ISTEL

HR-2000
ECG RECORDER

INSTRUCTION MANUAL

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Thank you for your purchase of the Istel HR-2000 ECG Recorder medical device, which is used to register an ECG signal.

Please read this instruction manual carefully before using the device for the first time. Keep this manual, since the information it contains may be useful in the future. For detailed information about your health condition, please consult a doctor.

The Istel HR-2000 ECG Recorder is intended for use according to its purpose.

1. INTRODUCTION

1.1 Description of medical device Istel HR-2000 ECG Recorder

The Istel HR-2000 ECG Recorder is a portable, easy-to-use medical device that records ECG signals and sends them to mobile devices (smartphone, tablet, etc.) via Bluetooth. The ECG recorder operates according to the same principle as devices used in hospitals. It has four built-in electrodes that make it possible to obtain 6 leads (I, II, III, aVR, aVL, aVF). It is also portable and easy to use. The device is intended for both home use by a patient as well as for use by doctors as a source of information about a patient's health condition. This solution allows a patient to perform an ECG test at home at any time or place. Results saved in the application allow for later analysis by a doctor.

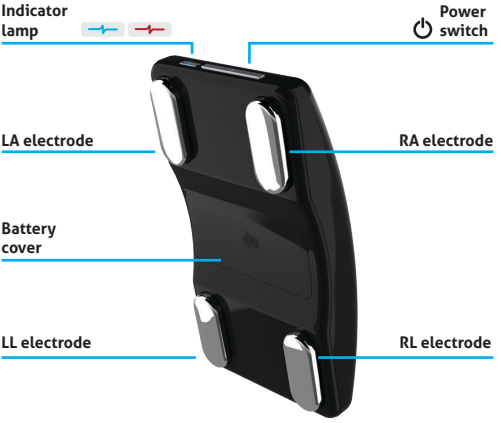


Fig. 1 Istel HR-2000 ECG Recorder

LA, LL, RA, RL electrodes: applied to the body, at the height of the sternum (see Fig. 23).

Indicator lamp informs of the device's operating status. A change of the lamp's color from blue to red means that the battery is discharged.

Power switch (ON) Turns on power supply. When not in use, the Istel HR-2000 recorder switches off automatically after about one minute.

View of the device

Fig. 2 View of the device

1.2 Advantages of the device

The ECG recorder serves to monitor the heart's activity. It is a basic diagnostic tool for all cardiac diseases. Here are some advantages of the Istel HR-2000 ECG Recorder.

- Possibility of performing ECG measurement 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 prophylactics and healthcare for adults.

1.3 Counterindications to use of ECG Recorder

- Implanted pacemaker.
- Allergy to silver, which is a component of electrodes.

2. IMPORTANT SAFETY GUIDELINES

Measurement results obtained using the Istel HR-2000 ECG Recorder serve only for monitoring a patient's health condition. Self-testing is not equivalent to a medical diagnosis and should never be the basis for starting or changing treatment without an independent medical opinion.

ECG records sent by Istel HR-2000 are values at the instant of measurement. If you observe worrying symptoms, perform an ECG measurement using Istel HR-2000 and consult a doctor regardless of the obtained result.

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 reach of children!

3. APPLICATION OF ISTEL ECG

Before starting a measurement, download and install the Istel ECG application from Google Play, from the istel.com.pl or diagnosis.pl website Direct link:
https://play.google.com/store/apps/details?id=pl.cronsoft.istelecg

Want to download the application faster?

Scan the QR code!

3.1 Measurement using the Istel ECG application

After installing and starting the Istel ECG application, press the power button on the HR-2000 ECG Recorder and the ⏻ indicator lamp will flash blue ⊣⊢ two to three times per 1 s. It will flash more rapidly (several times per second) when a connection to a mobile device is initiated, and after a connection has been made, it will be lit up continuously.

Select the „**Perform measurement**“ icon (see Fig. 3) on the Istel ECG application installed on the mobile device (tablet/smartphone) and apply the device to the chest as shown in Fig. 23.

