Trans-illumination PPG Ulnar Holter

Introduction

Photoplethysmography (PPG) is the non-invasive technology that uses light interaction with blood to estimate physical parameters of the cardio-vascular and respiratory system[1]. Monitoring of vital signs is critical for patient triage, management and disease deterioration prediction. Principal assessments of patient conditions include respiratory rate, heart rate and heart rate variability, blood oxygen saturation and blood pressure parameters. However, these assessments are usually spot checks and carried out with multiple sensors placed in different body locations.

The aim of this white paper is to present a new fundamentally distinct method of acquiring, processing and reporting information called trans-illumination PPG technology. This technology enables a single non-invasive PPG sensor to simultaneously measure and report heart rate (HR), heart rate variability (HRV), blood oxygen saturation (SpO2), respiratory rate (RR) and blood pressure (BP) in continuous manner and of medical grade at a single location on the human anatomy.

Background

In general, PPG technology is based on generating a specific optical response to intensity of light transmitted through the pulsatile blood volume. According to the simplified Lambert–Beer model, the measured intensity is described by[2]:

$$I(\lambda,t)=I_0 \exp(-\mu_t \cdot c \cdot d(t)) \quad ,$$

Where d (t) is the optical path which is modulated by incoming arterial wave. It is clear that the signal-noise ratio (SNR) increases with the amplitude of signal fluctuation and long optical path d. This value is entirely predetermined by the number of photons – blood cells and probability of interaction events at the surface of the tissue. Knowing intensity extinction coefficients and wavelengths of the incident light, one needs to calculate the optimized photon path lengths, which depend on tissue anatomy at the sensor location. The light path optimization will result in high probability of the photon-blood cell interaction and avoidance an exposure to venous blood and other noise-induced blood-tissue analytes.

Depending on the detector location with respect to the light sources there are two conventional (prior art) measurement modes: reflected (back scattered light) and transmitted (forward scattered light)[3]. As known, there are some problems in the reflectance SpO2 and other vital parameters measurements at the hand wrist location comparing to fingertip biosensors[4]. The major practical limitation is the comparatively low-level PPG signal, which may be assigned to the low-density effective vascularization of the skin. This very poor vascularization results in the very short effective optical path. Both factors contribute to the reduced signal to noise ratio at the wrist area. In the reflection geometry, it is possible to increase the optical path by using a distant location of detector from the LED sources. However, this produces a dramatic decrease in the signal intensity and SNR because of increased diffusing of photons out of measurement area. Therefore, the quality of the PPG measurements depends on ability to locate and design an optical biosensor that can reliably and accurately detect PPG signal with high SNR.

In addition, recent study revealed that there is some inaccuracy in SpO2 and other vital parameters measurements resulting from diverse skin colors and tones. An article in NEJM reports that pulse oximeters missed occult hypoxemia in more black patients than white[5]. The FDA warns that pulse oximeters, devices used for estimating blood oxygen levels, may be less accurate in people with darker skin pigmentation.

Trans-illumination PPG technology

Location, location, location….

Oxitone medical developed a new, patented trans-illumination technology and method that exploits unique anatomic location on the wrist that obeys all physiological and optical requirements to generate reliable and accurate PPG signal, thereby almost all PPG-related physiological parameters can be accurately and continuously monitored.

Oxitone's biosensors cannot be considered as having a pure reflection or transmission configuration in accordance with the conventional definitions. Specifically, light propagates deeply inside the tissue, scattered on blood cells, reflected, focused or scattered on tissue components and ~~bones~~ ligaments, then again scattered on blood cells and being reflected back from the papillary structure of the dermis multiple times and, finally, part of the light reaches the detector.

The technology advantages attribute to the game-changing combination of a high light scattering coefficient of wrist Ulnar Joint Ligaments[6], connected to Proximal Radio Ulnar Joint (Fig. 1)[7] and high light scattering coefficient of Papillary Dermis at the same region (Fig. 2)[8]. The probability of the photons interaction with the blood cells is dramatically increased around the ligaments of Ulnar Joint area because of the multiple diffusive reflections that contributes into pulsatile signal.

