INSTRUCTION FOR USE

ISTEL

HR-2000
ECG RECORDER

Bluetooth®

TABLE OF CONTENTS

Thank you for purchasing the Istel HR-2000 ECG Recorder medical device, which is designed to record an ECG signal. The Istel HR-2000 ECG Recorder should be used according to its intended purpose.

Please read these instructions carefully before using the device for the first time. Keep these instructions for future reference as they contain useful information.

Never perform any medical procedure without consulting a physician first. Consult your physician for more detailed information about your health status.

1. INTRODUCTION

1.1 DESCRIPTION OF ISTEL HR-2000 ECG RECORDER

The Istel HR-2000 ECG Recorder is a portable, easy-to-use medical device recording ECG signals and sending them to mobile devices (smartphone, tablet, etc.) via Bluetooth. **The ECG recorder works in the same manner as devices used in hospitals. It has four built-in electrodes allowing to obtain 6 leads (I, II, III, aVR, aVL, aVF). It is portable and easy to use.** The product is intended for patient use in a home setting, and by physicians as a source of information about a patient's health status. This solution allows a patient to perform an ECG test at home at any time or place. Results saved in the application can then be analysed by a physician.

Fig. 1 View of the device

Fig. 2 Description of the device components

LA, LL, RA, RL electrodes: applied to the body, at the height of the sternum (see Fig. 3).

Indicator : informs about the device's operating status. When the lamp's colour changes from blue to red this means that the battery is discharged.

Power switch ⏻: Turns on power supply. When Istel HR-2000 ECG Recorder is not used for about one minute, it is switched off automatically.

1.2 ADVANTAGES OF THE DEVICE

The ECG recorder is used to monitor heart activity. ECG test is the basic tool for diagnosing cardiac diseases. Some advantages of the Istel HR-2000 ECG Recorder are listed below.

- Possible performance of an ECG test at any place and at any time.
- Assistance in diagnosing cardiac diseases.
- Early prevention of cardiac diseases.
- Easy to use.
- Broad range of applications: for people with cardiac diseases, people in poor health, as well as for prevention and healthcare purposes in adults.

1.3 CONTRAINDICATIONS FOR USE OF ECG RECORDER

- Implanted pacemaker.

2. IMPORTANT SAFETY GUIDELINES

Test results obtained with the help of the Istel HR-2000 ECG Recorder serve for monitoring a patient's health only. Self-testing is not equivalent to a medical diagnosis and it should never be the basis for starting or changing treatment without consulting a physician.

ECG test results sent by Istel HR-2000 are values recorded at the time of taking the test. If you observe any worrying symptoms, perform an ECG test using Istel HR-2000 and consult a physician regardless of the result obtained.

2.1 WARNINGS

- Do not use the device if you have an implanted pacemaker,
- Do not use the device simultaneously with a defibrillator,
- Do not use the device in the presence of flammable anaesthetics, medications or pressurized oxygen (e.g. in a hyperbaric chamber, UV sterilizer or oxygen tent),
- Do not expose the device to strong shocks, vibrations and protect it from falling and other mechanical damage,
- Do not perform measurements through clothing,
- Do not perform measurements on wet or moist skin,
- Do not perform measurements if the device is exposed to a strong electromagnetic field or static electricity,
- Do not perform measurements while driving a car,
- Do not use contact gel,
- 

Keep out of the reach of small children and dependent persons.

3. TESTING METHOD

3.1 MEASUREMENT ON CHEST

Before taking the ECG test for the first time, read these instructions carefully and make sure that you follow these guidelines before every test.

- Make sure that electrodes are in direct contact with the skin. Improper contact of electrodes with the skin will be signalled by the application on your mobile device (smartphone, tablet, etc.).
- If the electrodes are dirty, wipe them with a soft cloth moistened with alcohol.
- Alcohol may be used only for disinfecting the electrodes.
- Stay calm during the test. Any movement, including speech, coughing or sneezing may affect the test results.

If during the test the ECG recorder is positioned incorrectly, the obtained result may be unreliable. Before starting a test, check whether the device is in proper contact with the body (Fig. 5).

3.2 METHODS OF DETERMINING THE APPLICATION SITE ON THE BODY

1. Apply the device along the central part of the chest, so as to locate the two top electrodes (RA and LA) just above the nipple line (Fig. 3)

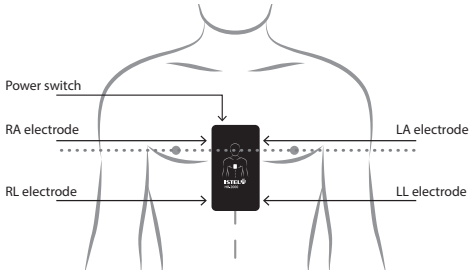


Fig. 3 Method of applying the device

2. Put your palm to the chest and place your thumb in the suprasternal notch (dip in between the clavicles and above the manubrium of the sternum). Apply Istel HR-2000 device in the extended line of the little finger, along the axis of the chest (parallelly to the rib line) (Fig. 4).

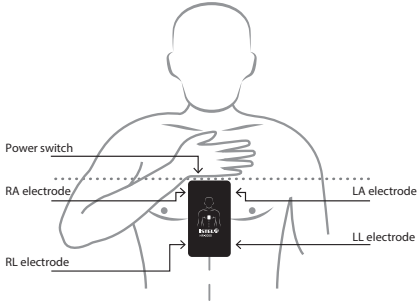


Fig. 4 Method of applying the device

3.3 RECOMMENDED BODY POSITION DURING THE TEST

1. Do the test in a relaxed position: while sitting or lying. When seated, legs cannot be crossed, and feet should stand flat on the floor. Your back should be straight and supported.

2. Hold the Istel HR-2000 Recorder with electrodes directed towards the chest and the power button facing upwards. The recorder should be kept in mid-sternum position, directly on the skin.
3. The device should not be in contact with any clothing.
4. Make sure that the electrode is in direct contact with the skin.
5. If you have any doubts as to how to apply the device, contact the physician or the Diagnosis S.A. helpdesk.

NOTE! If the Istel ECG application displays a message of no contact between an electrode and skin (application highlights the electrode in red), the Recorder will not start the measurement (Fig.5). Position of the device on the chest must be corrected so that all electrodes are in direct contact with the skin.

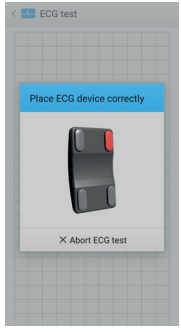


Fig. 5 Message about no contact of the electrode with skin

4. HOW TO USE THE DEVICE AND THE ISTEL ECG APPLICATION

4.1 INSTALLATION AND REPLACEMENT OF BATTERIES IN THE DEVICE

To install or replace the batteries, slide the battery cover as indicated by the arrow on the cover (see Fig. 6).

