Proposal of a Validation Protocol for Wearable Systems Reliability Assessment

Application to PEGASO sensors' system

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***Abstract*—This paper describes the proposal of a validation procedure to assess the reliability of wearables systems. According to the two main categories of devices we have defined an integrated experimental protocol composed by two parts: the first one applies to sensorized garments or similar devices (also including belts or patches) while the second part is dedicated to body worn activity trackers like smart bracelets or smart watches, belt-worn devices, sensors embedded in necklace or other garment accessories. This protocol applied a sequence of real life activities and posture changes to be properly identified in value and in time. It has been applied to the case study of the sensors developed and used in the frame of the Pegaso Fit 4 Future EU project. This test has demonstrated the protocol feasibility, applicability, easy to use and easy data processing and its sensitivity. We are adopting this protocol as standard procedure in any further study regarding the reliability assessment of wearable devices.**

Keywords-wearable systems; validation protocol; reliability; accuracy; real life testing.

I. INTRODUCTION

In the last years, a worldwide spreading category of devices used in sport, fitness and also healthcare are wearable systems [6]. Wearable devices are a popular and growing market for monitoring physical activity, sleep, and other behaviors [2]. In particular, for healthcare applications, activity trackers like wrist-worn systems (bracelets) or similar devices are now in progress, but this requires a deep and structured reliability analysis of their performances before their deployment into clinical practice. Several studies are ongoing [2], each using its own protocol. For this reason, and to methodologically have the opportunity to compare homogeneously these technologies, we have decided to study and propose a dedicated standard protocol for reliability assessment here described.

The paper is divided into two sections: Section 2 highlight the experimental protocol underlining the difference between the first part (static test) and the second one (dynamic test). Section 2 continues with the explanation of the wearable sensors tested and closes with reporting the validation procedure and parameters. Section 3 reports the results on both testing procedure and the application of this on specific wearable device. Then Section 4 ends the paper with the conclusion and future development.

II. MATERIALS & METHODS

A. Experimental protocol

The experimental protocol is methodologically based onto a paired video and bio-signal acquisition during different postural tasks in controlled environment and locomotion (walking and running) at different velocities on treadmill (Woodway Inc., USA). The video is recorded by a digital camera with lateral acquisition of subject. The subjects followed a supervised protocol divided in two parts (protocol part I and part II), with the aim of testing the capability of the sensor to recognize body position changes and transitions from rest to activity and vice-versa (protocol part I) and to detect gait and speed of locomotion together with kinematic parameters, during activities on treadmill ranging from sedentary to vigorous intensity physical activity (part II).

The experimental activity is to be conducted in controlled conditions during different postural tasks and locomotion on treadmill with simultaneous video-recording.

A methodologically coherent subject sample, different in age, sex and anthropometry, has to be properly selected.

a) Part I

The first part of the protocol (Part I) is specifically dedicated to assess the capability of the systems to detect posture, its transitions and the related activity level through HR (heart rate). The first part of the protocol (Part I) consists of 10 postural tasks (phase from 1 to 10). More precisely, there is a sequence of postural transitions alternating phases of resting (lying, standing and sitting) and walking/running phases. The overall Part I protocol is described in the following table I.

Contextually, the video of the experiment is recorded by a digital camera with lateral acquisition of the subject.

The assessments indexes are activity recognition, posture recognition and computational time.

a) Part II

Instead, the second part of the protocol (Part II) is specifically designed for assessing the reliability of systems during the progressively increase of activity level. It consists of 10 stages (phase from 1 to 10).

TABLE I. PROTOCOL PART I

Phase no.	Wearable validation protocol – Part I	
	Activity description	*Posture*
1	20 seconds sitting	sitting
2	20 seconds resting with arms at the sides	standing
3	20 seconds walking onto a treadmill	standing
4	30 seconds running onto a treadmill	standing
5	10 seconds sitting	sitting
6	20 seconds lying onto the back	lying (supine)
7	20 seconds lying onto the right side	lying (right)
8	20 seconds lying onto the left side	lying (left)
9	20 seconds lying onto the belly	lying (prone)
10	20 seconds resting with arms at the sides	standing

