# *ECS recorder*

***Model 06000.3X***

*Version: 3.03.en*


# *Operation Manual*

*for operation as a part of:*

*internet–monitoring Telecardian*

*and Holter system **DiaCard***

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## Designations and abbreviations

This document applies the following designations and abbreviations:

| | |
|---|---|
| DC | DiaCard (DC) compatible operation mode |
| TC | Telecardian compatible operation mode |
| BT | Bluetooth 1.0÷3.0 wireless communication interface |
| BLE | BLE 4.0÷5.0 (Bluetooth Low Energy or Smart Bluetooth) wireless communication interface |
| PSU | power supply unit |
| ECD | external control device (tablet, smartphone) |
| BC | battery charger |
| EBC | electrode break control |
| MC | microcontroller |
| min | minute |
| OS | operating system |
| PC | personal computer |
| r-r | recorder |
| s | second |
| FT | functional test |
| h | hour |
| HR | heart rate, beats per minute |
| ECG | electrocardiogram |
| ECS | electrocardiosignal |

# Introduction

**Dear user!**

"Solvaig" Joint Stock Company expresses gratitude and appreciates confidence you have put in us.

For our part, we ensure maximum extent of responsibility and operability of the purchased equipment.

This equipment is a modern and technically sophisticated device requiring certain knowledge and operating skills.

***We recommend:***

- to review this Operation Manual;
- to use genuine accessories and standard interchangeable consumables;
- to visit doctors with appropriate qualification (cardiologists) for data analysis.

If any questions arise during operation of this device or should you have any suggestions or comments, please contact Manufacturer or authorized representatives.

**!**

*The Manufacturer retains the right to change and add the scope of supply and version of the recorder internal software not deteriorating its technical parameters and functional properties.*

*The Manufacturer warrants the obtaining of stated technical parameters only in case of recorder usage together with its genuine accessories and high-quality consumables.*

*If non-genuine accessories and improper consumables are used, the user takes all risks and consequences deliberately.*

# General provisions

**Purpose**

ECG recorders series DC model 06000.3X are designed for ECS recording in 1 bipolar or 6 standard leads (depending on the model).

The feature of these recorders is extra-low power consumption and built-in memory for ECG fragment storage.

Recorders can operate in two modes:

**online** electrocardiograph (console), for ECS real-time recording and transmission to ECD;

**offline** event recorder – ECS is recorded into internal memory with the following transmission to ECD: on schedule, upon request (by pressing the button), upon alarm (bradycardia, tachycardia, arrythmia, pause).

Any device (tablet, smartphone, IPTV or game console) running under Android 4.4+ OS can be used as ECD.

Software "**DiaCard – ECS recorder**" is installed from Google Play Market free of charge.

Recorders 06000.3X are compatible with IOS OS – control software is under development.

## ***Scope***

Recorder can be used as a personal electrocardiograph, observation monitor or event recorder in **Telecardian** internet-monitoring system and ***Dia*Card** Holter system:

- in cardiology and functional diagnostics departments;
- in call-centers and remote monitoring centers;
- in general-purpose emergency services;
- in disaster medicine, hospitals, primary healthcare units;
- in sports medicine, expeditions and for scientific research reasons;
- domiciliary (at home, at work, on vacation, on the trip) according to doctor's recommendations and under medical supervision.

## ***Capabilities***

In spite of simple appearance and very small dimensions, the recorders have high specifications typical for professional equipment.

Capabilities:

- ECS recording: 1 channel or 6 channels - 10 s. to 30 days;
- ECD displaying on ECD monitor, selection of channels, filters, change of speed, scale, electrode break control;
- HR measurement, alarm indication: bradycardia, tachycardia, arrythmia, pause, no signal;
- Operation in event recorder mode with record of ECG fragments lasting 30 to 120 s.: on schedule, upon request, upon alarm, history of events – up to 60 s.;
- Records storage in ECD archive, printout, support of portable BT/BLE printers, record sending to: e-mail, “Telecardian” system, Google Drive, software “Phasegraph”;
- Operation as a part of “Telecardian” remote internet-monitoring system or “DiaCard” Holter system;
- Integration with another systems and services (SDK&API);
- Record export to HL7_aEcg, import from SCP-ECG (EN 1064).

