



Unified Arrhythmia Diagnostic System

PocketECG IV

DUAL CHANNEL

Instructions For Use for patients



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1 INTENDED USE

The PocketECG transmitter is intended to acquire, analyze, visualize, record or/and transmit the ECG and acceleration data. The results of arrhythmia and ST elevation detection are displayed, stored or/and transmitted along with the ECG signals. The acceleration signals are analyzed in order to determine the physical activity of the patient. It is assumed that the device can further transmit the ECG and acceleration signals along with analysis results using available wireless technologies.

The Medicalgorithmics' Unified Arrhythmia Diagnostic System PocketECG IV is intended for use under the 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.

1.1 INTENDED PATIENT POPULATION

PocketECG transmitter is intended for patient with:

- age: no limits
- weight: >10 kg
- 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 recorded and transmitted by PocketECG device can be reviewed by qualified person using PC Client application. Patient does not have access to the PC Client application.

2 CONTRAINDICATIONS

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

3 COMPLIANCE

The PocketECG IV complies with the requirements of the United States Food and Drugs Administration and the requirements of the Health Canada Medical Devices Regulations.



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

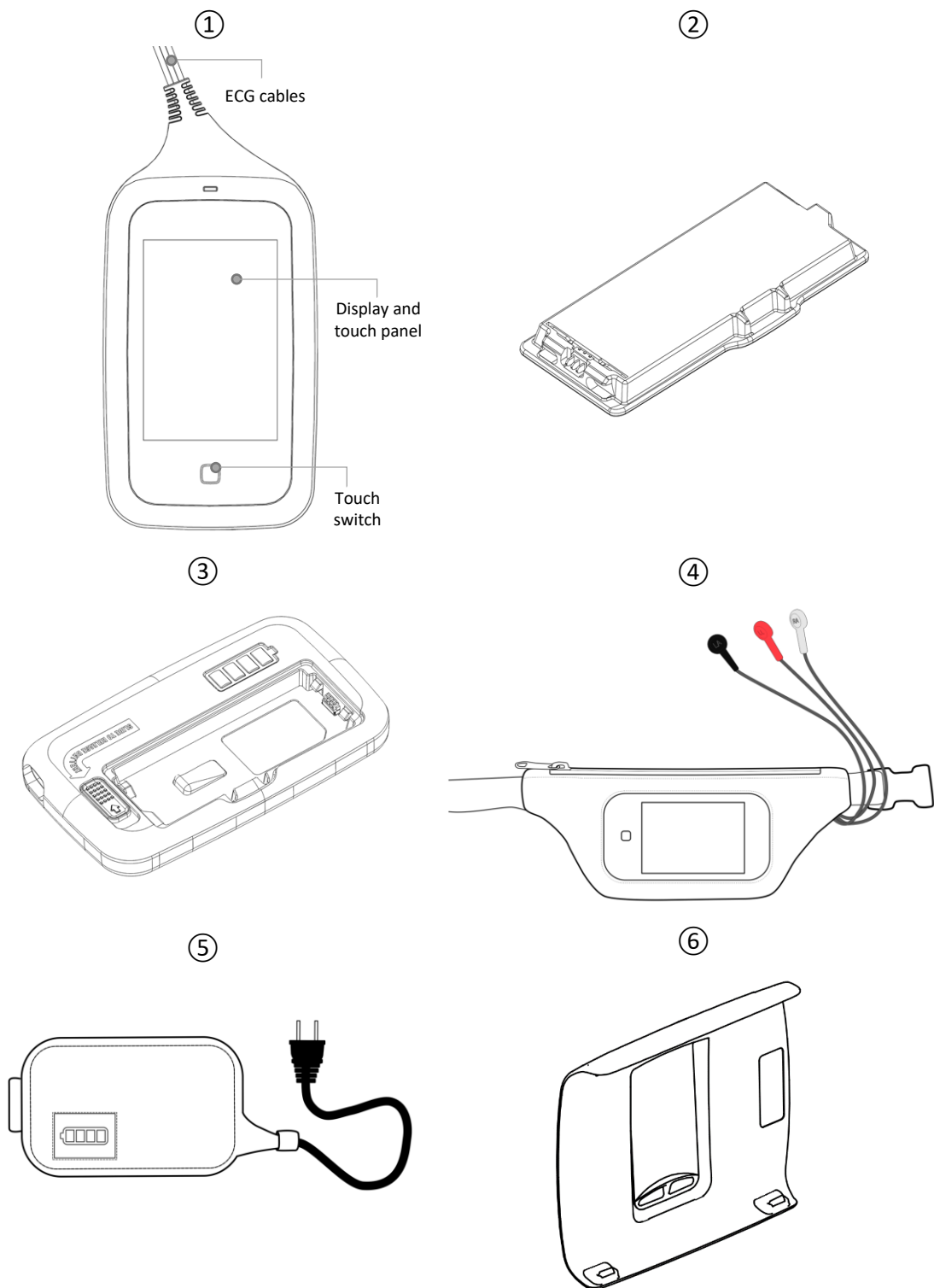
3.1 FCC REQUIREMENTS

FCC ID: 2AB2MP4TRA & 2AB2MP4TRAA & 2AB2MP4TRCA

The device complies with part 15 of the FCC Rules. Operation is 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 user's authority to use ECG.

4 COMPONENTS & ACCESSORIES



- ① The PocketECG transmitter, model: PocketECG IV, type: P4TR-AA-ADS, P4TR-AB-ADS (LTE version for Verizon), P4TR-CA-ADS (LTE-M version, American color-coding standard of ECG cables) or P4TR-CE-ADS (LTE-M version, European color-coding standard of ECG cables)
- ② A Lithium-ion battery, type: P4BA-AA-UNI or P4BA-AB-UNI, manufactured by Medicalgorithmics S.A., rated 3,7 VDC, 1700 mAh

- ③ An AC plug-in charger type P3CH-AB-UNI suitable for charging battery type P4BA-AA-UNI or P4BA-AB-UNI, manufactured by Medicalgorithmics S.A., rated 100 VAC – 240 VAC, 0.2 A, 50/60 Hz (charger type PEEGC-III can also be used)
 - ④ PocketECG transmitter pouch, type: P4TP-AA-UNI
 - ⑤ PocketECG charger pouch, type: P3CP-AA-UNI
 - ⑥ PocketECG holster (transmitter holder), type: P3HL-AB-UNI (optional, use only in the professional healthcare environment)
- MicroSD memory card

Accessories which are needed to the proper operation but are not included in the PocketECG IV package:

- SIM card,
- ECG electrodes.

5 WARNINGS

Warning statements alert to situations which, if not avoided, could result in illness or injury of the patient. Specific warnings can also be found in other sections of this instructions for use. All of them should be obeyed.



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

WARNING. DO MAINTAIN A MINIMUM DISTANCE OF 15CM (6 INCHES) BETWEEN THE TRANSMITTER AND PACEMAKER FOR PATIENTS WITH A PACEMAKER. TURN THE TRANSMITTER OFF IMMEDIATELY AND PROVIDE APPROPRIATE PATIENT CARE IF YOU SUSPECT THE TRANSMITTER AFFECTED THE PEACEMAKER.**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 KEEP THE DEVICE AND ITS ACCESSORIES IN DRY CONDITIONS WHEN SHOWERING, BATHING OR WASHING. PRODUCT IS NOT WATERTIGHT.

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

WARNING. DO NOT USE THE DEVICE IN INFANTS WEIGHING LESS THAN 10 KG.

WARNING. DO NOT USE THE DEVICE IN INTENSIVE CARE UNITS. IT SHOULD NOT BE USED WITH HIGH-FREQUENCY SURGICAL DEVICES OR DIRECTLY ON THE HEART.

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



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.

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 THE DEVICE IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR OXYGEN OR NITROUS OXIDE.

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

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

WARNING. DO NOT ATTEMPT TO OPEN OR SERVICE NEITHER THE BATTERY PACK NOR THE TRANSMITTER. THERE IS A RISK OF FIRE AND BURNS IF THE BATTERY PACK IS HANDLED IMPROPERLY.

WARNING. DO NOT DISASSEMBLE, CRUSH, PUNCTURE THE BATTERY, AND DO NOT SHORT EXTERNAL CONTACTS OR CIRCUITS, DISPOSE OF IN FIRE OR WATER OR EXPOSE TO TEMPERATURES HIGHER THAN 60 °C (140 °F). REPLACE A LITHIUM-ION BATTERY 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 DEVICE AT GAS STATIONS, FUEL DEPOTS, CHEMICAL PLANTS OR WHERE BLASTING OPERATIONS ARE IN PROGRESS, OR IN POTENTIALLY EXPLOSIVE ATMOSPHERES SUCH AS FUELING 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 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. RESULT OF PATIENT'S ACTIVITY DETECTION MAY NOT CORRESPOND TO THE ACTUAL ACTIVITY, IF PATIENT IS MOVING BY VEHICLE.

