Product Manual

VitalJacket® SDK

WEARABLE ECG

www.sdk.vitaljacket.com

Biodevices S.A.
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O NOVO NORTE
PROGRAMA OPERACIONAL REGIONAL DO NORTE
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VitalJacket® SDK

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Product Information

T-shirt

The VitalJacket® 1L has 3 springs and the VitalJacket® 5L Motion has 6 springs where the signal acquisition electrodes should be connected. The t-shirt also has a plug, inside of a pocket, where the electronic device should be connected.

Electronic Device

The electronic device allows acquiring the Electrocardiogram (ECG) signal and the heart rate. All data acquired will be stored in a SD Card (provided as accessory). Furthermore, this device has Bluetooth communication for sending/receiving data. The electronic device has 3 lights that indicate the state:

- Red light: heart rate
- Green light: device charging
- Blue light: Bluetooth connected.

Battery charging and charger

To charge the battery of the electronic device, it should be connected to the battery charger provided. The green light (power supply) should switch on. While this light is on, the device is charging.

Accessories

A SD Card is provided to be used with the electronic device. The VJ Desktop Reader must be used to configure the SD Card.

The electrodes can be bought from Biodevices, S.A. or at a specialized store.

We call your attention to the fact that the system was tested with electrodes provided by Biodevices, S.A. Biodevices, S.A. does not take any responsibility for any bad results deriving from the use of other electrodes.

Note: There are electrodes on the market with different features and applications. You should choose the most suitable electrodes.

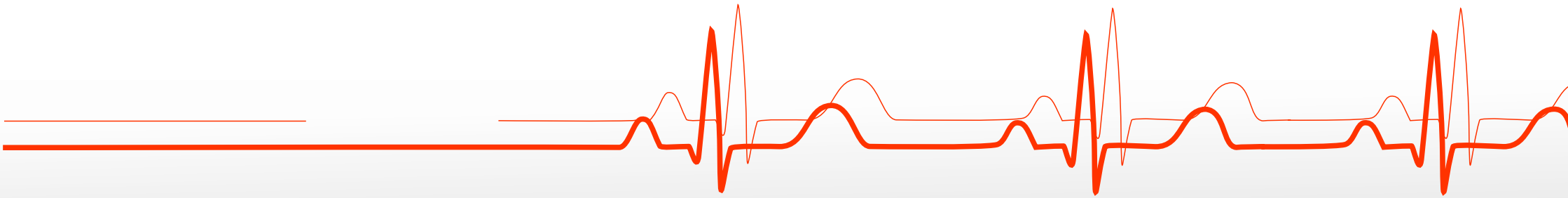
Safety Precautions

Symbols

Symbol	Description
	Bluetooth
	Caution (consult safety manual)
	Ponto verde
	Recycable package
	Waste Electrical and Electronical Device
	Manufacturer
	Fragile
	Keep dry
	Keep away from heat

Handling Scope

The VitalJacket® t-shirt is an ECG signal and heart rate monitoring system.



LEGAL NOTICE AND DISCLAIMER

ATENTION: Although VitalJacket is a certified medical device, its developer version is NOT certified for diagnosis usage. It is intended for R&D and development purposes only. Users of VJ SDK can submit their final developments to medical certification. All contents of our product are compliant with the European Medical Device directive 93/42/EEC but, being a developer's version, it's not certified.

Warranty

Biodevices, S.A. guarantees that the VitalJacket® electronic device is free from material or manufacture defects, for a period of 2 years from the date of the purchase (except for the battery-6 months and disposable electrodes). For that purpose, the owner should make proof of purchase.

Exclusions

The warranty does not cover damages caused by repairs done by people or agents not authorized by Biodevices, S.A.

The warranty does not cover damages caused by bad handling, accidents, or incorrect maintenance of the VitalJacket® t-shirt.

The warranty does not cover cracked, broken boxes or that present signs of visible impacts.

Do not open this electronic device. Such violation will render the warranty null and void.

Handling Safety Precautions

Read the user's instructions provided before using the VitalJacket® t-shirt.