Fig. 3

The tablet/smartphone will display all available mobile devices - select Istel HR-2000 (see Fig. 4).

Note: Bluetooth connectivity must be active on the mobile device (smartphone, tablet, etc.).

The Istel ECG application will open a panel, where the attempted connection to the Istel HR-2000 ECG Recorder must be confirmed (see Fig. 5). In addition, default device selection is selected automatically (the application will connect only to this device).

When using multiple ECG recorders, deselect the „Set as default“ box.

Fig. 4

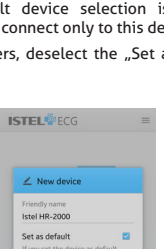


Fig. 5

The Istel ECG application will display the accuracy of electrodes' application to the skin. If any of the four electrodes is not properly applied to the body, the application will highlight it in red. When all electrodes are in proper contact with the skin, the application will display them in grey and measurement will begin.

Example 1

One electrode is not in proper contact with the body - electrode highlighted in red (see Fig. 6).

Example 2

Appearance of application during measurement Fig. 7.

After measurement, to identify the saved results, fill out information concerning Name, Surname, and ID number. (see Fig. 8).

Next, the result of measurement will be saved in the memory of the mobile device (see Fig. 9).

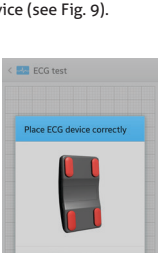


Fig. 6

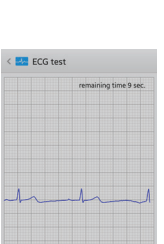


Fig. 7

Fig. 8

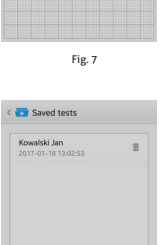


Fig. 9

To display results, select the „Saved measurements" icon (see Fig. 3) and select the desired measurement. The entire record of ECG signals from six leads: I, II, III, aVR, aVL, aVF (see Fig. 10 and 11) can be viewed on the display. The record of measurement can be scrolled up, down, right and left.

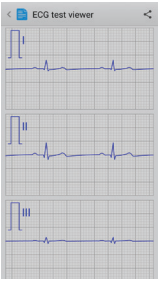


Fig. 10

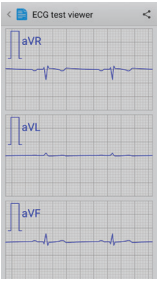


Fig. 11

Measurement results can be exported as a PDF file by using the icon in the upper right corner (see Fig. 12, enlarged area of the screen Fig. 13).

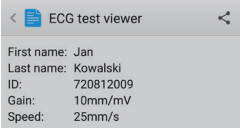


Fig. 11

Examples of exporting measurements in PDF format, see Fig. 13.

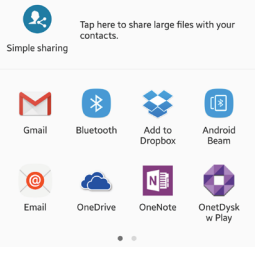


Fig. 13

3.2 Settings

Settings are found in the upper right corner of the application (see enlarged area of the screen Fig. 14).

Fig. 14

This icon will open up a panel with available settings of the Istel ECG application (see Fig. 15).

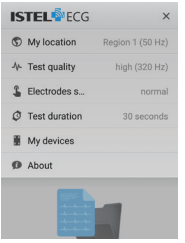


Fig. 15

Settings of the Istel HR-2000 recorder

- My location. Select the anti-disturbance filter protecting against disturbances from the electrical grid. (see Fig. 16).

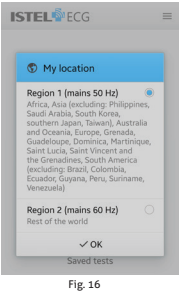


Fig. 16

- Quality of measurement. The Istel HR-2000 ECG Recorder can perform and save measurements at three different sampling frequencies. Example: medium quality (320 Hz) means that measurement has been performed 320 times per second (Recommended frequency 320 Hz) (see Fig. 17).