6 USING POCKETECG IV

6.1 SAFETY PRECAUTIONS

- One device is intended to monitor only one patient at a time.
- It is recommended for the device to work at room temperature (working temperature is: from 10 °C to +45 °C (from 50 °F to 113 °F)).
- Air in rooms where the device works should be free of caustic gasses, steam, and dust. Although the device is powered from 3.7 VDC and does not allow for power intake larger than 3 A it is not guaranteed that it cannot produce a spark which could initiate the explosion.
- The patient should check with the appropriate airline carrier to confirm that the PocketECG transmitter which is similar to a regular mobile phone may be used on the airplane during take-off, flight, and landing.
- During handling the device, it is necessary to avoid excessive stretching and sudden jerking of cables connecting the PocketECG transmitter with electrodes placed on the patient's body. The ECG cables should not be bent, pulled and wrapped around the device.
- Parts that wear out and are intended for single use should be used in accordance with binding regulations and cannot be re-used. The electrodes placed on the patient's body should be replaced with new ones after no longer than 24 hours if the diagnostic session is to be continued.
- The manufacturer is not liable for damage caused by improper use of the device or neglecting guidelines included in the instructions for use.
- The manufacturer accepts liability only when the device is used as intended and in accordance with the instructions for use.
- 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.
- 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.
- The capacity of the PocketECG Li-Ion battery decreases with normal use over time. The manufacturer recommends replacing the battery with a new one after 300 charging cycles or after 2 years of use. Recycle or dispose of used batteries according to the local regulations.
- The use of PocketECG holster (transmitter holder) is permitted only in the professional healthcare environment.
- Label of PocketECG transmitter is located under the battery.
- ECG signal is not transmitted if the PocketECG device is out of mobile network access. Keep the PocketECG transmitter in the area where the mobile network is accessible.

6.2 PROTECTIVE POUCHES AND HOLSTER

6.2.1 Pouch for transmitter

The PocketECG device is not waterproof. In order to provide IP22 protection for transmitter in the home healthcare environment, use the device in the pouch.

Before starting the device, put the lead wires through a dedicated slot in pouch (Fig. 1).

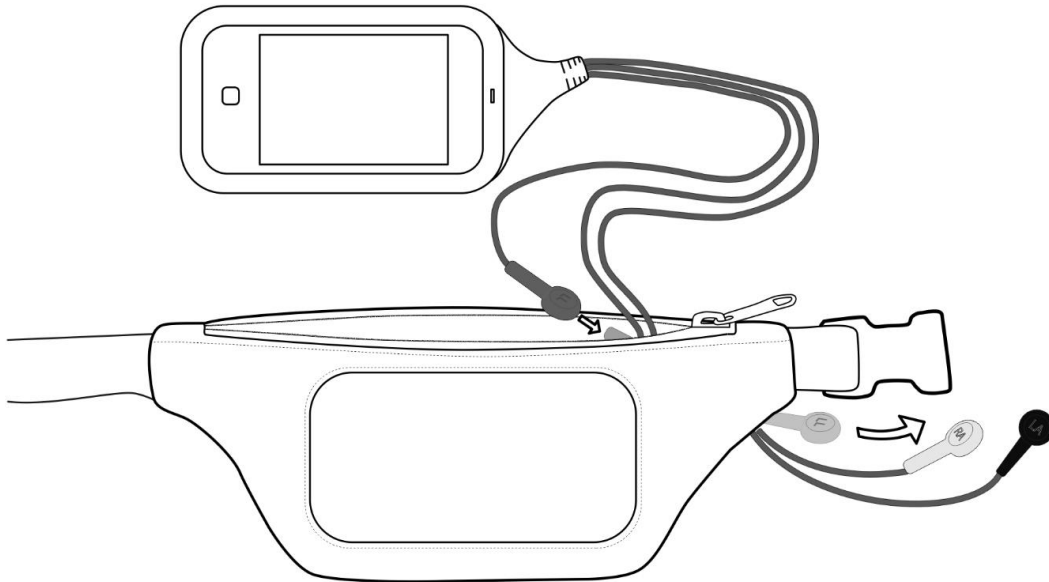


Fig. 1 Putting lead wires through the dedicated slot

Next, put the device in the pouch and zip the pouch (Fig. 2).

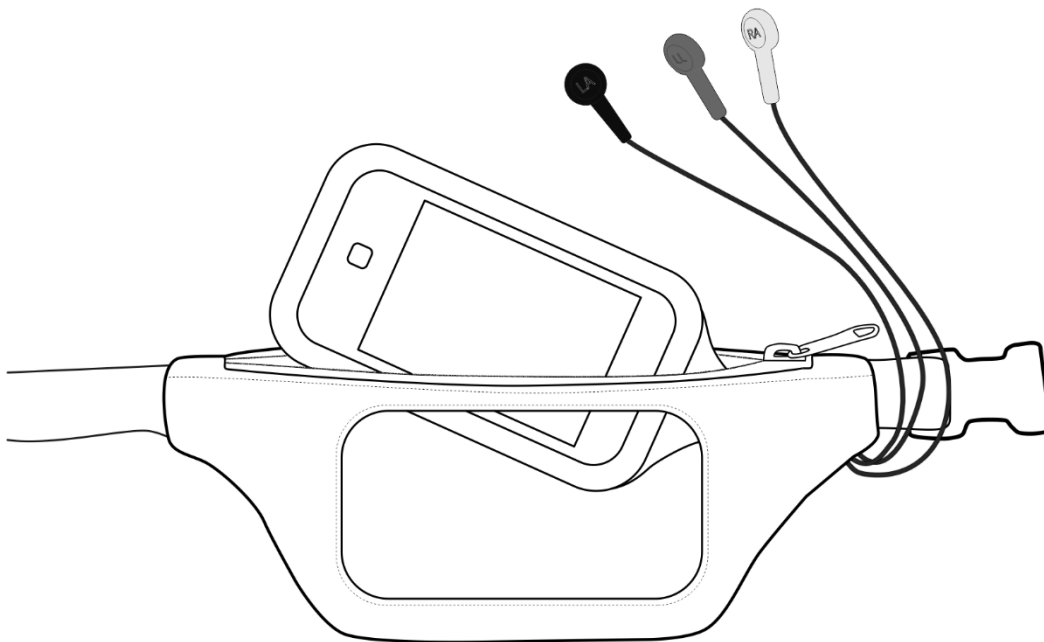


Fig. 2 Putting the device into pouch

The correct transmitter placement in the closed pouch is presented in *Fig. 3*.

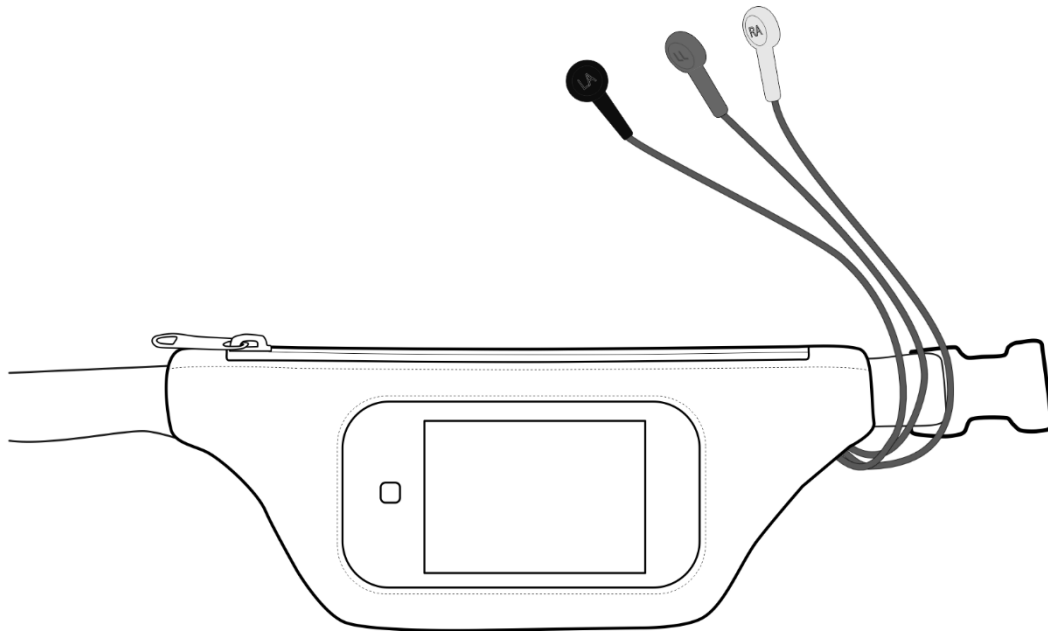


Fig. 3 Correct transmitter placement in the closed pouch

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. 4*).

