INSTRUCTION FOR USE

ISTEL
Cardic-100BT

ARM-TYPE FULLY AUTOMATIC

DIGITAL BLOOD PRESSURE MONITOR
WITH BLUETOOTH®

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CE 0197

MD REF 5150BT

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ENGLISH

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1. INTRODUCTION

Dear Client,
Thank you for buying the blood pressure and pulse monitor ISTEL Cardic-100BT. The 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 for use before the first use of the device. Please keep the instruction for use. The information contained herein may be needed in the future. Do not take any medical action without first consulting your doctor.

1.1 Intended purpose

The ISTEL Cardic-100 BT 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.
- Taking measurements too frequently can cause blood to accumulate in the brachial artery, which can lead to inaccurate results. Therefore, each subsequent blood pressure measurement should be performed after a 5-minute break.
- Wrapping the cuff on a wound may lead to a deterioration of its condition
- Application of the cuff on the treated arm may lead to injury as a result of temporary obstruction of blood flow during pressure increase.
- Do not put on and inflate the cuff, on the side where the mastectomy procedure has been performed.
- Inflation of the cuff 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.
- The air duct or power supply cable poses a risk of suffocation to infants.
- Small parts of the kit pose a risk of choking if swallowed by infants.

- Do not use the unit on infants or people who are unable to communicate.
- Blood pressure may vary depending on the measurement site, the patient's position, exercise, or the patient's mental state.
- Cuff pressure may temporarily cause a loss of function of another electrical device used simultaneously on the same arm.

⚠ **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.**

Electromagnetic interference
The device contains sensitive electronic components. Therefore, you should avoid strong electric or electromagnetic fields in its immediate vicinity (e.g. mobile phones, microwave ovens). Otherwise, the measurement accuracy may be temporarily impaired. Do not use this device adjacent to or stacked with other electrical equipment, as this could result in improper operation. If such use is necessary, this device and the other equipment should be observed to check that they are operating normally. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

Reporting of serious incidents
Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user resides.

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 results obtained to change the dosage of medications prescribed by your doctor on your own.

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	to 120	to 80	Self-measurement
Normal blood pressure	from 120 to130	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

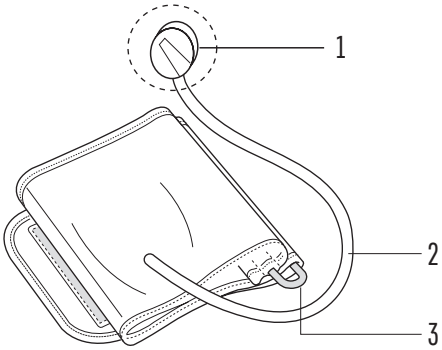
- If the values of your blood pressure at rest are usually normal, but elevated during stress, you may suffer from labile (latent) hypertension. If you suspect that this might be possible, contact your doctor.
- Correctly measured diastolic pressure above 120 mmHg requires immediate medical treatment.
- The device's performance or readings may be affected by the following factors: arrhythmia, pregnancy, age, diabetes, kidney disease, movement, shivering, tremors, etc.

3. PRESSURE MONITOR DESIGN

3.1 BLOOD PRESSURE MONITOR

1. Air tube connector
2. TIME button
3. START/STOP button
4. MEMORY button Ⓜ
5. Power supply socket
6. LCD display

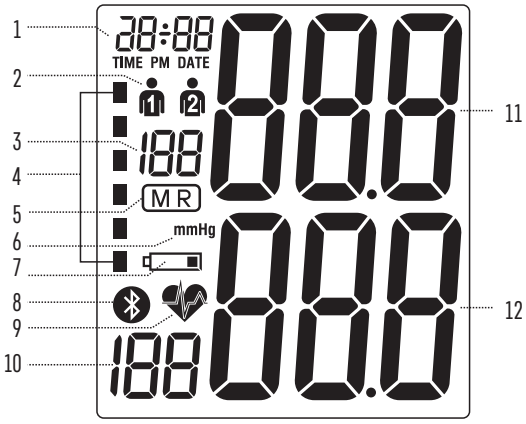
3.2 Cuff



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

(Applied part type BF)
Arm circumference range: 22–24 CM

3.3 Display



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. exhausted battery symbol
8. Bluetooth
9. Irregular heartbeat detection symbol after measurement/pulse symbol during measurement
10. Pulse **(PUL/min.)**
11. systolic pressure **(SYS)**
12. diastolic pressure **(DIA)**

