Biosigns™ Unit

HW9 Series

Instructions for Use

Medeia Inc.

80 S.W. 8th Street, Suite 2000
Miami, FL, 33130, USA
Version: 1.0
Date: April 20, 2017

CONTENTS

REVISION SHEET

Release No.	Date	Revision Description

COPYRIGHT NOTICE

DISCLAIMER

This document may contain typographical errors or technical inaccuracies.

Medeia does not accept any liability for the use or misuse whether direct or indirect of the products, or for damages arising out of the use of or inability to use the products. Users must accept all responsibility for any results obtained by or concluded from data obtained by the products including software from Medeia Inc.

All clinical conclusions and decisions that are based on the use of this product are the responsibility of the user.

MANUFACTURER

Manufacturer contact details:

Medeia Inc.
80 S.W. 8th Street, Suite 2000
Miami, FL, 33130, USA
Tel: +1 800 433 4609
E: info@medeia.com
www.Biosigns.com

AUTHORIZED REPRESENTATIVE

Your local supplier of the Biosigns™ product is:

INSTRUCTIONS FOR USE PURPOSE

This instruction for use contains the instructions necessary to operate the telemetry monitoring system safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This instruction for use is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

INTENDED AUDIENCE

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of (critically) ill patients.

ILLUSTRATIONS

All illustrations in this manual serve as examples only. They may not necessarily reflect your monitoring setup or data displayed on your telemetry monitoring system.

TERMS USED IN THIS MANUAL

WARNING	Identifies an exceptionally hazardous situation. If you fail to take note of this information, serious irreversible or fatal injury may result.
CAUTION	Identifies a hazardous situation. If you fail to take note of this information, minor to moderate injury may result.
ATTENTION	Indicates that the product may have been operated incorrectly. If you fail to take note of this information, the device may be damaged or the measured results may be incorrect.
NOTE	Contains additional information on how to use this device.

READ INSTRUCTIONS FOR USE

In this manual you will learn how to use the Biosigns™ device and how to connect it to a patient. To use the device you will need the Biosigns™ Telemonitoring System. Instructions on how to use this software are supplied separately with the software.

Please follow the instructions in these "Instructions for Use" as they will assist you in getting the best possible results with the product. May you have further questions, remarks for the supplier or in the case you need more assistance, please contact the manufacturer or your local representative.

Read this entire instructions for use carefully before using the Biosigns™ device.

INTENDED USE

The Biosigns Telemonitoring System is a wireless ambulatory monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This includes the following vital-signs: Electrocardiography (EGG), Heart Rate, Heart Rate variability (R-R interval), Peripheral Capillary Oxygen saturation (SpO2), Skin Temperature, Respiration rate and Blood Pressure changes.

Data is transmitted wirelessly to a central location where it is stored for analysis. The Biosigns™ system can be configured by Authorized Persons to notify healthcare professionals when physiological data falls outside selected parameters.

Data from the Biosigns™" system is intended to be used by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients.

INTENDED USERS

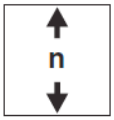
The Biosigns™ Telemonitoring System is used by trained operators who are used to monitor patient's vital signs and performing remote diagnostic services. Typical users are physicians, nurses and technicians involved in (tele) monitoring applications.

PHYSICIAN`S RESPONSIBILITY

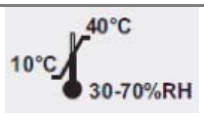
Biosigns™ is provided for the exclusive use of qualified physicians or personnel under their direct supervision. The numerical and graphical results and any interpretation derived from a recording must be examined with respect to the patient`s overall clinical condition. Patient preparation and the general recorded data quality, which could affect the report data accuracy, must also be taken into account. It is the responsibility of the physician to make the diagnosis or to obtain expert opinion on the results, and to institute correct treatment if indicated.

GUIDE TO SYMBOLS AND MARKINGS

MARKERS/ SYMBOLS	DESCRIPTION
CE 0120	CE marked product by notified body
FDA	FDA pending
	WARNING. Indicates conditions that could lead to illness, injury, or death.
	Caution. In this manual, indicates conditions that could damage equipment or other property.
	Caution. On the product, means “Consult the accompanying documentation.”
	Follow Instructions for Use
	No SpO2 Alarm
SpO2	SpO2 connection port
Temp	Temperature connection port
ECG	ECG connection port.
	Patient connections are Type B
	Type CF applied part. The unit displaying this symbol contains an F-type isolated (floating) patient part providing a high degree of protection against shock, and is suitable for use during defibrillation.

sk	Non-ionizing electromagnetic radiation. This device contains an approved RLAN module frequency 2402 to 2480 MHz.
	Non-ionizing electromagnetic radiation. This device contains an approved RLAN module frequency 5150 to 5825 MHz.
	Manufacturer location
	Manufacturer date
	Serial number
	Batch code
	European community representative
	Altitude limit
	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it. * For system products, this label may be attached to the main unit only.
	Separate batteries from other disposables for recycling.
	USB not connected: LED is off / USB is connected: LED is on
	On-off button
	Mode selection button

	Mode confirmation button and event button
	LCD display on front panel with start-up screen
	Device is in USB mode
	WIFI Device is in WiFi mode and is connecting to WiFi network
	WiFi connection established message
	Indication that device is sending to IP address of Biosigns Server via WiFi SSID. Flashing upwards arrow indicates transmission
	GSM connection established message
	Flashing upwards arrow indicates transmission
	Connection with Biosigns Server lost
	Battery status indicator fully charged, with 80% power level and charger connected symbol

	Charging with USB cable on charger. When charging on PC, the message is “Slow charge…”, when charging on wall charger,, the message is “Fast charge…”.
	Device shutting down
	Temperature and humidity limitation
	Ingress Protection marking. It classifies and rates the degree of protection provided against intrusion (body parts such as hands and fingers), dust, accidental contact, and water by mechanical casings and electrical enclosures.
	Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
	Keep away from rain.
	Fragile, handle with care.

TRAINING

The manufacturer offers training after the product is delivered. The training is provided to trained medical personnel (nurses, physicians, technicians and others who are generally working with the product type in clinical and (para) medical settings). The duration of the training in average takes three hours and is limited to instructions about the warnings, cautions and limitations and on how to use the device for the intended use. The training can be provided at the location of the user or at the manufacturer’s / authorized representative’s facility.

GENERAL WARNINGS AND CAUTIONS

Familiarize yourself with all warnings and cautions before using the Biosigns™ unit. In addition to the following, other warnings and cautions appear throughout this manual.

				
Warnings	Caution – possible damages	Caution – check manual	Follow instructions for use	MR unsafe

WARNING

- Healthcare providers, responsible for using Biosigns™, must be trained in the system and be aware of the inherent risks of misinterpretation of the collected and displayed parameters.
- Read these Instructions for Use carefully and in its entirety before using the product.
- When using the Biosigns™ Telemonitoring System always follow the Instructions for Use.
- In the case you have questions about this instructions for use or the Biosigns™ Telemonitoring System software, please contact your supplier. The contact details can be found in these Instructions for Use.
- When additional assistance, training or support is required, please contact the manufacturer or the supplier of your product.
- Biosigns™ is to be operated by qualified personnel only.
- Use of Biosigns™ is restricted to medically trained staff, such as a physician and / or registered nurse.
- Safe and effective use of this device requires proper set-up and operation by trained personnel.
- Biosigns needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the instruction for use.
- This equipment needs to be installed and put into service in accordance with the information provided in this manual.
- Safe interconnection between the Biosigns™ unit and other devices must comply with applicable medical systems safety standards such as IEC 60101-1. Within certain governmental jurisdictions, all interconnected accessory equipment must be labeled by an approved testing laboratory. After interconnection with accessory equipment, risk (leakage) current and grounding requirements must be maintained.
- Do not connect more than one patient to a monitor.
- Do not connect more than one monitor to a patient.
- It is allowed to use Biosigns™ on a patient when connected to the mains or the power adaptor. However, we recommend to make sure that the mains or power adaptor are not used in wet environment.
- Do not place Biosigns™ or accessories in any position that might cause it to fall on the patient. Do not lift the Biosigns™ by the patient cable(s).

WARNING

- As with all medical equipment, carefully route the patient cabling to reduce the possibility of patient entanglement or strangulation.
- Only use accessories and sensors provided and approved by Medeia. Possible patient injury can result.
- Misapplication of a pulse oximeter probe with excessive pressure for prolonged periods can induce pressure injury.
- No alarm for SpO2.
- The system transmits data through wireless connection. Risk of data loss is possible. Keep a close eye on the critical patient.
- Biosigns™ unit use wireless connections to transmit data to the Biosigns™ Telemonitoring System. The manufacturer has no control over the availability of this network. Biosigns™ Telemonitoring System features alerts to indicate when the connection between the Biosigns™ unit and the Biosigns™ Telemonitoring System is not available and the connection with the Biosigns™ Unit cannot be established.
- We strongly recommend you to always use this alert feature in the software to alert you when the connection with the device is lost.
- Biosigns™ sends real-time data to the server. In optimal situations the delay of data transmission is less than one second. When the connection with the wireless connection is poor, the delay may increase to up-to a maximum of 10 seconds. There is no data loss as the device uses internal buffers to store data packages, which are sent when the connection improves. In the case the communication is not sufficient to send data for a 10 seconds period, the server will consider this as “connection lost” and the Biosigns™ Telemonitoring System show this in the software as a red cross through the patient display.
- The Biosigns™ System software shows the delay between each Biosigns™ unit and the software. Be aware that the maximum delay between the time the data was collected and when it is displayed in the software can be 10 seconds.
- Biosigns™ unit is battery operated. When the battery is depleted the unit cannot measure and transmit data. Biosigns™ Telemonitoring System features alerts to indicate when the level of the Biosigns™ unit is depleted. We strongly recommend you to always use this alert feature in the software to indicate that the battery is almost depleted. In this case the patient can be informed to recharge the battery of the unit before it is fullydepleted.
- The Biosigns™ unit has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Biosigns™ in the MR environment is unknown. Risk of projectile injury due the presence of ferromagnetic materials in the device; risk of burns to the patients due the current induced by strong electromagnetic fields present in MR environment. Scanning a patient who has this device may result in patient injury.
- Do not operate this product in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide; explosion can result.
- Impedance pneumography may not operate properly when used in conjunction with high-frequency jet ventilation or high-frequency oscillatory ventilation.

WARNING

- Electronic equipment that emits strong electromagnetic or radio frequency signals can cause electrical interference with ECG monitor operation. This interference may distort the displayed or recorded ECG signal, thereby preventing accurate rhythm analysis. Avoid operating this device near equipment of this type.
- Portable and Mobile RF Communications equipment can affect the performance of the product.
- This product contains no user-serviceable components. Any unauthorized changes to the product invalidate Medeia's warranty and also invalidate all applicable regulatory certifications and approvals.
- Do not use the pulse oximeter as a replacement or substitute for ECG-based arrhythmia analysis.
- Changes or modifications not expressly approved by Medeia International could void the purchaser's authority to operate the equipment.
- Do not autoclave the Biosigns™ unit or its accessories. Autoclave accessories only if the manufacturer's instructions clearly approve it. Many accessories can be severely damaged by autoclaving.
- Healthcare providers, responsible for using Biosigns™ Telemonitoring System, must be trained in the system and be aware of the inherent risks of misinterpretation of the collected and displayed parameters.
- Biosigns™ is not intended for ST-monitoring.
- The final decision regarding the treatment of patients lies with the prescribing physician.

May you have further questions or remarks for the supplier or in the case you need more assistance, please contact the manufacturer or your local representative.

