User Manual

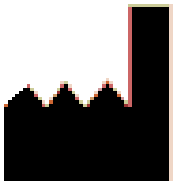
Basics
EEG
EEG Plus
PSG
PSG Plus

NEUROVIRTUAL

DMR-BWIII-94
Rev.13
06/30/2025

Table Contents

1. Manufacturer information



Corporate Name: Neurovirtual USA Inc.
Address: 3303 W Commercial Blvd. Suite #100, Fort Lauderdale, FL, USA 33309
Tel: +1 (786) 693-8200
Call Free: 1-877-NEURO-40 (USA only)
E-mail: customerservice@neurovirtual.com
Website: www.neurovirtual.com

2. European Authorized Representative – EC

EC REP

Obelis S.A.
Bd. Général Wahis, 53
1030 Brussels, Belgium

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 BWIII family equipment is mandatory.

This document aims to help the user to install the BWIII family (BWIII Basics, BWIII EEG, BWIII EEG Plus, BWIII PSG, and BWIII PSG Plus) equipment safely. This User Instruction is exclusively for the operation of BWIII family equipment.

The BWIII family 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 BWIII 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.

3. Safety Specification

The BWIII equipment complies with the safety standard requirements for electromedical equipment: IEC 60601-1, IEC 60601-1-2, IEC 62304 and IEC 60601-2-26, according to the Test Report issued by a laboratory accredited.

The BWIII family 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, without any water penetration protection. For indoors use only. Short term – Normally indicated for continuous use for no more than 30 days.

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

4. General Description

The BWIII family equipment is a medical device that records physiological signals. The system can capture electroencephalograph, respiratory, electromyography, plethysmography, and body position. The signals are captured using electrodes and sensors and a recording station with the software.

4.1. Modules Functionality

The BWIII family equipment can use up to four main modules: The amplifier, the power supply, the headbox module 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 **7. Models**.

4.1.2 Power supply module

The power supply 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 Headbox module

The headbox works as an extension of the amplifier. It allows the user to extend the reach of the connections and simplifies the process of disconnecting the patient. The headbox requires to be connected using the patient cables. The design of the headbox can change depending on the model. The models BWIII Basics and BWIII EEG do **not** use a headbox. For more details refer to **7. Models**.

4.1.4 Flash stimulation module

The photic or flash stimulation module is used for photo stimulation protocols on EEG studies. It requires to be connected to the amplifier and can be used multiple routines.

The protocols are activated from the Software BWAnalysis. The model BWIII PSG does **not** include this module.

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.

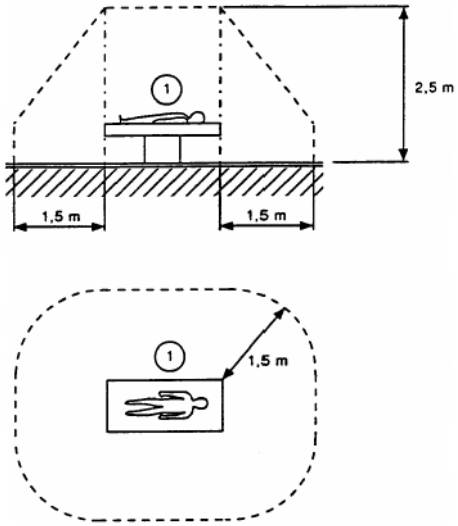
The software contains features to navigate through the signals, change montage view, see graphics, mark events, write reports, etc. It requires to be installed on the recording station to enable the amplifier. For more details, refer to the Software user manual.

5. Indications for use (Intended Purpose)

The BWIII system may be used for electroencephalography (EEG) and sleep recordings (Polysomnography) in research and clinical environments. It acquires, displays, and archives EEG and PSG data for on-screen review, annotation, and event-marking by the user.
The BWIII requires competent user input, and its output must be reviewed and interpreted by a trained physician who will exercise professional judgment in using this information.
The BWIII does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way, none of the functions can be considered diagnostic by themselves.

6. Safety Advisory and Considerations

	1. The BWIII 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 BWIII 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 BWIII 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 60601-1-1 and IEC 60601-1-2 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 BWIII Family 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 BWIII 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 BWIII Family. Risk of electric shock.
	16. The sensors and electrodes should not be in contact with the patient's skin if it is irritated or if it presents any kind of illness. Discontinue use if there is any sign of irritation/redness/itching.

	17. The BWIII family 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 BWIII family 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 BWIII 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. Equipment has no protection against water.
	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 BWIII Family 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 BWIII 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 BWIII Device
	26. The Family of BWIII 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 BWIII 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 BWIII Family 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 BWIII family
	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 it responsible for any modification 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 BWIII 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 finds 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 BWIII 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 BWIII 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 BWIII 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 radiofrequency. The user would require taking mitigation measurements such as relocate or reorientate the device.
	41. Follow the instructions in the accompanying documents where the BWIII 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 BWIII, it can affect the performance of BWIII.
	43. Sensitivity adjustment values below the BWIII 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 BWIII 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

7. Models

The BWIII family consists of 5 different models: BWIII **Basics**, BWIII **EEG**, BWIII **EEG Plus**, BWIII **PSG** and BWIII **PSG Plus**.

7.1. Comparative table between BWIII family models

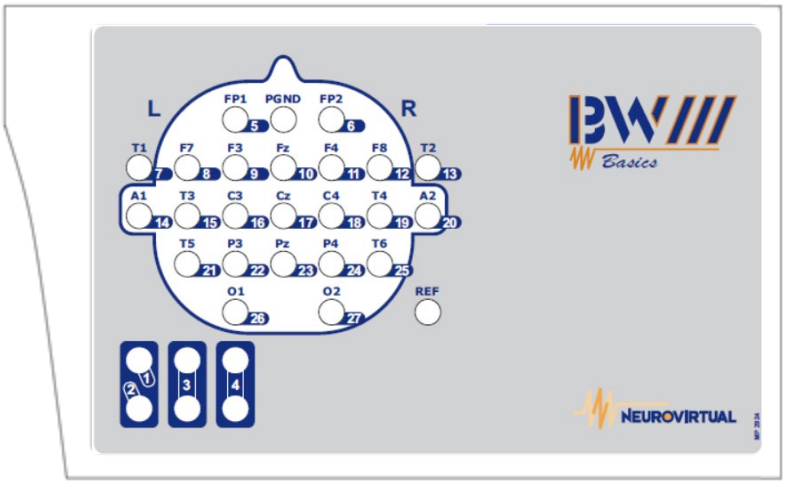
The following table compares the models within the BWIII Family to comply with INMETRO Ordinance No. 384, December 18, 2020, regarding the constitution of equipment families:

Features	BWIII Basics	BWIII EEG	BWIII EEG Plus	BWIII PSG	BWIII PSG Plus
Does it have the same functional technology?	Yes	Yes	Yes	Yes	Yes
Does the model have a similar indication, purpose or use?	Yes	Yes	Yes	Yes	Yes
Does the model share the same DMR (Device Master Records / Technical File / Technical Report)?	Yes	Yes	Yes	Yes	Yes
Are all models equipped with precision analog signal amplifiers?	Yes	Yes	Yes	Yes	Yes
Does the model have the same A/D converters (Analog to Digital signal converter)?	Yes	Yes	Yes	Yes	Yes
Does the model have the same manufacturing process?	Yes	Yes	Yes	Yes	Yes
Does the model have the same use and safety restrictions?	Yes	Yes	Yes	Yes	Yes
Does all models have the same storage and transportation instructions?	Yes	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	Yes
The manufacturer's certifying body (OCP) has accepted that the models form a family of equipment.	Yes	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 (BWIII PSG Plus), which is the most complete method of use.

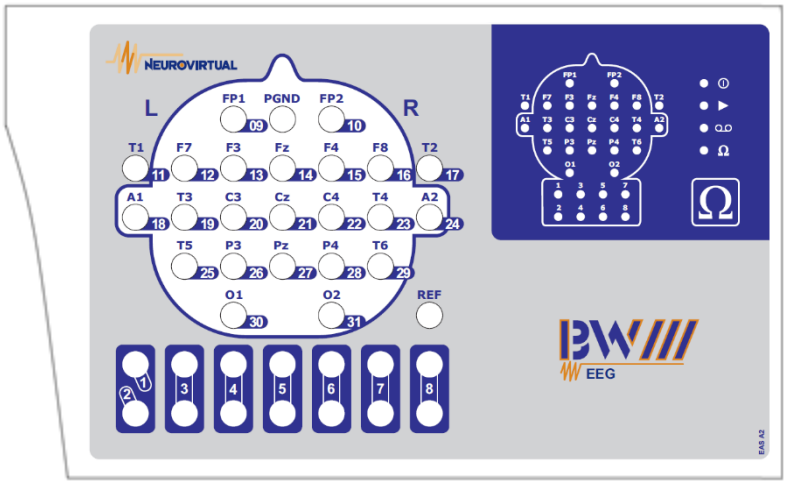
7.2.BWIII Basics



BWIII EEG Basics Amplifier Module

#	Channel Name	#	Channel Name
1	FP1 (EEG System 10-20)	16	A2 (EEG System 10-20)
2	FP2 (EEG System 10-20)	17	T5 (EEG System 10-20)
3	T1 (EEG System 10-20)	18	P3 (EEG System 10-20)
4	F7 (EEG System 10-20)	19	PZ (EEG System 10-20)
5	F3 (EEG System 10-20)	20	P4 (EEG System 10-20)
6	FZ (EEG System 10-20)	21	T6 (EEG System 10-20)
7	F4 (EEG System 10-20)	22	O1 (EEG System 10-20)
8	F8 (EEG System 10-20)	23	O2 (EEG System 10-20)
9	T2 (EEG System 10-20)	24	Flash Stimulator
10	A1 (EEG System 10-20)	25	Monopolar Auxiliary
11	T3 (EEG System 10-20)	26	Monopolar Auxiliary
12	C3 (EEG System 10-20)	27	Bipolar Auxiliary
13	CZ (EEG System 10-20)	28	Bipolar Auxiliary
14	C4 (EEG System 10-20)		
15	T4 (EEG System 10-20)		