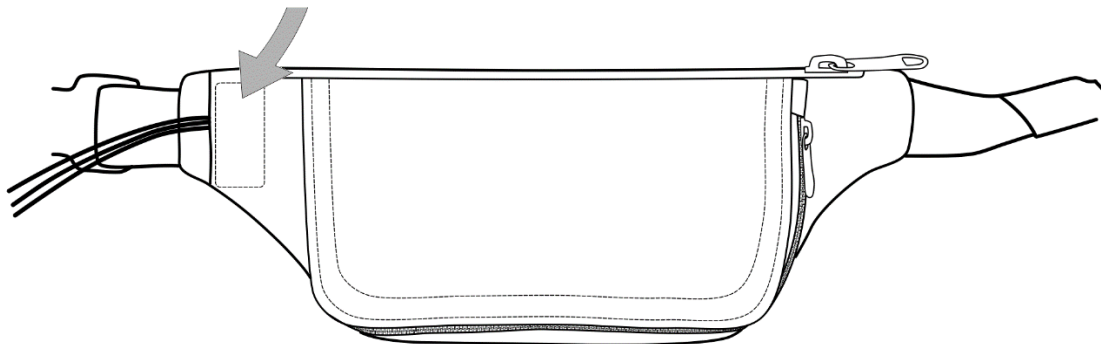


Fig. 4 Back of the pouch, placement of hook-up-loop to press

The pouch for transmitter is recommended to be fasten around the waist (Fig. 5).

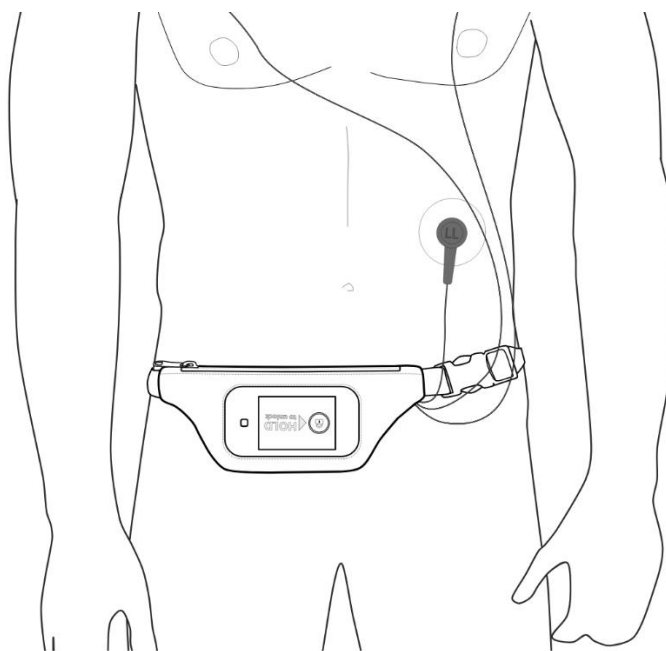


Fig. 5 Pouch fasten around the waist

6.2.2 Pouch for battery charger

The battery charger isn't waterproof. In order to provide IP21 protection in the home healthcare environment, keep charger inside the pouch. Put the charger into the protective pouch before connecting its power cable to the mains.

First, put the cable through the dedicated slot (Fig. 6).

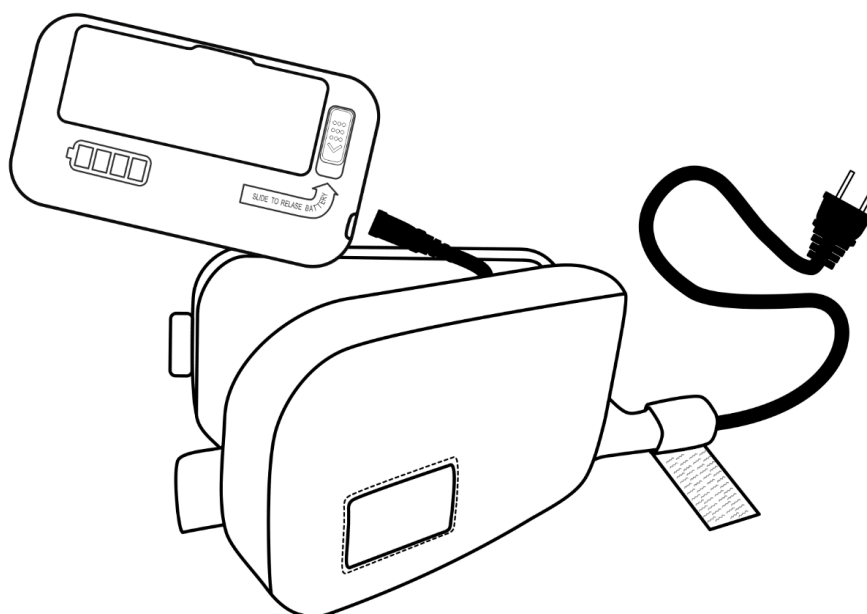


Fig. 6 Putting the cable through the dedicated slot

Fasten the hook-up-loop around the cable (Fig. 7).

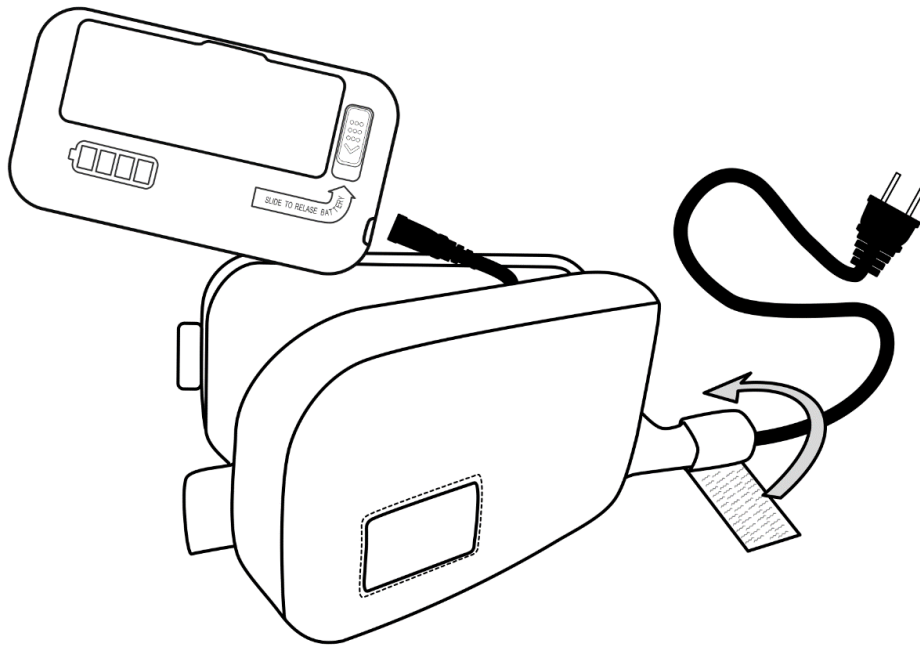


Fig. 7 Fasten hook-up-loop around the cable

Connect the cable with the charger. Fit the charger into the pouch (Fig. 8),

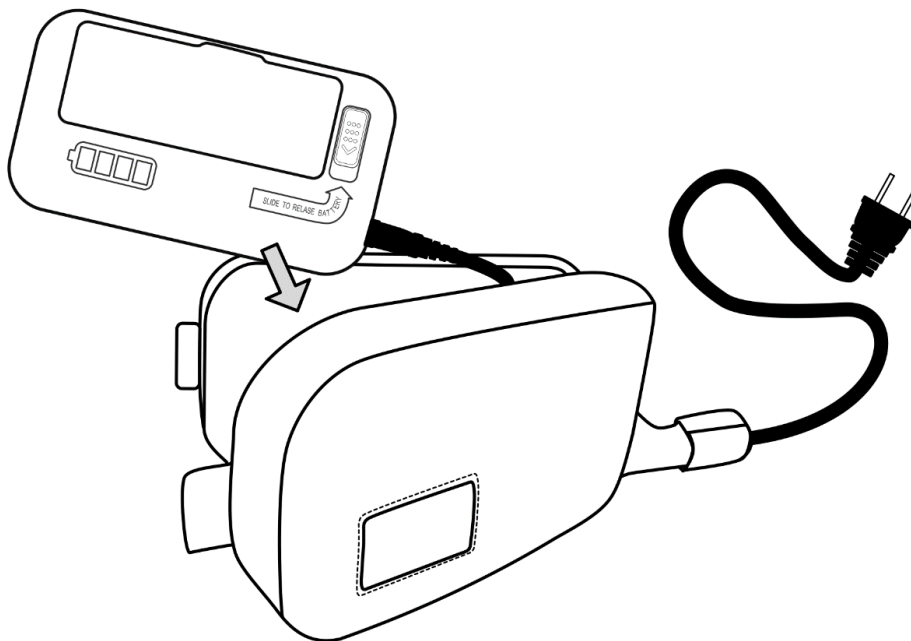


Fig. 8 Putting the charger into the pouch

Close the pouch flap and fasten the hook-and-loop (Fig. 9).

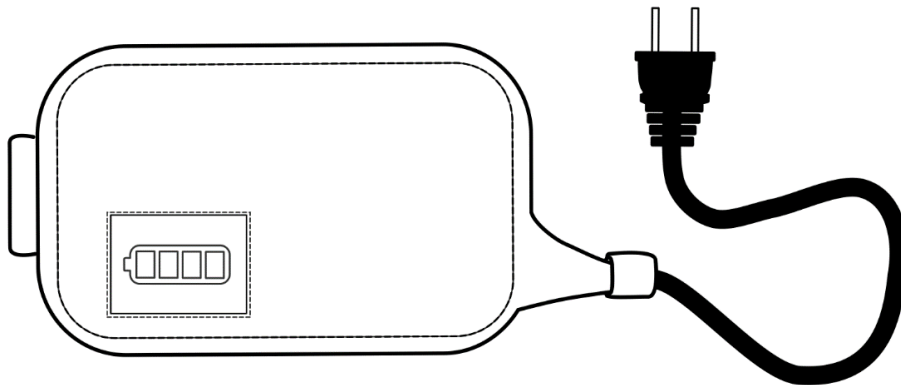


Fig. 9 Battery charger protected against ingress of water

6.2.3 Holster

In the professional healthcare environment holster (transmitter holder) can be used instead of the pouch.