PRECAUTIONS AND LIMITATIONS

CAUTION

- Do not connect other machines, devices, sensors or cables to Biosigns™ or its accessories unless approved by Medeia, because damage to Biosigns™, the machines, devices or cables may occur. Using other parts may also result in increased emissions or decreasaed immunity of the device.
- Do not use the patient cable to move or lift the Biosigns™ unit. It might cause the Biosigns™ unit to fall, which might damage the Biosigns™ unit or injure the patient.
- Risk of electrical shock; do not attempt to service electrical components; refer servicing to qualified personnel.
- Do not use if any of Biosigns™ components is visibly opened or damaged.
- Do not flood Biosigns™ components with excessive amounts of fluids.
- If liquids enter the equipment, turn off the Biosigns™ unit immediately. Do not operate the device until trained personnel have inspected the interior.
- Check all external parts of Biosigns™ prior to use
- When connecting auxiliary equipment approved by Medeia Inc., ensure that the summed leakage current does not exceed local standards.
- The Biosigns should not be used next to or stacked with other equipment and that if next to or stacked use is necessary, the Biosigns should be observed to verify normal operation in the configuration in which it will be used.
- Do not open the cover or back of the Biosigns™ unit. There are no user serviceable components inside the system. Doing so may void equipment warranties.
- Authorized service personnel should do all internal troubleshooting and repair or replacement using only parts and accessories approved by Medeia Inc.
- Periodically check all connector cables and power receptacles for damage. Do not operate the equipment if the integrity of these items is questionable.
- People who are qualified and competent and have the right knowledge about the law's regarding telemedicine should only use this device.
- The device has not been tested above 3000 meters above sea level or air pressure less than 850 mBar.
- Wireless communications equipment, such as cell phones, should be kept at a distance of 3.3 m, to not influence the device.
- Do not use the 3G mode or WiFi mode with patients who have a pacemaker, to avoid any influence of the device on the pacemaker.

NOTES

- Due to continuing product innovation, specifications in this manual are subject to change without notice. The information in this manual is subject to change without notice.
- Medeia shall not be liable for technical or editorial omissions made herein, nor for incidental or consequential damages resulting from the furnishing, performance, or use of this guide.
- All illustrations in this manual are provided as examples only. They may not necessarily reflect your monitoring setup or data displayed on your system.
- In this manual, all names appearing in examples and illustrations are fictitious. The use of any real person's name is purely coincidental.
- This device has been validated and tested for compliance with ISO 80601-2-61:2011 International Standard for pulse oximeter monitors.

USER RESPONSIBILITY

This product is designed to perform in conformity with the description thereof contained in this manual and accompanying labels and inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. A defective product should not be used.

Parts that are broken, plainly worn, missing or incomplete, distorted or contaminated should be replaced immediately. Should any repair or replacement become necessary, we recommend that service be performed at the nearest approved service center. The user of the product shall have the sole responsibility for any malfunction, which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than Medeia Inc. or their authorized service personnel.

APPLIED STANDARDS

- EN 60601-1 (2006): General requirements for basic safety and essential performance
- IEC 60601-1-2 2007: Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-2-49 2011: Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
- IEC 60601-1-47: 2012: Electrocardiographs
- ANSI/AAMI EC 57:2012: Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms
- ISO 15223-1:2012: Graphical symbols for use in the labeling of medical devices
- IEC 62366: 2008 Medical devices – Application of usability engineering to medical devices
- ISO 80601-2-61:2001: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC 80601-2-59 2008 Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature

screening

- EN 12470-4: 2000 Part 4 Performance of electrical thermometers for continuous measurement
- IEC 62304:2006: Medical device software. Software life-cycle processes.
- IEC 60601-1-11:2010: Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

ACCESSORIES

Medeia only accepts warranty claims if Medeia approved accessories and replacement parts are used. Use of accessories other than those recommended by Medeia Inc. may compromise product performance.

RADIO FREQUENCY INTERFERENCE

This product emits radio frequency energy, but the radiated output power of this device is far below the FCC radio frequency exposure limits. Nevertheless, the device should be used in such a manner that the potential for human contact with the antenna during normal operation is minimized.

CAUTION

- Exposure to radio frequency radiation.
- Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment.
- The distance “d” is calculated by Medeia from the 800 MHz to 2,5 GHz column of Table 5 or Table 6 of IEC 60601-1-2:2007, as appropriate.
- The device should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- Electrostatic discharges (ESD) may cause artifacts in the signal from the device. Avoid conditions where electrostatic charge can build up because of low humidity and friction against carpets, clothing and sheets made from artificial fibers.
- The use of accessories, sensors, and cables other than those listed in this manual may result in increased emission and/or decreased immunity of this device.
- Other equipment may interfere with this system, even if that equipment complies with CISPR emission requirements.
- Refer to the tables below in this section for specific information regarding the Biosigns™ compliance to the standard IEC60601
- Radio Frequency (RF) interference between Biosigns™ and any existing RF transmitting or receiving equipment at the installation site, including electrosurgical equipment, in close proximity to the cardiograph should be evaluated before the equipment is operated as they may seriously degrade performance.
- Biosigns™ is susceptible to interference from RF energy sources (lowered RF immunity) which exceed the IEC 60601-1-2 limits, such as power line bursts, other medical devices, cellular products, information technology equipment and radio/television transmission. To reduce EMC interference Biosigns™ shall be separated from the emitting source as much as possible. If assistance is needed, call your local Medeia Inc. service representative
- A physician should evaluate artifact on the ECG caused by electromagnetic interference or physician authorized personnel to determine if it will negatively impact patient diagnosis or treatment. Like all electronic devices, Biosigns™ is susceptible to electrostatic discharge (ESD). Electrostatic discharge typically occurs when electrostatic energy is transferred to the patient, the electrodes, or to Biosigns™.
- ESD may result in ECG artefact that may appear as narrow spikes on the cardiograph display or on the printed report. When ESD occurs, the ECG interpretation with Biosigns™ may be inconsistent with the physician’s interpretation. Medeia Inc. assumes no liability for failures resulting from RF interference between Medeia Inc.’s medical electronics and any radio frequency generating equipment when these levels exceed those established by applicable standards.
- U.S. Federal law restricts this device from being sold by or on the recommendation of a physician.

PATIENT AND OPERATIONAL SAFETY

CAUTION

- Any system components (e.g. treadmill, personal computer, ergo meter) that require to be connected to an outlet socket shall use only grounded power cords (three-wire power cords with grounded plugs). Also make sure the outlet accepts the plug and is grounded.
- Never adapt a grounded plug to fit an ungrounded outlet by removing the ground prong or ground clip.
- Multiple portable outlet sockets shall not be placed on the floor.
- Multiple portable outlet sockets or extension cord shall not be connected to the system.
- Do not connect items, which are not part of the system.
- The use of multiple (non) medical electrical equipment connected to the same patient may pose a safety hazard due to the summation of leakage currents from each instrument. Any combination of (non) medical electrical equipment should be evaluated by local safety personnel before put into service.
- Multiple portable outlet sockets use without an isolation transformer is disapproved unless casual access for additional equipment is impeded or prevented.

Biosigns™ isolates all connections to the patient from electrical ground and all other conductive circuits in the Biosigns™ unit. This reduces the possibility of hazardous currents passing from Biosigns™ through the patient's heart to ground.

SELF CHECK

Both the Biosigns™ Telemonitoring Software and the Biosigns™ Unit have auto- calibration built in. During booting the software, it will check the original file format of the program. When the software is not considered "original" it will automatically reset to the pre-use installation setting.

ACCESSORIES

Use of accessories other than those recommended by Medeia Inc. may compromise product performance. Medeia Inc. can only accept warranty if you use Medeia Inc. approved accessories and replacement parts.

LIABILITY NOTICE

Failure to follow the conditions set forth in this document shall absolve Medeia Inc. from any responsibility for the safety, reliability, and performance of the equipment. Each operator must read this manual in full before using the system. Only authorized personnel may carry out assembly, modification, or repairs of the system. Electrical wiring must comply with local standards. Equipment must be used in accordance with its intended use.

TERMS OF WARRANTY

Medeia Inc. ("MEDEIA") warrants that its products are free from defects in material and workmanship. Subject to the conditions and limitations set forth below, MEDEIA will, at its option, either repair or replace any part of its product(s) that prove defective by reason of improper workmanship or materials. Repaired or replacement parts/products will be provided by MEDEIA on an exchange basis. This warranty does not cover any damage to this product that results from accident, abuse, misuse, natural or personal disaster, or any unauthorized disassembly, repair, or modification. Biosigns™ units sold by MEDEIA are warranted for 12 months. All accessories, supplies, and disposables are warranted for ninety days. This warranty covers only repair or replacement of defective MEDEIA products, as provided above. MEDEIA is not liable for, and does not cover under warranty, any costs associated with patient care, servicing, and/or the installation of MEDEIA products. MEDEIA will not discontinue support of its products, nor obsolete its products, as long as there are component materials and products available in the marketplace and reasonable customer demand for the products. The foregoing is the complete warranty for Medeia products and supersedes all other warranties and representations, whether oral or written. Except as expressly set forth above, no other warranties are made with respect to Medeia products and Medeia expressly disclaims all warranties not stated herein, including, to the extent permitted by applicable, any implied warranty of merchantability or fitness for a particular purpose. In no event will Medeia be liable to the purchaser or to the user of a Medeia product for any damages, expenses, lost revenues, lost savings, lost profits, or any other incidental or consequential damages arising from the purchase, use or inability to use the Medeia product, even if Medeia has been advised of the possibility of such damages.

COPYRIGHT

Medeia Inc.
80 S.W. 8th Street, Suite 2000
Miami, FL, 33130, USA
T: +1 800 433 4609 / F: +1 800 433 4609
www.Biosigns.com

GETTING HELP

To get help with either technical or user issues:

1. Call Medeia Help Desk at +1 800 433 4609 Monday – Friday 8AM – 5PM CET, or
2. You local representative / supplier.

DYNA-VISION™ SPECIFICATIONS

DEVICE

Dimensions:	118 x 65 x 33 mm
Weight:	+/- 260 gram
Power:	Internal battery (3.7 V)
Capacity:	4,500 mAh
Operation time:	22 hours 3G / 30 hours Wi-Fi
Memory:	4 GB embedded micro SD card
Controls:	Ruggedized Foil with integrated buttons
Power consumption:	200 mAh (WiFi) - 300 mAh (3G)
Charger:	USB charger
Measuring during charging:	Yes, on USB power connector
Event button:	Yes
Defibrillation protection:	Yes

LCD

Pixels:	128 x 64 pixels
Dimensions:	34.50 x 23.00 x 1.45 mm
Display mode:	Passive matrix (1.3")
Display color:	Monochrome White Color

ECG/RESPIRATION

Leads:	3, 5 or 10 lead wires
ECG cable:	Regular & ECG flat cable
Connector:	Sub-D type with temperature intertemperature interface- 200 – 400 – 800 – 1.000 Hz
R-peak analysis:	Yes, automatically
RR intervals:	Yes, automatically
Heart rate:	30-250 bpm
Accuracy:	+/- 2 bpm (based on QRS detection accuracy of 99.2%)
Respiration principle:	Impedance pneumography Sensing
electrodes:	Auto-selected by device (RA/LA/LL)
Impedance dynamic range:	20 ohms
Respiration rate range:	3 to 150 breaths/min (technical range) 3-120 breaths/min (software limitation)
Respiration source (RR):	ECG signal
Resolution:	5 seconds

SPO2

Display Range (SpO2):	0% – 100%
Accuracy Range (SpO2):	70% to 100%
Type:	Infrared: 910 nanometers @ 1.2 mW nominal Red: 660 nanometers @ 0.8 mW nominal
SpO2 Accuracy:	+/- 2 digits (no motion for combination of sensor with device)

SpO_2 Accuracy (A_{rms}) 70% to 100%:

TEMPERATURE

Type:	STS-400 (Smiths Medical)
Sample rate:	1 kHz
Accuracy:	+/- 0.4°C

WIFI

Type:	2.4 GHz IEEE 802.11 b/g transceiver
Frequency:	2.402 to 2.480 MHz
Encryption:	WEB 128-bit/WPA-PSK/WPA2-PSK/None
Certificates:	FCC/CE/ICS and RoHS compliant
Antenna:	Built-in
WPA2-PSK:	Wi-Fi Alliance certified

GSM/GPRS/GPS

Operation frequency:	UMTS: 800 – 850 – 900 – 1900 – 2100 MHz Quad: 900 – 1800 MHz
Certificates:	R&TTE/FCC/GCF/PTCRB/UL/IC/CE, RoHS and WEEE compliant
Antenna:	Built-in
SIM card:	Local SIM card to be installed by manufacturer
GPS:	GPS and GLONASS

USB

Type:	2.0

Note: the device is classified as not waterproof. The IP classification is IP22.

