OWLET SMART SOCK GENERATION 3 CLINICAL ACCURACY REPORT

White Paper
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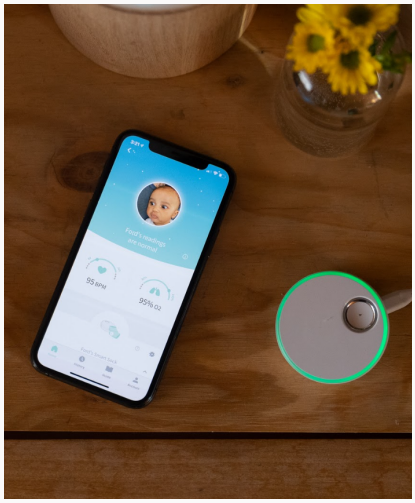
INTRODUCTION TO THE OWLET SMART SOCK

In 2015, Owlet Baby Care introduced the first wireless infant pulse oximeter, The Owlet Smart Sock (OSS). Like other pulse oximeters, the OSS tracks infant oxygen levels (SpO2) and heart rate (HR) by comparing the absorption of two passing light sources (red and infrared) through an infant's foot to a photo detector.[1] However, unlike other pulse oximeters, the OSS was specifically made with parents in mind, by prioritizing features such as safety and ease of use. These features allow parents and caregivers to feel empowered with the information they need to bring peace of mind about their baby's wellbeing.



The newest version of the OSS, the Owlet Smart Sock Generation 3 (OSS3) was released Summer 2020. Like the previous versions, the updated OSS3 is intended for monitoring and tracking HR and SpO2 while the infant is sleeping. The product includes significant hardware enhancements to the Sensor making it Owlet's most accurate monitor yet. Additionally, a smaller Base Station provides faster, more convenient wireless drop-and-go charging and upgraded wireless antennas to offer a wider Bluetooth range. The new Sock design comes in two sizes (designed to fit newborns to children up to 30 lbs, or approximately 18 months) improving Sock fit for every baby. Moreover, the materials used for the OSS3 are durable, hypoallergenic, and tested for infant use. Product enhancements also include new machine learning algorithms that track SpO2 and HR even when the baby is asleep in an environment with gentle movement.

Though the OSS3 advancements have been beneficial, it can only be trusted if it accurately monitors SpO2 levels and HR. In order to show the effectiveness of OSS3, multiple studies were completed to determine its accuracy and reliability.

PRECLINICAL DEVELOPMENT

Prior to clinical testing, over 100 hours of internal studies were completed on participants who varied in age, weight, sex, skin tone, and foot circumference to develop and evaluate the OSS3 detection algorithm over various conditions and user behaviors.

Conditions included an infant asleep in the following scenarios:

Non-motion
- In a crib
- In a bassinet

Gentle Motion
- On a vibrating pad
- In a motion bassinet (i.e. Snoo)

Owlet Baby Care also tested in situations outside of our intended use while the baby was either awake or asleep:

Unintended use
- Changing the baby's diaper
- In a swing
- Bottle or breastfeeding
- Riding in a stroller
- Being rocked or walked in their parent's arms
- In a car seat while being rocked or riding in a car

Furthermore, we tested in various lighting scenarios to monitor pulse oximetry light absorption.

CLINICAL VALIDATION

Two independent studies were done by external third party labs to validate the OSS3 SpO2 and HR readings. To verify SpO2 measurements with the OSS3, The Hypoxia Research Lab at the University of California, San Francisco completed an IRB approved study, by comparing the percentage of oxyhemoglobin in arterial blood, or oxygen saturation (SaO2), to OSS3 SpO2 levels. To confirm OSS3 HR estimates, the company Physio Monitor completed a study reporting the accuracy of the HR readings from the OSS3 to the Fluke Prosim 8 Vital Signs Simulator.

SPO2 VALIDATION

PURPOSE

The object of this study was to communicate on the accuracy for the SpO2 readings of the OSS3 Sensor compared to arterial blood sampling using an ABL-90 multi-wavelength oximeter (Hemoximeter, Radiometer, Copenhagen, serial 1393-090R0359N0002).[2]

EXPERIMENTAL DESIGN

The study was performed in accordance with federal regulations for non-significant risk medical device studies and applicable Pulse Oximetry Standards.* Due to safety concerns, arterial blood sampling is generally not performed in healthy infants, therefore comparisons of SpO2 and SaO2 were performed on healthy adults wearing the OSS3 on their thumb to get SpO2 readings.

For the study, 14 participants were given medical grade mixtures of oxygen and nitrogen to induce stable oxygen saturation measurements across a range of 100% to 70%. SaO2 hemoximeter measurements were simultaneously compared with SpO2 from the OSS3.

*ISO 80601-2-61:2017 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment, Clause 201.12.1.104, Pulse Rate ACCURACY

RESULTS

In order for a pulse oximeter to pass industrial standards, the Accuracy Root Mean Square (ARMS) must be less than 3.0%.[3] An ARMS of 2.1% was reported for the OSS3, shown in Table 1, which is well below the required 3% standard.[2] Table 1 also shows the average difference in SpO2 and SaO2 over four 10% intervals. For SaO2 levels greater that 70%, the average differences between OOS3 and the hemoximeter measurements were less than 2%. Differences of this magnitude are unlikely to pose a clinical concern.

