# ECG Recorder

# Model 12010

version 1.07.en



# **Operating Manual**

For use with the system of Internet – monitoring **Telecardian** and Holter **DiaCard**  © Copyright SOLVAIG Joint Stock Company.

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## Symbols and abbreviations

In this document are used the following symbols and abbreviations:

DC	operation mode compatible with the standard DiaCard
тс	operation mode compatible with the standard Telecardian
PS (PSU)	power supply (power supply unit)
ECD	external control device (Tablet, smartphone)
СН	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	Electrocardiosignal

# 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 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 software 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

ECG Recorder model 12010 - portable battery-powered device, designed for the registration of ECS in 1  $\div$  12 standard (monopole) leads and for transmission the data to an external control device (ECD) in real time.

As the ECD can be used: a personal computer, laptop, tablet or smartphone; running on OS Android 4.0 +, on which is installed the software "**DiaCard – ECG Recorder**".

# **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;
- ✓ For ECG control of patients in real conditions;
- ✓ At emergency services of general (civil) profile;
- ✓ Medicine of catastrophes, the hospitals, medical units;
- ✓ Transport: road, rail, air, river and sea;
- ✓ Sports medicine, for research purposes, expeditions;

## **Capabilities**

The Recorder 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 in 1 ÷ 12 leads with the transmission of data to ECD in real time;
- ✓ support for working with cables on 3, 4, 5, 7 or 10 wires electrodes;
- ✓ viewing the ECG on the display of ECD: 3, 6 (7) or 12 channels, change of speed, amplification, digital filtering, monitoring breakage of the electrodes, the HR calculation;
- ✓ "Heart monitor" mode with the installation of alarms: bradycardia, tachycardia, a pause;
- ✓ The ECG recording in the internal memory of ECD (up to 24 hours);
- ✓ operating with the archive, report generation, output to a printer or to a file (.pdf);
- ✓ Dispatch (transfer) of records and / or reports by e-mail, to the call-center, and so on.

## Specifications:

Number of leads (of electrodes in the cable)	1 (3), 6 (4), 7 (5), 9(7), 12 (10)
Input voltage range, ~ / =	±0.005 ÷ ± 5.0 / ± 300 mV
Frequency range	0 ÷ 100 Hz
Input impedance	> 10 MOhm
Suppression of common mode noise	≥100 dB
The ADC: capacity, type	24-bit ΔΣ
The frequency of conversion / transmission	2000 / 250, 500, 1000 Hz
Digital filtering	0.005, 0.01, 0.05, 0.1, 50/60; 75 Hz
Electrodes breakage control	Yes
Protection against defibrillator pulses	*Yes
Communication interfaces	BT-3.0 (SPP)
Display	OLED 0,96" 128x64 (monochrome)
Power, battery type	Li-Pol; 3,7 B; 950 mA/h
Duration of operation / standby	under 6hour/ 1 year
Dimensions (without external connection)	106x60x19 mm
Weight (with the battery, without cable)	118 g

\* using a lead cable with built-in ballast resistors.

## Contents of delivery:

The Recorder model DC-12010, pcs.	1
Fixing belt, pcs.	1
Instruction manual, brochure, pcs.	1
Cardboard package, pcs	1

#### Accessories:

Lead wires of 3, 4, 5, 7 or 10 wires - electrodes with different endings (plug 3 mm, 4 mm, button, clip), with instrumental connector DB-15M, D-SUB Chips - extenders for 3, 5, 7 or 10 sockets DIN-1.5mm. DB-15M. D-SUB Lead Wires DIN-1.5mm, 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 External control device (tablet, smartphone) with the OS Android 4.0 + Power supply AC ~ / 1.0A + 5V (USB-AF), to charge the recorder Power supply unit AC ~ / 2,0A + 5V (USB-AF), to charge the tablet A source of the autonomous energy supply of Powerbank type from 2200 mA/h and above Interface micro USB cable (BM) / USB (AM), 1.8 m Cable OTG micro USB (BM) / USB (AF), 0.2 m Bag-packing with the logo «Paramedic. DiaCard», 305x260x70 mm Bag-cover for mounting the recorder on the waistband Bag-Case for mounting Powerbank, on the belt 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 ABS – plastic housing.



