

Letters

RESEARCH LETTER

Accuracy of Pulse Oximetry-Based Home Baby Monitors

Smartphone-integrated consumer baby monitors that measure vital signs are popular among parents but are not regulated by the US Food and Drug Administration (FDA).¹⁻⁴ This study measured the accuracy of pulse oximetry-based consumer baby monitors using an FDA-cleared oximeter as a reference.

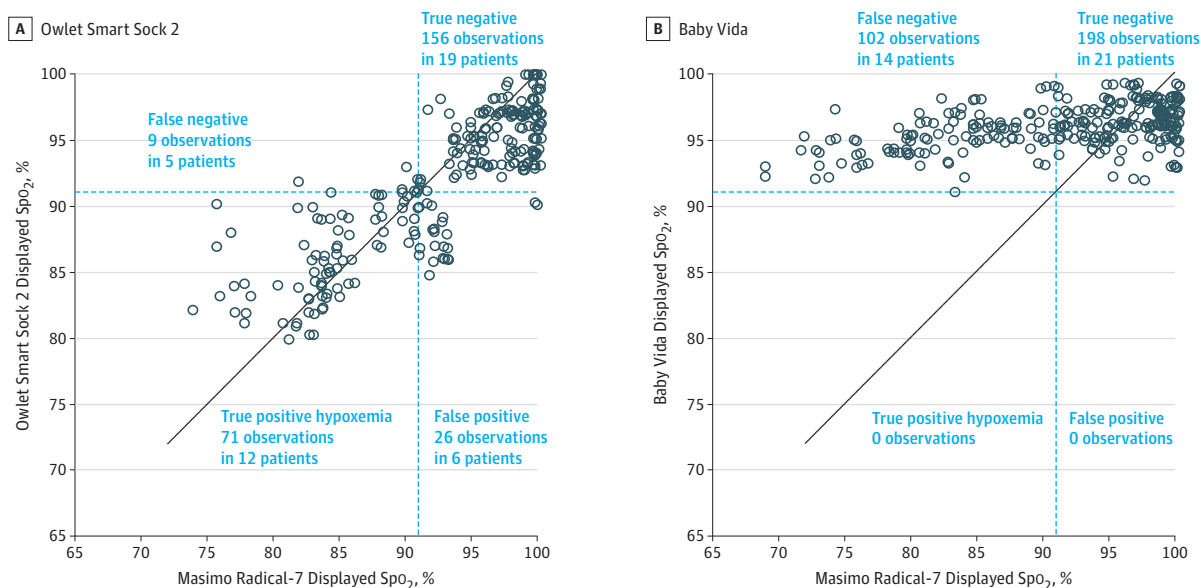
Methods | We purchased the only 2 currently marketed smartphone-integrated consumer baby monitors that use pulse oximetry, the Owlet Smart Sock 2 (consumer monitor A) and Baby Vida (consumer monitor B). We enrolled infants aged 0 to 6 months hospitalized in general pediatrics and cardiology wards at the Children's Hospital of Philadelphia from July through December 2017. Infants were excluded if born before 34 weeks' gestation, critically ill, anemic (hemoglobin <10 g/dL), febrile ($\geq 38.0^{\circ}\text{C}$), hypothermic ($<36.0^{\circ}\text{C}$), hypotensive (systolic blood pressure <60 mm Hg if 0-28 days old or

<70 mm Hg if 29 days-6 months old), or had compromised perfusion. Written informed consent was obtained from infants' parents. The Children's Hospital of Philadelphia's institutional review board approved the study.

On 1 foot, infants were monitored using a Masimo Radical-7 with 16-second averaging (reference monitor). Each consumer monitor was applied to the other foot of all infants in a random sequence for 60 minutes while asleep or awake and calm.

We identified "stable" paired reference monitor-consumer monitor points that met criteria: (1) for the reference monitor, during the prior 30 seconds, oxygen saturation (SpO_2) varied by 1 percentage point or less in either direction for SpO_2 comparisons or pulse rate varied by 5 beats/min or less in either direction for pulse rate comparisons and (2) for the consumer monitor, during the prior 30 seconds, no dropout (defined as failure to display a value). To minimize ascertainment bias, we randomly selected up to 10 stable points per patient for analysis. We generated scatterplots and calculated sensitivity and specificity for hypoxemia ($\text{SpO}_2 < 91\%$)⁵ and bradycardia (pulse rate <90 beats/min),⁶ accounting for

