Usability of a photoplethysmography device for a biomedical garment

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Introduction. The fashion industry is one of the largest consumer goods categories [1]. The necessity of innovations in apparel and textile industry is determined economic conditions, social tendencies and the demographical situation [2], and shows up as high competition in the apparel and textile market, new requirements to clothing and textiles, i.e. extra features, specific design, growing interest in health individual control by remote monitoring of physiological parameters, as well as increasing percentage of elderly among inhabitants of Europe. New technological opportunities (e.g. miniaturization of electronic components, development of nanotechnologies etc.) and all of the abovementioned factors do stimulate the development of smart textiles.

At present, state institutions, several well-known brands of electronic technologies (e.g. "Nokia", "Philips", "Ericsson", "Pioneer Corporation") and fashion brands ("Adidas", "Nike" etc.) work in the sphere of smart textiles development.

As far as the functional application is concerned, the segment of smart clothing and wearable electronics could be divided into three groups: art, haute couture, and prêt-*a*-porter (for example, LED dresses); leisure and sports (for instance, coats with integrated music player and sport T-shirts for heart rate monitoring); healthcare and medicine (clothing for remote monitoring of physiological parameters).

From the practical application point, one of the promising areas in the field of smart textiles and wearable electronics is development of biomedical garments for telemonitoring of physiological parameters [3].

Since healthcare problems become more urgent in society, especially cardiovascular diseases considering the high percentages of cardiac patients and cardiac related deaths [4, 5], the demand for non-invasive remote monitoring methods is increasing.

At present, most of the developed biomedical garments are still prototypes and there are fewer developments that are available on the market[1]. The major requirements for biomedical garments are generation and transmitting of

[1] At this moment only one biomedical garment „LifeShirt®" has been approved by the European Medicine Agency and The American Food and Drug Administration agency. Recently, another development, entitled "VitalJacket®" has been certificated according to medical equipment standards as ISO9001 and ISO13485[17].

qualitative signals, automatic processing of data, ergonomic features and reusability (e.g. washability) [6]. Developed biomedical garments give opportunity of monitoring cardiovascular, respiration and musculoskeletal systems, but mostly present researches concentrate on registration and analysis of cardiac parameters by electrocardiography (ECG). Another promising cardiovascular parameters registration method is photoplethysmography (PPG), which is relatively simple.

Methods and materials. Photoplethysmography (PPG) ensures detection of blood volume pulsations by time-resolved analysis of the tissue back-scattered or absorbed optical radiation [7]. The PPG signal is composed of two components: a pulsatile component (AC) attributed to cardiac synchronous changes in the blood volume with each heart beat, and a slowly varying baseline (DC) attributed to respiration, thermoregulation and sympathetic nervous system activity. Although the origins of the PPG signal components still has no definite interpretation, it is generally accepted they can provide valuable information about the cardiovascular system. The PPG technology is spread in clinical physiological measurements and monitoring, vascular assessment and autonomic functions (for example, blood oxygen saturation, heart rate, respiration rate and the evaluation of blood vessels condition in case of artery disorders, epithelial dysfunctions, vasospastic reactions, e.g. Raynaud's syndrome, etc.) [8, 9].

There are two methods of PPG signal registration: light absorption, which is applied in commercial medical devices, and light reflection, which could be appropriate for integration in garments. Reflection PPG method was chosen for developing the prototype of a biomedical garment. Features of PPG signal registration (i.e. pulse points and the necessary pressure force for the contact of the optical sensor contact with skin to receive the optimal signal), detect the type of garment. A prototype of a biomedical garment (head bandage) was developed to register PPG signal from superficial temporal artery.