## ***Technical parameters***

| Parameters/modifications | 06000.33 | 06000.34 | 06000.35 |
|---|---|---|---|
| Number of leads | 1 | | 1 or 6 |
| Type of leads | Ch1+/L, Ch1-/R | | I,II,III,aVR, aVL, aVF |
| Input voltage range, mV | ±0.005÷±5.0 mV | | |
| Frequency range, Hz | 0.005÷75Hz | | |
| Common mode rejection, dB | >90 | | >86 |
| AD converter/ data width | $2^{24}/2^{16}$ | | |
| AD converter frequency in "online" mode<br>- BLE-4.0÷4.1 (ECD);<br>- BLE-4.2 (ECD);<br>- BLE-5.0 (ECD);<br>- in "offline" mode | 250 Hz<br>250, 500 Hz<br>250, 500, 1000 Hz<br>250 Hz | | |
| Digital filtering, Hz | 0.005, 0.01, 0.005, 0.1, 50/60, 75 | | |
| Electrode break control | available | | |
| Internal data storage | 8 MB (flash) | | |
| Maximum quantity of fragments | 100 (per 2 min.) | | 50 (per 2 min.) |
| History (loop) record, s. | - | 30 or 60 | |
| Impulse defibrillator protection | ≤ 80 J | | - |
| ECD communication interface: | BLE 4.0÷5.0 | | |
| Control:<br>- local<br>- remote | button<br>ECD (smartphone, tablet) | | |
| Light indication:<br>- battery charging<br>- recorder operation | LED (green)<br>LED (blue) | | |
| Sound indication | + | | |
| Power, battery, built-in | LiPol 3.7 V, 40 mAh | | 70 mAh |
| Operation time, not less than,<br>- hold mode, days<br>- "online" mode, h.<br>- "offline" mode, without alarms, h.<br>- "offline" mode, with alarms, h.<br>- history records, h. | <br>≥ 100<br>≤ 48<br>≤ 168<br>≤ 72<br>- | <br>≥ 100<br>≤ 40<br>≤ 168<br>≤ 72<br>≤ 48 | <br>≥ 200<br>≤ 72<br>≤ 168<br>≤ 72<br>≤ 48 |
| External charger<br>- source, voltage, current<br>- charging time, disconnection | PSU = 5÷6 V, 0.1 A<br>1.5÷2 h., automatic | | |
| Dimensions, without cable, mm | 34x56 x 6.6 | | |
| Weight (with lead wires), g | <25 | | <29 |
| Protection type, IP protection code | BF, IP64 (IP67 – upon request) | | |

## *Scope of supply*

| | |
|---|---|
| ECG recorder, model 06000.3X, series DC, pcs. | 1 |
| Cable – USB adapter (AM), pcs. | 1 |
| Suspension strap, set | 1 |
| Operation Manual, booklet, pcs. | 1 |
| Packing (cardboard box), pcs. | 1 |

## *Accessories*

| |
|---|
| Extremity electrodes, pin-type (for adults, for kids) |
| Chest electrodes, suction-type (for adults, for kids) |
| Disposable ECG electrodes, other |
| Conducting gel-paste, ECG/EEG |
| ECD (tablet, smartphone), Android OS |
| Power supply unit ~110÷220V 50÷60Hz / 5V 1A, USB (AF) |
| Self-contained power supply source like Power bank, 2200 mA/h and higher |

* *accessories and consumables are not included into the standard scope of supply and shall be ordered optionally.*

**Recorder arrangement**

The recorder is assembled in leak-tight enclosure made of impact-resistant ABS plastic, IP64 protection code.


Controls and indication:

1 LED indicator:
- green light — battery charging mode;
- blue light — functions, modes and states;

2 Tact switch;

3 R/RA electrode cable button;

4 F/LL electrode cable button (only in 06000.35);

5 L/LA electrode cable button;

6 Recorder attaching point to suspension;

7 Charger adapter connecting point.

Electronic circuit of recorder operates under control of 32-bit microcontroller of ARM CORTEX M4F architecture.

