

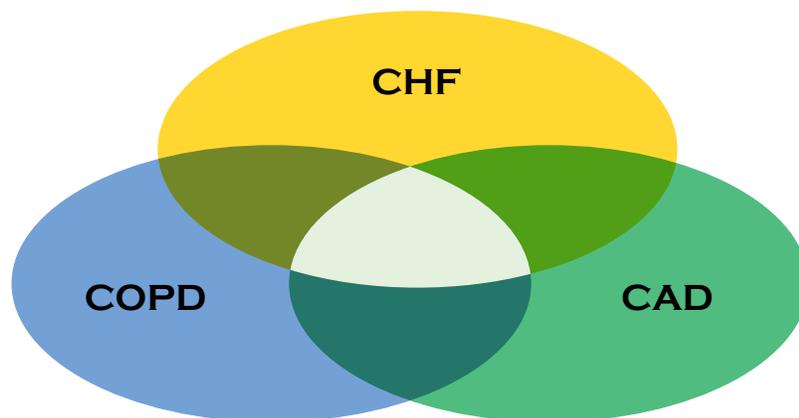


## Trust Nonin Oximeters, Even For Your Sickest Patients

An oximeter comparison study of healthy subjects in an independent hypoxia lab simulating the symptoms of COPD patients

# Does your oximeter work for all of your patients? How can you know?

## COPD PATIENTS OFTEN PRESENT WITH COMPLEX CO-MORBIDITIES



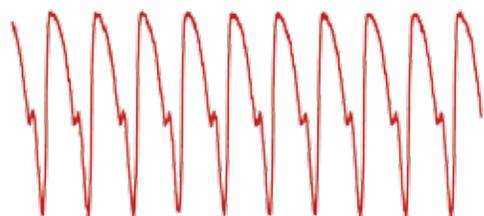
Up to 49.5% of COPD discharges have congestive heart failure (CHF) and/or coronary artery disease (CAD).<sup>1</sup>

## PULSE WAVE DISTORTIONS CAN CAUSE INACCURATE OXIMETER READINGS<sup>2</sup>

When a COPD patient is desaturating, the following may be present:

- **Low pulse strength** – poor blood circulation can result in low pulse strength. Cold hands from a variety of reasons/conditions can also result in low pulse strength.
- **Little or no oxygen reserve** – COPD patients have little or no oxygen reserve capacity in their lungs and can be living on the edge of hypoxemia.<sup>3</sup>
- **Labored breathing** – dyspnea can cause labored breathing and chest heaving, which can create pulse wave distortions.

As a result... it becomes harder for the oximeter to find the true pulse, particularly when the patient's oxygen level is dropping.



Normal Pulse Strength\*



Low Pulse Strength\*



Low Pulse Strength with  
Labored Breathing\*

\* Simulated waveforms

# Which oximeters are accurate in tracking desaturations?

Following Nonin Medical's invention of the fingertip oximeter in 1995 there has been a proliferation of brands introduced.



## **MANY OF THE NEW OXIMETERS ARE MADE BY TWO MANUFACTURERS:<sup>2</sup>**

- Beijing Choice Electronic Technology Co Ltd. (Beijing, China)
- Contec Medical Systems Co Ltd. (Qinhuangdao, China)

These two companies make over 30 different oximeter brands and models<sup>2</sup> – major retailer brands, distributor brands, and internet brands. Some are FDA-cleared while some are “health and wellness” devices.

## **CURRENT ACCURACY ASSESSMENT METHODS CAN BE FLAWED**

- Often clinicians assess an oximeter by comparing the oximeter to a tabletop or multi-parameter oximeter using a healthy individual or a COPD patient who is in stable condition.
- Accuracy assessment is most relevant when done on a COPD patient who is desaturating with associated labored breathing (dyspnea) and low pulse strength.

## WHITE PAPER SUMMARY

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

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### CLINIMARK, LLC – CLINICAL TESTING AND VALIDATION SERVICES FOR MEDICAL DEVICES

