

Evaluation of the Ohmeda 3700 Pulse Oximeter: Steady-state and Transient Response Characteristics

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The authors determined the accuracy of the Ohmeda 3700 (version J) pulse oximeter in healthy volunteers rendered hypoxic (SaO_2 from 60–98%) by breathing mixtures of O_2 in N_2 . When equipped with an ear probe, the pulse oximeter reading (y) reliably predicted arterial saturation (x) under steady-state conditions ($y = 1.05x - 4.66$, $r = 0.98$) as well as when oxygen saturation was rapidly decreasing ($y = 1.05x - 6.38$, $r = 0.96$). Conversely, when equipped with a finger probe, the oximeter tended to significantly underestimate steady-state arterial saturation ($y = 1.21x - 19.1$, $r = 0.98$, $P < 0.001$). In response to this information, the manufacturer modified the oximeter's software (version XJ1), resulting in improved agreement between oximeter readings and arterial values ($y = 0.96x + 4.59$, $r = 0.99$). Despite the close correlation between steady-state oximeter readings and arterial saturation, the 99% prediction limits for both the ear and finger probes (version XJ1) were $\pm 8\%$. Finger probe readings did not reliably reflect radial arterial oxygenation during rapid desaturation ($y = 0.55x + 45.2$, $r = 0.78$). This may be related to the time required to "arterialize" the blood in the finger; during acute resaturation, we found that the ear- to finger-probe delay was 24.0 ± 2.3 s ($\bar{x} \pm \text{SE}$, $P < 0.001$). (Key words: Measurement techniques: pulse oximeter. Oxygen: blood levels—arterial.)

CONTINUOUS, NON-INVASIVE MONITORING of arterial oxygenation promises to increase patient safety while decreasing the need for arterial blood gas analysis.^{1,2} Recent advances in electronic and microprocessor technology, along with the development of inexpensive, single wavelength light emitting diodes (LED's), have led to the development of compact pulse oximeters for use with ear or finger capillary beds.^{3,†}

Recently, Ohmeda introduced the Biox (R) 3700 pulse oximeter (Ohmeda, Boulder, CO). Although this device uses new algorithms for determining oxygen saturation, there are no published studies confirming its accuracy. Therefore, we conducted the present study to test the accuracy of this oximeter under steady-state conditions

of arterial hypoxia, as well as its response characteristics in rapidly changing oxygenation states.

Methods

Eight healthy, non-smoking, male physician volunteers, aged 21–35 yr, consented to participate in our Institutional Review Board approved study. The three black subjects were known to have normal hemoglobin composition. Subjects took nothing by mouth for 8 h before the study. After starting an intravenous infusion and EKG monitoring, we assured the adequacy of ulnar collateral circulation (Allen's test), inserted a 22-G catheter into each subject's left radial artery, and continuously monitored intraarterial pressure throughout the study. We then placed Ohmeda 3700 (version J) probes on the right earlobe and index finger of all eight subjects. The oximeters were set to respond in the fastest mode (3-s averaging). A Mapleson D breathing circuit and mask delivered various oxygen/nitrogen mixtures from an Ohio anesthesia machine; fresh gas flows of 5 l allowed a small amount of rebreathing. A Godart Rapox® continuously measured airway O_2 tension; a TI Servo Riter II® chart recorder recorded the pulse oximeter and Rapox outputs.

With subjects breathing room air, we obtained our first set of steady-state measurements. Each set consisted of simultaneously recorded ear and finger oximeter readings, as well as an arterial blood sample. We immediately placed arterial samples in ice water and determined their O_2 saturation and carboxyhemoglobin content within 60 min⁴ using a Corning 2500 Co-oximeter, which was calibrated according to the manufacturer's instructions immediately before each group of samples was analyzed. We then allowed subjects to breathe 100% O_2 . When a steady state (as defined by unchanging end-tidal oxygen and pulse oximeter readings for 1 min) was achieved, we obtained a second set of measurements. Subjects then breathed a hypoxic gas mixture containing an inspired oxygen fraction of 0.14, corresponding to an arterial oxygen saturation of approximately 90%. Upon achieving steady-state conditions as defined above, we obtained a third set of measurements. After allowing subjects to re-equilibrate with room air for approximately 5 min, we administered 12% oxygen. At the moment the ear oximeter reading reached the same value as we observed during the steady state with $\text{FI}_{\text{O}_2} = 0.14$, we obtained a set of measurements to help in determining the oximeter's