The bluetooth symbol, in relief in the electronic device, should be directed to the outside of the t-shirt.

Battery charging must be done with the electronic device outside the t-shirt.

Handle the electronic device with care, avoid dropping and strong impacts.

The electronic device is not waterproof and may be irretrievably damaged if water is allowed inside.

Environmental Information

Packing

The packing is made of 100% recyclable material, and it contains the respective symbol.

For its disposal, it is mandatory to comply with a certain number of rules on packing legislation. The packing material (plastic bags, etc.) should be kept out of the children's reach, given that it is potentially dangerous.

Electronic Device

This electronic device complies with the European Directives 2002/96/EC, Waste Electrical and Electronic Equipment (WEEE) and 2002/95/EC, Restriction of Hazardous Substances (RoHS). The symbol contained in the product or accompanying documentation indicates that rather than handle this product as household waste it should be delivered at specialized centres that collect and recycle electrical and electronic equipment. Disposal of this product must be carried out in accordance to the regulations of your local authority.

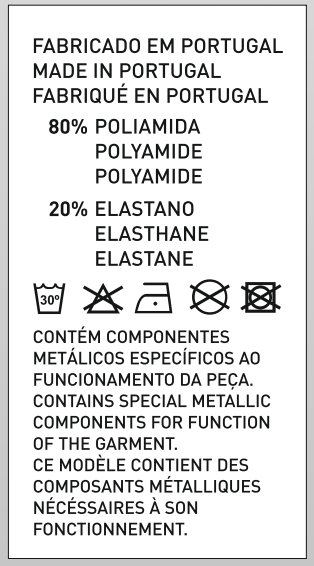
For information on handling, recovery and recycling this product, contact the respective centre in your local area, the household waste pick up service, or the shop where this product was purchased.

Requirements for Cleaning and Disinfection

Remove the electronic device before wash the t-shirt.

T-shirt

Wash:



Machine wash at 30 º C.

Do not bleach.

Iron at low temperature.

Do not clean dry.

Do not tumble dry.

Equipment

T-shirt

Electrodes

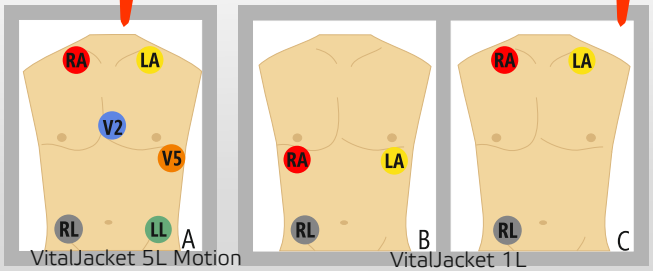
SD Card

Electronic Device

Charger

Dress the t-shirt

1.A. Clean with alcohol and dry very well the zones of the body where the electrodes will be placed.
In version **VitalJacket® 5L Motion**, the placement of the electrodes must follow the image placed inside the t-shirt (image A).
In version **VitalJacket® 1L**, the placement of the electrodes should follow the orientation of the image B or image C.

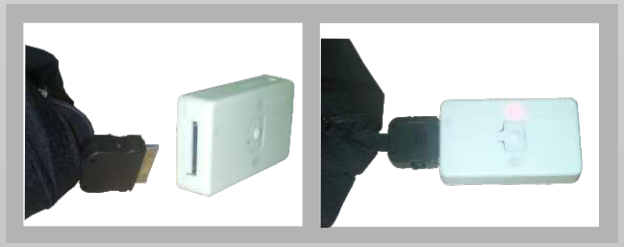


1.A Correct placement of the electrodes.

1.B. Dress the t-shirt.
Fix the springs inside the t-shirt to the electrodes placed in your body. **You should hear a click**.


1.B Fixing the springs.

1.C. Check that the electronic device has a SD card and afterwards connect it to the plug inside the pocket of your t-shirt. A red light should start blinking.
When the **red light is blinking normal** (1 time per second) the device is acquiring the signal and write data on SD card.
If the **red light don't blink**, remove the SD card from the electronic device and put it back again.
If the **red light is blinking fast** (3 times per second) the SD card is full and don't record the data.


