

## SAFETY MANUAL VITALJACKET SDK

### What is VitalJacket SDK?

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), Tri-axial accelerometer (X,Y,Z; +/-4g)
- Windows DLL for QRS detect (Pan & Tompkins [1], MIT-BIH database validated [2])

[1] Pan J and Tompkins WJ. A Real-Time QRS Detection Algorithm. IEEE Transactions on Biomedical Engineering 32(3):230-236, 1985

[2] MIT-BIH Arrhythmia Database: <http://www.physionet.org/physiobank/database/mitdb/>



### Please read before proceeding

BATTERY IS NOT FULLY CHARGED UPON PACKAGE OPENING.

WARRANTY WILL NOT BE VALID IF DEVICE IS OPENED OR SHOWS SIGNS OF ABUSE.

**INFORMATION ABOUT INTELLECTUAL PROPERTY RIGHTS**

Biodevices licenses the power to use VitalJacket equipment. All equipment and software is property of Biodevices and the company grants the Client the rights of use.

Biodevices reserves the right to withdraw the software license if confirmed violation, misappropriation, copy or alteration is proved, without previous knowledge of the company and written consent.

This license is limited by:

- Prohibition of sublicensing for production or resale
- Maintenance of Biodevices intellectual property rights

**SAFETY PRECAUTIONS FOR VITALJACKET SYSTEM USE**

Before using VitalJacket all instructions should be carefully read.

The *Bluetooth* symbol (presented slightly raised) at the face of the digital recorder must be directed to the plastic window on the t-shirt.

The battery charging of the digital recorder must be performed with the equipment outside the t-shirt pocket.

The digital recorder must be handled with care without dropping or submitted to great shocks.

**IMPORTANT INFORMATIONS ABOUT HEALTH AND SAFETY PRECAUTIONS**

While using the VitalJacket system several safety warnings must be taken into consideration in order to avoid possible damages or assignment of legal liabilities.

Save and follow all operation and safety instructions. Sought through all operation instructions advisories.

To minimize risk of body injury, electrical shock, fire or equipment damage read carefully the following instructions.

## Digital Recorder

### ELECTRICAL SAFETY

This product must be used with the assigned battery. Any other use may be dangerous and invalidate the approval of the system.

### SAFETY PRECAUTIONS FOR GROUND CONNECTION INSTALATION

- ⚠ **The connection of any equipment with improper ground connection may result in an electrical shock.**

This product is equipped with an USB cable for connection to a personal computer, laptop or AC adaptor provided with the VitalJacket system. Make sure you plug the AC adaptor or computer to a ground connection before charging the digital recorder. The personal computer adaptor incorporates a ground connection conductor and plug. The plug must be connected to an electrical socket correctly installed with a ground connection according to local rules.

### SAFETY PRECAUTIONS FOR THE ELECTRICAL SOURCE UNIT

- **Use the correct external electrical source unit**

The product must be operated only with the external electrical source unit indicated in the electrical classification label. If you are not sure of the type of required electrical source unit consult your local distributor or the local electricity company.

- **Handle the battery set with care**

This product contains a lithium ion battery. Do not attempt to open the equipment or repair the battery. Do not dismantle, compress, pierce or provoke a short circuit in any of the internal or external circuits of the battery; do not place inside a water or heat container and do not expose to temperatures above 60°C (140°F). Fire and burn hazards are possible if the battery is handled inadequately.



**SAFETY PRECAUTIONS FOR DIRECT SUN EXPOSURE**

Keep the product away from excessive humidity and extreme temperatures. Do not leave the product in places where the temperature may reach 60°C (140°F) or above, for e.g. closed automobiles, windowsills or behind a glass with direct sun light or ultraviolet light exposure. These reckless procedures damage the product, overheats the battery and may constitute a potential hazard for the user.

**GENERAL PRECAUTIONS****• Avoid applying excessive pressure on the recorder**

Do not apply excessive pressure on the recorder to avoid any damages. Plug the recorder only inside dedicated pocket on the t-shirt, closing the zipper after it is properly connected. While pressing the pushbutton use only the tip of your finger, verifying the lights change according to the required action (see Simple Guide).

**• Pay attention to assistance instructions**

Unless any instruction is written and allowed, do not attempt to repair any product. Any repair needed must be performed by a brand authorized technician or your local distributor.

**• Malfunctions which need technical assistance**

Unplug the recorder from the t-shirt or electrical socket and contact the Technical Department or your local distributor if any of the following situations occur:

- Liquid spilt or object dropped on the recorder.
- Exposure of the device to rain or water.
- Damage by pressure or fall to the device.
- The device presents evident signs of overheating.
- The device does not function according to instructions.

