MEDICALgorithmics
INNOVATIVE SOLUTIONS IN MEDICINE

PocketECG IV

DUAL CHANNEL

Instructions For Use

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CE
0197

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 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.

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 III 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.

COMPLIANCE

The Medicalgorithmics Unified Arrhythmia Diagnostic System PocketECG IV complies with the following regulations:

- the essential requirements of the Council Directive 93/42/EEC,
- the requirements of the United States Food and Drugs Administration,
- the requirements of the Health Canada Medical Devices Regulations.

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

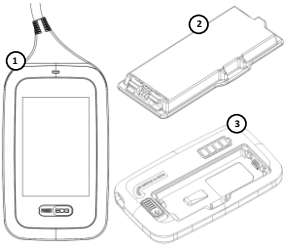
FCC REQUIREMENTS

FCC ID: 2AB2MP4TRA

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.

COMPONENTS & ACCESSORIES



1. The PocketECG transmitter, model: PocketECG IV, type: P4TR-AA-ADS (LTE version for Verizon), P4TR-BA-ADS (LTE version for AT&T)
2. A Lithium-ion battery, type: PECGB-III, rated 3,7 VDC, 1700 mAh
3. An AC plug-in charger type PECGC-III suitable for charging battery type PECGB-III, manufactured by Medicalgorithmics S.A., rated 100 VAC – 240 VAC, 0.2 A, 50/60 Hz

MicroSD memory card

PocketECG pouch

Holster (optional, for indoor use only)

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

- SIM card,
- ECG electrodes.

USING POCKETECG IV

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 0 °C to +43 °C (from 32 °F to 109 °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.

2. Starting the device

- Slide the battery into its compartment, until it will snap.
- The device turns on automatically, and it is ready for starting a new recording session about 30 seconds after the battery is placed in its compartment.
- 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: 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.

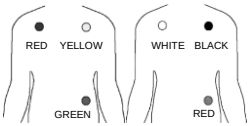
CAUTION: The batteries should be charged before the first usage.

CAUTION: If no image is displayed within 30 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.

3. Connecting the ECG electrodes

- Remove hair from the place where the electrode will be attached.
- Wipe the chosen site with a damp cloth/wet wipes (do not use high-proof alcohol as it may dry up the epidermis and distort the ECG signal).

- Place the electrodes on the patient's body and connect the ECG cables of the PocketECG transmitter as shown.



cable clips colors complying with
the EU requirements – left,
the US requirements – right

- 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.
- 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.

4. Reporting symptoms in a patient view

- Press the 'Report Symptoms' button.
- Select observed symptom from the list.
- Indicate when symptoms occurred and then confirm your choice.
- If you select wrong symptom, you can always modify it. Otherwise, the selected symptom is confirmed automatically after 5 seconds.

1. Button for patients to report symptom
2. Battery level indicator
3. Signal strength indicator

5. Stopping the device

- To switch the transmitter off ensure that the recording session is finished. Then you can remove the battery from its compartment.

WARNING: Never ship the PocketECG transmitter/charger with the main battery inserted into its compartment.

6. Replacing the main battery

- The discharged battery should be charged immediately if the diagnostic session is intended to be performed for a period longer than 24 hours.
- Slide the battery lock to release the battery.
- Remove the battery.
- Place fully charged battery into compartment and push it until the lock clicks.
- 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.
- When the battery gets damaged or is worn out, follow standard disposal procedure for Lithium-ion batteries.

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.

7. Charging the main battery

- 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).
- 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).
- 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 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.
- 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 backup battery is activated only when a recording session is ongoing.

8. 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.