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accuracy during rapid changes in oxygenation. When oximeter readings and end-tidal oxygen fraction ($F_{ET}O_2$) stabilized ($Sa_{O_2} \approx 80\%$), we obtained a fourth set of steady-state measurements. After subjects re-equilibrated with room air, we administered 10% oxygen. We obtained two blood samples during this desaturation, at times when the ear oximeter readings equaled each of the two previously recorded steady-state hypoxic saturation values. When $F_{ET}O_2$ and oximeter readings had stabilized ($Sa_{O_2} \approx 70\%$), we obtained a fifth set of steady-state measurements, and then allowed subjects to breathe room air.

Upon analysis of the steady-state data, we found that the Ohmeda 3700 version J finger probe readings differed significantly ($P < 0.001$) from simultaneously measured arterial saturations (vide infra). Based on this finding, the manufacturer developed modified software (version XJ1). Using eight new consenting volunteers, we repeated the steady-state portion of the experiment; for each of these subjects, we obtained data at six oxygen saturations. In addition to the version XJ1 finger and ear probes, we obtained simultaneous readings with a version J finger probe (to verify our previous findings) and a Nellcor N100D oximeter finger probe.

To determine the steady-state accuracy of the Ohmeda ear and finger probes, as well as of the Nellcor finger probe, we used linear regression analysis to calculate 99% prediction intervals. A Student's t test determined the significance of the difference between the slope of the regression line and the line of identity.⁵ We plotted the values of version J ear probe reading *versus* Sa_{O_2} obtained during acute desaturation (vide supra) to assess its performance under these conditions. However, before evaluating the transient response of the finger probe, it was necessary to correct the readings to compensate for the inaccuracy observed at steady state. For each individual, we constructed the regression of steady state oximeter readings *versus* Sa_{O_2} , and used this relation to predict what the oximeter would have indicated during desaturation had its steady state response been ideal. We then plotted these corrected values *versus* Sa_{O_2} . To determine the speed of response to an acute increase in O_2 saturation, we measured the time from the removal of the hypoxic gas mixture until the 50% recovery point of the ear oximeter reading; we also measured the time delay between the 50% recovery points for the ear and finger probes. We used two-way analysis of variance to determine if ear or finger probe recovery depended significantly upon the initial degree of desaturation. A value of $P < 0.05$ indicated significance for all analyses.

Results

At all times during the study, we maintained verbal contact with the subjects; no subject experienced mental

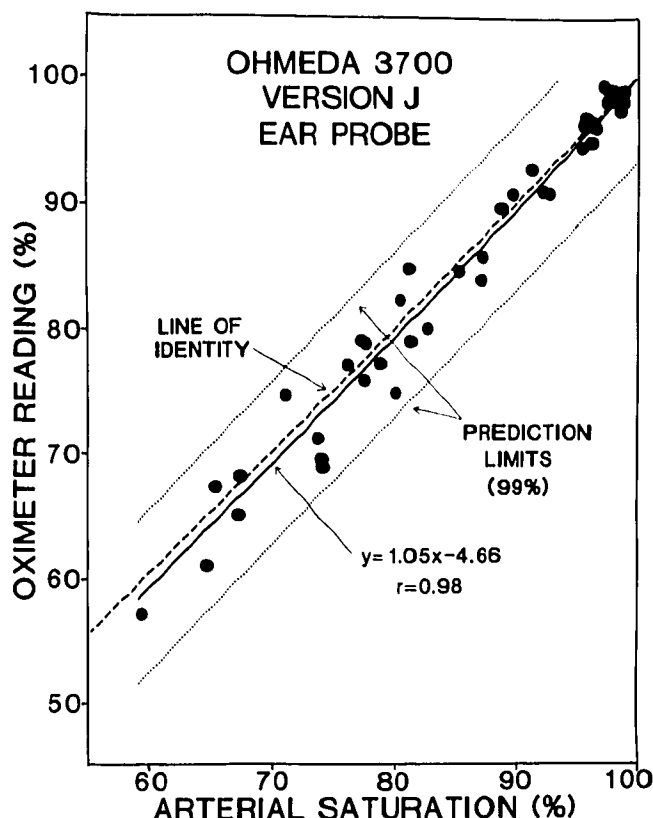


FIG. 1. Response characteristic of the Ohmeda 3700 (version J) pulse oximeter, equipped with an ear probe, under steady-state conditions. The line $y = 1.05x - 4.66$ represents the least-squares linear regression ($N = 40$).

