

ECG Recorder

Model 06000

Version: 1.06.en



Operating Manual

For use with the system of
Internet - monitoring **Telecardian**
and Holter **DiaCard**

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Symbols and abbreviations

In this document, the following symbols and abbreviations are used:

DC	operation mode compatible with the standard DiaCard
TC	operation mode compatible with the standard Telecardian
PS	power supply
ECD	external control device (Tablet, smartphone)
CH	Charger
MC	microcontroller
min	minute
OS	operating system
PC	personal computer
SW	software
r-r	recorder
s	second
FT	functional test
h	hour
HR	heart rate in beats per minute
CMC	central microcontroller
ECG	electrocardiogram
ECS	electric cardiac signal

Introduction

Dear user!

Joint Stock Company "SOLVAIG" expresses its appreciation and thanks for your trust.

From our side we guarantee the highest degree of responsibility and efficiency of the equipment purchased.

The equipment is modern and a technically complex device to work with requiring certain knowledge and skills.

To the attention!

- ✓ carefully read the instruction manual;
- ✓ use only the original accessories and interchangeable standard consumables;
- ✓ for the purpose of data analysis and interpreting, please refer to the appropriately qualified specialists (cardiologists).

For any questions that may arise during the operation of the device, as well as suggestions and comments, please refer to the company - the manufacturer or an authorized representative.

Manufacturer reserves the right to amend and supplement the scope of delivery and the version of the internal SW of the recorder, without impairing its technical parameters and functional properties.



The manufacturer guarantees the stated technical parameters only when the recorder is used together with the original accessories and consumables.

In the case of non-original consumables and accessories the user knowingly assumes all risks and consequences.

General provisions

Purpose

Electrocardiogram (ECG) Recorder model 06000 – portable battery-powered device, designed for the registration of the electric cardiac signal (ECS) in 1 (bipolar) or 6 standard (mono-pole) leads and for transmission the data to the external control device (ECD) in real time.

As the ECD such devices can be used, as: a personal computer (PC), laptop, tablet or smartphone; running on operating system (OS) Android 4.0 +, on which the special «**DiaCard-ECG Recorder**» software (SW) has been installed.

Application

The Recorder can be used as part of the online monitoring system **Telecardian**, Holter **DiaCard**, as well as in computer electrocardiography systems of different profile, namely:

- ✓ Department of cardiology and functional diagnostics;
- ✓ In call-centers; remote monitoring centers;
- ✓ At emergency services of general (civil) profile;
- ✓ Medicine of catastrophes, the hospitals, medical units;
- ✓ Sports medicine, for research purposes, expeditions;
- ✓ On an outpatient basis (at home, working place, during the rest or travel).

Capabilities

The Recorder, being user-friendly and small-sized, has the high performance, inherent to the High End class of equipment.

Application of the recorder bundled with ECD provides broad functionality, namely:

- ✓ the registration of ECS with leads wire (3 or 4 electrodes), or with finger electrodes, built-in in recorder box;
- ✓ viewing the ECG on the display of ECD with the options of control (change):
 - number of displayed channels: 1, 3 or 6;
 - sweep speed: 6.25; 12.5; 25; 50; 100 or 200 mm/s;
 - signal calibration: 2.5; 5; 10; 20 mm/mV;
 - ECS amplification factor: 0.5; 1; 2; 4 or 6;
 - digital filter: 0.005; 0.01; 0.05; 0.1; 50/60; 75 Hz;
- ✓ Hear rate (HR) calculation, electrode breakage control;
- ✓ «Heart monitor» mode with the installation of alarms: bradycardia, tachycardia, a pause;
- ✓ the operation as a part of the observation station (up to 6 recorders) in local and remote modes; remote control of view/record functions; call for doctor;
- ✓ dispatch (transfer) of records and/or reports (.pdf) by e-mail;
- ✓ «patient-doctor» data exchange by the use of cloud storages (Google Drive, Dropbox, etc.);
- ✓ data transfer to the Internet system “**Telecardian**”;
- ✓ ECG records import to the Holter system “**DiaCard**”;
- ✓ integration with the different hospital information systems (HIS).

