BW Mini

EEG
HST
PSG
HST Compass

User Manual

NEUROVIRTUAL

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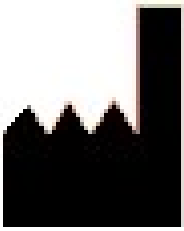
Table Contents

1. Manufacturer information



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Important

For the safety of all users and the correct use of this equipment, the complete reading of such manual before starting the installation and the operation of BWMini equipment is mandatory.

This document aims to help the user to install the BWMini (BWMini EEG, BWMini HST, BWMini PSG and BWMini HST Compass) equipment safely. This User Instruction is exclusively for the operation of BWMini equipment.

The BWMini equipment must only be used by licensed professionals. It is recommended that this User Manual be maintained at the same place as the equipment for consultations and referrals as there is important information which must be read and understood during the installation and operation of the BWMini equipment.

The equipment installation must be performed by a Neurovirtual technician, or medical facility technician, under supervision of the physician responsible, following the instructions included in this manual.

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

In the case of home studies is recommended that healthcare professionals provide a copy of this manual for the user for correct use of the product.

3. Safety Specification

The BWMini equipment complies with the safety standard requirements for electromedical equipment: IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26 and ISO 14971, according to the Test Report issued by a laboratory accredited.

The BWMini equipment is classified as "Class II" concerning its protection against electric shock.

The device contains parts of the BF type concerning the patient's degree of protection against electric shock.

Ordinary equipment, with protection against water and penetration class IP22, when using with the carrying case. For indoors use only. Short term – Normally indicated for continuous use for no more than 30 days.

The BWMini equipment does not feature alarms and are not designed for use as automated apnea monitors or multiparameter life support monitors.

4. General Description

The BWMini equipment is a medical device that records physiological signals. The system can capture electroencephalograph, respiratory, electromyography, plethysmography, and body position as a home sleep test (HST). The signals are captured using electrodes and sensors and a recording station with the software and/or on a memory card.

4.1. Module Functionality

The BWMini equipment can use up to three main modules: The amplifier, the battery, and the flash stimulation module. To use the device properly it is mandatory to have all the modules that the device includes. Not all the modules are included in all the models. To get more details about your device's model you can access the manufacturer's website or contact the technical support department.

4.1.1. Amplifier Module

The amplifier contains the main processor and the communication interface of the device. The amplifier translates physiological signals into digital data. Depending on the model it will include different channels. For more details refer to *Item 7 on page7***.**

4.1.2. Battery Module

The battery provides electric energy to turn on the device. It is a medical grade device and must not be replaced by any other type of power supply. In case the module fails contact the manufacturer's technical support department.

4.1.3. Flash stimulation Module

The photic or flash stimulation module is used for photo stimulation protocols on EEG studies. It requires it to be connected to the recording station and can use multiple routines. The protocols are activated from Software BWAnalysis. None of the models include this module, to acquire a flash stimulation module contact the manufacturer.

4.2. BWAnalysis Software

The software, BWAnalysis, translates the signals captured from the device to digital information to reviewed and interpreted by a trained physician who will exercise professional judgment in using this information.

The software contains features to navigate through the signals, change montage view, see graphics, mark events, draft reports, etc. It requires to be installed on the recording station to enable the amplifier. For more details, refer to the Software user manual.

5. Indications for Use (Intended Purpose)

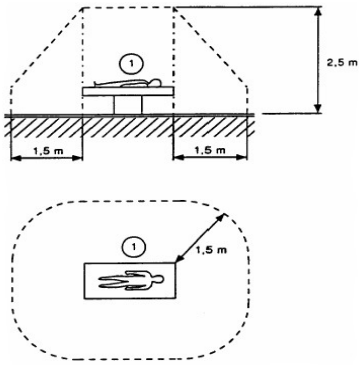
The BWMini system may be used for electroencephalograph (EEG) by measuring and recording the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

The BWMini is a multi-channel (up to 60 channels) system designed for Electroencephalograph (EEG), Polysomnography (PSG) and Home Sleep Testing (HST) recording and may be used in research, home sleep studies, ambulatory and clinical environments.

The BWMini does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

6. Safety Advisory and Considerations

	1. The BWMini equipment should be positioned on a mobile cart or flat, wooden, concrete, and ceramic surface. If the floors are covered with synthetic material, the relative air humidity should be at least 30% to avoid electrostatic discharges. Some electrostatic discharge may cause the unit to stop responding. In this situation the equipment must be turned off for 5 seconds and turned on again.
	2. Keep the operating and storage environment free from dust, vibration, liquid, chemicals, substances that emit or that might come to emit gases, corrosive, or flammable materials.
	3. Do not use the equipment in a flammable atmosphere where concentrations of flammable anesthetics or other materials can cause a risk of explosion.
	4. Do not use the BWMini equipment in the presence of any flammable anesthetic mixture with air, oxygen, or nitrous oxide.
	5. The equipment should not be turned on before detailed analysis is made of the physical integrity of the cables and connections.
	6. In case you have any problem with the equipment, do not try to perform maintenance. Contact the manufacturer to receive the correct instructions for maintenance.
	7. Make sure all electrode/sensor wires are well to avoid the risk of patient strangulation.
	8. The connection of any other equipment to the BWMini being used can cause an increased possibility of current leakage. Contact the manufacturer before proceeding with connecting other equipment.
	9. To avoid current leakage to the patient, the operator must not be in contact with non-medical devices and the patient simultaneously.

	10. The IEC 60601-1 standards determine that the expression "Patient's Environment" refers to the name of the place where the examination is performed. In this environment, the due care for the operation of BWMini equipment must be taken, as follows: - The computer should not touch the patient, because it is not considered electromedical equipment. - Keep the computer as well as any other non-electromedical device at a radius of 1.5 m away from the patient. The dimensions for the patient's environment are as follows: 
	11. Periodically inspect the BWMini equipment and its accessories, to assure that they do not have any visible evidence of damage that might affect the patient's safety or the analysis performance. Do not use them if there are any visible signs of damage.
	12. This equipment might interfere with the operation of nearby equipment. It might be necessary to take mitigation measures, such as re-orientation or relocation of equipment.
	13. Never use sharp tools to operate the equipment.
	14. The sensors, electrodes, and even the patient must not be in contact with any other conductive material including the grounding equipment
	15. The sensors and electrodes must not be directly connected to the electric grid or to another device different to the BWMini. Risk of electric shock.
	16. The sensors and electrodes should not be in contact with the patient's skin if it is irritating or if it presents any kind of illness. Discontinue use if there is any sign of irritation/redness/itching.
	17. The BWMini of equipment does not judge the normality or abnormality of those signals indicated or even the results of an analysis. Only a competent professional can render the diagnosis.
	18. The BWMini of equipment was **not** developed to be used / replace a Multiparametric monitor or a life support monitor. The devices were not designed to be used along with surgical equipment unless a written authorization is provided by the manufacturer.

	19. The BWMini equipment was not designed to be used during the action of a defibrillator. Take all electrodes and sensors off the patient before performing the defibrillation.
	20. There are no restrictions on the use of this equipment in people who have an implanted pacemaker.
	21. This equipment was only tested on human beings.
	22. Ordinary equipment, with water and penetration protection IP22, when using with the carrying case.
	23. Warnings and Specific Considerations for oximetry may be found in the topic Pulse Oximeter in this Use Instruction.
	24. Using a device from the BWMini simultaneously with another active device could increase the levels of current leakage. This is a risk for the patient. Contact the manufacturer before connecting the BWMINI device with any other equipment.
	25. Using accessories, sensors, cables, or inner pieces that are not specified by the manufacturer could increase emissions or reduce the EMC immunity of the BWMini Device
	26. The Family of BWMini devices must not be used right beside or piled up over another device. In case it is necessary, the device must be observed to verify it works properly.
	27. The BWMini device and its accessories must be inspected periodically. This guarantees they do not show visual evidence of damage that can affect the patient's safety during the recording. Avoid using the equipment if there are visible indicators of equipment damage
	28. The conductive parts of the electrodes and its connectors (including the neutral electrode for EEG types of BF or CF), must not get in contact with conductive parts including ground.
	29. The BWMini has manual sensibility controls that are adjusted with the BWAnalysis software. It has various amplitude signals that only a professional could diagnose. Therefore, IEC 60601-1 User instructions (6.8.2.201) are not applicable to the BWMini
	30. To obtain additional documentation, please get in contact with the technical support team through the manufacturer's official site.
	31. The manufacturer does not authorize nor makes responsible for any modification performed to the equipment by third party users. Inadequate modifications could cause device malfunctioning and erroneous diagnostics.
	32. The manufacturer does not provide documentation related to circuit diagrams, list of components, and technical information related to its hardware or software.
	33. After the installation or after a modification of the BWMini device's location and/or its parts and accessories. The user/operator must ensure the environment security parameters comply with this manual's instructions. If required, contact the technical support team for more details.
	34. Follow the installation instructions to verify the cables are located properly to avoid cable bottlenecks or strangulations. In case the patient or the operator find one or multiple loose pieces of the equipment. Contact immediately the technical support team. If the patient ingests any of the parts of the system or is harmed by the device, he/she must be taken to a hospital.

	35. Do not connect the conductive parts and/or the electrodes, including the reference (REF) with the ground.
	36. Do **not** use the BWMini device simultaneously with a high frequency surgery device.
	37. Some types of electrostatic discharge (ESD) event could result in a system crash. Onwards, it is necessary to manually reset. Removing and replacing the power supply might be necessary.
	38. Portable communication devices that use radio frequencies (including peripherals as cables or antennas) should not be used as near as 11.81 inches (30 cm) or closer to the BWMini device or its cables. It can have a negative impact on the performance and the signal quality.
	39. The cables provided with the equipment (ethernet cable, power supply cable and the patient's cable) will not be longer than 9.84 feet (3 meters).
	40. The family BWMini was developed to be used in an industrial and hospital environment. If the device is used in a home environment, the device could not offer proper protection against radio-frequencies. The user would require taking mitigation measurements such as relocate or reorientate the device.
	41. Follow the instructions in the attached documents where the BWMini needs to be installed and placed properly so as not to cause problems with EMC, follow the EMC information.
	42. Beware of RF-emitting equipment near the BWMini, it can affect the performance of BWMini.
	43. Sensitivity adjustment values below the BWMini Technical Specifications may result in incorrect results.
	44. Essential Performance IEC 6060-1 (Item 4.3): All input signals must remain the same as output but amplified according to the parameter and characteristic of the equipment, the functions after testing must comply with the parameters mentioned in item 12
	45. Simultaneous use of the BWMini with any other active equipment can increase leakage current levels, consequently creating a possible risk to the patient. Contact Neurovirtual before proceeding with the connection with other equipment.
	46. There are no restrictions on the use of this equipment by people who have a pacemaker implanted.
	47. If any serious incident has occurred in relation to the device, please report to the manufacturer and the competent authority of the Member State in which your and/or patient is established
	48. The device is designed for standalone operation, without requiring a computer or external power supply for normal use. A computer connection is used for downloading the study data, and the external power supply is intended only for charging the battery. During the battery charging process, the patient must not be connected to the device.
	49. Before using the device, allow it to acclimate for at least 4 hours after being removed from storage if the storage environment conditions exceed the operational environment minimum and maximum specifications.

	50. The user must be aware of the following potential effects on different beings: • **Pets:** Chewing on cables, biting or scratching the device, causing physical damage or electrical hazards. • **Pests:** Infestation in internal components, gnawing of wiring, or contamination, which can lead to malfunctions or fire risks. • **Children:** Unsupervised use or tampering, resulting in incorrect operation, physical damage, or safety hazards such as electrical shock or injury.
	51. Please follow the recommended actions: • **Storage:** Keep the device in a secure, elevated, and enclosed location, out of reach of children and animals. • **Inspection:** Regularly inspect the device, cables, and surrounding area for signs of chewing, damage, or pest activity. • **Supervision:** Ensure the device is only operated by authorized and trained individuals under appropriate supervision. • **Maintenance:** If any damage or contamination is detected, stop using the device immediately and contact a qualified technician for inspection and repair.
	52. Failure to follow these precautions may result in: • Malfunction or permanent damage to the device. • Compromised safety, leading to electrical or fire hazards. • Voiding warranty or service agreements. Call technical support in case of any of these events for further assistance

7. Models

The BWMini consists of 4 different models: BWMini **EEG**, BWMINI **PSG**, BWMINI **HST** and BWMini **HST Compass**.

7.1. Comparative table between BWMini models

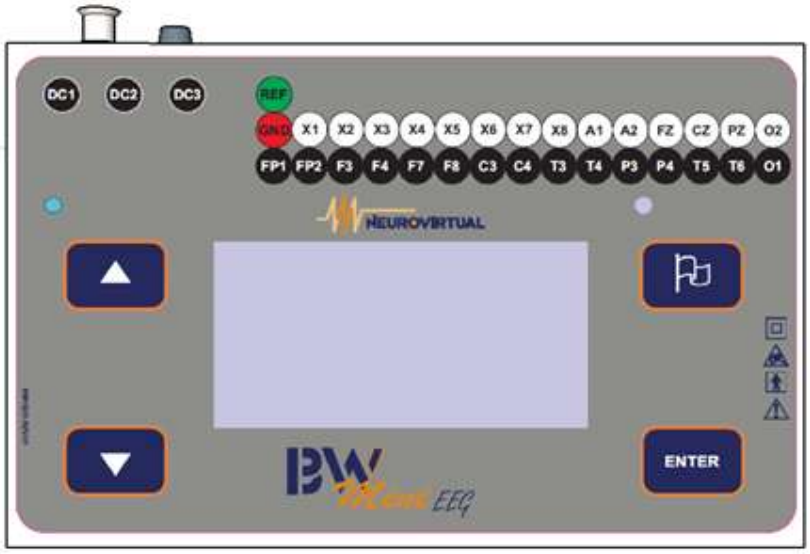
The following table compares the models within the BWMini in order to comply with INMETRO Ordinance No. 384, December 18, 2020, regarding the constitution of equipment families:

Features	BWMini EEG	BWMini PSG	BWMini HST	BWMini HST Compass
Does it have the same functional technology?	Yes	Yes	Yes	Yes
Does the model have a similar indication, purpose or use?	Yes	Yes	Yes	Yes
Does the model share the same DMR (Device Master Records / Technical File / Technical Report)?	Yes	Yes	Yes	Yes
Are all models equipped with precision analog signal amplifiers?	Yes	Yes	Yes	Yes
Does the model have the same A/D converters (Analog to Digital signal converter)?	Yes	Yes	Yes	Yes
Does the model have the same manufacturing process?	Yes	Yes	Yes	Yes
Does the model have the same use and safety restrictions?	Yes	Yes	Yes	Yes
Does all models have the same storage and transportation instructions?	Yes	Yes	Yes	Yes
Does the model meet the same electrical safety / electromagnetic emission standards (ABNT and IEC) as determined by the certifying body (OCP)?	Yes	Yes	Yes	Yes
The manufacturer's certifying body (OCP) has accepted that the models form a family of equipments.	Yes	Yes	Yes	Yes

Below are the details of each model:

All the EMC and Safety/Electrical tests were carried out with the equipment in its complete configuration (BWMini PSG), which is the most complete method of use.

