

Product Manual



VitalJacket® WEARABLE ECG

www.vitaljacket.com | www.biodevices.pt



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CE1011

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O NOVO NORTE
PROGRAMA OPERACIONAL
REGIONAL DO NORTE

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QUADRO
DE REFERÊNCIA
ESTRATÉGICO
NACIONAL
PORTUGAL 2007-2013



UNIÃO EUROPEIA
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VitalJacket®

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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. A set of 25 electrodes is also provided for the first usages. 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

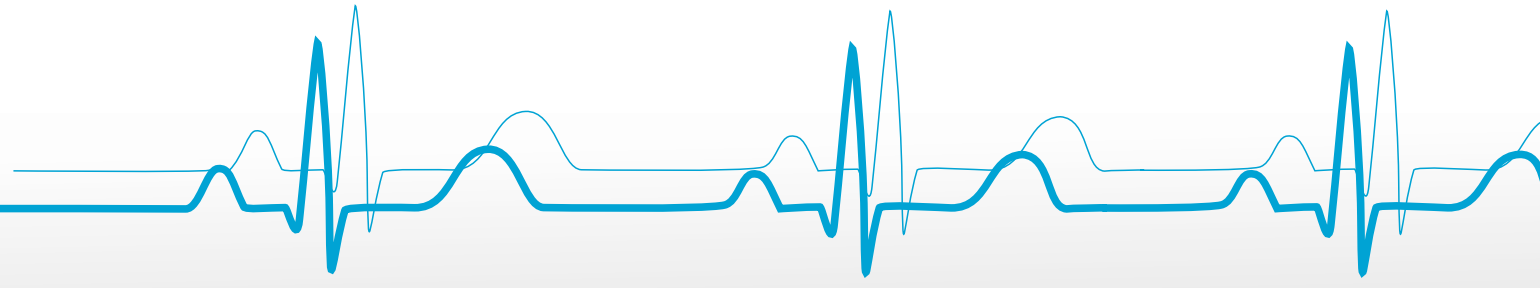
Symbols

Symbol	Description
	Bluetooth
	Caution (consult safety manual)
	Ponto verde
	Recyclable package
	Waste Electrical and Electronic Device
	Manufacturer
	Fragile
	Keep dry
	Keep away from heat
CE1011	CE Mark Medical Device

Handling Scope

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

The VitalJacket® is a medical device and, as such, it can be used for therapeutic or diagnosis purposes.



Disclaimer of responsibility

The handling should comply with the instructions described in this user's manual.

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:

FABRICADO EM PORTUGAL
MADE IN PORTUGAL
FABRIQUÉ EN PORTUGAL

80% POLIAMIDA
POLYAMIDE
POLYAMIDE

20% ELASTANO
ELASTHANE
ELASTANE



CONTÉM COMPONENTES
METÁLICOS ESPECÍFICOS AO
FUNCIONAMENTO DA PEÇA.
CONTAINS SPECIAL METALLIC
COMPONENTS FOR FUNCTION
OF THE GARMENT.
CE MODÈLE CONTIENT DES
COMPOSANTS MÉTALLIQUES
NÉCESSAIRES À SON
FONCTIONNEMENT.



Machine wash at 30 ° C.



Do not bleach.



Iron at low temperature.