1.C Connecting electronic device.

1.D. Place the electronic device inside the pocket with the red light **facing outward** and close the pocket. The **VitalJacket®** is now working and acquiring the ECG signal.
In the center of the electronic device there is an event button that allows to switch on or off


1.D Electronic device in operation.

Color code of the electronic device

Red light (Working)

Blinking normal (1 time per second) - device is acquiring signal and writing data in SD card

Blinking fast (3 times per second) - device is acquiring signal but is not recording data, the SD card is full

Don't blink - remove the SD card from the electronic device and put it back again

Green light (Battery)

Blinking slow (1 time per 5 seconds) - battery under 30%

Blinking normal (1 time per second) - battery under 15%

Blinking fast (3 times per second) - battery under 5%

Light on - battery charging, when the light turns off the battery is fully charged

Blue light (Bluetooth)

Blinking normal (1 time per second) - Bluetooth is active but is not connected to any electronic device

Blinking 5 times and from then blinks slowly (1 time per 8 seconds) - Bluetooth is on and the electronic device is empaired with another device (PC, PDA, etc....)

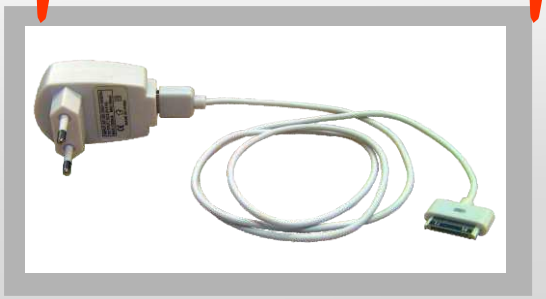
Prepare the next exam

1.A. Connect the USB cable to the USB charger supplied in the box.

Unplug the electronic device from the t-shirt and plug it to the power supply using the USB cable and the USB charger. **Alternatively you can plug the electronic device to your PC using the USB cable.**

A green light will turn on. It will turn off when the battery is fully recharged.

In use, a green blinking light indicates that remains only 5% of the battery, about 30 minutes.

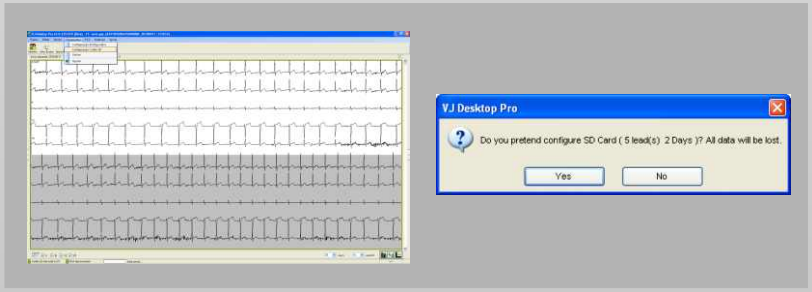


1.A USB cable and USB charger.

1. B. Place the SD card in your PC's card reader.

Open VJ Desktop Reader and select the option **Configure SD Card** in the **Tools Menu**.

A message asking to confirm the format is displayed. Click **Yes** to confirm to finalize the configuration.



1.B SD card configuration.

FAQs

What it is?

VitalJacket is a monitoring system of ECG signal and heart rate.

VitalJacket SDK is a tool to provide all stream control parameters (Sampling Frequency, Gain, etc.), Mode Switching (Configuration/ Recording); RTC settings; Pushbutton event (on Bluetooth stream and SD Card)

*App Windows for test and data acquisition

*App Android

*Tools for data export: full ECG wave (1-5 leads), beat-by-beat R-R (ms), QRS position (sample offset), Triaxial accelerometer (X,Y,Z; +/-4g)

*Windows DLL for QRS detect (Pam & Tompkins, MIT-BIH database validated)

Why should we use VitalJacket SDK?

