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Accuracy Report for the Owlet Smart Sock 2.0

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1 Introduction

The Owlet Smart Sock™(OSS) is a wireless pulse oximeter that is intended for healthy infants between 6 and 25 pounds to wear while sleeping. It is embedded in a sock that is comfortably placed on a baby's foot and measures an infant's heart rate and oxygen levels. The OSS connects via Bluetooth to a base station that pushes the data the the cloud through a secure Wi-Fi connection. The information is then served to a mobile app called the Owlet app; see Figure 3.1. Although it passes stringent requirements applicable to medical devices [2], the OSS is marketed as a consumer wellness product [1] available at major in-store and online retailers and the `owletcare.com` website.

If an infant's heart rate or oxygen levels go outside of pre-set ranges, both the base station and app will sound a notification, thus prompting parents to check on their baby. The Owlet app also lets parents check on their sleeping baby's vitals at any time.

Here we discuss two accuracy studies performed by Clinimark, a highly-respected independent and internationally recognized clinical research organization (CRO). The first study compared OSS oxygen readings against arterial blood-gas (ABG) draws, which is the "gold standard" for testing O2 levels in blood [3]. This was performed on an adult population across a range of 67-100% SaO2. The device *passed* and was found to be within 2.4% *accuracy root mean square* (ARMS); see [5] for details about ARMS. In the second study, the OSS was compared against a leading hospital pulse oximeter on *still or sleeping* babies and found to be within 2.0% ARMS.

Figure 1: Owlet Smart Sock with base station and the Owlet app.

2 Background

A pulse oximeter work by passing beams of red and infrared light through the blood. The ratio of red to infrared light that is absorbed by blood gives a measure of the oxygen saturation. Because oxygenated blood absorbs more infrared light than red light and deoxyhemoglobin absorbs more red light than infrared light, the oximeter can determine the intensity of both shades of red and calculate the fractions of the blood with and without oxygen [4, 5].

Since a pulse oximeter is attached to a peripheral body part (e.g., finger, foot, thumb or earlobe), the oxygen ratio is referred to as *peripheral oxygen saturation* (SpO2) and represents the percentage of blood that is oxygenated. This is in contrast with arterial oxygen saturation (SaO2) or venous oxygen saturation (SvO2), both of which can be determined with blood gas draws.

Although ABG is the gold standard for measuring oxygen, it is impractical to use for monitoring over time because of the expense of testing and delays in getting results. Moreover, ABG doesn't provide information about whether tissues are receiving the oxygen whereas pulse oximetry does; for more details about the relative merits between ABG and pulse oximetry, see [3, 5].

When there is little to no motion, pulse oximetry provides an accurate estimate of blood oxygen [6, 7]. In the presence of motion, however, accuracy can be compromised. As a result, the OSS has an accelerometer on the sensor that is used to stop sensing when there is too much motion. This reduces false alarms, but also means that the OSS is not monitoring when sufficient motion is present. For this reason, the OSS is only recommended for still or sleeping infants.

SpO2 levels in the 94-100% range are considered normal. Hospital pulse oximeter alarms are usually set between SpO2 85-92%, but experience frequent false alarms as a result of motion artifacts and poorly placed sensors. It can also happen that healthy babies can momentary dips below 90% [8, 9], especially when feeding or sleeping deeply at higher altitudes. However, prolonged exposure to oxygen under 90% is considered too low resulting in hypoxemia [5]. Blood oxygen levels below 80% may compromise organ function, such as the brain and heart, and should be promptly addressed. Continued low oxygen levels may lead to respiratory and/or cardiac arrest.

To avoid false alarms and increasing parental anxiety, the OSS monitor is set to alarm at 80% SpO2. That said, if a baby is below 92% for longer than a few minutes at a time, it is generally recommended that a physician be consulted [9, 10].