Figure 1. Oxygen Saturation (SpO_2) for Oxygen Baby Monitors Owlet Smart Sock 2 and Baby Vida (Consumer Monitors) vs US Food and Drug Administration-Cleared Masimo Radical-7 (Reference Monitor)



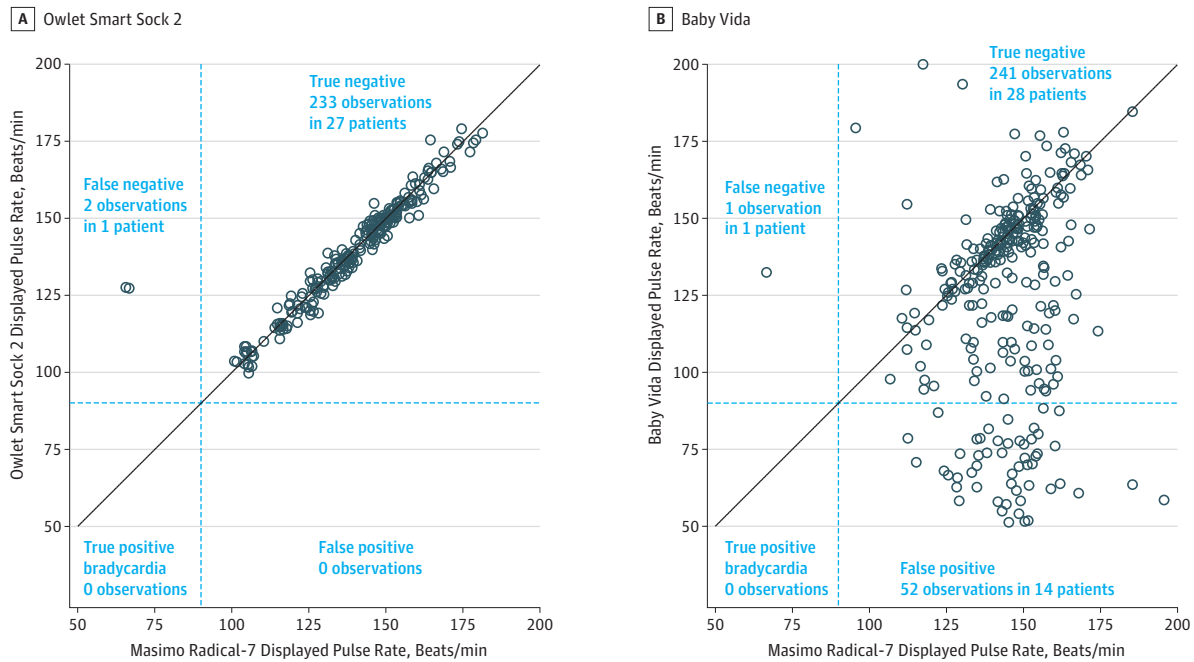
To minimize ascertainment bias, we randomly selected up to 10 stable points per patient per consumer monitor for analysis. The dotted lines indicate cut points for hypoxemia ($\text{SpO}_2 < 91\%$). The solid line represents perfect agreement between consumer monitor and reference monitor. Jitter (spherical random noise) added to prevent data points from overprinting using Stata graph option "jitter(1)."

A, Plot displays 262 randomly selected observations from 28 patients.

Hypoxemia prevalence was 30.5%; sensitivity, 88.8% (95% CI, 79.4%-98.1%); specificity, 85.7% (95% CI, 72.6%-98.8%).

B, Plot displays 300 randomly selected observations from 30 patients. Hypoxemia prevalence was 34.0%; sensitivity, 0.0% (97.5% CI, 0.0%-3.6%); specificity, 100.0% (97.5% CI, 98.2%-100.0%).

Figure 2. Pulse Rate for Oxygen Baby Monitors Owlet Smart Sock 2 and Baby Vida (Consumer Monitors) vs US Food and Drug Administration–Cleared Masimo Radical-7 (Reference Monitor)



To minimize ascertainment bias, we randomly selected up to 10 stable points per patient per consumer monitor for analysis. The dotted lines indicate cut points for bradycardia (pulse rate <90 beats/min). The solid line represents perfect agreement between the consumer monitor and reference monitor. Jitter (spherical random noise) added to prevent data points from overprinting using Stata graph option "jitter(1)."

A, Plot displays 235 randomly selected observations from 28 patients. Bradycardia prevalence was 0.8%; sensitivity, 0.0% (97.5% CI, 0.0%-84.2%); specificity, 100.0% (97.5% CI, 98.4%-100.0%).