ECG recording is based on specific amplifier ADS129X (TI).

Recorder operation algorithm is the simplest possible and user-friendly.

User level – without limitations, except for children under 5 and persons with mental disorders – under supervision.

ECS recording requires no professional knowledge and special skills; however, qualified medical specialist-cardiologist is required for interpretation of data obtained.

## ***Controls***

Only one “START” button is used for recorder operation control.

All other control is performed automatically or with ECD.

### “START” button

“START” button is used:

- In all modes:
  - recorder switching-on;
  - “sleep” mode control input / output;
  - start / stop of fragment record;
- in “offline” mode:
  - research start;
  - research stop;
  - research termination.

Button pressing differs by the following:

- duration
  - short 0.1÷0.2 s.;
  - long 1÷6;
  - undefined <0.1 s., >6, with interval between pressings <0.25 s. or >1 s.;
- quantity
  - single 1 pressing with the following interval ≥250 ms;
  - multiple 2 or more pressings with interval between pressings ≥0.25 s., ≤1 s.

Each button pressing is followed by short sound signal.

Detailed description of button usage is given in the corresponding section of this Manual.

## ***Indication***

Recorder has sound and light indication.

Indication is applied for update of processes and states in progress.

**Sound indication**

Sound indicator of buzzer type is used in the following cases:

- recorder switching on /off;
- acknowledgement of "START" button pressing;
- acknowledgement of start and stop of processes and states.

All sound signals can be divided per quantity and duration.

Tonality and signal sound level of sound indicator ARE NON-ADJUSTABLE.

"Research" mode provides for switch-off of fragment record sound indication on schedule and upon alarm.

Sound indicator state is controlled from ECD.

**Light indication**

Two LED are used as light indication: green and blue color.

Green LED is used for indication of battery charging process.

Blue LED is used for indication of recorder operation (rf. to Table 1).

Table 1.

| Indication | Mode |
|---|---|
| 1 pulse 1 s. | Recorder switch-on, recovery from sleep mode |
| | Start of data transmission in “online” mode |
| | Start of “Research” mode |
| | Start of fragment record in “offline” mode |
| 1 pulse 0.1 s. | By any button pressing |
| 1 pulse 0.1 s., period 60 s. | “Offline” mode, connection with ECD is not established (constantly). |
| 1 pulse 0.1 s., period 10 s. | “Online” mode, connection with ECD is established (constantly). |
| 1 pulse 0.1 s., period 2 s. | “Online” mode, data transmission on ECD (constantly). |
| 1 pulse 0.1 s., period 0.25 s. | “Offline” mode, fragment record on flash memory (constantly). |
| 1 pulse 0.1 s., period 5 s. | “Offline” mode, “Research”, record upon alarm (constantly). |
| 2 pulses 0.1 s., period 0.25 s. | “Online” mode, stop, completion of transmission |
| 2 pulses 0.5 s., period 1 Hz | Start of record “upon alarm” |
| 2 pulses 0.1 s., frequency 10 Hz, period 0.7, within10 s. | EBC function activation in the beginning or in the process of recording. |
| 3 pulses 0.1 s., period 0.25 s. | “Online” mode – cancellation of record due to EBC function activation |

Light indication cannot be switched off or changed.

## ***Clock-calendar***

When recorder operates in “offline” mode, each recorded fragment contains the date and time of record.

At the first switching-on of recorder, clock-calendar unit is automatically activated – initial date and time: 00:00:00 01.01.2000. Correction of clock-calendar values is performed automatically at each connection of recorder with ECD.

**!** *If date and time are not set, all recorded fragments will have date and time calculating from 00:00:00 01.01.2000, record “on schedule” is impossible during research.*

When recorder switches to sleep mode, internal clock-calendar continues working.

In case of complete battery discharge and recorder switching-off, clock-calendar is reset.

## ***Communication interface***

The recorder is equipped with wireless communication module Smart Bluetooth supporting BLE 4.0÷5.0, enabling to establish wireless communication with compatible ECD at a distance of not less than 5 metres of direct visibility without prior pairing and password entry.

