VIDA APP SPIROMETER
BLUETOOH LOW ENERGY SPIROMETER

What is the VidaApp Spirometer?

The VidaApp™ Spirometer is a medical device used to measure the respiratory capacity of the lungs. This device is placed in the mouth and when blowing through the mouthpiece makes biometric readings of people's lung function. The main vital signs measured by the VidaApp™ Spirometer are:

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1. **Forced Vital Capacity (FVC)** is the maximum capacity to capture and expel air, under forced conditions.	2. **Maximum expiratory volume in the first second (FEV_1)** is the amount of air expelled during the first second of maximal expiration, performed after a maximum inspiration.

Who is it for?

The product is indicated for people with chronic respiratory diseases such as COPD, asthma, apnea, smoking and pneumonia.

How does it work?

VidaApp™ Spirometer device 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.
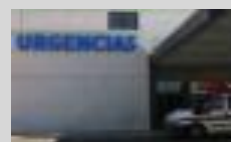
For interior scenarios, such as a residence or a medical center, the VidaApp™ Spirometer can dispense with the user's mobile phone to send the events and use the Solar Node VidaApp™ which acts as a collection node for several spirometers and displays a GSM / GPRS and low-energy Bluetooth gateway to connect to the Medical Control Center.
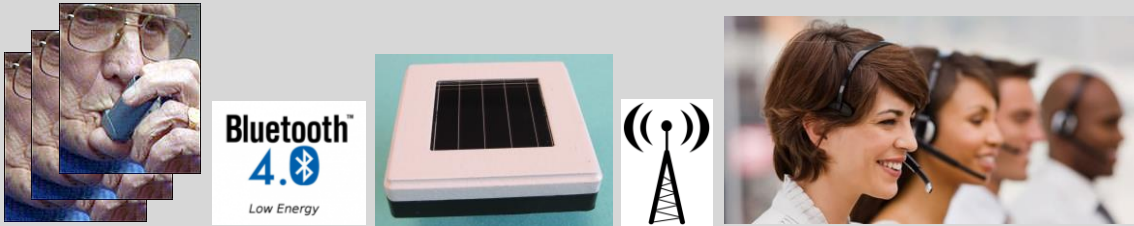
In a mobility scenario, the VidaApp™ Spirometer can be a satellite device of the VidaApp Vest. The spirometer connects via Bluetooth with the VidaApp vest, which acts as a collection node to send the information to the Medical Control Center through a 3G modem integrated in the second PCB.
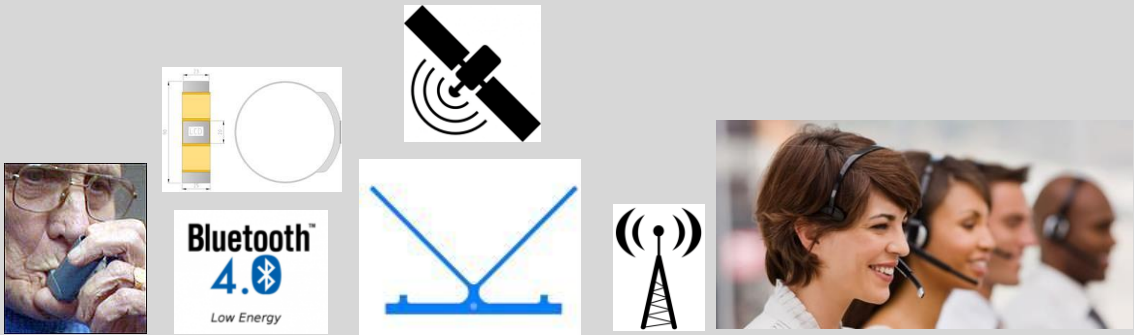
When using the VidaApp™ Spirometer in conjunction with the VidaApp™ Vest, the following variables of pulmonary activity are multiplied to be transmitted to pneumologists:

- **Spirometry**: Forced Vital Capacity (FVC) and Maximum expiratory volume in the first second (FEV_1).
- **Impedance pneumonography:** senses the respiratory rate in number of ventilations per minute.
- **Pedometer** to measure steps and km traveled.
- **GPS** for geolocation of the user in case of exacerbations.
- **Pulse oximetry by reflection,** with capacity to determine the oxygen content in blood and the heart pulse.
- **Panic button** to alert emergency services in case of exacerbations.
- **Body temperature.**
- **Therapeutic adherence:** control of the medication through the app.
- **Remote auscultation.** (Premium vest function requires second PCB).
- **Pre-recorded audio chips for medication reminder.** (Premium vest function requires second PCB).

On the other hand, the VidaApp™ Blood Pressure Monitor can be paired to VidaApp™ Vest as a third device providing blood pressure measurement (systolic and diastolic in mmHg) for the monitoring of people with respiratory diseases.

VidaApp Neumo Mobile Application (doctor and patient user):

- Display of:
  - Panel of Vital Constants.
  - Map with the position of the user.
  - Summary sheet of user data.
- Triggering of medical alarms:
  - Espirometry.
  - Breathing frequency.
  - Heart rate.
  - Temperature.
  - High oxygen saturation: hyperventilation, anxiety.
  - Low oxygen saturation: chronic lung diseases, decompensation or asthma crisis, heart disease.
  - Blood Pressure: systolic and diastolic.
- Remote auscultation.
- 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.
- Holter service informed.
- Personal support for anti-smoking program.
- 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.

Service Dynamics

These sensors emit data in continuous streaming and the information is stored and analyzed in real time. The development of a platform with a frontend adapted to the needs of the users, with a profile for the doctor that supervises and a profile for the patient is foreseen. A centralized database will be made up of patient information that will enable Big Data Analysis and reporting of mass behavior. An Android and iOS operating system app is expected to be developed so patients can view relevant information, provide information about their illness, and schedule medication alarms to improve therapeutic adherence.

Through the whole system, it is proposed the design of a remote monitoring service for patients with respiratory diseases that allows:

● Transform the access of the health of patients with COPD through information and communication technologies to improve their quality of life.
● Promote active participation and self-management of the patient in the care of their health.
● Establish predictive algorithms based on biometric data and offer preventive medicine services. Grouping, analysis and dissemination of data to physicians, to achieve a true personalized treatment when necessary. Construction of predictive models with techniques such as linear regression, generalized linear models, logistic regression and classification trees.
● Design personalized health plans according to the needs of each patient focused on a precision medicine.
● Use Big Data to improve system efficiency and costs and to aid clinical decision making in real time.
● Proactively manage health care using accumulated information to predict future events.
● Improve therapeutic adherence.
● Improve adherence to home-based respiratory rehabilitation plans based on home aerobic training supervised by physiotherapists and pneumologists.

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IMPORTANT NOTICE:

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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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