ENGLISH

INSTRUCTION FOR USE

ISTEL
Cardic-100BT

ARM-TYPE FULLY AUTOMATIC DIGITAL
BLOOD PRESSURE MONITOR WITH BLUETOOTH®

REF 5150BT

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CE 0197

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CONTENTS

Thank you for buying the blood pressure and pulse monitor Istel Cardic-100BT. This model can be used with irregular pulse. If the device detects irregular pulse, the symbol appears on the display. In such a case, it is advisable to consult your physician.

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

1. INTRODUCTION

1.1. Product features

The Istel Cardic-100BT 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 in pre-eclampsia.
- 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 operation with high-frequency electrosurgical equipment (HF).
- 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.

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 the doctor.

- The air tube or the adapter cord may cause the suffacation of infants.
- The small parts of the set present a choking hazard if swallowed by infants
- Do not use the device on infants or incapacitated persons.

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):

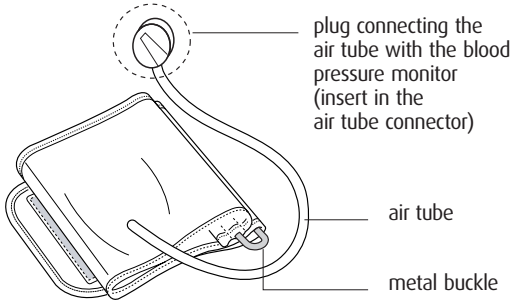
Range	Systolic pressure	Diastolic pressure	Remedial measures
Optimal blood pressure	up to 120	up to 80	Self-measurement
Normal blood pressure	from 120 to 130	from 80 to 85	Self-measurement
Slightly elevated blood pressure	from 130 to 140	from 85 to 90	Consult your doctor
Too high blood pressure	from 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.

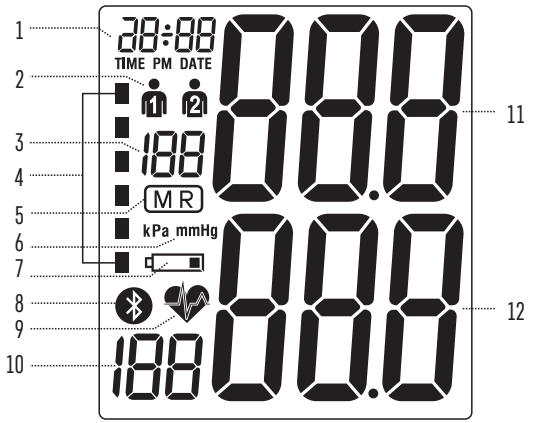
3. PRESSURE MONITOR DESIGN

CUFF

(Applied part type BF)



DISPLAY ELEMENTS



1. date / time
2. users / groups
3. number of the stored measurement
4. blood pressure classification indicator according to the World Health Organization (WHO)
5. average measurement value symbol
6. unit of measurement
7. discharged battery symbol
8. Bluetooth
9. irregular heart rate symbol
10. pulse
11. systolic pressure
12. diastolic pressure

4. STARTING THE DEVICE

4.1. Batteries installation

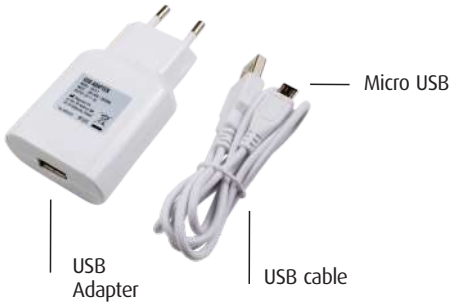
1. Remove the battery cover.
2. Insert 4 standard AA alkaline batteries.
   - Use batteries of the same brand.
   - Note that all the batteries are properly installed, observing polarity.
3. Reinstall the battery cover.
4. If the battery icon is displayed on the screen, it means that there is 20% power 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.
   - Do not mix old and new batteries.
   - 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.
   - If the pressure monitor is left without use for an extended period of time, you should remove the batteries.

4.2. Battery life

- Four new LR6 (AA) batteries last for approximately 1000 measurements (1 per day, at room temperature 23°C), battery life varies depending on the temperature in which they are used, and may be shorter at lower temperatures.
- You can check the battery status in the left bottom corner of the screen. If the low battery symbol , is displayed, they should be replaced with new ones.

