



Device validation LifeVit Vital, 2023. IEB Group, UPC

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

## **VALIDATION PROTOCOL**

### **PREVIOUS STEPS TO DATA COLLECTION**

#### **Before the start of the study:**

1. Contact the participant by phone or email.
2. Briefly explanation to the participant of what the study will consist of using the following text:

*"Hello \_\_\_\_\_, in the biomedical electronics and instrumentation group we are validating a device, we are testing its operation and reliability of blood oxygen saturation measurements (SpO<sub>2</sub>) and heart rate comparing it with an electrocardiogram and pulse oximeter of reference. The device is the "Vital" model of the Lifevit brand. There is no economic remuneration, but the test is simple, does not require great physical effort and will not last more than an hour. It would help us a lot if you were part of the study. If you are interested, please let us know and we will contact you to arrange the day and time of the test. Thanks a lot! "*

#### **Before the session:**

1. Contact the patient to confirm: date, place and time of the data collection session.
2. Remind the patient to bring comfortable clothes and if He/She needs help should come accompanied.
3. On the day of the test, have the entire evaluation system and material ready:
  - a. Clear measuring table.
  - b. Have all the material ready: 3 electrodes per patient, inductive band, pulse oximeter for MP36, additional pulse oximeter, Lifevit Vital, alcohol, toilet paper, questionnaire, informed consent form and a pen.
  - c. Turn on lab PC and laptop.
  - d. Turn on MP36 hardware. Let the green light be constant on the power button, important before opening the BLS Lab Pro software.



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- e. Open BLS Lab Pro software. Biopac Student Lab Pro.
- f. Open a new measurement file.
- g. Set up the channels: MP36 settings, add to each CHX channel the corresponding measurement and acquisition model (indicated on the cable of each instrument).
- h. Add timestamp to MP36 measurements: As easy as pressing F9.

### **DATA COLLECTION:**

- 1. Write environment room temperature. It should be between 15-24°C. Otherwise, write the temperature.
- 2. Sign informed consent.
- 3. Fill out the questionnaire.
- 4. Start with measurements.

### **STEP-BY-STEP PROCEDURE WITH THE VOLUNTEER**

#### **PRESENTACION**

*"Hello, welcome to the laboratory of Biomedical electronics and instrumentation group of the UPC. Now, we will start with the experiment that we are carrying out in order to see the effectiveness of the LifeVit Vital activity bracelet (show device) measuring blood oxygen saturation (SpO2) and heart rate (HR) comparing values against a reference device. Basically, you should be sitting, standing and finally, walking or doing squats, whichever is more comfortable while we record all the activity with both devices. Remember that you can leave the experiment at any time.*

*Now, sit in the chair we'll start. First of all, for your privacy and the veracity of the experiment we need you to sign the informed consent form in order to continue. Read it calmly, if you have questions, I will be happy to answer them and once you have finished please fill in all the spaces with your personal data and sign it."*



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1. Give informed consent and a pen to the volunteer. Give it some time to read and fill it out and make sure everything is well filled in and signed.
2. Once everything is signed and understood, we pass him the simple questionnaire.

*"Next, we pass you a little questionnaire. Read it calmly, there are a few questions for the statistics of the study and to be able to draw conclusions from the results obtained."*

3. Check that everything is filled.

*"Thank you for filling it all out and signing the consent. Now that everything is clear, do you have any more questions? In case you have no further doubt, I will now proceed to place the devices will measure your SpO2 parameters and heart rate."*

4. Show the MP36 with the ECG, inductive band and pulse oximeter in addition to the LifeVit Vital and explain how to place everything.

*"These devices measure your heart rate and blood oxygen saturation. Now you will see it when everything is in place. You can place the watch on your left hand and the pulse oximeter on your index finger. Now we will place the inductive band to control the respiratory rate and the ECG electrodes, which to work better, we will clean the skin with a little alcohol. The electrodes will be placed on the shoulders."*

5. Researcher applies alcohol on the shoulders and places the electrodes as follows: the red one on the patient's left shoulder, the black one on the patient's right shoulder and the white one in the iliac crest area.
6. The inductive band is placed on the patient's chest.



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## MEASUREMENT PHASE

7. We proceed to explain the study to the volunteer.

*"This experiment has three phases: first we will ask you to sit, then stand up and finally with a light exercise such as walking or squats."*

8. Sit him in a chair and get him into a position where he feels comfortable.

*"Now that he is sitting and comfortable, if it seems good to him, start, we will be 6 min in this position."*

9. Measure SpO<sub>2</sub> with pulse oximeter and annotate on a paper/word file.
10. We start with the acquisition of the data simultaneously on both devices, Biopac with MP36 hardware and the LifeVit Vital activity bracelet activating it through the SDK on the acquisition Smartphone. You have to stop the acquisition after 3 min for each parameter.
11. After the 6 min of acquisition, measure the SpO<sub>2</sub> again and write down.
12. Change the volunteer's position, now we will measure in the standing position.

*"Perfect, we have already collected the data we needed, now if you can stand up and we will start with the next phase of measurement."*

13. Measure SpO<sub>2</sub> with pulse oximeter and annotate on a paper/word file.
14. We start with the acquisition of the data simultaneously on both devices, Biopac with MP36 hardware and the LifeVit Vital activity bracelet activating it through the SDK on the acquisition Smartphone. You have to stop the acquisition after 3 min for each parameter.
15. After the 6 min of acquisition, measure the SpO<sub>2</sub> again and write down.
16. Change the position of the volunteer, we will measure below performing a light exercise.



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*"Very well, we have finished the second phase. Now if you are not tired, we will move on to the next phase. You can choose or perform some squats or just walk, we leave it to your choice. We will be like this about 6 min, if at any time you need to stop or rest just let us know. "*

17. Measure SpO<sub>2</sub> with pulse oximeter and annotate on a paper/word file.
18. We start with the acquisition of the data simultaneously on both devices, Biopac with MP36 hardware and the LifeVit Vital activity bracelet activating it through the SDK on the acquisition Smartphone. You have to stop the acquisition after 3 min for each parameter.
19. After the 6 min of acquisition, measure the SpO<sub>2</sub> again and write down.
20. Ask the volunteer to stop with the light exercise and sit down to rest.

*"Good! We have finished with all the measurements, now I will proceed to remove all the devices. Are you tired? Do you want some water?"*

21. Stop the acquisition on all devices, remove the devices and give the option to go to the bathroom to remove the band and clean yourself with paper and alcohol, offering you what you need for that purpose.

*"Perfect! For our part it would already be, we have everything necessary to carry out the study, we thank you very much for your collaboration. Do you have any questions? Are you feeling well or tired?"*

22. The BSL Lab Pro software acquisition file is saved : File, Save in .mat format on the desktop with the following format *"Patient\_numerOfPatient\_Date.mat"*.



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*"Thank you once again for your participation in our study and for holding out until the end. Let's hope he felt comfortable at all times. If you know someone who might be interested in participating, please contact us. Again, thank you very much. "*

23. Escort the volunteer to the exit and say goodbye.
24. Clean all the material well and disinfect it with alcohol.
25. Save the material or prepare everything for the next volunteer.
26. Close the lab.