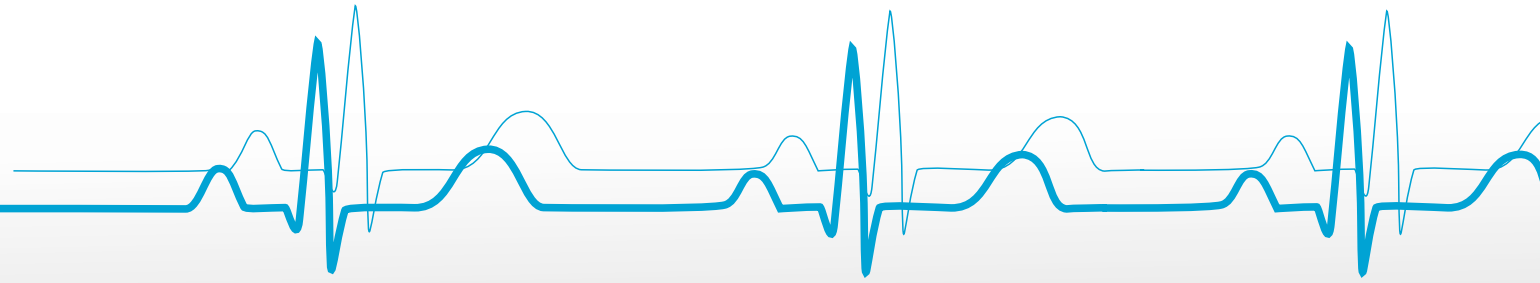


Do not clean dry.



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.B. Dress the t-shirt.

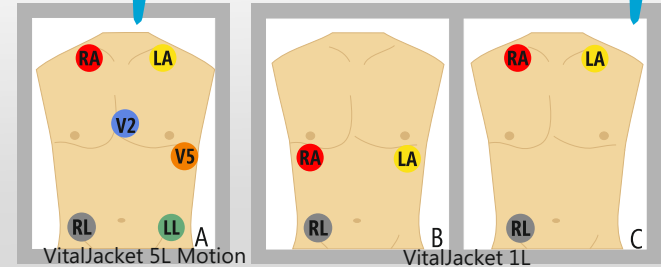
Fix the springs inside the t-shirt to the electrodes placed in your body. **You should hear a click.**

1.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.

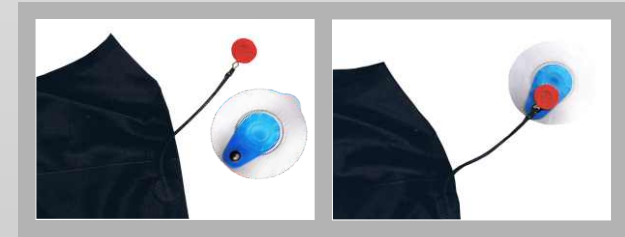
When the **red light is blinking normal** (1 time per second) the device is acquiring the signal and write data on SD card.

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.A Correct placement of the electrodes.



1.B Fixing the springs.



1.C Connecting electronic device.



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....)

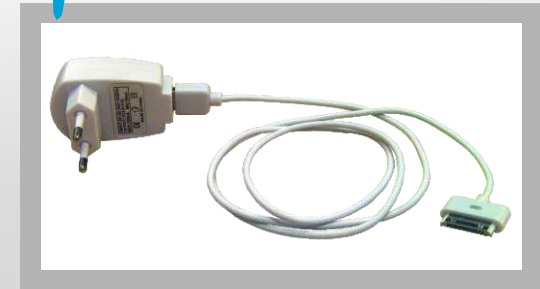
Prepare the next exam

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.

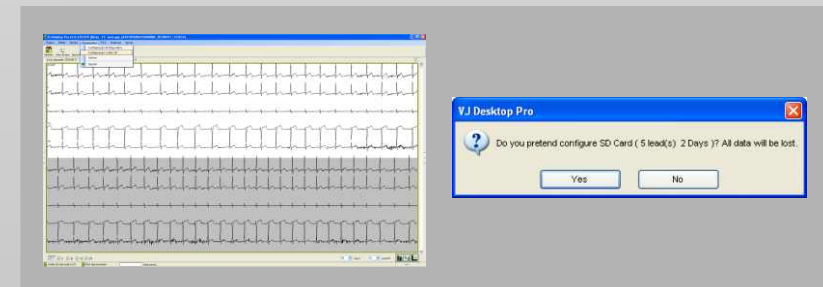


1.A USB cable and USB charger.

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 medical monitoring device that allows the user to perform a ECG with all confort while wearing a t-shirt with a small electronic device in the pocket.

Who should use it?

Everyone is suitable for Vitaljacket® as it is a non-invasive device with no contra-indications. Vitaljacket® is recommended for everyone needing to monitorize vital signals, namely people with illness, cardiac problems and Professional/amateurs atheletes.