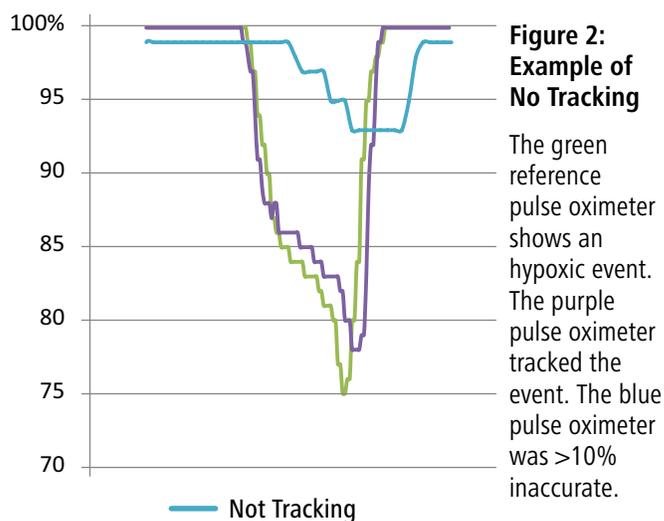
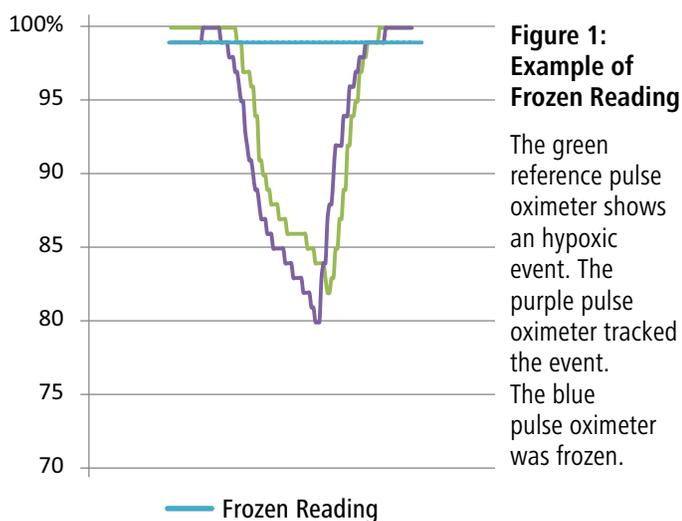
Clinimark is an independent laboratory whose purpose is to provide impartial research and clinical laboratory testing for medical device development and FDA regulatory validation in invasive and non-invasive monitoring intended for the medical setting. Clinimark is actively involved with standards organizations, such as the ASTM, ISO, and IEC, working with the FDA in development of worldwide harmonized pulse oximetry standards.

### OXIMETER PERFORMANCE COMPARISON TEST DESIGN

Clinimark conducted a test on human subjects in which they induced the conditions typical of a COPD patient with low pulse strength, dyspnea, experiencing a desaturation, or hypoxic event. They then tested devices from three manufacturers to see which ones could track the hypoxic event.

### TEST METHODOLOGY

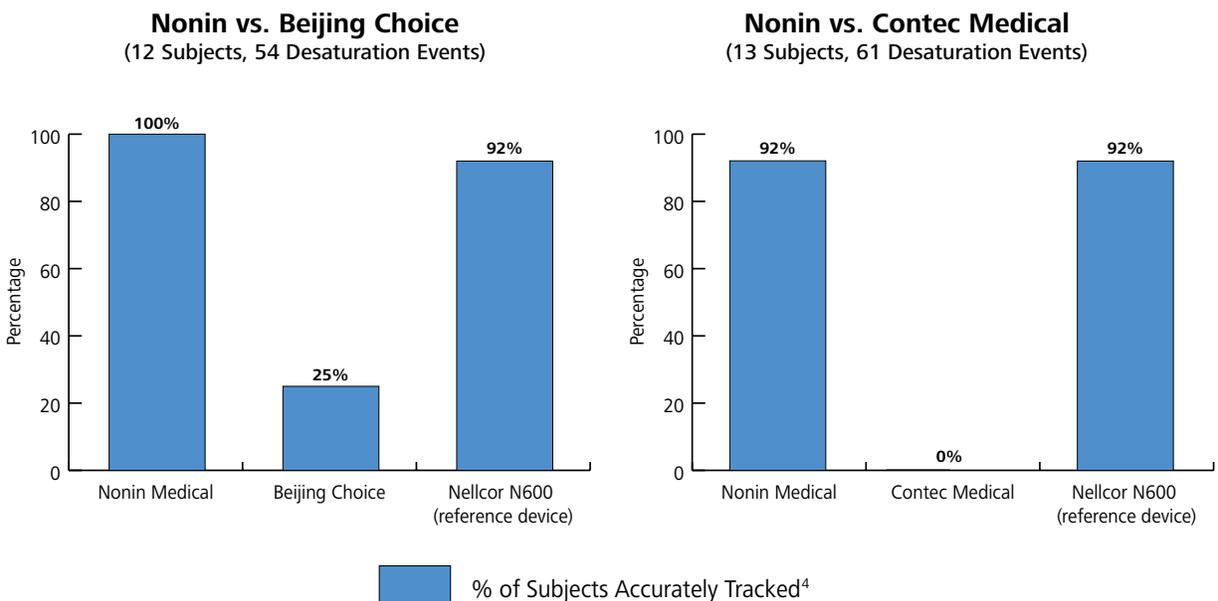
- An arm of each subject was cooled with cold air to reduce the blood circulation and create a low pulse strength condition.
- Multiple desaturation events were induced along with dyspnea (labored breathing).
- A Nonin oximeter along with a Beijing Choice or Contec Medical fingertip pulse oximeter and a reference device were placed on the test hand.
- A Nellcor N600x tabletop oximeter was used as the reference device.



