

## User Manual and Software

To download the software and latest user manual go to: <http://www.biosignalsplux.com/learn/documentation>

## Intended Use

Research Use Only, not for Use in Diagnostic Procedures. biosignalsplux products are intended for use in life science education and research applications; they are not medical devices nor are they intended for medical diagnosis, cure, mitigation, treatment or prevention of disease.

## Contraindications

- Do not use this device in patients with implanted electronic devices of any kind, including pace-makers, electronic infusion pumps, stimulators, defibrillators or similar
- Do not apply electrodes over damaged skin.
- Do not use the system in patients with allergies to silver.

## Warnings and Precautions

- See all the documentation that came with the system for instructions on safety and precaution.
- See the User's Guide for detailed instructions about bioPLUX and sensors.
- Always keep the device and its accessories dry. The presence of liquid contact can compromise the safety operating characteristics of the system. Do not immerse the sensors or the bioPLUX, nor clean with liquid or with abrasives. Read the manual to learn how to clean up the bioPLUX and sensors.
- Fragile. Handle with caution. Do not expose the device or accessories to high accelerations and vibrations.
- Do not use this equipment in an environment with operating magnetic resonance imaging devices (MRI).
- Do not use the device near the fire or in potentially explosive atmospheres, such as atmospheres with flammable gas.
- The use of damaged accessories or not recommended by PLUX may result in changes to the technical characteristics and features of your bioPLUX. Use only approved accessories purchased from PLUX or an PLUX agent.
- Use only the detection surfaces provided on the packaging of the system or acquired from PLUX or an PLUX agent.
- The detection surfaces provided are single-user and disposable.
- Use only the transformer supplied with the package of the system or purchased from PLUX or an PLUX agent.
- Inspect the sensors on a regular basis to ensure that they remain in good working order.
- If you experience any kind of discomfort or skin irritation when using the clinical bioPLUX, discontinue using it immediately.
- Do not place the device in the microwave.
- If the bioPLUX system or accessories reach uncomfortable temperatures, turn off the bioPLUX immediately and contact Technical Support.
- Do not insert objects into the holes of the device, it may affect the operating characteristics, and safety.

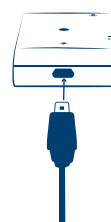
- Do not open the bioPLUX or its accessories. The repair of the same should be only done by properly authorized PLUX personnel.
- By connecting the bioPLUX to the transformer for batteries recharge, place the device so that the cable is free, away from places where it can be walked on or damaged. Make sure the cable does not obstruct the passage of people.
- Use the sensor cables with extreme caution to avoid risk of strangulation.
- The bioPLUX may suffer or cause interference to other equipment with radio receiver / transmitters, even those that comply with international standards. Keep a safe distance between the bioPLUX and other devices to ensure their proper functioning. The bioPLUX should not be used in noisy environments in relation to RF radiation which can cause communication failures with the computer.
- If your bioPLUX stops working properly, do not use it until you send it for repair by qualified PLUX personnel.
- Complies with Requirements put forth by the Medical Device Directive 93/42/EEC. Class I device, Annex VII.
- Type BF Device (IEC 60601-1)
- Isolated device. (Class II, EEC 60601-1)
- In compliance with the European Directive on Waste of Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not deposit the bioPLUX in the trash. Instead, contact your Reseller or PLUX for properly recycle your bioPLUX. You can get information about the contact nearest to you in <http://www.plux.info>.
- Date of Manufacturing (appears on product packaging).
- Serial Number (appears on product packaging and bioPLUX).
- The bioPLUX device should be used at temperatures between 10° and 40°C and stored at temperatures between 10° and 30°C because it has rechargeable Li-Ion batteries and detection surfaces with limitations on operating temperatures. Operating or storing the device outside this range may compromise the integrity and security of it.
- This equipment complies with International Standard EN 60601-1-2:2001 for electromagnetic compatibility for medical equipment and systems. This pattern is used to provide reasonable protection against harmful interference in a typical medical environment. However, the proliferation of devices using radio frequencies can cause interference that can reach the limit to prevent the proper functioning of your bioPLUX. Keep your equipment installed in accordance with their instructions.
- Use bioPLUX within the limits of communication with the receiving equipment of the wireless signal: in a radius of approximately 10 meters for the Bluetooth connection. Working with the device outside of this range of communication can lead to data loss and faulty communications. See user manual for more details.

