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NONOBTRUSIVE MONITORING OF CARDIO-VASCULAR FUNCTIONS WITH A NOVEL CUSTOMIZED IN-EAR-SENSOR STRATEGY

Vladimir Blazek [1, 2], Boudewijn Venema [1], Steffen Leonhardt [1] and Paul Blazek [3]
[1] Philips Chair for Medical Information Technology, Helmholtz-Institute for Biomedical Engineering, RWTH Aachen University, Aachen, Germany
[2] The Czech Institute of Informatics, Robotics and Cybernetics (CIIRC), Czech Technical University in Prague, Prague, Czech Republic
[3] cyLEDGE Media GmbH, Vienna, Austria

Abstract: *In Western countries the increasing number of heart cases due to an ever-aging society and the coincidental financial pressure of the healthcare system lead to a precarious situation in clinical facilities. Hence, a home related care that is customized according to physical and social needs of individuals becomes increasingly important. We present a novel sensor concept for monitoring vital human functions that is based on the simple easy-to-use classical photoplethysmogaphy (PPG) technology but is attached to the ear, measuring at the inner tragus. The discussed diagnostic system consists of customizable sensor forms, customizable biodata mining and customizable communication protocols to the medical control center. There are physiological and technological advantages by mining the vital signs in the ear channel. Due to the unobtrusive wearing this sensor technology can be recommended not only for patients with high cardiovascular risk; it has high potential also for homecare appliance and sportive fitness activity control. From our preliminary results could be concluded, that the patient/applicant comfort and the robustness of the vital signs detection is higher by mass customized sensor applications in relation to classical non-customized sensors.*

Key Words: ***Customized medical sensors, cardio-vascular function control, trends in biomedical applications, patient usability, signal robustness***

1. BASICS OF NON-INVASIVE PPG MONITORING OF BLOOD VOLUME CHANGES

Optoelectronic sensor concepts have come to play an important role in functional blood circulation diagnosis because of their non-invasive and non-damming nature. They are generally accepted by patients not only during vascular screening-examinations since they cause neither pain, nor harmful radiation or ionizing phenomena. And last but not least, they can/will operate also just in the near future remotely, that means completely unobtrusive.

After the pioneering work by Cartwright [1], Haxthausen [2], Matthes [3] and Molitor et al. [4], Alrick B. Hertzman, Physiologist at St. Louis University School of Medicine, discovered a relationship between the intensity of backscattered polychromatic light and blood volume in the skin in 1938. His instruments consisted of three essential components still found in modern systems: a light source, a light detector (Fig. 1 left) and a registration unit. He called the device photoelectric plethysmograph and described his findings ([5], p. 336):

- "Volume pulse of the skin as an indicator of the state of the skin circulation at rest" and
- "amplitude of volume pulse as a measure of the blood supply of the skin".

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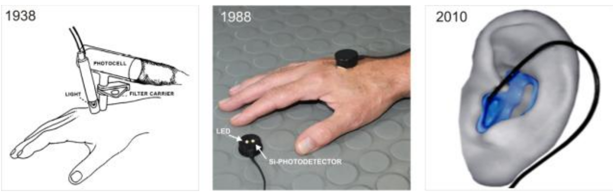

Fig. 1. *Progress in photoplethysmography and its sensor concepts: First optoelectronic sensor by Hertzman [5] with incandescent lamp as polychromatic light source and selenium cell as photo detector (left); an universal reflective PPG sensor on the market today (middle); and novel personalized in-ear rPPG sensor (right).*

The basic principle behind the measurement of blood volume changes in the skin by means of PPG is the simple fact that hemoglobin in the blood absorbs infrared light many times more strongly than the remaining skin tissues (Fig. 2), [6-10]. For example, as blood pressure in the skin vessels decreases, the surface area of the vessels is reduced. This increases the average reflection in the measuring window under the sensor, so it will be recorded as an increase in PPG signal. Following this principle, the PPG signal reflects the blood volume changes in the cutaneous and partially also the subcutaneous vessel plexus and consists of a high constant part which is independent from the perfusion (light scattering in tissue), a smaller quasi static vein signal and a very small, periodical modulated arterial signal (Fig. 3). Therefore, this non-invasive technique allows one to acquire functional data from the dermal venous and/or arterial circulation.