Digital recorder circuit is configured by a modular principle. Each module is a complete self-contained unit working under the control of a separate microcontroller and specially developed software (SW).

Recorder consists of two basic units:

- ✓ ECG module;
- ✓ CMC module.

# ECG module

ECG module is designed to perform the following tasks::

- ✓ the registration of ECS in standard 1 ÷ 12 leads;
- ✓ input amplifiers unit protection of the defibrillator pulses;
- ✓ ECG amplifying, the conversion to a digital signal, math, processing (digital filtering) and the formation of data packets to be sent to CMC module.

ECG module work is implemented on the basis of a specialized chip ADS1298 (Texas Instruments) and 32-bitMC ARM Cortex-M3 (ST).

ECG module works in slave mode, under the control of CMC module, with a full galvanic isolation (up to 6000V) from the CMC module.

After switching on and testing recorder, ECG module is switched off, and only switched on for the time registration ECS.

## CMC module

CMC module (of central microcontroller) designed to perform the following tasks:

- ✓ Operation control of ECG module;
- ✓ operation control of the Bluetooth module;
- ✓ control of the USB mode;
- ✓ work with the internal clock and calendar;
- ✓ operation control of graphical OLED display;
- ✓ managing audible indication "Buzzer";
- ✓ monitoring the battery voltage;
- ✓ operation control of battery charge controller;
- ✓ calculation of charging time battery discharge;
- ✓ control of clicks on the button «I/O»;

- ✓ work with ambient light sensor;
- ✓ CMC software update;
- ✓ MC of ECG module software update.

Electronic scheme of the recorder is implemented on the basis of the microcontroller architecture of ARM CORTEX-M4, running under control of OS Free RTOS.

### 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;
- ✓ request confirmation; cancellation of data messages;
- ✓ cancellation of sound indication.

Detailed use of the button  $\ll\!I/O\!\!>$  is given in the following sections of this guide.

#### «RESET» button

«RESET» button is a service button, and is intended for emergency restart of CMC in case of undeclared situations during operation of the recorder.

The «RESET» button is located inside the recorder to the left (view on the indicator) at the junction of the upper and lower housing lids - round-shaped hole of 1 mm in diameter, has no external pushers or other mechanical controls that extend beyond the recorder housing. The hole location to access the «RESET» button is applied to the lower lid of recorder housing.

Pressing the button «RESET» is performed by using any available pusher up to 1 mm in diameter, which may be made of metal wire with a diameter of 1 mm. For these purposes, it may well come a paper clip (in the unbent state).

To trigger the CMC restart function, you must click on the button «RESET», to a lightly tangible click. The Recorder must switch off, that will be evidence of the transition to a standard operating condition - waiting for enabling by the button «I/O».

#### Power supply

Recorder is powered by built-in lithium - ion battery.

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

When power is on, the consumption depends on the selected operating mode and the communication interface with ECD.

#### Accumulator charging

To charge the recorder battery can be used any external power supply with an output DC voltage 5,0  $\pm$  0,25 V and current of 1.0 A and more.

An external power supply is connected to the micro-USB connector of the recorder using a special power supply cable. You can use a standard interface available wires USB-2 (AM) / micro-USB (AM), with a low internal resistance of power wires.

To control the charging process in the recorder used a specialized charge controller, which ensures compliance with all the requirements for charging the lithium - ion batteries and battery protection for current, voltage, temperature of the element and the maximum charging time.

Charge Controller provides three modes that are set by CMC automatically depending on the type of power supply:

Mode 1 from the USB - small current - 100 mA;

Mode 2 of the USB - high current - up to \*500 mA;

Mode 3 from an external PS, high current, up to \*\*750 mA.

provided that USB host controller supports mode 500mA;

 $^{\ast\ast}$   $\,$  - provided that the external power supply is designed for the operating current >1,0 A.

Battery charging time depends on the remaining capacity and the selected charging mode.

When connected to an external power source to the recorder, the recorder is automatically enabled. On the display in the toolbar icon is displayed about the connection to the recorder of external power source and a text message of the selected mode.

Later on, the charging process is indicated on the display by the battery icon, and when you turn off the display, using green LED - lights up during the charging time.