Bluetooth is used in the following cases:

- recorder setting (parameters and operation modes);
- ECS transmission from recorder to ECD;
- update of internal software of recorder MC.

Data transmission range and rate between recorder and ECD depends on BLE module. For steady and assured data transmission between recorder and ECD, limitations of ADC sampling frequency selection are put, depending on BLE module installed in ECD.

Selection of available settings of recorder ADC sampling frequency for “online” mode:

Table2.

| | |
|---|---|
| BLE-4.0, 4.1 (ECD); | 250 Hz |
| BLE-4.2 (ECD); | 250, 500 Hz |
| BLE-5.0 (ECD) | 250, 500, 1000 Hz |

ADC sampling frequency in “offline” mode is 250 Hz (not selected).

### ***Power supply***

The recorder is powered from 3.7 V built-in (stationary) lithium-polymer battery:

- 40 mAh for models 06000.33 and 06000.34;
- 70 mAh for model 06000.35.

When the recorder is switched-on, MC constantly measures voltages across battery enabling to control operation modes and inform the user on the need to charge battery in a timely manner.

Dependence of operation modes on battery voltage level is shown in Table 3.

Table 3.

| Mode | Voltage, V | Indication |
|---|---|---|
| **operation** | **> 3.5** | During start – without sound indication |
| **reduced** | **3.3÷3.5** | During start – without sound indication |
| | | During operation - 1 short sound signal with 60 s. interval, up to recorder switching-off or switching to another subrange |
| **discharged** | **3.2÷3.3** | During standard operation - 9 short sound signal with 1 s. period, the 10$^{th}$ is long, then recorder switches off. |
| **critical** | **<3.2** | During start - 1 long sound signal, then recorder switches off |

In “online” mode, the value of measured voltage is transmitted and displayed on ECD, refer to Table 4:

Table 4.

| B | ≤3.2 | 3.2÷3.30 | 3.30÷3.40 | 3.40÷3.50 | 3.50÷3.60 | 3.60÷3.70 | 3.70÷3.8 | >3.80 |
|---|---|---|---|---|---|---|---|---|
| % | 0 | 0÷10 | 10÷30 | 30÷50 | 50÷70 | 70÷90 | 90÷100 | 100 |

**Operating time**

Duration of recorder operation depends on the selected mode, time of communication with ECD, ECS recording mode, sampling frequency, fragment record duration and frequency.

In “online” mode, continuous transmission of data to ECD is not less than 36 hours.

In “offline” mode:

- Without start of research – not less than 30 days, provided the record of 3÷5 fragments per 2 minutes a day;
- without function of record upon alarm – not less than 7 days, provided the record of 30 fragments per 2 minutes a day;
- with function of record upon alarm – not less than 3 days, provided the record of 30 fragments per 2 minutes a day.

If recorder is not connected to ECD and research is not started, 1 hour hold time switches on – automatic transition to sleep mode (it is switched off during research).

**Battery charging**

For charging of recorder battery, external power supply with 5.0±0.25 V output constant voltage and at least 100 mA current is used - USB-A jack (not included to the standard scope of supply).

External power supply is connected to recorder by means of adapter cable (included to the standard scope of supply).

Battery charging process is controlled by special built-in controller.

While connecting recorder to external power supply, charging starts automatically – green LED indicator is on. Upon completion of charging, LED indicator is off.

Charging time depends on battery state, discharge point and ambient temperature.

It is recommended to charge battery at ambient temperature of +10÷+35°C.

While decreasing ambient temperature to 0°C, charge capacity decreases 1.5÷2 times, and at minus 10°C battery charging process almost stops.

In case of ambient temperature over +35°C, the risk of recorder breakdown increases due to overheating. Controller is equipped with temperature sensor enabling to reduce the risk of breakdown due to overheating, though the risk still remains.

Charging time of completely discharged battery is up to 2 hours.

In case the battery is in deep discharge state, charging time can increase by 10÷30 minutes.

