only after fitting 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.



5.4 Body posture during 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.

5.5 Measurement procedure

5.5.1 MEASUREMENT IN STANDARD MODE

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

Fig. 1

a. Press the button START/STOP, the cuff will start inflating. Cuff pressure increasement is displayed on the screen. (Fig. 1).
b. Cuff fit indication: the icon will appear and flash during measurement if the the cuff is too loose. The icon will appear during measurement if the cuff is correctly applied. (Fig. 1).
c. Arm movement detected during measurement: this icon will be displayed if movement is detected which may adversely affect the accuracy of the measurement. In case the movement was slight the measurement can continue; in case of a significant movement, the measurement cannot be continued, error Err5 will be displayed.
d. Once the correct pressure is reached, the device will stop and the pressure will start decreasing slowly. During measurement, the cuff pressure is displayed (large characters). When a pulse is detected the heart icon on the screen will flash. The systolic, diastolic blood pressure readings and the heart rate value are now displayed.

Fig 2

EXAMPLE

Systolic blood pressure is 126, diastolic blood pressure is 85, heart rate is 78. (Fig. 2)

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 off to save batteries.

5.5.2 MAC MEASUREMENT (2-MEASUREMENT MODE)

MAC mode, the device automatically takes 2 consecutive measurements and the result is automatically analysed and displayed. As the blood pressure is constantly changing, the result determined in this way is more reliable than a single measurement.

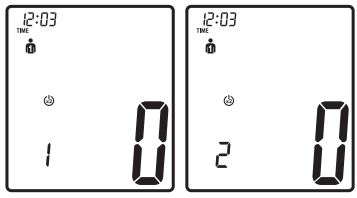


Fig. 3

- If you press and hold the ON/OFF button for approx. 2 seconds, the display will show the symbol .
- Numbers 1, 2 appear in the centre of the left side of the display to indicate which of the two measurements is being taken. (Fig. 3)
- There is an interval of 15 seconds between measurements. A countdown indicates the remaining time.
- The device does not display individual results. Your blood pressure values will only be displayed after 2 measurements have been taken.
- Do not remove the cuff between measurements.
- If one of the measurements is questionable, the device will automatically perform a third measurement.

5.5.3 MEASUREMENT PROCEDURE

As the cuff inflates, the device will automatically detect the level of optimal inflation. This device detects blood pressure and heart rate during the inflation process. The symbol flashes with each heartbeat. Once heart rate is detected, the heart icon on the screen will start flashing with each heartbeat.

5.5.4 MEASUREMENT RESULTS

The values of the measured systolic, diastolic pressure and heart rate will be displayed.

Fig. 4

EXAMPLE 1

Systolic pressure 126, Diastolic pressure 85, pulse 78.
The cuff has been fitted properly . (Fig. 4)

EXAMPLE 2

Systolic pressure 128, diastolic pressure 70, pulse 80. Irregular pulse detected , the cuff has been fitted too loosely (Fig. 5).

Fig. 5

5.5.5 Interruption of the measurement

To stop the blood pressure measurement (for example, when the patient does not feel well), you can press the START/STOP button immediately 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.

6.1 Memory viewing

- To access the memory resources, press the MEMORY button Ⓜ.
- The device will display the average result of the last 3 measurements M R A (Fig. 6). After the next pressing the MEMORY button Ⓜ, the last measurement will be displayed.
- Pressing the MEMORY button Ⓜ again allows the user to view the measurement results from the newest (maximum M R 120 (Fig. 7)) to the oldest (M R 1 (Fig. 8)).
- If the symbol is displayed with the memory data, it indicates that during this measurement irregular pulse was detected.

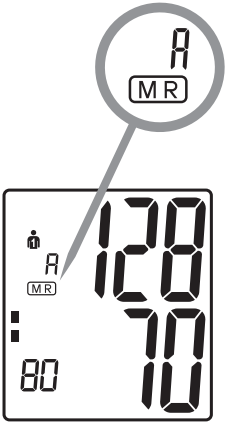


Fig. 6

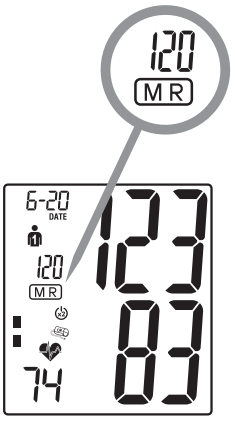


Fig. 7

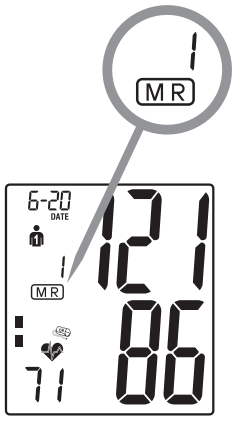
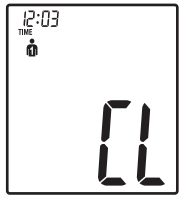


Fig. 8

6.2 Memory – deleting all measurement results



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 Ⓜ with the device OFF 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. When the results will be deleted, press the MEMORY button Ⓜ while flashing "CL".

7. EARLY DETECTION OF IRREGULAR HEARTBEAT

If an irregular pulse 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.

