LifeVit Vital device validation, 2023. IEB Group, UPC

Biomedical Electronics and Instrumentation Group (IEB) - ETSETB (UPC)

INFORMED CONSENT FORM

Name and Surname: _____ Num.: ____
Email: _____ Birth Date (ddmmyyyy): ____/____/_____
Phone Number:(+__) _____

***Explanation**:* The overall objective of this assessment is to validate the heart rate and oxygen saturation record of the "*LifeVit Vital*" device. The device is an activity bracelet similar to others on the market such as "*Fitbit*" or "*Apple Watch"*. The study should take us about 1 hour. To achieve sufficient data and to validate the device we will need you to be connected by *electrodes, a pulse oximeter and an inductive band* to the *Biopac MP36* device as a reference as well as to the *LifeVit Vital device*.

Participation: To achieve the objective, we ask you to collaborate in a one-session study in our laboratory that will consist of:

1. Answer a questionnaire.
2. Record heart rate from an electrocardiogram and wrist activity bracelet, during three situations.
3. Record oxygen saturation from a pulse oximeter and wrist activity bracelet during three situations.
4. Record respiratory rate from an inductive band throughout the procedure.
5. The three situations shall not last more than 6 -10 minutes in each case and will be as follows: first sitting, then standing and finally walking.

Considerations: Laboratory sessions should not last more than one hour, please take care of the following:

1. Consider the previous considerations.
2. Bring comfortable clothes and shoes that allow you to walk and perform experiments comfortably.
3. During the session the patient will wear: *three electrodes to measure the ECG, a pulse oximeter on the index finger of* the left hand*, an inductive band type "Polar"* and the *LifeVit Vital on the left wrist.*
4. In principle there are no known risks derived from the use of the devices that are going to be used in the study except for one: the smart bracelet to be validated by carrying a lithium-ion battery has a slight risk of explosion or burns, if it is disassembled, handled, or catches fire, in our case none of these circumstances will occur.
5. Agreeing to participate in the study will help us achieve the objectives of our evaluation and be able to help future users of the device know with certainty that their device is reliable.

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Confidentiality: All data obtained are completely **confidential** and will be analyzed anonymously by the specific department of the UPC. Only the research team will have access and they will be protected from misuse. If you have any questions, you can contact with the responsible researcher, Juan José Ramos Castro or Antoni López Giménez as a research fellow in the validation of the device. In addition, I want to tell you that the promoter is committed to compliance with the EU General Data Protection Regulation ("RGPD") 2016/679. The data will only be processed in the context of the study and we remind you that you have the rights of access, modification, opposition and cancellation of data by contacting one of the two previously mentioned persons.

Free Consent: *I agree to participate voluntarily in the validation, being aware of the information included in this form, and that is why I sign it in* the Laboratory of the Electronics and Biomedical Instrumentation group of the *UPC, at*

Barcelona, __- _____2023

1. I have read/understood the study and have had time to evaluate my participation. ☐
2. I have been answered satisfactorily ☐
3. I voluntarily agree to be part of the study, follow its procedures, and provide the information requested by the researcher. ☐
4. I understand that I can withdraw from the study at any time without affecting my medical care or rights. ☐
5. I agree that if I decide to withdraw, the information and data collected about me until the time of withdrawal may continue to be used. ☐
6. I have received a copy of this consent document to save it. ☐

Juan Jose Ramos Castro

Principal Investigator

Biomedical Electronics and Instrumentation Group, UPC

Signature: Participant in the session