Note: Do not use the device in wet environment such as rain, bathrooms, showers and other areas where water could reach the device.

END OF LIFE STATEMENT

The life expectancy of the Biosigns™ unit has been determined to be five (5) years.

PARTS

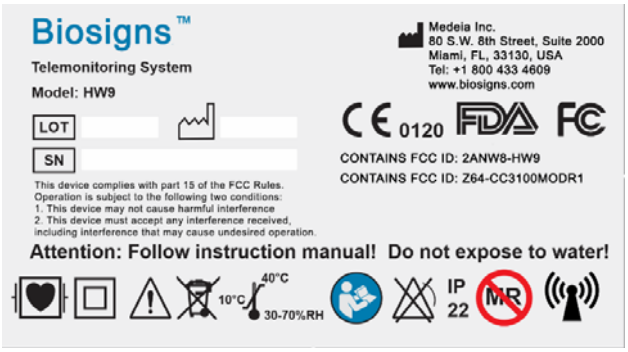
In this section you will find all the parts that come with you package. Your product is delivered in a carton box with indication of the content.

Cover of the carton box

Inside of the carton box

BIOSIGNS™ UNIT

The Biosigns™ unit is a small, portable, battery powered and light weight device, which can be worn on a belt. It is attached to the patient by cables and skin electrodes.

	
Device picture	**Backside Sticker**

BIOSIGNS™ HW9 SERIES

Biosigns™ is delivered in 3 variants, depending on the features that are activated in the unit:

ARTICLE CODES

- HW9G-SLP: Biosigns™ unit with ECG and 3G
- HW9S-LCD: Biosigns™ unit with ECG, SpO2, WiFi and LCD display
- HW9SG-LCD: Biosigns™ unit with ECG, SpO2, WiFi, 3G, GPS and LCD display

Note: each unit can be used with a temperature sensor for temperature monitoring.

SERIAL NUMBER

(1) DV
(2) Xx Y
(3) Xx B
(4) xxxx

The serial number indicates the type of device (1), the manufacturing year (2), the batch number (3) and the device number manufactured within that batch (4).

ECG CABLE

The ECG cables are regular cables with special connection plug to connect to the device.

Note: Biosigns™ does not work with other cables than the ones supplied to you by Medeia!

There are three cables available:

1) ECG cable with regular 3-lead wire ECG snaps
2) ECG cable with regular 5-lead wire ECG snaps
3) ECG cable with 10-lead wire crocodile snaps (regular ECG snaps be used as well)

3-lead wire ECG cable

(RA/LA/LL) and (R/L/F)

* **Note**: with the 3-lead ECG cable, only lead I is available for monitoring. The F acts as the Right Leg Drive (RL) identical to a 5-lead or 12-lead ECG configuration.

5-lead wire ECG cable

(RA/LA/RL/LL/C) and (R/L/F/N/C)

10 -lead wire ECG cable

(LA/RA/RL/LL/V1-V6) and (L/R/F/N/C1-C6)

ECG ELECTRODES

Biosigns™ works with standard ECG adhesive electrodes. However, we do recommend you to use high quality electrodes as they greatly determine the quality of your measurement. Interrupted skin contact results in poor quality ECG signals.

SPO2 SENSOR

Biosigns™ is designed for monitoring the photoplethysmogram (PPG) and arterial oxygen saturation level and works with the following Nonin® brand sensors:

- 8000 SS
- 8000 SM
- 8000 SL

Note: do not use other sensors than the ones supplied to you by Medeia Inc.

Note: for separate instructions of the Nonin® sensors, refer to Annex I to this instructions for use

SpO2 finger clip sensor

USB CABLE

The USB cable is used to change the configuration of the device to the different user modes. The USB cable is also used to monitor the patient with the computer and to download data from the internal memory card to the PC.

DV-USB (USB cable with micro-USB connector)

Connection port for USB cable

The USB cable has a micro USB plug on one side and a regular USB plug on the other side. The regular USB plug is connected to the PC or a charger and the micro USB plug is connected to the device.

POWER SUPPLY UNIT

The Biosigns™ unit has an integrated rechargeable lithium-polymer battery. Recharching the battery is done using a USB power supply. Biosigns™ is delivered with a power supply, which is identified as DV-PSU. This charger has been tested in combination with the Biosigns™ unit for patient safety and electromagnetic compatibility. Also, this charger allows for fast charging the Biosigns™ unit as it is recognised by the device.

	
DV-PSU wall charger	DV-PSU label

ACCESSORIES

Please check with your supplier for more details about available accessories.

USING THE DEVICE

CONNECTING THE ECG CABLE

WARNING	♦ Do not use other cables than the ones supplied by Medeia as this may damage the device or cause injury to the patient or the user of the product.

CAUTION	" Do not misuse the cable and the snaps as damage to the cable might occur. This will influence the ECG signal quality.

CONNECTING THE CABLE TO THE PATIENT

The quality of the ECG signal highly depends on the contact with the skin. To optimize results, prepare the skin before you place the ECG adhesive electrodes. The proper technique is to remove hair from the place where the electrodes have to be placed. Avoid skin lesion in the case you have to shave the area. Clean the area with alcohol and make sure that the skin is completely dry before placing the ECG adhesive electrodes. Then attach the ECG adhesive electrodes to the snaps of the ECG cable.

Attach the colored snaps of the cable to the sticker electrodes. Remove the back foil of the electrodes and attach them to the skin. Placement of the electrodes depends on the lead configuration. You can choose between 3, 5 and 12 lead ECG.

Note: placement of the electrodes other than normal makes that the morphology of the ECG signal changes.

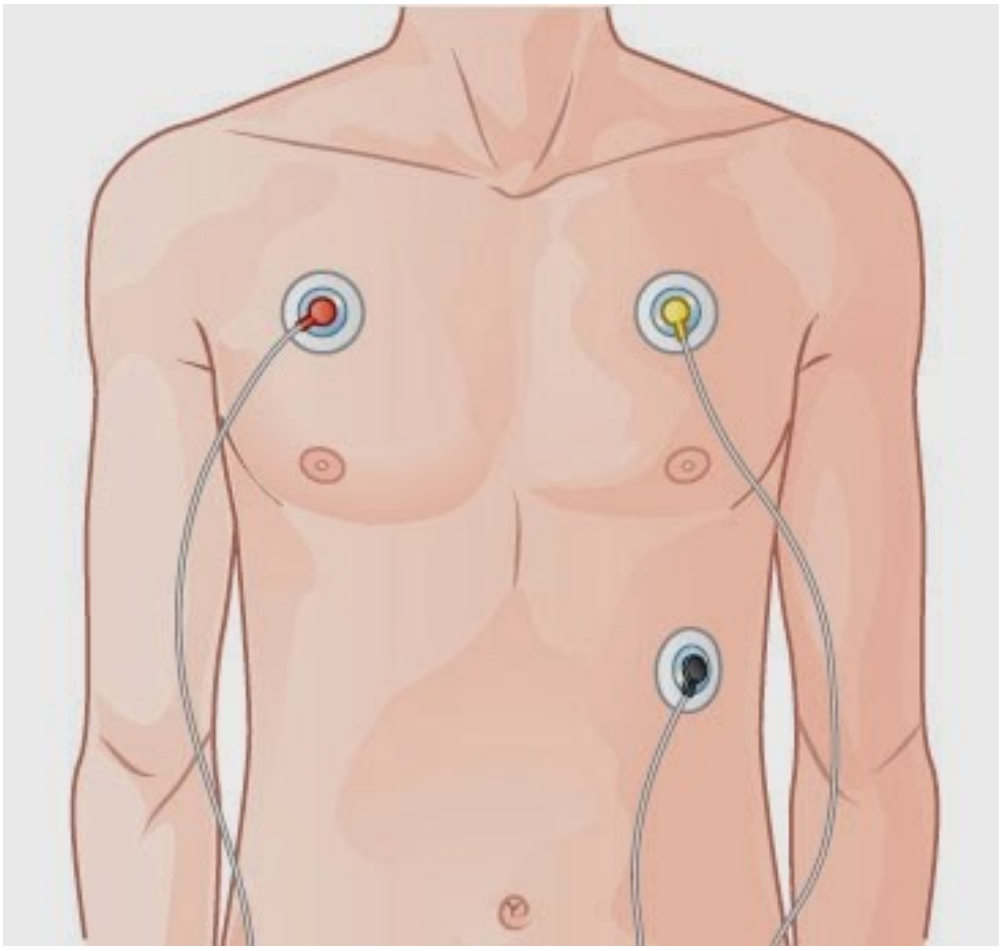
Note: we recommend you to place the electrodes over bone structures. Avoid placement of the electrodes over large muscles or fatty tissue because these will cause artefacts and noise in the ECG signal (see Artifact due to poor electrode applicatons" section for more details).

Note: always tape the snap and the electrode to the skin to avoid movement of the ECG snap, leads and trunk cable as this creates noise on the ECG signal.

PLACEMENT OF THE ELECTRODES

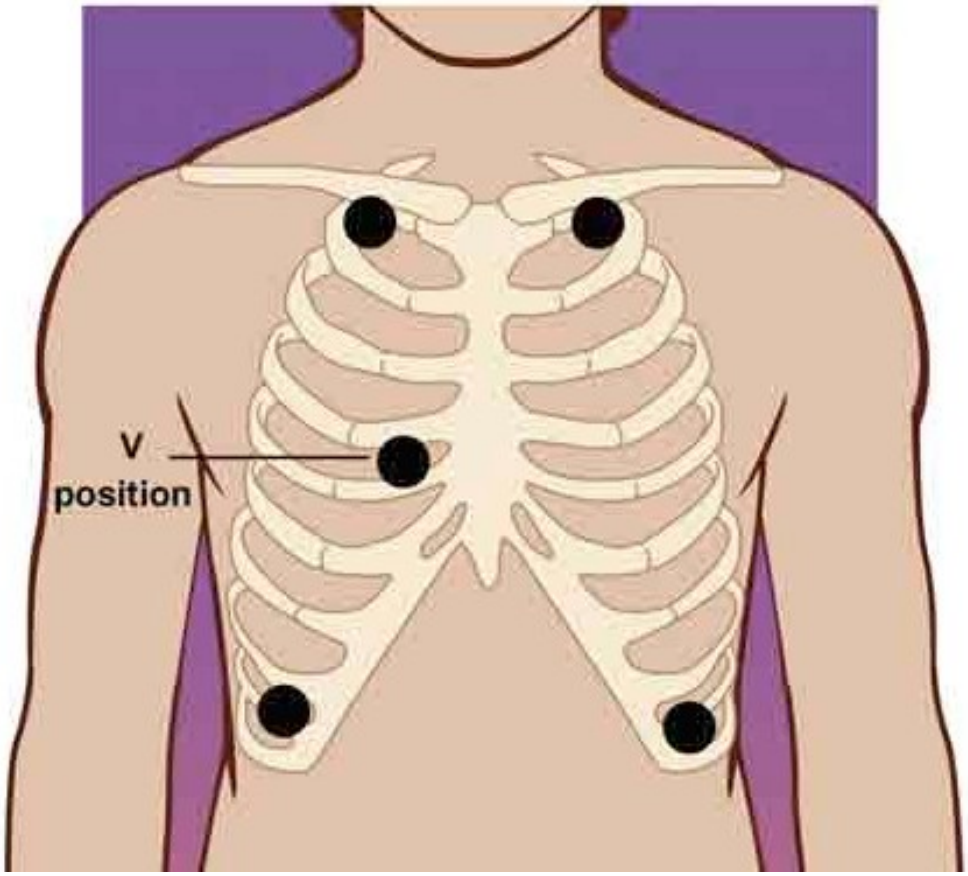
In order to make good diagnosis based on the ECG signals recorded with Biosigns™ it is important to place the ECG electrodes and the ECG cable the correct way. Otherwise a physician will not be able interpret the collected signals. Proper placement for the 3 available cables is shown in the images below. Note that placement over bone structures results in the best possible signal quality.