4. STARTING THE DEVICE

4.1 Batteries installation

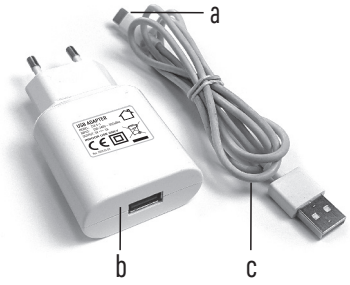
1. Remove the battery cover.
2. Insert 4 standard AA alkaline batteries.
   - Use batteries of the same brand.
   - Note that all the batteries are properly installed, observing polarity.
3. Reinstall the battery cover.
4. If the battery icon, is displayed on the screen, it means that there is 20% power 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 new and expired batteries simultaneously.
   - 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 lower left corner of the screen. If the low battery symbol, is displayed, they should be replaced with new ones.

4.3 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, 50/60 Hz; output: Micro USB DC 5 V, 1 A ⊕-⊂-⊖
   - 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



a. Connector 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.

1. 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).
2. 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 ⏻.
3. We recommend that the first person who takes measurement is user 1.

4.4.2 Time/date settings and PIN display

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). Enter year by pressing the MEMORY button Ⓜ. Confirm with the TIME button Ⓛ.
2. Now the date with the flashing month icon appears on the screen. Set the month using Ⓜ the MEMORY button. Confirm with the TIME button Ⓛ.
3. Now the two characters will flash (day). Set the day using the MEMORY button Ⓜ. Confirm with the TIME button Ⓛ.
4. Now the hours character will flash. Set the hour using the MEMORY button Ⓜ. Confirm with the TIME button Ⓛ.
5. Now the two characters will flash (minutes). Set the minutes using the MEMORY button Ⓜ. Confirm with the TIME button Ⓛ.
6. Press the button again Ⓛ, again to display the PIN code required for pairing with your mobile device. The PIN code is a 6-digit number, e.g $\frac{345}{678}$, that must be entered into

your mobile device (smartphone/tablet) during pairing. After completing all settings, press the button Ⓛ again.

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. Pressing the button ⏻ at any time saves the settings and completes the programming process.

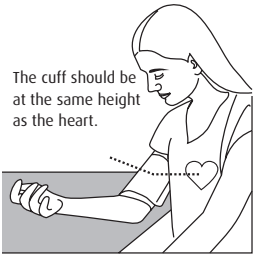
5. TAKING MEASUREMENTS

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)
- Measurements should be taken regularly, at the same time each day, as blood pressure varies throughout the day.

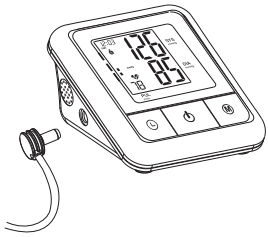
5.2 Most frequent errors

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

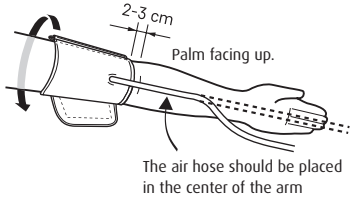


- All the patient's efforts to support the arm may result in increased blood pressure. Select a comfortable and relaxed position. During the measurement, do not stretch any muscles of the arm on which the cuff is wrapped. If necessary, use a pillow as a support.
- The operation of the pressure monitor 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

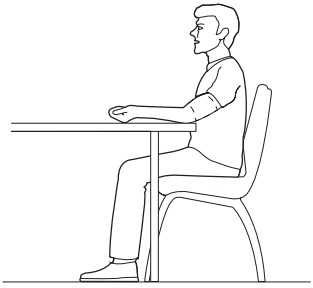


1. Insert the tip of the air duct firmly in the opening on the left side of the unit (air tube socket).
2. Insert the end of the cuff under the metal buckle, with the velcro facing out.
3. Wrap the cuff approximately 2-3 cm above the elbow. For best results, wrap the cuff on bare skin, at heart level.
4. The compression of arm caused by tucked up sleeve may prevent accurate reading.
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 bend the cuff or 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.
- To ensure accurate readings, use only the manufacturer's cuff.

