POCKET ECG

MEDICALgorithmics

INNOVATIVE SOLUTIONS IN MEDICINE

Instructions for Use

Unified Arrhythmia Diagnostic System PocketECG IV

PocketECG IV.

INSTRUCTIONS FOR USE

FOR PROFFESIONAL USE

Warsaw 2022

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MEDICALGORITHMICS assumes no responsibility for any injury or for any illegal or improper use of the product that may result from failure to use this product in accordance with the instructions, cautions, warnings, or statement of intended use published in this manual.

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POCKET ECG

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1 POCKETECG IV DESCRIPTION

1.1 PocketECG IV components

The Medicalgorithmics' *Unified Arrhythmia Diagnostic System PocketECG IV* consists of:

- PocketECG transmitter, model: PocketECG IV, type: P4TR-AA-ADS, P4TR-AB-ADS (LTE version for Verizon mobile network operator), P4TR-CA-ADS (LTE-M version, American color-coding standard of ECG cables) or P4TR-CE-ADS (LTE-M, European color-coding standard of ECG cables) with the following accessories:
    - Two rechargeable batteries, type: P4BA-AA-UNI or P4BA-AB-UNI,
    - The AC plug-in battery charger, type: P3CH-AB-UNI (PECGC-III can also be used),
- PC Client software,
- Instructions for use (hardcopy) for the patients.

The Medicalgorithmics' *Unified Arrhythmia Diagnostic System PocketECG IV* is compliant with the requirements of the United States Food and Drugs Administration and the requirements of the Health Canada Medical Devices Regulations.

This Instructions for Use (IFU) describes PocketECG transmitter, its accessories and PocketECG PC Client software.

1.2 PocketECG IV architecture

The functional block diagram of PocketECG IV – Medicalgorithmics Unified Arrhythmia Diagnostic System in combination with the data transmission to the remote server is presented in Fig. 1.

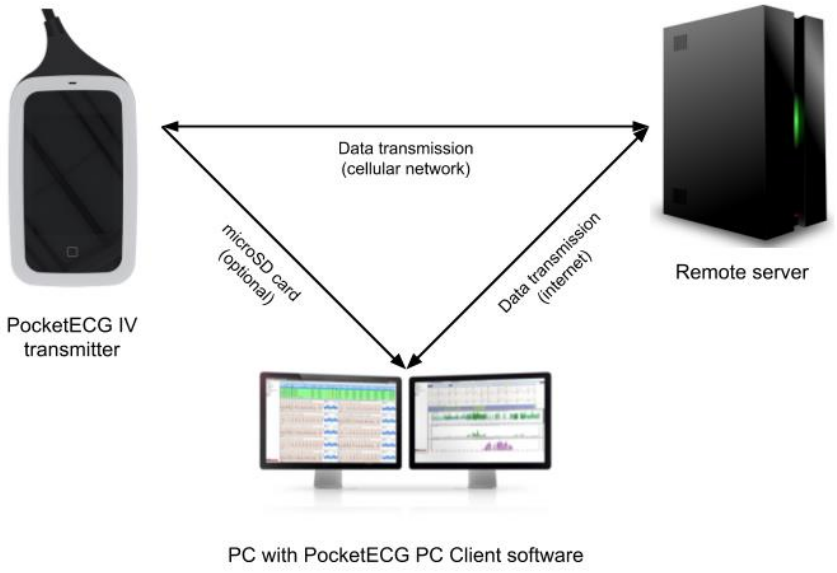


Fig. 1 Functional block diagram of PocketECG IV

The patient heart activity is digitized using a PocketECG transmitter. The transmitter is equipped with digital accelerometer, generating signals corresponding to the patient physical activity. The algorithm, operating on the PocketECG transmitter automatically analyzes the acquired ECG in real-time and transmits both: the ECG and acceleration data to the remote server accessible by a Monitoring Center for reviewing by trained medical staff. The ECG data comprises of ECG annotations for all detected heart beats and the entire ECG signal. The acceleration data comprises of results of patient activity estimation along with the waveforms of the acceleration signals. All detection results along with the waveforms of the ECG and acceleration signals may be reviewed using a PocketECG Client - PC based application. Optionally, the ECG and acceleration data may be downloaded to the PC Client application from the SD card of PocketECG transmitter using standard SD card reader connected to the PC through USB interface.

1.2.1 Transmission and analysis delay

The ECG signal is interpreted by the software of PocketECG transmitter with few seconds delay, which is relatively quick considering the monitoring duration of a patient – i.e. which may last from one day to several weeks. Therefore, analysis with such short delay is considered as performed in real-time. The transmission of data chunks is also performed fairly frequently, with regard to the potential monitoring. The use of this approach is to provide the arrhythmia analysis results to the physician with short delay on an ongoing basis, which allows for making a decision whether monitoring should be carried on (in order to collect more data) or whether it should be terminated, assuming that conclusive results were generated. This is beneficial for the patient, who do not have to wear the device unnecessarily and also allows for limiting the cost of monitoring – no need to transmit and analyze unnecessary data.

In the worst-case conditions, which are lack of mobile network signal, the data will not be transmitted at all. However, acquired data is stored on the microSD card and can be optionally downloaded to the PC using wired USB connection when the recording session is finished (microSD card reader is required). In case of limited access to the mobile network, the data may be transmitted when the patient is in the network range – limited times per day. Therefore, the user has to be aware of limitations related to monitoring and transmission using a mobile network infrastructure.

The ECG signals are presented on the device screen about 1 second after they are sampled by the PocketECG transmitter.

The PocketECG transmitter initializes the data transmission to the remote server:

- at least every 75 minutes,
- when the ECG event/abnormality is detected,
- when ‘Report symptoms’ button is pressed by the patient.

The PC Client software polls the remote server every 30 seconds. If new data related to the selected recording session are available, the PC Client downloads them automatically.

In order to download data stored on the microSD card of the PocketECG transmitter, the card must be removed from the transmitter and inserted into the USB microSD card reader. The PC Client user may request to download the data from the microSD card when successful USB connection between microSD card reader and PC is already established.

1.3 Data transmission technologies

The description of the data transmission technologies utilized by the PocketECG IV device is given in the following subsections.

1.3.1 Mobile telephony network

The PocketECG transmitter P4TR-AA-ADS and P4TR-AB-ADS is equipped with communication module providing access to mobile telephony network 4G LTE bands B4(AWS 1700 MHz) and B13(700 MHz). The P4TR-CA-ADS and P4TR-CE-ADS transmitters are equipped with LTE-M communication module operating on numerous frequency bands depending on the mobile service provider used. The wireless data transmission technology, used by the mobile telephony network carriers, is utilized to transmit the ECG and acceleration data along with the results of automated signals analysis to the remote server.

The data transmission is triggered automatically based on results of the automated ECG signal analysis, manually by the patient or periodically. The data transmission is initiated immediately after detecting irregularities in the ECG signal or after pressing the 'Report symptoms' button on the transmitter by the patient (refer to Section 9.3 for detailed description). Otherwise, the data transmission is triggered at least once every 75 minutes. Depending on the transmission quality of service the time needed to upload patient related data to the remote server may vary.

There is no minimal rate for data upload required for proper operation of the PocketECG. However, a user must be aware that when the data rate is extremely low the period of time required to transmit the data may be very long. Therefore, it is recommended to ensure that the mobile network allows data uploading with at least 10 kbps (average) on the area where the patient is going to be monitored. It is easily achievable in most of the existing mobile networks in the US/EU.

The PocketECG transmitter only transmits ECG and acceleration data along with automatic analysis results related to a specific recording session ID. The session ID is a unique identifier which consists of the timestamp of the session start with 1 second accuracy and the unique ID of the PocketECG transmitter. No personal data is entered on the PocketECG transmitter nor transmitted through mobile telephony network. The connection to the server comprises TCP/IP sockets and is based on the transfer of the data files.

1.3.2 Encrypted internet channel

The internet encrypted channel is used by the PC Client application for reviewing the ECG and acceleration data that was sent to the remote server by the patient monitors (PocketECG transmitter). Since the data which is exchanged between the PC Client and the server includes personal data, all of the communication channels need to be encrypted. The PocketECG IV uses an SSL-like authentication, authorization and encryption mechanisms. The encrypted data is transmitted over TCP/IP sockets in a binary form. The symmetric key exchange algorithm uses the RSA cryptographic model while the block encryption utilizes Triple Data Encryption Algorithm (TDEA). The recommended minimal download and upload speed of the internet connection is 512 kbps and 64 kbps, respectively. The internet connection of a lower speed may also be used. However, the user must be aware that the access and reviewing of the ECG and acceleration data stored on the remote server will be more time-

consuming. Only the server listens on TCP/IP sockets to accept incoming connection requests. Neither the PocketECG transmitter nor the PC Client needs to open any ports, so the incoming connection rules don't have to be changed in the firewall software. If the PC Client is installed in an environment which filters the outbound traffic, a rule which enables connecting to the remote TCP port needs to be added to the firewall software.

1.3.3 MicroSD card (optional)

The PocketECG transmitter is not equipped with USB connector. It does not have any external connector and cannot be connected to any other electronic equipment. The only data path for ECG and acceleration data goes through mobile phone link between PocketECG transmitter and a remote server. The ECG and acceleration data processed by the PocketECG transmitter are:

1. stored on the flash memory card (microSD) of the PocketECG transmitter,
2. transmitted using cellular networks technology to the remote server.

In some circumstances like:

- no cellular phone service on the area where the patient is monitored,
- mobile network failure,
- problems with internet connection on the PC with PC Client application installed - data cannot be downloaded from a remote server

the data may be downloaded from the microSD card to the PC using card reader. The card reader either integrated with PC (most laptops do have them) or connected to the PC through USB 2.0 interface may be used. The data can be downloaded by the medical staff providing the service to the patient when the recording session is already finished. The USB transmission should be performed using wired connection established between USB card reader and PC. The microSD card must be removed from the PocketECG transmitter and inserted into the socket of USB card reader. The communication based on the file transfer is safe as no personal data is stored on microSD card.

1.3.4 FCC Requirements

FCC ID: 2AB2MP4TRA & 2AB2MP4TRAA & 2AB2MP4TRCA

This device complies with part 15 of the FCC Rules. Operation is a subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications of any kind not expressly approved by Medicalgorithmics S.A. could void the uses authority to use ECG.

2 SYMBOLS GLOSSARY

The following symbols appear on the label placed on the PocketECG transmitter's casing and in this Instructions for Use:

	Type BF applied part
	Manufacturer’s name and address
	Date of manufacture
	Refer to Instructions for use
	Caution
	Warning
	PocketECG transmitter includes radio wave transmitters
	Keep dry
IP20	Protection against solid particles up to 12.5 mm (fingers or similar objects), lack of protection against ingress of water
	Dispose the device in compliance with appropriate regulations
	MR unsafe
SN	Serial number

SIM card symbol

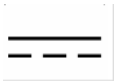
MicroSD memory card

Unique device identifier

The following symbols appear on the label placed on the PocketECG IV accessories and in this Instructions for Use:

Recyclable materials

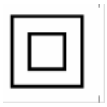
Indoor use only



Direct current

Alternating current

Date of manufacture



Class II equipment

Serial number

Minimum Ingress Protection class provided by protective pouch

FCC Logo (Declaration of Conformity)

Dispose the device in compliance with appropriate regulations

Unique device identifier

3 WARNINGS AND CAUTIONS

This section is to familiarize the user with applicable warnings and cautions. Specific warnings and cautions can also be found in other sections of the Instructions for Use.

3.1 Warnings

Warning statements alert to situations which, if not avoided, could result in illness or injury of the patient.

3.1.1 PocketECG transmitter

WARNING. THE POCKETECG TRANSMITTER DOES NOT PROTECT AGAINST DEFIBRILLATION EFFECTS AND MAY BE DAMAGED IF PLACED ON A PATIENT UNDERGOING DEFIBRILLATION. REMOVE ELECTRODES, PATIENT LEAD WIRES, AND THE POCKETECG TRANSMITTER FROM PATIENT BEFORE DEFIBRILLATION.

WARNING. THE POCKETECG TRANSMITTER DOES NOT DISTURB THE PACEMAKER OPERATION. HOWEVER, FOR PATIENTS WITH A PACEMAKER, MAINTAIN A MINIMUM DISTANCE OF 15 CM (6 INCHES) BETWEEN THE TRANSMITTER AND PACEMAKER. TURN THE TRANSMITTER OFF IMMEDIATELY AND PROVIDE APPROPRIATE PATIENT CARE IF YOU SUSPECT THE TRANSMITTER AFFECTED THE PACEMAKER.

WARNING. THE POCKETECG TRANSMITTER IS NOT INTENDED FOR INFANTS WEIGHING LESS THAN 10 KG.

WARNING. THE POCKETECG TRANSMITTER IS NOT INTENDED FOR USE IN INTENSIVE CARE UNITS. IT SHOULD NOT BE USED WITH HIGH FREQUENCY SURGICAL DEVICES OR DIRECTLY ON THE HEART.

WARNING. DISCARD ELECTRODES AFTER EACH USE.

WARNING. IF THE DEVICE IS USED AT AN AMBIENT TEMPERATURE OF 45 °C, AFTER SOME TIME IT MAY ADAPT AND WARM UP TO THIS TEMPERATURE. IN CASE OF SIGNIFICANT INCONVENIENCE PATIENT MAY TAKE THE DEVICE OFF FOR ABOUT 15 MINUTES TO LET IT COOL DOWN. THE DEVICE DOES NOT PROVIDE HEAT NOR ANY ENERGY TO THE PATIENT.

WARNING. DO NOT USE IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR OXYGEN OR NITROUS OXIDE.

WARNING. DO KEEP THE DEVICE AND ITS ACCESSORIES AWAY FROM INFANTS AND CHILDREN TO AVOID DANGER OF SWALLOWING.

WARNING. DO NOT USE ACCESSORIES OTHER THAN THOSE RECOMMENDED BY THE MANUFACTURER. IT MAY BE DANGEROUS TO THE USER AND MAY AFFECT ELECTROMAGNETIC COMPATIBILITY OF THE POCKETECG TRANSMITTER.

WARNING. THE POCKETECG TRANSMITTER CONTAINS A LITHIUM-ION BATTERY. THERE IS A RISK OF FIRE AND BURNS IF THE BATTERY PACK IS HANDLED IMPROPERLY. DO NOT ATTEMPT TO OPEN OR SERVICE NEITHER THE BATTERY PACK NOR TRANSMITTER. DO NOT DISASSEMBLE, CRUSH, PUNCTURE, AND SHORT EXTERNAL CONTACTS OR CIRCUITS, DISPOSE OF IN FIRE OR WATER, OR EXPOSE TO TEMPERATURES HIGHER THAN 60 °C (140 °F). REPLACE ONLY WITH BATTERIES SPECIFIED BY THE DEVICE MANUFACTURER. RECYCLE OR DISPOSE OF USED BATTERIES ACCORDING TO THE LOCAL REGULATIONS OR REFERENCE GUIDE SUPPLIED WITH YOUR PRODUCT.

WARNING. DO NOT USE THE POCKETECG TRANSMITTER AT GAS STATIONS, FUEL DEPOTS, CHEMICAL PLANTS OR WHERE BLASTING OPERATIONS ARE IN PROGRESS, OR IN POTENTIALLY EXPLOSIVE ATMOSPHERES SUCH AS FUELLING areas, FUEL STOREHOUSES, BELOW DECK ON BOATS, FUEL OR CHEMICAL TRANSFER OR STORAGE FACILITIES, AND AREAS WHERE THE AIR CONTAINS CHEMICALS OR PARTICLES, SUCH AS GRAIN, DUST, OR METAL POWDERS. THE USER SHOULD OBSERVE RESTRICTIONS ON THE USE OF RADIO EQUIPMENT IN SUCH PLACES. PLEASE BE AWARE THAT SPARKS IN SUCH AREAS COULD CAUSE AN EXPLOSION OR FIRE RESULTING IN BODILY INJURY OR EVEN DEATH.

WARNING. DO KEEP THE DEVICE AND ITS ACCESSORIES IN DRY CONDITIONS WHEN SHOWERING, BATHING OR WASHING. PRODUCT IS NOT WATERTIGHT.

WARNING. DO KEEP THE POCKETECG TRANSMITTER IN THE PROTECTIVE POUCH FROM THE MANUFACTURER OR ANY OTHER WITH PROTECTION CLASS AT LEAST IP02 IN HOME HEALTHCARE ENVIRONMENT (INCLUDES OUTDOOR APPLICATIONS).

WARNING. DO KEEP THE BATTERY CHARGER IN THE PROTECTIVE POUCH FROM THE MANUFACTURER OR ANY OTHER WITH PROTECTION CLASS AT LEAST IP01 IN HOME HEALTHCARE ENVIRONMENT.

WARNING. DO NOT USE THE DEVICE IN A MANNER SUCH THAT IT IS IN DIRECT CONTACT WITH THE BODY. THE DEVICE NEEDS TO BE WORN IN SUCH A WAY THAT DISPLAY IS FACING AWAY FROM PATIENT BODY. POCKETECG IV HAS BEEN TESTED AND MEETS FCC RF EXPOSURE GUIDELINES WHEN USED WITH AN ACCESSORY THAT CONTAINS NO METAL AND THAT POSITIONS THE DEVICE IN A MINIMUM OF 1.0 CM FROM THE BODY. USE OF OTHER ACCESSORIES MAY NOT ENSURE COMPLIANCE WITH FCC RF EXPOSURE GUIDELINES.

WARNING. DO NOT SERVICE THE DEVICE WHILE IN USE WITH A PATIENT, EXCLUDING MAIN BATTERY REPLACEMENT.

WARNING. DO NOT POSITION POCKETECG BATTERY CHARGER SO THAT IT IS DIFFICULT TO OPERATE THE DETACHABLE POWER SUPPLY CORD.

WARNING. RESULT OF PATIENT'S ACTIVITY DETECTION (BY ACCELEROMETER) MAY NOT CORRESPONT TO THE ACTUAL ACTIVITY, IF PATIENT IS MOVING BY VEHICLE.

3.1.2 PC Client applications

WARNING. THE PC CLIENT APPLICATIONS ARE NOT INTENDED FOR USE IN INTENSIVE CARE UNITS.

WARNING. THE PC CLIENT SOFTWARE IS NOT INTENDED FOR INFANTS WEIGHING LESS THAN 10 KG.

WARNING. DEVICE OPERATING PC CLIENT APPLICATIONS SHOULD BE USED IN THE TEMPERATURE RANGE DEFINED BY THE MANUFACTURER.

WARNING. DO NOT USE DEVICE OPERATING PC CLIENT APPLICATION IN GAS STATIONS, FUEL DEPOTS, CHEMICAL PLANTS OR WHERE BLASTING OPERATIONS ARE IN PROGRESS, OR IN POTENTIALLY EXPLOSIVE ATMOSPHERES SUCH AS FUELLING AREAS, FUEL STOREHOUSES, BELOW DECK ON BOATS, FUEL OR CHEMICAL TRANSFER OR STORAGE FACILITIES, AND AREAS WHERE THE AIR CONTAINS CHEMICALS OR PARTICLES, SUCH AS GRAIN, DUST, OR METAL POWDERS. THE USER SHOULD OBSERVE RESTRICTIONS RELATED TO THE USE OF RADIO EQUIPMENT IN SUCH AREAS. BE AWARE THAT SPARKS IN SUCH AREAS COULD CAUSE EXPLOSION OR FIRE AND MAY RESULT IN BODY INJURY OR EVEN DEATH.

3.2 Cautions

Caution statements alert to situations which, if not avoided, may result in equipment failure, equipment damage, or data loss.

Caution. Prior to starting a diagnostic session read the PocketECG device manual carefully.

Caution. US Federal Law restricts this device to sale by or on the order of a physician.

Caution. The ECG cables should not be bent, pulled and wrapped around the device.

Caution. The batteries should be charged before the first usage.

Caution. Inspect the device and all accessories before each use (see section 12).

4 INTENDED USE

The PocketECG transmitter constitutes a part of the Medicalgorithmics' *Unified Arrhythmia Diagnostic System PocketECG* IV and is intended to:

- acquire,
- analyze,
- visualize,
- record or/and transmit

the ECG and acceleration data. The PocketECG transmitter is attached to patient's body with three electrodes. The device is battery powered from Lithium-ion battery with rated voltage of 3.7 V and is designed for continuous use. The results of arrhythmia and ST elevation detection are displayed, stored or/and transmitted along with ECG signals. The acceleration signals are analyzed in order to determine the physical activity of patient. It is assumed that the device can further transmit the ECG and acceleration signals along with analysis results using available wireless technologies.

The PocketECG IV is intended for use under supervision of a physician or those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmias. Having fulfilled the working conditions specified in the manual, the device may be used when the patient is in the following places: clinic, hospital, outpatient cardiology clinic, house, business establishment, etc.

The PocketECG IV is intended to be used by:

- patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for:
    a) non-life-threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy;
    b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and
    c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease;
- patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as:
    a) dizziness or lightheadedness;

b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and
c) dyspnea (shortness of breath);

- patients with palpitations with or without known arrhythmias to obtain a correlation of rhythm with symptoms;
- patients who require monitoring of the effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation);
- patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.
- patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias.
- patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.

Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.

The PC Client software is used for reporting and reviewing ECG/arrhythmia diagnostic sessions. The reviewed ECG and acceleration data are being transmitted from patients' PocketECG transmitter, to a remote server through mobile telephony network. The PC Client software connects with the remote server and downloads the data which then can be viewed locally. The PC Client software allows for reviewing of the ECG and acceleration signals along with the annotations and creating the reports summarizing the recording session results.

4.1 Intended patient population

Both PocketECG transmitter and PC Client are intended for patient with:

a) age: no limits
b) weight: >10 kg
c) health: It is not intended for individuals who are at high risk of developing lethal arrhythmias such as primary ventricular fibrillation or sustained ventricular tachycardia. The PocketECG IV is not intended for infants weighing less than 10 kg. Patients unable to operate the device alone should be diagnosed under the supervision and supported in actions like starting and stopping the device, or replacing and charging the battery.

The operator, who is responsible for an ECG review and has supervisor access must be trained medical staff, physician or those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia. ECG signal can be reviewed by qualified person using PC Client, the patient does not have access to the PC Client software.

5 CONTRAINDICATIONS

The Medicalgorithmics' *Unified Arrhythmia Diagnostic System PocketECG IV*, which consists of the PocketECG transmitter, and/or PC Client software is not intended to be used by patients who have been diagnosed with life threatening arrhythmias and require hospitalization or patients who require inpatient monitoring using a life-saving device.

The PocketECG IV is not intended for use in surgical rooms, intensive care units, intermediate or step-down units and emergency vehicles. The PocketECG IV is MR unsafe and should not be used in any magnetic resonance environment.

6 ACCESSORIES

The following accessories are provided by the manufacturer in a package with the PocketECG transmitter:

① A Lithium-ion battery pack providing rated voltage of 3.7 V, type: P4BA-AA-UNI or P4BA-AB-UNI, with capacity of 1700 mAh. Use only battery of this type,

② AC plug-in charger type P3CH-AB-UNI suitable for charging P4BA-AA-UNI or P4BA-AB-UNI type batteries, rated 100 VAC – 240 VAC, 0.2 A, 50/60 Hz (charger type PECGC-III can also be used),

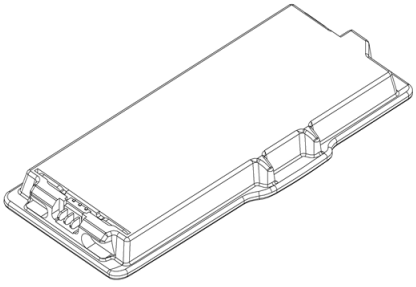
③ PocketECG transmitter pouch, type: P4TP-AA-UNI,

④ PocketECG charger pouch, type: P3CP-AA-UNI,

⑤ Optional, use only in the professional healthcare environment: PocketECG holster (transmitter holder), type: P3HL-AB-UNI,

MicroSD memory card.

①



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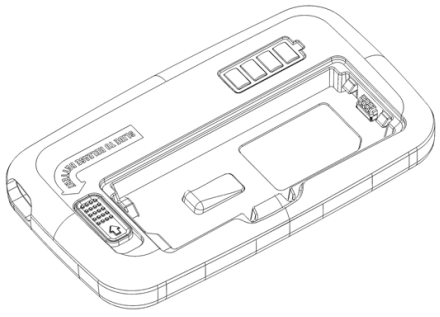

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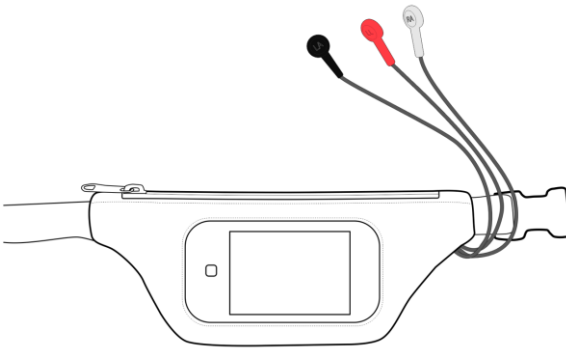

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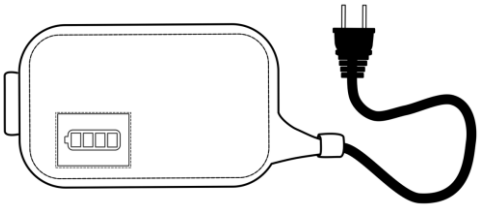

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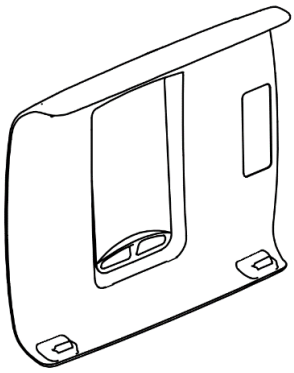


The following other accessories are needed for proper operation of the device but are not enclosed in the PocketECG transmitter package:

- SIM card,
- ECG electrodes.