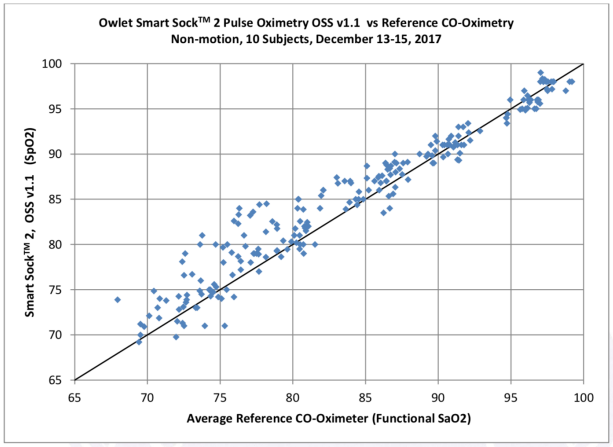
3 Testing

We describe two third-party studies which validate the OSS sensor accuracy for SpO2. The first compares OSS readings against arterial blood gas analysis on adults, and the second compares OSS readings against a leading hospital device on an infant population. Both studies were performed by Clinimark, an independent laboratory and industry leader for clinical testing and bench validation for medical monitoring devices.

The studies were conducted in accordance to the FDA Guidance for the Pulse Oximeters for Premarket Notifications and Code of Federal Regulations (CFR) for Non-Significant Risk studies [2]. The requirement for both tests is that the oximetry system have an ARMS of 3% or less in non-motion conditions for the range of 70-100% SpO2.

3.1 First Test: Arterial Blood Gas in Adults

The purpose of the study was to evaluate the accuracy of the blood oxygen saturation (SpO2) of the OSS sensor, using arterial blood gas (ABG) draws as the reference over the range of 70-100% SaO2. Because the test subjects were adults, the sensor was fashioned to fit on their fingers.



Following IRB approval, the SpO2 accuracy of the OSS pulse oximetry sensor was tested on 10 healthy adult subjects across several values of oxygen (226 data points). Subjects were given breathing devices that regulated their mixture of oxygen and nitrogen so that their oxygen levels could be brought down to lower levels, specifically in the range of SpO2 67-100% to give coverage over the desired range of 70-100%.

The results of the study found that the SpO2 accuracy of the OSS sensor has an ARMS of 2.4%, which is well below the required 3% and therefore passes the industry standard. This study is assigned an identified number of NCT03630016 and can be found at ClinicalTrials.gov (see also [11]).

3.2 Second Test: Comparison with Hospital Monitor

The purpose of this second study was to evaluate the accuracy of the blood oxygen saturation (SpO2) on the OSS, using leading hospital devices, specifically the Masimo Rainbow II and LNCS-inf sensors. In addition, this test addressed the accuracy of the OSS sensor, general performance and fit, and results reproducibility in infants between the ages of 1 and 17 months. Following IRB approval, a total of 14 infants were screened, enrolled, and included in the data analysis.

Sensors were placed on each infant to collect room-air data to evaluate the performance of the pulse oximeter sensors under non-motion conditions for up to 20 min. ARMS value was 2%, which is below the required 3%, hence providing more evidence of accuracy. For more details, see [12].

4 Disclaimers

Although the OSS satisfies the standards for accuracy set by the FDA for pulse oximetry, it is not a medical device and is not marketed for any medical uses. The OSS is marketed as a consumer *wellness* device under the FDA's General Wellness guidance [1] to give parents of healthy babies peace of mind, to help them manage parental and postpartum anxiety, and to help them sleep better.

At the time of this writing, the FDA has not approved any over-the-counter (OTC) pulse oximeters for infants, and so the only way a parent can have access to this technology without a prescription is as a consumer wellness device for healthy babies.

5 Future Work

Owlet Baby Care is currently preparing a 510(k) medical device submission with the FDA. If approved, this would allow a medical version of the OSS to be marketed and prescribed. We hope that one day an over-the-counter medical device version of the Owlet Smart Sock that will also be FDA approved, thus giving parents affordable medical grade health sensing technology in their homes without a prescription.

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