Maximum possible charging time has 6 hours software limitation. If battery is not charged during this period, charging process will be automatically interrupted. In this and similar cases, the battery is considered to be faulty and shall be replaced.

**!** *It is strongly PROHIBITED to operate recorder with faulty battery!*
*Faulty battery shall be replaced immediately.*
*Failure to follow these recommendations can hurt user and cause recorder damage.*

Upon completion of charging process, recorder may be still connected to external power supply for some more time without causing any damage to battery. When battery voltage is decreased to 3.9 V, charging process can be restored automatically.

## ***Safety***

The recorder is manufactured in accordance with DSTU EN 60601-1 requirements specified for electric equipment with internal power supply source and BF-type applied part.

**!** *The recorder has no built-in complete protection against defibrillator pulses. In order to ensure recorder safe operation, it is required to disconnect lead cable from a patient before defibrillation.*

# Pre-starting procedure

This section describes pre-starting procedure of recorder considering the general requirements and specific separate methods.

**General requirements**

Take recorder and all its components necessary for operation out of packing. If the equipment was stored in wet unheated premises, it shall be kept at least 2 hours at a temperature of 18÷20°C and relative humidity up to 80% before switching-on.

Disinfect the recorder and all its accessories that may contact with patient's body with a wipe wet in 3% hydrogen peroxide solution or any other disinfecting solution appropriate for these purposes.

**!** *It is strongly prohibited to disinfect and clean the recorder and its accessories with solutions containing any alcohols and solvents.*

The recorder is supplied with partially charged battery. Irrelevant the supposed operation mode (short-term recording or long monitoring), it is recommended to charge battery to the full.

**!** *It is strongly prohibited to perform simultaneously ECG recording mode and battery charging from utility power source.*

**Program setup on ECD**

Before operating the recorder, it is necessary to install special software on ECD - "**DiaCard – ECG Recorder"**, its basic version is free.

Software is installed from Google Play Market at QR-code.

Software operation manual is available in electronic form (PDF) in main menu after software installation on ECD.

**ECG cables and electrode application circuits**

In recorder 06000.3X, electronic forces of the heart are taken from patient's body with a help of special lead cables with wires terminated with buttons; they can be connected to disposable or non-disposable electrodes.

Depending on the recorder model, lead cables differ from wire (electrode) quantity:

- 06000.3X 2 wires: L/LA (Ch1+), R/RA (Ch1-) - 1 bipolar lead, any;
- 06000.35 3 wires: L/LA, R/RA, F/LL - 6 unipolar leads: 3 standard (I, II, III) and 3 intense (AVR, AVL, AVF).

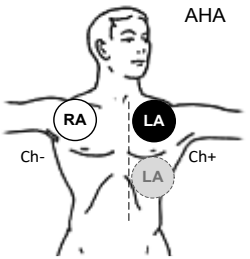
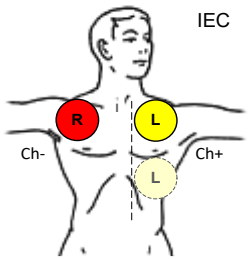
*Electrode color coding, AHA and IEC standards.*

| Name | AHA / IEC | AHA, (electrode color) | IEC, (electrode color) |
|---|---|---|---|
| Left hand | LA/ L | **Black** | **Yellow** |
| Right hand | RA/ R | **White** | **Red** |
| * Left foot | LL /F | **Red** | **Green** |

* - *only for recorders 06000.35.*

## Bipolar application circuit for 2 electrodes:

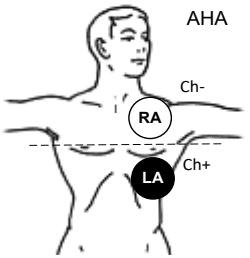
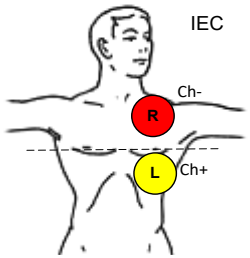
Horizontally: electrode "+" is installed to the left of assumed heart vertical axis, electrode "-" to the right (Figure 1 and 2)

| Cable:**2A(AB)** | Cable:**2I(IB)** |
|---|---|
|  |  |
| Fig. 1 | Fig. 2 |





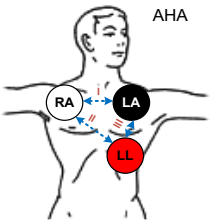
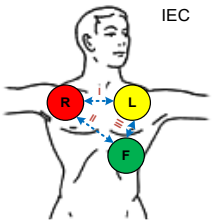
Vertically: electrode "+" is installed lower than assumed heart horizontal axis, electrode "-" higher (Figure 3 and 4).