Specifications

Number of leads (of electrodes)	1 (2, 3), 6 (4)
Input voltage range	$\pm 0.005 \pm 5.0$ mV
Frequency range:	
- finger electrodes;	0.1 \div 45 Hz
- cable	0.005 \div 100 Hz
Input impedance	> 10 MOhm
Suppression of common mode noise:	
- finger electrodes;	≥ 90 dB
- cable	≥ 100 dB
The ADC: capacity, type	24-bit $\Delta\Sigma$
The frequency of conversion	250, 500, 1000 Hz
Digital filtering	0.005; 0.01; 0.05; 0.1; 50/60; 75 Hz
Electrodes breakage control	Yes
Communication interfaces	Bluetooth (SPP), class 2
Power, battery type	Li-Pol; 3.7 V; 650 mA/h
Duration of operation / standby	Up to 14 hours / 1 year
Dimensions	66x52x12.7 mm
Weight (with the battery)	47 g

Contents of delivery

ECG recorder, model DC-06000 (modification 01, 02 or 03), pcs.	1
PS $\sim 110 \div 220$ V 50 $\div 60$ Hz / 5V 1A, USB (AF)	1
Power cable microUSB (BM) / USB (AM), pcs.	1
Instruction manual, brochure, pcs.	1
Cardboard package, pcs.	1

Accessories

Lead wire of 3 wires – electrodes with 3.5 mm stereo connector

Lead wire of 4 wires – electrodes with 3.5 mm stereo connector

Chip - extender for 3 sockets DIN-1.5 mm with 3.5 mm stereo connector

Chip - extenders for 5 sockets DIN-1.5 mm with 3.5 mm stereo connector

Lead Wires DIN-1.5 mm, button / clip

Electrodes on the limbs of the "clothe spin" type

Thoracic suction bowl electrodes, for different age groups

Disposable electrodes for ECG, different

Gel-electrode conductive paste, ECG / EEG

ECD (tablet, smartphone) with the OS Android

PS AC ~110÷220V 50÷60Hz / 5V 2A, USB (AF), to charge the tablet

A source of the autonomous energy supply of Powerbank type from 2200 mA/h and above

Bag-packing with the logo «Paramedic. DiaCard », 305x260x70 mm

Bag-cover for mounting the recorder on the waistband

Waist belt

* *consumables and accessories in the standard package are not included and must be ordered separately.*

Structure of the Recorder

Recorder is a compact, ultra-lightweight self-powered electronic device, made in shockproof ABC – plastic box.



Elements of control and indication:

- 1 Bluetooth module indicator
- 2 PS charge indicator
- 3 MicroUSB socket
- 4 Button «I/O»
- 5 Finger electrode (left hand)
- 6 Finger electrode (right hand)
- 7 Socket for ECG cable

Electronic scheme of the recorder is implemented on the basis of the MC architecture of ARM CORTEX-M3. ECG module work is implemented on the basis of a specialized chip ADS1292 (Texas Instruments).

The algorithm of operating with the Recorder is simple as most as possible and intuitive.

Category of users - without any restrictions, with the exception of children under-5 years of age, patients with limited physical activity and mental disorders.

The ECG registration does not require professional knowledge and special skills, however, the appropriately qualified specialists (cardiologists) have to be involved in the data analysis and interpreting.

Control elements

For managing the work of recorder is used only one button «I/O».

Everything else is managed in automatic mode or from ECD.

Button «I/O»

Button «I/O» is used in following cases:

- ✓ switching on and off the recorder;
- ✓ remote control by ECD (requires on programming on ECD);
- ✓ cancellation of sound indication.

Detailed use of the button «I/O» is given in the following sections of this guide.

Indication

Recorder information interface is implemented by sound and LED indicators.

Sound indicator

Recorder has the sound indicator of the «Buzzer» type. The sound indicator is used in the following cases:

- ✓ enable / disable the recorder;
- ✓ confirmation «I/O» button is pressed;

- ✓ confirmation of the beginning and the end of the process: connection/ disconnection, ECG amplification factor adjustment, connection of the external PS, the charge / discharge of the battery, etc.

All audio signals are divided by the number and duration.

Sound tonality and volume – CANNOT BE ADJUSTED.

LED indicators

Two LED indicators are used while the recorder operation: green and blue.