4.3. Power adapter (Optional)

1. Connect the plug of the power cord into the power supply connector.
2. Plug the power adapter unit into electrical outlet.
   - Use power adapter suitable for local mains voltage.
   - Power adapter specification: 100~240 V, 50/60Hz; output: Micro USB DC 5V, 1A
   - We recommend using only the power adapter supplied by the manufacturer, model Diagnostic ZUI 5-1.
   - 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.



4.4. User selection, date and time settings

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 ⏻ button.
c) We recommend that the first person who takes measurement is user 1.

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. Press the "TIME" button. A PIN code (code is needed to pair monitor with a mobile device through Bluetooth) consisting of 6 digits will appear, e.g. 148624. This code must be entered into the mobile device (smartphone / tablet) during the pairing.
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.

Further information

After pressing the TIME or MEMORY buttons, data is entered (e.g. switching from hours to minutes or changing the value by +1). After pressing and holding these buttons, the switching is much quicker. When you press START/STOP button at any time, the device saves all settings and finishes the programming process.

5. TAKING MEASUREMENTS

5.1. Before the measurement

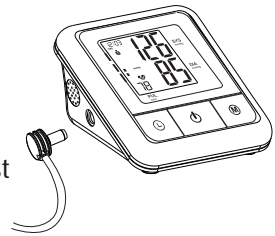
- Directly prior to measurement one should not: eat, smoke and avoid physical effort because all these activities have an impact on measurement results. Prior to measurement you should relax, sitting on a chair in a quiet environment for approximately 10 minutes.
- Measurements should always be taken 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).

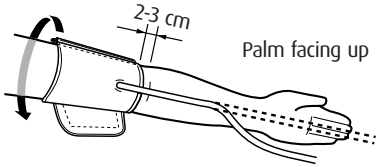
- All the patient's efforts to support the arm may result in increased blood pressure. Select a comfortable and relaxed position. During the measurement, do not stretch any muscles of the arm on which the cuff is wrapped. If necessary, use a pillow as a support.
- The operation of the pressure monitor may be disturbed by extreme temperatures, humidity and 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 or after lifting the arm, to facilitate the outflow of the accumulated blood (after at least 3 minutes).

5.3. 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).
2. Insert the end of the cuff under the metal buckle, with the velcro facing out.
3. Wrap the cuff approximately 2-3 cm above the elbow. For best results, wrap the cuff on bare skin, at heart level.
4. The compression of arm caused by tucked up sleeve may prevent accurate reading.

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

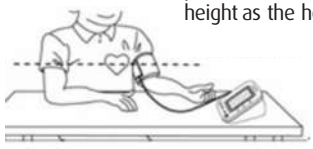


5. The cuff should be wrapped easily on the shoulder and the Velcro should fasten easily.
6. After wrapping the cuff, make sure that there is sufficient space under the cuff to fit a finger.
7. If the cuff does not fit on the arm, the accuracy of measurements may be incorrect.

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

5.4. Body posture during the 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.



5.5. Measurement procedure

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

a) Press the START/STOP button, all the elements will be displayed on the screen (FIG. 1), the cuff will start inflating. The increasing cuff pressure is displayed continuously.
b) When the appropriate pressure is reached, it starts to decrease slowly. When the pulse is detected, the heart icon will start blinking on the screen (FIG. 2)
c) After completing the measurement, the values of systolic and diastolic pressure and the pulse rate appear on the screen (FIG. 3)

Example (FIG. 3): Systolic pressure 126, diastolic pressure 75, Pulse rate 78

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.

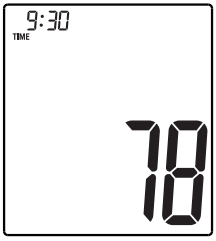


Fig.1

Fig.2

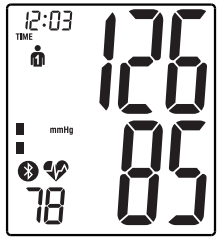


Fig.3

5.6 Finishing the measurement

To interrupt blood pressure measurement (e.g. if the patient is feeling unwell), you can press the START/STOP button at any time. The device will automatically reduce the pressure of the cuff.