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. 10).

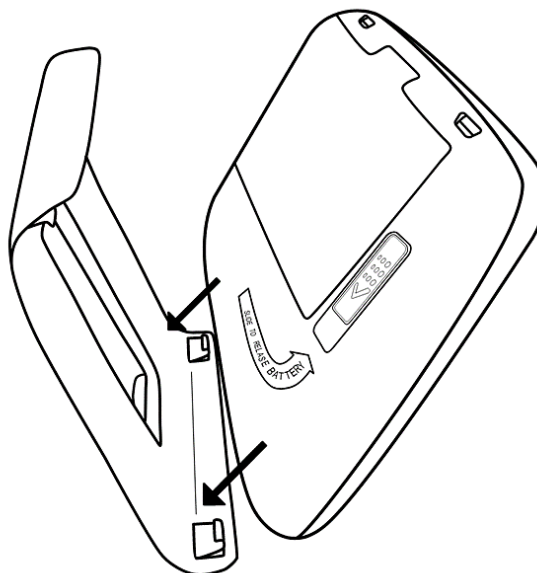


Fig. 10 Putting the device into holster

Ensure that the back of the PocketECG device touches the holster (Fig. 11).

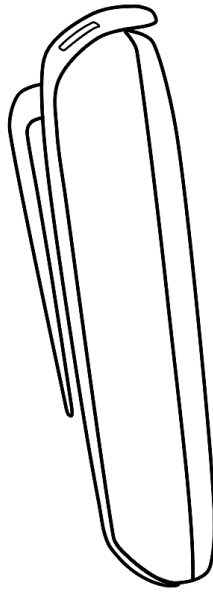


Fig. 11 Transmitter fitted in holster correctly

Holster with the PocketECG device should be placed on the belt or trousers (Fig. 12).

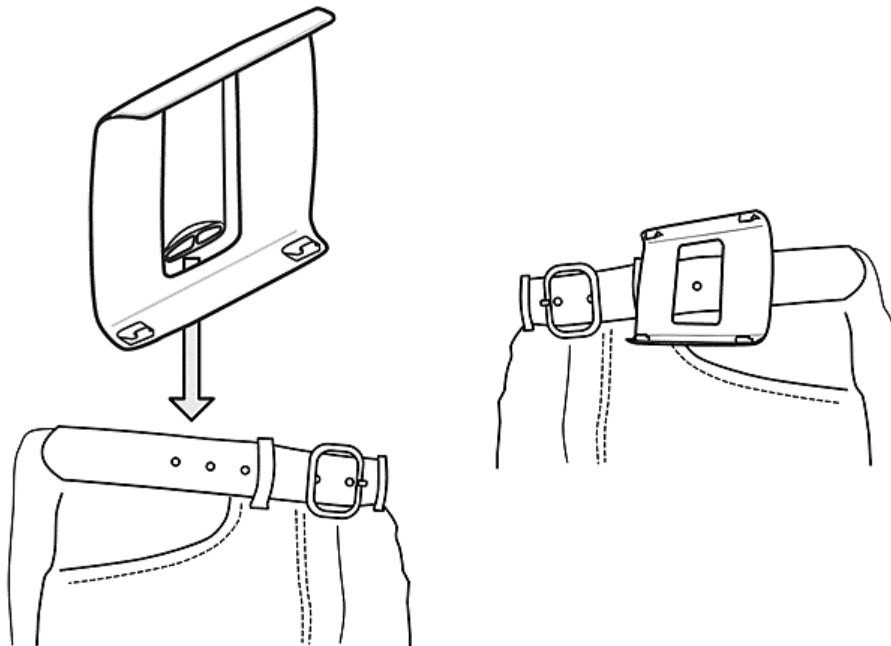


Fig. 12 Holster placement

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

6.3 STARTING THE DEVICE

To provide IP22 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 0.



CAUTION: Prior to starting a diagnostic session read the PocketECG IV instructions for use carefully.

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

CAUTION: The batteries should be charged before the first usage.

In order to start the device, follow the instructions:

- 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. 13).

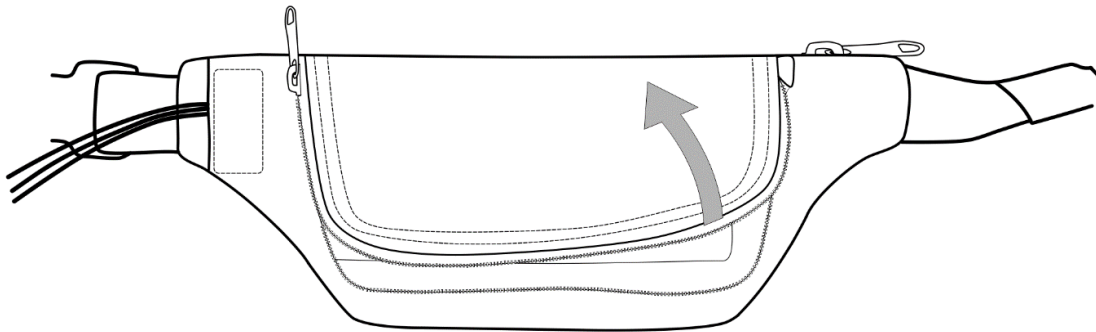


Fig. 13 Opening the flap

- Slide the battery into its compartment until it snaps (Fig. 14).

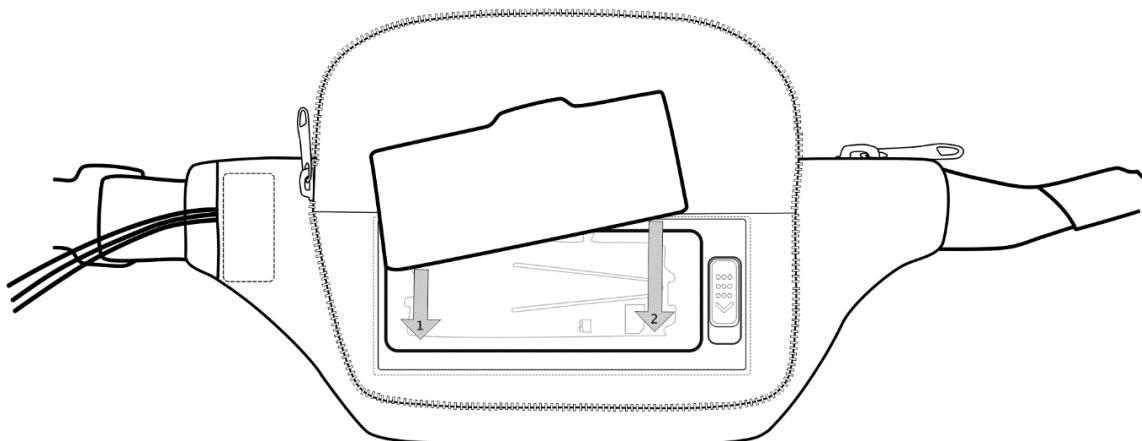


Fig. 14 Inserting the battery

- Close the pouch flap and fasten the zip (Fig. 15).

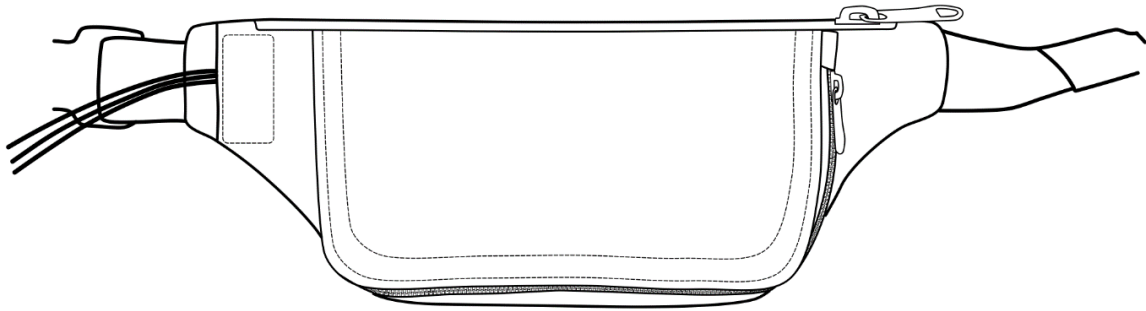


Fig. 15 Closed pouch flap. Transmitter protected against ingress of water.

- The device turns on automatically, and it is ready for starting a 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.
- 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.



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

6.4 STARTING THE RECORDING SESSION

When you are ready for session, press 'Start session' button (Fig. 16). After pressing the button, ECG signal is recorded.

