

Fingertip Pulse Oximeter Performance in Dyspnea and Low Perfusion During Hypoxic Events

P.B. Batchelder, RRT, LRCP, Clinimark Laboratories, Boulder, Colorado

INTRODUCTION

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METHODS

Prior to study start, Institutional Review Board approval was obtained.¹ The study was registered at *clinicaltrials.gov* (NCT00881829) and written informed consent was obtained from each subject prior to conducting the study.

DEVICES UNDER TEST

Fingertip pulse oximeters from three widely used manufacturers were studied. They were the Nonin 3230 (using the same PureLight® and PureSAT® technology as the Onyx® Vantage 9590 and Onyx® II 9550), the Beijing Choice MD300 and the Contec Medical CMS50. The latter two manufacturers distribute under several different names and are representative of many newer fingertip pulse oximeters. All devices are FDA-cleared.

STUDY DESIGN

Dyspnea and low perfusion were simultaneously induced in each volunteer test subject. During the dyspneic and low perfusion periods, multiple hypoxic events down to the 70–85% SpO₂ range were induced to verify that the fingertip pulse oximeter was able to track saturation changes during these challenging conditions.

Reference Devices. Two Nellcor N-600x tabletop pulse oximeters were used as reference devices. One was placed on the warm, normal perfusion hand (warm reference) and the other was on the cooled, low perfusion hand (cooled reference). Due to the dynamic nature of this trial (in which the saturation changed rapidly from ~95%, down to the 70–85% range, then back up to ~95%) this trial did not use arterial blood as a reference. This is because arterial blood reference measurement requires a stable saturation for at least one minute.²

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Sample Size. The sample size was as follows: Beijing Choice and Nonin = 12 subjects with 54 hypoxic events. Contec and Nonin = 13 subjects with 61 hypoxic events.

Low Perfusion. The low perfusion (cooled hand) condition was created by directing chilled air (~55°F) over the right arm and right side of the body. Warm, normal perfusion conditions were created by covering the left arm and shoulder with a blanket. A warm water bottle was placed under the left hand. This allowed the left hand to remain warm with normal perfusion, while the right hand exhibited low perfusion.

Dyspnea. Dyspnea was created in healthy volunteer subjects by having the subjects hyperventilate continuously for extended periods of time. After one minute of this intense ventilatory breathing exercise, all subjects in this trial began to fatigue and exhibit labored breathing.

Hypoxic Events. Intermittent hypoxic events down to a nadir of 70–85% SpO₂ (based on the reference device) were produced by administration of ~14% oxygen. The subject was asked to hyperventilate continuously during the test with the exception of short periods, at which times the subject was asked to hold their breath which created short hypoxic events down to 70–85%.

Analysis. The number of times and the duration for each of the following conditions were totaled:

1. **Frozen reading** – no change in reading of the test device during a hypoxic event.
2. **No tracking** – test device readings displayed were >10% high compared to the reference device during a hypoxic event.
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In this study, performance was considered acceptable if a test pulse oximeter showed a clear pattern in tracking a hypoxic event from ~95% down to ~85% then back up to ~95%.

Figure 1: Example of Frozen Reading

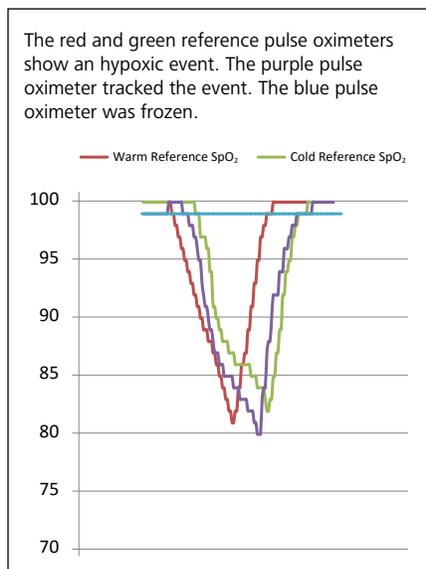


Figure 2: Example of No Tracking

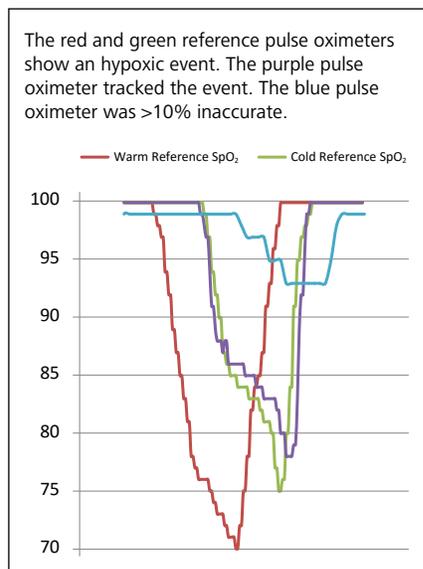
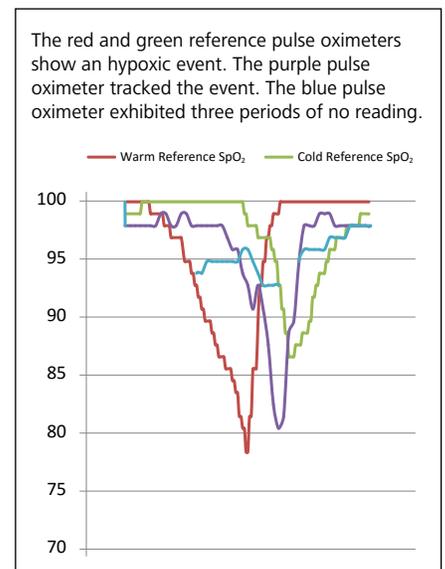


