Detection of critical cerebral desaturation thresholds by three regional oximeters during hypoxia: a pilot study in healthy volunteers

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Abstract

Background: Regional oximetry is increasingly used to monitor post-extraction oxygen status of the brain during surgical procedures where hemodynamic fluctuations are expected. Particularly in cardiac surgery, clinicians employ an interventional algorithm to restore baseline regional oxygen saturation (rSO₂) when a patient reaches a critical desaturation threshold. Evidence suggests that monitoring cardiac surgery patients and intervening to maintain rSO₂ can improve postoperative outcomes; however, evidence generated with one manufacturer’s device may not be applicable to others. We hypothesized that regional oximeters from different manufacturers respond uniquely to changes in oxygen saturation in healthy volunteers.

Methods: Three devices were tested: INVOS™ 5100C (Medtronic), EQUANOX™ 7600 (Nonin), and FORE-SIGHT™ (CASMED) monitors. We divided ten healthy subjects into two cohorts wearing a single sensor each from INVOS and EQUANOX (n = 6), or INVOS and FORE-SIGHT (n = 4). We induced and reversed hypoxia by adjusting the fraction of inspired oxygen. We calculated the magnitude of absolute rSO₂ change and rate of rSO₂ change during desaturation and resaturation, and determined if and when each device reached a critical interventional rSO₂ threshold during hypoxia.

Results: All devices responded to changes in oxygen directionally as expected. The median absolute rSO₂ change and the rate of rSO₂ change was significantly greater during desaturation and resaturation for INVOS compared with EQUANOX (P = 0.04). A similar but nonsignificant trend was observed for INVOS compared with FORE-SIGHT; our study was underpowered to definitively conclude there was no difference. A 10% relative decrease in rSO₂ during desaturation was detected by all three devices across the ten subjects. INVOS met a 20% relative decrease threshold in all subjects of both cohorts, compared to 1 with EQUANOX and 2 with FORE-SIGHT. Neither EQUANOX nor FORE-SIGHT reached a 50% absolute rSO₂ threshold compared with 4 and 3 subjects in each cohort with INVOS, respectively.

Conclusions: Significant differences exist between the devices in how they respond to changes in oxygen saturation in healthy volunteers. We suggest caution when applying evidence generated with one manufacturer’s device to all devices.

Keywords: Regional oximetry, Cerebral oximetry, Near infrared spectroscopy, Cerebral desaturation, Hypoxia
Background

A recent publication reported that surveyed cardiac anesthesiologists and perfusionists view regional oximetry as useful or essential for non-invasive monitoring of cerebral oxygen status during surgery [1]. Rapidly changing hemodynamic conditions can cause cerebral desaturation during cardiac, arthroscopic shoulder, major abdominal, and total knee replacement surgeries [2–5]. Originally published in 2007, clinicians continue to refine an interventional algorithm for maintaining cerebral oxygen saturation values (rSO2) close to baseline during cardiac surgery by manipulating oxygen supply and demand [6, 7]. Cerebral desaturation—often defined as a 20% relative decrease from baseline or an absolute rSO2 value of 50%—may trigger clinicians to consider a range of possible interventions to restore oxygen saturation, such as ruling out mechanical obstructions or increasing mean arterial pressure [7]. Several cardiac studies suggest postoperative outcomes may improve when cerebral oxygen saturation is monitored and desaturation episodes are recognized and reversed, compared to no or blinded monitoring [8–13].

We propose that published evidence generated with one manufacturer’s regional oximeter is unique to that device since they may reach an interventional threshold at different times or not at all. Each manufacturer uses a proprietary algorithm, as well as different emitter/detector spacing, number of wavelengths, and light source. We hypothesize that regional oximeters will react differently to clinically challenging situations where rSO2 is fluctuating.

To test our hypothesis, we subjected healthy volunteers to two cycles of desaturation and resaturation to characterize the differences in absolute rSO2 change and rate of rSO2 change between three FDA-cleared regional oximeters: INVOS™ 5100C (Medtronic, Dublin, Ireland), EQUANOX 7600 (Nonin Medical, Plymouth, MN), and FORE-SIGHT™ (CASMED, Branford, CT). All devices report regional oxygen saturation (rSO2) of the tissue beneath the sensor based on near infrared spectroscopy, the technical aspects of which are reported elsewhere [14, 15]. Two monitors were tested per subject with one INVOS sensor (SAFB-SM) on the left side of the forehead, and either an EQUANOX (8000CA or 8004CA) or FORE-SIGHT™ (standard large, medium, or small) sensor on the right, placed 2 cm apart if possible (Fig. 1). Six were studied with INVOS and EQUANOX, and four with INVOS and FORE-SIGHT.