3-lead ECG



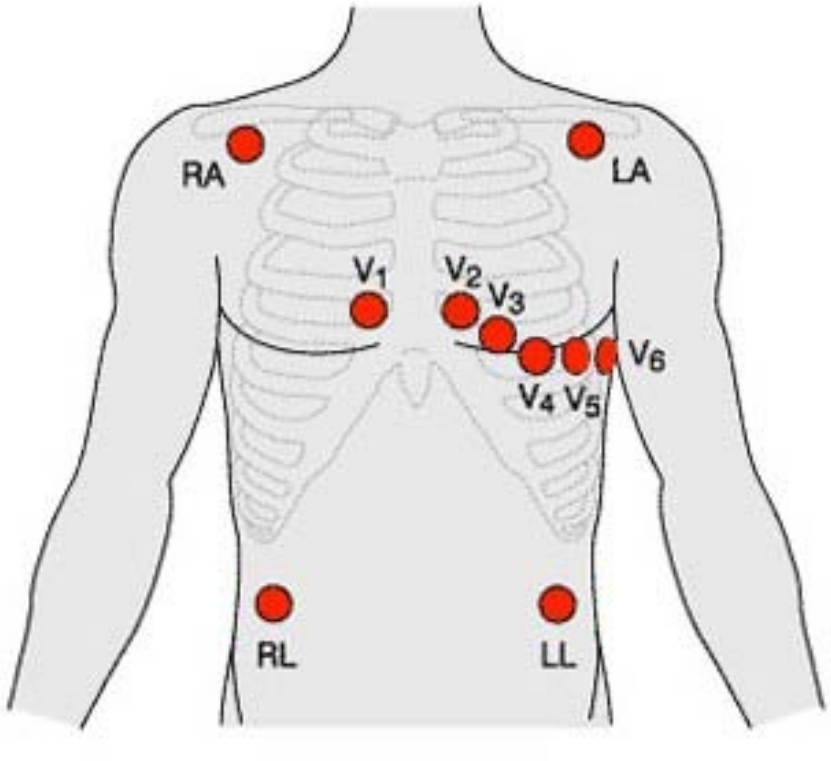
RA = right shoulder
LA = left shoulder LL
= left thorax or hip

5-lead ECG



RA = Right front side of the shoulder
LA = Left front side of the shoulder
LL = Left hip
RL = Right hip
C1= Right of the sternum

12 -lead ECG



RA = Right front side of the shoulder
LA = Left front side of the shoulder
LL = Left hip
RL = Right hip
C1= Right of the sternum
C2 = Left of the sternum
C3 = Between C2 and C4
C4 = Under left nipple
C5 = Between C4 and C6
C6 = Left side of thorax in line with axilla

ARTIFACT DUE TO POOR ELECTRODE APPLICATONS

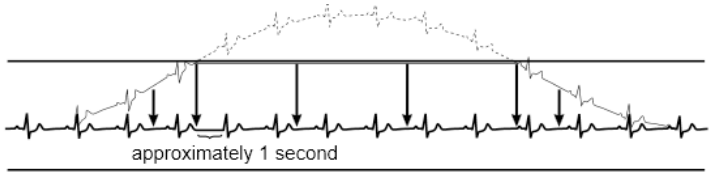
The Biosigns™ unit is equipped with state-of-the-art electronic utilities that ensure artifact-free recordings. Among these are the automatic baseline adjustment and the anti-drift system (cubic spline) (ADS).

At the beginning of the recording the automatic baseline adjustment algorithm verifies the incoming signal and adjusts the baseline position accordingly.

During the recording, the anti-drift system (cubic spline) continuously checks the baseline position and returns it to the normal level, if required (see Sample Recording figure).

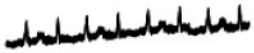
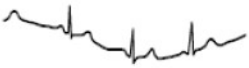
For the Manual Mode, the anti-drift system (cubic spline) can be enabled and disabled from the setup menu.

When electrodes are not properly applied, these measures may not fully compensate for artifact. High polarization voltages induced by electrodes applied without conductive gel may cause the amplifier to over range, so that a straight line will be recorded instead of the ECG (see figure). In this situation the device will automatically block and return the baseline to its normal position. A baseline is then recorded for approximately 1 second. It is possible to block the amplifiers manually by disconnecting the R electrode.



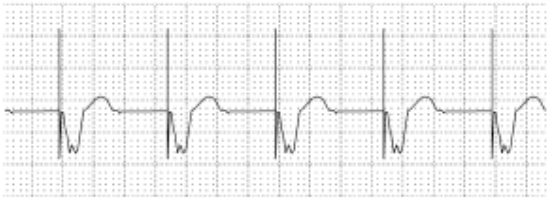
REMEDY

- Apply the electrodes according to instructions.
- Do not apply the electrodes on top of clothing.
- Use a contact agent (e.g. moistened electrode paper, electrode cream, spray, etc.).
- Wait approximately 10 seconds before initiating a recording. After the 10-second period, the automatic functions are enabled and the polarization voltages have stabilized, provided the electrodes are properly applied. In case of improper electrode application, an error message will appear on the display (RL, LL, LA, LL, V1 to V6).

Problem	Appearance	Cause	Corrective Action
Power Line Interference (50 / 60-Cycle Interference) 	Regular sawtooth baseline.	Poor electrode placement.	Reapply electrodes.
		Possible non-grounded instrument near patient.	Unplug AC power from electrical equipment near patient, one at a time. Have grounding checked.
Muscle Artifact 	Fuzzy, irregular baseline.	Tense, uncomfortable patient.	Make sure patient is comfortable and still.
		Tremors. Diaphoresis.	Check that electrodes are applied on flat, non-muscular areas of the torso.
		Poor electrode placement.	Reapply electrodes if necessary.
Irregular Baseline 	Rough, jagged baseline.	Poor electrical contact.	Reapply electrodes, using proper technique. Check for loose connections on leads/cable.
		Respiratory interference.	Move electrodes away from areas with greatest movement during respiration.
		Faulty or dry electrodes.	Apply new electrodes.
Baseline Wander 	Rhythmic up-and-down movement of the ECG baseline.	Movement of the patient.	Make sure patient is comfortable and still.
		Improperly applied electrodes.	Reapply electrodes. Check that patient cable is not pulling on electrodes.
		Electrical differences between two different brands or types of electrodes.	Make sure electrodes are all from the same manufacturer, and of the same type.
		Respiratory interference.	Move electrodes away from areas with greatest movement during respiration.
Poor Electrical Contact 	Trace switching from high to low in steps.	Loose electrodes.	Change all electrodes, using good skin prep.
		Defective leads/cables.	Replace leads/cables.

RECORDING ECGS OF PACEMAKER PATIENTS

Due to the slow display speed, it is not possible to display pacer pulses directly on the ECG recording. For this reason, the recorder reduces the pulse amplitude and expands the pulse width, so that the pacer pulse is easier to identify. The Biosigns™ records the pulse with the correct polarity, with a width of 5 ms and with the same amplitude in all leads (depending on the polarity of the pacer pulse in leads I and II, the pacer pulse in lead III may be suppressed) The amplitude of the reverse current in the figure below shows an ECG recording with pacer pulses.



WARNING	♦ Incorrect heart rate: if several adverse conditions exist at once, the possibility that the pacer pulses are interpreted (and counted) as QRS complexes should be considered. At the same time, however, QRS complexes might be suppressed in certain situations. Therefore, pacemaker patients should always be watched closely. ♦ Pacemaker patients: as Biosigns™ uses built-in radio's to transmit ECG data and vital signs to a central station we not recommend to use the device on patients with a pacemaker.

ECG RECORDING DURING DEFIBRILLATION

The patient signal input is defibrillation-proof so it is not necessary to remove the ECG electrodes before defibrillating the patient. However, when using stainless steel or silver electrodes, the defibrillator discharge current may cause complete polarization at the electrode/skin interface. This condition may prevent ECG signal acquisition for several minutes. With silver/silver chloride electrodes, this will not happen.

When using other electrodes, disconnect the patient cable from the recorder while defibrillating the patient.

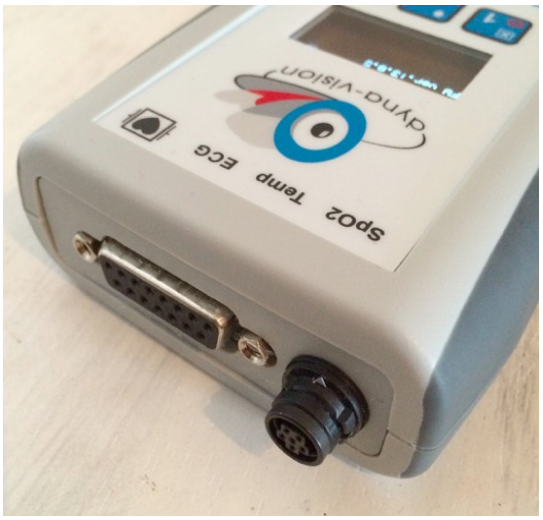
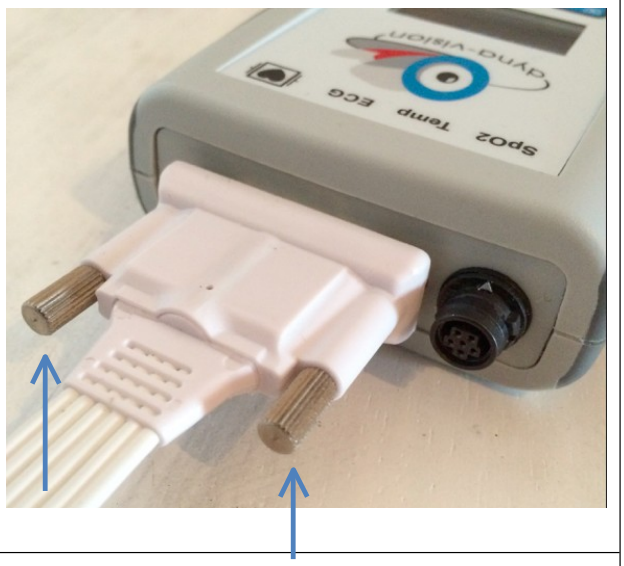
WARNING	♦ Equipment damage — For reasons of patient safety, use only the original Medeia patient cable. Before connecting the cable to the device, check it for signs of mechanical damage. Do not use a damaged cable. ♦ Patient hazard, delayed ECG displays — Use silver/silver chloride electrodes for ECG signal acquisition, if the patient may have to be defibrillated. ♦ Shock hazard — During defibrillation, do not touch the patient, the electrodes or the leadwires.

