Bodyguardian Control Unit Base Kit

Operator Manual

SPMHBGW1-MAN
Rev. A

EDITION:
November 2011

Preventice
Rochester, MN 55901, USA

Contents

CHAPTER 1
INFORMATION ABOUT SAFETY

1.1 INFORMATION ABOUT THE MANUAL

Information in this document is subject to change and revision without notice.

Issues:

First edition: SPMHBGW1-MAN - Rev. A - November 2011

This manual is to be considered as a component of the equipment. When installing the equipment for the first time, the user should accurately check the content of the Manual in order to verify its integrity and completeness.

In the event the Operator Manual should be ruined, incomplete or inadequate, please contact PREVENTICE in order to immediately restore or replace the uncompliant Manual.

The official version of the Operator Manual, of which PREVENTICE is directly responsible, is the English versions. For countries in which languages other than English are spoken, the official Manual is the one in the English version. PREVENTICE does not undertake any responsibility for any translations in other languages made by distributors or users.

The observance of the operating procedures and of the warnings described in this Manual is a basic requirement for the correct working of the equipment and to guarantee the patient's and the user's safety.

The Manual must be read in every part in front of the equipment before using it, in order to become familiar with the operating procedures, the commands, the connections to the peripheral instruments, and the precautions for a correct and safe usage.

The Operator Manual should be kept, complete and readable in every part, in a safe place, and, at the same time, it should be rapidly accessible to the user when using the equipment.

This Operator Manual is intended for System Builder and not for the end-user of the device.

The equipment Service Manual is available on request. This Manual contains all information directed to the qualified staff in charge for servicing.

1.1.1 CONVENTIONS

In this Operator Manual the following conventions are used:

NOTE

The NOTE messages contain important information, which must be noticeable with respect to the regular text. Usually they have useful information for the operator: detailed data on the correct operating procedures of the instrument.

WARNING

The WARNING messages show in the manual before operations and procedures, which must be strictly observed in order to avoid possible loss of data or damage to the equipment.

ATTENTION

The ATTENTION messages show in the manual in correlation with the description of procedures and operations, which could cause injury to the operator or to the patient, if not correctly performed.

`

1.2 DECLARATION OF RESPONSIBILITY BY THE MANUFACTURER

MANUFACTURER: **PREVENTICE**
1652 Greenview Drive SW
Rochester, MN 55092
Website www.preventice.com
Tel: +1 866-830-4043

PREVENTICE is responsible for safety, reliability and performances of the equipment only when the equipment is used in compliance with the following conditions:

- Calibrations, modifications or servicing must be performed by qualified staff expressly authorized by PREVENTICE.
- The equipment must be opened and its internal parts must be accessed to by maintenance qualified staff only expressly authorized by PREVENTICE.
- The environment where the equipment is used must be in compliance with the safety prescriptions.
- The electric wiring of the building must be designed according to the standards and perfectly working.
- Parts of the equipment that can be replaced by the user and accessories must be replaced with items of the same kind and with the same characteristics.
- The connection of the equipment with peripherals or other instruments supplied by the mains must be performed according to the IEC 60601-1-1 standards (standards for electrical safety of medical electric systems) and to the IEC 60601-1-2 standards (standards for electromagnetic compatibility).
- Usage and maintenance of the equipment and of its accessories must be performed in compliance with the instructions described in this Manual.
- This Manual must be kept complete and readable in every part.
- The equipment is used and serviced until its “End of Life”.

1.3 USAGE RESTRICTIONS AND SAFETY PRECAUTIONS

In order to guarantee the patient's and the user's safety as well as a correct working of the equipment, it is necessary to operate within the consented restrictions and adopt all the precautions listed below:

ATTENTION

Prior to usage, verify that all the safety requirements are satisfied.
The equipment must not be supplied by or connected to other instruments until such safety conditions are restored.

1.3.1 ELECTRIC SAFETY

Leakage current
The maximum patient leakage current from the equipment, measured according to the IEC 60601-1 standard (for Type BF) is less than 100 μA.
However take care when using the equipment at the same time with other instruments. In the event the patient is connected to several instruments at the same time, it is necessary to remember that the sum of the leakage currents determined by each instrument may exceed this value.

Patient Connection
All patient connections to the equipment are through the device using the proper adhesive electrode patch provided. Any patient electrodes connected to the device by any other means may constitute an unsafe condition that could result in injury or death to the patient.

ATTENTION

All patient connections on the device are isolated from AC power ground.
Do NOT join these connections to earth ground or AC power ground since such an action constitute an unsafe condition that could result in serious injury or accidental death to the patient.

ATTENTION

The electrode through which the signal is captured from the body of the patient are not part of the amplifier system, in any case it is MANDATORY to use only electrode or sensor approved for commercial use by FDA (USA) or/and CE marked (93/42 EEC directive and following amendment 2007/47/EC).

`

To ensure the safety of the patient and the operator, please follow all the warnings and caution listed in this manual.

- **Connect to the equipment the proper specified power supply only.** In order to guarantee the electrical safety requirements, the recharge of internal battery pack of equipment, must be performed by means the proper medical AC/DC adapter only. The power supply is supplied by PREVENTICE with the equipment. The allowed models are:

    - Trademark FRIWO, Model FW7662M/06

    To recharge the equipment place it on the Charging Cradle according to the appropriate orientation (only one is possible due to the mechanical constraints) and only after this operation connect the Charging Cradle to the AC/DC Power supply and this last to the mains.

    After the recharging operation is complete disconnect the AC/DC Power supply from the mains and only after this operation remove the equipment from the Charging Cradle.

- **Take care when using the equipment at the same time with other instruments**. In the event the patient is connected to several instruments at the same time, it is necessary to remember that the sum of the leakage currents determined by each instrument may endanger his life.

- **Take care when using the equipment at the same time with other radio-frequency instruments**. In the event the equipment is used in a surgery room at the same time with a radio knife (Radio-Frequency instrument = RF), it is necessary to hold the radio knife point as far as possible from the electrodes, in order to reduce as much as possible the risk of RF currents making on such electrodes and the consequent burns. Therefore it is necessary to use electrodes with a larger surface contacting the patient body, in order to limit the RF current density to acceptable values. In case it is not possible to use the proper electrodes, it is recommended to disconnect the patient from the equipment before using radio-frequency instruments.

- **The equipment is not protected against the defibrillator discharges**. Please remember that the equipment is not protected against the defibrillator discharges; for this reason, in the event it should be necessary to use the defibrillator, it is necessary to disconnect the patient from the equipment in order to avoid the patient being burned in the electrode contact areas and the equipment undergoing sever and irreversible damages.

- **Avoid contact of patient and electrodes with conductive metal items**. When the equipment is connected to other instruments supplied by the mains, the whole input circuit to which the patient is connected is electrically isolated (*floating* isolation). It is necessary to avoid the patient and any conductive part connected to the patient (electrodes, connectors, and transducers) coming into contact with conductive parts (ground included). Please observe this precaution to avoid compromising the equipment isolation level. This precaution must be observed in order to avoid that accessible metal parts of the device get in touch

with external conductive parts thus damaging the isolation level of the equipment.

- **Do not connect additional Multiple Portable Socket-Outlet or extension cord.** Multiple portable socket-outlet or extension cord shall not be connected to the system.

- **Observe the IEC 60601-1-1 and the IEC 60601-1-2 standards in case of connection with other instruments**. The connection of the equipment with other devices is allowed only when the safety requirements for the patient, the user and the environment are not compromised. If the Manual does not contain enough information about the possibility of interconnection with other devices, the user should contact the manufacturer or the nearest authorized servicing center to have information about the effects that coupling devices may have on the patient, the user and the environment.

- **Replace damaged parts immediately**. Cables, connectors, accessories, or other parts of the equipment must be replaced immediately when damaged or not working correctly. In these cases, contact the nearest authorized servicing center.

- **Do not connect items (accessories and peripherals) which are not specified as part of the system expressley indicated by PREVENTICE**. In order to guarantee all the safety requirements, it is necessary to use only the accessories and peripherals specified in this Manual as part of the system, which have been tested with the equipment. The usage of accessories and consumer goods supplied by other manufacturers or not specifically indicated by PREVENTICE does not guarantee the safety and the correct working of the equipment. Use only peripherals in compliance with the standards of the class they belong to.

- **Check the functionality of the system before starting any recording.** It is strongly recommended to check the overall functionality of the system before starting any recording. In case any anomalies or malfunctioning should be noticed, immediately disconnect the patient from the system (if a patient is already connected), switch off the system and ask for service to qualified personnel. In particular (for example) if, with a patient connected to the system, some anomalous tracing, like isoelectric or greatly artefacted signal, should be noticed on the monitor during recording: in this case if the problem should not be solved with the assembly standard technique (poor electrode connection, broken lead etc) immediately acts as above, disconnect the patient, do not use the system and ask for servicing.

- **Periodically check that all the system works regularly during "long term recording".** During "long term recording" (more than one hour) it is strongly recommended to periodically check that all the system works regularly without any sign of malfunctioning. If any anomalies or flat traces should be noted act as in the previous warning. In particular any electrode site used for long term must be checked for irritation and redness. Check each electrode periodically to

evaluate the skin condition under the electrode. Redness, blistering and permanent skin scarring can occur if electrodes are not regularly monitored.