# Only the Nonin oximeter, with PureSAT® technology, was able to accurately track desaturations in humans with low pulse strength and labored breathing.

## RESULTS

The charts below show the percentage of subjects in which oxygen level changes were accurately tracked.



- The oximeters made by Beijing Choice and Contec Medical failed to track many of the desaturations.
- These two companies make many of the oximeter brands sold by retailers, internet sellers and distributors.

**Trust Nonin oximeters,  
even for your sickest patients.**

Your oximeter needs to work on all your patients,  
especially the sickest. **Only Nonin makes Nonin.**

References:

- 1 PHC4-provided hospital discharges between Oct 1, 2007 and Sept 30, 2008, Pittsburgh Regional Health Initiative 2010.
- 2 Nonin Medical, Inc. Data on file.
- 3 Wild Iris Medical Education, Case Manager CEU, [www.nursingCEU.com](http://www.nursingCEU.com), Chronic Obstructive Pulmonary.
- 4 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%.

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

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

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## INTRODUCTION

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The first fingertip pulse oximeter was introduced in 1995 by Nonin Medical. For approximately 13 years, it was the sole device in this form factor in which the entire pulse oximeter was housed in the finger sensor (display, engine, power supply and sensor). Due to convenience of size and, apparently few reported performance issues, it saw rapid adoption in the clinical environment. In the last eight years several new portable fingertip pulse oximeters have been introduced. Many of these devices are low cost and available over the counter. Anecdotal information gathered from clinicians indicate that some devices have poor performance which might be due to a combination of poor signal strength (lower perfusion) and labored breathing (dyspnea) resulting in inaccurate SpO<sub>2</sub> and/or pulse rate.

*“Our patients have poor peripheral perfusion (due to beta blockers), dyspnea and motion. [We have seen] slow response time, poor low perfusion performance, freezing, inconsistent performance, no reading.”*

– ANGIE EBELING, RRT, PULMONARY REHABILITATION;  
NORTH MEMORIAL MEDICAL CENTER, ROBBINSDALE, MINNESOTA

*“Clinicians see discrepancies in the readings when they compare the cheaper home pulse oximeter to the ones used in the hospital.”*

– BARBARA SHERWOOD, BS RRT, NPS,  
C.O.R.E. RESPIRATORY SERVICES;  
MINNEAPOLIS, MINNESOTA

Clinimark Laboratories, an independent hypoxia lab, was asked to investigate the performance of two newer fingertip pulse oximeters and the Nonin Medical fingertip pulse oximeter during dyspnea and low perfusion. Multiple hypoxic events down to the 70–85% range were induced to verify that the pulse oximeter was able to track saturation changes during these challenging conditions. In order to do this in a repeatable, safe manner this study was conducted in a laboratory setting by creating dyspnea, low perfusion and hypoxia in healthy volunteer subjects.

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## METHODS

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Prior to study start, Institutional Review Board approval was obtained.<sup>1</sup> 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% SpO<sub>2</sub> 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.<sup>2</sup>

**Test Devices.** The Nonin fingertip pulse oximeter was placed on one finger of the cooled test hand. One of the *newer* fingertip pulse oximeters was placed on the remaining finger of the cooled test hand (either a Beijing Choice ChoiceMMed MD300 or a Contec Medical CMS50).

**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.

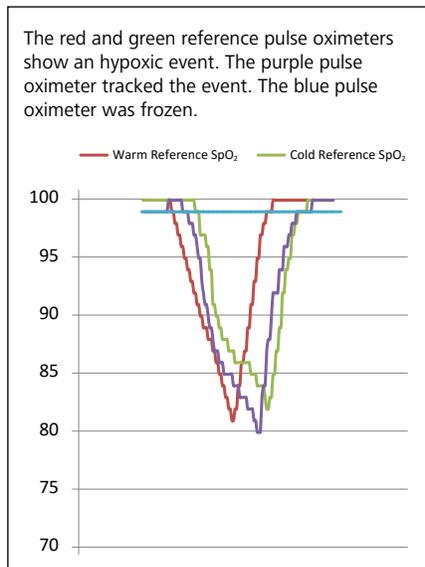
**Hypoxic Events.** Intermittent hypoxic events down to a nadir of 70–85% SpO<sub>2</sub> (based on the reference device) were produced by administration of ~14% oxygen. The subject was asked to hyperventilate continuously during the test with the exception of short periods, at which times the subject 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:

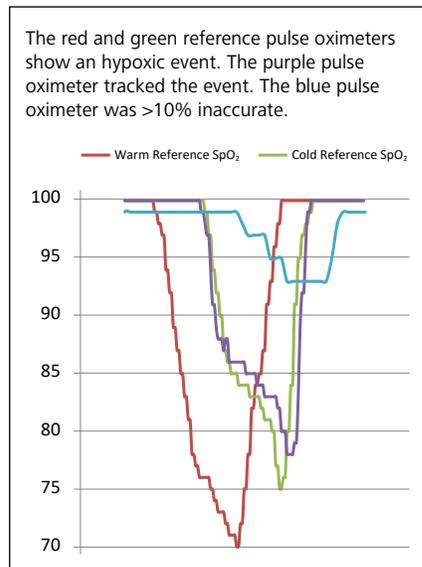
1. **Frozen reading** – no change in reading of the test device during a hypoxic event.
2. **No tracking** – test device readings displayed were >10% high compared to the reference device during a hypoxic event.
3. **No reading** – blank display.

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%.

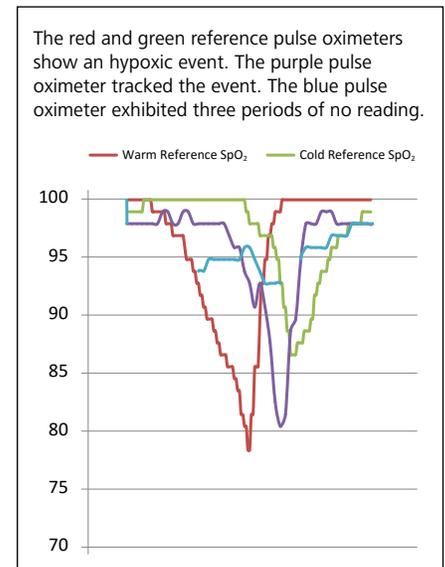
**Figure 1: Example of Frozen Reading**



**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
- Accurately tracked 100% of all hypoxic events

#### Nellcor normal perfusion (warm hand) reference

- Accurately tracked hypoxic events in 92% of subjects
- Accurately tracked 98% of all hypoxic events

#### Nellcor low perfusion (cooled hand) reference

- Accurately tracked hypoxic events in 100% of subjects
- Accurately tracked 100% of all hypoxic events

Table 1a: Results by Subject (12 Subjects)

Subjects Accurately Tracked: % of subjects in which the oximeter accurately followed the changing SpO <sub>2</sub> during all of that subject's hypoxic events		
Beijing Choice	4	25%
<b>Nonin Medical</b>	<b>12</b>	<b>100%</b>
Nellcor warm reference	11	92%
Nellcor cooled reference	12	100%

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 <sub>2</sub>		
Beijing Choice	37	69%
<b>Nonin Medical</b>	<b>54</b>	<b>100%</b>
Nellcor warm reference	53	98%
Nellcor cooled reference	54	100%

### 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

#### Nonin Medical

- Accurately tracked hypoxic events in 92% of subjects
- Accurately tracked 97% of all hypoxic events

#### Nellcor normal perfusion (warm hand) reference

- Accurately tracked hypoxic events in 92% of subjects
- Accurately tracked 98% of all hypoxic events

#### Nellcor low perfusion (cooled hand) reference

- Accurately tracked hypoxic events in 100% of subjects
- Accurately tracked 100% of all hypoxic events

Table 2a: Results by Subject (13 Subjects)

Subjects Accurately Tracked: % of subjects in which the oximeter accurately followed the changing SpO <sub>2</sub> during all of that subject's hypoxic events		
Contec Medical	0	0%
<b>Nonin Medical</b>	<b>12</b>	<b>92%</b>
Nellcor warm reference	12	92%
Nellcor cooled reference	13	100%

Table 2b: Results by Hypoxic Event (61 Events)

Hypoxic Events Accurately Tracked: % of total hypoxic events across all subjects in which the oximeter accurately followed the changing SpO <sub>2</sub>		
Contec Medical	10	16%
<b>Nonin Medical</b>	<b>59</b>	<b>97%</b>
Nellcor warm reference	60	98%
Nellcor cooled reference	61	100%

*"Use of the cheaper finger pulse oximeters in hospitals is rare, however patients commonly buy the least expensive option."*

– CURT MERRIMAN, RRT, CPFT; C.O.R.E. RESPIRATORY SERVICES, MINNEAPOLIS, MINNESOTA

\*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%
<b>Nonin Medical</b>	<b>97%</b>
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

- 1 Avista Adventist Hospital Institutional Review Board, FWA 00011584.
- 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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