Green	Battery charge mode
--------------	---------------------

Blue	Bluetooth module mode
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Detailed description of LED indicators is given in the following sections of this guide.

Power supply

Recorder is powered by built-in Lithium-polymer battery.

The recorder running time depends on the battery charge level. New fully charge battery allows ECG registration in the continuous ECD data transfer mode for up to 14 hours.

In the off condition recorder consumes almost nothing, that allows saving the battery power for an extended period of time.

Accumulator charging

To charge the recorder battery any external PS with an output DC voltage 5.0 ± 0.25 V and current of at least 500 mA can be used.

An external PS is connected to the micro-USB connector of the recorder using a special power supply cable (included in the delivery set). You can use a standard interface available wire USB-2 (AM) / micro-USB (AM).

To control the charging process in the recorder a specialized charge controller is used.

When connected the recorder to an external PS, the charging process automatically starts – green LED turns on and lights up during the whole charging time.

The LED indicator turns off at the end of the battery charge.

The charging time depends on the battery state, charge level, the external PS source and ambient temperature.

Battery charging should be performed at ambient temperature of $+10 \div +35^{\circ}\text{C}$.

At decrease of ambient temperature to 0°C the capacity of rechargeable battery is $1.5 \div 2$ times reduced. At decrease of ambient temperature up to minus 10°C the battery charging process is not performed.

When the ambient temperature exceeds $+35^{\circ}\text{C}$ the risk of battery output failure increases due to overheating.

The battery is equipped with a temperature sensor that reduces the risk of overheating, but does not exclude it completely.

The charge time of the completely discharged operable battery does not exceed 3 hours.

In case of the deep battery discharge (voltage less than 2.8 V), the charging time can be prolonged by $10 \div 30$ minutes.

The maximal allowable charging time is softwarely limited to

6 hours. If the battery is not fully charged within this period of time, the charging process will be terminated automatically, as evidenced by an intermittent sound signal (3 short beeps with 1 s pause) during the following 30 s. Any push the «I/O» button will terminate the sound indication. In this and similar cases, the battery is defective.



The recorder use with the defective battery is strictly PROHIBITED!

The defective battery has to be immediately replaced.

Non-compliance with present recommendations can be hazardous to the user's health, as well as lead to recorder damage.

After the battery charge is completed, the recorder can be connected to the external PS for some period of time without any hazard to the battery. When the battery voltage drops to a level of 3.9 V, the charging process will be resumed automatically.

Replacing the battery

Estimated battery life is up to 2 years or 500 charge / discharge cycles of the battery, the rate of use of recorder 8 hours 5 times a week.

In the case of operating the recorder at ambient temperatures below + 10°C or above + 35°C, battery life is reduced significantly, thus leading to the potential need for its premature replace.

The battery should be replaced after the expiration of 2 years from the date of the recorder issue. Recorder battery should also be replaced when the recorder operation time with fully charged battery is less than 2 hours.



Battery replacement must be performed by qualified personnel only in specialized service centers or at the manufacturer's enterprise.

Communication interfaces

Recorder is equipped with Bluetooth module, which allows wireless connection with ECD at a distance of not less than 10 m line of sight.

Bluetooth is used in such cases, as:

- ✓ recorder setting (operating parameters and modes);
- ✓ ECG transfer from recorder to ECD;
- ✓ maintenance (metrological verification, recorder's MC firmware upgrades).

Safety

Recorder complies with international standard IEC 60601-1, Type BF.



The recorder is not provided with the built-in defibrillator pulses protection. To save recorder operational capability, prior to performing defibrillation, you must disconnect the cable leads from the recorder.

Preparing the recorder

This section describes how to prepare recorder to the work with the general and specific requirements of individual methods.

General requirements

Remove the recorder and all the necessary components from the packaging before you start to work. If the equipment is stored before in a damp, unheated room, before switching on it must be kept for at least 2 hours at a temperature of $18 \div 20^{\circ}\text{C}$ and relative humidity of not above 80%.

Disinfect the recorder and all the accessories that may have contact with the body of the patient, with the cloth moistened with in a 3% solution of hydrogen peroxide or any other disinfectant solution intended for this purpose.