- **Using the equipment on patients with a heart pace-maker is not allowed**. It is not allowed using the equipment in the case of patients with implanted electric devices (or bed partners with implantable devices), especially heart pace-makers, because the equipment may cause the cardiac stimulator malfunctions. Patients with cardiac pacemakers should not undergo any examination with this equipment without authorization and under the severe control of a specialized physician. For the same reason it is also necessary to be careful when using the equipment in proximity of operators or persons with implanted electric devices

- **Rechargeable Battery Pack.** The rechargeable battery pack installed in the equipment contains one cell that is not accessible to the user and its replacement should be performed only by qualified personnel, authorized by PREVENTICE. Anyway, you should consider the following general warnings (e.g. in case of disposal of replaced parts with technical assistance).
    - Do not let the ends of the battery pack to come in contact with metal objects.
    - Keep away the battery pack from heat or flames.
    - Do not immerse the battery pack and avoid exposing it to rain or moisture.
    - Avoid direct mechanical trauma to the battery pack.
    - Do not attempt to disassemble, puncture, incinerate or short-circuit the battery. These operations may cause a fire or the emission of toxic chemicals.

- **Charge the battery pack**. In order to ensure the safety requirements, the battery pack must be recharged only by using the proper Charging Cradle and its medical AC/DC adapter, specifically provided by PREVENTICE together with the equipment. The model of adapter to be used is:

    - Trademark FRIWO, Model FW7662M/06

1.3.2 SAFETY OF THE OPERATING ENVIRONMENT

- **The equipment is not designed to be used in locations with inflammable vapors or gases that may cause explosions**. The equipment must not be used in atmospheres with a high concentration of oxygen or in buildings where inflammable substances or anesthetic agents are present. The atmosphere is considered as oxygen-saturated when the oxygen or nitrous oxide (NO_2) concentration contained in the environment is over 24%.

- **The equipment is not designed to be used in MRI area**. The equipment should be removed before Magnetic Resonance Imaging (MRI).

- **The equipment and its internal parts are protected against the inflow of liquids according to IPX4 degree of protection.** The equipment is protected

against the dripping, spraying and splashing of water and relevant harmful effects. Avoid submitting the equipment to the risk of water jetting or temporary and continue immersion because its protection degree do not guarantees protection of internal parts against ingress of liquids. Do not use the equipment where such risks are present. Devices in which liquids have accidentally penetrated must be immediately cleaned and checked by authorized qualified staff.

- **Use of the equipment in humid Environment** is allowed if conditions are compliant to the environmental limits defined in the following bullet, which are in accordance with the requirements of the applicable general and particular IEC 60601 standards.

- **Use the equipment within the environmental limits of specified temperature, humidity and pressure**. The equipment is designed to work in environmental conditions that, in compliance with the IEC 60601-1 directions and the 60601-2-47, are defined as standard:

  - temperature +10°C / +45°C

  - relative humidity 10% / 95% RH

  - atmospheric pressure 700 / 1060 hPa

  The equipment could heat up during its normal use or battery recharge. This aspect should be considered as a normal characteristic of the equipment due to the high integration of the electronic circuitry inside. Never the equipment heating up should be considered as a potential fault or as a defect of the equipment itself.

- **Make sure the electric wiring of the building is efficient before connecting the power supply to the mains**. When the equipment (power supply of Charging Cradle) is connected the environmental mains, make sure that the building wiring is correctly functioning and efficient and compliant to the local regulations and standards.

- **Be careful using the equipment in locations disturbed by strong magnetic fields**. The equipment is compliant with the EMC requirements (Electromagnetic Compatibility) according to what specified by the IEC 60601-1-2 standard and 93/42/EEC European Directive. In every case it is recommended to keep the equipment away from disturbance sources and induced electromagnetic fields surpassing the values prescribed by the standard in order to avoid any possible instabilities and malfunctioning of the equipment. For more detail about device classification and minimum distances, please refer to paragraph 1.11 “Electromagnetic compatibility” of the present manual.

- **Be careful using the equipment near short-wave or micro-wave devices**. If the equipment is used in an area where there are also short-waves or micro-wave devices, it is necessary to remember that these may cause instability and interfere with the correct working of the equipment. Do not use the equipment near X-ray or diathermy devices.

`

1.3.3 OTHER PRECAUTIONS

- **Take care when using the equipment on patients who are pregnant**. It is necessary to be careful when using the equipment in the case of patients who are pregnant. These patients should not undergo any examination with this equipment without authorization and under the severe control of a specialized physician.

- The equipment is intended for adult use only with a weight greater than 10 Kgs.

- **Take care when using the equipment on patients with potentially life-threatening arrhythmias requiring hospitalization.** These patients should not undergo any examination with this equipment without authorization and under the severe control of a specialized physician**.**

- **Take care when using the equipment on patients with known skin allergies or sensitivities to acrylic, hydrogel or silicone adhesives.**

- **Take care when using the equipment on patients with friable skin.** It is necessary to be careful when using the equipment in the case of patients with sensitive skin or skin disease, because the adhesive electrode may cause skin irritation. Patients with sensitive skin should not undergo any examination with this equipment without authorization and under the severe control of a specialized physician.

- **Do not apply creams or lotion to the skin prior to use equipment.** The application of creams or lotion could cause a bad contacts of the electrodes and a bas adhesion of the patch and consequently a bed signal acquisition

- **Bodyguardian is not waterproof.** The device should be removed by patient before bathing, showering or swimming.

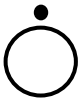
- **Bodyguardian has a usage limited to one patient at a time**.

1.4 GRAPHIC SYMBOLS IN COMPLIANCE WITH THE IEC 60601-1 STANDARD

The following table shows description and localization of all graphic symbols in compliance with the IEC 60601-1 safety standards present on the equipment panels and/or on any other instruments or external devices to which the equipment may be used in cojunction to or present in the same environment.

IEC 60601-1 SYMBOL	DESCRIPTION	POSITION
	**Alternating current**	Symbol placed on the connection points between the equipment and the mains (alternating current source).
	**Direct current**	Symbol placed on the connection points to direct current source.
	**Equipotential terminal**	Symbol placed on the outlet connecting the equipment to the equipotential node of the building, if any.
	**Protective earth (ground)**	Symbol placed on the connection points between the equipment and the protective grounding.
	**High voltage**	Symbol placed on circuits or equipment parts with high voltage.
	**Attention! Refer to the attached instructions.**	Symbol placed on items for which it is important to read the Operator Manual for relevant information (see ATTENTION paragraph).
	**Device with CF-type applied parts**	Symbol placed on applied parts to the patient with a CF-protection level.
	**Device with BF-type applied parts**	Symbol placed on applied parts to the patient with a BF-protection level.
	**Device with B-type applied parts**	Symbol placed on applied parts to the patient with a B-protection level.

`

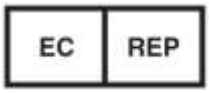
IEC 60601-1 SYMBOL	DESCRIPTION	POSITION
	**Off (disconnected from the mains)**	Symbol placed on the off/on positions of the whole equipment general power switch.
	On (connected to the mains)	Symbol placed on the off/on positions of the whole equipment general power switch.
	**Off (for a single part of equipment)**	Symbol placed on the off/on switch of a single part of the equipment.
	**On (for a single part of the equipment)**	Symbol placed on the off/on switch of a single part of the equipment.
	**Device with Class II protection type against electric shock**	Symbol placed in the identification label of the equipment.

1.5 OTHER GRAPHIC SYMBOLS

The following table shows description and localization of all symbols placed on the equipment panels and/or on any other instruments or external devices to which the equipment may be used in cojunction to or present in the same environment.

SYMBOL	DESCRIPTION	POSITION
	**Input**	Symbol placed on the signal input or mains voltage input connectors of the equipment.
	**Output**	Symbol placed on the signal output or the mains voltage output connectors of the equipment.
Rx Only	**Prescription Only**	Symbol placed on the identification label of the medical device indicating that Federal (USA) law restricts this product to sale by or on the order of a physician.
IPX4	**Degree of protection against ingress of water (spashing)**	Symbol placed on the identification label of the medical device indicating that the device is protected against the splahing of water.
	**Functional Mode and Communications status**	Symbol placed close the central led of device to indicate the functioning and communication status of the device
	**Radio Frequency emitting device (non-ionizing electromagnetic radiation)**	Symbol placed on the identification label of the medical device to indicate that the device emittes Radio-Frequency for its normal functioning.
	**Lot number**	Symbol placed on the identification label of the medical device together with the device lot number.
	**Battery charge status**	Symbol placed close the led of device to indicate the battery charge status and re-charge condition.
REF	**Reference number**	Symbol placed on the identification label of the medical device together with the device reference number.
SN	**Serial number**	Symbol placed on the identification label of the medical device together with the device serial number.