Methods

The Western Institutional Review Board (Puyallup, WA) approved an overarching protocol for a study of pulse oximetry devices, of which this was studied under. Written informed consent was obtained prior to participation. Twelve healthy subjects were enrolled from an existing hypoxia research pool and studied at the Medtronic Respiratory & Monitoring Solutions clinical laboratory (Boulder, CO) from April 16 to 18, 2013. Two subjects were withdrawn: one failed screening, and the other experienced tachycardia and anxiety during the study. The study pool included males and non-pregnant or -lactating females, 18 to 50 years of age, from various racial and ethnic backgrounds, who tolerated hypoxia in previous studies. Skin pigmentation was rated as very light, olive, dark olive, or extremely dark.

Subjects reclined to approximately 20° in the supine position with legs elevated. Peripheral capillary oxygen saturation (SpO2) was monitored using the Nellcor N600x™ and Max-A™ sensors (Medtronic, Dublin, Ireland) on the middle and index fingers. Standard monitoring included continuous electrocardiography, noninvasive blood pressure, end-tidal carbon dioxide, and respiration rate.

We tested three FDA-cleared regional oximeters: INVOS® 5100C (Medtronic, Dublin, Ireland), EQUANOX™ 7600 (Nonin Medical, Plymouth, MN), and FORE-SIGHT™ (CASMED, Branford, CT). All devices report regional oxygen saturation (rSO2) of the tissue beneath the sensor based on near infrared spectroscopy, the technical aspects of which are reported elsewhere [14, 15]. Two monitors were tested per subject with one INVOS sensor (SAFB-SM) on the left side of the forehead, and either an EQUANOX (8000CA or 8004CA) or FORE-SIGHT™ (standard large, medium, or small) sensor on the right, placed 2 cm apart if possible (Fig. 1). Six were studied with INVOS and EQUANOX, and four with INVOS and FORE-SIGHT.

![Fig. 1 Placement of INVOS, EQUANOX, and FORE-SIGHT sensors on healthy human volunteers. * 2 cm separation distance was not possible in all subjects](image-url)
Subjects were fitted with a gas delivery mask, through which the anesthesiologist adjusted the fraction of inspired oxygen (FiO₂) using an oxygen-nitrogen gas mixer. The hypoxia protocol used meets the guideline defined in the ISO standard 80601-2-61:2011 for non-invasive laboratory testing on healthy volunteers for pulse oximetry, and is outlined in Fig. 2. (1) The initial baseline readings were established while breathing room air through the mask. (2) The FiO₂ was decreased, based on the subject’s tolerance, to achieve an SpO₂ reading of approximately 70%. (3) SpO₂ was maintained at 70% for at least 60 s after the reading plateaued, up to 5 min. (4) The FiO₂ was instantly increased to 1.0 to achieve a fraction of exhaled oxygen concentration (FeO₂) of at least 0.85. (5–9) Plateau measurements were collected, and the desaturation cycle was repeated. (10) The mask was removed, and data collection continued for 5 min with the subject breathing room air. The anesthesiologist and lab clinician monitored vital signs and subject comfort throughout the experiment. Digital trending data from all monitors were collected and time-stamped.

Statistical analyses were performed using Minitab 17 (Minitab, Inc, State College, PA). Baseline rSO₂ and absolute percent changes in SpO₂ and rSO₂ were graphed as individual subject data and the median for each device within the cohort. Rates of absolute oxygen saturation change (% per minute) were reported as the median and 95% confidence interval (CI) for each device within the cohort. Given the small sample size, normality was not assumed and the Wilcoxon Signed-Rank test for paired samples was used to assess significant differences in baseline rSO₂ values, absolute rSO₂ changes, and rates of rSO₂ change between the devices within each cohort. Significant differences between devices in detecting critical rSO₂ thresholds were assessed using the exact binomial test. A P value of <0.05 was considered statistically significant for all analyses.

Results
We performed two rounds of desaturation and resaturation in ten healthy human subjects. The INVOS/EQUANOX and INVOS/FORE-SIGHT cohorts were similar in subject characteristics and gender distributions (Table 1). We included Caucasian (70%) and Asian (30%) subjects with a range of skin pigmentation from very light to dark olive; no African Americans were available to participate.