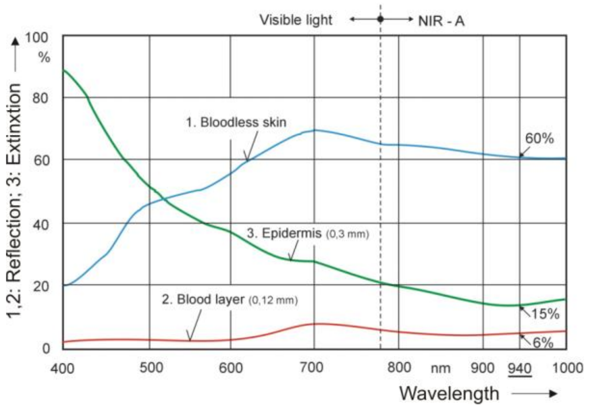

Fig. 2. *Optical properties of human skin and blood in the visible and near-infrared area of the spectrum. Typical reflection spectra of anemic skin and of a 0.12 mm thick blood layer on glass are shown as well as an extinction spectrum of a 0.3 mm epidermal layer. The difference in reflectivity between the skin tissue and the blood is evident and results in a high optical contrast between skin and dermal vessel plexus. The optical attenuation of the epidermis is very high in the ultraviolet and blue regions and lowest at IR wavelengths of about 950 nm.*

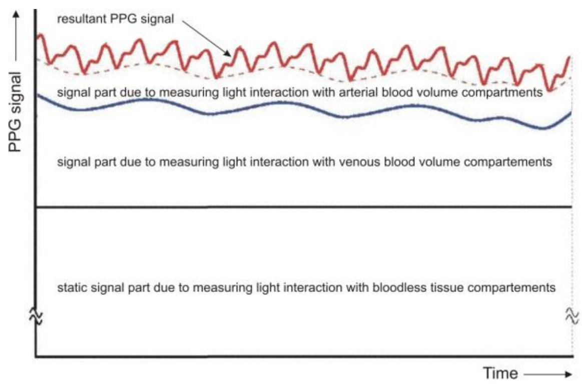

Fig. 3. *Typical composition of the photoplethysmographic signal in the ear channel. The intensity of the backscattered light depends on the blood volume in arterial and venous vessels in the measuring zone. Reducing blood volume in the transilluminated area under the PPG sensor increases the PPG signal. Separation of venous and arterial perfusion components of the detected signal is possible by selective post-processing of the signal.*

Compared to conventional PPG that is attached to finger or ear lobe, our novel in-ear PPG strategy provides some major advantages. Due to its proximity to the brain, the inner ear canal is expected to be less affected by centralization. This ensures a better performance in life-threatening situations like shock, hypothermia or sepsis. Furthermore, an in-ear sensor is convenient to wear and less disrupted by motion artifacts and hence, qualified for long term monitoring even for homecare appliance. During last 8 years two types of in-ear sensor module prototypes were developed at the RWTH Aachen University. The optoelectronic chip is sealed into a biocompatible ear mold, which is individually customized to the patient's ear (long-term usage: home care or intensive for example). This sensor type ensures highest wearing comfort, optimal fit and best reproducibility with regard to the sensors position. In contrast to this, sensors were developed which are made of an elastic material in five different sizes to ensure that they can adapt to individual ear structures and thus fit to a high extent nearly everybody (short term usage, emergency).

The remission in-ear-PPG sensor design was previously developed in BMBF (German Federal Ministry of Education and Research) and BMWI (German Federal Ministry of Economic Affairs and Energy) funded research projects INMONIT, LAVIMO and smart PPG). In Fig. 4, the progress in the construction of in-ear photoplethysmographic sensors is shown.

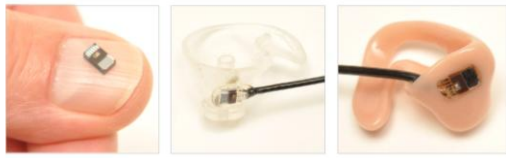

Fig. 4. *Different in-ear PPG sensor prototypes, developed at the RWTH Aachen University. The silicon chip containing both the light emitters and the photo-receiver (CiS Erfurt, Germany) is assembled on a flexprint board (left), universal in-ear sensor module (available in different size, middle), individually customized/personalized sensor module (right).*