`

	**Date of manufacture**	Symbol placed on the identification label of the medical device together with the device manufacture date.
	**Manufacturer**	Symbol placed on the identification label of the medical device together with the name and address of the device Manufacturer
	**Authorized Representative in the European Community**	Symbol placed on the identification label of the medical device together with the name and address of the device Authorized Representative in the European Community.
	**Crossed-out wheeled bin**	Symbol placed on the identification label of the medical device. This symbol indicates the prohibition of throw the medical device in the household wheeled bin device when at its “end of life”.
	**Recyclable**	Symbol placed on Battery Pack. The symbol indicates the components of the object are recyclable at the end of life.
	**Use by**	Symbol placed on the identification label of the medical device together with the device expiration date.
	**Do not reuse**	Symbol placed on the identification label of the medical device. This symbol indicates that the device is a disposable one and cannot be used more than once.
	**Sterile**	Symbol placed on the identification label of the medical device indicating a sterile device.
	**Sterilization with steam or dry heat**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (steam or dry heat).
	**Sterilization with ethylene oxide**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (ethylene oxide).
	**Sterilization by irradiation**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (irradiation).
	**Refer to the instructions for Use/functioning.**	Symbol placed on the identification label of the medical device recommending to refer to the instruction for use/functioning for more information about the usage of the device.

	**Temperature Limit**	Symbol placed on the identification label of the medical device together with the indication of temperature limits (high and low limits) for the usage/storage of device.

1.6 ATTENTION SYMBOL

The **ATTENTION** symbol shown below, placed on the equipment casing, refers the user to the Operator Manual for information, warnings and suggestions which are particularly important for a correct and safe use of the equipment.

In particular, when it is placed on connecting points or commands or led indicators, this symbol refers the user to carefully read the Operator Manual for instructions concerning the nature and safety of such connection and/or detailed description of the commands and meaning of indicated events/situations for the operator.

For location of the ATTENTION symbols placed on the equipment, please refer to chapter 2 "*Description of the Device*" of this Operator Manual. This chapter shows the pictures of the equipment panels with the corresponding commands, connections, symbols, and labels. Each attention symbol comes with a detailed explanation of its meaning.

1.7 PRODUCT TRACEABILITY

In order to guarantee the traceability of the product, according to what stated in the ISO 13485 quality standard, QSR 21 CFR Parte 820 FDA, and the 93/42/EEC European Directive on Medical Devices (and its revised version 2007/47/EC directive), PREVENTICE kindly requests the original owner of the equipment to give communication to our main offices of any conveyance of the product to third parts, by sending a photocopy of the proper duly filled-in *Product traceability form* **(see enclosure 1.7)**, or by communicating in writing the data indicated in the form. The data concerning the device can be found on its identification label.

The form shall be sent either directly or through any subsidiary or the nearest authorized distributor to the any PREVENTICE operating office. The list of the main PREVENTICE head and branch offices is contained in chapter "*Request for assistance*" of this manual.

1.8 VIGILANCE SYSTEM

The device is subject to a vigilance system (post-marketing vigilance) that PREVENTICE and their distributors and retailers apply to the products they put on the market to safeguard the patient and the physician from serious or

potentially serious hazards during the normal use of the equipment, in order to be able to remove the source of such hazards with the best efficiency and timing.

To the purpose of helping PREVENTICE take any timely and effective corrective measure, it is extremely important that the user performs a careful inspection of the equipment performances in order to identify or foresee any dangerous situation for the patient's and the user's health.

For this reason, the user shall give immediate communication of any malfunction or deterioration of the characteristics or the performances of the equipment or any mistake found in these instructions that caused or could cause serious damages to the patient's and the user's health.
In this case, the user may send a photocopy of the proper duly filled-in *Post-Marketing Vigilance Form* **(see enclosure 1.8)**, or communicate in writing the data indicated in the form.
The instrument's data can be collected from it's identification label.

The form shall be sent either directly or through any subsidiary or the nearest authorized distributor to the any PREVENTICE operating office. The list of the main PREVENTICE head and branch offices is contained in chapter "*Request for assistance*" of this manual.

Enclosure 1.7

PRODUCT TRACEABILITY FORM

To: PREVENTICE
1652 Greenview Drive SW
Rochester, MN 55092

c.a. Quality Assurance Department

System/device name…….....

Device code / reference number (REF) .....

Device serial (SN) / lot number (LOT) .....

Name and address of the former owner .....
.....
.....
.....

Name and address of the present owner .....
.....
.....
.....

Date:.....

Signature

.....

(please name in full)

Enclosure 1.8

POST-MARKETING VIGILANCE FORM

To: PREVENTICE
1652 Greenview Drive SW
Rochester, MN 55092

c.a. Quality Assurance Department

System/device name.....

Device code/reference number (REF) .....

Device serial (SN)/lot number(LOT) .....

Description of the real or potential hazard……
.....
.....
.....
.....

User's comments/suggestions .....
.....
.....
.....
.....

User's address.....
Phone..... Fax .....

Department where the device is installed.....
Person in charge of the department.....

Data:.....

Signature

.....

(please name in full)

`

1.9 INFORMATION ABOUT RECYCLING OF MATERIALS

In accordance with the specific worldwide regulations, PREVENTICE aims to continuously improve the design and the fitting of electromedical devices in order to reduce as much as possible any negative impact on the environment caused by the management of component parts, consumer materials, packaging and discharge of devices when at their "end of life".

Packaging materials were conceived and produced so as to allow the re-usage and the salvage, including recycling, of most part of materials and to reduce the quantity of garbage or residual products for discharge as much as possible. In particular, packaging materials have been produced so as to limit the presence of harmful metals and of other dangerous substances to minimum quantities in emissions, ashes or lixiviation residual products. The total concentration levels of heavy metals such as Lead, Cadmium, Mercury and hexavalent Chrome contained in the packaging materials are in accordance with the limits established by the directives in force related to this subject.

In order to cause minimum consequences to the environment, the design of the device includes the highest possible miniaturization of the circuits, with the least possible differentiation of materials and components, with a selection of substances that guarantee the highest possibility to recycle and re-use the components and to discharge them without risks for the environment.

The device is designed to guarantee the easy separation or disassembling of the materials containing polluting substances from the others, in particular during the operations of servicing and replacing parts. In particular, the largest plastic components are marked according to their plastic contents in order to make it easier to recycle the product.

ATTENTION

Please refer to local codes and regulations for proper disposal/recycle requirements of packaging and consumer materials and of the device when at its "end of life".

1.10 ELECTROMAGNETIC COMPATIBILITY

This medical device is designed for use in the electromagnetic environments declared in the tables below, in compliance with the IEC 60601-1-2:2001 (second edition) standard. The operator must assure that the device is used in an environment compliant to this standard.

This 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.

The device is labeled FCC-ID S9NMHBGW1.

Table 1 - Electromagnetic Emissions

Emission Test	**Compliance**	**Electromagnetic Environment**
Radiated and conducted RF emissions CISPR 11	Group 1	This medical device use RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Radiated and conducted RF emissions CISPR 11	Class B	This medical device is suitable for use in all establishments, including domestic directly connected to the public low voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Complies Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

`

Table 2 - Electromagnetic Immunity

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance**	**Electromagnetic environment**
Electrostatic Discharge (ESD) IEC 61000-4-2	6 kV in contact 8 kV on air	IEC 60601-1-2 Test Levels	Residential/Hospital (**Note 1**)
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply line 1 kV for input/output lines >3m	IEC 60601-1-2 Test Levels	Residential/Hospital (**Note 2**) (**Note 3**)
Surge IEC 61000-4-5	1/0.5 kv differential mode 2/1/0.5 kV common mode	IEC 60601-1-2 Test Levels	Residential/Hospital (**Note 2**) (**Note 3**)
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % of rated voltage (voltage dip 100 %) for 0.5 cycles 40 % of rated voltage (voltage dip 60 %) for 5 cycles 70 % of rated voltage (voltage dip 30 %) for 25 cycles 0 % of rated voltage (voltage dip 100 %) for 5 seconds		

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		

Table 3 - Electromagnetic Immunity for non-life supporting equipment

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance**	**Electromagnetic environment**
			Portable and mobile RF communications equipment should be used no closer to any part of this medical device**,** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter (table 4 - Recommended separation distance).
Radiated RF fields IEC 61000-4-3	3 V/m from 80 MHz to 2.5 GHz	IEC 60601-1-2 Test Levels 3 V/m	$d = 1.2\sqrt{P}$ 80 MHz a 800 MHz $d = 2.3\sqrt{P}$ 800 MHz a 2.5 GHz
Radiated RF fields IEC 61000-4-6	3 V from 150 kHz to 80 MHz	IEC 60601-1-2 Test Levels 3 V	$d = 1.2\sqrt{P}$
			Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths for fixed RF transmitter, as determined by an electromagnetic site survey, should be less then the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Measures to be taken
Note 1: The floor should be in antistatic material (wood, ceramic, ect.). If covered by synthetic material, relative humidity should be maintained at least at 30%. **Note 2:** The quality of the electrical power supply and the mains frequency magnetic fields should be typical of domestic, commercial and hospital environments. **Note 3:** If the operator has to work without a break while power supply is interrupted, it is necessary to have power supplied through a UPS (Uninterruptible Power Supply) unit.

1.10.1 RECOMMENDED DISTANCES FROM RADIOFREQUENCY (RF) COMMUNICATION SYSTEMS

As stated in the chapter 1 "Information about safety" of this operator manual, it is recommended to not use Radiofrequency (RF) transmission system near the medical device. RF systems can cause interference which may cause instability and interferences with the correct working of the equipment and it may alters the signal acquired tracing.