WARNING. DO NOT PLUG THE DEVICE TO A DIFFERENT SOURCE OF POWER THAN INTENDED BY THE MANUFACTURER. USING A DIFFERENT POWER SOURCE IS HAZARDOUS AND MAY IMPAIR THE FUNCTIONING OF THE EQUIPMENT OR RESULT IN SERIOUS INJURY TO THE USER.

A. POCKETECG TRANSMITTER

The PocketECG IV device (see Fig. 2) transmits both the ECG and acceleration signals along with the results of their analysis to a remote server.

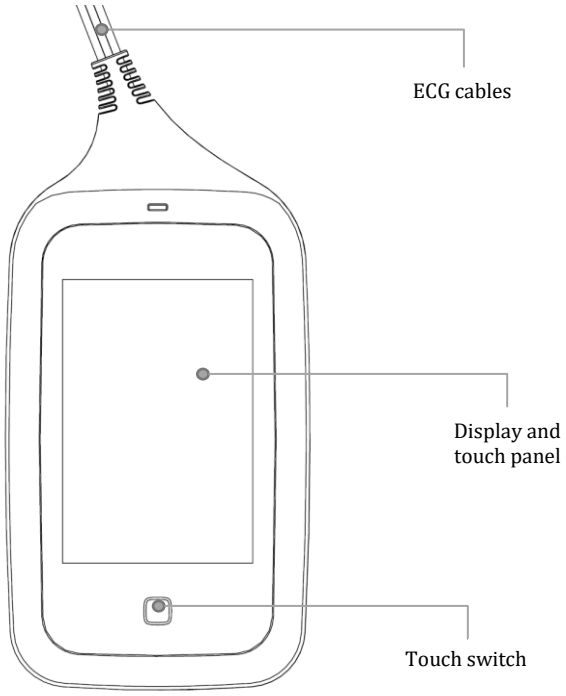


Fig. 2 PocketECG transmitter

The features of the PocketECG transmitter are as follows:

- processing of two ECG channels,
- 3-axis accelerometer - physical activity of patient is estimated basing on analysis of acceleration signal,
- 320x480 color display with touch panel,
- microSD/SDHC card socket,
- SIM card socket,
- backup power - main battery may be replaced without interrupting recording session.

7 HANDLING THE DEVICE AND ITS ACCESSORIES

Label of PocketECG transmitter is located under the battery.

CAUTION. A patient should be trained by qualified personnel before using the PocketECG transmitter.

7.1 Holster and protective pouches

7.1.1 Holster

The use of PocketECG holster (transmitter holder) is permitted only in the professional healthcare environment. To properly place the transmitter in the holster, insert the transmitter into the holster and press down so that the oval pins of the transmitter around its perimeter catch on the plastic latches of the holster (*Fig.* 3).

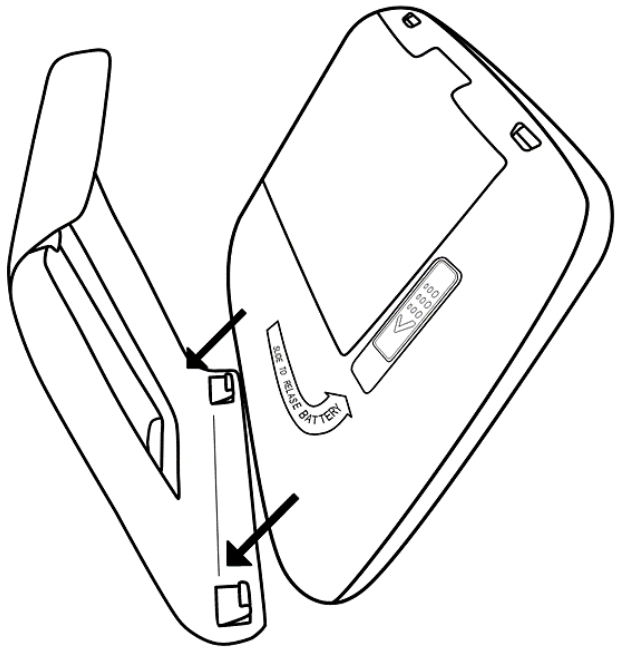


Fig. 3 Putting the device into holster

Ensure that the back of the PocketECG device touches the holster(*Fig.* 4).

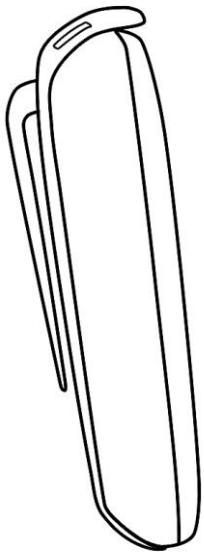


Fig. 4 Transmitter fitted in holster correctly

Holster with the PocketECG device should be placed on the belt or trousers(*Fig.* 5).

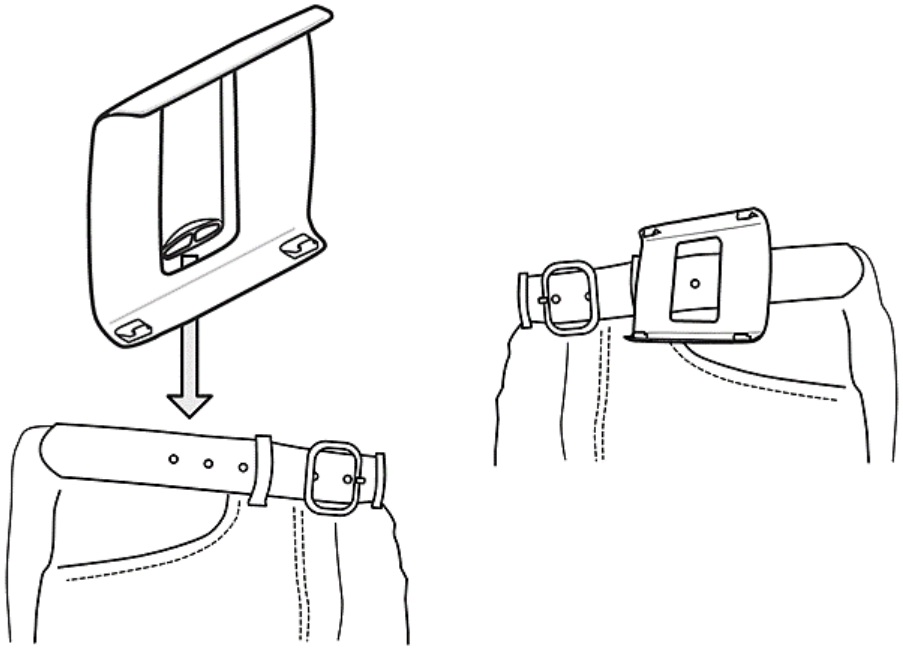


Fig. 5 Holster placement

To remove the transmitter from the holster, bend its upper, more protruding edge, which will release the transmitter from the holster's latches.

7.1.2 Pouch for the transmitter

WARNING. DO KEEP THE POCKETECG TRANSMITTER IN THE PROTECTIVE POUCH FROM THE MANUFACTURER OR ANY OTHER WITH PROTECTION CLASS AT LEAST IP02 IN HOME HEALTHCARE ENVIRONMENT (INCLUDING OUTDOOR APPLICATIONS).

The PocketECG device is not waterproof. In case of using the device outside of the professional healthcare environment, before starting the device, put PocketECG in the pouch, to provide IP22 protection.

Before starting the device, put the lead wires through a dedicated slot in pouch (*Fig.* 6).

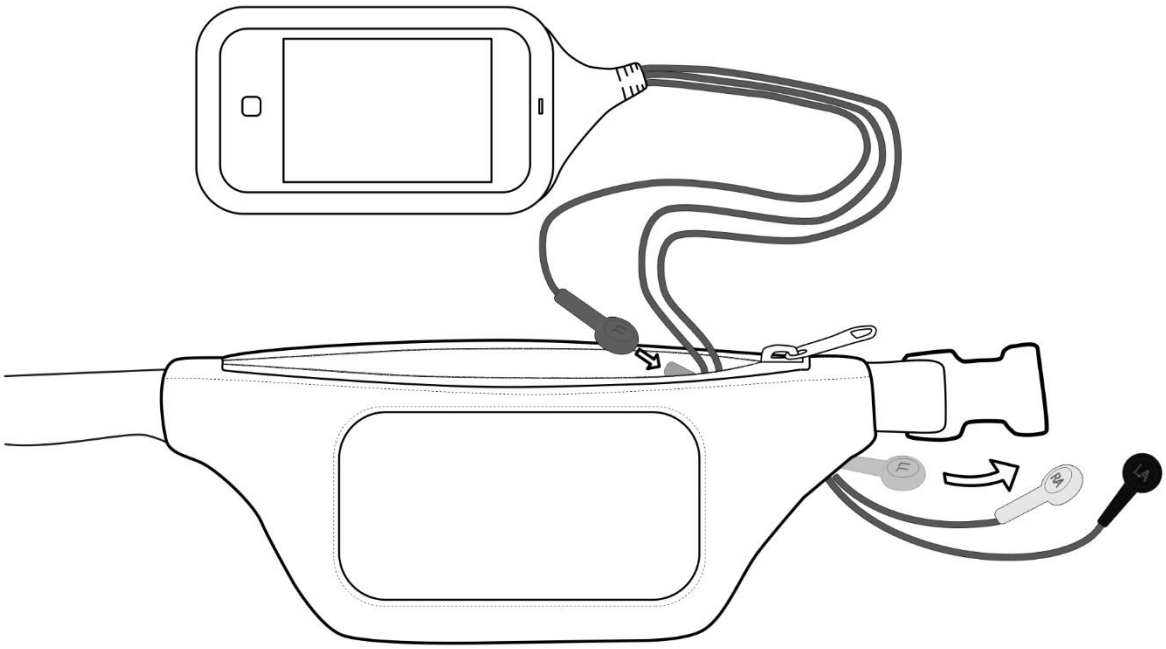


Fig. 6 Putting lead wires through the dedicated slot

Next, put the device in the pouch and zip the pouch (*Fig.* 7).

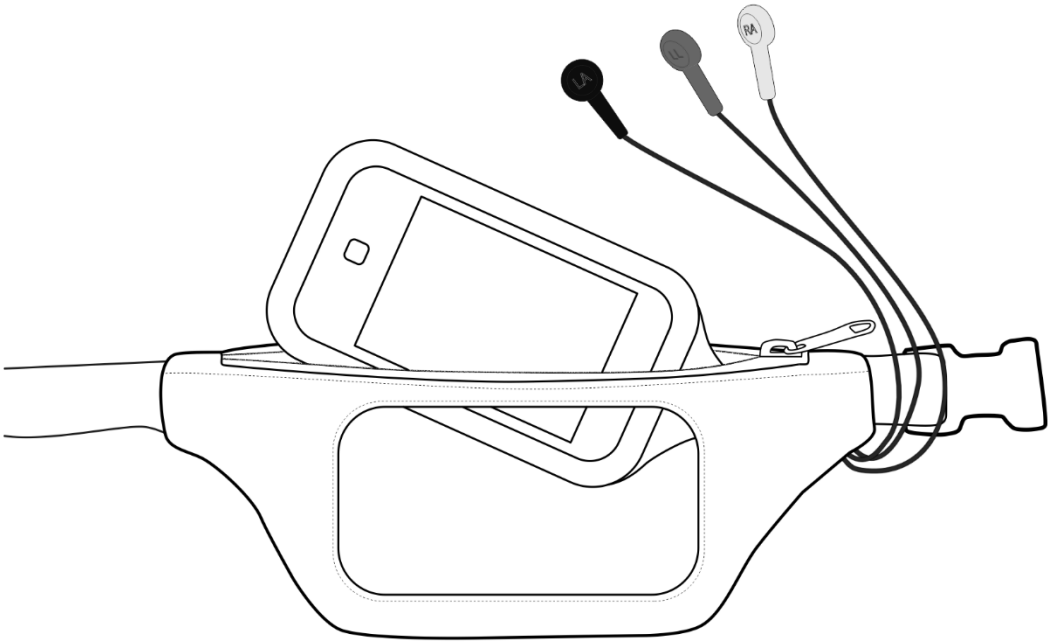


Fig. 7 Putting the device into pouch

The correct transmitter placement in the closed pouch is presented in *Fig.* 8

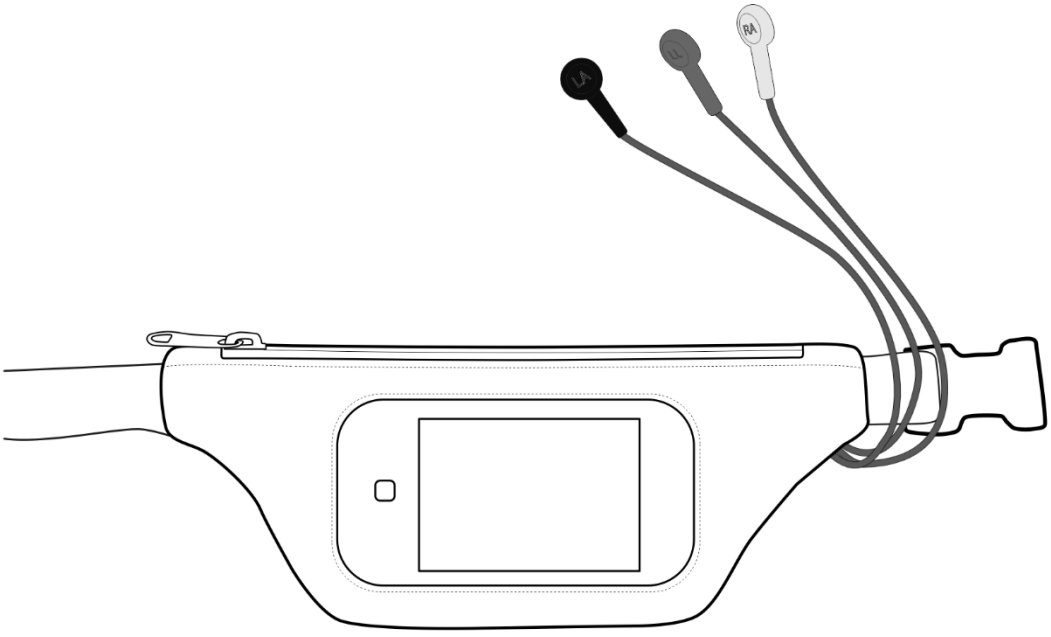


Fig. 8 Correct transmitter placement in the closed pouch

Ensure that flap on the back side of pouch is zipped. Press the hook-up-loop on the lead wires (pointed by arrow in *Fig.* 9).

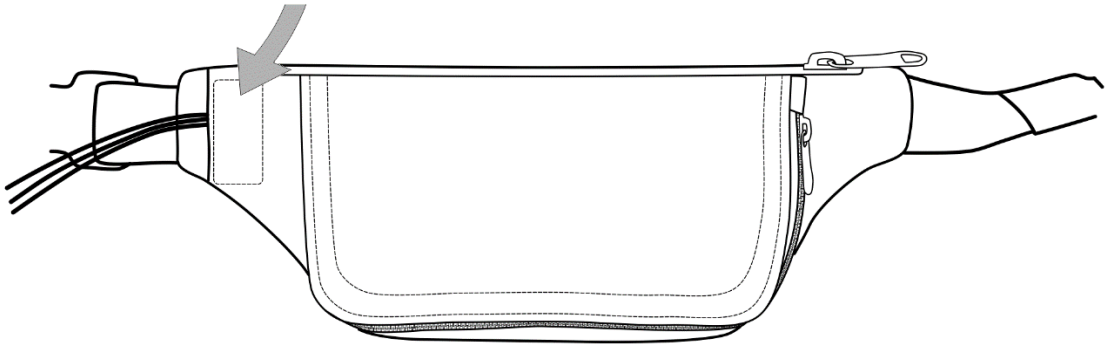


Fig. 9 Back of the pouch, placement of hook-up-loop to press

The pouch for transmitter is recommended to be fasten around the waist (*Fig.* 10).

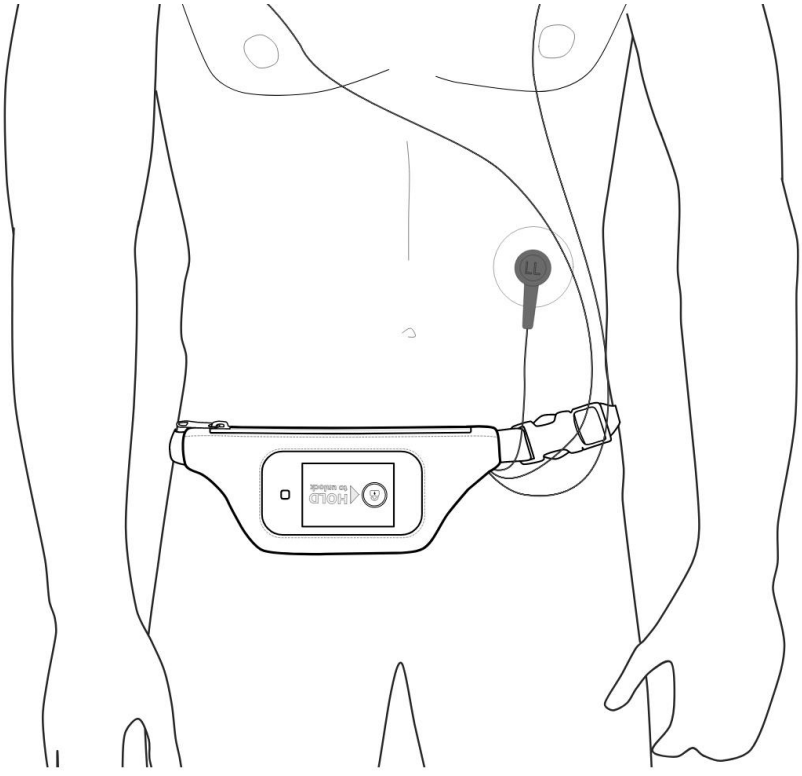


Fig. 10 Pouch fasten around the waist

7.1.3 Pouch for the battery charger

The battery charger isn't waterproof. In order to provide IP21 protection outside of the professional healthcare environment (in the home healthcare environment) keep charger inside the pouch. Before starting using the battery charger put it in the protective pouch.

First, put the cable through the dedicated slot (*Fig.* 11).

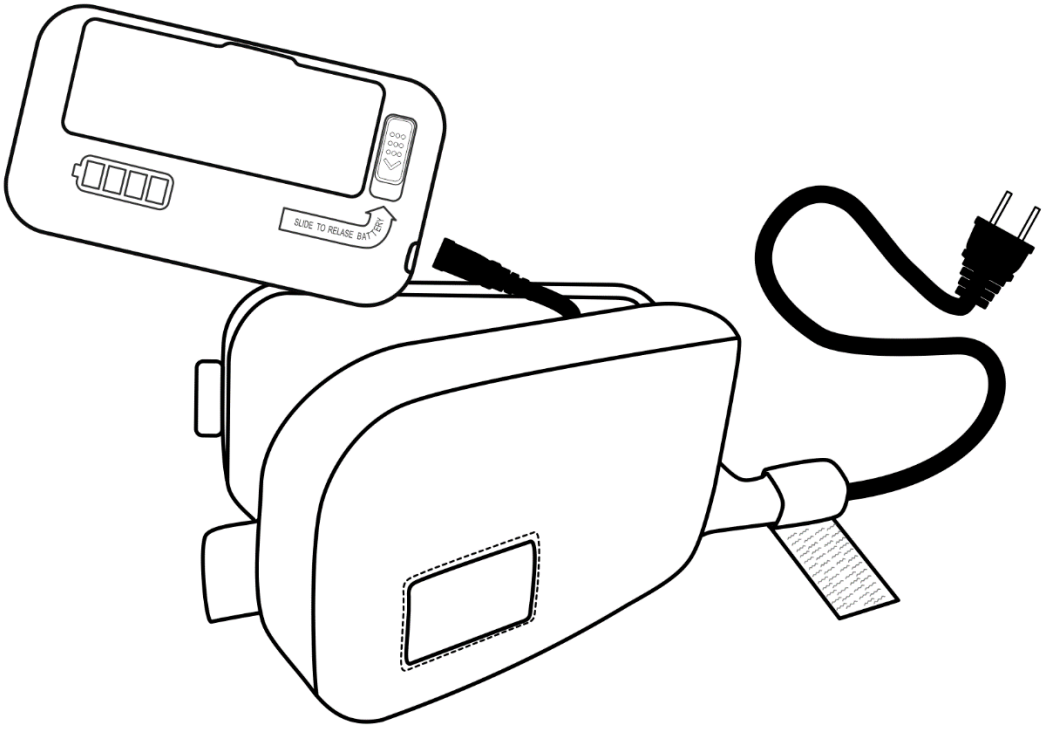


Fig. 11 Putting the cable through the dedicated slot

Fasten the hook-up-loop around the cable (*Fig.* 12).

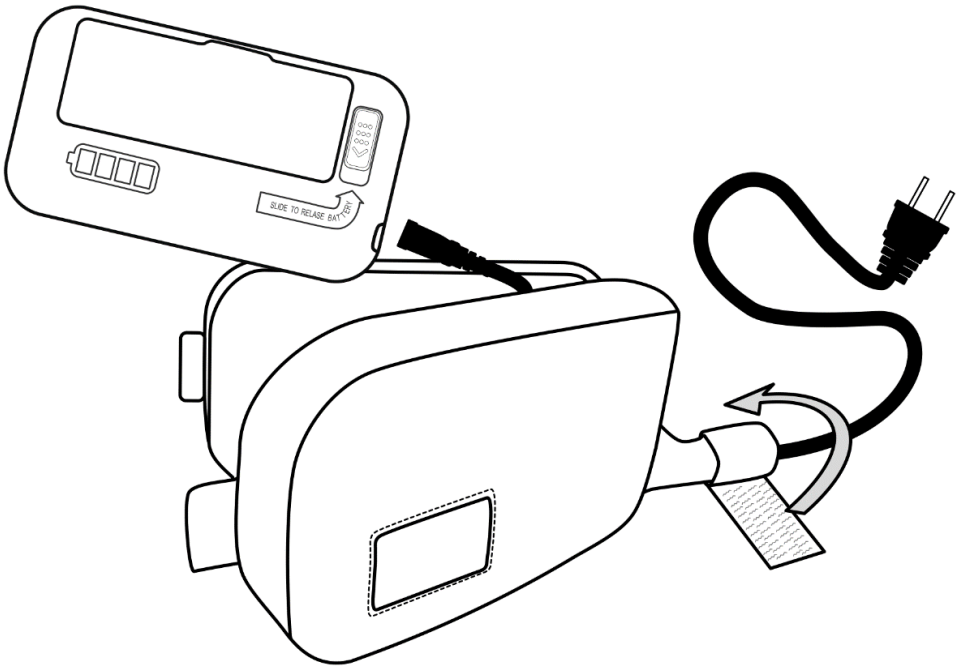


Fig. 12 Fasten hook-up-loop around the cable

Connect cable with the charger. Fit the charger into the pouch (Fig. 13).

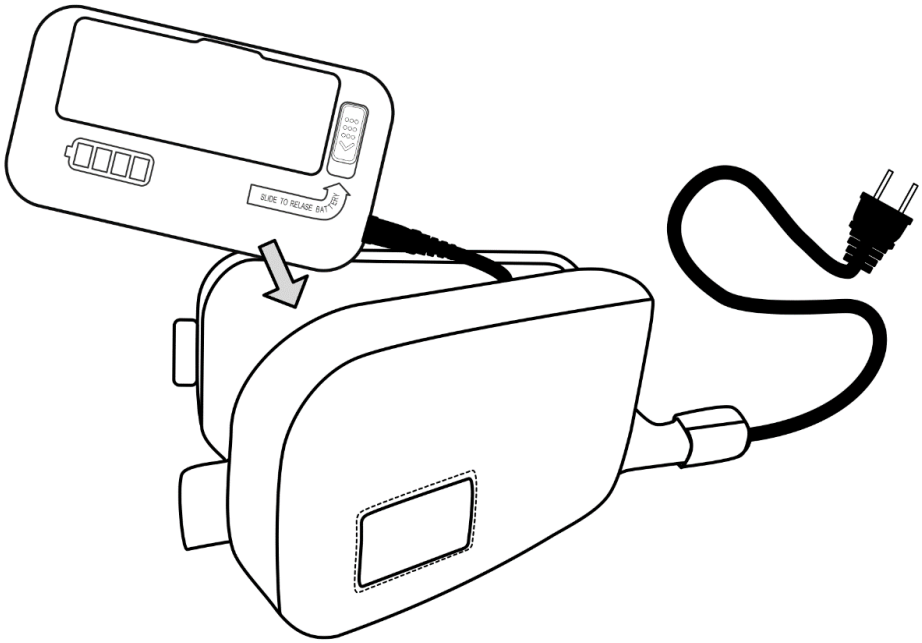


Fig. 13 Putting the cable into the charger

Close the pouch flap and fasten the hook-and-loop (*Fig.* 14).