TABLE II. PROTOCOL PART II

Phase no.	Wearable validation protocol – Part II	
	Activity description	*Posture*
1	Rest sitting for 30 seconds	sitting
2	Rest standing for 30 seconds.	standing
3	Walking at 2 km/h for 30 seconds	walking
4	Walking at 3 km/h for 30 seconds	walking
5	Walking at 4 km/h for 30 seconds	walking
6	Walking at 5 km/h for 30 seconds	walking
7	Walking at 6 km/h for 30 seconds	walking
8	Running at 6 km/h for 30 seconds	running
9	Running at 7 km/h for 30 seconds	running
10	Running at 8 km/h for 30 seconds	running
11	Running at 9 km/h for 30 seconds	running

More precisely, it consisted of 120s of resting (standing and sitting), 150s of walking and 120s of running. The subject carries out the following experimental procedure on a treadmill: from standing to running at 9 km/m then stop and recovery. The overall Part II protocol is described in table II.

Also in this case, contextually, the video of the experiment is recorded by a digital camera with lateral acquisition of the subject. The video of the subject's trial allows for the retrieval of the true values of the computed parameters (activity, steps, cadence, etc.) along with the acquisition.

B. *Wearable system*

To apply the protocol on a specific healthcare application we decided to adopt the sensors developed in the EU project PEGASO Fit 4 Future [3]. In the PEGASO project, the sensors system is composed by 2 elements (Figure 1):

- a sensorized t-shirt (male version) or bra (female version) including a pair of textile electrodes and mounting at the chest level a device named WES capable of recording and/or transmitting 1 ECG lead and 3D accelerations of the trunk.
- an activity tracker consisting in a smart bracelet named WWAT and integrating a 3D accelerometer to monito human kinetics. The WWAT embedded algorithm computes the steps number, the activity (resting, walking, cycling, running, swimming and sleeping) through. Energy expenditure is estimated too.

Figure 1: The PEGASO sensor system

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C. *Validation parameters, citeria and indexes*

According to the device differences, we have identified to different analyses that can be conducted on corresponding data.

a) Part I and Part II, devices with ECG/Heart Rate measurement

All the signals have to be processed to compute the following three values for each phase:

- Activity recognition (0=N, 1=Y),
- Posture recognition (0=N, 1=Y),
- Computational time (0 = time > 3 sec for activity and posture recognition, 1 = time <= 3 sec for activity and posture recognition).

The test is passed if the overall score is equal or greater than 90% during the complete test.

All the signals have to be processed to compute the beat-to-beat HR with standard algorithms. The values of HR recognition are 0=N and 1=Y. METs (Metabolic Equivalent of Task) estimated from sensor, are compared with values obtained with ACSM (American College of Sports Medicine) metabolic equations for walking/running [4]. The test is passed if the overall score is equal or greater than 90% during the whole test.

Analysis of video-recording, is carried out through Advene, an open source software (Advene, Lyon, France) [5], providing a model and a format to share annotations about digital video documents, as well as tools to edit and visualize

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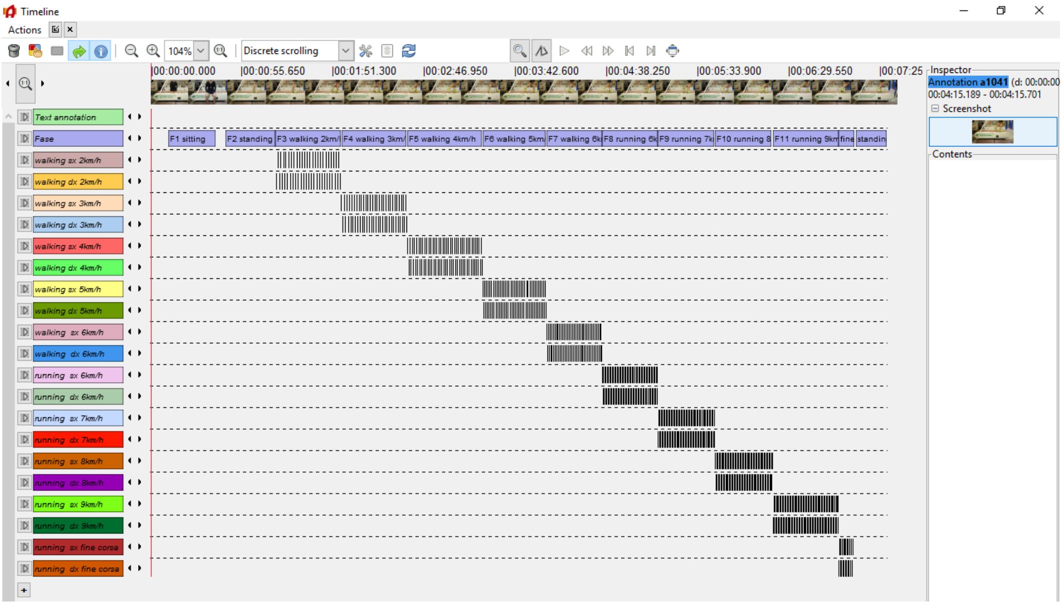