Place two LR03 (AAA) batteries in the compartment, making sure the polarity is correct (+ and –). Close the battery cover.

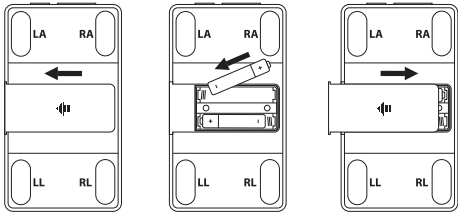


Fig. 6 Battery installation

Information about battery status is displayed by the indicator lamp next to the power switch.

Charged batteries:

Empty batteries:

When the indicator lamp changes from blue to red the batteries are empty. When the red light appears, replace both batteries with new ones.

Note:

- Do not mix old and new batteries,
- Do not use different types of batteries at the same time,
- Do not insert batteries with incorrectly positioned poles,
- If the device is not going to be used for a longer period of time (one month or longer), remove the batteries from the device,
- Do not throw used batteries into fire,
- Dispose of used batteries according to local legal regulations,
- We suggest using batteries compliant with domestic standards, manufactured by reliable manufacturers.
- Keep out of the reach of small children and dependent persons.

4.2 BATTERY LIFE

Two new batteries (AAA) will be enough to use the device for about 2 years and taking approx. 10 tests (at room temperature of 23°C). Battery life differs depending on temperature at which they are used, and may be shorter when used in lower temperatures.

4.3 HARDWARE REQUIREMENTS FOR YOUR MOBILE DEVICE

- Operating system: Android 6.0 or higher / iOS 10 or higher
- Bluetooth Low Energy interface
- Qualcomm Snapdragon S4 or higher
- Memory 1 GB
- Screen resolution of at least 540x960 pixels

4.4 ISTEL ECG APPLICATION

Before doing the test, download the Istel ECG application from the Google Play or Apple App Store and install it on your mobile device (tablet/smartphone) .

To improve performance of the device, Istel ECG app is updated. Make sure you have the latest version of the app installed on your device. You can check the currently installed version in the application, in the "About" option.

Want to download the application faster? Scan the QR code!

4.5 DEVICE SETTINGS IN THE ISTEL ECG APPLICATION

The settings mode is located in the upper right corner of the application ☰ (Fig. 7).

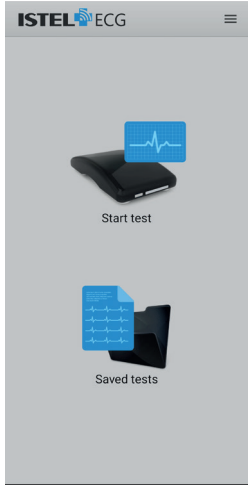


Fig. 7

This icon ☰ will open a panel with available settings of the Istel ECG application (see Fig.8).

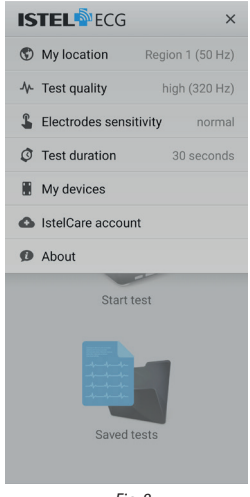


Fig. 8

My location. Select the electromagnetic inference (EMI) filter. In Poland, the frequency is 50 Hz (Fig. 9).

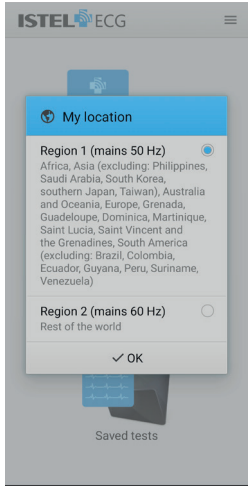


Fig. 9

Test quality. The Istel HR-2000 ECG Recorder can perform and save tests at three different sampling frequencies.

Example: high quality
(320 Hz) means that the test has been performed 320 times per second (Recommended frequency 320 Hz) (Fig. 8).

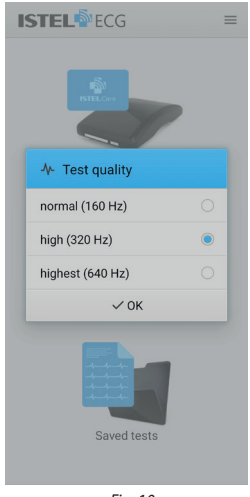


Fig. 10

Electrode sensitivity. During the test, do not press Istel HR-2000 ECG Recorder too strongly to the skin , so that the test is not disturbed by the shaking hand. If a message about incorrect contact of the electrode with the skin is displayed (Fig.5), change electrode sensitivity to high (Fig. 11).

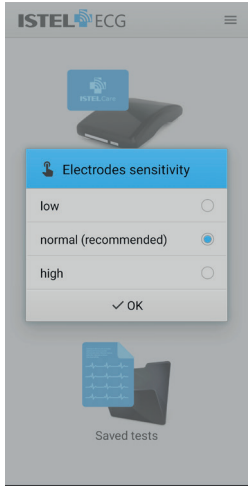


Fig. 11

Test duration. Set time over which Istel HR-2000 ECG Recorder will monitor the patient's ECG signal. You can choose from: 30 seconds, 1 minute, 2 minutes and 3 minutes (Fig. 12).

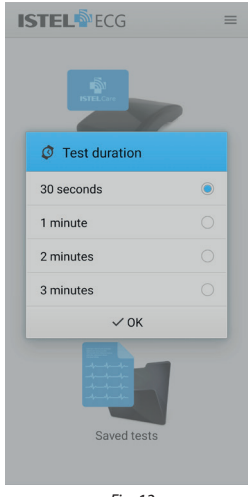


Fig. 12

My devices. The Istel ECG app can collect data from multiple Istel HR-2000 ECG recorders. In the My devices tab, you can see the names of ECG recorders with which the application has connected (Fig. 13 shows two ECG recorders).

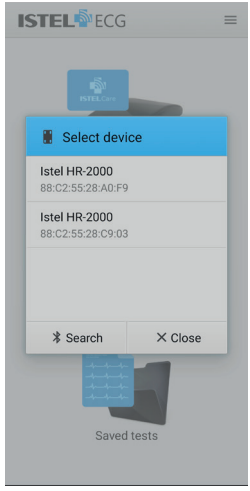


Fig. 13

You can search for, add or remove an ECG Recorder. It is possible to change the name of Istel HR-2000 and set a given ECG Recorder as the default device, then the Istel ECG application will connect only to the selected ECG Recorder (Fig. 14).