It is strictly forbidden to carry out disinfection and cleaning the recorder with the solutions containing any alcohol and solvents.

Depending on the intended mode of operation (short-term registration or continuous monitoring), take a decision on the type of registration: by means of finger electrodes or lead cable, - and then charge the battery. The recorder is delivered with the partially charged battery ($60 \div 80\%$).



The combining of operation mode and battery charge is strictly prohibited!

You may combine the ECG registration mode and battery charge in case of use the external autonomous compact battery sources, such as Powerbank; some deterioration of the quality of ECG registration is possible in such cases.

Finger electrodes

The special electrodes are built-in in the top cover of the recorder box, allowing the ECG registration from the fingers of both hands.

Finger electrodes are made of conductive plastic and coated with silver chloride (AgCl), allowing to minimize the level of polarization that occurs in a galvanic pair «skin-electrode».

ECG registration with finger electrodes requires less time, effort and professional skills to prepare for registration, than those needed for the patch of the electrodes when registering with the lead cable. However, it should be noted that due to the specific characteristics of this method, the quality of the ECG registration with the finger electrodes is significantly lower than the registration by means of lead cable. The ECG signal is more susceptible to a variety of noise and artifacts caused by patient movement, tremors in the hands and other parts of the body, uneven pressing of electrodes by fingers, PS noise and electromagnetic noise from the radio and electrical devices.

To reduce the impact of these factors is necessary to adhere to the following guidelines:

- ✓ to improve the contact between the electrodes and the fingers you need to apply a special conductive gel paste (after registration of the electrodes has to be cleaned of paste residues)
- ✓ registration is performed in a static quiescent state, preferably in the position of sitting or supine position;
- ✓ arms slightly flexed at the elbows, lie on a hard, flat surface or are pressed to the body (in dress); in the supine position – arms lie on the abdomen;
- ✓ recorder is held without excessive force and muscular tensions, and the thumbs are pressed against the surfaces of the respective electrodes (electrodes marking shown on the top cover of the recorder box);
- ✓ for ECG recording you have to control the patient's arms not to touch

with each other (Fig. 1); in case of breaking this rule the ECG recording is not possible (Fig. 2);

- ✓ in the absence of another person (assistant), use the button «I/O» to start ECG viewing/recording; the «I/O» button is located on the left side face of the recorder box;
- ✓ upon completion of registration electrodes should be wiped with a clean napkin, removing the remnants of the gel - paste or saline solution.

Correct



Fig. 1

Incorrect



Fig. 2

Lead cable

Recorder provides the use of 2 different types of lead wires 3 (Fig. 3) or 4 (Fig. 4) wires – electrodes with 3- or 4-pin stereo connector 3.5 mm, respectively (not included in the delivery set; have to be ordered separately).

The socket for ECG cable connector is located on the front side of the recorder box.

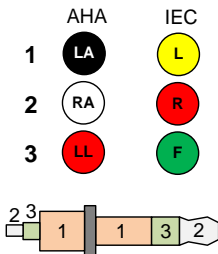
Color-coded electrodes, ANA and IEC standards.

Name	AHA / IEC	AHA (electrode color)	IEC (electrode color)
Left hand	LA / L	Black	Yellow
Right hand	RA / R	White	Red
Left leg	LL / F	Red	Green
Right leg	RL / N	Green	Black



In the case of using non-original ECG leads wires, the manufacturer cannot guarantee compliance with all declared technical parameters.

Cable: **3A(AB) / 3I(IB)**



Stereo 3.5 mm / 3-pin

Fig. 3

Cable: **4A(AS) / 4I(IS)**



Stereo 3.5 mm / 4-pin

Fig. 4

The scheme of electrodes patching of patient's body surface in case of lead cable with 3 wires – electrodes is presented in Fig. 5 and Fig. 6, respectively.