7.2.BWMini EEG



BWMini EEG

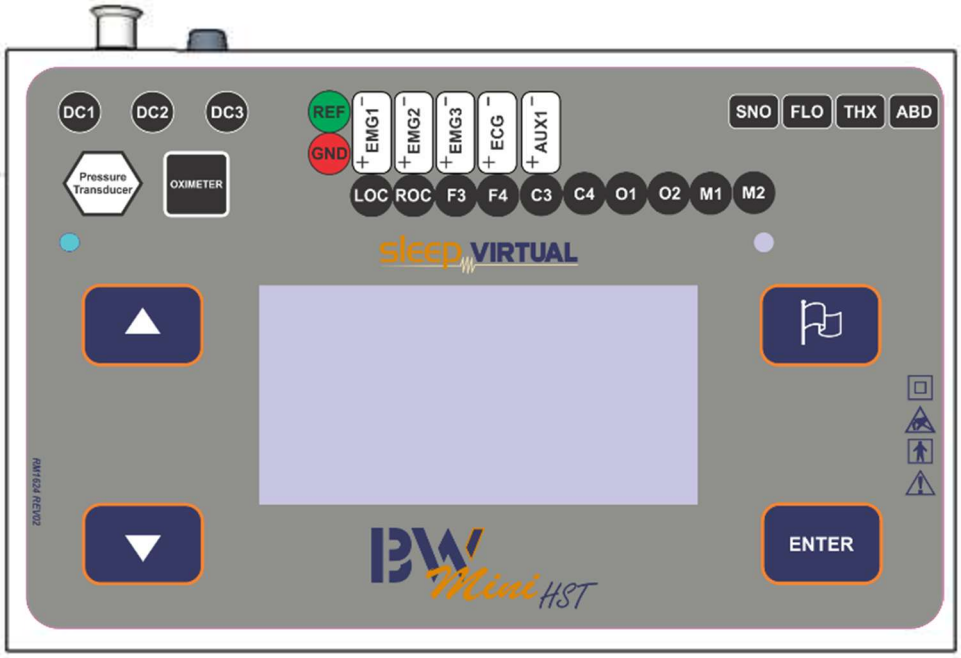
#	Channel Name	#	Channel Name
1	FP1 (EEG System 10-20)	22	X1 Monopolar
2	FP2 (EEG System 10-20)	23	X2 Monopolar
3	F3 (EEG System 10-20)	24	X3 Monopolar
4	F4 (EEG System 10-20)	25	X4 Monopolar
5	F7 (EEG System 10-20)	26	X5 Monopolar
6	F8 (EEG System 10-20)	27	X6 Monopolar
7	C3 (EEG System 10-20)	28	X7 Monopolar
8	C4 (EEG System 10-20)	29	X8 Monopolar
9	T3 (EEG System 10-20)	30	Oximeter (BPM) XPOD *
10	T4 (EEG System 10-20)	31	Oximeter (SpO2) XPOD *
11	T5 (EEG System 10-20)	32	Oximeter (Plesth Wave) XPOD *
12	T6 (EEG System 10-20)	33	Pressure Transducer *
13	P3 (EEG System 10-20)	34	Body Position
14	P4 (EEG System 10-20)	35	DC1
15	O1 (EEG System 10-20)	36	DC2
16	O2 (EEG System 10-20)	37	DC3
17	A1 (EEG System 10-20)		
18	A2 (EEG System 10-20)		
19	FZ (EEG System 10-20)		
20	CZ (EEG System 10-20)		
21	PZ (EEG System 10-20)		* Optional

7.3.BWMini PSG

BWMini PSG

#	Channel Name	#	Channel Name
1	FP1 (EEG System 10-20)	22	LOC
2	FP2 (EEG System 10-20)	23	ROC
3	F3 (EEG System 10-20)	24	EMG1
4	F4 (EEG System 10-20)	25	EMG2
5	F7 (EEG System 10-20)	26	EMG3
6	F8 (EEG System 10-20)	27	ECG
7	C3 (EEG System 10-20)	28	AUX1 Bipolar
8	C4 (EEG System 10-20)	29	AUX2 Bipolar
9	T3 (EEG System 10-20)	30	AUX3 Bipolar
10	T4 (EEG System 10-20)	31	Flow
11	T5 (EEG System 10-20)	32	Snore
12	T6 (EEG System 10-20)	33	ABD RIP
13	P3 (EEG System 10-20)	34	THX RIP
14	P4 (EEG System 10-20)	35	Oximeter (BPM) XPOD
15	O1 (EEG System 10-20)	36	Oximeter (SpO2) XPOD
16	O2 (EEG System 10-20)	37	Oximeter (Plesth Wave) XPOD
17	M1 (EEG System 10-20)	38	Pressure Transducer
18	M2 (EEG System 10-20)	39	Body Position
19	FZ (EEG System 10-20)	40	DC1
20	CZ (EEG System 10-20)	41	DC2
21	PZ (EEG System 10-20)	42	DC3

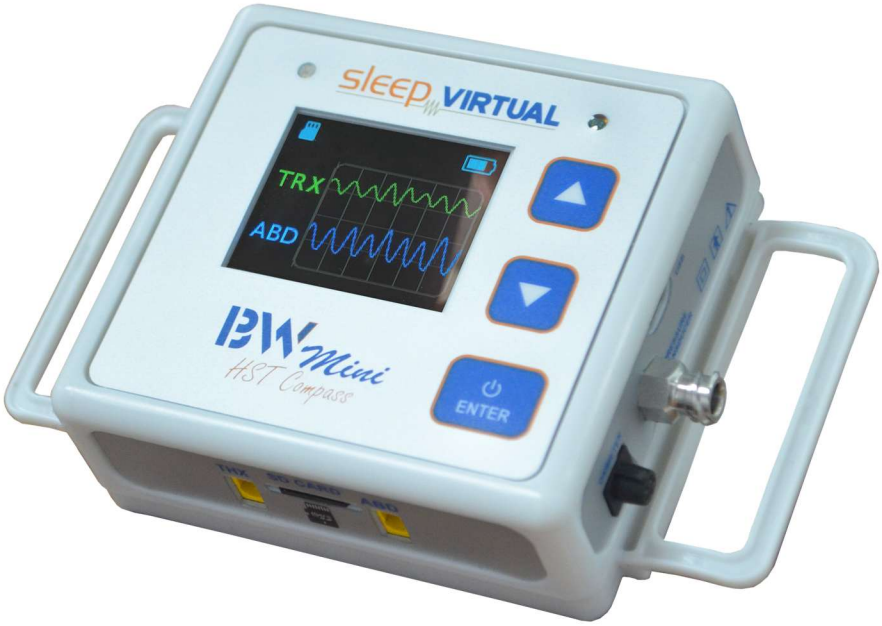
7.4.BWMini HST



BWMini HST

#	Channel Name	#	Channel Name
1	F3 Monopolar	16	Flow
2	F4 Monopolar	17	Snore
3	C3 Monopolar	18	ABD RIP
4	C4 Monopolar	19	THX RIP
5	O1 Monopolar	20	Oximeter (BPM) XPOD
6	O2 Monopolar	21	Oximeter (SpO2) XPOD
7	M1 Monopolar	22	Oximeter (Plesth Wave) XPOD
8	M2 Monopolar	23	Pressure Transducer
9	LOC Monopolar	24	Body Position
10	ROC Monopolar	25	DC1
11	ECG Bipolar	26	DC2
12	EMG1 Bipolar	27	DC3
13	EMG2 Bipolar		
14	EMG3 Bipolar		
15	AUX Bipolar		

7.5.BWMini HST Compass



BWMini HST Compass

#	Channel Name
1	AC Bipolar
2	AC Bipolar
3	Pressure Transducer (Flow and Snore)
4	RIP Channel (ABD)
5	RIP Channel (THX)
6	Oximeter (BPM) XPOD
7	Oximeter (SpO2) XPOD
8	Oximeter (Pleth) XPOD
9	Body Position
10	DC1
11	DC2
12	DC3

8. Purpose and Descriptions

8.1. Models: BWMini EEG

What is the purpose?

The BWMini EEG equipment is a biological signal amplifier used for the diagnosis and follow-up of neurophysiological pathologies.

How is the Electroencephalography exam performed?

After cleaning the patient's head, surface electrodes are placed on the scalp along with the conductive paste. Electrode placement must meet the International 10-20 Electroencephalography Electrode Placement System.

Where should BWMini EEG equipment be used?

The BWMini EEG model equipment can be used in hospitals, specialized clinics or doctor's office and *home care*, as long as it is under the supervision of a technician or nurse qualified for this purpose and that the safety requirements for operation are met.

What are the indications for performing this exam?

1- Neurophysiological pathologies,
2- Detection or evaluation of epileptic syndromes,
3- Coma assessment,
4- Brain Death / Brain Electrical Silence,
5- Poisoning and encephalitis,
6- Dementia syndromes,
7- Epileptic seizures,
8- Metabolic disorders,
9- Among others.

All the above evaluations must follow the appropriate and respective clinical protocols.

8.2. Models: BWMini PSG, BWMini HST and BWMini HST Compass

What is the purpose?

The BWMini PSG, BWMini HST and BWMini HST Compass equipment are biological signal amplifiers used for the diagnosis and follow-up of neurophysiological pathologies and sleep disorders.

How is the Polysomnography exam performed?

After cleaning the patient's head, surface electrodes are placed on the scalp along with the conductive paste. Electrode placement, if connected, must meet the International 10-20 Electroencephalography Electrode Placement System. Sensors and electrodes for polygraphy recording should be placed over the patient's body as determined by the American Academy of Sleep Medicine.

Where should BWMini PSG, BWMini HST and BWMini HST Compass equipment be used?

The equipment models equipos BWMini PSG, BWMini HST y BWMini HST Compass can be used in hospitals, specialized clinics or doctor's office and *home care*, as long as they are under the supervision of a technician or nurse qualified for this purpose and that the safety requirements for operation are met.

What are the indications for performing this exam?

1- Behavior disorders that occurred during sleep (parasomnias, sleepwalking, REM sleep behavior disorders, insomnia, epilepsies, etc.),
2- Excessive daytime sleepiness (narcolepsy, hypersomnia),
3- Breathing disorders during sleep (snoring, obstructive sleep apnea syndrome, increased upper airway resistance syndrome, etc.),
4- Titration with assistance of CPAP, BiPAP, VPAP,
5- Post-treatment control (surgery, sound design, oral appliances, etc.) of obstructive sleep apnea syndrome,
6- Heart rhythm disturbances that occur during sleep,
7- Restless leg syndrome and periodic limb movements,
8- Among others.

All the above evaluations must follow the appropriate and respective clinical protocols.

9. Package contents and Accessories.

The BWMini works with any good quality patient leads / electrodes and sensors (snore, flow, effort belts and position) that have safety touch connectors and are legally marketed in accordance with FDA requirements. If you identify a problem during use, please contact the Manufacturer. Depending on your region, the accessories kit included might be different due to regulatory reasons.

9.1.Components

9.1.1. Comparative Components table between BWMini modules

The following table compares the components within each of the models of the BWMini:

Components			
BWMini EEG	**BWMini PSG**	**BWMini HST**	**BWMini HST Compass**
BWMini EEG module	BWMini PSG Main Module	BWMini HST Main Module	BWMini HST Compass Main Module
Cable mini-USB	Cable mini-USB	Cable mini-USB	Cable micro-USB
Rechargeable lithium battery	Rechargeable lithium battery	Rechargeable lithium battery	AA Batteries

Note: This list shows the accessories that are compatible with each of the models from BWMini. The number of accessories included may vary according to the equipment acquisition process. To check which ones will be included, consult with your sales consultant.

9.1.2. Description of Components within BWMini

Model BWMini	Qty.	Description	Image
EEG	1	BWMini EEG Module	
PSG	1	BWMini PSG Module	
HST	1	BWMini HST Module	

Model BWMini	Qty.	Description	Image
HST Compass	1	BWMini HST Module Compass	
EEG / PSG	1	BWFlash Mini Module	
EEG/HST/PSG	1	Mini USB Cable - BWMini	

* The above pieces are for exclusive use and are part of the equipment of the BWMini EEG, BWMini PSG, BWMini HST and BWMini HST Compass which form part of the BWMini.

We ask customers to contact Neurovirtual Customer Service to obtain an updated reference code list, due to any changes that may occur.

9.2.Accessories

The BWMini works with any good quality patient leads / electrodes and sensors that have the safety touch connectors and the specifications according to the table below and are legally marketed in accordance with FDA requirements. As these accessories are already legally in the market from different manufactures, they are not part of this submission.

Sensor	Connector	Signal Type	Amplitude	Cable Length
Inductive Interface Abdomen sensor	DIN 1.5mm touch proof male	Sine Wave	200uVpp	96”
Inductive Interface Thorax sensor	DIN 1.5mm touch proof male	Sine Wave	200uVpp	96”
Inductive Bands	Button Snap	Sine Wave	NA	NA
Thermocouple Flow Sensor	DIN 1.5mm touch proof male	Sine Wave	200uVpp	96”
Piezo Snore Sensor	DIN 1.5mm touch proof male	Sine Wave	0.5mVpp-1mVpp	96”
AC Body Position Sensor	DIN 1.5mm touch proof male	Square Wave	0.5mVpp-1mVpp	96”
Flex Oximeter Sensor	D-Sub 9 Male (DB9)	Serial Signal	0-100% SpO2	96”
Cup Electrodes	DIN 1.5mm touch proof male	General	NA	96”

9.2.1. Comparative Accessories table between BWMini Modules

The following table compares the accessories within each of the models of the BWMini:

Accessories			
BWMini EEG	**BWMini PSG**	**BWMini HST**	**BWMini HST Compass**
USB with Installation Software and User Manual	USB with Installation Software and User Manual	USB with Installation Software and User Manual	USB with Installation Software and User Manual
Maxxi Gold Cup Electrode Set	Maxxi Gold Cup Electrode Set	Maxxi Gold Cup Electrode Set	Maxxi Gold Cup Electrode Set
SD card	SD card	SD card	Micro SD card
SD-USB Converter	SD-USB Converter	SD-USB Converter	SD-USB Converter
SD Card Organizer	SD Card Organizer	SD Card Organizer	
Nylon Protector	Nylon Protector	Nylon Protector	
Set of harness straps	Set of harness straps	Set of harness straps	
USB charger	USB charger	USB charger	
Kangaroo bag	Kangaroo bag	Kangaroo bag	
Jumper connector	Jumper connector	Jumper connector	Jumper connector
Ten20 Cream	Ten20 Cream	Ten20 Cream	Ten20 Cream
Nuprep	Nuprep	Nuprep	Nuprep
Neurovirtual Briefcase	Neurovirtual Briefcase	Neurovirtual Briefcase	Neurovirtual Briefcase
Patient Event Button (optional)	Patient Event Button (optional)	Patient Event Button (optional)	Patient Event Button (optional)
Black Box (optional)	Black Box (optional)	Black Box (optional)	Black Box (optional)
Battery Bank Backup (optional)	Battery Bank Backup (optional)	Battery Bank Backup (optional)	Battery Bank Backup (optional)
Connection Kit	Connection Kit	Connection Kit	Connection Kit
Storage Box	Storage Box	Storage Box	Storage Box
BWFlash Mini (option)	Oronasal cannulas	Oronasal cannulas	Oronasal cannulas
	Cannula filter	Cannula filter	Cannula filter
	XPOD Adapter	XPOD Adapter	XPOD Adapter
	Flex Oximeter Sensor	Flex Oximeter Sensor	Flex Oximeter Sensor
	Maxxi Rip Inductive Belts	Maxxi Rip Inductive Belts	Maxxi Rip Inductive Belts
	Thermistor Maxxi Flow	Thermistor Maxxi Flow	
	Piezo-electric snore sensor Maxxi Snore	Piezo-electric snore sensor Maxxi Snore	
	Maxxi Gold SNAP Button Electrodes	Maxxi Gold SNAP Button Electrodes	

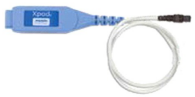
Note: This list shows the accessories that are compatible with each of the models from BWMini. The number of accessories included may vary according to the equipment acquisition process. The kit content may vary according to each territory. To check the content included, consult with your sales consultant or call Customer Service.

9.2.2. Description of Accessories within BWMini

The accessories listed below are manufactured for **exclusive** use with BWMini equipment. They are only compatible with BWMini equipment.

These are medical products intended to connect to another active medical product, in this case, the BWMini equipment. They have a lower risk classification (Class I) compared to the risk class of BWMini equipment (Class II).

The accessories below are sold only by Neurovirtual and may be offered as an option depending on the model of equipment purchased.

Model BWMINI	Qty	Description	Image
EEG/HST/PSG	1	Neurovirtual Waist Bag	
EEG/HST/PSG	1	Electrode Glove	
EEG/HST/ PSG	8	Rechargeable Lithium Batteries (3.7V 2500mAh)	
EEG/HST/ PSG	1	SD Card	
HST/PSG	1	Interface XPOD	
EEG/HST/ PSG	1	Pen Drive with BWAnalysis Software and Instruction for Use	
EEG/HST/PSG	30	MaxxiGold - Electrode for electroencephalography - 1.52 meters - Pin: TP.	

Model BWMINI	Qty	Description	Image
EEG/HST/PSG	25	MaxxiGold - Electrode for electroencephalography - 2.44 meters - Pin: TP.	
HST/PSG	25	Snap Button Electrodes for PSG	
EEG/PSG	1	MaxxiCap – Electrode Cap for electroencephalography – 2.44 meters – Pinto TP.	
HST/PSG	2	MaxxiBelt - Respiratory Effort Strap for PSG - 2.44 meters - Pin: TP.	
HST/PSG	5	Nasal/Oral Cannulas	
HST/PSG	1	MaxxiFlow - Respiratory Flow Sensor for PSG - 2.44 meters - Pin: Key.	
HST/PSG	1	Sleep Virtual - Respiratory Flow Sensor for PSG - Pediatric - 2.44 meters - Pin: TP Key.	
HST/PSG	1	Sleep Virtual - Respiratory Flow Sensor for PSG - Adult - 2.44 meters - Pin: TP Key.	
HST/PSG	1	MaxxiSnore - Snore sensor for PSG - 2.44 meters - Pin: TP.	
PSG	1	MaxxiPosition - Position sensor for PSG - 2.44 meters - Pin: TP.	

Model BWMINI	Qty	Description	Image
PSG	1	AC Pressure Transducer for PSG.	
PSG	1	Maxxi Inductive Respiratory Effort Belt Rip Belt - Size: Adjustable - Reusable.	
PSG	1	Maxxi Rip Belt Inductive Respiratory Effort Belt – Size: Child 40cm - disposable.	
HST/PSG	1	Sleepvirtual - Adult Inductive Belt	
HST/PSG	1	Sleepvirtual - Large Adult Inductive Belt	
HST/PSG	1	Sleepvirtual - Adult Extra Large Inductive Belt	
HST/PSG	1	Sleepvirtual - Children's Inductive Belt	
HST/PSG	1	Sleepvirtual - Pediatric Inductive Belt	
HST/PSG	1	Sleepvirtual - Neonatal Inductive Belt	
HST/PSG	1	Nonin 8000J-3 meter Oximeter Sensor - Adult - Pin: DB9.	
HST/PSG	1	Nonin 8000J-1 meter Oximeter Sensor - Adult -Pin: DB9.	
HST/PSG	1	Nonin 8008J-1 meter Oximeter Sensor - Child - Pin: DB9.	

Model BWMINI	Qty	Description	Image
PSG	1	Neurovirtual USA Oximeter Sensor - 3 meters - Adult - Pin: DB9.	
PSG	1	Neurovirtual USA Oximeter Sensor - 1 meter - Adult - Pin: DB9.	
EEG/HST/PSG	1	USB x Mini USB Extension Cable - 5P - Plus Cable PC-USB1803	
EEG/HST/PSG	1	Battery Backup Bank (Optional)	

The above parts are included in the same registration (ANVISA) of the BWMini as provided in step 3 of the Manual for the Regularization of Medical Equipment at ANVISA – GQUIP – Nov/2009.

10. Pulse Oximeter – Warnings, Specifications and Considerations

The BWMini PSG, BWMini HST BWMini HST Compass equipment, part of the BWMini of equipment, have an integrated pulse oximeter (Nonin® OEM III). This oximeter is manufactured by the American company Nonin Medical Inc.