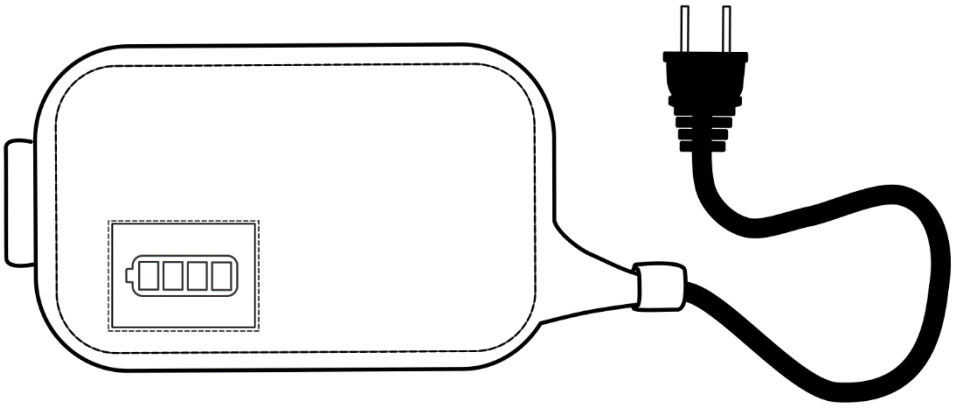


Fig. 14 Battery charger protected against ingress of water

7.2 Starting the device

To provide IP 22 protection keep the PocketECG device in the protective pouch when using in the home healthcare environment. For instructions showing how to put the device in the pouch see section 7.1.2.

Turn the PocketECG transmitter pouch with an inserted transmitter to the side opposite the display and touch panel. Unzip and open the pouch flap upwards (*Fig. 15*).

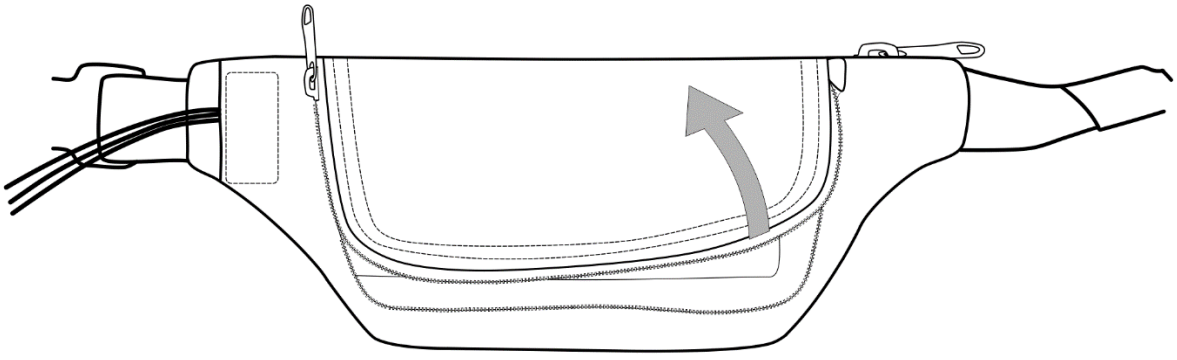


Fig. 15 Opening the flap

To start the PocketECG transmitter slide the battery into its compartment, until it snaps shut (see Fig. 16).

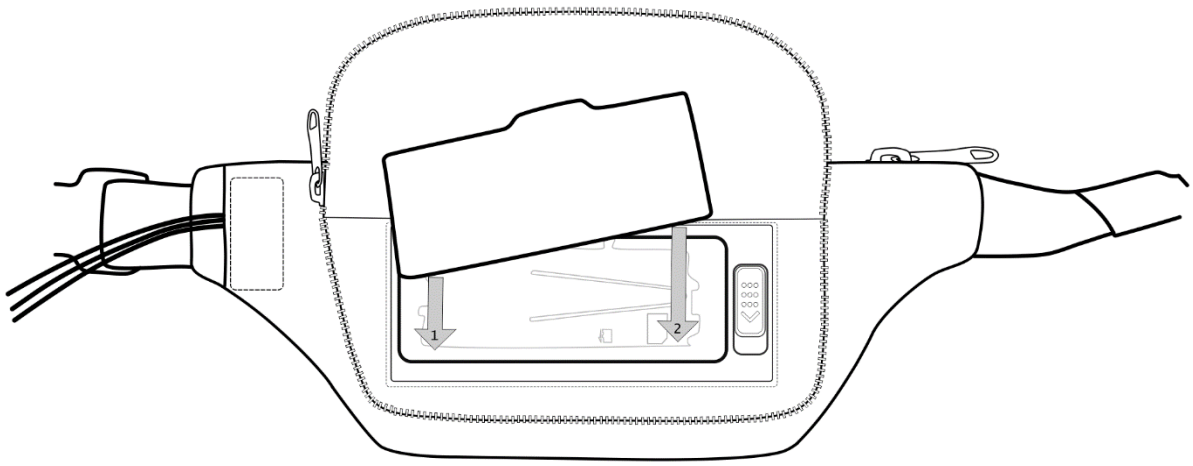


Fig. 16 Inserting the battery

Close the pouch flap and fasten the zip (*Fig.* 17).

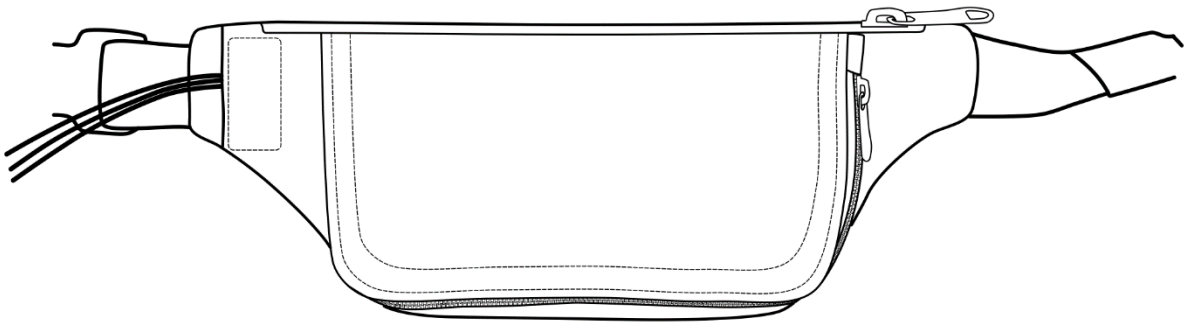


Fig. 17 Closed pouch flap. Transmitter protected against ingress of water.

After the battery is placed in the appropriate compartment of the PocketECG transmitter, the device turns on automatically. The device is ready for starting new recording session about 90 seconds after the battery is placed in its compartment. A graphical user interface comes on when the device is properly supplied with power and ready to work. Then the screen goes blank but it is still working.

Caution. If no image is displayed within 90 seconds after placing the battery in the compartment, the battery is fully discharged or device does not operate correctly due to the abnormal temperature or humidity conditions.

In the professional healthcare environment the PocketECG transmitter can be used without the pouch. The way of starting the device is the same. Slide the battery into its compartment, until it snaps (*Fig.* 18).

Fig. 18 Starting the device

7.3 Main and backup batteries

A fully charged battery makes it possible to continuously monitor the patient's ECG and acceleration signals using the PocketECG transmitter for at least 24 hours.

The PocketECG transmitter is equipped with backup battery that is intended to supply the device when the main battery is being replaced. Removing main battery when the recording session has not been initiated or has already been finished does not activate backup power (the device turns off). When the main battery is being removed during ongoing session, the transmitter operates continuously for up to 1 minute powered from backup battery. After placing fully charged main battery into its compartment, the transmitter starts to be powered from main battery automatically.

Caution. The backup power is activated only when recording session is ongoing.

Caution. If the level of main battery is low, replace it with fully charged one, immediately. If the main battery remains removed from its compartment for period longer than 1 minute, the transmitter is switched off and the transmission is suspended.

WARNING. REMOVE THE BATTERY FROM ITS COMPARTMENT WHEN THE POCKETECG TRANSMITTER IS NOT GOING TO BE USED. THE BATTERY RELIABILITY MAY BE DEGRADED WHEN LEFT IN THE TURNED OFF POCKETECG TRANSMITTER FOR A LONG PERIOD OF TIME.

In order to replace the battery, follow the instructions:

1. Turn the PocketECG transmitter pouch with an inserted transmitter to the side opposite the display and touch panel.
2. Unzip and open the pouch flap upwards (*Fig.* 19).

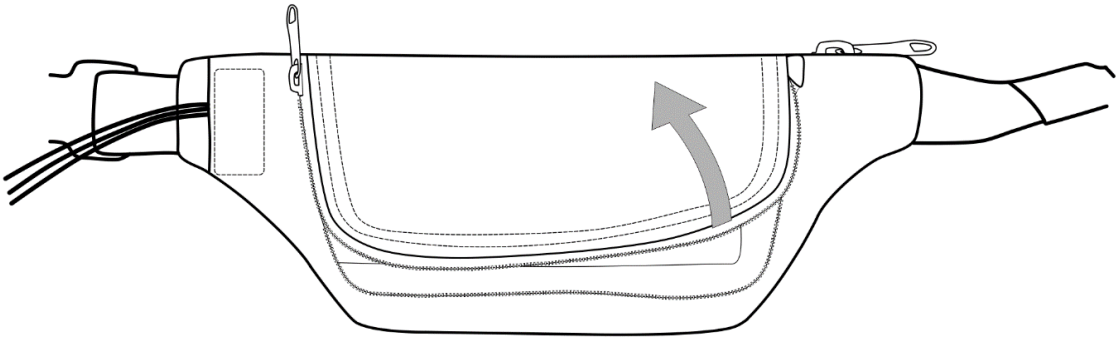


Fig. 19 Opening the flap

3. Slide the battery lock to release the battery and remove the battery(*Fig.* 20).

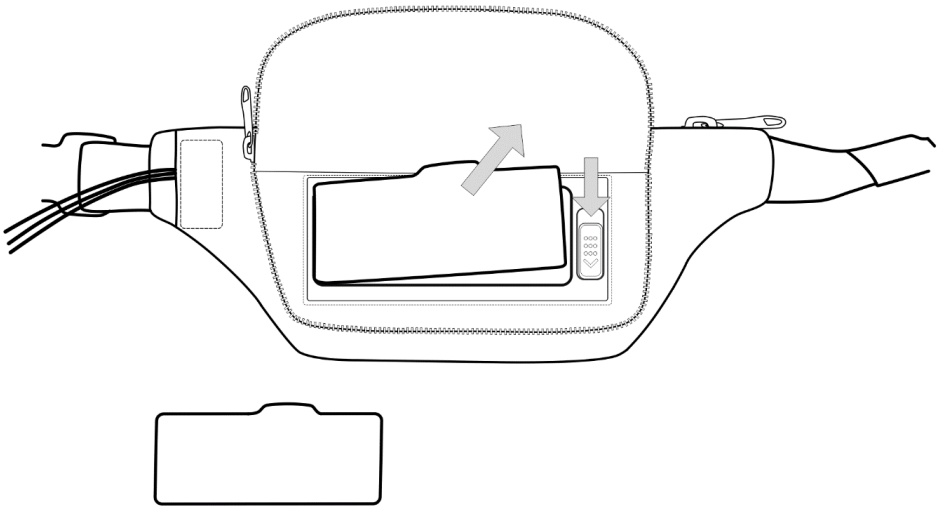


Fig. 20 Taking the battery out

4. Place fully charged battery until the lock clicks back into its original position(*Fig.* 21).

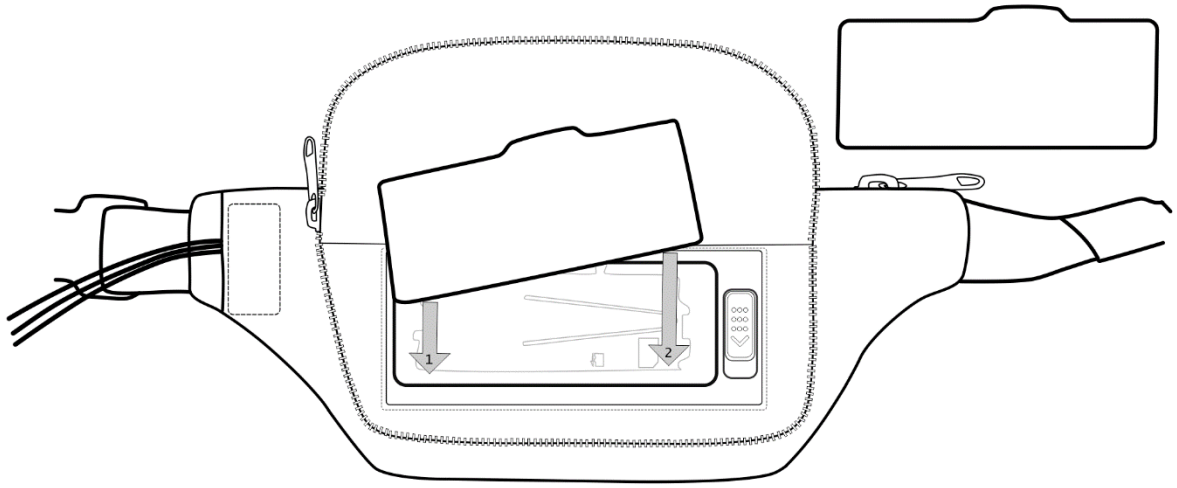


Fig. 21 Replacing the battery

5. Close the pouch flap and fasten the zip (*Fig.* 22).

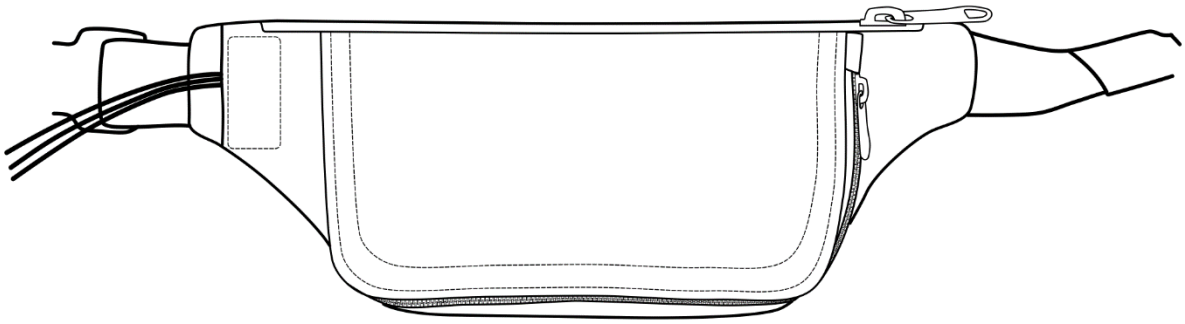


Fig. 22 Closed pouch flap. Transmitter protected against ingress of water.

Caution. When replacing the battery, make sure the contacts face the interior of the battery compartment. If slipping the battery in requires excessive force, check if you are putting it into the battery compartment the right way.

7.3.1 Main battery charging

The discharged battery should be charged immediately if the diagnostic session is intended to be performed for a period longer than 24 hours. On average the battery requires 4 hours to be fully charged. Use charger provided along with PocketECG transmitter. If the device is not going to be used for a longer time period, remove the battery.

Caution. The AC plug-in charger may require suitable adapter and/or converter to convert to the proper voltage when used outside the territory of a country where it was provided by the Medicalgorithmics distributor.

Caution. The battery charger can be supplied only by the AC voltage specified on the charger label.

WARNING. DO NOT USE OTHER CHARGERS THAN THOSE INTENDED FOR THE TYPE OF BATTERY USED IN THE POCKETECG TRANSMITTER IN ORDER TO PREVENT DANGER OF BATTERY EXPLOSION.

In order to fully charge the battery, follow the instructions:

1. Plug the charger into the AC mains.
2. Check whether all light indicators blink simultaneously and emit orange light (the sound is generated if the battery is not inserted into the charger cradle within 15 seconds starting from the moment of powering the charger on).
3. Open the PocketECG charger pouch flap upwards (*Fig.* 23).

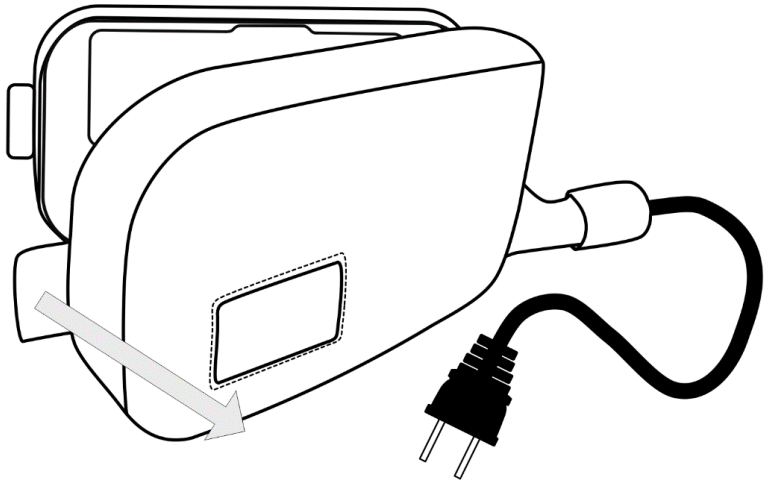


Fig. 23 Opening the flap

4. If there is a battery in the charger take it out (*Fig.* 24)

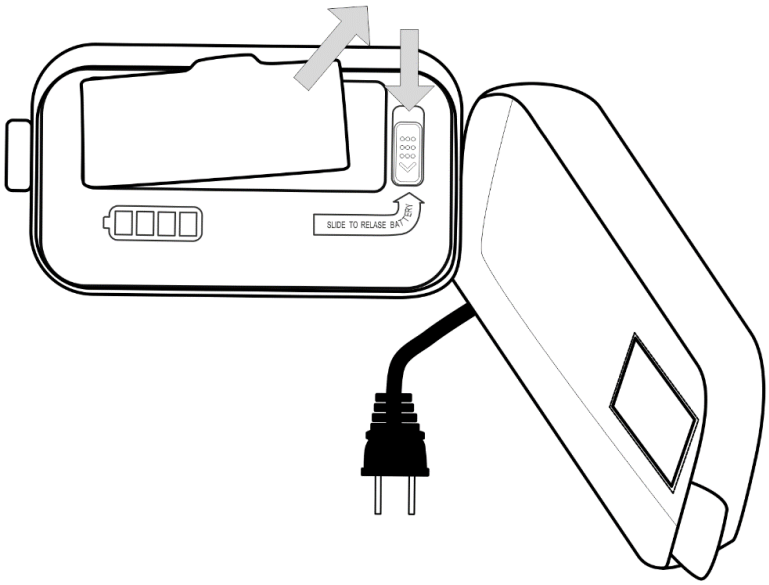


Fig. 24 Taking the battery out

5. Put the battery into the charger cradle and verify whether light indicator flashes orange indicating that the charging is in progress (the sound is no longer generated) - *Fig.* 25.

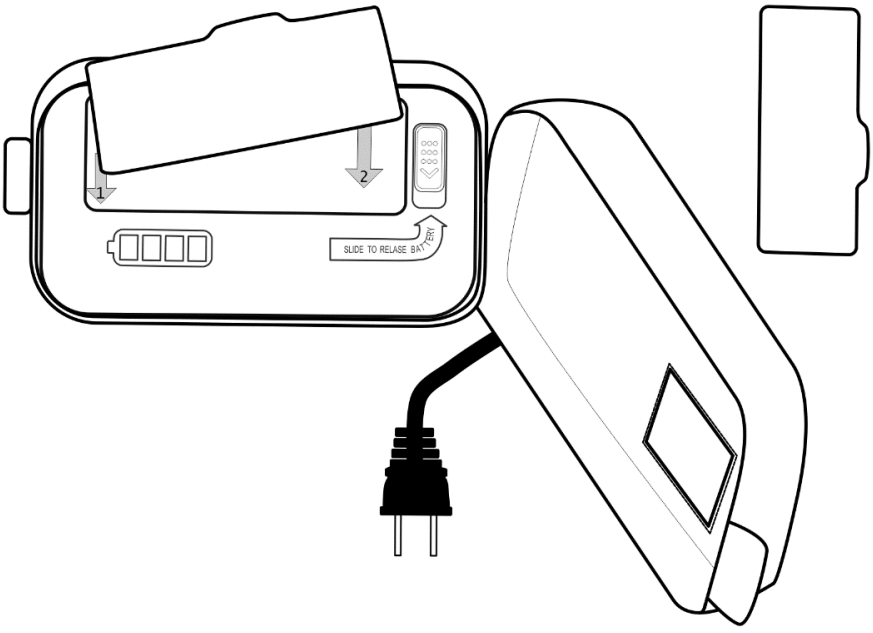


Fig. 25 Replacing the battery

6. Close the pouch flap and fasten the hook-and-loop (*Fig.* 26).

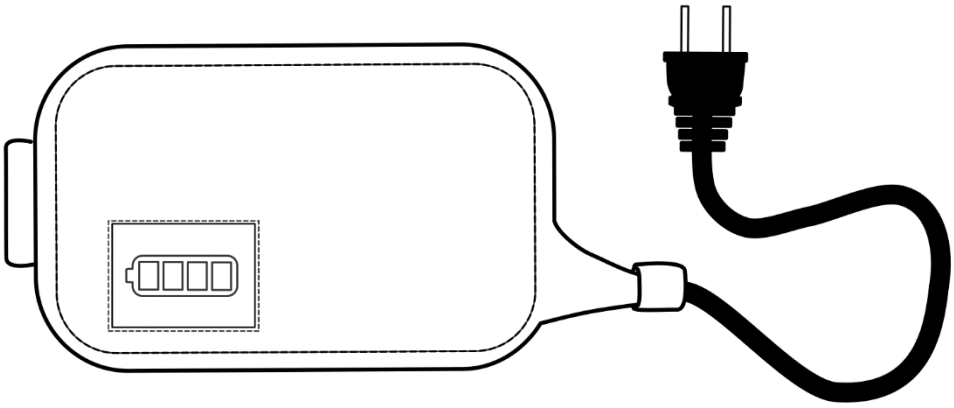


Fig. 26 Battery charger protected against ingress of water

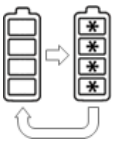
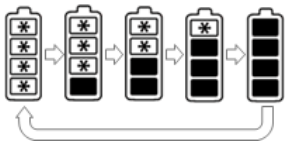
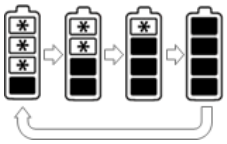
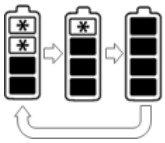
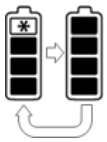
7. Wait until all light indicators of the charger changes from orange to green indicating that the battery is fully charged.

Caution. The charging process does not start if the battery is damaged or has been deeply discharged (e.g. kept in the turned off PocketECG transmitter for a long period of time).

The charging process starts immediately after placing the battery into its compartment when the battery has been used and stored according to the Instructions for Use recommendations. If the charger generates the sound when the battery is already inserted into its cradle the battery may be damaged or deeply discharged. In order to verify whether deeply discharged battery may be safely used keep it in the charger for 5 minutes. If the charging process starts within 5 minutes the battery tends to operate properly. Otherwise, remove the battery from the charger – the battery is damaged and should be no longer used.

When the battery gets damaged or worn out, follow standard disposal procedure for Lithium-ion batteries.

The battery charger reports the battery level using four light indicators. The behavior of the light indicators corresponding to the particular battery levels is described in the following table.

Light indicators	Description	Battery level
 (orange light)	All light indicators blink simultaneously.	unknown
 (orange light)	All light indicators are being turned on and off sequentially.	0-25 %
 (orange light)	First (bottom) light indicator is turned on; second-third-fourth indicators are being turned on and off sequentially.	25-50 %
 (orange light)	First (bottom) and second light indicators are turned on; third-fourth indicators are being turned on and off sequentially.	50-75 %
 (orange light)	First (bottom), second and third light indicators are turned on; fourth (top) indicator blinks.	75-99 %
 (green light)	All light indicators are turned on.	100 %

7.3.2 Backup battery charging

The backup battery is installed inside the PocketECG transmitter and cannot be removed. The charging of the backup battery is started automatically and does not require interaction from the user. The charging of backup battery is initiated when its state of charge falls below predefined level and the main battery powering the device is fully charged. Therefore, the discharged main battery should be always replaced with a fully charged one.

7.4 Stopping the device

In order to switch the transmitter off ensure that the recording session is finished and remove the battery from its compartment.

WARNING. NEVER SHIP THE POCKETECG TRANSMITTER/CHARGER WITH THE MAIN BATTERY INSERTED INTO ITS COMPARTMENT.

7.5 SIM and flash memory cards

The PocketECG transmitter is equipped with a socket for a SIM and microSD memory cards. The ECG and acceleration data are stored on SD card during recording session and further transmitted through mobile telephony network to a remote server.

The SIM card in transmitter is required in order to allow data transmission through a mobile telephony network. This card is provided by the mobile network operator. If your transmitter is not already equipped with SIM card please contact your PocketECG service provider for assistance.

In case of limited access to mobile telephony network data are stored on SD card until they can be successfully transmitted. It is recommended to use reliable SD cards of minimum 4 GB capacity produced by the Verbatim, SanDisk and other experienced manufacturers. The PocketECG transmitter operates with the microSD and micro SDHC (high capacity) cards.

Caution. In PocketECG IV the SIM and microSD cards must be placed in its compartment before new recording session is started.

8 TEST PREPARATION

8.1 Unlocking a new recording session

An ‘Unlock new session‘ option is presented after starting the device (Fig. 27).

Fig. 27 ‘Unlock new session’ option

To enable recording the ECG signal in the next step, first, press ‘Unlock session button’ and enter a code created during the enrollment (Fig. 28).