Cable: **3A(AB)**

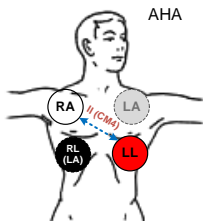


Fig. 5

Cable: **3I(IB)**

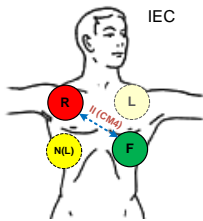
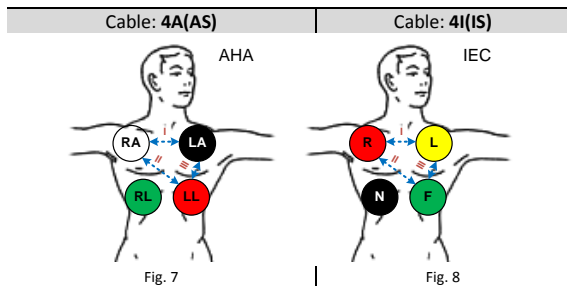


Fig. 6

The scheme of electrodes patching of patient's body surface in case of lead cable with 4 wires – electrodes is presented in Fig. 7 and Fig. 8, respectively.



The ECG cable connector has no blocking lock, thus needed to be fixed by means of case-handbag is case of continuous ECG monitoring (not included in the delivery set; has to be ordered separately).

Case-handbag

Case-handbag intended for fixing the recorder on the patient during the examination against a backdrop of physical training and/or increased patient mobility, as well as during observational monitoring, Internet-monitoring, event recording or Holter monitoring.

Case-handbag is fastened to the patient's belt in a vertical position with the waist belt up to 40 mm wide (not included in the delivery set; has to be ordered separately).

Operating with the Recorder

Before working with the recorder with the ECD it is necessary to install special software «**DiaCard-ECG Recorder**», the base version of which is distributed free of charge.

Installing the software is executed from Google Play Market from the link in the QR-code.



User's Guide to the software « **Dia-Card-ECG Recorder**» is available in electronic version (PDF format) after installing the software on ECD (in main menu).

Turning on the recorder

Recorder is activated by pressing the button «I / O» and holding it down for 2 seconds.

Recorder is switched on, provided that the battery voltage is in the "working" range 3.6÷4.2 V.

Switching on the recorder is accompanied by two short beeps.



The voltage and charge level of the battery are displayed on ECD in the window «Operations / Recorder», once the recorder is connected to the ECD.

While a switching on the recorder, a check of basic elements, modules and assemblies is performed. In case of any critical error, 10 long beeps are heard, with the subsequent switching off the recorder.



To determine the cause of the malfunction and fix it one must apply to the specialized service center.

The operating status of recorder is indicated by blue LED indicator, presenting the Bluetooth module (flashing or static light).

When the battery voltage becomes lower than 3.6 V, it sounds the short beep, repeated every 60 s.

When the battery voltage becomes lower than 3.3 V, nine short beeps sound with the 1 s pause, with the following tenth long beep, after which the recorder turns off irrespective of the current operation mode.

Connecting via Bluetooth

Bluetooth is turned on immediately after the recorder is on and remains on throughout the working period.

When you first connect the recorder to the ECD, it is necessary to turn on the ECD Bluetooth. Then find in the broadcast area the device named «**DC06000_num**» and connect to it. The password for connection is «0000».

When you turn on the recorder and launch the ECD SW the next time, the recorder will automatically connect to the ECD. You do not need to type the password again.

There are three modes of the Bluetooth module work:

Indicator	Mode
Flashes	<i>Searching of compatible ECD in the broadcast area.</i>
Static	<i>Connected to ECD, data transfer is not carried out.</i>
	<i>Data is being transmitted between the recorder and ECD.</i>

Distant control of ECD by the recorder

The recorder provides distant control of some ECD functions. The control is carried out by means of «I/O» button when the recorder is enabled.



Distant control of ECD by the recorder is possible in local and remote modes only in case of established connection and data transferring between both devices. The ECG registration has to be launched, and the window of ECG view and monitoring has to be opened.

Local mode: a single short push the «I/O» button initiates the recording. Any push the «I/O» button until the end of 120 s period from the beginning of the recording initiates the end of the recording. Any push the «I/O» button outside the 120 s period from the beginning of the registration initiates the recording of «Event label».

Remote monitoring mode: any push the «I/O» button initiates the message (event) transfer from the recorder to the remote ECD. In majority of cases this push is initiated by the patient, and the transferred message is a call for medical staff, or aimed to attract attention to the current patient's state.