B, Plot displays 294 randomly selected observations from 30 patients. Bradycardia prevalence was 0.3%; sensitivity, 0.0% (97.5% CI, 0.0%-97.5%); specificity, 82.3% (97.5% CI, 72.5%-92.0%).

clustering within patients. We used R (R Foundation), version 3.3.3, and Stata (StataCorp), version 15.1, for analysis.

Results | Of the 30 infants (50% female; 33% black; median birth at 39 weeks' gestation [interquartile range {IQR}, 38-40]; median age, 50 days [IQR, 26-90]), the most common diagnoses were bronchiolitis (27%), apnea or brief resolved unexplained event (10%), hypoplastic left heart syndrome (10%), and double outlet right ventricle (10%).

We recorded 2466 stable SpO₂ and 1801 stable pulse rate points. Using monitor A, 5 patients had fewer than 10 stable SpO₂ points and 10 patients had fewer than 10 stable pulse rate points. Using monitor B, 3 patients had fewer than 10 stable pulse rate points.

Figure 1 and **Figure 2** display scatterplots for SpO₂ and pulse rate. During testing of monitor A, 12 patients experienced hypoxemia according to the reference monitor and all 12 had at least 1 simultaneous hypoxemia reading on monitor A, although 5 of the 12 each had at least 1 stable normoxemic reading on monitor A during hypoxemia. During testing of monitor B, 14 patients experienced hypoxemia according to the reference monitor, but none had simultaneous hypoxemia readings on monitor B. All SpO₂ readings on monitor B were in the normal range. Monitor A had 0 instances of falsely displaying bradycardic pulse rates when the reference

monitor rate was normal. However, in 14 patients, monitor B falsely displayed bradycardic pulse rates when the reference monitor rate was normal.

For monitor A, the sensitivity and specificity for hypoxemia were 88.8% and 85.7%, respectively, and for bradycardia were 0.0% and 100.0%, respectively.

For monitor B, the sensitivity and specificity for hypoxemia were 0.0% and 100.0%, respectively, and for bradycardia were 0.0% and 82.3%, respectively.

Discussion | Accuracy testing of 2 SpO₂-based baby monitors that are not FDA-regulated revealed concerning findings. Monitor A detected hypoxemia but performed inconsistently. Monitor B never detected hypoxemia and also displayed falsely low pulse rates. Beyond their accuracy, other concerns about consumer monitor use include the lack of medical indications for monitoring infants at home, the absence of FDA oversight, and the potential for unintended consequences.¹ The main study limitation is the use of a pulse oximeter as the reference standard; arterial blood gas measurements would be preferred but limit feasibility.

As more neonate and infant vital sign monitors emerge in this largely unregulated market, physicians and parents should exercise caution incorporating data from these monitors into medical decisions.

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Author Contributions: Dr Bonafide had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The analysis was performed by Drs Orenstein and Bonafide with oversight from Dr Localio.

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COMMENT & RESPONSE

Sodium Excretion in Population Subgroups

To the Editor Dr Cogswell and colleagues analyzed data from the 2014 National Health and Nutrition Examination Survey (NHANES) on sodium.¹ Only body mass index, male sex, and diabetes were significantly associated with salt intake, suggesting that calorie intake is the main determinant of salt intake. The sodium intake in the US population demonstrated in this analysis confirms previous findings also based on 24-hour urinary excretion.²

However, some additional results deserve attention. For instance, it has been assumed that sick individuals with hypertension, diabetes, chronic kidney disease, and cardiovascular disease have a lower salt intake than healthy individuals due to an illness-related reduction in food consumption or an intended change in salt intake following medical advice.³ The present analysis showed that these patient groups did not have a salt intake lower than the healthy population (Table 3 and eTable 6 in the article). Also, the study found that even individuals who reported having reduced their salt intake had a salt intake similar to that of healthy individuals. This may reflect that neurohormonal regulation of salt intake makes it difficult to reduce salt intake despite intentions to do so. However, the most interesting consequence of these findings is that they weaken the reverse causality argument,³ which questions the association between a salt intake below the recommended upper limit (2300 mg/d) and increased mortality, as demonstrated in population studies.^{4,5} According to this argument, this association is due to sick individuals eating less salt than healthy individuals. This analysis demonstrated that this is not the case. The analysis indicated that individuals who report reduced salt intake should not be excluded from population studies linking salt intake with health outcomes because the individual's sense of a reduced salt intake seems to be incorrect. These findings are not due to small sample size because there were no borderline-significant trends to support such an interpretation.

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