The 8000J-1 and 8000J-3 oximetry sensors are also manufactured by Nonin Medical Inc.

The Nonin® 8000J-1 and 8000J-3 sensors are marketed by Neurovirtual exclusively for the BWMini PSG, BWMini HST y BWMini HST Compass equipment.

The following information is of paramount importance for the correct and safe operations of the oximetry system integrated into the BWMini equipment.

- Instructions on the correct placement of the 8000J-1 and 8000J-3 sensors on the patient's finger should be obtained from the instructions for use of the sensors located inside their respective packaging.

- The oximetry module (Nonin® OEM III) built into the BWMini PSG, BWMini HST y BWMini HST Compass equipment and the Nonin® 8000J-1 and 8000J-3 Flex Sensor sensors do not need to be calibrated.

- Measurement wavelengths and output power*:
  ➔Red: 660 nanometers @ 0.8 mW maximum average
  ➔Infrared: 910 nm @ 1.2 mW maximum average

  * This information is especially useful for performing photodynamic therapy.

- Factors that may degrade pulse oximeter performance include the following:

Excessive ambient light	Incorrect sensor type / Out of specification
Excessive movement	Poor pulse quality
Electrosurgical interference	Venous pulsations
Arterial catheters, blood pressure cuffs, infusion line etc.	Anemia or low hemoglobin concentrations
Humidity in Sensor	Cardiovascular dye
Incorrect Sensor Application	The sensor is not at the level of the heart
Carboxyhemoglobin	Dysfunctional hemoglobin
Methemoglobin	Varnish / Nail Polish / Artificial Nail

Accuracy: SpO2 (A_{rms}*) 70 to 100%	**Sensor**	**Adult / Pediatric**	**Neonatal**
No movement	8000J-1, 8000J-3	± 3 digits	± 3 digits
With Movement	8000J-1, 8000J-3	± 3 digits	± 4 digits
Low Perfusion	8000J-1, 8000J-3	± 2 digits	± 3 digits

* ± 1 Arms represents approximately 68% of measurements (population).

Accuracy: Heart Rate	**Sensor**	**Adult/ Pediatric**	**Neonatal**
No Movement (18-300 BPM*)	8000J-1, 8000J-3	± 3 digits	± 3 digits
With Movement (40-240 BPM*)	8000J-1, 8000J-3	± 5 digits	± 5 digits
Low Perfusion (40-240 BMP*)	8000J-1, 8000J-3	± 3 digits	± 3 digits

* BMP = Beats per Minute

- A functional tester cannot be used to assess the accuracy/precision of a pulse oximeter monitor or sensor.

Oxygen saturation display range	0 to 100% (SpO2)
Heart rate display range	18 to 321 beats per minute (BPM)

- Oximeter response time:

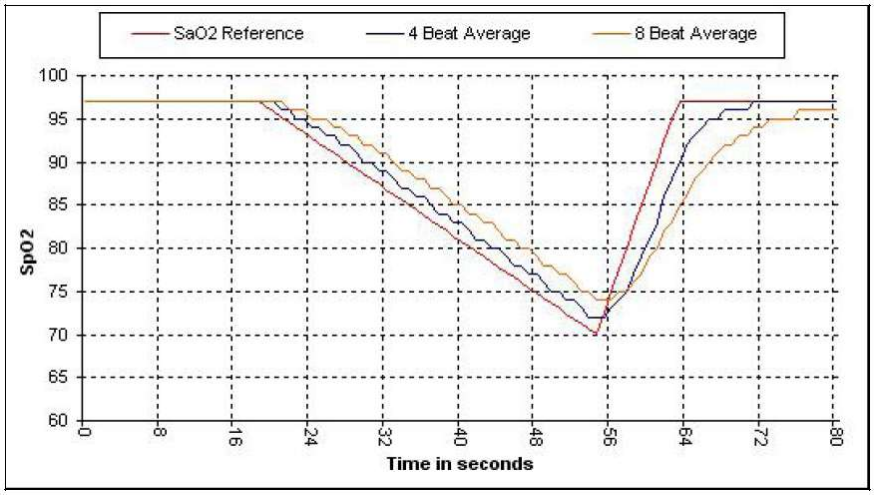
SpO2	**Average**	**Latency**

Standard / Fast Average	4 exponential beats	2 beats
Extended Average	8 exponential beats	2 beats

Pulse Values Rate	Average	Latency
Standard / Fast Average	4 exponential beats	2 beats
Extended Average	8 exponential beats	2 beats

Example - Exponential Mean SpO2:

SpO2 decreases by 0.75% per second (7.5% over 10 seconds) / Pulse Rate: 75 BPM



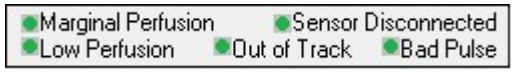
Specific to the example above:

- The answer for 4 average beats is 1.5 seconds.
- The answer for 8 average beats is 3.0 seconds.

- The oximeter integrated into the BWMini PSG, BWMini HST y BWMini HST Compass equipment **does not** provide alarms for physiological conditions (e.g. low SpO2).

- Inadequate Signal Indicator (SpO2):

Occurrence (red)	Meaning
Marginal Perfusion	Medium quality signal
Sensor Disconnected	The oximeter sensor is not connected to the BWMini PSG, BWMini HST y BWMini HST Compass or dead sensor equipment
Low Perfusion	Poor signal quality
Out of Track	Absence of consecutive pulse signals
Bad Pulse	The detected pulse does not correspond to the pulse current interval



Occurrence (green)	Meaning
Marginal Perfusion	Poor quality signal not detected
Sensor Disconnected	The oximeter sensor is connected to the BWMini PSG, BWMini HST y BWMini HST Compass or operating equipment
Low Perfusion	Poor quality signal not detected
Out of Track	Presence of consecutive pulse signals
Bad Pulse	The pulse detected corresponds to the pulse current interval

- The oximeter integrated into the BWMini equipment **does not** have an alarm with adjustable limits. (example: low SpO2).

- The oximeter integrated into the BWMini equipment **does not** have an alarm, because the intended function of oximetry in a polysomnography does not require an alarm. The inclusion of alarms in such a product would create an unacceptable situation for its use, as the patient must be and continue to sleep for the product to perform its intended use.

- The oximeter integrated into the BWMini PSG, BWMini HST y BWMini HST Compass equipment, Nonin® OEM III, has been tested and validated to work with the sensors manufactured by the company Nonin Medical, Inc, according to the following models:

Code	Model
8000J-1	Adult Flex, 1 meter cable
8000J-3	Adult Flex, 3 meter cable

Note. Do not use the above sensors in other equipment/pulse oximeters, other than those of the BWMini. Using the above sensors in other equipment or the use of other pulse oximeters may pose a risk to patient safety.

- For commercial and marketing purposes, the 8000J-1 and 8000J-3 Sensor manufactured by Nonin Medical Inc. may be referred to as the MaxxiOximeter - Oximetry Sensor.

- The oximeter integrated into the BWMini PSG, BWMini HST y BWMini HST Compass equipment, Nonin® OEM III, has been tested and validated to work with Nonin Medical, Inc extenders, according to the following models:

Model
Patient Extension Cable 6 meter
Patient Extension Cable 9 meter

Note. Do not use the above sensors in other equipment/pulse oximeters, other than those of the BWMini. Using the above sensors in other equipment or the use of other pulse oximeters may pose a risk to patient safety.

- To prevent improper performance and/or injury to the patient, confirm the compatibility of the sensor with the BWMini PSG, BWMini HST y BWMini HST Compass equipment prior to use. As a reminder, only the sensors, model 8000J-1 and 8000J-3, manufactured by the company Nonin Medical Inc. are compatible with the equipment of the BWMini.

- A maximum recommended application time for the use of the Model 8000J-1 and 8000J-3 Pulse Oximeter Sensor in a single location is not determined. However, it is **mandatory** to inspect the sensor application site (8000J-1 and 8000J-3) at least **6 to 8 hours**, to ensure the correct alignment of the sensor and the integrity of the skin. If any change in the skin is noticed, the sensor must be repositioned or its use must be suspended. Patient sensitivity to sensors may vary due to medical pathology or skin condition. Neurovirtual is not responsible for damages caused by negligence in the operation.

- The OEM III oximetry module manufactured by Nonin Medical Inc. an integral part of the BWMini PSG, BWMini HST y BWMini HST Compass equipment, is designed not to allow temperatures above 41°C and does not have controls adjustable by the operator.

- The Nonin® OEM III oximetry module (electronic module) manufactured by Nonin Medical, Inc, an integral part of the BWMini PSG, BWMini HST y BWMini HST Compass equipment, does not come into contact with the patient's skin because it is inside the equipment cabinet / not accessible to the user (patient / operator technician).

- The 8000J-1 and 8000J-3 oximetry sensors, manufactured by Nonin Medical Inc. encounter with the patient's skin so they have been tested by the manufacturer using ISO 10993-5 (in vitro cytotoxicity tests), ISO 10993-10 (irritation and sensitization test) according to the procedures determined in the ISO 10993-12 standard.

- The 8000J-1 and 8000J-3 oximetry sensors, manufactured by Nonin Medical Inc. are reusable and are not available in sterile packaging.

- The 8000J-1 and 8000J-3 oximetry sensors, manufactured by Nonin Medical Inc. are reusable. To clean and disinfect the sensor, wipe it with a soft cloth dampened with a mild detergent solution or isopropyl alcohol solution. Do not use abrasive or caustic cleaning agents on the sensors. Do not pour or vaporize any liquids onto the sensor. Allow the sensor to dry completely before reuse.

- Do not take the 8000J-1 and 8000J-3 sensors to an autoclave or immerse them in any type of liquid.

- The Nonin® OEM III oximetry module as well as the Nonin 8000J-1 and 8000J-3 oximetry sensors are not protected against the effect of a defibrillator.

- Do not use the Nonin 8000J-1 and 8000J-3 oximetry sensors if they are damaged. If the sensor is damaged in any way, immediately discontinue use and replace the sensor with a new one.

- It is not recommended to use reconditioned and/or refurbished sensors, even if they are Nonin (model 8000J-1 and 8000J-3).

- It is necessary that the 8000J-1 / 8000J-3 oximetry sensors, manufactured by the company Nonin Medical Inc. be disconnected from the BWMini PSG, BWMini HST y BWMini HST Compass equipment before proceeding with cleaning or disinfection.

- It is recommended that the 8000J-1 / 8000J-3 oximetry sensors, manufactured by Nonin Medical Inc. be cleaned before use.

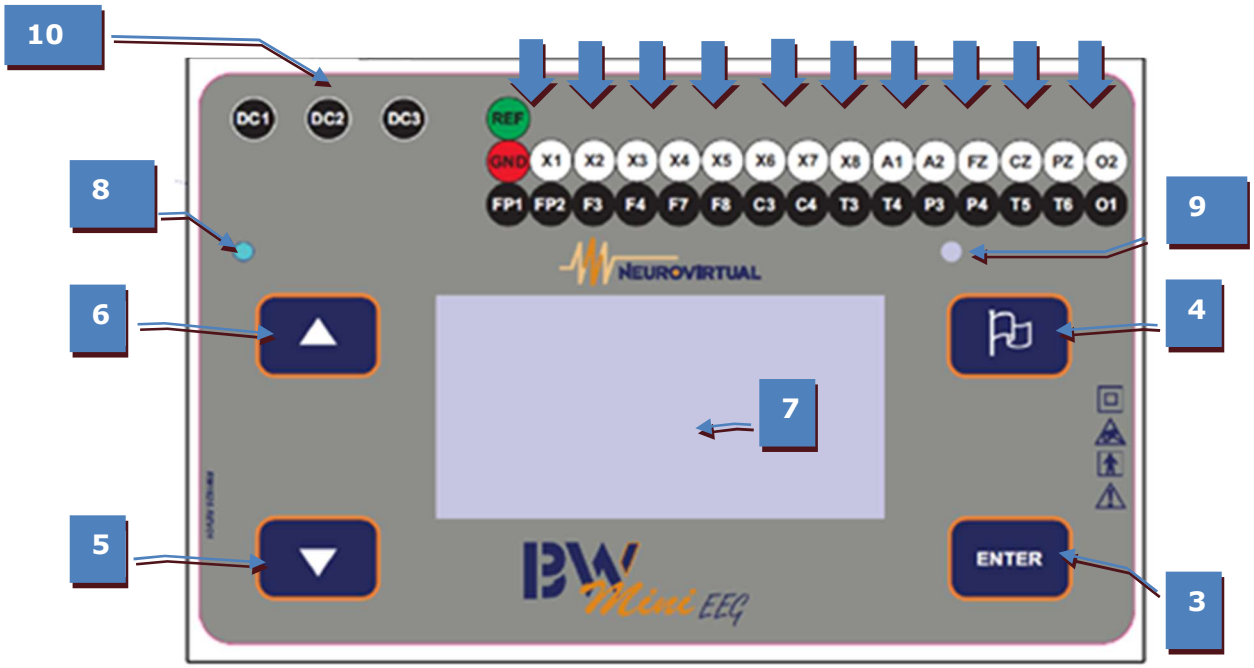
- The 8000J-1 / 8000J-3 oximetry sensors, manufactured by Nonin Medical Inc. are designed for continuous monitoring in adult and pediatric patients (weighing more than 20 kilograms, regardless of age) and in conditions where sensor movement may occur.

- Information on the correct disposal of the 8000J-1 and 8000J-3 Sensors can be found in chapter Error! Reference source not found. Error! Reference source not found. of this Instruction for Use.

The 8000J-1 and 8000J-3 sensors manufactured by Nonin Medical Inc. are not given a cut-off date for safe use.

11.Identification of BWMini equipment parts

11.1. Parts Identifications BWMini EEG

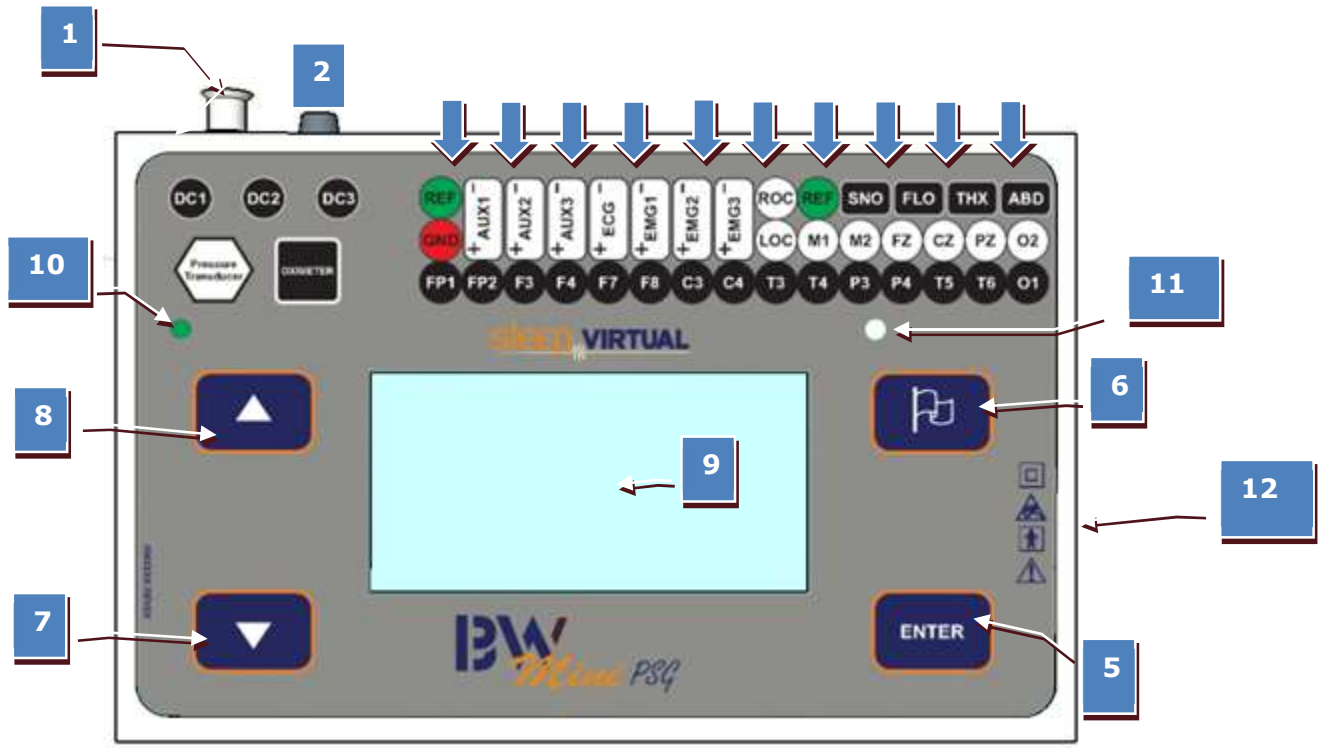


Top view

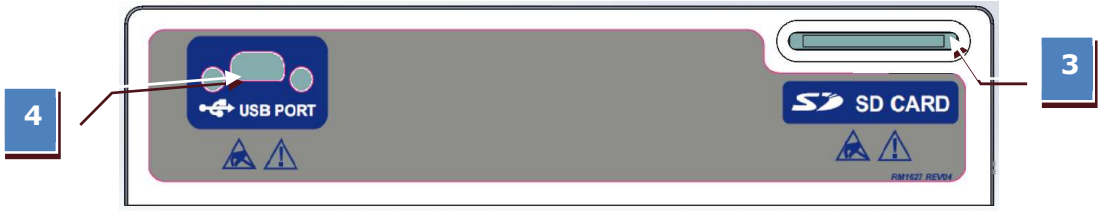
Front view

#	Descriptions
1	SD card slot
2	Mini-USB connector
	AC and DC connectors (TP 1,5mm)
3	Enter button
4	Event button
5	Down Navigation key
6	Up navigation key
7	Display LCD
8	Power on light indicator
9	Luminosity sensor
10	DC aux 3.5mm inputs