The operator can prevent interference caused by electromagnetic field by maintaining a minimum distance between the medical device and the RF communication system being used (cell phones, mobile phones, etc,).
The following table shows the minimum distances in meters, according to the maximum power at RF system output.

Table 4 – Recommended separation distance for non-life supporting equipment

Rated maximum output power of the transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150KHz to 80MHz $d=1.2\times\sqrt{P}$	**80Mhz to 800MHz** $d=1.2\times\sqrt{P}$	**800MHz a 2.5GHz** $d=1.2\times\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at the maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated the equation applicable to the frequency of			

`

the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:

(1) at 80MHz and 800MHz, the separation distance for the higher frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

The operator must remember that the intensity of the electromagnetic fields generated by fixed transmitters (radio-base stations for cellular or cordless phone, TV and radio transmissions, amateur radio transmission, etc.) cannot be predicated on theoretical basis.
Consequently, a direct measure may be necessary in the environment where is used the medical device.

If the intensity of the electromagnetic fields exceeds that specified in the immunity levels shown in the previous tables, and the medical device behaves incorrectly working, additional measures may be necessary. I.e. orienting or locating the medical device in a different way.

1.11 BIOCOMPATIBILITY AND INFECTIONS CONTROL

No system component is intended to be in contact with the patient during the usage.
Electrodes and sensors are not intended to be parts of the Bodyguardian Control Unit product.
All the body contacting material are not part of the MD, in any case remember that electrodes and sensors MUST meet the requirements of 93/42/EEC Medical Devices Directive and its revised version (CE marked) for the European Community and MUST have FDA clearance/approval for the U.S. market.

1.12 CAUTION FOR THE U.S. MARKET

Federal law (USA) restricts the device to sale by or on the order of a licensed practitioner or therapist.

Medical professionals prescribe the Bodyguardian system to obtain physiological data from their patients. It does not replace direct communication between physicians and patients and does not summon physicians or emergency personnel.

`

CHAPTER 2
DESCRIPTION OF THE DEVICE

2.1 GENERAL OVERVIEW

The Bodyguardian Control Unit is a wearable battery power device intended for use as a part of a Multi-Parameter Analysis System and is designed to be used by a System Builder in a Multi-Parameter Analysis Application.
The Bodyguardian Control Unit is worn on the chest for the acquisition, recording and transmission via a Bluetooth radio link of physiological parameters to external host devices which can analyze by the suitable proper Application Software and/or forward the data to additional storage elements or system.
The Bodyguardian Control Unit is also capable to record symptomatic and asymptomatic events. The Bodyguardian Control Unit continuously records, stores and periodically transmits the following physiological data:

- Single lead ECG
- Heart rate
- Respiratory rate
- Posture
- Activity
- Event marker

The Bodyguardian Control Unit is used for ambulatory monitoring of non-lethal cardiac arrhythmias. Bodyguardian Control Unit is a wearable electronic device that is worn on the chest. The device includes a disposable fabric adhesive component that attaches to the subject and connects to the enclosed electronic components.
The device will be worn intermittently or continuously for up to a 30-day period. The recordings will be stored on the Bodyguardian Control Unit and transmitted by the device via Bluetooth communication to an external Associated Device (Android smartphone or other). The device is prescription only.

The Bodyguardian Control Unit recorder is intended to be used in a:

- *"Home Care"* environment without clinicians surveillance.
- *"Clinic Care"* environment with clinicians surveillance

The device is intended to be used by two different categories of end-users:

1. The patient which will use the device for continuous monitoring applications and who will have to:

    - apply the device to the body by connecting the Bodyguardian Control Unit to the disposable patch and attaching it to the selected body area;

- turn it on and off by using the appropriate button;
- manage the recharging of the Bodyguardian Control Unit using the dedicated charging station and power supply cable;
- monitor the status of the device by looking at the led lights and colors
- manage the devices by using the mobile phone application

2. The clinicians who will eventually subscribe the use of the device to the patient and who will be in charge of:
   - Setting the initial thresholds and baselines for the parameters based on patient's conditions to personalize it (on Multi-Parameter Analysis System side)
   - Reviewing the data acquired and transmitted from the device to the remote server location (Multi-Parameter Analysis System) for diagnosis, trends monitoring and in general clinical evaluations.

Depending on the Environment, optional algorithms and/or thresholds (settable via host software) can be used to generate measurements on an advisory basis for patients. These are presented for:

- Review and interpretation by the clinician, based upon knowledge of the patient.
- Results of the physical examination.

The data provided by the Bodyguardian Control Unit are exclusively intended to be used by trained medical personnel to assist patients that requires monitoring of physiological parameters with reference of the followings context:

- Screening of patients with symptoms suggesting arrhythmia over a minimum 24-hour period.
- Screening and off line evaluation of HR and Breath variability if the nature of this variability cannot determine a Life-threatening for the patient.
- Not intended to allow direct diagnosis or monitoring of vital physiological processes parameters (for instance cardiachearth rate, respiration), where the nature of variations is such that it could result in immediate danger to the patient.
- Not intended for therapeutic purpose.

The "Body Guardian" Recorder is intended for adult use only with a weight greater than 10 Kgs, without race exclusion. Patient with implanted device are excluded to wear this device.
The Bodyguardian Control Unit is intended for System builder user in order to create a complete remote ambulatory monitoring system including Bodyguardian Control Unit kit, communication hub (Android smartphone or other) and System Server.

`

All aspects related to safety and effectiveness of the whole ambulatory multi parametric monitoring system is under the complete responsibility of System Builder.

The Bodyguardian Control Unit is provided with a Base Kit containing the following base elements:

- The Bodyguardian Control Units (2 units)
- The Bodyguardian Charging Cradle
- The AC/DC medical power supply
- The Disposable adhesive electrodes patch
- The User Manual
- The Android Smartphone

The Bodyguardian Disposable adhesive electrodes patch, the AC/DC medical power supply, the User Manual and eventually the Smartphone are provided by the System Builder.
Here below the pictures of the different elements composing the Bodyguardian Control Unit base kit:

Figure 2-1 Components of Bodyguardian Control Unit base kit

`

2.2 BODYGUARDIAN CONTROL UNIT DESCRIPTION

The following figures (2-2 and 2-3) show the Bodyguardian Control Unit:

Figure 2.2 – Bodyguardian Control Unit: front view

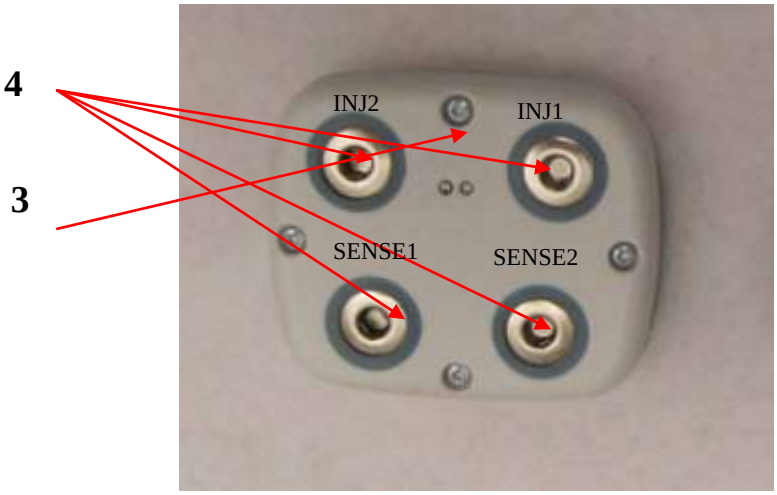


Figure 2.3 - Bodyguardian Control Unit: back view

In the previous figures the following components can be found:

1. Signaling Leds
2. Push button
3. Charger connectors (n° 2 contacts)
4. Patient connectors (n° 4 snap contacts to connect to Disposable adhesive electrodes patch) with the following configuration reading in clockwise sense from the Top-Left angle: INJ2, INJ1, SENSE1, SENSE2. The connection of the device to the disposable adhesive patch is possible, due to mechanical constraints, only in one correct way.

2.2.1 PATIENT CONNECTION

Biologic input signals are acquired by Bodyguardian Control Unit through the patient connectors (fig. 2.4).

Figure 2.4 - Patient connectors

which uses the 4 ECG snaps to interconnect the Bodyguardian Control Unit with the Disposable electrodes patch.

The connection is guaranteed through the four snaps on the SnapStrip.

Figure 2.5 - Patient connection

ATTENTION

All the patient applied parts and corresponding input sockets of Bodyguardian Control Unit (patient inputs) are electrically isolated according to IEC 60601-1 standard requirements for internally powered, Type BF equipments. This characteristic is indicated to the operator with the proper symbol placed on the external cover of the device.

2.2.2 BLUETOOTH CONNECTION

The Bodyguardian Control Unit is equipped with an integrated Bluetooth network interface (for Protocol Specification please refer to the document BGP110006_Commend_Interface_Specifciations) that allows to establish a pairing connection with an external Associated Device (e.g. Android smartphone or other).

The Bluetooth interface can be used to configure the Bodyguardian Control Unit and to transmit the data registered and stored on the Bodyguardian Control Unit to the Associated Device.

The communication between Bodyguardian Control Unit and the external Associated Device is handled via software.

2.2.3 SIGNALING LEDS

The following figure shows the signalling Leds placed on the front cover of the Bodyguardian Control Unit.