7.3.BWIII EEG

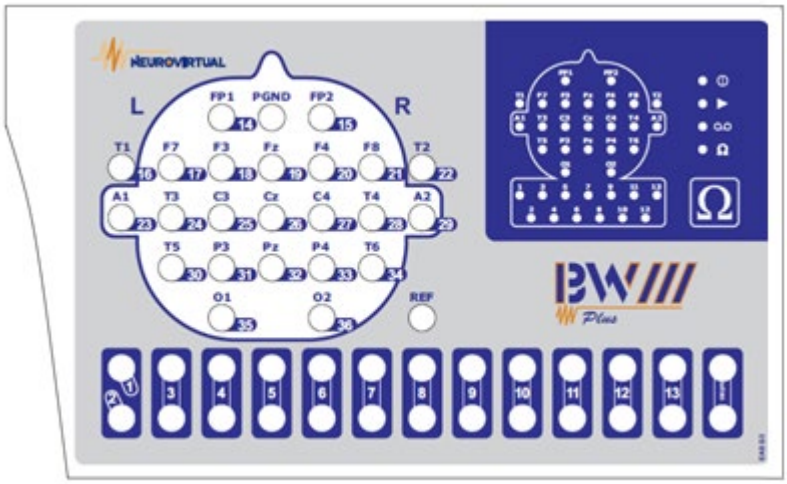


BWIII EEG Amplifier Module

This model of equipment is designed for professionals who want to carry out digital electroencephalography exams with photo-stimulation, audio-stimulation and brain mapping, but with a further 8 auxiliary AC inputs for polygraphy recording, 4 DC channels. Below is the list of channels available for this model of equipment:

#	Channel Name	#	Channel Name	#	Channel Name
1	FP1 (EEG System 10-20)	13	CZ (EEG System 10-20)	25	Monopolar Auxiliary
2	FP2 (EEG System 10-20)	14	C4 (EEG System 10-20)	26	Monopolar Auxiliary
3	T1 (EEG System 10-20)	15	T4 (EEG System 10-20)	27	Bipolar Auxiliary
4	F7 (EEG System 10-20)	16	A2 (EEG System 10-20)	28	Bipolar Auxiliary
5	F3 (EEG System 10-20)	17	T5 (EEG System 10-20)	29	Bipolar Auxiliary
6	FZ (EEG System 10-20)	18	P3 (EEG System 10-20)	30	Bipolar Auxiliary
7	F4 (EEG System 10-20)	19	PZ (EEG System 10-20)	31	Bipolar Auxiliary
8	F8 (EEG System 10-20)	20	P4 (EEG System 10-20)	32	Bipolar Auxiliary
9	T2 (EEG System 10-20)	21	T6 (EEG System 10-20)	33	DC Channel - 1
10	A1 (EEG System 10-20)	22	O1 (EEG System 10-20)	34	DC Channel - 2
11	T3 (EEG System 10-20)	23	O2 (EEG System 10-20)	35	DC Channel - 3
12	C3 (EEG System 10-20)	24	Flash Stimulator	36	DC Channel - 4

7.4. BWIII EEG Plus



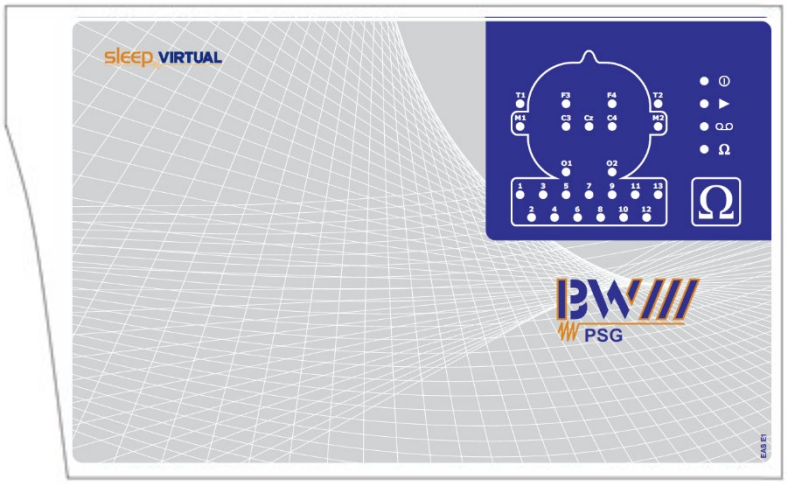
Amplifier Module BWIII EEG Plus

BWIII EEG Plus Head Box

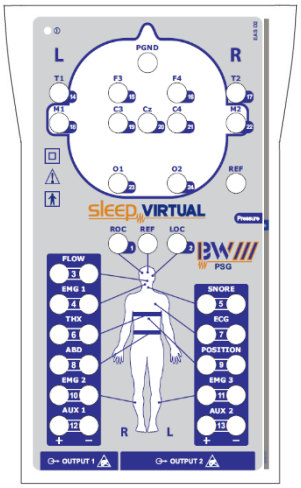
This model of equipment is designed for professionals who want to carry out digital electroencephalography exams with photo-stimulation, audio-stimulation and brain mapping, but with a further 13 auxiliary AC inputs for polygraphy recording, 8 DC channels and a remote head module (optional) for LTM (Long Term Monitoring). Below is the list of channels available for this model of equipment:

#	Channel Name	#	Channel Name	#	Channel Name
1	Auxiliar Monopolar	19	FZ (EEG Sistema 10-20)	37	Flash Stimulator
2	Auxiliar Monopolar	20	F4 (EEG Sistema 10-20)	38	Canal DC - 1
3	Auxiliar Bipolar	21	T2 (EEG Sistema 10-20)	39	Canal DC – 2
4	Auxiliar Bipolar	22	F8 (EEG Sistema 10-20)	40	Canal DC – 3
5	Auxiliar Bipolar	23	M1 (EEG Sistema 10-20)	41	Canal DC – 4
6	Auxiliar Bipolar	24	T3 (EEG Sistema 10-20)	42	Canal DC – 5
7	Auxiliar Bipolar	25	C3 (EEG Sistema 10-20)	43	Canal DC – 6
8	Auxiliar Bipolar	26	CZ (EEG Sistema 10-20)	44	Canal DC – 7
9	Auxiliar Bipolar	27	C4 (EEG Sistema 10-20)	45	Canal DC – 8
10	Auxiliar Bipolar	28	T4 (EEG Sistema 10-20)	46	Sp02 (Oxímetro)
11	Auxiliar Bipolar	29	M2 (EEG Sistema 10-20)	47	BPM (Oxímetro)
12	Auxiliar Bipolar	30	T5 (EEG Sistema 10-20)	48	Plesth Wave (Oxímetro)
13	Auxiliar Bipolar	31	P3 (EEG Sistema 10-20)	49	PRESSURE Transdutor AMP
14	FP1 (EEG Sistema 10-20)	32	PZ (EEG Sistema 10-20)	50	PRESSURE Transdutor Head box
15	FP2 (EEG Sistema 10-20)	33	P4 (EEG Sistema 10-20)		
16	T1 (EEG Sistema 10-20)	34	T6 (EEG Sistema 10-20)		
17	F7 (EEG Sistema 10-20)	35	O1 (EEG Sistema 10-20)		
18	F3 (EEG Sistema 10-20)	36	O2 (EEG Sistema 10-20)		

7.5. BWIII PSG



Amplifier Module BWIII PSG



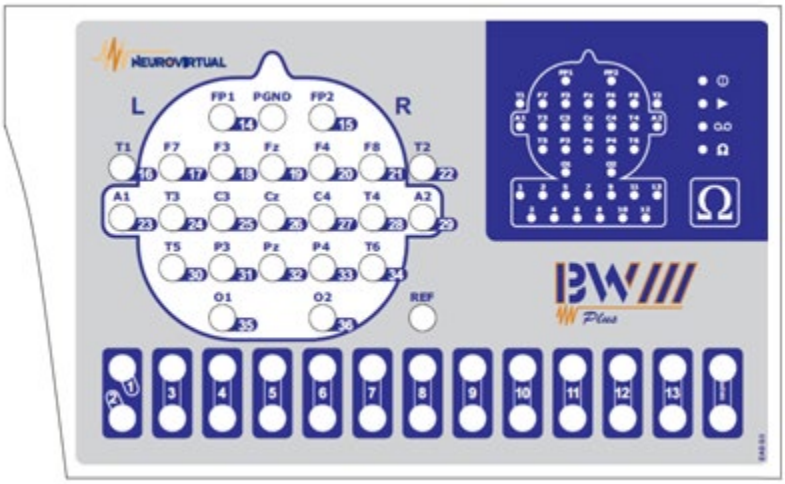
Head Box BWIII PSG

This equipment is intended for professionals who want to carry out complete polysomnography tests in accordance with the American Academy of Sleep Medicine (AASM) manual. Below is the list of channels available for this model of equipment:

#	Channel Name	#	Channel Name
1	LOC	20	CZ (EEG System 10-20)
2	ROC	21	C4 (EEG System 10-20)
3	FLOW	22	M2 (EEG System 10-20)
4	SNORE	23	O1 (EEG System 10-20)
5	CHIN EMG	24	O2 (EEG System 10-20)
6	ECG / EKG	25	BPM (Oximeter)
7	THORAX	26	SpO2 (Oximeter)
8	POSITION	27	Plesth Wave (Oximeter)
9	ABDOMEN	28	Pressure Transducer AMP
10	LEG EMG L	29	Pressure Transducer HB
11	LEG EMG R	30	DC Channel - 1
12	Auxiliary Bipolar	31	DC Channel - 2
13	Auxiliary Bipolar	32	DC Channel - 3
14	T1 (EEG System 10-20)	33	DC Channel - 4
15	F3 (EEG System 10-20)	34	DC Channel – 5
16	F4 (EEG System 10-20)	35	DC Channel – 6
17	T2 (EEG System 10-20)	36	DC Channel – 7
18	M1 (EEG System 10-20)	37	DC Channel - 8
19	C3 (EEG System 10-20)		

More EEG headbox (EEG System 10-20 complete) and more DC amplifiers are also available (as an optional extra) in the model above.