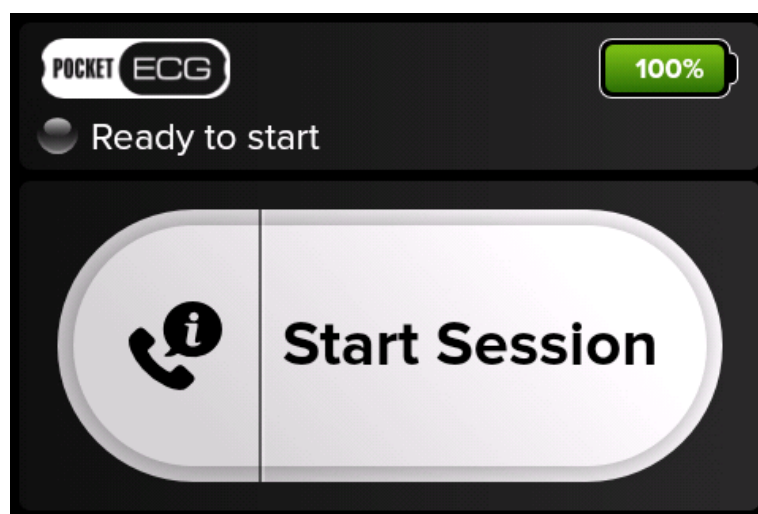


Fig. 16 Starting a new session



WARNING: If after pressing 'START SESSION' button the process is not completed and 'STARTING' status message is presented, contact the device provider. This problem can be a consequence of time synchronization error, communication error or device malfunction.

6.5 CONNECTING THE ECG ELECTRODES

Follow the hook-up procedure:

- Remove hair from the place where the electrode will be attached (places are shown in Fig. 18 and Fig. 18, Fig. 19 and Fig. 20).
- Wipe the chosen site with a damp cloth/wet wipes.



WARNING: DO NOT USE HIGH-PROOF ALCOHOL TO WIPE AS IT MAY DRY UP THE EPIDERMIS AND DISTORT THE ECG SIGNAL TRANSMITTED BY THE DEVICE.

- Place the electrodes on the 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. 18 and Fig. 18, American standard – Fig. 19 and Fig. 20):

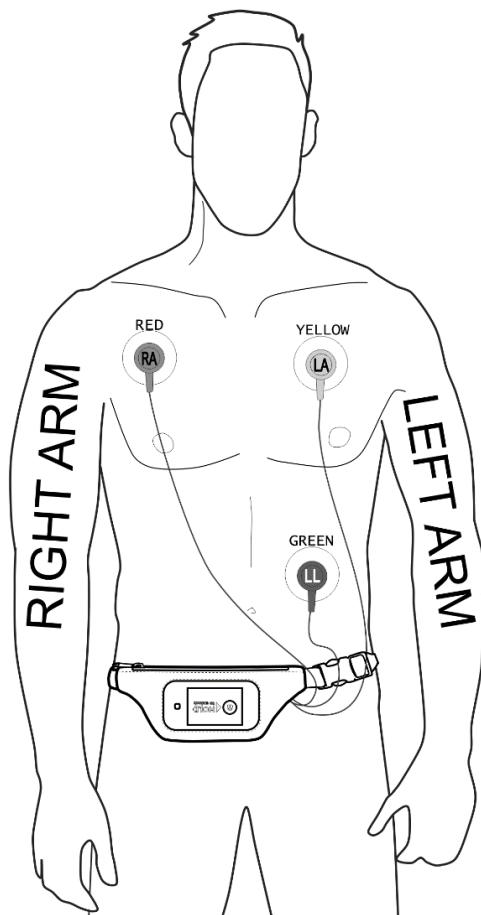


Fig. 17 ECG electrodes and cable clips placement – colors coded according to the European standard

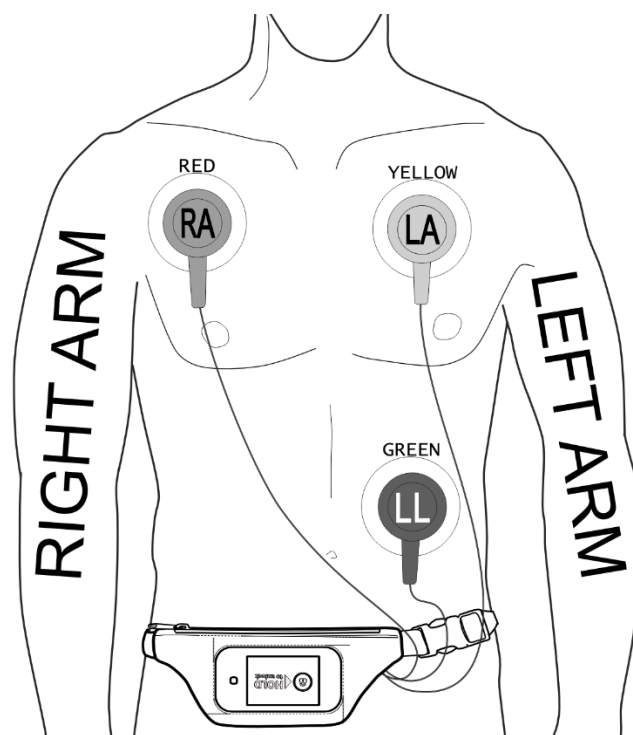


Fig. 18 Enlarged electrodes and cable clips - colors coded according to the European standard (ECG electrodes and ECG snaps are presented oversized to allow user easy distinguishing of their coding and proper hook-up)

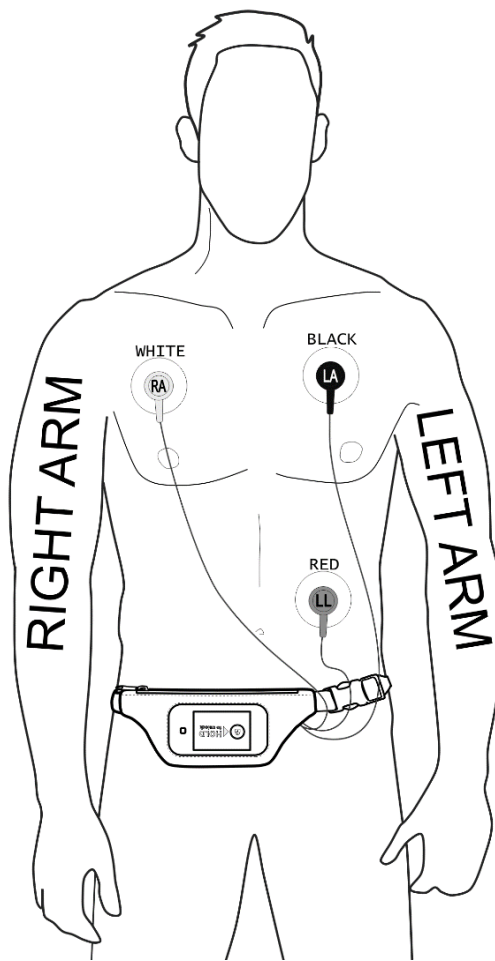


Fig. 19 ECG electrodes and cable clips placement – colors coded according to the American standard

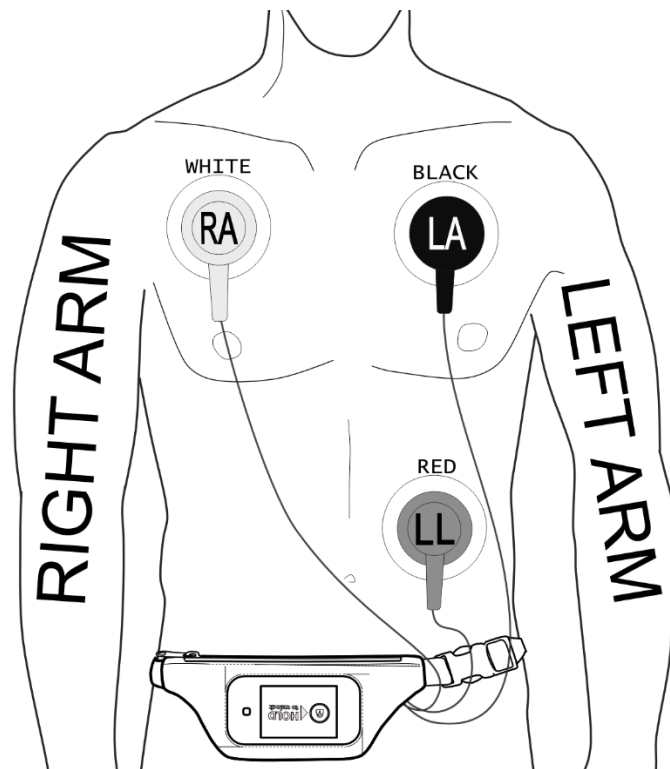


Fig. 20 Enlarged electrodes and cable clips - colors coded according to the American standard (ECG electrodes and ECG snaps are presented oversized to allow user easy distinguishing of their coding and proper hook-up)

- Use only high-quality electrodes with fast conducting gel. Always obey instructions for use provided by the electrode's manufacturer. It is recommended to use electrodes designed for Holter monitoring.
- Single-use electrodes last for a limited 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.
- Secure each lead wire. Cables of the PocketECG transmitter should be attached to the electrodes in a way that reduces movements causing signal artifact.



