
VI-BioTelemetry
THE DRIVER AT THE CENTER STAGE


SanDisk
SanDisk

USE AND MAINTENANCE GENERAL MANUAL

This manual contains the instructions and describes the procedure to the safely and correctly use VI-BioTelemetry kit.

VI-grade reserves the right to make changes to this Manual at any time. The updated version will be downloadable from the website upon notice to users/customers

www.vi-grade.com

	WARNING PLEASE READ THIS MANUAL CAREFULLY AND COMPLETELY BEFORE INSTALLING, USING OR PERFORMING ANY OTHER OPERATION ON THE DEVICE VI-Biotelemetry

INDEX

1. INDEX 3
2. MANUFACTURER 4
3. INSTRUCTION FOR USE 4
3.1. Manual of Instruction for the correct use 4
3.2. Manual structure 4
3.3. Manual storage 5
3.4. Manual reproduction 5
4. VI GRADE SERVICE ASSISTANCE 5
5. WARRANTY 6
6. TERMS AND DEFINITIONS 6
7. SAFETY WARNINGS 6
7.1. General signs 6
7.2. Identification plates 7
7.3. Symbols used 7
7.4. General warnings 7
7.5. Specifics warnings and cautions 8
8. DESCRIPTION AND IDENTIFICATION 8
8.1. VI-Biotelemetry components 9
9. CERTIFICATION 10
10. TECHNICAL DATA 11
11. SCOPE OF USE OF THE DEVICE 11
11.1. Intended USE 11
11.2. Use not allowed ..... **Errore. Il segnalibro non è definito.**
11.3. Limitations of use of radio communications 12
12. RESIDUAL RISK 13
13. PSYCHO-PHYSICAL AND FITNESS REQUIREMENTS FOR THE USE OF THE VI-BIOTELEMETRY 14
14. PACKING AND TRASPORT 14
14.1. Packing 14
14.2. Storage place 14
14.3. Receipt and check of the goods 14
14.4. Integrity check of internal equipment 14
15. ASSEMBLY AND INSTALLATION 16
16. USE OF THE DEVICE 16
17. MAINTENANCE 17
17.1. Checks 17
17.2. Spare parts 17
17.3. Chest vest cleaning 17
18. DISPOSAL 18
19. TECHNICAL INFORMATION 18
20. TESTING/INSPECTION/TRAINING 19
21. DEVICE INFO ..... **Errore. Il segnalibro non è definito.**

MANUFACTURER

VI-grade s.r.l. (VI-grade)

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INSTRUCTION FOR USE

1.1. Manual of Instruction for the correct use

This Use and Maintenance Manual ("Manual") contains the instructions for a correct and safe use of VI-Biotelemetry device; this Manual has been issued by the Manufacturer and it is an integral part of the VI-Biotelemetry package.

The information contained in the Manual is intended for use and maintenance of the device.

The Manual must be used by:

- Carrier agents;
- Authorized installers;
- Installers, assigned to the network connections,
- Qualified personnel in charge of operating and monitoring the simulations;
- Qualified maintenance staff;
- Qualified personnel in charge of demolition and disposal.

1.2. Manual structure

This Manual is divided into chapters. Each chapter is divided into paragraphs.

On the bottom margin, and bottom right, of each page it is shown the page number.

At the end of the Manual, there is a general summary to be used for a quick consultation.

In addition to chapters and paragraphs, this Manual also provides visual (images) and representative details (sketches or labels).

This Manual is also provided with technical documentation, inserted herein as an attachment.

1.3. Manual storage

This Manual must be kept with care for the entire lifetime of the VI-Biotelemetry product package; duration of life means the time from the date of purchase to the date of disposal.

This Manual must follow the VI-Biotelemetry product package even if it was transferred to a third party.

The Manual must always be kept by the user, in a dry place, near the final installation site and in places where it can be accessed and easily consulted by the User.

1.4. Manual reproduction

IT IS STRICTLY FORBIDDEN TO REPRODUCE THIS MANUAL IF NOT EXPRESSLY PERMITTED BY THE MANUFACTURER.THE COURTESY COPY SHOULD BE REQUESTED IN THE WRITTEN FORM BY SPECIFYNG THE CODE INSERTED UPPER ON THE RIGHT.