6. TAKING/SYNCHRONIZING MEASUREMENTS WITH ISTEL HEALTH APPLICATION

Blood pressure monitor ISTEL Cardic-100[BT] can be used with Istel Health application installed on a smartphone / tablet. Data from the monitor memory can be transferred to a smartphone / tablet via Bluetooth®.

6.1. Connecting the monitor with the Istel Health Application through Bleutooth®.

ISTEL HEALTH APPLICATION

To start using Istel Health app, download it from Google Play or App Store, from website istel.com.pl or diagnosis.pl and install it on your smartphone / tablet.

GET IT ON Google Play

Available on the iPhone App Store

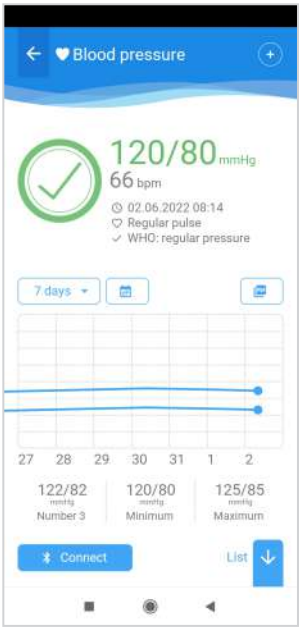
1. Turn on the Bluetooth® function on your phone or tablet.
2. Launch the Istel Health app on your phone or tablet and create a new profile by entering your username and PIN. Confirm with the OK button. (View 1).

NOTE! Remember your user PIN code, otherwise you will lose your measurement results.

3. Display PIN code of your monitor in order to pair the device with mobile Application. To display the PIN code, hold ◷ button on the monitor for at least 3 seconds until the user icon starts flashing. Then press ◷ button repeatedly to display the PIN code. 6 digits will appear on the screen of the monitor (View 6), enter them to the Application in order to pair the device with the Application. Press ◷ or ⏻ to exit the settings.
4. (View 2) In the main window of Istel Health App select "Blood pressure." The "Blood Pressure" window appears. (View 3)

View 1

View 2

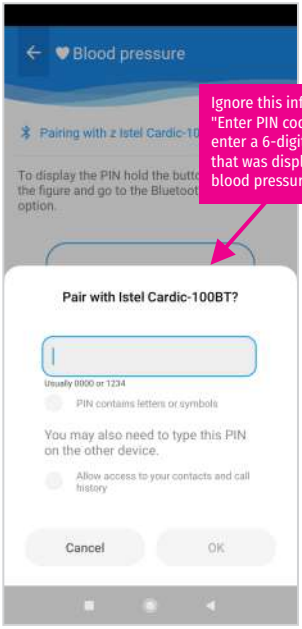


View 3

View 4

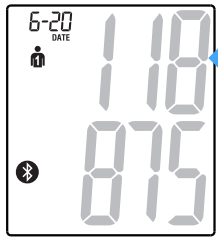
(View 3) The "Blood Pressure" window appears. Choose **Connect**

(View 4) „Searching for device" window will appear.



View 5

View 6

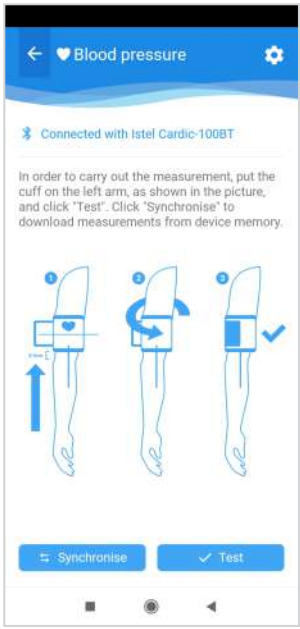


EXAMPLE OF A PIN CODE. Each device has an individual Pin code.

(View 6) EXAMPLE OF A PIN CODE. Each device has an individual Pin code.

(View 5) Enter the PIN that will appear on the display of the monitor.

View 7



View 8

The application has 2 functions: taking measurement and synchronization of all measurements from the memory of the device. Choose the proper button.

(View 7) The window connecting the App with blood pressure monitor will appear. When the device is connected, the symbol ✱ will start flashing on the display. When the device is not connected ✱ is lightning up all the time.