11.2. Parts Identifications BWMini PSG



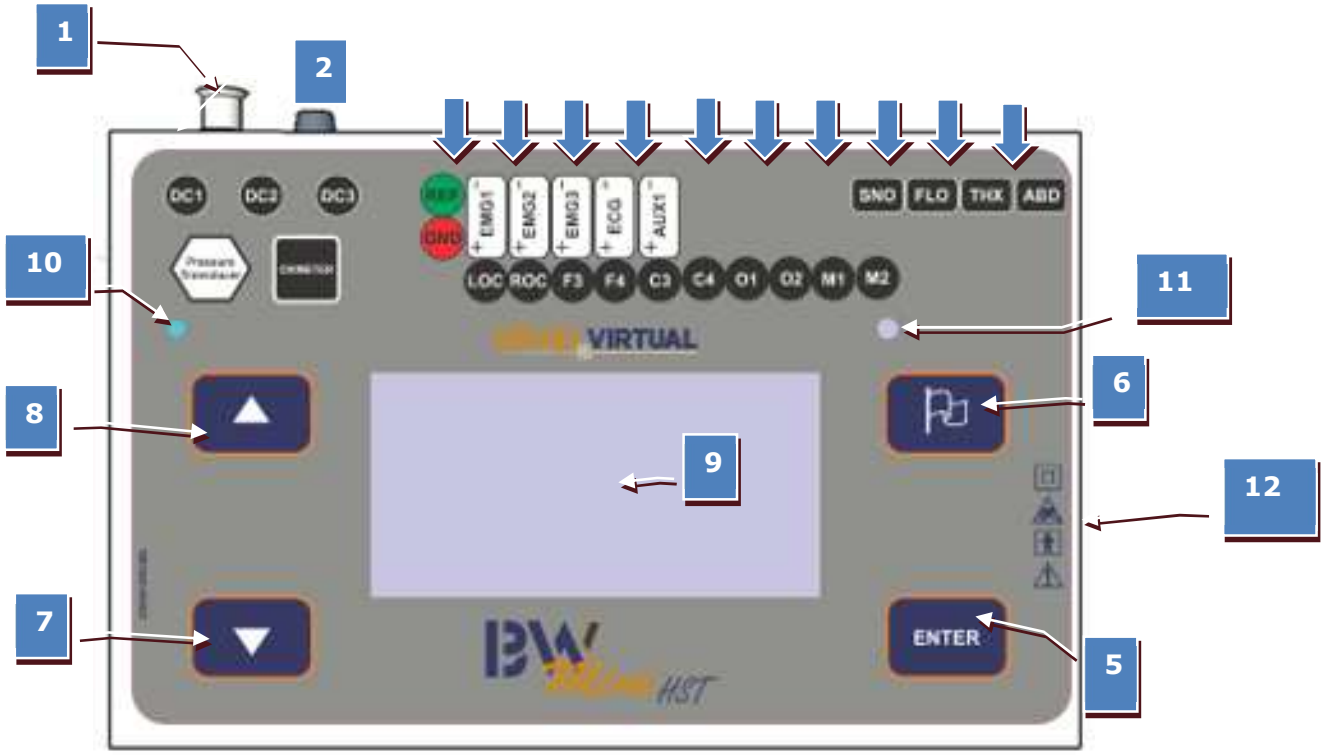
Top View



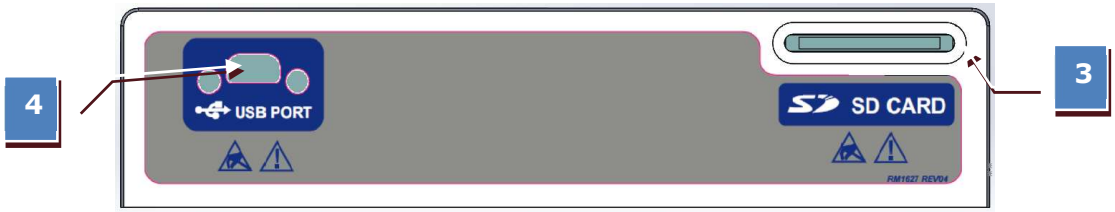
Frontal View

#	Description
1	Pressure Cannula Input (Luerlock connector)
2	Oximeter sensor probe input
3	Memory SD card slot
4	Mini USB Connector
	AC and DC inputs (Touch proof 1.5mm Connector)
5	Enter Key
6	Event Button
7	Down Navigation key
8	UP navigation key
9	Display LCD
10	Power on light indicator
11	Luminosity sensor
12	ON/OFF Switch (on the back of the system)

11.3. Parts Identifications BWMini HST



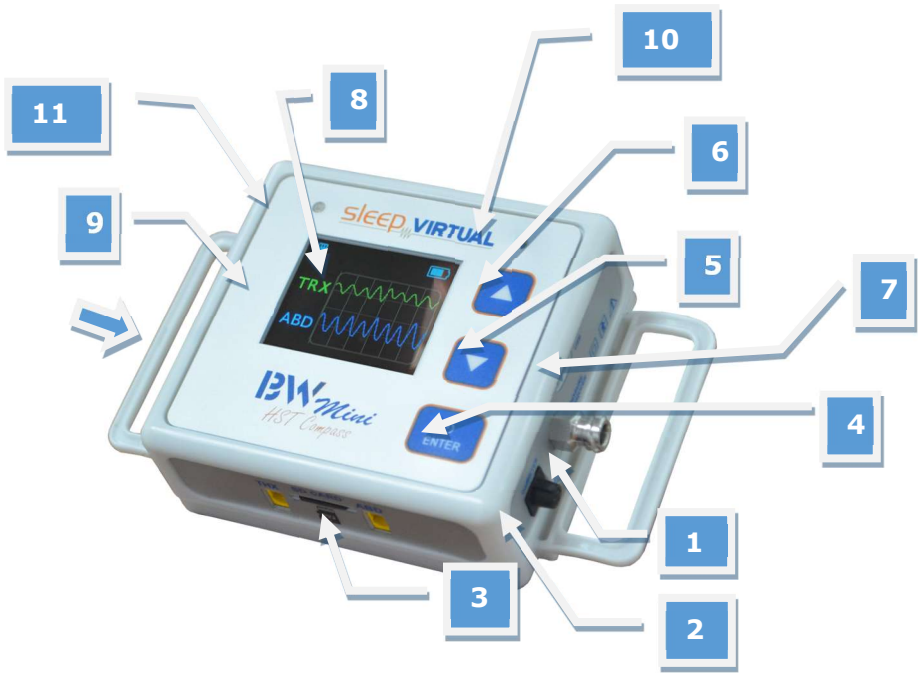
Top View



Frontal View

#	Description
1	Pressure Cannula Input (Luerlock connector)
2	Oximeter sensor probe input
3	Memory SD card slot
4	Mini USB Connector
	AC and DC inputs (Touch proof 1.5mm Connector)
5	Enter Key
6	Event Button
7	Down Navigation key
8	UP navigation key
9	Display LCD
10	Power on light indicator
11	Luminosity sensor
12	ON/OFF Switch (on the back of the system)

11.4. Parts identifications BWMini Compass HST



#	Description
1	Canula connector input (Luer-lock connector)
2	Oximetry sensor input
	AC and DC input (1.5mm Connector Touch proof)
3	Micro SD card slot
4	Navigation button "Enter"
5	Navigation button "Down"
6	Navigation button "Up"
7	Mini USB Connector
8	LCD Display
9	State LED
10	Illumination Sensor

11.5. Symbols, Descriptions and Definition

SYMBOLS	DESCRIPTION	DEFINITION
	Caution	When it is used, check the BWMini User's Manual.
	Class II Equipment	It indicates the protection against electric discharge that the amplifier- BWMini contains.
	Type BF equipment	It indicates the level of protection against electric discharge that the equipment BWMini contains.
	LED Power On	It indicates the system is on or off.
	Serial Number	It indicates the serial number of the system.
	REF code	It indicates the reference code of the system.
	CE Mark	Declaration by the manufacturer that equipment complies with all the requirements of all the applicable European Union (EU) directives.
	Electrostatic Discharge Protection - ESD	Special care against Electrostatic Discharge must be taken. Do not apply electrostatic discharge (ESD) to the points marked with this symbol.
IP22	International Protection Classification	Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15 ° from its normal position and effective in protecting objects of 12.5 mm or greater. **You must use the cases provided by the manufacturer to get the protection level described above.**
	Prescription Only	Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.
	Do not throw it in the trash.	Consumers are obliged by law to bring batteries to an appropriate collection point. See the topic "disposal" in this manual for more information.
	Follow operation instructions	It indicates that user instructions must be followed to safely use the device.
	Date of manufacture	
	Date of expiration	

12. System Installation

12.1. Computer minimum requirements

The user will have to have a PC with a minimum configuration to operate the BWAnalysis software. This configuration will provide fast and safe operation.

Processor:	Intel® Core™ i5 or i7 Processor
Operating System:	Windows 11 Professional 64-bit or 32-bit
Memory:	8 GB or higher
Hard disk:	1TB capacity or higher
Video:	Intel(R) UHD Graphics - evaluate according to needs
Monitor Size:	24 inches, suggested
Monitor Resolution:	1024x786 or higher
Laptop Monitor:	15 inches, suggested
Wireless:	802.11 n/g/b
Ethernet:	1 RJ45 Port
USB port:	3 ports available or more
Microsoft Word:	Office 2013 or higher

Neurovirtual recommends the use of DELL® microcomputers because they are certified IEC 60950 standard, however nothing prevents the user from purchasing computers from any other certified manufacturer.

Use Neurovirtual Customer Support to check the minimum setting the computer must have for the proper functioning considering the equipment of BWMini and BWMini.

The computer, audio and video systems can be sold by Neurovirtual as computer items.

12.2. Software Security Warnings (User responsibilities)

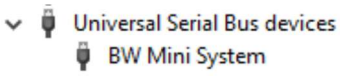
	**1. Data Security:** The security of the device and data is the sole responsibility of the customer. We strongly recommend that you: ○ Install and maintain up-to-date antivirus and anti-malware software. ○ Regularly update your operating system and all installed software to protect against vulnerabilities. ○ Use a reliable firewall and secure your network with strong passwords and encryption. ○ Other applicable security actions.
	2. **Software Updates:** ○ Regular updates to our software are necessary to maintain compatibility and security. The customer is responsible for ensuring that all updates are installed promptly. Failure to do so may result in security risks and reduced functionality. ○ Backup your data before installing any updates to avoid data loss.

	3. **User Access Control:** ○ Restrict access to the software to authorized personnel only. The customer is responsible for managing user permissions and safeguarding login credentials. ○ Any unauthorized access or misuse of the software is the customer's responsibility.
	4. **Compliance:** ○ The customer must ensure that their use of the software complies with all applicable local, state, and federal regulations. ○ Any breach of regulatory requirements due to improper use or inadequate security measures is the customer's responsibility.
	5. **Disclaimer:** Neurovirtual is not responsible for any damage, data loss, or security breaches that occur due to failure to meet the above requirements or follow the recommended security practices. It is the customer's responsibility to ensure that their system is adequately protected and maintained.

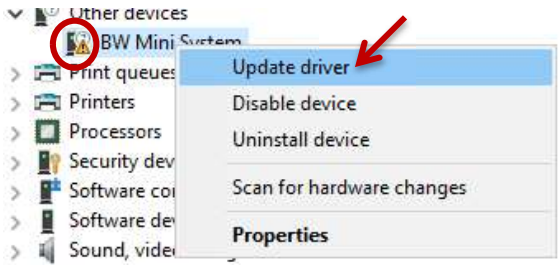
12.3. BWMini Driver Installation

To establish connection for BWMini family amplifiers, it is required connection to the computer with a USB cable. For proper detection of those amplifiers, the Driver must be installed. To do this, open *Device Manager*.

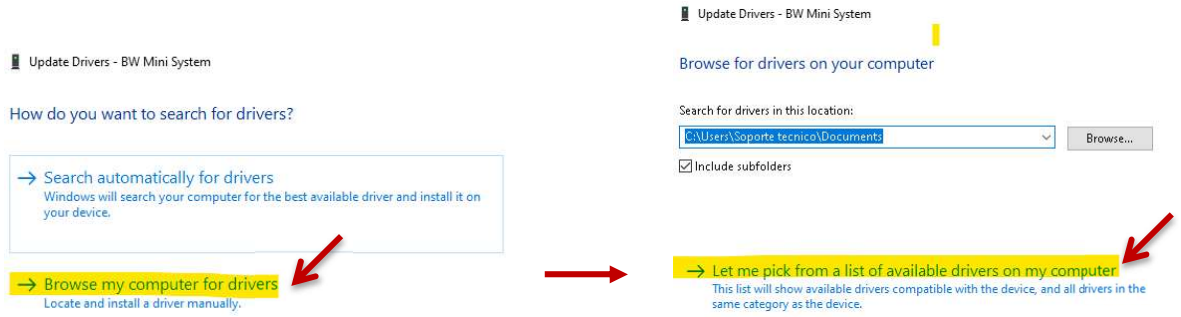
A new pop-up window will list the different types of devices. Search for BWMini System on Other Devices, libusb (WinUSB) devices, Universal Serial Bus devices, etc.



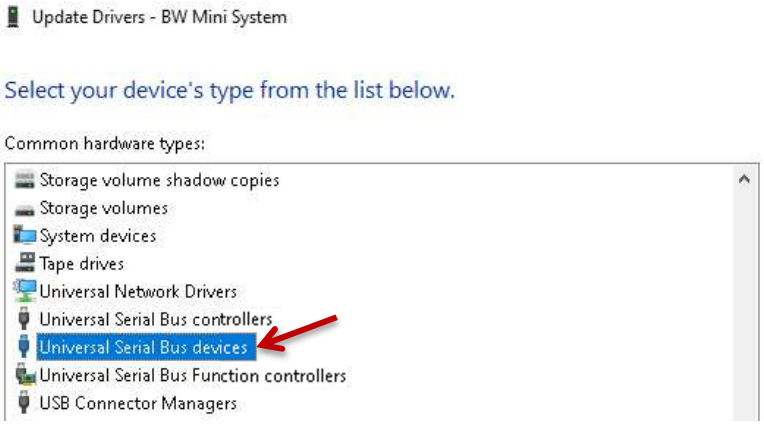
If the device BWMini System shows a warning sign (yellow triangle), do a right-click on it, then select *Update driver*.



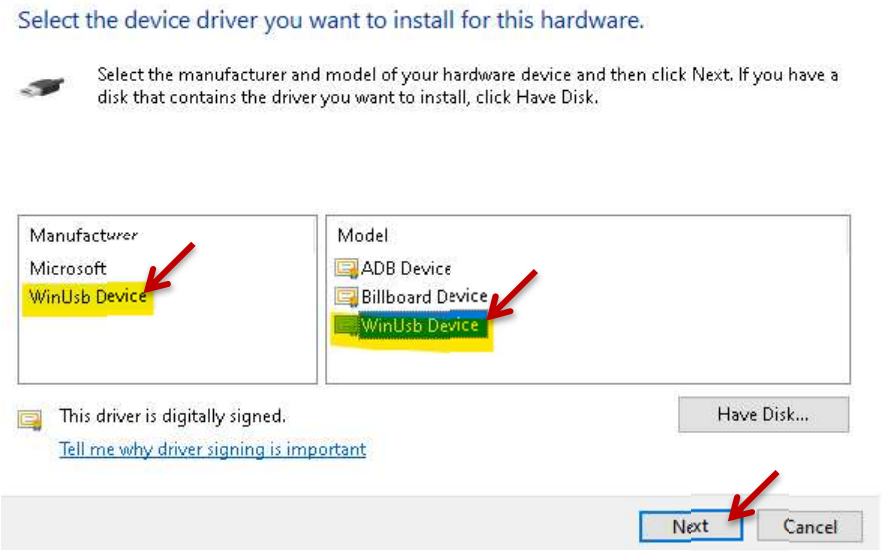
A window will appear in which it must be choosen *Browse my computer for drivers...*, then click on *Let me pick from a list of available drivers on my computer*.



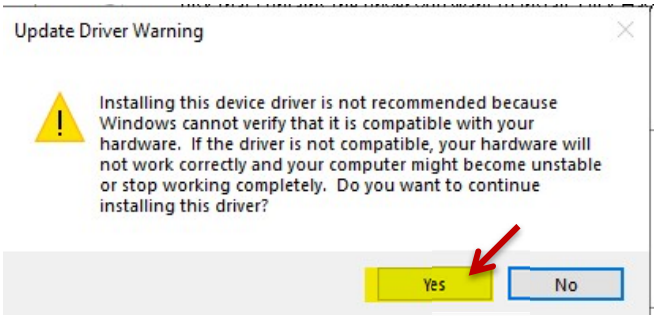
From the displayed list, select with double-click the option *Universal Serial Bus Device*.



Select WinUsb Device on both Manufacturer and Model sections. Then click on *Next*.

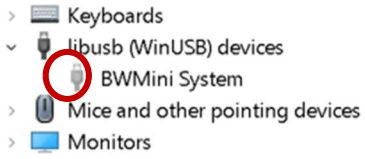


Following warning will appear, click *Yes*.

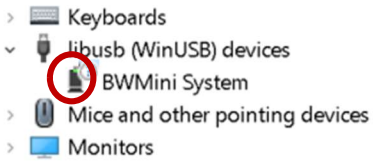


Then confirm that the device BWMini appears available.