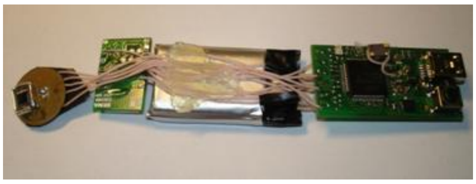

Fig. 1. PPG prototype device for remote monitoring

Wearable PPG device (21x112 mm) (see Fig. 1) was developed for integration into garment. The device incorporates an Li-Ion accumulator that provides ~5 h of continuous operation (the actual time depends on the operating mode), the accumulator charging circuit, Bluetooth module (operation frequency 2.4 GHz), Mini-USB contact that ensures connection of the accumulator with the charging and software systems, 2 LEDs that indicate the operation mode of the device (active mode- transmission of data, capacity of accumulator and charging mode), and integrated on-off operation mode button (with digital filter). The registration of PPG signals is insured by the developed software (see Fig. 2).

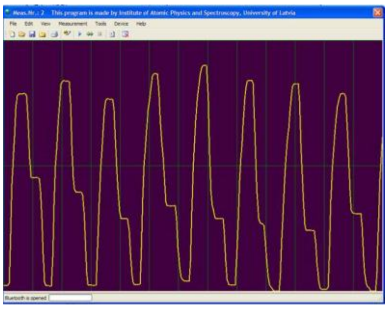

Fig. 2. Interface of the software

Block diagram of the device is represented in the figure 3. 32-bit ARM7 (NXP, ARM7TDMI-S, LPC2148) microcontroller runs at speed 48 MHz. Li-ion accumulator provides power supply of the system. LDO regulator provides stable 3.3 V supply voltage. Discharge of the accumulator is controlled by a microcontroller with 10-bit ADC (analog-to-digital converter). Registered PPG signal measurements are processed and filtered by 250 sample FIR digital filter in real time. The filter smoothes the signal efficiently reducing noises (50 Hz) and interferences of surrounding light. The filter is developed specifically to escape distortion of PPG signal form, amplitude and phase. The processed data is being transferred to Bluetooth module which transmits the data for storing and display to a computer or another programmable device in distance approx. 20 m. The processor captures PPG signal by 32-bit capture timer module. The sensor incorporates the light-emitting diode (LED) and light-absorbing photodiode (PD). The infrared (IR) LED consists of a GaAs emitting diode (diameter of the emitting area 2 mm, power ~ 10 mW, and peak wavelength 940 nm). The IR LED is being turned on during measuring and then turned off for energy saving.

The device operation is based on measurements of discharge time of the PD. The PD is periodically charged by 30 μs LED emitted radiation pulse. The PD exponentially discharges and this discharge time is captured by microcontroller. The integrated voltage stabilizer provides measurement accuracy during the whole discharge process of accumulator (3.7-4.2 V) [10]. Discharge time is inversely proportional to radiation received by the PD. The achieved time resolution of PPG signal is 1 ms.

The major problem with the development of a biomedical garment was finding the technological solution for the optical sensor integration. The sensor was integrated into the textile with silicone coverage (300 μm thick) that ensured splicing of the sensor and the textile, as well as protection of the sensor from bodily oozed moisture (sweat) and possible mechanic damage [9].

The textile sample is 15x15 mm (viscose 94%, elastane 6%) with one side covered with 2-component silicone "Lassil-S" (solidification time 40 min); then,

a 6x9 mm wide slot was made in accordance with the sensor dimensions. The coverage of the sensor that was integrated into the textile sample was provided on both sides (9x11 mm on the right side and 20x24 mm on the left side) (see Fig. 4).