OWLET SMART SOCK 3 BIAS

Hemoximeter Range	60-70%	70-80%	80-90%	90-100%	70-100%
Mean	4.47	1.69	0.22	-1.36	-0.30
Count	6	38	69	104	211
Missing Data	19	65	42	8	115
Standard Deviation	3.19	2.24	1.61	1.61	2.09
Standard Error	1.30	0.36	0.19	0.16	0.14
95% Confidence Interval	3.35	0.74	0.39	0.31	0.28
Limits of Agreement	N/A	-2.79 to 6.16	-3.00 to 3.43	-4.57 to 1.85	-4.41 to 3.82
Maximum	7.50	7.71	5.03	2.40	7.71
Minimum	0.03	-1.73	-2.88	-6.82	-6.82
Root mean square (ARMS)	5.33	2.78	1.61	2.10	**2.10**

Table 1: Table summarizing the comparison between the difference in the Owlet Smart Sock 3 and a hemoximeter. SaO2 measurements were between 60 and 100%. The Accuracy Root Mean Square (ARMS) was 2.1%, passing industry standards for pulse oximeters.[2]

HR VALIDATION

PURPOSE

The goal of this study was to provide an accuracy report for the OSS3 HR readings. The OSS3 was validated by the Fluke Prosim 8 Vital Signs Simulator, a device that imitates various physiological parameters of a patient, including ECG (HR), respiration, invasive blood pressure, non-invasive blood pressure, temperature, and cardiac output. This device is FDA cleared under K110429.[4]

EXPERIMENTAL DESIGN

The test was performed using an optical sensor to compare the OSS3 light output and the Simulator. In order to resemble real HR as well as possible, a variety of pulse amplitudes were used by the Fluke Prosim 8. Additionally, the HR setting of the Simulator was increased from 30 beats per minute (bpm) to 250 bpm at intervals of 5 bpm then similarly decreased over the same range. At each setting, the OSS3 was allowed 30 seconds to stabilize. The OSS3 was unable to report readings at 30 or 31 bpm, so results are reported from 32 bpm-250 bpm.

RESULTS

In Figure 1, the frequency of the bpm error between the OSS3 and the Fluke Prosim simulator is represented. The OSS3 was always within -1 to +4 bpm of the Fluke Prosim simulator. For each 5 bpm increment, the OSS3 reported it's detected HR (Figure 2). The reported ARMS was 1.96 bpm (Table 2), providing evidence that the OSS3 HR accurary passes an ARMS specification of 3.0 bpm over the pulse rate range of 32-250 bpm when compared to Fluke Prosim 8 Vital Signs Simulator.

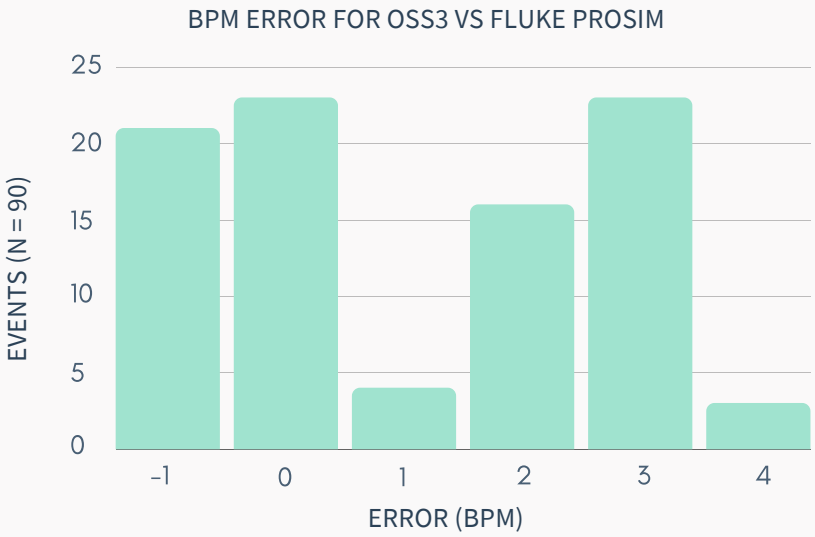


Figure 1: Frequency of the bpm error when comparing The Owlet Smart Sock 3 with the Fluke Prosim 8 Vital Signs Simulator.