status changes, chest pain, or electrocardiogram changes during his hypoxic exposure. Following removal of the radial artery catheter, normal arterial pulsations were present distal to the cannulation site in all subjects. For Ohmeda pulse oximeter readings, signal strength was always "full scale;" the Nellcor unit does not quantitate signal strength. Measured arterial saturations ranged from 59.6–98.1%; carboxyhemoglobin was less than 2%, and methemoglobin was less than 1% in all subjects.

From the first eight subjects, we obtained 40 steady-state data points for both the Ohmeda 3700 version J ear and finger probes. The ear probe proved to be highly accurate; the regression of ear probe readings (y) *versus* arterial saturation (x) was $y = 1.05x - 4.66$ ($r = 0.98$) (fig. 1). In contrast, the corresponding equation for the version J finger probe in these subjects was $y = 1.33x - 30.8$ ($r = 0.98$, $P < 0.001$ *vs.* line of identity). When all 16 subjects were included, the regression equation for the version J finger probe still differed significantly from the line of identity ($y = 1.21x - 19.1$, $P < 0.001$) (fig. 2); the regression line for the 5 black subjects did not differ

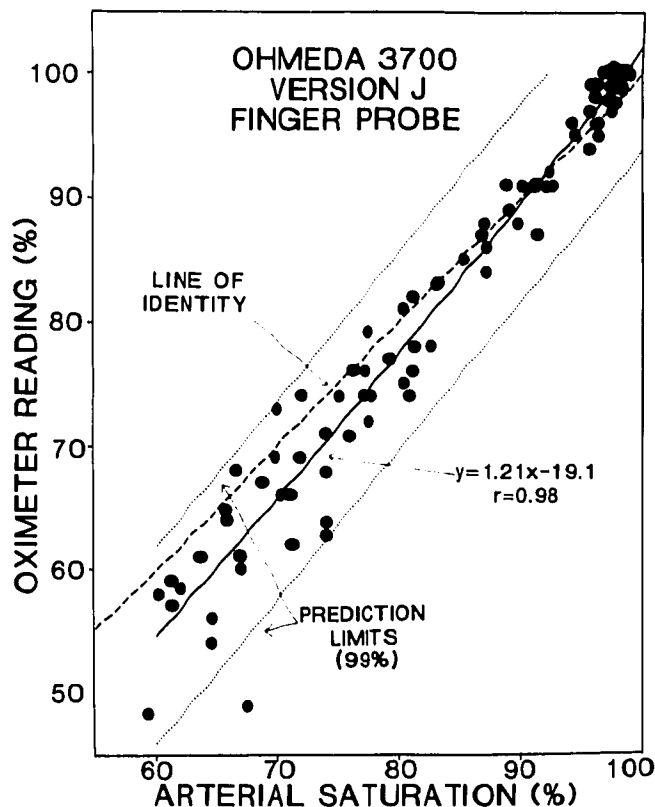


FIG. 2. Response characteristic of the Ohmeda 3700 (version J) pulse oximeter, equipped with a finger probe, under steady-state conditions (N = 88).

significantly in slope or intercept from that for the 11 caucasian subjects.

With version XJ1 software, the Ohmeda 3700's finger probe performed significantly better. The regression equation relating oximeter reading to arterial saturation was $y = 0.96x + 4.59$ ($r = 0.99$) (fig. 3). The version XJ1 software was unchanged with regard to its handling of ear probe data; the corresponding regression equation was $y = 0.96x + 3.40$ ($r = 0.98$). The Nellcor N100D finger probe also performed well; its regression equation was $y = 0.96x + 5.34$ ($r = 0.99$) (fig. 4).

For each of the first eight subjects, we obtained three data points (version J software) from both the ear and finger probes, while O_2 saturation was rapidly declining. The ear probe readings reflected arterial saturation fairly accurately under these conditions ($y = 1.05x - 6.38$, $r = 0.96$) (fig. 5). Conversely, the finger probe consistently overestimated arterial oxygenation during acute desaturation, even after correction (vide supra) for the inaccuracy of its steady state response ($y = 0.55x + 45.2$, $r = 0.78$) (fig. 6).