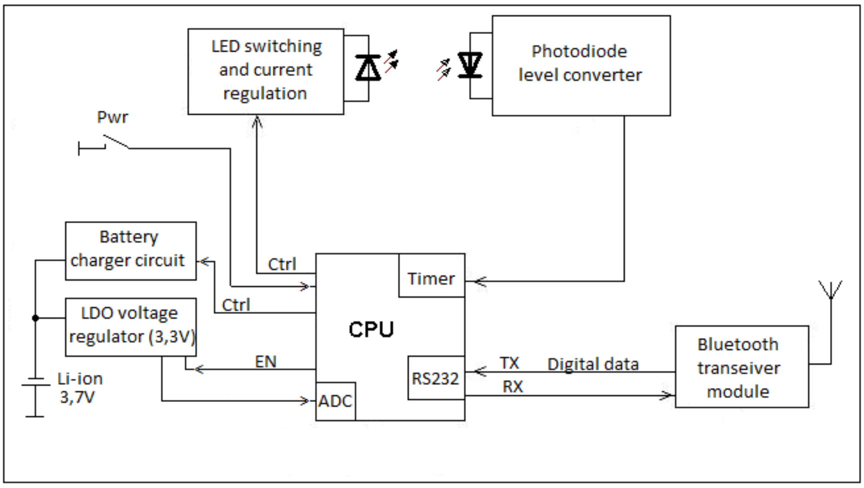

Fig. 3. Block diagram of the device

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Fig. 4. Optical sensor integrated into a fabric sample

The developed prototype (head bandage) has a Velcro fastener to provide the accessibility of the Mini-USB contact and the button point to ensure for the changing of the mode.

Prototype testing. A range of physiological measurements was taken to evaluate the prototype measuring accuracy by detecting cardiac cycle length (R-R interval). Data from five participants (age 20-25) were continuously and simultaneously recorded using the prototype and finometer (*Finometer Midi, FMS,Amsterdam)* during the baseline condition and the exercise condition, which was walking on a treadmill (SportArt Fitness 6300HR, USA) with speed 6 km/h (see Fig. 4). The PPG signal was registered by the prototype from the superficial temporal artery while the finometer was registering the signal from a finger. The signals were recorded during 2.5 minutes. The collected data of each participant were analyzed using *Matlab 5.3* script (*Matlab 5.3 Mathworks Inc, USA*). The heart rate values were detected from the PPG signal wave form by identifying the minimum values of one period of PPG signals. Then compared with finometer detected values and were automatically calculated by *Beatscope* software.

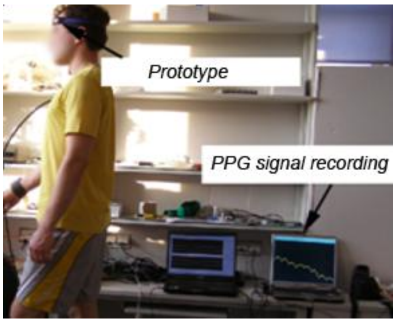

Fig. 5. The procedure of prototype testing during the exercise condition

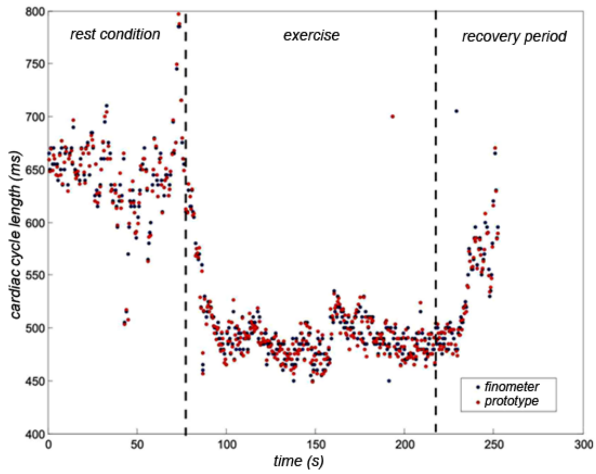

Fig. 6. Cardiac cycle length dynamics of the participants walking on a treadmill

Results. Summary statistics (t-test, Mann-Whitney Rank Sum Test) were used to evaluate detection errors of the prototype and compared with the reference device results by analyzing the ms deviations in timing precision of R-R intervals (test confidence level $p<0.05$). Across each data file (252 second long signal record) the length of 469 heart cycles was identified. The samples of R-R interval signals registered by both devices did not satisfy requirements for normal distribution (the data were verified with Kolmogorov-Smirnov test, *K-S Dist. = 0.239, P < 0.001, Failed; K-S Dist. = 0.220, P < 0.001, Failed*), therefore nonparametric methods were used for the further analysis. Mann-Whitney Rank Sum Test did not show significant deviations *(T = 221203.000 n(small) = 469, n(big)= 469, (P = 0.808*)).