Note: Observe the defibrillator safety information.

CONNECTING THE ECG CABLE TO THE DEVICE

The ECG cable has a plug. Insert the plug in the port at the topside of Biosigns™. On the front side of the device you will find the indicators for the correct port. The plug is a large flat Sub-D type of plug that corresponds with the ECG port on the device.

Note: The plug fits in one direction only!

	
ECG connector on top of device	Insert ECG cable and always tighten the 2 screws to avoid the cable from detaching the device when in use

Note: do not force (!) the plug into the port. Damage to the plug and/or the device may occur.

SPECIFICATIONS OF THE ECG

The specifications of the ECG are provided in the table below.

ECG Amplifier	Simultaneous, synchronous registration of all 8 active electrode signals (= 12 standard leads)
Sampling frequency	100/200/400/800/1.000 Hz
Digital resolution	5 µV
Dynamic range	± 10 mVAC
Max. Electrode potential	±300 mVDC
Time constant	>3.2 s
Frequency response	0.05 to 150 Hz (-3 dB)
Input impedance	> 10 MOhms
Line Frequency Filter	Distortion-free suppression of superimposed 50 or 60 Hz sinusoidal interferences.
Low Pass	50 or 150Hz
High Pass	0.05Hz or 3.5Hz
Patient Leakage Current	< 10 µA
Patient Input	Fully floating and isolated, defibrillation protected.
Common Mode Rejection	-80dB (minimum) -100dB (with filter)
Leads Off Indicators	Connection status for each lead is shown on "Recording ECG" screen

Gain/Sensitivity	5 mm/mV

Sweep Speed	12.5, 25 ,50 mm/sec
Input Range	+/- 10 mV
A/D Conversion	16bit
EMG Filter	35Hz (-3dB) / 25Hz (-3dB)
T-wave amplitude (aT)	Rejects T waves = 1.2 * R-wave
Heart Rate Range	30-250
Heart Rate averaging	1 beat
Heart Rate Resolution	1 bpm
Heart Rate Accuracy	+/- 2 bpm
Heart Rate and QRS detection stabilization period	20s
Response time of heart rate meter to change in heart rate	HR change from 80 to 120 bpm: 9 to 12 seconds HR change from 80 to 40 bpm: 9 to 13 seconds
Isolation	Isolated from ground related circuits by >4 kV rms, 6 kV peak

ECG FILTERS

Biosigns can be configured with 3 ECG filter settings. These are configured in the Biosigns™ Telemonitoring Software and cannot be changed in the device but the operator of the device. The available filters are:

Filter	Specifications	Comments
Notch filter	60 Hz	For USA mains
	50 Hz	For Europe mains
High pass filter	0,05 Hz	This setting does not alter the ECG trace and is the recommended setting for diagnostic ECG
	3,5 Hz	This setting does alter the ECG trace and is the recommended setting for ambulatory patients as it filters our noise caused by movement
Low pass filter	50 Hz	This setting is recommended for ambulatory patients
	150 Hz	This setting is recommended for resting patients

Note: The software automatically forces the low pass filter to 50 Hz when the selected sample rate for the ECG is selected to be 100 Hz to avoid aliasing of the ECG signal.

Note: the accuracy of the QRS heart beat detection was validated against the MIT database, AHA database and the NST database. The average accuracy of the beat detection is found to be 99,2 %.

Note: The sensitivity of the QRS detection is valid for persons with a normal QRS complex.

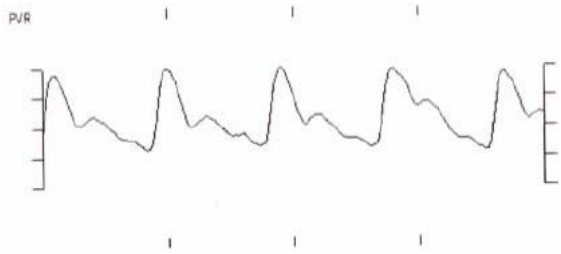
RESPONSE TO IRREGULAR RHYTHM

1. Ventricular bigeminy: the Biosigns™ counts both large and small QRS complexes to display a rate of 80 bpm.
2. Slow alternating ventricular bigeminy: the Biosigns™ counts both large and small QRS complexes to display a rate of 60 bpm.
3. Rapid alternating ventricular bigeminy: the Biosigns™ counts all QRS complexes to display a rate of 120 bpm.
4. Bi-directional systoles: the Biosigns™ counts all QRS complexes to display a rate of 90 bpm.

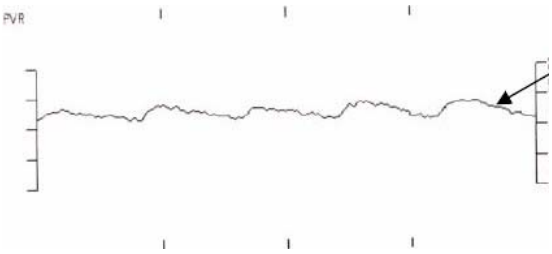
ABOUT PHOTOPLETHYSMOGRAPHY

PULSE VOLUME RECORDING (PVR) WAVEFORM INTERPRETATION:

PVR serves as a qualitative aid in the assessment of peripheral hemodynamics. Normal plethysmographic waveforms resemble the arterial pressure pulse. The normal PVR waveform (shown below) has a sharp systolic upstroke, and a somewhat narrow peak. After peaking, the waveform drops quickly during diastole with its slope bowing in toward the baseline. Normal waveforms usually have a dicrotic notch between the peak and baseline. However, the dicrotic notch may become less noticeable with vasodilation or may become more pronounced during vasoconstriction.



Distal to an arterial occlusion, the waveform becomes more rounded with a more gradual up slope, and the down slope may bow away from the baseline. Amplitude of the abnormal waveform (shown below) is usually diminished, but this condition is not sufficient for diagnosis because amplitude is influenced by additional factors such as blood pressure, arrhythmia, vasomotor tone, and limb position.



Again, note that the waveform contour may be altered during vasodilation or vasoconstriction.

PVR waveforms are given a Recommendation of Class II in the ACC/AHA P.A.D. Guidelines (Hirsch, 2005).

PPG WAVEFORMS:

PPG waveforms are made available as an aid for obtaining systolic pressures. PPG waveform contour interpretation is similar to the interpretation of PVR waveforms. However, because the PPG waveform is obtained at a digit, distortion of the PPG contour due to vasoconstriction or vasodilation is more common.

OXIMETRY THEORY

The pulse oximeter shines red and infrared light through the tissue and detects the fluctuating signals caused by arterial blood pulses. The ratio of the fluctuation of the red

and infrared light signals received determines the oxygen saturation content.

Conditions such as steady venous blood flow, skin thickness, fingernail thickness, etc., do not affect the saturation reading because they are constant and do not cause fluctuations.

The function, f, depends on the physical properties of the LEDs producing the light. These physical properties are fixed by the manufacturing material and processes.

$$SpO_2 = f\left[\frac{\ln\left(\frac{\min}{\max}\right)_{Red}}{\ln\left(\frac{\min}{\max}\right)_{IR}}\right]$$

Note that the pulse oximeter readings do not depend upon the absolute light intensity, rather upon the fluctuations in light intensity.

Characteristics such as thick skin or skin pigmentation will affect the min and max proportionally, thus the ratio min/max does not change. However, if too little light passes through, the pulse oximeter will not display values. Pulse oximeters use two different wavelengths of light (red and infrared), providing the ability to determine one component of blood. The pulse oximeter is calibrated to closely approximate functional oxygen saturation values. These values will closely approximate laboratory instrument fractional saturation values if the dysfunctional hemoglobin saturation levels are negligible.

In summary, because the pulse oximeter performs all computations from the internal software and there are no critical parts to drift, no re-calibration is needed.

If the dysfunctional hemoglobin is carboxyhemoglobin or methemoglobin, the difference between the oxygen saturation value displayed by the pulse oximeter and the oxygen saturation values determined by the laboratory instrument will be greater as the dysfunctional hemoglobin levels rise approximately in accordance with the following formulas, where:

$$SpO_2 = O_2Hb + COHb + MetHb$$

$$SaO_2 = 100\left(\frac{O_2Hb}{100 - COHb - MetHb}\right)$$

SpO2 = 950 determined and numerically displayed oxygen saturation in percent

O2Hb = Fractional oxyhemoglobin saturation in percent

COHb = Carboxyhemoglobin saturation in percent

MetHb = Methemoglobin saturation in percent

SaO2= Functional oxygen saturation in percent

PLACING THE SPO2 SENSOR

WARNING

- Severe anemia may cause erroneous SpO2 readings.
- Interfering Substances: SpO2 is a functional calculation of arterial oxygen saturation. Carboxyhemoglobin and methemoglobin may erroneously increase SpO2 readings. The level of increase is approximately equal to the amount of carboxyhemoglobin and/or methemoglobin present. Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Do not connect/use other than provided SpO2 sensor with that equipment, readings may be inaccurate. SpO2 probes are designed for use with that specific equipment only.
- Oxygen saturation measurements using pulse oximetry are highly dependent on proper placement of the sensor and patient conditions. Patient conditions such as shivering and smoke inhalation may result in erroneous oxygen saturation readings. If pulse oximetry measurements are suspect, verify the reading using another clinically accepted measurement method, such as arterial blood gas measurements on a co-oximeter.
- Tissue damage can be caused by incorrect application or use of a sensor (e.g., wrapping the sensor too tightly, applying supplemental tape, failing to periodically inspect the sensor site, leaving a sensor on too long in one place). Refer to the Directions for Use provided with each sensor for specific instructions on application and use, and for description, warnings, cautions, and specifications.
- Sensors exposed to ambient light while not applied to a patient can exhibit semi-normal saturation readings. Be sure the sensor is securely placed on the patient and check its application often to ensure accurate readings.
- The pulse oximetry channel must NOT be used as an apnea monitor.
- Inaccurate measurements may be caused by venous pulsations.
- The pulse oximetry option can be used during defibrillation, but the readings may be inaccurate for a short time.
- A very sudden and substantial change in pulse rate can result in erroneous pulse rate readings. Be sure to validate the patient data and patient condition before intervention or change in patient care.
- Interfering Substances: Carboxyhemoglobin may erroneously increase readings; the level of increase is approximately equal to the amount of carboxyhemoglobin present. Methemoglobin may also cause erroneous readings. Dyes, or any substances containing dyes, that change usual arterial pigmentation may cause erroneous readings
- The pulse oximetry system might misinterpret motion as good pulse quality. Minimize finger motion or change the type of sensor being used.
- Do not fasten the pulse oximeter too tightly around the wrist. Inaccurate readings and patient discomfort could result.
- Biosigns™ unit and sensor has not been clinically validated for motion accuracy and during Low Perfusion. Biosigns™ SpO2 is not intended for use during motion and during Low Perfusion.

WARNING

- Biosigns™ unit and sensor has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory Oximeter and ECG monitor. 1% was added to account for the properties of fetal hemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- Do not expose the Biosigns™ to excessive moisture such as direct exposure to rain. Excessive moisture can cause the Biosigns™ to perform inaccurately or fail.