7.6. BWIII PSG Plus



Modulo Amplifier BWIII

BWIII PSG Plus Head Box

This equipment is intended for professionals who want to carry out polysomnography tests according to the American Academy of Sleep Medicine (AASM) manual and complete digital electroencephalography tests (10/20 system), either simultaneously with the polysomnography test or not. Below is the list of channels available for this model of equipment:

#	Channel Name	#	Channel Name	#	Channel Name
1	LOC	18	F3 (EEG System 10-20)	35	O1 (EEG System 10-20)
2	ROC	19	FZ (EEG System 10-20)	36	O2 (EEG System 10-20)
3	FLOW	20	F4 (EEG System 10-20)	37	Flash Stimulator
4	SNORE	21	T2 (EEG System 10-20)	38	SpO2 (Oximeter)
5	CHIN EMG	22	F8 (EEG System 10-20)	39	BPM (Oximeter)
6	ECG / EKG	23	M1 (EEG System 10-20)	40	Plesth Wave (Oximeter)
7	THORAX	24	T3 (EEG System 10-20)	41	Pressure Transducer AMP
8	POSITION	25	C3 (EEG System 10-20)	42	Pressure Transducer HB
9	ABD (Abdomen)	26	CZ (EEG System 10-20)	43	DC Channel - 1
10	LEG EMG L	27	C4 (EEG System 10-20)	44	DC Channel - 2
11	LEG EMG R	28	T4 (EEG System 10-20)	45	DC Channel - 3
12	Auxiliary Bipolar	29	M2 (EEG System 10-20)	46	DC Channel - 4
13	Auxiliary Bipolar	30	T5 (EEG System 10-20)	47	DC Channel – 5
14	FP1 (EEG System 10-20)	31	P3 (EEG System 10-20)	48	DC Channel - 6
15	FP2 (EEG System 10-20)	32	PZ (EEG System 10-20)	49	DC Channel - 7
16	T1 (EEG System 10-20)	33	P4 (EEG System 10-20)	50	DC Channel - 8
17	F7 (EEG System 10-20)	34	T6 (EEG System 10-20)	51- 58	Expansion Module up to 16 DC

8. Purpose and Descriptions

8.1. Models: BWIII Basics, BWIII EEG and BWIII EEG Plus

What is the purpose?

The BWIII Basics, BWIII EEG and BWIII EEG Plus equipment are biological signal amplifiers 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 BWIII Basics, BWIII EEG and BWIII EEG Plus equipment be used?

The BWIII Basics, BWIII EEG and BWIII EEG Plus model equipment can be used in hospitals, specialized clinics or doctor's office and *home care*, if 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: BWIII PSG and BWIII PSG Plus

What is the purpose?

The BWIII PSG and BWIII PSG Plus 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 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 BWIII PSG and BWIII PSG Plus equipment be used?

The equipment models BWIII PSG and BWIII PSG Plus 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- Same indications as for the BWIII EEG model cited above,
2- Behavior disorders that occurred during sleep (parasomnias, sleepwalking, REM sleep behavior disorders, insomnia, epilepsies, etc.),
3- Excessive daytime sleepiness (narcolepsy, hypersomnia),
4- Breathing disorders during sleep (snoring, obstructive sleep apnea syndrome, increased upper airway resistance syndrome, etc.),
5- Titration with assistance of CPAP, BiPAP, VPAP,
6- Post-treatment control (surgery, sound design, oral appliances, etc.) of obstructive sleep apnea syndrome,
7- Heart rhythm disturbances that occur during sleep,
8- Restless leg syndrome and periodic limb movements,
9- Among others.

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

9. Package contents and Accessories

The BWIII 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 BWIII family modules.

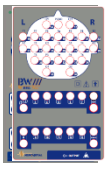
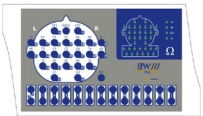
The following table compares the components within each of the models of the BWIII Family:

Components				
BWIII Basics	**BWIII EEG**	**BWIII EEG Plus**	**BWIII PSG**	**BWIII PSG Plus**
BWIII Basics Amplifier Module	BWIII EEG Amplifier Module	BWIII EEG Plus Amplifier Module	BWIII PSG Amplifier Module	BWIII PSG Plus Amplifier Module
Ethernet cable	Ethernet cable	Ethernet cable	Ethernet cable	Ethernet cable
Power Supply with Power Cord	Power Supply with Power Cord	Power Supply with Power Cord	Power Supply with Power Cord	Power Supply with Power Cord
Flash Stimulator module	Flash Stimulator module	Flash Stimulator module	Flash Stimulator module	Flash Stimulator module
Flash Stimulator cable	Flash Stimulator cable	Flash Stimulator cable	Flash Stimulator cable	Flash Stimulator cable
		BWIII EEG Plus Headbox Module	BWIII PSG Headbox Module	BWIII PSG Plus Headbox Module
		Patient Cable - Thick	Patient Cable - Thick	Patient Cable - Thick
			Patient Cable - Thin	Patient Cable - Thin

Note: This list shows the accessories that are compatible with each of the models from BWIII Family. 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 BWIII Family

Model BWIII	Qty.	Description	Image
EEG	1	BWIII EEG Amplifier Module	

Model BWIII	Qty.	Description	Image
EEG	1	BWIII EEG Plus Amplifier Module	
EEG	1	BWIII EEG Plus Headbox Module	
EEG	1	Flash Stimulator Module	
EEG	1	Stimulator Flash Communication Cable	
EEG/PSG	1	Power Supply Module	
EEG/PSG	1	Ethernet Communication Cable	
EEG/PSG	1	Pen Drive	-
PSG	1	BWIII PSG Amplifier Module	
PSG	1	BWIII PSG Headbox Module	
EEG/PSG	1	BWIII Plus Amplifier Module	
PSG	1	Headbox Module BWIII PSG Plus	

Model BWIII	Qty.	Description	Image
PSG	3	DC Cable – Jack 3.5mm Communication Cable	
EEG/PSG	1	Communication Cable - 50-way Remote Head	
EEG/PSG	1	Communication Cable - 14-way Remote Header	
PSG	1	Nonin® OEM III – SpO2 Module	

* The above pieces are for exclusive use and are part of the equipment of the BWIII Basics, BWIII EEG, BWIII EEG Plus, BWIII PSG and BWIII PSG Plus which form part of the BWIII family.

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 BWIII works with any excellent 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 manufacturers, 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 BWIII family Modules.

The following table compares the accessories within each of the models of the BWIII Family:

Accessories				
BWIII Basics	**BWIII EEG**	**BWIII EEG Plus**	**BWIII PSG**	**BWIII PSG Plus**
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	USB with Installation Software and User Manual
Maxxi Gold - Gold Cup Electrode Set	Maxxi Gold - Gold Cup Electrode Set	Maxxi Gold - Gold Cup Electrode Set	Maxxi Gold - Gold Cup Electrode Set	Maxxi Gold - Gold Cup Electrode Set
USB-Ethernet Adapter	USB-Ethernet Adapter	USB-Ethernet Adapter	USB-Ethernet Adapter	USB-Ethernet Adapter
Flexible Arm for Flash Stimulator	Flexible Arm for Flash Stimulator	Flexible Arm for Flash Stimulator	Ten20 Cream	Flexible Arm for Flash Stimulator
Ten20 Cream	Ten20 Cream	Ten20 Cream	Nuprep	Ten20 Cream
Nuprep	Nuprep	Nuprep	Jumper Connector	Nuprep
Jumper Connector	Jumper Connector	Jumper Connector	Neurovirtual Briefcase	Jumper Connector
Neurovirtual Briefcase	Neurovirtual Briefcase	Neurovirtual Briefcase	Connection Kit	Neurovirtual Briefcase
Connection Kit	Connection Kit	Connection Kit	Maxxi Gold SNAP Button Electrodes	Connection Kit
Storage Box	Maxxi Gold SNAP Button Electrodes	Maxxi Gold SNAP Button Electrodes	Storage Box	Maxxi Gold SNAP Button Electrodes
	Storage Box	Storage Box	Wall Bracker	Storage Box
		Wall Bracker	Cannula	Wall Bracker
			Cannula filter	Cannula
			Maxxi Snore Sensor	Cannula filter
			Thermistor Maxxi Flow	Maxxi Snore Sensor
			ABD Sensor Interface	Thermistor Maxxi Flow
			THX Sensor Interface	ABD Sensor Interface
			Maxxi Rip Inductive Belts	THX Sensor Interface
			Flex Oximeter Sensor	Maxxi Rip Inductive Belts
			Maxxi POS Sensor	Flex Oximeter Sensor
				Maxxi POS Sensor

Note: This list shows the accessories that are compatible with each of the models from BWIII Family. 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.

9.2.2. Description of Accessories within BWIII Family

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

These are medical products intended to connect to another active medical product, in this case, the BWIII family equipment. They have a lower risk classification (Class I) compared to the risk class of BWIII family 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 BWIII	Qty	Description	Image
EEG/PSG	30	Maxxi Gold - Electrode for electroencephalography – 60" - 1.52 meters - Pin: TP.	
EEG/PSG	25	Maxxi Gold - Electrode for electroencephalography – 96" - 2.44 meters - Pin: TP.	
PSG	1	Maxxi Cap – Electrode Cap for electroencephalography – 96" - 2.44 meters – Pinto TP.	
PSG	2	Maxxi Belt - Respiratory Effort Strap for PSG – 96" - 2.44 meters - Pin: TP.	
PSG	1	Maxxi Flow - Respiratory Flow Sensor for PSG – 96" - 2.44 meters - Pin: TP.	
PSG	1	Respiratory Flow Sensor for PSG - Pediatric – 96" - 2.44 meters - Pin: TP.	
PSG	1	MaxxiSnore - Snore sensor for PSG – 96" - 2.44 meters - Pin: TP.	