Upon completion of the charging process on the recorder is displayed the appropriate message. After turning off the recorder the LED display blinks while the recorder remains enabled in the low-power mode, it is powered by an external power source (not the battery).

Battery charging should be performed at ambient temperature of +  $10 \div + 35^{\circ}$ C. At decrease of ambient temperature below +  $10^{\circ}$ C the capacity of rechargeable battery is significantly reduced. At decrease of ambient temperature up to minus  $10^{\circ}$ C the battery charging process is not performed.

When the ambient temperature exceeds + 35 °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.

### Running time

Recorder is equipped with the "current monitor", which allows you to calculate the remaining operating time, based on the current consumption and remaining battery capacity. The

value of the remaining operating time of recorder is displayed in the toolbar. The maximum possible value for the induction is (hours, minutes). At the time of switching-on the recorder information about the remaining operating time of recorder is absent. Primary calculation is performed for the first 5 minutes. During this time, in the time remaining icon is displayed Further, the time remaining value is updated once in 10-15 seconds.

Continuous working time of the recorder in data transfer mode (communication interface - Bluetooth), when powered by the internal battery is up to 6 hours.

When using the USB-interface, the recorder is powered by ECD. In this case, the internal power supply recorder turns off automatically. If USB host controller f the ECD provides the current of  $\geq$ 250 mA, the recorder CMC automatically activates one of the battery charging modes (1st or 2nd).

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.

Recorder battery should 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.

# Indication

Recorder information interface is implemented by graphic display, LED and sound indicators.

### Graphic display

In the recorder is used compact monochrome graphical OLED (Organic Light Emitting Diode) display with the size of the active area of 0.96"and a resolution of 128x64 pixels (hereinafter - the display).

The displays made on OLED technology, have a balanced intake, have a good readability in all ambient light range and a wide viewing angle.

Conceptually, the active display area is divided into two unequal parts (000) vertically, from the top - down:

- ✓ ¼ part icons and mnemonics area , «toolbar»;
- ✓ ¾ parts working area, «workspace».

Toolbar:

- ✓ battery charge level;
- external power supply connection;
- estimated working time;
- ✓ the state of the audio signal "on / off";
- ✓ information on connecting to ECD by USB;
- Information on connecting to ECD by Bluetooth;
- ✓ data transfer from recorder to ECD;
- ✓ Deferred mode timer.



# Toolbar - description of icons and mnemonics

lcon.	Description (what means and how it works)
\$	Power indicator of Bluetooth module: - searching and waiting to connect the ECD, flashing at 1 Hz - established the connection to ECD through another interface, static
*	Connected to ECD using Bluetooth, static
* *- **	Connection to ECD by USB, the mode is not chosen
*	USB, terminal, the service mode
$\odot$	ECG is enabled, no data transmission
X	ECG module is enabled, data is being transferred, is displayed statically
4	Sound LED is on, when switched off - nothing is displayed
¥	An external power supply is connected: - Static - the battery charging is performed; - Flashing 1 Hz - the charge is completed.
-:	Estimated time at the start time of recorder is absent
9:59	Maximum estimated time of operation of the device is 9 hours and 59 minutes, if it is more, it is still 9:59
Î	The voltage on the battery $\geq$ 4,10V, static
Ô	Battery voltage <3.6V, static
٥	The voltage on the battery ≥3,50V; <3,55V, flashing at 1 Hz
?	Battery is defective, flashing at 1 Hz
×	The battery is missing: recorder powered from an external power source

Workspace:

- ✓ start screen saver with information on the recorder;
- reporting of current events;
- ✓ the current date and time

Any message that is displayed in the work area of the display, is displayed for no more than 3 seconds, or until you press the button «I / O».

Display interface is multilingual, by default - English. Whenever you connect the recorder to ECD, the interface language of ECD is checked.

If the interface language of ECD is in the list of languages supported by the recorder, the recorder interface language is changed automatically on the interface language of ECD.

If ECD interface language is not in the list of languages supported by the recorder, the recorder interface language is defined by the "default" - English.

To reduce consumption, on the expiration of a specified period of time, the display turns off, and the recorder remains in working condition, as indicated by the blinking LED.