Figure 2-9 – Signaling Leds

The 3 Monocolor Leds indicate device status and conditions.

The Leds indicates the following conditions:

LED 1 – Yellow: indicates the Device Charging Status;

LED 2 – Green: indicates the Device Operative Mode Status;

LED 3 – Yellow: indicates special Events occurrences.

The following table summarizes the possible Leds configuration status and relative significance:

Led states

OFF	*Led Off*
SLOW	*Led Turned on every 10 Sec & OnTime 1000 ms*
MEDIUM	*Led Turned on every 1 Sec & OnTime 500 ms*
FAST	*Led Turned on every 0.5 Sec & OnTime 100 ms*
ON	*Led On*
d.n.c.	Do Not Care

LED Priority	High	H
	Medium	M
	Low	L

		HW/SW driven	**SW driven**		**SW driven**	
		LED1	LED2		LED3	
		Charging Led	Operative Led		Event Led	
		Yellow	Green		Yellow	
		STATE	STATE	Priority	STATE	Priority
Device	*BGD OFF*	**OFF**	**OFF**		**OFF**	
	ON charge	**ON (by HW)**	*d.n.c.*		*d.n.c.*	
	FULL charge	**OFF**	*d.n.c.*		*d.n.c.*	
	Identification	*d.n.c.*	**Medium-Q**	**H**	**Medium-QN**	**H**
Modes	*IDLE*	*d.n.c.*	**ON**	**L**	**OFF**	
	ENGAGED	*d.n.c.*		**L**	*d.n.c.*	
	SERVICE	**ON (by SW)**	**Medium-Q**	**H**	**Medium-QN**	**H**
	---> SERVICE (FOTA)	**ON (by HW)**	*d.n.c.*		*d.n.c.*	
	---> SERVICE (ACCEPT-TEST)	**Test driven**				
	MONITORING	*d.n.c.*	**SLOW**	**L**	*d.n.c.*	
	STREAMING	*d.n.c.*	**FAST**	**M**	*d.n.c.*	
Events	*Symptomatic Event*	**Not considered**				
	Electrodes Detached	*d.n.c.*	*d.n.c.*		**FAST**	**M**
	Low Battery Level	**SLOW (by SW)**	*d.n.c.*		*d.n.c.*	
Communic.	*Active Connection (In/Out)*	*d.n.c.*	**FAST**	**M**	*d.n.c.*	
	Data Transfer Failure	*d.n.c.*	*d.n.c.*		**ON**	**L**

`

2.2.4 MULTIFUNCTION PUSH BUTTON

The following figure shows the multifunction push button placed on the front cover of the Bodyguardian Control Unit.

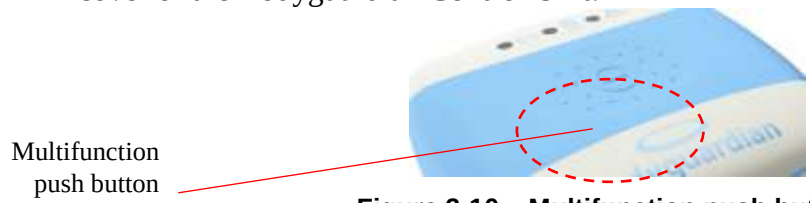


Figure 2-10 – Multifunction push button

The push Button turns ON and OFF the device and insert symptomatic events notification from the patient. The button has the following functional modes:

- Power on/off

- When the device is OFF, press the button with a short pressure to Turn ON the device (T>0sec).
- When the device is ON, press the button with a long pressure to Turn OFF the device (T>10sec).

- Additional functions

- When the device is ON and operative, click the button to record a symptomatic event. The pressure time must be < 10sec to prevent the device to Turn OFF.

2.3 BODYGUARDIAN CHARGING CRADLE

The Bodyguardian Control Unit is provided with a proprietary Charging Cradle which must be used to re-charge the internal battery (Figure 2.11).

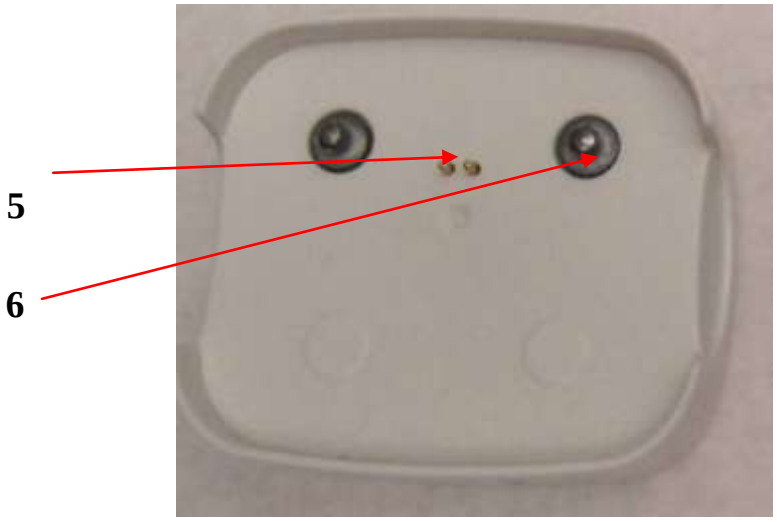


Figure 2-11 – Bodyguardian Charging Cradle – Upper view

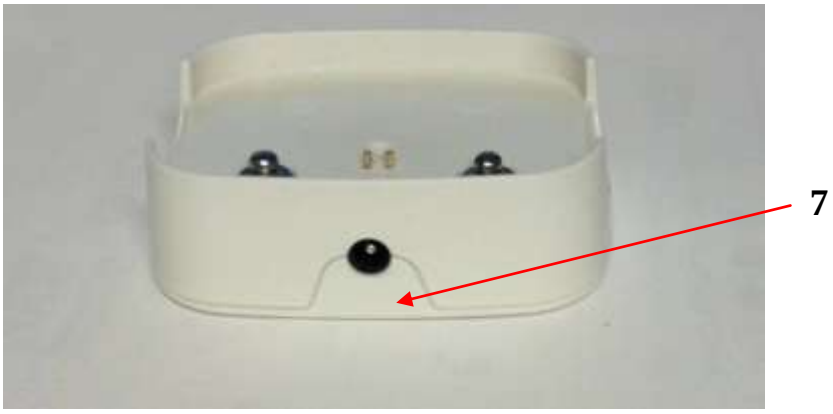


Figure 2-12 – Bodyguardian Charging Cradle – Side view

In the previous figures the following components can be found:

5. Recharging contacts (to charge the Bodyguard Control Unit)

6. Snaps (to properly place and hold the Bodyguardian Control Unit)

7. Input voltage connector (connection of AC/DC medical adapter)

2.4 AC/DC MEDICAL POWER SYPPLY

The following figure shows the specified medical AC/DC adapter for Bodyguardian Charging Cradle powering up and their parts:

8. AC/DC Medical power supply

9. Mains plug

10. Isolated voltage output connector with cable

Figure 2-13 – AC/DC Medical Power Supply

2.5 DISPOSABLE ADHESIVE ELECTRODES PATCH

The following figure shows the disposable adhesive electrodes patch, which integrates four electrodes used to acquire ECG and Bio-impedance signals.

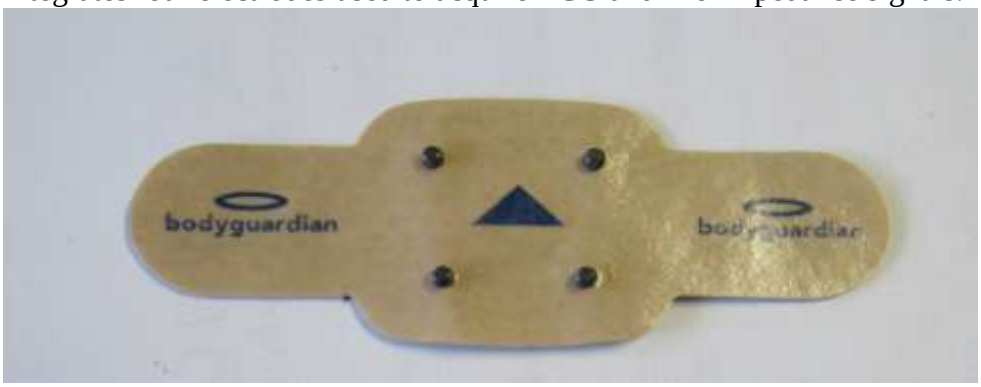


Figure 2-14 – Disposable adhesive electrodes patch

It is attached to the patient's skin and is connected to the Bodyguardian Control Unit using four snaps. Each SnapStrip has a water resistant layer, ECG electrodes and snaps that create an electrical connection to the Bodyguardian Control Unit.

CHAPTER 3
POWERING UP THE DEVICE

The Bodyguardian Control Unit is powered through an internal battery. The battery is rechargeable by means of the Bodyguardian Charging Cradle connected to the mains trough the AC/DC power supply.

