oxiPAD—Oxygenation Measuring and Mapping Platform

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The oxi-PAD project aims to develop a mobile, flexible, easy to handle Peripheral Artery Disease (PAD) monitoring oxygenation sensor/platform for in- and out-patient usage. Once realized the oxi-PAD will allow early detection of PAD, assessment of early interventions (like drug treatment), real-time assessment of surgical interventions, monitoring after surgical interventions and possibly homecare monitoring. The oxi-PAD will be applied on the skin of the patient and acquire data continuously while the patient moves or walks. Overall, the oxi-PAD sensor can be integrated into a CSEM's breakthrough wearable monitoring / diagnostic system i.e. re-usable sensor and processing systems for e.g., cardiovascular monitoring of the vessels.

The CSEM's oxi-PAD concept consists of a re-usable wireless oxygen sensor and processing system (for PAD diagnosis / continuous monitoring) packaged in a compact wearable device. The currently used ankle-brachial-index (ABI) method has several drawbacks: it is not applicable to patients with arterial calcification (hardening of the arteries), renal patients and diabetics, thus resulting in false negative results. As such, more than 50% of all patients, especially suffering from mild PAD are not diagnosed and are thus not treated in time.

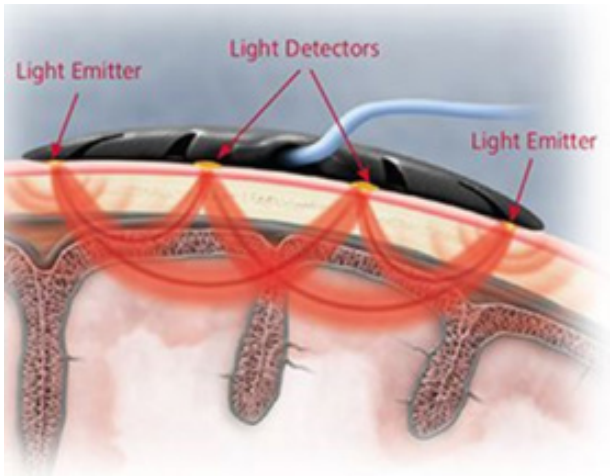

Figure 1: Principles of the proposed oxygenation sensor.

The key enabling advantage of CSEM's oxi-PAD is the possibility to acquire data continuously while the patient moves or walks. The parameter "pain when walking" often used in the diagnosis of PAD is very subjective. In contrast quantified oxygenation would allow a better classification of PAD since the walking distance of a patient can then be correlated with muscle oxygenation. The proposed oxi-PAD data acquisition system is a non-invasive device wrapped around the patient leg. Alternatively the oxi-PAD could successfully collect data when wrapped around the patient arm as well.

The oxi-PAD consists of arrays of Light Emitting Diodes (LEDs) and Photo Diodes (PDs) on a flexible foil. Two predominant wavelength bands are selected 750 nm (red) and 850 nm (infrared). Depending on the distance between the PDs and the LEDs the light propagates through deeper tissue/muscle layers. The ratio of red to infrared transmitted light gives a measure of the oxygen saturation of the blood or muscle and thus an indicator for tissue oxygenation (Figure 1). Such light propagation could be simulated in LightTools® in order to position the PDs with respect to the LEDs.

The layout of the proposed oxi-PAD device is shown in Figure 2 (first generation).

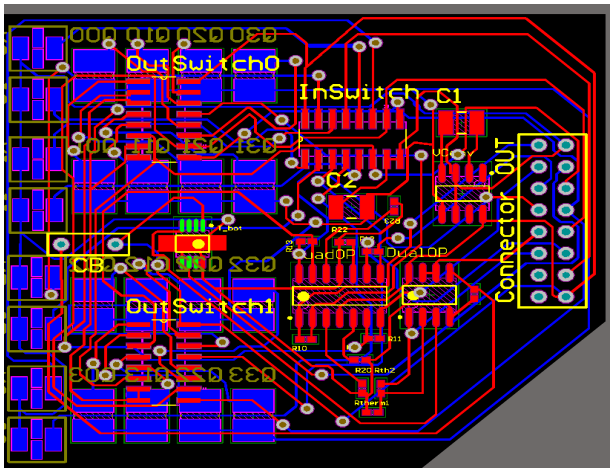

Figure 2: CSEM's oxi-PAD – layout of the first generation with 4 sensing channels.

In addition to the array of LEDs and PDs, the oxi-PAD allows embedding electronic components, such as temperature sensor, sweat sensor, battery, micro-controller, and GPS for measuring walking distances. This enables autonomous data acquisition while the patient walks/moves. The acquired data will be transmitted wirelessly to a computer or smartphone, and stored in order to track the PAD history.

The main novelties of the CSEM's oxi-PAD (Figure 2) are listed below:

- Flexible / wearable device.
- Smart packaging and proper skin fixation.
- Smart device i.e. algorithms for oxygenation mapping and quantification.
- Continuous monitoring with warning and alarm functions when critical data are collected.

The main oxi-PAD use case is by general practitioners during the regular check-up. The user-friendly oxi-PAD will further revolutionize in- and out-patient PAD diagnostics and enable real-time monitoring, and patient monitoring after surgical interventions.

Once realized the oxi-PAD will replace the currently used expensive and non-accurate PAD identification techniques.