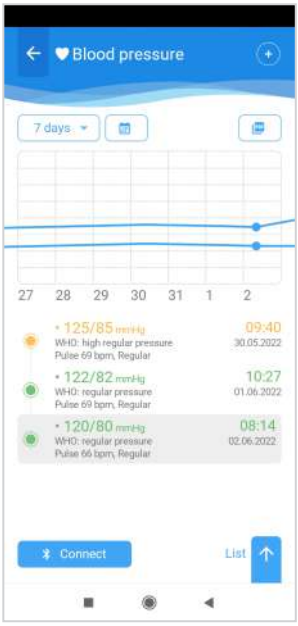
(View 8) In order to take the measurement select **Test**. The device will automatically start the measurement. Choose **Synchronize** to send measurements from the device memory too the App. Measurements will be sent automatically and the list of measurements will appear on the phone / tablet screen. (View 11).

View 9

View 10

(View 9) Measurement window.

(View 10) When the measurement is finished, the result will appear on the screen of mobile device.



(View 11) List of measurements after Synchronization.

View 11

7. MEMORY

Internal memory stores up to 2x120 of measurement results.

1) Recalling results from memory

- To access memory, press the MEMORY button.
- The device will display the average score of the last 3 measurements and the last measurement MR (FIG. 4).
- After pressing the MEMORY button, the user can view the data from the newest to the oldest, the symbol MR with measurement number will appear (FIG. 5).
- If the ♥, is displayed together with the data stored in the memory, it indicates that irregular pulse rate was detected during the measurement.

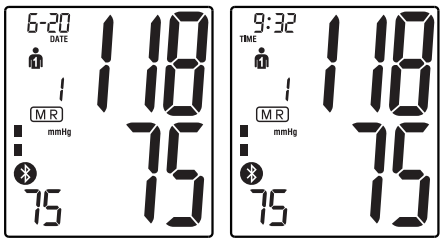


Fig. 4

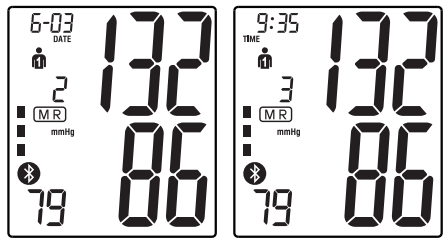


Fig. 5

7.1. Full memory

Do not exceed the available memory. When the memory is full, the old values will automatically be deleted. When the memory capacity has been exhausted, the "memory full" message will display for 1 second.

7.2. Deleting all measurements

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.

7.3 Early arrhythmia detection

If this symbol is displayed after the measurement is completed, it means that during the measurement an irregular heartbeat is detected. In this case, the result may be different from yours normal blood pressure - repeat the measurement.

In most cases, there is no reason to worry, but if this symbol appears regularly (e.g. several times a week within daily measurements), we recommend you to inform your doctor.

Provide the following explanation to your doctor.

Inform the doctor about frequent occurrence of the arrhythmia index. The device is an oscillometric sphygmomanometer, which also analysis heart rate during the measurement. The device has been tested in clinical conditions. If the device detects an irregular pulse, the arrhythmia symbol will be displayed after the measurement. If this symbol appears regularly (e.g. several times a week with daily measurements), we recommend that you contact your doctor.

The device is not a substitute for a cardiological examination, but can detect early stage arrhythmia.

8. ERROR MESSAGES

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

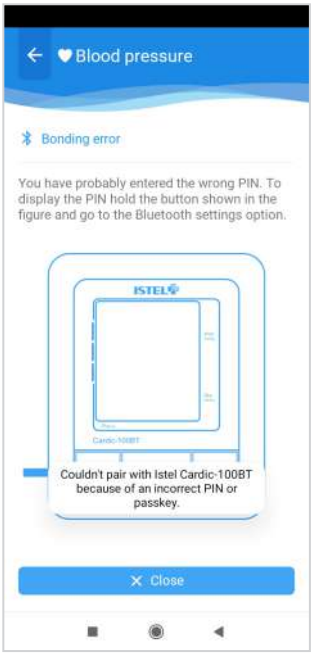
ERROR CODE	POSSIBLE CAUSE ERR
ERR 1	No pulse detected.
ERR 2	Measurement results affected by interference. Cause: there was an arm movement during measurement.
ERR 3	Inflation of the cuff has taken too long. The cuff has not been wrapped properly.
ERR 5	Measurement has indicated unacceptable difference between the systolic and diastolic pressure values. Perform another measurement carefully following the instructions. If unusual results persist, contact your doctor.
ERR 8	Pressure is above 280 mmHg

Further information. Blood pressure varies even in healthy people, that is why it is important to take measurements always 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 Diagnosis S.A.