3.1 BATTERY CHARGING

While operating, if the Bodyguardian Control Unit detects that the battery level is below a certain level (Low Battery Level as defined in the Preventice Requirement Document) of the full capacity, LED 1 ( ) starts blinking with a slow frequency, 1 second every 10 seconds, indicating that the device needs to be recharged.
In this case, switch off Bodyguardian Control Unit and remove it from the strip placed on the patient.
Additionally, if the Bodyguardian Control Unit detects that the battery level is below a safety level (Critical Battery Level as defined in the Preventice Requirement Document) of the full capacity, the Bodyguardian Control Unit starts an automatic power off procedure to safely close the application and guarantee the integration of the data sampled and stored up to that moment.

ATTENTION

If the device is not switched off manually by the user, when approaching a very low battery level, the device will initiate an automatic power down procedures which will allow uploading all the data acquired and safely switch off the device.

To recharge the Bodyguardian Control Unit place it on the Charging Cradle according to the appropriate orientation (only one is possible due to the mechanical constraints) and only after this operation connect the Charging Cradle to the AC/DC Power supply and this last to the mains.
If the Bodyguardian Control Unit is properly placed and connected, the LED 1 ( ) turns ON indicating that the device is charging. When the device battery is fully charged the Led 1 turns OFF.
After the recharging operation is complete disconnect the AC/DC Power supply from the mains and only after this operation remove the equipment from the Charging Cradle.
.

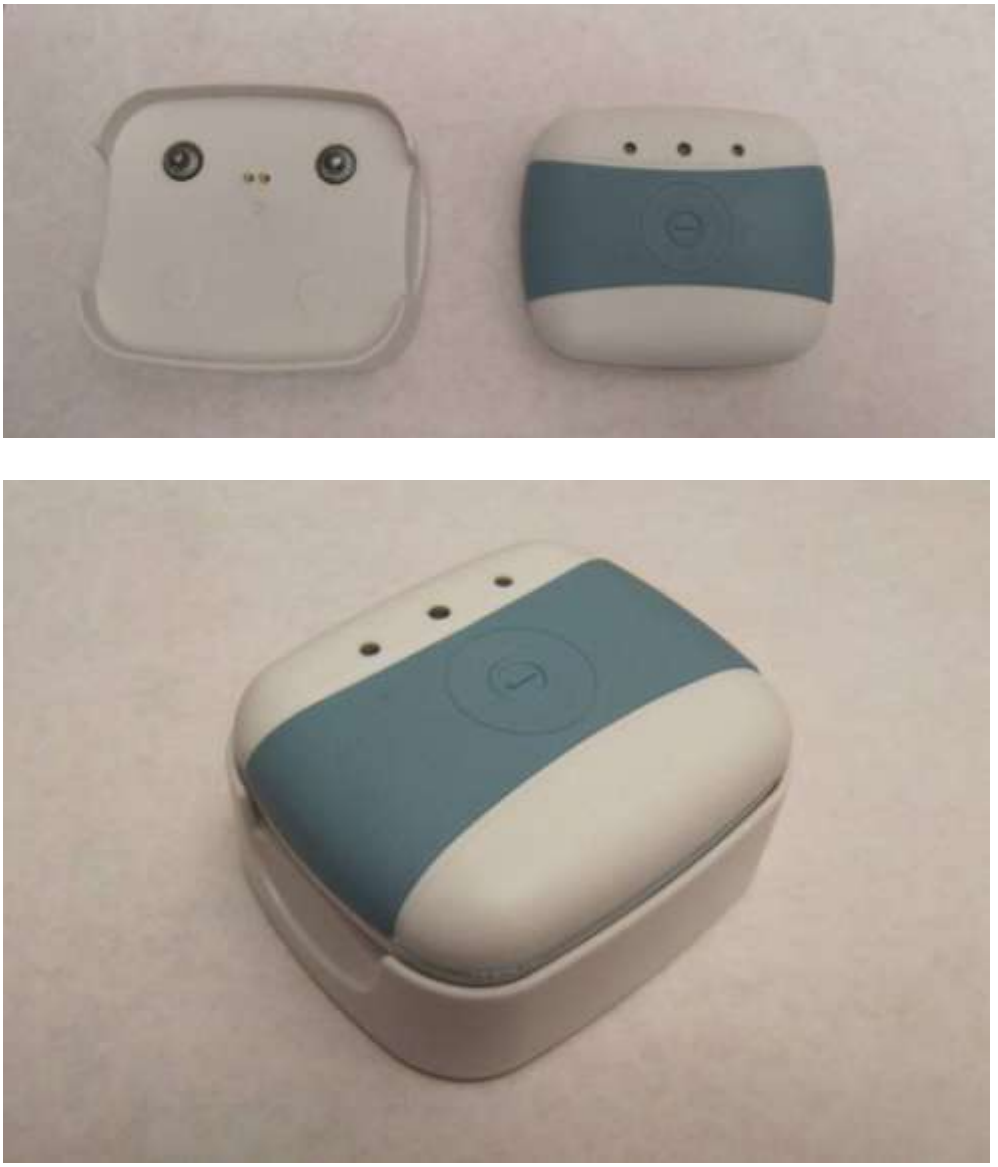


Figure 3-1 – Connection to Bodyguardian Charging Cradle

3.1.1 RECORDING AUTONOMY

The autonomy of operating and recording of the Bodyguardian Control Unit is determined by many factors linked each other.
Main factors determining the duration are the following:

- Battery charge level
- Batteries performance
- Data Sampling frequencies
- Operative Mode.

The Rechargeable battery integrated in the device has a capacity of 380mA. When fully charged, the battery guarantees an autonomy which span from 3 hours,in continuous Streaming mode of all the data at the maximum sampling frequency, to 24 hours ,in Monitoring mode with data sampled at the lowest frequency and stored in the internal memory for uploading at the end of the usage.

3.2 SWITCHING ON/OFF THE DEVICE

In order to switch ON the Bodyguardian Control Unit, push with a short pressure the button area in middle of the upper face (Push button). LED 2 and LED 3 will flash when the Bodyguardian Control Unit is turned on. After the Bodyguardian Control Unit completes its initialization, the middle led ( ) will flash green.
The Bodyguardian Control Unit can be switched OFF by pressing the Push button with a long pressure (more than 10 seconds). All the LEDS will turn OFF.

`

CHAPTER 4
WORKING MODE

4.1 PREPARING THE PATIENT

The stage of preparing the patient is very important in order to obtain a good acquisition of the biological signals and can be divided in the following phases:

- Identification of the Disposable adhesive electrodes patch application site.
- Preparation of the skin.
- Application of the Disposable adhesive electrodes patch.

4.1.1 DISPOSABLE ADHESIVE ELECTRODES PATCH APPLICATION SITE

Attach the BodyGuardian Device at one of three positions on your chest. Your healthcare provider will show you correct placement on your chest. Follow the instructions carefully. Correct placement is very important to get accurate readings from your heart.

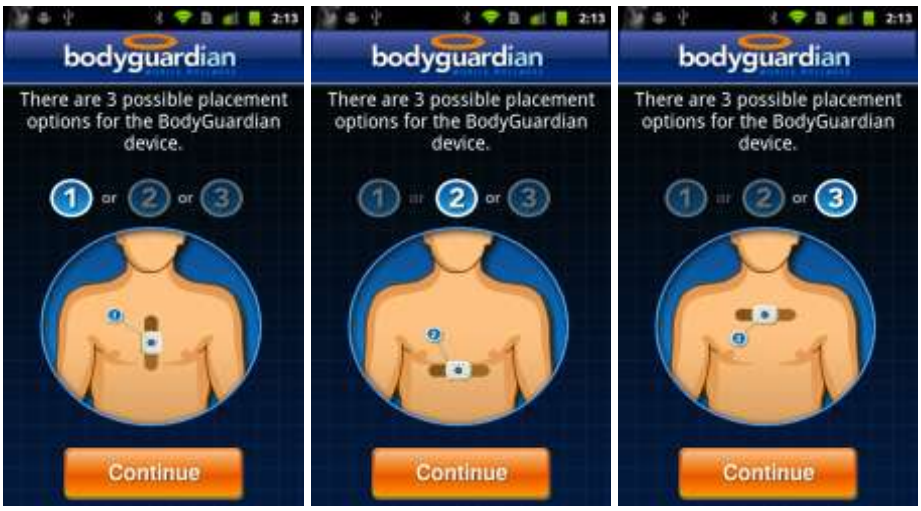


Figure 4-1 Preferred Bodyguardian Placement

4.1.2 PREPARING THE SKIN

The phase of preparing the body area on which placing the Bodyguardian Control Unit, has an important role in establishing a good electric contact, thus allowing the best kind of recording.
Here below the recommended procedure:

- Prepare the skin area by cleaning with soap and water.
- If hair is present, shave the area.
- Make sure application area is dry with no lotion or cream applied.

4.1.3 PLACING THE DISPOSABLE ADHESIVE ELECTRODES PATCH

Follow the following instructions in order to correctly place the Bodyguardian Control Unit.

1. Before removing the Bodyguardian Control Unit from its charging station, ensure that the control unit is fully charged; the light LED 1 ( ) should be OFF indicating a full charge.

2. Attach the Bodyguardian Control Unit to the four snaps on the Electrodes Patch. Make sure all four snaps are connected; see **Error! Reference source not found.**2.