Model BWIII	Qty	Description	Image
PSG	1	Maxxi Position - Position sensor for PSG – 96” - 2.44 meters - Pin: TP.	
PSG	1	AC Pressure Transducer for PSG.	
PSG	1	Maxxi RIP System - Inductive Respiratory Effort Belt Rip Belt - Size: Adjustable - Reusable.	
PSG	1	Maxxi RIP Belt Inductive Respiratory Effort Belt – Size: Child 15” - 40cm - disposable.	
PSG	1	Maxxi RIP Belt Inductive Respiratory Effort Belt – Size: Child 23” 60cm - disposable.	
PSG	1	Maxxi RIP Belt - Size: Child 35” - 90cm - disposable.	
PSG	1	Maxxi Inductive Respiratory Effort Belt RIP Belt – Size: Child 47” - 120cm - disposable.	
PSG	1	Maxxi RIP Belt - Size: Child 59” - 150cm - disposable.	
PSG	1	Abdominal Interface for Maxxi RIP Inductive Respiratory Effort Belt – 7ft - 213cm – TP Pin.	
PSG	1	Thoracic Interface for Maxxi RIP Inductive Respiratory Effort Strap – 7ft -213cm – TP Pin.	
PSG	1	Nonin 8000J-3-meter Oximeter Sensor - Adult - Pin: DB9.	
PSG	1	Nonin 8000J-1 meter Oximeter Sensor - Adult -Pin: DB9.	

Model BWIII	Qty	Description	Image
PSG	1	Nonin 8008J-1 meter Oximeter Sensor - Child - Pin: DB9.	
PSG	1	Neurovirtual USA Oximeter Sensor – 10ft - 3 meters - Adult - Pin: DB9.	
PSG	1	Neurovirtual USA Oximeter Sensor – 3ft - 1 meter - Adult - Pin: DB9.	

The above parts are included in the same registration (ANVISA) of the BWIII family 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 BWIII PSG and BWIII PSG Plus equipment, part of the BWIII family of equipment, have an integrated pulse oximeter (Nonin® OEM III). The American company Nonin Medical Inc. manufactures this oximeter.

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 BWIII PSG and BWIII PSG Plus equipment.

The following information is of paramount importance for the correct and safe operations of the oximetry system integrated into the BWIII family 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 BWIII PSG and BWIII PSG Plus 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 represent 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)

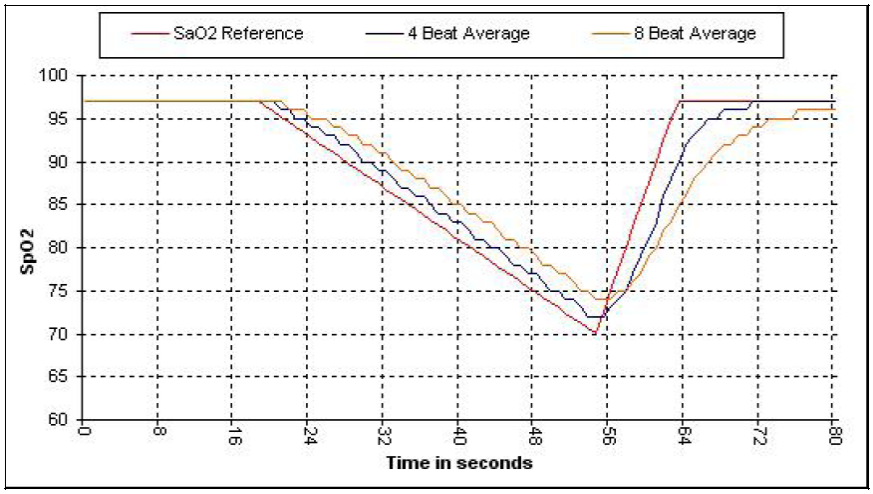
- Oximeter response time:

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

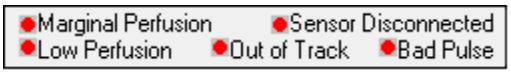


Specific to the example above:

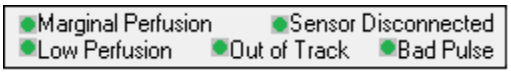
- The answer for 4 average beats is 1.5 seconds.
- The answer for 8 average beats is 3.0 seconds.

- The oximeter integrated into the BWIII PSG and BWIII PSG Plus 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 BWIII PSG, BWIII PSG Plus 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 BWIII PSG, BWIII Plus 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 BWIII family equipment **does not** have an alarm with adjustable limits. (example: low SpO2).

- The oximeter integrated into the BWIII family 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 BWIII PSG and BWIII PSG Plus 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 BWIII family. 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 Maxxi Oximeter - Oximetry Sensor.

- The oximeter integrated into the BWIII PSG and BWIII PSG Plus 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 BWIII family. 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 BWIII PSG and BWIII PSG Plus 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 BWIII family.

- A maximum recommended application time for the use of the Model 8000J-1 and 8000J-3 Pulse Oximeter Sensor in a specific 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 damage caused by negligence in the operation.

- The OEM III oximetry module manufactured by Nonin Medical Inc. an integral part of the BWIII PSG and BWIII PSG Plus 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 BWIII PSG and BWIII PSG Plus 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 BWIII PSG / BWIII PSG Plus 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.

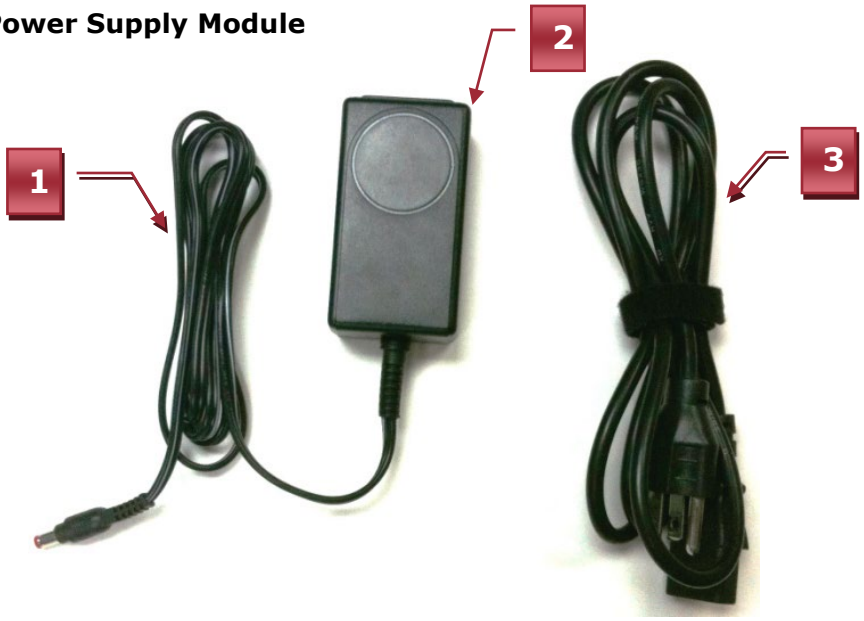
- The 8000J-1 / 8000J-3 oximetry sensors, manufactured by Nonin Medical Inc. are designed for continuous monitoring in adult and pediatric patients (weighing more than 20 kilograms, regardless of age) and in conditions where sensor movement may occur.

- Information on the correct disposal of the 8000J-1 and 8000J-3 Sensors can be found in chapter **20 Disposal** 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.

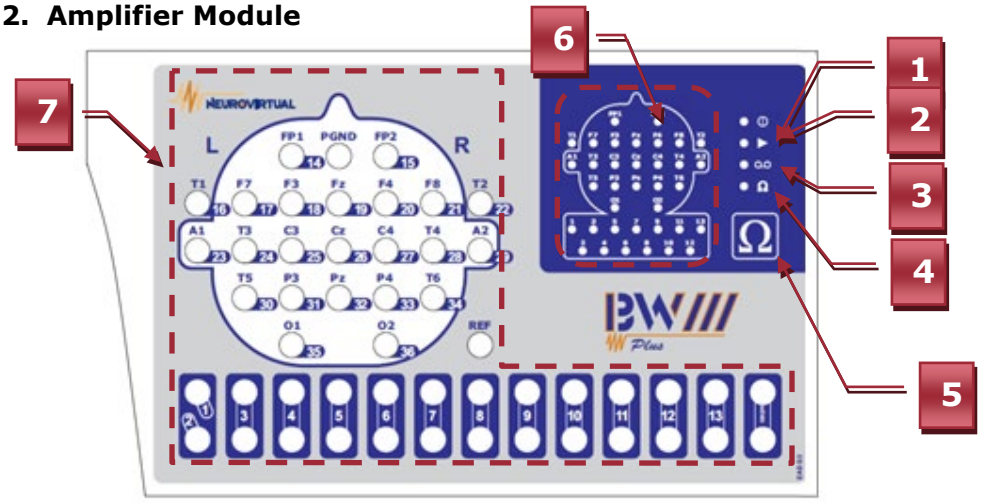
11.Identification of BWIII equipment parts