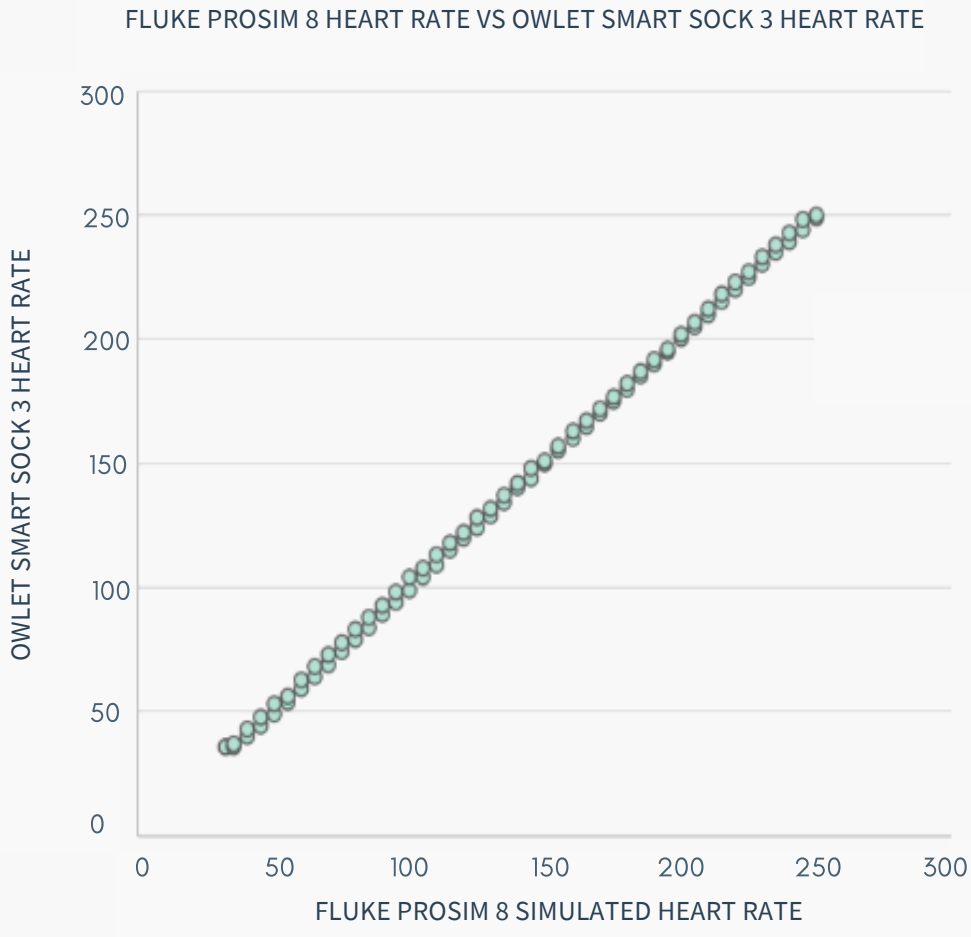


Figure 3: The Fluke Prosim 8 Simulated heart rate vs. The Owlet Smart Sock 3 heart rate. Heart rate ranged from 32 to 250 bpm.

OWLET SMART SOCK 3 HR COMPARISON TO FLUKE PROSIM 8 (FOR BPM LEVELS 32-250)	
ARMS	1.96 BPM
ARMS INDUSTRIAL STANDARDS	PASS

Table 2: Owlet Smart Sock 3 Accuracy Root Mean Square (ARMS) for heart rate compared to The Fluke Prosim 8 Vital Signs Simulator. The Owlet Smart Sock 3 passed industrial standards for pulse oximeters.

CURRENT RESEARCH

In addition to the two completed studies above, Owlet is currently collaborating with the University of Utah in a comparison study. SpO2 and HR measurements will be compared using the OSS3 and a standard wired pulse oximeter in premature infants in the Neonatal Intensive Care Unit.

CONCLUSIONS AND FUTURE RESEARCH

In conclusion, these studies have shown that the OSS3 Sensor is accurate and corresponds to industry standards on pulse oximetry (SpO2: ARMS = 2.1% and HR: ARMS = 1.96 bpm). This suggests that medical professionals and consumers can trust the SpO2 and HR outputs from the OSS3. Furthermore, additional clinical comparison studies are in progress to further support the product's accuracy.

In addition to being accurate, the OSS3 has been proven to lower parent anxiety and improve parent sleep. In a study involving more than 47,000 participants, Owlet Baby Care found that 96% of parents using the OSS felt less anxious and 94% reported better sleep quality while using the OSS.[5] Also the device is wireless, portable, and simple to use. The OSS3 exemplifies what a baby monitor should be by providing parents with critical information to ensure the wellbeing of their baby.

Owlet Baby Care values product research and validation and will continue to improve the Owlet Smart Sock to provide the precise, continuous, and user friendly experience. If you are interested in using our products in a research study, please reach out to us by sending an email to clinical@owletcare.com with your research proposal. The clinical team will evaluate your proposal and determine if it aligns with their current goals.

CONSIDERATIONS WHEN WEARING THE SOCK

The OSS3 is a consumer product and is not regulated by the FDA as a medical device. It is not intended to be used to diagnose, treat, prevent, or cure any disease. The OSS3 is designed to provide wellness information to a baby's caregiver while the baby is sleeping on their back, in their own sleep space, and in a home setting. It should not be used on children older than 18 months or weighing more than 30 lbs.

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