Baseline rSO₂ prior to desaturation
We plotted individual baseline rSO₂ and median rSO₂ values to visually compare the range and central tendency for each device (Fig. 3). The median baseline rSO₂ prior to desaturation trended higher for FORE-SIGHT by approximately 10 percentage points compared with INVOS, although the differences were not statistically significant. Median INVOS and EQUANOX baseline rSO₂ values differed by less than 2 percentage points. INVOS reported a wider range of individual baseline rSO₂ values (54–93%) compared to EQUANOX (58–84%). FORE-SIGHT reported a narrower range of baseline values (69–81%) than both INVOS and EQUANOX.

Absolute % change in rSO₂ during desaturation and resaturation
INVOS reported a significantly greater median absolute percent rSO₂ change during both desaturation cycles compared with EQUANOX (P = 0.04), with a trend towards a greater change compared with FORE-SIGHT (P = 0.10) (Fig. 4). Although we did not compare the values statistically, the absolute percent change reported by INVOS (19.5–22.5%) followed closer in magnitude to the absolute

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**Fig. 2** Method for inducing desaturation and resaturation in healthy subjects. Desaturation was induced by adjusting the gas mixture of oxygen and nitrogen through a facemask in healthy subjects. (1) Subjects breathed room air until a stable baseline rSO₂ was achieved. (2–3) FiO₂ was titrated down slowly to achieve a stable plateau SpO₂ of approximately 70%. (4–5) FiO₂ was increased instantly to 1 to achieve a stable FeO₂ of 0.85. Steps (6) through (9) represent a second desaturation and resaturation cycle, after which (10) the subjects were returned to room air.
changes in SpO₂ (21.0–24.9%) compared with EQUANOX (12.0–15.5%) and FORE-SIGHT (13.5–15.0%). We discovered similar results during the two resaturation cycles, although the difference in absolute percent change in rSO₂ for INVOS compared with EQUANOX during resaturation #2 only trended towards significance ($P = 0.06$) (Fig. 5).

**Rate of rSO₂ change during desaturation and resaturation**

We report the rates of rSO₂ change during desaturation for each of the devices in Table 2, with SpO₂ change shown for comparison. For both desaturation cycles, INVOS reported a significantly greater percent rSO₂ change than EQUANOX ($P = 0.04$), with a trend towards a greater change than FORE-SIGHT ($P = 0.10$). The median rates of rSO₂ change for INVOS (3.0–4.0%/min) followed closer in magnitude to rates of SpO₂ change (3.6–4.3%/min) than EQUANOX (2.3–3.0%/min) or FORE-SIGHT (2.2–2.4%/min).

The rate of rSO₂ change during resaturation is reported in Table 3. INVOS reported a significantly greater rate of change compared with EQUANOX during resaturation #1 ($P = 0.04$), with a trend towards a greater rate during resaturation #2 ($P = 0.06$). Although numerically higher than FORE-SIGHT, the rates of rSO₂ change for INVOS during both resaturation cycles were not statistically different. The median rates of rSO₂ change for INVOS (9.6–15.9%/min) were closer in magnitude to rates of SpO₂ change (11.75–19.1%/min) than EQUANOX (9.2–11.2%/min) or FORE-SIGHT (6.6–9.5%/min).

**Critical desaturation thresholds**

We reviewed the rSO₂ values from desaturation #1 for the following thresholds: 1) 10% relative change from baseline, 2) 20% relative change from baseline, and 3) an absolute value of 50%. For each subject, we determined whether the devices reached the threshold, and the mean time difference when the threshold was met by both devices.

We considered a 10% relative change from baseline as an early indicator that cerebral oxygen saturation is decreasing and may require early intervention [2]. All three devices reached the 10% relative change in all subjects of both cohorts. On average, INVOS reached the 10% threshold 28 s earlier than EQUANOX, and 43 s earlier than FORE-SIGHT.