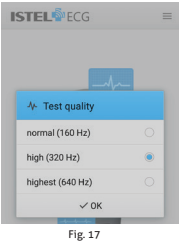


Fig. 17

- Electrode sensitivity. The Istel HR-2000 ECG Recorder should not be pressed to the skin too strongly during measurement, so that trembling of arm muscles does not disrupt measurement. If there is a problem with contact between an electrode and the skin, it will be signaled in red (see Fig. 6), and electrode sensitivity should be changed to high (Fig. 18).

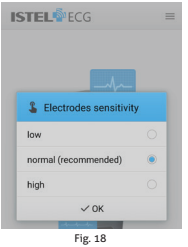


Fig. 18

- Time of measurement. The time for which the Istel HR-2000 ECG Recorder will monitor the patient's ECG signal must be set (see Fig. 19).

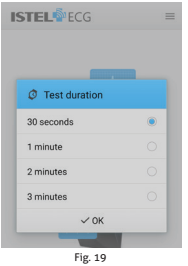


Fig. 19

- My devices. The Istel ECG application can gather data from multiple Istel HR-2000 ECG recorders. In the My devices tab, you can see the names of ECG recorders that the application has connected to; two ECG recorders are visible in Fig. 20.

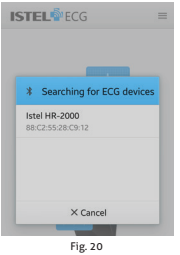


Fig. 20

An ECG Recorder can be searched, added or removed. There is a possibility to change the name of Istel HR-2000 and set an ECG recorder as the default device, then the Istel ECG application will connect only to the selected ECG recorder (see Fig. 21).

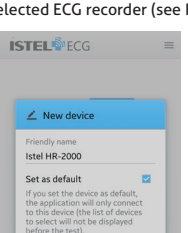


Fig. 21

- About the application. Manufacturer's information, Istel ECG application version (Fig. 22).

Fig. 22

3.3 Minimum hardware requirements for mobile devices

- Android 4.4 operating system or higher
- Bluetooth Low Energy interface
- Qualcomm Snapdragon S4 class processor or better
- 1 GB memory
- Display resolution at least 540 x 960 pixels

Recommended devices - Galaxy S series phones and tablets from Samsung - s4, s5, s6, phones: Sony Xperia Aqua, Samsung A3, LG G2 Mini, LG G3, Samsung S4 Mini, Huawei P8 Lite, Huawei P9 Lite, tablets: Teclast x98, Samsung Galaxy Note 2014 Edition 10.1, Galaxy Tab, Lenovo TAB 2 A8-50.

4. METHOD OF MEASUREMENT

Measurement on chest

Before performing a measurement for the first time, read this instruction manual carefully and make sure that you follow the following guidelines before every measurement.

- Make sure that electrodes are in direct contact with the skin. Improper contact of electrodes with the skin will be signaled by the application on the mobile device (smartphone, tablet, etc.).
- If the electrodes are dirty, should be wiped with a soft cloth moistened with disinfectant alcohol .
- Alcohol may be used only for cleaning electrodes.
- Keep calm during measurements. Any movement, including speech, coughing or sneezing may affect the results of measurements

If the position of the ECG recorder is incorrect during measurement, the obtained result may be unreliable. Before starting a measurement, check whether the device is in proper contact with the body (see Fig. 23).

The Istel HR-2000 device is to be held with electrodes directed towards the chest and the power button facing up. The recorder's position should be the central at the height of the sternum, directly on the skin (see Fig. 23). The device should not be in contact with any clothing. Make sure that the electrode is in direct contact with the skin. If you have any doubts as to how to apply the device, contact a doctor or the Service or local Distributor.