2. THE MEANING OF CUSTOMIZED EVERYDAY MEDICAL SENSORS

In Western countries, the number of people requiring care, long-term and high-risk patients is steadily increasing; mainly due to an aging society and an increasing prevalence of diseases such as diabetes, obesity, arteriosclerosis or hypertension, which are often due to an unhealthy lifestyle. The resulting strain on the health care system increasingly pushes health issues into the social focus, sub-dividable into preventive and curative aspects: how can the number of people dependent on long-term medical care be reduced? Can treatment be more cost-effective? One promising approach to cost reduction for curative long-term care is to shift therapeutic processes to a home environment to avoid costly hospital stays. Sensor systems that continuously record vital signs and integrate them as unobtrusively and unobtrusively as possible into everyday life open up new perspectives for optimizing and further developing treatment methods and improving the quality of life of people in need of care and at-risk patients. One of the main tasks of medical-related engineering is the development of everyday sensor systems for hemodynamic health monitoring, which can be used on a mobile basis. An almost ideal technological basis is the proven non-invasive and cost-effective PPG datamining process, which allows the development of systems for continuous long-term use. The first devices for the unobtrusive measurement of vital processes based on reflexive PPG are already commercially available (fitness wristband). They are the first harbingers of a medical technology trend that envisages the integration of personalized vital signs in all areas of life. So far, these systems measure only elementary vital functions, such as heart rate, which far from exhausting the metrological and diagnostic potential of PPG. In addition to the heart rate, modern smart PPG devices have been providing information on heart rate variability, respiratory activity or hematological parameters such as the concentration of oxygen, hemoglobin or dysfunctional hemoglobin in the blood for many years. The possibility of obtaining metrological insights into the autonomic nervous system via heart rate variability or vasodilation is especially of societal interest, since this directly leads to a quantification of physical well-being. On the one hand, this measurable physical stress can address a large number of clinical pictures, but can also represent a measurable variable in a performance society in everyday life. The everyday use of sensors is in the starting blocks and with you go challenges and opportunities. While the engineering sciences are faced with the great challenges of adapting a clinical measuring method for robust everyday use, medicine will be able to design new forms of therapy and optimize treatment processes.

3. VITAL DATA COLLECTION AND MONITORING SYSTEM DESIGN

With a constantly aging society national health systems will need to cope with an expected vulnerability for diseases of affluence increase of the elderly population. Encouraging the population to take over a more active role when it comes to prevention, therapy and rehabilitation with personalized training and relaxation exercises will not only lead to optimize the treatment and prolongue the lives of the individuals but eventually economize public health expenses.

Non-invasive sensor concepts and portable 24/7 monitoring systems may take over a crucial role in this medical self-awareness driven society in being responsible for the constant monitoring vital bodily functions and thus for creating data to improve the individual health situation and for supplying support in times of crises. Pre-requisition of a mobile, unobtrusive monitoring system was the development of a remission PPG sensor element to be placed in the outer ear channel. This measuring modality does not disturb the user during his daily life demands. It can even be assumed that due to the proximity to the brain a more robust measurement during critical hemodynamical situations is the outcome since the head is not affected by centralization issues like the fingers or toes. From this point of view, the ear channel can be seen as a monitoring *keyhole to the heart*. To analyse the potential of this measuring approach a number of customizable types of sensor-interface-devices were developed in our lab: Bluetooth enhanced sensor-PC interfaces, USB based sensor-PC interfaces and stand-alone devices (Fig. 5) with several firmware-related energy saving strategies. One of the most difficult aspects in low power wireless sensor applications is the continuous wireless transmission of vital data with the needed power consumption. In the developed interface electronic, we implemented the Bluetooth (BT) 4.0 communication standard using a BLE112-A Bluetooth module including low energy profile. This offers the most energy effective, standardized wireless transmission for Smartphone applications available today. Although the BLE112-A consists of a programmable microcontroller, an additional MSP430F169 (Texas Instruments, ultra-low mixed signal processor) microcontroller as main processing unit is used with respect to the complexity of the digital signal processing. More technical details can be found in [11-17].

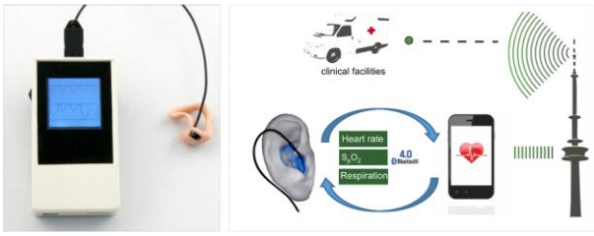

Fig. 5. *Function diagram of the in-ear PPG monitoring system strategy - as a single device (left) or as a system part of a medical support monitoring chain (right).*

4. ADVANCED (CUSTOMIZED) ALGORITHM STRATEGIES

Typical PPG signal recordings assessed in the ear cannel is shown in Fig. 6. From this, fundamental heart and respiratory activity parameters can be derived. But also, autonomous rhythmical phenomena analysis in the dermal perfusion or stress/pain analysis can be performed using advanced algorithm strategies in the time or frequency domain.

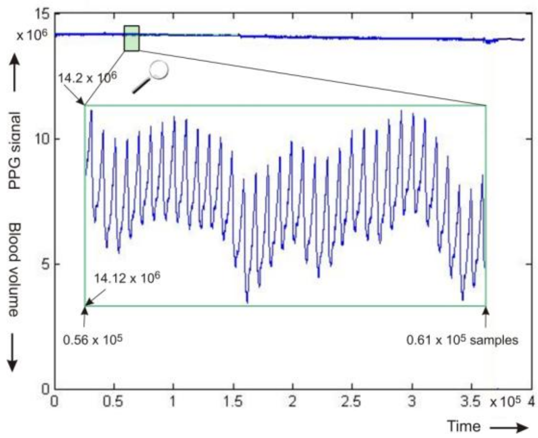

Fig. 6. *Typical phoptoplethysmogram detected in the ear. In this case, the DC-signal amplitude is approximately 14.15 x 10^6, the AC-signal 0.5 x 10^4.*

In order to be able to differentiate relaxation from stress for example, analysis of heart rate and respiration rate are needed, for stress is likely to go along with increases in these parameters. Nevertheless, stress is a physiological phenomenon with very high inter- and intra-individual variation. Therefore, an “absolute” quantification of a *stress-level* is challenging.