With an initial $F_{IO_2} = 0.12$, the time delay from removal of the hypoxic gas mixture until 50% recovery of the ear oximeter reading was 6.0 ± 0.4 s ($\bar{x} \pm SE$). This was significantly longer than the delay when the initial

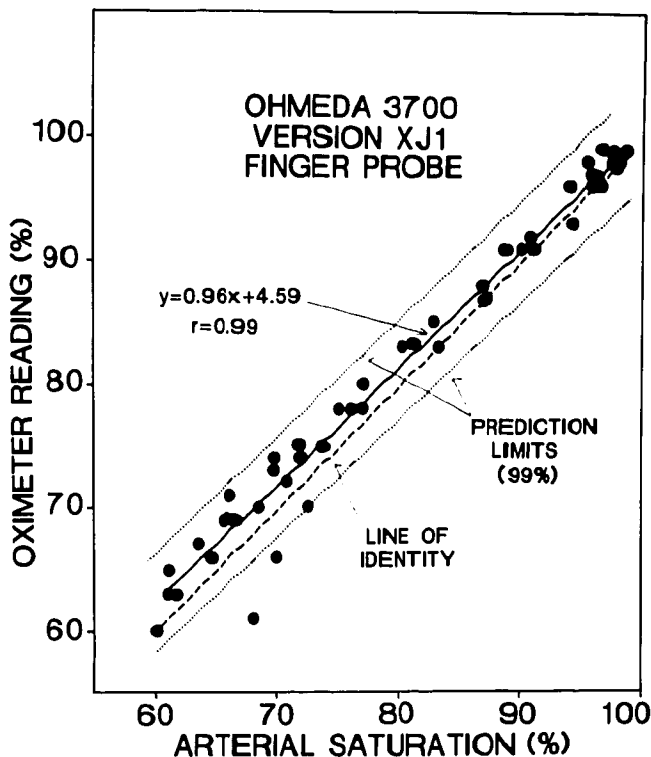


FIG. 3. Response characteristic of the Ohmeda 3700 (version XJ1) pulse oximeter, equipped with a finger probe, under steady-state conditions (N = 48).

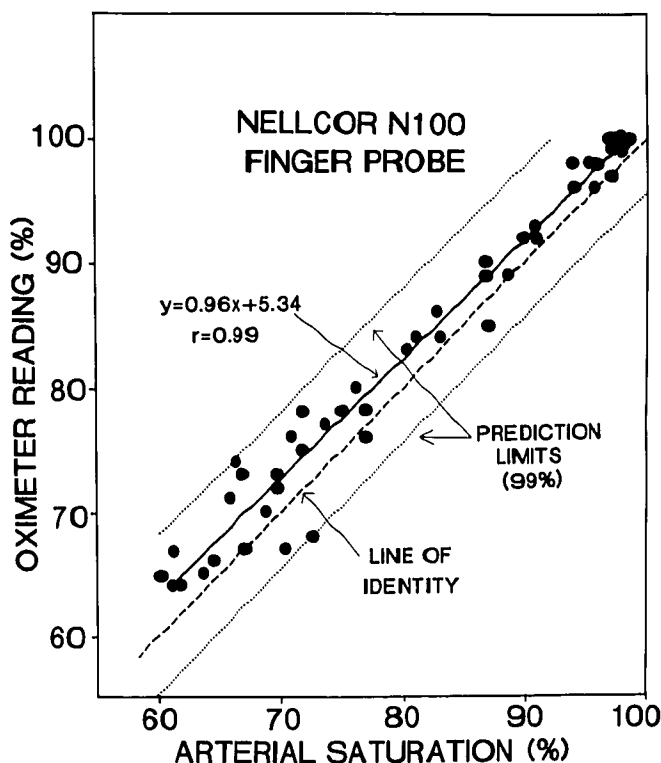


FIG. 4. Response characteristic of the Nellcor N100 pulse oximeter, equipped with a finger probe, under steady-state conditions (N = 48).