11.1. Power Supply Module



#	Descriptions
1	Power DC cable
2	Power Supply Module
3	Power Cord AC *Cable supplied with 1.5mt length

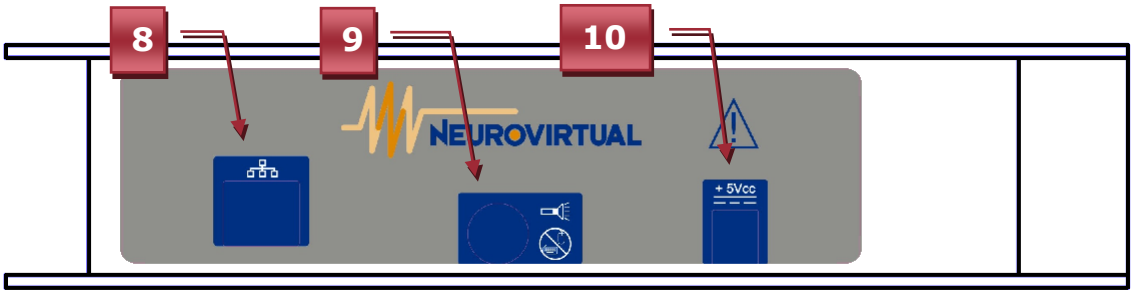
11.2. Amplifier Module



Top View

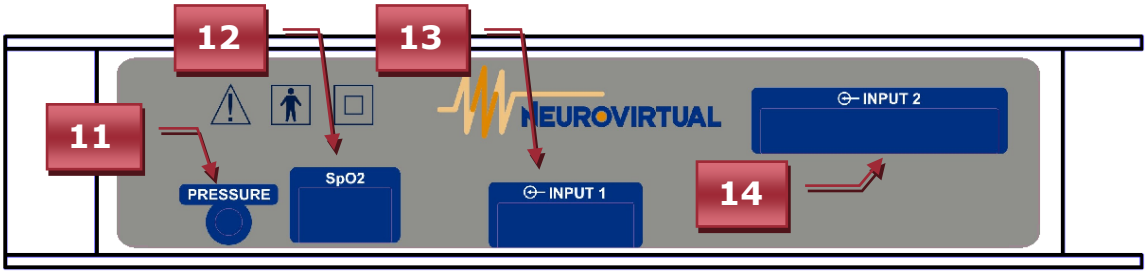
#	Descriptions
1	Power On Indicator
2	Run Indicator (Indicates that it is picking up the signals)
3	Recording Indicator (Indicates that it is saving the signals)
4	Impedance measuring Indicator (Indicates that impedance measurement is running)
5	Impedance Measuring button
6	Channels impedance Indicators (When on, it indicates that impedances are adequate)
7	AC Channels Input (Touch Proof Connectors)

Note: *The BWIII PSG Plus model was used to demonstrate the view above.*
In the BWIII EEG Plus model, the number of auxiliar channels is smaller.
On the BWIII EEG model, the number of channels is lower.
For the BWIII PSG model this label is not applied.



Rear View

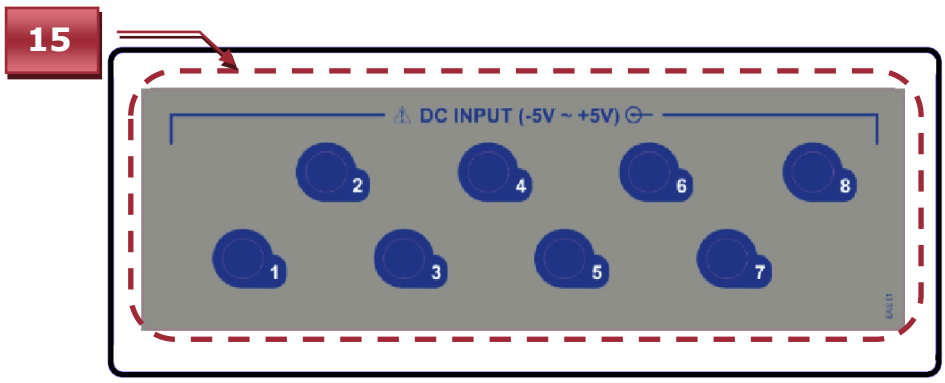
#	Descriptions
8	Ethernet Connector
9	Flash Stimulator Connector
10	Power Supply Connector



Front View

#	Descriptions
11	Pressure Cannula Input (Luerlock Connector)
12	Oximeter Sensor Input (Nonin 8000J-1 or 8000J-3 Input Connector)
13	Head Box Input (SCSI 14)
14	Head Box Input (SCSI 50)

Note: *The BWIII PSG Plus model was used to demonstrate the frontal view.*
For the BWIII EEG Plus model the Pressure (11) and SpO2 (12) inputs are not available.
For the BWIII EEG model this label may not be applied.

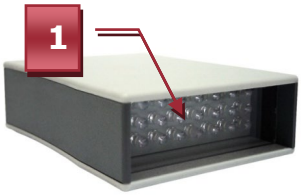


Right Side View

#	Descriptions
15	DC Channels Input (P2 Connectors)

Note.: *BWIII PSG Plus models were used to demonstrate the side view.*
For the other models, this label contains only 4 DC channels.
On the BWIII Basic model may not be available.

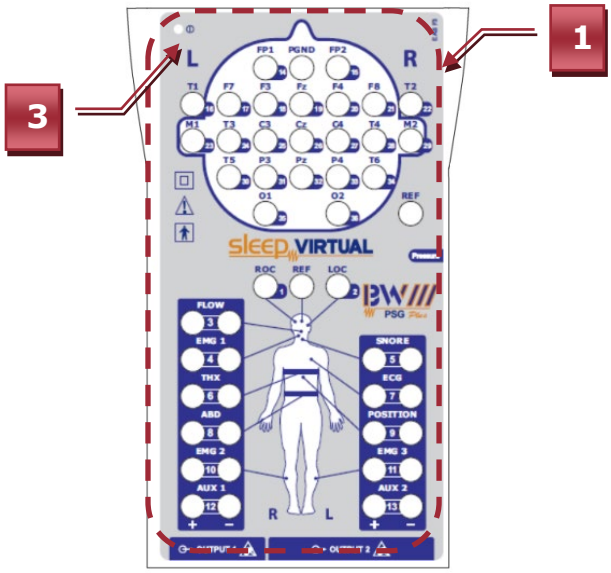
11.3. Flash Stimulator Module



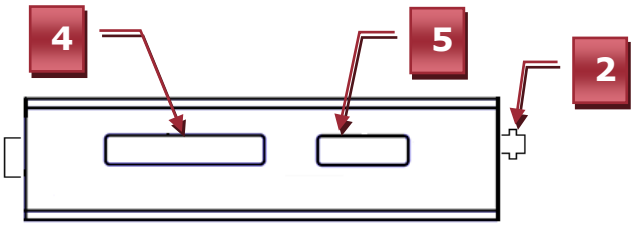
#	Descriptions
1	Flash's Output
2	Flash Stimulator Cable Input

Note: *The Flash Stimulator Module is not available on the BWIII PSG model.*

11.4. Remote Head Box Module



Top View

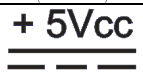
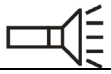


Front View

#	Descriptions
1	AC Channels Input (Touch Proof Connectors)
2	Pressure Cannula Input (Luerlock Connector)
3	Power On Indicator (Indicates that the equipment is energized)
4	Head Box Output (SCSI 50)
5	Head Box Output (SCSI 14)

Note.: *The BWIII PSG Plus model was used to demonstrate the above views.*
For the BWIII PSG model, this tag may have fewer EEG channels.
The Remote Head Module is not available on all models or is offered as a retail option.

11.5. Symbols, Descriptions and Definitions

SYMBOLS	DESCRIPTION	DEFINITION
	Caution	When it is used, check the BWIII User's Manual.
	Class II Equipment	It indicates the protection against electric discharge that the amplifier- BWIII contains.
	Type BF equipment	It indicates the level of protection against electric discharge that the equipment Brain Wave contains.
	LED Power On	It indicates the system is on or off.
	LED RUN	It indicates the system is running or not.
	LED REC	It indicates the system is recording the signals or not.
	LED Impedance	It indicates the system is measuring the impedances or not.
	Impedance Button	Button to activate the impedance measuring.
	DC voltage +5V	It indicates the correct voltage value and type for energize the system.
	Ethernet Output	It indicates the equipment communication output
	Flash Stimulator Input	It indicates the connector to connect the Flash stimulator
	Warning for flash stimulator connector	Warning: Do not connect mouse or keyboard here.
	Signal Input connector	Input signals
	Serial Number	It indicates the serial number of the system.
	REF code	It indicates the reference code of the system.
	Left side of head	Left side of head
	Right side of head	Right side of head
	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.
	Signal Output Connection	Signal Output
	Manufacturer Data	Manufacturer's data is available on the packaging, the amplifier module, and the Instruction for Use

12.System Installation

12.1. Computer 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 BWIII family and BWMini family.

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.

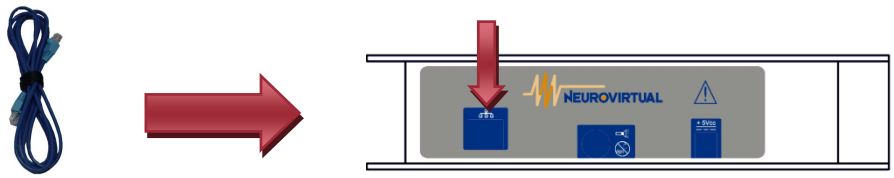
	3. **User Access Control:** ○ Restrict access to the software to authorized personnel only. The customer is responsible for managing user permissions and safeguarding login credentials. ○ Any unauthorized access or misuse of the software is the customer's responsibility.
	4. **Compliance:** ○ The customer 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.

The computer is not an electromedical equipment, see *6 Safety Advisory and Considerations* for correct positioning of the computer.

12.3. BWIII device installation

Step 1:

Remove the equipment from the package and place it on a clean, dry, and stable surface. Remove the Ethernet Communication Cable from the transportation briefcase and connect to the BWIII Amplifier Module.



Step 2:

Connect the other end of that Ethernet Communication Cable to the Ethernet input of your computer.

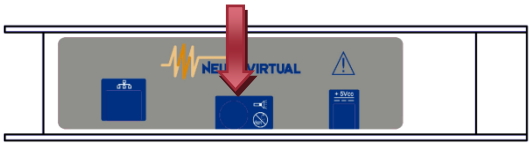
Step 3:

Connect the Power cord in power supply module and connect the power cable in BWIII Amplifier module.