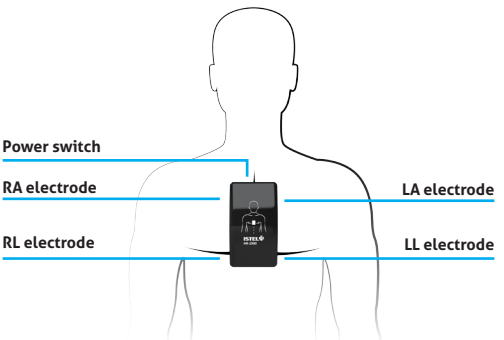


Fig. 23 Method of applying the device

Note: If the Istel ECG application displays a message of no contact between an electrode and the skin (application highlights electrode in red), the recorder will not begin measurement. The device's position on the chest must be corrected so that all electrodes are in direct contact with the skin.

5. BATTERIES

5.1 Inserting batteries

- Slide the battery cover in the direction of the arrow on the cover.
- Insert two LR03 (AAA) batteries as shown in the drawing. Make sure that the positive (+) and negative (-) poles of inserted batteries correspond to the poles marked under the battery cover, as shown in Fig. 24.

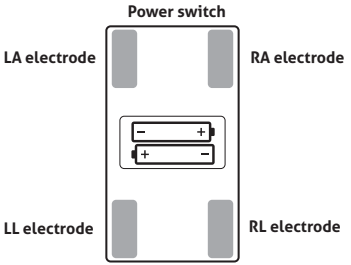


Fig. 24

- Close the battery cover.

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

Charged batteries

Discharged batteries

When the indicator lamp changes from blue to red the batteries are discharged, both batteries should be replaced with the new ones.

Note:

- **Do not use new and used batteries together.**
- **Do not use different types of batteries at the same time**
- **Do not insert batteries with incorrectly positioned poles.**
- **If the device will not be used for a long period of time (month or longer), remove the batteries from the device.**
- **We suggest using batteries compliant with domestic standards, manufactured by reliable manufacturers.**
- **Do not throw used batteries into fire.**
- **Dispose of used batteries according to local legal regulations.**

6. TROUBLESHOOTING

The table below presents solutions to problems that a user of the Istel HR-2000 ECG recorder may encounter.

Problem	Cause	Solution
No reaction after pressing power button.	No batteries.	Insert new batteries correctly.
	Batteries are discharged.	Replace both batteries with new ones.
	Batteries are inserted incorrectly.	Insert batteries so that their poles are properly positioned.
		Remove batteries and put them back in. Repeat measurement.
Measurement was interrupted.	No ECG signal was detected.	Check the user's manual and repeat the measurement.
	Contact with electrode broken.	Repeat measurement and make sure that electrodes are in direct contact with the skin throughout the entire measurement.
Measurement does not start.	Electrodes are not in proper contact with naked skin.	Check the instruction manual and repeat the measurement.
	Your body is too tense.	Loosen up and repeat the measurement.
	After a minute of inactivity, the ECG recorder switched 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" tab Fig. 18.

Problem	Cause	Solution
Disturbances of measured signals	Every person has different skin, and if the horny layer is too thick, excessive resistance may occur, which may have an impact on measurement.	Make sure that electrodes are properly applied, and increase the recorder's sensitivity to „high" in the „Electrode sensitivity" tab. Fig. 18.
	The device is exposed to an excessively strong electromagnetic field.	Check whether electromagnetic disturbances are present. If so, switch off the device that may be causing them or change the environment, and then repeat the measurement.
	Electrodes are improperly positioned.	Check the proper electrode positioning in the instruction, manual and repeat the measurement. Fig. 23.
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 one that is compatible with Bluetooth Low Energy technology.
Application message: Connection failed, check whether the ECG device is 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 on.	Switch on the Istel HR-2000 recorder.
	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. 20.
Application message: Connection with ECG device 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 disturbances or recorder failure.	Switch off devices that could potentially emit electromagnetic disturbances.
		Repeat the measurement, and if the problem repeats itself, please contact the Service or your local Distributor.

