

VIDA APP CARDIO-PULMONARY VEST



MULTIPARAMETER MONITORING SYSTEM OF CARDIOPULMONARY BIOMEDICAL CONSTANTS

What is VidaApp Cardiopulmonary Vest?

VidaApp vest is a neoprene harness that monitors cardiopulmonary activity. It includes a miniature electronic device of 36mm diameter, designed to monitor the cardiovascular and respiratory function of people. The vest consists of a strap to the chest with straps, and uses electrodes and non-invasive electronic technology to perform biometric readings of people.

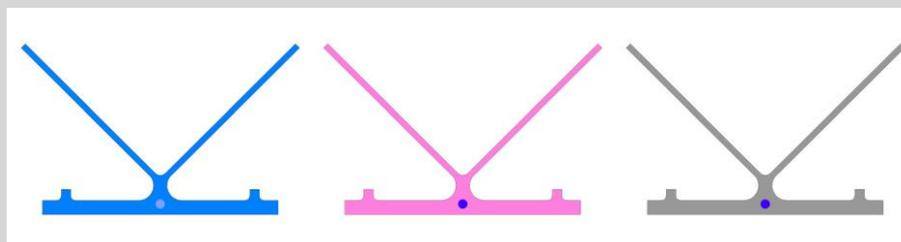
FACT SHEET



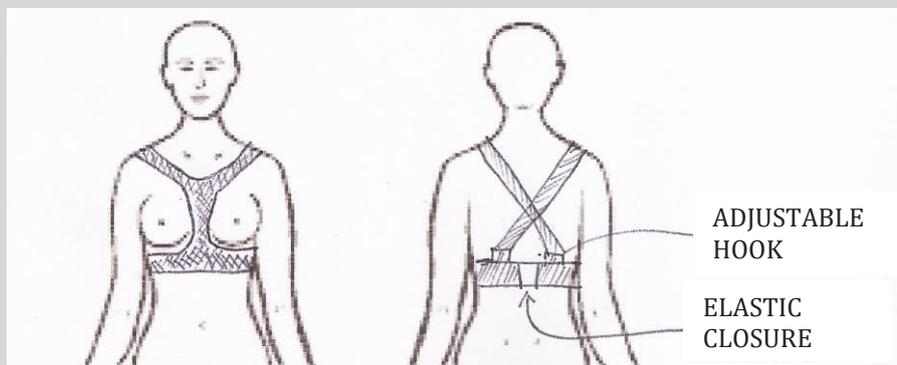
PCB 1 VIDA APP VEST



ELECTRODE PATCH Vs PCB OF VIDA APP VEST



SCHEME OF VIDA APP VEST



SCHEME OF VIDA APP VEST

Among the main clinical functions measured by the Vest we can indicate the following:

<p>1. Electrocardiogram (ECG) in 8-lead configuration allowing pre-diagnosis ability of symptoms related to heart malfunction such as the detection of arrhythmias, pre-infarctions, angina pectoris, among other cardiovascular diseases.</p>	<p>3. Impedance pneumonography: determines the respiratory rate measured in ventilations per minute. Helps to diagnose apnea, COPD, stress and other pathologies including alarms programmed under established parameters.</p>
<p>2. Pulse oximetry by reflection, with capacity to determine the oxygen content in blood and heart pulse</p>	<p>4. Touch-less body temperature through infrared sensor with an accuracy of 0.03°C.</p>

The printed circuit board (PCB-1) shown in the photographs includes a **(5.) High-performance 32b Microcontroller**, with real-time clock and perpetual calendar. This MCU allows pre-diagnostics of biomedical signals and their comparative analysis to perform early alarms of many cardiac conditions. 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 to generate early alarms of parameters of cardio, blood oxygen, body temperature, mobility, as well as autonomous respiratory frequency detection and apnea detection, among other important parameters.

This first board, includes also the following circuits and features:

<p>6. 3-axis accelerometer that detects body mobility, verticality, permanent use pedometer for obesity control, fall detection and unconsciousness.</p>	<p>9. 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.</p>
<p>7. GNSS type GPS with antenna included in the same PCB for geo location of people, including Geofencing. Determine the steps and kilometers traveled in combination with the pedometer.</p>	
<p>8. Man-machine interface with 4 LED indicators: 2 for instrument and 2 for battery (on load and full charge).</p>	

10. **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.

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

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

13. Use a **charging backpack** to replenish the internal battery power of the device without having to remove it to recharge it.

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

With an additional board (PCB-2) or implementing different components in PCB-1 the following premium functionalities can be implemented in the VidaApp Vest:

15. **12-lead ECG** for more comprehensive cardio diagnostics, this module would replace the 8-lead of the PCB-1 in miniature version.

16. **Remote auscultation** by means of an additional PCB of equal dimensions in the same box.

17. **Medication Reminder** and generator of pre-recorded voice messages by means of a microchip for the reproduction of messages stored in the EEPROM memory plus IP67 speaker with 300mW of audio power.

18. **GSM / GPRS communication, UHF radio and/or WiFi** included in an additional PCB or board that is connected to the already developed sensor board.

19. **EEPROM memory extensions (32Mb)**

20. **Vibration motor** for human-machine interface.

Applications

- As a real-time biometric multiparameter sensor for the use of people with chronic diseases related to cardio, obstructive pulmonary, hypertension, obesity, among others.
- Use in field hospitals and institutes that attend many people in critical condition, post-surgery, terminal patients or to monitor people in situations of catastrophes and epidemics.
- Work and sports medicine with real-time monitoring.
- Real-time sport players monitoring using the GPS GLONASS in the differential mode allowing to position players accurately to a few centimeters.
- Real-time biomedical constant sensor for soldiers on the battlefield, including determination of wound severity, triage, emergency voice communication, traceability, etc.

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Conformity assessment to request the CE mark in the Spanish Agency of Medicines and Medical Devices.

Taking into account 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. The vest product corresponds to class IIb (IIa if there is no pre-alarm / clinical feedback) 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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