Step 4: (Except for BWIII PSG model)

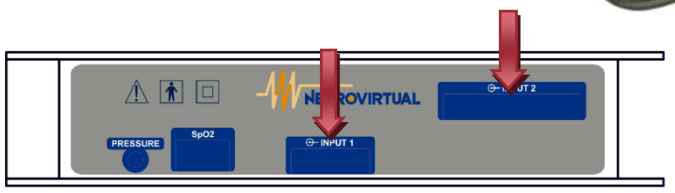
To use the photo-stimulation, connect the Stimulator Flash Module to the Communication Cable for the Flash Stimulator.

Thus, you can activate the photo-stimulation through the BWAnalysis software version.

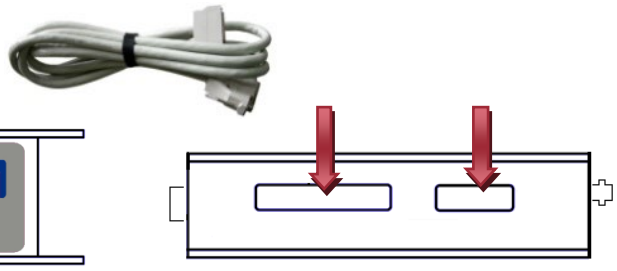


Step 5: (Just for BWIII PSG and BWIII PSG plus)

Connect the Remote Head to Amplifier Module using the Head of Communication Cable remote.



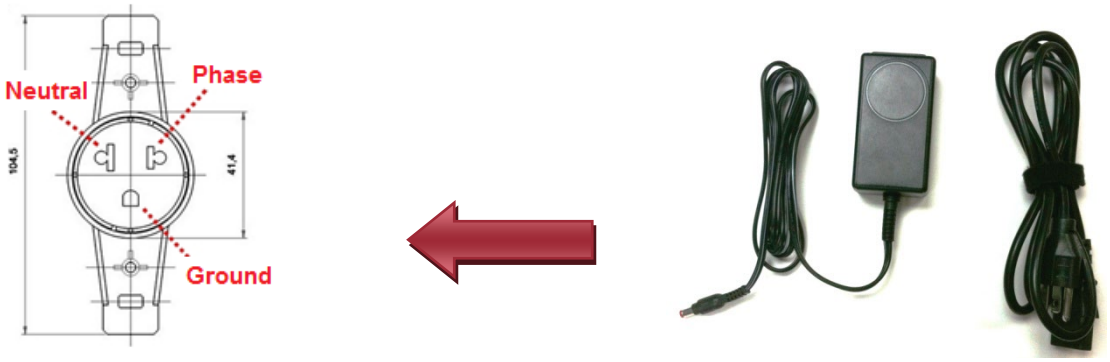
Front View of the Amplifier Module



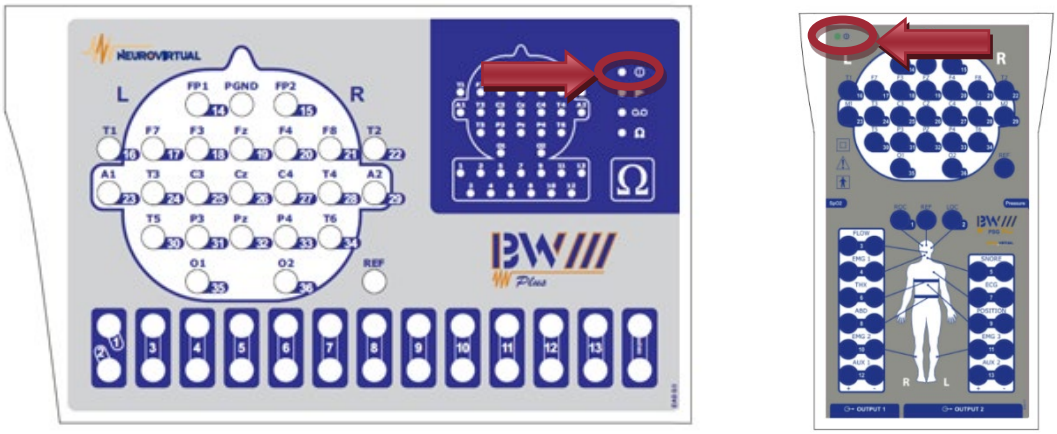
Front View of the Headbox Module .

Step 6:

Connect the Power cord of power supply module in an outlet (110VAC-240VAC).



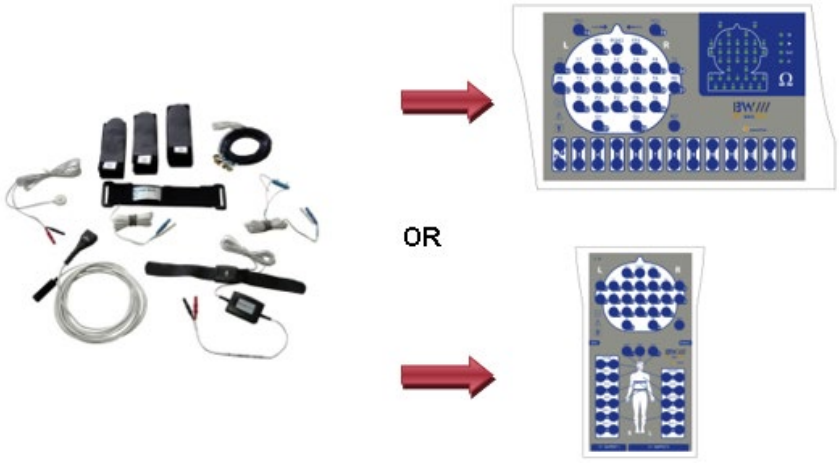
Note that now the key will be lit green and "Power On" Amplifier Module will also be lit.



Step 7:

Connect all sensors and electrodes, either to the remote head module or to the amplifier module. At this time the equipment is installed.

If the BWAnalysis software is not installed on your computer, install it directly from the Installation USB and start the operation.



The electrodes and sensors must be connected directly to the Amplifier Module OR the Headbox, never use both modules at the same time.

Step 8:
To start data acquisition, insert the USB installation that comes with the equipment and execute the installation of BWAnalysis software following the instructions that will automatically appear on screen.

On the USB installation is available the BWAnalysis Software Manual with explanations of how to take an exam and how to review an exam.

For more information or questions about registration and activation process, please contact the Neurovirtual Support Team.

To ensure a correct and safe operation of the BWIII family of equipment, we recommend the installation instructions to be regularly followed and reviewed. Any anomaly and/or suspected anomaly regarding use and/or handling, immediately suspend its use and contact Neurovirtual Support Team for instructions on correct use and/or intervention for repair.

13.System Shutdown

To shut the system down, unplug the Power Cord AC cable from the electrical outlet.

14. Technical Specifications BWIII family

14.1. General

Features	Models and Specifications	
Total Channel Quantity	Basics	28
	EEG	36
	EEG Plus	50
	PSG	37
	PSG Plus	50
AC Channels (qty)	Basics	23
	EEG	31
	EEG Plus	36
	PSG	24
	PSG Plus	36
DC Channels (qty)	Basics	0
	EEG	4
	EEG Plus	8
	PSG	8
	PSG Plus	8
Impedance Check	Basics	- By Software
	EEG	- By button and LEDs - By Software
	EEG Plus	
	PSG Plus	
	PSG	
Oximeter channel	Basics	NO
	EEG	NO
	EEG Plus	Optional
	PSG Plus	YES (SpO2, BPM and Plethysmography signal)
	PSG	YES (SpO2, BPM and Plethysmography signal)
Flash Stimulator	Basics	YES (LED Technology)
	EEG	YES (LED Technology)
	EEG Plus	YES (LED Technology)
	PSG Plus	YES (LED Technology)
	PSG	NO
Intended to Use	Basics	EEG
	EEG	EEG
	EEG Plus	EEG *Upgradeable for PSG
	PSG	PSG
	PSG Plus	EEG and PSG
Pressure Transducer built in. 0 to 1 PSI	Basics	NO
	EEG	NO
	EEG Plus	Optional
	PSG	YES
	PSG Plus	YES
PSG Head Box	Available for PSG and PSG Plus models	
EEG Head Box	Available for EEG plus model	

Low Frequency Filter	Adjustable by software. 0.01-100Hz
High Frequency Filter	
Notch Filter	50 o 60 Hz
Sensitivity Range	1μV/mm - 1000μV/mm
Software	BWAnalysis
Essential performance IEC 60601-1 (Item 4.3)	The essential performance of the BWIII family is characterized by amplified signal reproduction. During the immunity tests, the parts used (positive and negative inputs of the amplifiers) must remain in short-circuit. In this condition, imposed by the IEC 60601-2-26 standard, the signal acquired by the BWIII Family consists of an isoelectric signal which must be observed and maintained before and after electromagnetic disturbances, following the evaluation criteria below.