Problem	Cause	Solution
Application message: No new ECG devices found.	No active Istel HR-2000 ECG recorders.	Make sure that the ECG recorder is 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 ECG recorder and the device on which the Istel ECG application is installed.
Application message: Battery level too low to finish measurement.	Battery level too low.	Replace both batteries with new ones.
Application message: Communication protocol error.	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 contact the Service.
Application message: Your device does not support the data transfer speed required by the Istel ECG application.	The mobile device (tablet/ telephone) does not support the data transfer speed required by the Istel ECG application.	Change sampling frequency in the „Measurement quality" tab. Fig. 17.
Application message: An error occurred during saving of the measurement	The mobile device (tablet/ smartphone) cannot save the measurement.	Make sure that there is sufficient memory on the mobile device (tablet, telephone).
Application message: A problem occurred with the ECG recorder.	An error of the Istel HR-2000 ECG Recorder has occurred.	Switch off the device by removing the batteries. After starting it again, repeat the measurement. If the problem repeats itself, please contact the Service or your local Distributor.
Application message: Attention! Not all devices with the Android OS support high-quality ECG measurement.	The telephone or tablet does not support the data transfer speed required by ECG.	Reduce sampling frequency in the „Measurement quality" tab. Fig. 17.
		Use a different telephone or tablet with an Android OS supporting high-quality ECG measurement.

Problem	Cause	Solution
Application message: Bluetooth transmission error, connection with device 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 contact the Service or your local Distributor.
	Electromagnetic disturbances.	Switch off the devices causing electromagnetic disturbances.
	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.

If problems persist or problems other than those listed above appear, contact the Service or your local Distributor.

7. SERVICE AND MAINTENANCE

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, 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 the Service or your local Distributor.
- The device's housing should be wiped with a soft, slightly moist cloth. Do not use agents containing chlorine or free oxygen – these substances may damage the housing.

Besides maintenance, the user should perform basic inspections of the ECG Recorder independently:

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

7.1 Guarantee

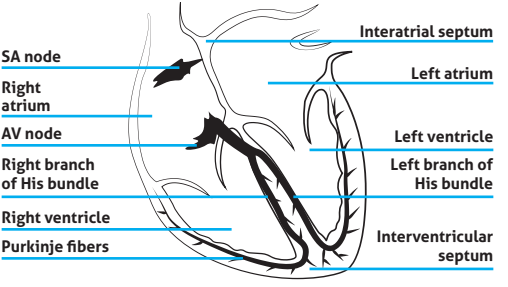
The Istel HR-2000 ECG Recorder has a 2-year guarantee from the date of purchase. After this period or in any other case, if you notice that the Istel HR-2000 ECG Recorder is not operating properly, please

contact the Service or your local Distributor to arrange an inspection. Under no circumstances is the manufacturer liable towards the buyer of the device or any other person for losses related to the purchase or use of the Istel HR-2000 ECG Recorder. Services in the scope of the manufacturer's guarantee require prior contact with the Service or your local Distributor. This guarantee 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.

8. GENERAL INFORMATION ABOUT THE HEART AND ECG

The heart is the most important organ in the circulatory system. Thanks to its rhythmic contraction and relaxation, blood can flow continuously in a closed circulation, supplying oxygen to different parts of the body and receiving carbon dioxide, which is the foundation of humans' life functions. To learn about the principle of ECG, you must understand how the heart works.

The heart's electrical conduction and stimulus generation system has been presented below.



Normal electrical conductivity 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. Since 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.

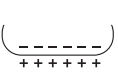
Changes in the electrical signal propagate from the heart through the liquid electrolytes surrounding it to the body's surface, causing different parts of the body to send electrical signals in every cardiac cycle with a certain regularity.

8.1 Principle of ECG operation

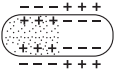
Because tissues and bodily fluids around the heart are conductors, the human body can be perceived as a three-dimensional conductor with length, width and depth. In this case, the heart is the power supply source and the sum of the action potentials of numerous cardiac muscle cells, transmitted to and 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 cardiac muscle cells change their electrical activity is described below.