Figure 2. Example of the video-recording data visualization and values together with relative annotations in the Advene software.

the hyper videos generated from both the annotations and the audiovisual documents [7]. An example of the processing procedure of the video-recordings is shown in Figure 2.

b) Part I and Part II, devices with human kinetics measurement only

All the signals have to be processed to compute the following three values for each phase:

- Activity recognition (0=N, 1=Y),
- Posture recognition (0=N, 1=Y),
- Computational time (0 if time > 3 sec for activity and posture recognition, 1 if time <= 3 sec for activity and posture recognition).

This general test is passed if the overall score is equal or greater than 90% during the complete test.

More in detail data are processed in order to verify the correct step identification, count and categorization according to the different activities and/or speed. Also in this case, the test is passed if the overall score is equal or greater than 90% during the complete test. The analysis of video-recording, through Advene, provides the true and reference values.

The experimental activity was conducted in the Laboratory of Biomechanics "Franco Saibene" (Istituto di Bioimmagini e Fisiologia Molecolare del CNR, Segrate, Milan, Italy) in controlled conditions during different postural tasks and locomotion on treadmill with simultaneous video-recording.

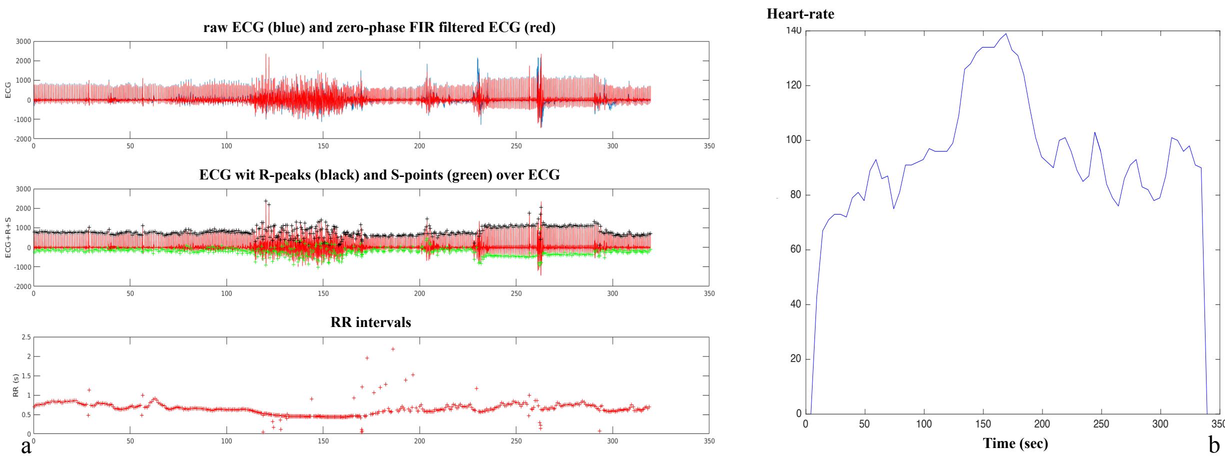

Figure 3: Data comparison for indexes computation: (a) raw signals and related offline processing with standard algorithms, (b) 5-sec average HR computed by WES system.

10 subjects took part in the Part I and Part II experiments for the test of the sensorized garment and the WES device. Their anthropometric data are reported in Table III. Three subjects applied the Part II of the protocol to assess its proper feasibility and reliability on the WWAT device (smart bracelet): they are the subjects no. 1, 8, and 9 in the same Table III.

The study was approved by the competent Institutional Review Board. Subjects were properly informed about testing procedures, personal data treating, and aims of the research, and they provided informed written consent before participation.

III. RESULTS

The results of this study can be divided into two sections: the first one relates to the assessment of the method itself in terms of its sensitivity, feasibility and robustness; the second set of results is about the reliability assessment of the sensors used in the PEGASO project.