The correlation analysis identified high correlation coefficient (*Spearman Rank Order Correlation r=0.973; p<0.001)* (see Fig. 5). To evaluate the differences of the data, ms deviations of R-R interval values were calculated (see Fig. 7), the mean absolute deviation was 5.2±16.1 ms (mean±std) (see Fig. 8).

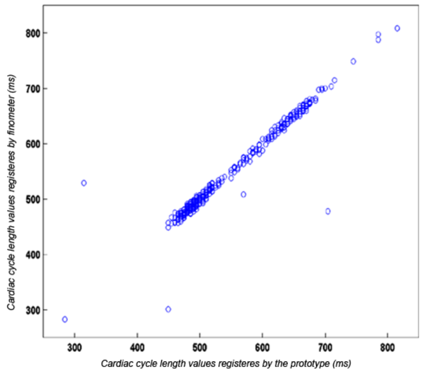

Fig. 7. Comparison of cardiac cycle length registered with finometer and the prototype

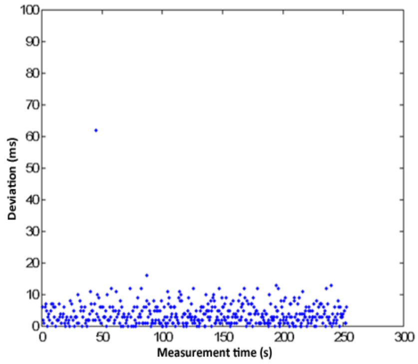

Fig. 8. Deviations of cardiac cycle length registered with finometer and the prototype

Discussion. Biomedical garments are a new promising area, where presently dominate research developments. Evidently such garments can be applied to the individual health control and clinical practices for different patient groups, especially those with cardiovascular disorders.

This paper describes the developed prototype with and integrated PPG device that registers PPG signals from the superficial temporal artery. This prototype was developed to evaluate the usability of the PPG device in a biomedical garment, the integration opportunities of the optical sensor into textiles, and the accuracy of measurements of the integrated device. According to the evaluation results, it is possible to make a positive conclusion about the PPG device's usability in biomedical garments for further researches.

It is quite complicated to compare the prototype with similar biomedical garment developments due to different evaluation criteria (analyzed data and testing procedures). Thus, evidently such developments as "LifeShirt®" have a higher accuracy of measurements and potential practical value. For example, the absolute deviation of R-R intervals timing was 2±11 ms on the requirement that data was collected from 15 participants during exercise on a bicycle for 10 minutes (the reference device cardiograph "Biopac")[12], while the absolute deviation of the prototype measurements was 5.2±16.1 ms on the requirement that data was collected from five participants during walking on the treadmill for 2.5 minutes.

The improvement of the optical sensor and device integration technologies and software is necessary for the further potential application of the PPG device in a biomedical garment. Integration of other sensors can expand the area of the potential application and make further research more valuable.

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The application of garments performing remote monitoring of physiological parameters is spread within the healthcare sphere and it might be especially useful for patients with cardiovascular system dysfunctions during rehabilitation and clinical conditions, e.g. as an auxiliary device for diagnostics. Present researches mostly concentrate on registration and analysis of cardiac parameters by electrocardiography (ECG). Another promising cardiovascular parameters registration method is photoplethysmography (PPG), which is relatively simple. The PPG absorption method is applied by developing commercial medical devices, but obviously the method of remission gives a wider range of possibilities for registration of cardiovascular parameters and is more appropriate for integrating an optical sensor into textiles. A prototype (head bandage) of a biomedical garment with an integrated wearable PPG model device has been developed and tested for remote monitoring of cardiac parameters (e.g. heart rate, R-R intervals). The major task of this paper is to evaluate usability of the PPG device for a biomedical garment, as well as to test reliability of the data registered by the developed prototype and by comparing them with cardiac parameters (heart rate and cardiac cycle length) registered by commercial medical reference devices.