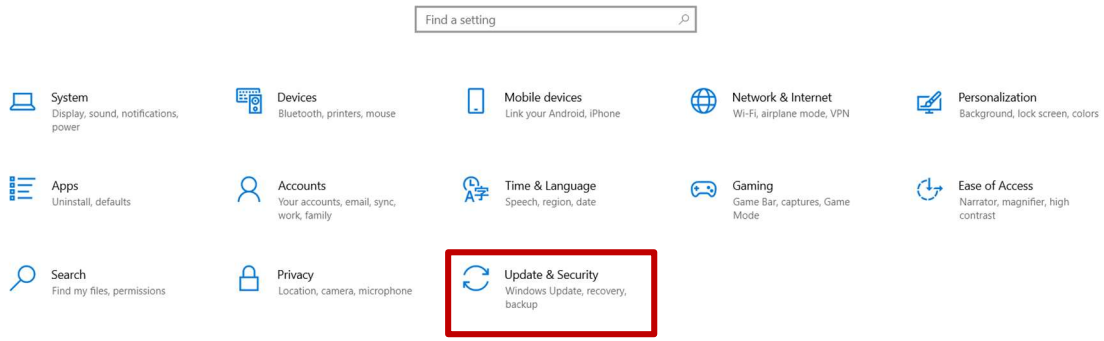
If the icon shows gray out, unplug the USB cable from the computer, let the computer identifies the disconnection (by sound or wait for 10 seconds), then reconnect to reestablish the identification and new driver installation.

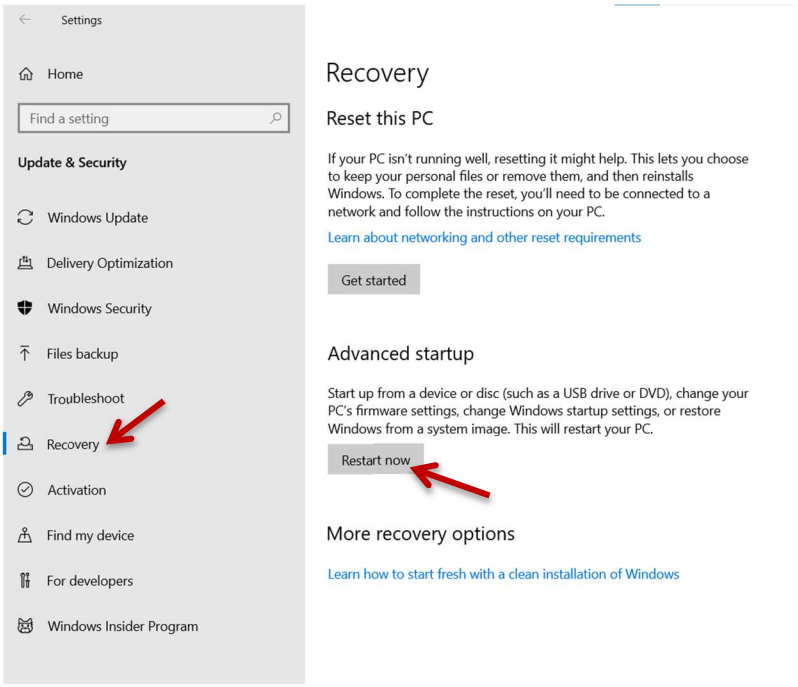


If the icon shows a circle with a question mark icon, Windows Signature is required to disable.

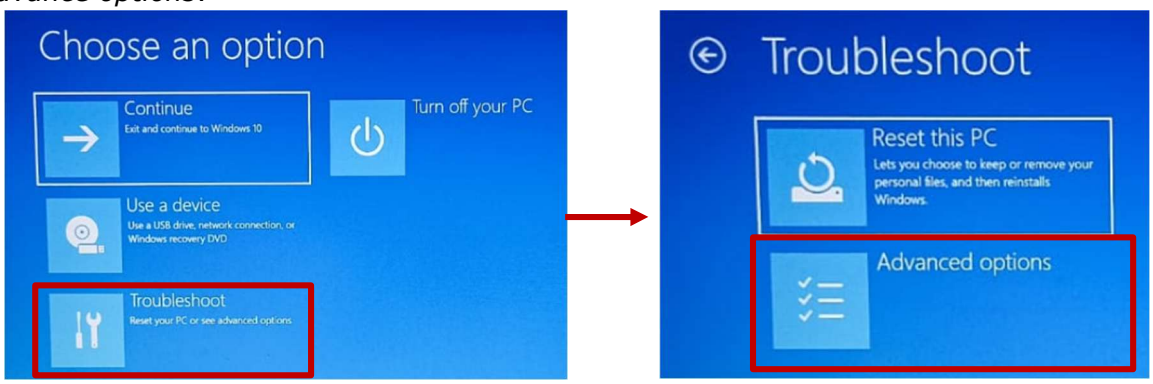


To start the process, open Windows settings and select *Update & Security* option. Then select *Recovery* options on the left of the list. Click on *Restart now* button from Advanced startup section.

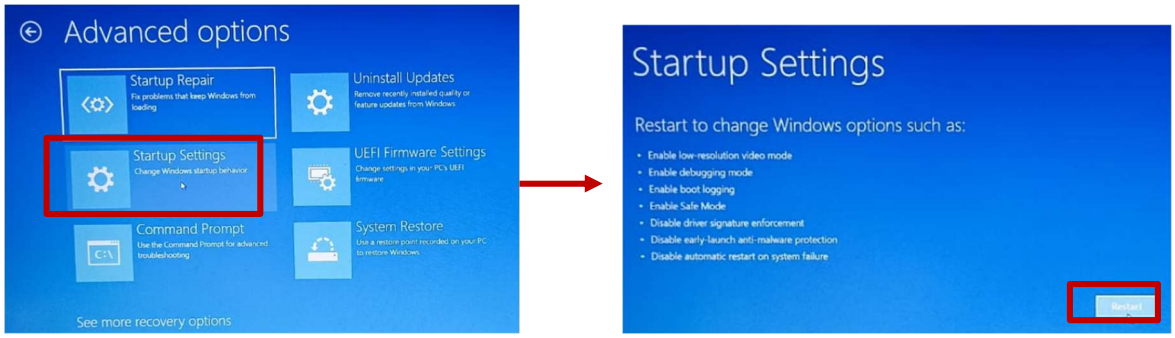




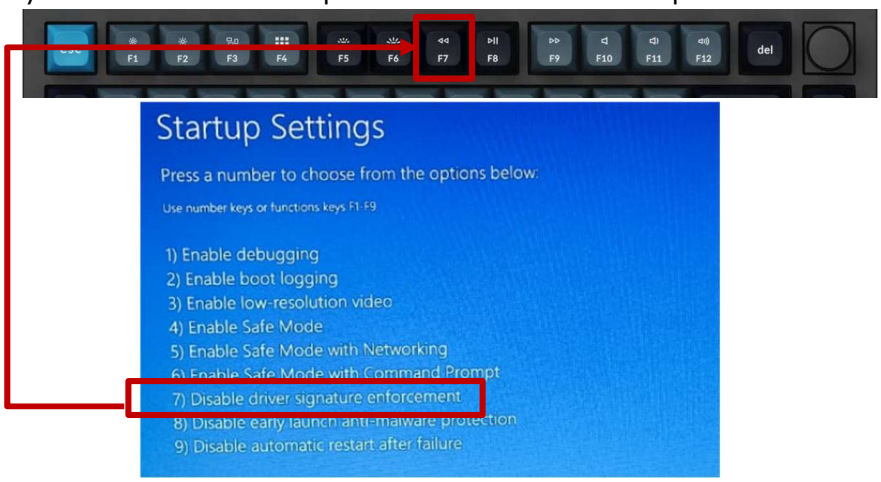
The computer will start the Advance restart (guided by blue screens appearance). Finish the process without forcing the computer to restart or shut down.
Once the Blue Screen appearance shows, it will start with the section *Choose an option*. Click or move with the arrow keys and select *Troubleshoot*. On the new blue screen select *Advance options*.



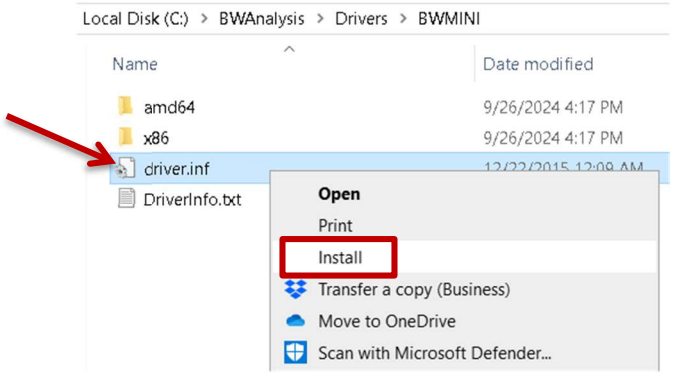
On the blue screen select the option *Startup Settings*. Then click on the button *Restart*.



The screen might show black as the restart is being processed. Wait for a couple of minutes until the blue screen appears again with a numeric list option. From the keyboard, press once the F7 key. Then leave the computer to finish the restart process on its own.



Once the computer is on, navigate to the folder BWAnalysis, then Drivers folder, then BWMINI folder. Do a right-click on the file driver and select the *Install* option. Accepts the installation. A confirmation message should appear. Otherwise, try again.



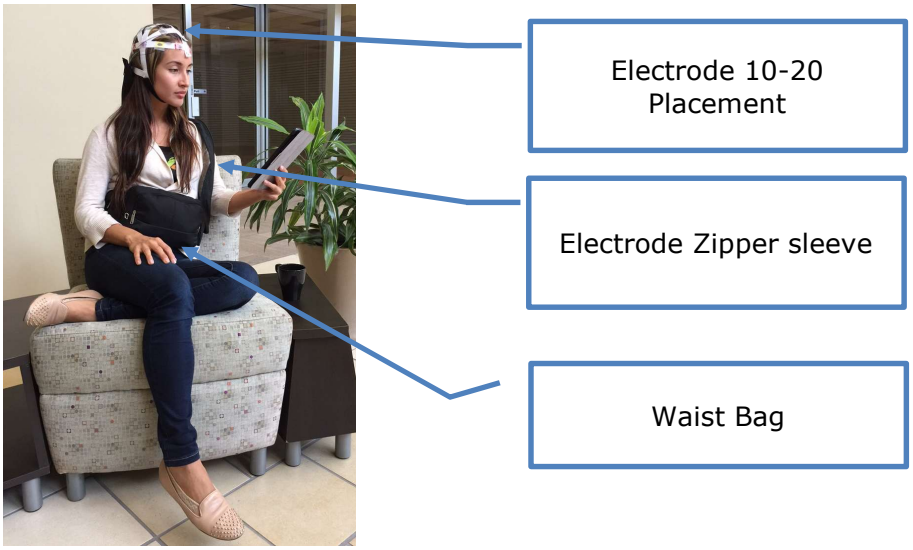
Restart the USB connection and confirm that the device BWMini appears available.

12.4. BWMini EEG

a. Get the BWMini device from the package and place it on a clean, dry, and stable surface.
b. Set the switch to the "ON" position to switch on the machine.

c. Get the protective nylon case from the package and insert the module in the case.
d. Remove the attachment strap from the packaging and place it on the back of the main module nylon cover
e. Connect the electrodes to the device box and apply them to the patient following the guidelines.
f. Place the main module and the head box module inside of the waist bag. The waist bag is necessary to get the IP22 level of protection against water and penetration.

g. Secure the electrodes cables using the electrodes zipper jacket that is included in the package of the device. This sleeve will help to organize the cables and avoid the risk of patient injury.
h. After the above steps, the device is ready to start the study.



Before sending the patient home, make sure the device is recording.

12.5. BWMini PSG

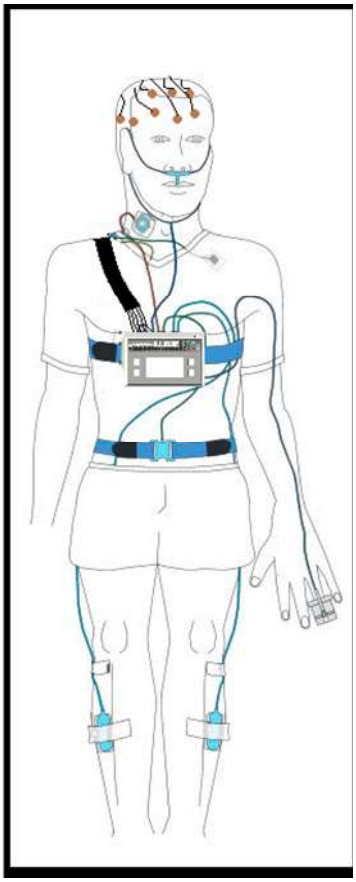
a. Get the BWMini device from the package and place it on a clean, dry, and stable surface.

b. Set the switch to the "ON" position to switch on the machine.

c. Get the protective nylon case from the package and insert the module in the case.

d. Apply the device on the patient using the buckle belt provided with the kit.

e. Connect the electrodes and sensors to the head box and main module.



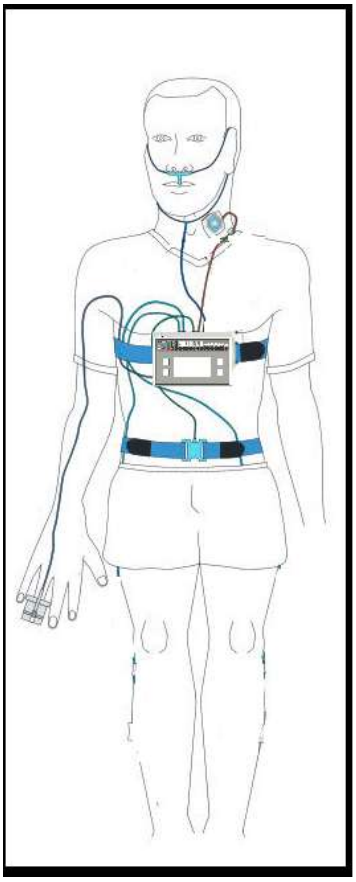
f. Secure the electrodes cables using the electrodes zipper jacket that is included in the package of the device.

g. After the above steps, the device is ready to start the study.

12.6. BWMini HST

a. Using the buckle belt from the package and put in the back of the main module nylon case.
b. Set the switch to the "ON" position to switch on the machine.

c. Apply the belt around the patient chest (on top of the clothes).
d. Adjust the belt using the buckle to get not too tight and not too loose. The belt may not be loose enough to rotate in the body.
e. Connect all electrodes and sensors to the BWMini main module and head box following the clinical standards.



f. After the sensors are applied on the patient, the device is ready to start the study.

12.8. Black Box (Optional Product)

a. Verify that the Black Box Model IC 282A set is complete with the following items:

Communication modules and USB cable

b. Plug the USB cable into the USB Extender Module of the Black Box and the other end into the computer you are using.

Connection on USB Extender Module

c. Plug the equipment's USB into one of the two inputs on the Remote Black Box Module.

Connecting BWMini to the Remote Module

d. Connect the ETHERNET network cable to the Remote Module and the USB Extender Module for their communication.

***Note:** The USB Extender Module should be close to the computer and the Remote Module should be close to the machine.
****Note:** ETHERNET Network Cable not included in the package, all tests were performed with network cable up to 40 meters in length

12.9. Battery Bank Backup (Optional Product)

a. To use the backup battery, it is recommended that the user check that it is at the maximum charge indicated on the product:

Charge level indication

b. If it is not fully charged, it is recommended to charge the device with an external power source.
c. If the device is fully charged, plug the BWMini USB cable into one of the device's USB ports.

BWMini USB cable connection to battery backup

***Note:** Recommended backup batteries according to the specification in that manual.
****Note:** No external power supply is provided for this device.

13.System Operation

13.1. Turning the device on / off (only BWMini Compass HST)

If the device is off, press and hold the Enter button until the Neurovirtual logo appears on the display.
To turn off the device hold the Enter key for 6 seconds until the display goes out.

13.2. Verifications before starting the study (BWMini EEG, PSG and HST)

a. Batteries

The BWMini EEG, PSG and HST work with lithium internal batteries.
Before using it, please check if the battery is fully charged.

Use the charger that comes with the package to charge the battery by connecting the charge in the device's mini-USB connector.

The BWMini Compass HST works with AA batteries.
To get a full-night recording make sure the batteries are new.

Before starting any study, check if the batteries are new and the charge capacity is full, otherwise the device will stop working before the estimate time.

b. SD Card

The BWMini works with SD memory cards, but the only compatible models are listed below.

- SanDisk Ultra Class 10 SDHC Memory Card - SDSDUN-0016G-G46
- Transcend Class 6 SDHC Flash Memory Card - TS8GSDHC6
- The maximum size compatible with BWMini is 32GB.

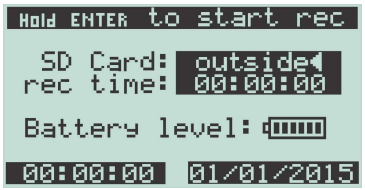
Before starting any study, check if the SD card contains any studies otherwise any previously recorded study will be deleted.

c. LCD information (BWMINI EEG, PSG and HST)

With the batteries inserted into the device, check if the display is showing the status of the device.

SD card status: the device will automatically detect the SD card status, showing it next to the word "SD Card", being possible 4 possibilities:

- **SD card not inserted:** The following screen appears with a flashing arrow next to the word "outside" next to "SD Card":



- **SD Card with Write Protection:** If this protection is detected, the screen shown below, with a flashing arrow next to the word "locked" next to "SD Card":

- **SD Card Defective or Fails to Start:** If a failure occurs on the card initialization process, the displayed screen will have the word "fail" flashing next to "SD Card"**:**

- **SD Card Ready for Recording:** When the card is ready to start the study, the following screen appears with the word "ready" next to "SD Card":

Recording time: Next to the "rec time" words, as you can see in the picture above, it is where the equipment will show the recorded time during data acquisition. If the device is not recording, the displayed time will reflect the total recorded time of the last study.