CAUTION

- Because PULSE OXIMETER EQUIPMENT measurements are statistically distributed, only about two-thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER. When a PULSE OXIMETER MONITOR is suitable for use with a variety of PULSE OXIMETER PROBES, SpO2 ACCURACY information shall be made available for each type of PULSE OXIMETER PROBE.
- To prevent the sensor from falling off secure the wire to the digit with medical tape.
- Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
- To prevent improper performance and/or patient injury, verify the sensor and pulse oximeter compatibility before use.
- Factors that may degrade pulse oximeter performance include the following:
  - excessive ambient light
  - excessive motion
  - electrosurgical interference
  - arterial catheter
  - blood pressure cuffs
  - infusion lines
  - moisture in the sensor
  - improperly applied sensor
  - carboxyhemoglobin
  - methemoglobin
  - artificial nails
  - incorrect sensor type
  - poor pulse quality
  - venous pulsations
  - anemia or low
  - hemoglobin concentrations
  - cardiovascular dyes
  - sensor not at heart level
  - dysfunctional hemoglobin
  - fingernail polish
- Each SpO2 sensor is designed for application to a specific site on the patient within a certain size range. To obtain optimal performance, use an appropriate sensor and apply it as described in the sensor's directions for use.

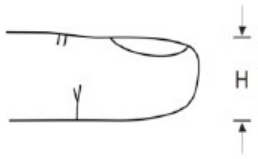
CAUTION	" If excessive ambient light is present, cover the sensor site with opaque material to block the light. Failure to do so may result in inaccurate measurements. Light sources that can affect performance include surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight. " If non-invasive blood pressure (NIBP) will be monitored while using SpO2, place the NIBP cuff on a different limb than the SpO2 sensor to help reduce unnecessary SpO2 alerts. For optimal measurements, avoid placing the SpO2 sensor on the same limb as an arterial catheter or intravascular line. " Loss of pulse signal can occur if the sensor is too tight, there is excessive ambient light, an NIBP cuff is inflated on the same limb as the sensor, there is arterial occlusion proximal to the sensor, the patient is in cardiac arrest or shock, or the patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia

The choice for the type of sensor depends on the application for use. For normal SpO2 testing at home or in the hospital we recommend to use a re-usable sensor. For the long-term SpO2 monitoring or sleep study we recommend to use disposable sticker sensors to avoid the sensor to loose contact with the skin.

CHOOSING SENSOR SIZE

FOR SOFT SENSOR

Soft sensor size recommendations are based on digit height (thickness). The digit height (H) is measured as shown in the figure below.



- For digit height from 7.5 mm (0.3 in) to 12.5 mm (0.5 in), size small should be selected (8000SS).
- For digit height from 10.0 mm (0.4 in) to 19.0 mm (0.75 in), size medium should be selected (8000SM).
- For digit height from 12.5 mm (0.5 in) to 25.5 mm (1.0 in), size large should be selected (8000SL).

FOR FLEX SENSOR

Flex sensor size is determined from the patient's weight.

- For a patient who weighs 2-20 kg (4.4-44 lbs), size infant should be selected.
- For a patient who weighs over 20 kg (44 lbs), size adult should be selected.

CHOOSING THE SENSOR APPLICATION SITE

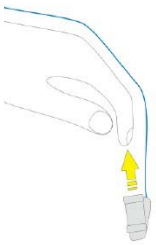
The preferred application site for patients over 20 kg is the left index finger. However, other fingers or toes may be used where the tissue thickness is between 5 and 21 millimeters. Other sites may not give acceptable results because of inadequate light transmission or perfusion.

ATTACHING THE SENSOR

1. Insert the selected digit (refer to the sizing recommendations above) into the sensor as illustrated in Figures 1 and 2. The patient's digit must reach the end of the sensor.
2. Direct the cable along the patient's finger/toe, parallel to the arm/leg. (Optional: Secure the sensor cable as needed.)
3. Connect the sensor cable to the pulse oximeter or to the patient cable.
4. Verify proper operation as described in the pulse oximeter operator's manual.

Note: Proper sensor placement is critical for good performance. If the sensor is not positioned properly, light may bypass the tissue and result in SpO2 inaccuracies.

We recommend the placement of the fingertip sensor as depicted below.

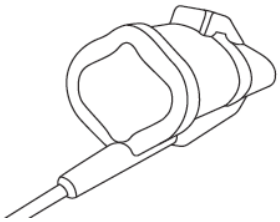
		
Slide sensor over index finger	Wire over the hand	Make sure the sensor is placed comfortable for the patient.

CLEANING THE SENSORS

CAUTION	" Clean the sensor before applying it to a new patient. " Unplug the sensor from the pulse oximeter before cleaning. " Do not sterilize, autoclave or immerse the sensor in liquid of any kind. Do not pour or spray any liquids onto the sensor. " Do not use caustic or abrasive cleaning agents on the sensor. Do not use cleaning agents containing ammonium chloride. Use of these chemicals may shorten the life of the product. " Do not misuse the cable and the snaps as damage to the cable might occur. This will influence the ECG signal quality.

1. To clean the sensor, wipe all patient contact surfaces with a soft cloth dampened with a mild detergent, isopropyl alcohol, or a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]).

   Reference sensor in figure below;



2. Allow the sensor to dry thoroughly before reusing.

COMPLIANCE

This product complies with ISO 10993-1.
Not made with natural rubber latex.

CONNECTING THE SPO2 CABLE TO THE DEVICE

The SpO2 cable can be connected to the Biosigns™ unit using the plastic plug at the end of the cable. On the top-side of the device you can find the port for the SpO2 cable.

		
SpO2 connection port with white arrow marker	SpO2 sensor connector with white arrow marker	SpO2 connector inserted in the device

There is a white arrow indicator on the plug that corresponds with a white arrow indicator on the connector on the device. The plug only fits in one direction.

Notes

- If inserting the plug does not go smoothly, never force the plug… damage to the plug and/or the device may occur.

- Connect the SpO2 cable to the designated connection port at the topside of the

Biosigns™.

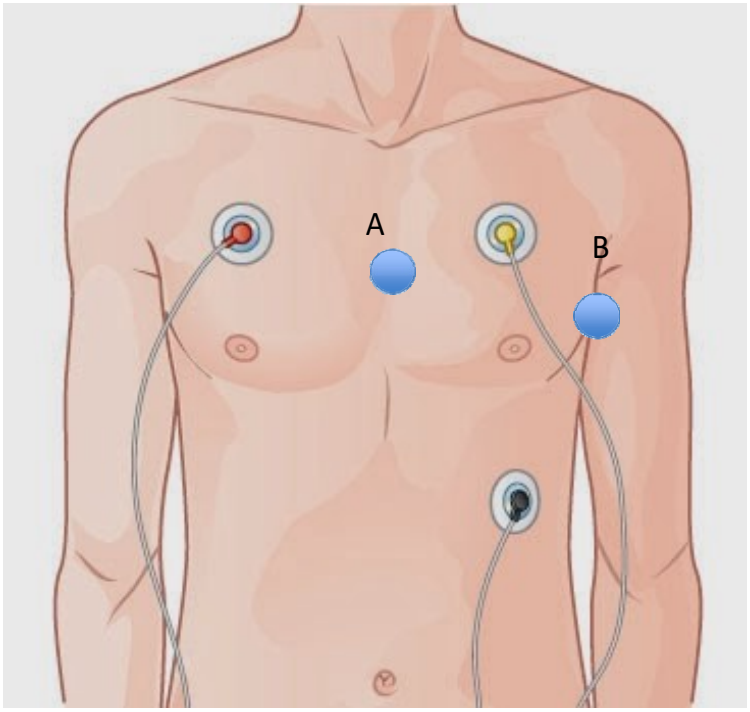
- SpO2 sensors can be purchased at Medeia Inc. or from your local Biosigns™ representative.
- If patient movement interferes with measurements, consider the following possible solutions:
    - Be sure the sensor is secure and properly applied.
    - Use a new sensor with fresh adhesive backing.
    - Select a different type of sensor.
    - Move the sensor to a less active sit

CONNECTING THE TEMPERATURE SENSOR

 **WARNING**	♦ Application and use of metal-jacketed temperature probes that come in contact with conductive objects or clinical personnel during electrocautery may cause burns at the patient-probe/electrode contact points. ♦ Do not touch conductive temperature sensors during defibrillation or cautery. ♦ Use only temperature probes listed by Medeia. Other probes may produce incorrect temperature readings.

Biosigns™ unit works with the disposable STS-400 sensor of Smiths Medical.

- The STS-400 sensors should preferably be placed in the left axillary cavity or on the sternum.



Placement of Temperature sensor

- On the sternum (A)
- In the left axillary cavity (B)

The sensor can be connected to the Biosigns™ unit using the temperature connection cable as displayed below. This cable is inserted in the phone jack port at the bottom side of the Biosigns™ unit.

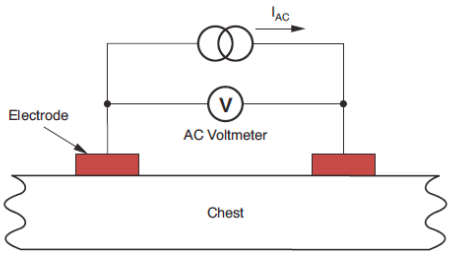
Connected temperature cable

RESPIRATION RATE

Biosigns™ is intended to detect the respiratory effort, deriving the signal by measuring the AC impedance between selected terminals of ECG electrodes. This method is called impedance pneumography. Impedance pneumography is a commonly- used technique

to monitor a person’s respiration rate, or breathing rate. It is

implemented by using two electrodes. The objective of this technique is to measure changes in the electrical impedance of the person's thorax caused by respiration or breathing.



Arrangement of Electrodes for Impedance Pneumography

In this method, a high-frequency ac current is injected into the tissue through the drive electrodes (see Ref. 1). The ac current causes a potential difference to develop across any two points between the drive electrodes. This potential difference is related to the resistivity of the tissue between the voltage-sensing or *receive* electrodes. The equivalent resistance is defined as the ratio of the voltage difference between the two receive electrodes and the current that flows through the tissue. The normal ECG electrodes are used for this method.

WARNING	♦ Impedance pneumography detects respiratory effort via changes in chest volume. Artifact due to patient motion, or electrocautery use may cause respiration to go undetected. Always monitor SpO2 when using impedance pneumography to monitor respiratory function. ♦ Don't place the Biosigns unit in close proximity to another respiration monitor because the Impedance pneumography measurement frequencies may interfere with one another. ♦ Because pacemaker pulses in some instances may be falsely counted as breaths, impedance pneumography is not recommended for use on paced patients. ♦ Motion artifact can cause incorrect breath rate or heart rate readings. Minimize patient motion whenever possible. ♦ If a disconnected lead is in too close proximity to other electrical devices, it may cause false respiration rates.

