

GENERAL INFORMATION

FCCID: 2A223-NNPRECV1

1.1. Product description



NEURONAUTE®
The new generation of connected EEG

An EEG acquisition system to:

- Simplify the application of an EEG headset
- Record an EEG study in inpatient or outpatient settings
- Remotely monitor and interpret EEG studies

1 Set up 2 Monitor 3 Review

Adaptable

- Routine EEG
20 minutes
- Prolonged EEG
Up to 72 hours
- Emergency EEG
- With or without video

Connected

- EEG trace streaming on the NEURONAUTE® Mobile APP
- EEG study interpretation via the CLOUD Platform

Mobile

- Eases EEG study in ambulatory and at the patient's bedside
- Small and lightweight

Compatible

- With single-use ICECAP® Bioserenity's EEG net
- With the other electrodes products on the market
DB25 connection, gold cups and subdermal EEG needles*

3 interchangeable adapters



ICECAP®

For the ICECAP® Bioserenity's EEG net



DB25

For all DB25-compatible EEG headset on the market



Gold cups and subdermal needles*

For the gold cups and subdermal* needles connections : 21 unipolar EEG channels, 2 references, 2 grounds
4 additional unipolar channels

*Soon available

BIO SERENITY



LCIE

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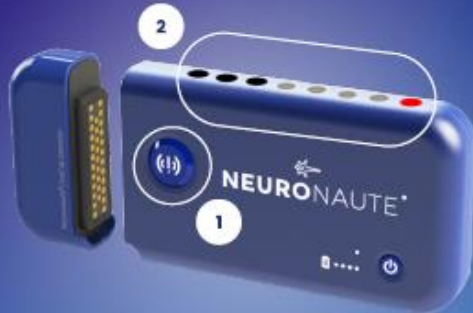
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Technical specifications



Lifetime	Up to 72h without interruption
Weight	Around 200 g (battery included)
Size	155 mm x 73 mm x 23 mm
Chargers	100 - 240 V, 50-60 Hz
Battery	More than 24 hours of lifetime
Wifi & Bluetooth	Automatic data transfer to the web platform
EEG connectors	3 adapters*

*Gold cups and subdermal needles adapter soon available

1

Event button

Notifies patient's clinically-relevant events and activities: symptoms, feelings, discomfort

2

Additional channels

1 ECG channel
4 bipolar channels
3 unipolar channels



Monitoring and Diagnostic softwares



Acquisition

Mobile application

- Unlimited and customizable montages
- Video feedback via a connected HR/IR camera/router: Bioserenity-Link
- Integrated photic stimulation and hyperventilation protocols
- Simplified annotation system
- Collaborative monitoring

Review

Web platform

- Electronic Medical Record (EMR)
- Secure HDS access (Health Data Hosting)
- Remote analysis of EEG study
- EEG-video synchronization
- Spike&Seizure AI-based algorithm



Accessories



Bioserenity-Link

Camera device
(IR et HD) / mobile Wi-Fi hotspot



Holding band

Ergonomic textile band to secure
EEG recording NEURONAUTE®




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1.2. Antenna description


The product uses two antennae for wireless communications :

- One antenna is dedicated to BLE (Bluetooth Low Energy 5.0) communication. It is a chip antenna integrated into the BLE module referenced ISP1507.
- One antenna is dedicated to Dual Band WiFi communication. The WiFi operates on 2.4GHz and 5GHz bands. The antenna is a PIFA antenna model Laird 001-0016.
- The grounding of antennae is made of the electronic circuit board ground plane. The device is not connected to ground since it is body-worn and battery-powered. Nevertheless, the ground of the device is AC-coupled through a capacitor and connected to the patient through a medical device patch electrode.



FlexPIFA

3-dBi Antenna with MHF1/U.FL Cable
2.4 GHz/5.5 GHz



FEATURES AND BENEFITS

- Dual band antenna – 2.4 GHz and 5.5 GHz
- Quick and easy installation
- Adhesive holds to surface during humidity exposure and hot/cold cycles
- RoHS-compliant

- Can be installed in the following ways:
 - On different non-conductive surfaces and thicknesses
 - Near metals or the human body
 - On flat or curved surfaces

SPECIFICATIONS		
Frequency (MHz)	2400 - 2480	4900 - 5900
Peak Gain (dBi)	+2.5	+3.0
Average Gain (dBi)	> -2.5	> -3.4
VSWR (MHz)	<2.5:1	<3.0:1
Impedance (Ω)	50	
Antenna Type	Flexible Planar Inverted F (FlexPIFA)	
Polarization	Linear	

1.3. Tested System Details

Equipment information: (Declared by provider)

Apparatus Description	EEG			
Type of power source:	<input checked="" type="checkbox"/> AC power supply	<input type="checkbox"/> DC power supply	<input checked="" type="checkbox"/> Battery (Select Type)	
Test source voltage:	Vmin-Vmax:	<input type="checkbox"/> 120 - 240 V / 50 - 60 Hz	<input checked="" type="checkbox"/> 3.7 VDc	
Operating Modes	Mode 1	electrocardiogram mode on battery (continuous acquisition)		
	Mode 2	battery charge mode		
	Mode 3	-		
	Mode 4	-		
Highest internal frequency (PLL, Quartz, Clock, Microprocessor...):	F _{Highest} :		160	MHz

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LCIE**Inputs/outputs - Cable:**

Access	Inputs / Outputs	Type	Length used (m)	Declared <3m	Shielded	Under test	Comments
Power supply	Output	L1-N	2	Yes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Battery charger
Data	Input	Others	1	Yes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	IceCap 2
Data	Input	Others	1	Yes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	BAS-00534

1.4. Test Methodology

Both conducted and radiated testing were performed according to the procedures in ANSI C63.4 or/and ANSI C63.10, FCC Part 15 SubPart 15B and 15C.

Radiated testing was performed at an antenna to EUT distance of 10 meters. During testing, all equipment's and cables were moved relative to each other in order to identify the worst case set-up.

1.5. Test facility

Tests have been performed: **March 9, 2023**

This test facility has been fully described in a report and accepted by FCC as compliant with the radiated and AC line conducted test site criteria in ANSI C63.4 or/and ANSI C63.10.

This test facility has also been accredited by COFRAC (French accreditation authority for European Union test lab accreditation organization) according to NF EN ISO/IEC 17025, as compliant with test site criteria and competence in 47 CFR Part 15/ANSI C63.4 and EN55032/CISPR32 norms for 89/336/EEC European EMC Directive application. All pertinent data for this test facility remains unchanged.