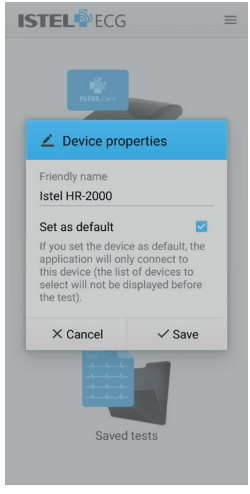


Fig. 14

Istel Care Account: ECG measurements can be sent directly to the Istel Care system. Simply create an account on www.istelcare.pl and log in to the application using the data you provided when registering your account (Fig. 15).

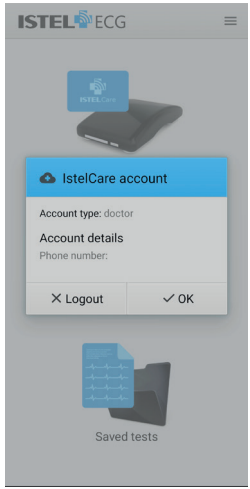


Fig. 15

About the application: The manufacturer of the Istel ECG application software is:

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

The Istel ECG application is a class IIa medical device. CE 0197

4.6 MEASURING WITH THE ISTEL ECG APPLICATION

In the Istel ECG application, you can take the test in two ways by selecting:

1. Start test (Fig.16)
2. Test for Istel Care – the icon will appear when you log in to the Istel Care telemedicine system (Fig. 17).

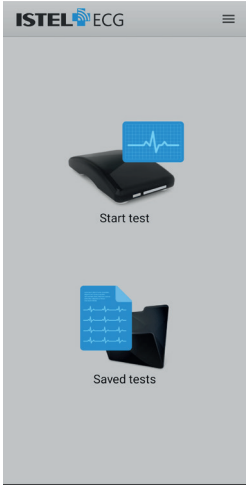


Fig. 16

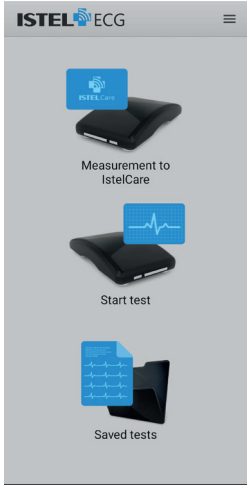


Fig. 17

Istel Care is an innovative telemedicine system allowing to monitor patients' health remotely. It enables simple and safe sharing of results with a physician or sharing of data with a guardian. To start a test for the Istel Care system, you must first create an account in the system at istelcare.pl, a and then log in to the Istel ECG application.

After launching the Istel ECG application on the HR-2000 ECG recorder, press ⏻. The blue indicator will start flashing two to three times per second. The symbol will flash faster (several times per second) when initiating the connection with the mobile device. Once the connection is established, it will be on continuously.

To take an ECG test, select “Start test” from the app (Fig. 18), then place the switched-on device on your chest as shown in Fig. 3.

REMEMBER! Bluetooth and location must be enabled on the mobile device (smartphone, tablet, etc.).

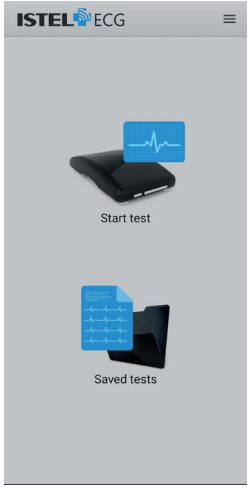


Fig. 18

The Istel ECG application will open a window where the searched device appears – confirm the connection attempt with the Istel HR-2000 ECG recorder by clicking on the searched device (Fig. 19).

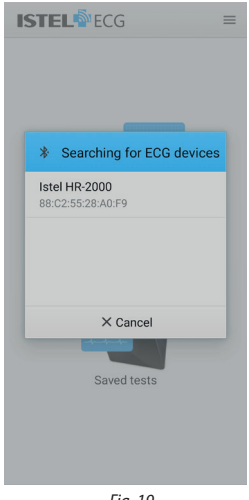


Fig. 19

You can set the name of the ECG and select the device as default (the application will only connect to this device). This option is selected by default (Fig. 20). **REMEMBER! When using multiple ECG recorders, uncheck the Set as default box.**

Once the device is switched on, placed against the chest and connected to the app, an ECG test will start automatically (Fig. 21, 22).

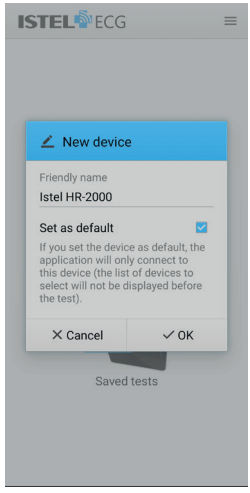


Fig. 20

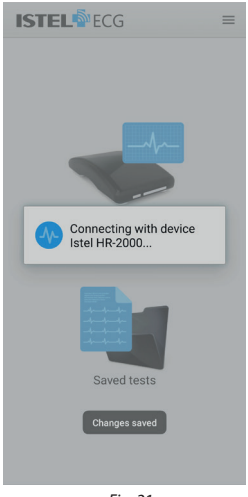


Fig. 21

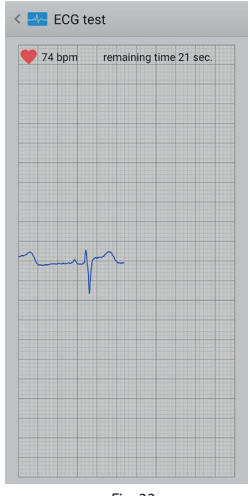


Fig. 22

The Istel ECG app will show whether the electrodes are accurately applied to the skin. If any of the four electrodes does not adhere properly, the app will highlight it in red (Fig. 23). If all electrodes are correctly in contact with the skin, the test will start.

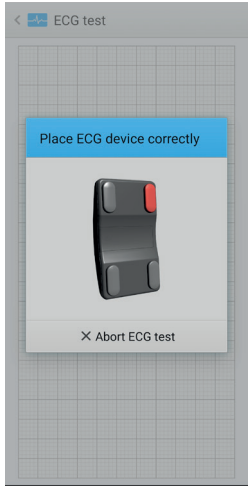


Fig. 23

During the test, a flashing heart symbol ♥ and the pulse value appear in the upper left corner. The remaining test time is counted down in the upper right corner (Fig. 24).