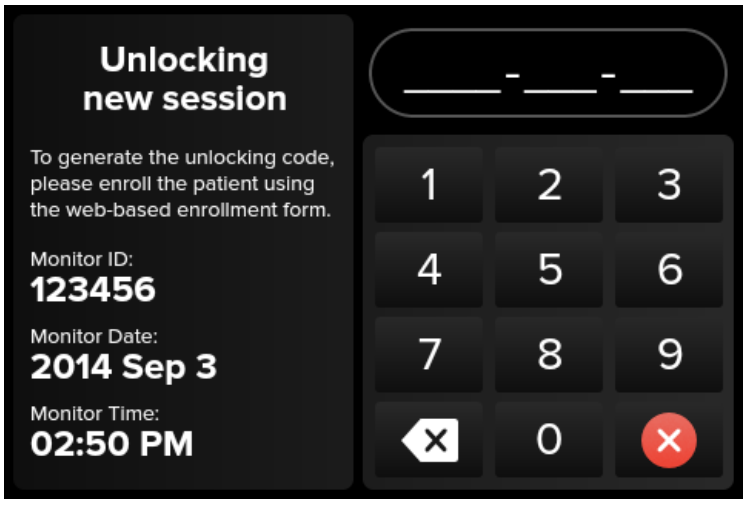


Fig. 28 Entering unlocking code.

Now the session is unlocked and the device is ready for session starting and recording ECG signal (section 8.3).

8.2 Electrodes and their placement

Only high-quality electrodes with fast conducting gel should be used with the PocketECG transmitter. We recommend using electrodes designed for Holter monitoring. Single-use electrodes last for a limited time period and should not be used for longer than specified by their manufacturer. Fresh electrodes contain wet gel; if the gel is spongy the electrodes are of poor quality or past their use-by date. Usually, electrodes last no longer than 2-3 weeks after opening the box.

Caution. Verify the use-by dates on applied electrodes to make sure they have not expired.

Caution. ECG electrodes can cause skin irritation. Examine the skin for signs of irritation or inflammation and avoid placing of the electrode in those areas.

WARNING. THE SNAPS OF THE ECG LEAD WIRES ARE MADE OF METAL CONDUCTING THE CURRENT AND ARE INTENDED TO BE CONNECTED WITH ELECTRODES PLACED ON A PATIENT'S BODY. THE SNAPS OF THE LEAD WIRE SHOULD BE CONNECTED NEITHER TO ANY OF THE POCKETECG ACCESSORIES NOR OTHER EQUIPMENT. NEVER CONNECT THE LEAD WIRE SNAPS WITH ANY SOURCE OF ELECTRIC POWER SUCH AS POWER OUTLETS, POWER SUPPLIERS AND BATTERIES.

Because of the high importance in producing a good recording, a special preparation should be applied to patient's skin before placing the electrodes. Do not use high-proof alcohol as it may dry up the epidermis and distort the ECG signal transmitted by the PocketECG device. In order to prepare patient's skin, follow these instructions:

1. Explain the procedure to the patient.
2. Remove hair from the place where the electrode is to be attached.
3. Wipe the chosen sites with a damp cloth/wet wipes.

Place the electrodes on patient's body and connect the ECG cables of the PocketECG transmitter as shown in the following diagram (cable clips colors complying with the European standard - *Fig.* 29 and *Fig.* 30, American standard –*Fig.* 31 and *Fig.* 32).

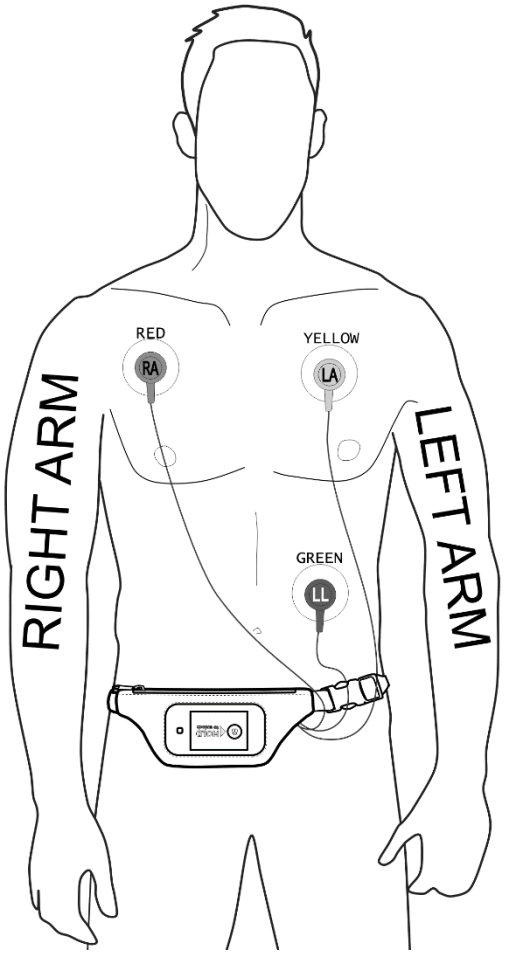


Fig. 29 ECG electrodes and cable clips placement – colors coded according to the European standard

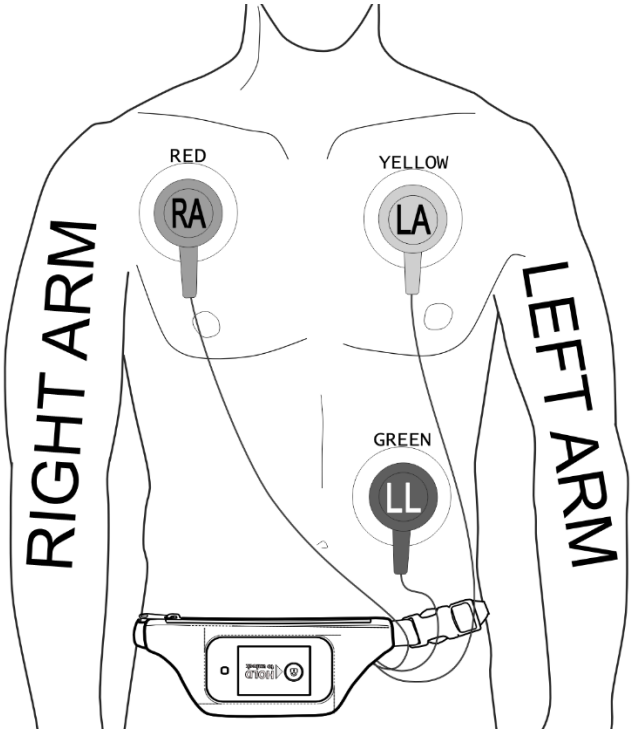


Fig. 30 Enlarged electrodes and cable clips - colors coded according to the European standard (ECG electrodes and ECG snaps are presented oversized to allow user easy distinguishing of their coding and proper hook-up)

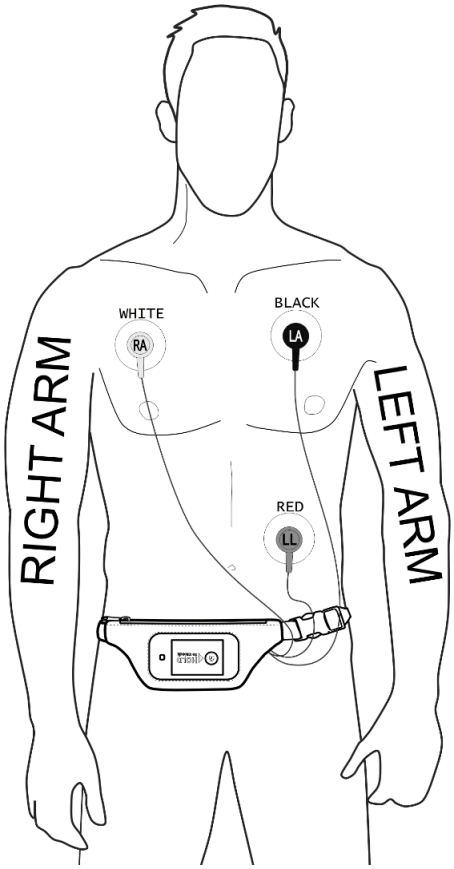


Fig. 31 ECG electrodes and cable clips placement – colors coded according to the American standard

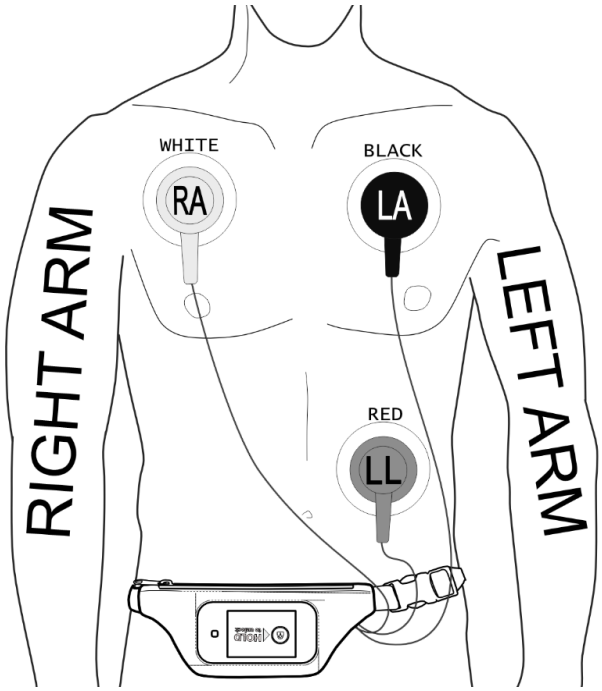


Fig. 32 Enlarged electrodes and cable clips - colors coded according to the American standard (ECG electrodes and ECG snaps are presented oversized to allow user easy distinguishing of their coding and proper hook-up)

Caution. Always make sure that the electrodes are placed correctly.

Secure each lead wire. Cables of the PocketECG device should be attached to the electrodes in a way that reduces movements causing signal artifact.

When the amplitude of the ECG recording is very low (below 0.5 mV), we recommend gently wiping the epidermis with a very fine, disinfected, special sandpaper or putting the electrodes in a new place. Transmitting signal at a level lower than indicated could negatively impact its analysis.

When electrodes are connected to the PocketECG transmitter as shown in *Fig.* 29/*Fig.* 31 and it is possible to monitor limb lead II and III. Green (or red according to American standard) cable snap is attached to a referential electrode of both ECG leads. A physician may order monitoring of other profiles.

8.3 Starting the recording session

When patient is ready for session, press ‘Start session’ button (Fig. 33). After pressing the button ECG signal is recorded.

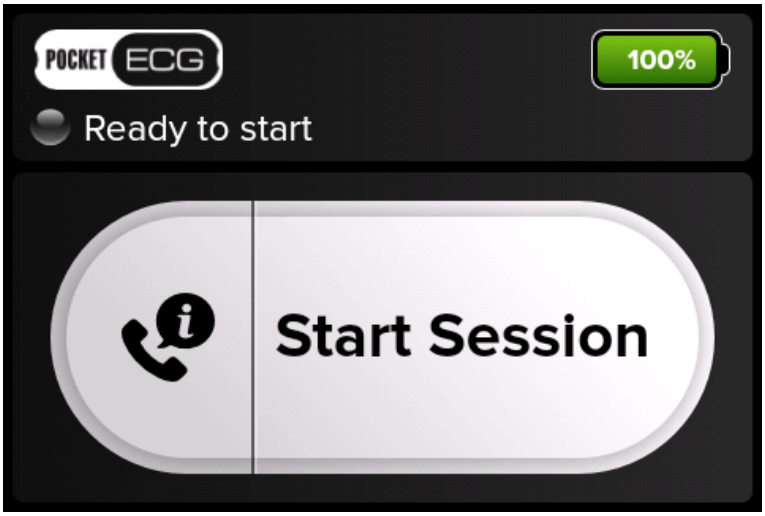


Fig. 33 Starting a new session

⚠ WARNING: IF AFTER PRESSING 'START SESSION' BUTTON THE PROCESS IS NOT COMPLETED AND 'STARTING' STATUS MASSEGE IS PRESENTED, CONTACT THE DEVICE PROVIDER. THIS PROBLEM CAN BE A CONSEQUENCE OF TIME SYNCHRONIZATION ERROR, COMMUNICATION ERROR OR DEVICE MULFUNCTION.

9 SUPERVISOR AND PATIENT VIEWS

There are two main views of the graphic user interface: the supervisor view and the patient view. The 'supervisor view' is intended to be used by the medical staff and provides access to all options of the software. The 'patient view' is presented to the patient during entire recording session and gives only limited access to software functions.

9.1 Supervisor view

The graphical user interface presented to the user in the 'supervisor view' mode is shown in

Fig. 34. The waveforms of recorded ECG signals together with annotations generated by the analysis algorithm are plotted in three rows. Each row corresponds to six seconds of recording. Basing on displayed signals and annotations trained user may verify the proper electrode placement and proper initialization of the recording session. Furthermore, the heart rate in beats per minute is presented in the upper right corner of the screen.
There are three tabs located in the bottom of the screen providing access to the software options:

- **Stop/Start** – used for starting and finishing of the recording session,
- **View** – channel selection, signal scaling, etc.,
- **Settings** – session settings.

The icons indicating the battery level and signal strength of the mobile network are displayed in right bottom corner of the screen. Detailed description of these both indicators is given in the section 9.3.

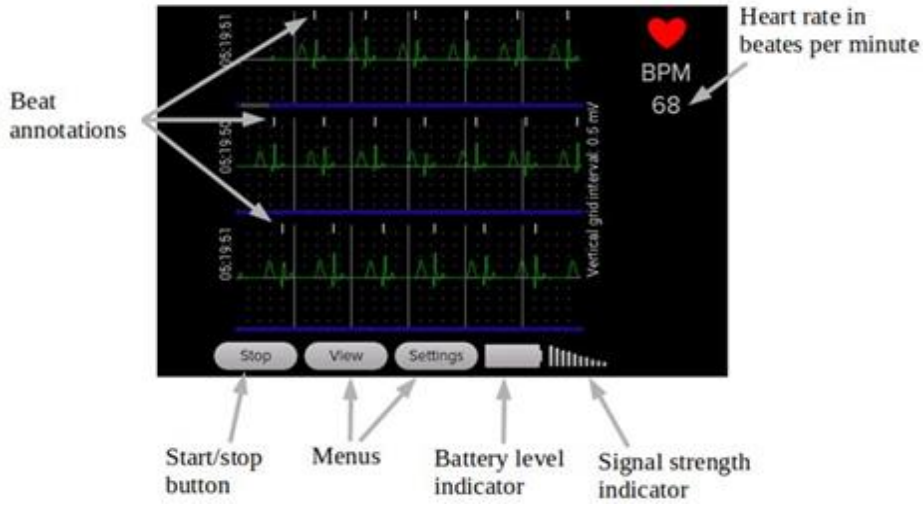


Fig. 34 'Supervisor view' of the graphical user interface

9.1.1 Start/stop button

The Start/Stop button enables starting and finishing recording sessions. When session is not yet initiated the button is displayed as the 'Start' button. Otherwise, the button is marked with 'Stop' command - when pressed cause the recording session to finish.

When the recording session begins the ECG, signal is displayed on the screen along with annotations of the classified beats and arrhythmias. The patient's heart rate is displayed in the top right corner of the screen of the PocketECG transmitter. After starting a new recording session, verification of electrodes placement should be performed. In order to verify the electrodes placement, follow the instructions:

1. Make sure that colors of the ECG clips correspond to those presented in Fig. 33 / Fig. 34.
2. Verify the ECG signal quality for both available channels by observing the ECG signal waveform on the screen.

Caution. If the ECG signals are not presented on the PDA display and/or the 'EL' annotation is displayed, the ECG signal is not analyzed due to the overload of the PocketECG transmitter or incorrect connection between lead wires and patient's electrodes. The similar effect may occur when ECG electrodes are used and should and signal quality is insufficient.

9.1.2 View tab

The View tab contains the following options:

- **Patient view** – switches the user interface into the 'patient view
- **Resize ECG** – switches the length of the ECG waveforms displayed on the screen,
- **Zoom in amplitude** – doubles the ECG amplitude zoom,
- **Zoom out amplitude** – reduces the ECG amplitude zoom by half,
- **Reset zoom** – restores the default amplitude zoom of the ECG signal,
- **Switch ECG channel** – switches between the first and the second ECG channel to be displayed on the device screen.

The user may select whether small or large ECG waveforms should be displayed (see Fig. 35).

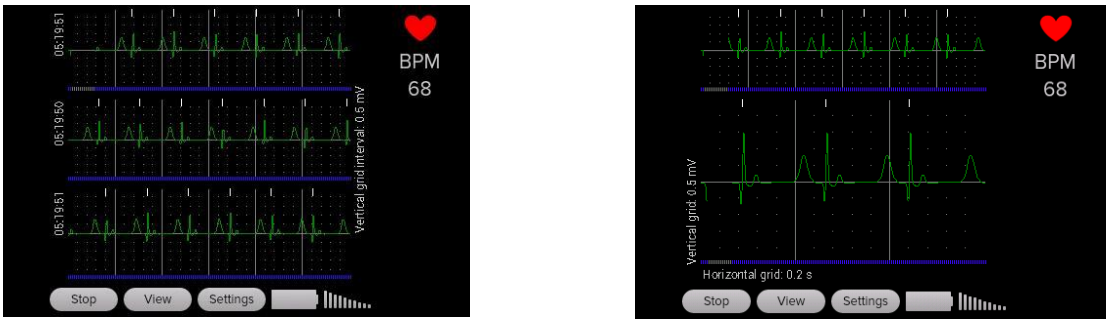


Fig. 35 Small (left) and large (right) ECG waveforms

Standard waveforms correspond to 18 seconds of ECG signal (each row corresponds to 6 seconds). When 'Resize ECG' mode is selected, 6 seconds of signal is presented in the top of the screen. Additionally, zoomed waveform corresponding to 3 seconds of ECG is presented below.

9.1.3 Settings tab

Analysis settings can be accessed any time during software operation. The Settings tab contains following options:

- **Send examination** – allows reuploading a previously recorded session to the server;
- **Arrhythmia Settings** – parameters for arrhythmia classification:
  - **Pause:** N ms – pause above N milliseconds,
  - **Asystole:** above N ms – asystole above N milliseconds,
  - **Bradycardia:** below N BPM – bradycardia below N beats per minute,
  - **V tachycardia:** above N BPM – ventricular tachycardia above N beats per minute,
  - **SV tachycardia:** above N BPM – supraventricular tachycardia above N beats per minute,
  - **Premature:** above N % – premature ectopic beats above N %
  - **Multiform:** sensitivity N – N level of sensitivity for detection of multiform ventricular events,
  - **Pacer:** On/Off – pacemaker switched on/off;
- **Session Settings** – configuration of the PocketECG transmitter:
  - **Power saving** – when set the device is automatically switched to power saving mode after a short period of inactivity on the patient view (display is off, etc.),
  - **Send ECG events through Internet** – ECG events are transmitted when this option is selected (default),
  - **Stream ECG and annotations** – ECG data are streamed to the remote server when this option is selected (default is off),

- **ECG strip at least every N minutes** – ECG transmission is triggered at least once every N minutes,
- **Comm. srv** – remote server address and port number, where processing results and signals are sent,
- **Ftp srv** – remote server address,
- **Path:** /XXX – remote server folder name,
- **User name:** – name of the user logging in to remote server,
- **Password:** ******* – hidden password – area showing whether password was entered,
- **Restore Defaults** – button for restoring standard remote server settings;

- **About** - contains following options:
  - **Software version** – displays version of software operating PocketECG transmitter;
  - **Session info** – displays window with following information related to the recording session:
    - **COM:** [xxx][nnnnnnn][nnnnnnnnn] – communication status (first brackets from the left), the number of files transmitted to the server (second brackets from the left), the number of files queued for transmission (third brackets from the left),
    - **TIME:** DDd HHh MMm SSs – time elapsed since the beginning of the session (DAYS HOURS MINUTES SECONDS),
    - **MEM:** XXXXX MB free: space available on the microSD memory card,
    - **ID:** YYYYMMDDHHMMSS_XXXXXXXXXXXXXXXXX(…): Unique session ID,
    - **UN** – name of the user logging in to remote server,
    - **Stats** – button for displaying transmitter's statistics.

Caution. The first bracket of the communication text field informs about the status of the wireless connection between the PocketECG transmitter and the remote server. The '[OK]' text string indicates that the connection has been established successfully. Otherwise, an error code will be displayed.

The settings related to the connection with the remote server (Comm. srv, Ftp srv, Path, User name, Password) are read-only. These parameters are configured automatically during the installation and are stored in the 'settings.xml' file. The user should not modify the settings.xml file unless instructed by the PocketECG service technical support.

Caution. The PocketECG transmitter configures the connection with the remote server automatically. If any problems with the configuration occur, please contact your PocketECG distributor or service provider.

9.2 Screen unlocking

The device screen is turned off and locked automatically when not used. In order to turn and unlock the screen follow the instructions:

- Tap the touch button marked with rounded rectangular located next to the screen.
- Press lock icon displayed on the screen as presented below (Fig. 36):

Fig. 36 Unlocking screen

9.3 Patient view

The graphical user interface should remain in the 'patient view' (see Fig. 37) when recording session was successfully initiated and electrode placement was verified by the medical staff. The patient has no access to the settings of the application and other information when the graphical user interface is switched to the 'patient view'. All functions accessible for the patient were designed in a way that ensures patient safety.

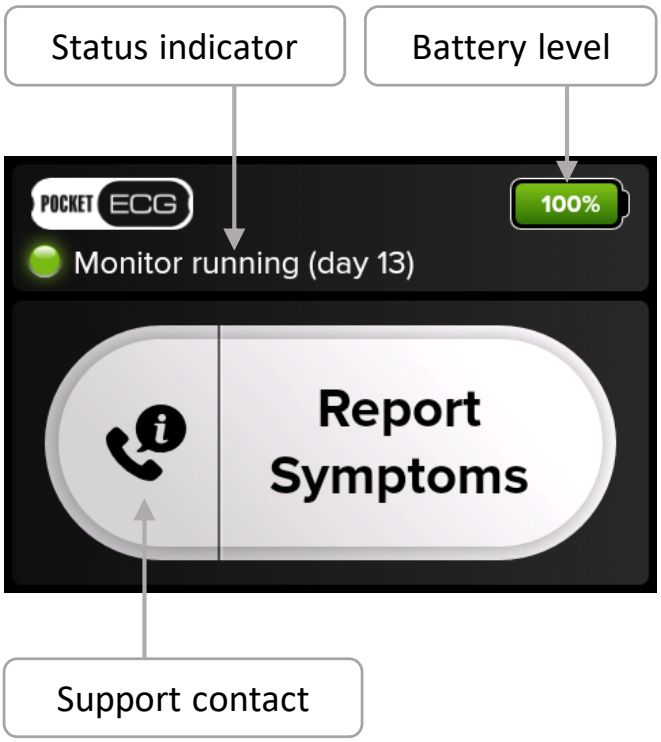


Fig. 37 'Patient view' of the graphical user interface

The PocketECG logo and battery level indicator are displayed on the top of the screen.

Battery level indicator is accompanied by the textual information expressing the battery charge state. Additionally, the color of the battery indicator represents its state of charge in the following way:

Icon color	Battery level/status
Green	between 100 % and 30 %
Yellow	between 30 % and 10 %
Red	below 10 %

Below PocketECG logo device status is presented. Device status contains graphical indicator and text message. The status indicator is blinking when the examination is running. The icon reflects device status in the following way:

- Green – device works properly,
- Yellow – warning message is presented next to the icon informing about action that needs to be taken:

- Insert battery
- Replace battery
- Connect electrodes
- Critically low battery level
- No network (it means time synchronization error)
- No memory card
- No SIM card
- Not enough storage

In the middle of the screen contact button and large 'Report Symptoms' button are displayed. The patient can press contact button to get contact information with support line (see Fig. 38). The logo of service provider is displayed on the top of the screen and phone number is displayed in the middle of the screen. There are 4 data sections displayed on the bottom of the screen placed in square brackets. Every data section contains single letter identifier:

- S - last known signal strength,
- T - time of last successful data transmission or "NA" if there was no successful transmission,
- F - failed data transmission counter - it is reset after successful transmission,
- R - indicates whether device was successfully registered to the network in last attempt - displays "T" or "F" - true/false.

After pressing ‘OK’ button the screen get back to the ‘patient view’.

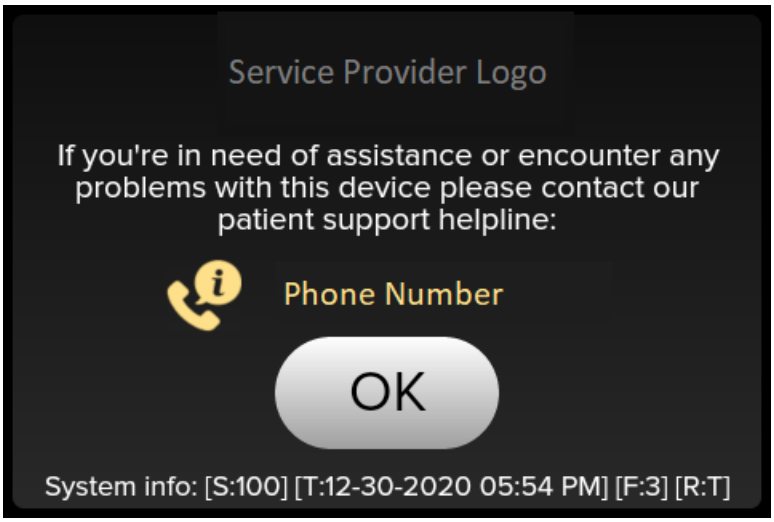


Fig. 38 Support contact view

'Report Symptoms' button can be pressed in order to report symptom. Patient can select the particular symptom from the list (see Fig. 39). Patient has to indicate when symptoms occurred and afterwards symptom must be confirmed (see Fig. 40). If the selected symptom is wrong the patient may modify it after pressing 'Modify' button. Otherwise, the selected symptom is confirmed automatically after 15 seconds.