WARNING: DISCARD ELECTRODES AFTER EACH USE.

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. NEVER CONNECT THE LEAD WIRE SNAPS WITH ANY SOURCE OF ELECTRIC POWER SUCH AS POWER OUTLETS, POWER SUPPLIES, AND BATTERIES.



CAUTION: Always make sure that the electrodes are placed correctly.

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.

6.6 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. 21):

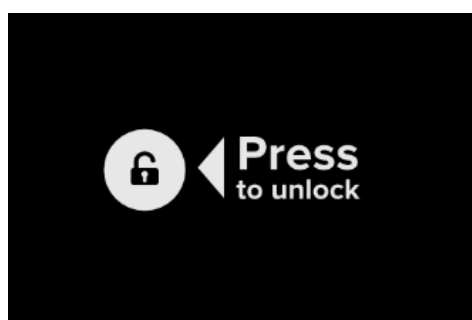


Fig. 21 Unlocking screen

6.7 REPORTING SYMPTOMS

As a patient, you may experience symptoms during monitoring. In order to report symptoms first unlock the screen and then follow the instructions:

- Press the 'Report Symptoms' button (Fig. 22):

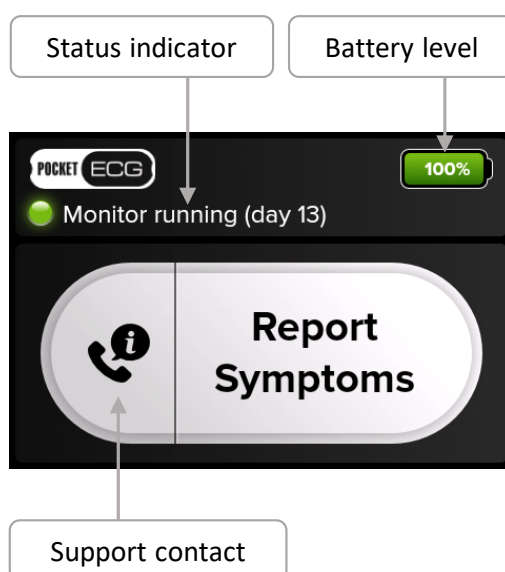


Fig. 22 Dashboard view

- Select experienced symptom by pressing adequate button (Fig. 23):

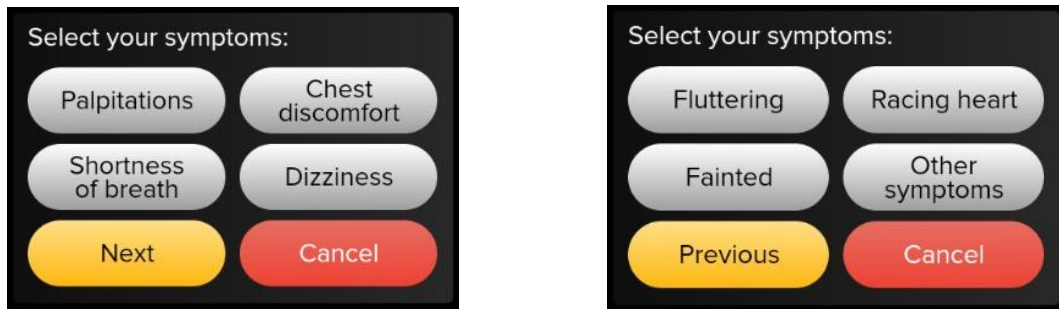


Fig. 23 Selecting experienced symptom

- Press 'Confirm' button to confirm selected symptom. If you want to modify symptom, press 'Modify' button and select another symptom from the list (Fig. 24). Selected symptom is confirmed automatically after 15 seconds if neither 'Modify' nor 'Confirm' button is pressed.

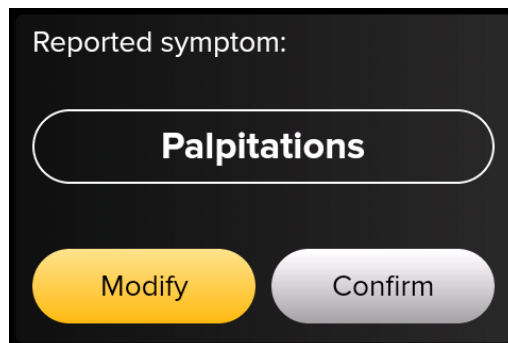


Fig. 24 Symptom confirmation

- Select your activity at the moment of symptom occurrence (Fig. 25):

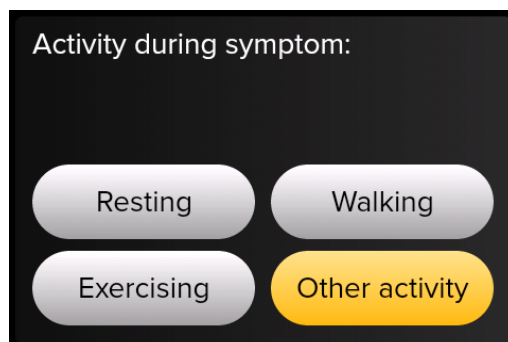


Fig. 25 Selecting activity

6.8 DEVICE STATUS INDICATOR

Device status is presented on the unlocked screen by a dedicated icon and text message presented next to it. 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

6.9 BATTERY STATUS INDICATOR

The 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 %

6.10 STOPPING THE DEVICE

The monitoring session will stop automatically after period of time defined by a physician. In order to turn off the device when session is already finished, remove the battery from its compartment and the device shuts down automatically.



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

6.11 REPLACING THE MAIN BATTERY

The PocketECG transmitter is equipped with backup battery that is intended to supply the device when the main battery is being replaced. When the main battery is being removed during an ongoing session, the transmitter operates continuously powered from the backup battery up to 1 minute.



CAUTION: The backup battery is activated only when a recording session is ongoing.



CAUTION: If the main battery charge level is low, replace it with fully charged one, immediately. If the main battery remains removed from its compartment for a period longer than 1 minute, the transmitter will switch off and the transmission will be suspended.

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.

In order to replace the battery, follow the instructions:

- 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. 26).

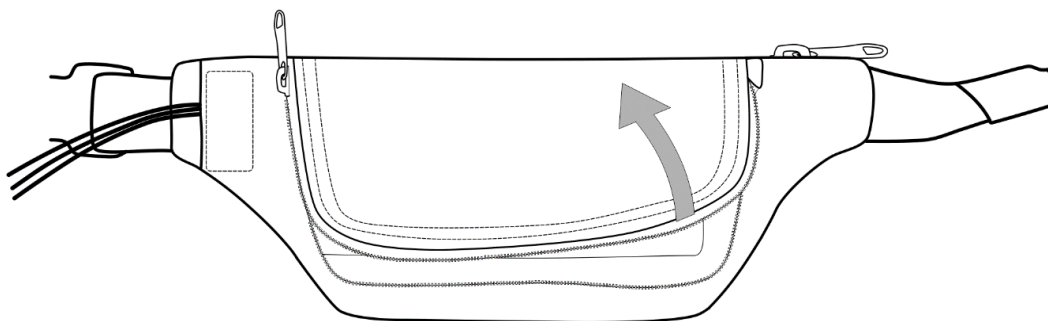


Fig. 26 Opening the flap

- Slide the battery lock to release the battery (Fig. 27) and remove the battery from its compartment.

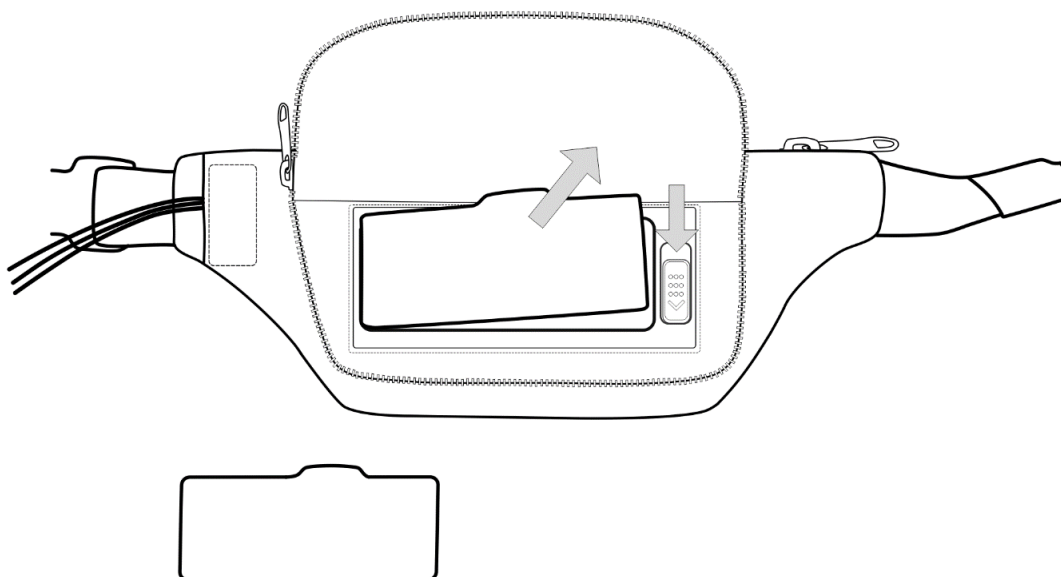


Fig. 27 Taking the battery out

- Place fully charged battery into compartment and push it until the lock clicks (Fig. 28).