Provided manual switching on-off of the display and is performed by a single short press on the button «I/O».

Recorder is equipped with a photosensor that measures the level of ambient light, allowing you to automatically change the brightness of the display illumination, which has a positive effect on consumption and improving the perception of the display.

### LED indicator

In the recorder is used green LED, which indicates the operation modes of recorder when the display is off, namely:

Recorder is enabled, the display is turned off, charging is com- pleted (if connected to an external power supply) mode
The external power source is connected to the recorder, the charging mode is performed.

#### 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 button is pressed;
- ✓ confirmation of the beginning and end of the process;
- information messages: installation / disconnection, connect an external power source, the charge / discharge of the battery, etc.

All audio signals are divided by the number, duration, and tonality. Sound volume cannot be adjusted.

Sound recorder display can be turned on or off with ECD (see. OM the Software « **DiaCard - ECG Recorder** ", "Settings / Audio" section).

### Communication interfaces

Recorder is equipped with Bluetooth wireless interface to connect with ECD (requires installation of special related software).

### Bluetooth

Wireless Interface: BT-3.0 Class 2 (up to 10m), SPP profile; used in the following cases:

- ✓ establishing a connection with ECD to work in the online monitoring system Telecardian, software « DiaCard - ECG Recorder, running Android 4.0 and above;
- ✓ ECD connection setup to work in the Holter DiaCard system software «DiaCard-2.1», OS Windows XP ... 10 (32/64);
- ✓ maintenance (metrological verification, recorder's MC firmware upgrades).

## Clock, calendar

The recorder has a function of "real time clock" that always works, even when the recorder is turned off.

When the recorder is turned on the current date and time are displayed continuously, and are interrupted only in the case of indicating the service messages and requests.

Correcting the date and time in hours of real-time recorder is performed automatically each time you connect the ECD to the recorder. Manually correction of the date and time IS NOT PROVIDED.

The display format of date and time can not be edited.

# Safety

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

#### Galvanic isolation of ECG module

In order to protect and fulfill the requirements of standard IEC 60601-1 ECG module with all the input circuits are galvanically isolated from all other electrical parts of the recorder as for power circuits and circuits for signal (communication interface).

For galvanic isolation is applied specialized chip ADuM64HH (Analog Devices), ensuring implementation of the standards of IEC 60601-1 and IEC 950-1, and a withstand voltage of 5000 V (RMS) for 1 minute (UL 1577) and a maximum leakage current of <10 mA.

#### Protection from defibrillation

The input circuits of the ECG signal amplifiers are protected against defibrillator pulses:

- up to 200 J without using a cable with ballast resistors;
- more 200 J with using a cable with ballast resistors 4,7  $\div$  20kOhm 1  $\div$  2 W.

When using the special cable protection level increases, which ensures complete recovery of the signal within the operating range in less than 10 seconds, which corresponds to the requirements of standard IEC 601-2-27 and AAMI EC13-1992.

# 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  $18 \div 20$  °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.

Turn on the recorder. Not making the connection to ECD, visually estimate the battery charge, or wait for the calculation of the remaining operating time. Depending on the intended mode of operation: short-term registration or continuous monitoring, take a decision on the need to charge the battery.

It is allowed the combination of operating modes and charging using any, including the power supply network.

When conducting long-term monitoring studies, it is recommended to use the autonomous compact battery sources such as **Power bank** with the power capacity of 1.6 A / h and more.

## Lead cable

Recorder provides the use of 5 different types of lead wires 3, 4, 5, 7 and 10 wires - electrodes with instrumental connector DB-15M, Series D-SUB (pin assignment of wires on the instrumental connector is given in Table 1).