**• Avoid hot environments**

The product must be placed away from heat sources such as radiators, heaters, stoves and other heat generating products (including sound amplifiers).

**• Avoid damp environments**

Do not use the product in damp environments.

**• Avoid using the recorder after drastic temperature changes**

When the device is moved between environments with different humidity and temperature rates, condensation may occur in and on the recorder. To avoid permanent wait enough time for the humidity to evaporate before using the recorder.

**WARNING:** Before plugging the recorder wait until the device is adjusted to the surrounding temperature, if moved from a low temperature environment to a warmer one or vice versa.

- **Avoid to introduce foreign objects in the product**

Never introduce foreign objects in the openings of the product. The openings exist for to allow external connections and ventilation purposes only. The openings must not be covered or obstructed.

## **SPECIAL ATENTIONS IN OPERATION AND HANDLING OF THE RECORDER**



**Biodevices does not repair equipments under the warranty's general conditions if abusive use is proved according to the following situations:**

- Liquid spilt on the recorder (for e.g. water, hot beverages or rain).
- The recorder submerged in any liquid (for e.g. washing machine, bathtub or pool).
- Torn plug, broken pins or smashed due to use of excessive force, attempted to insert the connector sideways or attempt to open the recorder by the plug opening.
- Signs of attempt to open the recorder such as smashed plastic, cracked or broken box and traces of glue and weld.
- Foreign components which did not make part of the original assembling by Biodevices.
- Changes in color and shape of the plastic box by sun or heat exposure.
- Cracked or broken due to the use of excessive force or by fall, throw or excess weight applied to the recorder.

### T-shirt

VitalJacket 1L has 3 springs and VitalJacket 5L Motion has 6 springs where the disposable electrodes must be connected for ECG signal acquisition. The t-shirt also has a plug inside a pocket where the digital recorder should be plugged and placed.

#### WASHING INSTRUCTIONS



Hand or machine wash at 30° C (85°F)



Do not bleach



Iron at low temperature (100° C or 210° F)



Do not dry clean



Do not machine dry

Do not centrifuge above 800 rpm

**Note:** Before washing the t-shirt do not forget to remove the digital recorder.

#### SPECIAL ATTENTION IN OPERATION AND HANDLING OF THE T-SHIRT

**⚠ Biodevices does not repair equipments under the warranty's general conditions if abusive use is proved according to the following situations:**

- Washing instructions were not properly followed proved by visible signs such as unglued textile, tubes and transfers (with logotypes, serial numbers and washing and use instructions).

- Broken or twisted springs by use of excessive force while connecting or disconnecting the electrodes of the t-shirt.

- Unencapsulated conductive wires or absence of the protective textile which protect the spring and codes the corresponding lead.

- Damaged connector by use of excessive force, attempt to connect the plug sideways or to connect other systems.

## Accessories

The VitalJacket system includes 1 SD card 1 Gb to be used with the digital recorder. Do not use SD cards with higher storage capacity or not provided by Biodevices. You may not obtain a correct recording of the ECG data or even damage the equipment.

The disposable electrodes can be ordered directly to Biodevices or in your local supplier.

The VitalJacket system was tested with the electrodes provided by Biodevices and will not be liable for the bad results obtained by the use of lower quality electrodes.

**Note:** There are several electrodes in the market for different applications e functions. You must choose the disposable electrodes more suitable according to the intended monitoring.



## ENVIRONMENTAL INFORMATION

### Packaging


The package is 100% recyclable as mentioned in the presented symbol .

For the elimination it is mandatory to comply to the local norms of packaging disposal. The material must be kept away from children, for it constitutes a potential hazard source.

### Digital Recorder

The digital recorder is compliant with European Directive 2002/96/EC “Waste Electrical and Electronic Equipment (WEEE)”.



The symbol  present on the product and legal documentation indicates the product must not be treated as a domestic residue and must be delivered to recycle center specialized in gathering and recycling electric and electronic equipments. Dispose according to local legislation.

For more information about treatment, recovery and recycling of the product contact the specialized center of your area of residency or local distributor.

**WARRANTY**

The VitalJacket digital recorder has a 2-year warranty and the VitalJacket t-shirts have a 3-month warranty.

The warranty includes malfunctions due to factory or installation defects being the company Biodevices obliged to substitute the defected equipment with no cost to the client and no right to indemnity.

**EXCLUSIONS**

The warranty does not cover damages caused by repairs performed by persons or agents non-authorized by Biodevices S.A.