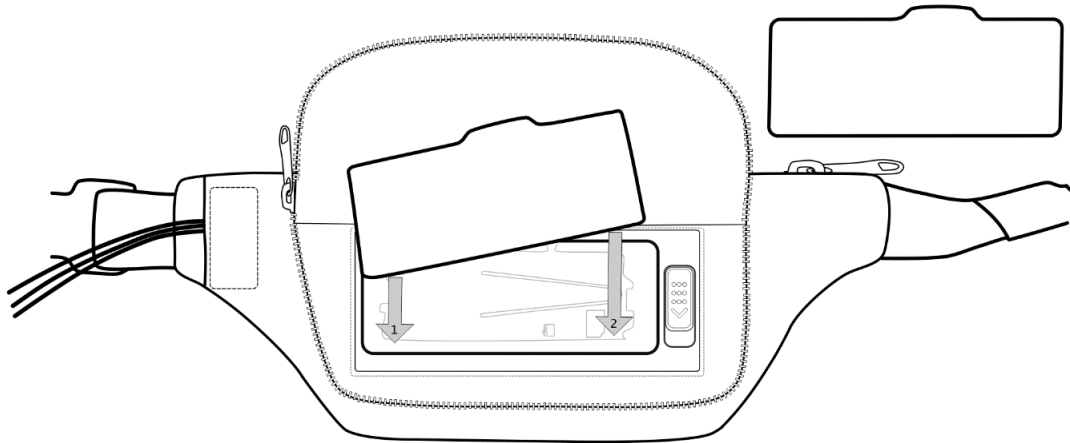


Fig. 28 Replacing the battery

- Close the pouch flap and fasten the zip.(Fig. 29).

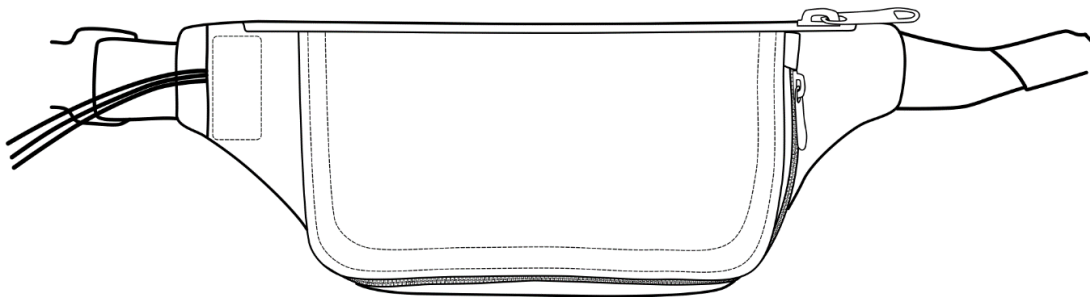


Fig. 29 Closed pouch flap. Transmitter protected against ingress of water.



WARNING: IF THE DEVICE IS NOT GOING TO BE USED FOR A LONGER TIME PERIOD, REMOVE THE BATTERY. THE BATTERY RELIABILITY MAY BE DEGRADED WHEN LEFT IN THE TURNED OFF DEVICE FOR A LONG PERIOD OF TIME.



CAUTION: If the main battery charge level is low, replace it with fully charged one, immediately. If the main battery remains removed from its compartment for a period longer than 1 minute, the transmitter will switch off and the transmission will be suspended.

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.

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

6.12 CHARGING THE MAIN BATTERY

The discharged battery should be put into charger immediately after it is removed from the transmitter if the diagnostic session is intended to be performed for a period longer than 24 hours. In order to set-up the charger and charge the battery follow the instruction:

- Plug the charger into the AC mains.
- Check whether all light indicators blink simultaneously with orange light (the sound is generated if the battery is not inserted into the charger within 15 seconds from the charger powers on).
- Open the PocketECG charger pouch flap upwards (Fig. 30).

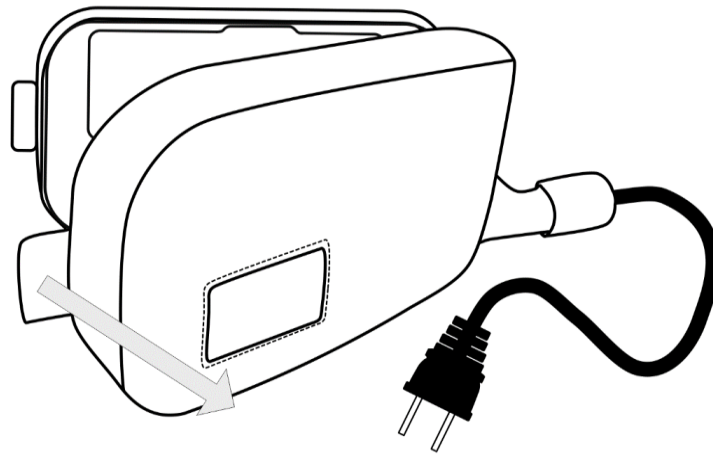


Fig. 30 Opening the flap

- If there is a battery in the charger take it out (Fig. 31).

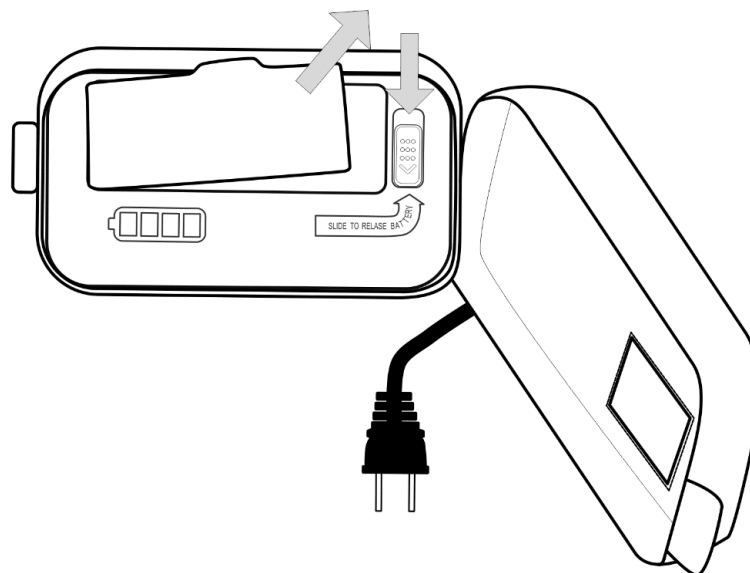


Fig. 31 Taking the battery out

- Put the battery into the charger and verify whether the light indicator flashes orange, indicating that the charging is in progress (the sound is no longer generated) Fig. 32.

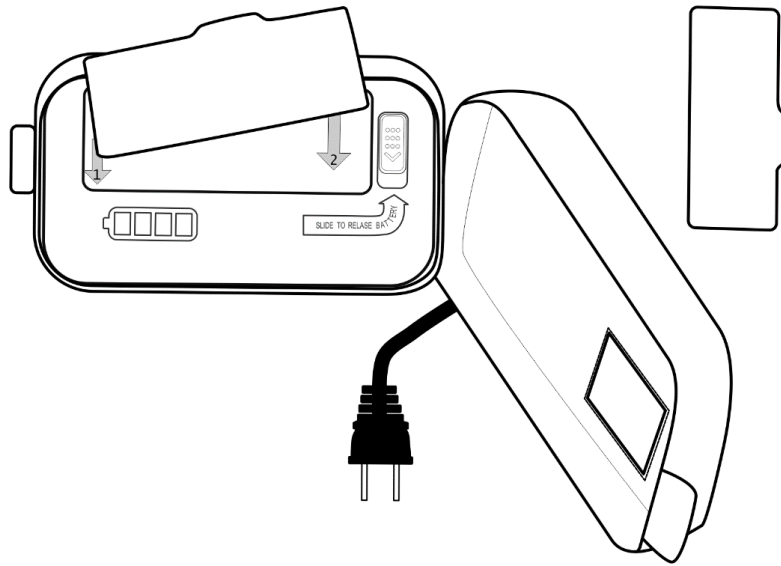


Fig. 32 Replacing the battery

- Close the pouch flap and fasten the hook-and-loop (Fig. 33).