Table1

-						10	DIET
Nº of the	Name	Wires – electrodes, the number in the					
contact of the	of the electrode	cable					
lead wire	IEC / AHA	3 (I)	3 (II)	4	5	7	10
1	C2 /V2	-	-	-	-	+	+
2	C3 /V3	-	-			+	+
3	C4 /V4	-	-			1	+
4	C5 / V5	-	-	1	1	1	+
5	C6 / V6	-	-			1	+
6	Screen	+	+	+	+	+	+
7	- / screen	-/+	-/+	-/+	-/+	- /+	-/+
8	- / screen	- /+	- /+	- /+	- /+	- /+	- /+
9	R / RA	+	+	+	+	+	+
10	L/LA	+		+	+	+	+
11	F/LL	-	+	+	+	+	+
12	C1 / V1	-	-	1	+	+	+
13	- / screen	- /+	-/+	-/+	-/+	- /+	- /+
14	N / RL	+	+	+	+	+	+
15	- / screen	- /+	- /+	- /+	- /+	- /+	- /+
housing	- / screen	- /+	- /+	- /+	- /+	- /+	- /+
Number of leads		1	1	6	7	9	12

contact is not connected (free);

a contact connected to the corresponding electrode

- / + the contact is not connected, allows connection to the screen

You can use any non-original ECG cables used in cardiographs and heart monitors, which have a similar socket and pinout of wires-electrodes, coinciding with soldering shown in Table 1.

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

Name of the electrode	Abbreviation IEC / ANA	<u>IEC</u> (electrode color)	<u>ANA</u> (electrode color)
Right hand	R / RA	Red	White
Left hand	L / LA	Yellow	Black
Right leg	N / RL	Black	Green
Left leg	F / LL	Green	Red
Chest 1	C1 / V1	White / Red	Brown / Brown
Chest 2	C2 /V2	White / Yellow	Brown / Yellow
Chest 3	C3 /V3	White / Green	Brown / Green
Chest 4	C4 /V4	White / Brown	Brown / Blue
Chest 5	C5 / V5	White / Black	Brown / Orange
Chest 6	C6 / V6	White / Violet	Brown / Purple

Color-coded electrodes, IEC and ANA standards.

To connect the ECG cable to the recorder on the lower side of the recorder is the instrumental connector DB-15F, Series D-SUB (socket). If necessary, the plug of the ECG cable is fixed to the recorder by means of screws.

## Fixing the recorder

For the convenience and safety of using the recorder has 2 mounting options:

- ✓ *fixing belt* in stationary conditions or during transportation;
- ✓ *case-handbag* on an outpatient basis, during monitoring.

The user can select the appropriate version of the fixing and transportation.

#### **Fixing belt**

Fixing belt is intended for operative fastening the recorder when used in hospitals, in bedridden patients, but also during transportation. Recorder mounting is performed to the medical equipment, furniture, stand, tripod, etc. This ensures safe operation and free access to medical staff and the patient to the recorder. The fixing belt is attached to the recorder through a special

opening of elongated shape, located in the upper part, above the display (not connected to the recorder at a sale).To attach the belt to the recorder is necessary to:

- ✓ remove the belt from the packaging;
- ✓ untwist the "belt" screw and remove plastic buckle from a belt ribbon;
- ✓ freed end of belt ribbon threaded through the mounting hole in the recorder from the bottom - up;
- to return plastic buckle on the belt ribbon (as it was) and fix the assembly with the "belt" screw.



#### Case-handbag

Case-handbag intended for fixing re-

corder on the patient during the extensive research according to Holter method or the internet-monitoring.

When using case-handbag the fixing bell must be removed

Case-handbag is fastened to the patient's belt in a vertical position with the waist belt up to 40 mm wide.

To attach an external power supply battery of Powerbank type there is a separate case with internal dimensions within 100\*25\*25 mm.

# **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 «**DiaCard** - **ECG Recorder**" is available in electronic version (PDF format) after installing the software on ECD.



# Turning on the recorder

Recorder can be enabled in two ways:

- ✓ by using «I/O» button;
- ✓ by connecting an external power source.

#### About the button

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.

The display shows the message (001) containing the following information:

- ✓ name, type, model and series of the recorder;
- ✓ serial number;
- ✓ CMC Software version number;
- ✓ Manufacturer name.

While displaying a message, a check of basic elements, modules and assemblies of the recorder is performed.

As the check is performed in the icons are displayed the test results (002).



If a fault is detected, the display shows a message (003) indicating the reason.

When powered on and the voltage on the battery is below admissible, then a message (004) is displayed.



If the recorder was turned on by "the button", then on completion of testing the test message appears on the display about the type of power supply, which operates the recorder (005).