Turning off the recorder

Recorder remains off and turned on only for the duration of the examination.

Recorder can be turned off:

- ✓ with the «I/O» button;
- ✓ after the time is out;
- ✓ according to voltage.

With the button

To turn off the recorder using the «I/O» button, press the button for 3 s.

The long beep sounds, right after which the recorder turns off.



Recorder is turned off «by the button», irrespective of what mode it is, except the mode «SW update».

After «Time is out»

To save the battery power, it is provided the switching off by «Time is out», according to the timer.

If the recorder is not in the data transfer mode, OFF Timer is started.

The off time intervals:

5 min for the standby mode without a connection to ECD;

30 min for the standby mode without data transfer (when the connection to ECD is established).

Pushing the «I/O» button or the beginning of the data transferring from the recorder to ECD sets OFF Timer to the initial state.

According to voltage

In all recorder modes the battery voltage level is continuously monitored.

The current voltage level of the battery is displayed in the ECD windows: «Operation» and «Registration».

The possible operating mode of the recorder is chosen by MC depending on the current battery voltage level.

When the battery voltage lowers up to 3.6 V (10% of battery charge), it sounds a single repetitive beep, while the recorder continues to operate.

At decrease of voltage less than 3.3 V, the recorder is turned off automatically.

Service maintenance

This section describes the warranty conditions and the procedure for updating the internal SW recorder modules.

Warranty

The term of the warranty of the recorder is 18 months from the date of purchase, but not more than 24 months from the date of manufacture.

The term of the warranty on the battery (installed) is 12 months from the date of recorder purchase.

Under the warranty to be understood the free elimination of any malfunctions, as well as replacement of any component, which is an integral part of the whole.

The guarantee does not apply to cases:

- ✓ violation of the integrity - opening evidence of tampering;
- ✓ mechanical damage of any housing component, including buttons and sockets;
- ✓ exposure to high temperatures, liquids, entering inside of the foreign objects;
- ✓ the use of non-original accessories, in particular PS's.

Accessories (PS's, wires, cables, adapters, electrodes, cases, belts, etc.) are consumables with a conditional warranty period of 1 to 6 months from the date of purchase. The warranty is valid only in the case of factory defects.

The cost of transporting the recorder or any accessory to the service center and back is paid by the user.

Guarantee requirements of the customer are confirmed by a copy of the document on the acquisition with the obligatory indication of the seller and the date of sale.

Estimated battery service life - up to 2 years, after which it is

obligatory to be replaced.



Delayed battery replacement can lead to its destruction and irreversible damage to recorder.

Average life of the recorder is at least 5 years.

Recorder SW Update

The recorder supports the embedded SW update function.

Checking the recorder embedded SW versions is performed for each communication session with ECD.

The internal recorder SW is renewed forcibly. This is a compulsory measure to maintain compatibility of the embedded recorder SW and SW of the ECD.

SW update function has the highest priority. If, after the connection with ECD, an update is detected, it automatically starts the download mode of the new SW version into the recorder and reprogramming.

If the battery voltage of the recorder is less than 3.7 V, the SW update is not performed.

If, for some reason, the update function cannot be started, the update procedure is canceled.

During the SW update a progress indicator in percentage is displayed on the display of the ECD.

Update time of recorder embedded SW is no more than 2 minutes.



It is strictly prohibited to interrupt the process of SW updating. This can result in damage to the recorder and the need to restoration in the service department.

Upon successful completion of the update the corresponding message is displayed.

If, for some reason, the update of the recorder SW has been

completed with an error or was interrupted, the automatically restoration of the «factory» version of the embedded SW for the CMC module is provided. «Factory» version of CMC SW is a completely working and in most cases compatible with the basic functions of the « **DiaCard-ECG Recorder** » SW.

After restoring the factory version, it is possible to re-update the embedded SW of the recorder.

In the case of an unforeseen situation, the user has the right to ask for assistance from the service center.

Battery replacement

The recorder is equipped with lithium - ion battery, which is installed with the release of recorder at the manufacturing enterprise.

Replacing the battery involves disassembly of the recorder that refers to the violation of the integrity and entails the termination of the warranty.

The work of replacing the battery can only be performed in qualified service center by specially trained personnel.