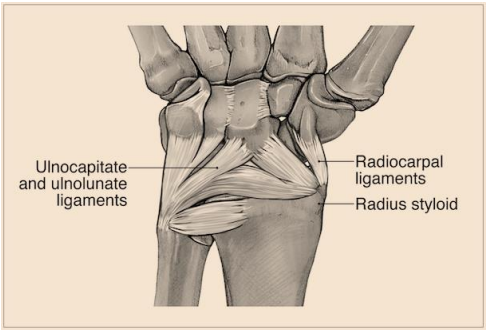

Fig. 1: Proximal Radio Ulnar Joint

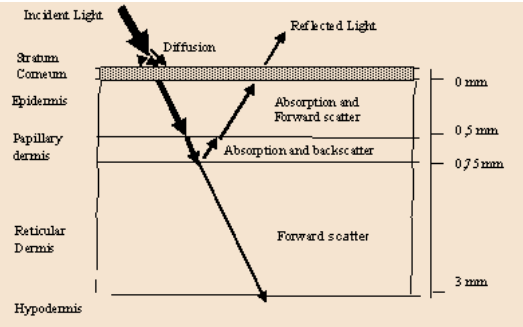

Fig. 2: Papillary Dermis light scattering

In addition, wrist Ulnar Joint area is highly penetrated by the arterioles. As a result, we have been able to get the AC/DC ratio around 0.5% while any other standard reflection configuration yields 0.02-0.05%. It has to be pointed out that AC/DC ratio of 0.5% for ulnar trans-illumination PPG is not far from the commonly accepted 1-1.5% for the finger (Fig. 3).

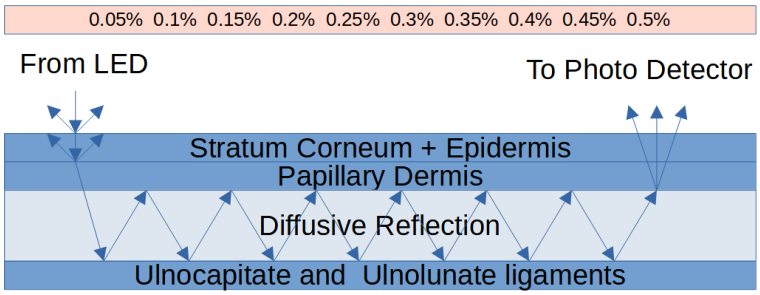

Fig. 3: AC/DC modulation as a function of LED-photodetector distance in Ulnar trans-illumination PPG

Accurate PPG measurements are possible for tissue volumes with homogeneous and balanced architecture of small arterial and venous blood vessels (arterioles and venules). Inclusion of larger blood vessels to the measured tissue volume will lead to additional interfering signal components and artifacts. Another unique property of the wrist Ulnar Joint area is absence of large blood vessels (Pic. 4).

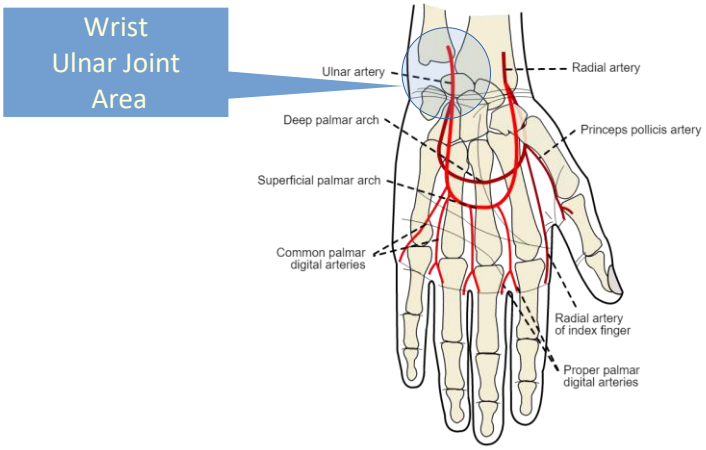

Fig. 4: Wrist Ulnar Joint area

Trans-Illumination PPG Ulnar technology provides highest quality and sensitivity for the measured blood volume related PPG signals, providing exceptionally accurate SpO2 data, pulse and Respiratory signals and others physiological parameters that were never accessible by PPG technique before.

Oxitone biosensor configuration and performance

The trans-Illumination technology and, specifically, biosensors design and configuration represents a breakthrough in wrist PPG measurements. Specifically, PPG biosensors are enclosed in a dome-shape flexible structure to fixate an area above an Ulnar Joint, so that the light sources and detector are ideally located around the Ulnar Joint making some angle with respect to each other for detection of the trans-illumination signal, as shown in fig. 5. The optimal distance between light sources and detector is about 15mm that enables an increase in the photons' path without affecting SNR and signal quality.