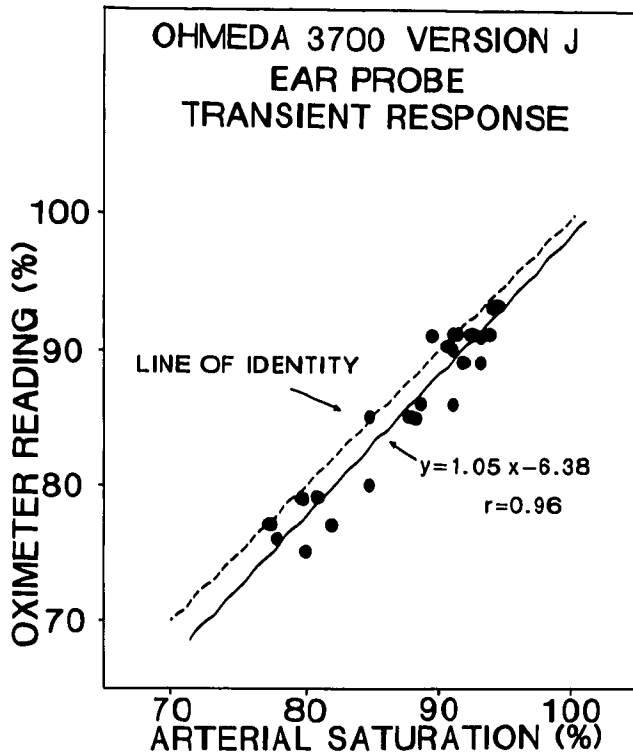


FIG. 5. Response characteristic of the Ohmeda 3700 (version J) pulse oximeter, equipped with an ear probe, during rapidly decreasing oxygen saturation (N = 24).

$F_{I}O_2 = 0.10$ ($5.1 \pm 0.3s$, $P < 0.05$), probably because of the increased cardiac output associated with the lower $F_{I}O_2$. The delay between the finger and the ear probe, for 50% recovery, was 24.0 ± 2.3 s, the ear probe being significantly faster ($P < 0.001$); this was not affected by the initial degree of hypoxia.

Discussion

Pulse oximetry employs the principles of transmission oximetry and photoelectric plethysmography to measure the oxygen saturation of the pulsatile component of tissue blood flow.⁶ Although transmission oximeters, such as the Hewlett Packard 47201, also provide non-invasive data on arterial oxygenation, they suffer from the need to "arterialize" capillary blood, the inconvenience of their large, cumbersome probes (to allow for eight different wavelengths), and their susceptibility to interference from skin pigmentation.⁷ The Ohmeda 3700 shares the light weight and ease of use of previously available pulse oximeters; additionally, it features a graphic display of waveform, signal strength, and trend data, as well as employing advanced interference detection techniques.

Our data confirm that, as previously reported, the regression of the Nellcor N-100 pulse oximeter reading on measured arterial saturation does not differ significantly from the line of identity.^{6,8} We found that the

Ohmeda 3700 version J (ear probe) and version XJ1 (ear and finger probe) shared this accuracy.

Previous papers have not addressed the usefulness of oximeter readings in predicting arterial oxygen saturations; *i.e.*, for a given oximeter reading, how accurately can we predict SA_{O_2} ? These "prediction limits," shown in figures 1–4, are much wider than the "confidence limits," which indicate the range of variability of the regression lines were the experiment repeated. (For all of our steady state curves, the 99% confidence limits never differ from the calculated regression lines by more than 2%.) Based on our data, it appears that, for all oximeters and probes tested, the 99% prediction limits are within $\pm 8\%$ of the calculated regression line. For all but the version J with finger probe, they also lie within 8% of the line of identity; therefore, with these units, one can be 99% certain that arterial saturation and oximeter reading will differ by no more than 8% in the 60–100% range. Conversely, the prediction limits (as well as actual data points) indicate that, when the SA_{O_2} is 60%, Ohmeda 3700 version J finger probes could conceivably give readings as low as 47%. Interestingly, previous investigators have demonstrated that earlier Ohmeda oximeters (Biox II and III) share this tendency to underestimate low oxygen saturations.⁹