SPECIFICATIONS OF THE RESPIRATION RATE

Sweep speed:	3.13, 6.25, 12.5 mm/s: user-selectable
Amplitude range:	1x, 2x, 4x, 8x, 16x
Sensing electrodes:	Auto selected by device
Impedance dynamic range:	20 ohms
Signal bandwidth after detection:	0.06 Hz (single pole) to 3.2 Hz (2 pole) Breath detection threshold 140 milliohms or 2x CVA, whichever is greater

Respiration rate range Adult:	3 to 150 breaths/min (technical range) 3-120 breaths/min (software limitation)
Respiration rate source (RR):	ECG impedance signal
Resolution:	5 seconds
Cardiovascular artifact rejection (CVA):	Presence of CVA is detected automatically. Breaths will be picked in the presence of CVA unless the Breath Rate is within 5% of the Heart Rate or a sub-multiple of the heart rate.
Motion artifact rejection:	Not rejected
Obstructive apnea:	Not detected

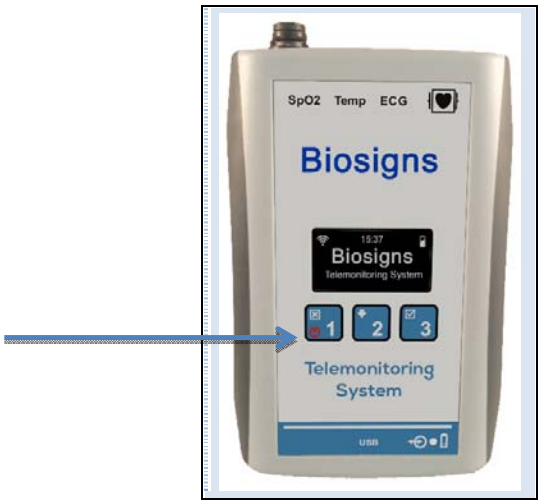
Notes:

- Impedance pneumography is not recommended for use with high frequency ventilation.
- Since respiration rate is derived from the same leads as the ECG channel, the device determines which signals are cardiovascular artifact and which signals are results of respiratory effort. If the breath rate is within five percent of the heart rate or a multiple or sub-multiple of the heart rate, the monitor may ignore breaths.
- When monitoring respiration rate it is highly recommended that you use SpO2 monitoring as a backup monitoring method.
- It is recommended that Biosigns respiratory measurements not be made in close proximity to electrically radiated equipment. When Biosigns is operated per EN 60601-1-2 (radiated RF immunity 3 V/m), field strengths above 2 V/m may cause erroneous measurements at various frequencies.
- Biosigns counts as “breaths” respiratory efforts that are larger than two times background cardiovascular artifact.
- Severe artifact and interference (such as defibrillation interference) can cause the waveform to move off the display for a few seconds before it is restored.

USING THE DEVICE

SWITCH-ON THE UNIT

After you connect the patient to the device, switch it on by pressing the On/Off button for one second.



The device will start and the LCD display will show the Biosigns Telemonitoring System logo.

	
On/ off button	**Start-up screen**

To switch the unit off, keep the on/off button pressed for 3 seconds until the device shows the message “Turnoff in Progress”.

	
On/ off button	**Turn-off screen**

MODES OF OPERATION

The device has 3 modes of operation, which are described in the next sections. Each mode can only be configured using the Biosigns™ Telemonitoring System software. Please refer to that manual for more detailed information.

USB MODE

To place the device in USB mode, switch off the Biosigns™ unit and connect it to the PC using the USB cable. When the cable is connected, switch the Biosigns™ unit on and it will show the USB connection message on the screen.

	
PC recognised device	Device is in USB mode

When the device switched on when connecting it to the PC, it will not be placed in USB mode but in charging mode. The screen will show the message below.


When charging via PC, the message is “Slow charge…”

When the device is connected to the USB ports of the computer where the Biosigns™ software is installed, the following features are available;

- Configuration of the modes of the device: with the software it is possible to configure the device for the operational mode. For the WIFI mode and the 3G mode, the network settings can be configured. When the device is configured via USB it needs to be restarted for the new settings to take place.
- Configuration of the sensors used with the device: the device can be used for different configurations with ECG, SpO2 and Temperature. This configuration is done via the software on the PC.
- Monitoring of the realtime vital signs and ECG of the patient: the device can be used for realtime monitoring when the patient is connected to the device. In this case, the data is received via the USB cable connection.
- Downloading data from the internal memory of the device: the device records the data during operation. Via the software on the PC, the data on the internal memory card can be (partially) downloaded to the PC and added to (one more) patient records for review, reporting and storage.

- Charging the internal battery of the device: as soon as the USB is plugged in the unit, it will power the unit and charge the internal battery. The device can be charged with a laptop, PC, phone charger, car charger and other means that provide charging power. With the different charging sources, the time of the charging process is different (see recharging the device section in the instructions for use).

WIFI MODE

 **WARNING**	♦ Sometimes the connection with the server can be interrupted. In that case the device will show the message that the server connection is dropped. The Biosigns Telemonitoring System software will show the same message to indicate that monitoring the patient is not available.

In this mode, the Biosigns™ unit communicates via a local WiFi network. In order for the device to connect to the network, it needs to be configured with the appropriate settings. This is done using the Biosigns™ Telemonitoring System software. For instructions, please refer to the specific user manual.

The device is designed to automatically connect to the predefined WiFi network. Therefore, the operation is limited to switching on the unit and waiting for it to connect. During the connection process, the display shows the message “WiFi module on”. The WiFi radio indicator flashes until it is connected to the WiFi network. The unit display then indicates “WiFi connection established”.

The bars of the WiFi status indicator display the signal strength. The more bars, the more radio strength available. The range of reception of the WiFi signal may be affected by equipment used in the direct vincinity of the Biosigns™ unit or WiFi router. Ensure that when using the WiFi mode there is sufficient coverage of the network to adequately monitor the patient.

As soon as the Biosigns™ server is receiving the data from the device, the display shows the message “Joined WiFi network” and an upwards flashing arrow shows active transmission of data to the Biosigns™ Telemonitoring System software.

Note: Biosigns unit will automatically try to reconnect to the server with a one- minute interval.

			
WIFI Device is in WiFi mode and is connecting to WiFi network	WiFi connection established message.	Indication that device is sending to IP-address of Biosigns Server via WiFi SSID. Flashing upwards arrow indicates transmission.	Connection with Biosigns Server lost.

Now, monitoring by the remote workstation is available.

3G MODE

WARNING	♦ Sometimes the connection with the server can be interruped. In that case the device will show the message that the server connection is dropped. The Biosigns Telemonitoring System software will show the same message to indicate that monitoring the patient is not available.

In this mode, the Biosigns™ unit communicates via the cellular network. In order for the device to connect to the cellular network, it needs to be configured with the appropriate settings. This is done using the Biosigns™ Telemonitoring System software. For instructions, please refer to the specific user manual.

When the device is in 3G mode, the device connects to the local cell phone network. During the connection process, the display shows the message “GSM module on”. The GSM radio indicator will flash until it is connected to the 3G network. Then the 3G-radio indicator tells you “GSM connection established”.

The bars of the 3G-status indicator displays the signal strength. The more bars, the more radio strength available. Please note that although the coverage of the 3G network may be great in many places, sometimes it can be very poor. In places like the basements, buildings with metal rasters in the windows or sun blocking window foils, the connection may be poor or even not existing. In that case the device cannot connect to the cellular network and monitoring is not available.

When the server is receiving the data from the device, the display shows an upwards-flashing arrow.

Device is in 3G mode and is connecting to cellular network	GSM connection established message	Indication that device is sending to IP-address of Biosigns Server via GSM network. Flashing upwards arrow indicates transmission	Connection with Biosigns Server lost

Now, monitoring by the remote workstation is available.

Note: Biosigns unit will automatically try to reconnect to the server with a one- minute interval.

STATUS INDICATIONS ON THE DISPLAY

The display may show the following status indications after turning it on:

USB	USB mode: indicates the device is connected to the USB port of the PC	USB connection established: indicates that the USB communication between the device and the PC is started	
WiFi	WiFi module on: indicates the device is in WiFi mode	WiFi connection established: indicates that the device is connected to the WiFi network	Wifi joined to ****: indicates that the device is connected to a WiFi network Open 209.126.110.91 + WiFi symbol: indicates that data transmission between the device and the Biosigns Server is active
GSM	GSM module on: indicates the device is in GSM mode	GSM connection established: indicates that the device is connected to the GSM network	Open 209.126.110.91 + 3G symbol: indicates that data transmission between the device and the Biosigns
Battery	Battery indicator: is always displayed and shows the level of the battery in 5 steps.	Flashing battery indicator means that the battery is almost empty	Charging indicator: indicates that the device is connected to a power source and is being charged

GENERAL STATEMENT OF SERVICE OF OPERATION

Biosigns™ is a telemedicine solution. This means that it requires transmission of data via the built-in WiFi or cellular modem.

It should be clear to the user that the connection quality is important for the performance of the device. The device has the ability to work with changing bandwidths as it buffers the data to cope with changing signal strengths. The device requires a bandwidth of 20 Kb/sec to send data to the central server. The device uses internal buffers to cope with fluctuations of bandwidth. These buffers ensure that there are no data losses or latency issues. When the bandwidth falls below 20 KB/sec, the device is not able to send its data to the WiFi or cellular network. If this condition remains for

more than 10 seconds, the software considers the device to be “offline’ and displays that the device is not monitored by a “red cross” through the patient name in the software.

CONFIGURATION AND OPERATION

Biosigns sends real-time data to the server. In optimal situations the delay of data transmission is less than one second. When the connection with the wireless connection is poor, the delay may increase to up-to a maximum of 10 seconds. There is no data loss as the device uses internal buffers to store data packages, which are send when the connection improves. In the case the communication is not sufficient to send data for a 10 seconds period, the server will consider this as “connection lost” and the Biosigns™ Telemonitoring System show this in the software as a red cross through the patient display and the data packages will be stored in the Biosigns.

SECURITY OF WIRELESS SIGNALS

Medeia delivers a high-end telemonitoring solution allowing healthcare providers to remotely monitor vital-signs and other (para) medical data.

To comply with the Privacy Rule and Security Rule of the US Health Insurance Portability and Accountability Act (HIPAA) for the processing of personal data the Biosigns provides the Physical Safeguards as required by 45 CFR 164.310 and the technical safeguards as required by 45 CFR 164.312.

However the safeguards, mentioned in the 45 CFR 164.310 and 312, need to be implemented and activateD by the healthcare providers.

An overview of the security:

- The Website portal Software uses a https connection and is username and password protected
- Wi-Fi WPA2-PSK password protected
- The 3G communication is done by a APN connection with the cellular network and directly to the Linux server’s IP address via one data port
- The data transmission of the Biosigns has no direct link to the patient references “name”.

RF SAFETY

This device has been evaluated in accordance with the FCC bulletin 56 “Hazards of radio frequency and electromagnetic fields” and Bulletin 65 “Human exposure to radio frequency and electromagnetic fields.”

- Combine (GSM and WiFi) Specific Absorption Rate (SAR).
- The SAR is a value that corresponds to the relative amount of RF energy absorbed in the head of a user of a wireless handset. The FCC limit for public exposure from cellular telephones is an SAR level of 1.6 watts per kilogram (1.6 W/kg). Specific Absorption Rate (SAR) for Wireless Phones and Devices are available at OET Bulletin 65 Supplement C. The device SAR is within the FCC limit

BUTTONS ON THE DEVICE FRONT PAD

The device is operated with the 3 buttons on the front pad. These buttons have indicators for their operational tasks.

	On-off button: • Keep the button pressed for one second to start the device. • Keep the button pressed for 3 seconds to stop the device.
	Mode selection button: Press the button to select the USB, WiFi or 3G mode. The display shows the selected mode. Press button 3 to confirm the mode of choice.
	Mode confirmation button: Press the button to confirm the selected mode. To create an event, keep the button pressed for 3 seconds.

EVENT BUTTON

To create a manual event, keep button 3 pressed for 3 seconds. This creates an event in the Biosigns Telemonitoring System. The remote operator can see that the button on the device was pressed.

	To create an event, keep the button pressed for 3 seconds.

BATTERY INFORMATION AND RECHARGING THE DEVICE

When the battery indicator on the LCD display flashes, the battery is almost depleted and should be recharged.

	
Battery status indicator with 80% power level	Charger connected symbol

To charge the battery, connect the device to the power supply unit and the mains, using the USB connection cable. Insert the USB cable in the port with the USB indication.

Note: The power supply unit delivered to you by Medeia complies with the applicable standards and has been tested in combination with the Biosigns™

device. The supplied charger is recognised by the device and allows fast charging procedure. Therefore we highly recommend you to not use other chargers with your device.

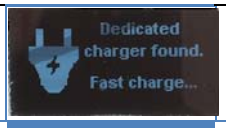
		
DV-USB (USB cable with micro-USB connector)	DV-PSU wall charger	Connection port for USB cable

When the USB cable is connected to the device and a power source, the LED with the battery symbol on the front pad will be lid.