The research of the very individual set of generated health data shows that customized data analysis strategies need to come in place.

Newest research focus on variations in respiration and heart frequency since this is more promising for stress-level quantification.

Also, pain is a subjective feeling that is influenced by many various endogenous and external factors. In general, pain assessment is stress assessment as well. Due to a narcosis during surgical interventions external influences are reduced. Currently used algorithms for pain assessment like for example the Analgesia Nociception Index (*ANI*) [18] or Surgical Stress Index (*SSI*) [19] analyze the heart rate, pulse amplitude and heart rate variability based on the ECG or PPG recordings [20]. In our experience, also the waveform of the peripheral arterial blood volume pulse, analyzed using the Oliva-Roztocil algorithm, is a promising new way to quantify pain [21-23].

5. RESULTS AND DISCUSSION

Our current in-ear PPG measuring & data acquisition system offers the following possibilities:

- Intelligent front-end sensor concept (using a miniaturized PPG device, without any controls, executable and manageable via the associated software),
- long term perfusion studies (also 24/7),
- multi-channel and multi-wavelength design,
- full signal-recording (recording of the complete PPG signal without signal distortion by the filter in the chain),
- 200 measurement values per channel and second,
- 24-bit digitalization precision,
- future-proof PC-connection via USB,
- bus-powered via USB-Bus (no battery needed),
- data saving in data files, offering the possibility of reloading for advanced algorithmical studies.

In five human trials we could prove the clinical relevance of the discussed in-ear monitoring system. As the first, human hypoxia studies were performed in 2011 in collaboration with the University Hospital of Schleswig Holstein in Lübeck (Prof. Gehring) including 20 participants in order to calibrate the system. In addition, the system was tested under realistic clinical conditions with patients undergoing surgery in 2011/2012. These trials (43 patients) were also performed at University Hospital of Schleswig Holstein. In a third study, our system was evaluated for sleep diagnostic. This study took place at the University Hospital Aachen in collaboration with Prof. Schiefer. 20 Patients were included which probably suffer from OSA. First results indicate excellent nocturnal performance of the system which can be due to darkness and reduced motion scenario.

Nevertheless, motion artifacts can always disrupt the signal, especially face-related motion like chewing, cuffing etc. Although studies indicate that walking up to 5km/h doesn't affect the signal quality significantly, it would be useful to spend further research on this topic (i.e. accelerometer assisted PPG, piezo/ultrasound enhanced contact pressure measurement, intelligent artifact algorithm).

In the fourth study, we tested our system and the feasibility of continuous health monitoring during high altitude mountaineering at approx. 3000m in 10 healthy subjects with promising results.

Finally, the wearing comfort of both sensor concepts was evaluated within an orienting study. Ten subjects rated the wearing comfort of an individual and a universal in-ear sensor after 45 minutes on a scale from 0 (imperceptible) to 10 (unbearable). The custom-made sensors were averaged 0.75 and the universal sensors 1.8. The personalized sensors also gained in the comparative assessment of the achieved average signal quality of both sensor types. The normalized Root Mean Square Error was here 0.13% (-40.7 dB), for the universal sensors it was 0.20% (-32.3 dB) [24].

In further developing the sensors that support the health systems of the future we see that the three dimensions of customization – fit, functionality and form – are all relevant when developing the sensor product features as well as the sensor data services. Modern production technologies and a better understanding of individual health data will further support the creation of customized medical devices and will lead to a highly personalized medicine.

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CORRESPONDENCE

Dr. Vladimir Blazek, Prof.
Philips Chair for Medical Information Technology
RWTH Aachen University
Pauwelsstr.20, D-52074 Aachen
blazek@hia.rwth-aachen.de

Dr. Boudevijn Venema
Philips Chair for Medical Information Technology
RWTH Aachen University
Pauwelsstr.20, D-52074 Aachen
venema@hia.rwth-aachen.de

Dr. Dr. Steffen Leonhardt, Prof.
Philips Chair for Medical Information Technology
RWTH Aachen University
Pauwelsstr.20, D-52074 Aachen
leonhardt@hia.rwth-aachen.de

Dr. Paul Blazek
cyLEDGE Media
Wiedner Hauptstr. 118/39
1050 Vienna, Austria
p.blazek@cyledge.com