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. Your feet should not be crossed and rest flat on the floor; shoulders and arms should be supported. The patient should not talk during the measurement.

5.5 Measurement procedure

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

a. Press the ⏻ button, all the elements will be displayed on the screen, the cuff will start inflating. The increasing cuff pressure is displayed continuously. (Fig. 1)
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. 4): Systolic pressure 126, diastolic pressure 85, 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.

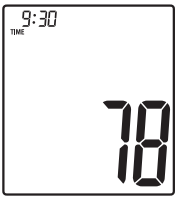


Fig. 1

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 ⏻ button at any time. The device will automatically reduce the pressure of the cuff.

6. PERFORMING / SYNCHRONIZING MEASUREMENTS WITH ISTEL HEALTH APPLICATION USING BLUETOOTH®

The ISTEL Cardic-100BT blood pressure monitor can be used in conjunction with Smartphone / tablet running the Istel Health Application. The results will be automatically transferred via Bluetooth®.

6.1 Connecting the blood pressure monitor to the Istel Health app using Bluetooth wireless communication.

1. **ISTEL HEALTH APP**

In order to start using the Istel Health App, download it from the Play Store, Apple App Store, and then install it on your Smartphone / tablet.

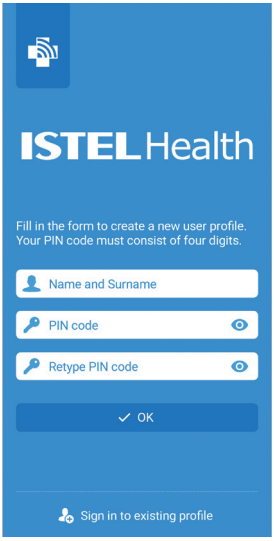
GET IT ON Google Play

Available on the iPhone App Store

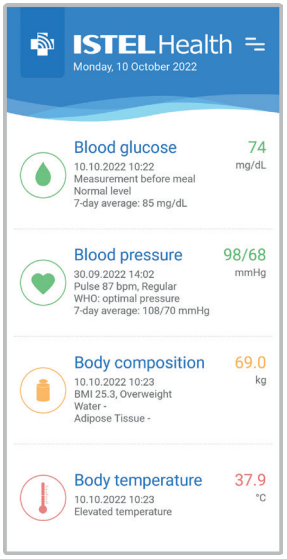
2. Turn on the Bluetooth® function on your phone or tablet.
3. Run the Istel Health App on your phone or tablet and create a new profile by entering the username and creating PIN number. Accept with OK.(Fig.1.)

NOTE! Remember your Application user PIN number, otherwise you will lose access to the measurement results.

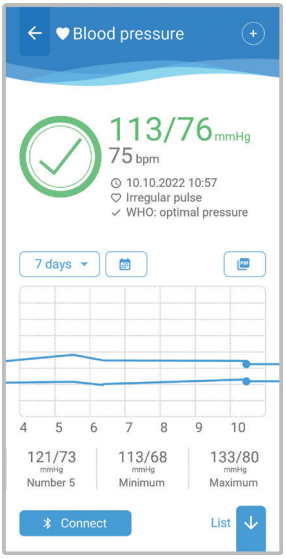
4. Display the blood pressure monitor's PIN code. To display the PIN code on the blood pressure monitor (required for pairing), hold down the button Ⓛ on the blood pressure monitor for at least 3 seconds until the user icon starts flashing. Then press the button 7 times Ⓛ, to display the 6-digit PIN (View 6). The PIN will be required when pairing the blood pressure monitor with your smartphone/tablet.