To facilitate VJ integration for R&D projects, new prototypes and products To provide developers a new Software Development Kit and API for different programming environments with drivers and sample code To allow VJ configuration trough a simple messaging protocol/ Mode switching to enhance its adaptability

Where to buy?

Vitaljacket® can be directly bought to Biodevices S.A. (www.sdk.vitaljacket.com)

How many ECG leads?

There are two versions of the product, the VitalJacket® 1L with 1 lead and the VitalJacket® 5L Motion with five leads, both have the function of screening and comfortable monitoring of ECG for long periods of time. The VitalJacket® 1L uses three electrodes to record an ECG lead (D1). The VitalJacket® 5L Motion uses six electrodes to record three limb leads (D1, D2 and D3) and two precordial leads.

Troubleshooting and Corrective Measures

Problem	Cause	Corrective Measure
No signal or heart rate.	The electrodes are badly positioned.	Check the position of the electrodes according to the instructions provided in the User's Manual.
	The electronic device battery is low or completely worn out.	Charge the electronic device battery
The electronic device will not turn on.	The electrodes are badly positioned.	Check the position of the electrodes according to the instructions provided in the User's Manual.
	The electronic device is badly directed.	The Bluetooth symbol in the electronic device should be facing the outer part of the T-Shirt.
The signal and the heart rate shown are out of control.	The electrodes are badly positioned.	Check the position of the electrodes according to the instructions provided in the User's Manual.

Specifications

Product Description

The VitalJacket® is a Class IIa medical device that allows to do an continuously and noninvasively electrocardiogram (ECG). The product consists of a t-shirt and an electronic device.

Electronic Device

Dimensions:

66 x 38 x 16 mm

Weight (including battery pack):
50 g

Communications Specifications (Bluetooth 2.0):

Class: 2

Power: 2.5 mW

Frequency: 2.4 Ghz

Range: 10 m (direct line)

Transport and storage specifications:

Temperature	-20ºC a + 45ºC
Humidity	10% a 90% non-condensing
Air pressure	700 a 1060 hPa

Operating Conditions:

Temperature	-20ºC a + 45ºC
Humidity	10% a 90% non-condensing
Atmospheric pressure	700 a 1060 hPa
Current	40 mA/h
Power	132 mW/h
Tension	3.3 V
Max. Autonomy	72h

⚠ Note: The index of protection against electric shock is not applicable because the electronic device is never a charge when in use.

⚠ **Note:** The electronic devices are all identified by a MAC address with the following format: 00-23-FE-xx-xx-xx.

Precautions, Restrictions and Warnings

Guideline and Manufacturer's Declaration - Electromagnetic Emissions

The VitalJacket®t is intended for use in an electromagnetic environment as specified below. The consumer or user of VitalJacket® must ensure it is used in this environment.		
Tests	Conformity	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The VitalJacket®sends electromagnetic energy in order to perform the planned function. Nearby electronic equipment may be affected.
RF emissions CISPR11	Class B	The VitalJacket® is suitable for use in all establishments other than domestic and those directly connected to public low-voltage network, which supplies buildings for domestic use, provided that the following notice misunderstood: Warning: This equipment is intended for use only by healthcare professionals. This equipment may cause radio interference or disrupt equipment operations nearby. It may be necessary to adopt procedures for mitigation, such as reorienting or relocating the VitalJacket or shielding of the place.
Harmonics emissions IEC 61000-3-2	Class B	
Voltage fluctuations emissions IEC 61000-3-3	N/A	

Note: It is very important that the true effectiveness of the RF shielding and the RF filter real attenuation of the shielded place are checked to ensure they meet or exceed the specified minimum values.

Guideline and Manufacturer's Declaration - Electromagnetic Immunity

The VitalJacket® is intended for use in an electromagnetic environment as specified below. The consumer or user of VitalJacket® must ensure it is used in this environment.