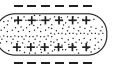
Cardiac muscle cell in resting state: a system of cations surrounds the exterior side of the cellular membrane, endowing it with a positive charge, while the system of anions inside the cellular membrane, with a negative sign, preserve polarization equilibrium, and no changes in potential occur. When 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) Cardiac muscle cell in resting state (repolarization state)



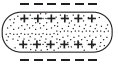
b) Cardiac muscle cell is stimulated (depolarization process)



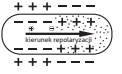
c) Completely depolarized cardiac muscle cell (depolarization state)

Depolarization of cardiac muscle cells

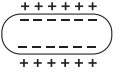
Next, the cellular membrane returns to polarization state – this process is called repolarization. Repolarization takes place similarly to polarization, but the charges are reversed, negative in the front, positive in the back, and they move slowly until the entire cell is repolarized.



a) Depolarization state



b) Repolarization process

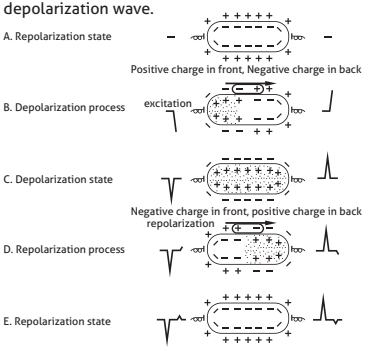


c) Repolarization state

Repolarization of cardiac muscle 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 center. 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.

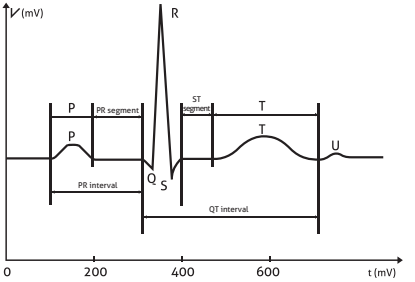


Relationship between waves generated by cardiac muscle cells during repolarization and depolarization.

The principle according to which electrical signals are generated by individual cardiac muscle cells has been described above. In reality, an ECG is generated as a result of complex changes of many cardiac muscle 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 cardiac muscle cells which are simultaneously detectable on the body's surface.

8.2 Electrocardiogram

An electrocardiogram (ECG) is a representation of the heart's electrical activity measured on the body's 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 0.11s, and its amplitude should not exceed 2.5mm.

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 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 then 0.4s, 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.

8.3 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 minutes (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.

8.4 What is arrhythmia

Arrhythmia is a disease involving disruptions of the heart's rhythm related to irregularities in the function of the biolectrical 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: anxiousness, nausea, fatigue, etc. Different people react differently to arrhythmia, mainly because it comes in different forms.

9. TECHNICAL DATA

Technical data of device	Istel HR-2000 ECG Recorder
Electrical safety	Device with internal power supply, CF type device
Power supply	2 LR03 (AAA) batteries
Protection rating	IP22
Device type	CF
Operating temperature and humidity (alkaline batteries)	Temperature: +5°C~+40°C, Humidity: ≤93%
Storage temperature and humidity (without batteries)	Temperature: -25°C ~+80°C, Humidity: 10%~95%
Operating atmospheric pressure range	870 hPa - 1084 hPa
Storage atmospheric pressure range	870 hPa - 1084 hPa
Weight	Approx. 75g (without batteries)
Dimensions	118x66x26mm
Packaging contents:	Istel HR-2000 recorder, Instruction manual, carrying case, guarantee card, batteries, soft cloth

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

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.

Standard IEC60601-1-2 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 standard IEC60601-1-2:2007/AC:2010 with regard to both resistance and emissions.

Nevertheless, special precautions should be taken.

Do not use devices that generate 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 are intended for use in the electromagnetic environment as described below. The customer or the user of the device should assure that the device is used in such an environment.

Emission test	Fulfillment of requirements	Guidelines regarding electromagnetic environment
The emission of radio frequency waves; CISPR standard	Group 1	The 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.
The emission of radio frequency waves; CISPR standard	Group B	The ISTEL HR-2000 can be used in all buildings, including residential buildings, and those that are directly connected to the public low-voltage network, supplying power to buildings intended for residential purposes.
Harmonic emissions IEC 61000-3-2	non applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	non applicable	

Guidelines and manufacturer's declaration regarding electromagnetic immunity.