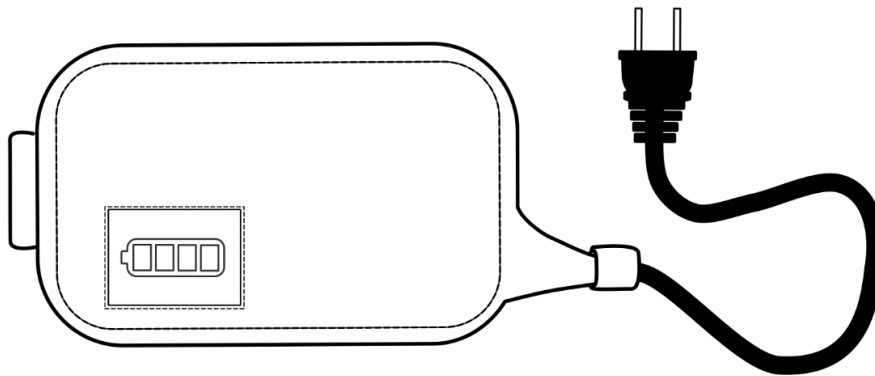


Fig. 33 Battery charger protected against ingress of water

- Wait until all light indicators of the charger change color from orange to green indicating that the battery is fully charged.
- The battery requires ca. 4 hours to be fully charged.
- If the charger generates the sound when the battery has been already inserted into its cradle, the battery may be damaged or deeply discharged.
- To verify whether the 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 because it is damaged and should be no longer used.



WARNING: DO NOT USE OTHER CHARGERS THAN THOSE INTENDED FOR USE WITH THE BATTERY DEDICATED FOR THE POCKETECG TRANSMITTER TO PREVENT THE DANGER OF BATTERY EXPLOSION.

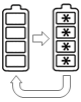
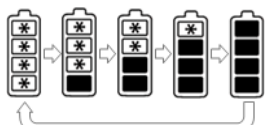
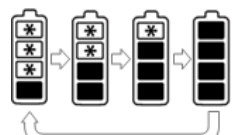
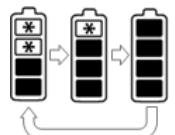
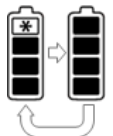



CAUTION: The charging process does not start if the battery is damaged or has been deeply discharged (e.g. kept in the turned off PocketECG transmitter for a long period of time).

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

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.

- 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 %
	All light indicators are turned on.	100 %

Light indicators	Description	Battery level
(green light)		

6.13 CHARGING THE BACKUP BATTERY

- The backup battery is installed inside the PocketECG transmitter and cannot be removed.
- The charging of the backup battery is started automatically.
- The charging of the backup battery is initiated when the charge level falls below the predefined minimum level and the main battery powering the device is fully charged.

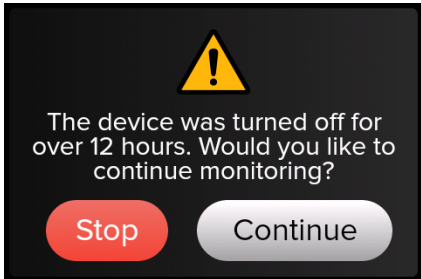




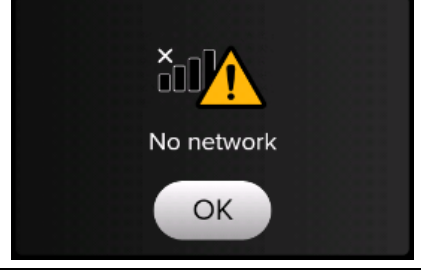
6.14 CONTACT WITH DEVICE PROVIDER

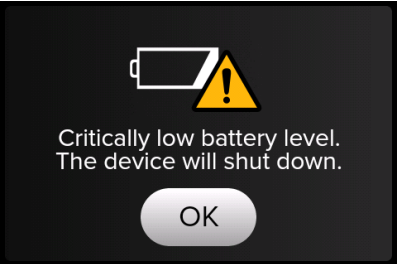

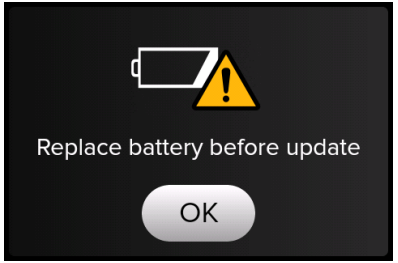
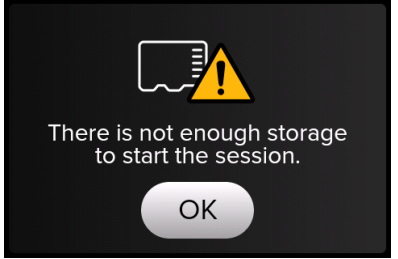
If you are in need of any assistance or encounter any problems with the device you can contact support. To get contact information first unlock the device screen and then press button with phone icon on the main screen.

7 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 °C to 45 °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 condition	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

8 NOTIFICATIONS

NOTIFICATION	DESCRIPTION & ACTION
	<p>The PocketECG transmitter was turned off for over 12 hours.</p> <p style="text-align: center;">↓</p> <p>Make sure, that you have to stop or continue session, call a service provider.</p>
	<p>Battery state of charge is less than or equal to 10 %. The data are not transmitted to the remote server.</p> <p style="text-align: center;">↓</p> <p>Replace the battery with the fully charged.</p>
	<p>The PocketECG transmitter cannot find the battery.</p> <p style="text-align: center;">↓</p> <p>Insert the battery to the PocketECG transmitter.</p>
	<p>Electrodes contact loss. The ECG signal data are not transmitted to the remote server.</p> <p style="text-align: center;">↓</p> <p>Put on the electrodes to your body.</p>
	<p>The microSD card is not installed in its compartment and the session cannot be initialized.</p> <p style="text-align: center;">↓</p> <p>Install microSD card or replace damaged one.</p>
	<p>The PocketECG transmitter cannot connect to the mobile phone network - data cannot be transmitted.</p> <p style="text-align: center;">↓</p> <p>Keep the PocketECG transmitter in the area where the mobile network is accessible.</p>

	<p>Battery state of charge is 2 %, the device will shut down.</p> <p style="text-align: center;">↓</p> <p>Replace the battery with the fully charged.</p>
	<p>The SIM card is not installed in its compartment.</p> <p style="text-align: center;">↓</p> <p>Install SIM card.</p>
	<p>Battery state of charge is less than or equal to 29 %, update will not be initiated.</p> <p style="text-align: center;">↓</p> <p>Replace the battery with the fully charged.</p>
	<p>There is less than 100MB free space on SD card.</p> <p style="text-align: center;">↓</p> <p>Clear memory card data.</p>

User can close notification screen and return to the main application window by pressing OK button. Unless action related to the notification is taken by user the orange colored device status indicator is displayed and adequate information is displayed next to it. The screen with “Connect electrodes” notification displayed in main application window is presented below (Fig. 34).



Fig. 34 Example view with notification

9 ELECTROMAGNETIC COMPATIBILITY & OTHER INTERFERENCES

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.

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 listed diagnostic systems while being monitored with the PocketECG IV device, it is recommended to:

- 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;
- disconnect the ECG lead wires of the PocketECG transmitter from the electrodes placed on your body;
- 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;
- when the examination/treatment is finished, replace the electrodes if necessary and connect the lead wires of the PocketECG transmitter to the electrodes.

10 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

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



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

WARNING: USE OF ACCESSORIES OTHER THAN THOSE RECOMMENDED BY THE MANUFACTURER, WITH THE EXCEPTION OF THE ACCESSORIES SOLD BY THE MANUFACTURER AS REPLACEMENT PARTS FOR INTERNAL COMPONENTS, MAY RESULT IN INCREASED EMISSION OR DECREASED IMMUNITY OF THE DEVICE.

WARNING: 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 THE AUTOMATED ECG SIGNAL ANALYSIS.

WARNING: 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:
 - Wi-Fi (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,
- DIATHERMY, LITHOTRIPSY, ELECTROCAUTERY, RADIOFREQUENCY IDENTIFICATION (RFID), NEAR FIELD COMMUNICATION (NFC), ELECTRONIC ARTICLE SURVEILLANCE (EAS)

CAN AFFECT THE POCKETECG TRANSMITTER.

11 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. Then the device should be recycled according to the local recycling program or refurbished by the manufacturer.

12 CLEANING & STORING











- 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 (70 % ethanol or 70 % isopropyl alcohol).
- 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 room for at least 24 hours).

















CAUTION: Neither the PocketECG transmitter nor the accessories are waterproof.

- Remove the battery from either the transmitter or charger before storing them. This prevents the battery from accidental discharge and reduces the risk of its damage.

13 SYMBOLS USED ON POCKETECG ACCESSORIES

	Recyclable materials
	Indoor use only
	Direct current
	Alternating current
	Date of manufacture
	Class II equipment
	Serial number
IP02	Minimum Ingress Protection class provided by protective pouch
	FCC Logo (Declaration of Conformity)
	Dispose the device in compliance with appropriate regulations
	Unique device identifier

14 SYMBOLS USED ON POCKETECG TRANSMITTER CASING

	Type BF applied part
	Manufacturer's name and address
	Date of manufacture
	Refer to Instructions for use
	Warning
	Caution
	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
	Serial number
	SIM card
	MicroSD memory card
	Unique device identifier

15 MEDICAL INCIDENT, SERVICE, DECLARATION OF CONFORMITY

- In the event of a medical incident, please notify the manufacturer immediately.
- If you would like to receive the declaration of conformity, please contact the manufacturer.
- Service is provided only by Medicalgorithmics S.A. In case of any product malfunction, it 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

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