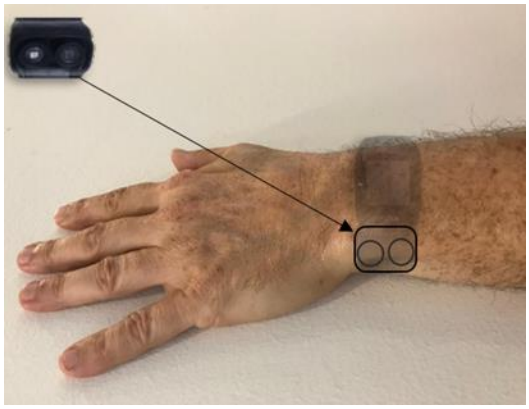

Fig. 5: Trans-illumination biosensor location

Another particular of the Oxitone biosensor is its flexible base that enables:

a) to avoid pressing the skin and squishing out the blood from the measurement site;
b) to eliminate shot light induced artifacts;
c) to accept the local surface topography that changes during wrist movements.

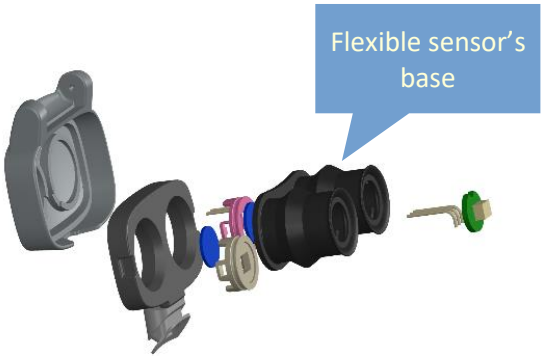

Fig.6: A full Oxitone's trans-illumination sensor configuration

Clinical studies of the Oxitone's trans-illumination biosensor have proved its superior, medical-grade accuracy and reliability. As an example, a SpO_2 accuracy comparison was conducted as part of the final Pulse Oximetry validation for the SpO_2 Ulnar Holter Oxitone 1000. The study was conducted in accordance to Code of Federal Regulations (CFR) for Nonsignificant Risk (NSR) investigational studies, following ISO 14155:2011 as appropriate and the pulse oximetry guidelines of ISO 80601-2-61:2011 applicable sections, and Pulse Oximeters – Premarket Notifications Submissions [510(k)s] Guidance For Industry and Food and Drug Administration Staff (issued: March 4, 2013).

To evaluate the SpO_2 and pulse rate accuracy performance of Oxitone 1000 placed on the left wrist over the range of 70-100% SaO_2, arterial blood samples, assessed by CO-Oximetry. The Accuracy Root Mean Square (ARMS) performance of the oximetry system meets the required specification of ARMS of 2% or less in range of 70 – 100% SaO2. In addition, it proved independence of results from skin color. Some example of the SpO_2 and pulse rate accuracy versus reference CO-Oximetry are presented in Fig. 7 and 8. The first trans-illumination biosensor was cleared by FDA and received CE Mark certification in 2017.

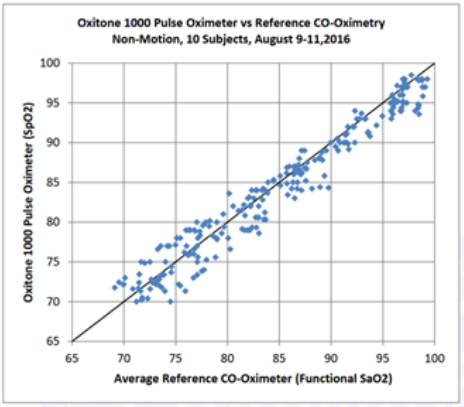

Fig. 7: Oxitone SpO2 vs reference CO-Oximeters

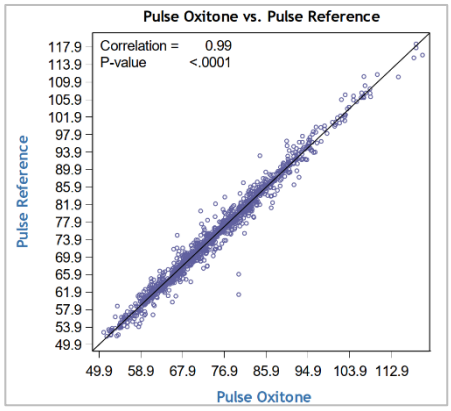

Fig. 8: Oxitone PR vs reference monitor

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