VIDA APP
SENSOR BAND
HAIR BAND AT THE FOREHEAD
EEG+SLEEP+MENTAL HEALTH MONITOR
MUSCULOSKELETIC EMG MONITOR

What is Vida-App Sensor Band?

The VidaApp™ Sensor Band is composed of a neoprene fabric material that integrates electrodes and a 36mm diameter miniature electronic equipment designed for monitoring people who want to improve their mental and musculoskeletal health. This device is placed on the forehead, and uses non-invasive electronic technology to perform biometric readings of people. The main vital signs measured by the VidaApp™ Sensor Band are:

1. **Electroencephalogram (EEG)** of up to 8 electrodes, which allows to obtain the electrical signal of the brain.	3. **Touch-less body temperature** using an infrared sensor with an accuracy of 0.03 °C.
2. **Electromyograma (EMG)** with possibility of multiple electromyography of several muscles.	4. **Reflective Pulse Oximety,** with the ability to determine on the forehead, blood oxygen content and heart rate.

On the other hand, it has GPS and accelerometer to monitor the physical activity of the user (steps and km traveled), GPS geolocation and anatomical position (standing, sitting, lying down).

Who is it for?

Persons requiring a record of brain bioelectrical activity, during wakefulness or sleep, indicated for all kinds of cerebral dysfunction, especially in the symptomatic phase such as epilepsy, dementia, neurodegenerative diseases, cerebrovascular diseases, etc.

Electro partial encephalograms, for real-time alarm emission when detecting the onset of epilepsy seizures.

Safe driving control for drivers, pilots and operators of dangerous machinery, determining the moment of occurrence of the initial phases of sleep through the detection of REM sleep phases and the blinking speed alerting the drivers, operators and transport companies.

Electromyography for corrections of maxillofacial muscle abnormalities during the sleep process. Electromyography of specific muscle zones in real time (removal of dental splints).

System to improve the memory in normal people and Alzheimer's syndrome, using brain wave analysis in combination with external stimuli in real time. (Application under study).

Applications related to sports medicine.

How does it work?

VidaApp™ Sensor Band senses the vital signs and performs a first analysis (pre-alarm) of variables out of range, according to the limits established by the Medical Control Center. In case of an event, it is connected through low-energy Bluetooth with the mobile of the user, which communicates through the mobile network with the Medical Center, including the alarm data and the geolocation of the user, to determine an appropriate course of action.

For interior scenarios, such as a residence or a medical center, the VidaApp™ Sensor Band can dispense with the user's mobile phone to send the events and use the Solar Node VidaAppTM which acts as a collection node for several bands and displays a GSM / GPRS and low-energy Bluetooth gateway to connect to the Medical Control Center.
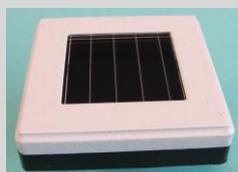
In a mobility scenario, the VidaApp™ Sensor Band can be a satellite device of the VidaApp Vest. The spirometer connects via Bluetooth with the VidaApp vest, which acts as a collection node to send the information to the Medical Control Center through a 3G modem integrated in the second PCB.

Mobile Application (doctor and patient user profile):

- Display of:
    - Vital Signs Panel.
    - Map with the position of the user.
    - Summary sheet of user data.
- Triggering of medical alarms:
    - Electroencephalography.
    - Electromyography.
    - Fever.
    - Hypothermia
    - High oxygen saturation: hyperventilation, anxiety.
    - Low oxygen saturation: chronic lung diseases, decompensation or asthma crisis, heart disease.
- Medical orientation.
- Control of medicines.
- Training plan (physical activity).
- Interoperability with clinical records (ISO 13606 / HL7).

Medical control center

- Follow up, control and monitoring reports.
- EEG and EMG Holter service informed.
- Configure alarms for the custom app.
- Control and follow up of continuous monitoring.
- Control and monitoring of physical activity.
- Control of the medical history and treatment of the patient.
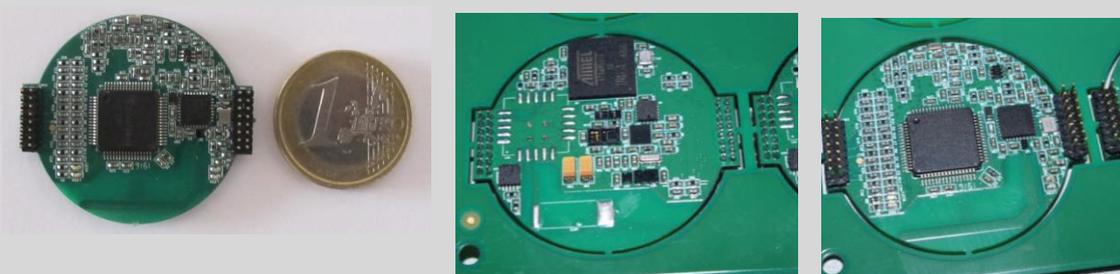
The VidaApp™ Sensor Band PCB shown in the photographs includes a (5.) **32b high performance microcontroller** with real time clock and perpetual calendar. This MCU allows pre-diagnostics of biomedical signals and their comparative analysis to perform early mental health alarms. This is possible by means of a system integrated in the same MCU that allows to make comparative recognition of biomedical patterns in real time. This system allows the generation of early alarms of parameters of EEG, EMG, blood oxygen, body temperature, mobility, as well as autonomous

recognition of REM phases, among other important parameters. The VidaApp™ Sensor Band also includes the following circuits:

6. **3-axis accelerometer** that detects body mobility, verticality, permanent use pedometer for obesity control, fall detection and unconsciousness.

7. **GNSS type GPS** with antenna integrated in the same PCB for geo location of people, including Geofencing. Determine the steps and kilometers traveled in combination with the pedometer.

8. **Low energy Bluetooth 4.0** communication with integrated antenna. This system allows communication with mobile phones equipped with an APP and serves as a collecting node for other wireless biometric sensors that can be installed in people, such as blood pressure monitors, spirometers and additional remote auscultation sensors for monitoring COPD processes.

9. Internal management of a **real-time clock (RTC)** for issuing alarms for medication reminders, and the broadcasting of voice messages in any language.

10. **Non-volatile 2Mb EEPROM memory** (250,000 characters), for the storage of biomedical data in holster mode, programming, biometric behavior patterns, voice messages, among others. This report may also be used to keep the complete medical records of the persons as well as the legal and general information of the same.

11. **Man-machine interface with 4 LED** indicators: 2 for instrument and 2 for battery (on load and full charge).

12. **Intelligent LIPO battery charging circuit** integrated in the PCB.

13. It is **IP67** which implies that it can be used under the shower and is dust resistant.

FACT SHEET

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Conformity assessment to request the CE mark in the Spanish Agency of Medicines and Medical Devices.
Considering the potential risks that may arise from their use, medical devices are grouped into four classes: I, IIa, IIb and III, applying decision rules based on the vulnerability of the human body and requires:

A. The preparation of a **Technical File**, composed of:
1) Documentation corresponding to the design and validation of the medical device (identification of essential requirements and related harmonized standards, risk analysis ...).
2) Results of electrical safety tests and electromagnetic compatibility.
3) Clinical evaluation of the product.
B. The documentation and implementation of a **Quality System**, based on the harmonized standard **ISO 13485** (Medical Devices. Quality management systems. Requirements for regulatory purposes).

This documentation is reviewed by an independent entity (Notified Body), which also audits the implementation of the quality system.

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