ISTEL HR-2000 The device 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	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wooden, concrete or made of ceramic tiles. If floors are covered with synthetic materials, the relative humidity should be at least 30%. If ESD interferes with the device, you should consider the use of compensatory elements i.e. wrist strap, grounding.
Fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for	Non applicable	The quality of power supply should be adequate for typical commercial installation or hospital environment.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Non applicable	The quality of power supply should be adequate for typical commercial installation or hospital environment.
Voltage dips, short interruptions and voltage changes on power supply inlets	<5 % UT (>95 % clip in UT) for 0,5 cycle 40 % UT (60 % clip in UT) for 5 cycle 70 % UT (30 % clip in UT) for 25 cycle <5 % UT (>95 % dip de UT) dla 5 s	Non applicable	The quality of power supply should be adequate for typical commercial installation or hospital environment. If the user [of the device or system] requires continuous use even during power interruptions, it is recommended to connect the device or system to emergency power supply.

Magnetic field of the power supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	The level of magnetic fields of power sources should be within the limits applicable for typical commercial installations or hospital environment.

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

GUIDELINES AND MANUFACTURER'S DECLARATION REGARDING ELECTROMAGNETIC IMMUNITY.
The ISTEL HR-2000 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	Wskazówki dotyczące środowiska elektromagnetycznego
Conducted radio-frequency signal IEC 61000-4-6	3 Vrms od 150 kHz do 80 MHz	3V	Portable and mobile radio communication measures should be used at a distance from any of the elements [of the DEVICE or system], including cables, which is not lower than the recommended distance calculated from the transmitter frequency equation. Recommended distance d = 1.2 d = 1.2 80 MHz to 800 MHz d = 2.3 800 MHz to 2.5 GHz where P is the maximum power rating of the transmitter in watts (W) as specified by the manufacturer, and (d) is the recommended distance in meters (m). Field strengths from fixed RF transmitters, as determined in field measurements of electromagnetic fields, should be lower than the compatibility level for each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Emitted radio-frequency signal IEC 61000-4-3	3 V/m od 80 MHz do 2,5 GHz	3V/m	

Recommended distance between portable and mobile radio communication equipment and the ISTEL HR-2000.

The ISTEL HR-2000 is intended for use in the electromagnetic environment in which the interference caused by the emission of radio waves is controlled. The buyer or the user of the ISTEL HR-2000 can help prevent electromagnetic interference by keeping a minimum distance between portable and mobile radio communication equipment (transmitters) and the ISTEL HR-2000, as recommended below, according to the maximum output power of the communication equipment

Maximum rated power of the transmitter W	Distance according to frequency of the transmitter M		
	150 kHz do 80 MHz d = 1,16	80 MHz do 800 MHz d = 1,16	800 MHz do 2.5 GHz d = 2,33
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters assessed at the maximum output power not listed below, the recommended distance d in meters (m) can be estimated using the equation corresponding to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

NOTE 1 at 80 MHz and 800 MHz, the distance for the higher frequency range applies.

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

11. SYMBOLS

	Storage humidity
	Indication of battery polarity
	Direct curret
SN	Serial number
	Manufacturing date
	Manufacturer
	Must not be used by people with peacemakers
	Typ CF
IP 22	IP22 is protected from touch by hands greater than 12,5 millimeters. Protected from water spray less than 15 degrees from vertical
CE 0197	Symbol attesting compliance with the European Union Directive 93/42/ECC for medical devices
REF 8003	Product catalog number
Rev.	Date of the last revision
	Protect against moisture
	Keep away from sunlight
	Read the user manual before use
	Warnings

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 or your local Distributor.

Warning: Any changes and/or modifications of this product that have not been expressly approved by the party responsible for ensuring compliance may result in termination of your rights to operate the product.

MANUFACTURER'S DATA

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E-MAIL: info@diagnosis.pl
www.diagnosis.pl

CE 0197

REF 8003

Rev. 2016.11.17
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