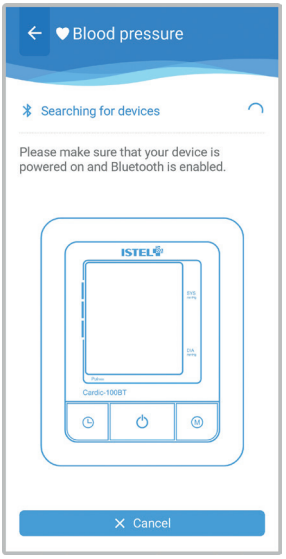
View 1



View 2

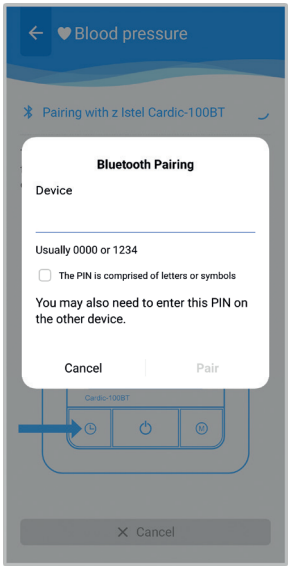


View 3

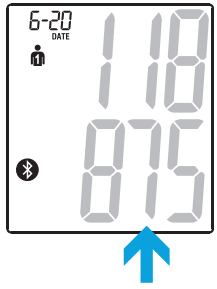


View 4

5. On the main screen of the Istel Health app, click **Blood Pressure (View 2)** and then the Connect button (**View 3**).
6. The Searching for Device screen **(View 4)** will appear, and then the Bluetooth Pairing screen **(View 5)**, where you should enter the 6-digit PIN from the blood pressure monitor **(View 6)**.



View 5



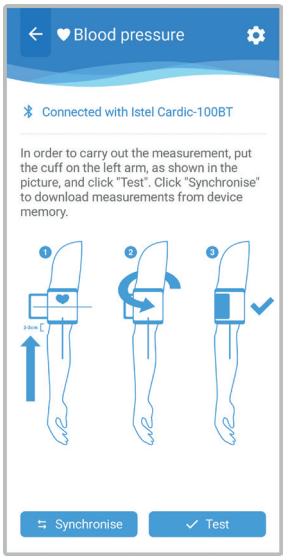
EXAMPLE PIN CODE. Each device has an individual PIN code.

View 6

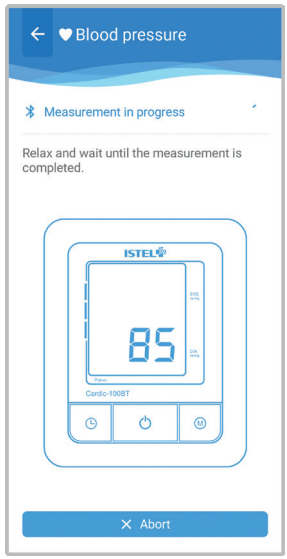
To display the 6-digit PIN on your blood pressure monitor, see point 4 above.

When a connection is established, the symbol flashes on the blood pressure monitor display.

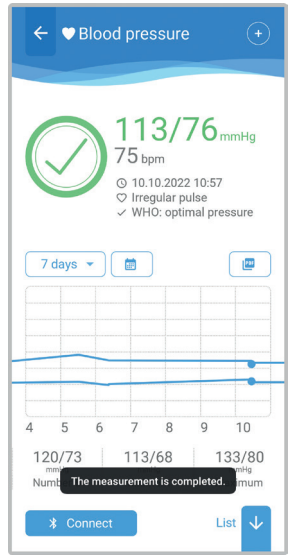
If there is no connection, it lights up continuously.



View 8

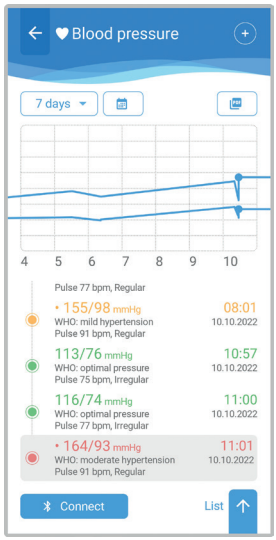


View 9



View 10

7. The app has two functions: taking a measurement and synchronizing all measurements from the blood pressure monitor's memory. Select the appropriate button in the app. **(View 8)**.
   To perform a measurement, select ✓ Test. The device will start measuring automatically. To download measurements from the device's memory, select ⇆ Synchronise. The measurements will be transferred automatically and will appear in the measurement list in the application **(View 11)**.