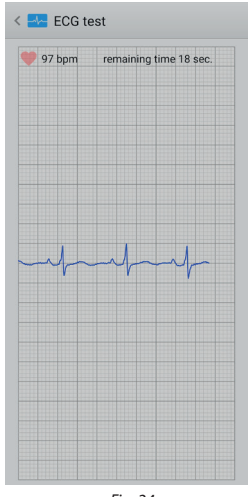


Fig. 24

If interference occurs during the test, the - - bpm symbol appears (Fig. 25).

If the interference does not allow the recording to be analysed, a message will appear: Automatic analysis of the ECG graph failed. Do you want to repeat the test? Press YES or NO (Fig. 26).

If the test is successful, a summary of the test will appear (Fig.27):

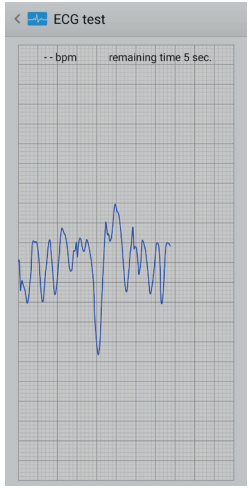


Fig. 25

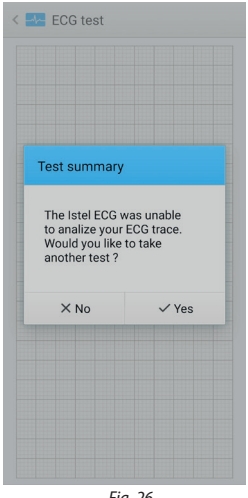


Fig. 26

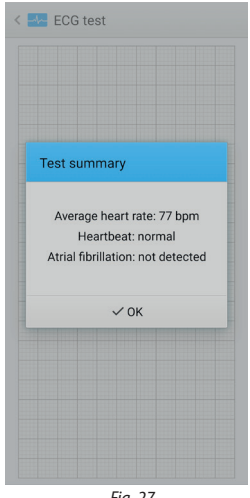


Fig. 27

Average pulse: [value] bpm (beats per minute)

Pulse: normal / irregular / slow / accelerated / accelerated – irregular / slow – irregular

Atrial fibrillation: not detected or detected

After the test is completed, the following data must be entered to identify the recorded result: first name, surname and ID number (Fig. 28).

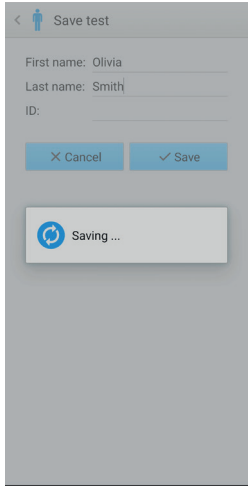


Fig. 28

The test result will be stored in the mobile device's memory. To view the results, select the Saved tests icon (Fig. 29) and then select a test (Fig. 30).

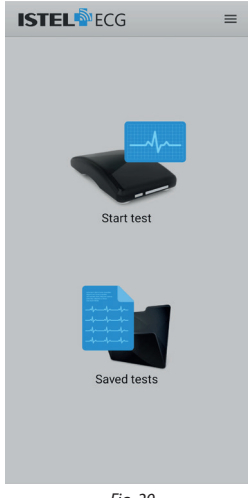


Fig. 29

The display shows the complete ECG signal from six leads: I, II, III, aVR, aVL, aVF (Fig. 31, 32). The app allows for entering and reading out tests done by more than one user. The record can be scrolled up, down, right and left, and zoomed in and out.

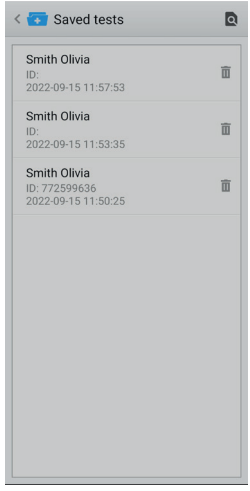


Fig. 30

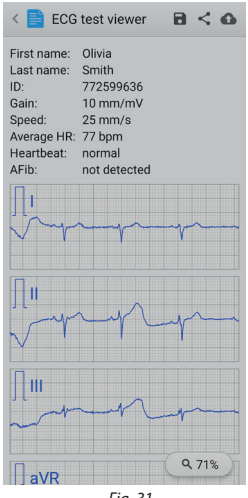


Fig. 31

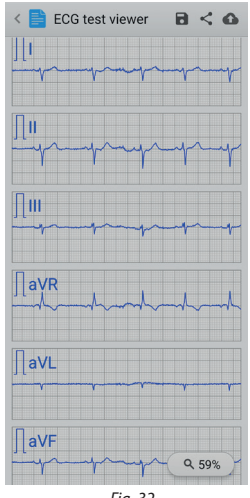


Fig. 32

You can save the test result as a PDF document, export it as a PDF document (send it to the physician via e.g. e-mail) by using the icon and sending it to your account in the Istel Care system by selecting the icon.

NOTE: Do not interpret test results yourself; self-examination is not a medical diagnosis. Consult your physician.

5. GENERAL INFORMATION ABOUT THE HEART AND ECG

Heart is the most important organ in the circulatory system. Thanks to its rhythmic contractions and relaxation, blood can flow continuously in a closed loop, supplying oxygen to different body parts and removing carbon dioxide, which is the foundation of human life functions. To learn about the principle of ECG test, you must understand how the heart works.

The cardiac conduction system is shown below.

Normal electrical conduction in the heart allows for the impulse generated in the sinoatrial (SA) node to be distributed to the atria and ventricles, stimulating the entire heart. More precisely, the SA node generates an impulse that travels to the right and left atria, causing them to contract and pump blood to the right and left ventricle, respectively. As the impulse travels over

a special path from the atrium to the ventricle, it reaches the ventricle after a short time, causing it to contract. Thus, in every cardiac cycle, different parts of the heart send an electrical signal as they are stimulated, meaning that changes of direction, type, sequence occur with a certain regularity over time.

Changes in the electrical signal propagate from the heart through the surrounding liquid electrolytes to the body surface, causing different parts of the body to send electrical signals in every cardiac cycle with a certain regularity.

5.1 PRINCIPLE BEHIND ECG

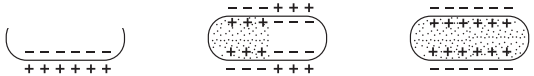
Since the tissues and body fluids around the heart are conductive, the human body can be perceived as a three-dimensional conductor with length, width and depth. In this case, the heart is the power supply source and the sum of the action potentials of numerous myocardial cells, transmitted to and detectable on the body's surface. There are many points with a difference of potentials between them, as well as isoelectric points.