It is unlikely that our finding that the Ohmeda 3700

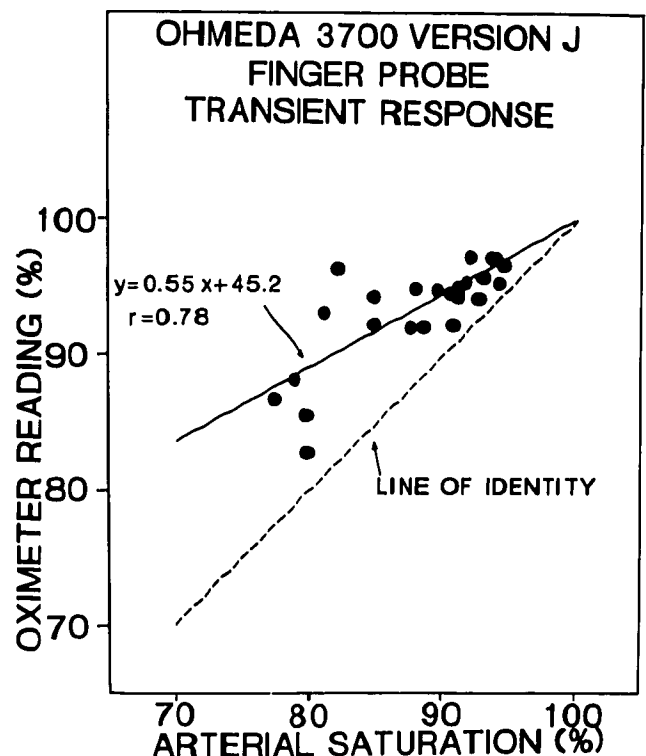


FIG. 6. Response characteristic of the Ohmeda 3700 (version J) pulse oximeter, equipped with a finger probe, during rapidly decreasing oxygen saturation (N = 24). Oximeter readings have been corrected to compensate for the observed steady-state inaccuracy of this software-probe combination (see text).

version J finger probe became inaccurate at low oxygen saturations resulted from a flaw in our experimental design. We used three different oximeters and finger probes, to rule out a defective unit or probe as a source of the error. We ensured steady-state oxygenation conditions by maintaining a constant $F_{ET}O_2$ for one minute before recording oximeter readings and obtaining blood samples. Additionally, we obtained readings from the Ohmeda ear probes, as well as from the Nellcor finger probes, simultaneously with those from the version J finger probes, but only the version J finger probe data was inaccurate. Finally, the value of $r = 0.98$ for the version J finger probe suggests that the observed error in slope resulted from a systematic problem, rather than from random variations.

The error in the Ohmeda 3700 version J finger probe calibration may be related to the inherent delay in finger saturation measurements. Pulse oximeters are empirically calibrated devices. Ohmeda's calibration studies were performed while subjects' O_2 saturations were falling. However, there was no measure of airway O_2 tension or means (other than the oximeter readings themselves) of ensuring steady state conditions. Therefore, their subjects may not have reached a true steady state. Under these conditions, the more slowly responding finger probe would always indicate a higher saturation than would exist at equilibrium. The unit's internal calibration would reflect this, resulting in falsely low readings at a true steady state. Furthermore, we showed that a simple modification to the oximeter's software results in a highly accurate unit.

The 24-s delay in finger as compared to ear probe readings is certainly within acceptable limits for most clinical situations. This delay is probably physiologic in origin; because ear and finger-probe data are averaged identically by the Ohmeda 3700, any delay in the response of the finger probe, as compared to the ear probe, must originate outside of the oximeter (possibly as a result of the time constant for mixing of arterial blood in the finger). Furthermore, we used the fast response mode for both the finger and ear measurements; it is inconceivable that 3-s averaging could result in a 24-s delay.**

** Ohmeda Biox 3700 Pulse Oximeter Operating/Maintenance Manual, Revision D. Ohmeda, Boulder CO, 1985, pp. 8-20

Because they are two-wavelength devices, pulse oximeters are incapable of distinguishing between oxyhemoglobin and carboxyhemoglobin;¹⁰ therefore, their readings reflect $(Hb-O_2 + Hb-CO)/(Total\ Hb)$. Making this correction would have moved our regression lines about 1.5% to the right, without affecting the slope; this change is small compared with 7.5% variability implied by the 99% prediction intervals. Because, in the clinical setting, we are concerned with available oxygen rather than dysfunctional hemoglobin, we chose to use $(Hb-O_2)/(Total\ Hb)$ as the independent variable in our calculations.

In conclusion, we demonstrated that the Ohmeda 3700 (version J) pulse oximeter is highly accurate when used with an ear probe, and responds quickly enough to be used for hypoxic drive determinations during acute desaturation. When used with a finger probe, version J software tends to underestimate arterial oxygenation when the SA_{O_2} is below 90%.

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