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**Table 1** Descriptive characteristics of study participants, mean ± SD or n (%); $N = 10$

| Characteristic      | INVOS/EQUANOX (n = 6) | INVOS/FORE-SIGHT (n = 4) |
|---------------------|------------------------|---------------------------|
| Age (yrs)           | 35.2 ± 10.2            | 31.8 ± 7.9                |
| Male                | 3 (50%)                | 2 (50%)                   |
| Race/ethnicity      |                        |                           |
| Asian               | 2 (33%)                | 1 (25%)                   |
| Caucasian           | 4 (67%)                | 3 (75%)                   |
| Skin pigmentation   |                        |                           |
| Very light          | 4 (68%)                | 3 (75%)                   |
| Olive               | 1 (16%)                | 0 (0%)                    |
| Dark olive          | 1 (16%)                | 1 (25%)                   |
| Height (cm)         | 172.6 ± 4.7            | 176.6 ± 11.5              |
| Weight (kg)*        | 75.1 ± 20.6            | 68.3 ± 7.1                |

*Weight was unavailable for one participant

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Fig. 3 Individual baseline and median rSO₂ values prior to desaturation #1 (a) and #2 (b). INVOS demonstrated a wider spread of individual baseline values than both EQUANOX and FORE-SIGHT. Although the median FORE-SIGHT baseline rSO₂ was consistently higher than INVOS by approximately 10%, the differences were not statistically significant (two-tailed Wilcoxon Signed-Rank test for paired samples).
Table 4 shows the number of subjects in which only one monitor for each pair detected a critical drop in rSO\textsubscript{2}. In the INVOS/EQUANOX cohort, INVOS met the 20% relative decrease for all six subjects in the cohort. In five of six subjects, EQUANOX did not detect a 20% relative decrease. There were no subjects for whom EQUANOX reached the threshold and INVOS did not, and although numerically different, the results only trended towards statistical significance ($P = 0.06$). We found similar results with the INVOS/FORE-SIGHT cohort, where INVOS met the 20% threshold in all four subjects compared with two subjects with FORE-SIGHT. There were no subjects for whom FORE-SIGHT detected a 20% relative change when INVOS did not. The difference was not statistically significant.

When we used an absolute threshold of 50%, INVOS reached the threshold in four of six subjects, whereas EQUANOX did not in any subjects, with a trend towards statistical significance ($P = 0.06$). In the INVOS/FORE-SIGHT cohort, INVOS reached the threshold in three of four subjects, while FORE-SIGHT did not in any subjects. Again, the results were not statistically significant.

**Discussion**

All three devices reported changes in rSO\textsubscript{2} during the course of desaturation and resaturation. We found that the median absolute change in rSO\textsubscript{2}, and the rate of rSO\textsubscript{2} change per minute, was significantly greater with INVOS compared with EQUANOX during desaturation. The magnitude and rate of change was numerically greater with INVOS compared to FORE-SIGHT, but the differences were not statistically significant. When we reversed desaturation, we found similar significant differences in the magnitude and rate of change between INVOS and EQUANOX, with a trend towards significance between INVOS and FORE-SIGHT.

The most interesting finding was the discordance in detecting critical desaturation thresholds during desaturation when comparing devices on the same subject. All three technologies detected a minimum 10% relative decrease in rSO\textsubscript{2} from baseline in all subjects; EQUANOX and FORE-SIGHT reached the threshold on average 28 to 43 s after INVOS, respectively. INVOS detected a 20% relative decrease in rSO\textsubscript{2} in all subjects...
of both cohorts, compared to one with EQUANOX, and two subjects with FORE-SIGHT. Neither EQUANOX nor FORE-SIGHT met the 50% absolute rSO₂ threshold in any subjects, compared to four and three subjects with INVOS, respectively. While our findings lacked statistical significance, they may have important clinical implications.

The randomized, controlled evidence reporting improved postoperative outcomes compared with no monitoring is based on detecting a critical drop in rSO₂ in the monitored subjects that the clinician observes and intervenes to reverse [4, 8–12]. These studies usually cite a threshold of either a 20 to 25% relative decrease from baseline, or absolute value of 50 to 60%. Our study has shown that regardless of whether a relative or absolute threshold is used, disparities may exist between devices in detecting desaturation events. These disparities may result in clinicians intervening, for example, earlier and/or more often when using one device compared to another. A clinician may employ cerebral oximetry to

**Table 2** Median rates (95% CI) of absolute oxygen saturation change during desaturation

| Device       | SpO₂ | INVOS | EQUANOX | INVOS/EQUANOX | INVOS/FORE-SIGHT |
|--------------|------|-------|---------|---------------|-----------------|
| Desaturation | n = 6|       |         | (n = 6)       | (n = 4)         |
| #1           |      |       |         | %/min | %/min | %/min | %/min | %/min | P value |
| SpO₂         | 4.2  (2.7, 5.2) | 3.5  (2.9, 4.3) | 2.3  (1.7, 2.8) | 0.04* |
| INVOS        |      |       |         | %/min | %/min | %/min | %/min | %/min | P value |
| EQUANOX      |      |       |         | %/min | %/min | %/min | %/min | %/min | P value |