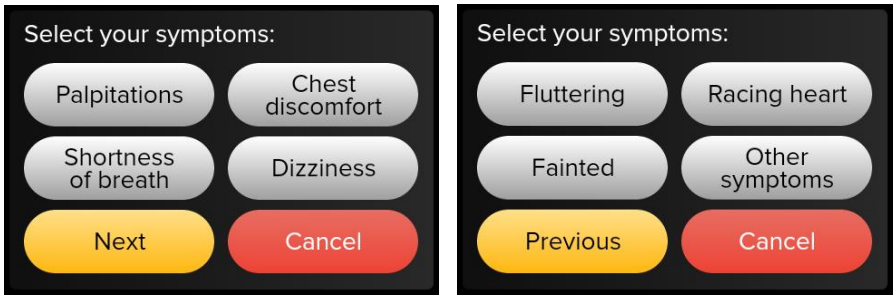


Fig. 39 Symptoms list

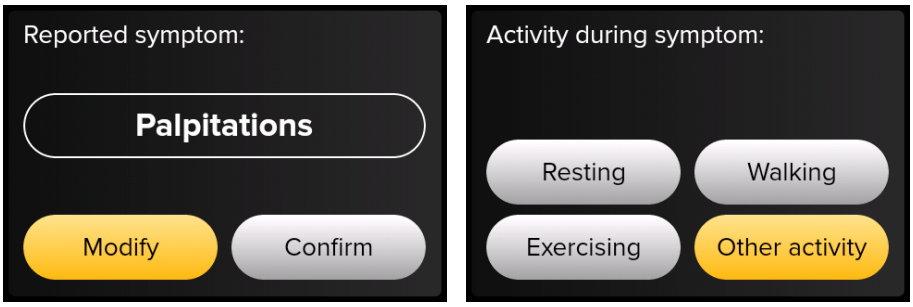


Fig. 40 Activity during symptom and symptoms confirmation screen

In order to switch to the 'supervisor mode' the PocketECG logo must be kept pressed for at least 3 seconds and then the unique code must be typed (see Fig. 41).

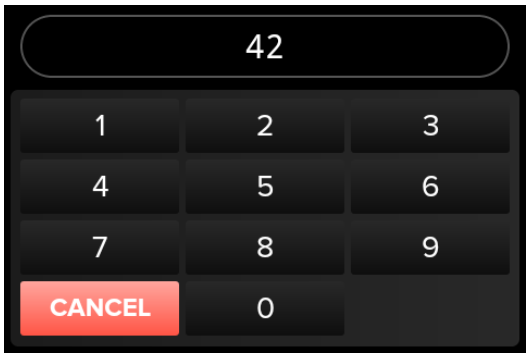


Fig. 41 Terminal for entering the unlocking code

Caution. The unlocking code is: 1 2 3 6.

9.4 Method for calculating pause and heart rate

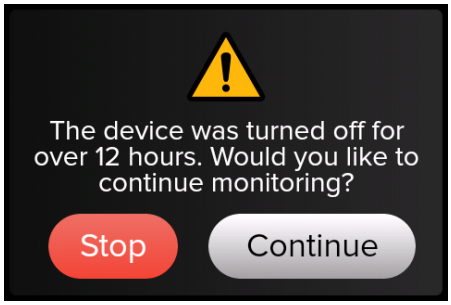
Pause is calculated using (as an input) QRS detection results. If a distance between consecutive QRS complexes exceeds predefined (pause) threshold, then the beat label annotation is marked as pause.

Heart rate is calculated using (as an input) QRS detection results. HR is calculated for minute intervals: If within the analyzed minute, there is a sufficient number of QRS complexes, then minutely HR value is a median value of R-R intervals within that minute.

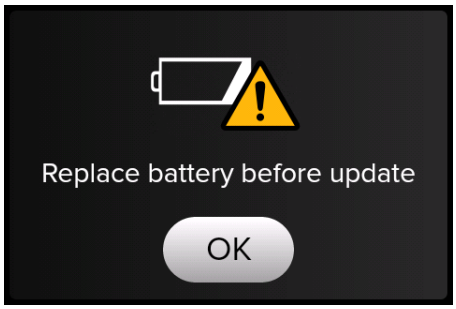
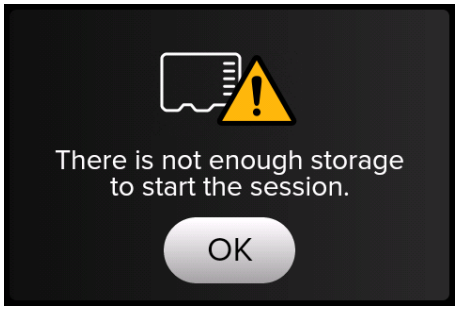
Practically at least 10 R-R pairs are required to calculate the heart rate.

10 NOTIFICATIONS

The PocketECG transmitter generates following notifications requiring user attention:

NOTIFICATIONS	DESCRIPTION & ACTION
	The PocketECG transmitter was turned off for over 12 hours. ↓ Make sure, that you have to stop or continue session, call a service provider.
	Battery state of charge is less than or equal to 10 %. The data are not transmitted to the remote server. ↓ Replace the battery with the fully charged.
	The PocketECG transmitter cannot find the battery. ↓ Insert the battery to the PocketECG transmitter.
	Electrodes contact loss. The ECG signal data are not transmitted to the remote server. ↓ Put on the electrodes to your body.

NOTIFICATIONS	DESCRIPTION & ACTION
	The microSD card is not installed in its compartment and the session cannot be initialized. ↓ Install microSD card or replace damaged one.
	The PocketECG transmitter cannot connect to the mobile phone network - data cannot be transmitted. ↓ Keep the PocketECG transmitter in the area where the mobile network is accessible.
	Battery state of charge is 2 %, the device will shut down. ↓ Replace the battery with the fully charged.
	The SIM card is not installed in its compartment. ↓ Install SIM card.

NOTIFICATIONS	DESCRIPTION & ACTION
	Battery state of charge is less than or equal to 29 %, update will not be initiated. ↓ Replace the battery with the fully charged.
	There is less than 100MB free space on SD card. ↓ Clear memory card data.

11 DATA STRUCTURE AND TRANSMISSION TO THE REMOTE SERVER

The PocketECG transmitter analyzes the ECG signal on a beat-by-beat basis. Each beat is annotated and described by the so-called *beat annotation structure*. The structure contains:

- beat type annotation,
- arrhythmia type annotation,
- ST level elevation/depression in micro volts, for each ECG channel,
- PQRST shape coefficients,
- Noise level (in micro volts),
- ADC interference level (in micro volts).

Depending on the circumstances and signal characteristics, registered data can be sent to a remote server specified in the settings if the 'Send ECG events through Internet' option has been selected. Signal is transmitted automatically based on the data analysis, or periodically or the transmission is triggered by the patient (by pressing the 'Report symptoms' button. The data is transmitted via the mobile telephony network.

12 MAINTENANCE

The PocketECG transmitter type: P4TR-AA-ADS, P4TR-AB-ADS, P4TR-CA-ADS or P4TR-CE-ADS and battery charger type P3CH-AB-UNI, manufactured by Medicalgorithmics S.A. are designed for 5 years continuous use if properly operated. After the devices have been used for 5 years it should be recycled according to the local recycling program or refurbished by the manufacturer. If you have any questions or problems, please contact Medicalgorithmics S.A. service using contact details from section 32 Service.

The capacity of the PocketECG Li-Ion battery decreases with normal use over time. Manufacturer recommends replacing the battery with a new one after 300 charging cycles or after 2 years of using. Recycle or dispose of used batteries according to the local regulations.

The maximal life-time of a particular version of PC Client software is determined either by support period provided by Microsoft for the latest version of MS Windows operating system, that is compatible with technical specification of a particular version of PC Client software, or by support period provided by Microsoft for the Microsoft.NET Framework version used to build a particular version of PC Client software, whichever expires first.

Besides the inspection and preventive maintenance activities described in below sections, patient can safely perform following maintenance activities:

- main battery replacement,
- main battery charging.

12.1 Inspection of the device

Prior to starting a recording session, the user should check the device in accordance with the following instructions:

1. Inspect the patient cable bends, cuts and cracks on the enclosure of transmitter.
2. Inspect the cracks on the enclosure of transmitter, charger and batteries. Verify whether the battery label is not damaged.
3. After placing the fully charged battery into its compartment (transmitter) check whether proper graphical interface is displayed.

Plug the charger into the AC mains, wait 15 seconds and check whether a sound is generated indicating ready to use state.

12.2 Testing the device

At least one a year the user responsible for efficient operation of the device, should check its functional efficiency and verify the correctness of displayed messages and check the condition of the equipment, especially the cables by performing the following operations:

1. Connect ECG simulator (e.g. Netech MiniSim 1000 or similar) to the patient cable of the PocketECG transmitter and adjust typical parameters (heart rate, amplitude) of generated ECG signal.
2. Start a new recording session.
3. Check for normal appearance of the waveforms with appropriate amplitude and without excessive noise. Check if signal annotations are properly displayed. If ECG simulator allows for arrhythmia simulating, you may decide to check whether they are properly detected (it will prove appropriate operation of the device).
4. Try to bend the patient cable simulating typical bending caused by patient's movements and verify whether this causes distortions of the ECG signal.
5. Remove the main battery and check whether device operates without interruptions (device is switched to a backup power automatically).

If the PocketECG transmitter falls or gets hit, a functional efficiency check should be performed by the patient (simply try to start new diagnostic session) or person responsible for efficient operation of the device according to the above instructions. If you suspect that something is wrong with the device contact the manufacturer's service.

Caution. Do not remove the casing of the PocketECG transmitter and do not attempt to repair the device if it does not function properly. This may damage the device.

In order to check the functional efficiency of the charger and batteries follow the instructions given in the section 7.3.1 Main battery charging.

12.3 Cleaning the device

The outer surface of the transmitter, ECG lead wires and transmitter accessories (charger, batteries) can be wiped with a wet soft cloth and soft soap dissolved in water or an alcohol-based disinfecting agent. The device should be cleaned appropriately for intended use and following procedures binding for the institution where the equipment is used.

Caution. Do not let soap or water get inside the PocketECG transmitter neither its accessories. They are not waterproof.

When cleaning or using the equipment, never get the cables and the connectors wet.

Should the PocketECG transmitter or its accessories get accidentally wet, dry it immediately (leave the device with removed battery cover in the warm and dry room for at least 24 hours). After drying turn the device on to check if it functions properly. Should you have doubts whether the device functions properly, contact the manufacturer's service.

12.4 Storing the device

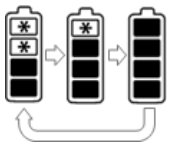
Remove the rechargeable battery from either the transmitter or charger before storing them. This prevents the battery from accidental discharge and reduces the risk of its damage. Observe the environmental storage conditions. See section 31 *Technical parameters* of PocketECG transmitter.

The PocketECG transmitter is equipped with the backup battery that is installed inside the device and cannot be removed. The backup battery discharges slowly when the device is not in use. In order to prevent the backup battery from damage it is recommended to follow the procedure every 3 months of transmitter storage:

1. Put a fully charged main battery into its compartment of the PocketECG transmitter (the charging of the backup battery starts automatically);
2. Wait 1 hour;
3. Verify that the backup battery level is within 70-100 % range (backup battery level can be checked through the 'Supervisor view'->Settings->About->Stats);
4. Turn off the transmitter and remove the main battery.

It is recommended to keep the main batteries charged to about 50 % of its nominal capacity during long period storage. The battery state of charge should be verified every 3 months when the battery is not in use. In order to verify the battery state of charge follow the instructions:

1. Put the battery into its compartment of the PocketECG charger.
2. If the battery state of charge is below 50 % level wait until light indicators behave as presented below.



(orange light)

First (bottom) and second light indicators are turned on; third-fourth indicators are being turned on and off sequentially.

3. If the battery is already charged to more than 50 % remove it from the charger. The battery may be stored and charging is not necessary.

Although the main batteries may be stored in the temperature and humidity conditions defined in section 31 *Technical parameters* of PocketECG transmitter, it is recommended to keep the temperature within -20 °C to +25 °C (-4 °F to 77 °F) range during long period storage (> 3 months).

12.5 Software updates

WARNING. DO NOT REMOVE THE BATTERY DURING THE INSTALLATION PROCESS.

The software operating PocketECG transmitter should not be modified or updated by anyone except the manufacturer or technical staff responsible for its servicing. There are two methods for updating the software of the PocketECG transmitter:

- The installer of new software version must be stored on the microSD card. After powering the device, the installer is automatically launched. It removes previous version of the software and installs the new one.
- The PocketECG transmitter must be connected to the computer using USB port available after casing removal. When the connection is successfully established, the software installer must be executed on the PC. The installer updates the software version in the PocketECG internal memory.

13 SAFETY RULES FOR USING THE POCKETECG TRANSMITTER

1. One device is intended to monitor only one patient at a time.
2. It is recommended for the device to work in room temperature.
3. Air in rooms where the device works should be free of caustic gasses, steam and dust. Although the device is powered from 3.7V and does not allow for power intake larger than 3 A it is not guaranteed that it cannot produce spark which could initiate explosion.
4. The patient should check with the appropriate airline carrier to confirm that PocketECG transmitter which is similar to the regular mobile phone may be used on the airplane during take-off, flight and landing.
5. Due caution should be exercised when handling the device. It is necessary to avoid excessive stretching and sudden jerking of cables connecting the PocketECG transmitter with electrodes placed on patient's body.
6. Parts that wear out and are intended for single use should be used in accordance with binding regulations and cannot be re-used. This especially concerns the electrodes placed on patient's body, which should be replaced with new ones after no longer than 24 hours if the diagnostic session is to be continued. Users (physicians, patients, etc) are trained in this respect and are advised to get familiar with this instruction.
7. The ECG cable is permanently attached to the PocketECG transmitter. In case of damage, do not repair or replace it, because it may negatively influence the electromagnetic compatibility of the device. Damaged ECG cable can be replaced only by the manufacturer's service.
8. Manufacturer is not liable for damage to the PocketECG transmitter caused by improper operation of the device or neglecting guidelines included in the Instructions for Use.
9. Manufacturer accepts liability for safe operation of the PocketECG transmitter, only when the device is used as intended and in accordance with the Instructions for Use.
10. The PocketECG QRS detection algorithm adapts to noise and disturbances level obscuring the signal, i.e. in case of higher noise level, the QRS detection procedure becomes less sensitive. The minimum QRS detection level is set to 0.16 mV.

WARNING. THE RESULTS OF AUTOMATED ECG SIGNAL ANALYSIS MAY BE INACCURATE IF AMPLITUDE OF THE QRS COMPLEXES IS LOWER THAN 0.16 mV.

11. The capacity of the PocketECG Li-Ion battery decreases with normal use over time. Manufacturer recommends to replace the battery with a new one after 300 charging cycles or after 2 years of using. Recycle or dispose of used batteries according to the local regulations.
12. The conductive parts of ECG cables are intended to be connected only to the ECG electrodes. They should not be connected to any conductive parts of any objects including earth.
13. Neither PocketECG transmitter, nor its accessories, should be serviced while in use with a patient, excluding main battery replacement.

13.1 Electromagnetic compatibility (EMC)

The PocketECG transmitter needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Instructions for Use.

WARNING. THE POCKETECG TRANSMITTER IS MR UNSAFE, AND SHOULD NOT BE USED IN ANY MAGNETIC RESONANCE ENVIRONMENT.

WARNING. USE OF ACCESSORIES OTHER THAN THOSE SPECIFIED IN SECTION 0, WITH THE EXCEPTION OF THE ACCESSORIES SOLD BY THE MANUFACTURER OF THE POCKETECG TRANSMITTER AS REPLACEMENT PARTS FOR INTERNAL COMPONENTS, MAY RESULT IN INCREASED EMISSION OR DECREASED IMMUNITY OF THE POCKETECG TRANSMITTER.

Caution. Sources of electromagnetic radiation like:

- portable and mobile radio frequency (RF) communications equipment (e.g. cellular phones, mobile radio),
- radio frequency identification systems (RFID),
- devices using one or more of the following wireless technologies: WiFi (IEEE 802.11), Bluetooth (IEEE 802.15), ZigBee (IEEE 802.15.4), WiMax (IEEE 802.16), Ant, etc.,
- base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast,
- metal detectors

can affect the PocketECG transmitter.

Caution. Sources of strong electromagnetic radiation such as radio transmitters, wireless personal transmitters working in the 80-2500 MHz frequency band may disturb the ECG signal and disturb the automated ECG signal analysis.

It is recommended to keep the PocketECG transmitter as far as possible from all equipment combining RF transmitters. Try to reorient or/and relocate PocketECG transmitter when the ECG signal displayed on the screen of is partially masked by disturbing signal despite the ECG electrodes are properly placed on the patient skin.

In case of further problems with the equipment operation, the medical service provider should be contacted for support.

The PocketECG IV device and any of its components should not be used for patient monitoring during any diagnostic tests or medical treatment performed using:

- computed tomography (CT) systems,
- positron emission technology (PET),
- diathermy, lithotripsy, electrocautery systems.

If the patient is going to be examined/treated using any of the above diagnostic systems while being monitored with the PocketECG IV device, it is recommended to follow the instructions:

1. Contact your medical service provider or medical professional supervising your recording session to inform that you are going to remove the PocketECG transmitter for some time due to the medical examination/treatment.
2. Disconnect the ECG lead wires of the PocketECG transmitter from the electrodes placed on your body.
3. Leave the PocketECG transmitter in a place where it will not be exposed to any disturbing radiation generated by the medical system that is going to be used. Do not stop the recording session.
4. When the examination/treatment is finished, replace the electrodes if necessary and connect the lead wires of the PocketECG transmitter to the electrodes.

Guidance and manufacturer's declaration- electromagnetic immunity		
The PocketECG transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the PocketECG transmitter should assure that it is used in such emission environment.		
Equipment classification: CISPR 11, Group 1, Class B		
Phenomenon	**Basic EMC standard or test method**	**Immunity test levels**
Electrostatic discharge	61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz
Fast Transients [a]	61000-4-4	± 2 kV, 100 kHz repetitions frequency
Surge Immunity Test [a]	61000-4-5	Line-to-line: ± 0.5 kV, ± 1 kV
RF Continuous Conducted [a]	61000-4-6	3 V RMS, in freq. range 0.15 MHz to 80 MHz 6 V RMS, in ISM and amateur radio bands 0.15 MHz to 80 MHz 80 % AM at 1 kHz
Voltage Dips and Interruptions [a]	61000-4-11	Dips: 0 % U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % U_T; 1 cycle at 0° 70 % U_T 25 and 30 cycles at 0° Interruptions: 0% U_T; 250 (50 Hz), 300 (60 Hz) cycles
Power-frequency magnetic field	61000-4-8	30 A/m 50 Hz and 60 Hz
[a] applicable only to the PocketECG battery charger (P3CH-AB-UNI)		

13.2 Output power

In order to resolve and prevent interference issues, below table presents the operating frequencies of the PocketECG transmitter and the associated conducted output power.

Frequency range (MHz)	Output Watts
779.5 – 784.5	0.23
779.5 – 784.5	0.18
782.0 – 782.0	0.16
782.0 – 782.0	0.12
1712.5 – 1752.5	0.22
1712.5 – 1752.5	0.18
1720.0 – 1745.0	0.16
1720.0 – 1745.0	0.14

B. POCKETECG PC CLIENT SOFTWARE

15 EQUIPMENT REQUIREMENTS

The PocketECG PC Client software should be used with personal computers or tablets with Microsoft Windows 8, 8.1 or 10 OS installed. The PC/tablet should meet the following requirements:

- At least 2 GB of RAM (4 GB recommended),
- 1 GHz CPU (2 GHz recommended),
- Free space on HDD – at least 2 GB (4 GB recommended),
- Internet connection – at least 512 kbps (downlink),
- Screen resolution – at least 1024 x 768.

16 INSTALLATION

In order to install the PocketECG PC Client software, the PC user is required to have administrative rights. The installation wizard will guide the user through the entire installation process which consists of a few steps. It is recommended to close all running applications before starting the installation. The PC Client software is normally installed in the Program Files folder; however, the user may select alternative directory. After user selects the destination folder, copying of the PocketECG files starts. During this step the user will be requested to accept installation of the following software packages that are distributed along with the PocketECG program: VC++ 2008 SP1 redistributable, Windows Mobile Device Center, Microsoft J# Redistributable and Adobe Reader. These packages are required for proper PocketECG Client operation.

During the installation of the PocketECG PC Client, a Windows registry entry are created which specify the server aliases along with their specific configuration parameters. Each alias consists of its own name and server parameters which are needed to establish a proper connection. One of them is set as default and is used for first login action. Each installer is dedicated for one of the servers and normally there should be no need to change the default alias. It is impossible to create a new server alias using the PC Client software as all of them are included in the installer. If there is such need, it is necessary to contact service provider or a distributor of the PocketECG software.

17 DISTRIBUTION

The PC Client application is distributed to users using either a traditional method (DVD-R / CD-R), or electronically. The electronic distribution process is through password protected access to an SSL FTP server to obtain the installer.

18 OVERVIEW

The PC Client application allows for managing the recording sessions and reviewing the ECG data that was sent to the remote server by the patient monitors. The PC Client user is able to manage ongoing sessions, review and modify the results of the ECG analysis and generate reports which summarize the detection results. After selecting a recording session in the 'Navigator' window, the user may start reviewing the ECG and the labeled arrhythmias. The ECG data, analysis results and application functions can be accessed through five viewing modes:

- 'Navigator' – main session's manager window. Allows for selecting a particular session, which can be accessed through the following viewing modes:
  - 'Event View'– contains a list of ECG events/arrhythmias detected by the system.
  - 'Full Disclosure' – allows for viewing the ECG waveform recorded during the monitoring.
  - 'Trends' – contains diagrams illustrating variations of the averaged heart rate and other ECG parameters.
  - 'Impressions and Findings' – notepad for entering comments which will be included in the generated reports.
  - 'Reports'– contains a list of reports which summarize the analysis results.
- 'Garbage' – folder containing deleted recording sessions.
- 'Archive' – folder containing archived recording sessions.
- 'Web Navigator' – opens web browser and shows recordings connected with current workstation.

18.1 Communication with remote server

The PC Client application utilizes regular internet connection in order to perform its functions. The application monitors the state of the connection with the remote server. If connection cannot be established or is disturbed the 'No internet' warning is displayed in the upper left corner of the screen. The internet connection is required only for transferring ECG data between the PC Client application and the remote server. Only those functions of the application that require internet communication are disabled when the problems with internet connection occurs. A user can still review the already downloaded ECG data, review trends, generate reports, etc.

If 'No internet' warning is displayed in the upper left part of the screen, the user should verify the state of internet connection. In order to do this, a user should run an internet browser and check whether it is possible to connect with any server and visit popular websites. Following below instructions can be helpful in solving the problem with the remote server communication.

- **If the internet browser responds properly:**
  - Check configuration of the firewall application installed on the PC. The firewall application should allow PocketECG PC Client to make outgoing connections. If there is no rule already created for the PocketECG PC Client software, the solution may be to create a rule allowing PocketECG PC Client software to make outgoing connections.

  - The PC Client stores information related to the connection quality to remote server in log files. The log files with *.csv extension are saved in LocalDataRoot\Log directory. In order to verify the quality of communication with remote server, open the log file using any spreadsheet application or simple text editor.

The sample of the log file is presented below.

Ping test at:	2011/Oct/19 10:15:20 AM				
Ping test duration:	60 s				
Alias	Successful	Failed	Avg successful time (ms)	Pings above 200 ms (%)	Quality (%)
ma1x3	37	1	71.294	0.0	97.4
ma1x1516	37	1	71.101	0.0	97.4
intermountain	37	1	69.668	0.0	97.4
google	27	1	35.822	0.0	96.4

The last column of the table presents quality of communication with the remote server. If the quality is low (under 50 %) for one or more of the servers, contact the PocketECG service provider or distributor for assistance.

- **If the internet browser cannot connect to any web page:**
    - Check whether all cables required for internet access are properly plugged into the PC and internet outlet. If the PC uses wireless access to the internet, verify that the wireless functions of the PC are enabled.
    - If the PC is a member of a local network, ensure that the local network operates correctly and is connected to the internet (check all devices like routers, access points, etc.).
    - Use operating system utilities in order to diagnose the problem:
        - press the right mouse button over the network icon in the notification area, and then select 'Diagnose and repair'. Follow the instruction given by the operating system;
        - open the Network Connections menu (Start→Control Panel→Network and Internet→Network and Sharing Center→Manage network connections). Follow the instructions given by the operating system.

If none of the abovementioned solutions help in establishing the reliable communication with remote server, contact the PocketECG provider or distributor for assistance.

19 'NAVIGATOR'

19.1 Introduction

The 'Navigator' window of the PC Client application consists of a table listing recording sessions stored on the remote server and a toolbar with three menus (see Fig. 42).

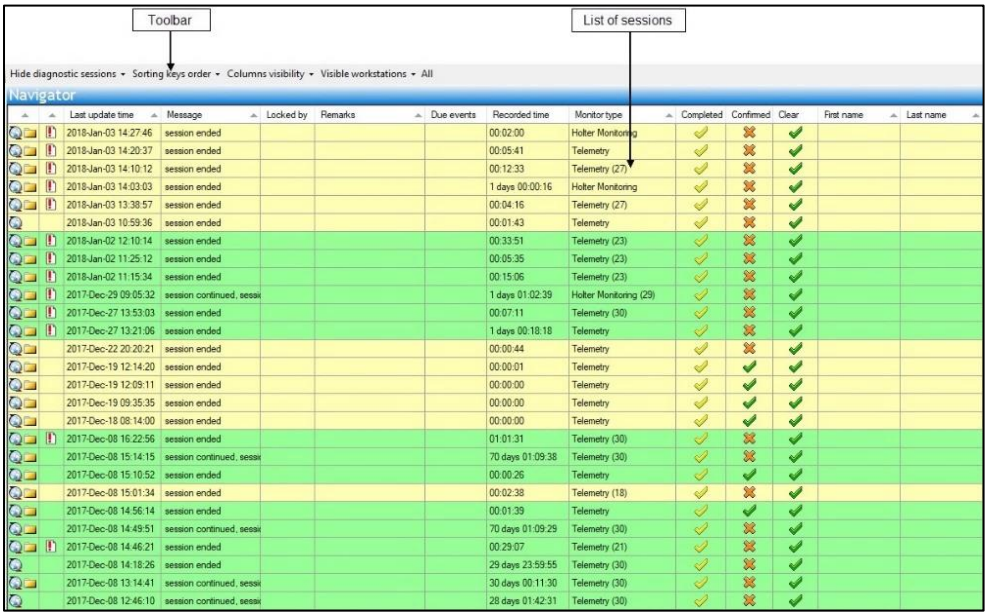


Fig. 42 'Navigator' view

Every row of the table corresponds to a single recording session. Information describing the recording sessions are presented in subsequent columns. The table has columns which provide the following information:

1) **'Location status'** – informs the user about the location of the session data. There are five icons representing five available locations:

   - session data is located on a remote server
   - session data is located on a local hard disk
   - session data is being downloaded
   - session data is located on the local hard drive and is not up to date - new data is ready to be downloaded from the server.