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Questions? Contact us at [support@plux.info](mailto:support@plux.info)

## 1 Charge your Device

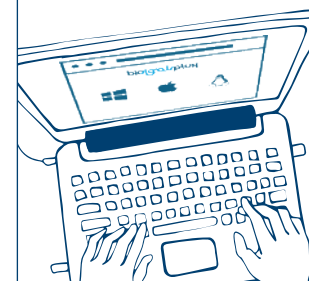
Make sure your OpenBAN has enough battery to complete a task before using it. While charging, the charging LED will turn green and turned off automatically when the battery is fully charged.



To fully charge your OpenBAN's battery connect it to the charger provided with your kit charging LED turns off.

## 2 Download OpenSignals

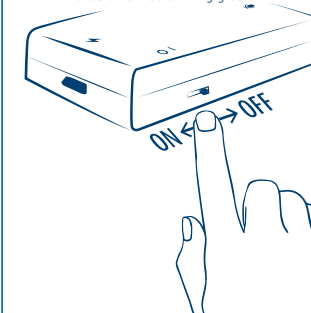
Go to our website [www.biosignalsplux.com/software](http://www.biosignalsplux.com/software) to download and install the software for your operative system.



The software will issue notifications whenever new releases and improvements are available.

## 3 Turn On the Device

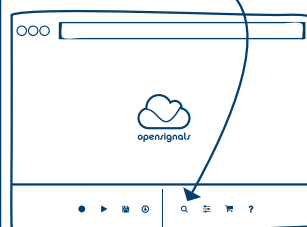
Slide the switch to the ON position. The LED at the centre of your OpenBAN should now be blinking green.



You will find detailed information about the different states indicated by the light in the user manual or data sheet.

## 4 Configure the Device

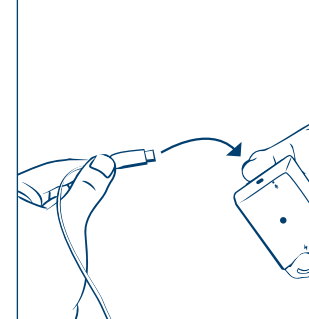
To find and configure your new device in OpenSignals, click the button.



Bluetooth settings depend on your OS. Please refer to the device manual.

## 5 Connect a Sensor

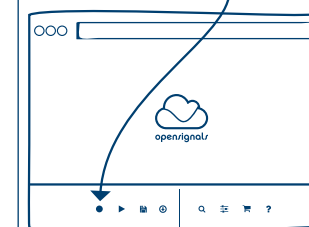
Connect your sensor to the analog input of your OpenBAN.



Some sensors require the use of electrodes which need to be positioned correctly. Please refer to your sensors datasheet for more information.

## 6 Start Acquiring Data

To start a data visualization and recording session in OpenSignals click the button.



After stopping your recording, data can be saved through the button; please refer to the OpenSignals manual to learn about all its features.

Questions? Contact us at [support@plux.info](mailto:support@plux.info)

## EMG



High performance bipolar sensor with low noise characteristics for seamless muscle data acquisition.

## EEG



Ideal for evoked potentials and other localized EEG applications; provides a single channel per sensor.

## ECG



Single-lead local differential bipolar sensor, designed for improved user acceptability.

## PZT



Affordable piezoelectric sensor with adjustable chest strap... perfect for basic sensing in low mobility settings.

## FSR



Thin film membrane force sensor... perfect for minimally intrusive setups.

## EDA



Discrete form factor, enables sympathetic nervous system monitoring at the hand or foot palms.