The mechanism according to which myocardial cells change their electrical activity is described below.

Myocardial cell at rest: a system of cations surrounds the exterior side of the cellular membrane, endowing it with a positive charge, while the system of anions inside the cellular membrane, with a negative sign, preserve polarization equilibrium, and no changes in potential occur.

When one part of the cellular membrane is stimulated, its permeability changes, positive and negative ions switch places, depolarization occurs, the positive charge of this part of the membrane disappears, and the part of the membrane that was not depolarized is still positively charged – and a dipole is created in this manner. Positive charges from the front, negative charges in the back, and as a result, current flows from the positive to the

negative charge, and local depolarization moves in a certain direction until the entire cell is depolarized. At this time, the exterior part of the membrane is positively charged, while the interior has a negative charge – this state is called depolarization.



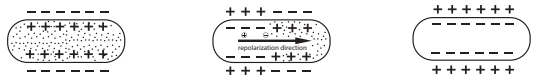
a) Myocardial cell at rest (repolarization state)

b) Myocardial cell is stimulated (depolarization process)

c) Completely depolarized myocardial cell (depolarization state)

Depolarization of myocardial cells

Next, the cellular membrane returns to polarization state – this process is called repolarization. Repolarization takes place similarly to polarization, but the charges are reversed, negative at the front, positive at the back, and they move slowly until the entire cell is re-polarized.



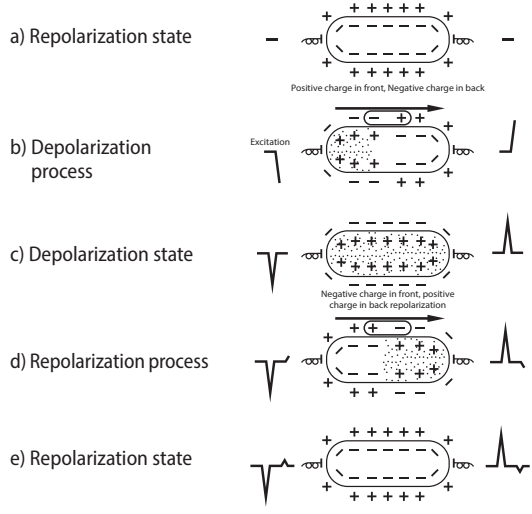
a) (Depolarization state)

b) (Repolarization process)

c) (Repolarization state)

Repolarization of myocardial cells

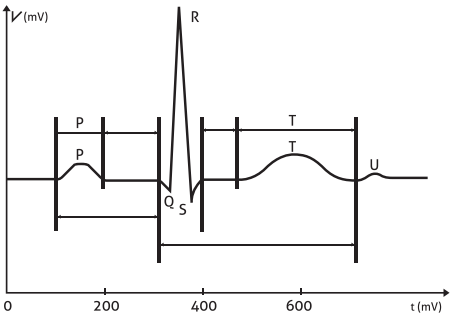
In the case of an individual cell, measuring electrodes generate a growing wave in the direction of depolarization and a declining wave in the repolarization direction. In this way, they measure a two-sided wave at the cell's centre. The repolarization direction is the same as the depolarization direction, however charges are inverted (negative charge in the front, positive in the back during repolarization), therefore the measured repolarization wave is the reverse of the depolarization wave.



Relationship between waves generated by myocardial cells during repolarization and depolarization. The principle according to which electrical signals are generated by individual myocardial cells has been described above. In reality, an ECG is generated as a result of complex changes of many myocardial cells. ECG reflects complex bioelectric changes of the entire heart during the cardiac cycle. Therefore, the potential values on an ECG at a given time correspond to complex changes in myocardial cells which are simultaneously detectable on the body's surface.

5.2 ELECTROCARDIOGRAM

An electrocardiogram (ECG) is a representation of the heart's electrical activity measured on the body surface. It shows the heart's electrical activity during excitation, conducting and repolarization. The typical shape of an ECG wave is presented below:



Typical ECG wave

P wave: The P wave shows depolarization of the right and left atria. Proper conductivity in the heart allows the impulse generated in the sinoatrial node of the heart to reach the atria first. Thus, the first change on the chart corresponds to small upward wave, called the P wave. The initial part of the P wave mainly corresponds to depolarization of the right atrium, and the final part – of the left atrium. The P wave is small and rounded, and it may differ slightly between consecutive readings. The P wave should not be longer than 0.11 s, and its amplitude should not exceed 2.5 mm.

QRS complex: The QRS complex shows depolarization of the right and left ventricles. A typical QRS complex consists of three closely linked waves, the

first downward wave being the Q wave, then the first upward deflection after the P wave called the R wave, and then the downward deflection after the R wave called the S wave. The width of the QRS complex, sometimes called the complex duration, shows the time required for depolarization of ventricles. The QRS complex of a healthy person should not be longer than 0.10 s.

T wave: The T wave corresponds to repolarization of ventricles. The amplitude of a correct T wave is approx. 0.1-0.8 mV, and it increases as the R wave increases. The T wave should not be lower than 1/10 of the R wave.

U wave: The U wave is found after the T wave. The U wave may occur at reduced potassium concentration or ventricular overgrowth, and an inverse U wave may occur as a result of elevated potassium concentration.

Typical intervals and segments

PQ interval: The PQ interval is measured from the start of the wave to the beginning of the QRS complex. It corresponds to the time required for the electrical impulse to depolarize atria and reach the conducting system of the lower part of the heart, the ventricles. This interval typically extends with age.

QRS interval: The QRS interval is measured from the beginning of the R(Q) wave until the end of the S wave. It shows ventricular depolarization.

Q-T interval: The Q-T interval is measured from the beginning of the Q wave until the end of the T wave. It corresponds to the total time of ventricular depolarization and repolarization, usually shorter than 0.4 s, and it is strongly controlled by heart rate.

PR segment: The PR segment is measured from the end of the P wave to the beginning of the QRS complex. The PR segment is close to the isoelectric line in a healthy person.

ST segment: The ST segment is measured from the end of the QRS complex until the beginning of the T wave. It corresponds to ventricular repolarization. The ST segment in a healthy person is also close to the isoelectric line, and the distance between the ST segment and isoelectric line is less than 0.05 mm.