INFORMATION FOR A DOCTOR IN CASE OF FREQUENT APPEARANCE OF THE IRREGULAR HEART BEAT INDICATOR

The device is an oscillometric blood pressure monitor with an extra function of pulse measurement. The device was clinically tested. If the device detects irregular heart beat two or more times during the measurement, on the screen with the measurement results, there appears the irregular heart beat indicator 💔. An irregular heartbeat rhythm is defined as a rhythm that varies by less or more than 25% from the average rhythm detected while the monitor is measuring the systolic and diastolic blood pressure. Using the device is not a substitute for cardiological examinations, but it allows early detection of the presence of an irregular pulse.

8. 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	Systolic blood pressure is over 280 mmHg

Further information. Blood pressure varies even in healthy people, that is why it is important to take maesurements always 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!

9. TROUBLESHOOTING

If, during the use of the device, a problem occurs, please check the following items and undertake the listed remedial 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 (page 11). 2. Take another blood pressure measurement in a quiet and peaceful environment, following the instructions for use (page 9).
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 "6.2 Most frequent errors" on page 10. 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).

If your blood pressure monitor does not operate correctly after applying the above solutions, please contact the distributor or the manufacturer, helpdesk: 800 70 30 11 or 85 874 60 45, 85 874 69 28 (between 8 AM and 4 PM; Polish language only).

INCIDENTS REPORTING. Any serious incident that has occurred in connection with this product should be reported to the manufacturer and the competent authority of the member state where the notifier is residence.

10. CALIBRATION AND MAINTENANCE

a. Do not expose the device to extreme temperatures, humidity, dust or direct sunlight. The cuff has a sensitive, impermeable reservoir (bladder).
b. 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.

11. SAFETY AND DISPOSAL

- 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.

12. SYMBOLS

Symbols description			
Symbol	**Explanation**	**Symbol**	**Explanation**
⊕ AAA ⊖	Indication of battery polarity		Isolation Class II
	Type BF Applied Part		Follow instructions for use
REF	Catalogue number		Caution
SN	Serial number		Direct current
UDI	Unique Device Identifier		Date of manufacture
MD	Medical device		Manufacturer
Rev.	Date of the last revision		Indoor use only
	Humidity limitation		Atmospheric pressure limitation
	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.		Temperature limit
			Keep dry
			Keep away from sunlight
		IP	Classification IP – means degree of protection provided by housing in accordance with in accordance with the requirements of IEC 60529 standard.

13. TECHNICAL SPECIFICATION

Product description	Fully automatic digital device for measuring blood pressure on the upper arm	
Model	PRO SENSE	
Measurement method	Oscillometric	
Display	LCD display	
Measurement range	Pressure	30–280 mmHg
	Blood pressure measurement accuracy	±3 mmHg
	Pulse	40–199 beats per minute
	Pulse measurement accuracy	±5% reading

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 AAA alkaline batteries or power adapter Micro USB DC 5,0 V / 1,0 A (optional)
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	135×90×41 ±1 mm
Weight	365 ±5 g with batteries and cuff
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
Operating mode	Continuous operation
Product lifetime	Blood pressure monitor: 5 years Cuff: 2 years
IP Classification	IP20 – protection against finger touch and against the ingress of foreign bodies inside. Protection against foreign solids with a diameter of 12.5 mm and larger.
Contains	Blood pressure monitor, cuff size M/L (22–42 cm), 4 × AAA alkaline batteries, instruction for use, power adapter, carrying case

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

14. STANDARDS USED

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 / EN 60601-1-6:2010+A1:2015
IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A11:2011+A1:2013+A12:2014
IEC 60601-1-2:2014 / EN 60601-1-2:2015
IEC/EN 60601-1-11:2015; IEC 80601-2-30:2009+A1:2013 / EN 80601-2-30:2010+A1:2015
The provisions of the EU Guideline 93/42/EEC for Class IIa medical devices are met

15. GUIDELINES AND MANUFACTURER'S DECLARATION

15.1 Electromagnetic emissions

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

15.2 Electromagnetic immunity

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

Pro Sense is intended for use in the electromagnetic environment specified below. The customer or the user of Pro Sense 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 Pro Sense operates exceeds the appropriate level of compliance, normal operation of Pro Sense should be checked. If improper operation is observed, it may be necessary to take appropriate preventive steps such as moving or relocating the Pro Sense.

(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

15.3 Recommended separation distance between portable and mobile radio communication equipment and Pro Sense

Pro Sense 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 Pro Sense can help prevent electromagnetic interference by keeping a minimum distance between portable and mobile radio communication equipment (transmitters) and Pro Sense, 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.

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

MAIN SERVICE Diagnosis S.A.
Przemysłowa 8,
16-010 Wasilków
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:

- 5 years for blood pressure monitor PRO SENSE
- 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.

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

Diagnosis S.A.
Gen. W. Andersa 38A,
15-113 Białystok, Poland
www.diagnosis.pl
tel. : + 48 85 732 22 34
fax : + 48 85 732 40 99

Helpdesk (Polish language only)

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.
ul. Przemysłowa 8, 16-010 Wasilków, Poland
tel. 85 874 60 45
serwis@diagnosis.pl