## TMP



High resolution medical-grade sensor, especially designed for body temperature monitoring.

## BVP



Transmissive sensor with infrared emitter and integral finger clip for low noise and easy application.

## RFID



The perfect accessory for synchronous recording of biosignal data and ID-mappable events.

## RIP



Inductive sensor with adjustable chest strap... high performance even in dynamic settings.

## VAG



This sensor is especially designed for high performance pelvic floor EMG data acquisition.

## Load Cell



Precision sensor for handgrip, traction, and other heavy duty force sensing applications.

## Electromagnetic emissions

See the table below for specific information regarding the OpenBAN's electromagnetic emissions.

| Emissions test                                       | Compliance | Electromagnetic Environment - Guidance                                                                                                                                                                  |
|------------------------------------------------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF Emissions   CISPR 11                              | Group 1    | This device must emit electromagnetic energy in order to perform its function. Electronic equipment near it, may be affected.                                                                           |
| RF Emissions   CISPR 11                              | Class B    | This device is suitable for use in all establishments, including domestic and those directly connected to low-voltage energy public network supply which supplies buildings used for domestic purposes. |
| Harmonic Emissions   IEC 61000-3-2                   | A          |                                                                                                                                                                                                         |
| Voltage fluctuations / Flicker Emission IEC 1000-3-3 | Conforms   |                                                                                                                                                                                                         |

**Table 1: Electromagnetic Emissions**

This device is suitable for use in all establishments, including domestic and those directly connected to low-voltage energy public network supply which supplies buildings used for domestic purposes.

## Technical specifications

| OpenBAN device |                                                                                                                                                                                                                                                   |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Specifications | Analog Ports: 1 generic input<br>Resolution: up to 16-bit<br>Sampling Rate: up to 1000Hz (per channel)<br>Communication: Bluetooth Class II<br>Range: up to ~10m (extendable)<br>Battery Life: ~18h streaming<br>Size: 54x35x15mm<br>Weight: 33gr |

## Charger | FW7600/09 charger with universal battery

|               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Input         | 100 to 240 V~, 50 to 60 Hz, 0.5A                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Output        | 5V, 1.2A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Conforms with | Medical grade charger safety approvals and certifications: UL60601-1, CUL TO 22.2 no. 601.1-M90, INNOVA BAUART to EN60601-1, CE CLASS II, PSE to J60601-1, CB REPORT TO IEC 60601-1:2005 (3rd edition), AS/NZ to 60601-1, C-TICK to EN55011, CCC<br>CE marked: tested to comply with EN61000-3-2, EN61000-3-3, EN60601-1-2 2001, INCLUDING EN61000-4-2, EN61000-4-3, EN61000-4-4, EN61000-4-5, EN61000-4-6, EN61000-4-8, EN61000-4-11. Complies to section 301 of energy independence and security act. |

## Maintenance recommendations

### Cleaning

- The bioPLUX equipment and sensors should be visually checked before each use to ensure that no mechanical damage has occurred.
- The bioPLUX equipment and sensors (including the cables) should be cleaned with a slightly damp cloth or suitable absorbent paper, ensuring that no liquid enters the equipment or sensors. Do not use detergent or any type of cleaning liquid.
- Clean the bioPLUX equipment separately from the sensors
- Do not clean or re-use detection surfaces. They are only suitable for single use, and should be disposed of after usage.

### Transport and storage

- When the equipment and accessories are not being used, they should be stored in the original box in a dry place.
  - Relative humidity: up to 95% with no condensation
  - Ambient temperature: 10°C to 30°C
  - Atmospheric pressure: between 500 hPa and 1060hPa
- Whenever the equipment needs to be transported, it should be placed in the original box, since this was designed and tested to ensure the equipment and accessories are securely stored;
- Take care while handling the bag and avoid dropping it, since the device is not shock-proof and should not be placed under stress or sudden acceleration.

PLUX can not be held responsible if the system is transported outside it's original box or in any other type of unsuitable packaging, which may invalidate the guarantee.