⚠ YOU SHOULD NEVER ATTEMPT TO REPAIR THE DEVICE BY YOURSELF! ALL UNAUTHORIZED ATTEMPTS AT OPENING THE DEVICE WILL VOID THE WARRANTY!

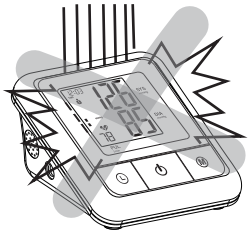
If, during the use of the device, a problem occurs, please check the following items and undertake the listed remedial measures.

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).



(View 11) Errors in the connection of the blood pressure monitor with Bluetooth. In case of a wrong connection, check whether the entered PIN code is correct

9. MAINTENANCE AND CALIBRATION



- Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
- The cuff has sensitive, airtight reservoir. During its operation be careful and avoid its deforming 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. Otherwise calibration performed by the manufacturer will be invalid!

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.

⚠ 10. SAFETY AND DISPOSAL

- The device may be used only for its intended purpose as described in the instruction 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 wrapped
- The device is not intedud for use in the electromagnetic environment 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.

Keep away from children and pets. Some parts of the device are small and can easily be swallowed.

11. SYMBOLS

SYMBOL	FUNCTION/MEANING		
⊕ AA ⊖	Indication of battery polarity	⚠	Warnings
SYS	Systolic blood pressure in mmHg	⎓	Direct curret
DIA	Diastolic blood pressure in mmHg	SN	Serial number
PUL./min	Pulse. Number of beats per minute.		Manufacturing date
	Irregular heartbeat symbol		Manufacturer
	Symbol of the detected heart rate during the measurement	Rev.	Date of the last revision
	Protect against moisture		Class II insulation
IP	Protection against ingress of water		Application part type BF
	Cuff socket	REF	Product catalog number
	Before use read the instruction for use		Keep away from sunlight
	For internal use only		Bluetooth connectivity

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.

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: ±3 mmHg 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 Micro USB DC 5.0 V/1,0 A (optional)
Operation Conditions	Temperature: 5–40°C Humidity: 15–85% R.H. Atmospheric pressure: 860–1060 hPa
Storage and Transportation Conditions	Temperature: -10–55°C Humidity: 10–95% R.H. Atmospheric pressure: 600–1060 hPa
Cuff size	22-42 mm
Dimensions	135×115×72 ±1.0 mm
Weight	498 g ±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
Protection against ingress of water	IP20
Data transfer method	Bluetooth® 5.0 Frequency band 2402 MHz-2480 MHz Maximum power in the frequency range +2 dBm
Product Lifetime	5 years
Contents	Blood pressure monitor, cuff, 4x batteries AA, instruction for use, carrying case, adaprer

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

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. Recommended distance d = 1.2 d = 1.2 80 MHz to 800 MHz d = 2.3 800 MHz to 2.5 GHz where P is the maximum power rating of the transmitter in watts (W) as specified by the manufacturer, and (d) is the recommended distance in meters (m). Field strengths from fixed RF transmitters, as determined in field measurements of electromagnetic fields, should be lower than the compatibility level for each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: Recommended distance d = 1.2 
Emitted radio-frequency signal IEC 61000-4-3	3 V/m 80 MHz do 2,5 GHz	3V/m	

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 to 80 MHz d = 1,16	80 MHz to 800 MHz d = 1,16	800 MHz to 2.5 GHz d = 2,33
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters assessed at the maximum output power not listed below, the recommended distance d in meters (m) can be estimated using the equation corresponding to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.
NOTE 1 at 80 MHz and 800 MHz, the distance for the higher frequency range applies.
NOTE 2: these guidelines do not apply in all situations. The propagation of electromagnetic waves is affected by the absorption and reflection from the buildings, objects and people.

The product should only be used in EU Member States or in the country of purchase. If used in other countries, the user may be in violation of the laws and regulations of that country regarding radio communications.

Diagnosis S.A.
Gen. W. Andersa 38A,
15-113 Białystok, Poland
www.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 ISTEL Cardic-100^{BT} 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 instruction for use, 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 to the Distributor 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.

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