2) **'Cumulative report status'** – informs the user about the status of cumulative report.

    Publication date of cumulative report is set and is overdue.

3) **'Last update time'** indicates the time of the most recent transmission from the PDA to the remote server.

4) **'Message'** – displays information related to the ECG data or status of the recording session.

   - **'Important/critical events'** – events defined as important/critical are contained in files delivered to the server from the PDA monitor;
   - **'electrode problem'** – problem with electrode has been detected in session data;
   - **'matching problem'** – matching session to enrollment failed;
   - **'notification required'** – session contains events that fulfil notification criteria but the notification has not been performed;
   - **'no-ekg'** – the EECG signal has not been delivered to the server for more than 2 hours;
   - **'continuation pending'** – continuation of session is pending;
   - **'session continued'** – session was continued;
   - **'session ended'** – session is finished;
   - **'report completed'** – session is finished and report has been completed and finalized.

5) **'Locked by'** – information about user locking the session for editing.

6) **'Remarks'** – place where users can write their own remarks e.g. expected recording duration.

7) **'Due events'** – time since oldest unprocessed important/critical event.

8) **'Recorded time'** – session duration.

9) **'Monitor type'** – type of session.

10) Columns with icons ✔ ('YES') and ✖ ('NO'):
    - **'Completed'** – informs whether the session has been already completed.
    - **'Confirmed'** – informs whether all events in a session have been confirmed.
    - **'Clear'** – informs whether a session is free of questionable events.
11) **'First name'** – patient's first name,
12) **'Last name'** – patient's last name.
13) **'Workstations'** – up to 3 workstations linked with session.
14) **'Ordering physician'** – ordering physician's name.
15) **'Interpreting physician'** – interpreting physician's name.
16) **'Start time'** – date and time when the session has started.
17) **'Session ID'** – record ID, comprising of two segments separated by underscore. The first segment consists of the session starting time; the second segment contains the unique ID of the PocketECG transmitter used for monitoring.

The rows of the table are highlighted with one of three colours. The colours indicate a role of the currently logged-in user (i.e. supervisor, technician, etc.). The colours denote the following roles:

Green	means that the current workstation is assigned to the session,
White	means that all specialists and at least one workstation have been assigned to the session, and the current workstation is not assigned to the session,
Yellow	means that at least one of the specialists for the session is missing or no workstation is assigned and the current workstation is not assigned to the session,
Red	means that there are important/critical events for the session that are unprocessed for longer than 6 hours

19.2 'Navigator' toolbar

Recording sessions presented in the 'Navigator' view may be filtered and/or sorted. The user can hide/show particular columns of the navigator table. All the above-mentioned functions are available through three menus located in the application toolbar in the left upper part of the screen (see Fig. 43):

- '**Hide diagnostic sessions**' - allows for selecting sessions that should not be presented in the 'Navigator',
- '**Sorting keys order**' - used for selecting the sorting order of the sessions presented in the 'Navigator',
- '**Columns visibility**' - allows for selecting the 'Navigator' columns which are going to be hidden/shown,
- '**Visible workstations**' - allows for selecting visible workstations.

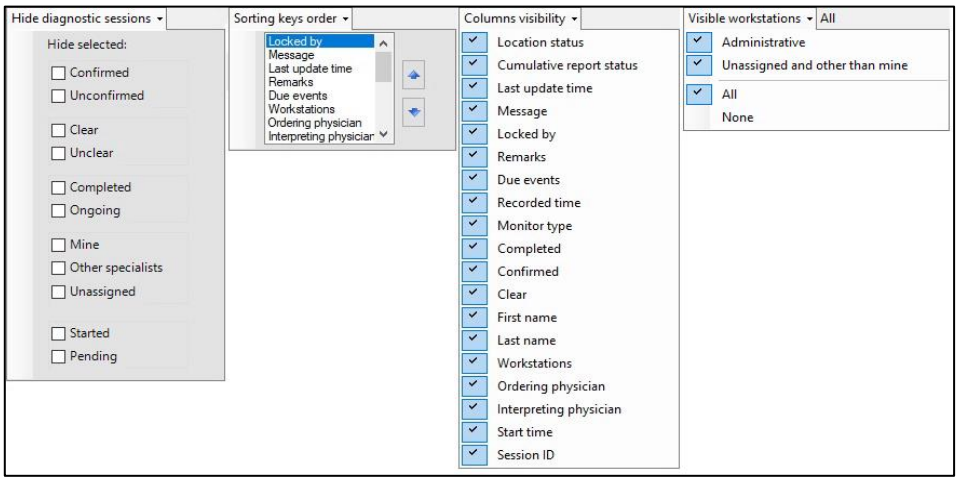


Fig. 43 Hide diagnostic sessions', 'Sorting key orders', 'Columns visibility', 'Visible workstations' menus

The '**Hide diagnostic sessions**' menu contains criteria for hiding the sessions in the 'Navigator' view. All of the sessions meeting particular criterion are not displayed on the list. User may select one or more of the following criteria:

- **'Confirmed',**
- **'Unconfirmed',**
- **'Clear'**,
- **'Unclear'**,
- **'Completed'**,
- **'Ongoing'**,
- **'Mine',**
- **'Other specialists',**
- **'Unassigned',**
- **'Started',**

- **'Pending'.**

'**Sorting keys order**' menu allows for changing the order of the recording sessions that are sorted in the 'Navigator'. The sessions are initially sorted based on the criterion placed on the top in the 'sorting keys order' menu list. Then, all sessions meeting the first criterion are sorted based on the second criterion, etc. For example: if the first sorting criterion is 'Last name' and the second is 'Start time', then all sessions for patients with the same last name, e.g. *Smith,* will be sorted by their start time. Instead of using 'Sorting keys order' menu, the first sorting criterion may be selected by clicking on the column heading. The result is equivalent to moving the key to the top of the list in the 'Sorting keys order' menu.

'**Columns visibility**' menu allows for selecting the information that is going to be presented in the columns of the 'Navigator' table.

'**Visible workstations**' menu allows to specify to which workstations presented data should be limited to.

19.3 'Adding and editing patient and specialist' data

19.3.1 'Patients'

The window 'Patients' (see Fig. 44) allows for 'adding and editing patients' personal information. It can be opened by selecting 'Add/Edit patients' option from the 'Tools' Menu. Selecting option 'Assign/Edit patients' from the context menu in the 'Navigator' view, accessible when right-clicking on the recordings list, opens a window which allows for assigning a patient to the highlighted recording session.

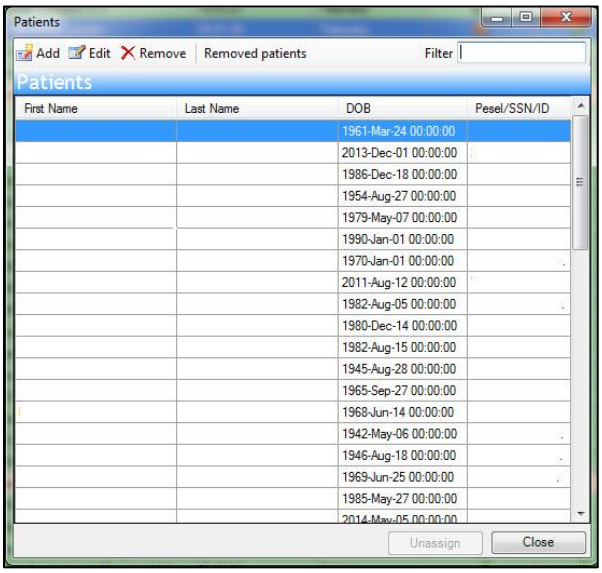


Fig. 44 'Patients' window in 'Active patients' mode

Initially, the 'Patients' window shows a list of active patients. List of deleted patients can be accessed through 'Removed patients' option. Options available in the 'Patients' window include:

- **'Add'** – shows a form used for adding a new patient to the database and filling patient personal data, i.e. Last name, First name, Sex (male/female), Date of birth ID/SSN/PESEL No., phone, e-mail and address. Additional (descriptive) information regarding the patient may be added/edited in the 'Auxiliary patient info' section,
- **'Edit'** – activates a form for editing personal data of a selected patient,
- **'Remove'** – removes the selected patient from the list of active patients. The patient's data can be viewed after switching to the 'Removed patients' mode (see Fig. 45),
- **'Removed patients'** – switches to the list of removed patients ('Remove patients' mode).

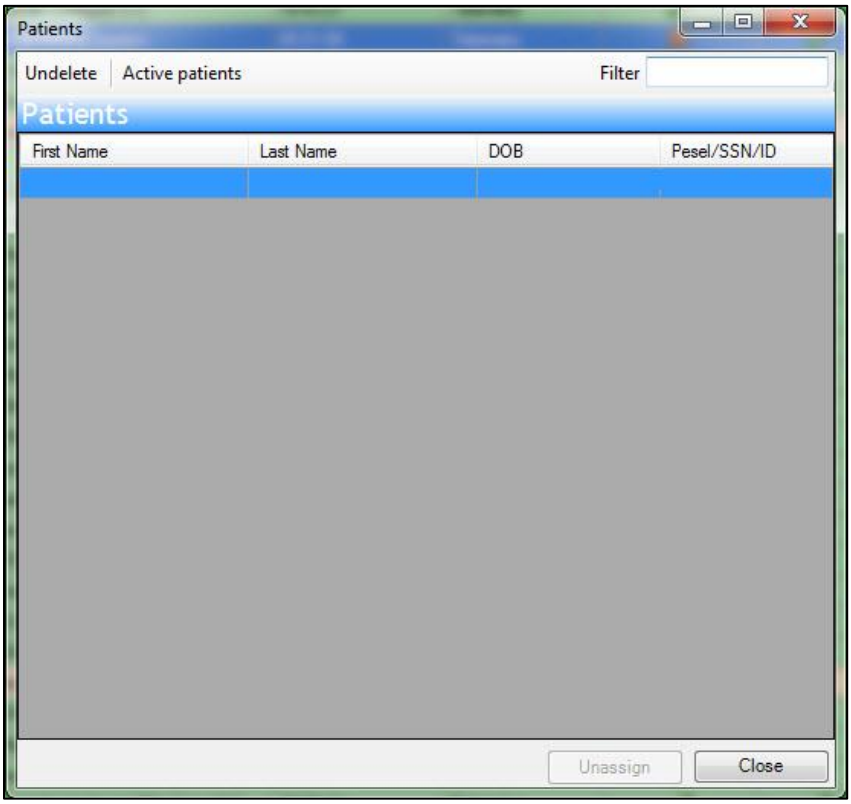


Fig. 45 'Patients' window in 'Removed patients' mode

The 'Removed patients' window (see Fig. 45) contains the list of removed patients and two options:

- **'Undelete'** – restores the selected patient to the 'Active patients' list,
- **'Active patients'** – switches the view to the 'Active patients' mode.

If a patient is already assigned to a session, right-clicking on the session and selecting 'Edit / View patient information' opens a window where patient information can be viewed or edited (see Fig. 46). The same form is opened when selecting the 'Edit' in the 'Active patients' view.

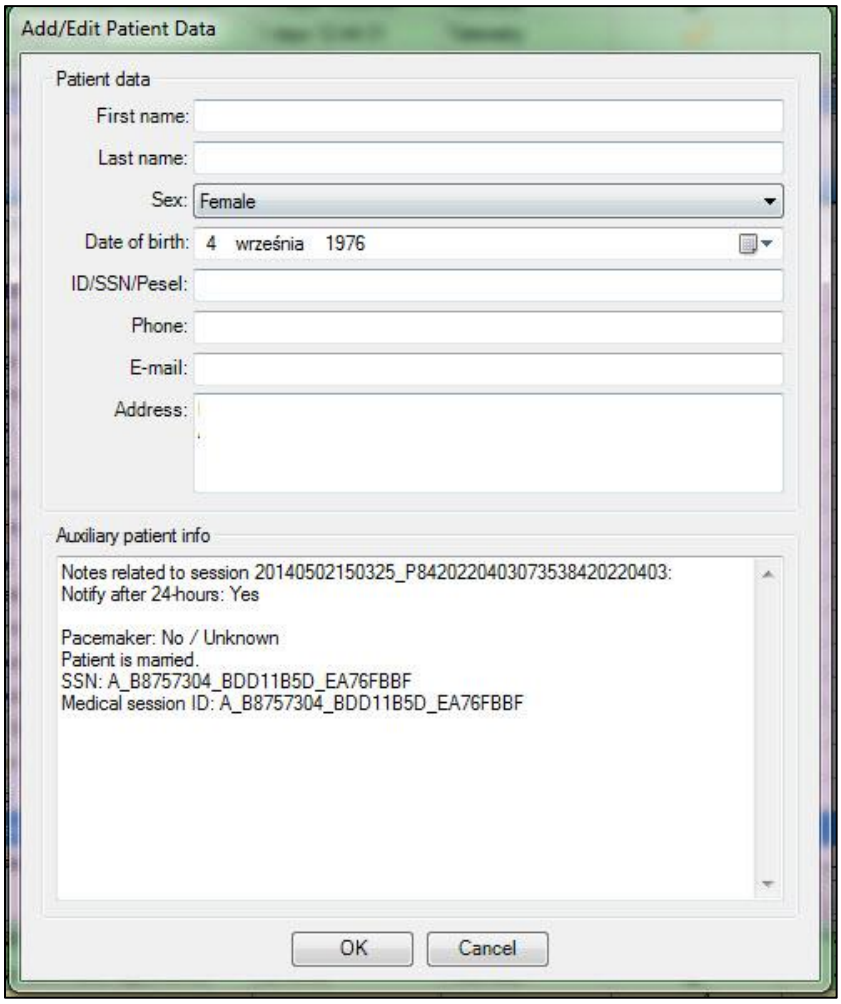


Fig. 46 'Add/Edit Patient data' window contains patient's personal information

19.3.2 'Specialists'

The 'Specialists' window is used for adding and editing specialists' personal data. It can be opened by selecting 'Add/Edit specialists' option from the 'Tools' Menu  or by selecting 'Assign/Edit specialists' from the context menu. The 'Specialists' window has been designed in a similar way to the 'Patients' window (see Fig. 46 and Fig. 47).

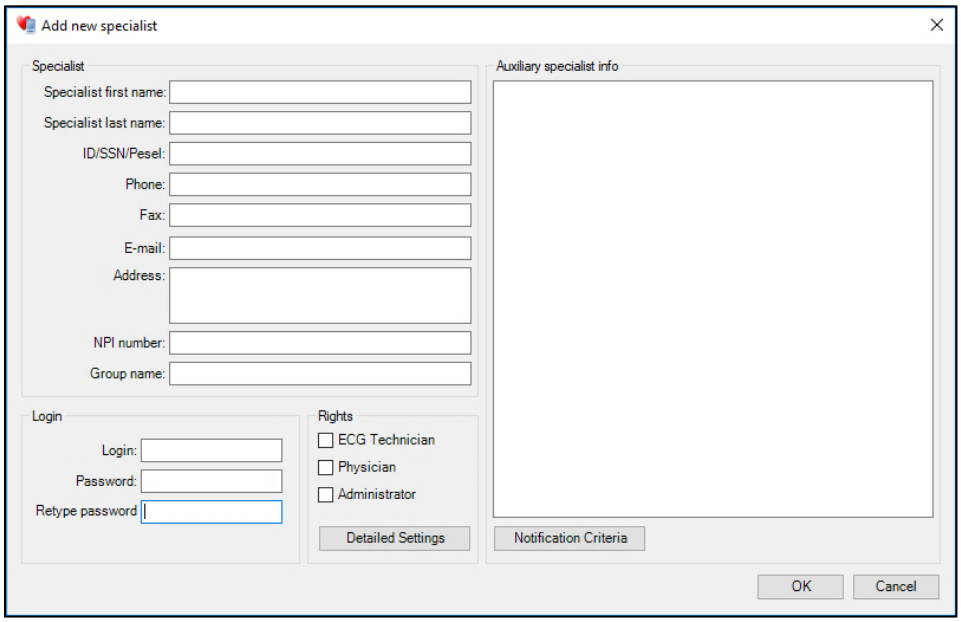


Fig. 47 'Specialist' window for adding/editing specialists' data

A single specialist may be assigned to multiple roles. The available roles in the system are:

- 'ECG Technician',
- 'Physician',
- 'Administrator'.

The 'Detailed Settings' button allows for setting up specific rights of the edited specialist. Specialists may have the following rights:

- **'ECG Technician'**: show popup dialog on new session, ability to modify technician's diagnostic findings, ability to modify physician interpretation,
- **'Physician'**: physician type ('Ordering' or 'Interpreting'), show annotations in Web 'Full Disclosure', sign reports for other physician in the group, enroll sessions for other physician in the group, reports options, notifications,
- **'Administrator'**: ability to assign sessions, ability to modify specialist data, ability to modify patient data, full administrator access (show administrator options in 'Tools' menu, ability to view all sessions in 'Navigator').

The ‘Notification Criteria’ button opens the ‘Edit notification criteria’ window which contains a table listing specialist's notification criteria (see Fig. 48).

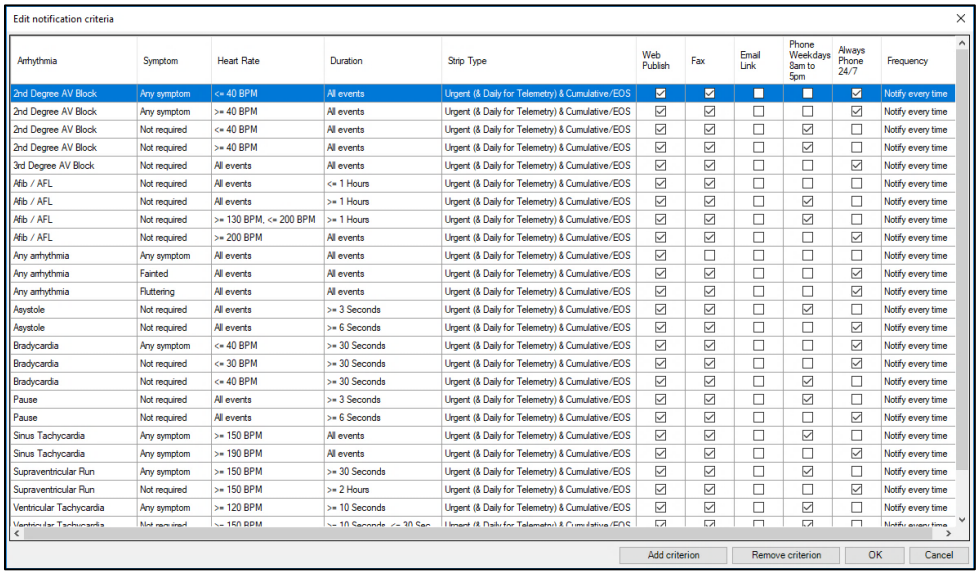


Fig. 48 ‘Edit notification criteria’ window

Every row of the table corresponds to a single notification criterion. Information describing the notification criteria are presented in subsequent columns. The table has columns which provide the following information:

1. ‘Arrhythmia’ – informs about the arrhythmia of events that fulfilled criterion.
2. ‘Symptom’:
    a) ‘Any symptom’ – informs that any symptom is required,
    b) ‘Not required’ – informs that symptom is not required,
    c) ‘Fainted, Fatigue’ – informs that symptom is required and have to be one of specified.
3. ‘Heart rate’ – informs about the heart rate of events that fulfilled criterion.
4. ‘Duration’ – informs about the duration of events that fulfilled criterion.
5. ‘Strip Type’ – field specifying what type of events (urgent/normal events) should be included in daily/cumulative reports.
6. ‘Web publish’ - field should be checked for all active criteria. Informs, that report should be published for event.
7. ‘Fax’ – if checked, fax will be automatically sent during report publication.
8. ‘Email Link’ – if checked, email will be automatically sent during report publication.

9. ‘Phone Weekdays 8am to 8pm’ – if checked, ordering physician should be informed about event during office hours by phone.
10. ‘Always Phone 24/7’ – if checked, ordering physician should be informed about event as soon as possible.
11. ‘Frequency’ – field, specifying if specialist should be notified every time or on the first occurrence of event with given criteria.

19.3.3 ‘Workstations’

The ‘Workstations’ window is used for adding, editing or changing workstations. It can be opened by selecting ‘Add/Edit/Change workstation’ option from the ‘Tools’ Menu  or by selecting ‘Assign/Edit specialists’ from the context menu. The ‘Workstations’ window has been designed in a similar way to the ‘Patients’ and ‘Specialists’ windows (see Fig. 47).

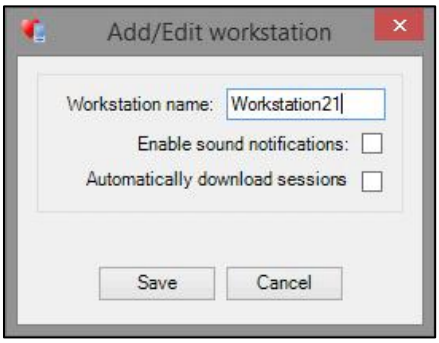


Fig. 49 ‘Add/Edit workstation’

For each workstation it is possible to set its name and to choose whether to automatically download sessions or enable sound notification (see Fig. 49).

To change current workstation just select one from ‘Workstations’ window.

19.4 'Assigning patients / specialists' to recording session

Every time a new recording session is detected by the software, the PC Client pops up a window for assigning patients and specialists (see Fig. 50). The patients or specialists can be assigned to the new session through 'Select' buttons.

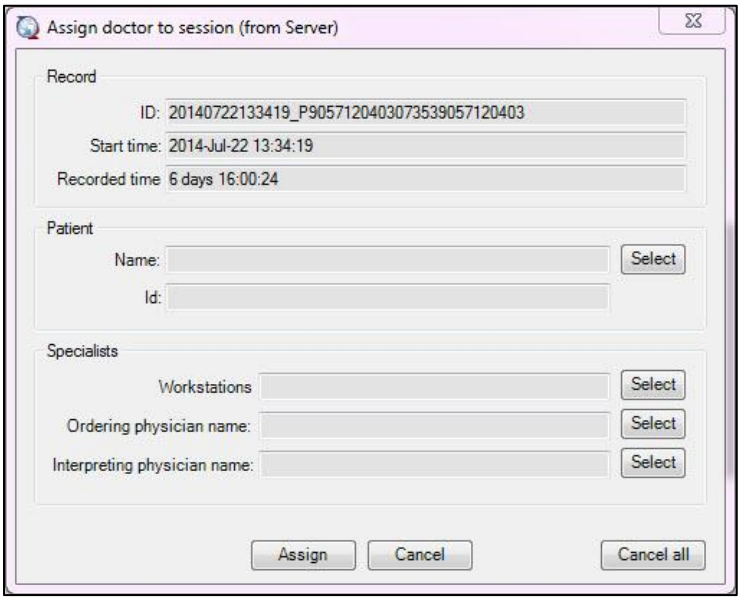


Fig. 50 Window for assigning patients and specialists

Patients and physicians may also be assigned to recording sessions using 'Navigator' of the PC Client application, by double-clicking on the table cells with patient's or specialist's name. Alternatively, it is possible to assign patients and specialists by right-clicking on the list and selecting the appropriate option from the context menu, i.e. 'Assign / Edit patient' or 'Assign / Edit specialist'.

19.5 Downloading and removing recording session data

Session data is downloaded automatically under the following conditions:

- the current workstation is assigned to the session
- the current workstation has set 'automatically download sessions' option
- new data is available on the server
- the session has not yet been completed.

It is possible at any time to download the selected recording manually by right-clicking on the session and selecting the 'Download' option from the context menu. The icon appears in the 'Location status' column of the 'Navigator' when the session data is successfully downloaded to the local hard drive.

The recording session data may be removed either from the local hard disk drive (HDD) or marked as removed – i.e. moved to the 'Garbage' folder on the server and removed from all users' HDDs. In order to remove the session data, right-click on the chosen session and select one of the following options:

- **'Remove' → 'from local HDD'** – removes recording session data from the local disk (available only for already downloaded sessions),
- **'Remove' → 'from server and all users' HDDs'** –marks the session as removed on the server and removes it from local disks of all users that have downloaded the session,
- **'Remove' → 'from PDA through USB'**.

Normally, in order to finish a recording session, an appropriate option should be selected through the transmitter. It is possible, however, to set the session status to 'finished' through the PC client software – by right-clicking on the selected session and selecting the 'Finish' option from the context menu.

19.6 Remote communication with the transmitter

After right-clicking on a session shown on the 'Navigator' list, two main options related to the transmitters are available: 'PDA Settings' and 'View PDA log'. After selecting the 'PDA Settings' option, all arrhythmia settings of the PocketECG transmitter are displayed and are available for modification.

In order to display a window containing information related to the state of patient's equipment (see Fig. 51), the 'View PDA log' option should be selected.