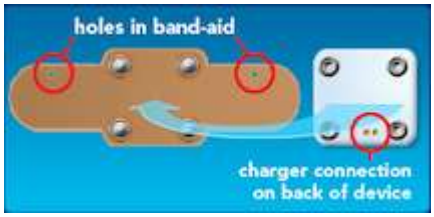


Figure 4-2 Connecting Bodyguardian Control Unit to Electrodes Patch

3. Peel plastic off the back of the Electrodes Patch.

4. Ensure that the arrow on the Electrodes Patch points towards your left arm if the patch is placed vertically (**Error! Reference source not found.**) or up towards your head if placed horizontally (**Error! Reference source not found.**).

5. Apply adhesive side of the Disposable adhesive electrodes patch to the skin on the established placement (§ 4.1.1), and gently press.

NOTE

The Disposable adhesive electrodes patch should be comfortable when properly positioned on the chest.

`

4.2 OPERATIVE MODES

The Bodyguardian Control Unit can be configured to run in different operative modes depending from the conditions (i.e. presence of Bluetooth connection with an Associated Device, configuration settings received, etc.) as described below:

- **IDLE Mode**: is when the Bodyguardian Control Unit is powered ON and it is waiting to establish a Bluetooth pairing connection with the Associated Device.
- **ENGAGED Mode**: is when the Bodyguardian Control Unit is powered ON, waiting for a command from a paired Associated Device or a request for pairing from a new Associated Device.
- **MONITORING Mode**: is when the Bodyguardian Control Unit is powered ON, gathering and storing in the internal memory data at the frequency specified in the Configuration Settings, and sending the data as requested by the Associated Device.
- **STREAMING Mode**: is when the Bodyguardian Control Unit is powered ON and sampling the data as specified in the Configuration Settings, sending them directly to the Associated Device with periodicity specified by the last configuration commands received from the Associated Device.

The two main operative modes which characterize the functionalities and intended use of the device are Monitoring Mode and Streaming Mode.

4.2.1 MONITORING MODE

In monitoring mode the Bodyguardian Control Unit operates as a recorder of the physiological data. The acquired signals are stored in the internal memory of the device and works as an Holter. The data are sent from the Bodyguardian Control Unit to the Associated Device according to the configuration parameters received from the Associated Device during the configuration settings. The Associated Device is responsible for forwarding the data to a remote storage server for later analysis and evaluation.
In Monitoring Mode the Bodyguardian Control Unit can acquire and store the following data, depending on the configuration received:

- Raw Data
  - ECG (128 or 256 Hz)
- Derived values
  - Activity level
  - Body position values
  - Breathing rate values
  - Heart rate values
  - Heart rate reliability
  - RR interval variability
  - Battery level

The upload frequency depends on the Configuration Specifications. The Bodyguardian Control Unit is equipped with an internal memory capable to store up to 24 hours of data recording, enabling the device to work as an Holter equipment.

4.2.2 STREAMING MODE

In Streaming mode the Bodyguardian Control Unit operates as an acquisition and transmitter of the physiological data. The acquired signals are not stored in the internal memory of the device but are sent directly from the Bodyguardian Control Unit to the Associated Device according to the configuration parameters received from the Associated Device during the configuration settings. The Associated Device is responsible for forwarding the data to a remote storage server for later analysis and evaluation.
In Streaming Mode the Bodyguardian Control Unit can acquire and transmit the following data, depending on the configuration received:

- Raw signals:
  - ECG (128 or 256 Hz)
  - 3-axis accelerometer (50 Hz)
  - dZ bioimpedance (32 Hz)
  - Z0 bioimpedance (32Hz)
- Derived values:
  - Heart rate values,
  - Heart rate reliability,
  - Breathing rate values,
  - Activity level,
  - RR interval variability,
  - Body position values.

4.2.3 EVENT MONITORING

The Bodyguardian Control Unit has the capabilities to register symptomatic and asymptomatic events during the functionalities.
Symptomatic Events recording: while wearing the Bodyguardian Control Unit the user has the possibility to initiate an event recording, if is feeling symptoms that suggest the need for further evaluation, by pressing the push button in the middle of the device. The functionality is enabled either in Monitoring or Streaming Modes. In case of symptomatic event button push, Bodyguardian Control Unit will send a notification of the event to the Associated Device. If the Associated Device is not available, the Bodyguardian Control Unit will retry according to implementation and configuration requirement and eventually store in the internal memory the undelivered notifications.

`

Asymptomatic Events recording: while wearing the Bodyguardian Control Unit some asymptomatic events can be recorded. Asymptomatic events occurs when the values of physiological parameters detected violates the medical protocol specified by the configured thresholds. In case of asymptomatic event detection the Bodyguardian Control Unit will send a notification of the event to the Associated Device. If the Associated Device is not available, the Bodyguardian Control Unit shall retry according to the implementation and configuration requirement and eventually store in the internal memory the undelivered notifications.

4.3 INSTALLATION AND INSTRUCTIONS FOR THE PATIENT

The Bodyguardian Control Unit does not require specific installation procedure, except for the configuration section which must be executed by the external Associated Device.

WARNING

In order to configure the Bodyguardian Control Unit and to know the software details please refer to the indications contained in the User Manual provided by the System Builder.

In order to turn ON the Bodyguardian Control Unit push the button area in the middle of the device (Figure 4.4). The LED 2 and LED 3 will flash when it is turned on. After the Bodyguardian Control Unit completes its initialization, the middle led will flash green.
According to the configuration established, the Bodyguardian Control Unit will start the data acquisition and transmission.

During the monitoring, if you want to mark a symptomatic event, press the push button in the middle of the Bodyguardian Control Unit.

Figure 4-3 Bodyguardian Control Unit Push Button

CHAPTER 5
MAINTENANCE

5.1 GENERAL INFORMATION ABOUT MAINTENANCE

In order to keep the Bodyguardian Control Unit working for a long time and to ensure the patient's and the operator's safety, it is necessary that the general checks indicated below are periodically performed by medical or paramedical qualified staff or by technical staff authorized by Preventice.

- Perform a sight inspection of all the components, the accessories, in order to identify any traces of failure, damage, or disconnection.
- Verify that all labels and any warning or instructions printed on the device are readable.
- Check that the performances of the device are correct.
- Clean the external surface of the device carefully with the recommended products only.
- Replace parts or accessories only with those having the same characteristics or expressly indicated by Preventice.
- Discard replaced parts, accessories, and the device at its "end of life" according to the local standards and directives currently in force.

For all ordinary maintenance operations pertaining to the components to which the device is connected or auxiliary components not produced by Preventice such as external Associated Device (Android smartphone or other), please refer to the corresponding user's manual provided with them.

5.2 SAFETY CHECKS

It is essential to periodically check the equipment and the devices or systems it is connected to and all the connections in order to ensure that the equipment continues working efficiently and safely. It is also necessary to check the equipment to remove any dust deposits. Preventive or corrective maintenance operations must be performed by qualified technical staff expressly authorized by Preventice.

A sight inspection of the interconnections, with particular care for the snaps between equipment and the Disposable adhesive electrodes patch, can be performed also by the user in order to remark any breaking or disconnection. In case of need, immediately contact a qualified technician to solve the problem detected before continuing to use the equipment or connecting it to other devices. For the technical assistance request procedures, please refer to chapter "Request for assistance" of this manual.

ATTENTION

Safety checks must be accurately performed periodically.

5.2.1 CONNECTORS

Check the connector on the Bodyguardian Control Unit for broken or damaged contacts. If you find a damaged connector refer to qualified technical support service.

5.2.2 BATTERY PACK

The rechargeable battery pack installed on the device is not accessible to the user and its replacement should be performed only by qualified personnel expressly authorized by Preventice. Anyway, you should consider the following general warnings (e.g. in case of disposal of replaced parts with technical assistance).

- Do not let the ends of the battery pack come into contact with metal objects.
- Keep the battery pack away from heat or flames.
- Do not immerse the battery pack and avoid exposing it to rain or moisture.
- Avoid direct mechanical trauma to the battery pack.
- Do not attempt to disassemble, puncture, incinerate or short-circuit the battery. These operations may cause a fire or emit toxic chemicals.

ATTENTION

When a battery is replaced, it cannot be reused and must be discarded according to the standards and directives currently in force in the country where the equipment is used.

WARNING

The state of battery charge is not guaranteed for inactivity periods longer than 1 month of storage at temperatures up to +45 ° C.
It is generally recommended to perform a cycle of discharge/charging the battery after periods of inactivity.

5.3 CLEANING THE DEVICE

It is necessary to keep the equipment clean in order to avoid dust deposits, which could interfere with the efficiency of all the system components.
It is possible to clean the equipment external surface with a cloth lightly moistened with warm water and soap. Wipe the washed parts with a dry cloth.

WARNING

Do not immerse the equipment nor its parts in liquids, do not oil any part of it and avoid cleaning the external surface with alcoholic disinfectants that could cause damages and discoloration of the printed surfaces.

ATTENTION

Before cleaning any part of the equipment disconnect the equipment from the power supply and disconnect the device from any other equipment or external devices.

ATTENTION

Make sure no liquid seeps into the instrument and check it's complete dryness before to reconnect to the patient or before connecting it with other devices, thus switching it on.

WARNING

Use Isopropyl Alcohol or equivalent products in order to disinfect the BodyGuardian Control Unit, without immersing them into the liquids. Use products according to directives and regulations of the country in which the device is used.

WARNING

All disposable (band-aid) must be destroyed after using them and cannot be used again in any way. Please refer to the directives and regulations concerning disposable requirements of the country in which the device is used.