***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. Analog/Digital Converter Characteristics.

Characteristics	**Values**
Resolution:	16 Bits
Conversion time:	15μs
Data flux:	Microprocessor
Sample rate:	Up to 2048 Hz
Hardware Gain:	500
Deblock:	YES

14.3. Amplifier Input Characteristics.

Characteristics	**Values**
Frequency response	0,01Hz to 100Hz
Storage Rate	Up to 512 Hz
AC channels Input Range	2000 μVpp
DC channels Input Range	-5Vdc to +5Vdc
Flash Stimulator	LED lights
AC Channels connector type	Touch Proof 1.5mm
DC Channels connector type	P2 - 3.5mm
Transducer pressure connector type	Luer Lock
Signal Noise	< 1μV RMS.
Noise – Referential Input	< 1 μVRMS (Input Referring)
Noise – Bipolar Input	< 1 μVRMS (Input Referring)
Input Impedance	> 100MΩ per input (> 200MΩ per channel)

Calibration Signal	0,5Hz, 100µVpp Square Wave
Signal reproduction precision	+- 20% precision in 2Hz/2mVpp and 6Hz/1mVpp *verified with the printed signal
Common mode rejection	>80 dB in 50/60 Hz
Digital filter – rejects track	50 / 60 Hz
Digital Filter Low frequency	Adjusted via software per channel 0 Hz to 100Hz
High-frequency digital filter	Adjusted via software per channel 0 Hz to 100Hz

14.4. Power Supply Characteristics

Characteristics	**Values**
Input Voltage (AC)	100VAC or 240VAC +/- 10%
Frequency	50-60 Hz
Consumption	0,23 A @ 120 VAC 0,16 A @ 230 VAC
Output Voltage (DC)	+5VDC
Ripple Vpp Max	50mV
Certification	Approved by UL, CSA and EN standards.
Isolation	Double and reinforced (IEC 60601-1, BF type)
Classification	Class II

This Power Supply should only be used in BWIII family equipment. No other power supply can replace the original power supply provided by the manufacturer, as only it has been tested to ensure patient and user safety.

14.5. Communication Characteristics.

Communication through RJ45 Ethernet TCP / IP port.
Recommended IP address for the network card: 192.168.100.1
IP address (default) of amplifiers: 192.168.100.3

The 9.84 feet (3 meter) Ethernet cable used for communication between the BWIII equipment and the microcomputer, with crossover connection (standard: T568A at one end of Ethernet cable and the T568B at the other end - RJ45 standard connector) is part of the equipment.

We do not recommend the use of cables out of specification. Not using them could increase the levels of EMC emission and a reduction of electromagnetic immunity.

14.6. Dimensions

Power Supply Module

Length (inch)	Width (inch)	Height (inch)	Weight (g)
3.2	1.6	1.6	150

Amplifier Module

Length (inch)	Width (inch)	Height (inch)	Weight (g)
5.7	10.7	2.2	950

Flash Stimulator Module

Length (inch)	Width (inch)	Height (inch)	Weight (g)
4.8	3.6	1.4	140

Remote Head Box Module

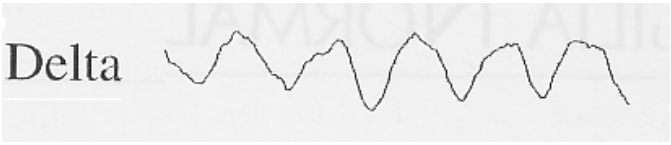
Length (inch)	Width (inch)	Height (inch)	Weight (g)
7.8	4.7	1.2	250

15.Physiological signals that the equipment can show.

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

Delta Waves:

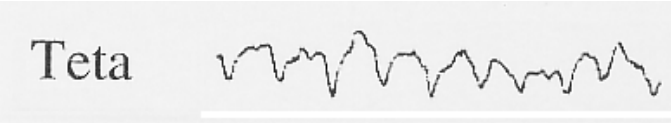
Example:



Characteristics:
Frequency: < 4 Hz

Theta Waves:

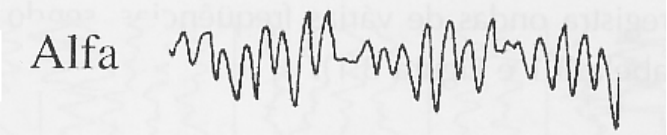
Example:



Characteristics:
Frequency range: 4-8 Hz

Alfa Waves:

Example:

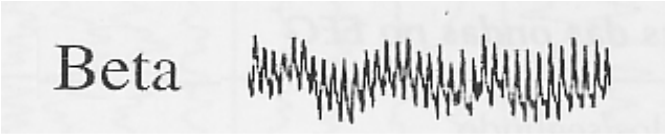


Characteristics:
Frequency range: 8-13 Hz

Beta Waves:

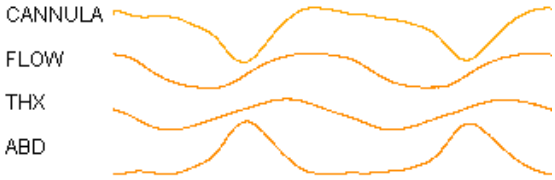
Example:

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:

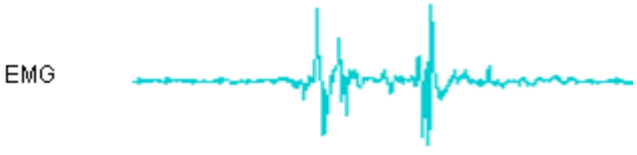
Example:

Electromyography (tibia):

Example:

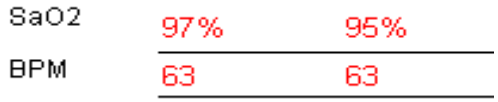
Electromyography (Mentonian):

Example:



Oximeter (Oxygen Saturation and BPM):

Example:

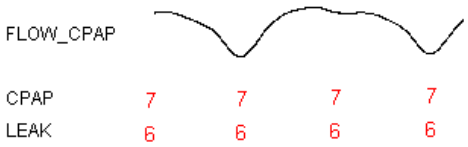


Body position:

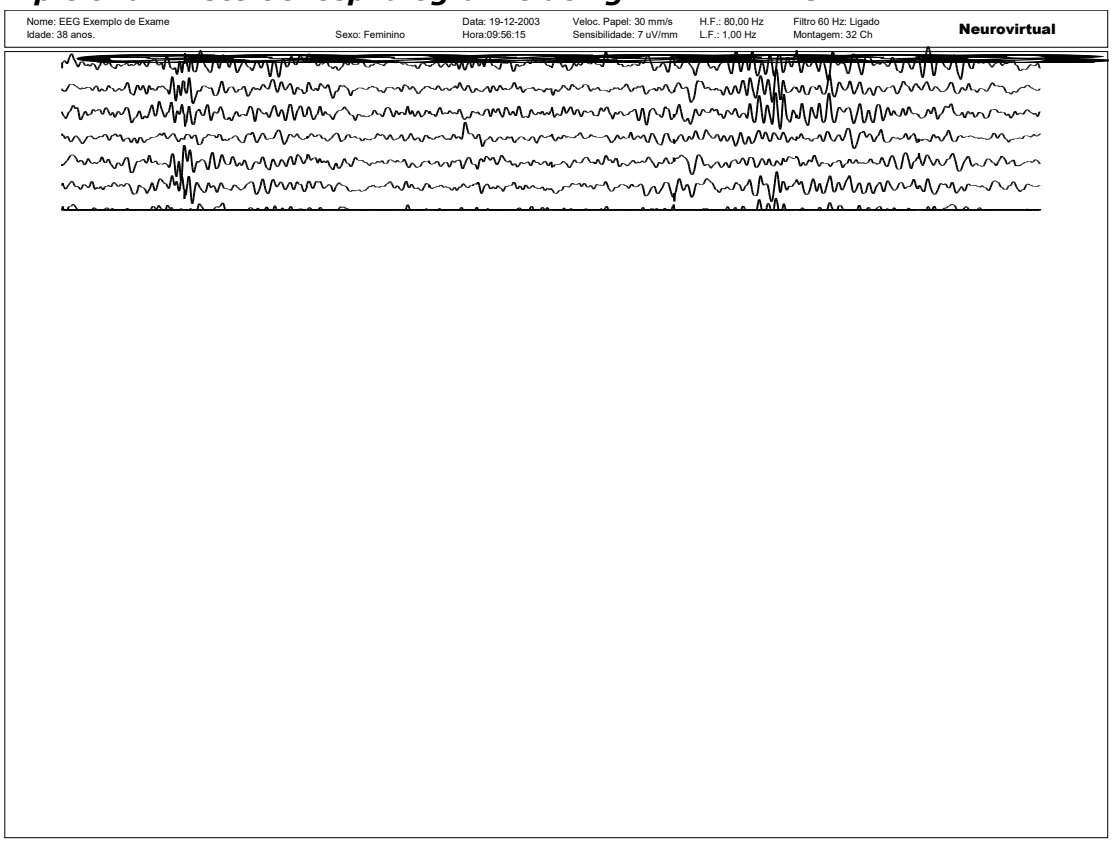
Example:

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

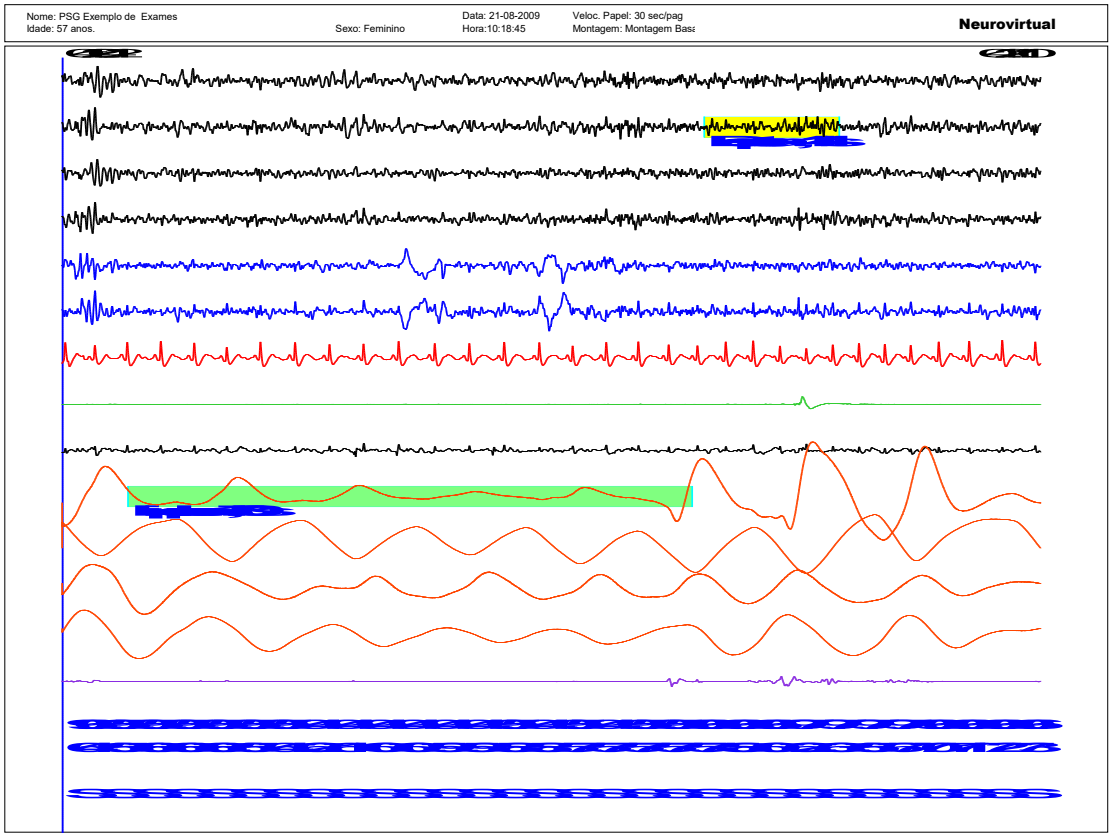
Example:



Example of an Electroencephalogram tracing – BWIII EEG:

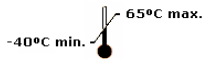
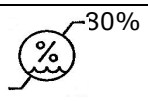
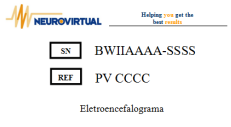


Example of a Polysomnography tracing – BWIII PSG:



16. Handling, Packing, Transport and Preservation Specifications

Every BWIII is supplied with a small, cushioned suitcase for transport, which provides a protection guarantee 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:

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. * *
	Identification Label containing: - Manufacturer's Brand Logo: Neurovirtual - S/N: Serial Number - SKU: Product Reference Code - Technical Name of the Equipment: Electroencephalogram/Polysomnogram

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

17. Operation and Environmental Specifications

17.1. Power Requirements

BWIII Power Supply

Input Voltage	100Vac - 240Vac +/- 10%
Network Frequency	50 or 60 Hz

Note: If you are unsure about the outlet to be used, call a trained electrician to check your electrical network.

This power supply is intended for use only in BWIII family equipment.

BWIII Amplifier Module

Input Voltage	+5Vdc

To power the BWIII amplifier module, No use a power supply other than the one provided by Neurovirtual

17.2. Environment Requirements

	Temperature	**Unit**	**Atmospheric pressure**
Operation	0°C to 40°C	20% to 80% RH	70 to 102 KPa
Storage	-40°C to 65°C		

Do not operate the BWIII family equipment 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 BWIII family of equipment (Parts and Accessories) does not need to be sterilized since they are Non-invasive use, non-sterile.

20. Pieces that touch the patient's skin

For those pieces and accessories that touch with the patient, we recommend them to comply with ISO 10993-1, ISO 10993-8 standard for the biocompatibility guarantee.

21. Disposal

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 BWIII 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 an act, which is the client's express responsibility and initiative. There is no restriction regarding the disposal in public landfills, however, with environmental awareness, Neurovirtual can offer an adequate disposal for those products that it manufactures.

22. Preventive and Corrective Maintenance and Calibration

22.1. Lifetime

The lifetime of equipment BWIII 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 warranty 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. Calibrations

The BWIII family 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.

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.

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 be identified 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 of the interference, please contact Neurovirtual Customer Service 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 BWIII family equipment. Avoid the use of such equipment in the vicinity of BWIII equipment (models: BWIII EEG and BWIII PSG).

Environments close to equipment such as Magnetic Resonance, Tomography, X-ray, equipment operating at high frequencies and high sources of electromagnetic emission (EMC) can cause the BWIII family equipment to suffer interference (easily detected by the operator because they differ from the physiological electrical patterns). However, the use in these environments is not risky for the operator or the patient. In case there is any deficiency during the use in these environments, we recommend the BWIII family equipment to be re-oriented.

BWIII family Equipment can be connected to public power grid or the electrical network of hospitals because it does not emit high levels of electromagnetic emissions.

The use of accessories other than those specified in such User Instructions might result in increased emissions of electromagnetic emission (EMC) or decreased immunity.

23.3. Equipment that can be connected to the Amplifier Module of BWIII

We ask our clients to ask for orientation from Neurovirtual Technical Support before connecting any equipment (Electromedical Active) to any of the BWIII Modules to ensure its correct compatibility and operation, thus ensuring operator's and the patient's safety.

Equipment such as CPAP, BiPAP and VPAP (ventilators) can be connected to the equipment model BWIII PSG through the DC input (isolated inputs), if they are electrical equipment certified by the electrical safety standards (IEC 60601-1 series). However, we ask customers to get in touch with the Neurovirtual Customer Service to obtain the list of approved devices, as well as Instructions and Recommendations for a perfect and safe connection.

Any electromedical equipment that is not certified (assets) should not be connected to any of the BWIII Modules without written consent from Neurovirtual.

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 BWIII simultaneously with high frequency surgical equipment.
d) Avoid stacking the BWIII 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 BWIII, including cables specified by the manufacturer. Otherwise, performance degradation of this equipment may occur.

23.6. Tables and guidelines on Electromagnetic Emissions - EMC

Below are the tables containing important information regarding electromagnetic compatibility.

Ref.: IEC 60601-1-2 - Table 201

Guidance and Manufacturer's Declaration – Electromagnetic Emission – EMC – for all EQUIPMENTS and SYSTEMS (VER 6.8.3.201 a) 3).

Guidance and manufacturer's declaration – Electromagnetic Emission - EMC		
The BWIII family equipment is intended for use in the electromagnetic environment specified below. The customer or user of BWIII family equipment should ensure that it is used in such an environment. **IMMUNITY pass/fail criteria - Professional facility environment (C)**		
Emissions test	**Compliance**	**Electromagnetic environment guidance**
RF Emissions IEC CISPR11	Group 1	The BWIII family equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions ABNT IEC CISPR11	Class A	The BWIII family equipment II is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic and hospital purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Ref.: IEC 60601-1-2 - Table 201

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS (VER 6.8.3.201 a) 6)

Immunity Tests for the Electromagnetic Environment Compliance - Guidelines

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The BWIII family equipment is intended for use in the electromagnetic environment specified below. The customer or user of BWIII family equipment should ensure that it is used in such an environment. **IMMUNITY pass/fail criteria - Professional facility environment (C)**			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+- 8 kV contact +- 15 kV air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	±1 kV 100 kHz repetition rate	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±2 kV	Complies	Mains power quality should be that of a typical commercial or hospital. environment.
Voltage dips, short interruptions and	< 5 % UT	Complies	If the user of the BWIII

voltage variations on power supply input lines IEC 61000-4-11	(>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec		Family equipment requires continuous operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery, considering that such equipment comply with the norms of electrical security / appropriate certification.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	Complies	Power frequency magnetic fields 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 204

Guidance and manufacturer's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING (ver 6.8.3.201 b)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The BWIII family equipment is intended for use in the electromagnetic environment specified below. The customer or user of BWIII family equipment should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 V 0,15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	[3]V Complies	Portable and mobile RF communications equipment should be used no closer to any part of the BWIII Family equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d= [1,2] √P d= [1,2] √P 80 MHz to 800Mhz d= [2,3] √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
Radiated RF	10 V/m		

IEC 61000-4-3	80 MHz to 2,7 GHz 80 % AM at 1 kHz	[3] V/m Complies	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 206

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING (ver 6.8.3.201 b)

Recommended separation distances between portable and mobile RF communications equipment and the BWIII.			
The BWIII family equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BWIII family equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BWIII family 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 d= [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 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

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.

24.Electrostatic Discharge (ESD) Training

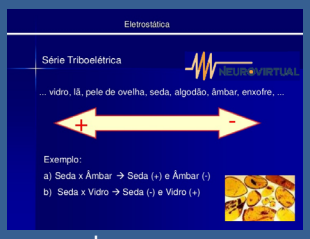
Note: For contact with connectors identified with the ESD warning symbol you must follow the ESD training topic in this manual, including Clinical Engineering / Biomedical / Health Personnel.

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

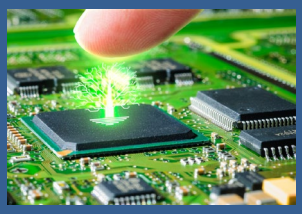
All materials (Insulators and Conductors) are sources of ESD. They are grouped together and known as the triboelectric series, which defines the materials associated with positive or negative charges.



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 Solutions

25.1. Failure connecting to the data server.

1st Check if the equipment is correctly connected to the electrical network.
2nd Check if the equipment has its Ethernet communication cable correctly connected to the computer.
3rd Check if the network connection IP address is correct (192.168.100.1).
4th Check if the green and orange lights, close to the Ethernet connection are on.
5th Check "Control Panel ➔ network connections" if the network connection used is enabled.
6th Check if the driver of the computer Ethernet card is correctly installed.
7th Check if the Ethernet communication cable (crossover, standard: T568A at one end and T568B at the other).

25.2. High-Frequency Interferences "Bold Trace".

1st Check if the outlet being used is 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 Green Light is not lit.

1st Check if the source is connected to the electrical grid.
2nd Check if the source is connected to the amplifier module.

25.4. Photo-Stimulator (Stimulator Flash) does not light.

1st Check if the Flash Stimulator communication cable is connected to the EEG Amplifier Module and Flash Stimulator.
2nd Check if there is no damage to the Flash Stimulator Cable Communication.
3rd Check the integrity of the pins connector.

25.5. Interruption of electrical power system

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.

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

Any perception or suspect of abnormal functioning, we recommend the operator to immediately get in touch with Neurovirtual Customer Service 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©