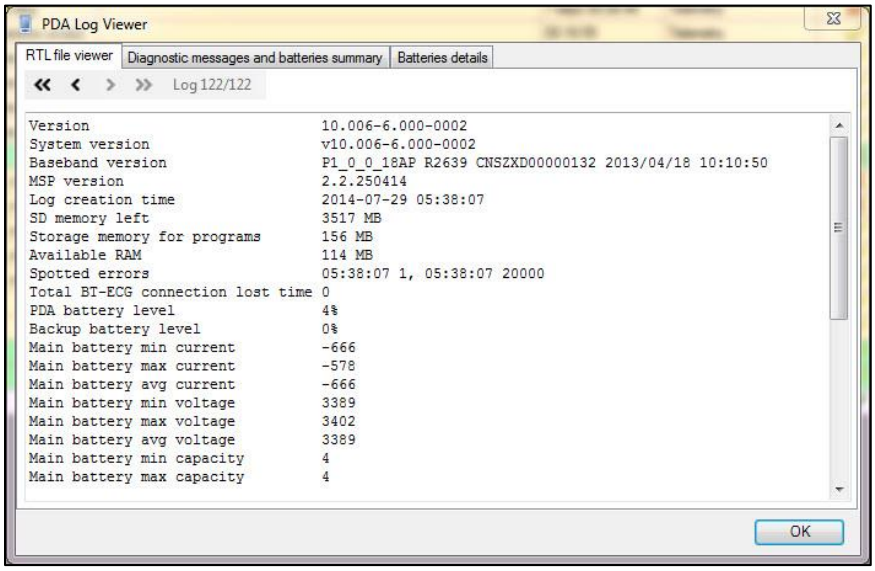


Fig. 51 'Transmitter Log Viewer' window displaying session logs

The ‘Transmitter Log Viewer’ provides the following information:

- Components’ versions,
- Log creation time,
- Device battery info,
- Backup battery info
- SD memory left,
- Storage memory for programs,
- Available RAM,
- Spotted communication errors.

The logs are generated by the transmitter's software every hour and transmitted to the PocketECG PC Client. In order to navigate through all generated logs, the arrows displayed on the top of the window should be used. The single arrows (< and >) allow for switching between subsequent logs. The double arrows (<< and >>) jump to logs generated every 24 h.

20 'EVENT VIEW'

20.1 Introduction

In order to get access to the ECG data presented in the 'Event View', 'Full Disclosure', 'Trends' or 'Reports', the ECG data corresponding to the selected session must be earlier downloaded to the local hard drive. The results of the ECG signals analysis performed by the PocketECG transmitter are presented in the 'Event View' of the PC Client application (see Fig. 52).

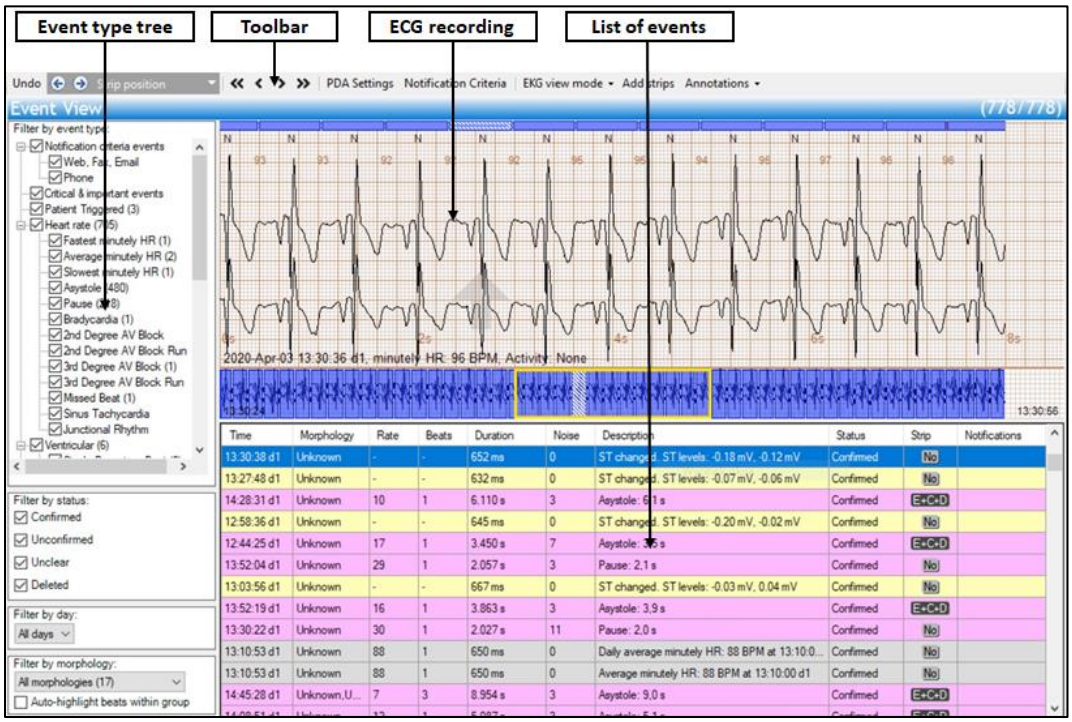


Fig. 52 'Event view' window

All detected events are presented in a table (every row corresponds to a single event). After selecting a particular event from the table, the relevant ECG strip is displayed in the upper sub-window. The table presented in the 'Event View' has columns providing the following information which describe all events:

- '**Time**' – day number and the exact time of event occurrence,
- '**Morphology**' – index of recognized morphology class – recognition is performed after clicking on the head of the column for sorting;
- '**Rate**' – heart rate during the event;
- '**Beats**' – number of successive heartbeats in a given event;
- '**Noise**' – noise level in microvolts,

- '**Duration'** – duration of the event;
- '**Description'** – event's description;
- '**Status'** – event status. There are four different options:
  - **'Confirmed'**,
  - **'Unconfirmed'**,
  - **'Deleted'**,
  - **'Unclear'**;
- **'Strip'** – this field is selected when an ECG strip corresponding to the event will be shown in the report;
- **'Notifications' –** allows to perform notifications' actions, preferred by the specialist.

Every line of the table presenting detected events is highlighted with one of colors, corresponding to certain types of events:

Pink	'Heart rate'
Violet	'Junctional rhythm'
Red	'Ventricular'
Green	'Supraventricular'
Orange	'Pacemaker'
Yellow	'ST changes'
Grey	'Other'
White	'Marked beat'

A detailed description of the ECG annotations displayed in the upper part of the screen is given in section 0 *'Full disclosure'.*

20.2 Filtering and sorting the events list

The list of events may be filtered by type - using the tree-organized filter located in the left part of the screen. Additionally, the list may be filtered by events status, day or morphology.

The tree-organized list contains the following elements:

- 'Notification criteria events':
  - 'Web', 'Fax', 'Email',
  - 'Phone';

- ‘Critical & important events’;
- ‘Patient triggered’;
- ‘Heart rate’:
  - ‘Fastest minutely HR’,
  - ‘Average minutely HR’,
  - ‘Slowest minutely HR’,
  - ‘Asystole’,
  - ‘Pause’,
  - ‘Bradycardia’,
  - ‘2nd Degree AV Block’,
  - ‘3rd Degree AV Block’’,
  - ‘Missed Beat’,
  - ‘Sinus Tachycardia’,
  - ‘Junctional Rhythm’;
- ‘Ventricular’:
  - ‘Single Premature Beat’,
  - ‘Couplet’,
  - ‘Triplet’,
  - ‘VT’,
  - ‘Bigeminy’,
  - ‘Trigeminy’,
  - ‘IVR’,
  - ‘AIVR’,
  - ‘R on T’;
- ‘Supraventricular’:
  - ‘Single Premature Beat’,
  - ‘Couplet’,
  - ‘Triplet’,
  - ‘SVR’,
  - ‘AF’,
  - ‘AF – Fastest minutely HR’,
  - ‘Bigeminy’,
  - ‘Trigeminy’;
- ‘ST Changes’;

- ‘Operator selected’;
- ‘Other’:
  - ‘Paced beat’,
  - ‘Marked beat’,
  - ‘Electrode contact loss’,
  - ‘Signal synchronization loss’,
  - ‘Unknown/Artifact’.

‘Filter by status’ allows for limiting the list of events to those with selected status and similarly ‘Filter by day’ limits the list to events that took place during a selected day, or during all days. ‘Filter by morphology’ limits the list to events containing beats with selected morphology index – the filter activates after performing morphology grouping.

19.3. Events reviewing

In order to change an event description, right-click on the event and select **‘Edit description’** option from the context menu. All changes introduced to the description of events may be undone using **‘Reset description’** option. All beat annotations generated by the PDA can be modified using the following keyboard shortcuts:

- v – to ventricular,
- s – to supraventricular,
- a – to atrial fibrillation,
- n – to normal,
- x – to artifact,
- b – to bradycardia,
- j – to junctional rhythm.

The ‘Status’ of events may be modified in two ways:

- by clicking on the ‘Status’ cell on the event list – the status changes in the following order: ‘Unconfirmed’ → ‘Confirmed’ → ‘Deleted’ → ‘Unclear’ → ‘Unconfirmed’;
- by selecting a given event on the list and using one of the keyboard keys:
  - c – changes status to ‘Confirmed’,
  - d – changes status to ‘Deleted’,
  - u – changes status to ‘Unclear’,
  - shift+u – changes status to ‘Unconfirmed’,
  - ctrl+g – selects morphology group.

If none of the events has ‘Unconfirmed’ status, the recording session status is presented as ‘Confirmed’ using the green ✔ icon on the ‘Navigator’ list. If none of the events has ‘Unclear’ status, the recording session status is presented as ‘Clear’ using the green ✔ icon on the ‘Navigator’ list.

The ECG strip containing the detected event may be added to the following reports generated by the PC Client application (see Fig. 53):

- 'Daily only',
- 'Cumulative and daily',
- 'Urgent, cumulative and daily'.

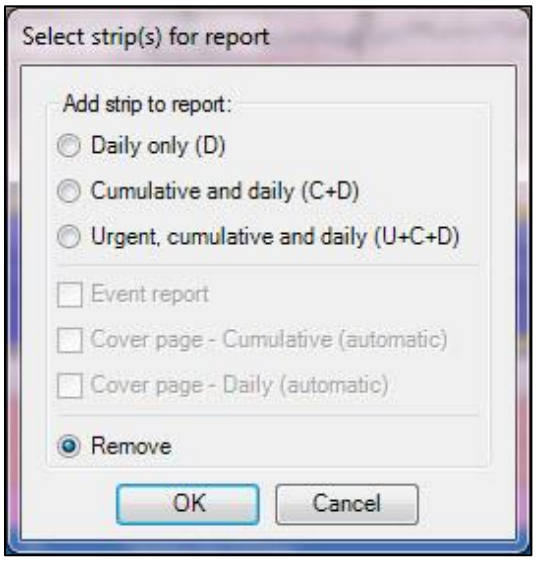


Fig. 53 Selection of strips for report

20.3 Notifications

When clicking on icons representing requested notifications, an 'Urgent Report' is generated and shown. The bottom part of the Report View window is used for checking status of requested and performed notifications for given episode, as well as for marking manual (phone) notifications as performed (see Fig. 54).

Fig. 54 Event view

The left section contains 'Web', 'Fax' and 'Email notifications' info. They are automatically performed by system upon report publication after ''Notify physician' button is pressed.

'Phone notifications' are not performed automatically by system. After calling physician, the user should change notification status of phone notification from 'requested' option to 'performed'.

20.4 Navigation through the ECG recording

The ECG waveform displayed in the upper part of the screen corresponds to the event marked on the list. To navigate through the ECG, use the transport buttons (<, <<, >>, >) on the toolbar or the arrow keys of the keyboard:

- pressing the double arrow buttons on the toolbar moves the ECG record backward or forward by the length of the displayed strip (8 seconds),
- pressing the single arrow buttons moves the record backward or forward by 200 milliseconds,
- horizontal arrows on the PC keyboard move the record backward or forward by 200 milliseconds.

20.5 ECG display settings and transmitter settings

Tools for changing the ECG waveform vertical scale and other parameters related to ECG display are described in section 21.3 Transmitter settings are described in sections 19.6.

21 'FULL DISCLOSURE'

21.1 Introduction

The PocketECG PC Client provides access to full disclosure ECG recording. The ECG waveforms may be viewed using the 'Full Disclosure' view of the PC Client application, as shown in Fig. 55.

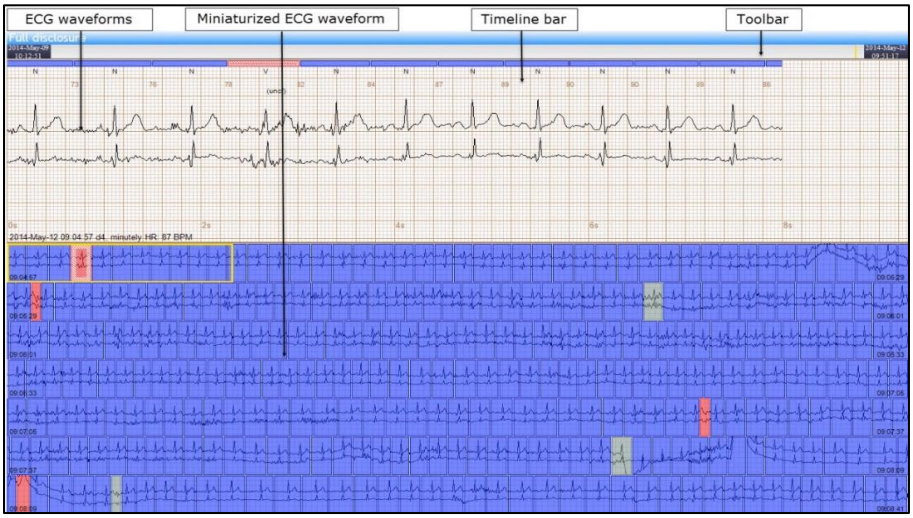


Fig. 55 'Full Disclosure' view

The timeline bar is displayed in the upper part of the screen. The user may click on the timeline bar in order to navigate directly to any time in the recording. The ECG waveform is displayed in normal size - as 8 s strip in the upper part of the screen and as a miniaturized signal in the bottom part of the screen (30 s of the signal in each row). User may click on the miniaturized ECG and the corresponding full-size strip will be displayed in the upper part of the screen. The displayed strip is indicated by yellow frame highlighting the corresponding miniaturized ECG fragment. The enlarged fragment of the 'Full Disclosure' view containing the ECG strip is presented in Fig. 56. The PocketECG automatically detects and classifies QRS complexes. The annotations for all detected complexes are displayed above the ECG beats (2). The instantaneous heart rate is displayed between the ECG beat labels (3).

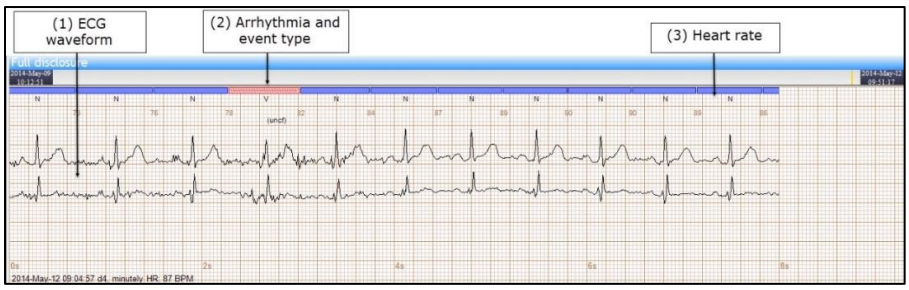


Fig. 56 ECG waveforms presented in the upper part of the screen

The PocketECG transmitter allows the patient to report symptoms manually. The ECG strip reported (marked) by the patient is presented in the 'Full Disclosure' view with a long grey stripe marked with 'triggered by patient' label located under the ECG waveform (see Fig. 57).

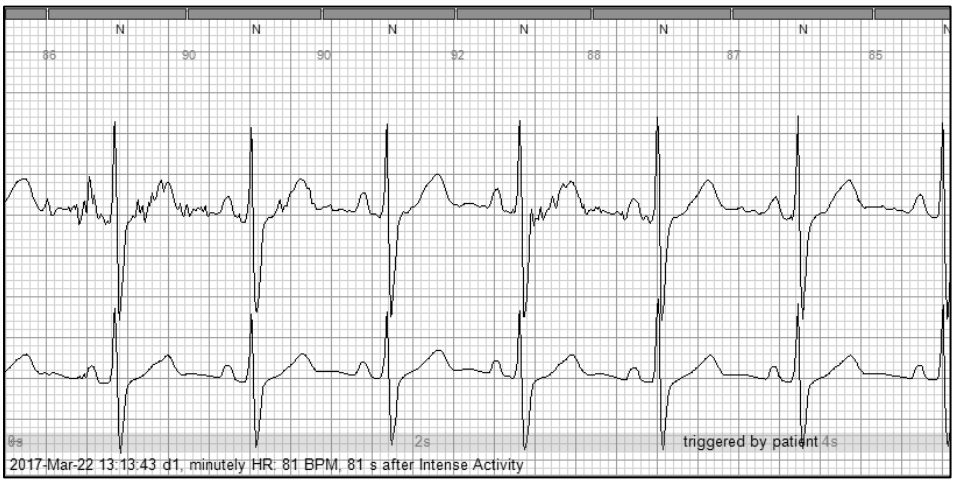


Fig. 57 ECG waveforms marked as 'triggered by patient'

21.2 Navigation through the ECG recording

The user can jump to the next selected ECG region or to heart beats meeting pre-defined criteria (see Fig. 59). After clicking on the drop-down menu located in the left upper corner of the window it is possible to define the navigation criteria for the arrow buttons (see Fig. 58).

Fig. 58 Navigation menu

If the 'Selected region' option is selected, then the arrow buttons will skip to the next/previous selection onset/offset. The 'Strip position' allows to navigate within selected event, from beats just before event, to middle part of event, and to beats just after event. Selecting 'Beat type' option will show a window which will allow the user to specify beat-type and other beat related criteria for navigation (see Fig. 59).

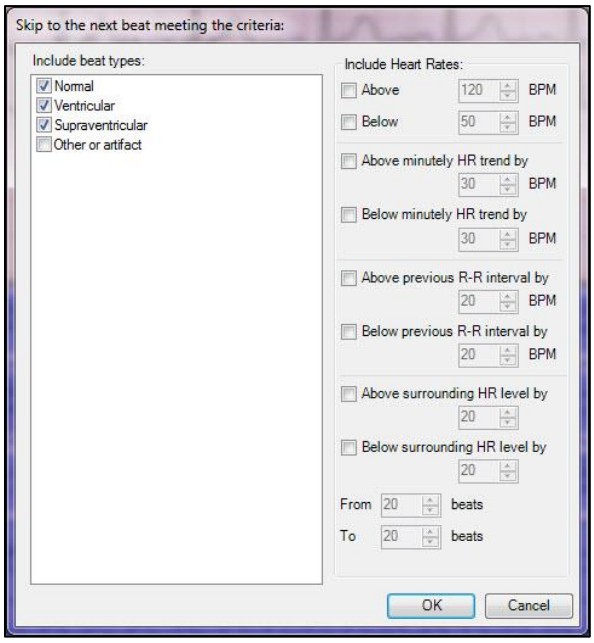


Fig. 59 'Skip to the next beat meeting the criteria' window

The transport toolbar has three options:

- 'skip by one hour',
- 'skip by the size of the whole bottom view',
- 'move the record by 200 ms periods'.

Pressing 'Jump to' button opens a drop-down list with five options:

- 'Time' – jumps to specified time,
- 'Max sinus HR' –jumps to the max HR strip for sinus,
- 'Min sinus HR' –jumps to the min HR strip for sinus,
- 'Max afib HR'f – jumps to the max HR strip for afib,
- 'Min afib HR' – jumps to the min HR strip for afib.

21.3 ECG display settings and re-annotations

The toolbar in the 'Full Disclosure' view contains 'EKG view mode' menu. This menu allows for changing settings which influence the way the ECG waveform is displayed. The following options are available:

- **'Automatically scroll when new data arrives'** - when new data is received, strip corresponding to the last 8 seconds of the signal is presented automatically in the upper part of the screen and the miniaturized ECG is updated.

- **'Brighten/darken annotation boxes'** - used for brightening or darkening colors of the annotation boxes presented in the bottom part of the window.
- **'EKG baseline up/down'** - moves the ECG signal up or down,
- **'Increase/decrease the number of EKG rows'** - modifies the number of miniaturized ECG rows displayed in the bottom of the screen (and automatically changes the amplitude range of each row),
- **'Vertical scale'** - used for modifying the amplitude scale of the displayed full-size ECG strip (upper part of the screen),
- **'R-R intervals'** - changes the R-R interval display format from beats per minute (BPM) to milliseconds (ms).
- **'Waveform'** - allows for filtering out/retaining the interferences and disturbances in the presented waveforms.

There are also three other tabs located in the toolbar of the 'Full Disclosure' view:

- **'Add strips'** – creates 'Operator selected' event and allows for attaching the strip to the report,
- **'Filters'** - allows for switching between single and all-day displaying modes
- **'Annotations'** - there are two options under this menu item:
  - **'Re-annotate/modify selection'** - opens a window presented in Fig. 60 (described below),
  - **'Modify status of events within selection'**.

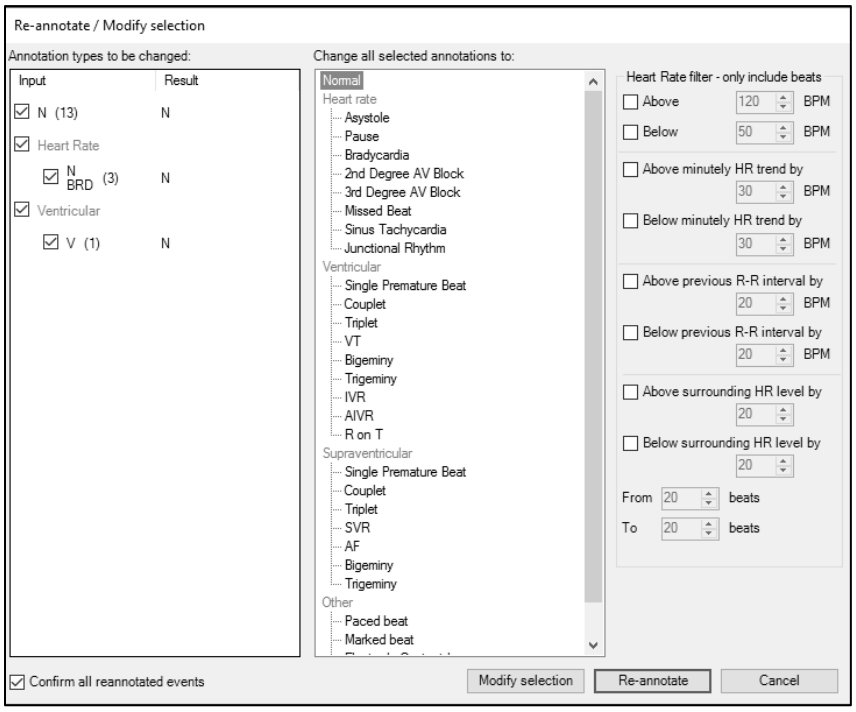


Fig. 60 'Re-annotate/Modify selection' window

The window '**Re-annotate/Modify selection'** (see Fig. 60) allows for modification of beat labels generated by the PocketECG transmitter software. The modification is applied to the annotations listed and checked in the left section of the screen. The filters located in the right section of the window allow for limiting the pre-selected beats based on HR criteria. The center section of the window allows for selecting the target beat annotations (to which the input beat annotations will be modified).

It is possible to measure heart rate/R-R interval and signal peak-to-peak amplitude manually using the ECG caliper (see Fig. 61). In order to activate this tool, hold the mouse button and then move the cursor to the right adjusting the size of the displayed caliper. The measured parameters are displayed under the tool.

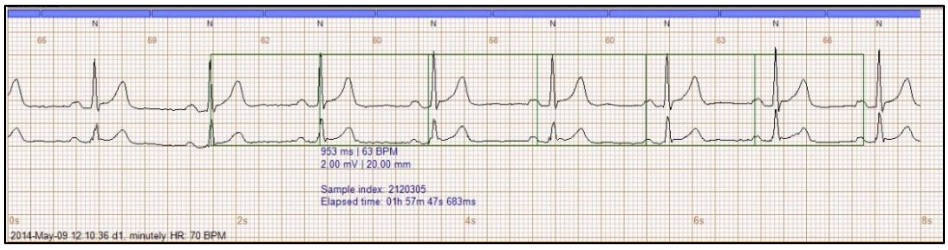


Fig. 61 Ruler tool

22 'TRENDS'

Interactive trends illustrating variations of the averaged HR, AF burden, bradycardia burden, ventricular or supraventricular beats and runs count, as well as ST levels are available in the Trends view of the PC Client software. The trends may be displayed in two modes:

- **'Continuous trends'** - the upper part of the screen shows the full-size ECG strip and the bottom part of the screen shows the trends (see Fig. 62).
- **'Daily trends'** - each daily trend for each parameter is presented in a separate tab. Each day is presented in a separate row (see Fig. 63).

The control buttons and options located in the toolbar are similar to those already described in section 0. However, the buttons with double arrows (<< and >>) rewind the recordings by 24 hours. The buttons with single arrows rewind the waveforms by 1 hour. There are also additional buttons located in the upper toolbar, which are not available in the 'Full Disclosure' view ('Hide/show ECG strip' and 'Zoom in/out'). The daily trend of a particular parameter may be attached to the final report. If this is desired, mark the checkbox located in the right corner of every window containing trend diagrams.