5.3 WHAT IS HEART RATE

Heart rate is the number of beats per unit of time, usually per minute. The resting heart rate of a healthy person is within the range of 60 to 100 beats per minute (BPM), approx. 75 BPM on average. Among adults, women's heart rate is usually higher than men's. The heart usually slows down during rest or sleep and increases due to exertion or emotions. The heart may also slow down or speed up under the influence of certain medications or neurohumoral agents. The normal heart rate of people who exercise regularly is slower, and this is a normal physiological phenomenon.

5.4 WHAT IS ARRHYTHMIA

Arrhythmia is a disease involving disruptions of the heart's rhythm relat- ed to irregularities in the function of the bioelectrical system that drives the heart. Arrhythmia may occur in persons with cardiac diseases and in healthy persons. The correct rhythm is stable and regular – the heart of a healthy adult beats from 60 to 100 times per minute (BPM). Normally, an impulse is generated before every beat. Humans do not perceive rhythmic beating of the heart, but in the case of arrhythmia, they will feel badly, exhibiting various symptoms such as: anxiety, nausea, fatigue, etc. Different people react differently to arrhythmia, mainly because it comes in different forms.

6. CLEANING OF THE DEVICE

To extend the lifetime of the Istel HR-2000 ECG Recorder and its components, perform maintenance from time to time. Detailed requirements are as follows:

- If the electrodes are dirty, they should be wiped with a soft cloth moistened with disinfectant alcohol,
- Make sure that disinfectant alcohol does not come into contact with parts of the device other than electrodes,
- The device may not be exposed to high temperatures, direct sunlight, high humidity, strong vibrations or places with a large amount of dust.
- The device may not be disassembled, repaired or modified.
- If you have any questions, please contact Diagnosis hotline,
- The device's housing should be wiped with a soft, slightly moistened cloth. Do not use agents containing chlorine or free oxygen – these substances may damage the housing.

In addition to cleaning, the user should perform basic maintenance of the ECG recorder themselves:

- Make sure the housing is not damaged.
- Check whether the diode lights up after the ECG recorder is switched on.
- Check whether the label is readable.

7. TROUBLESHOOTING

The table below presents solutions to problems that may be encountered by users of the Istel HR-2000 ECG Recorder.

Problem	Cause	Solution
No reaction after pressing the power button.	No batteries.	Insert new batteries correctly.
	Batteries are empty.	Replace both batteries with new ones.
	Batteries are inserted incorrectly.	Insert batteries so that their poles are properly positioned.
		Remove and reinsert the batteries. Repeat test.
Test was interrupted.	ECG signal was not detected.	Check the instruction for use and repeat the test.
	Contact with the electrode has been broken.	Repeat the test and make sure that electrodes are in direct contact with the skin throughout the entire test.
Test does not start.	Electrodes are not in proper contact with naked skin.	Check the instruction manual and repeat the test.
	Your body is too tense.	Relax and repeat the test.
	After one minute of inactivity, the ECG recorder is turned off.	Switch on the ECG recorder.
	Electrodes were applied through clothing.	Apply electrodes directly onto the skin.
	ECG signal is too weak.	Increase the Recorder's sensitivity in the "Electrode sensitivity" Fig.11.
Disturbances of test signals.	Each person's skin is different, if the calloused part of the skin is too thick, too much resistance may be created, which may affect the test.	Make sure that electrodes are properly applied, and increase the Recorder's sensitivity to "high" in the "Electrode sensitivity" tab. (Fig.11).
	The device is exposed to an excessively strong electromagnetic field.	Check for electromagnetic interference. If there is interference, turn off the device that may be causing it or change the environment, and then re-measure.
	Electrodes are improperly positioned.	Check the proper electrode positioning in the instruction, manual and repeat the measurement (Fig. 5).

Problem	Cause	Solution
Application message: This device is not compatible with Bluetooth Low Energy technology.	The telephone or tablet does not support Bluetooth Low Energy technology.	Replace the telephone or tablet with one that is compatible with Bluetooth Low Energy technology.
Bluetooth connection problems	Bluetooth error	• switch off and then switch on the mobile device, • disable and then enable Bluetooth on your mobile device, • make sure you have enabled Bluetooth on your mobile device • check if you have installed the latest version of the app (the latest version can be downloaded from Play or App Store), • make sure you have granted Instel Health app access to your phone's/tablet's location (Select Location settings on your mobile device), • enable the „Bluetooth scanning" option in the Settings of your mobile device and disable „ Wi-Fi scanning" option, • make sure that you have entered PIN correctly, • check if your mobile device searches for ECG recorder using the "Bluetooth" option. If yes, connect your ECG recorder with the mobile device via Bluetooth, not via the app. In case of subsequent connection problems, call Diagnosis hotline given on the cover of this manual.
Application message: Failed to establish connection, check if the ECG device is turned on.	The Istel HR-2000 ECG Recorder is too far from the device on which the Istel ECG application is installed.	Reduce the distance between the devices, the recommended distance is no greater than 10 meters.
	The ECG recorder is not turned on.	The Istel HR-2000 ECG Recorder must be turned on.
	A different device is set as default in the Istel ECG application.	Remove the unused Istel HR- 2000 recorder saved in the Istel ECG application in the„My devices"tab. (Fig. 13).

Problem	Cause	Solution
Application message: Connection with ECG device was lost.	The Istel HR-2000 ECG Recorder is too far from the device on which the Istel ECG application is installed.	Reduce the distance between the devices, the recommended distance is no greater than 10 meters.
	Electromagnetic inferences or recorder failure.	Switch off devices that could potentially emit electromagnetic disturbances.
		Repeat the measurement, and if the problem repeats itself, please contact helpline Diagnosis.
Application message: Your device fails to support data transfer rate required by Istel ECG .	Mobile device (tablet/ phone) fails to support data transfer rate required by Istel ECG app.	Change sampling frequency in the "Test quality" tab (Fig. 10).
Application message: Error during saving the test.	Mobile device (tablet/ smartphone) cannot save the test.	Make sure that your mobile device (tablet, phone) has enough available storage space.
Application message: Bluetooth transmission error, connection to device has been lost.	An error occurred during Bluetooth communication of the Istel HR-2000 ECG Recorder and the Istel ECG application.	Repeat the measurement, and if the problem repeats itself, please con- tact helpline Diagnosis.
	Electromagnetic interference.	Devices causing electromagnetic interference should be turned off.
	The Istel HR-2000 ECG Recorder is too far from the device on which the Istel ECG application is installed.	Reduce the distance between the devices. The recommended distance is no longer than 10 meters.