VI GRADE SERVICE ASSISTANCE

Welcome to the **VI-grade Online Support.** You will find below an email contact for the product you are using. After you sent your request for support, our product specialists will work on your request/issue and provide you with solutions for modelling issues or additional documentation, and software updates all targeted at your specific needs.

- For **VI-CarRealTime** contact: carrealtime@VI-grade.com
- For **VI-Biotelemetry**: biotelemetry@VI-grade.com

Once the first contact is established, VI-grade will use any means of communication convenient for all VI-BioTelemetry users including email, phone and Skype. In order to continuously improve our product quality, we also appreciate to learn about issues you encounter with our products.

WARRANTY

The product warranty, except for different contractual agreements, has a duration of 24 months.

TERMS AND DEFINITIONS

Manual: The present Use and Maintenance Manual

Device: The whole set of the VI-Biotelemetry

User: who wear the chest vest

Operator: who use the VI-Biotelemetry but not wear the vest

Customer: who buy the VI-Biotelemetry

SAFETY WARNINGS

1.5. General signs

The symbols shown below are used (if relevant) in the Manual. These symbols have been inserted to warn personnel against the dangers or any sources of danger.

 **DANGER**

 **PROHIBITION**

 **OBBLIGATION**

1.6. Identification plates

1.7. Symbols used

	Electrical insulation class II
Position: on the label	

	Read and understand the operating Manual before using the device. Failure to follow the operating instructions can result dangerous risk
Position: nearby	

1.8. General warnings

This Manual has been prepared by VI-grade owning its intellectual property.
Reproduction, even partial, of this Manual without the explicit consent of VI-grade is prohibited.
It is forbidden to amend, even in part, this Manual without the explicit authorization of VI-grade
This Manual is prepared in Italian as the original language; in any case you must take into consideration the original version as the original one.

This Manual must be read and understood completely by the Owner and by the Operator.

It is absolutely forbidden to modify the device and/or the components of the device without the explicit consent of Vi-grade.

Installation and the settings must be performed by qualified personnel trained by the manufacturer.
An incorrect installation and setting can cause dangerous situations.

Handle the device with care

Do not use aggressive chemical products for cleaning and sanitizing

1.9. Specifics warnings and cautions

PROHIBITION OF USE WITH PACEMAKER OR ANOTHER ELECTRONIC MEDICAL DEVICES PERMANENTLY PRESENT ON OR IN THE USER'S BODY

PROHIBITION OF USE CELL PHONES

PROHIBITION TO ACCESS THE AREA OR THE PREMISES WHERE THE ACTIVITIES ARE CARRIED OUT

DESCRIPTION AND IDENTIFICATION

VI-Biotelemetry is a hardware and software turn-key solution provided by VI-Grade to acquire, elaborate and display some biological signals generated by human body.

The acquired data are not used for medical purposes.

The VI-Biotelemetry is a not medical device

1.10. VI-Biotelemetry components

BioBox: acquisition and processing device

Chest vest: wearable support element for bio box and electrodes

Electrodes: element capable of detecting impulses and transforming tem into electrical signal

Conductive gel: component that allows to put the electrode in conduction

Access Point: the device that provides the wi-fi network where BioBox sends acquired data

Power supply Biobox: device for recharging the bio box battery

Gloves: are needed to improve signal stability

SD card: memory device where the data collected by bio box is saved

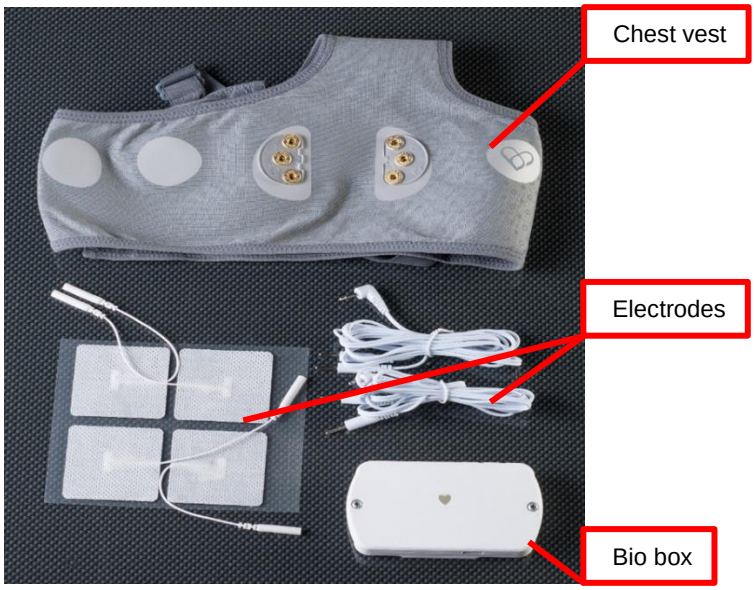

Figura 0.1-wearable objects

Figure 7.2 – BioTelemetry package

In the underlying image a functional diagram of the VI-Biotelemetry:

1- BioBox
2- Access Point
3- Concurrent RealTime PC

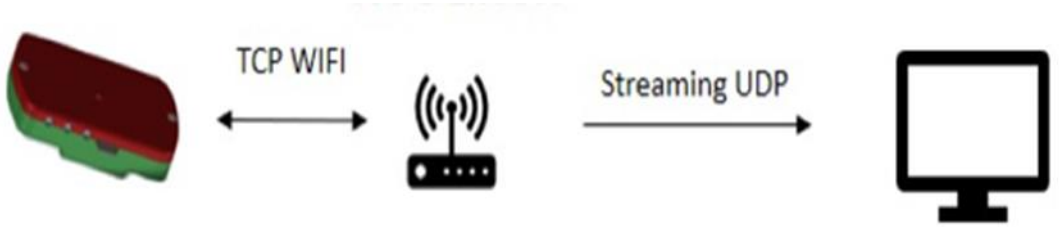

Figura 0.2 – Functional diagram VI-BioTelemetry

CERTIFICATION

The device VI-Biotelemetry is certified as shown in the Certifications List enclosed to this Manual.

certifications	
CE	yes
FCC	yes
ISED	yes

TECHNICAL DATA

ELECTRICAL DATA			
Description		M.U.	Added
Supply voltage		Vdc	3.7
Maximum nominal current consumed		mA/h	200
Ratead capacity		mA/h	400
DIMENSIONS			
VI-Biotelemetry		g	18
ENVIROMENTAL			
Working temperature (based on the temperatures of a working environment)		°C	+15/30
WI-FI			
Firmware vers: SF-BT0001			
		MIN	MAX
OPERATING FREQUENCY			
Bluetooth (only for maintenance services, not used for data transmission)	**Frequency MHz**	2402	2480
	Max power (dBm)	8	10
WI-FI	**Frequency MHz**	2412	2472
	channel number	1	15
	Max power (dBm)	14.5	20

SCOPE OF USE OF THE DEVICE


1.11. Intended USE

The VI-BioTelemetry package is intended for

- verifying human physiological reactions under certain driving conditions, working under operator supervision

The VI-BioTelemetry package can be used

- only indoor (in a weather-protected environment)
- at working temperature between 5 °C and 35 °C and Air humidity between 10% and 80%
- At heights less than 2.000m above sea level

1.12. Forbidden usage

The uses of the device are not allowed:

- outdoor
- in presence of flammable, explosive and/or toxic gas, vapours or mixtures
- close to high emissions of Electro Magnetic Fields (EMF)
- for people under the age of 18y/o
- for people with motor and mental handicaps
- for pregnant women
- for people using pacemakers or other medical devices
- With highs ambient temperatures above 50°C
- With batteries other than those specified by the manufacturer
- With expired or badly stored batteries

1.13. Limitations of use of radio communications

The Radio Equipment Directive (RED) is an European Directive to regulate the use of frequency spectrum; the RED is adopted by all EU countries as well as by Lichestein, Iceland, Norway, Turkey, Switzerland.

There are no limitation for use of the radio spectrum for the VI-Biotelemetry in the Countries where the device is certified, expect where different information are shown in the Certifications List enclosed to this Manual.

RESIDUAL RISKS

PLEASE READ THIS PARAGRAPH CAREFULLY.
THE FOLLOWING RISK BELOW ARE ASSESSED AS "RESIDUAL". THERE IS THE REMOTE, BUT POSSIBLE PROBABILITY THAT AN ACCIDENT CAN TAKE PLACE

The residual risks are those that cannot be reduced by technical means and requires specific instruction, warnings and procedures for a safe use of the device.