TABLE III. DATA OF SUBJECTS PARTICIPATING IN WEARABLE DEVICE VALIDATION

Subj. no.	Subjects recruited in the validation protocol					
	sex	*Age (yrs)*	*heigth (m)*	*weigth (kg)*	*garment*	*BMI*
1	M	47	1,860	105,2	t-shirt	30,41
2	F	33	1,555	56,2	bra	23,24
3	F	33	1,665	52,9	bra	19,08
4	F	34	1,570	53	bra	21,50
5	F	33	1,685	68,9	bra	24,27
6	M	53	1,730	68,8	t-shirt	22,99
7	M	33	1,780	85,6	t-shirt	27,02
8	F	29	1,710	64,5	bra	22,06
9	M	51	1,815	79,6	t-shirt	24,16
10	M	63	1,745	68,7	t-shirt	22,56

A. Methodological results

The protocol we designed try to answer in an integrated test to all the parameters a wearable device is usually designed for. It is robust and sensitive to raw and processed temporal, kinematic and cardiac data. The validation indexed and intuitive and easy to be computed, as well as they are representative of the needed accuracy assessment.

The application case study demonstrated its good applicability and repeatability in a standard sample size of 10 subjects.

B. Results of the protocol on the reliability of the PEGASO Sensors system

The WES sensors have a mean accuracy of 99%±2% in the first part and 93%±7% in the second part; moreover 7 subjects on 10 had an accuracy of 100% in the detection of steps. These data show that WES sensors are reliable and accurate in their measurements, appropriately for the applications they are design to be used for.

TABLE IV. DATA OF SUBJECTS PARTICIPATING IN WEARABLE DEVICE VALIDATION

Percentual Accuracy			
Condition	***Speed (km/h)***	***Total***	***walk/run***
walk	2	65,85%	45,05%
walk	3	18,00%	9,36%
walk	4	10,54%	3,45%
walk	5	12,08%	3,54%
walk	6	12,98%	3,54%
run	6	9,23%	0,97%
run	7	9,26%	0,88%
run	8	9,23%	0,80%
run	9	8,55%	7,26%
	Average	17,30%	8,32%
	St.Dev	0,18	0,14

The WWAT bracelets presented the results shown in table IV. Algorithms refinement for low speed step detection was identified as needed.

IV. CONCLUSIONS

This study aims at setting up a standard protocol for wearable sensor validation before their introduction in research projects. This has particular relevance when clinical applications of wearable sensors have been carried out. The protocol we have defined is up-to-date with current technologies and their applications. The results showed both methodologically and for its application a good performance in usability and outcomes. Further application will confirm these findings and other developments could be done for specific detail of garments or activity trackers depending on peculiar applications.

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REFERENCES

[1] K. R. Evenson, M. M. Goto, and R. D. Furberg, “Systematic review of the validity and reliability of consumer-wearable activity trackers,” International Journal of Behavioral Nutrition and Physical Activity. Vol. 12:159, pp.68–73, 2015.

[2] P. Perego, M. Tarabini, M. Bocciolone, and G. Andreoni, “SMARTA: Smart Ambiente and Wearable Home Monitoring for Elderly,” Internet of Things. IoT Infrastructures, Second International Summit, IoT 360° 2015, Rome, Italy, October 27-

29, 2015. Revised Selected Papers, Part I, Lecture Notes of the Institute for Computer Sciences, Social Informatics and Telecommunications Engineering, vol. 169, pp 502-507, 18 November 2016.

[3] M. R. Guarneri and G. Andreoni, "PEGASO Fit for Future," In: Antonello Rizzi and Antonio Pedotti (eds): European Project Space on Computational Intelligence, Knowledge Discovery and Systems Engineering for Health and Sports, SCITEPRESS Publications. Lda, pp. 77-96, 2015.

[4] ACSM certification, "Metabolic Equations for Gross VO2 in Metric Units," https://certification.acsm.org/metabolic-calcs, last access 27 february 2017.

[5] Advene, "Advene Software, " http://liris.cnrs.fr/advene/, last access 27 february 2017.

[6] R. Nensli, E. Gunnarson, and T. Gundersenm, "Wearable medical devices for tele-home healthcare," Proceedings of The 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 2004, pp. 5384-5387.

[7] O. Aubert and Y. Prié, "Advene: active reading O. hypervideo," Proceedings of ACM Hypertext'05, Sep 2005, pp. 235-244.