| Cable:**2A(AB)** | Cable:**2I(IB)** |
|---|---|
|  |  |
| Fig. 3 | Fig. 4 |

Unipolar application circuit for 3 electrodes:

Standard Einthoven leads (Figure 3 and 4):

**I** – R/RA "-", L/LA "**+**";**II** – R/RA "-", F/LL "**+**";**III** – L/LA "-", F/LL "**+**".

| Cable:**3A(AS)** | Cable:3**I(IS)** |
|---|---|
|  |  |
| Fig. 5 | Fig. 6 |





Replacement of lead cables requires recorder opening and can be performed only in service center of Manufacturer of its authorized partners.

## ***Recorder strapping***

The recorder is fastened on patient's body with a help of strap (suspension) fastened on the patient's neck.

Micro-cord is used as a strap terminated with a plastic detachable lock enabling to take the recorder on and off quickly.

Strap length is selected by user individually. Cord ends are fixed in lock elements by nodes from each side.

The example of strapping is shown in Fig. 7-10.


Fig. 7


Fig. 8


Fig. 9

Fig. 10

**Recorder switching-on**

Recorder is supplied in completely switched-off state enabling to store it within a long time (not less than 1 year), transport it safely by any transport mode.

Recorder is switched on automatically while connecting to the external power supply of charger, irrelevant the battery voltage.

Recorder can be switched on by pressing “START” button and holding it down for 2 seconds.

Depending on the battery voltage level, the corresponding modes are available; their states and indication are described in section “Power supply”, p.17.

Every time it is switched on, main modules and units are checked. In case of detection of any ADC critical error, 6 long sound signals are heard, in case of flash memory error – 7 signals, then recorder switches off.

**!** *In order to detect failure cause and eliminate it, contact specialized service center.*

## *Connection to ECD*

In order to connect to ECD, the recorder shall be switched on and shall not be connected to any other ECD.

During the first connection to ECD, it is necessary to find device with a name of your recorder (refer to the label on the reverse side of recorder) in the list of transmittable devices on ECD, for instance "**DC06000.33_3017"**, where DC06000.33 - type, model, and 3017 – serial number of recorder, and connect to it. From now on, during recorder switching-on and program start on ECD, the recorder will connect to ECD automatically.

## *Operation modes*

Recorders 06000.3X operate in two modes: "online" and "offline".

**"Online" mode**

In "online" mode the recorder connects to ECD and transfers complete control to it.

All parameters are set from ECD: cable type, sampling frequency, digital filter settings, EBC, control of recorder battery voltage level, etc.

ECS digitized data are transmitted to ECD in real time mode without storing in recorder.

In ECG view mode on ECD monitor, duration is limited only with continuous operation of recorder from one battery charging and ECD operation time – ECD operation with connected charger is allowed.

**!** *Operation of recorder with connected charger is strongly PROHIBITED!*

*Recording procedure*

1. Switch on the recorder.
2. Start software “DiaCard – ECG. Recorder” on ECD.
3. Connect to recorder.
4. Select operation mode: Electrocardiograph, Stress-test or Monitoring.
5. Select a patient.
6. Depending on selected mode, adjust recorder settings.
7. Select mode “Recording” on ECD.
8. Make sure visually in signal quality, filter settings and selected circuit of electrode application.
9. In order to start record, press pictogram “Record - Start” on ECD monitor or button “START” on recorder.
10. The record will be completed automatically upon the expiry of the set time interval (10 s. to 168 hours), it can be completed beforehand by pressing pictogram “Record - Stop” on ECD monitor or button “START” on recorder.