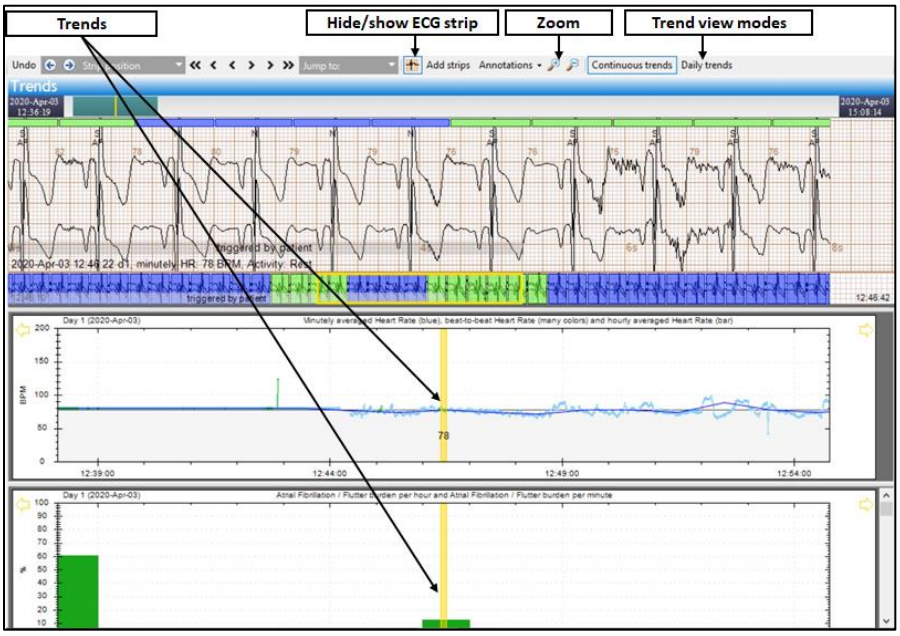


Fig. 62 Continuous trends

Fig. 63 Daily trends

22.1 Acceleration trend

The PocketECG transmitter sends to the remote server both ECG and acceleration data. The acceleration data can be reviewed in the 'Trend' view together with other trends e.g. heart rate. The sample ECG strip together with heart rate trend and acceleration trend is presented in Fig. 64.

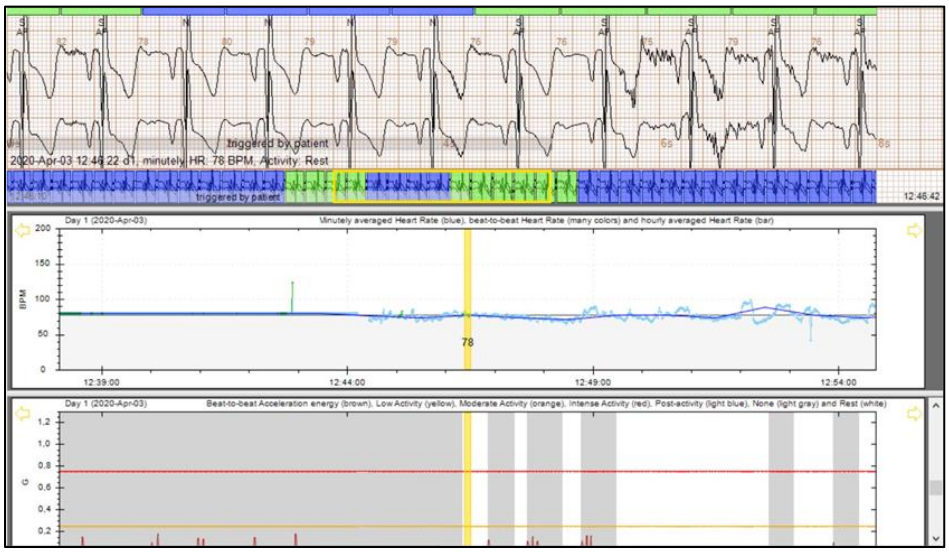


Fig. 64 Heart rate and acceleration trends

23 'IMPRESSIONS AND FINDINGS'

'Impressions and Findings' is a notepad for user's remarks. The user is able to add comments related either to a single day of the recording or make general notes regarding the entire recording session. The arrows in the upper part of the screen allow for navigation through the notes. If 'Day x' is displayed between the navigation arrows, the added comment relates to day number *x*. The 'All days' notice displayed between navigation arrows indicates that the comments refer to the entire recording session. The notes are attached to the reports generated by the PC Client application – the main note is attached to the summary report, while the daily notes are attached to the corresponding daily reports. Depending on session's Ordering Physician settings, impressions and findings may also be automatically generated basing on session statistics – if automatic generation of findings is turned on either on Ordering Physician or on session level, the content in Impressions and Findings is just a preview, and actual content is generated at report generation time. User may also choose to generate findings automatically basing on current session statistics, and then use it as starting point for further edition.

24 'REPORTS'

24.1 Introduction

The 'Reports' view consists of a table containing a list of all reports generated during the recording session (see Fig. 65). There are five types of reports presented in the 'Reports' view of application:

- 'cumulative reports',
- 'end of study reports',
- 'daily reports',
- 'urgent reports',
- 'event reports'.

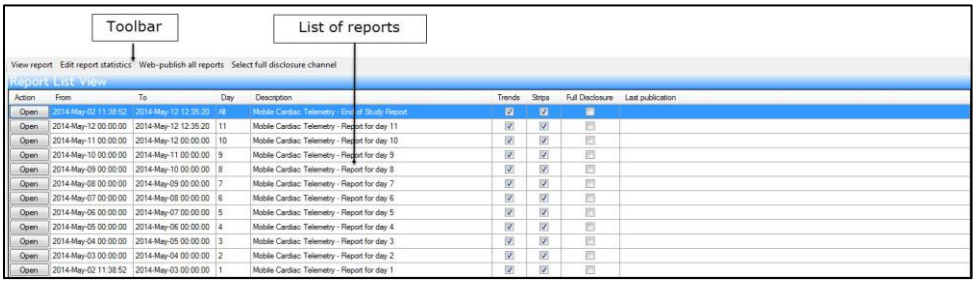


Fig. 65 Reports view

The table containing generated reports has columns with the following headers:

- **'Action'** – contains 'Open' button which allows to open the report,
- **'From'** – defines the start time of the period covered by the report,
- **'To'** – defines the end time of the period covered by the report,
- **'Day'**– defines the day covered by the report; 'All' stands for the cumulative/end of study report,
- **'Description'** – description of the report,
- **'Trends'** – the diagrams selected using the 'Trends' view of the application are attached to the report if this checkbox is selected,
- **'Strips'** – the ECG strips chosen using the 'Event View' of the application are attached to the report if this checkbox is selected,
- **'Full disclosure'** –the miniaturized ECG waveforms are attached to the report if this checkbox is selected,
- **'Last publication'** – date of last publication of the report with the author's name.

24.2 Reports viewing

In order to display a report, select it from the list and then choose the 'View report' command (toolbar) or press the button 'Open'. Double-clicking on the particular row in the table also opens the corresponding report. The report contains the ECG strips previously selected to be attached using the 'Event View' of the application. Furthermore, the notes added using the Impressions and Findings view are also included in the report.

24.3 Reports editing

Reports may be modified manually after clicking the 'Edit report statistics' button located in the toolbar of the application. The window for editing reports is presented in Fig. 66.

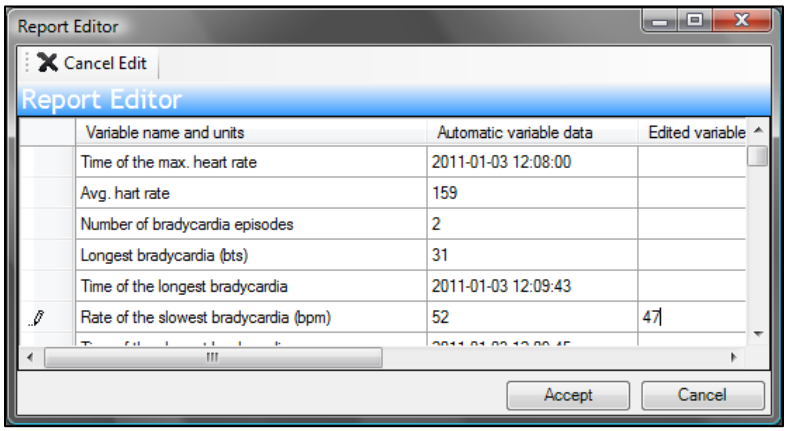


Fig. 66 'Report editor' window

All introduced modifications must be confirmed by clicking the 'Accept' button. In order to reject the changes and restore the original report select 'Cancel' or 'Cancel Edit'.

25 'GARBAGE'

The list of all recording sessions removed from the remote server is presented in the 'Garbage' view of the PC Client application. The list may be sorted and filtered using the pop-out menus located in the toolbar. The following menu options: 'Hide recording sessions', 'Sorting key order' and 'Columns visibility' are identical to the options available in the 'Navigator' and described in detail in section 19.2. The recording sessions placed in the 'Garbage' folder may be moved back to the main folder and further accessed using the 'Navigator'. In order to restore a recording session, press the right button on the PC mouse and then select the 'Undelete' command. If the restored session has no specialists assigned, the window for assigning patients and specialist is displayed (see section 19.4).

26 'ARCHIVE'

It is a list of all recording sessions which were located on the remote server and then archived in the 'Archive' view of the PC Client application. The list may be sorted and filtered using menu options located in the toolbar. The following menu options: 'Hide diagnostic sessions', 'Sorting key order' and 'Columns visibility' are identical to the options available in the 'Navigator' and described in detail in section 19.2. The recording sessions placed in the 'Archive' folder may be moved back to the main folder and further accessed using the 'Navigator'. In order to restore a recording session, press the right button on the PC mouse and then select the 'De-archive' command. If the 'De-archived' session has no specialists assigned, the window for assigning patients and specialist is displayed (see section 19.4).

27 'WEB NAVIGATOR'

'Web navigator' is a system function that allows an ECG specialist to access Web platform. Using it the specialist can easily view and manage recordings on the Web platform.

28 'TOOLS' MENU

The main menu of the application called the **'Tools' Menu** is located in the upper left corner of the main window and is represented by the  icon. The pop-out menu has the following options/commands:

'Lock workstation'	Logs out the current user and displays a window for entering a new login and password.
'Add / Edit specialists'	Activates a window for adding and editing specialists' personal data, as described in section 19.3.2.
'Manage groups'	Activates a window for managing user groups.
'Add / Edit patients'	Activates a window for adding and editing patients' personal data, as described in section 19.3.1.
'Add / Edit / Change workstations'	Activates a window for adding and editing workstations' data, or changing workstation, as described in section 19.3.3.
'Clean local database'	Removes both: ECG data and recording session files already downloaded to the hard drive and initiates a restart of the application.
'Import session from hard disc'	Activates a window for choosing the session data that are going to be imported from the local hard drive.
'Export billing data'	Saves the ECG data of selected session to csv or pdf file.
'Export enrolments'	Saves enrolments' data from selected period to csv file.
'Open session directory'	Opens the folder which stores all the session files.
'Settings'	Opens a window which contains the global setting related to the remote server and the user interface.
'Clear all reannotations'	Clears all re-annotations introduced by the user during reviewing.
'Archive all from PDA'	Moves data from recording sessions stored on the SD card (connected through the USB card reader with PC/tablet) to the Archive folder of the PC Client.
'Generate code to unlock new session'	Generates code to unlock transmitter for a new session.
'Export action log'	Exports a list of actions performed by the user for the highlighted recording session along with time stamps.

‘Load data from backup’		
Export ECG	**‘Signal data’**	Exports the signal data to a text file.
	‘Annotations data’	Exports the ECG annotations to a text file.
‘Show matching history’		Shows history of enrolments' matching for chosen sessions.

C. ADDITIONAL INFORMATION

29 MEDICAL INCIDENT

Caution. In the event of a medical incident, please notify the manufacturer immediately.

MEDICALGORITHMICS S.A.
Aleje Jerozolimskie 81
02-001 Warsaw, Poland
e-mail: technical@medicalgorithmics.com

30 TROUBLESHOOTING

Problem	Probable cause(s) and solution
It is impossible to turn on the PocketECG transmitter.	The battery is discharged. Replace the battery with a fully charged one.
The ECG signals displayed by the PocketECG transmitter are of low amplitude and disturbed.	Poor skin preparation or the electrodes past their use-by date. Remove hair and grease from where the electrode is to be attached and use single-use electrodes designed for long-term ECG monitoring.
It is impossible to start new recording session.	The recording session cannot be initiated if: • the SD card is not installed, • the device is powered from backup battery. If you cannot initiate recording session after checking abovementioned issues, contact PocketECG service provider.
Recording session stopped unintentionally.	The memory card is full. Format the memory card.
The monitoring data is not stored properly – the application notifies about errors.	The writing and/or reading speed of the memory card is not sufficient. Use memory cards of at least 100 kbps reading and writing speed.
The device screen cannot be unlocked.	Press the service provider logo for 3 seconds and then type the unlocking code: 1 2 3 6.

Problem	Probable cause(s) and solution
The recording session has been successfully started on the PocketECG transmitter, but it is not listed in the PocketECG client application.	Check the session status in the 'supervisor view' → 'About' → 'Session info' - the '[OK]' text string indicates that the wireless connection between PocketECG transmitter and remote server has been successfully established. If instead of '[OK]' an error code is displayed in the brackets, the transmitter cannot connect to the remote server. Ensure that the Internet connection is properly configured on the phone and that it is within the mobile network range. If the '[OK]' status is displayed and the newly started recording session still cannot be found in the PocketECG Client application, the PC operating PocketECG Client does not have an active Internet connection. Consult your PocketECG distributor or service provider for support.
The recording session has been finished, but the mobile phone network is not working (ECG data cannot be transmitted) or internet is inaccessible due to its infrastructure failure.	Finish the recording session and remove SD card from the PocketECG transmitter. Use microSD card reader equipped with USB interface and connect it to the PC operating the PocketECG Client application and download the ECG data from the SD card to the local hard drive (refer to subsection 19.6).
The PocketECG Client application cannot communicate with the remote server - the ECG data cannot be downloaded.	Refer to subsection 18.1.

31 TECHNICAL PARAMETERS

Model	PocketECG IV
Type	P4TR-AA-ADS P4TR-AB-ADS P4TR-CA-ADS P4TR-CE-ADS
Wireless communication	P4TR-AA-ADS & P4TR-AB-ADS: B4 (AWS1700), B13 (700) P4TR-CA-ADS & P4TR-CE-ADS: B1*, B2, B3, B4, B5, B8, B12, B13, B18*, B19*, B20, B25*, B26*, B27*, B28, B66*, B85* (bands denoted with asterisk are supported by communication module but not used)
Group/class according to CISPR 11	I/B
Powered by	a Lithium-ion battery 3.7 V type: P4BA-AA-UNI or P4BA-AB-UNI (1700 mAh)
Power consumption	< 2.5 A (in transmission mode)
Working time	at least 24 hours
Input impedance	> 10 MΩ
CMRR	> 60 dB
Sampling rate	300 Sa/s
Registered signal band	0.05 Hz to 60 Hz
Input dynamic range	± 5 mV
Acceptable constant component	± 300 mV
Type of Applied part	BF Applied part, whole device
Operating conditions	1) Ambient temperature range of 10 ^{0}C to 45 ^{0}C (50 °F to 113 °F); 2) Relative humidity range of 10 % to 95 %, without condensation; 3) Atmospheric pressure: 700 hPa to 1060 hPa

Transport conditions, Storage conditions, Storage between uses conditions	1) Temperature: -20 °C to 60 °C (-4 °F to 140 °F) 2) Relative humidity: up to 95 %, non-condensing 3) Atmospheric pressure: 700 hPa to 1060 hPa
Dimensions	6.5 by 3.1 by 0.58 in 167 x 79 x 14.5 mm (without cable)
Weight	161 g

32 SERVICE

Service is provided only by Medicalgorithmics S.A. In case of any product malfunction a device shall be returned directly to manufacturer to the following address:

MEDICALGORITHMICS S.A.
Aleje Jerozolimskie 81
02-001 Warsaw, Poland
e-mail: technical@medicalgorithmics.com

33 DECLARATION OF CONFORMITY

If you would like to receive the declaration of conformity, contact the manufacturer on the following address:

MEDICALGORITHMICS S.A.
Aleje Jerozolimskie 81
02-001 Warsaw, Poland
e-mail: technical@medicalgorithmics.com

34 LIMITED WARRANTY STATEMENT

This limited warranty shall apply to a product ("Product") supplied by MEDICALGORITHMICS. MEDICALGORITHMICS warrants that at the time of its original purchase the product is free of defects in materials and workmanship ("Limited Warranty"). THIS LIMITED WARRANTY DOES NOT AFFECT YOUR STATUTORY RIGHTS.

This Limited warranty is subject to the following terms and conditions:

1. This Limited Warranty is given only to the original purchaser of the Product ("Customer"). This Limited Warranty may, however, be transferred to any individual to whom the Product is sold, where MEDICALGORITHMICS has consented in writing to the transfer (All claims made under MEDICALGORITHMICS Warranty shall be governed exclusively by the terms set out in this warranty document.

This Limited Warranty shall neither exclude nor limit:

a) any statutory rights of the Customer or
b) any of the Customer's rights against the seller/dealer of the Product.

2. This Limited Warranty shall last for twelve (12) months from the date of original purchase for the ECG transmitter, twelve (12) months for the charger (whether included in the ECG transmitter sales package or sold separately) and three (3) months for the battery (whether included in the ECG transmitter sales package or sold separately) ("Warranty Period").

Customer shall present **AN ID NUMBER, SERIAL NUMBER OF PRODUCT AND AN ALLEGED DEFECT/S DESCRIPTION** upon claiming this Limited Warranty. This Limited Warranty is only valid and enforceable in the countries where the Product is sold. However, if you have purchased the Product in a member state of the European Union, Iceland, Norway, Switzerland or Turkey and MEDICALGORITHMICS originally intended the Product for sale in one of these countries, this Limited Warranty is valid and enforceable in all of the above listed countries. Moreover, if Product is purchased in places other than those stated above, MEDICALGORITHMICS will attempt to repair such Product but cannot guarantee the outcome. Warranty service availability and response times may vary from country to country and may also be subject to a registration requirement in the country of purchase.

3. Throughout the Warranty Period MEDICALGORITHMICS or its authorized agent will, at their discretion repair or replace a defective Product free of charge, subject to Clause 6, except for the battery, which may only be replaced. Repair or replacement may involve the use of functionally equivalent reconditioned unit. MEDICALGORITHMICS will return the repaired Product or will replace it with another functionally equivalent Product in good working condition. All replaced faulty parts or components will become the property of MEDICALGORITHMICS.

4. This Limited Warranty applies only to the hardware components of the Product, listed under Clause 6 above, as originally supplied and does not apply to any software, non-Medicalgorithmics branded products or other equipment., even if packaged or sold together with Products.
5. If Medicalgorithmics repairs or replaces the product, the repaired or replaced Product shall continue to be warranted for the remaining time of the original Warranty Period or for three (3) months from the date of repair or replacement, whichever is longer.
6. This LIMITED WARRANTY SHALL NOT APPLY IF:
   a) the Product serial number, the accessory date has been removed, erased, defected, altered or is illegible; or
   b) deterioration of the Product is due to normal wear and tear; or
   c) the Product was used other than as described in the Instructions for Use, subjected to rough handling, exposed to moisture, dampness or extreme thermal or environmental conditions or a rapid change in such conditions, corrosion, oxidation, subjected to unauthorized modifications or connections, unauthorized opening or repair, repair by use of unauthorized spare parts, accidents, forces of nature, or other actions beyond the reasonable control of Medicalgorithmics (including but not limited to deficiencies in consumable parts) unless the defect was caused directly by defects in materials or workmanship. This Limited Warranty does not cover physical damage to the surface of the Product; or
   d) there are cosmetic damages to the Product, including but not limited to scratches, dents and broken plastic on ports;
   e) a damage to the Product is caused by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause;
   f) the defects result from the fact that the battery has been short-circuited or from the fact that the seals of the battery enclosure or the cells are broken or show evidence of tampering or from the fact that the battery has been used in equipment other than those for which it has been specified; or
   g) the Product software needs to be upgraded due to changes in cellular network parameters; or
   h) the defect was caused by the fact that the Product was used with or connected to an accessory not approved or provided by Medicalgorithmics or used not as intended and where it can be shown by Medicalgorithmics that such defect is not the fault of the Product itself; or
   i) the Product is stolen or Medicalgorithmics reasonably believes that the product is stolen based on information provided by law enforcement authorities; or
   j) representations and warranties were made by any person or entity other than Medicalgorithmics.

7. Your Product may contain country specify elements, if the Product has been re-exported from its original destination country to another country, the Product may contain country specific elements that are not considered to be a defect under this Limited Warranty.

CUSTOMER MUST NOTIFY MEDICALGORITHMICS OR A MEDICALGORITHMICS AUTHORIZED SERVICE AGENT OF A CLAIM UNDER THIS LIMITED WARRANTY AND OF THE ALLEGED DEFECT WITHIN A REASONABLE TIME AFTER NOTICING THE DEFECT AND IN ANY EVENT NO LATER THAN BEFORE THE EXPIRY OF THE WARRANTY PERIOD.

8. IN the event of Product failure, the Customer should take the following actions:
   a) refer to the Instructions for Use in order to identify and possibly correct the problem,
   b) if the problem cannot be resolved by referring to the Instructions for Use the Customer should contact MEDICALGORITHMICS Single Point of Contact or the dealer where the Product was purchased, via email.
   c) before the Customer contacts the Medicalgorithmics or the dealer, please ensure the following information is at hand:
      – the ID and serial number of the Product,
      – the Customer's full address and contact information.
      – if applicable, a copy of the Customer's original invoice, receipt or bill of sale for the purchase of the Product.
   d) the Customer should properly secure, pack and send the defective Product to MEDICALGORITHMICS. MEDICALGORITHMICS Single Point of Contact shall provide Customer with instructions regarding where, how and when the defective Product should be returned.

MEDICALGORITHMICS will pay both for the return of the defective product to MEDICALGORITHMICS and for sending the repaired Product back to the Customer if the defective Product is within the Warranty Period and if the Limited Warranty protection applies.9. THIS LIMITED WARRANTY STATES THE ENTIRE WARRANTY GIVEN BY MEDICALGORITHMICS TO THE CUSTOMER.

9. IN NO EVENT SHALL MEDICALGORITHMICS BE LIABLE UNDER THIS LIMITED Warranty FOR LOSS OF PROFIT OR OPPORTUNITY, LOSS OF ANTICIPATED SAVINGS, LOSS OF DATA OR INDIRECT LOSS OF USE OF THE PRODUCT OR ANY ASSOCIATED EQUIPMENT, INCIDENTAL OR CONSEQUENTIAL LOSSES OR DAMAGES OF ANY NATURE WHATSOEVER TO THE FULLEST EXTENT THAT THOSE LOSSES OR DAMAGES CAN BE DISCLAIMED BY LAW.
10. In any case MEDICALGORITHMICS and its suppliers' entire liability under any provision of this Limited Warranty shall be limited to the amount actually paid by the Customer for the hardware. MEDICALGORITHMICS does not exclude or limit liability for personal injury or death resulting from its own negligence, for defects in the Product arising out of its or its manufacturers' negligence, under Part I of the Consumer Protection Act 1987 or for fraudulent misrepresentation.

11. The laws of some countries prohibit Medicalgorithmics from excluding or limiting its liability. In such cases, the exclusions and limitations of liability in this Limited Warranty will not apply.
12. No Medicalgorithmics reseller, agent, or employee is authorized to make any modification, extension, or addition to this warranty.
13. This Limited Warranty gives the Customer specific legal rights; the Customer may also have other rights, which may vary from country to country.
14. This Limited Warranty does not affect the Customers' statutory rights in law specific to the country of purchase, such rights remain protected.
15. If any term is held to be illegal or unenforceable, it shall be severed from this Limited Warranty and the legality or enforceability of the remaining terms shall not be affected.

35 SOFTWARE LICENSE AGREEMENT

Terms and definitions:

- AGREEMENT – this License Agreement.
- PRODUCER – Medicalgorithmics S.A.
- LICENSEE – party that is entering into this Agreement with Producer
- PRODUCT – software, data and related material contained in the PocketECG package

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LIMITED WARRANTY

Producer warrants that the media upon which Product is provided will be free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of receipt. If a defect is found that was not caused by improper use, Producer at its own discretion will exchange Product for a defect-free or reimburse the price paid by Licensee. Producer made every effort to provide flawless operation of Product's functions. Nonetheless Licensee understands that Product may contain some errors, defects, omissions or nonconformities. Therefore, Producer and the respective third-party licensor(s) discourage Licensee from relying exclusively on data generated by the Product.

EXCLUSIVE REMEDY AND LIMIATATION OF LIABILITY

Producer's entire liability and Licensee's exclusive remedy during the warranty period shall be the return of the license fee paid for the Product or exchange of Product as described in the Limited Warranty above. Producer shall not be liable for indirect, incidental or consequential damages related to Licensee's use of Product, even if Producer is advised of the possibility of such damage.

WAIVERS

No failure or delay by Producer in enforcing any right or remedy under this Agreement shall be construed as a waiver of any future or other exercise of such right or remedy by Producer.

ORDER OF PRECEDENCE

Terms expressed in this Agreement have precedence over those expressed in purchase order or other purchase arrangements unless agreed otherwise.

GOVERNING LAW

All rights and duties under this Agreement shall be governed by the commercial law of the country where the license is purchased with exception of copyright, patent, and trademark issues. Those shall be governed by the laws of Poland and the applicable international treaties and conventions.

ENTIRE AGREEMENT

The parties agree that this Agreement constitutes the sole and entire agreement of the parties as to the matter set forth herein and supersedes any previous agreements, understandings and arrangements between Producer and Licensee and is effective, valid and binding upon parties


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