The following steps may help you solve a problem in operating the Istel HR-2000 ECG Recorder and the Istel ECG application. Check whether:

1. The batteries are not dead,
2. The phone/tablet has Bluetooth and location enabled,
3. The Istel ECG application has permission to access Bluetooth and location on the phone/tablet,
4. The option "Bluetooth scanning" is turned off (in the settings of the Android phone),
5. The environment is not disturbed by 2.4 GHz radio waves (WiFi, Bluetooth), (WiFi, Bluetooth)
6. Another ECG Istel HR-2000 device is already set as a compatible device (then uncheck this option),

7. What measurement quality is selected in the Istel ECG application: not all phones/tablets work properly at the highest measurement quality; high measurement quality is recommended.

If problems persist or other problems than those listed above occur, please contact the Diagnosis helpdesk: +48 800 70 30 11, +48 85 874 60 45 or +48 85 874 69 28 (from 8 a.m to 4 p.m., Polish language only). The cost of the call is in accordance with the operator's tariff.

8. TECHNICAL DATA

Name of the device	Istel HR-2000 ECG Recorder
Electrical safety	Device with internal power supply, CF type device
Power supply	2 LR03 (AAA) batteries
IP classification	IP22 Protection against solid foreign objects (larger than 12.5 mm in diameter), protection against the vertically dripping water when the enclosure is titled at an angle of 15° from its normal position
Device type	CF
Operating temperature and humidity (alkaline batteries)	Temperature: 5–40°C Humidity: ≤ 93%
Storage temperature and humidity (without batteries)	Temperature: –25–80°C Humidity: 10–95%
Operating atmospheric pressure range	870–1084 hPa
Storage atmospheric pressure range	870–1084 hPa
Weight	Approx. 75 g (without batteries)
Dimensions	118 x 66 x 26 mm
Packaging contents:	Istel HR-2000 Recorder, Instructions for use, carrying case, warranty card, batteries
Product lifespan:	4 years

NOTE! Specifications may change without prior notice. After two years of use, it is recommended to send the device to the Service centre for inspection.

9. WARRANTY

The Istel HR-2000 ECG Recorder has a 2-year warranty from the date of purchase. If you notice that the ECG is not working properly, please contact the Diagnosis helpdesk.

Under no circumstances shall the manufacturer be liable to the buyer of the device or any other person for damages related to the purchase or use of the Istel HR-2000 ECG Recorder. Services in the scope of the manufacturer's warranty require prior contact with the helpline Diagnosis. This warranty is not applicable in the case where the Istel HR-2000 ECG recorder has been: damaged, improperly used or maintained in a manner not compliant with the manufacturer's guidelines.

10. ELECTROMAGNETIC COMPATIBILITY (EMC)

Due to the large number of electrical devices such as computers, applied medical devices may be susceptible to the electromagnetic action of other devices. Electromagnetic disturbances may result in improper operation of the medical device and create potentially dangerous situations.

IEC60601-1-2 standard was introduced to regulate electromagnetic compatibility requirements for the purpose of preventing dangerous situations related to the product. This standard defines levels of electromagnetic resistance as well as maximum levels of electromagnetic emissions.

The medical device manufactured by DIAGNOSIS S.A. is compliant with IEC60601-1-2 standard with regard to resistance and emissions. Nevertheless, special precautions should be taken.

Do not use devices that emit strong magnetic or electromagnetic fields near the medical device. This could lead to improper operation.

Guidelines and manufacturer's declaration – electromagnetic emissions

The ISTEL HR-2000 is intended for use in the electromagnetic environment as de- scribed below. The customer or the user of the device should assure that the device is used in such an environment.

Emission test	Conformity	Guidelines regarding electromagnetic environment
Emissions within the RF CISPR 11	Group 1	The ISTEL HR-2000 uses radio frequency energy only for its internal functions. Therefore, these emissions are very low and should not cause interference in nearby electronic equipment.
Emissions within the RF CISPR 11	Class B	ISTEL HR-200 is suitable for use in all premises, including residential premises and those directly connected to the public low-voltage network that supplies buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	not applicable	

Guidelines and manufacturer's declaration regarding electromagnetic immunity

The Istel HR-2000 ECG Recorder is intended for use in the electromagnetic environment specified below. The buyer or user of the ISTEL HR-2000 should assure that it is used in such an environment.

Immunity test	Test level, IEC 60601	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 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 Repetition frequency 100 kHz ±1 kV for input/output lines	Not applicable	Not applicable
Surges IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode Line-line	Not applicable	Not applicable
Voltage dips, short interruptions and voltage changes on power supply inlets power line IEC 61000-4-11	0% UT (100% clip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0% UT (100% clip in UT) for 1 cycle at 0° 70% UT (30% clip in UT) for 25/30 cycles at 0 0% UT (100% clip in UT) for 250/300 cycles at 0	Not applicable	Not applicable
Magnetic field with frequency (50/60 Hz) of electric power network IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Magnetic field levels from power sources should be within the limits of a typical commercial or hospital installation.

NOTE: UT means the AC network voltage before the test voltage is applie.

Guidelines and manufacturer's declaration – electromagnetic immunity – for devices and systems that are not life support.

Guidelines and manufacturer's declaration regarding electromagnetic immunity

The Istel HR-2000 ECG Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the ISTEL HR-2000 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 from 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM bands	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Model 8003, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d=(3.5/V1)√P d=(3.5/E1)√P 80–800 MHz d=(7/E1)√P 800 MHz do 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 in field measurements of electromagnetic fields a, should be lower than the compatibility level for each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following symbol: 
Emitted radio frequency signal IEC 61000-4-3	10 V/m od 80 MHz do 2,7 GHz	10 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines do not apply in all situations. Propagation of electromagnetic waves is affected by the absorption and reflection from the buildings, objects and people.

a. ISM bands (industrial, scientific and medical) from 0.15 MHz to 80 MHz to 6765 MHz to 6,795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. Amateur radio bands from 0.15 MHz to 80 MHz to 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

b. Compatibility levels for ISM frequency bands between 150 kHz and 80 MHz and frequency range between 80 MHz and 2.7 GHz are intended to reduce the likelihood that the mobile/portable device may cause interference, if accidentally brought into the patient area. For this reason, formulas for calculating the recommended separation distance for transmitters in these ranges include the additional 10/3 coefficient.

c. The strength of the electromagnetic field emitted by fixed transmitters, such as base stations of mobile/portable phones and fixed-line and portable radiotelephones, amateur radio stations, AM and FM radio stations and television stations cannot be accurately predicted in theoretical terms. In order to assess the electromagnetic environment in terms of fixed RF transmitters, electromagnetic survey of the area should be considered. If field strength measured in the area where 8003 device is used exceeds the above-mentioned RF compatibility level, monitor 8003 device in order to check for its normal operation. In case incorrect operation of the device is observed, it may be necessary to take additional actions, such as to change orientation or location of the 8003 device.

d. In the bands between 150 kHz and 80 MHz field strength should be less than 10 V/m.