The warranty does not cover damages caused by misuse, accidents or incorrect maintenance of all VitalJacket products.

The warranty does not cover cracked, broken or visibly damaged boxes.

The digital recorder must not be open. This violation annuls the warranty of the device.

The substitution of any VitalJacket accessory will be fully charged if at least one of the misuse allegations is proved.

**Storage and transport specifications**

|                      |                          |
|----------------------|--------------------------|
| Temperature          | -20° to +45° C           |
| Humidity             | 10 to 90% non-condensing |
| Atmospheric Pressure | 700 to 1060 hPa          |

**Operation specifications**

|                      |                          |
|----------------------|--------------------------|
| Temperature          | -20° to +45° C           |
| Humidity             | 10 to 90% non-condensing |
| Atmospheric Pressure | 700 to 1060 hPa          |
| Current              | 40 mA/h                  |
| Power                | 132 mW/h                 |
| Tension              | 3.3 V                    |
| Battery Autonomy     | 72 h                     |

**Main characteristics of the digital recorder**

- Dimensions: 66 x 38 x 16 mm
- Weight (including rechargeable battery): 50 g
- Communication specifications (Bluetooth 2.0):
  - Class: 2
  - Potency: 2.5 mW
  - Frequency: 2.4 GHz
  - Range: 10 m (straight line)
- Protection Class: IP 20

### 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.

| Test  | Conformity     | Guidelines - Electromagnetic environment   |
|---|----------------|--|
| RF Emissions<br>CISPR 11                        | Class 2        | The VitalJacket sends electromagnetic energy in order to perform the planned function. Nearby electronic equipment may be affected.  |
| RF Emissions<br>CISPR 11                        | 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 is understood:<br><br>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. |
| Harmonic Emissions<br>IEC 61000-3-2             | Class B        |  |
| Voltage fluctuations emissions<br>IEC 61000-3-3 | Non Applicable |  |


**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 Test  | Test Level IEC 60601   | Conformity Level             | Guidelines - Electromagnetic environment   |
|--|--|------------------------------|--|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2   | ± 6 KV contact<br>± 8 KV air   | ± 6 KV contact<br>± 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<br>IEC 61000-4-4   | ± 2 KV power lines<br>± 1 KV input/output lines  | Non Applicable               | The quality of the power source must be of a typical commerce or hospital environment.   |
| Power surge<br>IEC 6100-4-5  | ± 1 KV diferential mode<br>±2 KV common mode   | Non Applicable               | The quality of the power source must be of a typical commerce or hospital environment.   |
| Voltage drops, short interruptions and voltage fluctuation/flicker                             | <5% UT<br>( >95% drop on UT) to 0,5 of the cycle;<br>40% UT to<br>(60% drop on UT) 5 cycles;<br>70% UT<br>(30% drop on UT) to 25 cycles;<br><5% UT<br>( >95% drop on UT) to 5 cycles | Non Applicable               | The quality of the power source must be of a typical 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 (50/60 Hz)<br>IEC 61000-4-8 | 3 A/m  | 3 A/m                        | The magnetic fields in the power frequency should be at levels of a typical commercial or hospital characteristic environment.   |

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 Test   | Test Level IEC 60601       | Conformity Level | Guidelines - Electromagnetic environment   |
|---|----------------------------|------------------|--|
| Interference immunity to power-line-based interference<br>IEC 61000-4-6 | 3 V/m<br>150 KHz to 80 MHz | Non Applicable   | 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).  |
| Interference immunity against radiated interference<br>IEC 61000-4-3    | 3 V/m<br>80 MHz to 2,5 GHz | 3 V/m            | Field strengths outside the shielded place from fixed RF transmitters, determined by an electromagnetic site inspection, should be less than 3 V/m <sup>a</sup> .<br><br>Interference may occur in the vicinity of equipment marked with this symbol:<br> |

**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.

<sup>a</sup> 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 cannot 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 abnormal 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.

## Conformity with the European requirements

### Applicable Directives

DIRECTIVE 2006/95/CE: Electrical equipment designed for use within certain voltage limits (LV)

DIRECTIVE 2004/108/CE: Electromagnetic compatibility (EMC)

DIRECTIVE 1999/5/CE: Radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (R&TEE)

DIRECTIVE 2002/96/CE: Waste electrical and electronic equipment (WEEE)

### Harmonized standards

ETSI EN 300 328 V1.7.1: Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques;

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.

**Conformity with the requirements of the United States of America and Brazil**

**Requirements Applicable**

FCC Certification and Anatel radio.

This device complies with FCC and Anatel rules. Any transaction with the same is subject to 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.

**Contactos**

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