`

5.4 PARTICULAR WARNINGS FOR CRITICAL COMPONENTS

ATTENTION

The internal battery installed in the equipment cannot be accessed by the user and its replacement must be performed only by qualified staff expressly authorized by Preventice.

In every case please follow the general warnings listed below (for exemple in case of discard of components replaced by servicing technicians).

- Avoid terminal parts of the battery pack coming in contact with metal objects.
- Keep the battery pack away from heat sources or flames.
- Do not immerse the battery and avoid to exposure to rain or humidity.
- Avoid directly hitting the battery.
- Do not attempt to disassemble, burn or cause short-circuits to the battery. Such operations may cause a fire or emission of toxic chemical substances.

In the event that electrolytes escape, make sure you do not touch it. Wash with water for at least 15 minutes any body part that may have been in contact with it. Should you experience any symptom after this period, ask for immediate medical help.

ATTENTION

When a battery is replaced, it cannot be reused and must be discarded according to the standards and directives currently in force in the country where the equipment is used.

CHAPTER 6
TECHNICAL CHARACTERISTICS

6.1 BODYGUARDIAN CONTROL UNIT

Product name **Bodyguardian Control Unit**

Description Active, non-invasive medical device

Intended use The Bodyguardian Control Unit is used for ambulatory monitoring of non-lethal cardiac arrhythmias. Bodyguardian Control Unit is a wearable electronic device that is worn on the chest. The device includes a disposable fabric adhesive component that attaches to the subject and connects to the enclosed electronic components.
The device will be worn intermittently or continuously for up to a 30-day period. The recordings will be stored on the Bodyguardian Control Unit and transmitted by the device via Bluetooth communication to an external Associated Device (Android smartphone or other). The device is prescription only.

The Bodyguardian Control Unit recorder is intended to be used in a:

- *"Home Care"* environment without clinicians' surveillance.
- *"Clinic Care"* environment with clinicians surveillance

Depending on the Environment, optional algorithms and/or thresholds (settable via host software) can be used to generate measurements on an advisory basis for patients. These are presented for:

- Review and interpretation by the clinician, based upon knowledge of the patient.
- Results of the physical examination.

The data provided by the Bodyguardian Control Unit are exclusively intended to be used by trained medical personnel to assist patients that require monitoring of physiological parameters with reference of the followings context:

- Screening of patients with symptoms suggesting arrhythmia over a minimum 24-hour period.
- Screening and off line evaluation of HR and Breath variability if the nature of this variability cannot determine a Life-threatening for the patient.
- Not intended to allow direct diagnosis or monitoring of vital physiological processes parameters (for instance cardiachearth rate, respiration), where the nature of variations is such that it could result in immediate danger to the patient.
- Not intended for therapeutic purpose.

`

The "Body Guardian" Control Unit is intended from adult without race exclusion. Patient with implanted device are excluded to wear this device.

Applied Standards

Standard	***Edition / year***	***Description***
IEC 60601-1	Ed. 2 + A1 + A2 + Deviation UL/CSA	Medical Electrical Equipment – General requirement for safety
IEC 60601-1-1	Ed. 2	Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2	Ed. 2 + A1	Collateral standard: Electromagnetic compatibility Requirements and tests
IEC 60601-1-4	Ed. 1	Collateral standard: Programmable electrical medical systems
IEC 60601-1-6	Ed. 1	Collateral standard: Usability
IEC 60601-2-47	Ed. 1	Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC 60601-2-49	Ed 1 + Ec1	Particular requirements for the safety of multifunction patient monitoring equipment
IEC 60529	Ed. 2 + A1	Degrees of protection provided by enclosures (IP Code)
EC38	2007	Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
EC57	Ed. 2	Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
UL 60601-1	Ed. 1	Safety of Medical Electrical Equipment Part 1 – General requirements for Safety
CAN/CSA C22.2	Ed. 2 + A1 + A2	Medical Electrical Equipment Part 1 – General requirements for Safety

Type of protection against electric shocks

Internal powered equipment.

Protection level against electrical direct and indirect contacts

BF type (patient inputs)

Protection level against inflow of solids and liquids

IPX4 Device protected against

Operational mode

Continuous, within the specified limits

Environmental conditions for usage

- Temperature: from +10°C to +45°C
- Relative humidity: from 10% to 95% RH
- Atmospheric pressure: from 700hPA to 1060hPA

Environmental conditions for storage (max. 15 weeks)

- Temperature:	from -30°C to +60°C
- Relative humidity:	from 5% to 95% RH (excluding condensation)
- Atmospheric pressure:	from 500hPA to 1060hPA

External dimensions and weight

Height:	~ 17 mm
Width:	~ 60 mm
Depth:	~ 50 mm
Max Weight:	~ 35 g

Case Material: PC Polycarbonate

Battery Capacity 350 mAh min, 380 mAh typical, 1.5Wh

Battery Charger Input Power Requirement 100-240 VAC, 50-60 Hz,

Battery Charger Output Power Requirement 6 VDC, 200mA,

Battery Life 500 Cycles > 70% of initial capacity

Battery Voltage **3.7**V

ECG

- **Sampling Rate** 128/256 Hz
- **Digital Resolution** 12 bit
- **Input Dynamic Range** ± 10 mV
- **Input Offset Dynamic Range** ± 300 mV

Bio Impedance

- **Bio-impedance injection** 100µA @ 50KHz
- **Bio-impedance sampling** 32/second
- **Impedance** 0 to 120 Ohms
- **Maximum allowed Load** 7KOhms

Accelerometer

- **Accelerometer activity sampling** 50/second

`

• **Accelerometer**	3 axis 12-bit
Sampling Rate	
• **ECG**	128/256 Hz
• **Impedance**	32 Hz
• **Accelerometer**	50 Hz
Measurement Ranges	
• **Heart Rate**	25 to 240 BPM
• **Respiration**	0 to 30 BrPM
• **Posture**	± 2g range in x,y,z direction
Data Storage	
• **Capacity**	24 hours continuous recording
• **Type**	Internal NAND Flash
Communication Means	Bluetooth communication between Bodyguardian Control Unit and Smatphone
Communication Frequency	2.4 GHz
Electrode connections	- 4 ECG snaps connectors
Other interface	- 1 yellow Led for Device Charging Status - 1 green Led for Device Operative Mode Status - 1 yellow Led for special Events occurrences - 1 multifunction push button
Power supply	Battery powered (Rechargeable built-in Lithium Battery)
Absorption during Recharging	<600mW

6.2 DISPOSABLE ADHESIVE ELECTRODES PATCH

The characteristics specification of this component is responsibility of the System Builder

6.3 AC/DC MEDICAL POWER SUPPLY

6.3.1 OPTION 1

Manufacturer	FRIWO
Model	AC/DC ADAPTER FW7662M/06
Input	100-240 VAC – 50-60 Hz
Output	5.9VDC @ 1A
Safety standards	Fulfils Class II SELV for IEC 60601-1, UL 2601, VDE, CE label, SIQ, Fulfill medical application class B / BF / CF
Electrical protection level	Class II
Case	Material: Plastic Dimensions: 52 x 52 x 35.5 mm

6.4 BODYGUARDIAN CHARGING CRADLE

Input/Output	Operative 5.9VDC nominal. Connection with specified AC/DC adapter (model FRIWO FW7662M/06)
Input connector	THT POWER SUPPLAY JACK 4,4mm opening diameter p/n 1613_05
Output connector	Spring-Loaded Contacts Pins
Case	Material: PC Policarbonate Dimensions: 63 x 54 x 21 mm
Operational mode	Continuous, within the specified limits

Environmental conditions for usage

- Temperature:	from +10°C to +45°C
- Relative humidity:	from 10% to 95% RH
- Atmospheric pressure:	from 700hPA to 1060hPA

Environmental conditions for storage (max. 6 months)

- Temperature:	from -30°C to +60°C
- Relative humidity:	from 5% to 95% RH (excluding condensation)
- Atmospheric pressure:	from 500hPA to 1060hPA

`

CHAPTER 7
REQUEST FOR ASSISTANCE

7.1 OBTAINING SERVICE

In case of problems such as failure of the device or anyway in case of partial or incorrect working that cannot be solved through usual maintenance operations, please contact one of the main offices or branches of Preventice or the nearest retailer or authorized servicing center.

ATTENTION

In case of failure of the device or if it starts working in a way not complying with what is written in the manual, especially as far as safety is concerned, STOP USING IT IMMEDIATELY and contact the technical service. Do not use the device until the safety conditions have been checked and restored.

NOTE

In order to speed up the procedures to start the intervention of the technical service and to make it easier for the specialized technical staff to identify the problem on the first phone call by the customer, please fill in the form below in this page.
The equipment data may be found on the equipment identification label.

REQUEST FOR ASSISTANCE

Preventice Device/system name.....

Preventice Device code/reference number (REF) .....

Serial number (SN) or lot number (LOT) .....

Current software version (Rel) .....

7.2 PREVENTICE MAIN OFFICES

OPERATING OFFICES

PREVENTICE
1652 Greenview Drive SW
Rochester, MN 55902
Phone 800-509-0503
Fax 507-281-3630
Website www.preventice.com

Any other authorized assistance center or Technical assistance numbers.

`