View 11

8. Screen during measurement **(View 9)**.
9. Once the measurement is complete, the result will appear on the screen of mobile device **(View 10)** and will also be saved in the blood pressure monitor's memory.

7. MEMORY

Internal memory stores up to 2x120 of measurement results.

7.1 Recalling results from memory

- To access memory, press the MEMORY button Ⓜ.
- The device will display the average score of 3 most recent measurements MR A (Fig. 1). After pressing the Ⓜ button,the device will display the last measurement.

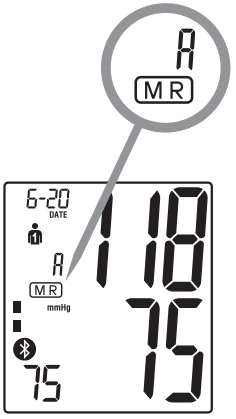


Fig. 1

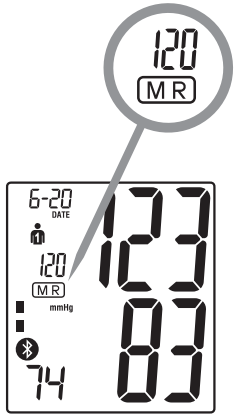


Fig. 2

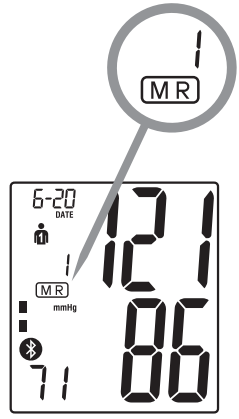


Fig. 3

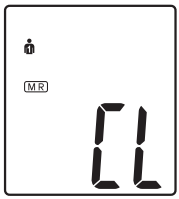
- After pressing the Ⓜ the user can view the data from the newest (maximum MR 120 (Fig. 2)) to the oldest MR 1 (Fig. 3).
- If the sign is displayed together with the data stored in the memory, it indicates that irregular pulse rate was detected during the measurement.

7.2 Full memory

Care should be taken not to 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.

7.3 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 Ⓜ button (WHEN THE DEVICE IS TURNED OFF) for at least 5 seconds. Release the button when the screen displays "CL". To permanently delete the entire memory, press the Ⓜ button while the "CL" is flashing.



8. EARLY DETECTION OF IRREGULAR HEARTBEATS

If this symbol appears after the measurement, it means an irregular heartbeat was detected during the measurement. In this case, the result may differ from your ISTEL Cardic-100BT normal blood pressure – repeat the measurement. In most cases, there is no cause for concern,

but if this symbol appears regularly (e.g., several times a week during daily measurements), we recommend informing your doctor.

INFORMATION FOR THE PHYSICIAN REGARDING FREQUENT IRREGULAR HEART RATE SIGNALING

This device is an oscillometric blood pressure monitor that also analyses your pulse during measurement. The device has been clinically tested. If the device detects an irregular pulse, the irregular pulse symbol will be displayed after the measurement is complete. An irregular heart rhythm is one that is 25% slower or faster than the average rhythm measured during systolic and diastolic pressure measurement. The device does not replace a cardiological examination, but it does help to detect irregular heartbeats at an early stage.

9. TROUBLESHESOOTING AND 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	The systolic pressure value is over 290 mmHg.

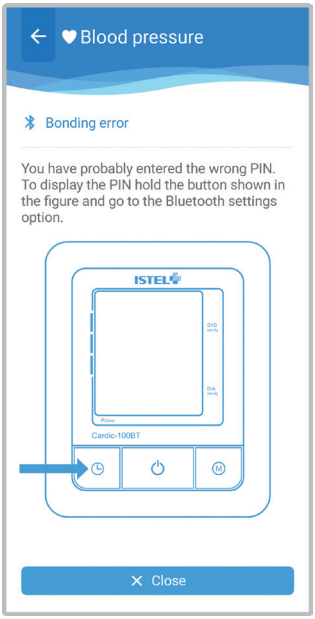
Blood pressure varies even in healthy people, that is why it is important to always take measurements under the same conditions (peaceful environment). If, despite following these principles, the fluctuations will be higher than 15 mmHg and irregular pulse rate occurs repeatedly, consult your doctor. 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.