Recommended separation distance between portable and mobile radio communication equipment and devices and systems that do not support life.

Recommended separation distance between portable and mobile RF communications equipment and the ISTEL HR-2000 ECG Recorder

The ISTEL HR-2000 ECG Recorder is intended for use in the electromagnetic environment in which the interference caused by the emission of radio waves is controlled. The user of the ISTEL HR-2000 ECG Recorder should take steps to limit electromagnetic interference by ensuring that the minimum distances between the device and portable and mobile telecommunications equipment that emit radio waves (transmitters) are maintained as recommended below, assuming the maximum power of the telecommunications equipment.

Maximum rated power of the transmitter [W]	Distance according to frequency of the transmitter [m]		
	150 kHz – 80 MHz $d=(3,5/V1)\sqrt{P}$	80 MHz – 800 MHz $d=(3,5/E1)\sqrt{P}$	800 MHz – 2,7 GHz $d=(7/E1)\sqrt{P}$
0,01	0,12	0,04	0,07
0,10	0,37	0,12	0,23
1	1,17	0,35	0,70
10	3,70	1,11	2,22
100	11,70	3,50	7,00

For transmitters rated at a different output power than that listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE! At 80 MHz and 800 MHz, the distance for the higher frequency range applies.

NOTE! These guidelines do not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended distances between RF wireless communication devices

The device is intended for use in an electromagnetic environment in which radio interference is controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, depending on the maximum output power of the communications equipment.

Frequency [MHz]	Maximum power [W]	Distance	Test level IEC 60601	Compatibility Level	Electromagnetic environment – recommendations
385	1,8	0,3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended distance** **$E=(6/d)\sqrt{P}$** 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
450	2	0,3	28	28	
710	0,2	0,3	9	9	
745					
780					
810	2	0,3	28	28	
870					
930					
1720	2	0,3	28	28	
1845					
1970					
2450	2	0,3	28	28	
5240	0,2	0,3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNING!

- This device should not be used near or stacked with other electronic devices, such as mobile phones, transceivers or radio control products. If this is necessary, observe the device to check whether it is operating normally.

- Use of accessories and power cord other than specified, except for cords and cables sold by the device or system manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the device or system.

11. CUSTOMER SERVICE

If you have any questions or doubts related to this product or its operation, or if you need to solve any emerging problems, please contact our Customer Service Department.

HELPDESK (Polish language only):

OPEN:
Monday–Friday

WORKING HOURS:
8:00–16:00

+48 800 70 30 11
for landline phones (free call)

+48 85 874 69 28
for mobile phones
(the cost of the call is borne by the callers according to the operator's tariff)

Service Diagnosis S.A.
Przemysłowa 8; 16-010 Wasilków, Poland
Tel.: 85 874 60 45
e-mail: serwis@diagnosis.pl

NOTE! Wireless communication devices may affect electrical medical devices.

12. GLOSSARY OF SYMBOLS

	Humidity in storage
	Battery type
	Direct current
SN	Serial number (located in the battery compartment)
	Date of manufacture
	Manufacturer
	Do not use a medical device if you have a pacemaker!
	CF Type
IP22	Degree of protection. Protection against foreign solid objects (larger than 12.5 mm in diameter), protection against the vertically dripping water when the enclosure is titled at an angle of 15° from its normal position.
CE 0197	Marking proving compliance with the Council Directive 93/42/ECC for medical devices.
REF	Product catalogue number
Rev.	Date of the last revision
	Protect from humidity
	Protect from sunlight
	Warnings
	Read instructions for use before use

This marking on the product or its related materials indicates that it should not be disposed of together with other household waste at the end of its service life.

The product lifespan is 4 years

Take the used device to a waste collection point. It contains components hazardous to the environment. By disposing of the device correctly, you can preserve valuable resources and avoid negative effects on health and the environment, which may be endangered by inappropriate waste handling. If you have any doubts as to where to return your used device, please contact the Diagnosis hotline.

The Bluetooth® word mark and logo are registered trademarks of Bluetooth SIG, Inc. and any use of such marks by Diagnosis S.A. is under license. Other trademarks and trade names are the property of their respective owners.

The Apple name and logo are trademarks of Apple Inc., registered in the, U.S. and other countries. App Store is a service mark of Apple Inc. The Android and Google Play logos are trademarks of Google Inc.

WARRANTY CARD

Diagnosis S.A.

Gen. Władysława Andersa 38A
15-113 Białystok, Poland

FREE HELPLINE 800 70 30 11
tel./fax 85 732 46 22, 732 40 99
www.diagnosis.pl

shop stamp and the seller's signature

MAIN SERVICE CENTRE
Diagnosis S.A.
Przemysłowa 8, 16-010 Wasilków, Poland
tel. 85 874 60 45, serwis@diagnosis.pl

DEVICE NAME: .....

MODEL: .....

SERIAL NUMBER: .....

DATE OF SALE: .....

WARRANTY CONDITIONS

1. Diagnosis S.A. grants the following warranty:
   - 24-month warranty for the Istel HR-2000 ECG Recorder

Defects discovered in the device during the warranty period will be repaired free of charge within 21 days. The repair period runs from the date of delivering the device to the service centre.

2. The Buyer has the right to have the device replaced with a defect-free device if:
   - the repair was not made within the time specified in item 1
   - during the warranty period, 2 ineffective repairs were made to the same component, and the equipment still shows defects making it impossible to use it for its intended purpose
   - The service detects a manufacturing defect that cannot be removed.

The term "repair" does not include inspection and cleaning of the device.

3. The warranty does not cover:
   - batteries;
   - devices with illegible or damaged serial numbers;
   - damage resulting from use and storage contrary to the instructions for use, ingression of liquids or foreign bodies, power surges , repairs by unauthorised persons and random events.
4. The defective equipment should be delivered to the address of the main service centre.
5. The warranty for the sold consumer products does not exclude, limit or suspend the purchaser's rights resulting from the non-conformity of the product with the contract.
6. The only basis for warranty rights is the warranty card with the date of sale, stamp and signature of the seller. The card is invalid if it is incomplete, incorrectly completed, bears traces of corrections and entries by unauthorised persons, or is illegible due to destruction.

SERVICE CENTRE'S NOTES

Item.	Date of notification	Date of repair	The warranty was extended until	Description of operations	Stamp and signature of the contractor

www.diagnosis.pl

CE 0197

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