Validation of a Multi-wavelength Photoplethysmogram Sensor to Measure Blood Pressure at Chest in Anesthetized Patients

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For more than ten years, CSEM has been a pioneer in the development, implementation, and validation of novel solutions for non-invasive continuous blood pressure (BP) monitoring. One of the central devices in CSEM's catalog on BP-monitoring is a multi-wavelength reflective photoplethysmogram (PPG) sensor that allows to accurately estimate BP at the chest. As a part of the validation procedure to characterize the sensor's performances in an acute setting, CSEM is conducting a clinical trial on anesthetized patients in collaboration with the Lausanne University Hospital (CHUV). The results demonstrate that in the acute conditions a widely-used conventional single-wavelength approach remains unreliable, while the innovative multi-wavelength device considerably increases the BP-estimation performances.

CSEM multi-wavelength PPG sensor at chest[1,2] allows to estimate BP via a pulse wave velocity approach. The optical signal captures the pressure waves propagating from the aortic valve towards the chest vasculature. Both the velocity of those waves and the related time of propagation, i.e. pulse arrival time (PAT), provide a surrogate measure of BP[3].

The biomedical community sees various advantages of PPG technology, in particular in ambulatory or sub-acute settings, for which form factors such as patches and/or wearable sensors are required. For these form factors PPG allows to measure BP continuously without interfering with the comfort of the patients. Unfortunately, there is only a limited number of studies investigating the performances of the PPG technology against invasive references during hemodynamic changes.

To perform a realistic validation of the multi-wavelength PPG sensor, CSEM is conducting a clinical trial (clinicaltrials.gov: NCT02651558) on 17 anesthetized patients in collaboration with Lausanne University Hospital (CHUV). This scenario involves the administration of the anesthetic drugs inducing considerable variations in the hemodynamic parameters that could not be induced in sub-acute studies. Under these conditions the performances of both the novel multi-channel and the conventional single-channel approaches were evaluated against invasive gold-standard BP reference measurements (radial-artery catheter).

The investigation revealed that the administration of anesthetic drugs may transiently compromise the PPG waveform. The results of Kruskal-Wallis statistical test suggest that the waveform alterations are induced by the extreme changes in hemodynamics parameters occurring during anesthesia. As illustrated in Figure 1, 60% of the patients showed significant ($p < 0.05$) link between the amount of compromised waveforms and the changes in the hemodynamic parameters.

Furthermore, on the 17 patients processed, the PAT estimations from the single-wavelength sensors correlated with reference catheter-derived PAT values in 5, 4 and 6 patients for the green, red and infrared channel, respectively. Meanwhile, the novel multi-wavelength approach allowed to obtain PAT estimates that correlated with the benchmark in 12 patients. PAT estimations were considered to correlate to benchmark if p-values smaller than 0.05 were measured. An illustrative example of one patient is reported in Figure 2.

The presented findings illustrate that in a setup where anesthetic drugs are administrated and no additional pressure is applied onto the optical probe, multi-wavelength reflective PPG sensors are required to obtain reliable hemodynamic measurements at the chest. The very low reliability of single-channel PPG sensors at the chest questions the feasibility of developments claimed by other groups.

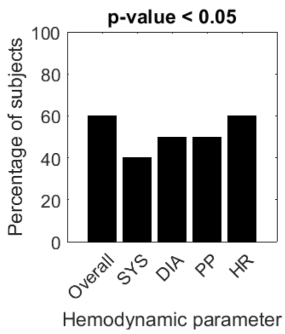

Figure 1: Percentage of patients in which the shape of the waveform was altered by one of the hemodynamic parameters, SYS, DIA, PP and HR stands for systolic, diastolic, pulse pressures and heart rate.

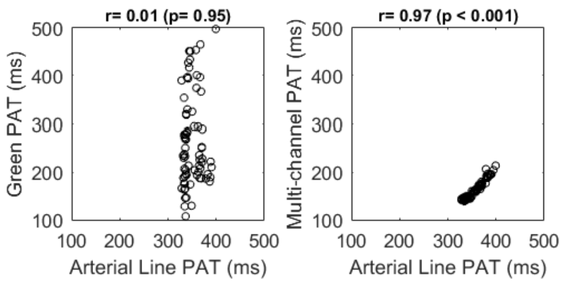

Figure 2: Example of the performances with a single-wavelength and a multi-wavelength reflective PPG approach.

[1] J. Sola, *et al.*, "Chest Pulse-Wave Velocity: A Novel Approach to Assess Arterial Stiffness", doi : 10.1109/TBME.2010.2071385.

[2] J. Sola, *et al.*, "Sensor device and method for measuring and determining a pulse arrival (pat) time", WO 2011120973 A1.

[3] R. Mukkamala, *et al.*, "*Toward Ubiquitous Blood Pressure Monitoring via Pulse Transit Time: Theory and Practice", doi: 10.1109/TBME.2015.2441951.