⚠ **NOTE:** Use only parts and accessories supplied by the manufacturer. Parts and accessories not approved for use with this device may cause damage to it.

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 (p. 9). 2. Take another blood pressure measurement in a quiet and peaceful environment, following the instructions for use (p. 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 "5.2 Most frequent errors". Repeat the measurement. Please remember: Blood pressure varies constantly, which is why subsequent measurements will be characterized by some variability.

FAULT	REMEDIAL MEASURES
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).
Errors in connecting the blood pressure monitor to Bluetooth. 	If you are experiencing difficulties connecting your device to the application, please perform at least one of the following actions: • check that you have installed the latest version of the application (the latest version is available for download from the Play Store or App Store), • make sure you have granted Istel Health permission to access the location of your phone/tablet, • check that you have enabled location services on your mobile device • make sure you have Bluetooth enabled on your mobile device, • turn the phone power off and on, • turn Bluetooth off and on on your mobile device, • Check if the device is paired correctly by checking the list of connected devices on your mobile device (Bluetooth settings). If it appears in the list, unpair the device ("forget device", "unpair") and pair it again.

If your blood pressure monitor does not work properly after applying the above solutions, please contact the helpline on + 48 800 70 30 11 or +48 85 874 60 45, +48 85 874 69 28 (between 8 a.m. and 4 p.m. Monday to Friday). The cost of the call is according to your operator's tariff.

10. MAINTENANCE AND CALIBRATION

a. Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
b. The cuff has a sensitive, airtight reservoir (bladder). When wrapping the cuff, be careful and avoid 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, the 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. For more information, please contact Diagnosis S.A. at the helpline: +48 800 70 30 11.11.

11. SAFETY

- 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 intended 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.
- Use only original elements supplied by the manufacturer. The use of other elements may reduce the level of safety.

Use only original elements supplied by the manufacturer. The use of other elements may reduce the level of safety.

12. SYMBOLS

The meaning of symbols

Symbol	FUNCTION/MEANING	Symbol	FUNCTION/MEANING
⊕ AA ⊖	Indication of battery polarity		Insulation class 2
	Application part type BF		Read instructions before using
REF	Product catalog number		Warnings
SN	Serial number		Direct curret
UDI	Unique device identifier		Manufacturing date
MD	Medical device		Manufacturer
LOT	Batch code		For internal use only
	Humidity limitation		Atmospheric pressure limitation

The meaning of symbols			
Symbol	**FUNCTION/MEANING**	**Symbol**	**FUNCTION/MEANING**
	The worn out product and batteries should be taken to a waste collection facility.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.		Temperature limit
			Protect against moisture
			Keep away from sunlight
		Rev.	Date of the last revision
		IP	IP rating – indicates the degree of protection provided by the enclosure in accordance with the requirements of the IEC 60529 standard

13. TECHNICAL DATA

Product description	Arm- type fully automatic digital blood pressure monitor for measuring blood pressure and pulse	
Model	ISTEL Cardic-100BT	
Measurement method	oscillometric	
Display method	LCD display	
Measurement range	Pressure	SYS: 60–255 mmHg DIA: 30–199 mmHg
	Pressure measurement accuracy	±3 mmHg
	Pulse	40–199 beats per minute
	Pulse measurement accuracy	±5% reading
Inflating	Automatic pumping device	
Deflating	Automatically through air valve	
Memory function	2x120 measurements with date and time	
Power supply	4×alkaline batteries alkaline batteries Micro USB DC 5,0 V / 1,0 A (optional)	
Conditions of use	Temperature: 5–40°C (41–104°F) Humidity: 15–85% RH Atmospheric pressure: 700–1060 hPa	
Transportation and storage	Temperature –10–55°C (14–131°F) Humidity 10–95% RH Atmospheric pressure: 500–1060 hPa	
Dimensions	135×115×72 mm ±1 mm	
Weight	498g ±5 g including batteries and cuff	
Protection against electric shock	Internally powered medical electrical equipment (when operating on batteries only) Class II, medical electrical equipment (power supply)	
Safety classification	Type BF	
Operation	Continuous	
IP Classification	IP 20 – Protection against contact with hazardous parts (like a finger) and solid foreign bodies larger than 12.5 mm in diameter	
Method of data transfer	Bluetooth® Low Energy Frequency range 2 402–2 480 MHz Maximum power in the frequency ranges +2 dBm	
Device lifetime	Blood pressure monitor 5 years Cuff 1 year	
Package contents	Blood pressure monitor, cuff M/L (22-24 cm), 4x batteries AA, instruction for use, carrying case, power supply	