Figure 3: Example of No Reading



RESULTS

BEIJING CHOICE / NONIN MEDICAL COMPARISON

(See Table 1a and 1b)

Sample Size: 12 subjects, 54 hypoxic events

Beijing Choice

- Accurately tracked hypoxic events in 25% of subjects
- Accurately tracked 69% of all hypoxic events

Nonin Medical

- Accurately tracked hypoxic events in 100% of subjects
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Nellcor normal perfusion (warm hand) reference

- Accurately tracked hypoxic events in 92% of subjects
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Table 1a: Results by Subject (12 Subjects)

Subjects Accurately Tracked: % of subjects in which the oximeter accurately followed the changing SpO ₂ during all of that subject's hypoxic events		
Beijing Choice	4	25%
Nonin Medical	12	100%
Nellcor warm reference	11	92%
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Table 1b: Results by Hypoxic Event (54 Events)

Hypoxic Events Accurately Tracked: % of total hypoxic events across all subjects in which the oximeter accurately followed the changing SpO ₂		
Beijing Choice	37	69%
Nonin Medical	54	100%
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CONTEC MEDICAL / NONIN MEDICAL COMPARISON

(See Table 2a and 2b)

Sample Size: 13 subjects, 61 hypoxic events

Contec Medical

- Accurately tracked hypoxic events in 0% of subjects*
- Accurately tracked 16% of total hypoxic events

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Table 2a: Results by Subject (13 Subjects)

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*No individual subject tracked accurately through all of their hypoxic events.

DISCUSSION

In this study the Beijing Choice and Contec Medical fingertip pulse oximeters performed significantly worse than the Nonin Medical fingertip pulse oximeter in dyspneic, low perfusion conditions.

Table 3: Total Hypoxic Events Accurately Tracked

Nellcor warm reference	98 %
Nonin Medical	97 %
Nellcor cooled reference	92 %
Beijing Choice	69 %
Contec Medical	21 %

In the last few years fingertip pulse oximeters have been available in the U.S. as “health and wellness” devices without FDA clearance or need for a prescription. Patients have begun to purchase and use these devices to guide self-care. And to a lesser degree, some clinicians are using these uncleared devices as well as similar inexpensive FDA-cleared devices in their practice.

Concerned clinicians often conduct impromptu evaluations of these devices by putting the oximeter on themselves or on a stable patient under non-stressful conditions and comparing the values to a reference device. Performance in this type of impromptu evaluation is not representative of the dyspneic patient who may have paradoxical chest movement from labored breathing and low peripheral perfusion. Additionally, hypoxic events must be included in the testing to verify that a device is not frozen and is able to track a saturation change.

This study indicated that when performance might be most needed—during labored breathing with low perfusion—the two newer low cost oximeters tested in this study failed to track many of the hypoxic events and, instead froze the readings, read >10% high or blanked the display when the saturation was critically low.

REFERENCES

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- 2 ISO 80601-2-61 First edition 2011-04-01 Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.



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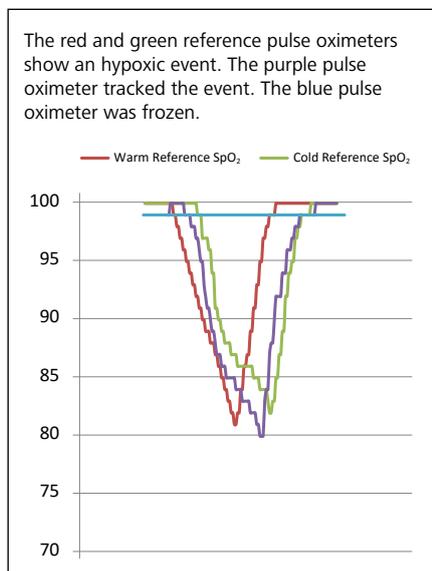


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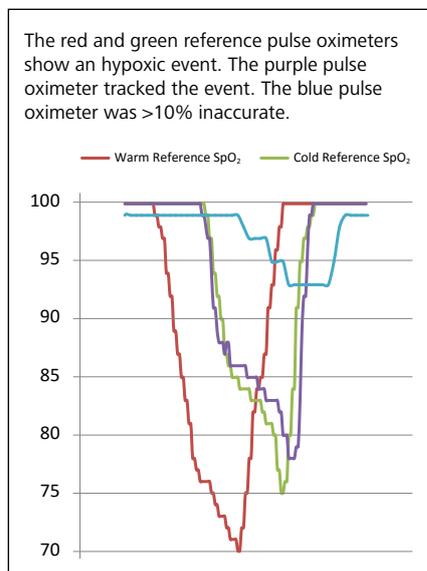
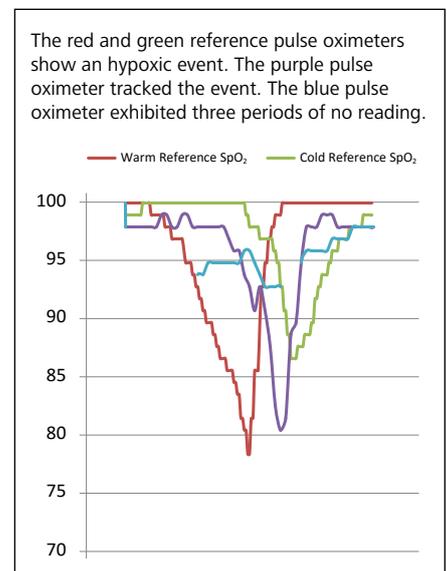


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