Depending on the settings, the following operations with record are available:

- adding of text comments: information on patient’s well-being, medicine taken, temperature, arterial pressure, etc.;
- automatic sending to Telecardian system, to user’s account cloud storage on Google Drive or to email of selected doctor;
- manual sending – all mentioned variants of the previous paragraph, function “share”;
- printout of selected ECG areas (stationary or portable printer).

**”Offline” mode**

In “offline” mode, recorder operates completely in standalone mode, without any control from ECD.

Special settings are used for operations stored in special zone of recorder memory.

During the first switching-on of recorder, settings are filled with “default” values (refer to Table 5) calculated from microcontroller program and can be edited from ECD.

Table 5.

| **Default parameters** | **06000.33** | **06000.34** | **06000.35** |
|---|---|---|---|
| Cable type | 2IB | 2IB | 3IS |
| Research duration, h. | 1 h. to 30 days, **24 h** | | |
| Fragment duration, s. | 0/30, **0/60**, 0/90, 0/120 | | |
| - with loop (history) | - | 30/30, 30/60, 30/90, 60/60 | |
| Filters, Hz | 0.005, 0.01, **0.05**, 25, 35, **50**, **75**, ФПЭ | | |
| Record on schedule: | On / **Off** | | |
| - day time, h. | 0- 2- 4- 6- 8- 10- 12- 14- 16- 18- 20- 22- | | |
| - interval between records, min. | - - - 120 - - - 120 - - - 120 | | |
| Record upon alarm: | On / **Off** | | |
| - tachycardia, at HR>, BPM | **120** (80÷240), **On**/ Off | | |
| -bradycardia, at HR<, BPM | **50** (20÷60), **On**/ Off | | |
| - arrythmia, at ΔRR>, % | **15** (10÷35), **On**/ Off | | |
| - pause, at t1 ≤ RR<t2, s | **t1=3**, **t2=10**, (t1≥3, t2<10), On / **Off** | | |
| - no signal, s | RR>10, On / **Off** | | |
| - guard interval, min. | **10** (5÷30) | | |
| Sound indication | **On** / Off | | |

Recorder settings also allow to store information on patient using this recorder as well as on his doctor in charge. If recorder was not connected to ECD after switching-on, it contains no such information.

**!** *Record of fragments with unfilled information on patient and / or doctor is allowed.*

Fragments are stored in internal flash memory of recorder as separate files and are transmitted to ECD automatically at the first opportunity (connection to ECD).

Each fragment contains headings of these ECS.

The heading stores a complete set of information enabling to read the record on any compatible device with installed software “DiaCard – ECG. Recorder”.

Fragment (s) with headings with no information on a patient cannot be read (saved) in ECD archive. Before reading these fragments, user will be offered to select a patient.

Quantity of recorded fragments is limited with recorder flash memory size and depends on record duration and channel quantity. Total duration is about 4 / 2 hours – for 1 /2 channels.

Fragments are read from ECD one at a time in the reverse order – from the newest (per date) to the oldest one.

After reading, fragment is removed automatically from recorder flash memory.

If recorder flash memory is completely filled (fragments are not read), the oldest fragment (by date and time) will be deleted automatically during recording the new fragment.

In “offline” mode, two operation submodes are possible:

- single record;
- during research.

*Single record*

Single record is performed by long pressing of “START” button provided that recorder is not in research mode and in “online” mode of data transmission to ECD.

Completion of single record is possible: at the specified duration, at activation of EBC function or at battery discharge.

Recorded fragment is transmitted automatically at any connection to ECD.

*Research mode*

Recorder can start research at any moment, if it is switched on, does not perform single record and is not in “online” mode of data transmission to ECD.

Parameters stored in recorder are used for research start.

During research, all parameters, including patient’s medical card and information on doctor in charge, can be edited from ECD.

Research starts after triple short pressing of “START” button with interval between pressings up to 1 s. At the moment of start, recorder performs the first mandatory record – with status “upon button”.