Charging indicator on the front pad

Also, the LCD display will indicate the device is charging.

When the charging process is completed, the LED will be off and the LCD will stop showing the Slow charge or Fast charge message.

	
When charging with a PC or or laptop, the message is "Slow charge…"	When charging with the supplied mains charger, the message is "Fast charge…"

Note: Charging the battery takes around 4.5-9 hours, depending on the charger used.

CHARGING TIMES

Charging times will vary but in general the table below may be used as reference:

Charger	**Time to fully charge**
PC or laptop charger (0.5A)	9 hours
Wall charger (1A)	4.5 hours

OPERATION TIME

The device can be used on the internal battery. The time between charges is shown in the table below.

Mode of operation	**Autonomy of device with single charge**
USB	Unlimited
Wi-Fi	30 hours
GSM / 3G	22 hours

General technical data	
Temperature range • Operation • Storage • Transport	 • 10°C to +40°C (50 to 104°F) • -40°C to +70°C (-40 to 158°F) • -40°C to +70°C (-40 to 158°F)
USB communication.	5V DC from the Computer/Notebook USB port. Biosigns™ USB communication power consumption not more than: 5V DC/200mA DC.
Power Supply Voltage	FRIWO FW7721W Friwo Geratebau GmbH Von-Liebig-St 11 D-48346 Ostbevern, Germany. Type: Medical Grade Supply Rated Mains Supply Voltage: Input: 100-240V~, 50/60Hz, 200 mA Output: +5. VDC ⎓, 1500 mA Protection Class II Max clock frequency: < 1 MHz Standard: EN 60601-1-2:2007
Setup location, maximum height above mean sea level	3000m
Atmospheric Pressure	50kPa to 106kPa
Air humidity • Operation • Storage • Transport	 30%- 70% non-condensing 5% - 95% non-condensing 5% - 95% non-condensing
Medical device in accordance with Directive 93/42/EEC	Class llb
EN 60601-1: • Insulated device, protection class II • Electric medical device, Defibrillator-proof Type CF	
Degree of protection against harmful ingress of water	Ordinary Equipment(enclosed equipment without protection against ingress of water)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Method(s) of sterilization or disinfection recommended by the manufacturer	Not applicable

Biocompatibility	The parts of the product described in this operator manual, including all accessories, that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards ISO 10993. If you have questions in this matter, please contact Medeia.

DECLARATION ELECTROMAGNETIC EMISSIONS AND IMMUNITY

Guidance and Manufacturer's declaration-electromagnetic immunity			
The Biosigns™ is intended for use in the electromagnetic environment specified below			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - guidance**
RF Common mode/ Conducted Susceptibility IEC 61000-4-6	20 Vrms 150 kHz to 80 MHz	20 Vrms	Portable and mobile RF communications Equipment should be used no closer to any part of the Biosigns™, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\ \sqrt{P}$ $d = 1{,}2\ \sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}4\ \sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF Electromagnetic Field IEC 61000-4-3	20 V/m 80 MHz to 2,5 GHz	20 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Biosigns™ is used exceeds the applicable RF compliance level above, the Biosigns™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Biosigns™.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

EXAMPLE 1 As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m.

EXAMPLE 2 As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 0,5 m at an IMMUNITY LEVEL of 20 V/m.

Guidance and manufacturer's declaration – electromagnetic emissions		
Biosigns™ is intended for use in the electromagnetic environment specified below		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	Biosigns uses RF energy for communication. Its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Biosigns is suitable for use in all establishments, including domestic.

Guidance and manufacturer's declaration – electromagnetic immunity			
Biosigns™ is intended for use in the electromagnetic environment specified below			
Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment –guidance
Electrostatic discharge (ESD)	± 6 kV contact ± 6/8 kV air	B B	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 15 %.
Electrical fast transient/burst	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	300 A/m	300 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Recommended separation distances between portable and mobile RF communications equipment and

is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz outside ISM bands ***d=[3,5/V1] √P***	**80 MHz to 800 MHz** ***d=[3,5/3] √P***	**800 MHz to 2,5 GHz** ***d=[7/3] √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 a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using 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 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

MAINTENANCE

The Biosigns™ device and accessories should be stored in a clean, dry place. Handle the Biosigns™ device with care and protect it against mechanical shocks, dirt and liquids. The device is not waterproof or splash proof.

ENVIRONMENTAL CONDITIONS

Temperature	Charge: 0 °C to +45°C (32°F to 113° F) Discharge: -20°C to +50°C (-4°F to 122° F) Operation: +10 °C to +40°C (50°F to 104° F) Storage: -40°C to +70°C (-40°F to 158°F)
Relative Humidity	Operation: 30%-70% (non-condensing) Storage: 5%-95% (non-condensing)

Pressure	Withstands atmospheric pressures from 700 hPa to 1060 hPa

CALIBRATION

The Biosigns™ device is factory calibrated. No further calibration is needed.

AVOID ELECTROSTATIC DISCHARGE

When humidity in the working environment decreases, the human body and other insulators can become charged with static electricity due to friction. To prevent unwanted electrostatic discharge (ESD), follow these standard guidelines:

- Maintain the recommended humidity of 40% to 60% in the work environment.
- Dissipate electrostatic charge before performing routine operator maintenance.

STERILIZATION, SHELF LIFE AND CLEANING

The device and the accessories are not provided sterile, not intended to be sterilized or provided with a shelf life. As such, these aspects are not applicable for the submission. However, the device and some of the accessories are intended to be re-used and instructions for reprocessing are included in the user manual. The reprocessing instructions provided in the next sections.

INSPECT AND CLEAN THE MONITOR AND ACCESSORIES

CAUTION

" Do not autoclave the Biosigns™ or its accessories. Do not immerse the monitor in liquid when cleaning. Do not immerse accessories in liquid when cleaning unless the accessory manufacturer's cleaning instructions explicitly instruct you to do so.

Before cleaning, thoroughly inspect the Biosigns™ and all accessories for any signs of damage, cracks, or improper mechanical function of keypads, switches, connectors, and printer paper door. While gently bending and flexing cables and tubing, inspect for damage, cracks, cuts, abrasions, extreme wear, exposed wires or bent connectors. Confirm connectors securely engage. Report damage or improper function to your service department.

DEVICE

Please make sure that you clean the Biosigns™ device after each use on a patient and before using it on a new patient. Avoiding cross contamination has to be taken seriously. The device and the cables can be cleaned using a mild detergent solution. Do not submerge or rinse the product or parts and do not allow any liquids to enter any opening on the device. Allow the unit to dry thoroughly before use.

CABLES

All cables used with Biosigns™ are reusable. Clean the cables with a moist cloth using a hospital grade cleaner.

- Disconnect the cable from the Biosigns™ unit before cleaning or disinfecting it. When disconnecting the cable, be sure to pull on the connector, not on the cable.
- Clean the cable by rubbing it down with a cloth moistened with soap water. Use a disinfectant for disinfection. Do not immerse the cable in liquid.
- Do not immerse the cables in liquid and avoid contract of the cleaning solution with the connectors.

ECG LEAD WIRE

- Disconnect cable. Wipe plastic parts with a cloth moistened in lukewarm water with alcohol-free neutral soap. Always wipe towards the patient connectors/ECG clips.
- Proceed carefully as to not damage the cable through excessive stretching, bending or kinking of the wires.
- Remove the cleaning agent wiping the cable with a cloth moistened in water. Wipe or air dry before use.
- Remove adhesive residues only with the alcohols listed below. Never use other organic solvents (i.e. acetone or toluol will damage the cable jacket)!

CLEANING AND DISINFECTING THE ECG ELECTRODES

In addition to the information given in this manual, observe the instructions for use of the respective electrode types. Discard disposable adhesive electrodes immediately after use to prevent that they are reused.

SPO2 SENSOR

CAUTION

" Do not spray, pour, or spill any liquid on the Biosigns™, their accessories, switches or openings.

Cleaning oximetry equipment is just as important as proper use. For surface-cleaning and disinfecting the Biosigns™ unit and reusable SpO2 sensors we recommend the following procedures:

- Turn off the Biosigns™ before cleaning
- Wipe exposed surfaces with a soft cloth or a pad moistened with a mild detergent solution or medical alcohol (70% isopropyl alcohol solution)
- Clean your Biosigns™ whenever you see any type of soil, dirt or obstruction in it
- Clean the inside of the elastic thimble and the two optical elements inside with a

cotton swab or equivalent moistened with a mild detergent solution or medical alcohol (70% isopropyl alcohol solution)

- Ensure that no dirt or blood is on the optical components inside the elastic thimble
- SpO2 Sensors can be cleaned and disinfected with same solutions. Let the sensor dry before using it again. The rubber inside of the SpO2 sensor belongs to medical rubber, which has no toxin and no harmful to the skin of human being.
- It is recommended that the Biosigns™ should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the oximeter

DISPOSAL

Follow local governing ordinances and recycling instructions regarding disposal or recycling of this device and accessories.

	• According to the regulation in Europe on Waste of Electrical and Electronic Equipment (WEEE) the components labeled with this symbol may not be disposed of as unsorted municipal waste. The components shall be collected separately and returned to the appropriate collection system available. • Please contact your distributor regarding take back or recycling of the components

WARRANTY

Your Biosigns™ unit comes with a 12 months warranty period. The sensors have a 90 days warranty. For warranty claims contact the manufacturer or your local representative for further instructions. Please note that only cleaned and disinfected parts will be services or repaired. Make sure that you only ship products and parts that are properly cleaned. Your warranty card can be found in the packaging of your device.

SERVICE AND SUPPORT

The Customer Service staff at Medeia encourages you to contact them for product assistance.

If you have questions please send them by email to support@Biosigns.com or +1 800 433 4609 for a prompt r e s p o n s e .

Medeia makes no claim that its products treat or heal. Medeia's products are designed to measure and monitor physiological change. Professionals should work within the scope of their licenses and/or certifications when interpreting or applying data derived from Medeia's products.

Your Biosigns™ unit does not need calibration. We recommend you to replace the internal battery every two years as the battery power and operation time decreases after this period. Contact Medeia or your supplier for changing out the battery.

Note: The operator of this device should read and gain a thorough understanding of this manual before use.

Note: do not open the device or replace parts yourself as damage to the device could occur.

MR I SAFETY INFORMATION

The Biosigns™ unit has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Biosigns™ in the MR environment is unknown. Risk of projectile injury due the presence of ferromagnetic materials in the device; risk of burns to the patients due the current induced by strong electromagnetic fields present in MR environment. Scanning a patient who has this device may result in patient injury.

FC C STA TE M E N T

The label at the backside of the product has the FCC logo and FCC registration number.

For the Biosigns™ product, the indication is shown below:

FC	**2ANW8-HW9**
FCC logo	FCC registration number

REGULATORY INFORMATION

FCC INFORMATION TO USER

This product does not contain any user serviceable components and is to be used with approved antennas only. Any product changes or modifications will invalidate all applicable regulatory certifications and approvals.

FCC RF EXPOSURE INFORMATION

This device meets the U.S. Government's requirements for exposure to radio frequency electromagnetic fields. This device contains a radio transmitter and receiver. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy as set by the FCC of the U.S. Government.

This device has been tested for body worn operation and meets the FCC RF exposure guidelines.

FCC ELECTRONIC EMISSION NOTICES

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
2. This device must accept any interference received, including interference that may cause undesired operation.

FCC RADIO FREQUENCY INTERFERENCE STATEMENT

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. Operation of this equipment in a residential area may cause harmful interference, in which case the user will be required to correct the interference at its own expense.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

- LAST PAGE OF INSTRUCTIONS FOR USE -