*Indicates statistical significance between devices (two-tailed Wilcoxon Signed-Rank test for paired samples)

**Fig. 5** Individual absolute and median rSO₂ changes during resaturation #1 (a, b) and #2 (c, d). Absolute changes in SpO₂, representing global saturation, are shown for comparison. Median absolute change in rSO₂ reported by INVOS during resaturation #1 was significantly greater than that of EQUANOX. Although FORE-SIGHT reported a smaller median absolute change during resaturation #1 and #2 compared with INVOS, the differences were not statistically significant (two-tailed Wilcoxon Signed-Rank test for paired samples). Data are missing for one INVOS/EQUANOX subject in graph C. *Indicates statistical significance.
improve outcomes and see different results from published trials if the same device is not used. We make no judgment about which device is “correct,” simply that they are different from one another.

Device design may contribute to the differences in reporting rSO2 during changes in cerebral oxygen saturation. Manufacturers make unique assumptions of arterial versus venous contribution of the tissue under the sensor: 25/75 for INVOS, and 30/70 for EQUANOX and FORE-SIGHT. Each device uses a distinct proprietary algorithm. INVOS 5100C has a 2-wavelength LED light source in the sensor, compared with a 3-wavelength LED in EQUANOX 7600 and a 4-wavelength laser in FORE-SIGHT. The devices also sample different tissue depths due to individual sensor/detector spacing.

Our findings corroborate those published from previous device comparisons in both healthy subjects and surgical patients, with some exceptions. Fellahi and colleagues found a greater percent maximum difference from baseline with INVOS compared with EQUANOX in healthy subjects during leg vascular occlusion tests [16]. In 42 off-pump coronary artery bypass surgery patients, Moerman and colleagues reported a greater area under the curve for INVOS during desaturation compared to FORE-SIGHT (−3.65%/min vs −2.36%/min) and resaturation (30.4 vs 16.8%/min) for INVOS compared with EQUANOX, similar to our own findings [16]. But Hyttel-Sorensen and colleagues reported a steeper desaturation slope with EQUANOX during arm vascular occlusion in 10 healthy volunteers compared with INVOS and FORE-SIGHT [19].

Few studies compared how and when different devices detect clinically relevant desaturation events. Pisano et al., compared devices in cardiac surgery and reported that INVOS detected 20 significant cerebral desaturation events in four of ten patients, compared with three events in one patient for EQUANOX (the same patient in which INVOS detected five events) [20]. Unlike our study, two sensors per device were placed bilaterally, with one sensor pair placed above the other on the forehead. We cannot compare these results to ours since Pisano et al., recorded rSO2 from only one device at a time due to interference, and as such would not have detected the same desaturation events.

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Table 3 Median rates (95% CI) of absolute oxygen saturation change during resaturation

|                  | INVOS      | EQUANOX   | P value |
|------------------|------------|-----------|---------|
| SpO2 INVOS/EQUANOX (n = 6) | (%/min)    | (%/min)   |         |
| Resaturation #1  | 19.1 (13.8, 25.7) | 15.9 (12.5, 18.5) | 0.04*   |
| Resaturation #2  | 15.3 (11.6, 21.9) | 12.7 (8.5, 17.7) | 0.06    |

|                  | INVOS      | FORE-SIGHT | P value |
|------------------|------------|------------|---------|
| SpO2 EQUANOX/FORE-SIGHT (n = 4) | (%/min)    | (%/min)   |         |
| Resaturation #1  | 12.9 (10.1, 18.8) | 10.6 (8.1, 19.3) | 0.10    |
| Resaturation #2  | 11.7 (10.4, 13.1) | 9.6 (5.8, 12.5) | 0.20    |

Data are unavailable for one INVOS/EQUANOX subject. * Indicates statistical significance between devices (two-tailed Wilcoxon Signed-Rank test for paired samples)

Table 4 Detection of critical rSO2 thresholds during the first desaturation cycle (n, %)

|                  | INVOS: YES | EQUANOX: NO | P value |
|------------------|------------|-------------|---------|
| 20% relative rSO2 decrease from baseline met | n = 6 | 5 (83%) | 0.06 |
| 50% absolute rSO2 threshold met | n = 6 | 4 (67%) | 0.06 |

|                  | INVOS: YES | FORE-SIGHT: NO | P value |
|------------------|------------|----------------|---------|
| 20% relative rSO2 decrease from baseline met | n = 4 | 2 (50%) | 0.50 |
| 50% absolute rSO2 threshold met | n = 4 | 3 (75%) | 0.25 |

Data were not statistically significant (exact binomial test)
used per patient so there were no direct comparisons of detecting the same event [2].