The residual risks are:

1. Fire and explosion caused by batteries. Batteries shall be periodically checked.

SOLUTION RESIDUAL RISK : FIRE AND EXPLOSION	
RISK LOCATION: BATTERY	SOLUTION DESCRIPTION: COMPLY WITH THE MAINTENANCE PARAGRAPH
RISK RESOLUTION INDEX ☐ MODERATELY EFFECTIVE ☐ SUFFICIENTLY EFFECTIVE ☒ EFFECTIVE ☐ EXTREMELY EFFECTIVE	

2. Electromagnetic interferences with other electronic device, also medical device. The emission of the device are under the limits defined by the law in force in the Country where the device is sold. Anyway specific measures must be taken by the user when the device it is used in special conditions.

SOLUTION RESIDUAL RISK : ELECTROMAGNETIC INTERFERENCES	
RISK LOCATION: OPERATING ENVIROMENT	SOLUTION DESCRIPTION : INSTRUMENTAL TEST COMPLIANCE WITH HARMONIZED STANDARDS THE INSTRUMENTAL TEST OF SPECIFIC ABSORPTION RATE ARE COMPLIANT RESULTS
RISK RESOLUTION INDEX ☐ MODERATELY EFFECTIVE ☐ SUFFICIENTLY EFFECTIVE ☒ EFFECTIVE ☐ EXTREMELY EFFECTIVE	

3. Biological risk caused by an inappropriate sanitization of the device and the chest vest, glove and electrodes.

SOLUTION RESIDUAL RISK : BIOLOGICAL RISK	
RISK LOCATION: HUMAN BODY	SOLUTION DESCRIPTION : 1.ELECTRODES MUST BE REPLACED AFTER EVERY USE AS PROVIDED BY THE MANUFACTURER ELECTRODES ARE DISPOSABLE. NB THE ELECTRODES LAST 24 MONTHS FROM THEIR PRODUCTION DATE. 2.WASH SANITIZE THE CHEST VEST EACH TIME IT IS USED. DO NOT WEAR THE BODY WITHOUT DISINFECTING IT 3.EVALUTE POSSIBLE ALLERGIC DISEASES
RISK RESOLUTION INDEX ☐ MODERATELY EFFECTIVE ☐ SUFFICIENTLY EFFECTIVE ☒ EFFECTIVE ☐ EXTREMELY EFFECTIVE	

PSYCHO-PHYSICAL AND FITNESS REQUIREMENTS FOR THE USE OF THE VI-BIOTELEMETRY

	*READ THE MANUAL ON THE USE OF THE SOFTWARE WITH EXTREME CARE AND ACCURACY.*

Special physical psycho requirements are not required for the use of the device.

PACKING AND TRASPORT

	*PAY ATTENTION IF THE PACKAGE IS DAMAGED AND DO NOT OPEN IT. SEND AN EMAIL IMMEDIATELY TO THE MANUFACTURER DISCLOSING WHAT HAPPENED AND DOCUMENTING IT WITH PHOTOS.*

1.14. Packaging

1.15. Storage place

The package shall be stored after the use:

- Out of reach of children
- Protect against sunrays
- Protect against dust
- Keep within the recommended temperatures

1.16. Receipt and check of the goods

At the receival of the VI-BioTelemetry product package, the Customer must check its status. If the package does not have signs of damage or discrepancies, the Customer can check the status of the goods contained therein.

1.17. Integrity check of internal equipment

If the package shows no signs of damage, the Customer can check its contents in order to verify the presence of all the components (see 1.10). All components inside the package must be in good conditions without any sing of damage.

	*PAY ATTENTION IF THE COMPONENTS ARE DAMAGED. SEND AN EMAIL IMMEDIATELY TO THE MANUFACTURER DISCLOSING WHAT HAPPENED AND DOCUMENTING IT WITH PHOTOS.*

ASSEMBLY AND INSTALLATION

See the attached technical manual

USE OF THE DEVICE

a. Put some conductive adhesive gel on the 5 electrodes on the inner side of the chest vest and wear it under the clothes (it must be in contact with the skin). Be careful to properly fix the clips in the backside
b. Connect the BioBox to the vest using the 6 brass pins (see Figure 2), being careful to keep the upper side of the device upwards.
c. Put the four hand gelled electrodes on the hands. One must be attached on the palm and one on the back
d. Connect the wires provided with the package from the jack entrance of the BioBox to the gelled electrodes on the hands. Pay attention: the top and bottom electrode connection must be consistent for both hands. Usually the red wire is connected to the palmar electrode and the black one to the back electrode. Wearing the BioBox, the external right hole represents the SPR1 (usually referred to right hand) signal and the external left hole represents the SPR2 signal (left hand) .