If record “upon alarm” and history are switched off, after research start the recorder switches on only for the time of scheduled measurements and measurements upon request (upon button).

If record “upon alarm” and/or history mode are switched on, recorder remains switched on during the whole research period.

For operation of record “upon alarm” function, HR is calculated in recorder in real time mode. In case of activation of any alarm sign, fragment record starts.

For the purposes of rational use of flash memory, there is a limitation for record of one-type fragments as guard time interval with duration specified in settings. During guard interval, it is prohibited to record fragments caused by similar disorders. Guard interval for each sign is calculated separately. Countdown of guard interval starts after completion of record of the relevant fragment.

If scheduled measurement coincides with measurement “upon request” or “upon alarm”, it will shift for 1 minute from the end of record of the last fragment.

Fragment record “upon request” is performed always without guard interval.

History record mode operates under the principle of loop record where ECS is recorded continuously.

The start of history fragment record is a moment of record initiation minus history time.

During fragment recording, history record does not stop.

Each record “upon request” or “on schedule” starts from one long sound signal, record “upon alarm” – from two long sound signals.

Record can be completed: upon the set duration, upon activation of EBC function (> 10 s.) or upon battery discharging (≤ 3.2 V).

In case of successful completion of any record, two short sound signals can be heard, in case of error – three signals.

Research can be stopped any moment; for this it is necessary to switch off the recorder by means of “START” button – press and hold within not less than six seconds. In order to continue research, it is necessary to switch on the recorder. If research time is not over, recorder will continue research automatically.

Research can be interrupted any moment from ECD or by

pressing “START” button – with four short pressings with an interval between pressings up to 1 s.

# Service

This section describes warranty provision conditions and recorder module internal software update procedure.

**Warranty obligations**

Warranty obligations period for recorder is 18 months from the purchase date but up to 24 months from the manufacturing date.

Warranty obligations period for battery is 12 months from the date of recorder purchase.

Warranty obligations shall mean free of charge elimination of any defect, as well as replacement of any component being an integral part of the whole.

Warranty shall not cover the following cases:

- integrity violation – breaking open, intervention traces;
- mechanical damages of any enclosure element, including buttons and connectors;
- effect of high temperatures, liquids, ingress of foreign bodies inside the recorder;
- application of non-genuine accessories, in particular power supply sources.

Accessories (power supply sources, wires, cables, adapters, electrodes, casings, straps, etc.) relate to consumables with relative warranty period from 1 to 6 months from the date of purchase. The warranty is valid only in cases of manufacturing defect detection.

The user shall pay the transportation cost of recorder or any accessory to the service center and return.

Warranty obligations of Purchaser shall be confirmed with a copy of purchasing document with mandatory indication of the Seller and date of sale.

Design life of battery is up to 2 years, then it shall be replaced.

! *Late replacement of battery can result in its damage and irreparable damage of recorder.*

Average lifetime of recorder is not less than 5 years.

**Update of recorder software**

Recorder supports the function of internal software update.

Control of recorder internal software versions is performed by ECD.

Internal software of recorder updates forcedly in order to remain compatible with ECD software.

Update function has the highest priority. If after connection with ECD new version is detected to be available, ECD starts automatic update process.

If for any reasons update cannot be performed, update procedure is cancelled.

During updating, progress-indicator is displayed on ECD.

Time of recorder internal software update is up to 2 minutes.

! *It is strongly prohibited to disrupt the process of recorder software update.*

In case of successful completion of update, the relevant message is displayed on ECD.

If an unforeseen situation takes place, user shall be entitled to contact service center for assistance.

**Battery replacement**

Lithium-polymer battery applied in recorder is installed at recorder outlet by Manufacturer.

Battery design life is up to 2 years or up to 500 charging / discharging cycles.

Battery shall be replaced upon expire of 2 years from the date of recorder release, or in case of reduction of operating time from the fully charged battery to 2 hours and less.

Battery replacement considers recorder disassembly, and that is considered as violation of integrity and results in cessation of warranty obligations.

**!** *Battery shall be replaced only by qualified specialists at Manufacturer's or at specialized service centers.*