Remaining battery energy: This energy level is shown on the device's screen as "Battery Level" which is the amount of energy that the batteries have. The battery level has six subdivisions, and each portion is equivalent to 16.6% of the battery charge, totaling 100%. The estimated recording time using the recommended battery is 72-hours, but it can vary depending on the battery manufacturer and model.

For long term studies we recommend you use the external battery bank provided by Neurovirtual.

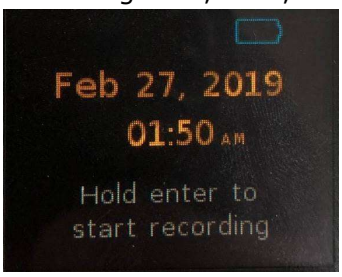
When the level of energy you get 20% of the total amount the system will automatically prompt the user with a message and beeps that the battery level is critical.

Time and date: This is the current date and time; this information is synced with the computer date and time every time the study starts.
Note: The LCD screen will turn off after 35 seconds if no interaction is made. This will save power during the study. To wake the system, press any button on the main panel.

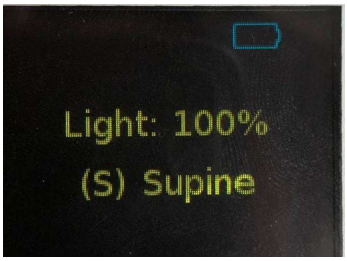
d. LCD information (only BWMINI Compass HST)

With the "up" and "down" keys, the user can navigate between signal information:

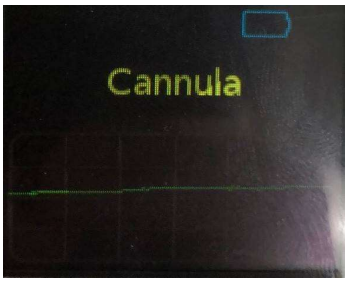
- **Screen 1:** Home screen showing date, time, and command to start recording.



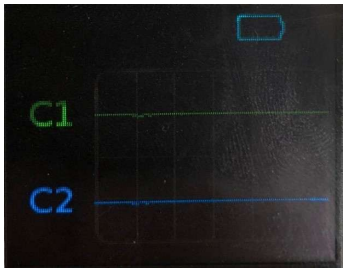
- **Screen 2:** Light information and patient's position.



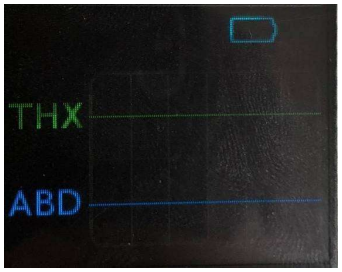
- **Screen 3:** Cannula signal.



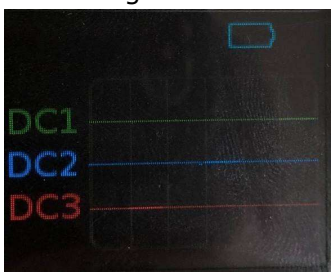
- **Screen 4:** AC channels 1 and 2 signals



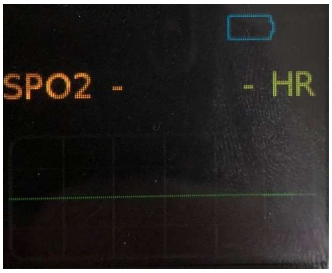
- **Screen 5:** RIP THX/ABD belts signals.



- **Screen 6:** DC channels 1,2 and 3 signals.



- **Screen 7:** SPO2, BPM and Plethysmography



Date and Time: This information is at the bottom of the screen; they will be synchronized with the computer date and time each time a study is started by the computer.
After preparing the system and connecting the sensors to the patient, on the home screen showing the date and time, press and hold the Enter button for 3 seconds until the recording time and time count information begins.

Note: The LCD screen will turn off after 30 seconds no interaction is made. This will save battery power during the study. To wake up the system, press any button on the main panel.

e. System error messages

At startup, if there is an error with the SD card, or if the battery charge does not meet the requirements, the system will display an error message on the display. Probable causes of errors:

- Battery not fully charged
- Corrupted / Damaged SD Card
- SD card not enough space

During recording, if the patient removes any sensors, the system will notify the user that the specific sensor has been disconnected. Home screen showing date, time, and command to start recording.

13.3. Creating a new Study

Connect the BWMini main module to a computer with the software BWAnalysis version 1.94 (1.100 only for BWMini Compass HST) or up installed using the USB cable that comes with the device.

Open a new study in the BWAnalysis clicking in the  button.
Select the device model and the study type.
Fill out the patient information and click "OK".
The study is now created, and it is ready to initiate.

13.4. Impedance Test

The impedance test can be executed by clicking on the  button (does not apply for BWMini Compass HST). The values will show up and it will be saved when you click on "OK" button.

13.5. Calibration Test

The Calibration signal can be enable clicking on  button (does not apply for BWMini Compass HST). The calibration signal will show up 50uVp – 0.5Hz.

13.6. Start recording (Local Mode)

If you will use the BWMini device connected to the computer all the time, you can start the recording clicking on  and right after clicking on  button.
Once you do that, the data will be recorded to the PC hard drive.
You must keep the system connected to the computer all the time.

13.7. Start Data Recording (Holter Mode)

a. Using Software

If you want the patient to take the device to remote areas with no connection to the computer, then you must click on  to start the recording stand-alone. All data will be saved in the SD card installed in the BWMini. The batteries must stay inserted to the device all the time. The Recording time in the LCD display will start to count.

b. Using panel button

To start recording data via the device's panel button without having to connect it to a computer, just press the "Enter" key for 4 seconds when the display is the same as displayed in "card ready for recording" (*Item 13.2 - c on Page 47*).

13.8. Finalizing Data Recording

a. Using Software

To finalize the study in Holter mode, the user must connect the device to PC via USB and click on  button.
If the batteries are discharged while recording the study, all data until that time will be safely saved in the SD card.

b. Using Software

To finalize the study without the need to connect it to a computer, just press the "Enter" key on the device's panel for 4 seconds.

13.9. Reading Data from SD Card

After the study is recorded in the SD card, the user must remove the SD card from BWMini and insert it into the computer with BWAnalysis installed.
Ignore any message about formatting that might show up on your screen.
Open the BWAnalysis and click on  and 

, or open BWAnalysis and click on download icon  .
The software will automatically look for any SD card connected to your computer. Once it finds the study, the software will ask you to put the patient information.
After the patient information is inserted, a confirmation message will show up indicating that the study was transferred to your computer.
The study will be listed in your study list. To open just select and click "OK".
After that, you must have all the data on your computer.
For more information about software features, please consult the **BWAnalysis Software User Manual.**

 **Ignore any Microsoft Windows automated message requesting the SD to be formatted that might show up on your screen.**

13.10. Troubleshooting

a. LCD message "Recording Error"

- Check if your SD card is inserted.
- Check if the SD card is empty.
- Check if the SD card is not corrupted or invalid.
- Format your SD card and try again.
- Remove the USB cable, put it back in and try again.
- Remove the batteries, remove the USB cable, put them back in and try again.
- Check if you are using the recommended SD Card.

b. LCD Message "UNUSABLE BATTERY ALERT!"

- This message indicates that the battery is not found or not useable.
- If you are using the device connected to the computer all the time, no action is necessary, but if you are planning to use it as Holter you must charge the batteries.

c. LCD Message "check the SD Card to allow startup of study recording."

- Make sure your SD card is inserted.
- Make sure the SD card is empty.
- Make sure the SD card is not corrupted or invalid.

- Format your SD card and try again.
- Remove the USB cable, put it back and try again.
- Remove the batteries, remove the USB cable, put them back and try again.
- Make sure you are using the recommended SD card.

d. LCD Message" waiting to start the schedule study."

- Finalize any operation that is being conducted at this time.
- Wait a few seconds and check if any scheduled study was initiated.

e. Software message "ER002 Failed to connect to the amplifier."

- Check if the device is connected to the USB.
- Check if the BWMini driver is installed correctly.
- Remove the USB cable, put it back in and try again.
- Remove the batteries, remove the USB cable, put them back in and try again.

f. Date and time incorrect.

- Start a new recording through the BWAnalysis software to update the date and time.

g. Interruption of system electrical power

- In case of loss of BWMini's USB connection (power source) with the computer, the software will keep the settings until the USB reconnection is reestablished.

h. Calibration and Impedance are not responding properly.

- Check if the head box cable is fully connected.

i. Recording stop without user action

- Study connected to a computer: Make sure the USB connection is established correctly. Remove the batteries and disconnect the USB cable and start the exam.
- Holter mode: If the device shuts down or stops the study recording for no apparent reason, contact your health care provider to return the equipment and reconfiguration.

j. Batteries are not lasting.

- Contact the Neurovirtual team, your battery might have reached the end of life, and a replacement might be required.
- Only for BWMINI Compass HST: Verify you are using the recommended type of battery, for more information contact the technical support team.

Any perception or suspect of abnormal functioning, we recommend the operator to immediately get in touch with Neurovirtual Customer Support for verification.

14. Technical Specifications BWMini

14.1. General

Characteristics	Models / Values	
Study Type	EEG	EEG only
	HST	HST Only
	PSG	EEG and PSG
	Compass HST	HST, PSG type III
Total Channels (Qty.):	EEG	Up to 37
	HST	Up to 27
	PSG	Up to 42
	Compass HST	12
AC Channels (Qty.):	EEG	29
	HST	19
	PSG	34
	Compass HST	2
DC Channels (Qty.):	EEG	Standard 3
	HST	
	PSG	
	Compass HST	
Oximeter channels:	EEG	Optional
	HST	3 channels: SpO2, BPM and plethysmography.
	PSG	
	Compass HST	
Pressure Transducer:	Built –in just for HST and PSG 0 to 1 PSI (Snore and Pressure Signals)	
Body Position Sensor:	Built-in (Left, Right, Prone, Supine and Stand)	
Impedance Check:	EEG	Yes
	HST	
	PSG	
	Compass HST	From hardware only
Calibration Signal:	0,5Hz, 50uV Square Wave	
Low Frequency Filter:	Software adjustable from 0.16Hz to 15Hz	
High Frequency Filter:	Software adjustable from 15Hz to 100Hz	
Notch Filter:	50Hz or 60Hz	
Sensitivity Range:	1mV to 500mV	
Light detector sensor:	Sensor sensible to luminosity changes	
Real time clock:	YES (LR44 or CR1220 battery with onboard holder)	
Memory Card:	Compass HST	Micro SD Card (32GB)
	EEG	Desirable SD Card but we can use micro-SD if space is needed.
	HST	
	PSG	
Data Transfer to PC:	SD Card or USB connection Current USB 2.0 Full speed: 60 minutes for 4GB	
Battery:	Compass HST	AA 1.5V battery
	EEG	Internal rechargeable Lithium battery 2500mAh (up to 72 hours of recording)
	HST	
	PSG	

Battery Recharge method:	External power charger; External battery power pack; USB to PC connection, Only for BWMini HST, PSG and EEG ***Only use recommended charger and batteries** HST Compass: No rechargeable.	
Battery Recharge time:	4 hours Only for BWMini HST, PSG and EEG	
Battery pack Expansion:	YES (up to 72 hours of study duration) **Only use recommended batteries.** Only for BWMini HST, PSG and EEG	
Resolution:	16 Bits	
Conversion time:	15µs	
Data flux:	Microprocessor	
Sample rate:	Compass HST	Up to 500Hz
	EEG	2000 Hz
	HST	
	PSG	
Bandwidth:	0.054 to 100Hz	
Storage Rate:	300Hz	
AC channels Input Range:	Up to 5mVpp	
DC channels Input Range:	-5Vcc to +5Vcc	
AC Channels connector type:	Touch Proof 1.5mm Touch Proof Key for PSG sensors	
DC Channels connector type:	P2 - 3.5mm	
Cannula connector type:	Luer Lock	
Input Noise:	1uVRMS	
Signal Reproduction Accuracy:	+-20% accuracy 2Hz/2mVpp and 6Hz/1mVpp *Verified on Print	
Common Mode Rejection:	> 80 dB at 50/60 Hz	
Input Impedance:	> 100 MΩ	
Communication connector:	Compass HST	Micro USB
	EEG	Mini USB
	HST	
	PSG	
Oximeter connector:	Binder	
Essential Performance	The essential performance of the BWMini electroencephalograph is characterized by the operation of the AC EEG amplifiers, in accordance with the requirements of table 201.101 of the IEC 60601-2-26:2019 standard, except 201.12.4.101 as the intended use of the BWMini electroencephalograph is diagnostic (201.12 .4.101 - Annex AA)	

***Note1:** The Sample Rate is higher than the storage rate. The storage rate is limited to the values shown in the table above but still exceeds the requirements for EEG and Sleep Studies.

****Note 2:** The filters are initially enabling with the recommended filters from AASM (American Academy of Sleep Medicine), but the user can view the raw data at any time disabling the digital filters.

14.2. Filter configurations

Channel	Low Frequency Filter	High Frequency Filter
EEG	0.3Hz	35Hz
EOG	0.3HZ	35Hz
EMG	10HZ	100Hz
ECG	0.3Hz	70Hz
Respiration	0.1Hz	15Hz
Snoring	10HZ	100Hz

14.3. Dimensions

BWMini PSG, EEG, HST.

Length (mm)	Width (mm)	Height (mm)	Weight (grams)
148	91	34	360

BWMini Compass HST.

Length (mm)	Width (mm)	Height (mm)	Weight (grams)
108	77	29	150

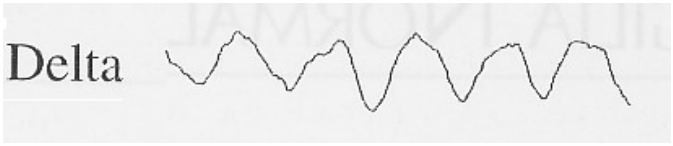
15. Physiological signals that the equipment can show.

Below are some **examples** of signals that can be collected with BWIII family equipment.

Delta Waves:

Example:

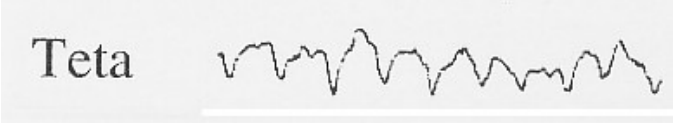
Characteristics:
Frequency: < 4 Hz



Theta Waves:

Example:

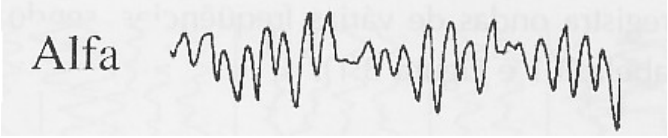
Characteristics:
Frequency range: 4-8 Hz



Alfa Waves:

Example:

Characteristics:
Frequency range: 8-13 Hz



Beta Waves:

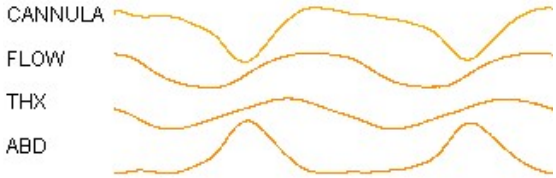
Example:

Characteristics:
Frequency range: 13-30 Hz

Respiratory Signals:

Example:

Cannula Pressure
Flow - Thermocouple
Respiratory effort sensor - Thorax
Respiratory effort sensor - Abdomen



Electrooculogram:

Example:

Snore:

Example:

Electrocardiogram:

Example:

Electromyography (tibia):

Example:

Electromyography (Mentonian):

Example:

Oximeter (Oxygen Saturation and BPM):

Example:

SaO2	97%	95%
BPM	63	63

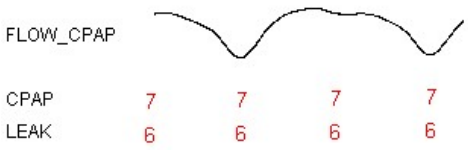
Body position:

Example:

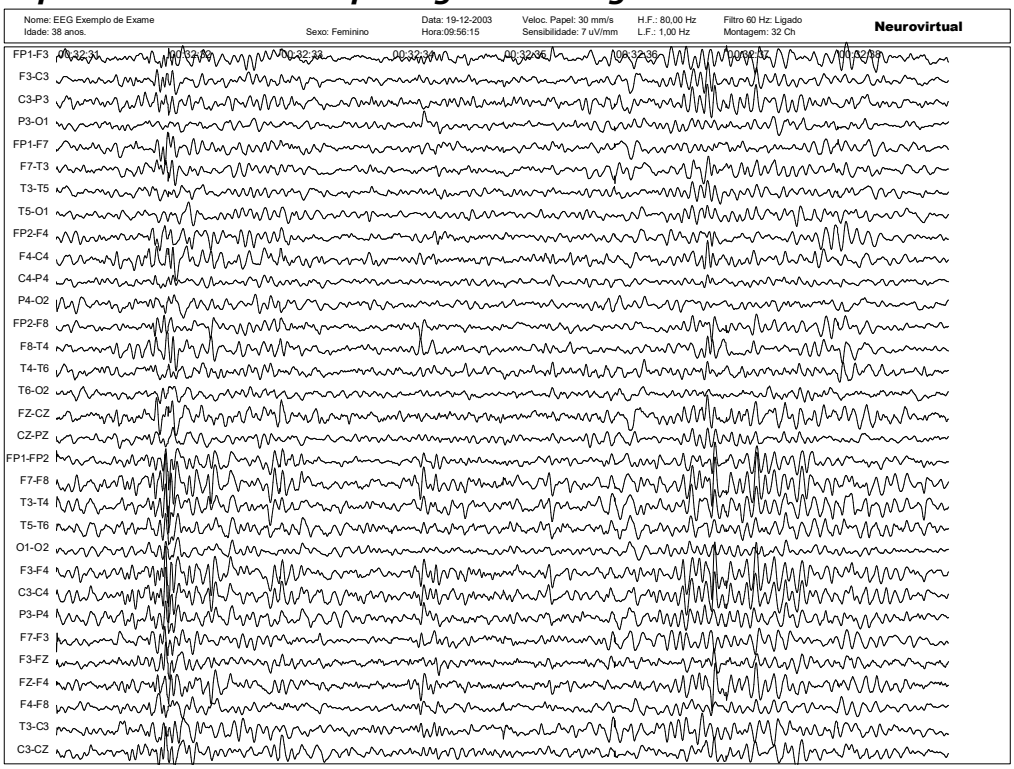
POS	Prone	Prone

Respiratory Flow Signal, Pressure and CPAP, BiPAP, Vpap leakage:

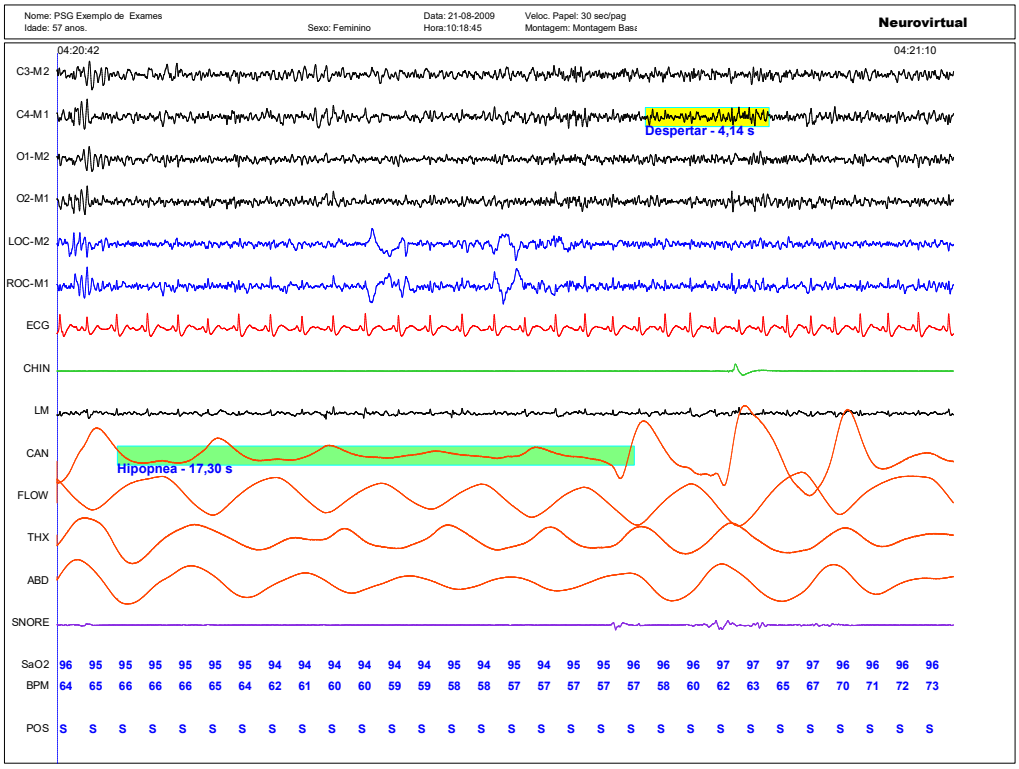
Example:



Example of an Electroencephalogram tracing – BWMini EEG:



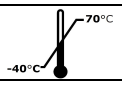
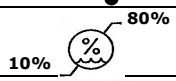
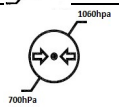
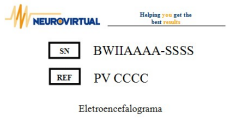
Example of a Polysomnography tracing – BWMini PSG:



16. Handling, Packing, Transport and Preservation Specifications

Every BWMini is supplied with a small, cushioned suitcase for transport, which provides protection against low intensity mechanical shocks and its degradation. Besides this suitcase, the equipment is packed in a double wave cardboard box to facilitate its transport and delivery to the customer. This box is the final packaging for the equipment. The packing contains the indication of some symbols that must be observed and followed:

Disconnect all cables and remove the battery from the equipment to begin the shipping process.

Symbols	Descriptions
	Fragile
	Protect against water
	Maximum piling
	Manufacturer's Data
	Device's end of life cycle
	European Distributor's Data
	Caution
	This side up.
	For the use, check the attached manuals.
	Protect against the sun.
	CE Mark: Declaration by the manufacturer that equipment complies with all the requirements of all the applicable European Union (EU) directives.
	Prescription use only: Caution: Federal law restricts this device to sale by or on the order of a physician
	Storage Temperature Limits. *
	Storage Humidity limits. * *
	Atmospheric pressure limits
	Identification Label containing: - Manufacturer's Brand Logo: Neurovirtual - S/N: Serial Number - SKU: Product Reference Code - Technical Name of the Equipment: Electroencephalogram

Once the conditions above are observed, the equipment will be appropriately protected against damage and deterioration.

17. Operation and Environmental Specifications

17.1. Environment Requirements

	Temperature	Unit	Atmospheric pressure
Operation	0°C to 40°C	20% to 80% RH Not condensed	700 to 1060 hPa
Storage	-40°C to 70°C	10% to 80% RH Not condensed	
Shipping	-40°C to 70°C	10% to 80% RH Not condensed	

Do not operate the BWMini if they are moist or wet due to condensation or spilling. If the equipment is exposed to any temperature out of the specified limits, return to the correct operating limit and wait for two hours before starting it again.

18. Cleaning

18.1. Cleaning of Parts

The cleaning of parts is recommended; however, the equipment must be unplugged, and it must be done using a dry cloth. It is not necessary to sterilize the modules and cables as they are non-invasive use and non-sterile.

We do not recommend the use of any type of liquid solution for the cleaning of any BWIII family of equipment. This equipment is not waterproof.

18.2. Cleaning of parts and accessories

We recommend the disinfection of sensors and electrodes (part that touches the patient's skin) with a piece of cloth slightly moistened by hydrated ethyl alcohol, except for the disposable accessories which are single-use only. It is not necessary to sterilize the pieces (electrodes and sensors). Non-invasive use, non-sterile. For more details on the cleaning of each of the parts and accessories, refer to their respective Instructions for Use that are inside or affixed to their packaging.

Do not leave the sensors and electrodes wet for more than 5 minutes.

19. Sterilization

The BWMini of equipment (Parts and Accessories) does not need to be sterilized. Non-invasive use, non-sterile.

20. Parts that touch the patient's skin

For those parts that touch the patient's skin, we recommend them to comply with ISO 10993 standard for the biocompatibility guarantee. See (Appendix 25) for all descriptions of the parts that get in contact with the patient.

21. Disposal

21.1. Device and Accessories

The disposal of parts, pieces and accessories is the manufacturer's responsibility.
Whenever it is necessary to dispose of any parts, pieces and accessories that are part of BWMini equipment, the client will be able to send that material to be disposed, duly identified, so that Neurovirtual can proceed with the disposal.

Arriving at the manufacturer, it will be forwarded to companies specialized in the disposal of: plastics, electronic components, connection cables and electrodes / sensors, ensuring non-contamination of the environment.

The client is responsible for the costs of sending those products to be disposed by Neurovirtual.

Neurovirtual is not responsible for the accomplishment of such act, which is the client's express responsibility and initiative. There is no restriction regarding the disposal in public landfills, however, with the environmental awareness, Neurovirtual can offer an adequate disposal for those products that it manufactures.

21.2. Batteries

Dispose of batteries according to local laws and regulations in your area. Some batteries can be recycled and may be accepted for disposal at your local recycling center. If you are unable to identify the rules in your area, please contact us for instructions.

22. Lifetime, Preventive and Corrective Maintenance and Calibration

22.1. Lifetime

The lifetime of the equipment and BWMini is 7 years.
The lifetime of the accompanying accessories is different depending on the sensor.

22.2. Authorization

In case the equipment presents any problem, the user should contact the manufacturer through Neurovirtual Customer Service to gather information regarding which companies are authorized to accomplish the maintenance service.

22.3. Preventive Inspection

We recommend a daily visual inspection to guarantee the integrity of connections, cables, cabinets, electrodes, and sensors.

22.4. Corrective Maintenance

In the event of any other type of defect, the user should contact Neurovirtual Customer Service to obtain the solution. Additional charges may apply to equipment whose guaranteed term is exceeded or for those defects that are not covered by the warranty terms.

Neurovirtual does not provide the Technical Files, the Product Master Registration and the Calibration and Measurement Instructions, except when requested by the client at the time of the equipment purchase. A confidentiality agreement might be demanded and there might some costs for the supply.

Neurovirtual is not responsible for any equipment repaired by those companies that do not have its express authorization, exempting itself from any legal responsibility that might arise to the patient, user, operator, owner and any third parties.

22.5. Calibration

The BWMini equipment is supplied fully tested and calibrated, and it is not necessary to perform these tasks again, as they are digital equipment that does not require adjustments.

Based on your location, local regulations may require annual calibration, in that case, please contact us to proceed with the service.

If the customer needs a Calibration Certificate issued by the manufacturer, usually required for audit purposes, he must contact Neurovirtual to hire this service, except when previously agreed at the time of purchase.

The user must contact Neurovirtual's Customer Service to hire the calibration service. Additional fees may apply to equipment outside the warranty periods or to those whose defects are not covered by the terms of the warranty.

Refer to chapter **10 Pulse Oximeter – Warnings, Specifications and Considerations** of this Instruction for Use for information on calibration of the Oximeter/Oximeter Sensor.

23. Electromagnetic Emission – EMC

23.1. Some types of interferences

60 Hz Interferences: Usually produced by the lack of proper grounding in the location where the examinations are conducted, broken electrodes, poor placement of electrodes causing high impedance, places with high incidence of radio frequency (RF).

Environment interference: They can come from several sources:
Examples: Power lines and transformers near the equipment, strong signals of broadcast TV, radio, airports, police, large equipment such as tomography, magnetic resonance, nuclear, electric treadmill.
The artifacts from these natures are easier to identify because the contamination is widespread, there is, it simultaneously appears on all channels.

Artifacts caused by phones: They are usually generators of electromagnetic waves generally coming in on the same frequencies of the equipment. Caused by modulation by pulse in phone dialing.
To avoid interference, it is necessary to have the equipment correctly installed by following all the requirements necessary to eliminate any interference from the power grid.
If you are experiencing some interference, please contact Neurovirtual Customer Support for guidance. There might be the recommendation for the hiring of a specialized technician by the client / owner so that he/she can check the immunity conditions of the environment where the tests are being conducted.
Neurovirtual is not responsible for the costs associated to such inspection / correction, as well as it does not have any responsibility to ensure that the environment where the tests are performed be immune to any interference. That responsibility lies with the client.

23.2. Electromagnetic Emission Safety Advisory - EMC

RF communication equipment (Radio Frequency) marked with the symbol  can affect the functioning of BWMini equipment. Avoid the use of such equipment in the vicinity of BWMini equipment (models: BWMini BASICS, BWMini EEG, BWMini HST, BWMini Compass HST, and BWMini PSG).

23.3. Equipment that can be connected to the BWMini.

We advise our customers to seek guidance from Neurovirtual Technical Support before connecting any (Active Electromedical) equipment to BWMini to ensure compatibility and proper operation, thus ensuring operator and patient safety.
Equipment such as CPAP, BiPAP and VPAP can be connected to the BWMini model via DC inputs (isolated inputs), if they are electrical equipment certified by the electrical safety standards (IEC 60601-1 series). However, we ask our customers to contact Customer Service for a list of approved devices, as well as Instructions and Recommendations for a perfect and secure connection.
Non-certified electromedical equipment should not be connected to BWMini without written consent from Neurovirtual.

Electromedical equipment that **is not certified** should not be connected to the BWMini EEG.

23.4. Electromagnetic disturbance

During eventual electromagnetic disturbances, which affect the essential performance of the device, there will be a noticeable degradation of the physiological signals displayed during registration, this degradation differs from the physiological signals and should be interpreted / considered as artifacts (interferences), in this situation we recommend that the user stop and disregard the record until disturbances cease.

23.5. Maintenance of the system regarding electromagnetic immunity

a) Periodic maintenance of the grounding circuit of the environment (annually)

b) Precaution to avoid sources of electromagnetic energy such as FM / AM TV antennas, and other potential sources of electromagnetic emission in the vicinity of the registration site.

c) Do not use the BWMini simultaneously with high frequency surgical equipment.

d) Avoid stacking the BWMini with other active devices.

e) Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used within 30 cm of any part of the BWMini, including cables specified by the manufacturer. Otherwise, performance degradation of this equipment may occur.

23.6. Tables and guidelines on Electromagnetic Emissions - EMC

Here are the tables containing essential information regarding electromagnetic compatibility.

Ref.: IEC 60601-1-2 - Table 1

Guidance and Manufacturer's Declaration – Electromagnetic Emission – EMC – for all EQUIPMENTS and SYSTEMS.

Guidance and manufacturer's declaration – Electromagnetic Emission - EMC		
The BWMini equipment is intended for use in the electromagnetic environment specified below. The customer or user of BWMini equipment should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment guidance**
RF Emissions ABNT NBR IEC CISPR11	Group 1	The BWMini equipment use RF energy only for its internal function. Therefore, its RF emissions are extremely low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions ABNT NBR IEC CISPR11	Class B	BWMini appliances are suitable for use in all environments, including home environments and those directly connected to the low voltage public power supply network that provides buildings used for home use.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

Ref.: IEC 60601-1-2 - Table 2

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Immunity Tests for the Electromagnetic Environment Compliance – Guidelines

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The BWMini equipment is intended for use in the electromagnetic environment specified below. The customer or user of BWMini equipment should ensure that it is used in such an environment.			
Immunity Test	**Immunity Test**	**Immunity Test**	**Immunity Test**
Electrostatic Discharge (ESD) IEC 61000-4-2	Direct Contact & HCP/VCP: ± 8 kV Air discharge: ± 2 kV, ± 4 kV, ± 8, ± 15 kV	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with Synthetic material, the relative humidity should be at least 30 %.
Fast Electric Transient / Break IEC 61000-4-4	± 2 kV for power supply line ± 1 kV For Input / Output line	Not applicable	
Outbreaks IEC 61000-4-5	+- 1 kV Differential Model +- 2 kV Common mode	Not applicable	
Voltage dips, interruptions and short voltage variations on the incoming power supply line IEC 61000-4-11	Voltage drops: 100% (0% UT) per 0.5 cycle at angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° *1 *2 100% (0% UT) for 1 cycle (single phase: at 0°) 30% (70% UT) for 25/30 cycles (single phase: at 0°) Voltage interruptions: 100% (0% UT) for 250/300 cycles for 5 sec	Not applicable	
magnetic field at the Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	Complies	Magnetic fields at the power frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a. c. mains voltage prior to application of the test level.			

Ref.: IEC 60601-1-2 - Table 4

Guidance and manufacturer's declaration – electromagnetic immunity –
For EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The BWMini equipment is intended for use in the electromagnetic environment specified below. The customer or user of BWMini equipment should ensure that it is used in such an environment.			
Immunity Test	**ABNT IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidelines**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	Frequency Range: 0.15MHz to 80MHz Level: 3 VRMS in full band and 6 VRMS in ISM bands between 0.15 and 80 MHz (professional healthcare facility environment) Modulation: AM 80%, 1 kHz Frequency range: 80 to 2700 MHz Level: 10 V/m (professional healthcare facility environment) Modulation: AM 80%, 1 kHz	[V1] V Not Applicable [E1] V/m Complies	Portable and mobile RF communications equipment should be used no closer to any part of the BWMini equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d= [3,5 / V1] √P d= [3,5 / E1] √P 80 MHz to 800Mhz d= [7/E1] √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) 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 is affected by absorption and reflection from structures, objects, and people.			
a Field strength 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 P-STIM is used exceeds the applicable RF compliance level above, the P-STIM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the P-STIM. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Ref.: IEC 60601-1-2 - Table 6

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the BWMini.			
The BWMini equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BWMini equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BWMini equipment as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance according to frequency of transmitter (m)		
Rated maximum. output of transmitter W	150 kHz to 80 MHz d= [3,5 / V1] $\sqrt{P}$	80 MHz to 800 MHz d= [3,5 / E1] $\sqrt{P}$	800 MHz to 2,5 GHz $'$= [7/E1] $\sqrt{P}$
0,01	0,116	0,116	0,23
0,1	0,36	0,36	0,73
1	1,16	1,16	2,33
10	3,68	3,68	7,38
100	11,66	11,66	23,33
For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (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.			

Ref.: IEC 60601-1-2 – Table 11

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields.

Test frequency	**Modulation**	**IMMUNITY TEST LEVEL (A/m)**
30 kHz a)	CW	8
134.2 KHz	Pulse Modulation b) 2.1 KHz	65 c)
13.56 MHz	Pulse Modulation b) 50 KHz	7.5 c)
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) r.m.s., before modulation is applied.		