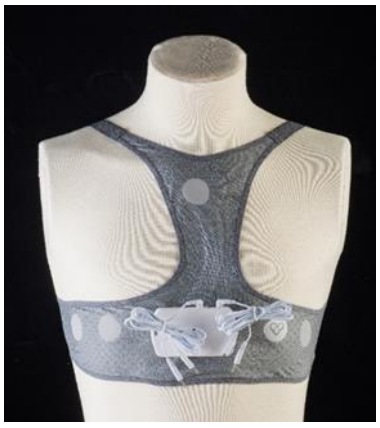

Figura 0.1- chest vest worn correctly

MAINTENANCE

1.18. Checks

Check the integrity of the device before each time you use it; check by visual e examination:

- Condition of batteries;
- Due date of batteries,
- Condition of electrodes,
- Chest-vest condition,

1.19. Spare parts

The Spare parts can be ordered by the following codes.

Spare part order codes		
Description	*Cod.order*	*Note*
Chest vest	0001	
Electrodes	0002	1 pack contains 4 electrodes
Conductivity gel	0003	1 tube
Gloves	0004	1 pair
Access Point	0005	
Power supply	0006	
Biobox	0007	
SD card	0008	Minimum purchase 2 SD card

17.3 Chest vest cleaning

The vest can be washed by ordinary washing machine.

More details are shown in the chest vest label.

DISPOSAL

The device must be disposed of in the following way:

1. Open the shell by means of the appropriated screws that ancor the two halves of the case.
2. Disconnected the battery.
3. Remove the battery.
4. Remove the electronic card.

The components listed below must be disposed of as required by national regulations where the device will be sold; below the list of parts to be disposed of:

1. Material plastic
2. Electronic circuit
3. Lithium battery.

	*IT IS ABSOLUTELY FORBIDDEN TO DISPOSE OF THE DEVICE OR ITS PARTS AT THE NORMAL URBAN WASTE COLLECTION SERVICE.*

TECHNICAL INFORMATION

See the attached technical manual

TESTING/INSPECTION/TRAINING

Description	*Result*
Check the condition of the kit	☐ C ☐ O ☐ NC
Observations	

Description	*Result*
Biobox check power ON	☐ C ☐ O ☐ NC
Observations	

Description	*Result*
Biobox recharge verification	☐ C ☐ O ☐ NC
Observations	

Description	*Result*
Biobox recharge verification	☐ C ☐ O ☐ NC
Observations	

Description	*Result*
Check electrode integrity and conductive gel	☐ C ☐ O ☐ NC
Observations	

Description	*Result*
NUC check power ON	☐ C ☐ O ☐ NC
Observations	

Description	*Result*
Correct verification of wearability chest vest	☐ C ☐ O ☐ NC
Observations	

Description	*Result*
Verify that the data are transcribed on the SD card	☐ C ☐ O ☐ NC
Observations	

Description	*Result*
Verifies the transmission between biobox and nuc	☐ C ☐ O ☐ NC
Observations	

Description	*Result*
Staff training	☐ C ☐ O ☐ NC
Observations	

Final results:

Testing, verification and training of personnel were carried out with positive results.

DEVICE INFO

PRODUCER NAME: **VI-grade s.r.l.**

ADDRESS: via Galileo Galilei 42

WEBSITE: www.vi-grade.com

Declares that the electronic device's model described as following:

COMMERCIAL NAME: **VI-Biotelemetry**

ITEM CODE: Not applicable

BRAND: VI-Biotelemetry

Complies with the following requirements:

FCC Rules 47 CFR Part 15 Subpart C: Radio Frequency Devices (Intentional Radiators)
RSS-Gen Issue 5 Amendment 1 – General Requirements for Compliance of Radio Apparatus
RSS-247 Issue 2 – Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and Licence-Exempt Local Area Network (LE-LAN) Devices

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s) (RSS-GEN and RSS-247) and with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. **This device may not cause harmful interference**
2. **This device must accept any interference received, including interference that may cause undesired operation**

FCC Radiation Exposure Statement: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 25 mm between the radiator and your body.

The full text of the FCC/ISED declaration of conformity can be obtained at www.vi-grade.com

Done at Tavagnacco, 10.11.2019

Name and function of the signer:

Brand manager

Diego Minen