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

14. GUIDANCE AND MANUFACTURER'S DECLARATION

14.1 Electromagnetic emissions

ISTEL Cardic-100BT 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 11 standard	Group 1	ISTEL Cardic-100 BT uses radio-frequency energy only for its internal functions. Therefore, these emissions are very low and should not cause interference in nearby electronic equipment
The emission of radio frequency waves; CISPR 11 standard	Class B	ISTEL Cardic-100 BT 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	Consistent	
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 GHzHz

14.2 Electromagnetic immunity

ISTEL Cardic-100BT 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV scontact ±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%. 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 lines I/O	±2 kV for power supply lines	he quality of power supply should be adequate for typical commercial installation or hospital environment.
Surges IEC 61000-4-5	±0,5 kV, ±1 kV differential mode ±0,5 kV, ±1 kV, ±2 kV podwójne zwarcie do linii	±0,5 kV, ±1 kV differential mode	he 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% dip in UT) for 0.5 cycle <5% UT (95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95% dip in UT) for 5/6 s	<5% UT (>95% dip in UT) for 0.5 cycle <5% UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95% dip in UT) for 250/300 cycles	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	30 A/m	Non applicable	Non applicable

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

ISTEL Cardic-100BT 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 to 80 MHz	Non applicable	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=[3,5/V1]×P1/2 d=1,2×P1/2 80 MHz do 800 MHz d=2,3×P1/2 800 MHz do 2,7 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: 
Emitted radio-frequency signal IEC 61000-4-3	6 Vrms in ISM and amateur bands 10 V/m, 80 MHz to 2.7 GHz, 385 MHz to 5785 MHz Test specifications for EXTERNAL PORT IMMUNITY to RF wireless communication devices (see Table 9 of IEC 60601-1-2:2014)	Non applicable 10 V/m, 80 MHz to 2.7 GHz 385 MHz-5785 MHz EXTERNAL PORT IMMUNITY test specifications for RF wireless communication devices (see Table 9 of IEC 60601-1-2:2014)	

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

14.3 Recommended distance between portable and mobile radio communication equipment and ISTEL Cardic-100 BT

The ISTEL Cardic 100-BT 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 ISTEL Cardic-100BT can help prevent electromagnetic interference by keeping a minimum distance between portable and mobile radio communication equipment (transmitters) and ISTEL Cardic-100 BT, 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 = 1,2√P	80 MHz to 800 MHz d = 1,2√P	800 MHz to 2,7 GHz d = 2,3√P
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 violate the laws and regulations governing radio communications in that country. The Bluetooth® word mark and logo are registered trademarks of Bluetooth SIG, Inc., and the use of these marks by Diagnosis S.A. is subject to the relevant licence. Other trademarks and trade names are the property of their respective owners.

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MAIN SERVICE
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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:
- 2 years for blood pressure monitor ISTEL Cardic-100BT
- 1 year for all accessories
- 1 year for Diagnostic power supplies

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.
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.

NOTE! Before sending the device for repair, please clean it of all kinds of contamination.

NOTES ABOUT INSPECTIONS AND REPAIRS

L.p.	Date of reporting	Repair date	The warranty has been extended to	Description of operation	Stamp and signature of the contractor

Manufacturer

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for landline phones

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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.)

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