VitalJacket® can, under medical prescription, replace the standard systems for ambulatory ECG.

How long can it be used?

VitalJacket® can be continuously used as long as needed, with no contra-indications.

Where to buy?

Vitaljacket® can be directly bought to Biodevices S.A. or to any local partner (see Partners in www.biodevices.pt).

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.

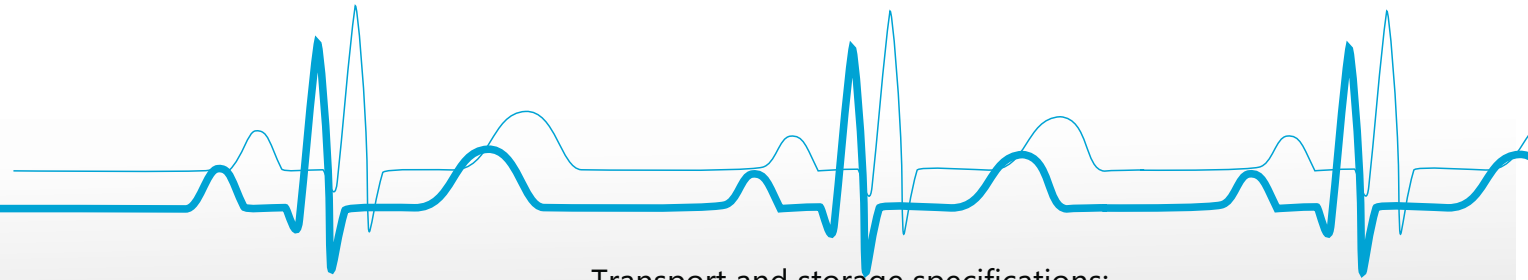
How to wash?

Remove the electronic device box from the t-shirt's pocket and follow the labeled instructions.

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 will not turn on.	The electronic device battery is low or completely worn out.	Charge the electronic device battery
	The electrodes are badly positioned.	Check the position of the electrodes according to the instructions provided in the User's Manual.
The signal and the heart rate shown are out of control.	The electronic device is badly directed.	The Bluetooth symbol in the electronic device should be facing the outer part of the T-Shirt.
	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)

 **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.

Transport and storage specifications:

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

Operating Conditions:

Temperature	-20°C a + 45°C
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

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 differential 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	N/A	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	<5% UT (>95% UT drop) to 5 s	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 interference 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

Manufacturer's Declaration



Conformity with the European requirements

Applicable Directives

DIRECTIVE 2006/95/CE

Electrical equipment for use within certain voltage limits (LV)

DIRECTIVE 2004/108/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)

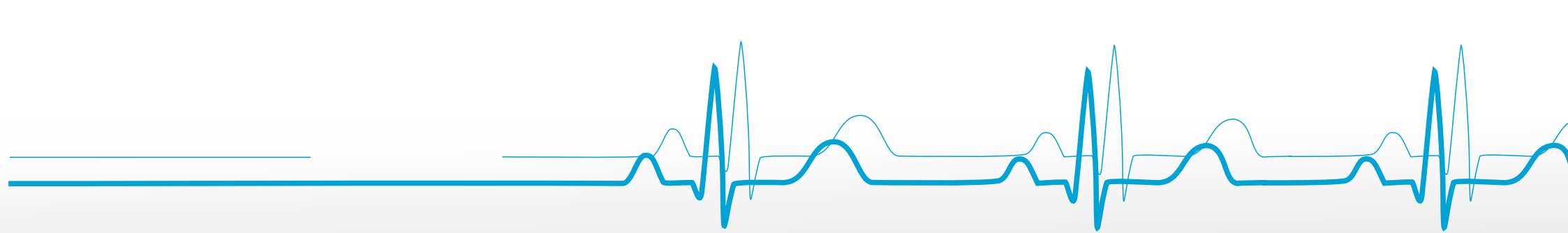
Harmonized Standards

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 2.4²¹



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.

Support and Customer Support

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



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