TECHNICAL PARAMETERS

Model	PocketECG IV	
Type	P4TR-AA-ADS (LTE version for Verizon), or P4TR-BA-ADS (LTE version for AT&T)	
Powered by	A Lithium-ion battery 3.7 V type: PECGB-III (1700 mAh)	
Wireless communication	Verizon version: B4(AWS1700) B13(700)	AT&T version: B2 B4(AWS1700) B12(700)
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	
Dimensions	167x79x14.5 mm (without cable)	
Weight	161 g	
Temperature	operating conditions	0 °C to 43 °C (32 °F to 109 °F)
	transport and storage conditions	-20 °C to 60 °C (-4 °F to 140 °F)
Relative humidity	operating conditions	15 % to 93 %, non-condensing
	transport and storage conditions	up to 93 %, non-condensing
Atmospheric pressure	operating conditions	700 hPa to 1060 hPa
	transport and storage conditions	

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.

- DO remove electrodes, patient lead wires, and the PocketECG transmitter from the patient before defibrillation.
- DO maintain a minimum distance of 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.
- DO keep the PocketECG transmitter in the protective pouch with protection class at least IP02 in all outdoor applications.
- DO keep the device and its accessories in dry conditions when showering, bathing or washing. Product is not watertight.
- DO keep the device and its accessories away from infants and children to avoid danger of swallowing.
- DO NOT use the device in infants weighing less than 10 kg.
- DO NOT use the device in intensive care units. It should not be used with high-frequency surgical devices or directly on the heart.
- 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.
- 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.
- DO NOT use the device in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
- DO NOT position PocketECG battery charger so that it is difficult to operate the detachable power supply cord.
- DO NOT service the device while in use with a patient, excluding main battery replacement.
- DO NOT attempt to open or service neither the battery pack nor the transmitter.
- 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 ºC (140 ºF). 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.
- 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.
- 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.

NOTIFICATIONS

NOTIFICATION	DESCRIPTION	ACTION
The device was turned off for over 12 hours. Would you like to continue monitoring?	The PocketECG transmitter was turned off for over 12 hours.	Make sure, that you have to stop or continue session, call a service provider.
ECG Module Error	The ECG module malfunction.	Turn off and then turn on the device. If the module still does not operate correctly, call a service provider.
Replace Battery	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.
Insert Battery	The PocketECG transmitter cannot find the battery.	Insert the battery to the PocketECG transmitter
Connect Electrodes	Electrodes contact loss. The ECG signal data are not transmitted to the remote server.	Put on the electrodes to your body.
No Memory Card	The microSD card is not installed in its compartment and the session cannot be initialized.	Install microSD card or replace damaged one.
No Network	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.
Critically low battery level. The device will shut down.	Battery state of charge is 2 %, the device will shut down.	Replace the battery with the fully charged.
Replace battery before update	Battery state of charge is less than or equal to 29 %, the update will not be initiated.	Replace the battery with the fully charged.
Software update in progress	Transmitter software is being updated.	Do not remove the battery when the message is visible.
Data synchronization is required. Make sure that this device has 3G network coverage.	Data need to be transmitted to the remote server.	Ensure that 3G network coverage is available.

ELECTROMAGNETIC & 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.

EFFECTIVE RADIATED POWER (ERP)

Frequency (MHz)	Mode	ERP (dBm)

In order to resolve and prevent interference issues, above table presents the operating frequencies of the PocketECG CRS transmitter and the associated Effective Radiated Power (ERP).

Commented [KW1]: Above table will be filled after completion of the measurements.

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.

MAINTENANCE

- The PocketECG transmitter type: P4TR-AA-ADS, and P4-TR-BA-ADS and battery charger type: PECGC-III, 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.

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. Neither the device nor the accessories are waterproof. 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).
- 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.

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)

SYMBOLS USED ON POCKETECG TRANSMITTER CASING

CE 0197	CE mark (Council Directive 93/42/EEC)
	Type BF applied part
	Manufacturer's name and address
	Date of manufacture
	Consult 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	MR unsafe
SN	Serial number
Segurança	Brazilian National Institute of Metrology, Quality and Technology (Inmetro) certification mark
	Australian Communications and Media Authority (RCM) certification mark
SIM	SIM card (GSM)
micro SD	MicroSD memory card

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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Medicalgorithmics S.A 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.

POCKET ECG