We point out several important limitations in our study for consideration. We were not able to place the sensors 2 cm apart on all subjects, and we did not investigate whether there was interference between the devices at close distances. We did not calculate a sample size a priori based on a predetermined difference between devices in either the magnitude or rate of rSO₂ change. In cases where we observed no significant difference between devices, we are unsure if there truly was no difference, or if our study lacked sufficient power. We tend to believe the latter, particularly with the 4-subject INVOS/FORE-SIGHT cohort.

Also, we suggest interpreting differences in rSO₂ rates of change during desaturation in our study with caution; the anesthesiologist titrated FiO₂ gradually as the subject tolerated it, which may introduce between-subject variation. Baseline rSO₂ reported by INVOS was notably lower in some subjects than EQUANOX and FORE-SIGHT, potentially influencing whether a device reached the 50% absolute rSO₂ threshold during desaturation. Also, unlike two of the papers cited here, we used each device unilaterally [17, 20]. We concede that one device could have reached a threshold earlier than (or in the absence of) another due to hemispheric differences. Finally, we did not directly sample arterial and venous blood for calculating a weighted saturation as a reference to compare with rSO₂ values. As such, we cannot comment on which device best represented cerebral oxygen status. But despite the small nature of our pilot study, the hypoxia protocol reported here is repeatable and widely used for validating regional oximeters for agency approval. We generated intriguing preliminary results to inform future hypotheses and hopefully generate interest in larger, more comprehensive device comparisons.

With these preliminary results, one might consider whether clinical evidence generated in one manufacturer’s regional oximetry device can be broadly applied to similar devices from other manufacturers. The three devices tested in our study reached critical interventional rSO₂ thresholds inconsistently in the same subject. Although the differences between devices in detecting critical rSO₂ thresholds were not statistically significant, we argue that the results may have clinical significance. A larger study with adequate power may clarify our findings.

Conclusions
To the best of our knowledge, our report is the first to show differences between INVOS and both FORE-SIGHT and EQUANOX in detecting the same desaturation event when subjects are monitored simultaneously. With this knowledge, one should take care in broadly applying evidence of improved patient outcomes to all devices when a single manufacturer’s device is used in a study. Larger studies in clinical settings are required to investigate the clinical impact of this finding.

Additional files

| Additional file | Description |
|----------------|-------------|
| Additional file 1: | Raw data subject #2234. (XLSX 107 kb) |
| Additional file 2: | Raw data subject #1228. (XLSX 123 kb) |
| Additional file 3: | Raw data subject #1654. (XLSX 174 kb) |
| Additional file 4: | Raw data subject #1657. (XLSX 122 kb) |
| Additional file 5: | Raw data subject #1667. (XLSX 139 kb) |
| Additional file 6: | Raw data subject #1791. (XLSX 116 kb) |
| Additional file 7: | Raw data subject #1806. (XLSX 128 kb) |
| Additional file 8: | Raw data subject #1824. (XLSX 118 kb) |
| Additional file 9: | Raw data subject #2142. (XLSX 124 kb) |
| Additional file 10: | Raw data subject #2174. (XLSX 112 kb) |
| Additional file 11: | Tabulated data from all subjects. (XLSX 62 kb) |

Abbreviations
- FeO₂: Fraction of exhaled oxygen
- FiO₂: Fraction of inhaled oxygen
- rSO₂: Cerebral oxygen saturation
- SpO₂: Peripheral capillary oxygen saturation

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Availability of data and materials
Datasets have been provided as Additional files 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11 as part of the manuscript submission.

Authors’ contributions
AMN and UB developed the protocol, coordinated the study, recruited subjects, and gathered informed consent; collected and interpreted data; and helped to critically revise the manuscript. KLT helped interpret and analyze the data, performed statistical analyses, wrote the first draft and revised subsequent drafts of the manuscript. All authors have read and approved of the final manuscript.

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Competing interests
The authors declare that they are employees of Medtronic and hold Medtronic stock.

Consent for publication
Not applicable.

Ethics approval and consent to participate
The Western Institutional Review Board (Puyallup, WA) approved an overarching protocol for a study of pulse oximetry devices, under which this
was a substudy (protocol #070808; Non-invasive Controlled Acute Hypoxia Studies). We obtained informed consent from all subjects prior to participating in the study.

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