Immunity tests	IEC 60601 test level	Conformity level	Guidelines - Electromagnetic environment
ESD IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	The soil must be wood, concrete or ceramic tiles. If soils are covered with synthetic material, the relative humidity should be at least 30%.
Burst IEC 61000-4-4	± 2 kV power-line ± 1 kV inputs/outputs	N/A	The quality of the power source must be like the typical commercial or hospital environment .
Surge IEC 61000-4-5	± 1 kV differencial mode ± 2 kV common mode	N/A	The quality of the power source must be like the typical commercial or hospital environment .
Voltage drops, short interruptions and voltage fluctuation/flicker	<5% UT (>95% UT drop) to 0,5 of the cycle 40% UT (60% UT drop) to 5 cycles 70% UT (30% UT drop) to 25 cycles <5% UT (>95% UT drop) to 5 s	N/A 3 A/m	The quality of the power source must be like the typical of commerce or hospital environment. If VitalJacket® requires continued operation during interruptions of the power source, it is recommended that the VitalJacket® is powered by an uninterruptible power source or a battery.
Interference immunity against magnetic fields with power frequency (50 Hz / 60 Hz) IEC 61000-4-8	3 A/m		The magnetic fields in the power frequency should be at characteristic levels of a typical commercial or hospital environment.

Guideline and Manufacturer's Declaration - Electromagnetic Immunity

The VitalJacket® is intended for use in an electromagnetic environment as specified below. The consumer or user of VitalJacket® must ensure it is used in this environment.

Immunity tests	IEC 60601 test level	Conformity level	Guidelines - Electromagnetic environment
Interference immunity to power-line-based intereference IEC 61000-4-6	3 Vrms 150 kHZ to 80 MHz	N/A	The VitalJacket® should only be used in a shielded location with a minimum efficiency RF shielding and, for each cable entering the shielded location, a minimum attenuation of the RF filter (efficiency shield / specification of the attenuation filter). Field strengths outside the shielded place from fixed RF transmitters, determined by an electromagnetic site inspection, should be less than 3 V/m **a**.
Interference immunity against radiated interference IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Interference may occur in the vicinity of equipment marked with this symbol: 

Note 1: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Note 2: It is essential that effectiveness and efficiency of the shielding and attenuation filter of the shielded location is checked to ensure they reach the minimum specification.

a The field strengths of fixed emitters, such as broadcast stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio and TV broadcast can not be theoretically predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, should be considered an electromagnetic local inspection. If the field strength far from the place where the shield is used VitalJacket® exceed 3 V/m, the VitalJacket® should be monitored to verify normal operation. If anormal performance is observed, additional measures may be needed, such as replacing the VitalJacket site or use a shield with an efficiency of RF shielding and attenuation filter higher.

Coding Set Element and Accessories

Description	Code
T-shirt	1
PCB	2
Charger	3
SD Card	4
Products Manual	5
CD with software	6
Electrodes	7

Manufacturer's Declaration

Conformity with the European requirements

Applicable Directives
DIRECTIVE 2006/95/CE
Electrical equipment for use within certain voltage limits (LV)
DIRECTIVE2004/108/CE
Electromagnetic compatibility (EMC)
DIRECTIVE 1999/5/CE
Radio equipment and telecommunications terminal equipment (R&TEE)
DIRECTIVE 2002/95/CE
Restricting the use of certain dangerous substances in electrical and electronic equipment (RoHS)
DIRECTIVE 2002/96/CE
Waste of electrical and electronic equipment (WEEE)

Harmonized Standards
ETSI EN 300 328 V1.7.1
Electromagnetic compatibility and radio spectrum (ERM); Systems for broadband transmission; Data transmission equipment operating in the frequency of 2.4 GHz ISM band that use modulation techniques in broadband.
EN 301 489 part 1&17 V1.4.1
Electromagnetic compatibility (EMC) standard for radio equipment and services, Part 17: Specific conditions for broadband transmission systems at 2.4 GHz and equipment RLANs high-performance 5 GHz
EN 60950-1:2006
Information technology equipment. Security. General requirements.

Support and Customer Support

Repairs and servicing shall be performed by an Authorized Service Center of Biodevices S.A.

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