After some period of time, the display shows the estimated operation time recorder, considering the regime and the actual battery charge (006).



#### Connecting an external power source

Recorder is automatically activated when you connect it to an external power source, while the display turns on and the LED indicator, which indicates the switching on the battery charging mode.

Starting procedure for the both enabling variants are identical.

Upon completion of the starting procedure, the display shows a message about the type of power supply and selected charging mode (007-009).



When connecting the recorder to USB-port via an external passive device the «hub» type, the connection type is not defined. In such cases, for safety reasons the charging mode is turned off (010).

At the end of the charging mode is displayed (011), and then sounds a single repetitive signal that stops after switching off the power supply or by pressing the button  $\alpha I/O_{\gg}$ .



### Connecting via Bluetooth

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

The initiator of the connection is always in the ECD. When installing or at disconnection with ECD, the display shows the relevant messages (012, 013).



Bluetooth module can be in 3 states:

≯	Searching f compatible ECD in the broadcast area. Bluetooth icon flashes, is displayed in thin lines.
≯	Connected to ECD, data transfer is not carried out. Bluetooth icon is static, is displayed in thick lines.
<mark>∦</mark>	Data is being transmitted between the recorder and ECD. Display supple- mented by ECG icon - data transmission. Both static icons are displayed in thick lines.

When transmitting the ECG data to the display, the ECG module icon changes.

## Turning off the recorder

Recorder remains off and turned on only for the duration of the study, except for the internal real-time clock module, which is permanently enabled.

The recorder can be turned off:

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

The recorder can not be turned off if it is connected to an external power source.

#### With the button

To turn off the recorder using the button «I/O», press the

button 3 times at intervals of not more than 1 second between pressings.

The display shows the message (014), and then the recorder immediately turns off.



014

Recorder is turned off "by the button", irrespective in what mode itis, except the mode "Software Update".

#### After "time is out".

To save battery power it is provided the switching off by "times is out".

If the recorder is not in the data transfer mode, off timer is started.

For the standby mode without a connection to ECD is provided 5-minute interval off time. For the mode when the connection is established with ECD - 30-minutes.

For 60 seconds before shutdown the message is displayed with a timer (015).

Clicking on the button «I / O» or the beginning of data transmission from the recorder to ECD set OFF Timer to the initial state.



#### According to voltage

In all recorder modes the battery voltage level is continuously monitored, converted into percentages.

On the display the current voltage level of the battery is displayed in the toolbar icons as "battery", with variable internal content. Icon has 10 grades, each of which corresponds to a certain level of voltage: 3.5 V - 0%, 4.1 V - 100%.



When the battery charge lowers up to 10% a message (016) is displayed, it sounds a single repetitive beep while the recorder continues to operate.

At decrease of charge less than 5%, the recorder is turned off.

# Service maintenance

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

# Warranty

The term of the warranty of the recorder is 24 months from the date of purchase, but not more than 36 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 connectors;
- ✓ exposure to high temperatures, liquids, entering inside of the foreign objects;
- ✓ the use of non-original accessories, in particular power supplies.

Accessories (power supplies, 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.

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

Average life of the recorder is at least 5 years.

# **Recorder Software Update**

The recorder supports the remote software update function.

Versions control is assigned to ECD, which is running **«DiaCard – ECG Recorder**". Checking the recorder internal software versions is performed for each communication session with ECD.

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

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



If the battery charge of the recorder is less than 50%, message (017) is displayed.

After initialization of the recorder updates function a message (018) is display.

If, for some reason, the update function cannot be started, then message (019) is displayed, then upgrade procedure is canceled.



During the software update on the display of the recorder is displayed a progress indicator in percentage (020).

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

It is strictly forbidden to interrupt the process of software 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 message (021) is displayed.



If, for some reason, the update of the recorder has been completed with an error or was interrupted, the display will show the message (022).

For the CMC module of the recorder the automatically restoration of "factory" version is provided.

"Factory" version of CMC software is a complete working



and in most cases compatible with the basic functions of the software  $\mbox{"DiaCard} - ECG \mbox{ Recorder}$ ».

After restoring the factory version, as evidenced by the number "0" in the toolbar on the left (023), it is possible to reupdate the internal software 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.