Ref.: IEC 60601-1-2 – Table 9 - Near field radiated immunity

Band [Mhz]	Test Frequency [MHz]	Service	Modulation	Test Level [V/m]
380 to 390	385	TETRA 400	Pulse, 18 Hz	27
430 to 470	450	GMRS 460 FRS460	FM, 1 kHz, ±5kHz deviation	28
704 to 787	710 745 780	LTE Band 13, 17	Pulse, 217	9
800 to 960	810 870 930	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse, 18Hz	28
1700 to 1990	1720 1845 1970	GSM 800/900 TETRA 800 iDEN 820 GSM1900, DECT LTE Band 1,3,4,25 UMTS	Pulse, 217 Hz	28
2400 to 2570	2450	Bluetooth, WLAN, 802.11 b/g/n RFID 2450 LTE Band 7	Pulse, 217 Hz	28
5100 to 5800	5240 5500 5785	WLAN 802.11 a/n	Pulse, 217 Hz	9

24. Electrostatic Discharge (ESD) Training

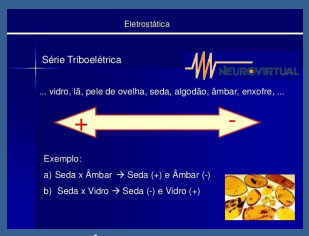
Note: For contact with connectors identified with the ESD warning symbol you must follow the ESD training topic in this manual, including Clinical Engineering / Biomedical / Health Personnel.

Introduction to ESD

Electrostatic discharge (ESD) has been occurring since the beginning of time. However, this natural phenomenon has become a problem with the widespread use of solid-state electronic components.

ESD Generating sources.

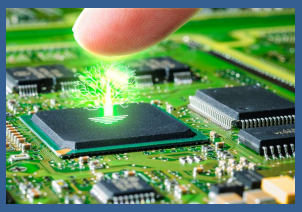
All materials (Insulators and Conductors) are sources of ESD. They are grouped together and known as the triboelectric series, which defines the materials associated with positive or negative charges.



Positive charges accumulate predominantly on human or animal skin. Negative charges are more common to synthetic materials such as Styrofoam or plastic cups. The amount of electrostatic charge that can accumulate on any item depends on its ability to store a charge. For example, the human body can store a charge equal to 250 picofarads. This correlates with a stored load that can be as high as 25,000Volts.

How does ESD damage electronic circuits?

ESD is a small sample of "lightning".



As current dissipates through an object, it looks for a low impedance path to ground to equalize potentials. In most cases, ESD currents travel to earth through the metal chassis frame of a device. However, it is well known that the current will travel on all available paths. In some cases, a path may be between PN junctions in integrated circuits to reach the ground. This current flow will burn openings invisible to the naked eye in an integrated circuit, with evidence of heat damage in the surrounding area. An ESD event will not interrupt equipment operation. However, repeated events will degrade the internal components of the equipment over time.

How does ESD occur?

ESD can occur in a variety of ways. One of the most common is through human contact with sensitive devices. Human touch is only sensitive at ESD levels exceeding 4,000 Volts. A recent investigation found the human body and its clothing capable of storing between 500Volts and 2,500Volts electrostatic during the normal working day. This is far above the level that damages circuits still below the threshold of human perception. Other sources of ESD damage to equipment include:

- Troubleshooting electronic equipment or handling printed circuit boards without using an electrostatic wrist strap.
- Placing synthetic materials (i.e., plastic, Styrofoam, etc.) in or near electronic equipment; and
- Rapid air movement near electronic equipment (including the use of compressed air to remove dirt from printed circuit boards, circulation fans that explode in electronic equipment or by using an electronic device near an air handling system).

In all these scenarios, the accumulation of static rates may occur, but you may never know. In addition, a loaded object must not necessarily contact the item for an ESD event to occur.
How do you measure electrostatic voltage?
One of the most effective ways to identify potential ESD problem areas is to take measurements using an electrostatic voltmeter. This meter will effectively measure electrostatic voltage up to 30,000V on all conductors and isolators. It will also show whether the charge is negative or positive. This can help you determine the source of electrostatic accumulation.

ESD Identification

A final element in our ESD control program is the use of appropriate symbols to identify ESD sensitive items as well as special products designed to control ESD. The two most widely accepted symbols for identifying ESD parts or ESD control protection materials are defined in the ESD ANSI / ESD S8.1 - ESD Association Standard.

The ESD Susceptibility Symbol (Figure 3) consists of a triangle, a reach hand, and a bar on the approaching hand. The triangle means "caution" and the bar across the reach hand means "do not touch". Due to its widespread use, the hand on the triangle has become associated with ESD and the symbol literally translates to "ESD sensitive material, not touch".

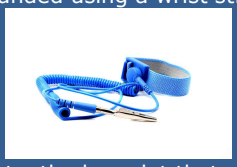
The ESD Susceptibility Symbol is applied directly to integrated circuits, boards, and assemblies that are ESD sensitive. Indicates that handling or use of this item may result in damage caused by ESD if proper precautions are not taken. Operators must be grounded prior to handling. If desired, the item's sensitivity level can be added to the label.

Static control on personnel and handling equipment

People are usually the generators of static electricity. The simple act of walking or the movements necessary to repair a circuit board can generate several thousand volts of electrostatic charge in the human body. If not properly controlled, this static charge can easily discharge into an ESD-sensitive device - a typical human body model discharge. In addition, a person may transfer charge to a circuit board or other item making it vulnerable to Device Model events loaded in a subsequent process.
Even in highly automated assembly and testing processes, people still deal with ESDS ... in the warehouse, in repair, in the lab, in transportation. For this reason, ESD control programs place considerable emphasis on personnel-generated electrostatic discharge control. Likewise, the movement of moving equipment (such as trolleys or carts) and other wheeled equipment through the facility can also generate substantial static loads that can be transferred to the products being transported in this facility.

Antistatic wire strap

Typically, wrist straps are the primary means of grounding personnel. When properly placed and grounded, a bracelet keeps the wearer close to the earth potential. Since the person and other grounded objects in the work area are at or near the same potential, there can be no hazardous discharge between them. In addition, static charges are removed from the person to ground and do not accumulate. When personnel are seated in a chair that is not EPA-appropriate, they should be grounded using a wrist strap.



Wrist straps have two main components, the bracelet that surrounds the person's wrist and the ground cable that connects the bracelet to the common point. Most wrist straps have a current limiting resistor molded into the grounding cable at the end that attaches to the strap. This resistor is most commonly a megohm, with at least 1/4 watt with a working voltage of 250 volts.
Wrist straps have various failure mechanisms and therefore should be tested regularly. Daily testing at specific test stations or using a continuous monitor on the workbench is recommended.

Floors, Rugs, Floor Finishes

A second method of grounding personnel is an ESD floor covering / footwear system in conjunction with ESD control footwear or foot bases. This combination of conductive or dissipative tread materials and footwear provides a safe dirt path for electrostatic charge dissipation, thereby reducing load accumulation on personnel. In addition to the dissipation load, some floor materials (and floor finishes) also reduce triboelectric charging. The use of a covering / footwear system is especially appropriate in areas where greater staff mobility is required. In addition, floor materials can minimize load accumulation on chairs, moving equipment (such as trolleys and trolleys), lifting trucks and other objects that move across the floor. However, these items require disabling or driving wheels or wheels to make electrical contact with the ground and components to be electrically connected. When used as a personnel grounding system, ground resistance, including person, footwear, and ground, must be the same as specified for the wrist straps (<35 megohms) and accumulation body tension in a standard stress test. (ANSI / ESD STM97. 2) must be less than 100 volts.

Shoes, bases, casters

Used in combination with ESD flooring, static control shoes, foot stands, casters and wheels provide the necessary electrical contact between the person or object and the floor. Footwear, casters or insulating wheels prevent static charges from flowing from the body or moving equipment to the ground floor and should therefore be avoided.

Clothing

Clothes

Clothing is a consideration in some ESD protection areas, especially in clean rooms and very dry environments. Garment materials, particularly those made of synthetic fabrics, can generate electrostatic charges that can discharge into ESDS or can create electrostatic fields that can induce charges. Because clothing is usually electrically insulated or insulated from the body, the charges on clothing fabrics are not necessarily dissipated on the skin and then ground. Statically controlled clothing may suppress or otherwise affect an electric field of clothing worn under the garment. By ANSI / ESD S20.20 and the ANSI / ESD STM2.1 clothing standard, there are three categories of ESD clothing:

- ESD Category 1 clothing; a static control suit without being earthed. However, without grounding, a charge can accumulate on conductive or dissipative elements of a garment, if present, resulting in a charged source.
- ESD Category 2 clothing; A static control clothing that can be grounded when grounded provides a higher level of suppression of the effects of an electric field from worn clothing under the garment.
- ESD Category 3 clothing; A static and isolable control garment system also links a person's skin with an identified land path. Total system resistance, including person, clothing, and grounding wire should be less than 35 megohms.

Workstations and work areas

An ESD protective workstation refers to a single individual work area that is constructed and equipped with materials and equipment to limit damage to ESD sensitive items. It can be a standalone station in a warehouse, warehouse, or assembly area, or in a field location, such as a computer bay on commercial aircraft. A workstation may also be in a controlled area, such as a clean room. The main ESD control elements that make up most workstations are a static dissipative work surface, personnel grounding (usually a wristband), a common point, and proper signaling and labeling. A typical workstation is shown in Figure 1.

The workstation provides a means to connect all work areas, electrical devices, handling equipment, and grounding devices to a common point. In addition, provision may be made for connecting additional personnel grounding devices, equipment, and accessories such as continuous or continuous monitors and ionizers.

Static protective work surfaces with 1 mega-ohm to 1 giga-ohm ground resistance provide a surface that has the same electrical potential as other ESD control items on the workstation. They also provide an electrical ground path for controlled dissipation of any static charges on surface contacting materials. The work surface also helps define a specific work area in which ESDS should be handled. The work surface is connected to the common point.

25. Problems and Possible Solution

25.1. Failure Connecting

1st Check if the equipment is correctly connected to the recording station.
2nd Check if the USB port and cable work properly.
3rd Check if the computer does recognize the device.
4th Check if any warning appears on the recording station.
5th Check if the device does display any warning on the screen.
6th Check if the driver of the BWMini device is correctly installed.

25.2. High-Frequency Interferences "Bold Trace"

1st Check if the recording station outlet being is used effectively grounded.
2nd Check if the electrode placement impedances are low.
3rd Check if there is any sweat or dirt residue on the patient's head.
4th Check if the electrodes are in perfect condition for use.

25.3. Amplifier Module does not turn on.

1st Check if the device does count with a charged battery.
2nd Check if the device does not charge, look for the restart point on the back of the device and restart it.

25.4. Interruption of system electrical power

In case of an interruption of electrical power for less than 30 seconds, the device and the software will keep the settings until the power is restored.

In case of an interruption of electrical power for more than 30 seconds, the device and the software will keep the last settings used to record the study.

After the tests, if the problem persists, the user should contact Neurovirtual Customer Support.

Any perception or suspect of abnormal functioning, we recommend the operator to immediately get in touch with Neurovirtual Customer Support for verification.

26. About this Manual

Neurovirtual reserves the right to modify the content of this manual without any previous notice.

The images shown in this manual are mere illustrations.
Many products shown in this material are optional. The images of other companies mentioned in this manual are the property of their respective manufacturers.

27. Copyright©

28. Attachment

Composition of the materials that make up the product and come into contact with the patient/operator:

1.22 meter (48" in) EEG Electrodes - Plastics One - Origin: USA - Sl 1052 - Brass with Gold Flash;
EEG Electrodes 2.44 Meters (96" in) - Plastics One - Origin: USA - Sl 1054 - Brass with Gold Flash;
Snap Button Electrode with 2.44 meters (96" in) - Plastics One - Origin: USA - Sl 1056 – do not contact the patient's skin, use on clothing;
Inductive Plethysmographic Respiratory Effort Belt - Size: Large Adult - SleepSense - Origin: USA - Sl 1037 - do not come into contact with patient's skin, use over clothing;
Inductive Plethysmographic Respiratory Effort Belt - Size: Adult Extra Large - SleepSense - Origin: USA - Sl 1038 - do not come into contact with the patient's skin, use over clothing;
Inductive Plethysmographic Respiratory Effort Belt - Size: Adult Extra Extra Large - SleepSense - Origin: USA - Sl 1039 - do not come into contact with patient's skin, use over clothing;
Inductive Plethysmographic Respiratory Effort Belt - Size: Infant - SleepSense - Origin: USA - Sl 1041 - do not come into contact with the patient's skin, use over clothing;
Inductive Plethysmographic Respiratory Effort Belt - Size: Pediatric - SleepSense - Origin: USA - Sl 1040 - do not come into contact with patient's skin, use over clothing;
Inductive Plethysmographic Respiratory Effort Belt - Size: Neonatal - SleepSense - Origin: USA - Sl 1042 - do not come into contact with the patient's skin, use over clothing;
Inductive Plethysmographic Respiratory Effort Belt - Adjustable Size - SleepSense - Origin: USA - Sl 1043 - do not come into contact with patient's skin, use over clothing;
Interface cable for Abdominal Inductive Respiratory Effort Strap - SleepSense - Origin: USA - Sl 1029 - do not contact patient's skin, use over clothing;
Interface cable for Abdominal Inductive Respiratory Effort Strap 2ft - SleepSense - Origin: USA - Sl 1478 - do not contact patient's skin, wear over clothing;
Interface cable for Thoracic Inductive Respiratory Effort Strap - SleepSense - Origin: USA - Sl 1030 - do not contact patient's skin, wear over clothing;
Interface cable for Thoracic Inductive Respiratory Effort Strap 2ft - SleepSense - Origin: USA - Sl 1477 - do not contact patient's skin, use over clothing;
Adult Nasal Cannula 7ft- SleepSense - Origin: USA - Sl 1057 - Biocompatible medical grade silicone;
Adult Nasal Cannula 2ft - SleepSense - Origin: USA - Sl 1195 - Biocompatible Medical Grade Silicone;
Pediatric Nasal Cannula 7ft - SleepSense - Origin: USA - Sl 1059 - Biocompatible medical grade silicone;
Adult Oral Nasal Cannula 7ft - SleepSense - Origin: USA - Sl 1058 - Biocompatible Medical Grade Silicone;
Adult Oral Nasal Cannula 2ft - SleepSense - Origin: USA - Sl 1196 - Biocompatible Medical Grade Silicone;
Pediatric Oral Nasal Cannula 7ft - SleepSense - Origin: USA- Sl 1060 - Biocompatible Medical Grade Silicone;
Nasal Respiratory Flow Sensor (thermocouple) Adult - SleepSense - Origin: USA - Sl 1034 - Biocompatible Medical Grade Silicone;
Nasal Respiratory Flow Sensor (thermocouple) Adult 2ft - SleepSense - Origin: USA - Sl 1479 - Biocompatible Medical Grade Silicone;
Pediatric Nasal Respiratory Flow Sensor (thhermocouple) - SleepSense - Origin: USA - Sl 1035 - Biocompatible Medical Grade Silicone;
Snoring Sensor - SleepSense - Origin: USA - Sl 1036 - Biocompatible Medical Grade Silicone;
Snore Sensor 2ft - SleepSense - Origin: USA - Sl 1480 - Biocompatible Medical Grade Silicone;
MaxxiPosition Position Sensor - Origin: Brazil - PV 1515-04 - do not come into contact with the patient's skin, use over clothing;
Reusable Adult Flex Oximeter Sensor 8000J-1 - Nonin - Origin: USA - Sl 1077 – Polyamide – Kapton;
Reusable Adult Flex Oximeter Sensor 8000J-3 - Nonin - Origin: USA - Sl 1047 - Polyamide - Kapton.;

Reusable Flex Oximeter Sensor for Children - Nonin - Origin: USA - Sl 1050 - Polyamide - Kapton.;
Small Soft Oximeter Sensor (9ft /3 meters) - Nonin - Origin: USA - Sl 1044 - Polyamide - Kapton.;
Soft Medium Oximeter Sensor (9ft / 3 meters) - Nonin - Origin: USA - Sl 1045 - Polyamide - Kapton.;
Soft Large Oximeter Sensor (9ft / 3 meters) - Nonin - Origin: USA - Sl 1046;
Small Soft Oximeter Sensor (1 meter) - Nonin - Origin: USA - Sl 1075 - Polyamide - Kapton.;
Soft Medium Oximeter Sensor (1 meter) - Nonin - Origin: USA - Sl 1064 - Polyamide - Kapton.;
Soft Large Oximeter Sensor (1 meter) - Nonin - Origin: USA - Sl 1076 - Polyamide - Kapton.;
Reusable Adult Clip Oximeter Sensor (9ft / 3 meters) - Nonin - Origin: USA - Sl 1354 - Polyamide - Kapton.;
Main Module BWMINI EEG - MF Medical Equipment Ltda - Origin: Brazil - PP 2523 - do not come into contact with the patient's skin, use on clothing;
Head Box EEG Module - MF Medical Equipment Ltda. - Origin: Brasl - PP 2537;
Head Box Communication Cable - MF Medical Equipment Ltda. - Origin: Brazil - MP 2672 - do not come into contact with the patient's skin;
Mini USB Cable - MF Medical Equipment Ltda. - Origin: Brazil - MP 2685 - do not come into contact with the patient's skin;
Main Module BWMINI PSG - MF Medical Equipment Ltda - Origin: Brazil - PP 2522 - do not come into contact with the patient's skin, use over clothing;
Head Box Module PSG - MF Medical Equipment Ltda - Origin: Brazil - PP 2538 - do not come into contact with the patient's skin, use over clothing;
Main Module BWMINI HST - MF Medical Equipment Ltda. - Origin: Brazil - PP2521 - do not come into contact with the patient's skin, use on clothing;
Nylon Cover for Main Module EEG/HST/PSG - MF Medical Equipment Ltda - Origin: Brazil - MP 2675 - do not come into contact with the patient's skin, use over clothing;
Nylon Cover for Head Box Module - MF Medical Equipment Ltda - Origin: Brazil - MP 2675 - do not come into contact with the patient's skin, use over clothing;
Neurovirtual Waist Bag - MF Medical Equipment Ltda. - Origin: Brazil - MP 2691- do not come into contact with the patient's skin, use over clothing;
Glove for Electrodes - MF Medical Equipment Ltda - Origin: Brazil - MP 2677 - do not come into contact with the patient's skin, use on clothing;